Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian regulatory guidelines for medical devices
(ARGMD)

Version 1.1, May 2011

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act* 1989 (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <www.tga.gov.au>.

Version history

Version	Description of change	Effective date
V1.0	Initial publication	28/04/10
V1.1	• Updated references and contact details to reflect TGA's new organisational structure post TGA21 • Made multiple amendments and additions in Section 3. Essenti Principles, Principle 14—Clinical Evidence. • Made multiple amendments in Section 22. Post-market vigi ce and monitoring requirements. • Added a fourth part titled 'Navigation and Refer ce' t t includes: – a bibliography – consolidated contact details – an index – a glossary of terms • Made various punctuatio d grammar amendments • Reformatted for comp e w new TGA style manual	04/0 /1

Contents

Part 1–Introduction

Section 1. Introduction to the regulatory guidelines

Purpose of the ARGMD

The Australian Regulatory Guidelines for Medical Devices (ARGMD) has been developed t

- provide guidance to assist manufacturers and sponsors of medical devices in me[illegible] regulatory requirements for legally supplying a medical device in Australia
- help ensure that medical device applications to the TGA meet all the neces[illegible] legislative requirements so that applications are processed with minimal delays
- enhance the clarity and transparency of the processes:
  - leading to the legal supply of medical devices in Australia
  - for meeting the ongoing requirements once a device is ava[illegible] for supply in Australia.

Scope of the ARGMD

The ARGMD is a consolidated reference document c[illegible] the regulatory requirements for medical devices in Australia.

The ARGMD describes the information to b[illegible] pplied with applications to:

- import
- export
- manufacture
- supply

medical devices in Aus[illegible]ia. The ARGMD also describes post-market requirements for medical devices.

Regulator[illegible] other therapeutic devices that are listed or registered is not included. The *Australian Medical Device Requirements Under the Therapeutic Goods Act 1989* (version 4), or DR4, available on t[illegible]GA website, provides guidance for these products. Therapeutic devices include:

- [illegible]
- [illegible]rface disinfectants
- [illegible] devices incorporating human materials

Please note: A new regulatory framework for in vitro diagnostic medical devices (IVDs) was introduced on 1 July 2010. Under this framework, IVDs are regulated as a subset of medical devices but there are several points of difference between the regulation of IVDs and medical devices. For information relating to the regulation of IVDs in Australia, see the TGA website.

Legislation applying to medical devices

The legislative basis for uniform Australian controls over goods used in the prevention, diagnosis, curing, or alleviation of a disease, ailment, defect, or injury are:

- the *Therapeutic Goods Act 1989* (the Act)
- the Therapeutic Goods Regulations 1990
- the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations)

It is important for stakeholders to know the current regulatory requirements. Copies of the legislation can be obtained from the Commonwealth of Australia Law website <http://www.comlaw.gov.au>. The website also provides details of how to purchase printed copies of the legislation.

There are also legislative instruments such as the:

- Therapeutic Goods Orders (TGOs)
- Excluded Goods Orders
- Medical Device Standards Orders (MDSOs)
- Conformity Assessment Standards Orders (CASOs)

Full details of these instruments are available on the TGA website <http://www.tga.gov.au>.

MDSOs and CASOs

Compliance with the MDSOs and CASOs can be used to demonstrate compliance with the medical device legislative requirements. The use of these orders is not mandatory, but is one way to establish compliance with the regulatory requirements. The standards cover topics such as:

- clinical evidence
- risk management
- medical devices required to be sterile
- quality management systems and quality assurance techniques
- sterility
- biological safety and biocompatibility
- quality assurance techniques for animal tissues and their derivatives

The legislative framework adopts the philosophies of the Global Harmonization Task Force (GHTF), an international forum that was established to achieve greater uniformity between national medical device regulatory systems.

Unless complementary legislation is enacted within a state or territory of Australia to apply the legislative requirements of the Commonwealth legislation, the Act has no application to activities undertaken by those who trade in therapeutic goods wholly within the borders of a single state or territory. That is, where therapeutic goods are produced and sold within a single state or territory, the Act does not apply.

Some provisions such as the safe storage of therapeutic goods are also covered by the relevant state or territory legislation.

Medical device advisory committees

Three committees provide advice on the regulation of medical devices. They are:

Committee	Function
Advisory Committee on Medical Devices (ACMD)	Provides independent medical and scientific advice to the Minister and the TGA on the safety, quality and performance of medical devices supplied in Australia, including issues relating to pre-market conformity assessment and post-market monitoring.
Therapeutic Goods Committee (TGC)	Advises the Minister on the adoption of standards for therapeutic goods for human use, matters relating to standards including labelling and packaging, and the principles to be observed in the manufacture of therapeutic goods for human
National Coordinating Committee on Therapeutic Goods (NCCTG)	Consists of representatives from the States and Territories, and the Australian Government. The committee discusses many aspects of the regulation of therapeutic good

More information on each of these committees is available from the TGA website <http://www.tga.gov.au>.

What is a medical device?

From the *Therapeutic Goods Act 1989*...

41BD What is a medical device

1. A medical device is:

   a. any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:
      i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
      ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;
      iii. investigation, replacement or modification of the anatomy or of a physiological process;
      iv. control of conception;
      v. and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or

   aa. any instrument, apparatus, appliance, material or other article specified under subsection (2A); or

   ab. any instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection (2B); or

   b. an accessory to such an instrument, apparatus, appliance, material or other article covered by paragraph (a), (aa) or (ab).

Medical devices:

- are used for humans
- have therapeutic benefits
- generally have a physical or mechanical effect on the body or are used to measure or monitor functions of the body

Medical devices range from bandages that would be put on a scratch to high-risk products such as pacemakers that are implanted in the body.

Other examples of medical devices include:

- artificial hips
- blood pressure monitors
- breast implants
- catheters
- condoms
- lubricating eye drops
- MRI scanners
- orthodontics—for example, braces or fillings
- syringes
- tongue depressors

How medical devices are regulated in Australia

The Therapeutic Goods Administration (TGA), a Division of the Australian Government Department of Health and Ageing, is responsible for administering the Act and associated legislation. The Office of Devices Authorisation (ODA) is the area within the TGA responsible for the pre-market regulation of medical devices, while the Office of Product Review (OPR) is responsible for post-market regulation of all therapeutic goods.

Regulatory systems are intended to ensure a high level of protection of public health and safety. Public trust and confidence in medical devices and in the administrative systems by which they are regulated are based on the safety and performance of devices throughout their life cycle.

In order for the TGA to maintain public confidence in the safety, performance, benefits and risks associated with the use of medical devices on the Australian market, assessments may be conducted:

- before a device is able to be supplied to the market in Australia, and
- while a medical device is available on the market.

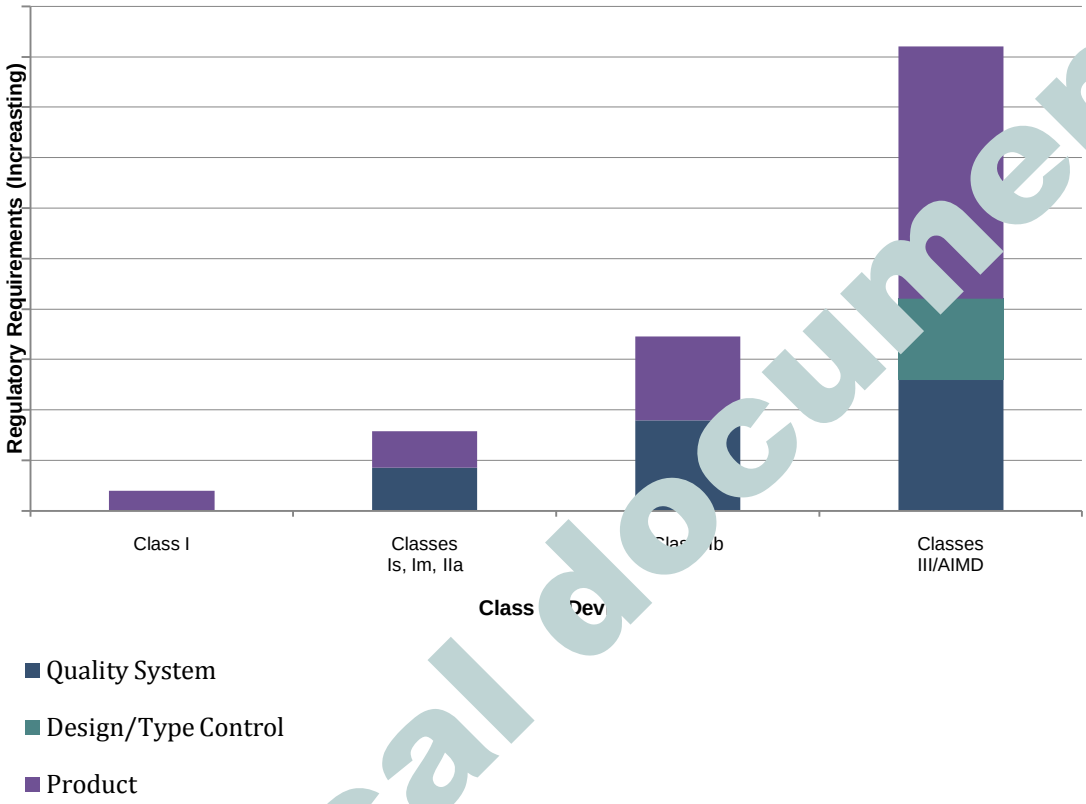
Before a new medical device can be supplied to the market in Australia, the TGA needs to be involved. The TGA's regulatory requirements vary, depending on what the device is and how it is to be used. The TGA is involved in most of the stages in the life cycle of a medical device.

The risks associated with using medical devices can range from little or low potential risk to patients and users to significant potential risks. As depicted in Figure 1, the level of assessment

performed by the TGA before the device is able to be supplied in Australia directly relates to the level of potential risk.

Figure 1

Risk vs Regulatory Requirements



One of the TGA's strategies to reduce the regulatory burden on industry is to negotiate agreements with other international regulators. These agreements can range from recognition and acceptance of regulatory decisions on specific products to the sharing of information about regulatory processes, such as what pre-market assessments occur before a product is able to be supplied.

The TGA operates on a 100% cost-recovery basis. Its operating costs are funded through fees and charges collected from the therapeutic goods industry. Applicants are required to pay fees for making applications to the TGA, and sponsors must pay annual charges for the devices that they are responsible for.

Key elements of the medical device regulatory scheme

The key elements of the medical device regulatory scheme include:

- product requirements (the Essential Principles) for the quality, safety, and performance of the medical device that must be complied with:
  - before the device is supplied to the market in Australia, and
  - on an ongoing basis while the device is supplied to the market in Australia
- a device classification scheme based on different levels of risk
- options as to how compliance with the Essential Principles can be demonstrated

- the optional use of recognised standards
- ongoing monitoring of medical devices that are available on the market
- regulatory controls for the manufacturing processes of medical devices
- the Australian Register of Therapeutic Goods (ARTG) as the central point of control for the legal supply of medical devices in Australia
- the provision for imposing penalties where regulatory requirements are breached
- a range of corrective actions that may be taken if there is a problem with a device

The legislation also makes provision for specific types of devices, including:

- single-use devices
- active medical devices (energy using)
- medical devices that contain:
  - medicines
  - materials of animal, microbial, or recombinant origin
- systems or procedure packs
- medical devices for export only
- custom-made medical devices

The majority of medical devices must be included in the ARTG before being made available for supply in Australia. The ARTG can be accessed via the TGA website <http://www.tga.gov.au>. The TGA eBusiness (eBS) services system allows users to access information about:

- Medicines
- Medical devices
- Biologicals
- Code tables and ingredients

Applications for inclusion of a medical device in the ARTG are submitted through eBS. There are different levels of access for registered users and the general public. Access to some areas of eBS are restricted by password.

For a medical device to be included in the ARTG, the TGA must be satisfied that evidence exists appropriate to the perceived risks of the device to support its safe and effective use, and that an appropriate system is in place for monitoring the ongoing performance and safety of the device.

If someone intends to supply a device that is identical to a device that is already in the ARTG, even if both devices are made by the same manufacturer, an application to include the device in the ARTG must still be made to the TGA. This is because the ARTG is not only a record of the devices that can be supplied in Australia; it is also a record of all the sponsors who are legally responsible for the medical devices on the market.

The legislation requires that the TGA conduct an evaluation of the conformity assessment documentation that demonstrates compliance with the Essential Principles for:

- Australian manufacturers
- specific high-risk devices, including devices that contain:

- materials of animal, microbial or recombinant origin
- derivatives of human blood or plasma
- a medicine.

There are other medical devices that must undergo a mandatory application audit prior to being included in the ARTG. These include:

- a medical device (other than a condom) that is indicated to be a barrier for contraception or for prevention of the transmission of disease in the course of penile penetration during sexual intercourse
- a medical device that is an implantable contraceptive device
- a medical device that is an implantable breast prosthesis containing material of fluid consistency (other than water only or a saline solution only)
- a medical device that is specifically intended by the manufacturer to be used for disinfecting another medical device
- a Class AIMD medical device
- a medical device that is a prosthetic heart valve
- a medical device that is an implantable intra ocular lens
- a medical device that is an intraocular visco-elastic fluid
- a Class III medical device that has not been assessed under the EC Mutual Recognition Agreement or the EFTA Mutual Recognition Agreement.

There are four mechanisms for accessing unapproved medical devices in Australia:

- clinical trials in Australia
- authorised prescribers
- the Special Access Scheme
- personal importation.

Life-cycle approach to the regulation of a medical device

Stage	Required regulatory action
Concept	Consider the Essential Principles
Prototype	Incorporate the Essential Principles into the design
Preclinical	Seek approval from or notify the TGA of intention to commence clinical trial
Clinical	• Follow clinical trial guidelines • Prepare clinical evaluation of clinical data
Manufacturing	Apply conformity assessment procedures and then obtain appropriate conformity assessment evidence
Marketing	Adhere to the Therapeutic Goods Advertising Code
Supply	• Apply to include the device in the ARTG • Monitor safety and performance of the device during its lifetime • Maintain conformity assessment evidence • Report any problems with the device to the TGA and to the users of the device • Recall and/or correct devices that have defects, design flaws, or unacceptable clinical risks or levels of performance
Obsolescence	Notify the TGA so the device can be removed from the ARTG

Who is the manufacturer of a medical device

From the *Therapeutic Goods Act 1989*...

41BG Manufacturers of medical devices

1. The manufacturer of a medical device is the person who is responsible for the design, production, packaging and labelling of the device before it is supplied under the person's name, whether or not it is the person, or another person acting on the person's behalf, who carries out those operations.

2. If subsection (1) does not apply to a medical device, the manufacturer of the device is the person who, with a view to supplying the device under the person's name, does one or more of the following using ready made products:

   a. assembles the device;
   b. packages the device;
   c. processes the device;
   d. fully refurbishes the device;
   e. labels the device;
   f. assigns to the device its purpose by means of information supplied, by the person, on or in any one or more of the following:
      i. the labelling on the device;
      ii. the instructions for using the device;
      iii. any advertising material relating to the device;
      iv. technical documentation describing the mechanism of the device.

3. However, a person is not the manufacturer of a medical device if:

   a. the person assembles or adapts the device for an individual patient; and
   b. the device has already been supplied by another person; and
   c. the assembly or adaptation does not change the purpose intended for the device by means of information supplied by that other person, on or in any one or more of the following:
      i. the labelling on the device;
      ii. the instructions for using the device;
      iii. any advertising material relating to the device.
      iv. technical documentation describing the mechanism of action of the device

   A person is not the manufacturer of a medical device if the person is included in a class of persons prescribed by the regulations for the purposes of this subsection.

Responsibilities of a medical device manufacturer

Manufacturers must:

- for each medical device, determine the:
  - classification
  - intended purpose
  - appropriate GMDN code
- select and apply appropriate conformity assessment procedures to demonstrate compliance with the Essential Principles

- ensure that they have appropriate processes in place and documentation to demonstrate this before they apply to the TGA or an EU Notified Body for conformity assessment evidence
- obtain the conformity assessment evidence and ensure the information on the certificate remains current and valid
- pay the application and assessment fees for obtaining the conformity assessment evidence
- prepare an Australian Declaration of Conformity that includes all the manufacturing details for the medical devices
- ensure that their conformity assessment procedures are appropriately maintained on an ongoing basis to obtain the necessary conformity assessment evidence, and that the ongoing requirements are met (for example, reporting adverse events, regular quality systems audits)
- notify the TGA of substantial changes to the design, production or intended purpose of the device.

The legislation requires that the TGA must be notified in writing by the appropriate legal representative, within 3 months of the event occurring, if the manufacturer:

- dies
- is declared bankrupt
- is a body corporate that is wound up.

A manufacturer may also be the Australian sponsor.

Please note: even though conformity assessment evidence is not required for manufacturers of Class I medical devices that are not supplied sterile and do not have a measuring function, the manufacturer is still required to prepare the necessary technical documentation and an Australian Declaration of Conformity and provide it to the TGA upon request.

Who is the sponsor of a medical device

From the *Therapeutic Goods Act 1989*...

Chapter 1—Preliminary, 3 Interpretation

sponsor, in relation to therapeutic goods, means:

a. a person who exports, or arranges the exportation of, the goods from Australia; or

b. a person who imports, or arranges the importation of, the goods into Australia; or

c. a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere);

but does not include a person who:

d. exports, imports or manufactures the goods; or

e. arranges the exportation, importation or manufacture of the goods;

on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia.

Before someone can supply a medical device for sale in Australia they are required to make an application to include the device in the ARTG. The sponsor is the person or company responsible for the importation of medical devices into Australia, and/or the supply of medical devices in Australia, and/or the export of medical devices from Australia, as well as making application to the TGA to have their device included in the ARTG.

The sponsor must be a resident of Australia or be an incorporated body in Australia and conducting business in Australia where the representative of the company is residing in Australia.

Responsibilities of a medical device sponsor

The medical device sponsor must:

- have procedures in place, including a written agreement with the manufacturer, to obtain information from the manufacturer when requested by the TGA
- ensure that
  - they have available sufficient information to substantiate compliance with the Essential Principles or have procedures in place to ensure that such information can be provided from the manufacturer to the TGA within 20 working days
  - an appropriate conformity assessment procedure has been applied to the medical devices
  - the manufacturer has appropriate conformity assessment evidence for the medical device
  - the conformity assessment evidence remains valid when the device is supplied in Australia
- for devices other than Class I not supplied sterile or with a measuring function, submit the conformity assessment evidence to the TGA
- apply to include the medical devices in the ARTG including certifying that the information provided is complete and correct
- pay the fee for applying to include the medical device in the ARTG, and where applicable pay the fees for an application audit to be conducted
- upon request
  - provide documentation relating to the medical device to the TGA
  - deliver samples of the medical device to the TGA
  - allow a person authorised by the TGA to enter and inspect any premises, including outside Australia, where the devices are manufactured or located
- notify the TGA of certain incidents and performance issues
- ensure the information about the device complies with the regulatory requirements
- pay the annual charges for ongoing inclusion of the medical device in the ARTG

There are criminal and civil penalties for making false statements.

Processes to supply medical devices in Australia

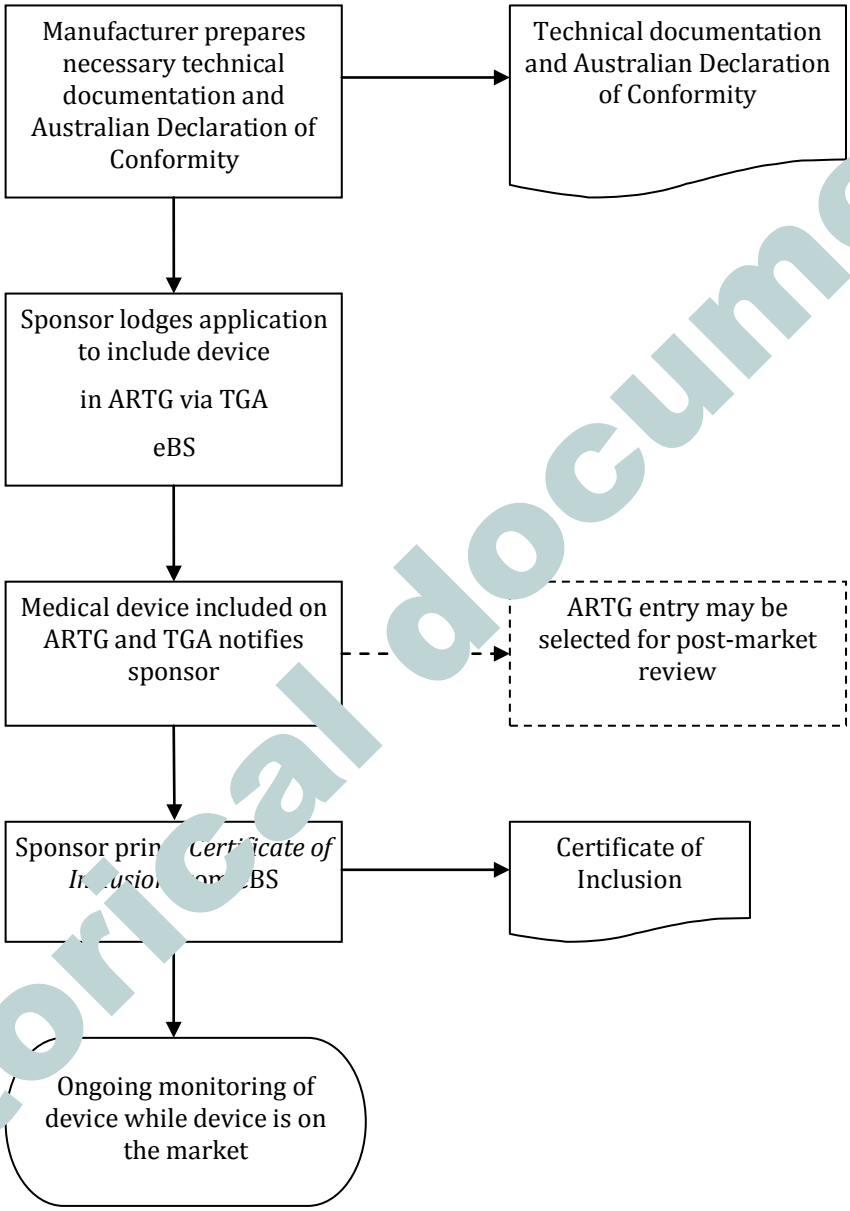
The legislation requires that there are different processes that must be followed to be able to supply medical devices for sale in Australia.

These processes have been summarised as follows:

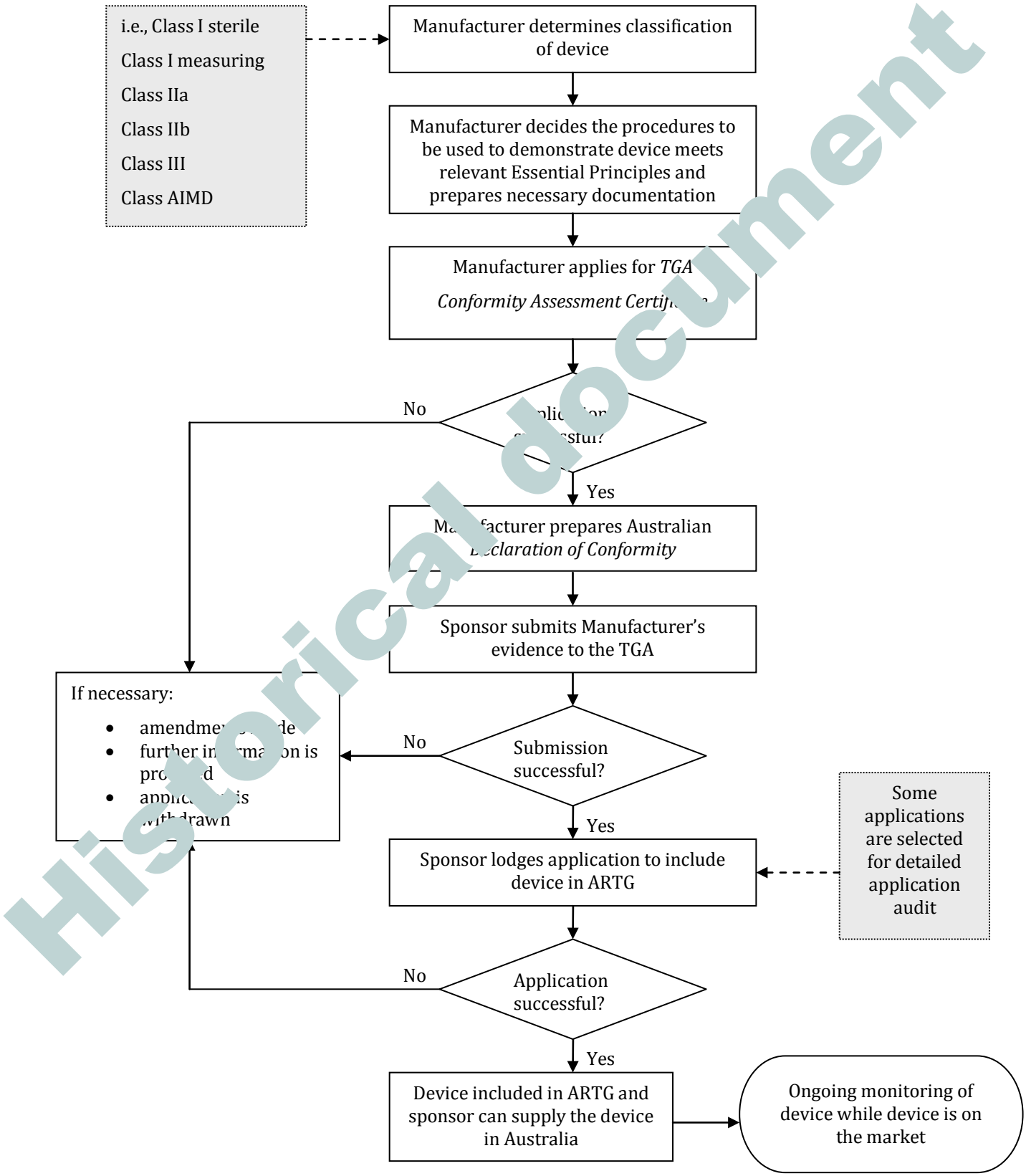
- Process to supply a medical device in Australia—all Class I non-sterile and non-measuring devices

- Process to supply a medical device in Australia—if the medical device is manufactured in Australia
- Process to supply a medical device in Australia—if the medical device is manufactured overseas

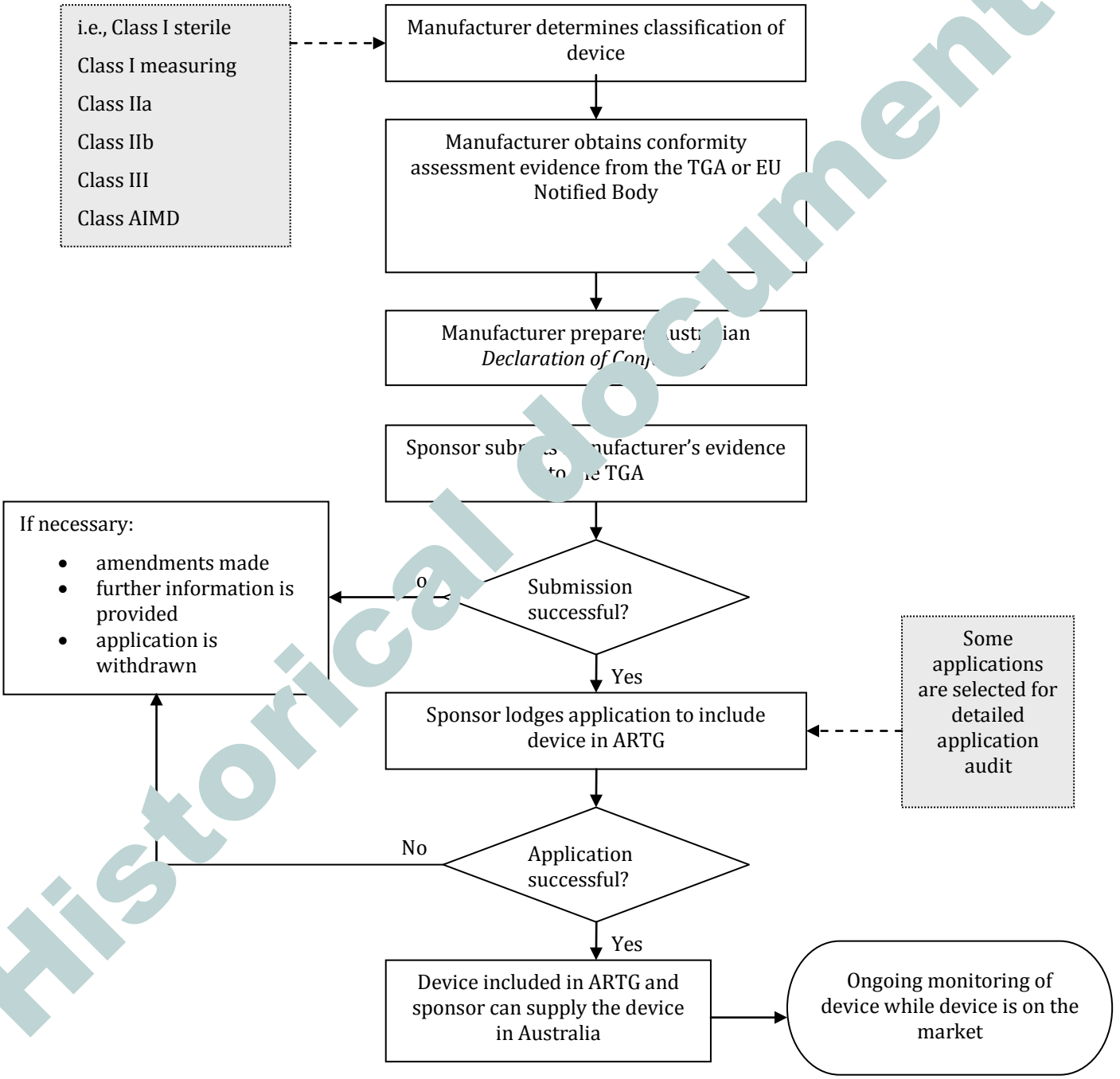
Process to supply a medical device in Australia—all Class I non-sterile and non-measuring devices



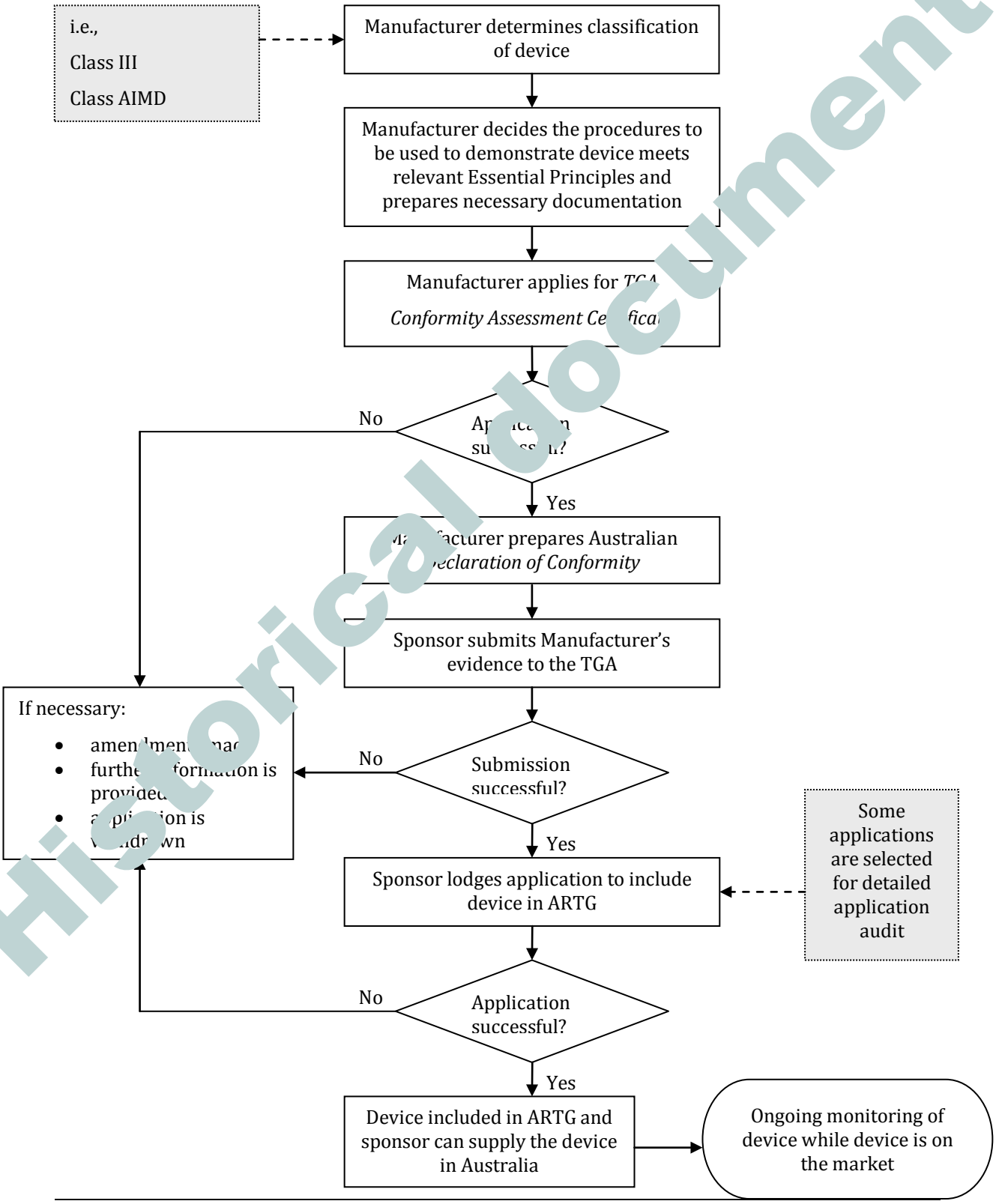
Process to supply a medical device in Australia—if the medical device is manufactured in Australia



Process to supply a medical device in Australia—if the medical device is manufactured overseas



Process to supply a medical device in Australia—if the device contains a medicine or materials of animal, microbial recombinant, or human origin



Currency of information

The guidelines contain many references to legislation. However, these references, although accurate at the time of publication, are not intended to be comprehensive. It is the sponsor's and manufacturer's responsibility to ensure that current regulatory requirements are fully met.

You should routinely check the TGA website for the latest version of these guidelines and not rely on printed copies. The guidelines are available on the TGA website.

While these guidelines reflect the views of the TGA and its evaluation committees at the time of publication, there may be occasions where a departure from the guidelines is warranted. If you believe this to be the case, a justification for the departure should be submitted with the application. You may wish to contact the Office of Devices Authorisation for advice in such instances.

The TGA welcomes comments and suggestions about the ARGMD; these should be directed to:

Email: <devices@tga.gov.au>

Post:
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Section 2. Fees and charges for medical devices

Overview

The TGA operates on a 100% cost-recovery basis and collects its revenue primarily through annual charges and application, evaluation, audit, and assessment fees. The fees and charges currently applicable to medical devices are available on the TGA website.

The TGA is very conscious of the costs associated with its regulatory responsibilities and is continually seeking to contain those costs through improvements in both efficiency and effectiveness. Each year, the level of fees and charges for medical devices is reviewed in consultation with industry associations, including:

- the Medical Technology Association of Australia
- the Australian Dental Industry Association
- AusBiotech Ltd
- IVD Australia

Annual charges are payable each financial year for medical devices that are on the Australian Register of Therapeutic Goods (ARTG) for any part of the financial year. The ARTG is the TGA's record of the devices that are able to be supplied.

Fees are charged for applications, assessments, and audits for new medical devices. Fees are also payable when there are changes that the TGA needs to assess.

Annual charges

An annual charge is payable for maintaining a medical device in the ARTG. The annual charges vary depending on the classification of the device. Different rates may apply for a:

- Class AIMD medical device
- Class III medical device
- Class IIb medical device
- Class IIa medical device
- Class I medical device—supplied sterile
- Class I medical device—incorporating a measuring function[1]
- Class I medical device

A medical device approved at any time during a financial year will be liable for the full annual charge for that financial year, in addition to the application and/or assessment fees paid. There is no reduction in the annual fee if a medical device is only on the ARTG for part of a year.

Annual charges are levied as a tax for cost-recovery purposes through the *Therapeutic Goods (Charges) Act 1989*. Invoices for annual charges are generally issued to sponsors in July/August each year for all products on the ARTG as at 1 July of that year.

Sponsors can elect to receive their annual charges invoice electronically by completing the form available on the TGA website. Electronic invoicing improves the timeliness and delivery of invoices.

[1] 'Medical devices with a measuring function' is defined in Regulation 1.4 of the Regulations.

The invoices include a complete list of ARTG entries for each sponsor. Any discrepancies or omissions from the list of product entries should be notified to the TGA immediately. Sponsors also have an opportunity to review the devices listed in the invoice and identify any products that should be cancelled (where supply ceased before 1 July of that year) and products for which a low volume – low value exemption will be sought.

Non-payment of annual charges for medical devices will result in the cancellation of the relevant products from the ARTG. Once cancelled, a new approved application is required before supply of the medical device can resume.

Low-value turnover

The annual charge is not payable for low-value turnover products. A sponsor must apply to the TGA providing a declaration that the turnover is of sufficiently low value to obtain an exemption from the annual charge.

To be eligible, the turnover in respect of an entry on the ARTG must be, or be estimated to be, no more than 15 times the annual charge for inclusion in the ARTG for a financial year. The turnover of a medical device means gross dollar receipts (excluding GST) from sales of the medical device in Australia for a financial year, including retail and wholesale sales.

Applications must be accompanied by a statement of actual turnover (for existing entries) or a statement of estimated turnover (for new entries) and be signed by a person who is a qualified accountant under section 88B of the *Corporation Act 2001*. There is a non-refundable application fee to declare that a product is of low value. For more information please refer to the TGA website.

Fees

The TGA has a variety of fees for medical devices. They include:

- application fees
- conformity assessment fees
- application audit fees

Application fees

To avoid delays, sponsors and manufacturers should pay the application fee at the time of submitting an application. The application will not proceed until the fee is paid.

The fees payable vary depending on the type of application.

The TGA charges application fees to:

- apply for a change to, or certification of, a TGA Conformity Assessment Certificate
- include a medical device in the ARTG
- vary an ARTG entry if the entry is incomplete or incorrect
- obtain a Certificate of Free Sale or an Export Certificate, which are required by some countries that devices are exported to
- lodge an application for consent to import into Australia, supply for use in Australia, or export from Australia a medical device that does not conform to the Essential Principles

notify the intention to sponsor a clinical trial of a medical device to be used solely for experimental purposes in humans—Clinical Trial Notification Scheme

- apply for approval to use a specified kind of medical device solely for experimental purposes in humans—Clinical Trial Exemption Scheme (CTX).

Conformity assessment fees

Conformity assessment fees are payable for:	Description of fees
applying for: • a TGA Conformity Assessment Certificate • re-certification of a TGA Conformity Assessment Certificate when it is due to expire	Application fee is payable for lodging the application with the TGA
assessment of the documentation supplied to demonstrate compliance with the Essential Principles, either for: • an initial application • a re-certification	• TGA will conduct a preliminary assessment to determine the appropriate conformity assessment fee • Where applicable, fees may also be payable for the assessment of a medicinal component of a device • An invoice will be raised and sent to the manufacturer for payment
application and assessment of documentation to issue a certificate under the EC-MRA or EFTA-MRA	• An application for a TGA Conformity Assessment Certificate must be made at the same time or have been made previously for an application to be processed • A standard fee is payable that assumes that no additional product assessment or QMS assessment is required—only a review of administrative and regulatory procedures and labelling etc. • Future fees may be payable if additional work is required • This is a commercial arrangement through a contract for service between the TGA and the manufacturer
surveillance audits of manufacturer	• The issue of a TGA Conformity Assessment Certificate may require an initial audit by the TGA • After this, audits will occur regularly—generally at least 18 months apart and no more than five years apart. Audits may be conducted more frequently if issues arise • In addition to the audit fee, reasonable travel, accommodation and allowance costs for travel both in and outside Australia are payable
changes to a TGA Conformity Assessment Certificate	• Fees vary depending on the procedures the manufacturer has used and the extent of the change
testing of medical devices by the TGA, if required	• Direct and/or indirect costs of conducting the tests, including the cost of any consumables used to conduct the tests

Application audit fees

Some applications to include medical devices on the ARTG will automatically undergo an application audit. For details of these medical devices and more information on application audits please see Section 11. Application audits of medical device applications.

Applications to include other classes of medical devices on the ARTG may also be randomly selected for an application audit. A fee is not payable for these audits.

There are two levels of application audits and different fees apply to each level.

Fee reductions

The therapeutic goods legislation:

- allows exemption from annual charges for low volume – low value products
- allows audit and assessment fees to be reduced
- has no provision to reduce application fees

Regulation 9.7 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations) includes provisions for reduced fees for application audits and conformity assessments, where information is available that allows the assessment to be abridged. Relevant information must relate to the medical device or some or all aspects of the conformity assessment procedures applicable to the device.

The applicant may provide the TGA with the details of previous conformity assessment evidence. The TGA may request copies of the documentation if the assessment was conducted by another conformity assessment body. This may allow the TGA to reduce the level of assessment and consequently the applicable conformity assessment fees. If the TGA determines that the information is sufficient for an abridged assessment to be conducted, the TGA will determine the appropriate reduced fee.

Application audit fees may be reduced if the evidence of conformity is applicable to several kinds of medical devices and the applications are submitted at the same time. This would usually apply to applications for Class III and AIMD devices that have different unique product identifiers. Normally application audit fees would be levied for each kind of medical device. The sponsor should apply to the TGA for a reduction in fees. For more information on the criteria and timeframes that must be met for a successful application to reduce the fees please refer to Section 11. Application audits of medical device applications.

By default, the TGA will undertake full assessment of an application at the full prescribed fee.

Payment of fees by instalments

In accordance with Regulation [illegible] of the Regulations, the TGA may approve an instalment payment plan where the assessment fees exceed $10,000 and the payment of the fee as a lump sum would result in financial hardship for the manufacturer or sponsor.

Instalment payment plans are designed to ensure full payment is made prior to the finalisation of an assessment. Conditions, including interest, may be applied for an approved instalment plan. Payment plans that extend beyond the financial year will usually have interest imposed on the debt.

Sponsors must:

- apply in writing for an instalment plan
- include supporting information demonstrating financial hardship (for example, financial statements, budget projections).

The instalment plan, as defined in the Regulations, is:

- 50% of the fee prior to commencement
- 25% to be made 30 days later
- balance payable on completion of the assessment/audit or withdrawal of the application by the applicant.

Failure to make an instalment payment by the agreed date will result in the balance of the amount being payable in full.

The TGA cannot consider a request for instalment payments while another fee or charge remains unpaid.

The TGA will advise the applicant in writing within 30 days if the decision to grant instalment payments is approved. Applicants are required to agree to the conditions relating to the instalment payment plan in writing.

Section 3. The Essential Principles

Overview

What are the Essential Principles?

From the *Therapeutic Goods Act 1989*...

41C The Essential Principles set out the requirements relating to the safety and performance characteristics of medical devices.

For a medical device to be supplied in Australia, it must be demonstrated that the relevant Essential Principles have been met. The regulatory framework provides flexibility for manufacturers and caters for technological advances and changes in the development of new medical devices by not dictating how a manufacturer must prove that they have met the Essential Principles.

It is the manufacturer's responsibility to demonstrate compliance with the Essential Principles for their medical devices.

There are six general Essential Principles that apply to all devices and there are a further nine Essential Principles about design and construction that apply to devices on a case-by-case basis.

General principles

- Use of medical devices not to compromise health and safety
- Design and construction of medical devices to conform to safety principles
- Medical devices to be suitable for intended purpose
- Long-term safety
- Medical devices not to be adversely affected by transport or storage
- Benefits of medical devices to outweigh any side effects

Principles about design and construction

- Chemical, physical and biological properties
- Infection and microbial contamination
- Construction and environmental properties
- Medical devices with a measuring function
- Protection against radiation
- Medical devices connected to or equipped with an energy source
- Information to be provided with medical devices.
- Clinical evidence
- Principles applying to IVD medical devices only

Demonstrating compliance with the Essential Principles

A checklist that manufacturers may complete to demonstrate how they have complied with the Essential Principles for a particular medical device is available on the TGA website <http://www.tga.gov.au>.

Once a design specification that minimises the identified risks has been defined, the manufacturer will need to decide how to demonstrate that it meets the relevant Essential Principles. In many instances this will be achieved through implementation, maintenance and regular inspection of a quality management system by the device manufacturer.

Manufacturers can demonstrate that the Essential Principles have been met for a device in many ways. Some examples include:

- a documented and detailed risk analysis
- the results of testing of the medical device
- literature searches
- copies of the label, packaging and *Instructions for Use* to demonstrate that information requirements have been met
- expert opinion
- the design dossier, if applicable.

This information must be held and maintained by the manufacturer and must be made available to the TGA upon request.

Standards

The most common way to demonstrate compliance with the Essential Principles is to meet a standard published by an Australian or International Standards Agency, a Pharmacopoeia, or a similar standard. If the manufacturer chooses to use other voluntary standards they must provide evidence that the chosen standard is applicable to the manufacturer's quality system and that its application satisfies the requirements of the Regulations. The use of such standards is not mandatory.

To comply with Essential Principle 2, the design and construction of a medical device must conform with safety principles, having regard to the 'generally acknowledged state-of-the-art'. Published standards for medical devices are developed through a process of consensus, and therefore are accepted to reflect the generally acknowledged state-of-the-art. This is why standards need to be considered by a manufacturer, even though compliance with any given standard is not compulsory under the legislation.

To ensure that a medical device continues to conform to the state-of-the-art, it is important for the manufacturer to regularly update the risk analysis of the device to account for changes and advances in knowledge. The expectation is that manufacturers will consider the application of standards as part of maintaining their quality management systems.

An update or change to a standard should trigger the manufacturer to undertake a risk assessment of complying or not with the latest standard or version. The outcome of the risk assessment will be a decision to apply the new standard or not. If the manufacturer decides to:

- update to the latest version of the standard, the TGA would expect a plan to be put in place for how and when compliance with the standard will be achieved
- not update to the latest version of the standard, the TGA would expect the manufacturer to hold justification for not complying.

When choosing which standards to apply to each device manufacturers should take into consideration the:

- intended purpose of the device
- environment in which it is likely to be used
- likely users of the device
- generally acknowledged state-of-the-art

Standards that are commonly used by medical device manufacturers are:

- ISO 14971—Application of risk management to medical devices
- ISO 13485—Quality management systems: Requirements for regulatory purposes
- ISO 10993—Biological evaluation of medical devices
- ISO 60601—Medical electrical equipment
- ISO 10282—Single-use sterile rubber surgical gloves

If a standard is used, the manufacturer should include in the technical file for the medical device:

- identification of the standards used
- for each standard used, a statement:
  - that all requirements are met, except for non-applicable requirements, or deviations noted separately
  - of any requirements that are not applicable to the device
  - describing any deviations to the standard that were applied in relation to the device
  - information on any ways in which the standard may have been adapted for application to the particular device (for example, if alternative tests are allowed, which ones are performed in relation to that device).

Manufacturers of medical devices must ensure that their devices comply with all applicable rules and regulations that relate to the operation or supply of their device in Australia, regardless of whether the requirements directly relate to medical regulatory aspects or not. For example, a manufacturer of an electrically powered medical device that has radio communications functionality must comply with each of the appropriate electrical, spectrum, communications, customs, medical, etc. requirements that apply nationally and in each of the states and territories.

Manufacturers should bear in mind that specific export markets may have additional requirements such as evidence of certification/standards compliance or test house evaluations.

Standards orders

The legislation creates a system of non-mandatory Medical Device Standards Orders (MDSOs) and Conformity Assessment Standards Orders (CASOs) that can be used to demonstrate compliance with the Essential Principles or conformity assessment procedures.

Compliance with MDSOs and CASOs is not mandatory, but is one way to establish compliance with Essential Principles. The standards cover topics such as:

- Clinical evidence
- Risk management
- Medical devices required to be sterile
- Quality management systems and quality assurance techniques
- Sterility
- Biological safety and biocompatibility
- Quality assurance techniques for animal tissues and their derivatives

Standards take effect from the date they are published in the Commonwealth Gazette. Details of the current MDSOs and CASOs are available on the TGA website <http://www.tga.gov.au>.

Risk management

When developing a medical device, the Essential Principles relevant to the device must be considered. For example, Essential Principles 1, 3, 4 and 6 require that the medical device achieve its intended performance during normal conditions of use as specified by the manufacturer, and the known and foreseeable risks and any undesirable effects are minimised and acceptable when weighed against the benefits of the intended performance.

These principles in particular require that the device concept be first evaluated using a risk analysis that starts by considering any known patient- or user- related medical hazard (for example, blood loss, electric shock). ISO 14971:2007[2] can provide further guidance on this, but is not a mandatory standard that must be used.

For each hazard, the analysis should list all potential causes and determine the probability and severity of their occurrence. Risk mitigation strategies should then be examined and tested. This type of analysis can and should be performed before beginning product development as it generates the safety requirements for the design specification.

Please note: These Essential Principles outline the Australian requirements. If you intend to supply the medical devices in other countries, it is recommended that you check the regulatory requirements in those countries. For details of the differences between the Australian and the European Union regulatory requirements, please see Section 8. Differences between the Australian and European Union medical device regulatory requirement

Meeting the Essential Principles—General Principl[illegible]

Principle 1—Use of medical devices not to compromise health and safety

From the Therapeutic Goods (Medical Devices) Regulations 2[illegible]—[illegible]hedule 1, Part 1

1. A medical device is to be designed and produced in [illegible]way that ensures that:
   a. the device will not compromise the clinical cond[illegible]or safety of a patient, or the safety and health of the user or any o[illegible]er [illegible]rson, when the device is used on a patient under the conditions [illegible]d fo[illegible]e p[illegible]rposes for which the device was intended and, if applicable, by a[illegible]r with appropriate technical knowledge, experience, educatio[illegible]r tr[illegible]ing; and
   b. any risks associated with the use o[illegible]device are:
      i. acceptable risks when [illegible]ighed against the intended benefit to the patient; and
      ii. compatible wit[illegible]h [illegible]evel of protection of health and safety.

How to demonstrate compliance

A fundamental concept in the d[illegible]sig[illegible]nd production of a medical device is how the device is intended to be safely used and by whom. A [illegible]ufac[illegible]rer is required to undertake a well-reasoned and documented analysis of the foreseeable risks that could occur by using the device and compare these with a well-reasoned and documented analysis of the benefits that would be provided for the patient or user of the medical device. These analyses have to recog[illegible]e that a patient or user's safety is paramount.

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-[illegible]as[illegible]d and documented risk analysis
- a d[illegible]me[illegible]d review of relevant published literature
- [illegible]cumented review of manufacturer's experience with device
- assessing and documenting compliance of the device and its packaging with specifications and standards
- reviewing and documenting the labelling and *Instructions for Use* provided with the device
- reviewing and documenting final release procedures

[2] ISO 14971:2007 specifies a process for a manufacturer to identify the hazards associated with medical devices to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. The requirements are applicable to all stages of the life-cycle of a medical device.

Principle 2—Design and construction of medical devices to conform with safety principles

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 1

2.

1. The solutions adopted by the manufacturer for the design and construction of a medical device must conform with safety principles, having regard to the generally acknowledged state of the art.

2. Without limiting subclause (1), in selecting appropriate solutions for the design and construction of a medical device so as to minimise any risks associated with the use of the device, the manufacturer must:

    a. first, identify hazards and associated risks arising from the use of the device for its intended purpose, and foreseeable misuse of the device; and
    b. second, eliminate, or reduce, these risks as far as possible by adopting a safety of inherently safe design and construction; and
    c. third, if appropriate, ensure that adequate protection measures are taken, including alarms if necessary, in relation to any risks that cannot be eliminated; and
    d. fourth, inform users of any residual risks that may arise due to any shortcomings of the protection measures adopted.

How to demonstrate compliance

The design and construction processes for a medical device need to take account of any foreseeable risks or hazards that may exist, or could be created by the device when it is used as intended by the manufacturer. The design and construction of the device should, wherever possible, eliminate the identified risks or hazards. Where risks or hazards can not be avoided methods must be established to alert and inform users of the medical device.

As for Essential Principle 1, a well-reasoned and documented risk analysis should be developed to demonstrate compliance with Essential Principle 2. It is also important to regularly update the risk analysis of the device to account for changes in knowledge or advances in technology to ensure that the design and construction of the medical device continues to conform to safety principles.

Compliance with the relevant Australian and international standards are generally accepted as meeting subclause (1) of this Essential Principle. However, the manufacturer may choose alternate methods for design, construction and testing. If the device does not comply with any relevant Australian and/or international standards, justification should be provided to explain why the manufacturer has made this decision.

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- a documented review of manufacturer's experience with device
- documented compliance and/or consideration of relevant product safety and performance standards

Principle 3—Medical devices to be suitable for intended purpose

From the *Therapeutic Goods (Medical Devices) Regulations 2002*—Schedule 1, Part 1

3. A medical device must:

    c. perform in the way intended by the manufacturer; and
    d. be designed, produced and packaged in a way that ensures that it is suitable for one or more of the purposes mentioned in the definition of medical device in subsection 41BD (1) of the Act.

How to demonstrate compliance

The work undertaken by the manufacturer could involve, but is not restricted to:

- appropriate test protocols and results to demonstrate that the design, production and packaging of the device enables it to perform as intended
- where the manufacturer makes specific claims in relation to, for example, antimicrobial efficacy of the medical device, appropriate data should support the claims
- where the manufacturer is operating an appropriate and certified quality system, this Essential Principle should be partly addressed by that certification

Principle 4—Long-term safety

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

4. A medical device must be designed and produced in a way that ensures that

   e. the device is used within the period, indicated by the manufacturer, in which the device can be safely used; and
   f. the device is not subjected to stresses that are outside the stresses that can occur during normal conditions of use; and
   g. the device is regularly maintained and calibrated in accordance with the manufacturer's instructions;

   the characteristics and performances mentioned in clause 1, 2 and 3 are not adversely affected.

How to demonstrate compliance

The manufacturer needs to have evidence that the design and production practices used for their medical device have taken into account the following to ensure that the device continues to comply with Essential Principles 1, 2, and 3:

- the expected lifetime of the device
- identified stresses experienced by the medical device during normal use
- any regular maintenance and calibration requirements

Any adverse effects of these stresses must be considered and included in a well-reasoned and documented risk assessment.

The lifetime of a device is considered to include the period prior to first use, and the period (or number of uses) expected or recommended by the manufacturer. Assessment of this can be done by bench testing, simulated shelf life testing and clinical evaluation.

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- assessment of lifetime of the device including bench testing, simulated shelf life testing and clinical evaluation
- a documented review of complaint history
- clinical evidence

Principle 5—Medical devices not to be adversely affected by transport or storage

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 1

5. A medical device must be designed, produced and packed in a way that ensures that the characteristics and performance of the device when it is being used for its intended purpose will not be adversely affected during transport and storage that is carried out taking account of the instructions and information provided by the manufacturer.

How to demonstrate compliance

The work undertaken by the manufacturer could involve, but is not restricted to:

- documented evidence of testing to demonstrate that the design, production and packaging of the device ensure that the device characteristics and performance is not adversely effected during transport and storage
- a documented review of complaint history

Principle 6—Benefits of medical devices to outweigh any undesirable effects

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 1

6. The benefits to be gained from the use of a medical device for the performance intended by the manufacturer must outweigh any undesirable effects arising from its use.

How to demonstrate compliance

To comply with this Essential Principle it is necessary, as part of a well-reasoned risk analysis, to identify and document any undesirable effects from using the device and compare these with the benefits expected to be achieved through the use of the device.

In addition to the risk analysis, manufacturers should provide evidence that the outcomes or conclusions of the risk analysis have been acted on.

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- a documented review of the manufacturer's experience with device

Meeting the Essential Principles—Principles about design and construction

Principle 7—Chemical, physical and biological properties

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

7.1 Choice of materials

In ensuring that the requirements of Part 1 are met in relation to a medical device, particular attention must be given to:

h. the chemical and physical properties of the materials used in the device; and
i. the compatibility between the materials used and biological tissues, cells, body fluids and specimens;

having regard to the intended purpose of the device.

7.1 Choice of materials

A manufacturer must be able to demonstrate that the materials used in the medical device are appropriate, given the intended purpose of the device. For example, a well-reasoned risk analysis should consider toxicity, flammability and biocompatibility risks, and examine if particular labelling or instructions could mitigate any residual risks.

Historical data on materials used in similar devices should be reviewed and included in the documented analysis.

A biological evaluation, based on relevant standards, should be made. It may be possible to limit any testing by considering the results of previous and relevant tests on the same or similar materials used in the same or similar applications.

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- documented analysis and review of historical data on materials used in similar devices
- conducting a biological evaluation based on relevant standards. ISO 10993[3] can provide further guidance on this, but is not a mandatory standard that must be used.

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

7.2 Minimisation of risks associated with contaminants and residues

1. A medical device must be designed, produced and packed in a way that ensures that any risks associated with contaminants and residues that may affect a person who is involved in transporting, storing or using the device, or a patient, are minimised, having regard to the intended purpose of the device.
2. In minimising risks, particular consideration must be given to the likely duration and frequency of any tissue exposure associated with the transportation, storage or use of the device.

7.2 Minimisation of risks associated with contaminants and residues

The contaminants and residues could include solvents, process and sterilisation residues, mould release agents, particulate contamination and fluid spillage. It may be necessary to use particular labelling or instructions supplied with the device to reduce or mitigate some risks if they cannot be eliminated.

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- if necessary, demonstrating that the labelling and *Instructions for Use* supplied with the device inform users of how to reduce or mitigate risks associated with contaminants and residues that cannot be eliminated.

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

7.3 Ability to be used safely with materials etc

1. A medical device must be designed and produced in a way that ensures that the device can be used safely with any material, substance or gas with which the device may come into contact during normal use or use in routine procedures.
2. If the device is intended to be used to administer medicine, it must be designed and produced in a way that ensures that the device:
   a. is compatible with the provisions and restrictions applying to the medicine to be administered; and
   b. allows the medicine to perform as intended.

[3] ISO 10993 is a multi-part standard for the biological evaluation of medical devices. Each part covers a different aspect of the evaluation.

7.3 Ability to be used safely with materials etc

The analysis should also consider any specified materials that may be required to clean, disinfect or sterilise the medical device, as well as the effects of these materials during these procedures.

It may be necessary to use particular labelling or *Instructions for Use* supplied with the device to reduce or mitigate some risks associated with the interactions of these materials, substances or gases with the device.

Warnings are required if it is foreseeable that an interaction between the device and incompatible materials could occur. These warnings should be included in the labelling or *Instructions for Use* included with the device.

If the device is intended to administer medicine, the design, production and packaging processes should take into account any provisions or restrictions for the medicine as well as ensuring that the medicine can perform as intended.

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- if necessary, demonstrating that the labelling and *Instructions For Use* supplied with the device informs users of how to reduce or mitigate risks associated with the use of the device with materials that cannot be eliminated
- labelling and *Instructions For Use* to include warnings relating to a foreseeable interaction between a device and an incompatible material
- if the device is to administer a medicine, demonstrating that the design, production and packaging of the device take into account any provisions or restrictions for the medicine

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

7.4 Verification of incorporated substances

1. If a medical device incorporates, or is intended to incorporate, as an integral part, a substance that, if used separately, might be considered to be a medicine that is intended to act on a patient in a way that is ancillary to the device:
   a. the safety and quality of the substance must be verified in accordance with the requirements for medicines; and
   b. the ancillary action of the substance must be verified having regard to the intended purpose of the device.
2. For the purposes of this clause, any stable derivative of human blood or human plasma is considered to be a medicine.

7.4 Verification of incorporated substances

A manufacturer of a medical device that contains a medicine as an integral part must show that the device components and the medicinal substance function together to achieve the intended purpose.

In addition, the manufacturer will need to provide evidence that the medicine meets all the necessary Australian regulatory requirements to be supplied as a medicine.

For more information, see Section 14. Medical devices incorporating a medicine and Section 15. Medical devices containing materials of animal, microbial or recombinant origin.

The work undertaken by the manufacturer could involve, but is not restricted to:

- evidence to demonstrate that the 'substance-device combination' works together as intended (for example, device specific tests to establish drug elution profile, coating integrity, device performance, degradation, particulate release)
- evidence of stability of the medicinal substance establishing that 'substance' incorporated in the device remains stable during manufacturing, transportation and storage (for example, sustained activity of regulated substance, evidence of tracking relevant characteristics during storage)

- evidence that the medicinal substance to be incorporated meets current relevant Australian regulatory requirements. The device manufacturer should include evidence of quality of manufacture and safety of the medicinal substance.

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

7.5 Minimisation of risks associated with leaching substances

A medical device must be designed and produced in a way that ensures that any risks associated with substances that may leach from the device are minimised.

7.5 Minimisation of risks associated with leaching substances

This Essential Principle deals specifically with leaching, which in this context means the removal of the soluble contents of a medical device by running water, another liquid or body fluids, leaving the insoluble portion behind and related to the use of the device. Examples of leachables are:

- additives
- sterilant residues
- process residues
- degradation products
- solvents
- plasticisers
- lubricants
- colouring agents
- fillers
- monomers

The design and production processes should take into account the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any foreseeable effects of a substance that could leach from a medical device and the effects it could have on users of the device and other people who may come in contact with the device, during the intended use of the device as specified in the *Instructions for Use*.

Please note: This is different from Essential Requirement 7.5 in the European Essential Requirements, which deals specifically with leaking—the escape, entry, or passage of something through a breach or flaw.

The work undertaken by the manufacturer could involve, but is not restricted to:

- well-reasoned and documented risk analysis addressing issues such as:
  - Does the medical device come into contact with water or another liquid?
  - Does the medical device contain any substances capable of leaching?
  - Are any of the substances that are capable of leaching from the device hazardous to humans?
  - Is the concentration of the leached hazardous substances like to approach the limit for toxic effects?

- biological evaluation including testing. ISO 10993[4] can provide further guidance on this, but is not a mandatory standard that must be used
- in vivo toxicokinetic studies where relevant. ISO 10993[3] Part 16 and 17 can provide further guidance on this, but is not a mandatory standard that must be used
- in vitro testing of the medical device (for example, assessing the kinds and levels of compounds leached from the medical device by physiologic media that contacts the device during normal use, such as blood).

From the *Therapeutic Goods (Medical Devices) Regulations 2002*—Schedule 1, Part 2

7.6 Minimisation of risks associated with ingress or egress of substances

A medical device must be designed and produced in a way that ensures that any risks associated with unintentional ingress of substances into, or unintentional egress of substances out of, the device are minimised, having regard to the nature of the environment in which the device is intended to be used.

7.6 Minimisation of risks associated with ingress or egress of substances

For the purposes of this Essential Principle, unintentional ingress means substances that are not intended to enter the device and unintentional egress means substances that are not intended to leave the device.

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- a preclinical study evaluating the biological safety of the device
- biological evaluation including testing. ISO 10993 can provide further guidance on this, but is not a mandatory standard that must be used
- in vitro testing of the medical device (for example, assessing the kinds and levels of compounds leached from the medical device by physiologic media that contacts the device during normal use, such as blood).

Principle 8—Infection and microbial contamination

From the *Therapeutic Goods (Medical Devices) Regulations 2002*—Schedule 1, Part 2

8.1 Minimisation of risk of infection and contamination

1. A medical device must be designed and produced in a way that ensures that the risk of infection to a patient, a user, or any other person, is eliminated or minimised.
2. The device must be designed in a way that:
   a. allows it to be easily handled; and
   b. if appropriate, minimises contamination of the device or specimen by the patient, user or other person by the device or specimen.

8.1 Minimisation of risk of infection and contamination

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- compliance with the MDSO (Standards for Medical Devices Required to be Sterile)

[4] ISO 10993 is a multi-part standard for the biological evaluation of medical devices. Each part covers a different aspect of the evaluation.

- sterilisation validation reports, bioburden data and evidence demonstrating the control of tissue of animal origin
- preservative efficacy reports for multi-dose, preserved medical devices (for example contact lens solutions) to demonstrate effectiveness of the preservative system, and to verify the expiry date and the open (in-use) shelf life assigned to the device
- verification of the integrity of the packaging system for medical devices packaged in a manner that minimises the risk of in-use microbial contamination, to verify the expiry date and the open (in-use) shelf life assigned to the device
- if the device is to be reprocessed, manufacturers must include instructions for the reprocessing in th *Instructions for Use*—for more information please see Essential Principle 13.4: *Instructions for use*

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, ar 2

8.2 Control of animal, microbial or recombinant tissues, tissue derivative ls and other substances

1. This clause applies in relation to a medical device that conta
   a. Tissues, tissue derivatives, cells or substances of anim rigin that have been rendered non viable; and
   b. tissues, tissue derivatives, cells or substance mic bial or recombinant origin.
2. If the tissues, tissue derivatives, cells or s ces originated from animals, the animals must have been subjec d to appr riate veterinary controls and supervision, having regard to the in de of the tissues, cells or substances.
3. If the medical device contains tiss tissue derivatives, cells or substances of animal origin, a record must be kept of the country of origin of each animal from which the tissues, tis derivatives, cells or substances originated.
4. The processing, prese tion sting and handling of tissues, tissue derivatives, cells or substances a microbial or recombinant origin must be carried out in a way that ens s the highest standards of safety for a patient, the user of the device, and any other person.
5. In parti lar e p duction process must implement validated methods of elimina or activation, in relation to viruses and other transmissible agent

8.2 Control of animal nic bial or recombinant tissues, tissue derivatives, cells and other substances

The work under n by e manufacturer could involve, but is not restricted to:

- evidence the v ous controls, supervisory procedures, records and processing requirements
  - for a ina ources Conformity Assessment Standards Order No. 2 and ISO 22442[5] can provide further g lance on this, but are not mandatory standards that must be used
- iding sufficient detail in the sourcing, handling and manufacturing process to demonstrate minimisation of the risk of transmitting Transmissible Spongiform Encephalopathies (TSEs)—refer to the TGA guidelines available on the TGA website in relation to minimising the risk of transmitting TSEs
- for microbial and recombinant sources, detailing the materials used in the manufacturing process including confirmation or not of those materials that are known to be sourced from both animal and non-animal sources.

[5] ISO 22442 is a multi-part standard for medical devices utilising animal tissues and their derivatives. Each part covers a different aspect of the evaluation.

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

8.3 Medical devices to be supplied in a sterile state

1. This clause applies in relation to a medical device that is intended by the manufacturer to be supplied in a sterile state.
2. The device must be designed, produced and packed in a way that ensures that the device is sterile when it is supplied, and will remain sterile, if stored and transported in accordance with the directions of the manufacturer, until the protective packaging is opened or damaged.
3. The device must be produced and sterilised using an appropriate validated method.
4. The device must be produced in appropriately controlled conditions.

8.3 Medical devices to be supplied in a sterile state

The work undertaken by the manufacturer could involve, but is not restricted to:

- compliance with the appropriate clean room standards for the manufacturing premises in which the device is manufactured
- compliance with packaging standards and/or results of package strength and integrity testing, as appropriate for the device
- protocols for validation of the sterilisation cycle in accordance with specific standards for the sterilisation method used and reports of testing to demonstrate compliance with the protocols and acceptable outcomes of the validation process. Medical Device Standards Order No. 3 can provide further guidance on this, but is not a mandatory standard order that must be used.

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

8.4 Medical devices to be supplied in a non sterile state

1. A medical device that is intended by the manufacturer to be supplied in a non-sterile state must be packed in a way that ensures that the device maintains the level of cleanliness stipulated by the manufacturer.
2. If the device is intended to be sterilised before it is used, the device must be packed in a way that:

   a. ensures that the risk of microbial contamination is minimised; and
   b. is suitable, having regard to the method of sterilisation that the manufacturer indicates is to be used for the device.

3. The device must be produced in appropriately controlled conditions.

8.4 Medical devices to be supplied in a non-sterile state

The work undertaken by the manufacturer could involve, but is not restricted to:

- compliance with the appropriate standards for air quality of the manufacturing premises in which the device is manufactured
- compliance with packaging standards and/or results of package strength and integrity testing, as appropriate for the device, to ensure that the initial cleanliness of the device prior to sterilisation is maintained
- results of studies demonstrating that the packaging can withstand the sterilisation process, and/or is permeable to the sterilising agent, and capable of maintaining sterility for a defined period after the sterilisation process.

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

8.5 Distinction between medical devices supplied in sterile and non-sterile state

If a medical device is supplied in both a sterile state and a non-sterile state, the information provided with the device must clearly indicate whether the device is in a sterile state or a non sterile state.

8.5 Distinction between medical devices supplied in a sterile and non-sterile state

The work undertaken by the manufacturer could involve, but is not restricted to:

- the labelling and *Instructions for Use* provided with the sterile and non-sterile device must clearly indicate in which state the device is supplied
- labelling should be in compliance with Essential Principle 13.

Principle 9—Construction and environmental properties

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

9.1 Medical devices intended to be used in combination with other devices or equipment

A medical device that is intended by the manufacturer to be used in combination with another medical device or other equipment (including a connection system) must be designed and produced in a way that ensures that:

a. the medical device, and any other device or equipment with which it is used, operate in a safe way; and
b. the intended performance of the device, and any other device or equipment with which it is used, is not impaired.

9.1 Medical devices intended to be used in combination with other medical equipment

The work undertaken by the manufacturer could involve, but is not restricted to:

- well-reasoned and documented risk analysis considering all the other devices meant to be used for the intended purpose of the device
- documenting how the device is designed for use with other medical devices and evidence of appropriate testing procedures that demonstrate that the combination of medical devices allows all medical devices to operate safely and without any impairment to the intended performance
- addressing the use of the device in combination with another medical device as part of the clinical evidence
- providing all the information for the use of the device in combination with another medical device as a part of the *Instructions for Use*
- for medical electrical systems, IEC 60601-1-1[6] can provide further guidance, but is not a mandatory standard that must be used

[6] IEC 60601-1-1 is a standard relating to medical electrical equipment and safety requirements for medical electrical systems.

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

9.2 Minimisation of risks associated with use of medical devices

A medical device must be designed and produced in a way that ensures that, as far as practicable, the following risks are removed or minimised:

a. the risk of injury arising from the physical features of the device;
b. any risks associated with reasonably foreseeable environmental conditions;
c. the risk of reciprocal interference involving other devices that are normally used in an investigation or treatment of the kind for which the device is intended to be used;
d. any risks arising if maintenance or calibration of the device is not possible;
e. any risks associated with the ageing of materials used in the device;
f. any risks associated with loss of accuracy of any measuring or control mechanism of the device;
g. the risk of fire or explosion occurring during normal use of the device, and in the event of a single fault condition, especially if the device is intended to be exposed to flammable substances or substances that could cause combustion;
h. the risks associated with disposal of any waste substance

9.2 Minimisation of risks associated with the use of medical devices

The design and production processes should take account of the circumstances or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any of the listed foreseeable risks when the device is used.

For each risk, the analysis should list all potential causes and determine the probability and severity of their occurrence. Risk-mitigation strategies should then be examined and tested.

The most common way to demonstrate compliance with the Essential Principles is to meet a standard published by an Australian or International Standards Authority, a Pharmacopoeia, or a similar standard.

More information on risk management and standards is available in the Overview of this section.

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- documented compliance or consideration of relevant product safety and performance standards

Principle 10—Medical devices with a measuring function

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

10 Medical devices with a measuring function

1. A medical device that has a measuring function must be designed and produced in a way that ensures that the device provides accurate, precise and stable measurements within the limits indicated by the manufacturer and having regard to the intended purpose of the device.
2. The measurement, monitoring and display scale of the device must be designed and produced in accordance with ergonomic principles, having regard to the intended purpose of the device.
3. The measurements made by the device must be expressed:
   a. in Australian legal units of measurement; or
   b. if the device measures a physical quantity for which no Australian legal unit of measurement has been prescribed under the *National Measurement Act 1960*, in units approved by the Secretary for the particular device.

How to demonstrate compliance

Essential Principle 10 only applies to medical devices with a measuring function (as defined in Regulation 1.4). Other kinds of measurement are not covered by Essential Principle 10. For examples and details please see Section 4. Classification of medical devices.

The device must perform a measuring function that provides an absolute quantitative measurement (legal units or reference to a fixed reference) of a physiological/anatomical parameter (or energy/substance delivered/removed from the body) in which the accuracy is critical for the intended purpose of the device.

Manufacturers are expected to consider product specific standards, pharmacopeial monographs, and applicable guidance documents in order to ensure the device is designed and produced in an appropriate way. For example, the manufacturer of a measuring cup or spoon might refer to the relevant pharmacopeial monograph in order to determine the specification and accuracy of the device. Manufacturers may also refer to production process controls that ensure the measuring function is accurate and reliable. This will usually involve calibration against an appropriate reference standard.

Ergonomic principles concerned with how a user of the device interprets the outputs from the device and uses the device must be incorporated in the design and production processes for the device. The usability standards: IEC 62366: *Medical devices—Application of usability engineering to medical devices*, and IEC 60601-1-6: *Medical electrical equipment—Part 1-6: General requirements for basic safety and essential performance—Collateral standard: Usability* is directly relevant to Essential Principle 10(2).

The measurement outputs must be in Australian legal or otherwise approved units.

Principle 11—Protection against radiation

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

11.1 Minimisation of exposure to radiation

A medical device must be designed and produced in a way that ensures that the exposure of a patient, the user or any other person, to radiation is minimised, having regard to the levels of radiation required to enable the device to perform its therapeutic and diagnostic functions and the intended purpose of the device.

11.1 Minimisation of exposure to radiation

This Essential Principle is intended to cover all forms of radiation.

Australian and international standards related to radiation exposure limits and other applicable legislation (for example, Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) and Australian Communications and Media Authority (ACMA) requirements and state/territory radiation protection legislation) are also relevant to Essential Principle 11.

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis
- evidence of appropriate radiation shielding
- Where can I find more information?
- ARPANSA: <http://www.arpansa.gov.au>
- ACMA: <http://www.acma.gov.au>
- additional information is also provided in Section 13. Active medical devices.

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

11.2 Medical devices intended to emit radiation

1. This clause applies in relation to a medical device that is intended by the manufacturer to emit hazardous levels of visible or invisible radiation because the emission is necessary for a specific medical purpose, the benefit of which is considered to outweigh the risks inherent in the emission.
2. The device must be designed and produced in a way that ensures that the user can control the level of the emission.
3. The device must be designed and produced in a way that ensures the reproducibility and tolerance of relevant variable parameters.
4. If practicable, the device must be fitted with a visual indicator or an audible warning, or both, that operates if potentially hazardous levels of radiation are emitted.

11.2 Medical devices intended to emit radiation

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- demonstrating that appropriate control and indicator mechanisms have been incorporated into the device to ensure the operational consistency of variable parameters relevant to the emission of the radiation and the operation of the device
- evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis.

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

11.3 Minimisation of exposure to unintended radiation

A medical device must be designed and produced in a way that ensures that the exposure of a patient, the user, or any other person, to the emission of unintended, stray or scattered radiation is minimised.

11.3 Minimisation of exposure to unintended radiation

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

11.4 Operating instructions

The operating instructions for a medical device that emits radiation must include detailed information about the following matters:

a. the nature of the radiation emitted;
b. the means by which patients and users can be protected from the radiation;
c. ways to avoid misusing the device;
d. ways to eliminate any risks inherent in the installation of the device.

1.4 Operating instructions

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- the *Instructions for Use* for the device must include particular information about the emitted radiation, appropriate protection measures, foreseeable misuse of the device and eliminating foreseeable risks arising from the installation of the device

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

11.5 Medical devices intended to emit ionising radiation—additional requirements

1. This clause applies, in addition to clauses 11.1 to 11.4, in relation to a medical device that is intended by the manufacturer to emit ionising radiation.
2. The device must be designed and produced in a way that ensures that, practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be controlled and varied, having regard to the intended purpose of the device.
3. If the device is intended to be used for diagnostic radiology, the device must be designed and produced in a way that ensures that when used in relation to a patient for a purpose intended by the manufacturer:
   a. the device achieves an appropriate image or output quality for that purpose; and
   b. the exposure of the patient, or the user, to radiation is minimised.
4. If the device is intended to be used for therapeutic radiology, the device must be designed and produced in a way that ensures that the delivered dose of radiation, the type and energy of the radiation beam and, if appropriate, the energy distribution of the radiation beam, can be reliably controlled and monitored.

11.5 Medical devices intended to emit ionising radiation—additional requirements

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis

Principle 12—Medical devices connected to or equipped with an energy source

Australian and international standards related to electromedical safety, electromagnetic compatibility, medical device software and active implantable medical devices are also relevant to Essential Principle 12.

Standards that may provide further guidance, but are not mandatory standards that must be used include:

- IEC 60601: a family of standards relating to the safety and performance of medical electrical equipment
- IEC 62304: Medical device software—Software life cycle processes
- AS ISO 9918: Capnometers for use with humans—Requirements
- AS ISO 9703: Anaesthesia and respiratory care alarm signals
- ISO 5356: Anaesthetic and respiratory equipment

Additional information on active medical devices is provided in Section 13. Active medical devices.

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

12.1 Medical devices incorporating electronic programmable systems

A medical device that incorporates an electronic programmable system must be designed and produced in a way that ensures that:

a. the performance, reliability, and repeatability of the system are appropriate for the intended purpose of the device; and
b. any consequent risks associated with a single fault condition in the system are minimised.

12.1 Medical devices incorporating electronic programmable systems

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

12.2 Safety dependent on internal power supply

1. This clause applies in relation to a medical device if the safety of a patient on whom the device is to be used will depend on an internal power supply for the device.
2. The device must be fitted with a means of determining the state of the power supply.

12.2 Safety dependent on internal power supply

This Essential Principle only applies if the safety of the patient will depend on the internal power supply for the device. If that is the case, there should be some form of indication (if it is possible) on the device showing the state of the internal power supply. Moreover there should be visual and/or audible alarms, if the state of the internal power supply goes below a certain range.

The work undertaken by the manufacturer could involve, but is not restricted to:

- addressing the safety issues as a part of the risk analysis and indicating what control measures are in place to reduce the risk
- documenting how the visual indication showing state of the internal power supply and alarms are designed and tested as part of the technical documentation
- providing information about the visual indication of the internal power supply and alarms as a part of the *Instructions for Use*

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

12.3 Safety dependent on external power supply

1. This clause applies in relation to a medical device if the safety of a patient on whom the device is to be used will depend on an external power supply for the device.
2. The device must be fitted with an alarm system that indicates whether a power failure has occurred.

12.3 Safety dependent external power supply

This Essential Principle only applies if the safety of the patient will depend on the external power supply for the device. For example, if there is an external power supply to a ventilator or anaesthetic machine and a power failure occurs, there should be visual and audible alarms.

External power supplies include:

- electrical
- battery powered
- gas powered
- pneumatic
- liquid or solid fuels

The work undertaken by the manufacturer could involve, but is not restricted to:

- addressing the safety issue as a part of the risk analysis and indicating what control measures are in place to reduce the risk to the patient
- documenting how the visual and audible alarms are designed and tested as a part of the technical documentation
- providing information about the visual and audible alarms as a part of the *Instructions for Use*

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

12.4 Medical devices intended to monitor clinical parameters

A medical device that is intended by the manufacturer to be used to monitor one or more clinical parameters of a patient must be fitted with an appropriate alarm system to warn the user if a situation has developed that could lead to the death of the patient or a severe deterioration in the state of the patient's health

2.4 Medical devices intended to monitor clinical parameters

Medical devices that monitor variations in cardiac performance, respiration and activity of the nervous system are relevant examples for this Essential Principle.

The work undertaken by the manufacturer could involve, but is not restricted to:

- as part of the risk analysis, indicating what control measures are in place to reduce the risk to the patient if the variation in any physiological parameters monitored are of a kind that could result in immediate danger to the patient
- documenting how the alarm system is designed and tested as a part of the technical documentation
- providing information about the alarm system as a part of the *Instructions for Use*

IEC 60601-1-8[7] can provide further guidance, but is not a mandatory standard that must be used.

[7] IEC 60601-1-8 is a standard relating to medical electrical equipment and general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

12.5 Minimisation of risk of electromagnetic fields

A medical device must be designed and produced in a way that ensures that the risk of an electromagnetic field being created that could impair the operation of other devices or equipment being used in the vicinity of the medical device is minimised.

12.5 Minimisation of risk of electromagnetic fields

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

12.6 Protection against electrical risks

A medical device must be designed and produced in a way that ensures that, as far as possible, when the device is installed correctly, and the device is being used for an intended purpose under normal conditions of use and in the event of a single fault condition, patients, users, and any other persons, are protected against the risk of accidental electric shock.

12.6 Protection against electrical risks

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

12.7 Protection against mechanical risks

A medical device must be designed and produced in a way that ensures that a patient, the user, and any other person, is protected against any mechanical risks associated with the use of the device.

12.7 Protection against mechanical risks

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

12.8 Protection against risks associated with vibration

1. A medical device must be designed and produced in a way that ensures that any risks associated with vibrations generated by the device are minimised.
2. If vibrations are not part of the intended performance of the device, particular attention must be given to relevant technical progress, and the available means, for limiting vibrations, particularly at source.

12.8 Protection against risks associated with vibration

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

12.9 Protection against risks associated with noise

1. A medical device must be designed and produced in a way that ensures that any risks associated with noise emitted by the device are minimised.
2. If noise is not part of the intended performance of the device, particular attention must be given to relevant technical progress, and the availabl[illegible]ar for reducing the emission of noise, particularly at source.

12.9 Protection against risks associated with noise

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis of the significance of any fo[illegible]ble noise emitted by the device, either intentional or unintentional
- evidence of appropriate testing to confirm the design and productio[illegible]sions resulting from the risk analysis

From the Therapeutic Goods (Medical De[illegible]egulations 2002—Schedule 1, Part 2

12.10 Protection against risks associate[illegible] terminals and connectors

A medical device that is [illegible]nded by the manufacturer to be connected to an electric, gas, hydraulic pne[illegible]atic or other energy supply must be designed and produced in a w[illegible]t ensures that any risks to the user associated with the handling of a te[illegible]r connector on the device, in relation to the energy supply, are mi[illegible]ise

12.10 Protection against risks a[illegible]ciated with terminals and connectors

The work undertaken by the [illegible]nufacturer could involve, but is not restricted to:

- a well-reasoned an[illegible]mented risk analysis
- evidence of [illegible] testing to confirm the design and production decisions resulting from the risk analysis

[illegible]om the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

12.11 Protection against risks associated with heat

A medical device must be designed and produced in a way that ensures that, during normal use, any accessible part of the device (other than any part intended by the manufacturer to supply heat or reach a given temperature), and any area surrounding an accessible part of the device, does not reach a potentially dangerous temperature.

12.11 Protection against risks associated with heat

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

12.12 Protection against risks associated with administration of energy or substances

1. This clause applies in relation to a medical device that is intended by the manufacturer to be used to administer energy or a substance to a patien
2. The device must be designed and produced in a way that ensures that:
   a. the delivered rate and amount of energy, or of the substance, can be set and maintained accurately to ensure the safety of the patient and the user; and
   b. as far as possible, the accidental release of dangerous levels of energy or of the substance is prevented.
3. The device must be fitted with a means of indicating or, if appropriate, preventing inadequacies in the rate and amount of energy, or of the substance, administered that might cause danger to the patient, the user or any other person.
4. The functions of each control and indicator on the device must be clearly specified on the device.
5. If the instructions for the operation of the device, or the operating or adjustment parameters for the device are displayed by means of a visual system incorporated into the device, the instructions or parameters must be able to be understood by the user and, if appropriate, the patient.

12.12 Protection against risks associated with administration of energy or substances

The work undertaken by the manufacturer could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- ensuring that operational information displayed by the device is clearly understandable
- evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

12.13 Active implantable medical devices

1. An active implantable medical device must display a code that can be used to identify:
   a. the type of device; and
   b. the manufacturer of the device; and
   c. the year of manufacture of the device.
2. The code must be able to be read without the need for surgery to the person in whom the device is implanted.

12.13 Active implantable medical devices

The format of the code is determined by the manufacturer.

One way to display this code is to inscribe the device using radio-opaque materials that can be viewed on an x-ray of the patient. For example, to enable medical staff to re-program a patient's implantable pacemaker in an emergency situation, an x-ray of the patient can be taken to read the radio-opaque code shown on the pacemaker, and this code can be used to determine the make and model of a suitable programming device.

The work undertaken by the manufacturer could involve, but is not restricted to:

- documenting how a unique code is assigned to the device
- documenting how the code is affixed to the device during manufacture
- documenting how the code can be read without the need for surgery (possibly as part of the *Instructions for Use*)
- producing technical drawings showing the artwork for the code on the device

Principle 13—Information to be provided with medical devices

From the Therapeutic Goods (Medical Devices) Regulations 20[illegible] Schedule 1, Part 2

13.1 Information to be provided with medical device[illegible] general

1. The following information must be provided with a medical device:
   a. information identifying the device;
   b. information identifying the manufacturer of the device;
   c. information explaining how to use the device safely;

   having regard to the training and knowledge of potential users of the device.
2. In particular:
   a. the information required by clause 13.3 must be provided with a medical device; and
   b. if *instructions for use* of the device are required under subclause 13.4, the information identified in subclause 13.4 (3) must be provided in those instructions.
3. The information
   a. must be provided in English; and
   b. may also be provided in any other language.
4. The format, content and location of the information must be appropriate for the device and its intended purpose.

   Any number, letter, symbol, or letter or number in a symbol, used in the information must be legible and at least 1 millimetre high.

   If a symbol or identification colour that is not included in a medical device standard is used in the information provided with the device, or in the *instructions for use* of the device, the meaning of the symbol or identification colour must be explained in the information provided with the device or the *instructions for use* of the device.

13.1 General information to be provided with a medical device

The work undertaken by the manufacturer could involve, but is not restricted to:

- ensuring that the label, packaging, and *Instructions for Use* meet the information requirements
- copies of the label, packaging, and *Instructions for Use* should be kept with the documentation that a manufacturer assembles and maintains to demonstrate compliance with the Essential Principles.

For more information on labelling and *Instructions for Use*, please see Section 12. Information about a medical device.

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

13.2 Information to be provided with medical devices — location

1. Unless it is impracticable or inappropriate to do so, the information required to be provided with a medical device must be provided on the device itself.
2. If it is not practicable to comply with subclause (1) in relation to the provision of the information, the information must be provided:
   a. on the packaging used for the device; or
   b. in the case of devices that are packaged together because individual packaging of the devices for supply is not practicable — on the outer packaging used for the devices.
3. If it is not practicable to comply with subclause (1) or (2) in relation to the provision of the information required under subregulation 10.2.1(1) or clause 13.3, the information must be provided on a leaflet supplied with the device.
4. If it is not practicable to comply with subclause (1) or (2) in relation to the provision of the information required under clause 13.4, the information must be provided in a printed document or using other appropriate media.

13.2 Location of information to be provided with a medical device

The work undertaken by the manufacturer could involve, but is not restricted to:

- ensuring that the label, packaging and *Instructions for Use* meet the information requirements
- copies of the label, packaging and *Instructions for Use* should be kept with the documentation that a manufacturer assembles and maintains to demonstrate compliance with the Essential Principles.

For more information on labelling and *Instructions for Use*, please see Section 12. Information about a medical device.

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

13.3 Information to be provided with medical devices — particular requirements

The information mentioned in the following table must be provided with a medical device.

Item	Information to be provided
1	The manufacturer's name, or trading name, and address
2	The intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used (if this information is not obvious)
3	Sufficient information to enable a user to identify the device, or if relevant, the contents of packaging
4	Any particular handling or storage requirements applying to the device
5	Any warnings, restrictions, or precautions that should be taken, in relation to use of the device
6	Any special operating instructions for the use of the device

7	If applicable, an indication that the device is intended for a single use only
8	If applicable, an indication that the device has been custom-made for a particular individual and is intended for use only by that individual or health professional
9	If applicable, an indication that: a) if the device is a medical device other than an IVD medical device—the device is intended for pre-market clinical investigation; or b) if the device is an IVD medical device—the devices is intended for performance evaluation only
10	For a sterile device, the word 'STERILE' and information about the method that was used to sterilise the device
11	The batch code, lot number or serial number of the device
12	If applicable, a statement of the date (expressed in a way that clearly identifies the month and year) up to which the device can be safely used
13	If the information provided with the device does not include the information mentioned in item 12 — a statement of the date of manufacture of the device (this may be included in the batch code, lot number or serial number of the device, provided the date is clearly identifiable)
14	If applicable, the words 'For export only'

13.3 Particular requirements

The work undertaken by the manufacturer could involve, but is not restricted to:

- ensuring that the label, packaging, and *Instructions for Use* meet the information requirements
- copies of the label, packaging and *Instructions for Use* should be kept with the documentation that a manufacturer assembles and maintains to demonstrate compliance with the Essential Principles.

For more information on labelling and *Instructions for Use*, please see Section 12. Information about a medical device.

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

Instructions for use

2. Instructions for the use of a medical device must be provided with the device.
2. However, instructions for the use of a medical device need not be provided with the device, or may be abbreviated, if:
   a. the device is a Class I medical device, a Class IIa medical device or a Class 1 IVD medical device; and
   b. the device can be used safely for its intended purpose without instructions.
3. Instructions for the use of a medical device must include information mentioned in the following table that is applicable to the device.

Item	Information to be provided
1	The manufacturer's name, or trading name, and address

2 The intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used

3 Information about any risk arising because of other equipment likely to be present when the device is being used for its intended purpose (for example, electrical interference from electro-surgical devices or magnetic field interference from magnetic resonance imaging devices)

4 Information about the intended performance of the device and any undesirable side effects caused by use of the device

5 Any contra-indications, warnings, restrictions, or precautions that may apply in relation to use of the device

6 Sufficient information to enable a user to identify the device, or if relevant, the contents of packaging

7 Any particular handling or storage requirements applying to device

8 If applicable, an indication that the device is intended for a single use only

9 If applicable, an indication that the device has been custom-made for a particular individual and is intended for use only by that individual or health professional

10 If applicable, an indication that the device is intended to be used only for clinical or performance investigations before being supplied

a) if the device is a medical device other than an IVD medical device — the device is intended for pre-market clinical investigation; or
b) if the device is an IVD medical device — the device is intended for performance evaluation only

11 For a sterile device, the word 'STERILE' and information about the method that was used to sterilise the device

12 For a device that is intended by the manufacturer to be supplied in a sterile state:

a) an indication that the device is sterile; and
b) information about what to do if sterile packaging is damaged; and
c) if appropriate, instructions for resterilisation of the device

13 For a medical device that is intended by the manufacturer to be sterilised before use — instructions for cleaning and sterilising the device which, if followed, will ensure that the device continues to comply with the applicable provisions of the Essential Principles

14 Any special operating instructions for the use of the device

15 Information to enable the user to verify whether the device is properly installed and whether it can be operated safely and correctly, including details of calibration (if any) needed to ensure that the device operates properly and safely during its intended life

16 Information about the nature and frequency of regular and preventative maintenance of the device, including information about the replacement of consumable components of the device during its intended life

17 Information about any treatment or handling needed before the device can be used

18 For a device that is intended by the manufacturer to be installed with, or connected to, another medical device or other equipment so that the device can operate as required for its intended purpose — sufficient information about the device to enable the user to identify the appropriate other medical device or equipment that will ensure a safe combination

19 For an implantable medical device — information about any risks associated with its implantation

20 For a reusable device:

a) information about the appropriate processes to allow use of the device (including information about cleaning, disinfection, packaging and, if appropriate, resterilization of the device); and
b) an indication of the number of times the device may be safely reused

21 For a medical device that is intended by the manufacturer to emit radiation for medical purposes — details of the nature, type, intensity and distribution of the radiation emitted

22 Information about precautions that should be taken by a patient and the user if the performance of the device changes

23 Information about precautions that should be taken by a patient and the user if it is reasonably foreseeable that use of the device will result in the patient or user being exposed to adverse environmental conditions

24 Adequate information about any medicinal product that the device is designed to administer, including any limitations on the substances that may be administered using the device

25 Information about any medicine (including any stable derivative of human blood or blood plasma) that is incorporated, or is intended to be incorporated, into the device as an integral part of the device

25A For a medical device, other than an IVD medical device, information about any tissues, tissue derivatives, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin that are included in the device

26 Information about precautions that should be taken by a patient and the user if there are special or unusual risks associated with the disposal of the device

27 Information about the degree of accuracy claimed if the device has a measuring function

28 Information about any particular facilities required for use of the device or any particular training or qualifications required by the user of the device

29 For an IVD medical device , information (including, to the extent practicable, drawings and diagrams) about the following:

a) the scientific principle (the 'test principle') on which the performance of the IVD medical device relies;
b) specimen type, collection, handling and preparation;
c) reagent description and any limitations (for example, use with a dedicated instrument only);
d) assay procedure including calculations and interpretation of results;
e) interfering substances and their effect on the performance of the assay;
f) analytical performance characteristics, such as sensitivity, specificity, accuracy and precision;
g) clinical performance characteristics, such as sensitivity and specificity;
h) reference intervals, if appropriate;
i) any precautions to be taken in relation to substances or materials that present a risk of infection

13.4 *Instructions for use*

The work undertaken by the manufacturer could involve, but is not restricted to:

- ensuring that the label, packaging and *Instructions for Use* meet the information requirements
- copies of the label, packaging and *Instructions for Use* should be kept with the documentation that a manufacturer assembles and maintains to demonstrate compliance with the Essential Principles.

For more information on labelling and *Instructions for Use* please see Section 12. Information about a medical device.

Principle 14—Clinical evidence

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

14 Clinical evidence

Every medical device requires clinical evidence, appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the Essential Principles.

What does this section mean?

The TGA expects manufacturers to hold evidence that demonstrates that:

- the medical device achieves its intended purpose(s) during normal conditions of clinical use
- the known and foreseeable clinical risks and any adverse effects have been minimised
- the risk of using the medical device is acceptable when weighed against the benefits inherent in the intended purpose(s)
- any clinical claims about the device's performance and safety (for example on the label and the *Instructions for Use*) are supported by clinical data

What does clinical evidence look like?

Clinical evidence may comprise:

- Full clinical study reports for the device in question used for the intended purpose(s) claimed, or reports for a similar device with reasoned argument as to why the safety and performance of that device may be

extrapolated to the device under assessment—paying particular attention to the intended purpose(s). Full study reports means complete reports, not publications.

- A literature review for such devices used for similar intended purpose(s) as the device under assessment, with a documented search strategy including databases searched, search terms used and any inclusion and exclusion criteria applied, in sufficient detail to enable the search to be reproduced if desired. This demonstrates an adequate review of current knowledge about a particular product or therapy in general. Then a critical discussion of the papers revealed by the search must be undertaken with particular emphasis on how the publications demonstrate safety and performance of the device under assessment for the indications claimed (i.e. in terms of similarity, predicates, the actual device, etc.).
- Post-market data of the specific device under assessment, or a similar or predicate device. These data may include adverse event or complaint information, for example.
- If there are no actual clinical data for the specific device, depending upon the nature of it, it may be possible to provide a full clinical justification for why clinical evidence is either not required, or only minimally required. Typically, this involves referencing the performance of a predicate or similar marketed device and critically examining each change or difference in terms of materials, design, clinical use and their likely impact on safety and performance. If it can be established via contention that the changes made should not pose any impact on safety and performance, a clinical justification can, in some circumstances, suffice for clinical evidence.
- All clinical reports should contain a critical review of all data presented, performed by a 'clinical expert' who should have appropriate clinical qualifications and experience to be able to provide an objective critical review of the clinical data for the device that is the subject of the submission. The appropriateness of this expert will clearly vary depending upon the nature of the device. A complete curriculum vitae for such an expert, or similar documentation, is also a necessary component of the clinical evidence submission.

A properly developed risk analysis is crucial in determining what type of clinical data is required for a particular device. An outcome of the analysis is the identification of any residual risks. The clinical data are expected to quantify and address those risks.

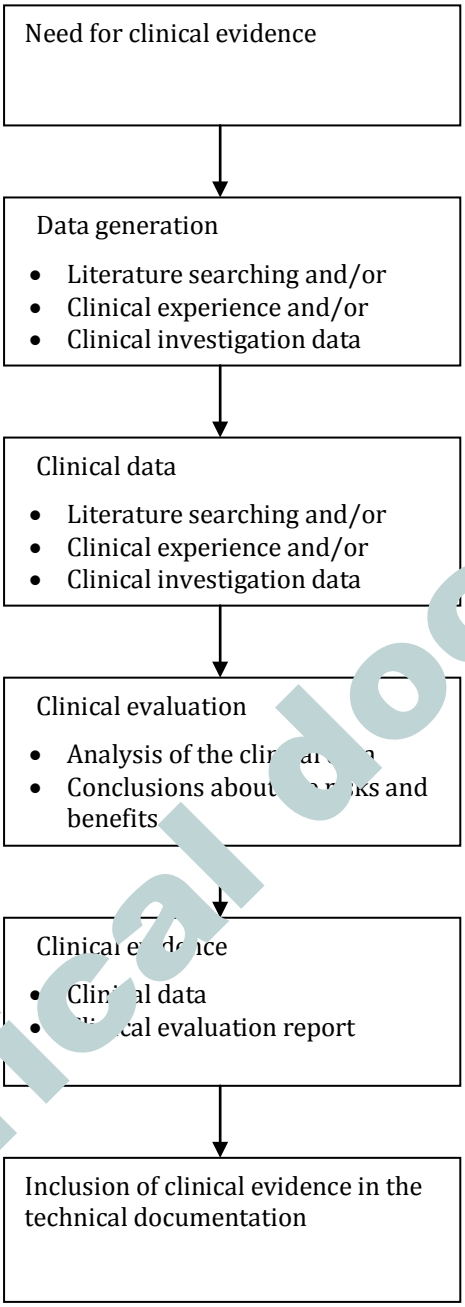
How should the clinical evaluation be conducted

The stages in performing a clinical evaluation are:

- identification of any pertinent standards and the clinical data required to meet them
- objective appraisal of each individual data set as described under clinical evidence above, in terms of its relevance, applicability, quality and clinical significance
- a subsequent analysis of all the data sets, whereby conclusions are reached about the performance, safety and presentational aspects (labelling, patient information and *Instructions for Use*) of the device. The evaluation should consolidate the findings of all clinical data and explain why such data demonstrate acceptable safety and performance of the device under assessment.

If the manufacturer concludes there is insufficient clinical evidence to be able to declare conformity with the Essential Principles, the manufacturer will need to generate additional data (for example, conduct a clinical investigation or broaden the scope of literature searching) to address any deficiency. In this respect clinical evaluation can be an iterative process.

Overview of process for data generation and clinical evaluation



What sources of clinical data can I use?

Data generated during a clinical investigation program for the device, including:

- data from all formal clinical trials carried out using finished products
- any other experimental use in humans using prototype devices or components for the purpose of developing or investigating their safety and performance

> *Please note: There is no requirement that clinical trials should be done in Australia.*

Data from clinical experience, including:

- manufacturer-generated post-market surveillance reports, registries or cohort studies (which may contain unpublished long-term safety and performance data)
- adverse events databases (held by either the manufacturer or regulatory authorities)
- data for the device in question generated from individual patients under Authorised Prescriber and/or Special Access Schemes (SAS) prior to marketing of the device
- details of clinically relevant field corrective actions (for example, recalls, notifications, hazard alerts)

Data obtained from a review of the literature:

- specifically about the device in question—where available, this must always be included in any review, and/or
- for comparative and well established devices including relevant post-market information. Adequate justification should be provided to explain how data for a similar device can establish the safety and performance of the device in question

For safety data, all reports, including individual case reports and overviews relevant to the device should be considered. This would include scientific reports not suitable for assessment of performance due to poor trial design or inadequate analysis but providing safety data about the device.

How do I decide what type of data I can use?

The level and nature of the data considered in a clinical evaluation should be appropriate to the use and classification of the medical device. The data requirements will also vary according to the nature and clinical application of the technology used or by the device.

Devices based on new or unproven technology and those that extend the intended purpose of an existing technology through a new clinical use must be supported with clinical investigation data.

Devices based on an existing technology and intended for an established and accepted use may rely on literature review.

What are the key elements of a literature review?

A literature review consists of the following components:

- a compilation, using documented methodology, of the relevant currently available scientific literature regarding the intended purpose of the device and the design features, consisting of:
  - clinical study reports
  - review papers
  - expert opinion
- a report, written by an expert in the relevant field, containing a critical appraisal of this compilation. Where the review relies in part or wholly on data for a comparable device, the report should also clearly justify how the devices described in the compiled literature are relevant to the safety and performance of the device in question

It is important that the published literature be able to establish the clinical performance and safety of the device in question, and demonstrate a favourable risk profile.

A review must be supported by a detailed search of the literature, using a reproducible search strategy across a range of appropriate scientific databases. The methodology should be documented in a written report.

The search output (that is, the citations) should be assessed against clearly defined selection criteria. The report should also summarise how each citation did or did not fit the selection criteria for inclusion in the review.

When selecting papers to be included in the assessment of performance and safety, the following aspects should be considered:

- the quality of the literature articles
- the design of any clinical trials reported in the paper
- the quality of the data reported in the literature
- the clinical significance of the results of those trials

The quality of the paper can be judged by assessing its:

- scientific impartiality
- the completeness of reporting
- clarity and logic of argument
- the validity of any conclusions drawn in the article

Where can clinical data be found?

Data relevant to the clinical evaluation may be:

- held by the manufacturer (for example, manufacturer sponsored pre- and post- market investigation reports and adverse event reports for the device in question)
- in the scientific literature (for example, published articles of clinical investigations and adverse event reports for the device in question or for comparable devices)

The manufacturer is responsible for identifying data relevant to the device and determining the type(s) and amount of data needed for the clinical evaluation.

There may be situations where demonstration of compliance with the Essential Principles is not possible through evaluation of the published clinical data alone. This can occur because clinical data from clinical investigation and/or the published literature are either lacking or are of poor quality and therefore not sufficiently useful.

One option for the manufacturer will be to generate additional clinical investigation data by conducting a clinical trial. Alternatively, other forms of data can be considered.

This can include data from device usage registries, post-market investigations, surveillance and adverse event reports. In the absence of any recent clinical data for simple devices of a traditional nature assessed to be low risk and safe, a justification as to why no clinical data is required.

What are the requirements for clinical trials?

There is no requirement that the dossier has to include clinical data generated from clinical trials conducted within Australia. However, where a trial of a new medical device is conducted in Australia, it must be conducted in accordance with Australian legislative and regulatory requirements (at both Commonwealth and state/territory level) and Australian ethical standards.

Clinical trials in Australia are conducted under either the Clinical Trial Notification (CTN) Scheme or the Clinical Trial Exemption (CTX) Scheme. Further details can be found at <http://www.tga.gov.au>.

Australian ethical standards are determined by the National Health and Medical Research Council. The current guidelines can be found at <http://www.nhmrc.gov.au>.

Clinical trials conducted overseas are required to comply with relevant jurisdictional legislative and regulatory requirements and must be in accordance with the principles of the Declaration of Helsinki.

Clinical trial design is an important consideration. The most desirable clinical trial design is a randomised, double-blind, controlled trial. This design has the lowest risk of bias that could potentially contribute to the outcomes observed in the trial. In cases where there are numerous published reports of such trials, it is possible to focus on these trials at the expense of other studies, which, because of their design, will have higher levels of bias.

However, it may be difficult to conduct double-blind studies with medical devices, particularly for implantable devices, or to use comparator groups. It is more likely in such cases that these studies have greater potential bias and/or that there are few published reports available to support the review. In this case, almost all papers retrieved by the search will need to be assessed. The issue of potential duplication of data in different papers will need to be addressed.

What should a sponsor look for in the manufacturer's technical dossier when checking to see if there is clinical evidence?

There should be a section in the technical dossier clearly labelled 'Clinical Evidence' that includes:

- the clearly stated intended purpose(s) and application of the device
- identification of the Essential Principles relevant to the specific design of the device
- clinical data or justification as to why no clinical data are required
- a clinical evaluation report containing a comprehensive analysis of the clinical data relevant to the device, authored by a clinical expert competent in the appropriate field and able to give an objective assessment of the clinical data that are present

Where can I find more information?

The TGA recognises that a flexible, case-by-case approach will be adopted so applicants are encouraged to discuss individual device requirements with the TGA.

The Global Harmonization Task Force (GHTF), an international body that was established to achieve greater uniformity between national medical device regulatory systems has developed a comprehensive guidance document on Clinical Evaluation: <http://www.ghtf.org/>. In addition to general guidance, the document provides:

- a possible format for a literature search report
- a possible methodology for documenting the screening and selection of literature within a literature search report
- some examples to assist with the formulation of criteria for data appraisal
- a possible method of appraisal
- a possible format for a Clinical Evaluation Report

Principle 15—Principles applying to IVD medical devices only

From the Therapeutic Goods (Medical Devices) Regulations 2002—Schedule 1, Part 2

15 Principles applying to IVD medical devices only

1. An IVD medical device must be designed and manufactured in a way in which the analytical and clinical characteristics support the intended use, based on appropriate scientific and technical methods.
2. An IVD medical device must be designed in a way that addresses accuracy, precision, sensitivity, specificity, stability, control of known relevant interference and measurement of uncertainty, as appropriate.
3. If performance of an IVD medical device depends in whole or part on the use of calibrators or control materials, the traceability of values assigned to the calibrators or control material must be assured through a quality management system.
4. An IVD medical device must, to the extent reasonably practicable, include provision for the user to verify, at the time of use, that the device will perform as intended by the manufacturer.
5. An IVD medical device for self-testing must be designed and manufactured so that it performs appropriately for its intended purpose, taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in the user's technique and environment.
6. The information and instructions provided by the manufacturer of an IVD medical device for self-testing must be easy for the user to understand and apply.
7. An IVD medical device for self-testing must be designed and manufactured in a way that reduces, to the extent practicable, the risk of error in the use of the device, the handling of the sample and the interpretation of results.

15. The manufacturer must have evidence, as demonstrated by appropriate testing protocols, that the IVD medical device (IVD) performs as intended.

There must be documented procedures in place to ensure that values assigned to controls and calibrators can be related to stated references through a chain of unbroken comparisons, thereby ensuring the ongoing accuracy of these materials.

The design and construction process for an IVD medical device for self-testing needs to take account of the foreseeable risks which could exist for, or be created by, the device when used as intended. This should consider where the device is intended to be used, and by whom. Identified risks or hazards should be eliminated wherever possible, and methods established to alert and inform users of any residual hazards. Also, where possible, the manufacturer of an IVD should consider a mechanism whereby the validity of a test result can be confirmed. This must be simple to perform and interpret.

For more information on IVD medical devices, please see the TGA website.

Section 4. Classification of medical devices

Overview

The medical devices regulatory framework has a classification system for medical devices. The detailed legislation is in:

- 41BD of the *Therapeutic Goods Act 1989* (the Act)
- Regulation 3.2 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations)
- Schedule 2 of the Regulations.

The classification levels are:

Classification	Level of risk
Class I	low
Class I—supplied sterile Class I—incorporating a measuring function Class IIa	low–medium
Class IIb	medium–high
Class III	high risk
Active implantable medical devices (AIMD)	high risk

The manufacturer is responsible for determining the classification of a device using a set of classification rules based on the:

- manufacturer's intended use of the device
- level of risk to patients, users and other persons (the probability of occurrence of harm and the severity of that harm)
- degree of invasiveness in the human body
- duration of use

Medical devices may be classified differently if they are to be used in different parts of the body. This is why the manufacturer's intended use of the device is so critical to determining the appropriate classification. The intended use can be obtained from the:

- instructions for use
- label
- manufacturer's advertising materials
- technical documentation

Please note: There are medical devices where the classification in Australia is different to the classification in other countries. The manufacturer should take into account the Australian legislation when determining the classification of a device that is to be supplied in Australia.

Principles for applying the classification rules

The classification rules are outlined in Schedule 2 of the Regulations and are based on the manufacturer's intended purpose, taking into account how the device works. In some cases, more than one rule can apply. It happens the higher classification applies, with the exception of medical devices for export only (Rule 5.8), which are classified as Class I.

Medical devices incorporating tissues, cells or substances of human origin are regulated as 'other therapeutic goods' in accordance with *Therapeutic Goods (Articles that are not Medical Devices) Order No. 1 of 2002* and will need to comply with the requirements outlined in DR4—Australian medical device requirements under the *Therapeutic Goods Act 1989*, available on the TGA website.

The medical devices regulatory framework has a separate classification system for In Vitro diagnostic medical devices (IVDs). Guidance information on the classification of IVDs is available on the TGA website.

All the classification rules must be considered to determine the classification of the medical device. Accessories are classified separate to the medical device they are used with.

If the device is to be used in combination with another medical device, the classification rules must be applied separately to each device.

For systems and procedure packs, the classification for the entire system or pack is the highest classification of any individual device in the system or pack. The presence of a medicine in a procedure pack does not effect the classification. For example, if there is a device in the pack that is classified as Class III, then the entire pack is classified as Class III.

Manufacturers should pay particular attention to *Rule 5—Special rules*, as these rules may not be applied consistently internationally.

Software:

- that fits the definition of a medical device is also an active medical device since it relies on an energy source for its operation
- that is intended to make a device operate, control a device, or influence the functions of a device generally falls in the same classification as the device
- intended as an accessory to a medical device should be classified separately from the device with which it is used
- is considered accessory when it is not essential to the operation of the device.

For more information on classifying software please see Section 13. Active medical devices.

If the intended purpose of the device is not clear, the TGA will request further clarification from the manufacturer. If the documentation requested is not provided or is unclear then the TGA will assume an intended purpose consistent with the purpose generally accepted in current clinical practice.

If a medical device is intended to be used in more than one part of a patient's body, the medical device is classified on the assumption that it will be used in the part of the body that poses the highest risk. For invasive devices, this may be the central circulatory or central nervous systems.

Medical devices with a measuring function

In accordance with Regulation 1.4 of the Regulations, a medical device is considered to have a measuring function if:

- the device is intended by the manufacturer to measure:
  - quantitatively a physiological or anatomical parameter
  - a quantity or a qualifiable characteristic of energy or of substances delivered to or removed from the human body.

The measurements given by a medical device must:

- display in Australian legal units of measurement or other units of measurement acceptable to the TGA, or
- be compared to at least one point of reference indicated in Australian legal units of measurement or other units of measurement acceptable to the TGA, and
- be accurate to enable the device to achieve its intended purpose.

The device must meet each of the above requirements to fit the definition of measuring function.

Manufacturers of medical devices that have a measuring function must prepare evidence that the device complies with the relevant Essential Principles, particularly Essential Principle 9. For more information please see Section 3. The Essential Principles.

For manufacturers of Class I devices that have a measuring function, in addition to preparing an Australian Declaration of Conformity, they must supply the TGA with conformity assessment evidence to demonstrate that the relevant Essential Principles have been met. For more information please see Section 6. What a manufacturer needs to know about conformity assessment.

Examples of medical devices and whether they have a measuring function

Device	Requirements to fit the definition of measuring function			Result
	Measurement of physiological/ clinical parameters?	Absolute measurement units/reference	Measurement critical to intended purpose	
Clinical thermometer that displays patient temperature in ºC	Yes	Yes	Yes	Measuring function
Forehead patch that indicates temperature via colour change	Yes	No	Yes	Does not have a measuring function
Time-of-day clock (HH:MM)	No	Yes	Yes	Does not have a measuring function
Medicine measuring cup with mL or defined Units marked	Yes	Yes	Yes	Measuring function
Medicine cup with no scale	Yes	No	No	Does not have a measuring function
"Biofeedback" electromyograph (relative scale)	Yes	No	Yes	Does not have a measuring function
Diagnostic electromyograph	Yes	Yes	Yes	Measuring function

Medical devices required to be sterile

Some medical devices are required to be sterile when used to minimise the risk of infection. Such medical devices should be terminally sterilised to a Sterility Assurance Level (SAL) of at least 10^{-6}, unless this is not possible due to device material incompatibility with the proposed sterilisation process.

It is the responsibility of the manufacturer to determine the most appropriate method for achieving the required SAL for a particular device after due consideration of the design and construction of the device. Some common sterilisation methods are:

- moist heat or steam
- dry heat
- ionising radiation
- ethylene oxide
- liquid chemical sterilisation

Devices that are required to be sterile, but cannot be subjected to terminal sterilisation, can be manufactured aseptically, for example by sterile filtration. Devices manufactured in this manner have a lower SAL than those subjected to terminal sterilisation.

Manufacturers of medical devices that are required to be sterile must prepare evidence that the device complies with:

- Essential Principle 8.3 for devices that are supplied sterile
- Essential Principle 8.1 for devices that are able to be reprocessed

For more information please see Section 3. The Essential Principles.

For manufacturers of Class I devices that are required to be sterile, in addition to preparing an Australian Declaration of Conformity, they must supply the TGA with conformity assessment evidence to demonstrate that the relevant Essential Principles have been met. For more information please see Section 6. What manufacturer needs to know about conformity assessment.

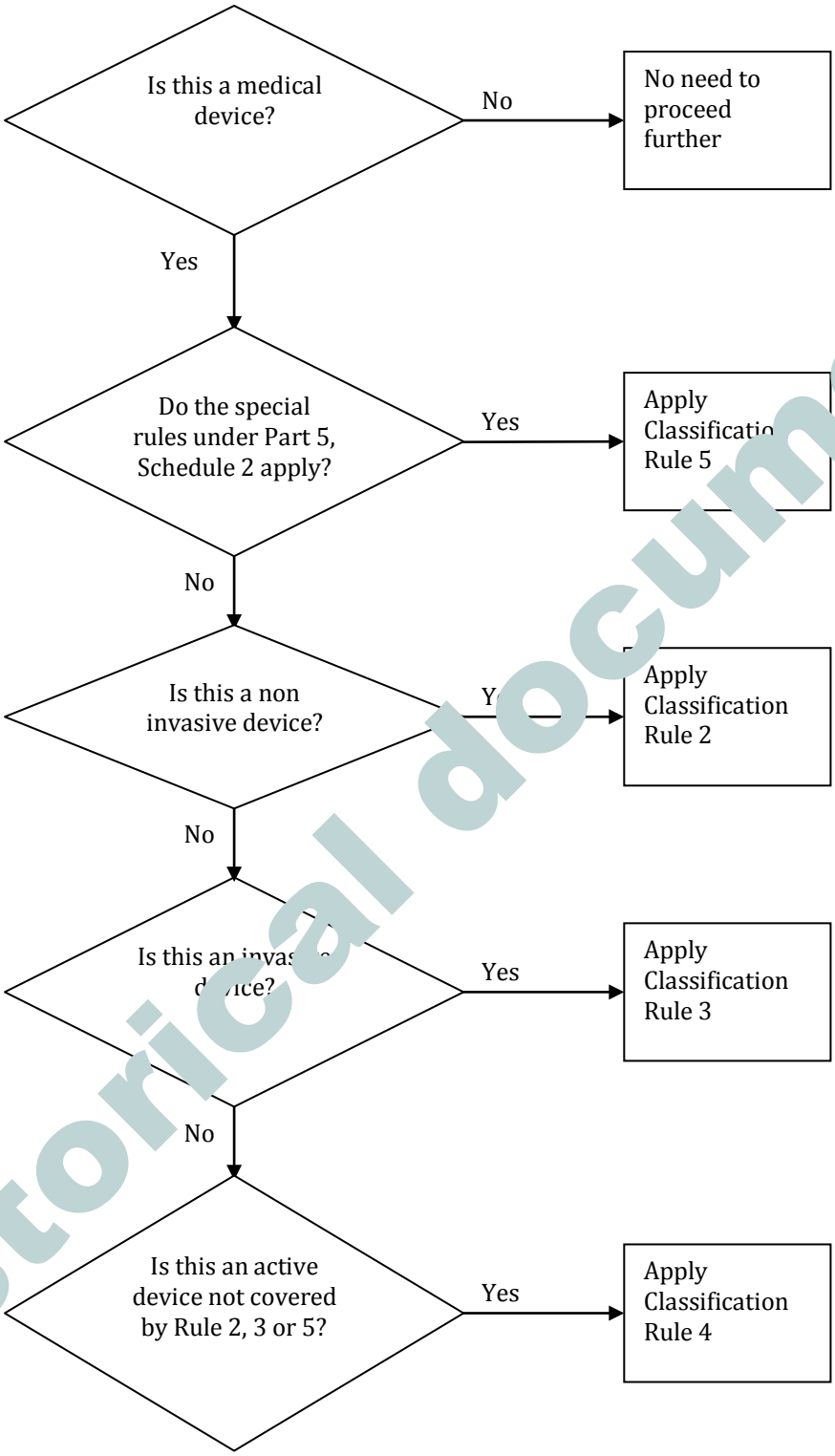
The *Medical Device Standards Order (Standards for Medical Devices Required to be Sterile) 2* available at <http://www.tga.gov.au>, is not mandatory but is one way to establish compliance with Principles. This Order references the following standards:

Standard	Title
AS EN 556-1: 2002 and EN 556-1: 2001	Sterilization of medical devices—Requirements for medical devices to be designated 'STERILE'—Part 1: Requirements for terminally sterilized medical devices. *Please note that AS EN 556-1:2002 is identical to EN 556-1: 2001*
EN 556-2: 2003	Sterilization of medical devices—Requirements for medical devices to be designated 'STERILE'—Part 2: Requirements for aseptically processed medical devices
EN ISO 11607-1: 2006	Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2: 2006	Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11135-1: 2007	Sterilization of health care products—Ethylene Oxide—Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
AS/NZS ISO 11137-1: 2006	Sterilization of health care products—Radiation—Part 1: Requirements for validation and routine control—Radiation sterilization
AS/NZS ISO 11137-2: 2006	Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose
AS/NZS ISO 11137-3: 2006	Sterilization of health care products—Radiation—Part 3: Guidance on dosimetric aspects
EN ISO 17665-1: 2006	Sterilization of health care products—Moist heat—Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

Standard	Title
AS ISO 14160: 2002 and ISO 14160: 1998	Sterilization of single-use medical devices incorporating materials of animal origin—Validation and routine control of sterilization by liquid chemical Sterilants. *Please note that AS ISO 14160: 2002 is identical to ISO 14160: 1998.*
EN ISO 11737-1: 2006	Sterilization of medical devices—Microbiological methods—Part 1: Determination of a population of micro-organisms on products
EN ISO 11737-2: 2000	Sterilization of medical devices—Microbiological methods—Part 2: Tests of sterility performed in the validation of a sterilization process
ISO 13408-1: 2008	Aseptic processing of health care products—Part 1: General requirements
ISO 13408-2: 2003	Aseptic processing of health care products—Part 2: Filtration
ISO 13408-3: 2006	Aseptic processing of health care products—Part 3: Lyophilization
ISO 13408-4: 2005	Aseptic processing of health care products—Part 4: Clean-in-place technologies
ISO 13408-5: 2006	Aseptic processing of health care products—Part 5: Sterilization in place
ISO 13408-6	2005 Aseptic processing of health care products—Part 6: Isolator systems
ISO 14937: 2000	Sterilization of health care products—General requirements for characterization of a sterilizing agent and the development of routine control of a sterilization process for medical devices
EN ISO 17664: 2004	Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices

Electronic or hard copies of the above AS and ISO standards can be purchased from <http://www.saiglobal.com>

What classification rules apply?



Manufacturers should consider all the Classification Rules when determining the appropriate classification for a device as more than one rule may apply and the higher classification applies, except for devices for export only, which are Class I.

If the device	then apply Classification Rule	Some examples are:
is invasive—that is, the device penetrates the body through a body orifice or is inserted into the body during surgery	3—classifications vary depending on intended purpose	surgical eye probe, ophthalmic knife, eye cannula, ear/nose/throat forceps, internal tympanostomy tube, tongue depressor, intraoral x-ray sensor, oral gag, oral suction unit, thermometer, vaginal speculum, urethr bougie, anoscope, proctoscope, colonoscope, stor pe tracheostomy tube.
is active—that is, the device depends on a source of energy for its operation and converts energy	4—classifications vary depending on intended purpose	diagnostic x-ray sources, MRI, air driven su al drills and saws, patient monitors, electronic blo essure measuring devices, diagnostic ultr nd, ectronic stethoscopes/thermometers, so ar s regulators, radioactive seeds, mechanica inf n systems.
contains a medicine	5.1—these devices are Class III	antibiotic bone cements, c ns with spermicide, heparin coated catheters, dr sings incorporating an antimicrobial agent.
is for contraception or preventing sexually transmitted diseases	5.2—classifications vary depending on intended purpose	condo s, c trac tive diaphragms, contraceptive intrau e es (IUDs), surgically implanted cont ep devices.
is for disinfecting, cleaning, rinsing or hydrating	5.3—classifications vary depending on intended purpos	contact lens solutions, comfort solutions, disinfectants for emodialysis devices and endoscopes, sterilisers to s ilise medical devices, washer disinfectors.
not active and is intended to record x-ray diagnostic images	5.4—thes evic are Clas Ia	x-ray films, photostimulable phosphor plates.
contains non-viable animal tissues or derivatives	—these devices a lass III	biological heart valves, porcine xenograft dressings, catgut sutures, implants and dressings made from collagen, intra-ocular fluids, meniscul joint fluid replacement, anti-adhesion barriers, tissue fillers based on hyaluronic acid derived from bacterial fermentation processes.
is a b ood	5.6—these devices are Class IIb	blood bags (including those containing or coated with an anticoagulant).
i ve implantable edical device	5.7—these devices are Class AIMD	implantable pacemakers, defibrillators and nerve stimulators,
is an active device to control, monitor, or directly influence the performance of an active implantable medical device	5.7—these devices are Class III	clinician's programming devices for pacemakers, patient control devices for nerve stimulation devices.

If the device	then apply Classification Rule	Some examples are:
for export only	5.8—these devices are Class I	
is a mammary implant	5.9—these devices are Class III	mammary implants.
is not covered by any of the previous rules in this table	2—classifications vary depending on intended purpose	devices intended to: collect body liquid where a return flow is unlikely immobilise body parts and/or to apply force or compression channel or store substances that will eventually be delivered into the body treat or modify substances that will be delivered into the body dress wounds.

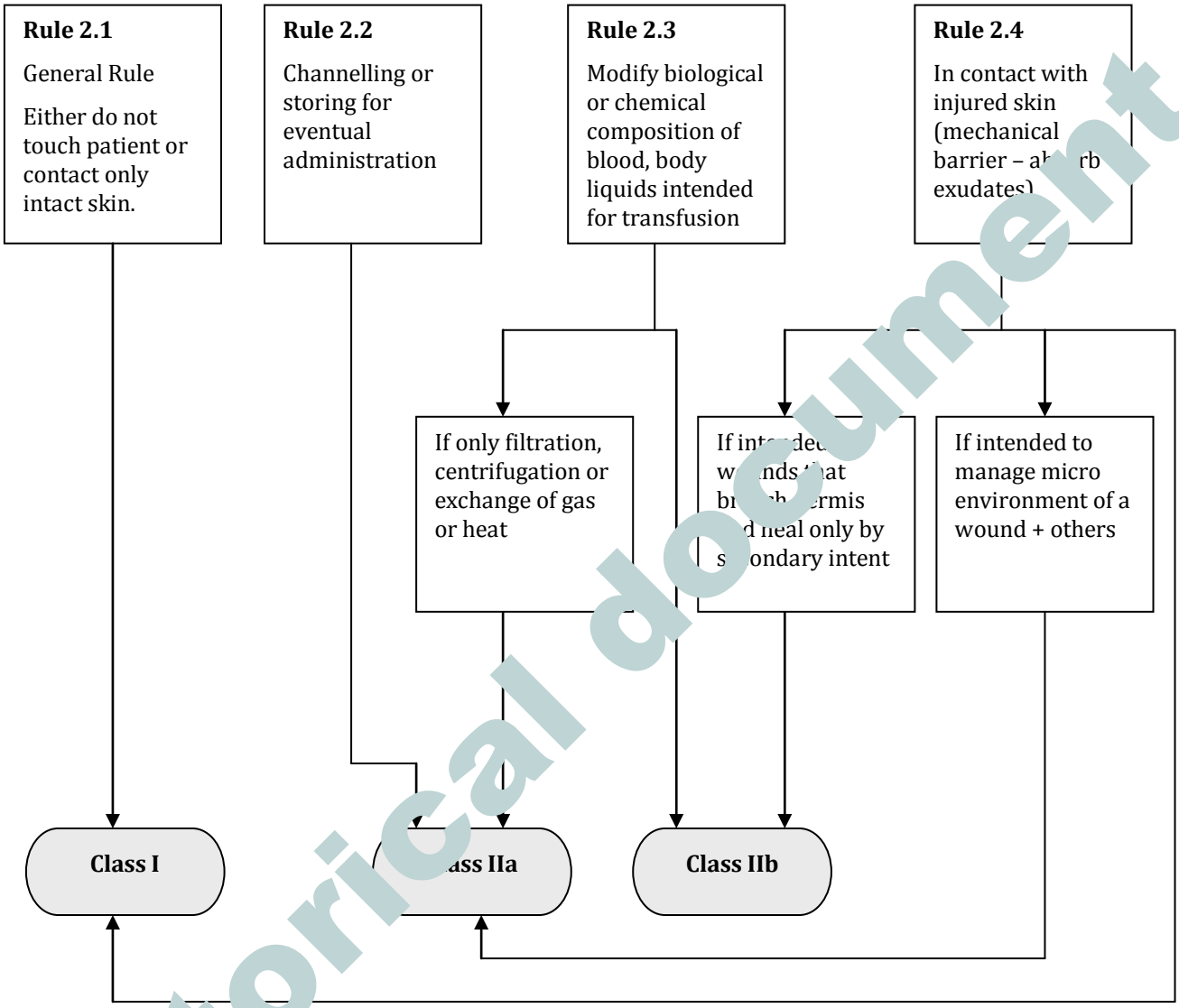
Classification Rule 1—Transient, short-term, and long-term use

The manufacturer, in determining the classification, must take into account the duration of use:

Period of continuous use	Description
less than 60 minutes	transient
at least 60 minutes but not more than 30 days	short term
more than 30 days	long term

Classification Rule 2—Non-Invasive Medical Devices

This flowchart is a summary of the rules described in Schedule 2, Part 2 of the Therapeutic Goods (Medical Devices) Regulations 2002.



Rule 2.1 Non-invasive medical devices—general

This rule applies to all medical devices that are not covered by a specific rule, devices that contact intact skin and devices that do not touch the patient.

Rule 2.1	Description
A non-invasive device is Class I, unless the device is classified at a higher level under another rule in Schedule 2 of the Regulations.	• Devices used to collect body liquid where a return flow is unlikely. Examples: urine collection bottles, ostomy pouches, wound drainage collection bottles and incontinence pads. • Devices used to immobilise body parts and/or to apply for[illegible] compression. Examples: non-sterile dressings, plaster b[illegible]dag[illegible] cervical collars and gravity traction devices or compressi[illegible] hosiery.

Rule 2.2 Non-invasive devices intended to channel or store blood, etc

Devices covered under this rule may include those that channel or store substances th[illegible] w[illegible]e eventually delivered into the body.

Rule 2.2	Description
2.2(1)(a) A non-invasive device used to channel or store blood or body liquids that are to be infused, administered or introduced into a patient—Class IIa.	Devices inte[illegible]ed t[illegible]e used to channel active drug delivery [illegible]te[illegible] Examples: intravenous tubing, gastr[illegible]oni[illegible]ubing, anaesthesia breathing circuits and [illegible]ssu[illegible]icator and syringes for infusion pumps.
2.2(1)(b) A non-invasive device to store an organ, par[illegible]n organ or body tissue that is to be later intr[illegible]u[illegible]e[illegible]to a patient—Class IIa.	Examples: Devices to temporarily store and transport of organs for transplant or for long-term storage of biological substances and tissues such as corneas, sperm and human embryos.
2.2(1)(c) A non-invasive device to cha[illegible]el o[illegible]ore a liquid or gas that is to be infused, adi[illegible]stered or introduced into a patient and may [illegible]nn[illegible]ted to an active medical device classi[illegible]d as [illegible]lass IIa or higher—Class IIa.	Examples: oxygen tubing and masks; anaesthetic tubing and breathing circuits; and syringes and tubing for infusion pumps.

Rule 2.3 Non-invasive devices intended to modify the biological or chemical composition of blood, etc

Devices in this category must be considered separately from those in Rule 2.2, as they treat or modify substances that will be delivered into the body.

Rule 2.3	Description
2.3(1) A non-invasive device to modify the biological or chemical composition of blood, other body liquids, or other liquids to be infused in the patient—Class IIb.	Devices intended to remove undesirable substances out of the blood by exchange of solutes such as hemodyalizers. Examples: Auto transfusion syste Devices used to separate cells such as gradien medium for sperm.
2.3(2) A non-invasive device to be used in treatment consisting of filtration, centrifugation or exchanges of gas or heat—Class IIa.	Examples: particulate filtration of blo d an extracorporeal circulation system, ce fu ation of blood for transfusion or autotra ion, removal of carbon dioxide from the blo d/ adding oxygen, and warming or cooling b d i e extracorporeal circulatory system.

Rule 2.4 Non-invasive devices intended to have contact with injured skin

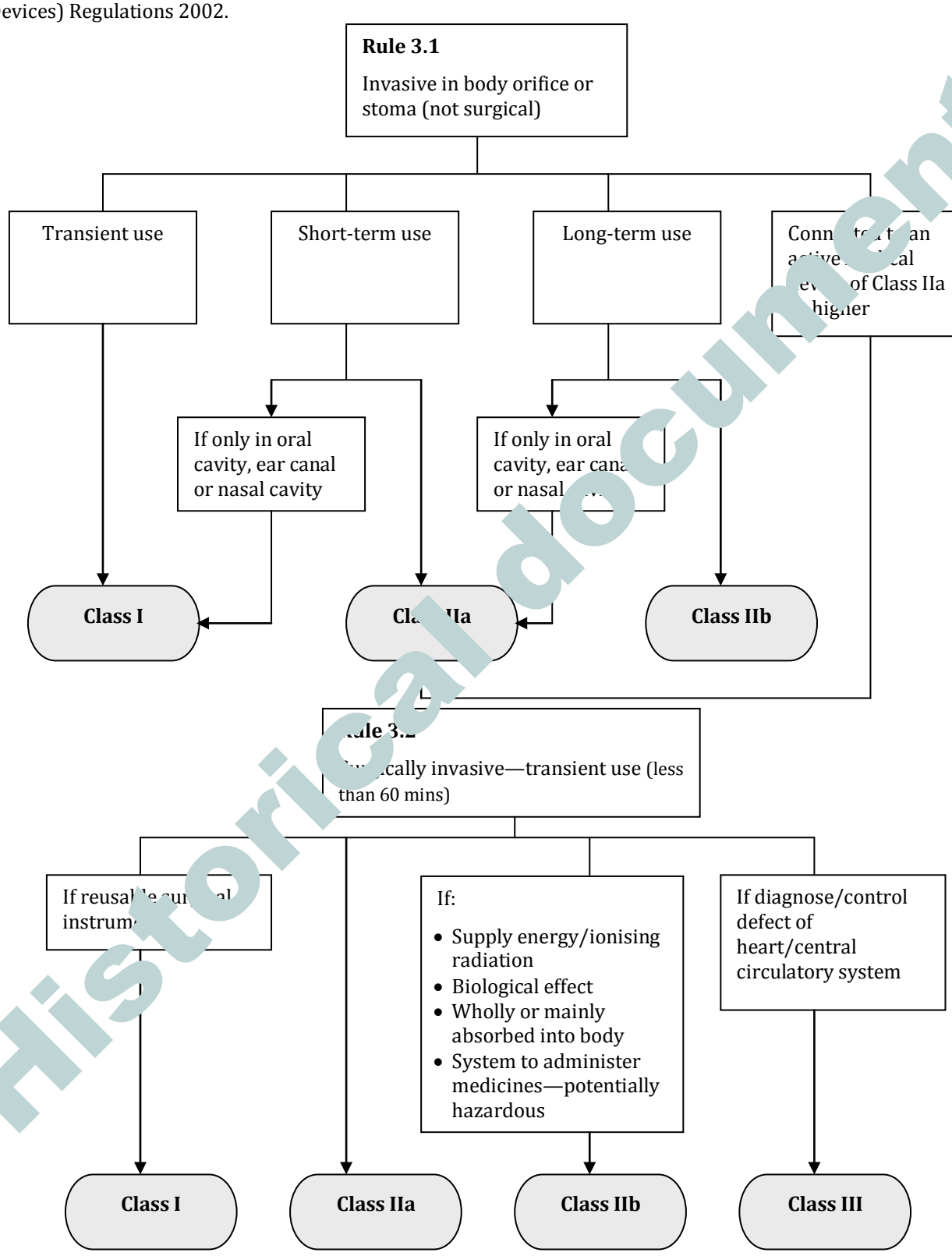
This rule covers wound dressings without consideration of the wound d th. T e technology associated with these devices is well understood and they are not considered potentially dous to the patient.

Rule 2.4	sc tio
2.4(1) A non-invasive device to be used in contact wit injured skin (including a device the principal inte n of which is to manage the microenvironment wound)—Class IIa.	ssi healing by controlling the level of moisture and ating the humidity, temperature, levels of oxygen, other gases and pH values of the wound environment, or by influencing the process by other physical means. Examples: adhesives for topical use, polymer film dressings, hydrogel dressings and non-medicated impregnated gauze dressings.
2.4(3) A non-invasive device to be d as a mechanical barrier or for compress or absorption of exudates—Class I.	Examples: absorbent pads, island dressings, cotton wool, wound strips and gauze dressings to act as a barrier or absorb exudates from the wound. Please note: if the device is sterile conformity evidence is required.
2.4(4) A no -i vasive evice to be used for wounds that have ach he dermis and where the wounds can only he y se ondary intent—Class IIb.	Intended for severe wounds that have extensively breached the dermis, and healing is by secondary intent (by granulation from the base of the wound). Examples: dressings for chronic extensive ulcerated wounds, severe burn, severe decubitus wounds, or dressings providing a temporary skin substitute.

Classification Rule 3—Invasive Medical Devices

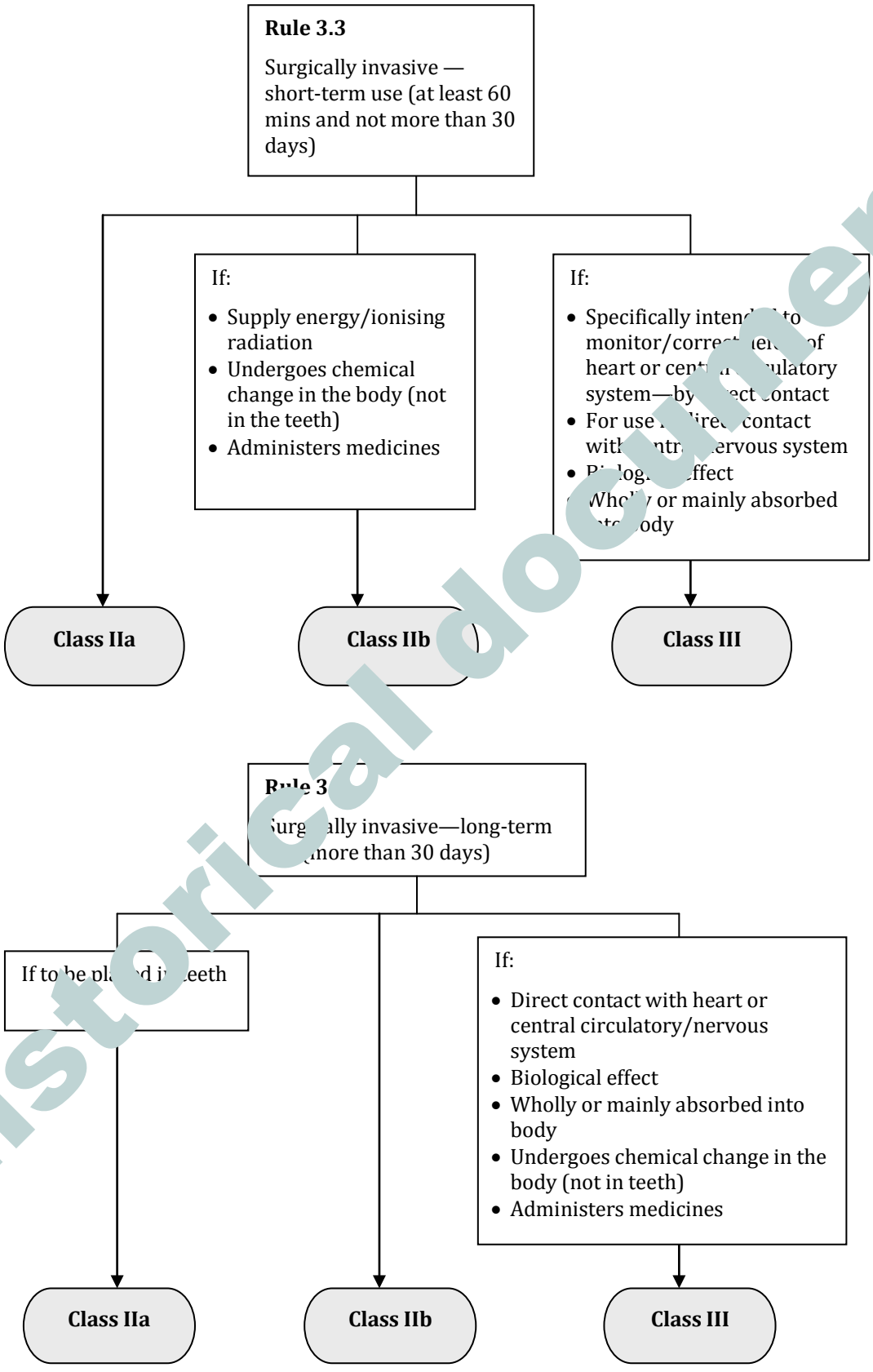
Classification Rules 3.1 and 3.2—Invasive Medical Devices—flowchart

This flowchart is a summary of the rules described in Schedule 2, Part 3 of the Therapeutic Goods (Medical Devices) Regulations 2002.



Classification Rules 3.3 and 3.4— Invasive Medical Devices—flowchart

This flowchart is a summary of the rules described in Schedule 2, Part 3 of the Therapeutic Goods (Medical Devices) Regulations 2002.



Rule 3.1 Invasive devices intended to be used to penetrate body orifices

This rule covers devices that enter the body through existing body orifices (for example, ear, mouth, nose, eye) and surgically created stomas. Devices covered by this rule tend to be for diagnostic and therapeutic use in particular specialities (ear, nose, and throat; ophthalmology; dentistry; proctology; urology; and gynaecology).

Rule 3.1	Description
3.1(2)(a) Invasive devices that are not connected to an active medical device, and are for transient use—Class I.	Examples: handheld dental mirrors, dental impression materials, exam gloves, prostatic balloon dilation catheters.
3.1(2)(b)(i) Invasive devices that are for short-term use—Class IIa.	Examples: contact lenses, urinary catheters, tracheal tubes, stents, vaginal pessaries, perineal reduction devices.
3.1(2)(b)(ii) Invasive devices that are for short-term use in the oral cavity as far as the pharynx, in an ear canal to the ear drum, or in a nasal cavity—Class I.	Examples: dressing for nosebleeds, dentures removable by the patient.
3.1(2)(c)(i) Invasive devices that are for long-term use—Class IIb.	Examples: long-term urinary catheters, artificial eyes, urethral stents.
3.1(2)(c)(ii) Invasive devices for long-term use in the oral cavity as far as the pharynx or in an ear canal to the ear drum, or in a nasal cavity and are not liable to be absorbed by the mucous membrane—Class IIa.	Examples: orthodontic wire, fixed dental prostheses, tissue sealants.
3.1(3) Invasive device to be connected to an active medical device that is classified as Class IIa or higher—Class IIa.	Examples: tracheostomy tubes connected to a ventilator, powered nasal irrigators, nasopharyngeal airways, heat and moisture exchangers, suction catheters or tubes for stomach drainage.

Rule 3.2 Surgically invasive devices intended for transient use

This rule covers devices that are to be used continuously for less than 60 minutes and are used to create a conduit through the skin (needles, cannulae), surgical instruments (scalpels, saws) and various types of catheters, suckers.

Rule 3.2	Description
3.2(2) Surgically invasive device for transient use—Class IIa.	Examples: suture needles, hypodermic needles and syringes, suckers, surgical swabs, surgical gloves.
3.2(3) Surgically invasive device for transient use to diagnose, monitor, control or correct a defect of the heart, or central circulatory system through direct contact—Class III.	Examples: cardiovascular catheters, angioplasty balloon catheters, coronary artery probes.
3.2(4) A reusable surgical instrument—Class I.	Examples: scissors, artery forceps, tissue forceps, tissue clamps, excavators, osteotomes, chisels.
3.2(5)(a) A surgically invasive device for transient use to supply ionising radiation—Class IIb.	Examples: catheters containing or incorporating radioactive isotopes where the isotope is not intended to be released into the body.
3.2(5)(b) A surgically invasive device for transient use to have a biological effect—Class IIb.	
3.2(5)(c) A surgically invasive device for transient use to be wholly, or mostly, absorbed by the body—Class IIb.	Examples: bone wax.
3.2(5)(d) A surgically invasive device for transient use to administer medicine via a delivery system, and where the administration is potentially hazardous to the patient—Class IIb.	*Devices for repeated self-application where the dose and the medicine are critical.* Examples: personal insulin injectors (commonly referred to as 'pens').

Rule 3.3 Surgically invasive devices intended for short-term use

This rule covers devices to be used continuously for at least 60 minutes but not more than 30 days and are used in the context of surgery or post-operative care (for example, clamps and drains), infusion devices (cannulae and needles) and catheters of various types.

Rule 3.3	Description
3.3(2) Surgically invasive device for short-term use—Class IIa.	Examples: clamps, infusion cannulae, skin closure devices or temporary filling materials, some surg retractors for example, chest retractors for cardiac surgery.
3.3(3)(a) A surgically invasive device for short-term use to supply ionising radiation—Class IIb.	Examples: bradytherapy devices.
3.3(3)(b) A surgically invasive device for short-term use to undergo a chemical change in a patient's body (except a device intended to be placed in the teeth)—Class IIb.	Examples: tissue adhesiv
3.3(3)(c) A surgically invasive device for short-term use to administer medicine—Class IIb.	Example ous cannula.
3.3(4)(a) A surgically invasive device for short-term use t specifically used to diagnose, monitor, control correct a defect of the heart, or central circ system, through direct contact with these pa the body—Class III.	ples: cardiovascular catheters, cardiac output probes and temporary pacemaker leads, thoracic catheters intended to drain the heart, including the pericardium and a carotid artery shunt.
3.3(4)(b) A surgically invasive devic short term use to be used in direct contact with th ntral nervous system—Class III.	Examples: neurological catheters, cortical electrodes, connonoid paddles.
3.3(4)(c) and (A surgicall ive device for short-term use to have biol ical ct Class III.	Examples: haemostatic sponge.
3. (d) surg cally invasive device for short-term use to be lly, or mostly, absorbed by a patient's body—Class III.	Examples: absorbable sutures.

Rule 3.3	Description
3.3(5) A surgically invasive device for short-term use that is intended by the manufacturer to be placed in the teeth and to undergo a chemical change in the body—Class IIa. Please note: for this clause, a medical device to be placed in the teeth includes a device that is intended to penetrate a tooth but that does not enter the gum or bone beyond the tooth.	Examples: dental adhesives used for root canal therapy.

Rule 3.4 Surgically invasive devices for long-term use and implantable devices

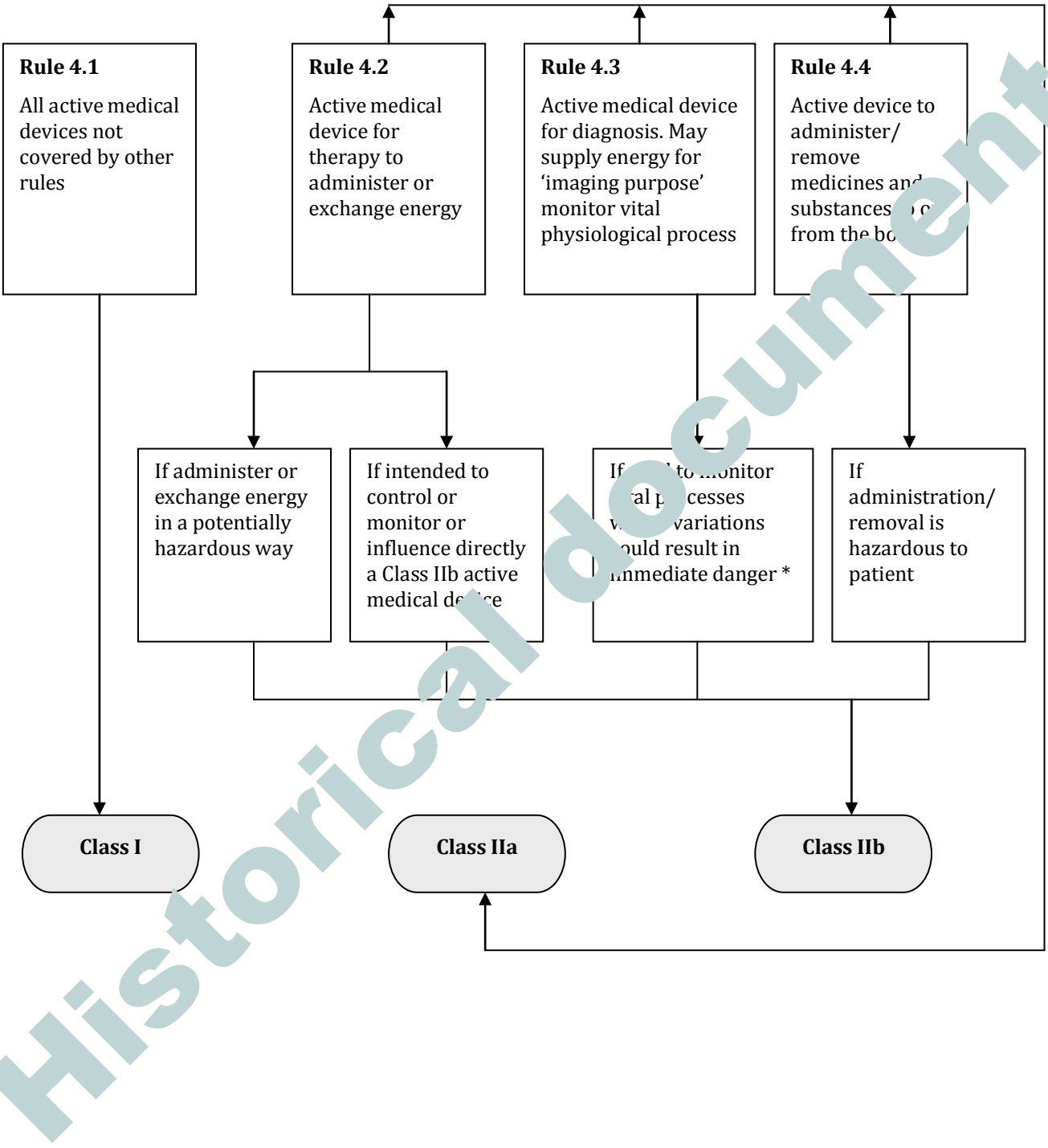
Devices covered by this rule include implants used in orthopaedic, dental, ophthalmic and [illegible]ovascular fields. In addition, soft tissue implants used in plastic surgery are covered by this rule.

Rule 3.4	Description
3.4(2) A surgically invasive device for long-term use and implantable devices—Class IIb.	Examples: implanta[illegible]nt replacements, shunts, stents, nails, [illegible]tes and screws, intra-ocular lenses, infusion por[illegible]per[illegible]neral vascular grafts, bone cement[illegible]xi[illegible]facial implants.
3.4(3) A surgically invasive device for long-term use to be placed in the teeth—Class IIa.	E[illegible]mp[illegible]ridges and crowns.
3.4(4)(a) A surgically invasive device for long-term u[illegible]e[illegible]) used in direct contact with the heart, th[illegible]cen[illegible] circulatory system or the central ner[illegible]ous s[illegible]stem—Class III.	Examples: prosthetic heart valves, aneurysm clips, vascular prostheses, spinal stents, vascular stents, CNS electrodes, cardiovascular sutures.
3.4(4)(b) A surgically invasive d[illegible]for [illegible]ong-term use intended by the manufacturer [illegible]hav[illegible]a biological effect—Class III.	
3.4(4)(c) A sur[illegible]ally in[illegible]sive device for long-term use to be [illegible]lly, [illegible]mostly, absorbed by a patient's body—Class II[illegible]	Examples: absorbable sutures, bioactive adhesives and implants through the attachment of surface coatings such as phosphorylcholine.
[illegible]4)(d) A surgically invasive device for long-term use to undergo a chemical change in the patient's body (except a device that is to be placed in the teeth)—Class III.	Examples: surgical adhesive.
3.4(4)(e)	Examples: rechargeable non-active drug delivery

Rule 3.4	Description
A surgically invasive device for long-term use to administer medicine—Class III.	systems.
3.4(5) A surgically invasive device for long-term use that is intended by the manufacturer to be placed in the teeth and to undergo a chemical change in the body is Class IIa. Please note: for this rule a medical device to be placed in the teeth includes a device that is intended to penetrate a tooth but does not enter the gum or bone beyond the tooth.	Examples: dentine adhesives.

Classification Rule 4—Active medical devices

This flowchart is a summary of the rules described in Schedule 2, Part 4 of the Therapeutic Goods (Medical Devices) Regulations 2002.



* Note: Regulation 4.3(3) also includes a device that is intended to emit ionising radiation and to be used for diagnostic or therapeutic interventional radiology; or a device that is intended to be used to control or monitor, or directly influence, the performance of a device that emits ionising radiation and used for diagnostic or therapeutic interventional radiology.

Active medical devices

An active medical device is defined in the Therapeutic Goods (Medical Devices) Regulations 2002 as being a medical device that is intended by the manufacturer:

- to depend on its operation on a source of electrical energy or other source of energy (other than a source of energy generated directly by a human being or gravity); and
- to act by converting this energy; but
- does not include a medical device that is intended by the manufacturer to transmit energy, a substance, any other element, between an active medical device and a human being without any significant change in the energy, substance or other element being transmitted.

For more information about active devices, please see Section 13. Active medical devices.

Rule 4.1 Active medical devices—general

This rule applies to active medical devices that are not covered by a specific rule.

Rule 4.1	Description
An active device is Class I, unless the device is classified at a higher level under another rule in Schedule 2 of the Regulations.	Examples: examination lights, surgical microscopes, diagnostic devices for thermography, active devices for recording, processing or viewing of diagnostic images, dental curing light

Rule 4.2 Active medical devices for therapy

Active medical device for therapy means an active medical device that is intended by the manufacturer to be used on a human being, either alone or in combination with another medical device, to support, modify, replace or restore biological functions or structures for the purpose of treating or alleviating an illness, injury or disability.

This rule covers devices that are electrical equipment used in surgery, devices used in specialised treatments and stimulation devices.

Rule 4.2	Description
4.2(1) An active medical device for therapy to administer energy to a patient, or exchange energy to or from a patient—Class IIa.	Examples: electrical—magnetic and electromagnetic energy muscle stimulators, external bone growth stimulators, TENS devices, electrical acupuncture thermal energy—cryosurgery equipment, heat exchangers mechanical energy—powered dermatomes, drills and dental hand pieces light—phototherapy for skin treatment and for neonatal care sound—hearing aids.
4.2(2) An active device to administer or exchange energy in a potentially hazardous way, having regard to the nature, density and site of application of the energy—Class IIb.	Examples: kinetic energy—lung ventilators thermal energy—infant incubators, warming blankets for unconscious patients, blood warmers, heat exchangers used in intensive care electrical energy—high-frequency electrosurgical

Rule 4.2	Description
	generators, electrocautery, external defibrillators, electroconvulsive therapy equipment coherent light—surgical lasers ultrasound—lithotriptors, physiotherapy ultrasound devices ionising radiation—radioactive sources for after-loading therapy, therapeutic cyclotrons, linear accelerators, therapeutic X-ray sources.
4.2(3) An active device to control or monitor, or directly influence the performance of an active medical device for therapy of the kind in the previous entry—Class IIb.	Examples: external feedback systems for active therapeutic devices, after-loading control devices.

Rule 4.3 Active medical devices for diagnosis

Active medical device for diagnosis means an active medical device that is intended by the manufacturer to be used on a human being, either alone or in combination with another medical device, to supply information for the purpose of detecting, diagnosing, monitoring or treating physiological conditions, states of health, illness or congenital deformities.

This rule covers devices that are used in ultrasound diagnostic and therapeutic of physiological signals and devices used in diagnostic radiology.

Please note: Active devices for diagnosis are classified as Class IIa in accordance with Rule 4.1, unless they are specifically covered by any of the clauses in Rule 4.3.

Rule 4.3	Description
4.3(2)(a) A device to supply energy that will be absorbed by a patient's body (except a device that illuminates the patient's body in the visible spectrum)—Class IIa.	Examples: magnetic resonance equipment, pulp testers, evoked response stimulators, diagnostic ultrasound.
4.3(2)(b) A device that is used to image in vivo distribution of radiopharmaceuticals in patients—Class IIa.	Examples: gamma cameras, positron emission tomography, single photon emission computer tomography.
4.3(2)(c) A device used for direct diagnosis or monitoring of vital physiological processes of a patient, excluding devices mentioned in the previous entry—Class IIa.	Examples: electrocardiographs, electroencephalographs, cardioscopes with or without pacing pulse indicators, electronic thermometers.
4.3(3)(a) A device to monitor vital physiological parameters of a patient, and the nature of variations monitored could result in immediate danger to the patient—Class IIb.	Examples: intensive care monitoring systems, biological sensors, blood gas analysers used in open-heart surgery, cardioscopes and apnea monitors including those in home care.

Rule 4.3	Description
Please note: For this clause 'variations monitored', is taken to mean that the result of monitoring could lead to immediate danger to the patient. This is typically, but not always, accompanied by an alarm.	
4.3(3)(b) A device to emit ionising radiation and to be used for diagnostic or therapeutic interventional radiology—Class IIb.	Examples: diagnostic x-ray sources, linear accelerators.
4.3(3)(c) A device to control, monitor or directly influence the performance of a device in the previous entry—Class IIb.	Examples: auto exposure control systems, radiotherapy afterloading controls systems.

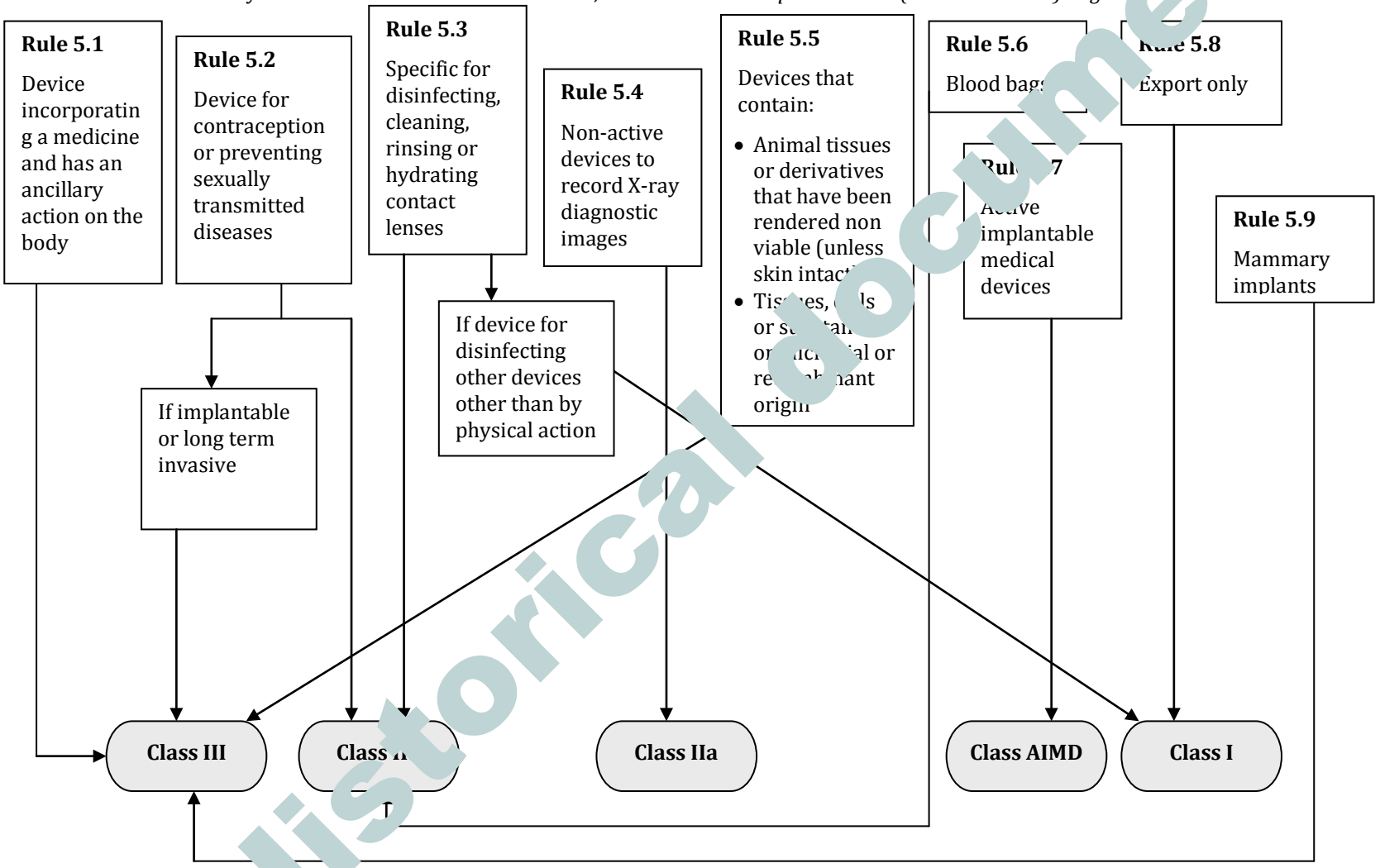
Rule 4.4 Active medical devices intended to administer or remove medicine from a patient's body

This rule covers drug delivery systems and anaesthesia equipment.

Rule 4.4	Description
4.4(1) An active device to administer or remove medicine, body liquids or other substances—Class IIa.	Examples: suction equipment, feeding pumps, jet injectors for vaccination.
4.4(2) An active device to administer or remove medicine, body liquids or other substances in a manner that is potentially hazardous to the patient having regard to the substances, the part of the body concerned, and the characteristics of the device—Class IIb.	Examples: infusion pumps, ventilators, anaesthesia machines, anaesthetic vaporisers, dialysis equipment, blood pumps for heart-lung machines, hyperbaric chambers, pressure regulators for medical gases, medical gas mixers, moisture exchangers in breathing circuits, nebulisers where the failure to deliver the appropriate dosage form could be hazardous.

Classification Rule 5—Special Rules

This flowchart is a summary of the rules described in Schedule 2, Part 5 of the *Therapeutic Goods (Medical Devices) Regulation 2002*.



Rule 5.1 Devices incorporating a medicine

This rule covers medical devices that incorporate a medicinal substance including stable derivatives of human blood and blood plasma that assists the function of the device.

Rule 5.1	Description
5.1(2) A device incorporating a substance that if used separately would be a medicine and has an ancillary action on the body—Class III. Please note: for this clause any stable derivative of human blood or human plasma is considered to be a medicine.	Examples: antibiotic bone cements, condoms with spermicide, heparin-coated catheters, dressings incorporating an antimicrobial agent where the purpose of such an agent is to provide ancillary acti on the wound.

Rule 5.2 Devices for contraception or prevention of sexually transmitted diseases

Some devices covered by this rule may perform both functions, for example, condom

Rule 5.2	Description
5.2(1) A device for contraception or the prevention of sexually transmitted diseases—Class IIb.	Examples: co oms contraceptive diaphragms.
5.2(2) An implantable or invasive device for long-term use—Class III.	E ples: contraceptive intrauterine devices (IUDs), urg ly implanted contraceptive devices.

Rule 5.3 Devices intended for disinfecting ing rinsing etc

This rule covers various contact lens fluids and ul stances or equipment to disinfect another medical device. It does not cover devices that clean by a sical action only.

Rule 5.3	Description
5.3(1) A device specifically f di fecting, cleaning, rinsing or hydrating co t t -Class IIb.	Examples: contact lens solutions, comfort solutions.
5.3(2) A de ce s ic ly for disinfecting another medical d ice lass IIb. P ote: this clause does not apply to a medical evice hat is intended only to clean another medical ice (other than contact lenses) by means of physical action—these devices are Class I (see Rule 2.1).	Examples: disinfectants for haemodialysis devices or endoscopes, sterilisers to sterilise medical devices, washer disinfectors.

Rule 5.4 Non-active devices intended to record x-ray diagnostic images

A non-active medical device to record x-ray diagnostic images such as x-ray films, photostimulable phosphor plates is Class IIa.

Rule 5.5 Devices containing non-viable animal tissues or derivatives, or microbial or recombinant tissues, cells or substances

This rule covers devices that contain or are made of animal tissues that have been rendered non-viable or derivatives from such tissues also being non-viable, or microbial or recombinant tissues, cells or substances.

Rule 5.5	Description
5.5(1)(a) Devices that contain animal tissues or derivatives that have been rendered non-viable are Class III. Please note: this rule does not apply to a device that only contains animal tissues that have been rendered non-viable and the device is only intended by the manufacturer to come into contact with intact skin—see Rule 2.1.	Examples: biological heart valves, porcine xenograft dressings, catgut sutures, implants, dressings ma from collagen. Examples: leather straps associated with li prostheses.
5.5(1)(a) Devices that contain tissues, cells or substances of microbial or recombinant origin are Class III, even if the device is only intended to come into contact with intact skin.	Examples: intra-ocular flu me iscul joint fluid replacement, anti-adh n b iers, tissue fillers based on hyaluron cid ived from bacterial fermentation proces

Rule 5.6 Devices that are blood bags

Rule 5.6	ption
A device that is a blood bag is Class IIb. Please note: if the blood bags have a function great than storing purposes and include systems f preservation other than anti-coagulants th ch rules (for example, Rule 5.1) may appl	Examples: blood bags (including those containing or coated with an anticoagulant).

Rule 5.7 Active implantable me al ces

Rule 5.7	Description
5.7(1) An active impla le medical device is classified as Class AIMD	Example: pacemakers.
5.7(2) A *pla ble* accessory to an active implantable device—Class III.	Example: electrode leads associated with pacemakers, defibrillators, nerve stimulators.
5. (3) An active device to control, monitor or directly influence the performance of an active implantable medical device—Class III.	Example: clinician's programming device for pacemakers, patient control device for nerve stimulation devices.

Rule 5.8 Medical devices for export only

A device that is intended by the manufacturer for export only is classified as Class I.

Rule 5.9 Devices that are mammary implants

A device that is a mammary implant is classified as Class III.

Classification examples

The following examples are provided to demonstrate the importance of considering all the Classification Rules for a device to ensure that the device is appropriately classified. The examples will not include all the possible devices that may be on the market—they are intended to demonstrate how different variables affect the classification of a device. There may be several Classification Rules that apply to a device—if this happens the higher classification applies, with the exception of medical devices for export only (Rule 5.8), which are classified as Class I.

Warming blanket

Intended purpose: To re-warm patients who are cold (hypothermic or recovering post-surgery). These patients may be unconscious.

Description	Variable/comments	Classification Rule	Classification
A large piece of fabric material blanket specially designed to keep a person warm and/or to prevent the further loss of body heat, often in an emergency situation	Not powered	Rule 2.1	Class I
Blanket used to blow warm air onto patient in hypothermia, post-surgery, (person unable to regulate own body temperature)	Electrically powered Potentially hazardous as patients may get burned or overheated; may have peripheral neuropathy (so not able to feel the intensity of the heat), may not be able to indicate if the blanket is too hot (e.g., neonates, unconscious patients). If a patient's blood pressure is critically low when the therapy is first applied, the applied heat may be detrimental to maintaining adequate blood pressure, as resulting vasodilation reduces blood pressure	Rule 4.2(2)	Class IIb

Nebuliser

Intended purpose: To deliver particles of medication/moisture (typically bronchodilators such as salbutamol) to the airways and lungs.

Description	Variable/comments	Classification Rule	Classification
A compressor that pumps compressed air through the fluid to be nebulised, thus forming droplets/vapour and carrying this into the airways during inspiration	Electrically powered	Rule 4.4(1)	Class IIa
A fast-track nebuliser is able to nebulise more fluid per minute, and with finer droplets that reach more deeply into the lungs	Electrically powered—delivers medication in a more potent form than a standard nebuliser and the administration of medicine at an incorrect rate can be life threatening	Rule 4.4(	Class IIb

Dressings

Intended purpose: To be applied to a wound in order to promote healing and/or prevent further harm.

Description	Variable/comments	Classification Rule	Classification
Adhesive dressing strip—not sterile	Not sterile	Rule 2.4.3(c)	Class I
Adhesive dressing strip—sterile	Sterile	Rule 2.4.3(c)	Class I (sterile)
Adhesive dressing strip—with silver	Has silver (microbial agent) to assist in healing. The silver is a medicine	Rule 5.1 (2)	Class III
Compression bandage used for sprains	Used for compression to assist in injury management	Rule 2.4(1)	Class I
A wound dressing for deep wounds and ulcers that have breached the dermis containing alginate to absorb exudate	Contains alginate of microbial origin	Rule 5.5(1)(a)	Class III
A wound dressing for deep wounds and ulcers that have breached the dermis containing alginate to absorb exudate	Contains alginate of non-microbial origin. Heals by secondary intent	Rule 2.4(4)	Class IIb
A wound dressing including materials of biological origin, such as collagen, sodium hyaluronate, chondroitin sulphate	Contains materials of biological origin	Rule 5.5(1)(a)	Class III
A non-sterile, trauma covering used to maintain the stability of a full thickness burn patient en route to a hospital. Dressing is coated in a gel containing [illegible]	Contains medicine	Rule 5.1(2)	Class III
A non-sterile, trauma covering used to maintain the stability of a full thickness burn patient en route to a hospital. Dressing is coated in a gel that does not contain any active medicine ingredients	Breached the dermis. Does not contain medicine	Rule 2.4(4)	Class IIb

Fixation screws

Intended purpose: To hold plates or nails to bone, fasten soft tissue to bone or provide interfragmentary stabilisation for bone.

Description	Variable/comments	Classification Rule	Classification
Metal fixation screw; permanent implant	Permanently implanted	Rule 3.4(2)	Class IIb
Metal fixation screw—used to hold bone together for up to 30 days (for example, to support healing of a fracture)	Short-term use	Rule 3.3(2)	Clas
Metal fixation screw—used to hold bone together temporarily during surgery	Transient use	Rule 3.2	Class IIa
Absorbable fixation screw; permanent implant, absorbed into body	Will be absorbed into body	ule 3.3(4)(d)	Class III
Fixation screw that has direct contact with central circulatory or central nervous systems	Location in body—direct c tac th high-risk areas (central circulato central nervous systems).	Rule 3.3(4)(a)	Class III

Section 5. Conformity assessment overview

What is conformity assessment of a medical device?

A manufacturer must be able to demonstrate that both the device and the manufacturing processes used to make the device conform to the requirements of the therapeutic goods legislation.

The Australian requirements are set out in the:

- *Therapeutic Goods Act 1989* (the Act)
- Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations)

Conformity assessment is the systematic and ongoing examination of evidence and procedures to ensure that a medical device complies with the Essential Principles.

Conformity assessment:

- provides objective evidence of the:
  - safety
  - performance
  - benefits
  - risks
  - for a specific medical device
- enables regulatory bodies to ensure that products placed on the market conform to the applicable regulatory requirements

There are several stages involved in the conformity assessment of a medical device:

Activity	Description	Who is responsible?
Conformity assessment procedures	• How a manufacturer demonstrates that they have met the Essential Principles for a particular medical devices • Manufacturers can choose the appropriate procedures to use, depending on the classification of the device • Involves assessment of the: – Technical documentation for the design of the devices – Manufacturing processes used to make the devices – Risk analysis – Clinical evidence – Ongoing monitoring and vigilance procedures that will be in place once the device is available for supply	Manufacturer
Issuing conformity assessment evidence	Conformity assessment evidence is the certificate issued by a regulatory body to demonstrate a manufacturer has been assessed and has the appropriate systems in place to manufacture the devices. Assessment includes: • confirming that the conformity assessment procedures are appropriate for the classification of the device and have been applied correctly • systematic examination of the documentation provided and procedures undertaken by the manufacturer • may include an on-site audit of the manufacturing premises • assessment processes will vary according to the conformity assessment procedure selected by the manufacturer • re-certification of conformity assessment evidence that is due to expire	the TGA or an European Union (EU) Notified Body
Australian Declaration of Conformity (DoC)	Once the manufacturer has obtained conformity assessment evidence, they must make an Australian DoC The DoC declares that the device complies with: • the applicable provisions of the Essential Principles • the classification rules • an appropriate conformity assessment procedure • if requested, the TGA must be provided with a copy of the DoC • the DoC must be maintained and updated when appropriate	Manufacturer
Ongoing conformity assessment responsibilities	Maintain appropriate records, including: • technical documentation • evidence that an appropriate conformity assessment procedure has been applied	Manufacturer

Activity	Description	Who is responsible?
	• the Australian Declaration of Conformity • details of any systematic reviews undertaken • details of any changes to the device and/or quality management system • implement appropriate means to apply any necessary corrective action in relation to the design or production of a device • notify the TGA and/or the sponsor as soon as practicable after becoming aware of information relating to any malfunction or adverse event • systematically review information gained after the device is supplied in Australia Please note: for more information on these requirements please see Section 22. Post-market vigilance and monitoring requirements • apply for re-certification prior to the expiry of existing conformity assessment evidence	

The classification of a medical device determines the conformity assessment procedures a manufacturer can choose to ensure that the device is adequately assessed. Higher classification devices must undergo more stringent conformity assessment procedures than lower classification devices.

The conformity assessment procedures have been modelled on those developed by the Global Harmonization Task Force (GHTF), an international forum that was established to achieve greater uniformity between national medical device regulatory systems.

The GHTF principles of conformity assessment are also closely aligned with the relevant EU Directives. Although the Australian and EU conformity assessment procedures are similar, there are some important differences manufacturers must be aware of and accommodate, before completing an Australian Declaration of Conformity. For more information please see Section 8. Differences between the Australian and European Union medical device regulatory requirements.

The Australian Government also has international agreements in place with other countries. For more information on these agreements please see Section 9. International agreements.

The conformity assessment evidence needs to be registered with the TGA for all medical devices, except Class I non-measuring and non-sterile medical devices.

Conformity assessment evidence is not required to be submitted to the TGA prior to inclusion in the ARTG for Class I medical devices unless they are supplied sterile or have a measuring function. However, an Australian Declaration of Conformity and supporting evidence in a suitable technical file must be maintained by the manufacturer for Class I medical devices. This documentation must be provided to the TGA if requested.

Conformity assessment evidence is also not required for some systems and procedure packs, however the manufacturer must hold and maintain evidence that each medical device in the system or procedure pack meets the Essential Principles and that the relevant conformity assessment procedures have been applied. For more information please see Section 16. Systems and procedures packs.

In accordance with the legislation, for devices manufactured outside Australia the TGA is able to accept the assessment of regulatory bodies that are considered to have the appropriate authority and expertise. As the Australian and the EU regulatory requirements are similar, the TGA has determined that certificates issued by EU Notified Bodies may be accepted as conformity assessment evidence for the supply of devices in Australia. There are medical devices that are exceptions to this determination. For more information see Section 8. Differences between the Australian and European Union medical device regulatory requirements.

EU Notified Bodies may sometimes issue conformity assessment evidence for products that are not regulated as medical devices in Australia. It should not be assumed that a product is a medical device because a certificate has been issued—the product must fit into the Australian definition of a medical device.

The EU Notified Bodies have been designated as competent and authorised to carry out conformity assessment according to the:

- EU Medical Device Directive 93/42/EEC (MDD)
- EU Active Implantable Medical Device Directive 90/385/EEC (AIMDD)

The designation process involves the regulatory authority in an EU Member State assessing an EU Notified B... as being competent and then notifying the EU Commission. The Australian Government and the TGA are... involved in the designation process since certification is for the EU and not directly linked to the Austr...n legislation. Details of the current MDD Notified Bodies can be found at <http://ec.europa.eu/enterprise/newapproach/nando/>.

Once the conformity assessment evidence has been accepted by the TGA, a sponsor can lodge an ...cation to include a medical device in the Australian Register of Therapeutic Goods (ARTG).

More detailed information on conformity assessment is available in the following sec...ns.

- Section 6. What a manufacturer needs to know about conformity assessment
- Section 7. What a sponsor needs to know about conformity assessment

Types of conformity assessment eviden...e

The TGA accepts the following certificates as conformity assessm...t ev...ence:

- a TGA Conformity Assessment Certificate[8] issued by the ...A—...is is mandatory for some manufacturers
- certificates of conformity issued under the Australia–E...MR...A
- certificates of conformity issued under the Au...alia–EFTA MRA
- EC certificates issued by an EU Notified B... ...nde... the:
- EU Medical Devices Directive 93/42/EEC (M...D)
- EU Active Implantable Medi...al D...ices...irective 90/385/EEC (AIMDD).

In cases where there are differ...c... in the classification of a device between Australia and the EU, the conformity assessment procedure requi...ents ...ay be different in Australia. The manufacturer may be required to obtain additional conformity assessm... evidence. Where the manufacturer is not able to obtain the appropriate additional conformity a...ses...ent evidence from their EU Notified Body, they may need to obtain a TGA Conformity Asse...sme...Cert...icate. For more information, please see Section 8. Differences between the Australian and E...pean Union medical device regulatory requirements.

The TGA doe...not acc...pt the following certificates as evidence that the Australian regulatory requirements have been m...et:

- ...cert...ates from any countries outside Australia, the EU and EFTA
- ...tificate from the United States Food and Drug Administration (US FDA) because the US system does not align with the Australian regulatory framework
- an ISO 13485 Medical devices—Quality management systems—Requirements for regulatory purposes compliance certificate because it does not provide assurance that the Australian legislative requirements have been taken into consideration. While this standard specifies the requirements that are needed for a quality management system for device manufacturers, the TGA does not require that manufacturers have a

[8] *TGA Conformity Assessment Certificate* is a reference to a conformity assessment certificate issued by the TGA, as defined in the Australian legislation.

certificate that states they have complied with the requirements of ISO 13485 as the TGA or EU Notified Body will make this assessment as part of the conformity assessment procedures

For some manufacturers, the TGA can only accept TGA Conformity Assessment Certificates. These manufacturers are detailed below.

All other manufacturers that require conformity assessment evidence have the following options:

- arranging for the TGA to undertake the necessary assessments
- applying to an EU Notified Body
- if a European manufacturer is applying to an EU Notified Body, the application may be made under the Australia–EC or Australia–EFTA MRAs

Manufacturers who must have a TGA Conformity Assessment Certificate

The manufacturer of a medical device is the person who is responsible for the:

- design
- production
- packaging
- labelling

of the device before it is supplied under the person's name, whether the or another person acting on their behalf carries out those operations.

Some medical device manufacturers, must have a TGA Conformity Assessment Certificate if they want to supply devices to the market in Australia, regardless of whether they have a certificate issued by an EU Notified Body. These manufacturers are:

- any manufacturer who manufactures medical devices containing:
- materials derived from
  - animals that have been rendered non-viable—there are some exceptions to this requirement. For more information, please see Section 7. Medical devices containing materials of animal, microbial or recombinant origin.
  - materials of microbial or recombinant origin
  - stable human blood or plasma derivatives
  - medicinal substances (substances that if used separately would be considered medicines) for more information please see Section 14. Medical devices incorporating a medicine.
- all Australian manufacturers except for the following:
  - the manufacturer of a Class I medical device that is not supplied sterile or does not have a measuring function
  - sterile systems and procedure packs for which the special conformity assessment procedures have been applied—for details see Section 16. Systems and procedure packs.
  - devices supplied to individuals:
    - as part of a clinical trial
    - through the Special Access Scheme
    - by Authorised Prescribers
    - by personal importation

    For more information please see Section 20. Access to unapproved medical devices in Australia.
  - exempt devices, including custom made devices.

The TGA assessment will take into account any existing EU conformity assessment evidence. Manufacturers who obtain a TGA Conformity Assessment Certificate who plan to supply their devices in other countries, should

check with each jurisdiction to see if the TGA Conformity Assessment Certificate is acceptable conformity assessment evidence in that country.

Some medical device manufacturers, must have a TGA Conformity Assessment Certificate if they want to supply

What is the manufacturer responsible for?

Manufacturers should demonstrate that they have the appropriate processes in place to ensure compliance with the Essential Principles and conformity assessment procedures before they apply to the TGA or an EU Notified Body for conformity assessment evidence.

Once a manufacturer obtains the necessary conformity assessment evidence, they need to ensure that their conformity assessment procedures are appropriately maintained and that the ongoing requirements are met (for example, reporting adverse events, regular quality systems audits). For more information on these requirements please see Section 22. Post-market vigilance and monitoring requirements.

The manufacturer is responsible for obtaining the conformity assessment evidence and ensuring the information on the certificate remains current and valid.

The manufacturer must also prepare an Australian Declaration of Conformity that includes all the manufacturing details for the medical device. For more information on Declarations of Conformity please see Section 6. What a manufacturer needs to know about conformity assessment.

The legislation requires that the TGA must be notified in writing by the appropriate legal representative, within 3 months of the event occurring, if the manufacturer:

- dies
- is declared bankrupt
- is a body corporate that is wound up

A manufacturer may also be the Australian sponsor.

For more detailed information about the role and responsibilities of the medical device manufacturer please see Section 6. What a manufacturer needs to know about conformity assessment.

What is the Australian sponsor responsible for?

The Australian sponsor is responsible for:

- having procedures in place including a written agreement with the manufacturer, to obtain information from the manufacturer when requested by the TGA
- ensuring that
  - they have available sufficient information to substantiate compliance with the Essential Principles or have procedures in place to ensure that such information can be obtained from the manufacturer within 20 working
  - an appropriate conformity assessment procedure has been applied to the medical devices by the manufacturer
  - the manufacturer has appropriate conformity assessment evidence for the medical device
  - the conformity assessment evidence remains valid while the device is supplied in Australia

  obtaining a copy of the conformity assessment evidence from the manufacturer
- submitting the conformity assessment evidence to the TGA
- applying to include the device in the Australian Register of Therapeutic Goods (ARTG)
- meeting all the ongoing monitoring and reporting requirements applicable to sponsors once a device is included on the ARTG. For more information see Section 22. Post-market vigilance and monitoring requirements.
- providing samples of the medical device to the TGA upon request

- allowing a person authorised by the TGA to enter and inspect any premises, including outside Australia, where the devices are manufactured or located
- ensuring any advertising material relating to the medical device complies with the TGA requirements. For more information, see Section 12. Information about a medical device.

Please note: If a certificate passes its expiry date, the medical devices the certificate covers may be cancelled from the ARTG.

The Australian sponsor may also be the manufacturer.

For more detailed information about the role and responsibilities of the Australian sponsor, please see Section 7. What a sponsor needs to know about conformity assessment.

Section 6. What a manufacturer needs to know about conformity assessment

This section should be read in conjunction with Section 5. Conformity assessment overview.

Overview

Conformity assessment is the systematic and ongoing examination of evidence and pro[illegible]es to ensure that a medical device complies with the Essential Principles.

Manufacturers should demonstrate that they have the appropriate processes in pl[illegible] to ensure compliance with the Essential Principles and conformity assessment procedures before they ap[illegible] to the TGA or an EU Notified Body for conformity assessment evidence.

Once a manufacturer obtains the necessary conformity assessment evid[illegible]ce, they need to ensure that their conformity assessment procedures are appropriately maintained and that the ongoing requirements are met (for example, reporting adverse events, regular quality systems audits). For more information on these requirements please see Section 22. Post-market vigilance and monitoring requirements.

The manufacturer is responsible for obtaining the conformity assessment evidence and ensuring the information on the certificate remains current and valid.

The manufacturer must also prepare an Australian Declaration of Conformity that includes all the manufacturing details for the medical device.

The legislation requires that the TGA must be notified in writing by the appropriate legal representative, within 3 months of the event occurring, if the manufacturer:

- dies
- is declared bankrupt
- is a body corporate that is wound up

A manufacturer may also be the Australian sponsor.

For some manufacturers, the TGA can only accept TGA Conformity Assessment Certificates. These manufacturers are listed in Section 5. Conformity assessment overview.

Conformity assessment procedures for each class of medical device

The conformity assessment procedures and Australian Declaration of Conformity requirements are detailed in Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations). For more information, see Conformity assessment procedures in this section.

Depending on the classification of a device, there are a number of different conformity assessment procedures a manufacturer may use to demonstrate compliance with the Essential Principles. The table below summarises the most commonly used conformity assessment procedures for each medical device classification. Manufacturers may choose to complete procedures that are more comprehensive than the minimum, but this is not required by the TGA. The table also indicates the relevant clause of Schedule 3 that describes which Australian Declaration of Conformity is appropriate for each option.

Class of Medical Device	Most commonly used conformity assessment procedures	Declaration of Conformity legislative reference
Class I	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary)	Schedule 3, Part 6, clause 6.6
Class I (measuring) and Class IIa (non-sterile)	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 5 (Product Quality Assurance Procedures)	Schedule 3, Part 6, clause 6.6
Class I (sterile) and Class IIa (sterile)	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 4 (Production Quality Assurance Procedures)	Schedule 3, Part 6, clause 6.6
Class IIb	Part 1 excluding Clause 1.6 (Full Quality Assurance Procedures)	Schedule 3, Part 1 clause 1.8
Class III and Class AIMD	Part 1 (Full Quality Assurance Procedures) + Clause 1.6 (Examination of Design)	Schedule 3, Part 1 clause 1.8
Systems or Procedure Packs	Part 7 (Procedures for Medical Devices Used for a Special Purpose)	Schedule 3, Part 7, clause 7.5

The following conformity assessment procedures are rarely used as they are generally more expensive for manufacturers, but are options that can be considered:

- Part 2 (Type Examination) for specific models of Class IIb, Class III, and Class AIMD devices, in conjunction with Part 1 or Part 3 or Part 4 or Part 5.
- Part 3 (Verification Procedures) for non-sterile Class I measuring and IIa devices or, when used in conjunction with Part 2, for non-sterile Class IIb, Class III, and Class AIMD devices.

More information on all these options is provided in the next table.

Conformity assessment procedures

Summary of each conformity assessment procedure

Part	Requirements	Applicable classifications	Considerations for manufacturer
Part 1, Full quality assurance procedure Encompasses design, production, packaging, labelling, and final inspection of a medical device	Manufacturer must implement a full quality management system (that is, all clauses of ISO 13485 including clauses 7.3 and 7.5.2) and arrange for the quality management system to be audited by the TGA or EU Notified Body. The TGA or EU Notified Body also assesses the manufacturer's technical documentation for the medical devices, including clinical evidence.	All Please note: for Class III and Class AIMDs, Clause 1.6 must also be applied	• This conformity assessment procedure can be applied to all devices that they manufacturer • This means that new devices that are Class I measuring and/or sterile, Class IIa or Class IIb that fit into the scope of the certificate should not require additional assessment(s) by the TGA or EU Notified Body. Resources required establishing and maintaining appropriate procedures. • The quality management system must be maintained. • Periodic surveillance audits will be performed by the TGA or EU Notified Body.
Part 1, Clause 1.6, Examination of Design Involves an examination of the design dossier for medical devices to which the manufacturer has applied a Part 1 conformity assessment procedure	The technical documentation for the Class III and AIMD device (also referred to as a design dossier) must be submitted for examination to assess the compliance of the device with the Essential Principles.	Class III, Class AIMD	• The overhead cost of the assessment may be high. • This must be done in conjunction with Part 1 assessment of the quality management system; by either the TGA or the same EU Notified Body.
Part 2, Type examination Involves an examination of a representative sample of a medical device	Testing can be conducted by the TGA or EU Notified Body, OR The TGA or EU Notified Body can conduct tests on the device at the manufacturer's site and supervise or review the testing,	Class IIb, Class III, Class AIMD	• Only applies to a specific medical device model. • The overhead cost of the assessment may be high. • The production of subsequent devices still require conformity assessment under:

Part	Requirements	Applicable classifications	Considerations for manufacturer
	OR The TGA or EU Notified Body will subcontract the testing to an accredited test laboratory (either in Australia or overseas).		• Part 4 for sterile devi[illegible]. • Part 3, Part 4, or Part [illegible]other devices.
Part 3, Verification Procedures Involves an examination (including testing) of the medical device(s) prior to release for supply	The TGA or EU Notified Body will need to assess production records for each device (either on a statistical basis or a 100% sampling rate) and authorise release of the product or batch of products for supply.	Class I (measuring), Class IIa, Class IIb, Class III, Class AIM[illegible] Please [illegible]ot be used for [illegible]rile devices	• Ma[illegible]be a[illegible]opriate if the manufacturer does not have a quality man[illegible]ent system. • On[illegible] applies to the production processes for a specific medical [illegible]vice. Only applies to a particular production batch or particular production units. • Certification must be repeated prior to every new batch or device being released onto the market. • As many test procedures need to be designed, established and qualified before testing can begin, the overhead cost of the assessment may be high. • The design of Class I (measuring) and Class IIa devices still requires conformity assessment under Part 6. • The design of Class IIb, III and AIMD devices still requires conformity assessment under Part 2.
Part 4, Production quality assurance A quality management system encompassing the production and final inspection of a medical device	Manufactu[illegible]er mu[illegible]im[illegible]ement a quality manageme[illegible]ystem (i.e. all clauses of ISO 13485 exclud[illegible]lause 7.3 but including clause[illegible]and arrange for the quality [illegible]nagement system to be audited by the TG[illegible]r an EU Notified Body. [illegible]TGA or EU Notified Body also re[illegible]iews a sample of the manufacturer's	Class I (measuring and/or sterile), Class IIa, Class IIb, Class III,	• Assessment can cover a wide range of devices—not limited to a specific device. • For Class I (measuring and/or sterile) and Class IIa devices this only covers production—the design of each device still requires Part 6 conformity assessment. • For Class IIb, III and AIMD devices this only covers production—the design of each device still requires conformity assessment

Part	Requirements	Applicable classifications	Considerations for manufacturer
	technical documentation for the devices.	Class AIMD	under Part 2. • May be resource inte[illegible]o initially establish appropriate procedures. • The quali[illegible]ement system must be maintained • Period[illegible]ilance audits will be performed by the TGA or EU No[illegible]ed [illegible]y
Part 5, Product quality management system A system encompassing the final inspection and testing of a medical device	Manufacturer must implement a quality management system (that is, ISO 13485 excluding clauses 7.3 and 7.5.2) and arrange for the quality management system to be audited by the TGA or a EU Notified Body. The TGA or EU Notified Body also reviews a sample of the manufacturer's technical documentation for the devices	Class I (measuring), Class IIa Class IIb Please [illegible]an [illegible]ot be used for [illegible]ile devices	• As[illegible]ssment can cover a wide range of devices—not limited to a [illegible]ecific device. For Class I (measuring) and Class IIa devices this only covers production—the design of each device still requires Part 6 conformity assessment. • For Class IIb devices this only covers production—the design of each device still requires conformity assessment under Part 2. • May be resource intensive to initially establish appropriate procedures. • The quality management system must be maintained • Periodic surveillance audits will be performed by the TGA or EU Notified Body
Part 6, Declaration of Conformity (not requiring assessment by Secretary) Preparing technical documentation for a medical device and establish a post-market monitoring system	Manufacturer en[illegible]res[illegible]at the device(s) comply wi[illegible]the [illegible]er[illegible]al Principles and prepares d[illegible]mentation that demonst[illegible]ates [illegible]ormity.	Class I, Class I (measuring and/or sterile), Class IIa	• For Class I non-measuring and non-sterile devices the evidence (Declaration of Conformity) is not required to be submitted to the TGA but MUST be available upon request. • For Class I (measuring and sterile) and Class IIa devices, conformity assessment under Part 3, Part 4 (sterile devices) or Part 5 is also required.

Part	Requirements	Applicable classifications	Considerations for manufacturer
Part 7, Conformity Assessment Procedures for devices used for a Special Purpose	Applies to custom-made medical devices, systems and procedure packs	All *Please note: sterile systems and procedure packs also require Part 4 certification*	• For custom-made medical devices, see Section 18.Custom-made medical devices. • For systems and procedure packs, see Section 16. Systems and procedure packs.
Part 8, Clinical Evaluation procedures	The conformity assessment procedures the manufacturer must follow for obtaining and evaluating clinical data.	All	• See Section 3. The Essential Principles, Principle 14-Clinical evidence.

Part 1 Full quality assurance procedures (excluding Clause 1.6)

A manufacturer applies this procedure to Classes AIMD, Class III, Class IIb, or Class IIa medical devices by implementing a full quality management system that takes into account the regulatory requirements for the:

- design
- production
- packaging
- labelling
- final inspection processes
- implementation of an ongoing monitoring system.

A certificate will be issued by the TGA or an EU Notified Body if the quality management system is satisfactory. The certification will declare that the quality system conforms to the requirements of:

- Part 1 of the TGA regulatory requirements or
- Annex II section 3 of the EU Medical Device Directive (MDD) 93/42/EEC or
- Annex 2 section 3 of the EU Active Implantable Medical Devices Directive 90/385/EEC (AIMDD)

The assessment is against the requirements of the Australian legislation or the EU Directive. The assessment will include audit of the quality management system (all clauses of ISO 13485 or equivalent standard) and an assessment of the manufacturer's technical documentation for the devices, including clinical evidence.

The conformity assessment certification remains valid only if it is subject to periodic and satisfactory surveillance audits.

Changes to the quality system that broaden the scope of the quality system or substantially alter the approved system, design or production arrangements may require further assessment or approval by the conformity assessment body.

Once a manufacturer has obtained conformity assessment evidence under this Part they must then prepare an Australian Declaration of Conformity in accordance with clause 1.8 of Schedule 3 of the Regulations.

Please note: These requirements are similar to the EU AIMDD/MDD Annex II section 3 requirements.

Part 1, Clause 1.6 Examination of design

This procedure applies to Class III and AIMD medical devices and requires the TGA or an EU Notified Body to examine the design for each device. The assessment is based on the design and development records produced under the manufacturer's quality management system and compiled/summarised into a 'design dossier'. The manufacturer must lodge a separate application for the assessment of the design for each model of device.

Changes to the design or production of Class III and AIMD devices may also require further assessment or approval.

Re-examination of the design will be required after 5 years, based on post-market surveillance data, changes to relevant standards and any other changes that may affect compliance with the Essential Principles.

Once a manufacturer has correctly applied this part, they should prepare an Australian Declaration of Conformity in accordance with clause 1.8 of Schedule 3 of the Regulations.

Please note: These requirements are similar to the EU AIMDD/MDD Annex II section 4 requirements.

Part 2 Type examination procedures

The options available for Classes AIMD, Class III, or Class IIb medical devices with this conformity assessment procedure are that:

- the TGA or EU Notified Body will conduct tests on the device at the manufacturer's site and will supervise or commission the testing
- the testing can be conducted within the TGA or an EU Notified Bodies own laboratory
- the TGA or EU Notified Body will subcontract the testing to an accredited test laboratory (either in Aust[illegible] or overseas)

The manufacturer must make an application for the TGA or an EU Notified Body, to examine a represent[illegible]ativ sample of the type of device (the 'type'). The type must:

- have been designed and produced according to the Essential Principles
- be a finished device
- be constructed of the same materials and manufactured in the same way as intend[illegible] general production

The TGA or EU Notified Body will determine if the design of the type satisfies the [illegible]ent[illegible] Principles. This will be done through examination of the supporting documentation and testing for [illegible]omp[illegible]nce to a safety and performance standard or standards applicable to the device. Testing or the sup[illegible]ion of the testing may occur on the manufacturer's premises subject to the agreement of the manufac[illegible]er and the TGA or EU Notified Body.

The manufacturer must also seek further certification for the production [illegible]d final inspection and testing of the device.

- For Class AIMD, Class III, or Class IIb devices that are s[illegible]plied [illegible]e, the manufacturer must seek further certification against Australian Part 4 / MDD Annex V-[illegible]ction Quality Assurance Procedures
- For Class AIMD, Class III, or Class IIb devices that are n[illegible]pplied sterile the manufacturer may seek further certification against either Australian Part 3 / MDD Annex 4—Verification Procedures or Australian Part 4 / MDD Annex V—Production Quality Assurance P[illegible]edures.
- For Class IIb devices that are not supplie[illegible]s[illegible]e the manufacturer may seek further certification against Australian Part 5 / MDD Annex VI—Produ[illegible]uality Assurance Procedures.

Please note: These requirements are [illegible] to the EU AIMDD/MDD Annex III requirements.

Part 3 Verification proced[illegible]es

This part requires the [illegible]A o[illegible]U Notified Body to assess the production records for each Class I, Class IIa, Class IIb, Class III, or [illegible] A[illegible]edical device, batch by batch (either on a statistical basis or a 100% sampling rate). The devices can[illegible] released for supply until the certification is issued.

Manufactur[illegible]s of Classes AIMD, III, or IIb devices that are not supplied sterile and where Australian Part 2 / MDD [illegible]nex[illegible]na[illegible]e been applied may use this procedure. The TGA or EU Notified Body will determine if the de[illegible]ice c[illegible]forms to the 'type'.

Ma[illegible]turers of Class IIa devices or Class I devices with a measuring function that are not supplied sterile and [illegible]ha[illegible] followed the procedure described in Australian Part 6 may also use this procedure. The TGA or EU [illegible]fied Body will determine if the device conforms to the manufacturer's technical documentation.

The TGA or EU Notified Body will conduct examinations and tests, as the manufacturer chooses, on each:

- product (that is, 100% testing)
- product selected on the basis of a statistically determined sample of each uniform batch submitted

The manufacturer is also required to implement an ongoing monitoring system.

When a manufacturer has correctly applied this part they should then prepare an Australian Declaration of Conformity in accordance with clause 3.5 of Schedule 3 of the Regulations.

Please note: These requirements are similar to the EU AIMDD/MDD Annex IV requirements.

Part 4 Production quality assurance procedures

In this conformity assessment procedure, the manufacturer must implement a quality management system for the production and final inspection of Class I (measuring and/or sterile), Class IIa, Class IIb, Class III, and Cla AIMD medical devices that specifically includes regulatory requirements and an ongoing monitoring system.

The manufacturer must make an application for an assessment of the quality management system by th r an EU Notified Body. The assessment is against the requirements of the Australian legislation or the EU ective. The assessment will include audit of the quality management system (ISO 13485, excluding claus or equivalent standard) and review of the manufacturer's technical documentation for the devices.

Certification will be issued if the quality management system is satisfactory. The certificati ll declare that the quality system conforms to the requirements of Part 4 of the Regulations, or MDD A V, and not against a conformity assessment standard.

Manufacturers of Class AIMD, Class III, or Class IIb devices that have performed ty exa ination under Part 2/MDD Annex III may utilise the Part 4 conformity assessment procedures.

When Australian Part 2/MDD Annex III have been completed together wi his pa t, manufacturers of Class AIMD, Class III, and Class IIb devices may then prepare a Declaration of nfo ity in accordance with clause 4.7 of Schedule 3 of the Regulations.

Manufacturers of Class IIa devices, Class I devices with a me suri fu ion or Class I devices that are supplied sterile that have followed the procedure described in Austra Pa may also use this procedure.

For Class IIa and Class I devices, a Declaration of Conform is i ue under Part 6 with reference to the certification issued under Part 4/MDD Annex V in accordan ith clause 6.6 of Schedule 3 of the Regulations.

The certification only remains valid if it is subject t eriodic surveillance.

Changes to the quality system that alter or ad a tional product to the range covered by the approved system may require further assessment or approva

Please note: These requiremen are mila to the EU AIMDD/MDD Annex V requirements.

Part 5 Product quality a rance procedures

This part may be applic :

- non-sterile I s IIa, and Class I devices with a measuring function
- non-sterile Clas devices when Part 2 has been applied
- n -st s IIa devices or Class I devices with a measuring function where Part 6 has been applied

I is co mity assessment procedure, the manufacturer must implement a quality management system for the esses of final inspection and testing for particular identified products. The quality management system st s ifically include regulatory requirements. In particular, the quality system must implement an ongoing i itoring system.

Under this procedure, the manufacturer performs final inspection and testing on 100% of the product or on a representative sample of each batch according to the quality system.

The manufacturer must make an application for an assessment of the quality management system by the TGA or an EU Notified Body. The assessment is against the requirements of the Australian legislation or the EU Directive. The assessment will include audit of the quality management system (ISO 13485, excluding clause 7.3 and 7.5.2, or equivalent standard) and review of the manufacturer's technical documentation for the devices.

If the quality management system is defined, implemented and effective, certification will be issued for a particular product or range of products. The certification issued will declare conformity with the quality system requirements of Part 5 of the Regulations or MDD Annex VI for particular products and not against a quality management system standard (for example, ISO13485) used for the implementation and assessment of the system.

When conformity assessment procedures have been successfully completed for Class IIb devices the manufacturer may prepare a Declaration of Conformity in accordance with clause 5.7 of Schedule 3 of the Regulations. This Declaration and the certifications issued under Part 2 and this part form the basis for applying for supply in Australia.

For Class IIa and Class I devices that have a measuring function, a Declaration of Conformity is made under Part with reference to the certification issued under Part 5/MDD Annex VI, in accordance with clause 6.6 of Schedule 3 of the Regulations.

Certification only remains valid if it is subject to periodic surveillance.

Changes to the quality system that alter or add additional product to the range covered by the approved system may require further assessment or approval.

Please note: These requirements are similar to the EU MDD Annex VI requirements

Part 6 Declaration of conformity (not requiring assessment by Secretary) procedures

This part:

- can be used for Class I, Class I supplied sterile, Class I with a measuring function and IIa devices
- also requires Part 3, 4 or 5 conformity assessment procedures to be followed (except Class I non-measuring and non-sterile devices)

In this conformity assessment procedure, the manufacturer of the device ensures that the device complies with the Essential Principles and prepares documentation that allows the conformity to be self-assessed by the manufacturer.

When conformity assessment procedures have been successfully completed, the manufacturer may prepare a Declaration of Conformity under this part. This Declaration forms the basis for a sponsor's application to supply the device in Australia.

The manufacturer is also required to implement an ongoing monitoring system. For:

- Class IIa devices, the manufacturer must seek further certification against either Part 3, 4, or 5 (MDD Annexes IV, V, or VI)
- Class IIa devices that are supplied sterile the manufacturer must seek further certification against Part 4 (MDD Annex V)
- Class I devices that have a measuring function the manufacturer must seek further certification against either Part 3, 4 or 5 (MDD Annexes IV, V or VI)
- Class I devices that are supplied sterile the manufacturer must seek further certification against Part 4 (MDD Annex V)

When a manufacturer has correctly applied this Part they should then prepare an Australian Declaration of Conformity in accordance with clause 6.6 of Schedule 3 of the Regulations.

Please note: These requirements are similar to the EU MDD Annex VII requirements

Part 7 Medical devices used for a special purpose

Type of device	Requirements	More information is available from
Custom made medical devices	The manufacturer must: • prepare a written statement in relation to the device • prepare and maintain documentation in relation to the device • notify the TGA about any adverse events or problems with the device or its use • establish and maintain a post-market monitoring system	Section: Section 18. Custom-made medical devices
Systems and procedure packs	The manufacturer must: • make an Australian Declaration of Conformity • establish and maintain a post-market monitoring system	Section 16. Systems and procedure packs

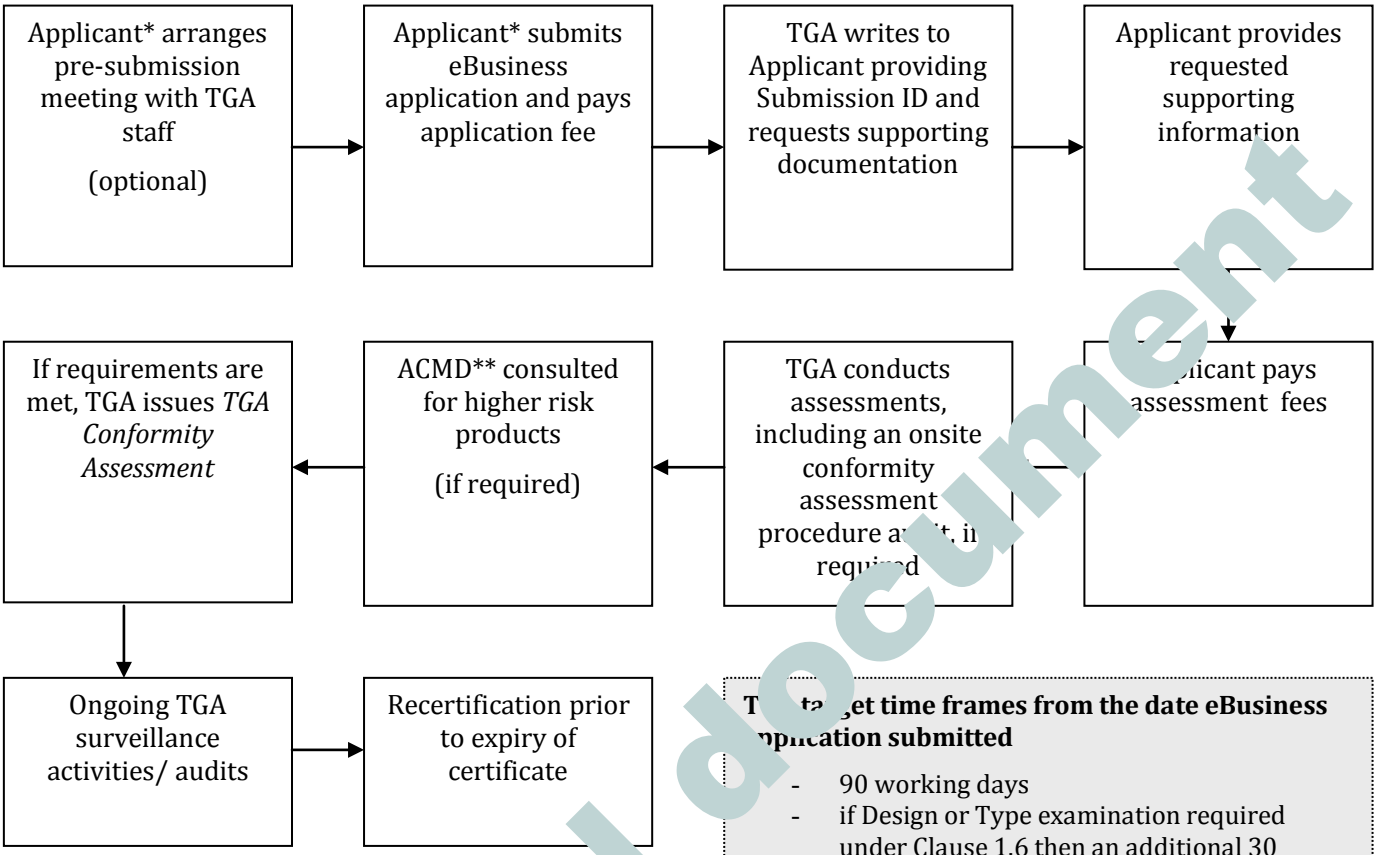
Please note: The requirements for custom made medical devices are similar to the EU MDD Annex VIII and AIMDD Annex VI requirements.
The requirements for systems and procedure packs are similar to the EU MDD Article 12 requirements.

Part 8 Clinical Evaluation procedures

Every medical device requires clinical evidence appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the Essential Principles. For more information, please see Section 7 The Essential Principles.

TGA Conformity Assessment Certificates

Application process flowchart



*Applicant may be a manufacturer or their authorised representative

Pre-submission meetings

Manufacturers are invited and encouraged to meet with the TGA prior to submitting their application for a TGA Conformity Assessment certificate. A meeting will assist to:

- ensure that the applicant understands the process and the time frames for the conformity assessment process
- introduce the devices to the TGA so that issues are considered before the application is lodged and documentation can be provided with the application to address any concerns

Pre-submission meetings may be face to face or via teleconference.

Meetings provide a valuable opportunity to discuss any anticipated difficulties and agree on an acceptable approach, which should assist in a timely completion of the assessment. However, please be aware that at the time of the meeting, the TGA cannot guarantee the acceptability of the application or anticipate the outcome of the assessment. To arrange a meeting please send an email to <devices@tga.gov.au>.

Applicants requesting a pre-submission meeting should be prepared to provide:

- a demonstration or presentation on the device, the use and design, with a sample if appropriate and possible
- a summary of the testing done and evidence held, including clinical evidence

- an outline of the dossier to be presented (for a Class III or Class AIMD device) or the technical file for a lower classification device—this should include the:
  - Specifications for the device
  - GMDN code
  - Classification
  - Functional description
  - Intended purpose
  - Essential Principles checklist
  - Risk management report
  - Labelling, *instructions for use*, and advertising material
  - Animal/human/recombinant/microbial-origin materials
  - Sterility
  - Details of third-party certifications and previous audits
  - Details of TGA certificates, licences, etc.
  - Proposed conformity assessment route(s)
  - Table of Critical Steps (manufacturing stage—manufacturer's facility or key supplie
  - Latest version of the quality manual
  - Procedure for a feedback system
  - Procedure for the issue and implementation of advisory notices and notifi ion adverse events
  - Design and development records/files
- a summary of readiness for quality management system audit of the m ufa er and/or description of other regulatory QMS certification for the manufacturer
- an expected date of submission of an application.

There are no fees for a pre-submission meeting.

Documentation for applications

Manufacturers who apply for a TGA Conformity A sessmen tificate are required to prepare technical documentation to demonstrate that the medical d ce complies with the Essential Principles. This will vary on a case by case basis, depending on the:

- type of device
- risk associated with its manufactu and us
- period that it has been on the mar

The technical documentation will alw ys include the following:

- clinical evidence
- risk manage ent r ort (see ISO 14971 for details)
- Essential Prin ples compliance summary (e.g., Essential Principle checklist or similar). For more inform on on the Essential Principles see Section 3. The Essential Principles.
- evi ence t support compliance with any standards or test methods utilised for compliance (for example, st r rts or assessment reports, labels and *Instructions for Use*)

For cla I medical devices assessed under Part 6, the manufacturer self-assesses the technical documentation compliance and makes a Declaration of Conformity accordingly.

For Class I sterile, Class I measuring and IIa medical devices assessed under Parts 4 or 5, the manufacturer self-assesses the technical documentation for compliance, but must also utilise the certified quality management system (ISO 13485) for the production of the device. The technical documentation must be controlled under the quality management system and must be available for review by the TGA, who verifies its existence and completeness without a thorough review of the design of the device.

For Class IIb, Class III, and Class AIMD medical devices assessed under Part 1, the manufacturer produces the technical documentation via the certified quality management system procedures for design and development

(ISO 13485 clause 7.3). The production of the device is also performed via the quality management system. The technical documentation must be available for review by the TGA, who verifies its existence and completeness, and who may also sample the documentation for more thorough review of the design of the device.

For Class III and AIMD medical devices assessed under Part 1, Clause 1.6, the manufacturer submits the technical documentation for review by the TGA, who performs a thorough review of the design of the device. The production of the device is then performed via the certified quality management system.

The GHTF has released the Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED), which provides guidance on the technical documentation that should be assembled and submitted to demonstrate conformity to the Essential Principl While it is not mandatory for manufacturers to adhere to all the requirements outlined in the STED, it provides useful guidance on the documentation required by the TGA. The STED can be accessed at <http://www.imdrf.org/>.

Manufacturers of devices containing materials of human blood or plasma derivati es animal, microbial, or recombinant origin; or medicinal substances

Manufacturers of devices containing materials of human blood or plasma derivatives, ani al, r obial or recombinant origin or medicinal substances should be aware that these devices are cl si as Class III in Australia. The manufacturer is required to obtain two certificates from the TGA, eithe

- Full Quality Assurance certificate (Part 1) + Design Examination certificate (Cla 1.6), or
- Production Quality Assurance certificate (Part 4) + Type Examination tifi (Part 2)

Only one conformity assessment application is required to obtain both c ifi es.

If these manufacturers hold a current EC Certificate under the MD 93 2/EEC, the TGA may, upon review of the documentation generated by the EU Notified Body, conduc ab assessment of the manufacturer's quality system and technical documentation. In some cases GA may waive conducting an on-site audit.

For devices that contain:

- animal-derived waxes
- heparin
- gelatin

and conform to pharmacopeial stand ds, a anufacturer may submit a MRA certificate of conformity to the TGA as support for a conformity asses en ication. This may result in the TGA conducting an abridged conformity assessment.

However, the TGA reserves th ght to conduct a full assessment if the TGA is not fully satisfied with the evidence of compliance de if an abridged assessment is considered sufficient for the application, the TGA may reduce the applic e as essment fees.

At a minimum, th GA requires evidence to support the quality and safety of animal derived material, in accordance wi the approach to minimising the risk of exposure to Transmissible Spongiform Encephalop thi TSEs) through medicines and medical devices, available on the TGA website. For more infor ation plea see Section 15. Medical devices containing materials of animal, microbial or recombinant o gin.

lease note: The Australian requirements for devices that contain materials of microbial or recombinant igin may differ to those in the EU. For more information please see Section 8. Differences between the Australian and European Union medical device regulatory requirements.

Manufacturers can contact the TGA to obtain advice on conformity assessment evidence

- email to <devices@tga.gov.au>
- the Medical Devices Information Line on 1800 141 144

MRA certificates of conformity issued by the TGA

Australia has signed a Mutual Recognition Agreement (MRA) with the European Union (EU) and the European Free Trade Association (EFTA), covering several industry sectors including the medical devices sector. For more information on MRAs please see Section 9. International agreements.

Under the MRAs, the Australian Government has designated the TGA as the Conformity Assessment Body responsible for assessing devices manufactured in Australia to the requirements of the Medical Devices Directive and the Active Implantable Medical Devices Directive. Australian manufacturers who receive a MRA certificate from the TGA are then able to affix the CE Mark and supply in Europe.

However, the TGA can only issue EC certificates to manufacturers established within Australia or New Zealand. For a manufacturer to be eligible for an EC certificate under the Australia-EU/EFTA MRAs the manufacturer must demonstrate that the device is fully (or mostly) manufactured within Australia and/or New Zealand. Some kinds of devices are also excluded from the agreement, or are subject to confidence building activities.

EC MRA certificates are not issued by the TGA in accordance with the *Therapeutic Goods Act 1989*, but are covered by a contractual arrangement between the manufacturer and the Commonwealth of Australia (which is represented by the TGA). The TGA issues EC certificates under the MRAs as an extension to an application for an Australian TGA Conformity Assessment Certificate.

An application for an EC certificate is submitted with an application for a TGA Conformity Assessment Certificate. The TGA conducts both assessments at the same time as the requirements are similar but there are some differences. If the applicant is issued with a TGA Conformity Assessment Certificate and is found to also satisfy the additional EU/EFTA requirements, the TGA will issue an EC certificate. Additional fees are payable for this assessment. For more information please see Section 2. Fees and charges for medical devices.

If a manufacturer intends to obtain EC certification from the TGA, it is important that they establish an European Representative in the EU/EFTA and seek advice on the particular requirements applying to the EU/EFTA area/state where they intend commercialising the medical device.

Manufacturers should obtain a copy of the relevant EU Directives before applying to the TGA for EC certification. More information on the European requirements can be obtained from <http://www.newapproach.org/DirectivesDirectiveList.asp>.

On-site audits

On-site audits are necessary for all manufacturers applying for a TGA Conformity Assessment Certificate. The TGA will conduct a risk assessment on the device and the manufacturer to determine if the on-site audit must be conducted prior to the TGA Conformity Assessment Certificate being issued. The risk assessment will take into account audits that have been conducted by EU Notified Bodies and Health Canada recognised registrars. The TGA will focus on the assessment of the critical production processes in the audit report, as well as any other issues that have been identified.

Audits are a mandatory condition for a manufacturer holding a TGA Conformity Assessment Certificate. These audits will occur regularly—generally at least 18 months apart and no more than five years apart. Audits may be conducted more frequently if issues arise. Fees are payable to the TGA for on-site audits.

The applicant will be notified in the formal acceptance letter if an on-site audit is required before a certificate is issued and the TGA will contact the applicant to arrange a suitable audit time.

Applications for certificates

A manufacturer should only lodge an application for a TGA Conformity Assessment Certificate when they are satisfied that their quality management system and associated technical documentation satisfies the requirements of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

All manufacturers can lodge an application for a TGA Conformity Assessment Certificate directly with the TGA. An overseas manufacturer may choose to engage an Australian agent to lodge the application on their behalf,

however this is not a TGA requirement. Applications can also be lodged on behalf of the manufacturer by another party. The certificate is issued to the manufacturer, not the agent.

An application fee is payable for lodging the application—details of the current fees are available on the TGA website. Further fees are payable for any assessments that are required and these fees vary, depending on the conformity assessment procedures the manufacturer has chosen to use. For more information on fees, please see Section 2. Fees and charges for medical devices.

If a manufacturer has not had any previous certifications from the TGA or an EU Notified Body (or other equivalent certifications) it is essential that they contact the TGA so they can obtain advice on their options for obtaining conformity assessment evidence, via:

- email to <devices@tga.gov.au>
- the Medical Devices Information Line on 1800 141 144

The documentation that a manufacturer needs to submit to the TGA in support of an application for a TGA Conformity Assessment Certificate varies depending on the medical device.

Creating an e-business account

Before making an application, the manufacturer or an authorised person acting on behalf of the manufacturer must be a client of the TGA. This is achieved by establishing an eBusiness account with the TGA. This provides access to the TGA's eBusiness system, which is used to make electronic applications for medical devices. The forms and instructions are at <http://www.ebs.tga.gov.au>.

Lodging an electronic application for a TGA Conformity Assessment Certificate

Once the applicant has access to the eBusiness system, they must lodge an electronic application for a TGA Conformity Assessment Certificate. No electronic attachments should be attached to this form, as the supporting information will be requested separately.

An invoice will be generated and the applicant must pay the application fee to the TGA. If a manufacturer does not pay the application fee the application will be terminated. No further fees are required at this stage. Any assessment fees applicable to the conformity assessment are calculated once the TGA determines the assessment needed and are invoiced separately to the applicant.

Submitting supporting documentation and declaration forms

Submitting supporting documentation and declaration forms

Once the electronic application is lodged with the TGA and the application fee is processed, the applicant will receive a letter from the TGA with the Submission ID number.

All documents submitted in support of the application should include the Submission ID number, regardless of whether they are electronic or hard printed copies.

In addition:

- Two hard copies of the supporting documentation are required. An additional copy in electronic format (in Microsoft Word or PDF format) may assist the TGA with the assessment.
- If the application is for devices that contain materials of animal, microbial, or recombinant origin, additional copies of the supporting information may be required for distribution to expert areas in the TGA. Please contact the TGA for further advice.
- The supporting information must be supplied in loose-leaf binders. Plastic sleeves or stapled material are not acceptable.
- The information should be sectioned for ease of reference, and a table of contents provided that details the content of the binders.
- The binders should be divided with appropriately named tab identifiers. For example, the labelling information should be separated from the other documents by a tab identifier named Labelling Information.
- Each page should be sequentially numbered.

- Standard A4 paper should be used for all submissions. Text and tables should be prepared using margins that allow the document to be printed on A4 paper. The left hand margin should be sufficiently large that information is not obscured through binding.
- Font sizes for text and tables should be of a style and size that are large enough to be easily legible, even after photocopying or when provided electronically.
- Information supporting an application must be in English and legible. Where material is not originally in English a full translation must be submitted, the accuracy of which is the responsibility of the applicant.

Where to deliver the information

The supporting documentation should be sent to:

Postal Address		**Courier Delivery**
Devices Conformity Assessment Section Office of Devices Authorisation Therapeutic Goods Administration PO Box 100 WODEN ACT 2606 AUSTRALIA	or	Devices Conformity Assessment Section Office of Devices Authorisation Therapeutic Goods Administration 136 Narrabundah Lane SYMONSTON ACT 2609 AUSTRALIA

TGA processing of applications

Once the application and supporting information is received by the TGA, a pre-assessment of the application will be conducted. If the TGA finds that the manufacturer or the documentation is not ready for assessment the application may be terminated. If this happens, the TGA will contact the manufacturer to discuss the options available. If the application is terminated the application fee will not be refunded.

Further information may be necessary to process the application. The TGA may send a formal request for more information under section 41JA of the Act.

> *Please note: Each request for information will be accompanied with a specified time frame for response. If the manufacturer is not able to provide the requested information within this timeframe (plus 10 working days) the application will automatically lapse, as per section 41EG. If the application has lapsed, the manufacturer will need to reapply to obtain a TGA Conformity Assessment Certificate.*

If the application has the necessary supporting information the manufacturer will be sent a formal acceptance letter and the relevant assessment fees will be invoiced.

The TGA may invoice reduced assessment fees if there are grounds to do so. This is only done if the TGA can utilise evidence of an equivalent assessment. Examples of when this might occur are:

- where the manufacturer holds a TGA manufacturing licence and only a 'top up' GMP assessment is required
- where the applicant provides EU Notified Body reports of similar assessment performed under a relevant EU Directive. However, the TGA reserves the right to conduct a full assessment with full fees, if the reports provide insufficient evidence of a thorough and comprehensive assessment

All applicants for a Conformity Assessment Certificate are required to self-assess whether they or certain other persons associated with the applicant meet the criteria set out in paragraph 43EC(3)(a) of the Act, and to certify the outcome by submitting this Certificate to the TGA. In deciding whether to issue a Conformity Assessment Certificate the TGA must consider whether an applicant or specified persons associated with an application has in the preceding 10 years failed to meet one or more of the specified criteria - for example, whether they have been convicted of an offence against the Act or a corresponding State law, or convicted of an offence involving fraud or dishonesty. More information about these requirements is available on the TGA website <http://www.tga.gov.au>.

The TGA may refer the application to the Advisory Committee on Medical Devices (ACMD) for advice at anytime during the assessment process. Sponsors should be aware that the decision to refer an application to ACMD is at the TGA's discretion. If the application is referred, sponsors will be advised and invited to make further submissions to the TGA on the basis of the interim outcome of the Design Examination. Both the interim assessment by the TGA and the manufacturer's response to the interim assessment will be considered by ACMD. An additional 60 TGA working days will be added to the target evaluation time frame for applications sent for review by ACMD.

Issue of certificates

Certificates will be issued to the manufacturer once:

- the assessment of the device's compliance to the Essential Principles is satisfactorily completed
- any quality system audit (if conducted) is closed out—all non-conformities are resolved
- the advice of Advisory Committee on Medical Devices (ACMD) has been sought and considered (if applicable)
- all contractual arrangements for CE Marking are completed (if applicable)
- all clearances (including the Fit-and-Proper Person certification) are completed
- all fees (assessment, additional audit fees) are paid in full

The applicant will be given an explanation and statement of reasons for any refusal to issue, or restriction on, the TGA Conformity Assessment Certificate. The decision is also appealable, subject to the legislative appeal provisions.

Next steps

Once the TGA Conformity Assessment Certificate is issued to the manufacturer, the Australian sponsor of the device will be required to register the certificate as manufacturer's evidence with the TGA through the e-Business system. For more information please see Section 7. What a sponsor needs to know about conformity assessment.

Once the certificates are accepted, the Australian sponsor can proceed with an application to include the medical device in the ARTG. The device cannot be legally supplied to the market in Australia unless the application for inclusion is approved as a valid ARTG entry must exist prior to supply.

Changes to current certificates

If any of the details on a TGA Conformity Assessment Certificate are no longer correct, the manufacturer must notify the TGA. Changes include:

- changes to details on the certificate (for example, name and/or address details)
- adding new devices
- changing details on the Schedule of Suppliers
- substantial modifications are made to the design or production processes for an existing device. For more information on what constitutes a substantial change, please see Section 21. Changes to ARTG Inclusions.

The manufacturer needs to submit an application to the TGA. Applications for changing an existing TGA Conformity Assessment Certificate should be lodged electronically using the eBusiness system. The application should indicate the existing certificate number that needs to be changed and the change required on the certificate.

Supporting documentation should be provided where appropriate:

- Two hard copies of the supporting documentation are required. An additional copy in electronic format (in Microsoft Word or PDF format) may assist the TGA with the assessment.
- If the application is for devices that contain materials of animal, microbial or recombinant origins, additional copies of the supporting information may be required for distribution to expert areas in the TGA. Please contact the TGA for further advice.
- The supporting information must be supplied in loose-leaf binders. Plastic sleeves or stapled material are not acceptable.
- The information should be sectioned for ease of reference, and a table of contents provided that details the content of the binder.
- The binder should be divided with appropriately named tab identifiers. For example, the labelling information should be separated from the other documents by a tab identifier named Labelling Information.
- Each page should be sequentially numbered.
- Standard A4 paper should be used for all submissions. Text and tables should be prepared using margins that allow the document to be printed on A4 paper. The left hand margin should be sufficiently large that information is not obscured through binding.

Details of the fees payable for changing a TGA Conformity Assessment Certificate are available on the TGA website.

The TGA will need to conduct an assessment of the documentation submitted with each application for a change and further evidence to support the change may be required before a new certificate is issued.

For more information please see Section 21. Changes to ARTG Inclusions.

Conditions on certificates

Under the *Therapeutic Goods Act 1989*, three types of conditions may be imposed when a TGA Conformity Assessment Certificate is issued. They are:

- automatic conditions imposed under section 41EJ
- conditions imposed at the time the certificate is issued under section 41EK
- conditions imposed after the certificate has been issued under section 41EL.

Automatic conditions on a TGA Conformity Assessment Certificate

Under section 41EJ of the Act, there are four types of conditions that will be imposed automatically when a TGA Conformity Assessment Certificate is issued:

1. Entry and inspection powers

The manufacturer will allow an authorised person to:

- enter premises, including premises outside Australia, at which the manufacturer or any other person deals with the medical devices covered by the certificate
- inspect those premises and the medical devices, and to take samples of the devices
- carry out tests or require tests to be carried out on the devices, on the premises
- to see and copy any requested documents relating to the medical devices or the manufacturer's quality management system

2. Review requirements

The manufacturer will cooperate with any review by the TGA of matters relating to the certificate, including:

- the application of quality management system
- compliance with the Essential Principles
- any other conformity assessment procedures specified in the Regulations

3. Notification of substantial changes

The manufacturer of a medical device will notify the TGA, in writing, of any plan for substantial changes to the:

- quality management systems
- product range
- product design

For more information please see Section 21. Changes to ARTG Inclusions.

4. Payment of fees

Any prescribed fees for a review of a TGA Conformity Assessment Certificate will be paid when they are due.

Conditions imposed when a certificate is issued

When a TGA Conformity Assessment Certificate is issued, in addition to the automatic conditions outlined above, other conditions may be imposed under section 41EK of the Act.

These other conditions may relate to:

- one or more of the devices covered by the certificate
- the manufacturer's quality management system

Conditions imposed after the certificate has been issued

After a TGA Conformity Assessment Certificate is issued, the TGA may vary, remove or impose new conditions on the certificate under section 41EL of the Act. This action can result from an initiative of the TGA or at the request of applicant for the certificate. The TGA will provide written notice of the proposed change to the manufacturer.

The new conditions may relate to:

- one or more of the devices covered by the certificate
- the manufacturer's quality management system
- varying or removing existing conditions.

The new conditions will take effect immediately if action is required to prevent the imminent risk of death or serious injury. In all other cases, they will take effect 20 working days after the notice has been provided.

A decision by the Secretary or a delegate to impose a condition on a TGA Conformity Assessment Certificate after the certificate has been issued would be an appealable decision as it would be an initial decision under section 60(1)(e) of the Act.

Suspension and revocation of certificates

If false statements are made in connection with an application for a TGA Conformity Assessment certificate, fines up to a maximum of $6600 can be imposed. There are both criminal and civil penalties for making false statements (section 41EI and 41EIA).

Please note: Financial penalties are specified in the Act as penalty units. The value for each penalty unit is currently $110, in accordance with section 4AA of the Crimes Act 1914*. This amount may change in the future.*

Grounds also exist for revoking the certificate by written notice to the person who has been issued with the certificate under section 41ET of the Act if the TGA is satisfied that:

- the conformity assessment procedures have not been applied to the medical devices covered by the certificate
- the manufacturer of the medical device covered by the certificate refuses or fails to comply with a condition on the certificate
- the manufacturer mentioned on the certificate no longer manufactures any of the kinds of medical devices covered by the certificate
- the manufacturer mentioned on the certificate is not a fit and proper person
- a person who is managing the affairs of the manufacturer mentioned on the certificate is not a fit and proper person
- a person who has effective control of the manufacturer mentioned on the certificate is not a fit and proper person to have that control
- a person fails to provide information or documents within 10 working days of a request from the TGA about:
  - a kind of medical device
  - a quality management system to which the certificate applies.

However, if it is likely that the grounds for revocation do exist, a TGA Conformity Assessment Certificate may be suspended prior to any revocation proceedings being put in place (section 41EM).

Suspension of a TGA Conformity Assessment Certificate leads to the suspension from the ARTG of the medical devices covered by the certificate. Supply of those devices in Australia is then suspended.

If a TGA Conformity Assessment Certificate is revoked, it will lead to the entry in the ARTG for the medical devices covered by that certificate being cancelled. Supply of those devices in Australia is then illegal.

Details of these procedures can be found in Divisions 3 and 4 of the Act, including the:

- notices of proposed suspensions
- duration of suspensions
- revocation of suspensions
- automatic revocation

- immediate revocation
- revocation
- limiting revocation
- publication of revocations
- dates of effect of revocations

Surveillance

TGA Conformity Assessment Certificates are subject to ongoing surveillance of the manufacturer and its products by the TGA.

Normally the initial onsite audit of a manufacturer is a full audit covering all applicable aspects of the manufacturer's quality management system.

Surveillance audits normally occur approximately every 18 months after certification, but may occur more frequently depending on the manufacturer's compliance status and the risk class of the products. Surveillance audits are normally shorter audits and do not cover every applicable aspect of the quality management system. Surveillance activities may also be associated with product compliance monitoring activities, such as monitoring of non-standard conditions on the certificate or follow-up of post-approval recommendations and agreements.

For overseas manufacturers, the TGA may request EU Notified Body or CMDCAS registrar audit reports, with the view to abridging the TGA surveillance activities. If those reports are available and provide evidence of a thorough and comprehensive assessment, the TGA may abridge the surveillance activities and charge reduced fees. However, the TGA reserves the right to conduct its own surveillance irrespective of such reports.

Recertification

TGA Conformity Assessment Certificates are normally issued for a 5-year period.

If the manufacturer intends to continue supplying the devices covered by the certificate in Australia, they need to apply for recertification prior to the expiry date.

An application to re-issue an existing TGA Conformity Assessment Certificate will need to be submitted to the TGA, allowing sufficient time for processing prior to the current certificate expiring. Recertification applications are lodged via the same process utilised for new applications. See Application for certificates earlier in this Section.

An application fee and assessment fees are payable for the recertification. Assessment fees are levied according to the level of assessment required.

Recertification will normally be associated with an onsite quality management system audit, dependent on the timing of the last TGA surveillance audit.

The manufacturer will be asked to provide a comprehensive concise summary of:

- all design, production, and labelling changes implemented since the certificate was issued
- clarification of the current critical suppliers
- sterilisation arrangements for each sterile product
- country of origin; species; tissue or cell or derivative; and production arrangements for all animal-, microbial-, and recombinant- origin materials
- details of all medicinal substances and their production arrangements, including the current Australian GMP status if relevant
- post-market performance data for each device including adverse events, recalls, and alerts since the certificate was issued
- review of:

- significance of new safety and performance standards since certification
- risk-management file for currency and relevance
- clinical evidence for currency and relevance, including new clinical literature, clinical trial data or other clinical data (for example, customer surveys)

Declarations of Conformity

As part of the conformity assessment procedures, the manufacturer of a medical device is required to make a Declaration of Conformity that declares that the device complies with:

- the applicable provisions of the Essential Principles
- the classification rules
- an appropriate conformity assessment procedures.

The declaration also requires the manufacturer to provide details that are relevant to the conformity assessment procedure and the manufacture of the medical device covered by the declaration. These details include:

- name and address
- details of the:
  - scope of the declaration (including product identification information)
  - certification
  - classification
  - nomenclature code
  - conformity assessment standards (quality management standards)
  - medical device standards (product standards)

The responsibility for the classification and the conformity assessment of a medical device rests with the manufacturer of the medical device. The choice of an appropriate conformity assessment procedure, which will be governed by the class of the medical device, is also the responsibility of the manufacturer.

The wording of the Declaration of Conformity will depend on the conformity assessment procedure chosen by the manufacturer.

Templates for each of the six possible types of declarations of Conformity under Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 are available at <http://www.tga.gov.au>.

The Declaration of Conformity can be signed and dated by the manufacturer of the medical device or a person authorised by the manufacturer. The declaration must set out the name and position of the person signing the declaration.

If requested, the sponsor or manufacturer must provide the TGA with a copy of the Declaration of Conformity.

Section 7. What a sponsor needs to know about conformity assessment

This section should be read in conjunction with Section 5. Conformity assessment overview.

Overview

Conformity assessment is the systematic and ongoing examination of evidence and processes to ensure that a medical device complies with the Essential Principles.

The Australian sponsor is responsible for:

- having procedures in place, including a written agreement with the manufacturer, to obtain information from the manufacturer when requested by the TGA
- ensuring that
  - they have available sufficient information to substantiate compliance with the Essential Principles or have procedures in place to ensure that such information can be obtained from the manufacturer within 20 working days
  - an appropriate conformity assessment procedure has been applied to the medical devices by the manufacturer
  - the manufacturer has appropriate conformity assessment evidence for the medical device
  - the conformity assessment evidence remains valid while the device is supplied in Australia
- obtaining a copy of the conformity assessment evidence from the manufacturer
- submitting the conformity assessment evidence to the TGA
- applying to include the device on the Australian Register of Therapeutic Goods (ARTG)
- meeting all the ongoing monitoring and reporting requirements applicable to sponsors once a device is included on the ARTG. For more information see Section 22. Post-market vigilance and monitoring requirements
- providing samples of the medical device to the TGA upon request
- ensuring any advertising material relating to the medical device complies with the TGA requirements—for more information, see Section 12. Information about a medical device

The Australian sponsor may also be the manufacturer.

Conformity assessment evidence is not required to be submitted to the TGA for Class I medical devices unless they are supplied sterile or have a measuring function. However, an Australian Declaration of Conformity must be held by the manufacturer for Class I medical devices and provided to the TGA when requested. It is strongly recommended the sponsor hold a copy of the Australian Declaration of Conformity. The TGA may require the sponsor to supply a copy of the Australian Declaration of Conformity.

Conformity assessment evidence is not required for some systems and procedure packs. For details, see Section 16. Systems and procedure packs.

The sponsor should ensure that they have appropriate conformity assessment evidence for the medical devices before submitting the evidence to the TGA. The details on a certificate should be carefully checked to ensure that they are appropriate for the devices to avoid delays in submissions being processed.

Conformity assessment evidence accepted by the TGA

The TGA accepts the following certificates as conformity assessment evidence:

- a TGA Conformity Assessment Certificate[9] issued by the TGA—this is mandatory for some manufacturers
- certificates of conformity issued under the Australia–EC MRA
- certificates of conformity issued under the Australia–EFTA MRA
- EC certificates issued by an EU Notified Body under the:
- EU Medical Devices Directive 93/42/EEC (MDD)
- EU Active Implantable Medical Devices Directive 90/385/EEC (AIMDD).

In cases where there are differences in the classification of a device between Australia and the E[illegible] conformity assessment procedure requirements may be different in Australia. The manufacturer may [illegible] to obtain additional conformity assessment evidence. Where the manufacturer is not able to obta[illegible] appropriate additional conformity assessment evidence from their EU Notified Body, they may nee[illegible] tain a TGA Conformity Assessment Certificate. For more information, please see Section 8. Differences between the Australian and European Union medical device regulatory requirements.

The TGA will make the final determination as to whether the evidence is accep[illegible]

Conformity assessment evidence not accepted by the TGA

The TGA does not accept the following certificates as evidence th[illegible] the [illegible]ustralian regulatory requirements have been met:

- certificates from any countries outside Australia, the [illegible] an[illegible]FTA
- a certificate from the United States Food and [illegible]rug Administration (US FDA) because the US system does not align with the Australian regulatory framewo[illegible]
- an ISO 13485 Medical devices—Quality [illegible]ment systems—Requirements for regulatory purposes compliance certificate because it does no[illegible]ide assurance that the Australian legislative requirements have been taken into consideration[illegible] while [illegible]s standard specifies the requirements that are needed for a quality management system for d[illegible]vice [illegible]anufacturers, the TGA does not require that manufacturers have a certificate that states they ha[illegible] co[illegible]d with the requirements of ISO 13485 as the TGA or EU Notified Body will make this assess[illegible]en[illegible] part of the conformity assessment procedures.

[9] *TGA Conformity Assessment Certificate* is a reference to a conformity assessment certificate issued by the TGA, as defined in the Australian legislation.

The following table provides the parallel references for the Australian and EU conformity assessment procedures:

Australian reference ***Therapeutic Goods (Medical Devices) Regulations 2002***	**EU reference** **93/42/EEC (MDD) and/or 90/385/EEC (AIMDD)**
Schedule 3 Part 1—Full quality assurance procedures	Annex II
Schedule 3 Part 1, Clause 1.6—Examination of design of Class AIMD or Class III	Annex II.4
Schedule 3 Part 2—Type examination procedures	Annex III
Schedule 3 Part 3—Verification procedures	Annex IV
Schedule 3 Part 4—Production quality assurance procedures	Annex V
Schedule 3 Part 5—Product quality assurance procedures	Annex VI (MDD only)
Schedule 3 Part 6—Declaration of conformity procedures	Annex VII (MDD only)
Schedule 3 Part 7—Procedures for medical devices used for a special purpose	Annex VIII & Article 12 (MDD only)

TGA Conformity Assessment Certificates

The TGA accepts TGA Conformity Assessment Certificates as conformity assessment evidence for any manufacturer. For details on how to apply for a TGA Conformity Assessment Certificate, please see Section 6. What a manufacturer needs to know about conformity assessment.

For some manufacturers, the TGA can only accept TGA Conformity Assessment Certificates. These manufacturers are detailed in Section 5. Conformity assessment overview.

MRA certificates of conformity accepted by the TGA

Australia has signed a Mutual Recognition Agreement (MRA) with the European Union (EU) and the European Free Trade Association (EFTA), covering several industry sectors, including the medical devices sector. For more information on international agreements that are in place see Section 9. International agreements.

Several European Notified Bodies have been designated by the European Commission as competent to assess medical devices manufactured in Europe for compliance with the Australian legislation.

This means that European manufacturers who receive an MRA certificate can apply to have their devices entered on the ARTG and supply in Australia without further assessment, subject to the eligibility requirements of the MRA.

Under the MRA, the TGA accepts certificates from a number of EU Notified Bodies who have been designated to be Approved Conformity Assessment Bodies for the purposes of the EC/EFTA MRAs. Details of the current approved bodies are available on the TGA website.

These MRAs are only applicable to manufacturers as defined in section 41BG of the *Therapeutic Goods Act 1989*, who are established in an EU or EFTA state. Manufacturers must also demonstrate that the device is manufactured within the European Union or EFTA member country.

Some types of devices are excluded from the agreement, including:

- radioactive materials to the extent that these may be considered to be medical devices
- medical devices incorporating tissues of animal origin. However, medical devices incorporating refined derivatives of animal-derived waxes, heparin and gelatin that conform to pharmacopoeial standards and sintered hydroxyapatite, or incorporating tissues of animal origin and where the device is intended to come into contact with intact skin only are included.

The therapeutic goods legislation does not allow the TGA to accept an MRA certificate for medical devices that contain:

- materials of animal, microbial, or recombinant origin
- derivatives of human blood or plasma
- a medicine

The TGA does not currently accept MRA certificates for the following devices, as confidence building arrangements have not occurred:

- Active implantable medical devices (AIMDs)
- intra-uterine contraceptive devices
- heart valves
- intra-ocular lenses
- intra-ocular visco elastic fluids
- powered drug-infusion pumps
- implantable breast prostheses (other than those containing only saline or water)
- barrier contraceptive devices (excluding condoms)
- instrument grade disinfectants

What information should be on an MRA certificate?

The following details should appear on the MRA certificate:

- certificate number
- date when the certificate was first issued
- revision date if applicable
- date of expiry of certificate
- a statement that 'This certificate is issued by a designated Conformity Assessment Body under the Medical Device Sectoral Annex of the EC/EFTA–Australia Mutual Recognition Agreement' or equivalent wording
- manufacturer details:
  - manufacturer's name
  - manufacturer's complete street address including country
- name and complete street address including country, of any critical suppliers for the product (in particular sterilisation services)
- device details:
  - scope of Certificate/product identification
  - Global Medical Device Nomenclature System (GMDN Code) and Preferred Term(s)
  - for Class III and AIMD provide the Unique Product Identifier (UPI) of devices manufactured

- a statement of compliance with an Australian conformity assessment procedure applied in accordance with Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002:
  - Full Quality Assurance Procedures—Schedule 3, Part 1 (without Clause 1.6)
  - Production Quality Assurance Procedures—Schedule 3, Part 4
  - Verification Procedures—Schedule 3, Part 3
  - Product Quality Assurance Procedures—Schedule 3, Part 5
  - Type Examination Procedures—Schedule 3, Part 2
  - Design Examination Certificate—Schedule 3, Clause 1.6.
  - The Part 1 and Clause 1.6 certifications may be combined in a single certificate or may appear on separate certificates.
- for Design or Type Examination Certificates—a statement of compliance with the Australian Essential Principles of Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002 must be provided
- Conformity Assessment Body details:
  - name
  - number
  - address
- name and signature of an authorised representative of the Conformity Assessment Body

In addition, for products incorporating animal-derived waxes, heparin, or gelatin, the Conformity Assessment Body must have the following available and provide the information to the TGA upon request:

- country of origin of the material
- species of the animal
- part of the animal used to manufacture the product
- Pharmacopeial standard reference
- European Directorate for the Quality of Medicines (EDQM) certificate reference and date of issue
- evidence of compliance with the TGA Transmissible Spongiform Encephalopathy Policy (TSE Policy), available on the TGA website.
- evidence of compliance to *Conformity Assessment Standards for Quality Assurance Techniques for Animal Tissues and their Derivatives utilised in the Manufacture of Medical Devices,* available on the TGA website.

It should be noted that:

- all certificates are to be written in English
- all certificates are considered to be valid for a maximum of 5 years after the date of first issue
- surveillance activities will be conducted over the 5-year period and recertification is required prior to the expiry of the certificate
- the certificate should be provided by the manufacturer to the Australian sponsor(s) so that it may be submitted to the TGA to support an application for inclusion of the devices on the ARTG
- the Conformity Assessment Body's MRA certification decision is expected to be made utilising its management system that has been accredited and monitored by the designating authority or its delegate. This would normally be the same management system utilised for CE certification under the relevant Medical Device Directives.

EC certificates issued by an EU Notified Body

In accordance with the legislation, for devices manufactured outside Australia the TGA is able to accept the assessment of regulatory bodies that are considered to have the appropriate authority and expertise. As the Australian and the EU regulatory requirements are similar, the TGA has determined that certificates issued by EU Notified Bodies may be accepted as conformity assessment evidence for the supply of devices in Australia. There are medical devices that are exceptions to this determination, which are outlined later in this document.

For Class I with a measuring function, Class I supplied sterile, Class IIa, and most Class IIb devices, EC Certificates are accepted by the TGA as generally sufficient to demonstrate compliance with the Australian Essential Principles and conformity assessment procedures.

For Class III, AIMD, and some Class IIb devices covered by EC Certificates a mandatory application audit will be conducted once the sponsor lodges an Application for Inclusion on the ARTG with the TGA. The application audit is to confirm that the manufacturer of a medical device has carried out conformity assessment procedures appropriate to the classification of the medical device. For more information, please see Section 4 Application audits of medical device applications. The following table outlines the EU MDD and Annex options:

Classification	Options	Directive
Class I Measuring	Annex II.3 Annex V Annex IV for non-sterile devices where specific batches are included on the certificate Annex VI	93/42/EEC (MDD)
Class I Sterile	Annex II.3 Annex V	93/42/EEC (MDD)
Class IIa	Annex II.3 Annex V Annex IV for non-sterile devices where specific batches are included on the certificate Annex VI for non-sterile devices	93/42/EEC (MDD)
Class IIb	Annex II.3 Annex V + III Annex IV for non-sterile devices where specific batches are included on the certificate Annex VI + III for non-sterile devices	93/42/EEC (MDD)
Class III	Annex II.3+II.4 Annex V+ III Annex IV for non-sterile devices where specific batches are included on the certificate	93/42/EEC (MDD)
AIMDs and their accessories	Annex 2.3 + 2.4 Annex 5 + 3 Annex 4 + 3	90/385/EEC (AIMDD)

There are some exceptions that apply, as follows:

MDD certificates issued under	that are limited to	are only acceptable for
Annex V	'sterility aspects' or equivalent wording	Class I sterile devices.
Annex VI	'metrology aspects' or equivalent wording	Class I measuring devices.

In addition, the manufacturer must complete an Australian Declaration of Conformity that includes details about the manufacturer and the devices and declares that the device complies with the applicable:

- provisions of the Essential Principles
- classification rules
- conformity assessment procedures

Some Notified Bodies in Europe may issue a special kind of CE certification known as 'OEM labelling', 'Private Labelling' or 'Own Brand Labelling'. These certificates are issued to a manufacturer who re-labels another manufacturer's medical device that has CE certification.

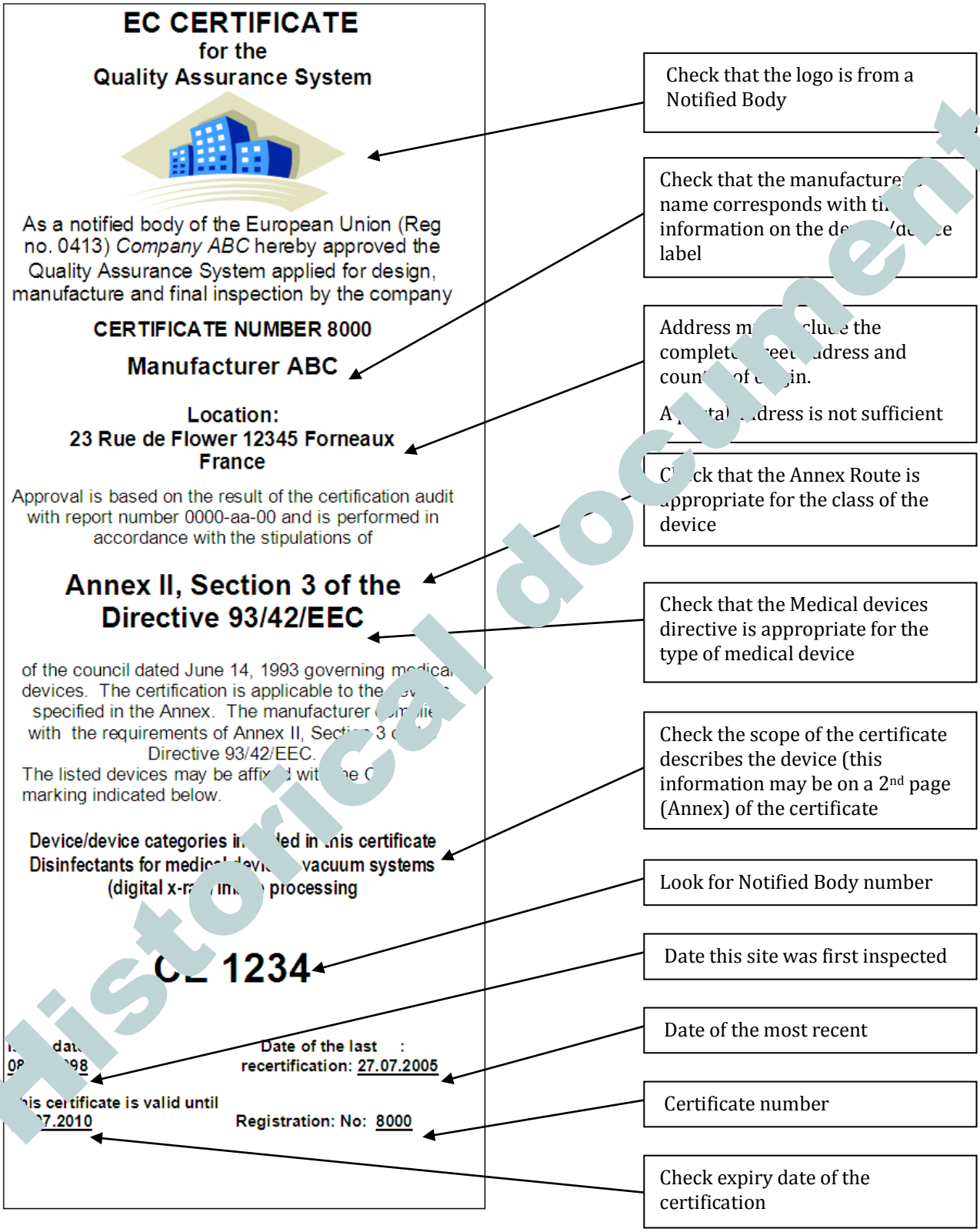
The TGA will accept CE certificates for 'Own Brand Labelling' as conformity assessment evidence, without requiring additional information, provided:

- the original manufacturer's CE certificate, quality management system documentation and product technical documentation must be available but will not always be requested
- the TGA will request the original manufacturer's CE certificate and other documents during application audit or post-market review of a device covered by an 'Own Brand Labelling' certificate
- failure to provide the additional information is sufficient grounds for rejection/suspension/cancellation

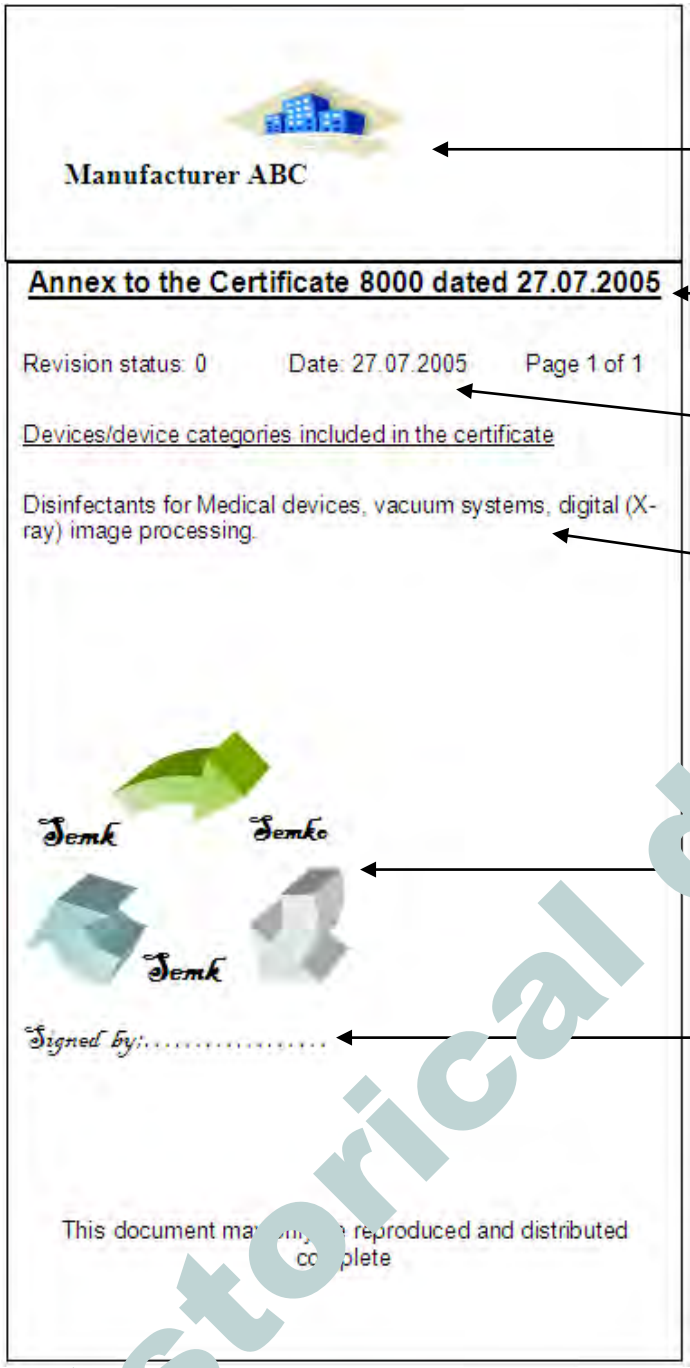
An example of an EC certificate is provided on the next page highlighting some of the key details that should be checked.

What information should be on an EC certificate

There are a number of important details that a sponsor should check to ensure that the certificate is valid for particular devices. Wording and formatting will vary between Notified Bodies. This is an example only.



Annex to EC certificate



Check Notified Body name and logo is the same as the certificate

Check certificate number fo this Annex is the same as the certificate

Look for date o recertificati

Check t the scope of the ce icate describes the e you intend to include o the ARTG

Look for the Notified body stamp

Look for a signature from an authorised signatory

Please note: Certificates may reference attachments or additional information such as:

- 'see overleaf'
- Annexes
- Enclosures
- Schedules
- Addendums
- MDD product lists

This information MUST be provided with the EC Certificate.

Manufacturer's Evidence

Manufacturer's Evidence is the conformity assessment evidence that demonstrates that a manufacturer has appropriate manufacturing processes to make the devices. The sponsor of a medical device must submit the Manufacturer's Evidence to the TGA, prior to applying to include a medical device in the ARTG.

A TGA Conformity Assessment Certificate or conformity assessment evidence issued by an EU Notified Body states that the certificate has been issued under one of the legislative references outlined in the table below to indicate that the manufacturing processes have been appropriately assessed. There are restrictions on the conformity assessment procedures that can be used for each classification of medical device, as follows:

Australian reference ***Therapeutic Goods (Medical Devices) Regulations 2002***	**EU reference** **MDD 93/42/EEC**	**Acceptable medical device classes**
Schedule 3 Part 1	Annex II.3	All
Schedule 3 Part 3	Annex IV	All except Class I sterile
Schedule 3 Part 4	Annex V	All
Schedule 3 Part 5	Annex VI	Class I measuring, Class IIa, Class IIb—cannot be used for sterile devices

Certificates that have been issued under other regulatory frameworks are not acceptable as manufacturer's Evidence for medical devices.

Certificates relating only to the design of the device are also not accepted for submission as manufacturer's Evidence. This includes Design Examination and Type Examination certificates issued by the TGA or a Notified Body under the MDD/MDD Annex II.4 or Annex III, or under Schedule 3, Clause 1.6 or Part 2 of the Australian Regulations. Where relevant, the TGA may request copies of such certificates during the device application and any subsequent audit processes, however, these certificates are insufficient for initial submission as Manufacturer's Evidence. Only the certificates listed in the table above are accepted for submission as Manufacturer's Evidence.

There is no fee for submitting Manufacturer's Evidence. The TGA has a target time frame of 15 working days to consider and where appropriate accept the Manufacturer's Evidence.

Submitting Manufacturer's Evidence

Before submitting the evidence, the Australian sponsor must establish an e-Business account with the TGA. This provides access to the TGA's eBusiness system, which is used to make electronic applications for medical devices. The forms and instructions are at <http://www.ebs.tga.gov.au>.

Additional detailed guidance regarding Manufacturer's Evidence is available as a fact sheet on the TGA website.

The sponsor must lodge Manufacturer's Evidence as an electronic submission through the eBusiness system.

To do this, the sponsor should open the eBusiness portal view, select the option 'Create a conformity assessment evidence' under Medical Devices and follow the prompts.

Please note: The notification process requires that an electronic copy of the evidence be attached to the submission. It will help the sponsor if they have a copy of the manufacturer's Australian Declaration of Conformity to refer to when completing the electronic application.

Maintaining currency of Manufacturer's Evidence

Expired certificates

In most cases the manufacturer's certifications are current for 5 years from the last date of issue.

The expiry date as stated on the certificate is recorded on eBS. This expiry date is then used to send reminder letters to sponsors advising that the Manufacturer's Evidence has expired and provide a timeframe for sponsors to submit updated evidence.

Variations to existing Manufacturer's Evidence

The information on the manufacturer's certificates may change over time. As a consequence, the EU Notified Body will generally audit the facility and/or issue a revised certificate.

These revised certificates must be submitted to the TGA as a 'variation to manufacturer's evidence' quoting the unique manufacturer's evidence ID number. Any changes to the certifications need to be incorporated in the variation notification form in eBS.

If there has been a change in manufacturer's name and/or site address, sponsors will need to attach documentation from the notified body that provides evidence of the change. This requirement is to prove to the TGA that the change in manufacturer's name and/or address is a result of corporate changes only and not:

- as a result of a new manufacturer taking on responsibility for the production of the devices
- as an alternate manufacturer to those devices already included on the ARTG

If either of the options listed above occur, each device is regarded as being a different kind of medical device under section 41BD of the Act and will require a new application to be submitted for the device to be included in the ARTG.

Changes to existing manufacturer's certificates

The changes to existing manufacturer's certificates that can occur over time include:

- expanding the range of products covered under the scope of the certificate
- reducing the range of products covered under the scope of the certificate
- updating the
  - certificate number following reissuing of a certificate
  - re-issue date following a surveillance audit and reissue of the certificate
- altering the conformity assessment procedures (change to the Annex route)
- changing the Notified Body undertaking the audit; or
- amending the manufacturer's details (change to name and/or address)

The TGA needs to be advised if any of these changes occur. The process for updating this information is to submit a variation to manufacturer's evidence via eBS.

Next steps

The TGA will notify the sponsor via email if the manufacturer's evidence submission is successful.

If the submission is rejected, the sponsor will be notified by email, outlining the reasons for the rejection.

Once the evidence has been successfully submitted, the sponsor can then lodge an application to include a device on the ARTG. Please see Section 10. Including medical devices in the ARTG.

Please note: The TGA may request an original or properly notarised paper copy of the Manufacturer's Evidence at any time. Sponsors should ensure that this can be provided to the TGA within 20 working days of such a request.

Section 8. Differences between the Australian and European Union medical device regulatory requirements

Overview

The Australian regulatory framework introduced in October 2002, has many similarities with that adopted by the European Union (EU). However, while similar, the two systems do have some differences.

This information will assist:

- Australian manufacturers who export medical devices to the EU or who intend to export to the EU
- Australian sponsors who wish to import CE-marked medical devices into the Australian market
- Overseas manufacturers who wish to manufacture for both the European and Australian markets

Regulatory frameworks

Australia regulates medical devices under:

- the *Therapeutic Goods Act 1989* (the Act)
- the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations).

The EU has multiple directives to cover medical devices:

- Medical Device Directive (MDD) 93/42/EEC
- Active Implantable Medical Device Directive (AIMDD) 90/385/EEC.

EU Directive 2007/47/EC, introduced on 5 September 2007 in the European Parliament, made significant amendments to the MDD and AIMDD. The changes introduced by the new Directive are fully effective from 21 March 2010.

This section of the ARGMD describes the differences between Australia and the EU now that the new Directive 2007/47/EC has come into effect.

In vitro diagnostic devices

The regulatory frameworks for in vitro diagnostic devices (IVDs) are different in Australia and the EU. In the EU, IVDs are covered by the IVD Directive 98/79/EC. In Australia, IVDs are regulated as a subset of medical devices but have distinct regulatory requirements. See the TGA website for IVD regulatory guidance.

Specific differences between Australia and the EU in relation to IVDs are not covered in this document.

Australian sponsor and European authorised representative

In Australia, sponsors take responsibility for the import, supply, or export of a medical device. A sponsor must be a resident or carrying on business in Australia.

In the EU, if the manufacturer does not have a registered place of business in a member state, the manufacturer must designate a single authorised representative in the EU responsible for placing the devices on the market. The authorised representative has the mandate to act and be contacted in lieu of the manufacturer in relation to meeting the obligations imposed by the MDD or AIMDD for all classes of devices. The authorised representative must be identified in the labelling supplied with the device.

Please note: Directive 2007/47/EC clarifies that manufacturers outside the EU require a single authorised representative who is established in the EU

Identification of sponsor and authorised representative

In Australia, the information provided with the medical device must allow both the sponsor and manufacturer to be identified. The sponsor's name and address must be provided with the device in accordance with Regulation 10.2 of the Regulations and must be located either:

- on the device itself, unless it is not appropriate or practicable to do so, or
- on the packaging of the device, unless it is not appropriate or practicable to do so, or
- in documents supplied with the device

For further information please see Section 12. Information about a medical device.

In the EU, Essential Requirements 13.3 and 13.6 require the manufacturer to place the name and address of either the person responsible or the authorised representative of the manufacturer or the importer established within the EU to be on the label or outer package or *instructions for use*.

Conformity assessment procedures

The EU and Australian conformity assessment procedures are closely aligned. For details see Section 7. What a sponsor needs to know about conformity assessment.

In the EU, manufacturers may need to engage a Notified Body to obtain conformity assessment certification. This certification is called CE Certification. Once this certification has been issued the manufacturer may affix the CE mark to their devices prior to supply.

Declarations of conformity

In the EU, manufacturers make a Declaration of Conformity (DoC) under the MDD or AIMDD. This is a formal statement signed by an authorised representative of the manufacturer. The DoC states that the device (including the name, type or model of the device) has been verified in accordance with the relevant conformity assessment procedure and meets the requirements of the MDD or AIMDD.

In Australia, the conformity assessment procedures require the manufacturer to make a DoC in accordance with the Australian legislative requirements. The Australian DoC:

- is made under the relevant clause of Schedule 3 of the Regulations
- states that the device (including the name, type or model of the device) has been verified in accordance with the relevant Australian conformity assessment procedure
- includes the GMDN code and classification of the devices
- indicates the Unique Product Identifier for each Class III and AIMD device

Australian Register of Therapeutic Goods (ARTG) and CE marking

The ARTG is the register of information about therapeutic goods for human use that may be imported, supplied in or exported from Australia. All medical devices, including Class I, must be included in the ARTG before supply in Australia. There are limited exceptions to this requirement specified in the legislation, such as for experimental use. These exceptions are detailed in Section 20. Access to unapproved medical devices in Australia.

In the EU, the manufacturer must affix the CE marking to medical devices prior to supply. CE marking or CE Certification alone does not authorise supply in Australia. The authorised representative of the manufacturer of Class I medical devices exported to the EU must register details with their EU Competent Authority. For higher class devices, the manufacturer's Notified Body must register details of CE certificates with their designating Competent Authority. The EU Competent Authorities have a centralised databank to store and share the above information as well as data relating to certificates, data obtained in accordance with vigilance procedures and

data related to clinical investigations, but is not used to control supply of product in the EU. The Directive 2007/47/EC requires the databank to be fully operational by 5 September 2012.

Global Medical Device Nomenclature (GMDN) system

GMDN codes may be used internationally by regulatory bodies as a nomenclature system to help identify medical devices.

In Australia, GMDN codes are included on all:

- entries in the ARTG
- Australian Declarations of Conformity

In the EU, the adoption of GMDN codes has not been implemented to the same extent as in Australia. C certificates are sometimes issued by EU Notified Bodies without reference to GMDN codes.

There may be differences between the GMDN Agency code table database and the TGA code tabl database. For further information regarding GMDN, please see Section 10. Including medical devices in the ART

Retention of records

In Australia, the manufacturer must keep all manufacturing records for at least 5 yea om the last date of manufacture or the lifetime of the device, whichever is longer. However, distribut rec ds relating to Class AIMD, Class III or implantable Class IIb medical devices must be retained by th po for inspection by the TGA for 10 years.

Similarly, the EU directives require the retention of manufacturing reco s for years from the last date of manufacture or the lifetime of the device, whichever is longer. Howe plantable devices, records must be kept for at least 15 years from the last date of manufacture.

> *Please note: Directive 2007/47/EC introduces the require at manufacturing records of implantable devices must be kept for at least 15 years fro the st date of manufacture.*

Differences between Australi Essential Principles and EU Essential Requirements

The Australian Essential Principles ar spec ed in Schedule 1 of the Regulations. The analogous requirements in the EU are referred to as the Esse ial rements and are specified in Annex I of the MDD. The following table compares the Australian Essen al ciples with the EU Essential Requirements.

Despite the differences, and w the exception of some medical device manufacturers who require a TGA Conformity Assessment ifica e, CE Certificates can be submitted in support of an application to include medical devices in the RTG his will continue once the amended MDD (due to Directive 2007/47/EC) becomes fully effective.

For more deta ls on Conformity Assessment Certificates, see Section 5. Conformity assessment overview.

Differences between Australian Essential Principles and EU Essential Requirements

Australian Essential Principles (EPs)	EU Essential Requirements (ERs)
EP 1 (and EP 2a) Australian EP 1 addresses the need to consider technical knowledge, experience, education or training of users. Australian EP 2a requires identification of hazards and risks arising from the use and foreseeable misuse of the device. The manufacturer must minimise any risks associated with the use of the device.	ER 1 Directive 2007/47/EC introduces more explicit requirements to ER 1, which are similar to EP 1 and EP 2a. That is, reduce risk of use error due to ergonomic features of the device and consider the technical knowledge, experience, education and training of intended users while designing the device.
EP 7.1 (a) EP 7.1(a) requires that "particular attention must be given to the chemical and physical properties of the materials used in the device". Moreover, ISO 10993-1: Biological evaluation of medical devices - Part 1 Evaluation and testing, which is included in the Medical Device Standards Order (Standards for Biological Safety Of Medical Devices) 2008 refers to the consideration of physical characteristics and properties in the selection of materials. The requirement of biophysical or modelling research is not explicitly covered in the Australian EPs.	ER 7.1 Directive 2007/47/EC clarifies requirements in ER 7.1: 'particular attention must be paid to: where, appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.'
EP 7.4—Verification of incorporated substance	ER 7.4 Please see Section 14. Medical devices incorporating a medicine for more details.
EP 7.5—Minimisation of risks associated with leaching substances. and EP 7.6—Minimisation of risks associated with ingress or egress of substances	ER 7.1, 7.5 and 7.6 Risks associated with leaching, egress or ingress of material or substances are addressed by the combination of the EU MDD ERs 7.1, 7.5 and 7.6.
EP 7.5 and 7.6 Controls for substances that are carcinogenic, mutagenic or toxic to reproduction are addressed in Australia by the general risk management requirements of EP 2. Users must be informed of any residual risks remaining after design-based risk minimisation or risk reduction is employed.	ER 7.5 (substances that are carcinogenic, mutagenic, or toxic to reproduction) Directive 2007/47/EC added the additional requirement to ER 7.5: 'special attention shall be given to substances that are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex 1 to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations, packaging and labelling of dangerous substances.'
EP 7.5 and 7.6 There are no specific labelling requirements for medical devices containing phthalates in Australia. However, the general requirements of EP 2 apply (see	ER 7.5. (phthalates) Directive 2007/47/EC also added: 'If parts of a device (or a device itself) intended to

Australian Essential Principles (EPs)	EU Essential Requirements (ERs)
above).	administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be lab[illegible] on the device itself and/or on the packaging for eac[illegible] unit or, where appropriate, on the sales pack[illegible]as a device containing phthalates. If the intended use of such devices in[illegible] treatment of children or treatment of pregnant [illegible]ng women, the manufacturer must [illegible]vide specific justification for the use of the su[illegible]nces with regard to compliance with [illegible]ential requirements, in particular of this paragr[illegible] within the technical documentation and, w[illegible] th[illegible] *instructions for use*, information on res[illegible]l r[illegible]s for these patient groups and, if applicab[illegible]on a[illegible]opriate precautionary measures.'
EP 8.2—Control of animal, microbial, or recombinant tissues, cells, and other substances.	ER 8.2 [illegible]se [illegible]ection 15. Medical devices containing [illegible]ls of animal, microbial or recombinant origin [illegible]ore details.
EP 10—Medical devices with a measuring functio[illegible] The Australian EP 10.1(3) requires that me[illegible]u[illegible]ents must be expressed in Australian legal units of measurement; or; if the device measu[illegible]a ph[illegible]ical quantity that is not prescribed [illegible]nde[illegible]he *National Measurement Act 1960*, the unit[illegible]ed[illegible]o be approved by the TGA.	ER 10.3 In the EU, ER 10.3 states that the measurements must be expressed in legal units conforming to the provisions of the Council Directive 80/181/EEC.
EP 12.1 The software d[illegible]e'lop[illegible]nt [illegible]ecycle is not explicitly addressed in th[illegible]stralian EPs. EP 12.1 addresses other requir[illegible]ment[illegible] medical devices incorporating electronic pr[illegible]mmable systems. S[illegible]e [illegible]n 1[illegible]ctive medical devices for more details o[illegible]edi[illegible]device software requirements.	ER 12.1(a) Directive 2007/47/EC introduced additional requirements to ER 12.1(a): 'for devices which incorporate software, or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.'
[illegible]13.1—Information to be provided with medical devices—general. The Australian EP 13.1(3) requires that the information must be provided in English and may also be provided in any other language. The Australian EP 13.1(5) requires that any number, letter, symbol, or letter or number in a symbol, used in	ER 13 Article 4 (4) of the MDD allows individual Member States to require the information made available to the user and the patient in accordance with ER 13, to be in a national language. In the EU the equivalent dimensional requirements are addressed in the standard EN1041—Information

Australian Essential Principles (EPs)	EU Essential Requirements (ERs)
the information to be legible and at least 1 millimetre high.	supplied by the manufacturer of medical devices.
EP 13.3—Information to be provided with medical devices—particular requirements. Australian EP 13.3, items 12 and 13 require that the label displays either a date up to which the device can be safely used (if applicable) or the date of manufacture of the device.	ER 13.3 In the EU, a use by date by which the device should be used (where appropriate) is required (ER 13.3 (e Active devices in the EU require the year of manufacture if the device doesn't have a use (ER 13.3 (i)).
EP 13.4—*Instructions for use* must include: Item 18 For a device that is intended by the manufacturer to be installed with, or connected to, another medical device or other equipment so that the device can operate as required for its intended purpose—sufficient information about the device to enable the user to identify the appropriate other medical device or equipment that will ensure a safe combination	ER 9.1 The EU has an equivalent requi t under ER 9.1: any restrictions on use, in r n to other devices or equipment, must be indic d on e label or in the *instructions for use*.
EP 13.4—*Instructions for use* must include: Item25 Information about any medicine (including any stable derivative of human blood or blood plasma) th s incorporated, or is intended to be incorporated, i the device as an integral part of the device	ER 13 13.3 (n) requires that devices incorporating um blood derivative must indicate this on the label. ding this information in separate *instructions for use* is insufficient in the EU.
EP 14 Australian EP 14 requires that very edi l device have clinical evidence, appropri fo use and classification of the device, de on ting that the device complies with the ap able provisions of the Essential Principles	ER 6(a) Directive 2007/47/EC added ER 6(a): 'demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.' Previously this requirement was addressed in ER 14. Now ER 14 is removed.

Devices with different requirements in Australia and the EU

Medical devices can be classified differently in Australia and the EU. To supply a medical device in Australia a manufacturer must classify their medical devices in accordance with the Australian classification rules in Schedule 2 of the Regulations.

For further information, please see Section 4. Classification of medical devices

Hip, knee, and shoulder joint replacements

Hip, knee, and shoulder joint replacements are classified as Class IIb in Australia (Schedule 2, Part 3.4(2) of t Regulations).

EU Directive 2005/50/EC of 11 August 2005 changed the classification of implantable component par f to hip, knee and shoulder replacements from Class IIb to Class III. Hip, knee and shoulder joint replac ent at have followed the Annex II conformity assessment procedures must undergo a design dossier ex mi ation (Annex II.4) to be placed on the EU market after 1 September 2009. Devices currently approved de Annex VI in conjunction with Annex III have until 1 September 2010 to upgrade the Annex VI confor ssessment certificate to Annex IV or Annex V of the MDD (Annex VI is not acceptable for Class III d s).

In order to maintain CE Certification for these devices, manufacturers may need to up de their conformity assessment certification. If the CE Certification lapses they may not have appropri evi nce to support ARTG inclusions for hip, knee and shoulder joint replacements as Class IIb devices i stra. If this occurs the manufacturer has the following options:

- Do not supply the device in Australia
- Obtain MRA certification (available only to EU manufacturers for e Australian Class IIb devices
- Obtain a TGA Conformity Assessment Certificate
- Support Australian health professionals to consider sp ial ess arrangements as described in Section 20. Access to unapproved medical devices in Au alia

Please note: The IIb classification of hip, knee d sh der replacements in Australia is subject to change pending the outcome of the public on that closed in December 2009. Further information and the consultation paper is av le on the TGA website.

Devices intended for direct ntact with the central nervous system

In the EU, all devices intende ecifically for use in direct contact with the central nervous system are Class III (Annex IX, Rule 6, 7, 8 of MD ‘Central nervous system’ is defined as the system in a human being that comprises the brain, m ning and spinal cord.

In Australia, dev inte d for transient use in direct contact with the central nervous system may be classified as Class I, IIa, or Class IIb (Schedule 2, Part 3.2 of the Regulations). Devices intended for short-term, long-t m implantable use in direct contact with the central nervous system are classified as Class III or Class MD hedule 2, Parts 3.3 and 3.4 of the Regulations).

Please note: Directive 2007/47/EC amended the MDD to classify transient devices intended specifically for use in direct contact with the central nervous system as Class III.

Definition of central circulatory system

In Australia, the definition of the central circulatory system extends beyond the current EU MDD definition to include the common iliac arteries. This means that some devices classified as Class III in Australia (Schedule 2, Parts 3.2(3), 3.3(4)(a) and 3.4(4)(a) of the Regulations) will have a lower classification in the EU.

In the EU, implantable or long-term surgically invasive devices will usually be Class IIb (Rule 8 of Annex IX of the MDD) and transient or short-term surgically invasive devices will usually be Class IIa (Annex IX, Rules 6 and 7 of the MDD), if intended to be used in the common iliac arteries.

Depending on the conformity assessment procedures performed by the manufacturer in Europe, a TGA Conformity Assessment Certificate may be required before including the device in the ARTG. For example, the EU Annex III Type Examination and EU Annex V Production Quality Assurance procedures for a Class IIb device are also sufficient for a Class III device. However, the EU Annex II.3 Full Quality Assurance procedures for a Class IIb device are insufficient for a Class III device, which requires design examination under EU Annex II.4.

Please note: Directive 2007/47/EC adds the following vessels to the 'central circulatory system':

- arcus aorta (aortic arch)
- aorta descendens (descending aorta) to the bifurcatio aortae (aortic bifurcation)

This means that some devices in contact with these blood vessels are Class III in Europe now, which is the same classification as in Australia.
However, the EU definition of 'central circulatory system' was not extended to include the common ... arteries, which are included in the Australian definition.

Devices for recording x-ray images

In Australia, non- active medical devices that are intended by the manufacturer to be used to record x-ray diagnostic images are classified as Class IIa (Schedule 2, Part 5.4 of the Regulations). This classification rule captures x-ray films, but not digital image receptors, as they are active medical devices. Digital receptors that capture x-ray images are classified as Class I in Australia (Schedule 2, Part 1 of the Regulations).

However, in the EU, all the devices that are specifically intended for recording of x-ray diagnostic images are Class IIa. This means that in the EU, x-ray films and digital image receptors are both Class IIa medical devices.

Please note: Directive 2007/47/EC replaced the wording 'non-active devices' with 'devices' in Annex IX, Rule 16 of the MDD in order to capture digital image receptors.

Active implantable medical devices and accessories

In Australia, active implantable medical devices (AIMD) are classified as Class AIMD (Schedule 2 Rule 5.7(1) of the Regulations). Accessories to AIMDs are classified in their own right and accessories may be Class I, Class I sterile, Class I measuring, Class IIa, Class IIb, or Class III depending on the intended purpose.

Implantable accessories to AIMDs are classified (Schedule 2 Rule 5.7(2) of the Regulations). This means implantable pacing leads (Class III) are classified differently to the implantable pulse generator (Class AIMD). Active medical devices intended for controlling, monitoring or directly influencing the performance of active implantable medical devices are also classified as Class III in Australia (Schedule 2 Rule 5.7(3) of the Regulations). This means devices that are not implanted such as pacemaker programmers and external cochlea implant speech processors are Class III, and are classified differently to the implantable pulse generator, which is Class AIMD.

In the EU, the AIMD Directive (AIMDD) does not include a device classification scheme. All AIMDs and AIMD accessories are considered under the AIMDD and are treated in an equivalent manner to Class III medical devices in the EU. MDD low risk AIMD accessories are not classified as Class III or AIMD in Australia.

AIMDs must meet the Australian Essential Principles for medical devices. All of the EU AIMD Directive 90/385/EEC Essential Requirements are addressed in the Australian Essential Principles, including the following:

- AIMD Directive Essential Requirement 12 requires that AIMDs incorporate an identifying code that can be read without the need for surgery.
- This is equivalent to Essential Principle 12.13.
- AIMD Directive Essential Requirement 7 requires implantable devices to be presented in a non-reusable pack to ensure they are sterile when placed on the market.

This is equivalent to Australian Essential Principles 3, 8.1, and 8.3.

Medical devices that are considered machinery

In Europe, medical devices that are also considered 'machinery' within the meaning of Article 2(a) of Directive In Europe, medical devices that are also considered 'machinery' within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery will be required to meet the essential health & safety requirements of Annex I to that Directive as well as the Essential Requirements of the MDD. The Notified Body will assess against the requirements of both Directives when assessing for CE Certification under the MDD.

In Australia, the medical devices regulatory framework does not impose additional requirements for medical devices that are also considered machinery or 'Plant'. This does not preclude, however, some requirements to comply with State or other Commonwealth legislation where they exist, for example, the National Standard for Plant NOHSC: 1010(1994) or other appropriate Australian Standards.

Please note: Directive 2007/47/EC included additional requirements for medical devices that are considered machinery

Medical devices that are considered personal protective equipment

In the EU, medical devices that are also considered personal protective equipment within the meaning of Article 1(2) of Directive 89/686/EEC on Personal Protective Equipment will be required to meet the basic health & safety requirements of Annex II to that Directive as well as the Essential Requirements of the MDD. The manufacturer may require separate certification under both Directives.

In Australia, the medical devices regulatory framework does not impose additional requirements for medical devices that are also considered personal protective equipment. This does not preclude, however, some requirements to comply with state, territory or other Commonwealth legislation where they exist. For example, performance and safety standards applying under consumer safety legislation.

Please note: Non-sterile protective or safety apparel or equipment used in the home or for occupational or recreational use is excluded from the jurisdiction of the TGA. Please see the Therapeutic Goods (Excluded Goods) Order No. 1 of 2008 *for more details.*

Please note: Directive 2007/47/EC included additional requirements for medical devices that are considered personal protective equipment

Medical devices intended for disinfecting, cleaning, etc

In Australia a medical device that is intended to specifically be used for disinfecting another medical device is Class IIb (Schedule 2, Item 5.2(2) of the Regulations). These devices include sterilants, sterilisers, and instrument-grade disinfectants intended to disinfect both invasive and non-invasive devices.

In the EU, all devices intended specifically to be used for disinfecting medical devices are Class IIa unless they are specifically intended for disinfecting invasive devices, in which case they are Class IIb (Annex IX, Rule 15 of the MDD).

Please note: Directive 2007/47/EC amended the MDD to classify the devices intended specifically to be used for disinfecting invasive devices as Class IIb. These devices are also Class IIb in Australia.
However, devices intended specifically to be used for disinfecting non-invasive devices are Class IIa in the EU but are Class IIb in Australia.

Medical gas and connection systems

Medical devices intended for connection to Australian medical gas systems are required to be compatible with these systems (see Essential Principle 9.1).

In Australia, medical gas pipeline systems are outside the scope of the medical device legislation (see Therapeutic Goods (Excluded Goods) Order No.1 of 2008). The TGA does not regulate these systems. However, Australian Standard, *AS 2896-1998: Medical gas systems—Installation and testing of non-flammable medical gas pipeline systems* and its subordinate standard *AS 2902-2005: Medical gas systems—Low pressure flexible hose assemblies*, specify requirements in relation to installation of medical gas pipeline and connection systems.

Medical gases stored in gas cylinders are classified as medicines in Australia, and therefore are outside the scope of the medical device legislation. However, Australian Standard, AS 2030, the Gas Cylinders Code, and its subordinate standards, including *AS 2473.3 –2007: Valves for compressed gas cylinders—Outlet connections for medical gases* (including pin-indexed yoke connections) and *AS 4484-2004: Gas cylinders for industrial, scient medical and refrigerant use—Labelling and colour coding* specify requirements for gas cylinders supplied with medical gases in Australia.

In the EU, medical gas pipelines when 'placed on the market' are medical devices. However, they are co idered not placed on the market when purpose-built for a hospital. Medical gases stored in gas cylinders lso classified as medicines in the EU. The international standard *ISO 7396—Medical gas pipeline syst ms* is harmonised under the MDD. Requirements for medical gases stored in gas cylinders are giv in Eu pean standards. The requirements for labelling, colour coding, and connections for medical gas ys s and for medical gases stored in cylinders will be different to those of Australia, and may vary d pe ing on the country.

Devices with radio-communication transmitters and/or that connect to te communications networks

Medical devices intended for connection to Australian telecommunication wo or that use Australian radio communication spectrum are required to be compatible with these syst s (s Essential Principle 9.1).

In Australia, medical devices that connect to a public telecommunic ns work must comply with the Australian Communications and Media Authority (ACMA) A-Tick qu ments. Medical devices with radio communication transmitters (for example, Bluetooth devic mu ply with the ACMA spectrum licensing and C-Tick requirements. Further details are available in S 13. Active medical devices.

The EU radio spectrum and telecommunications requirem or example, Radio & Telecommunications Terminal Equipment(R&TTE) Directive 1999/5/ are different to those in Australia.

Medical devices that connect to public mains ectricity networks

Medical devices intended for connection to A 'a public mains electricity networks are required to be compatible with these systems (see Essential iple 9.1).

The Australian mains electricity supp ope tes at 230 volts, 50 Hz. All electrical equipment, including medical devices, connect to the mains ele icity pply using a plug with active and neutral pins partially insulated and with Australia-specific pin con gu n as required by *AS/NZS 3112—Approval and test specification—Plugs and socket-outlets*.

For more details, pleas ction 13. Active medical devices.

In the EU, the ma co on requirements will be different to that of Australia and will vary depending on the country.

Medical de ices incorporating a medicinal substance

In Aust lia, m cinal substances that are incorporated or intended to be incorporated in the device must meet th stri n regulatory requirements for medicines. Manufacturers of these devices must obtain a TGA Co ity Assessment Certificate. See Section 14. Medical devices incorporating a medicine for more details.

he EU, for devices incorporating a medicinal substance, the Notified Body has to consult with one of the C petent Authorities, or the European Medicines Agency (EMEA) to verify compliance with Annex 1 of Directive 2001/83/EC relating to medicinal products for human use. For devices incorporating human blood derivatives, the Notified Body is required to consult the EMEA.

Any stable derivative of human blood or human plasma is considered a medicine in both the EU and Australia.

> *Please note: Directive 2007/47/EC included the option for the Notified Body to consult with the EMEA (European Medicines Agency) or one of the Competent Authorities.*

Medical devices containing substances of animal origin

In the EU, medical devices containing substances of animal origin must comply with Transmissible Spongiform Encephalopathy (TSE) Directive 2003/32/EC.

Manufacturers need to obtain a TGA Conformity Assessment Certificate to supply these devices in Australia. The Australian regulatory framework requires demonstration of compliance with risk-management procedures, controls on sourcing, collection and handling of animal origin materials and validation of inactivation processes for viruses and transmissible agents. See Section 15. Medical devices containing materials of animal, microbial or recombinant origin for details.

Catgut sutures

Catgut sutures are absorbable sutures manufactured from animal intestinal tissue, commonly bovine or ovi. Catgut sutures are no longer supplied in the EU. In Australia, catgut sutures are classified as Class III m al devices because they contain substances of animal origin. Animal material must only be sourced f countries that have not reported indigenous cases of Bovine Spongiform Encephalopathy (BSE), unless it c be stified otherwise.

As manufacturers of catgut sutures are not able to obtain valid CE certification, the TGA ssi t of the conformity assessment procedures cannot be abridged and an on-site audit of the ma fac ng facilities will be required.

Medical devices containing gelatine and collagen

There are differences between the EU and Australia in terms of requirem s for bovine-bone derived gelatine and collagen used with medical devices.

In the EU, collagen and gelatine used for the manufacturing of me vices shall meet at least the requirements as fit for human consumption (Article 1.3, TS Dire ive 03/32/EC).

In Australia, bovine-derived gelatine and collagen raw mat bone) must not be sourced from high-risk countries. See Supplementary requirements for therapeut od for minimising the risk of TSEs on the TGA website for more details.

Medical devices containing tissues, cells, o bstances of microbial or recombinant origin

In Australia, medical devices containing tiss s, or substances of microbial or recombinant origin are Class III (Schedule 2, Part 5.5 of the Regulations). M u acturers of these devices must obtain a TGA Conformity Assessment Certificate.

There is currently no distinctio n th U garding such devices and they are classified according to the other rules on the basis of the intended p pose. This means that some devices classified as Class III in Australia will have a lower classification in e EU. enerally, implantable or long-term surgically invasive devices will be Class IIb and transient or short-ter rgically invasive devices will be Class IIa, but some devices that are Class I in the EU may contain sub s o microbial or recombinant origin.

Medical devic oni g mercury

In Australia, the me devices regulatory framework does not impose any additional requirements for medical devices con mercury.

In the E Dire e 2007/51/EC imposes restrictions on the marketing of certain measuring devices containing m ry. rcury-In-Glass fever thermometers may no longer be placed on the market. Mercury sph manometers may no longer be placed on the market for sale to the general public, but may still be lab or healthcare professionals.

M ical devices containing nanomaterials

The European Commission has endorsed the precautionary principle in relation to medical devices containing nanomaterials. As an example, some dental materials may contain nanomaterials. The manufacturer should therefore incorporate the precautionary principle into their risk-management system for these devices. This would require explicit consideration of the uncertainty associated with the potential hazards posed by nanomaterials and the limits of current scientific knowledge.

The TGA position is consistent with that of other Australian Government agencies and with the EU position. The precautionary principle is consistent with the Australian approach to nanomaterials, and with the requirement for manufacturers to implement a comprehensive risk-management system. The hazards posed by nanomaterials must be addressed within that framework. However, at this time, the precautionary principle has not been formally endorsed in Australia in relation to nanomaterials.

Reprocessing of single-use medical devices

In Australia, reprocessed single-use medical devices are treated as new distinct medical devices with a new manufacturer (usually the organisation performing the reprocessing) who is responsible for conformity assessment of the recycled devices. Full compliance with the Essential Principles must be demonstrated and appropriate conformity assessment procedure must be performed. See Section 19. Single-use devices (SUDS) for more details.

Recycled medical devices are not currently CE-certified under the MDD. This means that overseas manufacturers would need to obtain a TGA conformity assessment certificate in order to supply reprocessed single-use medical devices in Australia.

Medical devices intended for export only

Medical devices that are not supplied in Australia, but are exported need to comply with the regulatory requirements of the destination country, such as the countries of the EU. These devices will need to be included on the ARTG, but are treated as Class I, regardless of other rules. This provides basic controls over medical device exports in line with international treaty obligations.

There is no equivalent rule in the EU. These devices are classified in the same manner as other devices.

Special/particular procedure for systems and procedure packs

In the EU, the 'particular procedure' defined under Article 1 of the MDD can be applied for systems and procedure packs, if all products making up the system or procedure pack have the CE mark, including medical devices, medicines, and non-therapeutic goods.

In Australia, the special procedure requirements (Schedule 3 clause 7.5) for products making up a system or procedure pack are different from the EU. The special procedure can be applied if the manufacturer can meet the following requirements for the products included in the system or procedure pack:

- medicines, or other therapeutic goods, must have an appropriate ARTG entry
- medical devices must have undergone an appropriate conformity assessment procedure
- non-therapeutic goods are not required to have undergone conformity assessment

There are also other requirements for applying the Australian special procedure. For more details, please see Section 16. Systems and procedure packs.

Certification of sterilisation providers

In Australia, there are no requirements for certification of sterilisation providers under the regulatory framework.

Directive 2007/47/EC amended Article 12 of the MDD so that sterilisation providers, who sterilise CE-marked medical devices intended to be sterilised before use in the EU are limited to use conformity assessment procedures under Annex II or V.

Section 9. International agreements

Overview

The TGA's participation in international forums helps ensure Australia aligns its policies, regulatory framework and standards with international standards. This avoids unnecessary regulatory duplication, burden and cost on manufacturers of therapeutic goods. It also assists in enabling consumers, patients and practitioners to access therapeutic goods in a timely manner.

The TGA participates in a number of international forums such as:

- the European Pharmacopoeia Commission
- the Global Harmonization Task Force on medical devices
- the International Organization for Standardization
- various World Health Organization (WHO) committees including the WHO Global Regulator's Network

One of the TGA strategies to reduce the regulatory burden on industry is to negotiate agreements with other international regulators. These agreements can range from:

- recognition and acceptance of regulatory decisions on specific products, to
- sharing information about regulatory processes, such as when pre-market assessments occur before a product is able to be supplied

Types of international agreements

There are a range of international agreements that may be negotiated, including:

Type of agreement	Key features
Mutual Recognition Agreements (MRAs)	• usually an agreement between the Australian Government and another government to enable each government to recognise/accept the decisions made by the other • some MRAs have the force of a treaty at international law • an MRA is often, but not always, entered into following an international agreement between the two countries, for example, WTO Agreement on Technical Barriers on Trade
Memoranda of Understanding (MoUs)	• terms of the MoU are not usually legally enforceable • MoUs are generally used where the parties wish to formalise the arrangements between them but do not wish to create any legally binding obligations
Memoranda of Intention (MoIs), Records of Understanding (RoUs) and others	• generally described as an 'arrangement' between two agencies or governments • terms are not usually legally enforceable • very similar to a MoU, however, in some countries a MoU (as translated) can be taken to mean a legally binding agreement

Current international agreements

The details of the MRAs and MoUs with leading international regulatory agencies are available on the TGA website. As at 28 March 2011, there are agreements in place with:

- Canada
- Europe
- Singapore
- Switzerland
- the United States of America (USA)

The TGA has also established cooperative arrangements with a number of regulators in other jurisdictions to facilitate information sharing on regulatory practices and to enhance regulatory cooperation.

Agreements that are of particular significance to the medical devices program are:

Agreement	Key features
Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Community (EC) and Australia (known as the EC-MRA)	• signed on 24 April 1998 • applications to include a Class III device on the ARTG will not be selected for an application audit if a certificate of conformity has been issued for that device under the terms of the MRA • applies to medical devices manufactured in the European Community, Australia and New Zealand • recognises the competence of designated conformity assessment bodies in the EC to undertake conformity assessment of medical devices to Australian regulatory requirements, which means devices imported under the MRA from the EC can be placed on the Australian market without further assessment by the TGA • recognises the competence of the TGA to undertake assessment of medical devices for compliance with the requirements for certification (CE Marking) for entry onto the EC market • for Australian manufacturers, this means products for export to the EC can be assessed to European requirements in conjunction with assessment for the Australian market • devices incorporating animal-derived tissues, radioactive materials, in vitro diagnostics and devices manufactured in other countries, such as the USA, (even those devices that have CE marking) are excluded at the present time. *Please note: for more information on how to obtain a certificate under the MRA please see* Section 5 What a manufacturer needs to know about conformity assessment
Agreement on mutual recognition in relation to conformity assessment, certificates and markings between Australia and the Republic of Iceland, the Principality of Liechtenstein and the Kingdom of Norway (known as the EFTA-MRA) Please note Switzerland is not included in this agreement. The TGA has a separate MoU in place with Switzerland.	• signed on 2 April 1999 applications to include a Class III device on the ARTG will not be selected for an application audit if a certificate of conformity has been issued for that device under the terms of the MRA applies to medical devices manufactured in Iceland, Liechtenstein, Norway, Australia and New Zealand • recognises the competence of designated conformity assessment bodies to undertake conformity assessment of medical devices to Australian regulatory requirements, which means devices imported under the EFTA-MRA can be placed on the Australian market more quickly • recognises the competence of the TGA to undertake assessment of medical devices for compliance with the requirements for certification ('CE Marking') for entry onto the market • for Australian manufacturers, this means products for export can be assessed to European requirements in conjunction with assessment for the Australian market • devices incorporating animal-derived tissues, radioactive materials, in vitro diagnostics, and devices manufactured in other countries, such as the USA, (even those devices that have CE marking) are excluded at the present time

Agreement	Key features
	Please note: for more information on how to obtain a certificate under the MRA please see Section 6. What a manufacturer needs to know about conformity assessment
TGA – Health Canada Memorandum of Understanding on Quality Management Systems Certification for Medical Device Manufacturers	• signed on 1 June 2007 • assists industry by enhancing regulatory cooperation between the two regulatory bodies • allows for the recognition of Quality Management Systems certifications issued by each body, and as a result, will prevent duplicate assessments of their quality management systems *Please note: for more information on how Australian and New Zealand manufacturers can participate, please contact the TGA*

Please note: The EU-designated conformity assessment bodies have been designated as competent and authorised to carry out conformity assessment via a process that involves the regulatory authority in an EU Member State assessing a body as being competent and then notifying the EU Commission. Details of the current MDD Notified Bodies can be found at <http://ec.europa.eu/enterprise/newapproach/nando>.

Part 2–Pre-market

Section 10. Including medical devices in the ARTG

Overview

The ARTG is a register of therapeutic goods accepted for importation into, supply for use in, or export from Australia. The ARTG can be viewed from the TGA eBusiness Services (eBS) at <http://www.ebs.tga.gov.au>

Medical devices cannot generally be imported, supplied in, or exported from Australia unless they are included in the ARTG.

Only an Australian sponsor can apply to include a medical device in the ARTG. For more information please see Section 7. What a sponsor needs to know about conformity assessment

The exceptions to this requirement are devices that are supplied through one of the four mechanisms for supplying medical devices in Australia not included in the ARTG:

- clinical trials in Australia
- authorised prescribers
- Special Access Scheme
- personal importation
- custom-made medical devices

For more information on the first four mechanisms, please see Section 20. Access to unapproved medical devices in Australia.

For more information on custom-made medical devices, please see Section 18. Custom-made medical devices.

A sponsor can apply to include a medical device in the ARTG if:

- the device complies with the Essential Principles
- appropriate conformity assessment procedures have been applied to the device

There are also other requirements that must be complied with that are outlined in this section.

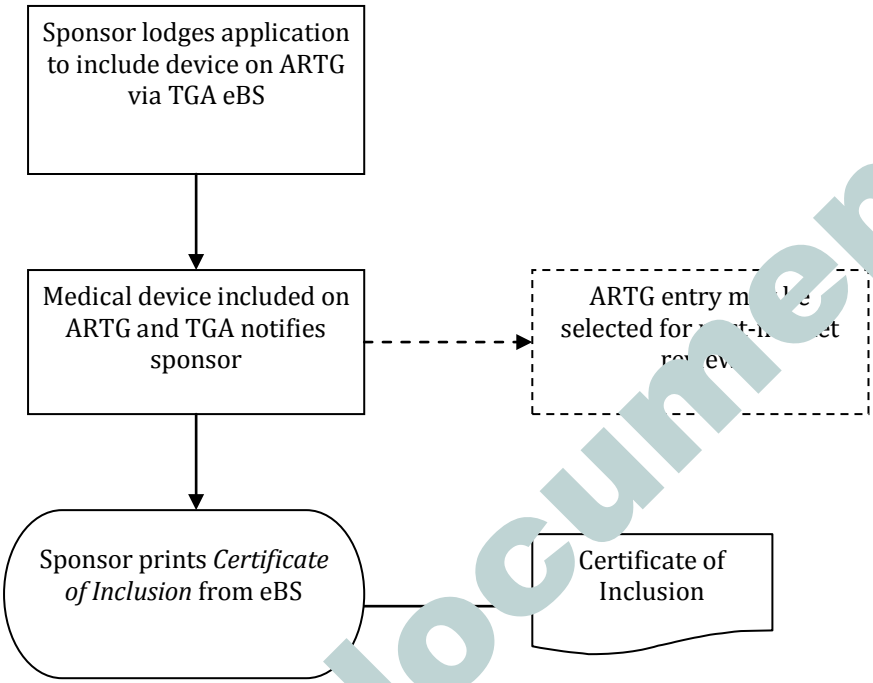
All inclusions in the ARTG are subject to automatic conditions and further conditions may be imposed by the TGA where it is appropriate.

There are three slightly different processes for including medical devices in the ARTG. There are processes for:

- Class I medical devices
- Export-only medical devices
- Medical devices other than Class I.

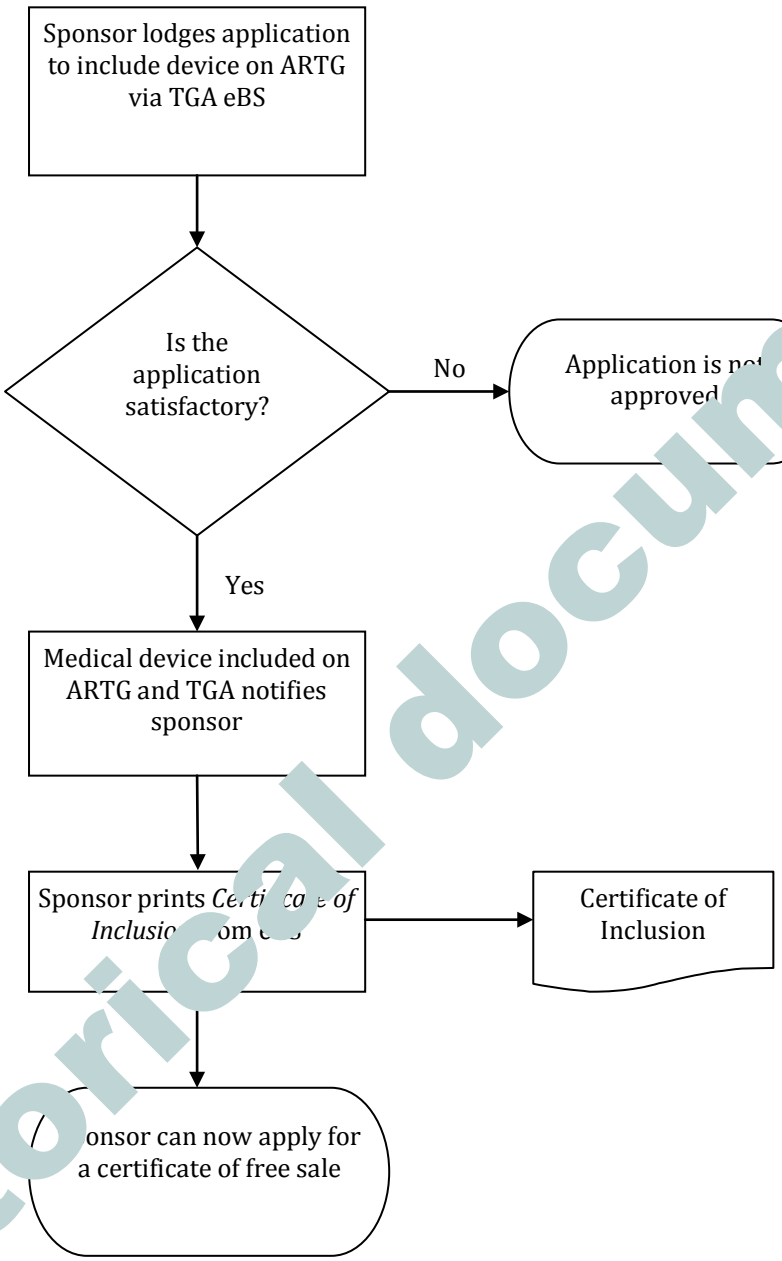
Process for including Class I devices in the ARTG

The following flowchart summarises the process for including Class I medical devices in the ARTG. For Class I measuring and Class I devices that are supplied sterile sponsors should refer to Medical devices other than Class I for supply in Australia.



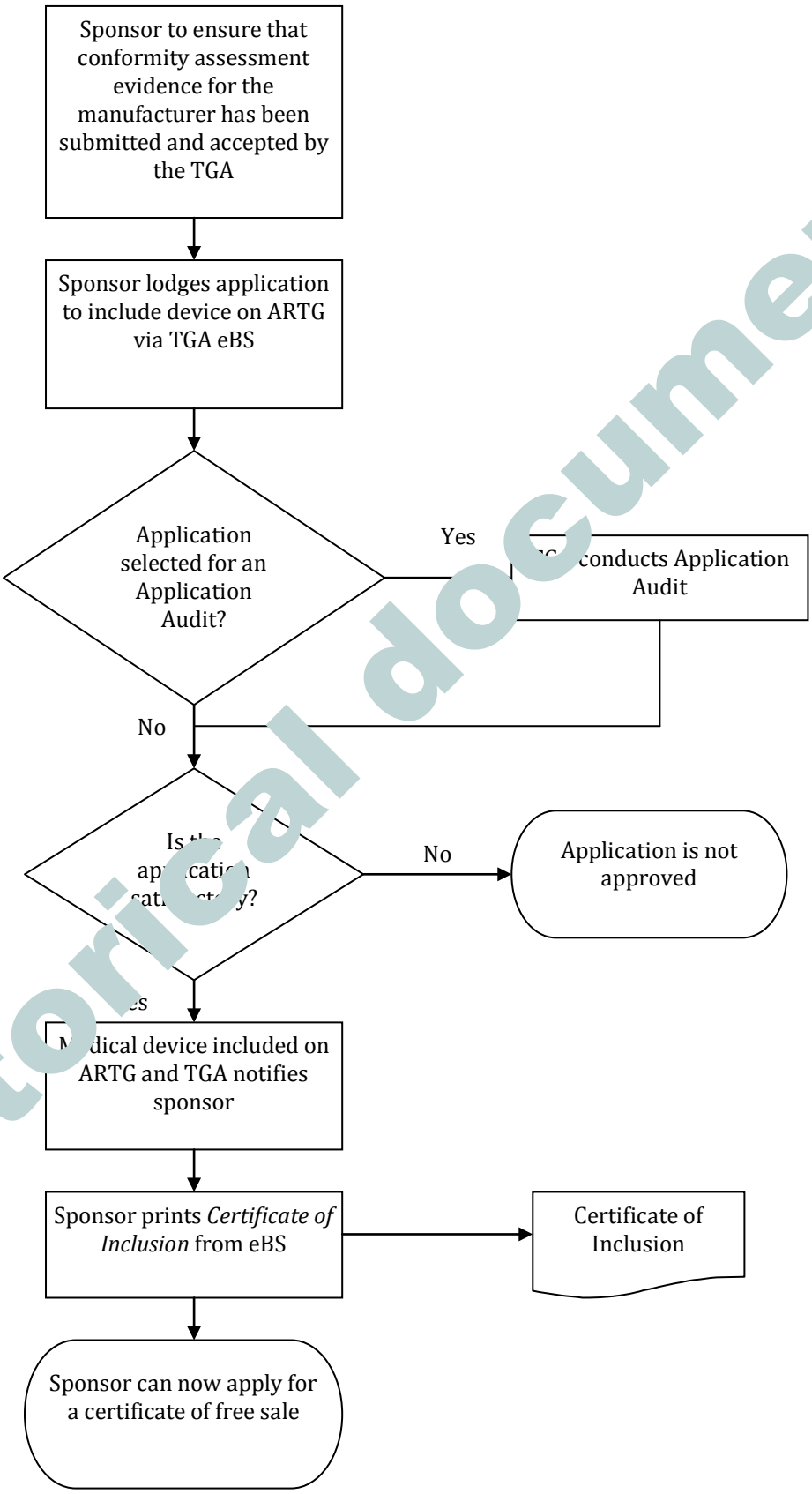
Process for including export-only devices in the ARTG

Export only medical devices are either manufactured in Australia for export only or are imported into Australia for export only. Export only medical devices are not supplied to users in Australia. The following flowchart summarises the process for including an export only medical device in the ARTG:



Process for including medical devices (other than Class I) in the ARTG

The following flowchart summarises the process for including a medical device that is to be supplied in Australia, other than Class I devices, in the ARTG:



Applications for inclusion in the ARTG

The Australian sponsor must lodge an application to include the devices in the ARTG using the eBS.

Manufacturers of Class I devices must apply a conformity assessment procedure and prepare an Australian Declaration of Conformity, however, it does not need to be submitted to the TGA prior to submitting a device application. However, once included on the ARTG, the sponsor must provide the evidence to the TGA upon request.

Manufacturer's Evidence is required for all other classifications of medical device. Before lodging an applica sponsors must submit and receive notification that the conformity assessment evidence has been accepted b the TGA. For more information on how to do this, please see Section 7. What a sponsor needs to know ab conformity assessment.

In order to lodge an application, the sponsor must in accordance with section 41FC of the Act:

- complete the appropriate application form
- submit the completed application to the TGA
- pay the prescribed application fee
- ensure that if conformity assessment evidence is required for the device that ap propriate evidence has been obtained
- ensure that the application does not contain information that is fals or mi eading

When lodging an application, the sponsor must certify in accordan h section 41FD of the Act that:

- the devices are medical devices
- the devices are intended for a specified purpose
- the devices are correctly classified according to the medical device classifications
- the devices comply with the Essential Principles
- they have:
  - available sufficient information to substantiate compliance with the Essential Principles or
  - procedures in place, including written agreement with the manufacturer of the devices to ensure that this information can be obtained from the manufacturer within the period required by the TGA
- an appropriate conformity assessment procedure has been applied to the devices
- they have:
  - available sufficient information to substantiate the application of those conformity assessment procedures
  - procedures in place, including a written agreement with the manufacturer of the device/ to ensure that this information can be obtained from the manufacturer within the period required by the TGA
- the devices comply with every requirement (if any) relating to advertising
- the devices do not contain substances that are prohibited imports for the purposes of the *Customs Act 1901*
- the information included in or with the application is complete and correct

Successful Class I (non measuring, non-sterile) applications, lodged in eBS will result in an 'automatic' inclusion in the ARTG. This means that there will not be any further assessment of the application by the TGA prior to the device being included in the ARTG.

However, all other applications may be selected for an application audit, which involves checking some or all aspects of the application and certifications.

Section 41FH of the *Therapeutic Goods Act 1989* (the Act) specifies that:

- applications to include certain higher risk medical devices in the ARTG must be selected for an application audit and an assessment fee will be charged. However, if the conformity assessment evidence is:
  - a TGA Conformity Assessment Certificate
  - for Class III devices—a certificate of conformity issued under the Australia – European Community or Australia – European Free Trade Association Mutual Recognition Agreement (MRA)
  - an audit will not be conducted as the necessary assessments are considered to have already been conducted
- the TGA may select any other applications for inclusion to undergo an application audit. An application a[u]dit assessment fee will not be charged for these audits.

For more information on Application Audits, see Section 11. Application audits of medical device applica[tions]

If	then	and
an application to include a device in the ARTG is successful	the TGA will notify the sponsor that the application has been successful	the sponsor c[onfirm]e Certificate [inc]on on eBS.
an application to include a device in the ARTG is not successful	the TGA will notify the sponsor in writing that the application has not been successful	the s[p]so[r] should ensure that [they] h[a]ve addressed any defi[c]ncies in the information [pr]ovided to the TGA before they re-[a]pply.

Kinds of medical devices

An inclusion in the ARTG is for a kind of medical de[vice]. This means that an entry in the ARTG may cover a range of products that are of the same kind rather th[an] [in]dividual devices.

From the *Therapeuti[c] Goods [Act] 1989*...

41BE

1. F[or] the p[ur]poses of this Chapter, a medical device is taken to be of the sa[me] kind as another medical device if they:
   a. have the same sponsor; and
   b. have the same manufacturer; and
   c. have the same device nomenclature system code (see subsection (3)); and
   d. have the same medical device classification; and
   e. are the same in relation to such other characteristics as the Regulations prescribe, either generally or in relation to medical devices of the kind in question.

From the *Therapeutic Goods (Medical Devices) Regulations 2002 ...*

1.6 Kinds of medical devices — other common characteristics

For paragraph 41BE (1) (e) of the Act, in relation to a Class III medical device, or Class AIMD medical device, a characteristic is the unique product identifier given to the device by its manufacturer to identify the device and any variants.

In the case of Class I, Class I sterile, Class I measuring, Class IIa, and Class IIb medical devices, one medical device is considered to be of the 'same kind' as another medical device, if both devices:

- have the same manufacturer and
- have the same sponsor and
- are the same classification and
- have the same GMDN code

Provided these criteria are met, a single entry in the ARTG may encompass multiple devices. There is no record kept in the ARTG of the product family name, model numbers, or catalogue numbers for these classes of device.

For Class III and Class AIMD medical devices a further requirement is added to the definition of same kind of medical device—they must have the same Unique Product Identifier (UPI).

An example of a *kind of medical device* is described below:

> Manufacturer 'Acacia Pty Ltd' manufactures nylon sutures intended for general purpose wound closure applications. The sutures come in a variety of different colours, lengths, and thickness. The manufacturer has classified them as Class IIb medical devices.
>
> Sponsor 'Waratah Pty Ltd' wishes to import the full range of sutures and supply them in Australia. Before the sponsor imports the sutures they obtain the manufacturer's Australian Declaration of Conformity and discover that they are classified as Class IIb medical devices, and categorised using GMDN code '13905 Suture, nylon'. The range of nylon sutures therefore have:
>
> - the same manufacturer (Acacia Pty Ltd)
> - the same classification (Class IIb)
> - the same GMDN code (13905 Suture, nylon)
>
> Because the difference in suture colour, length, and thickness do not result in a change to any of the above parameters, there is no need to have multiple ARTG entries, even though the sutures may have different trade names (for example, 'Acacia Blue Sutures', 'Acacia Red Sutures', etc.). The trade name of the product does not appear on the ARTG, and is not considered part of the definition of a kind of medical device. Therefore, sponsor Waratah Pty Ltd submits an application to the TGA to include the full range of nylon sutures under a single entry on the ARTG.
>
> Sponsor 'Grevillea Pty Ltd' also wishes to supply the same range of nylon sutures in Australia, and they discover that Acacia Pty Ltd already has an ARTG entry for the products. However, because they are not the same sponsor as identified in the existing ARTG entry, they will need to apply to the TGA to have the same range of nylon sutures included on the ARTG under their name before they import the sutures.

This is an example of where different sponsors supply the same products in Australia and, hence, why separate ARTG entries are required to cover the different kinds of medical devices.

Unique Product Identifiers (UPIs)

As specified in Regulation 1.6, of the *Therapeutic Goods (Medical Devices) Regulations 2002*, the UPI is the combination of words, numbers, symbols, or letters assigned by the manufacturer to uniquely identify the device and any of its variants.

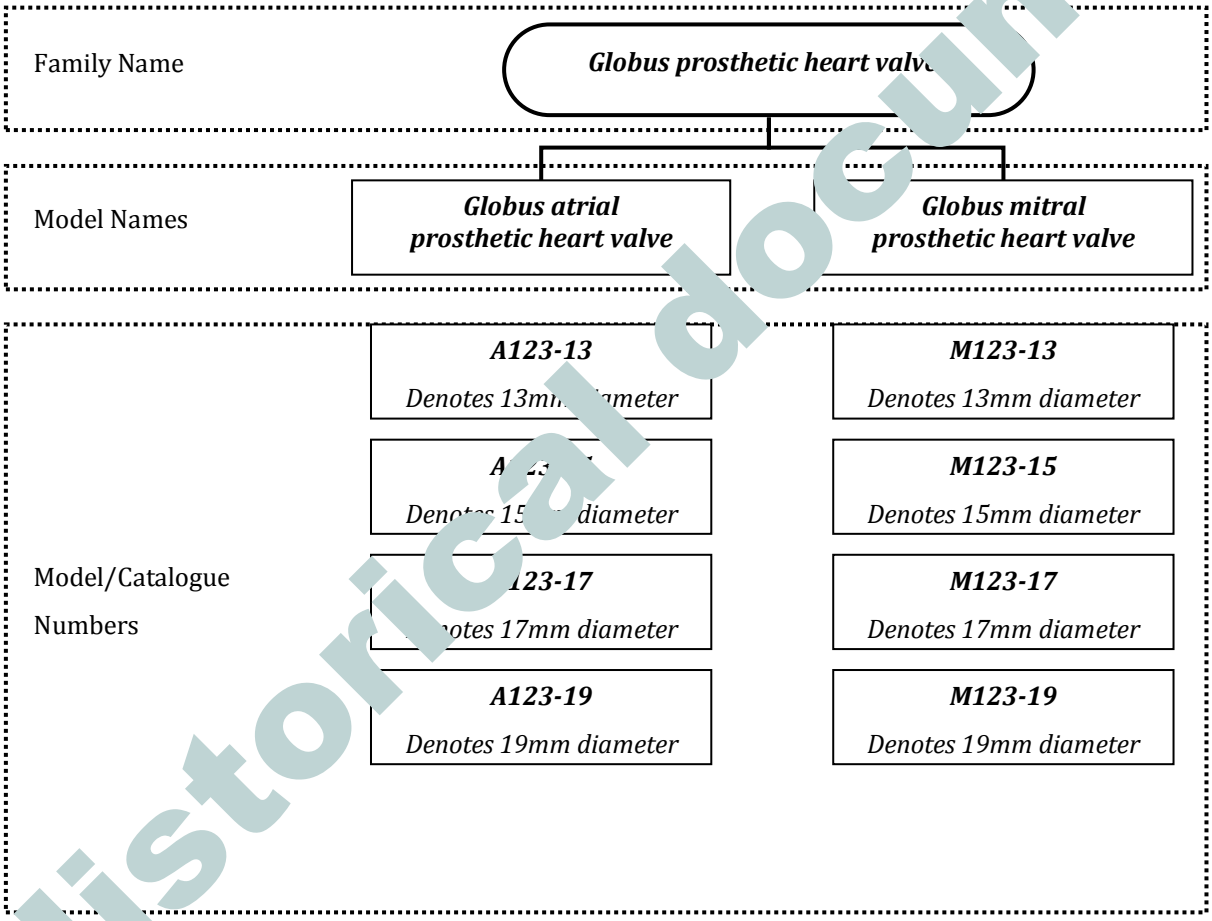
This is generally different to the catalogue or stock unit identifier assigned to the device.

Often, the family name, model names, and model/catalogue numbers will form a hierarchy in identifying the device.

Different manufacturers identify their product lines in different ways such as:

- using family names to identify a range of similar devices
- uniquely identifying each device with a model number
- a combination of both these approaches

For example, a family of prosthetic heart valves may be represented as follows:



In this example, the family name does not uniquely identify all of the device models in the product range. Therefore, the term 'Globus prosthetic heart valves' is not considered a UPI, because it does not distinguish between the different intended purposes of each model in the product range—atrial- versus mitral- valve replacement.

However, the model names:

- Globus atrial prosthetic heart valve
- Globus mitral prosthetic heart valve

are considered UPIs. This is because the model/catalogue numbers are only variations of the diameter of the device that do not change its intended purpose.

Global Medical Device Nomenclature (GMDN) Codes

GMDN codes are used by regional or national regulatory bodies to consistently describe medical devices. GMDN codes are used to assist in the:

- consistent assessment of devices before they are approved for supply
- ongoing monitoring of devices once they are available for supply

The GMDN database is a collection of terms that use a unique 5-digit code to describe particular devices. The database is maintained by a not-for-profit company based in the United Kingdom.

International regulatory authorities, including the TGA, liaise with the GMDN Agency to request amendments to existing codes and the creation of new codes. Other GMDN users may also make applications to the GMDN Agency. For more information please see the GMDN Agency website at <http://www.gmdnagency.org>.

When lodging an application to include a device in the ARTG, the sponsor must specify the GMDN code that best describes the devices that they want to include in the ARTG.

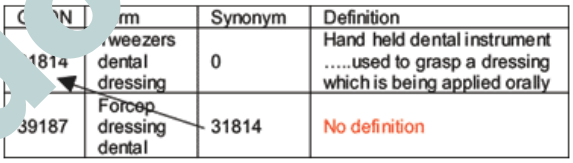
The manufacturer is responsible for determining the appropriate GMDN code for a device or range of devices, as manufacturers are best placed to determine the correct GMDN code. Sponsors are urged to seek the advice of the manufacturer and the manufacturer's Declaration of Conformity in order to verify the GMDN code before submitting an application to the TGA.

GMDN codes are available as a look-up table within eBS. Some GMDN codes within the TGA database may differ from GMDN codes in the GMDN Agency database. Sponsors should contact the TGA if there is a discrepancy that requires attention.

Please note: Where there is no clear GMDN term for a particular medical device, the GMDN term that most closely matches the product should be used by the sponsor for the purposes of including the medical device in the ARTG. This may mean that the GDMN 'description' associated with the GMDN 'term' may not be strictly accurate. To enable sponsors or manufacturers to include medical devices in the ARTG without the need to have new GMDN codes created, the TGA focuses on ensuring that the GMDN term and intended purpose are consistent, rather than the GMDN description. Any discrepancy between the GMDN description and the intended purpose of the device will not affect the validity of the ARTG entry, as the GMDN description does not appear on the ARTG certificate or the ARTG record.

GMDN structure

Each GMDN code is linked to a category and term(s). The GMDN structure consists of the following:

Level	Description	Examples
Device category	• 14 categories • broad break down of the entire medical device market	• dental devices • single-use devices • reusable devices • anaesthetic and respiratory devices • in vitro diagnostic devices
Template terms	broad names that group similar preferred terms	forceps
Preferred terms	represent a type of device that has the same or similar intended purpose or common technology	• forceps bone • forceps biops • forcep lung
Synonym and multi-linked synonym terms	From a previous coding system—eBS will default to the appropriate cross-referenced code	
Device name	UPI—Not spe de y the GMDN code dat ba e - the manufa er m t provide enoug nfor ation to en le ecific product be entified	May include make and/or model number. For more information please see Unique Product Identifiers.

The data required for ch c sification is:

	GMDN category	GMDN template term	GMDN preferred term	Device type (UPI)
E mp	Reusable devices	scissors	scissors suture	
ss	√	√	optional	n/a
Class I sterile Class I measuring Class IIa Class IIb	√	n/a	√	n/a
Class III	√	n/a	√	√

	GMDN category	GMDN template term	GMDN preferred term	Device type (UPI)
AIMD				

Please note: The UPI is not part of the GMDN code database.

Examples of GMDN codes and UPIs

The GMDN Agency uses the GMDN category for grouping similar devices but the category is not used in the actual GMDN code. The following examples of GMDN codes illustrate how the detail held increases with classification:

Classification	Information required	Examples - GMDN code	Examples - UPI
Class I non measuring and not sterile	Template term Optional preferred term	12340 Light for medical use 35079 Forceps	n/a
Class I sterile Class I measuring Class IIa Class IIb	Preferred terms	16668 Bur, dental, carbide [illegible] dental, steel 67[illegible]rr, dental, diamond	n/a
Class III AIMD	Preferred term UPI	34615 Dressing, absorbable,	Collatape Collacole Collaplug

Please note: It is important to ensure that the template and/or preferred term accurately describes the device. The sponsor should contact the TGA if they are unable to identify an accurate GMDN code after:

- checking the Declaration of Conformity
- contacting the manufacturer
- searching GUDID.

Variants for Class III and AIMD devices

From the *Therapeutic Goods (Medical Devices) Regulations 2002 – Dictionary...*

> *Variant* means a medical device the design of which has been varied to accommodate different patient anatomical requirements (for example, relating to the shape, size, length, diameter or gauge of the device), or any other variation approved by the Secretary for the purposes of this definition, if the variation does not change the intended purpose of the device.

The regulatory framework for medical devices recognises that many devices are provided in various configurations, or with varying characteristics, such as size and length, while the intended purpose of each device is exactly the same. For example, a cardiovascular stent may be supplied in four different diameters and six different lengths. These variations are only to accommodate differing vessel diameters and occlusion lengths for different patients.

Class III and Class AIMD devices can have one or more variants associated with a single ARTG entry. This minimises the number of entries required in the ARTG, but still provides a sufficiently concise level of identification of the products.

The list of currently allowable variants is available on the TGA website. In addition, the eBS electronic application form provides a drop-down list of variants that the TGA allows, which a sponsor will access when entering an application for a Class III or Class AIMD device.

Examples of the currently allowable variants are:

- Diameter (mm)
- Gauge (cm)
- Shape (of tip)
- Suture, no. of strands
- Volume (mL)

Adding new allowable variants

The TGA is responsible for considering a number of factors when deciding whether a variant is acceptable for identifying a medical device for the purpose of entry onto the ARTG:

- Are the devices the same classification?
- Do they have the same GMDN codes?
- Are the intended purposes of each of the devices the same?
- Do the devices operate or function in the same way?
- Are the physical design and construction the same or very similar?
- Are the devices made of the same material(s)?
- Are the risk profiles for each of the devices the same?

Please note: The intended purpose is determined from all sources of information that accompany the device. This includes information on the label, the Instructions for Use, and any other advertising

information or product literature for the device. If there is evidence in the accompanying information to suggest that the intended purpose of a device is more specific than what has been nominated in the eBS application, the more specific intended purpose will be used for assessment purposes.

If a sponsor considers a device to have a characteristic that is not listed in the current allowable variants list, but that fits within the concept and definition of a variant, they are encouraged to contact the TGA via email at <devices@tga.gov.au>.

The sponsor will need to provide a detailed written rationale supporting inclusion of the variant type in the list of allowable variants, and supporting documentation such as labelling, *Instructions for Use* and advertising material.

Additions to the allowable variants list must be approved by the Delegate to the Secretary before they can be included as an allowable variant in the eBS application form.

Medical device variant examples

Globus prosthetic heart valves

Using the example on Page 171 of the heart valve, a separate application for inclusion and subsequent entry in the ARTG would be required for both the Globus atrial prosthetic heart valve and the Globus mitral prosthetic heart valve. This is due to the difference in intended purpose and UPI of the two devices.

However, each of the heart valves is available in multiple diameters. This is an acceptable variant because the diameter of the heart valve is considered an allowable variant. These devices are supplied in differing diameters to accommodate the variation in size of the natural orifice within the heart between different patients. For example, patient A may be physically larger and so might need a larger diameter valve than patient B.

When entering variant details in the eBS application, the variant type would be 'Diameter (mm)', and the variant range would be: 13–19mm

Angiography Catheter Curve Styles

Angiography catheters are intended to inject contrast media into blood vessels of the cerebral, visceral, or peripheral vasculature for visualisation of the vascular system of a targeted area of the body. Patients undergoing this procedure vary greatly in the size and orientation of their vasculature. Angiography catheters are often supplied in a variety of different 'curve styles' to accommodate for this natural variation between patients.

Common catheter curve styles include:

- Amplatz
- Femoral
- Brachial
- Internal Mammary
- Ventricular Pigtail

For the purposes of this example, the delivery system for each curve style is identical and each curve style of the device has the same intended purpose, which is to inject contrast media for the visualisation of the vascular system. Each device has similar physical construction and is manufactured using the same process.

It is therefore acceptable to consider the 'curve style' of the catheter a variant.

Provided the devices can be covered by the same UPI, and the classification and GMDN code do not change as a result of the curve style, only one entry in the ARTG would be required.

When entering variant details in the eBS application, the variant type would be 'Shape (of tip)', and the variant range would include: Amplatz, Femoral, Brachial, Internal Mammary, and Ventricular Pigtail.

Catheter Delivery Systems

Cardiovascular catheters are directed to the central circulatory system using a pre-positioned guidewire. As an example, two differing designs can be used to locate the catheter using the guidewire either:

- inserting the catheter over and encasing the entire guidewire within the catheter
- constructing the catheter such that only a relatively small portion of the distal end of the catheter is hollow to encase the guidewire, allowing the catheter to be located at the treatment site within the central circulatory system

The intended purpose of both catheters is the same, however, for each of the catheters there are differences in the:

- construction of the catheters
- some or all of the materials used
- physical construction
- clinical use

As a consequence, the risk profile presented by each of the devices is also different, and separate entries in the ARTG are required for each device.

Sutures

Sutures generally follow the model of describing different variants of suture using a family name approach. The intended purpose of all types is to approximate the edges of an incision to assist in healing. They are also provided with:

- varying configurations
- with and without varying types of needles
- in different
  - lengths
  - pack sizes

They may be supplied constructed using either:

- a single filament of suture material – monofilament
- multiple filaments of material – multifilament

Provided the sutures all carry the same family name, and the relevant variants are listed in the eBS application, it is acceptable to have a single ARTG entry to cover all products within the family.

For example:

Unique Product Identifier – EXAN sutures

Possible variants:

Variant type	Variant range
Suture gauge	0.7 mm – 4.0 mm
Length (cm)	60–90
Suture, colour	undyed, violet
Suture, no. of strands	monofilament, multifilament
Suture, needle, physical attributes	curved, straight, blunt, cutting

Variant type	Variant range
Quantity/pack	1–10 sutures per pack

Isotope Activity Level

Small implantable seeds of the radioactive isotope Iodine125 are used in brachytherapy procedures to treat cancerous lesions in the body. The seeds are all of a consistent design and construction, but are available in different activity levels. The treating clinician selects the appropriate activity level of the isotope based on factors such as size and location of the lesion, to optimise treatment, while at the same time, minimising exposure to unnecessarily high levels of radiation.

It is appropriate that such a range of activity levels be considered a variant. Therefore, only a sin[illegible]ry in the ARTG is required, with 'Isotope, activity level' nominated as a variant type in the eBS applicatio[illegible]

However, should the radioisotope embedded in the seed be different to Iodine125, the con[illegible]tion, design, and possibly the intended purpose of the implant could not be considered the same. A separ[illegible]ntry in the ARTG would be required in this instance.

Method of Tissue Fixation

Manufacturers of prosthetic heart valves fabricated from porcine or other anim[illegible]tis[illegible]e use a fixation process to stabilise and render the tissue non-viable as part of the manufacturing pr[illegible]ss.

In recent years, a number of changes to the manufacturing techniques a[illegible]pr[illegible]esses have been used to minimise calcification build up on the valve once implanted. Where a chang[illegible]e process is implemented:

If	and	then
the manufacturer has the change assessed and implemented as part of process refinement	chooses not to cha[illegible]e product name	a new entry in the ARTG is not required. *Please note: the changed manufacturing process must be assessed and accepted by the TGA.*
the manufacturer has the cha[illegible]e assessed and implemented	adopts a new product name for valves produced using the new process, to differentiate the 'new' product from the 'old'	a new entry in the ARTG is required as the UPI of the device has changed.

Co[illegible]di[illegible]n on inclusion in the ARTG

All [illegible]sio[illegible] of medical devices in the ARTG are subject to conditions. There are:

- aut[illegible]matic conditions imposed when a device is included in the ARTG
- [illegible]other conditions that may be imposed by the TGA when a device is included in the ARTG
- conditions imposed after devices are included in the ARTG

Automatic conditions on inclusion in the ARTG

In accordance with section 41FN of the Act, the following conditions on inclusion apply automatically:

Type of condition	Description
Entry and inspection powers	An authorised person be allowed to: • enter and carry out inspections of premises where devices are dealt with • take samples • obtain and copy documents
Delivery for samples	If requested by the TGA, the sponsor will deliver a reasonable number of samples of a device
Availability of information about a device	The TGA may request information at any time while a device is included in the ARTG: • substantiating compliance with the Essential Principles • substantiating that conformity assessment procedures have been applied to the medical device • relating to changes to the: – medical device – product range – quality management system of the manufacturer of the device. The sponsor must have procedures in place, including a written agreement with the manufacturer of the device, to ensure that information required by the Regulations can be obtained from the manufacturer within 20 working days. The sponsor must also report adverse events to the TGA within the mandatory timeframes and assist with their investigation. For more information please see Section 22. Post-market vigilance and monitoring requirements
Advertising materials	Advertising material relating to the medical device is consistent with the intended purpose as certified in the application for inclusion in the ARTG.

Conditions that may be imposed on inclusion in the ARTG

In accordance with section 41FO of the Act, the TGA may impose additional conditions when including the kind of device in the ARTG. These conditions may be imposed to address any specific concerns regarding the manufacture, storage or disposal of products, keeping records and tracking devices, or any other issues relating to quality, safety, and/or performance.

Conditions imposed after devices are included in the ARTG

In accordance with section 41FP of the Act, the TGA may by written notice to the sponsor:

- impose new conditions on including the kind of device in the ARTG
- vary or remove existing conditions.

If the notice states that the action is necessary to prevent imminent risk of death, serious illness or serious injury, the new conditions or variation of a condition take effect on the day on which the notice is given to the person

In any other case, the new conditions or variation of a condition take effect on the day specified in the notice, not earlier than 20 working days after the notice is given to the sponsor.

Certificates of Inclusion

Sponsors will be notified by the TGA if their application for inclusion in the ARTG has been successful. The notification will include instructions for printing the Certificate of Inclusion from eBS.

Applications for amendments to entries in the ARTG

If a sponsor needs to amend the details of a medical device that is already included in the ARTG, they should access eBS and complete the appropriate form. For more information on changes to entries on the ARTG ple see Section 21. Changes to ARTG Inclusions.

Section 11. Application audits of medical device applications

Overview

The *Therapeutic Goods Act 1989* (the Act) and *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations) specify that:

- applications to include certain medical devices in the ARTG must be selected for an application audit—an application audit assessment fee will be charged
- the TGA may also select any other application for inclusion for an application audit. An audit assessment fee will not be charged for these audits

If an application audit is to be conducted the TGA will write to the sponsor who submitted the application to include the medical device on the ARTG advising:

- that the application has been selected for an application audit
- the documentation that the TGA requires the sponsor to provide
- if applicable, the fee that is payable. The TGA will send a separate invoice formally requesting the payment. The invoice will provide the payment options and the due date for payment

Section 41FI of the Act specifies that there are two aspects of an application that the TGA can consider when conducting an application audit, whether:

- the application complies with the requirements of the Act and the Regulations
- matters that the sponsor has certified in submitting the application are correct

The TGA has established two levels of application audit, Level 1 and Level 2.

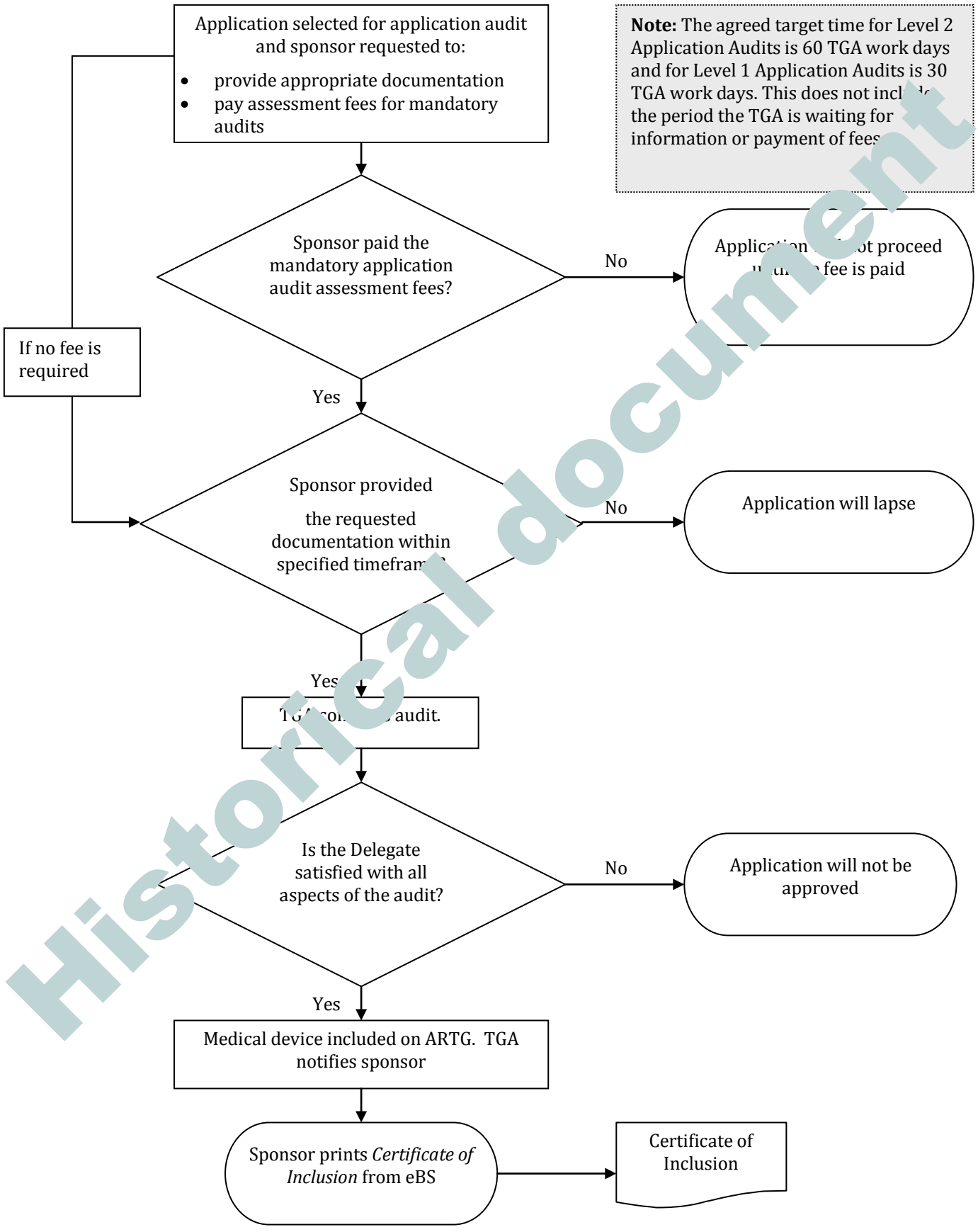
If an application audit is to be conducted the TGA will determine what level of application audit is appropriate for each application. There are different fees for each level of application audit. Details of the fees currently applicable are available on the TGA website at <http://www.tga.gov.au>.

The possible outcomes of an application audit are:

If the application audit	then	and
is successful and the sponsor has paid the appropriate fees	the TGA will notify the sponsor that the application for inclusion in the ARTG has been successful	the sponsor can print the Certificate of Inclusion on eBS.
lapses	the sponsor will need to re-apply to include the device in the ARTG	pay any associated fees again.
is not successful	the TGA will notify the sponsor that the application has not been successful and the reasons for the decision	the sponsor should ensure that any deficiencies in the information provided to the TGA have been addressed before an application to re-apply to include the device in the ARTG is made

Application audit process

The following flowchart summarises the process for the conduct of an application audit:



Applications that must be selected for an application audit

Regulation 5.3 of the Regulations specifies the medical devices that must be selected for an application audit. Where the conformity assessment evidence is a current TGA Conformity Assessment Certificate an application audit is not required.

The following devices will be selected for an application audit:

- a medical device (other than a condom) that is a barrier indicated for contraception or prevention of the transmission of disease in the course of penile penetration during sexual intercourse
- a medical device that is an implantable contraceptive device
- a medical device that is an implantable breast prosthesis containing material of fluid consistency (other than water only or a saline solution only)
- a medical device that is intended by the manufacturer to be used for disinfecting another medical device
- a Class AIMD medical device
- a medical device that is a prosthetic heart valve
- a medical device that is an implantable intra ocular lens
- a medical device that is an intra ocular visco elastic fluid
- a Class III medical device that has not been assessed under the EC Mutual Recognition Agreement or the EFTA Mutual Recognition Agreement
- Class III procedure packs using a declaration of conformity made under clause 7.5 of Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002*

All of these applications will undergo a Level 2 application audit, with the exception of a medical device that is an implantable Poly methyl methacrylate (PMMA) monofocal intra ocular lens, which will usually undergo a Level 1 audit.

Information requested for an application audit

The TGA will write to the sponsor requesting the information that is required to conduct the application audit. The TGA may ask for any documentation relating to the device and/or manufacturer.

Minimum documentation required for each level of application audit

Level	Documentation required
Level 1	Original or correctly notarised copy of the manufacturer's Australian Declaration of Conformity
	Copy of the latest and current conformity assessment evidence for the medical device and/or manufacturer
	Information about the device, including copies of the: • label • *Instructions for Use* • advertising material such as brochures, web pages, advertisements
Level 2	All the documentation listed above for a Level 1 audit
	Risk management report
	Clinical evaluation report
	Efficacy and performance data for medical devices that disinfect including sterilisation of other medical devices

Documents the sponsor is requested to provide

Document	Description	Legislative reference/guidance	Please note:
Original or correctly notarised copy of the manufacturer's Australian Declaration of Conformity	As part of the conformity assessment procedures, the manufacturer of a medical device is required to make a Declaration of Conformity that declares that the device complies with the Australian legislative requirements.	• Schedule 3 of the Regulations • Section 6. What a manufacturer needs to know about conformity assessment	The Declaration of Conformity must be for the Australian requirements. A European declaration of conformity is not acceptable.
Copy of the latest and current conformity assessment evidence for the medical device and/or manufacturer	Conformity assessment evidence is the certificate(s) issued by the TGA or Notified Body that demonstrates: a manufacturer has been assessed and has the appropriate systems in place to manufacture the devices the design of the device has been assessed where required by the conformity assessment procedure	• Conformity assessment procedures Schedule 3 of the Regulations • Section 3. Conformity assessment overview • Section 6. What a manufacturer needs to know about conformity assessment • Section 7. What a sponsor needs to know about conformity assessment	Includes: • quality assurance certificates • design examination certificates • type examination certificates that apply to the classification of the medical device. If the manufacturer has applied the conformity assessment procedure for system or procedure packs under Schedule 3, Clause 7.5 of the Regulations, the sponsor may be requested to provide copies of the manufacturer's certification for each Class III or AIMD device in the system or procedure pack. Certificates issued for an ISO standard (such as ISO13485 or ISO9001) or by the US FDA, are not considered to be suitable evidence.

Document	Description	Legislative reference/guidance	Please note:
Information about the device, including copies of the: label *Instructions for Use* advertising material such as brochures, web pages, advertisements	Information that is supplied with the device or used to promote the use of the device in Australia.	• Essential Principle 13, Schedule 1 of the Regulations • Section 12. Information about a medical device	• all information must be provided in English • labelling and *Instructions for Use* are not necessarily required for every model or variant, unless there are significant differences in content. The copies provided must be representative • include a document that lists the addresses where the device is advertised on the Internet.
Risk Management Report	The Essential Principles require a manufacturer to conduct a risk analysis to evaluate the known and foreseeable risks of using a device and ensuring that any undesirable side-effects are minimised and acceptable, when weighed against the benefits of the intended performance of the device	• Essential Principles, Schedule 1 of the Regulations • Section 3. The Essential Principles	The Risk Management Report required by the current accepted version of ISO14971 is acceptable.
Clinical evaluation report	A report that contains a comprehensive analysis of the clinical data relating to the device. The report should be objective and be prepared by an expert in the field relevant to the intended use of the device.	• Essential Principle 14, Schedule 1 of the Regulations • Part 8, Schedule 3 of the Regulations • Section 3. The Essential Principles	Evidence to support the clinical competence of the author must be provided, such as a short curriculum vitae
Efficacy and performance data for medical devices intended by the manufacturer to be used for disinfecting including sterilisation	Data that provides evidence that the devices meet relevant efficacy and performance requirements	• Essential Principles, Schedule 1 of the Regulations • Section 3. The	TGO 54 *Therapeutic Goods Order No. 54—Standard for Disinfectants and Sterilants* is a standard that may be used to demonstrate compliance with the relevant Essential Principles but it is not a mandatory standard

Document	Description	Legislative reference/guidance	Please note:
another medical device (for example, instrument grade disinfectants, bench top sterilisers)		Essential Principles	

General requirements for the information to be supplied

The TGA requires all the requested information to be provided as a complete stand-alone submission. Cross-referencing to information submitted in support of previous applications that are already included in the ARTG or are still being processed is not acceptable.

One hard copy of the documentation is required.

When compiling the application it is recommended that:

- The supporting information is supplied in loose-leaf binders. Plastic sleeves or stapled material should not be submitted
- The information is sectioned for ease of reference, and a table of contents provided that details the content of the binder(s)
- There is appropriately named tab identifiers. For example, the Labelling information should be separated from the other documents by a tab identifier named Labelling Information
- Standard A4 paper is used for all submissions. Text and tables should be prepared using margins that allow the document to be printed on A4 paper. The left hand margin should be sufficient to ensure that information is not obscured through binding
- Font sizes for text and tables are of a style and size that are large enough to be easily legible, even after photocopying or when provided electronically.
- Information supporting an application is in English and legible. Where material is not originally in English a full translation must be submitted, the accuracy of which is the responsibility of the sponsor
- Metric units are used. Units generally accepted in clinical practice may also be used (e.g. mmHg)
- All text and drawings are legible and drawings are clearly labelled

Timeframe for the provision of information

The Act and Regulations require that the sponsor either hold documentation to substantiate compliance with the Essential Principles, or have in place procedures to obtain that documentation from the manufacturer within 20 work days. The sponsor is required to certify that they have procedures in place to address these requirements when they submit the application to include a medical device in the ARTG.

Where to send the information:

Postal Address		Courier Delivery
Devices Application Section	or	Devices Application Section
Office of Devices Authorisation		Office of Devices Authorisation
Therapeutic Goods Administration		Therapeutic Goods Administration
PO Box 100		136 Narrabundah Lane
WODEN ACT 2606		SYMONSTON ACT 2609

What does an application audit involve?

Section 41FI of the Act specifies that there are two aspects of an application that the TGA can consider when conducting an application audit, whether:

- the application complies with the requirements of the Act and the Regulations
- matters that the sponsor has certified in submitting the application are correct.

Examples of what the TGA will consider when conducting an application audit are:

- Is the product a medical device as defined by section 41BD of the Act
- Are the variant and Unique Product Identifier (UPI) details used in the device application?
- Is the GMDN term in the device application appropriate for the device?
- Based on the manufacturer's intended purpose, the details in the application form, and the information provided by the sponsor, has the device been correctly classified in the Australian Declaration of Conformity and the device application?
- Is there any evidence of non-compliance with any of the Essential Principles in Schedule 1 of the Regulations?
- Is the manufacturer's Australian Declaration of Conformity in compliance with the requirements of Schedule 3 of the Regulations, and is it provided as an original or properly notarised copy?
- Is the conformity assessment procedure appropriate for the classification of the device?
- Has representative labelling and *Instructions for Use* been provided, and do they demonstrate compliance with Essential Principle 13?
- Has a risk management report been submitted and is it applicable to the medical device?
- Does the submitted clinical data meet the requirements of:

  Essential Principle 14, Schedule 1 of the Regulations
  Part 1, Schedule 3 of the Regulations?

During an application audit the TGA will not undertake any assessment or activity that would normally be performed as part of a conformity assessment procedure.

If there are any deficiencies identified during the application audit, the TGA may request the sponsor to provide information within the specified period to address the deficiencies prior to making a final decision.

When does an application selected for an application audit lapse?

In accordance with section 41FK of the Act, an application that has been selected for an application audit will lapse if:

- the sponsor does not provide the information requested by the TGA
- the sponsor does not provide a reasonable number of samples of the device, if they have been requested
- the information provided by the sponsor in support of an application is false or misleading
- the sponsor fails to pay the application audit assessment fee after being notified of the decision

Application audit assessment fees

An assessment fee is payable for each application audit that is required by the therapeutic goods legislation. For more information on the devices that are required to have an application audit please s

Applications that must be selected for an application audit. Fees are not payable for other application audits that the TGA conducts.

There are different fees for Level 1 and Level 2 application audits. Details of the fees currently applicable are available on the TGA website at <http://www.tga.gov.au>.

Level 2 application audit assessment fees can be reduced where a sponsor has more than one medical device application able to be grouped with other similar device applications (within the TGA called 'a submission'). The below rules must be followed by applicants to ensure reduced fees are applied. If these rules are not followed by default, the TGA will undertake assessment of an application at the full prescribed fee.

Applications will be eligible to be considered for a reduced assessment fee if:

- All the effective applications for inclusion are received on the same day (that is, the application fees are paid on the same day)
- All the applications are for the same medical device classification (that is, all Class III or all Class AIMD)
- A written request from the sponsor for reduced fees is electronically attached to each of the applications by the applicant. In particular, the written request must include:
  - A reference to each of the relevant application ID numbers to be considered for abridged assessment fees.
  - A statement from the sponsor that the standard supporting information package normally required for application audits is entirely common for all of the applications and will allow an abridged assessment to be performed (except for labelling, instructions for use, or promotional material).
- The Manufacturer's Evidence used to support each of the device applications must be the same (that is, the devices in each application must be covered by the same CE Quality Assurance certificate and the same Design or Type Examination certificate).
- Applications are selected for a mandatory pre-market application audit as per section 41FH of the Act, and Regulation 5.3 of the *Medical Devices Regulations 2002*.

If all of the above conditions have been met, then:

- A full scheduled Level 2 application audit assessment fee will apply to the first application in the group.
- A reduced assessment fee equivalent to 30% of the scheduled Level 2 audit assessment fee will be recommended to the Secretary for each of the other applications in the same group.
- Based on the information in each of the applications, and the written request for reduced fees from the sponsor, the delegate of the Secretary under Regulation 9.7 will make a decision whether to reduce the amount of the assessment fees.
- The sponsor will be notified of the outcome of this decision at the time the supporting information is requested for the application audit. A statement of reasons shall be provided where the decision is not to reduce the assessment fees.
- An invoice for the total assessment fees to be paid shall be issued to the sponsor under separate cover.

Please note: Application audit assessment fees will not be reduced on the basis of similarity to effective applications received on a different day, or medical devices already included on the ARTG.

The amount of the reduced assessment fee is not negotiable

For more information on fees and charges please see Section 2. Fees and charges for medical devices

Section 12. Information about a medical device

Overview

Users of medical devices must be provided with information about the medical device. Users of medical devices could be considered to be:

- an institution such as a hospital (and its employees)
- a healthcare professional in private practice
- a member of the public
- the patient or carer

It should be noted that for many devices there may be more than one user, depending on circumstances. For example, when used in the hospital setting a urinary catheter is used by a healthcare professional in the course of treating the patient, but when used at home for self catheterisation the user may be the patient or the patient's carer.

The Australian regulatory requirements for medical devices are specified in the therapeutic goods legislation. In particular, the detailed requirements for information to be provided with medical devices are outlined in:

- Essential Principle 13, Schedule 1, Part 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations)
- the *Therapeutic Goods Advertising Code* (TGAC)

Summary as follows:

Type of information	Description	Legislative reference
Label	Printed information supplied on or with the device or packaging. Where this is not practicable, other appropriate media may be used. Information: identifying the: • device • manufacturer • explaining how to use the device safely	Essential Principle 13.1, 13.2, 13.3, Schedule 1, Part 2, of the Regulations
Sponsor Details	Sponsor's name and address provided with the device so that a user of the device can identify the sponsor.	Regulation 10.2 of the Regulations
Instructions for Use	Information that must be provided with a device unless the device:	Essential Principle 13.1, 13.2, 13.4, Schedule 1, Part 2, of the Regulations

Type of information	Description	Legislative reference
	• is Class I or Class IIa and • can be used safely for the manufacturer 's intended purpose without instructions. • Appropriate electronic media may be used instead of printed information.	
Advertising	• any: – statement – pictorial representation – design • however made, that is intended whether directly or indirectly to promote the use or supply of a medical device • promotional samples • promotional seminars demonstrations and displ s	Divisions 3 and 4, t 5.1 of the *Therapeutic Goods Act 1989* (the Ac Part 2 of the *Therapeutic Goods egulations 1990* s on N(5) of the Act GAc

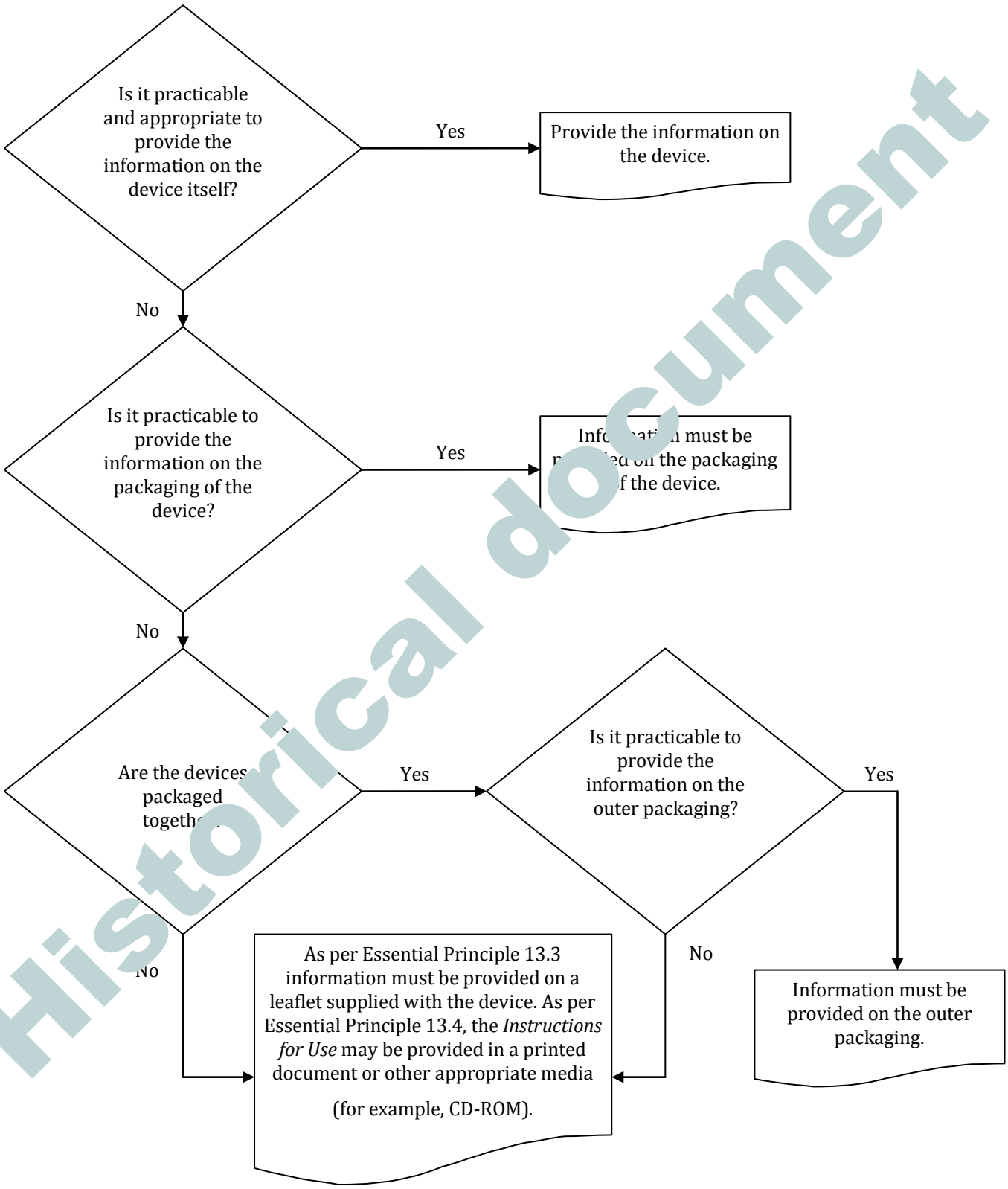
Please note: Electronic media such as information on websi and CDs may also be used to provide information about medical devices. Where a manufactur cho s to use a media other than the printed form, they must also be able to supply the information in p l form if requested by the user.

Providing the instructions for use through a webs identified on the product labelling only, is not sufficient to comply with Essential Principle 13.

These forms of media must comply with the e ui ents for printed materials.

Location of information

In recognition of the large range of medical devices and the variations in physical size, Essential Principle 13.2, Schedule 1, Part 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002* outlines where the information must be located:



This flexibility allows a manufacturer to vary the location of where the information is provided to accommodate the physical and other constraints of the device.

Where label space is limited, a manufacturer may choose to put some of the information on the individual packaging for the device. This information should include information to enable a user to identify the device and any critical warning statements. Other information such as the storage conditions and *Instructions for Use* may be provided on the outer carton in which multiple devices are supplied.

For example, it is not practical to include information on a suture, a hypodermic needle or winged infusion set. In such circumstances the required information would usually be contained on the individual packaging of each device.

It is expected that where there is sufficient surface area on a piece of equipment that all the information should be incorporated on the device. Examples of these devices are an infusion pump, cardiac monitor or x-ray machine. This information may be repeated on the packaging, leaflet and/or *Instructions for Use*.

Size of Text

In accordance with Essential Principles 13.1(5) and 13.1, Schedule 1, Part 2 of the Regulations any:

- number
- letter
- symbol
- letter or number in a symbol

used in the information must be legible and at least one millimetre high.

Language

In accordance with Essential Principle 13.1(3), Schedule 1, Part 2 of the Regulations, the information provided with the device and the *Instructions for Use* must be in English. To assist in the use of 'international' labelling by manufacturers, the information may also be provided in any other language.

Use of Symbols

Essential Principle 13.1, Schedule 1, Part 2 of the Regulations outlines the general requirements for information to be provided with medical devices. Many manufacturers use symbols on labelling to convey information about the device. The most commonly used symbols are defined in the international standard ISO 15223-1:2007—Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied—Part 1: General requirements. This standard identifies requirements for the development and use of symbols that may be used to convey information about the safe and effective use of medical devices. It also lists symbols applicable to a broad spectrum of devices that satisfy the requirements of the standard. These symbols may be used on the device itself, its package or in the associated documentation.

Manufacturers should note that to date this standard has not been adopted by the TGA in a Medical Device Standards Order. Accordingly, the meaning of all symbols or colour coding used in labelling or *Instructions for Use* must be explained in the information provided with the device.

Labelling

A medical device label is important as it communicates information including:

- identification of the
  - device
  - manufacturer of the device
- information explaining how to use the device safely

The Australian medical device labelling requirements adopt the Global Harmonisation Task Force (GHTF) principles for labelling practices.

The requirements adopt a risk based approach to the content and level of detail that must be provided on a label. In general the level of information required increases with the classification of a medical device. More complex and higher risk devices require more information to be provided to facilitate the safe use of the device.

The Australian labelling requirements are specified in Essential Principle 13.1, 13.2 and 13.3 of the Regulations. Essential Principle 13.3 details the particular requirements for information to be provided with medical devices.

Information to be provided with medical devices—particular requirements

From the *Therapeutic Goods (Medical Devices) Regulations 2002*—Schedule 1, Part 2…

13.3 **Information to be provided with medical devices — particular requirements**

The information mentioned in the following table must be provided with a medical device.

Contact details to be provided with a medical device

Both the manufacturer's and Australian sponsor's name and addresses must be provided with a medical device. The address is interpreted by the TGA to be the physical location with sufficient detail to enable the physical location of the manufacturer and sponsor to be determined by the end user of the device. A post office box address alone is not sufficient. Internet and email addresses are not considered to be physical locations.

Regulation 10.2 of the *Therapeutic Goods (Medical Devices) Regulations*; implemented on 4 October 2007 requires the name and address of the sponsor of a medical device to be provided in a manner that allows the sponsor to be readily identified by a user of the device. This is so that users of the device have a person in Australia who they can liaise with any queries or problems with the device.

As required by Essential Principle 13.2 the contact details must be provided on the device itself, unless it is not practicable to do so. The sponsor's name and address may only be included in a leaflet supplied with the device if it is not practicable for those details to be provided on the device or on the device's packaging.

For more information, please see Location of information.

Please note: 'Not practicable' does not include reasons of increased cost associated with providing the sponsor's details with the device. Reasons that would be considered genuinely not practicable include, but the device is:

- *too small to be able to provide the sponsor's details on the device itself*
- *in a sterile pouch and cannot be opened to place the sponsor's details on the device or in the pouch*

The sponsor must determine how compliance will be achieved, but common examples are the:

- manufacturer incorporating the name of the sponsor in labelling provided with the device
- sponsor applying a label to the device, such as with large devices like diagnostic imaging devices, monitoring and diagnostic electro-medical equipment and infusion therapy equipment
- sponsor applying a label to the packaging of the device, or devices when packed in multiples, or the *Instructions for Use* for the device
- sponsor providing a supplementary leaflet with the device

If the sponsor arranges for a label to be attached to the device with their contact details, the label must not in any way adulterate the device or obscure the information provided with the device by the manufacturer.

Examples relating to sponsor contact details supplied on medical devices

Devices that are pre-packaged

For devices that are supplied pre-packaged from the manufacturer, there should be adequate space to affix the sponsor's details to the device package or outer packaging.

Devices supplied to consumers

Devices supplied to consumers must have the sponsors contact details on or with the device in the following descending order:

- on the device itself, or if that is not practicable, then
- on the product label, or if this is not practicable, then
- on the packaging of the devices, or if this is not practicable, then
- on the outer packaging, or if this is no practicable, then
- on the leaflet or *instructions for use* supplied with the device

It would not be considered sufficient to provide the sponsor's details on the invoice for the place of purchase because the consumer of the device would not be able to identify the sponsor.

Devices supplied without packaging or labels

For devices that are supplied without packaging and require processing prior to use, for example, reusable surgical instruments supplied to a healthcare facility, it may be impracticable to place a label on the device or packaging as no label or packaging exists. In this case a leaflet or invoice supplied with the device could be an appropriate method of supplying the sponsor's details.

Guidance on how to achieve Regulation 10.2 (Information about sponsor)

The following table is provided as a general guide to assist sponsors to meet the requirements of Regulation 10.2

Methods for applying information about the sponsor must be considered in the following order:	Possible legitimate rationale for not using a particular method:
1. Can the sponsor's name and address be applied to the product without adulterating the device or obscuring information provided by the manufacturer? If NO, sponsor must consider method 2.	• the device is too small • labels cannot be stuck to the surface of the device due to an unusual shape or material • the device is pre-packaged (e.g., a sterile pouch) and cannot be opened prior to use • The device has to be processed or sterilised before use and any labelling on the device would be rendered unreadable

Methods for supplying information about the sponsor must be considered in the following order:	Possible legitimate rationale for not using a particular method:
	• The process of applying a label by the sponsor may compromise the performance of the device
2. Can the sponsor's name and address be included on the packaging of the device (or the outer packaging of a group of devices) without obscuring information provided by the manufacturer? If NO, sponsor must use method 3.	• insufficient free space on the packaging • the packaging is too small
3. Can the sponsor's name and address be supplied on a leaflet with the device? A leaflet is taken to be *instructions for use* or labelling supplied with the device.	• Instructions are not supplied with the device because the device can be safely used without instructions.
4. If methods 1, 2 and 3 are not practicable or appropriate, the sponsor's name and address must be supplied on a printed document supplied with the device. A printed document may be in the form of a packaging slip or invoice.	• This option is only available to the sponsor where they can demonstrate that Method 1, 2 or 3 is not practicable or appropriate • For example, this option might be appropriate for a disposable device that is supplied without any packaging or instructions.

Please note: It is the sponsor's responsibility to meet Regulation 10.2

The sponsor may instruct another party to affix their details on the device on their behalf (e.g. the sponsor may arrange for a distributor of the device to affix a label to the packaging of the device prior to shipment to the user).

Affixing the sponsor's contact details to a medical device to comply with Regulation 10.2 does not constitute a step in manufacture, and does not invalidate the manufacturer's certification or the manufacturer's Australian Declaration of Conformity

Although the manufacturer may choose to print the Australian sponsor's details on the labelling of the device, it is not a requirement of the manufacturer to do so under the Conformity Assessment Procedures or Regulation 10.2

If the sponsor uses option 3 above, the leaflet should be in a form that is physically supplied as close as possible to the medical device itself. For example, a leaflet placed in the box of a device would be considered more appropriate than an invoice supplied to the user independently from the device.

Implanted Devices

The user of an implanted device may be considered to be both the:

- recipient of the device—the person who has the device implanted in his or her body
- the health professional that implants the device

Essential Principle 13.4 (19) requires information about any risks associated with implantation of an implantable medical device to be provided with the device. Hence, it is recommended that the following information be provided for devices that are implanted:

Type of device	Information recommended	Examples
All implantable devices	Manufacturers should, wherever practical, provide information to the recipient about: • the materials the device is made from • the model and manufacturer • if the device might trigger security screening machines (for example at airports) • whether there will be safety issues if a MRI machine is used on the recipient *Please note: because of the simple nature of devices such as sutures, staples and tissue adhesive, and the way in that they are dispensed and used, it may not be necessary to provide any form of detailed information to the recipient or patient.*	• bone plates • bone screws • staples • tissue adhesives • sutures
Devices with an electronic or mechanical action	In addition to the recommendations for all implantable devices outlined above, manufacturers should provide device registration cards or similar documentation to the recipient, providing information about the implant, the manufacturer and the sponsor	• active implantable medical devices • major orthopaedic implants • heart valves
Devices that contain a medicine	In addition to the recommendations for all implantable devices outlined above, manufacturers should provide details of the medicine, in case of: • hazard alerts • adverse drug interactions between drugs in/on the device and other medicines the recipient may be taking or need to take • Any contraindications, warnings, restrictions, or precautions that may apply in relation to use of the device	• drug-eluting stents and leads

In accordance with Essential Principle 2(2) the manufacturers and sponsors should undertake a documented benefit/risk assessment where there is a question about the practicalities of supplying the required information to the patient. The assessment should take into account the requirement of Essential Principle 13.1(1) to have regard to the training and knowledge of potential users of the device when preparing the information to be provided with a device. This assessment must be available for review by the TGA if requested.

Instructions for Use

Essential Principle 13.4 of the Regulations details the Australian requirements for *Instructions for Use*. The Essential Principle is provided below.

Instructions for Use are not required or may be abbreviated if the device

- is Class I or Class IIa and
- can be used safely for the manufacturer's intended purpose without instructions

Instructions for Use may be provided on the device itself; however, it is generally not practical to include all the required information because of size constraints. The *Instructions for Use* are usually provided:

- where there is sufficient space:
- if the device is supplied individually on the packaging for the device
- when multiple devices are packaged together, on the packaging for the devices
- separately with the device in printed form, or using other appropriate media such as CD, DVD, or other electronic media

Please note: Where a manufacturer chooses to use a media other than the printed form, such as information on websites and CDs they must also be able to supply the information in printed form if requested by the user. Providing the instructions for use through a website identified on the product labelling only is not sufficient to comply with Essential Principle 13.

From the *Therapeutic Goods (Medical Devices) Regulations 2002*—Schedule 1, Part 2...

13.4 Instructions for use

1. Instructions for the use of a medical device must be provided with the device.
2. However, instructions for the use of a medical device need not be provided with the device, or may be abbreviated, if:
   a. the device is a Class I medical device, a Class IIa medical device or a Class 1 IVD medical device; and
   b. the device can be used safely for its intended purpose without instructions.
3. Instructions for the use of a medical device must include information mentioned in the following table that is applicable to the device.

Item	Information to be provided
1	The manufacturer's name, or trading name, and address
2	The intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used
3	Information about any risk arising because of other equipment likely to be present when the device is being used for its intended purpose (for example, electrical interference from electrosurgical devices or magnetic field interference from magnetic resonance imaging devices)
4	Information about the intended performance of the device and any undesirable side effects caused by use of the device
5	Any contraindications, warnings, restrictions, or precautions that may apply in relation to use of the device
6	Sufficient information to enable a user to identify the device, and if relevant, the contents of packaging
7	Any particular handling or storage requirements applying to the device
8	If applicable, an indication that the device is intended for a single use only
9	If applicable, an indication that the device has been custom-made for a particular individual and is intended for use only by that individual or health professional
10	If applicable, an indication that the device is intended to be used only for clinical or performance investigations before being supplied a) if the device is a medical device other than an IVD medical device — the device is intended for pre-market clinical investigation; or b) if the device is an IVD medical device — the device is intended for performance evaluation only
11	For a sterile device, the word 'STERILE' and information about the method that was used to sterilise the device

12 For a device that is intended by the manufacturer to be supplied in a sterile state:

a. an indication that the device is sterile; and
b. information about what to do if sterile packaging is damaged; and
c. if appropriate, instructions for resterilisation of the device

13 For a medical device that is intended by the manufacturer to be sterilised before use — instructions for cleaning and sterilising the device which, if followed, will ensure that the device continues to comply with the applicable provisions of the Essential Principles

14 Any special operating instructions for the use of the de[illegible]

15 Information to enable the user to verify whether t[illegible]vice is properly installed and whether it can be ope[illegible]d sa[illegible]y and correctly, including details of calibratio[illegible]f an[illegible]needed to ensure that the device operates prope[illegible]r an[illegible]fely during its intended life

16 Information about the nature and frequ[illegible] of regular and preventative maintenance of th[illegible]devic[illegible], including information about the replacem[illegible]t o[illegible]consumable components of the device[illegible]g its intended life

17 Information abou[illegible]y t[illegible]m[illegible]t or handling needed before the device can be [illegible]

18 For a device that [illegible]nded by the manufacturer to be installe[illegible]ith, or connected to, another medical device or other equi[illegible]ent so that the device can operate as required for its [illegible]end[illegible] purpose — sufficient information about the dev[illegible]e [illegible]ble the user to identify the appropriate other medi[illegible]evice or equipment that will ensure a safe combination

19 For an implantable medical device — information about any risks associated with its implantation

20 For a reusable device:

a. information about the appropriate processes to allow reuse of the device (including information about cleaning, disinfection, packaging and, if appropriate, resterilisation of the device); and
b. an indication of the number of times the device may be safely reused

21 For a medical device that is intended by the manufacturer to emit radiation for medical purposes — details of the nature, type, intensity and distribution of the radiation emitted

22 Information about precautions that should be taken by a patient and the user if the performance of the device changes

23 Information about precautions that should be taken by a patient and the user if it is reasonably foreseeable that use of the device will result in the patient or user being exposed to adverse environmental conditions

24 Adequate information about any medicinal product that the device is designed to administer, including any limitations on the substances that may be administered using the device

25 Information about any medicine (including any stable derivative of human blood or blood plasma) that is incorporated, or is intended to be incorporated, into the device as an integral part of the device

25A For a medical device, other than an IVD medical device, information about any tissues, tissue derivatives, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin that are included in the device

26 Information about precautions that should be taken by patient and the user if there are special or unusua[illegible] associated with the disposal of the device

27 Information about the degree of accuracy cla[illegible]d in[illegible]e device has a measuring function

28 Information about any particular faci[illegible]s r[illegible]quired for use of the device or any particular tr[illegible]ng o[illegible]qualifications required by the user of the dev[illegible]e

29 For an IVD medical devic[illegible]rmation (including, to the extent practicable, draw[illegible]gs a[illegible]l diagrams) about the following:

- j) the scien[illegible]ic p[illegible]ciple (the 'test principle') on which the perfo[illegible]e of the IVD medical device relies;
- k) [illegible]ecimen type, collection, handling and pr[illegible]ration;
- l) [illegible]age[illegible]t description and any limitations (for e[illegible]mple, use with a dedicated instrument only);
- m) [illegible]ssay procedure including calculations and interpretation of results;
- n) interfering substances and their effect on the performance of the assay;
- o) analytical performance characteristics, such as sensitivity, specificity, accuracy and precision;
- p) clinical performance characteristics, such as sensitivity and specificity;
- q) reference intervals, if appropriate;
- r) any precautions to be taken in relation to substances or materials that present a risk of infection

Advertising

From the *Therapeutic Goods Act 1989*...

> ***advertisement***, in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.

This includes:

- product labels
- pamphlets
- *Instructions for Use*
- promotional samples
- promotional seminars, demonstrations and displays
- advertorials
- advertisements for health services or treatments that identify a medical device

Regulation of advertising

Advertisements for therapeutic goods, including medical devices that are directed to consumers are required to comply with:

- Chapter 5 of the Act
- Divisions 3 and 4, Part 2 of the *Therapeutic Goods Regulations 1990*
- *Therapeutic Goods Advertising Code* (TGAC

The advertising of therapeutic goods, including medical devices, is regulated in Australia under a co-regulatory arrangement and involves:

- the TGA
- the therapeutic goods industry
- healthcare professionals
- consumers
- the advertising industry
- the Australian Competition & Consumer Commission (ACCC),
- Medsafe in New Zealand
- the media

The Therapeutic Goods Advertising Code Council (the Code Council) consists of 15 members and 6 observers. The Code Council is the principal body responsible for considering the requirements for advertising and making recommendations to the Minister on advertising issues, including amendments to the advertising requirements in the legislation and the TGAC.

Unlike medicines, advertisements for medical devices do not have to be approved prior to publication or broadcast, however, the advertisements must comply with:

- conditions of inclusion on the ARTG detailed in section 41FN(5) of the Act
- Division 3 and 4, Part 2 of the *Therapeutic Goods Regulations 1990*
- the TGAC

Please note: It is a condition of inclusion under section 4FN(5) that advertising material relating to medical devices of that kind is consistent with the intended purpose as certified in the device application. The ARTG inclusion and the stated intended purpose for Class I, IIa and IIb medical devices is representative of a kind of device that can cover several different models with varying intended purpose. The intended purpose of each specific model of device is provided in the product label or instructions for use that accompanies the device.

Therapeutic Goods Advertising Code (TGAC)

The object of the TGAC is to ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer.

The TGAC is based on a set of principles and when interpreting the code the total presentation and context of the advertisement is taken into consideration.

The TGAC is updated on a regular basis and therefore it is important to ensure that the current version is referred to. A copy of the code can be accessed via the TGACC website at <http://www.tgacc.com.au>.

Section 4 of the TGAC states that advertisements for therapeutic goods must:

- comply with the statute and common law of the Commonwealth, States and Territories
- contain correct and balanced statements only and claims that the sponsor has already verified

The principles for advertising as per Section 4 of the TGAC state that therapeutic goods must not:

- be likely to arouse unwarranted and unrealistic expectations of product effectiveness
- be likely to lead to consumers self-diagnosing or inappropriately treating potentially serious diseases
- mislead, or be likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions
- abuse the trust or exploit the lack of knowledge of consumers or contain language that could bring about fear or distress
- contain any matter that is likely to lead persons to believe:
  - that they are suffering from a serious ailment
  - that harmful consequences may result from the therapeutic good not being used- except for sunscreen preparations if the claims made in the advertisement are consistent with current public health messages
- encourage or be likely to encourage, inappropriate or excessive use
- contain any claim, statement or implication that:
  - it is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure
  - it is effective in all cases of a condition
  - the goods are safe or that their use cannot cause harm or that they have no adverse effects
- be directed to minors, except the goods listed in Appendix 5 of the TGAC. Examples include:
  - condoms and personal lubricants
  - bandages and dressings
  - devices for management of chronic conditions under medical supervision

Restricted representations

Restricted representations refer to claims made in relation to serious:

- diseases
- conditions
- ailments
- defects

In the context of advertising therapeutic goods, the term serious means a form of those diseases, conditions, ailments or defects that are generally accepted

- not to be appropriate to be diagnosed and/or treated without consulting a suitably qualified healthcare professional
- to be beyond the ability of the average consumer to evaluate accurately and to treat safely without regular supervision by a qualified healthcare professional.

The complete list of restricted representations are listed in Appendix 6 of the TGAC. Examples include:

- cardiovascular diseases
- dental and periodontal diseases
- diseases of joint, bone, collagen, and rheumatic disease
- diseases of the eye or ear likely to lead to blindness or deafness
- diseases of the liver, biliary system or pancreas
- endocrine diseases and conditions including diabetes and pituitary static disease
- gastrointestinal diseases or disorders
- haematological diseases
- infectious diseases
- immunological diseases
- mental disturbances
- metabolic disorders
- musculo-skeletal diseases
- nervous system diseases
- poisoning, venomous bites and stings
- renal disease
- respiratory diseases
- skin diseases
- substance dependence
- urogenital diseases and conditions

If a person wants to make reference to a restricted representation in an advertisement directed to consumers, they must first obtain an exemption from this section of the Code.

To obtain an exemption to use a restricted representation in an advertisement directed to consumers for a medical device, including labels, the advertiser must apply to the Head of the Office of Devices Authorisation

(ODA) of the TGA. The Application for approval to use a restricted representation in advertising form is available from the TGA website. The website also has guidance on submitting an application.

To facilitate the consideration of an application, applicants are encouraged to include:

- a copy of the proposed advertisement or advertising campaign
- product information such as product label and *Instructions for Use* to assist in establishing the manufacturer's intended purpose
- any clinical data or evidence to support the use of the device for the serious disease condition, ailment or defect

The decision to approve or refuse to approve an application is made by the TGA Delegate. The Delegate will, most cases, seek advice from the Code Council.

The decisions to grant or revoke an exemption are published on the TGA website.

Prohibited representations

Prohibited representations are described in Part 1, Appendix 6 of the TGAC and are prohibited to be used in advertisements directed to consumers and there are no provisions under the legislation to apply for an exemption.

Prohibited representations include any representation relating to abortifacient action or any representation regarding the treatment, cure or prevention of the following:

- neoplastic disease (for example, cancer, tumours, malignancies)
- sexually transmitted diseases (STDs)
- HIV AIDS and/or HCV
- mental illness

The exceptions are claims about the:

- prevention of skin cancer through the use of sunscreens
- devices used in contraception or in the prevention of transmission of disease between persons

These claims are restricted and an exemption must be granted prior to using the representation in an advertisement to consumers.

Complaints

Anyone can lodge a complaint about an advertisement for therapeutic goods and all complaints are treated in confidence. Anonymous complaints are also accepted.

When lodging a complaint please include where possible:

- a copy of the advertisement
- the name of the publication and the date published (if applicable)
- details of what it is about the advertisement that is unacceptable

Complaints in relation to advertisements for devices appearing in:

- radio
- television
- consumer magazines
- newspapers
- billboards

- cinema
- the Internet

are considered by the Complaints Resolution Panel.

Complaints about advertisements appearing in these types of media should be submitted on forms available at <http://www.tgacrp.com.au>. The forms can be submitted electronically on line or sent to

The Executive Officer
Complaints Resolution Panel
PO Box 764
NORTH SYDNEY NSW 2059

The determinations of the Complaints Resolution Panel are published on their website at <http://www.tgacrp.com.au/index.cfm?pageID=13>

The Advertising Unit of the TGA considers complaints about other forms of medical device advertisements (such as labels, leaflets, flyers, and promotional brochures) and recommendations are made [illegible]

These complaints should be sent to:

Recalls & Advertising Section
Office of Product Review
Therapeutic Goods Administration
MDP 122
PO Box 100
WODEN ACT 2606

Section 13. Active medical devices

Overview

An active medical device is a device that uses and converts energy in a significant way in order to operate. An active device may use any form of energy except for gravitational or direct human energies.

Active devices may run from internal or external power sources.

Some example active devices include:

- pacemakers (electrical energy)
- electric hospital beds (electrical energy)
- gas-powered suction pumps (pressure energy)
- software (electrical energy—software is a controlling agent for an electrical device)
- active warming blankets (electrical and thermal energies)
- X-ray machines (electrical and ionising electromagnetic radiation energies)
- surgical lasers (electrical and electromagnetic radiation energies)
- lung ventilators (electrical and pressure energies)
- ultrasound machines (electrical and acoustic energies)

Devices that are powered by gravity or directly by a human being are not active devices. Examples of these devices include:

- gravity fed intravenous infusion sets
- traction systems
- hand-operated bag/valve/mask respirators/resuscitators
- hand-powered drills

Some devices are intended by their manufacturer to transmit energy, a substance, or another element between an active medical device and a human being without any significant change occurring to the element being transmitted. These devices are not active. For example:

- electroencephalograph (EEG) leads (purely passive reduction in electrical signal)
- tubing sets (reduction in transferred pressure along the tubing).

What is an active medical device?

From the *Therapeutic Goods (Medical Devices) Regulations 2002*...

active medical device:

a. means a medical device that is intended by the manufacturer:
   i. to depend for its operation on a source of electrical energy or other source of energy (other than a source of energy generated directly by a human being or gravity); and
   ii. to act by converting this energy; but
b. does not include a medical device that is intended by the manufacturer to transmit energy, a substance, or any other element, between an active medical device and a human being without any significant change in the energy, substance or other element being transmitted.

Manufacturers of active medical devices must consider all classification rules and must meet all of the relevant Essential Principles. The following Essential Principles and classification rules are specific to active medical devices:

The requirements are outlined in	which is located in the	and
Essential Principle 9.2—Minimisation of risks associated with use of medical devices	Essential Principles, Schedule 1, *Therapeutic Goods (Medical Devices) Regulations 2002*	outlines requirements for the risk of reciprocal interference involving other devices
Essential Principle 12—Medical devices connected to or equipped with an energy source	Essential Principles, Schedule 1, *Therapeutic Goods (Medical Devices) Regulations 2002*	outlines requirements for the safety and performance of active devices.
Part 4 Special rules for active medical devices	Classification rules, Schedule 2, *Therapeutic Goods (Medical Devices) Regulations 2002*	provides information for determining the classification of an active device.
Part 5.7 Special rules relating to active implantable medical devices	Classification rules, Schedule 2, *Therapeutic Goods (Medical Devices) Regulations 2002*	provides information for determining the classification of active implantable medical devices and associated medical devices.

Different forms of energy

The following table describes different forms of energy in order to help the reader determine if his or her device is active or not.

Form	Description	Comments	Medical Device Examples
Chemical energy	Stored in batteries, liquids, gases, fuel, etc.		Chemical hot/cold packs
Elastic energy	Energy is stored when something is stretched, squashed, etc.	Includes clockwork-powered devices, spring-powered devices, elastic-powered devices, etc. Although human power is often applied to these devices in order to elastically deform, compress or stretch them, the energy of operation is a transformation of the stored potential energy into kinetic energy.	Spring-loaded syringe drivers Bellows drains
Electric energy	Electrical energy is used to drive the action of the device, for example, turn a motor, emit heat, emit light, or emit electrical signals	Mains (230V grid) power and batteries are primary sources of electrical energy, although there are other methods of generating electric energy.	Blood gas analysers (which measure electric potential relating to concentrations of gases in blood) Electric devices such as drills All electronic devices and computers Software (used to control a computer)
Radioactivity	Stored in the nuclei of atoms where energy is released from the nucleus rather than via the rearrangement of the electrons (see Electric energy above).	The decay of isotopes is used for medical imaging and for cancer treatments (radiation oncology).	Radioactive seeds/beads
Magnetic energy	Magnetic potential energy is closely related to electric potential energy (see above). A magnetic field can also impart energy to a	Electric motors operate from magnetic fields interacting with electric currents in order to rotate. An alternator or electric generator	Magnetic Resonance Imaging (MRI) machines use a magnetic field (and also radio waves) to excite particles within

Form	Description	Comments	Medical Devi[illegible]amples
	particle within it.	works in the reverse: a (motor) generator is externally rotated, resulting in the generation of an electrical current.	biolog[illegible]l tissues El[illegible]ic dentist drills
Electromagnetic radiation	Electromagnetic radiation is a flow of electromagnetic energy waves ranging from very long-wavelength radio waves to microwave, infrared, visible, ultraviolet, and x-rays, through to very short-wavelength gamma rays.	Electromagnetic radiation is microsc[illegible] kinetic (movement) energy.	UV phototherapy cabinets (for treating psoriasis); and x-ray imaging and therapy devices
Thermal energy	Thermal (or heat) energy is microscopic movement energy. It is often realised as infrared waves.	Hot water packs a[illegible]no[illegible]ive devices as there is no cha[illegible]e in[illegible]e form of energy.	Electric warming blankets; Respiratory humidifiers Chemical heat packs.
Pressure energy	Pressure is stored as potential energy and is often converted to kinetic (movement energy) via conversion of a high-pressure source to a low pressure one.	The conver[illegible]ion is then from an amount of p[illegible]ential energy to an amount of kinetic ene[illegible] and a smaller remaining amount of [illegible]tential energy.	Air turbine- powered dentist drill — a flow of released compressed air (potential pressure energy) pushes on the blades of the turbine (this is a conversion of potential to kinetic energy) and transfers some of this airflow into rotation of the turbine shaft
Sound/Acoustic/ Sonic	Sound or acoustic energy is a f[illegible]of kinetic energy, realised as sound/a[illegible]pres[illegible]e waves.	Many of these devices derive their primary power from an electrical source.	Ultrasound imagers; Hearing aids; Ultrasonic nebulisers; Tinnitus maskers; and Lithotripters.

Electromedical safety standards

Electromedical devices are powered by electricity—mains, battery and low-powered devices. Examples are pacemakers, pulse oximeters, and blood-pressure monitors.

There are potential safety risks to the patient and/or user if the medical device:

- causes the patient and/or user unintended exposure to electrical currents
- interferes with or affects another electromedical device—Electromagnetic Compatibility (EMC).

To ensure that manufacturers of electromedical devices have considered these risks they must demonstrate compliance with:

- Essential Principle 9.2—Minimisation of risks associated with use of medical devices
- Essential Principle 12—Medical devices connected to or equipped with an energy source.

The most common way to demonstrate compliance is to meet a standard published by an Australian or international standards agency, or a similar standard. If the manufacturer chooses to use other voluntary standards they must provide evidence that the chosen standard is applicable to the manufacturer's device and that its application satisfies the requirements of the Regulations. The use of such standards is not mandatory.

Standards that are commonly used to demonstrate compliance include:

Standard	Description
IEC 60601: General requirements for basic safety and essential performance of medical equipment and any applicable sub-parts	Applies to the basic safety and essential performance of all general medical electrical equipment such as defibrillators, electrical beds, ECG machines
AS/NZ 3200.1.0: Medical electrical equipment–General requirements for safety	Australian standard equivalent to the international standard IEC 60601-1
IEC 60601-1-2: Collateral standard for electromagnetic compatibility (EMC) of medical equipment	Specifies general requirements and tests for EMC of medical equipment. Collateral standards serve as the basis for specific standards by applying additional requirements to those prescribed in the associated general standard(s).
AS/NZ 3200.1.2: Collateral standard for electromagnetic compatibility (EMC) of medical equipment	Australian standard equivalent to the international standard IEC 60601-1-2
IEC 61010.1: General requirements for safety of electrical equipment for Measurement, Control, and Laboratory use (e.g., IVD equipment, sterilisers, etc.)	This international standard is applicable for some medical devices that are not in direct contact with patients. Example include bench-top sterilisers and ex vivo tissue-processing equipment

Medical devices that connect to the public mains electricity supply

In Australia, the public mains electricity supply is 230 volts, 50 Hz. In accordance with *AS/NZS 3112—Approval and test specification—Plugs and socket-outlets*, electrical equipment must be connected to a mains electricity supply using a plug with active and neutral pins partially insulated and with Australian-specific pin configuration.

In addition, *AS/NZS 3551—Technical management programs for medical devices* requires that a transparent plug cover should be used if the plugs are re-wireable. For moulded plugs, it is preferable that the plug cover is transparent but this requirement is not mandatory.

Electromagnetic Compatibility (EMC)

EMC and the influence of the expected environment should be considered when determining the risks associated with the use of a medical device. Environments include domestic, clinical, and critical-care. EMC requirements also apply to battery-powered devices.

The first step in determining compliance with EMC requirements is to perform a thorough risk analysis. Ideally, such an analysis should be undertaken as part of an overall risk management process as defined in ISO 14971. The risk analysis must form the basis for specifying EMC test requirements.

Manufacturers should consider the highest potential-risk environment to determine the amount and type of testing required. The standards provide guidance for the type and amount of testing required. Manufacturers may also need to consider specialised aspects not covered by a standard. It is generally expected that EMC testing be conducted by an accredited test laboratory due to the highly specialised nature of the testing.

The manufacturer should include testing for:

- protection of the public mains network—IEC 60601-1-2, clause 6.1.3 (AS/NZS 3200.1.2 clause 36.201.3). Mains network testing is not applicable to battery-powered devices unless a battery charger forms part of the device
- emissions—IEC 60601-1-2, clause 6.1 (AS/NZS 3200.1.2 clause 36.201)
- immunity—IEC 60601-1-2, clause 6.2 (AS/NZS 3200.1.2 clause 36.202)

Life-supporting equipment used in a clinical environment normally require full compliance with the IEC 60601-1-2 standard, including more stringent requirements imposed by an IEC 60601 part 2 standard, since higher levels of immunity are necessary in order to establish a broader safety margin. For example, the part 2 standard, IEC 60601-2-31, imposes additional EMC requirements for external pacemakers.

Less stringent requirements normally apply to non-life-supporting equipment used in a clinical environment (for example, suction pump). IEC 60601-1-2 makes allowance for waiving immunity testing, provided the manufacturer can justify essential performance via the risk analysis. As per Essential Principle 13.4 of the *Therapeutic Goods (Medical Devices) Regulations 2002*, the *Instructions for Use* for the device must also provide information to allow the user to manage the electromagnetic environment in the clinical setting.

Low-risk devices used exclusively in a non-clinical setting, such as a massager for domestic use, and that are clearly labelled as 'not for use in a clinical setting' or 'for domestic use only' may not require full compliance with IEC 60601-1-2. EMC compliance may be demonstrated by justifying essential performance via the risk analysis indicated in IEC 60601-1-2. If such an analysis demonstrates that the device does not pose any inherent hazards, either alone or in connection with other equipment, then the following minimum EMC requirements may apply:

- Labelling or *Instructions for Use* that indicate that the device was not tested to clinical EMC requirements
- Evidence to support the Australian Communications and Media Authority (ACMA) EMC C-Tick (however, the C-Tick may not be required on the label).

[10] These clauses are from the 2007-03 edition of IEC 60601-1-2, and 2005 edition of AS/NZ 3200.1.2.

Medical devices are exempt from the ACMA EMC C-Tick labelling requirement as they must comply with the more stringent requirements described by the Essential Principles, except for those incorporating radio-communications transmitters (see below).

Telecommunications and Radio-Communications Transmitters

The Australian Communications and Media Authority (ACMA) is responsible for the regulation of broadcasting, the Internet, radio-communications, and telecommunications. The ACMA administers regulatory systems relating to a device's compliance with:

- Australian telecommunications (A-Tick)
- electromagnetic compatibility requirements and radio-communications standards (C-Tick).

Medical devices with telecommunications ports must comply with ACMA A-Tick requirements, for example, in-home patient-monitoring devices that have modem ports.

Medical devices with radio-communications transmitters must comply with ACMA C-Tick requirements for radio-communications standards, for example, wrist-worn sphygmomanometers that connect with a mobile phone using Bluetooth.

However, electrically-powered medical devices do not require C-Tick marking in relation to electromagnetic compatibility. They must comply with the more stringent requirements described in the Essential Principles.

Active implantable medical devices (AIMDs) that utilise radio communications and the associated external radio transceiver such as an external programmer or data-logger, must also comply with ACMA radio spectrum licensing and C-Tick requirements. The ACMA Radiocommunications Class Licence (Low Interference Potential Devices) 2000 (also known as the LIPD Class Licence) makes specific allowance for some kinds of low-power radio communications for AIMDs, including those using Medical Implant Communications Systems (MICS), under specific conditions.

Further details are available on the ACMA website: <http://www.acma.gov.au>.

Radioactive medical devices

All medical devices that are radioactive are active medical devices. If radioactive medical devices are implantable they are classified as Class AIMD.

Radioactive medical devices are radioactive products that do not have a pharmacological, immunicological, or metabolic action, or that are administered locally rather than systemically, for example:

- brachytherapy spheres are active implantable medical devices. Their primary mode of action is radiation, and the basis for the therapeutic claims for the product are that the radiation affects the tissue irradiated. The mechanism of such action on the tissue is physical in nature. The only way that such an action can take place is via an energy conversion at the tissue interface—the precise nature of the energy conversion may vary from temperature effects to denaturing of cellular molecules, or other physical interaction that leads to tumour cell death.
- in vivo imaging agents (such as barium meals) are regulated in Australia as medicinal products.

The TGA regulates the supply of radioactive medical devices in Australia.

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), and state and territory authorities, regulate the use of radioactive materials. More information is available on the ARPANSA website at <http://www.arpansa.gov.au>. The TGA uses the expertise of ARPANSA when assessing radioactive devices.

Radiating medical devices

The manufacturers of radiating medical devices must comply with Essential Principle 11. Examples of radiating medical devices include:

- medical lasers
- phototherapy devices
- X-ray machines
- dental curing lamps

Radiating beauty therapy products such as:

- solariums
- laser combs
- dermal abrasion devices (or dermal abrasion products that apply energy to the patient)
- skin rejuvenation devices (or skin rejuvenation products that apply energy to the patient)
- hair removal products that apply energy to the patient
- are not medical devices unless:
- therapeutic claims are made or
- the product is:
  - surgically invasive
  - invasive via a body orifice

The TGA regulates the supply of radiating medical devices in Australia.

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), and state and territory authorities regulate the use of radiating medical devices and the use of radiating beauty therapy products on human beings. More information is available on the ARPANSA website at <http://www.arpansa.gov.au>. The TGA uses the expertise of ARPANSA when assessing radioactive medical devices.

Software

Software operates as a controlling agent for an electronic device, e.g., a microcontroller or computer.

Software is regulated in different ways depending on the manufacturer's intended purpose for the software how it is supplied:

Type of software	How is it regulated?	Examples
Software that is part of a device and is supplied with a medical device	Part of the device	Pacemaker firmware Embedded patient mo[illegible]ware
Software or an accessory to a device that is a device in its own right if it is supplied separately from the related device	A separate medical device	Image-processi[illegible]oft[illegible]e for use with an X-ray machi[illegible] Pacemak[illegible]pro[illegible]mmer and controller for use on a pe[illegible]l computer or laptop
Software that is used as a diagnostic or therapeutic tool	A separate medical device	Onc[illegible]mage-processing tool Ra[illegible]ation planning/treatment Software
Upgrades to software supplied separately	A separate m[illegible]ic device	Upgrade to image-processing software to add artificial colouring of images Upgrade to ultrasound equipment to allow 4-dimensional images
Corrections to software errors that have been supplied with a device Please note: must be a replac[illegible]ne[illegible]art with no additional functio[illegible]. This may be a product corre[illegible]u[illegible]r the Uniform Recall Proce[illegible]ure (Therapeutic Go[illegible]w[illegible] available from <http://w[illegible]tga.gov.au>.	N[illegible]t [illegible]medical de[illegible]ice	Bug fix to stop infusion pump indicating incorrect drug administration values Stability fix to image processing tool to reduce incidence of crashing or freezing
Soft[illegible]re [illegible]s[illegible]ed in combination w[illegible]th o[illegible]r eq[illegible]pment for handling g[illegible]ral p[illegible]ient-related information	Not a medical device	Patient record management system (admission dates, case notes, contact details) Conversion, compression, and encryption functionality/tool Clinical Information System (CIS) without diagnostic or therapeutic functionality

The legislation applies to all forms of medical device software including software that is embedded (for example, firmware in hardware) such as:

- field-programmable gate arrays (FPGAs)
- electronic programmable read only memory (EPROM)
- flash memory
- static or dynamic random access memory (RAM)

Software often forms an integral part of an electronic device, for example, in a pacemaker or patient monitor these cases, the software is a part of the device and is not considered to be a separate or distinct device.

Software that fits the definition of a medical device in its own right requires separate entry on the ART which means that the sponsor must lodge an application with the TGA to include the device in the ARTG.

Some devices have more than one type of software residing within them. For example, an infusion pump monitor system may have software:

- to control the infusion parameters—Class IIb
- for the logging of patient data—Class I

If the device is supplied as a complete unit, the classification of the complete device is the highest classification—Class IIb. If the software is supplied separately, the individual classification of each device applies.

The international standard *IEC 62304 Medical device software—Software life cycle processes* addresses requirements that are specific to software, while the *IEC 62366 Medical devices—Application of usability engineering to medical devices* standard addresses usability engineering requirements to all devices, including those that are wholly or partially software-based. The TGA considers these standards as representing the state-of-the-art for medical device software.

The labelling requirements apply to medical device software regardless of whether it is:

- downloaded from the Internet
- installed from a CD
- pre-installed on a device

Manufacturers need to ensure that the product information, such as the graphical user interface, screenshots, CD labels, and product demos meet the requirements of Essential Principle 13.

Section 14. Medical devices incorporating a medicine

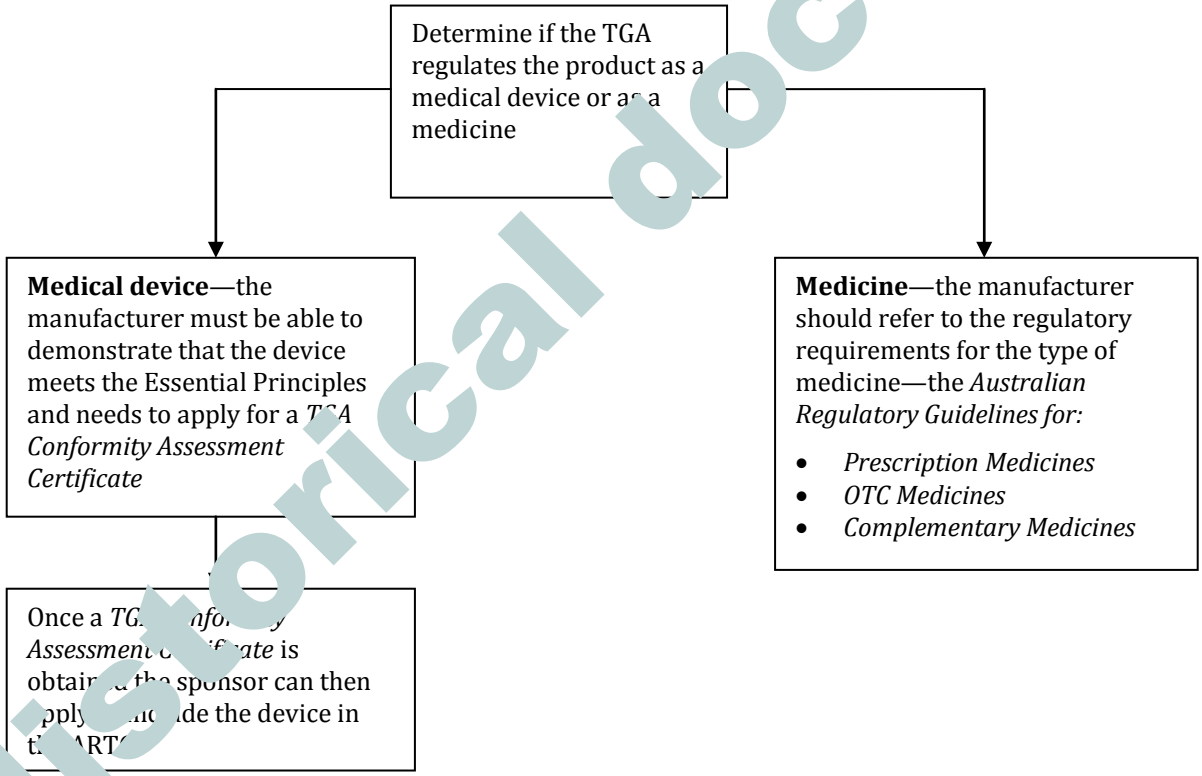
Overview

There are therapeutic goods that have both a medicine and a medical device component and it is the combination of the two components that deliver the desired therapeutic effect. In deciding how these products are regulated, the TGA considers:

- the primary intended purpose
- the mode of action of the product

as they relate to the definition of a medicine and a medical device.

The diagram below illustrates the two assessment pathways possible for such combination products:



Please note: Applicants are strongly encouraged to email the TGA <devices@tga.gov.au> prior to submitting an application for a TGA Conformity Assessment Certificate to discuss the characteristics and intended use of their product and to ascertain the TGA's requirements for the medicinal component in relation to these characteristics.

Examples of devices that this guidance applies to include (but are not limited to):

- catheters coated with an anticoagulant or an antibiotic agent
- medicine-coated coronary artery stents (drug-eluting stents)
- bone cements containing antibiotics
- sponge impregnated with antibiotics
- intraocular viscous solution with anaesthetic
- medicated root canal sealant
- silver impregnated dressings
- Surgical adhesive of collagen (medical device) and thrombin (medicine) packaged as two components that are not applied to patient until mixed together and 'intended to incorporate an ancillary medicine

System or procedure packs that include at least one medical device and may contain a medicine are regulated as medical devices. The medicine must be entered onto the ARTG in its own right before an application for the system and procedure pack can be lodged. For more information on system and procedure packs, please see Section 16. Systems and procedure packs.

This guidance does not apply to:

- chemicals that are not medicinal in nature
- contact lens solutions that contain an antimicrobial substance where the purpose of the substance is solely to preserve the solution and not intended to confer antiseptic properties to the eye
- products such as pre-filled syringes where the syringe serves as the container for the medicine, as these products are regulated as medicines

For a product considered to be:

- a medical device, an application must be submitted to the Office of Devices Authorisation and the product will be assessed by the medical device program with input from the relevant Office for medicines regulation
- a medicine, an application must be submitted to the relevant Office for medicines regulation and the product will be assessed by the medicines program, with input from the Office of Devices Authorisation

The decision on approval and issue of the relevant certificates will be issued by the Office to which the application is submitted.

If the decision for the product to be regulated as a medicine or a medical device is not obvious from consideration of the intended purpose and the mode of action, the matter should be referred to the TGA to determine the most appropriate Office. Direct queries through the medical devices email service at <devices@tga.gov.au>.

A list of some products that contain both a medical device and a medicine component, where the TGA has previously made a determination in relation to whether the type of product is to be regulated as a medical device or a medicine, is available on the TGA website: Medical device – medicine boundary products.

Even though the manufacturer may have an overseas issued conformity assessment certificate, this can not be accepted as the basis for inclusion in the ARTG for these devices. An application must be made for a TGA Conformity Assessment Certificate; please see Section 5. Conformity assessment overview.

Essential Principle 7.4 of Schedule 1 of the Regulations requires that:

- the safety and quality of the medicinal substance be verified in accordance with the requirements for medicines
- the ancillary action of the substance be verified having regard to the intended purpose of the device

Classification Rule 5.1 of Schedule 2 of the Regulations indicates that medical devices are Class III if they incorporate, or are intended to incorporate, as an integral part, a substance that:

- if used separately would be a medicine; and
- is liable to act on the patient's body with an action ancillary to that of the device.

For information on the classification of medical devices, please see Section 4. Classification of medical devices.

Where an application is made for a medical device incorporating a medicinal component, the relevant parts of the Design Dossier are referred to the appropriate area of the TGA by the Office of Devices Authorisation for evaluation of the medicinal component. The medicinal assessment is undertaken in parallel with the assessment of the medical device and the relevant fees for the assessment of the medicine component will also apply. The manufacturer should ensure that they have included data for the medicinal substance as part of the Design Dossier in submissions. The medicinal component documentation may be supplied directly to the TGA if there are proprietary information considerations; authorisations from the medicine supplier must be supplied to the TGA in relation to the specific medical device submission. Refer to the TGA website for the Letter of Access for the DMF/CEP template.

Some medical devices contain substances that are scheduled in the Standard for Uniform Scheduling of Drugs and Poisons (SUSDP). This includes medical devices incorporating medicinal substances. Entries in the SUSDP refer to all salts and derivatives of the substance unless specifically exempted. The TGA refers new chemical entities in medical devices incorporating medicinal substances to the National Drugs and Poisons Schedule Committee (NDPSC). Medical devices containing substances that are scheduled in the SUSDP must comply with any labelling requirements specified in the SUSDP.

Many, but not all, substances scheduled by the SUSDP are considered as medicines. Note that medical devices that contain substances cited in the SUSDP, but not considered to be a medicine, are not addressed by Classification Rule 5.1.

Medical devices classified as Class III because they contain a medicine that acts in a manner ancillary to the device are generally exempted from the requirements of the SUSDP.

However, the following five groups of products, irrespective of their device classification, must comply with the labelling requirements of the SUSDP:

- injectable tissue reconstructive, augmentation and restoration materials, including collagen
- medical devices that include anticoagulants
- artificial tears
- urinary catheters
- intra-articular fluids

Further information on the NDPSC is available on the TGA website.

What is a medical device incorporating a medicine?

There are three definitions from the therapeutic goods legislation that must be considered when determining whether a product that has both a medicine and a medical device component is to be regulated as a medicine or a medical device.

From the *Therapeutic Goods Act 1989*...

Section 41DB What is a medical device

1. A medical device is:
    a. any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person by whom whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:
        i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
        ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;
        iii. investigation, replacement or modification of the anatomy or of a physiological process;
        iv. control of conception;

    and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or
    aa. any instrument, apparatus, appliance, material or other article specified under subsection (2A); or
    ab. any instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection (2B); or
    b. an accessory to such an instrument, apparatus, appliance, material or other article covered by paragraph (a), (aa) or (ab).

From the *Therapeutic Goods Act 1989*...

Section 3 (1)

medicine means:

a. therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human; and
b. any other therapeutic goods declared by the Secretary, for the purpose of the definition of ***therapeutic device***, not to be therapeutic devices.

From the *Therapeutic Goods (Medical Devices) Regulations 2002*...

Medical devices incorporating a medicine:

means a medical device of any kind that incorporates, or is intended to incorporate, as an integral part, a substance that:

i. if used separately, would be a medicine; and
ii. is liable to act on a patient's body with action ancillary to that of the device

Data requirements for medicinal substances

A wide range of medicinal substances may be incorporated into medical devices. In recognition that the regulatory status and evaluation history of the medicinal component may vary considerably, the data requirements will be considered on a case-by-case basis. In general, the amount of data required depends on whether the:

- the medicinal substance is already available for supply in Australia (for example as an API)
- the medicine is already on the ARTG
- the clinical indications and or presentation are the same or different
- the medicinal substance originates from a manufacturer who has been satisfactorily audited for the manufacture of that substance and has current TGA-issued GMP certification or has a TGA GMP Clearance based on other evidence accepted by TGA
- the incorporation of the medicine within the device is consistent with its approved use, and whether it poses any concerns in relation to, for example:
  - local toxicity/tolerability
  - changes to the physico-chemical properties of the substance as a result of its incorporation into the device, including kinetics of release of the substance from the device.

The manufacturer must submit an additional component of the Design Dossier specifically dealing with the medicinal substance.

Detailed guidance on the Australian regulatory requirements for medicines is available on the TGA website. Regulatory requirements vary depending on the type of medicine and relative risk/benefit to the user. The following table provides a summary of each type of medicine—for full details, please refer to the appropriate regulatory guidelines as shown in the table below that are available on the TGA website:

Type of medicine	Description	Guidelines
Prescription	Generally, a prescription is needed to buy from a pharmacist. Otherwise, only authorised health care professionals can supply them, such as in a hospital setting. Examples include contraceptive pills, antibiotics, and strong painkillers	Australian Regulatory Guidelines for Prescription Medicines
OTC	Consumers can buy over-the-counter (OTC) medicines for self-treatment from pharmacies, with selected products also available in supermarkets, health food stores and other retailers. Examples include cough and cold remedies, anti-fungal	Australian Regulatory Guidelines for OTC Medicines

Type of medicine	Description	Guidelines
	treatments, sunscreens, non-prescription analgesics such as aspirin and paracetamol	
Complementary	Substances also known as 'traditional' or 'alternative' medicines. Examples include vitamins, minerals, nutritional supplements; and herbal, aromatherapy, and homoeopathic products	Australian Regulatory Guidelines for Complementary Medicines

If a medicine is considered to be a new chemical entity (NCE) in Australia the medicine is also required to undergo the approval processes for a NCE; this includes forwarding data relating to the medicinal component of the device to the Office of Prescription Medicines within the TGA for review, and to the Australian Drug Evaluation Committee (ADEC) in addition to the submission of the composite medicinal device combination to the Advisory Committee on Medical Devices (ACMD).

For prescription medicines, the data provided with the application should be presented in the format outlined in the Common Technical Document (CTD) format, which is available on the TGA website.

The following table is intended as a general guide to the TGA data requirements for the medicinal component of medical devices in wh[illegible] the medicinal substance would normally be a prescription medicine. Equivalent procedures may apply to OTC or complementary medicines. For example [illegible]rtificate of Suitability (CEP) may be acceptable for an OTC or complementary medicines:

Data Description	Medicine not in ARTG	Medicine in ARTG with different manufacturer	Cl[illegible]s to i[illegible]ations for [illegible]edicine in ARTG [illegible]h same manufacturer	Medicine in ARTG with same manufacturer
Chemical and pharmaceutical data				
Drug master files (DMF) for the substance—data may be provided as DMF or as part of the dossier for the medicine If a DMF change can alter anything about the medicine that is being used in the medical device, then the medical device manufacturer must have a formal arrangement in their supplier agreement to ensure they (the manufacturer) are aware of the change so that they can conduct a risk analysis to determine if there is any 'substantial' change to the medical device. If there is a substantial change, then the medical device manufacturer must notify the TGA (section 41EJ of the Act). *Please note: If the DMF is already lodged with the TGA, the medical device manufacturer may be able to provide written permission from the manufacturer of medicinal substances authorising the TGA access the DMF (that is, provide DMF File Reference Numb[illegible] in support of the device application* A template letter of access for the DMF/CEP is availabl[illegible] the TGA website.	Yes	Y[illegible]	Not normally required, but helpful if application includes overall description of manufacturing process	Not normally required, but helpful if application includes overall description of manufacturing process
Method of incorporation of medicine wit[illegible]he device. Includes: • description of the medicinal sub[illegible]ance and the amount incorporated into each d[illegible]ce • results of studies exa[illegible]ing w[illegible]ther the medicinal substance is modified during i[illegible] inc[illegible]ation onto the device (process	Yes	Yes	Yes	Yes

Data Description	Medicine not in ARTG	Medicine in ARTG with different manufacturer	Changes to indication [illegible] medicine in ARTG with the manufacturer	Medicine in ARTG with same manufacturer
treatments, effect of sterilisation, etc.) • controls of starting materials—the specification of the medicinal substance and any excipients used • control tests: – carried out at intermediate stages of manufacture – on finished product				
Stability—includes data to demonstrate the stability of the active medicinal substance in the medical device (potency, purity, release rate) throughout the defined shelf-life of the device under the manufacturer's recommended storage conditions	Yes	Yes	Yes	Yes
Labelling	Yes	Yes	Yes	Yes
Performance data				
Studies to address intended action of the medicine in the context of its incorporation into the device	Yes	Yes	Yes	Yes
Data in relation to its release from the device at the site of action and the subsequent distribution and elimination	Yes	Yes	Yes	Yes
Non-clinical studies conducted				
Full toxicity profile	Yes	May be required if substance is a	Local tolerance studies relevant to	Local tolerance studies relevant to

Data Description	Medicine not in ARTG	Medicine in ARTG with different manufacturer	Changes to indication [illegible] medicine in ARTG with [illegible] manufacturer	Medicine in ARTG with same manufacturer
		product of fermentation or other variable manufacturing process and where impurities and degradation products have been shown to be different	site of implantation of the medical device need to be included. Additional information may be requested by the TGA.	the site of implantation of the medical device need to be included. Additional information may be requested by the TGA.
Full pharmacology and pharmacokinetic profile	Yes	No	No	No
Data to address intended action of the medicine in the context of its incorporation into the device; and in relation to its release from the device at the site of action and the subsequent distribution and elimination	Yes however if a full pharmacology and pharmacokinetic profile is conducted that allows corollary to the use in the medical device then may not be required	Yes	Yes	Yes
Clinical studies				
Human pharmacology including pharmacodynamics and pharmacokinetics	Yes	No	No	No
Data to address intended action of the medicine in the context of its incorporation into the device; and in relation to its release from the device at the site of action and the subsequent distribution and elimination, as a min[illegible]	Not required if full human pharmacology is provided (see	Yes	Yes	Yes

Data Description	Medicine not in ARTG	Medicine in ARTG with different manufacturer	Changes to indication for medicine in ARTG with same manufacturer	Medicine in ARTG with same manufacturer
	previous item)			
Efficacy and safety studies, including adequately powered study to demonstrate performance and safety of the medical device	Yes	Yes—unless justification for not requiring clinical evidence is accepted	Yes—unless justification for not requiring clinical evidence is accepted	Yes—unless justification for not requiring clinical evidence is accepted

Quality control for manufacturing medicinal substances incorporated into medical devices

The manufacturing of a medicinal substance or Active Pharmaceutical Ingredient (API) that is incorporated into a medical device must be undertaken in accordance with an appropriate system for managing quality and is required to be in compliance with Good Manufacturing Practice (GMP), where appropriate.

To ensure that the incorporated medicinal substances are consistently produced and controlled to the quality standards appropriate to their indications, applicants for a TGA Conformity Assessment Certificate must pro[illegible] the following evidence:

Medicinal substance	Overseas	Australian
Prescription medicine	A TGA GMP Clearance. Sponsors must ensure that the currency of the evidence is maintained for as long as the device remains on the ARTG or TGA issued GMP certification if the TGA has conducted an on-site audit	TGA GMP Licence unless [illegible] under Schedule 7 of the *Therapeu[illegible]oods Regulations 1990*
OTC and complementary medicines	Not normally required, however, the TGA reser[illegible] th[illegible]right to request evidence and to audit the medicinal substance productio[illegible]ties if there are questions concerning the acceptability of the manufacturing[illegible]nd q[illegible]lity control procedures. Further information on what is a[illegible]t is not acceptable is available on the TGA website in the docume[illegible]*uidance on the GMP clearance of overseas medicine manufacturers*. In these circumstanc[illegible]e medicinal substance manufacturer may: • apply fo[illegible] TG[illegible]GMP licence (if located in Australian) • ap[illegible]r a GMP Clearance supported by acceptable evidence of GMP, issued by an [illegible]ersea[illegible]ssessment body (if located overseas) [illegible]g[illegible]e to be audited by the TGA as part of the medical device manufacturer's [illegible]pplication for a TGA Conformity Assessment Certificate.	

Section 15. Medical devices containing materials of animal, microbial or recombinant origin

Overview

Some medical devices contain materials that are of non-viable animal, microbial, or recombinant origin.

Medical devices incorporating these materials pose a special risk for both patients and healthcare providers due to, for instance, the potential for pathogen transmission to humans.

Please note: Products containing viable animal materials or that are viable animals are currently regulated under Chapter 3 of the Therapeutic Goods Act 1989 as therapeutic devices—see Australian Device Requirements Version 4 (DR4).

There is particular concern with regard to the possible transmission of Transmissible Spongiform Encephalopathies (TSEs) associated with materials originating from some animal species.

If a medical device or the cell-culture media used for microbial cell-culture contain animal-derived material, the TGA requires manufacturers to comply with the requirements outlined in the TGA approach to minimising the risk of exposure to Transmissible Spongiform Encephalopathies (TSEs) through medicines and medical devices, which is available on the TGA website.

Descriptions of the kinds of materials with some examples

Origin	Description	Examples
Animal	An invertebrate or vertebrate member of the animal kingdom	• Bovine, porcine, lapine, etc • Crustacean • Coral
Microbial	Micro-organisms	• Bacteria • Yeast
Recombinant	Genetically modified (GMO) biological organisms	• Microbial cells • Animals • Plants

Examples of medical devices containing these materials

Medical devices	Materials
Biological heart valves	Porcine valve, valves made of bovine or equine pericardium
Wound dressings	Gelatin or collagen from porcine skins; recombinant plant expressing human collagen genes
Collagen corneal shields	Collagen from porcine skins
Vascular grafts	Coated with porcine collagen or gelatin
Catgut sutures	Bovine or ovine animal intestine
• Intra-ocular fluids • Meniscus joint fluid replacement • Anti-adhesion barriers • Tissue augmentation • Catheters with 'lubricious' coating	Hyaluronic acid extracted from rooster combs or harvested from a microbial cell line
Blood cell separation devices	Monoclonal antibody derived from microbial cell line expressing human gene

Requirements for medical devices containing these materials

Requirement	Legislative reference	Description
Classification	Rule 5.5, Part 5, Schedule 2 of the Regulations	Medical device is Class III unless it: • only contains materials of animal origin that have been rendered non-viable AND • is intended by the manufacturer to only c into contact with int ski.
TGA Conformity Assessment Certificate	Section 41EA of the *Therapeutic Goods Act 1989* Regulation 4.1, Part 4 of the Regulations	A TGA Conformity s ssment Certificate mu be d before a valid applica on n be made to include th dical device in the Austra Reg ter of Therapeutic Goo (AR)
Essential Principles	Essential Principle 8.2, Schedule 1 of the *Therapeutic Goods (Medic Devices) Regulations 2002* (the Regulations)	Des bes requirements for risk nagement, control measures cluding sourcing, selecting, harvesting, processing and validation methods for elimination/inactivation of viral or TSE agents.

All medical devices require classification to determ he relevant applicable conformity assessment procedures, and all medical devices are requi co ply with all applicable Essential Principles. Some requirements apply specifically to medical d vi es ntaining materials of animal, microbial or recombinant origin.

The risk analysis that a manufa urer req red to perform to show compliance with the Essential Principles must take into account the prese or p ential contamination by the materials of animal, microbial, or recombinant origin. A risk-ma age t report for the medical devices containing materials of animal, microbial, or recombinant origin must b cluded in the Design Dossier for the medical device.

Medical devices included in Classification Rule 5.5

From the *Therapeutic Goods (Medical Devices) Regulations 2002 — Schedule 2…*

5.5 Medical devices containing non viable animal tissues, cells or other substances, or microbial or recombinant tissues, cells or other substances

1. This clause applies to a medical device if the device contains:
   a. tissues, cells or substances of animal origin that have been rendered non viable, or tissues, cells or substances of microbial or recombinant origin; or
   b. a combination of tissues, cells or substances of the kind described in paragraph (a).
2. The device is classified as Class III, unless:
   a. the device contains only tissues, cells or substances of animal origin that have been rendered non viable; and
   b. the device is intended by the manufacturer to come into contact with intact skin only.

Please note A medical device that conforms to the description in paragraphs (2) (a) and (b) is classified as Class I under clause 2.1 of this Schedule

Please note: The TGA defines 'rendered non viable' as referring to tissues and cells that have been processed to a point such that no further inherent capacity for cellular metabolic activity exists.

Products containing substances of microbial or recombinant origin are not captured in the EU by a special rule. For further information please see Section 8. Differences between the Australian and European Union medical device regulatory requirements

Classification Rule 5.5 includes medical devices:

- in which the animal tissues, cells and their derivatives are used as:
  - raw and starting materials (for example, collagen, hyaluronate, gelatin)
  - active substances (for example, heparin)
  - excipients in the device (for example, bovine serum albumin)
  - reagents used in production (for example, porcine pepsin, albumin, meat broth etc used in the culture of microbial cells)
- that contain tissues, cells or substances of:
  - microbial origin (production processes for example, biofermentation, harvested from microbial cell-culture; or in the finished product itself)
  - recombinant origin (for example, from any category of genetically modified organism and may be either during manufacture or in the finished product)

For further assistance, contact the Devices Conformity Assessment Area of the TGA at <devices@tga.gov.au> or on 1800 141 144.

If the medical device is captured by classification rule 5.5 then a TGA Conformity Assessment Certificate is required.

Medical devices containing materials of animal origin not classified under Classification Rule 5.5

The TGA has determined that Classification Rule 5.5 does not apply to:

- the following tissue or cellular derivatives:
  - bovine milk
  - silk
  - beeswax
  - hair
  - lanolin
  - sintered hydroxyapatite (process must be validated to demonstrate no evidence of organic material)
  - tallow or tallow derivatives
  - alcohols
  - simple sugars or salts fermented from cultures that do not have any animal reagents
  - microbial sourced enzyme cleaners
- a medical device that contains tissues, cells, or substances of animal origin that have been rendered non-viable where the device is intended by the manufacturer to come into contact with intact skin only (for example, leather straps associated with limb prostheses).

The TGA has determined that honey is not considered to be an animal-derived substance.

Self assessment for animal components where the device is not classified under Classification Rule 5.5 and conformity assessment by the TGA is not required

If a device contains materials of animal origin and the device is not considered class III by Classification Rule 5.5, the manufacturer is still required to comply with the TGA Supplementary requirements and conduct a self assessment for TSE risk.

Self assessment is described in more detail in the TGA Supplementary requirements for therapeutic goods for minimising the risk of transmitting transmissible spongiform encephalopathies (TSEs) (December 2004), available on the TGA website. This document includes the processing requirements for tallow and tallow derivatives. The document takes into account the requirements of the European Union Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (EMEA/410/01 Rev. 2 October 2003).

Records are required to be kept and maintained by the manufacturer for those animal origin components, as referred to in the TGA approach to minimising the risk of exposure to Transmissible Spongiform Encephalopathies (TSEs) through medicines and medical devices.

Manufacturers of medical devices containing ingredients identified as having animal origin must comply with the requirements for each of the animal-derived ingredients, in accordance with Essential Principle 8.2 of Schedule 1 of the Regulations.

Appropriate control measures must be implemented regarding animal material sourcing, selection, harvesting, and processing.

Conformity assessment procedures for medical devices that contain materials of animal, microbial or recombinant origin

Regulation 4.1 requires manufacturers of medical devices containing:

- tissues of animal origin that have been rendered non-viable (Sub-regulation 4.1(2)(a)), or
- tissues, cells, or substances of microbial or recombinant origin (Sub-regulation 4.1(2)(b)),

to obtain a TGA Conformity Assessment Certificate prior to applying to include the medical device in the AR

Essential Principle 8.2, part of Essential Principle 8—Infection and microbial contamination, is particular medical devices that contain materials of animal, microbial, or recombinant origin.

From the *Therapeutic Goods (Medical Devices) Regulations 2002*—Schedu...

8.2 Control of animal, microbial or recombinant tissues, ti... derivatives, cells and other substances

1. This clause applies in relation to a medical device t... contains:
   a. tissues, tissue derivatives, cells or substan... of a...mal origin that have been rendered non viable; a...
   b. tissues, tissue derivatives, cells or s...sta... of microbial or recombinant origin.
2. If the tissues, tissue derivatives, cells ... su...tances originated from animals, the animals must hav... subjected to appropriate veterinary controls and ...per...sion ...having regard to the intended use of the tissues, cells o... ...bst...s.
3. If the medical device c...tai... issues, tissue derivatives, cells or substances of animal o... in... record must be kept of the country of origin of each ...imal from which the tissues, tissue derivatives, cells or substa... originated.
4. The process...g, p...rvation, testing and handling of tissues, tissue derivativ..., c... or substances of animal, microbial or recombinant origin mus... be ...arried out in a way that ensures the highest sta...rds o... safety for a patient, the user of the device, and any ot... pe...on.

   b. In p...ular, the production process must implement validated ...thods of elimination, or inactivation, in relation to viruses and other transmissible agents.

When a manufac...r co...ucts a risk analysis during the design process for a medical device, the presence or possible presence o...mal origin material in the finished medical device must be taken into consideration. This analysis mu... be ...ndertaken, regardless of whether Classification Rule 5.5 is applicable to the medical device or not.

F...ned... devices constructed of recombinant or microbial origin material, or animal origin material that has bee... ...der...d non-viable, this analysis along with details of risk mitigation steps undertaken, must be provided ...n a ...esign dossier is submitted to the TGA in support of an application for a TGA Conformity Assessment ...ificate.

For medical devices not requiring a TGA Conformity Assessment Certificate, this analysis along with details of risk mitigation steps undertaken, must be maintained in the Technical File held by the manufacturer, and be made available to the TGA on request. Changes to the Technical File, in this case, do not require notification to the TGA unless this is specifically requested.

Incidental contact with various substances of animal, microbial, or recombinant sources material during manufacture must be considered when deciding whether a TGA Conformity Assessment Certificate is required. Note that lubricants and cleaning agents of animal or microbial sources used solely during manufacturing and

that do not end up in the finished medical device are not considered in the decision of whether a TGA Conformity Assessment Certificate is required.

The manufacturer must apply to the TGA for assessment prior to implementing a change to the design materials or manufacturing processes for medical devices for which the TGA has issued a TGA Conformity Assessment Certificate. Changes to the supplier of animal material are notifiable and assessable changes. The manufacturer needs to undertake a risk analysis to determine whether changes to sourcing, collection or handling have reduced the safety of the product. The manufacturer also needs to consider whether this change affects the validation of the inactivation or elimination of viruses or TSE agents.

After this risk analysis and conclusions has been documented, notify the medical devices conformity assessm area of the TGA on 1800 141 144 for confirmation of whether the proposed change(s) require TGA approv

For more information please see:

- Conformity Assessment Standards Order No 2—Conformity assessment standards for quality ra techniques for animal tissues and their derivatives utilised in the manufacture of medical de s (CASO No 2), which is available on the TGA website.
- Section 21. Changes to ARTG Inclusions

Specific requirements for animal-origin components

There are special requirements for:

- medical devices incorporating tissues, their derivatives, or other sub ces originating from animals
- materials of animal origin that are used or that come into contact w m ical devices during production processes where the materials are not included in the final de

The TGA has adopted EN 12442: 2000 Animal tissues and t de ves utilised in the manufacture of medical devices – Part 1, Part 2 and Part 3 as conformity assessme st ards (CASO No 2). Compliance with these standards is not mandatory. However if a manufacturer ch se to follow a different approach, its relevance and adequacy in achieving a satisfactory level of safet must be demonstrated. The TGA will also accept compliance to ISO 22442: 2007.

These standards specify relevant quality assu te niques for the analysis and management of risk in the manufacture of medical devices, such as sou ing, ecting, handling of animal materials and their derivatives, viral and transmissible agent elimination nd/ activation.

Documented compliance with th se s ndar s can form the evidence to demonstrate compliance with elements of Essential Principle 8.2.

Details of rigorous manufact ng pr esses for various materials are outlined in TGA Supplementary requirements for therapeutic g ds for minimising the risk of transmitting transmissible spongiform encephalopathies (TSE (D ember 2004).

The quality systems implemented by manufacturers of medical devices containing materials of animal origin must also ensure that the following are in place:

- quality control processes and procedures to prevent contamination with potential infectious/transmissible agents including TSEs and disinfection/decontamination procedures in the event of contamination; this includes adequate evidence of segregation between animal species in abattoirs or tissue supplier facilities
- a documented system for animal and tissue traceability
- procedures for the selection, review, and auditing of tissue suppliers
- records of audit reports for the supplier of animal tissue by the device manufacturer
- name and address for the supplier of any animal materials. The TGA treats animal-tissue material suppliers as key suppliers and the details of these suppliers are entered or referenced on the TGA Conformity Assessment Certificate

Specific requirements for microbial origin components

For medical devices containing components of microbial origin, manufacturers are also required to provide the following additional information:

- microbial species
  - identification
  - cell bank qualification to demonstrate that it has been fully characterised and tested for the absence of viruses
- composition of fermentation or growth media,
  - identification of all components
  - origin of components: animal, microbial, or plant
  - suppliers, specifications, and certificates of analysis of the components.

Specific requirements for recombinant origin components

For medical devices containing components of recombinant origin, manufacturers are also required to provide the following additional information:

- identification and source of nucleotide sequence coding
- source of expression construct or host animals
- composition of fermentation or growth media, including:
  - identification of all components
  - origin of components: animal, microbial, or plant
  - suppliers, specifications, and certificates of analysis of the components

In addition, there may be further requirements as specified by the Office of Gene Technology Regulator (OGTR). More information is available at <http://www.ogtr.gov.au.

SUSDP Considerations

Some medical devices incorporate substances of animal or microbial origin where that substance is scheduled in the Standard for Uniform Scheduling of Drugs and Poisons (SUSDP). Entries in the SUSDP refer to all salts and derivatives of the named substance unless specifically exempted. Some special clinical uses of collagen, hyaluronic acid and lactic acid are considered to be medical device subject to scheduling requirements- see Schedule 4 of the SUSDP. Medical devices containing substances that are scheduled in the SUSDP must comply with any labelling requirements specified in the SUSDP.

Options for conformity assessment certification for medical devices containing animal origin material

A manufacturer must apply to the TGA for conformity assessment certification for medical devices containing animal origin material.

However, if a medical device contains:

- tissues of animal origin that contact intact skin only
- refined derivatives of animal derived waxes
- sintered hydroxyapatite
- heparin that conforms to pharmacopoeial standards
- gelatin that conforms to pharmacopoeial standards

The TGA may consider an EC–Australia and EFTA–Australia MRA certificate to support the application to the TGA for conformity assessment certification.

Please note: An MRA certificate cannot be used as the sole basis for manufacturer's certification for inclusion in the ARTG

Applicants must contact the TGA prior to submitting an application using certificates issued under the MRA to determine the requirements. The eligibility requirements under the MRA do not completely align with the criteria under classification rule 5.5 previously described in this section.

For more information please see the Australia – European Community Mutual Recognition Agreement, which is available on the TGA website.

Import Permits

An AQIS import certificate is generally required for biological substances. More detail is provided at <http://www.daff.gov.au/aqis/import/biological/therapeutic-foods-dietary>.

Whether the item intended for importation contains material from a protected species or not should also be checked. For further information see <http://www.cites.org>.

Section 16. Systems and procedure packs

Overview

'System or procedure pack' is a term used in the legislation to identify products that are packaged together for a specific intended purpose. Such a package must include at least one medical device but it can also contain medicines, other therapeutic goods (OTGs), and non-therapeutic goods. A group of products packaged together that meets the definition of 'system or procedure pack' is considered to be a medical device for the purposes of the Act.

Other groupings of therapeutic products, such as therapeutic kits and composite packs, are also discussed in this section.

From the *Therapeutic Goods Act 1989*...

41BF System or procedure packs

1. A package and therapeutic goods in the package are a system or procedure pack if:
   a. the package and the therapeutic goods are for use as a unit, either in combination as a system or in a medical or surgical procedure; and
   b. the package contains at least one medical device; and
   c. the package and the therapeutic goods do not constitute a composite pack.
2. To avoid doubt, a system or procedure pack is a medical device.

The term 'system' and the term 'procedure pack' are used in order to accommodate different types of packages that contain medical devices. Additionally, some manufacturers might use the term 'procedure pack' for a particular collection or combination of products (for example, a collection of therapeutic goods for an appendectomy surgical procedure) while other manufacturers might refer to the same collection of therapeutic goods as a system. Nevertheless, no regulatory distinction is made between the two terms. The regulatory requirements are the same regardless of whether the package of goods meets the definition of 'system' or meets the definition of 'procedure pack' or meets the definitions of both.

The term 'component' is used to describe an individual item in a system or a procedure pack.

A system or procedure pack does not consist of:

- An individual item only
- A collection of miscellaneous items that are not intended by the manufacturer to be used for a specific purpose
- Bulk packs of one or more items

Regulatory and legislative requirements

The legislative requirements for systems and procedure packs are set out in the:

- *Therapeutic Goods Act 1989* (the Act)—41BF
- Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations)—Regulation 3.10 (3) and Part 7 of Schedule 3

The regulatory requirements for systems and procedure packs are the same as for other medical devices. Manufacturers of all medical devices must:

- ensure that their medical devices meet the Essential Principles
- apply appropriate conformity assessment procedures
- comply with the clinical evidence requirements
- undertake adequate post-market surveillance activities for all medical devices

regardless of whether they manufacture a system or procedure pack.

However, there are additional provisions in the legislation for systems and procedure packs. Manufacturers of systems and procedure packs:

- must ensure that any applicable regulatory requirements are met for each individual component in the system or procedure pack
- must ensure that all components are mutually compatible with the intended purpose of the system or procedure pack and:
  - the intended purpose of each device
  - the approved indications for medicines and OTGs

Manufacturers wishing to utilise the conformity assessment procedure already undertaken by the component manufacturers may be eligible to use the specific conformity assessment procedures under Clause 7.5, Schedule 3 of the Regulations. This procedure is available so that manufacturers of a system or procedure pack may not need to hold conformity assessment certification for the assembly of that system or procedure pack.

Systems and procedure packs are treated as medical devices in their own right and, unless they are exempt (for example, custom-made medical devices), must be included on the ARTG separately from the individual items in the system or procedure pack.

If individual or replacement component items in a system or procedure pack are supplied for use separately from the system or procedure pack, they require separate entry on the ARTG from the system or procedure pack.

Systems and procedure packs that are supplied on loan (for example, instrumentation for orthopaedic implant surgery) are regarded as medical devices and require inclusion in the ARTG.

Different therapeutic goods packages

Systems

Systems are comprised of components, including at least one medical device, that are intended by the manufacturer to be used in combination as a unit. A manufacturer will often supply one or more components of a system in a number of sizes in order to accommodate differences in patient anatomy. Some example systems include:

- orthopaedic drill system, incorporating
  - drill
  - drill bits
  - burs
  - cables
  - a foot pedal
- knee joint- replacement system, incorporating
  - a femoral component
  - an articulating surface
  - a stemmed tibial plate
  - wedges
  - pins
  - screws
- patient monitoring system, incorporating
  - a monitor
  - ECG leads
  - blood-pressure cuff with cable
  - an infusion pump with tubing set

Procedure packs

Procedure packs are comprised of components that are packaged together, including at least one medical device, and intended by the manufacturer to be used in a medical, surgical, or diagnostic procedure. Examples include:

- appendectomy surgical procedure pack incorporating:
  - clamps
  - drapes
  - sutures
  - needles
  - forceps
  - scalpels
  - gauze
  - swab
  - kidney dishes
- first-aid-kit, incorporating:
  - bandages
  - antiseptic ointment
  - tweezers
  - pain-relief tablets
  - adhesive strips
  - cotton buds
  - swabs

Boundary products and articles that are not medical devices

The *Therapeutic Goods (Articles that are not Medical Devices) Order No. 1 of 2004* is a declaration of those articles that are not, for the purposes of the Act, medical devices. The order includes:

> c) an article that is intended to administer a medicine in such a way that the medicine and the article form a single integral product that is intended exclusively for use in the given combination and that is not reusable (may be multi-dose);

Requirement	Legislative reference	Description
Classification	Rule 5.5, Part5, Schedule 2 of the Regulations	Medical device is Class III unless it: • only contains materials of animal origin that have been rendered non-viable AND • is intended by the manufacturer only come into contact with intact skin
TGA Conformity Assessment Certificate	Section 41EA of the *Therapeutic Goods Act 1989* Regulation 4.1, Part 4 of the Regulations	A TGA Conformity Assessment Certificate must be issued before a valid application can be made to include the medical device on the Australian Register of Therapeutic Goods (ARTG)
Essential Principles	Essential Principle 8.2, Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations)	Describe requirements for risk-management, control measures including sourcing, selecting, harvesting, processing and validation methods for elimination/inactivation of viral or TSE agents.

Examples include:

- a tube of cream with a specifically designed applicator to attach to the tube to deliver the required amount of cream
- eye or nasal medication with dropper that is specifically designed to attach or be attached to the medicine container to deliver the metered eye or nasal drops
- a syringe pre-filled with medicine

Therapeutic Goods Orders can be found on the TGA Internet site.

For further information, please see Guidance Document 35: Device–Medicine Boundary Products on the TGA Internet site.

Composite packs

Composite packs only contain medicines and their containers. They are entered on to the ARTG as medicines or other therapeutic goods (OTGs). Composite packs are used for a single treatment or for a single course of treatment. The components must either be combined before administration or be administered in a particular sequence. Examples include:

- vials of medicines administered in a sequence
- a powdered medicine for injection supplied with a diluting agent housed in a vial
- day and night cold and flu medicine

Composite packs cannot contain any medical devices as, by definition, a collection of goods that includes at least one medical device is defined to be a system or procedure pack.

The definition of composite packs is in Section 7B(2) of the Act.

Therapeutic kits

Therapeutic kits comprise a collection of medicines, other therapeutic goods (OTGs), and non-therapeutic goods, for example, a multi-vitamin pack supplied with fish oil capsules and iron tablets.

Kits are listed on the ARTG as medicines or as OTGs. Kits cannot contain any medical devices as, by definition, a collection of goods that includes at least one medical device is defined to be a system or procedure pack.

The legislative requirements for therapeutic kits are set out in the:

- *Therapeutic Goods Act 1989* (the Act) — Chapter 1, Section 7B(1)
- *Therapeutic Goods Regulations 1990* — Regulation 10 (Schedule 4, Part 1, Items 11–12)

The term 'kit' in the legislation has a specific meaning. Although some products use the word 'kit' in their name, they may not meet the definition of kit according to the Act. For example, first-aid-kits may meet the definition of procedure pack under the legislation but do not meet the definition of 'therapeutic kit'.

Custom-made medical devices

Some systems and procedure packs fit the definition of 'custom-made medical devices'. Custom-made medical devices are exempt from inclusion in the ARTG.

A system or procedure pack that contains one or more custom-made medical devices and no other kinds of therapeutic goods is also a custom-made medical device, and therefore is exempt from inclusion on the ARTG. However, a system or procedure pack that contains one or more custom-made medical devices, as well as medicines, OTGs, or non-custom-made medical devices, is not a custom-made medical device and must be included on the ARTG.

For more information, please see Section 18. Custom-made medical devices.

Classification of systems and procedure packs

When classifying a system or procedure pack the manufacturer should note that:

- The medical device component with the highest classification determines the overall classification for the system or procedure pack, for example, a procedure pack containing a Class III device will also be classified as Class III
- The highest classification rule is applied when two or more classification rules could be applied
- A system or procedure pack intended to be used in combination with another medical device is classified separately to the other medical device
- Any accessories to a system or procedure pack are classified separately
- The component manufacturer's intended purpose and classification applies. By changing the component manufacturer's intended purpose or classification, the system or procedure pack manufacturer assumes responsibility for the revised intended purpose for the component device
- The software used to drive or control a system has the same classification as the system
- Class I systems or procedure packs that are supplied sterile are included on the ARTG as 'Class I (supplied sterile)'
- Class I systems or procedure packs that are not supplied sterile but that contain a component that is supplied sterile are included on the ARTG as 'Class I' (non-sterile)
- Class I systems or procedure packs that contain a device with a measuring function are included on the ARTG as 'Class I (with a measuring function)'

- Systems and procedure packs are classified without considering any component medicines or other therapeutic goods (OTGs)

For more information on determining the appropriate classification of a medical device please see Section 4. Classification of medical devices.

Conformity assessment procedure options

Manufacturers of medical devices demonstrate that their devices conform to the Essential Principles by applying conformity assessment procedures.

Manufacturers of systems or procedure packs have two options:

- obtaining conformity assessment evidence for the entire system or procedure pack as a single kind of medical device, or
- using the special conformity assessment procedures for systems and procedure packs outlined in Clause 7.5 of Schedule 3 of the Regulations

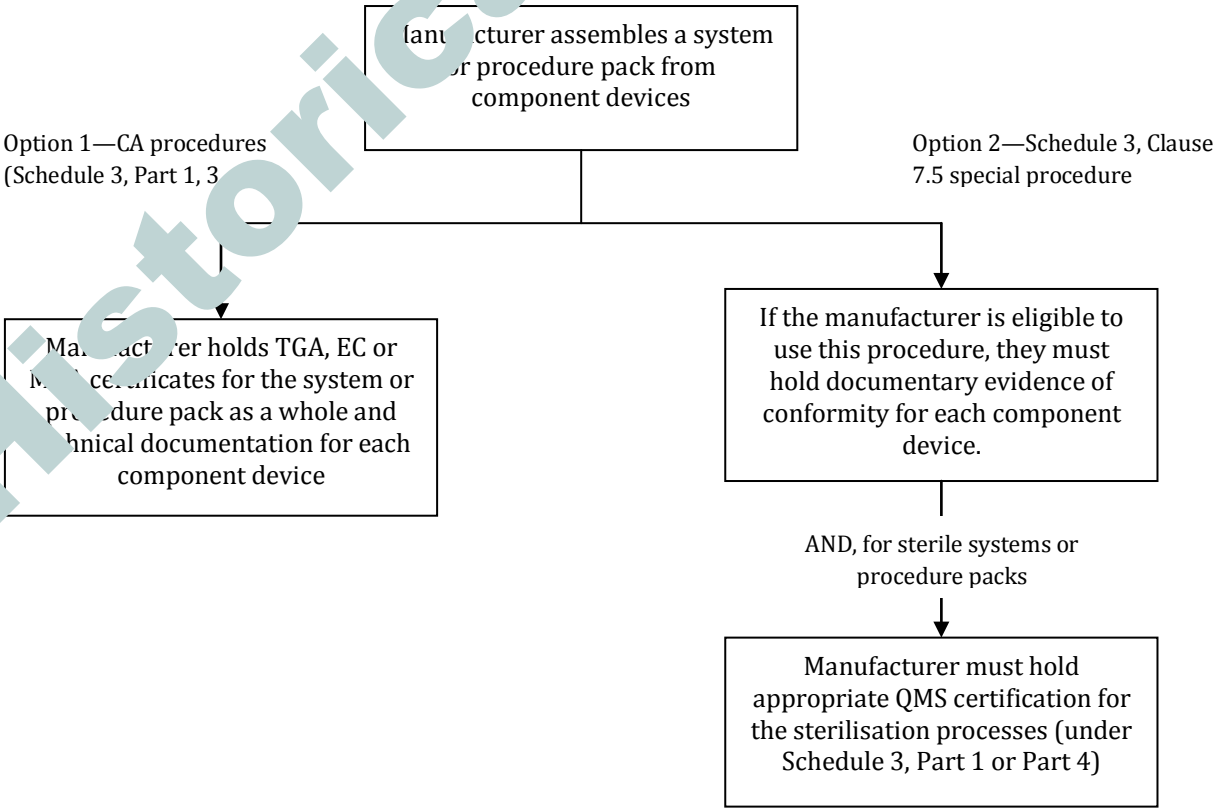
Some manufacturers assemble procedure packs or systems from devices and other therapeutic goods that are manufactured by other (component) manufacturers. These system or procedure pack manufacturers either need to:

- apply for and obtain conformity assessment evidence for the entire system or procedure pack from the TGA or from an EU Notified Body. For more information please see Section 5. Conformity assessment overview

or

- keep adequate documentary evidence of conformity for each of the component devices and prepare an Australian Declaration of Conformity in accordance with clause 7.5. The documentary evidence requirements are outlined later in this document in the section Documentary evidence for manufacturers using the special procedure.

Conformity assessment procedure options



Clause 7.5 special conformity assessment procedure

The special conformity assessment procedure allows manufacturers to assemble systems or procedure packs without being considered to be the manufacturer of each of the component devices (the component manufacturer); however, system or procedure pack manufacturers must keep adequate documentary evidence for each of the component devices.

For example, if a manufacturer assembles a surgical procedure pack that incorporates gauze, needles, sutures, scalpels, forceps, and some clamps, each supplied by different component manufacturers, they may use the Clause 7.5 special conformity assessment procedure if they can obtain documentary evidence for each component device within the pack from each of the component manufacturers.

An application to include a system or procedure pack in the ARTG that uses the Clause 7.5 special conformity assessment procedure is based on a Declaration of Conformity and does not require a conformity assessment certificate to be held by the manufacturer of the system or procedure pack, unless the system or procedure pack is supplied sterile. In this case, the system or procedure pack manufacturer must obtain certification for the sterilisation processes.

Eligibility for the special conformity assessment procedure

The Clause 7.5 special conformity assessment procedures can be used for systems and procedure packs if the manufacturer can meet the requirements of Regulation 3.10, Subsection (3) 'Medical devices used for a special purpose'; systems and procedure packs:

Item	Requirement
Medical device	The system or procedure pack manufacturer must have documentary evidence (outlined in the next table) to demonstrate that each of the medical device components have: • met the Essential principles • had the relevant conformity assessment procedures applied to them
Medicine	Medicines in the systems or procedure pack must be listed or registered on the ARTG, unless the medicine is exempt
Other therapeutic goods (OTGs)	OTGs in the system or procedure pack must be listed or registered on the ARTG, unless the OTG is exempt
All component devices, medicines, and OTGs.	All components must be mutually compatible with the intended purpose of the system or procedure pack and: • the intended purpose of each device • the approved indications for medicines and OTGs
Declaration of conformity	The system or procedure pack manufacturer must make an Australian Declaration of Conformity for the system or procedure pack in accordance with Schedule 3, Clause 7.5

If the criteria for the special conformity assessment procedures cannot be met, the system or procedure pack manufacturer must apply the general conformity assessment procedures. For more information, please see Section 5. Conformity assessment overview.

Documentary evidence for manufacturers using the special procedure

Item	Requirement
For each component device	the system or procedure pack manufacturer must hold at least one of the following: • an Australian Declaration of Conformity from the component manufacturer • a TGA Conformity Assessment Certificate from the component manufac • a CE certificate from the component manufacturer AND agreement w the component manufacturer to supply technical documentation to th GA request • an ARTG inclusion certificate from the component sponsor N a eement with the component sponsor to supply technical docum ta o the TGA on request
For each component medicine	The system or procedure pack manufacturer must ho copy of the ARTG listing/registration certificate for that component, ess the medicine is exempt.
For each component OTG	The system or procedure pack manufac rer ust hold a copy of the ARTG listing/registration certificate for th co ient, unless the OTG is exempt.
For each component including any non-therapeutic goods	The system or procedure p m cturer must hold evidence to demonstrate that the goods work toget chieve the intended purpose and are compatible with the othe od n the system or pack
For sterile systems or procedure packs	The system or pro ure pack manufacturer must hold appropriate conformity assessment e ce the sterilisation processes for the system or procedure pack as a w le does not apply to systems or procedure packs that are non-sterile but inc sterile component devices
For every component for the lifetime of the device and at least 5 years after manufacture of the last device	The m cturer must have access to technical documentation, including: • e component manufacturer's Australian Declaration of Conformity certification and technical documentation. The system or procedure pack manufacturer must either hold or be able to arrange for these to be provided to the TGA on request.
For each s kind of syst or p ure pack	The system or procedure pack manufacturer must provide a list of the contents.

Choosing to use the special procedure

The following examples describe when a system or procedure pack manufacturer may choose to use one of the usual conformity assessment procedure routes or to use the special procedure for systems and procedure packs:

Example: packs where evidence is not held for any of the component devices

Australian manufacturer *Gumtree Medical Manufacturing Pty Ltd* assembles Class IIa first-aid-kits from components it manufactures itself. The first-aid-kit includes some sterile device components but the first-aid-kit itself (as a whole) is not supplied sterile. The manufacturer does not hold the required documentary evidence for any of the component devices and consequently is not eligible for the Clause 7.5 special conformity assessment procedure for systems and procedure packs.

The manufacturer must apply for a TGA Conformity Assessment Certificate to cover:

- each of the component devices inside the first-aid-kit and thereby become eligible for the Clause 7.5 special conformity assessment procedure. The manufacturer would need to submit a change application any time they wanted to introduce a new component not included within the scope of the certificate. The certificate could also be used to support inclusions in the ARTG for the separate supply of the individual components of the first-aid-kit.

and/or

- the first-aid-kit as a whole. The manufacturer would need to submit a change application any time they wanted to introduce a new first-aid-kit not included within the scope of the certificate. The certificate could not be used to support inclusions in the ARTG for the separate supply of the individual components of the first-aid-kit.

Example: packs where evidence is held for some of the component devices

Manufacturer *Dryandra Medical Manufacturing Pty Ltd* assembles and sterilises surgical tubing procedure packs and wants to apply the Clause 7.5 special procedure for systems and procedure packs.

Some of the component devices purchased by Dryandra Medical are supplied to it sterile while others are supplied non-sterile. Some of the component devices are purchased from overseas suppliers and some from suppliers in Australia.

Dryandra Medical looks at the eligibility requirements for meeting the special procedure and finds that it is eligible to apply it to all of its component devices except for the tubing and gauze, as the component manufacturers of these devices do not hold the appropriate documentary evidence. Dryandra Medical therefore chooses to take on the role of the (component) manufacturer just for those components, and assembles appropriate technical files accordingly.

Dryandra Medical then applies for a TGA Conformity Assessment Certificate for:

- terminal sterilisation of surgical tubing procedure packs; and
- the component devices where it is assuming the role of component manufacturer.

Once the TGA Conformity Assessment Certificate is issued, Dryandra Medical applies the Clause 7.5 special procedure for systems and procedure packs for the entire procedure pack.

The sponsor then submits the Australian Declaration of Conformity that Dryandra Medical has completed in accordance with Clause 7.5 as the Manufacturer's Evidence.

Additional requirements of the special procedure

Item	Requirement
Labelling and *Instructions for Use*	Clause 7.5 requires that in addition to the requirements of Essential Principle 13, Part 2, Schedule 1 of the Regulations, the *Instructions for Use* must be included for each component item in a system or procedure pack whenever it is provided by the component manufacturer. The Aust L or Aust R number for all component medicines included in the system or procedure pack must be included on the labelling of the system or procedure pack. For more information please see Section 12. Information about a medical device. *Please Note: As per Essential Principle 13.3(3), manufacturers must provide a list of the contents of the system or procedure pack with the product.*
Declarations of Conformity to Clause 7.5	System and procedure pack manufacturers using the special procedure should ensure that the Declaration of Conformity is prepared in accordance with Clause 7 of Schedule 3 of the Regulations. Declarations of conformity made to the European special procedure for systems and procedure packs (Article 12.2) are not acceptable. Manufacturers must identify each item in the package, regardless of whether they are medical devices, medicines, OTGs, or non- therapeutic goods. When making an Australian Declaration of Conformity in accordance with Clause 7.5, system and procedure pack manufacturers must list the ARTG numbers for all medicines and OTGs in the pack; however, there is no requirement to list ARTG inclusion numbers or GMDN codes for the medical device components. Each medical device component in a system or procedure pack must be used for the intended purpose indicated by the component manufacturer. For example, a blood-collection container cannot be used as a container for a povidone iodine solution. A person who wants to change the intended purpose of a medical device becomes the manufacturer of that medical device and must apply appropriate conformity assessment procedures accordingly.
Manufacturer's evidence	Manufacturer's evidence for manufacturers using the special procedure consists of the manufacturer's Australian Declaration of Conformity to Clause 7.5. For systems or procedure packs that are supplied sterile the system or procedure pack manufacturer must hold appropriate QMS certification for the sterilisation processes, for example a Part 4 or MDD Annex V certificate for 'the sterilisation of surgical tubing procedure packs'. Manufacturer's Evidence in this case consists of an Australian Declaration of Conformity to Clause 7.5 as well as the Part 4 certificate for the sterilisation processes.
Post market requirements	Clause 7.5(3) of the special procedure for systems and procedure packs requires the manufacturer to establish a post-market surveillance system to: • systematically review experiences gained after the device is supplied in Australia • implement any necessary corrective action in relation to the production of the device • notify the TGA of adverse events and near miss events • notify the TGA as soon as practicable about information relating to malfunction or deterioration of its device • notify the TGA as soon as practicable about any inadequacy in the production, labelling, *instructions for use*, or advertising materials of its device

Item	Requirement
	• notify the TGA as soon as practicable about any use the device that might lead to, or might have led to, the death or serious deterioration of the health of a patient or user of the device • notify the TGA as soon as practicable about any information relating to technical or medical reasons that have led the manufacturer to recover the device for any of the reasons outlined above. For more information about these requirements, please see Section 22. Post-market vigilance and monitoring requirements.

Specific types of systems and procedure packs

Case	Description
Subsets of systems or procedure packs	If a system or procedure pack contains a large number of items, sponsors can supply systems or procedure packs that contain a subset of these items without additional ARTG inclusions, provided that the subsets of the system or procedure pack are of the same kind of medical device, that is, the same sponsor, manufacturer, GMDN, and Class.
Sterile systems or procedure packs	If a system or procedure pack is to be supplied sterile, the manufacturer must obtain Conformity Assessment Certification from the TGA or CE Certification from an EU Notified Body. For further information, please see Section 6. What a manufacturer needs to know about conformity assessment. The sterilisation process must be appropriate for all medicines, TGAs and medical devices in the system or procedure pack. This has particular significance where a sterile system or procedure pack contains a pre-sterilised component.
Class III and AIMD systems or procedure packs	If a system or procedure pack is classified as Class III or Class AIMD, each model of the system or procedure pack needs to be included on the ARTG at the Unique Product Identifier level. In accordance with Regulation 5.1 of the Regulations, Class III/AIMD systems and procedure packs will be selected for mandatory pre-market application audit unless a TGA Conformity Assessment certificate or MRA Certificate has been issued for the entire system or procedure pack. If a TGA Conformity Assessment Certificate has only been issued for sterilisation activities then a mandatory application audit will be conducted. For more information please see: • Section 11. Application audits of medical device applications • Section 10. Including medical devices in the ARTG
Single-use system or procedure pack	A single-use system or procedure pack should not be reprocessed for reuse. If the manufacturer of a system or procedure pack has provided instructions for reprocessing of unused components then unused components can be reprocessed according to those instructions. For further information, please see Section 19. Single-use devices (SUDs)
Reusable system or reusable pack	A reusable system or procedure pack can be reprocessed for reuse if the manufacturer has declared that it can be reused. Any reprocessing should be done in accordance with the manufacturer's instructions.
Medical devices containing materials of animal, microbial, or recombinant origin and medical devices incorporating a medicinal substance	A TGA Conformity Assessment Certificate is required for medical devices that incorporate a medicinal substance or that contain materials of animal, microbial, or recombinant origin. For systems and procedure packs that include such Class III components, the manufacturer may either obtain the TGA Conformity Assessment Certificate for:

Case	Description
	• the system or procedure pack as a whole OR • the relevant Class III component only—and then apply the special procedure for the system or procedure pack as a whole. The manufacturer's Clause 7.5 declaration of conformity would then be lodged as manufacturer's Evidence in order to include the system or procedure pack on the ARTG. For more information, please see: • Section 15. Medical devices containing materials of animal, microbial or recombinant origin • Section 14. Medical devices incorporating a medicine
Component medicine(s) and systems or procedure packs that incorporate other therapeutic goods (OTGs)	Systems and procedure packs are classified without considering any medicine or OTG components. However, component medicines or OTGs that are incorporated into a system or a procedure pack must meet the regulatory requirements for the medicine or OTG. The system or procedure pack containing the medicine must also satisfy the labelling requirements for the medicine. Where a sterilisation process is used to sterilise a system or procedure pack, the method must be appropriate for all medicines, OTGs, and medical devices in the system or procedure pack. The additional sterilisation process must be in accordance with the initial approval for Registration of the medicine on the ARTG, that is, an assessment must have been made to determine if the sterilisation process will affect the quality, safety, or efficacy of the medicine. For further information please see Section 14. Medical devices incorporating a medicine.

Changes to contents

If the contents in a system or procedure pack change, the system or procedure pack manufacturer needs to

- reassess:
  - the classification
  - the GMDN
  - the UPI (applicable to Class III and AIMD only)
  - whether the change is covered by the scope of the existing conformity assessment evidence
  - eligibility for the Clause 7.5 special conformity assessment procedures (if applicable), and then
- apply appropriate conformity assessment procedures
- update documentation, including the Australian Declaration of Conformity

If the changes result in a new GMDN and/or classification then a new application to include the system or procedure pack in the ARTG will be required.

For further information on changes and variations, please see Section 21. Changes to ARTG inclusions.

Accessories

If an accessory to a system or procedure pack is a medical device as defined under section 41BD of the Act, and it is supplied separately from the system or procedure pack, it will need a separate ARTG inclusion from that of the system or procedure pack.

If the accessory has a different GMDN or Classification to the system or procedure pack, or in the case of Class III/AIMD a different UPI, it is considered to be a different kind of medical device (under Section 41BE of the Act) to the system or procedure pack and hence requires a separate inclusion in the ARTG.

Section 17. Medical devices for export

Overview

Sponsors wanting to export medical devices from Australia must meet certain regulatory requirements set out in the *Therapeutic Goods Act 1989* (the Act) and the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Before a sponsor can export a medical device from Australia, the device must:

- be included in the ARTG for supply in Australia, or
- be included in the ARTG as an export only medical device, or
- be exempt under Item 1.2, Part 1, Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002*

When exporting medical devices from Australia, the sponsor will need to comply with the regulatory requirements of the importing country and should contact the relevant Embassy, High Commission or Consulate for advice on their importation requirements. These regulatory requirements could include conformity assessment procedures for the importing country. If additional certification is required by the importing country, medical device sponsors can apply to the TGA for an Export Certificate or a Certificate of Free Sale.

Included medical devices for supply in Australia

Sponsors of medical devices that are included in the ARTG for supply in Australia are also able to export these devices from Australia under the existing ARTG inclusion number. With the exception of class III and Active implantable medical devices (AIMDs), an inclusion in the ARTG is for a kind of medical device that can cover a range of individual models of that kind. This means that an inclusion in the ARTG only records the kind of device and no the individual device models.

If the importing country requires an Export Certificate or Certificate of Free Sale with an attached schedule of devices covered by the ARTG inclusion, there will be insufficient information on the ARTG inclusion for the TGA to certify the individual models of devices covered by the Inclusion.

In this situation the sponsor may submit an application for an export only inclusion and provide a list, on page 2a of the application, of all the devices of that kind to be exported under the ARTG inclusion.

Included medical devices for export only

Export only medical devices are either manufactured in Australia for export only or are imported into Australia for export only and cannot be supplied to the Australian market.

Export only medical devices are still subject to:

- the classification rules
- the Essential Principles for safety and performance
- the Conformity Assessment Procedures; and
- inclusion in the Australian Register of Therapeutic Goods (ARTG), unless the exemption under Item 1.2, Part 1, Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002* applies

From the *Therapeutic Goods (Medical Devices) Regulations 2002 — Schedule 2…*

Classification Rules Part 5 Special rule for particular types of medical devices

5.8 Medical devices intended for export only

Despite any other classification in this Schedule, a medical device that is intended by the manufacturer to be for export only is classified as Class I.

Medical devices that are intended by the manufacturer to only be exported from Australia are classified as Class I for entry in the ARTG. However, the products themselves would need to meet the classification and conformity assessment requirements of the importing country. For example, a cardiac catheter may be classified as a Class III in the importing country but would be included in the ARTG as a Class I "export only" device.

The minimum mandatory Conformity Assessment Procedure to be undertaken by the manufacturer for export only medical devices is described in Part 6, Declaration of Conformity, (not requiring assessment by the TGA) procedures in Schedule 3, the *Therapeutic Goods (Medical Devices) Regulations 2002*. It is recommended that sponsors check with the relevant Embassy, High Commission or Consulate for advice regarding the Conformity Assessment Procedures required by the importing country.

An application for an export only inclusion differs from an inclusion for supply in Australia in that the export only application:

- enables sponsors to provide a list the names of the export devices on Page 2a of the application form and consequently for an approved application, the export names will form part of the ARTG inclusion and
- is not subject to post-market review

Export-only devices exempt from inclusion in the ARTG

From the *Therapeutic Goods Act 1989…*

Schedule 4 Exempt goods, Part 1 General exemptions

Item 2 Medical device that is exported from Australia and:

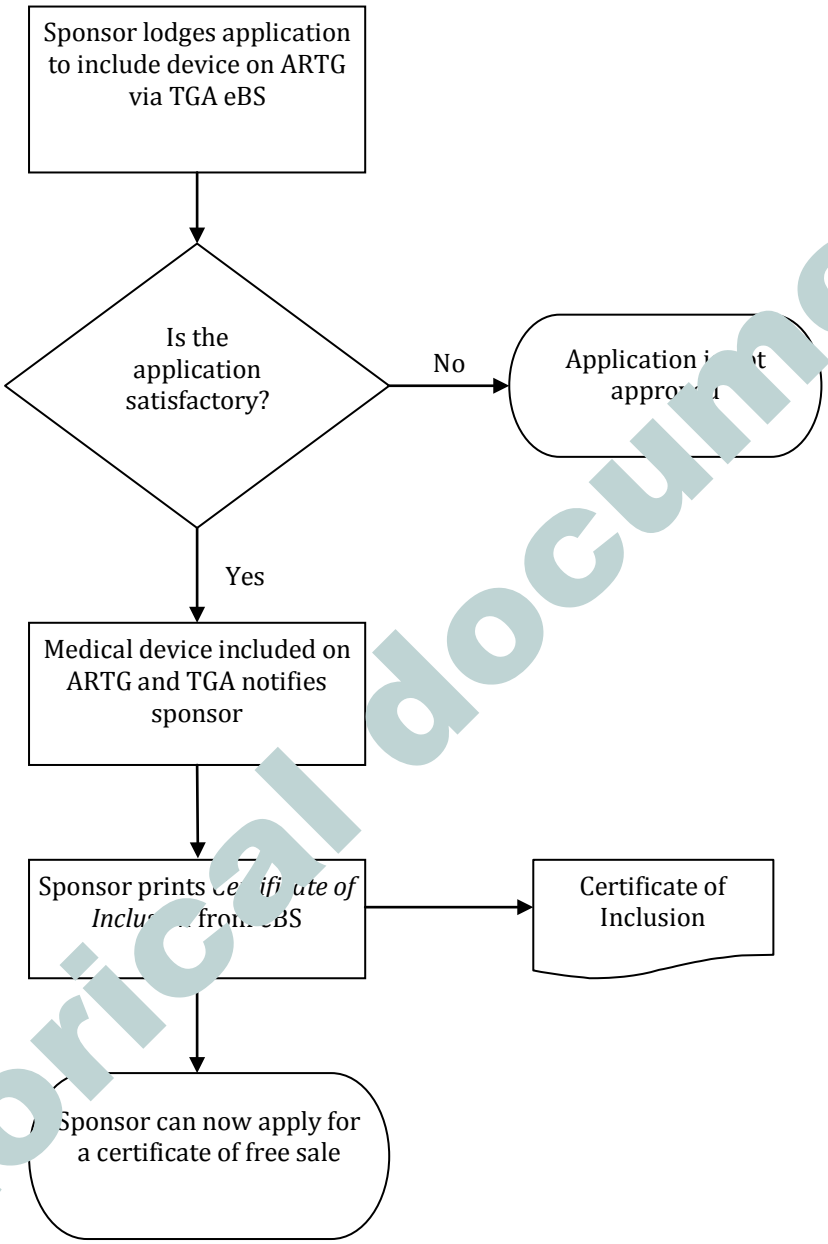
a. is not intended for commercial supply; and
b. does not contain a substance, the export of which is prohibited under the *Customs Act 1901*; and
c. is not intended for experimental purposes on humans

Medical devices that are exported from Australia for non-commercial supply and that do not contain a substance that is prohibited under the *Customs Act 1901*, are exempt from inclusion in the ARTG.

If a Certificate of Free Sale is required, the sponsor submits to the TGA a statement of exemption that contains a detailed explanation of the circumstances or purposes of the export and the products to be exported including the export destinations.

Process for including export only devices on the ARTG

The following flowchart summarises the process for including an export-only medical device on the ARTG via the TGA eBusiness Services (eBS):



F nor formation on how to include a medical device in the ARTG, please see Section 10. Including medical dev in t e ARTG.

ce the medical device is included in the ARTG, or the exemption under Schedule 4 applies, the sponsor may a for a Certificate of Free Sale, if it is required by the importing country.

Export Certificates

An Export Certificate is issued by the TGA for medical devices that are included in the ARTG for supply in Australia and the manufacturer has been issued with a TGA Conformity Assessment Certification.

An Export Certificate remains valid as long as the devices covered by the certificate remain unchanged and current on the ARTG.

Certificates of Free Sale

A Certificate of Free Sale is issued by the TGA for included medical devices or medical devices exempt under item 1.2, Part 1, Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002* in situations where the TGA has not issued or reviewed the manufacturer's Conformity Assessment Certification.

A Certificate of Free Sale also remains valid as long as the devices covered by the certificate remain unchanged and current on the ARTG or the exemption under Schedule 4 remains unchanged.

Application for an Export Certificate or a Certificate of Free Sale

From the *Therapeutic Goods Act 1989*...

Chapter 7 Miscellaneous Section 58

58 Export certifications

1. The Secretary may issue export certification for goods for therapeutic use in humans, including certifications for the purposes of the World Health Organisation Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.
2. A State or Territory must not issue export certifications for goods for therapeutic use in humans.
3. Such fees as are prescribed is payable in respect of:
   - an application for a certification under this section; and
   - where an inspection of manufacturing premises is necessary for the purposes of the issue of a certification under this section—the inspection of those premises.

The application form for a Certificate of Free Sale or an Export Certificate is available on the TGA website at <http://www.tga.gov.au>. The TGA aims to process applications for a Certificate of Free Sale or an Export Certificate within ten TGA work days.

Sponsors should ensure that the information provided in their application for a Certificate of Free Sale or Export Certificate is consistent with their eBS and ARTG records. Any inconsistencies in information currently in the ARTG or eBS client details should be rectified before making an application.

Some exporting countries also require a schedule of information to be attached to the certificate. The information provided in the schedule must also be consistent with the ARTG record. A single certificate may be issued to cover multiple inclusions on the ARTG provided these entries have the same sponsor and the same manufacturer.

A fee is payable for applications for a Certificate of Free Sale or Export Certificate. Details of the fees currently applicable are available on the TGA website at <http://www.tga.gov.au>. For more information on fees and charges, please see Section 2. Fees and charges for medical devices.

The Certificate of Free Sale or Export Certificate issued by the TGA may also need to be endorsed by the Department of Foreign Affairs and Trade, and authorised by the Embassy, High Commission, or Consulate of the importing country. This is the responsibility of the applicant, not the Therapeutic Goods Administration.

Section 18. Custom-made medical devices

This section to be drafted.

Section 19. Single-use devices (SUDs) and the reuse of SUDs

Overview

If a device is for:	The manufacturer's intention is that the device:
single use	can only be used once and should then be disposed of
single patient use	can be used multiple times on one patient. Single patient use devices are able to be reprocessed and reused on the same patient in accordance with the manufacturer's instructions

It is the responsibility of the manufacturer to determine whether a device should be for single use or single patient use. If the device is only intended to be for single use this must be clearly stated on the device, the label or the *Instructions for Use* in accordance with Essential Principle 13.4, Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

If a SUD (for example, an orthopaedic plate or screw) is trialled during the surgical/medical procedure and comes in contact with blood, tissue or bodily fluids during the surgical/medial procedure it is regarded as used.

The TGA will include the device in the ARTG based on the manufacturer's intended purpose. Therefore, the TGA does not conduct any pre-market assessments to determine if a device can be reused if the manufacturer states that the device is for single use or single patient use.

There may be several reasons why a medical device is for single use or single patient use, including that the:

- materials used in the manufacture of the device may not withstand repeated reprocessing
- design of the device may not facilitate adequate cleaning and sterilisation
- device may not perform as intended by the manufacturer if it is reused

The reuse of SUDs may lead to:

- Potential risks of cross infection/contamination associated with using inadequately cleaned and sterilised devices
- Failure of the device to perform as intended
- Material degradation
- Incompatibility issues
- Endotoxic reactions caused by the residues from reprocessing

SUDs that are opened but unused

The regulation of the remanufacture of SUDs does not include those SUDs that are opened but unused.

'Opened but unused' is the term used to refer to a SUD whose packaging has been opened but the device was not used and did not come in contact with blood, tissue or bodily fluids.

The TGA regards opened but unused as having the same meaning as packaging that is damaged. In the case of a sterile device the original manufacturer is required under Essential Principle 13.4, Item 12 to provide advice on what to do when the packaging is damaged.

From the *Therapeutic Goods (Medical Devices) Regulations 2002*—Schedule 1 Part 2...

13.4 *Instructions for use*

12 For a device that is intended by the manufacturer to be supplied in a sterile state:

a. an indication that the device is sterile; and
b. information about what to do if sterile packaging is damaged; and
c. if appropriate, instructions for resterilisation of the device

Users of sterile medical devices are expected to follow these instructions if the package is opened but the device is not used.

The *Instructions for Use* may be considered by the TGA if the application under goes a pre-market assessment before the device is included on the Australian Register of Therapeutic Goods (ARTG).

The TGA will assess the *Instructions for Use* against the Medical Device Standards Order (Standards for Medical Devices Required to be Sterile) 2008 that maps Essential Principle 13.4 Item 12 to the international standard *ISO 17664: 2004 Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilisable medical devices*.

Reusing SUDs

When a SUD is reused, the TGA considers that the device has been remanufactured as the:

- intended purpose and design specifications for the device are altered from single use to reusable
- device may undergo manufacturing processes, such as sterilisation
- device may need to have components replaced so that it can be reused
- original manufacturer can no longer be considered responsible for the safety and performance of the de

The person responsible for undertaking these remanufacturing activities is considered to be a manufact under section 41BG(2) of the *Therapeutic Goods Act 1989* and must comply with the therapeutic goods islation relating to the manufacture of medical devices.

From the *Therapeutic Goods Act 1989*...

41BG Manufacturers of medical devices

1. The manufacturer of a medical device is the per wi responsible for the design, production, packa ing labelling of the device before it is supplied under the person's , whether or not it is the person, or another person acti on the person's behalf, who carries out those operations.
2. If subsection (1) does not apply to ed device, the manufacturer of the device is th per who, with a view to supplying the device unde he p s name, does one or more of the following using ready products:
   a. assembles the dev e;
   b. packages the device;
   c. processe e device;
   d. fully refurbi s the device;
   e. label evice;
   f. assi s to e device its purpose by means of information ppli by the person, on or in any one or more of the foll ing:
      i. the labelling on the device;
      ii. the instructions for using the device;
      iii. any advertising material relating to the device;
      iv. technical documentation describing the mechanism of action of the device.

Once a medi l device has been re-processed, the original manufacturer no longer has any regulatory respo ibil r the therapeutic goods legislation for the reprocessed device. This includes:

- mai ning distribution records
- s g safety or hazard alerts
- ecall actions

People, including health professionals and health-care facilities, who want to reprocess SUDs may:

- become a manufacturer
- need to find a manufacturer to undertake the remanufacture of the SUDs

Reuse of SUDs for personal use

The TGA does not regulate the practice where people clean and reuse products such as single use enteral feeding tubes, urinary catheters, etc as long as it is for their own use.

Health professionals who give advice on reusing SUDs

Healthcare professionals often advise their patients about the reuse of the SUDs. They are not undertaking any work but are providing advice on how the device may be cleaned for reuse. The healthcare professional may be professionally liable if the information provided contradicts the information provided in the manufacturer's *Instructions for Use*.

Regulatory requirements for remanufacturing SUDs

The Australian regulatory framework for medical devices is designed to ensure that the reprocessing of devices that were not originally intended for reprocessing does not compromise the safety and effectiveness of the device. Under these regulatory controls, the reprocessing facility is regulated as a manufacturer and is required to demonstrate that the reprocessed device is equivalent to the original and will continue to perform without additional risk to the patient.

People wanting to remanufacture SUDs in Australia must be familiar with the Australian legislative requirements. The steps required to obtain approval to remanufacture SUDs are as follows:

Action	Relevant section of the ARGMD to refer to for more information
Determine the classification of the SUDs to be remanufactured	Section 4. Classification of medical devices
Select appropriate conformity assessment procedures *Please note: most require a manufacturer to develop and implement a quality management system*	Section 5. Conformity assessment overview Section 6. What a manufacturer needs to know about conformity assessment
Ensure compliance with the Essential Principles and that the necessary evidence to demonstrate this compliance is held, including: • a risk-analysis identifying all possible risks and the associated risk mitigation strategies • technical documentation about the device • appropriate clinical evidence	Section 3. The Essential Principles
For all devices except for Class I non-sterile non-measuring, apply for a TGA Conformity Assessment Certificate	Section 6. What a manufacturer needs to know about conformity assessment
Decide who is to be the sponsor (the person legally responsible for the supply of the device in Australia) for the remanufactured SUDs. The sponsor then needs to apply to the TGA to include the remanufactured devices in the ARTG	Section 7. What a sponsor needs to know about conformity assessment Section 10. Including medical devices in the ARTG
Establish and maintain compliance with the post-market requirements, including: • tracking the number of times the device is remanufactured and reused • tracing the device to the batch/serial number of the original device • recording who they supply the device to in case of recall or other regulatory action • reporting adverse events associated with the use of the device to the TGA	Section 22. Post-market vigilance and monitoring requirements

The manufacturer must ensure that the technical documentation addresses the following issues that are relevant to the remanufacturing process, that:

- the materials used to make the original device and the biocompatibility of those materials is not affected
- the cleaning and disinfection processes are validated as effective, including appropriate viral inactivation studies
- prion/TSE hazards are suitably mitigated and controlled
- the sterilisation processes have been validated to demonstrate the achievement of a sterility assurance level of at least 10^{-6}
- endotoxins do not exceed the allowable limit for medical devices
- the device will continue to perform as originally intended without additional risk to the patient or user

Costs of remanufacturing SUDs

Before making a decision to reprocess SUDs, it is recommended that an analysis be undertaken of the costs involved in opting for a single use policy compared to reusing devices. These costs may include, but not be limited to:

- reprocessing the devices—staff, equipment, materials
- developing and maintaining a quality management system
- demonstrating compliance with the Australian Essential Principles

This analysis should also take into account the fees payable to the TGA for:

- if applicable, an application for a TGA Conformity Assessment Certificate and the associated assessments of the documentation provided
- applications to include the remanufactured devices in the ARTG
- ongoing annual charges for each kind of device that is in the ARTG

Please refer Section 2. Fees and charges for medical devices for more information on fees and charges payable to the TGA.

Case studies

Single-use implants for use in orthopaedic procedures

It is common practice for manufacturers to supply orthopaedic implants for restocking implant sets prior to sterilisation for use in orthopaedic procedures. Examples of these implants are screws, hooks, rods, plates, cages, discs, washers, nuts and associated spinal and trauma implants.

The manufacturer provides instructions on how to process and sterilise these implants prior to use and although these are not intended to be used once, those unused implants have been designed and manufactured to undergo re-sterilisation in accordance with the manufacturer's instructions.

Once the sterilised set of implants is opened in the operating suite, the unused implants within the set are regarded as 'opened but unused single-use medical devices'. The subsequent re-sterilisation of the unused implants must be undertaken in accordance with the manufacturer's instructions. The intended use for the device has not been changed, there is no reuse occurring and the reprocessing and re-sterilisation is in accordance with the manufacturer's original instructions.

However, if one of these single use devices is used or comes into contact with blood, tissue, or bodily fluids, the device is taken to be used and cannot be remanufactured for reuse on another person unless the remanufacturing is undertaken in a TGA-certified manufacturing facility. The remanufacturer must have demonstrated to the TGA through scientific and clinical evidence that the remanufactured device performs as

intended and meets the Essential Principles. To be able to clean and sterilise the device and reuse it in another patient the TGA must have issued a:

- TGA Conformity Assessment Certificate to the new manufacturer who is responsible for the sterilisation
- certificate of inclusion in the ARTG to the sponsor for that device.

External fixation devices

External fixation devices either encircle or lie adjacent to the head or a limb, and are attached to the skeleton by pins, fine tensioned wires or screws. They are used to treat fractures or reconstruct bones and joints that ar deformed or damaged.

External fixation devices may be initially supplied as part of a system pack, which comprises component are intended by the manufacturer to be used in combination as a unit.

The component with the highest risk classification determines the overall classification for the st te pack. For example, the Ilizarov external fixation system contains sterile pins that secure the external fram th patient's bones. These would usually be considered Class IIb medical devices and as a consequence ntire system pack is classified as Class IIb.

However, there are occasions where it may be appropriate to supply individual comp nts r a system separately. In these circumstances each device that is individually supplied is clas ed s arately and requires a separate entry in the ARTG. The manufacturer will classify the individual dev us he classification rules and then apply the appropriate conformity assessment procedures to each of th vidual types of device.

The non-sterile external components of the external fixation systems, w n su lied separately to the system, are Class I medical devices. For example, the frame used in an extern f system is non-invasive, is not active and none of the special classification rules apply, so it is Cla s I. e reprocessing of these non-sterile external components may be within the capability of some tra ter sing supply departments.

Prior to the facility reprocessing and reusing the Class I ex xation frame labelled as single use, they will need to:

- prepare a Declaration of Conformity—for mo nformation, please see Section 6. What a manufacturer needs to know about conformity assessment
- apply to the TGA to have the reprocesse d included in the ARTG.

There is no TGA inspection of the repr ssing cility or pre-market assessment of the reprocessed device as it is a Class I device. This is only th cas for C ss I reprocessed devices. The only regulatory cost is an annual charge to maintain the entry in th R he TGA will monitor the safety and performance of the device as part of its post-market vigilance an mo ring program.

The regulatory controls also re ire that the reprocessing facility reports to the TGA any serious incidents or adverse events associa h the use of the reprocessed device.

Section 20. Access to unapproved medical devices in Australia

Overview

Medical devices are therapeutic goods. The TGA regulatory framework exempts some therapeutic goods from the need for inclusion in the Australian Register of Therapeutic Goods (ARTG) prior to supply in Australia, in certain circumstances.

This means that medical devices that have not been assessed by the TGA for quality, safety and performance and included in the ARTG may still be accessed in certain legitimate circumstances via specific exemptions in the therapeutic goods legislation. Such exempt medical devices are also typically referred to as 'unapproved medical devices' or 'unapproved therapeutic goods'.

There are four main mechanisms for legally accessing unapproved medical devices not included on the ARTG. These are:

- the Clinical Trial exemptions
- the Authorised Prescriber Scheme
- the Special Access Scheme (SAS)
- personal importation

This guidance document provides information on each of these mechanisms in relation to medical devices. If more information is required a comprehensive document Access to unapproved therapeutic goods in Australia is available on the TGA website, which outlines the Australian regulatory requirements for accessing medicines and medical devices that are not in the ARTG.

Substances subject to additional controls

Some substances are prohibited under the *Custom (Prohibited Imports) Regulations 1956*. Further information on prohibited imports can be obtained from the Australian Customs and Border Protection Service website at <http://www.customs.gov.au>.

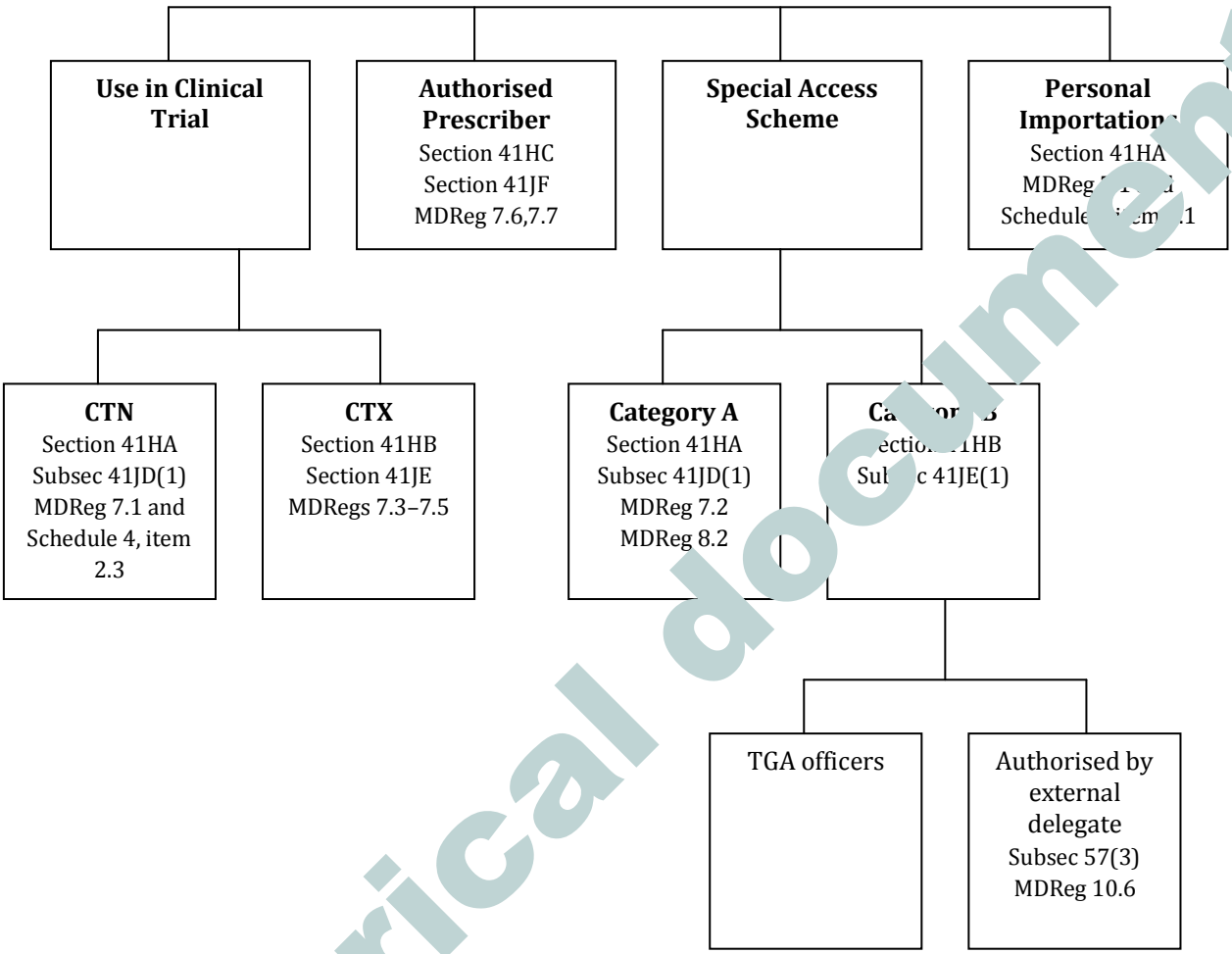
Prior quarantine clearance must be obtained to import any material of biological origin (human, animal, plant or bacterial). The importer should contact the Australian Quarantine & Inspection Service (AQIS) to see if an import permit is required. Further information can be obtained from the AQIS website <http://www.aqis.gov.au>.

The import or export of substances containing parts of animals and plants listed as endangered species required a permit issued under the *Wildlife Protection (Regulation of Exports and Imports) Act 1982*. Further information can be obtained from the Environment Australia website <http://www.biodiversity.environment.gov.au/wildlife>.

Legislative basis for access to unapproved medical devices

The following table outlines the legislative basis for each of the mechanisms for accessing unapproved medical devices. References to:

- Sections and Subsections refer to the *Therapeutic Goods Act 1989* (the Act)
- MDReg refer to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations).



In considering requests for supply medical devices that have not been included in the ARTG, the TGA has a responsibility to maintain a flexible and efficient means of ensuring individuals are able to gain timely access to important new therapeutic developments without jeopardising the broader community interest in ensuring that devices available in Australia are evaluated for quality, safety and performance.

Under the Special Access Scheme and Authorised Prescribers Schemes the TGA also has a responsibility to encourage at all times the availability of included devices in the ARTG. The various mechanisms for accessing unapproved devices are intended to be temporary measures pending inclusion of the device in the ARTG. There are some circumstances, however, when unapproved medical devices may be required for a prolonged period. For example, devices not marketed in Australia for whatever reason, yet fulfilling a legitimate clinical need. The TGA requires that applications to access unapproved devices clinically justify why available approved devices are not suitable for use focussing on quality, safety and performance issues. Practitioner preference or cost issues are not acceptable as clinical justifications to support an application for access to an unapproved medical device.

Release of information

Information provided to the TGA concerning the use of unapproved medical devices will be treated as confidential within the constraints of:

- Section 61 of the Act, which prescribes certain circumstances in which information may be released

- Section 27 of the *Freedom of Information Act 1982* requires that consultation occur between the TGA and the owner of the information prior to release of that documentation
- the *Privacy Act 1988* places limits on the disclosure of personal information by parties in possession or control of records. Such parties cannot disclose personal information about an individual to a person, body or agency other than the individual concerned except under certain circumstances. These circumstances include situations where the:
  - individual concerned has consented to the disclosure or is reasonably likely to have been aware that information of that kind is usually passed to that person or agency
  - holder of the record has reasonable grounds to believe that disclosure is necessary to prevent or lessen a serious, imminent threat to life or health of the person concerned
  - disclosure is required or authorised by or under law
  - disclosure is reasonably necessary for the enforcement of criminal law or of a law imposing a criminal penalty, or for the protection of the public revenue.

Under the Act, the TGA is able to release information concerning the use of unapproved therapeutic goods to State and Territory authorities. This may allow States and Territories to have information to take action on matters under their jurisdiction, such as medical or pharmacy practice. The circumstances under which this may occur include, but are not limited to:

- the TGA becoming aware that a medical practitioner is using notification mechanisms (for example, Category A SAS or the CTN Scheme) inappropriately so as to avoid having to obtain authorisation from the TGA for supply of an unapproved therapeutic good
- where audit of use of unapproved products establishes issues of negligence or unprofessional behaviour.

Doctors and sponsors reporting adverse events to the TGA associated with use of unapproved products should be familiar with and meet obligations in relation to the collection, use and disclosure of personal information in accordance with the National Privacy Principles based on the *Privacy Act 1988*. These obligations are set out in the *Guidelines on Privacy in the Private Health Sector, Office of the Federal Privacy Commissioner, November 2001*.

The information required to report an adverse event is dependent on whether the person reporting the event is:

- a sponsor
- the user of the device

There are two separate forms available on the TGA website.

The information provided to the TGA must identify the event rather than the patient. The TGA's requirement for information should not include data that could identify the patient; however the TGA may request details such as the patient's:

- age
- weight
- height
- ethnicity
- medications they are currently taking

Where disclosure of the patient's identity to the TGA is required, the patient's or relative's explicit consent to the release of the information must be sought.

Clinical trials in Australia

A clinical trial or clinical investigation is an experiment conducted in humans in order to assess the effects, efficacy and/or safety of a medicine, medical device or procedure/intervention. Clinical trials of medical devices are undertaken to answer questions about their performance and safety. The trial should be designed to collect the information necessary to provide evidence to answer the questions posed and should advance scientific

knowledge. It is therefore necessary that the trial be conducted using appropriate experimental designs to obtain valid data without exposing people to unnecessary risks.

The responsibility for monitoring a clinical trial rests with the:

- sponsor
- institution in which the trial is being conducted
- ethics committee
- investigator

Clinical trials must be approved by a Human Research Ethics Committee (HREC). The committee must be constituted and operating in accordance with the NHMRC's National Statement on Ethical Conduct in Human Research. With respect to the conduct of a trial at a specific site, approval of the trial is required from a HREC with jurisdiction at that site.

It is important to distinguish between clinical trials and use of a device in an individual patient as part of clinical practice. Use of unapproved medical devices in individual patients as part of clinical patient care should be done using the provisions of the Authorised Prescriber or Special Access Scheme and not as a clinical trial.

A person must not intentionally or recklessly make a claim, by any means, that the person or another person can arrange the supply of unapproved devices. This is an offence under Section 41MM of Chapter 4 of the Act and carries a financial penalty.

There are two schemes under which clinical trials involving medical devices may be conducted:

- the Clinical Trial Notification (CTN) Scheme
- the Clinical Trial Exemption (CTX) Scheme

These schemes are used for clinical trials involving:

- any device not included in the ARTG
- use of a device in a clinical trial beyond the conditions of its marketing approval

It is a decision of the clinical trial sponsor with respect to which scheme they wish to use. The two schemes are described in detail later in this document, but essentially the:

- CTN process involves a notification only to the TGA with a nominal notification fee (no approval or decision is made by the TGA)
- CTX process comprises an assessment by the TGA of summary data and usage guidelines for a proposed clinical development programme, and if approval is granted the subsequent trials must be carried out under the terms of the approval and be notified to the TGA

The assessment of a CTX application is fully cost-recovered, and the TGA has a timeframe of up to 50 working days to make a decision on the application. Reasons for deciding upon a CTX approval are varied, but might include the medical device:

- being a completely novel treatment method and thus an application could assist in the evaluation of pre-clinical and clinical data and the identification of any deficiencies prior to commencement of trials in Australia and potentially overseas
- incorporates biological substances for which specific pre-clinical data may be required and clinical trial sponsors may wish to have confidence that current data is sufficient to address pre-clinical concerns

Clinical trials in which medical devices are used within the conditions of their marketing approval are not subject to CTN or CTX requirements but still need to be approved by a HREC before the trial may commence.

All CTN and CTX trials must have an Australian clinical trial sponsor. The clinical trial sponsor is that person, body, organisation or institution that takes overall responsibility for the conduct of the trial and signs the relevant page of either the CTN form or the CTX form. The clinical trial sponsor usually initiates, arranges and supports a clinical study and carries the medical and legal responsibility associated with the conduct of the trial. Examples of possible clinical trial sponsors are:

- medical practitioners
- hospitals
- non-government organisations
- clinical research organisations
- medical device manufacturers

Clinical Trial Notification (CTN) Scheme

All material relating to the proposed trial is submitted directly to the HREC by the researcher at the request of the clinical trial sponsor. This would usually include:

- the trial protocol
- the investigator's brochure
- related patient information
- supporting data
- the Notification of intent to supply unapproved therapeutic goods under the clinical trial notification (CTN) scheme. This is available from the TGA website: <http://www.tga.gov.au>.

For more information on the CTN application please see *Access to Unapproved Therapeutic Goods—Clinical Trials in Australia*, which is available from the TGA website: <http://www.tga.gov.au>.

HRECs usually have their own standard format for applications to conduct a clinical trial at their institution. The TGA does not review any data relating to a clinical trial prior to notification under the CTN Scheme, although key documents may be subsequently requested and reviewed.

The HREC is responsible for assessing the:

- scientific validity of the trial design
- safety and performance of the device
- ethical acceptability of the trial process

The HREC is also responsible for approval of the trial protocol.

The institution or organisation at which the trial will be conducted, referred to as the 'Approving Authority', gives the final approval for the conduct of the trial at the site, having due regard to advice from the HREC.

The Notification of intent to supply unapproved therapeutic goods under the clinical trial notification (CTN) scheme form must be signed by the:

- clinical trial sponsor
- principal investigator
- Chairman of the HREC
- person responsible from the Approving Authority

Please note: Once the original CTN has been approved, each additional trial site(s) will require another CTN notification to the TGA.

CTN trials cannot commence until the Notification of intent to supply unapproved therapeutic goods under the clinical trial notification (CTN) scheme form is submitted to the TGA with the notification fee. The TGA will send the clinical trial sponsor an acknowledgement letter, providing the form has been appropriately completed. However notification of the CTN Form with the appropriate fee automatically creates the exemption necessary to allow lawful supply of the unapproved medical devices for the clinical trial.

The completed Notification of intent to supply unapproved therapeutic goods under the clinical trial notification (CTN) scheme form and a cheque for the notification fee should be forwarded to:

Postal Address		**Courier Delivery**
The Business Management Unit	or	The Business Management Unit
Therapeutic Goods Administration		Therapeutic Goods Administration
PO Box 100		136 Narrabundah Lane
WODEN ACT 2606		SYMONSTON ACT 2609
Australia		Australia

Clinical Trial Exemption (CTX) Scheme

The CTX Scheme is an approval process.

A clinical trial sponsor must submit an application of Unapproved Therapeutic Goods under the Clinical Trial Exemption (CTX) Scheme form (available from the TGA website) to the TGA for evaluation and comment. Submission of clinical data on medical devices under the CTX scheme must comply with ISO 14155[11].

[11] ISO 14155: *Clinical investigation of medical devices for human subjects* defines procedures for the conduct and performance of clinical investigations of medical devices.

A CTX application for medical devices should be presented in 7 parts. Two copies of the complete application are required to allow simultaneous evaluation in different sections of TGA.

Part	Contents
Part 1	Administrative information and information complementary to the summaries of scientific information.
Part 2	Summary report of risk analysis documentation
Part 3	Summary report of the design dossier, including concept
Part 4	Summary report of manufacturing and materials
Part 5	Summary report of preclinical and/or clinical documentation
Part 6	Documentation on all fatal or life-threatening adverse events that have been associated with the use of the device prior to the date of the application
Part 7	Information for Human Research Ethics Committees

For more information on the contents of each part of the CTX application please see *Access to Unapproved Therapeutic Goods—Clinical Trials in Australia* available from the TGA website.

It is important to note that the application submitted to the TGA does not need to include the clinical trial protocol(s). The primary responsibility of the TGA is to review the safety of the device and the HREC is responsible for considering the scientific and ethical issues of the proposed clinical trial protocols.

The completed Supply of Unapproved Therapeutic Goods under the Clinical Trial Exemption Scheme, Part 1—the CTX Application form and a cheque for the evaluation fee should be forwarded to:

Postal Address

The Business Management Unit
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
Australia

or

Courier Delivery

The Business Management Unit
Therapeutic Goods Administration
136 Narrabundah Lane
SYMONSTON ACT 2609
Australia

A copy of the form and accompanying data should be forwarded to:

Postal Address

Clinical Section
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
Australia

or

Courier Delivery

Clinical Section
Office of Devices Authorisation
Therapeutic Goods Administration
136 Narrabundah Lane
SYMONSTON ACT 2609
Australia

The TGA will send a formal acknowledgment of the application. A 50 working day period applies for CTX applications for medical devices. The evaluation time commences from the date of acceptance of the application or receipt of the appropriate fee; whichever is the later day. If the TGA seeks more information from the clinical trial sponsor, the evaluation time is suspended until the information is provided.

The TGA evaluates the safety of the device and considers the proposed Usage Guidelines for the device. If the data supplied with the CTX application is not complete, the application may be returned unevaluated.

The TGA decides whether or not to object to the proposed Usage Guidelines for the device. If an objection is raised, trials may not proceed until the objection has been addressed to the Delegate's satisfaction. Further information may be requested from the clinical trial sponsor, which will interrupt the 50 day evaluation per
If the sponsor can not respond within 30 working days they should contact the TGA or the application ma

If the application is acceptable, the clinical trial sponsor will be formally advised in writing that there
objections to the supply of the device under the CTX Scheme.

If the TGA decides to reject the application, this decision may be appealed under Section 60 of th
Applications may be rejected due to:

- insufficient pre-clinical data
- inappropriate Usage Guidelines

If no objection is raised, the clinical trial sponsor may conduct any number of
CTX, provided use of the device in the trials fall within the original approved Us
involve notification of such trials to the TGA in a similar manner to the C
making it clear they are being conducted under an approved CTX.

*Please note: Once a CTX application has been approved, th
summary information provided and the proposed usage gu
conducted under a CTX must be notified to the TGA as de
form, which is available on the TGA website: <http://www*

The clinical trial sponsor must seek approva
under a CTX approval, in a similar manner to t
sponsor if an HREC objects to a trial, a
protocol for a substantially simi
decision made by that HREC.

A clinical trial sponsor canno

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TGA fees for clinical trials

The fees for applications for clinical trials under the CTX scheme are higher than notifications under the CTN due to the increased work required by TGA to evaluate the data provided.

There is a single fee for the CTX application.

For the CTN there is a notification fee.

Notification	Fee
all sites notified at same time (including composite sites)	single notification fee
each site notified individually	notification fee for each separate notification
sites notified in groups	notification fee for notification of each group

The current fees for clinical trials for included devices are available on the TGA website.

Completion of clinical trials

The TGA maintains a record of each clinical trial and each trial site conducting a trial. To maintain the record for each trial, the TGA should be notified of the:

- date the trial was completed (That is, the last date of completion at all sites. It is not necessary to notify completion dates for individual sites.)
- reason the trial ceased (for example, concluded normally, insufficient recruits).

The clinical trial sponsor should complete the Clinical Trial Completion Advice—CTN and CTX Schemes form, which requests this information, and which is available from the TGA website.

Responsibilities of the clinical trial sponsor

The general responsibilities of sponsors of clinical trials are set out in section 5 of the CPMP/ICH Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) available from the TGA website. The clinical trial sponsor must also fulfil all regulatory requirements of the TGA and comply with state and territory legislation in relation to the supply of therapeutic goods.

The clinical trial sponsor is also responsible for establishing legal and financial agreements between the clinical trial sponsor, investigators and participating institutions/organisations. These should address issues such as indemnity of the parties involved in the trial and compensation and treatment of trial participants in the case of injury or death.

The TGA does not require protocol amendments to be notified by clinical trial sponsors where the amendments clarify the use of, and/or monitoring of treatment. However a new notification to the TGA may be required if there is a major change to the protocol and the HREC requires a change to the conditions of their approval, such as:

- the addition of new devices
- changes in addresses of sites where the clinical trial is conducted
- expansion of indications being treated
- changes to the treatment population being targeted

Adverse event reporting requirements for clinical trials

Reporter	What needs to be reported	Who to report to	In what format?	Timeframe
Sponsor of trial	Serious and unexpected adverse device events	TGA	Medical Device Incident Report form	• fatal or life-threatening adverse device events—initi report within calendar of first kn lec Complet port w in 8 a tic al calendar days. other serious unanticipated device events, full report no later than 15 calendar days of first knowledge.
	Other adverse device events and adverse events	TGA	bl ation/Line listing	On request by TGA
Clinical investigator	Adverse device events and adverse events	HREC	As required by HREC	As required by HREC
		sor of trial	As required by study protocol	As required by study protocol

For reports to the TGA, the re rt sh d be clearly marked 'Clinical Trial Incident' and sent to:

Post ddr s

Cli al S ction
Offic Devices Authorisation
Th ra utic Goods Administration
PO Box 100
WODEN ACT 2606
Australia

or

Courier Delivery

Clinical Section
Office of Devices Authorisation
Therapeutic Goods Administration
136 Narrabundah Lane
SYMONSTON ACT 2609
Australia

The Medical Device Incident Report form is available on the TGA website: <http://www.tga.gov.au>.

More information

More information on conducting clinical trials in Australia, including the forms to be completed, is available on the TGA website: <http://www.tga.gov.au>.

Authorised prescribers

The TGA is able to grant certain medical practitioners authority to prescribe a specified unapproved medical device or kind of medical device to recipients who have a particular medical condition. The medical practitioner becomes an 'Authorised Prescriber' and can prescribe that product for that condition to individual patients in their immediate care without further approval from the TGA.

The TGA cannot vouch for the quality, safety or performance of an unapproved device, therefore the use must be regarded as experimental. The granting of this authority does not render the Commonwealth or the TGA liable to a person in respect of loss, damage, or injury of any kind suffered by the person as a result of, or arising out of the use of the device by that person or another person.

The authorisation only allows the Authorised Prescriber to supply the device directly to specified patients and not to other practitioners who are not authorised to prescribe/administer the device to patients.

The basis for providing the approval is that the authorised medical practitioner has training and experience appropriate for the condition being treated and the proposed use of the device and that the Authorised Prescriber is able to best determine the needs of the patient and to monitor the outcome of the therapy.

Authorised Prescribers can supply individual patients with unapproved therapeutic goods under a range of circumstances, such as when devices:

- were provided initially to patients through a clinical trial while an application for inclusion on the ARTG is being considered
- are available overseas but not in Australia.
- no suitable alternative approved device is available in Australia

Patients who may access unapproved medical devices prescribed by an Authorised Prescriber are those suffering from an illness or condition that is either:

- life-threatening, or
- serious, being generally accepted as not being appropriate to be diagnosed or evaluated and treated safely without consulting a health practitioner

Applications to be an Authorised Prescriber

The following information is required by the TGA as part of an application to become an Authorised Prescriber:

Recipients	
Indication	Disease/condition to be treated
Clinical justification	An outline of the seriousness of the condition, and, if other approved treatment are available, justification for the use of the unapproved device in preference to those treatments
Medical Device	
Product details	Name of device, supplier
Performance/safety data	Performance and safety data sufficient to support the proposed use of the device. A copy of the reference articles from which the data have been obtained should be included
Prescriber	
Details	Name, postal address, phone number, fax number
Ethics committee Endorsement	Evidence of endorsement from an ethics committee must be submitted
Agreement to Treatment Directions	A completed and signed Agreement to Treatment Directions form must accompany the application *Please note: this form is available on the TGA website: <http://www.tga.gov.au>*

Applications should be sent to:

Chief Clinical Advisor
Clinical Section
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Phone: 02 6232 8615
Fax: 02 6232 8785

Once the TGA Delegate has considered the application, the applicant will be sent a letter advising that the application has been:

- accepted
- rejected, or
- more information is required

If an application is rejected there are various appeal mechanisms that can be considered. For more information please, refer to *Access to unapproved therapeutic goods—Authorised prescribers* available on the TGA website.

Endorsement from an ethics committee

Medical practitioners seeking to become Authorised Prescribers require endorsement from an ethics committee as follows:

- for a medical practitioner engaged in clinical practice in a hospital, endorsement from the ethics committee of that hospital
- for a medical practitioner treating patients outside a hospital setting, endorsement from an appropriate ethics committee

A special exemption exists for medical practitioners who can demonstrate that they do not have access to an ethics committee to get endorsement from an appropriate specialist college. Appropriate specialist colleges are listed in Schedule 4 to the *Health Insurance Regulations 1975*.

It is recommended that the letter of endorsement from the ethics committee should include:

- a clear statement that endorsement is being given for the purpose of the medical practitioner becoming an Authorised Prescriber
- the name of the medical practitioner being endorsed
- the device and the intended purpose for which endorsement has been given
- the sites at which use is covered by the endorsement
- any conditions the ethics committee has imposed on the endorsement
- the signature of the chairman of the ethics committee over his/her official title

Please note: Under the Act, an ethics committee must be constituted and operating in accordance with NHMRC guidelines and have notified its existence to the Australian Health Ethics Committee. Endorsement from ethics committees that do not satisfy these requirements will not be accepted by the TGA.

Once approval is given by the TGA

If the medical device is available from a supplier in Australia, the Authorised Prescriber should contact the supplier/sponsor to organise supply.

The supplier will require authorisation to lawfully release the device. A copy of the letter of Authorisation must be forwarded to the supplier.

If the device is not available from an Australian sponsor, the requesting doctor will need to find an overseas source. The device will also need to be imported from that supplier. This can be done by the doctor, a pharmacist, hospital, by the patient or by a licensed importer. Similarly, the overseas supplier will likely require a copy of the letter of authorisation. Please note that import controls may also apply to some devices, in particular those of animal origin or containing prohibited substances.

The doctor is responsible for reporting the number of patients treated on a six-monthly basis.

It is a condition of the approval that the treating doctor reports the details of any actual or suspected adverse device events to the TGA. For more information, please see Adverse event reporting requirements for clinical trials in this section.

Responsibilities of the patient

It is a condition of the approval to supply an unapproved therapeutic good for use in Australia that the patient or the patient's legal guardian must be in a position to make an informed decision regarding treatment. Informed consent should be in writing unless there are good reasons to the contrary. Informed consent should be freely given and includes an adequate knowledge of the condition and its consequences, an adequate knowledge of the treatment options, the likelihood of recovery and the long-term prognosis. Additional consent is required where the device contains products derived from biological tissue including human blood or plasma. Patients should complete the Authorisation of Supply Under S19(5) or Section 41HC *Therapeutic Goods Act 1989—Consent to Treatment and Indemnity for Use of Products Derived from Biological Tissue Including Human Blood or Plasma* form available on the TGA website.

A patient should be specifically informed of the following:

- that the device is not included on the ARTG for the intended purpose
- possible benefits of treatment and any risks and side effects that are known
- the possibility of unknown risks and late side-effects
- any alternative treatments using approved devices that are available.

Responsibilities of the supplier/sponsor

A company is under no obligation to supply an unapproved product just because it has been prescribed by an Authorised Prescriber. Applicants should ensure companies are willing to supply the device before making an application.

The supplier/sponsor is required to:

- provide the TGA with six-monthly reports detailing the supply of unapproved devices to Authorised Prescribers
- consider whether to submit an application to the TGA if long-term supply of their device is expected
- monitor the use of their devices
- report to the TGA all those serious unanticipated device related adverse events of which they have been informed. For more information, please see Adverse event reporting requirements for clinical trials.
- communicate rapidly to the TGA information that has an important bearing on the benefit–risk assessment of the device, particularly any information that may lead changes to the usage of the device by Authorised Prescribers

Adverse event reporting requirements for Authorised Prescribers

Reporter	What needs to be reported	Who to report to	In what format?	Timeframe
Authorised Prescriber	Any adverse device event	TGA	Medical Device Incident Report form	As promptly as possible, to reach TGA within 15 days
		Sponsor	As required by sponsor	As required by sponsor
		HREC (if applicable)	As required by HREC	As required by HREC
Sponsor	Serious unanticipated adverse device related events	TGA	Medical Device Incident Report form	• fatal or life-th[illegible]ea[illegible]ing adverse device ev[illegible] initial report within 7 calendar[illegible]s of first knowledge. Comp[illegible]e re[illegible]ort within 8 additional c[illegible]nda[illegible]ays other serious unanticipated device e[illegible]ents, full report no later than 15 calendar days of first knowledge
	Other adverse device events	TGA	Tabu[illegible]n/ Lis[illegible]ist	On request by TGA

For reports to the TGA, the report should be cl[illegible]y m[illegible]ked 'Authorised Prescriber Incident' and sent to:

The Medical Officer
Clinical Section
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
Australia

The Medical Dev[illegible]cident Report form is available on the TGA website: <http://www.tga.gov.au>.

Circumstances under which the TGA may revoke an authorisation

The TGA may give notice of revocation of an Authorisation at any time if:

- the ethics committee responsible for endorsement of the Authorised Prescriber has withdrawn its endorsement
- the Authorised Prescriber has failed to comply with conditions for Authorisation contained within the letter of authorisation
- a device similar to the unapproved device is evaluated and approved for treatment of the specified indication and included on the ARTG
- the TGA becomes aware of information from other use in Australia or from overseas that indicates major safety concerns with the use of the device

More information

More information on Authorised Prescribers, including the forms to be completed, is available on the TGA website.

Special Access Scheme (SAS)

The SAS is a mechanism to provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis. Applications are made by registered medical practitioners.

The SAS allows individual patients, with the support of their medical practitioner, access to unapproved devices in a range of circumstances, such as when:

- early access for terminally ill patients to almost any device, including experimental and investigational devices is needed (see Category A)
- devices were provided initially to patients through a clinical trial while a marketing application is being considered
- devices are available overseas but not in Australia

Final responsibility for the use of an unapproved device within an institution always rests with that institution. Medical practitioners working in an institution may also need approval from the institution's Ethics Committee or Drug and Therapeutics Committee prior to using a particular device.

There are two categories of patients who may use the SAS:

- Category A patients—medical practitioners can supply unapproved devices to some very seriously ill patients without the approval of the TGA as long as the medical practitioner notifies the TGA within 28 days.
- Category A patients are defined in the Therapeutic Goods legislation as 'persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment'.
- Category B patients—all other patients. Approval of an application to supply an unapproved device is required from a delegate in the TGA. Approval by the TGA is given on a patient by patient basis to reflect the needs of different patients.

The choice of classification of each patient lies with the treating medical practitioner. However, TGA is able to review, seek clarification and request information regarding the classification of patients under Category A.

Category A patients

Prior approval from the TGA is not required for the use of an unapproved device in a Category A patient. The treating registered medical practitioner is the approving authority in that he/she is prepared to use the device in question.

The practitioner is required to complete the Category A Form Special Access Scheme available from the TGA website, and send it to the sponsor of the device. This provides the sponsor with the legal authority to supply the device.

The practitioner must send a copy of the Category A Form Special Access Scheme to the TGA within 4 weeks of the date of signature on the form. Failure to do so is an offence that carries a financial penalty. The form should be faxed to 02 6232 8785.

The form requires the medical practitioner to certify that they:

- have determined that the patient is Category A
- are prepared to use the medical device requested
- have obtained the informed consent of the patient, or the patient's legal representative to the proposed treatment

A patient should be specifically informed of the following:

- that the device is not included on the ARTG for the intended purpose
- possible benefits of treatment and any risks and side-effects that are known
- the possibility of unknown risks and late side-effects
- any alternative treatments using approved devices that are available

Although the way in which a doctor prescribes a treatment for an individual in a particular clinical setting is a matter of medical practice and the TGA does not regulate medical practice, the TGA has responsibilities in relation to the safety of therapeutic goods supplied in Australia.

When the TGA identifies use of a device for an indication that is considered to fall outside the scope of the Category A definition, the TGA will inform the sponsor.

The TGA has the authority to review and seek clarification of the Category A classification of patients. This will occur on a case by case basis only if it is believed that the Category A provision is inappropriate for the particular clinical use. The TGA is also able to release such information to State and territory authorities, such as a Medical Board and/or Medical Complaints Units that are principally involved in the regulation of medical practice.

Category B patients

Approval from the TGA is required prior to the device being supplied. Applicants should complete the Category B Form Special Access Scheme.

Applications need to address criteria relating to the patient, the device and the prescriber. Applicants can also provide any other information they consider important. In considering whether to grant approval, the TGA Delegate will generally consider the quality and extent of the information provided in the application.

Applications should be sent to:

The Medical Officer, SAS
Clinical Section
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Phone: 02 6232 8679
Fax: 02 6232 8785

Phone requests may be made where there is an urgent medical need for access to the device.

Please note: The TGA can give no guarantee as to the quality, safety, or performance of devices containing biologically derived products, particularly in relation to any prion or viral inactivation. In view of the potential risks associated with the use of biological tissue-derived products, requests should not be made for non-essential uses of these devices. In addition, a specific consent form must be used when supplying biological products under the SAS Scheme, available on the TGA website.

If the application is approved, certain conditions may be placed on the medical practitioner, including:

- the quantity of a medical device that can be supplied
- that should treatment be discontinued before the end of the treatment period approved, the TGA must be notified of the reasons for discontinuation within 6 weeks of the treatment being discontinued
- the use of an unapproved device should be regarded as an experimental use. The principles set out in the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research should be observed
- the doctor and patient, or patient's guardian, accept responsibility for any adverse consequence of treatment. The Commonwealth accepts no responsibility for any defects in the device whatsoever, including defects related to manufacture, distribution and *instructions for use*
- on completion of the treatment all remaining supplies of the device should be returned to the supplier
- any special conditions appropriate to the specific patient and device
- the period for which the approval is valid, particularly in cases where importation is required. For example, for up to 18 months from the date of the decision
- that the total quantity imported and supplied is not to exceed that required for the treatment of the particular patient
- the approval is for supply for use only by the particular patient

If the TGA Delegate approves the application the medical practitioner will be sent a letter outlining the conditions of the approval, which will include the approval number.

If an application is rejected there are various appeal mechanisms that can be considered. For more information, please refer to *Access to unapproved therapeutic goods—Special Access Scheme available on the TGA website*.

Once approval is given by the TGA

If the medical device is available from a supplier in Australia, the medical practitioner should contact the supplier/sponsor to organise supply.

The supplier will require authorisation to lawfully release the device. For a Category A patient, the completed Category A Form Special Access Scheme form acts as the authorisation. For Category B patients, the approval number issued by the TGA must be quoted in all correspondence with the sponsor.

If the device is not available from an Australian sponsor, the requesting doctor will need to find an overseas source. The device will then need to be imported from that supplier. This can be done by the doctor, a pharmacist, hospital, by the patient, or by a licensed importer.

Responsibilities of the patient

It is a condition of the approval to supply an unapproved therapeutic good for use in Australia that the patient or the patient's legal guardian must be in a position to make an informed decision regarding treatment. Informed consent should be in writing unless there are good reasons to the contrary. Informed consent should be freely given and includes an adequate knowledge of the condition and its consequences, an adequate knowledge of the treatment options, the likelihood of recovery and the long-term prognosis. Additional consent is required where the device contains products derived from biological tissue including human blood or plasma. Patients should complete the Authorisation of Supply Under S19(5) or Section 41HC *Therapeutic Goods Act 1989—Consent to*

Treatment and Indemnity for Use of Products Derived from Biological Tissue Including Human Blood or Plasma form available on the TGA website.

A patient should be specifically informed of the following:

- that the device is not generally available in Australia
- possible benefits of treatment and any risks and side-effects that are known
- the possibility of unknown risks and late side-effects
- any alternative treatments using approved devices that are available

Responsibilities of the supplier/sponsor

A company is under no obligation to supply an unapproved device just because it has been approved under the SAS. Applicants should ensure companies are willing to supply the device before making an application.

The supplier/sponsor is required to:

- provide the TGA with six monthly reports detailing the supply of unapproved devices under the SAS
- consider whether to submit an application to the TGA if long-term supply of their device is expected
- monitor the use of their devices continually and record the safety of the device and the balance of its benefit and risk
  - report to the TGA all those serious unanticipated device related adverse events of which they have been informed. For more information please see Adverse event reporting requirements.
- communicate rapidly to the TGA information that has an important bearing on the benefit/risk assessment of the device

Adverse-event reporting requirements for devices supplied under the SAS

Reporter	What needs to be reported	Who to report to	In what format?	Timeframe
Treating Doctor	Any adverse device event	TGA	Medical Device Incident Report form	As promptly as possible, to reach TGA within 15 days
		Sponsor	As required by sponsor	As required by sponsor
		HREC (if applicable)	As required by HREC	As required by HREC
Sponsor	Serious unanticipated adverse device related events	TGA	Medical Device Incident Report form	• fatal or life-threatening adverse device events—initial report within 7 calendar days of first knowledge. Complete report within 8 additional calendar days. • other serious unanticipated device events, full report no later than 15 calendar days of first knowledge.
	Other adverse device events	TGA	Tabulation/Line listing	On request by TGA

For reports to the TGA, the report should be clearly marked 'SAS Incident' and sent to:

The Medical Officer
Clinical Section
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
Australia

The Medical Device Incident Report form is available on the TGA website <http://www.tga.gov.au>.

More information

More information on the Special Access Scheme, including the forms to be completed, is available through the TGA website.

Personal importation

Personal importation occurs when an individual:

- brings a medical device into Australia on their person
- arranges from within Australia for a device to be sent to them from an overseas supplier

The goods must be used by that individual or a member of his/her immediate family and must not be sold or supplied to any other person.

Individuals wishing to import unapproved devices for their personal use should be aware that in many cases the quality, safety and performance of the device may be unknown and they must therefore be prepared to accept any risks associated with the use of the device. If an individual suffers adverse consequences from using such devices, information about the goods and redress may be difficult to obtain.

Where the device is classified as low-medium risk (Class IIa) or higher, the quantity imported must not exceed the amount required to deliver three months' treatment using the device according to a treating medical practitioner's directions. The total quantity imported per year must not exceed 15 months treatment using the device according to a treating medical practitioner's directions. These supply restrictions do not apply to devices used for long-term treatment, such as a hip implant.

Individuals may import medical devices without the goods being included in the ARTG where:

- the goods are either for use by the importer or a member of the importer's immediate family
- the goods do not contain a substance that is a prohibited import under the *Customs (Prohibited Imports) Regulations 19*
- the device is not manufactured using tissues, cells or substances of animal origin that have been rendered non-viable or tissues, cells or substances of bacterial or recombinant origin
- the device either does not incorporate or is not intended to incorporate derivatives of human blood or blood plasma

In the case of a medical device that:

- is subject to Schedule 4—Prescription only medicines or Schedule 8—Controlled drugs, of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)
- incorporates or is intended to incorporate a substance that is subject to either of those Schedules, the device is acknowledged in writing by a State/Territory registered medical practitioner to be appropriate treatment for the importer

More information

More information on personal importation is available on the TGA website or contact the TGA:

The Medical Officer, SAS
Clinical Section
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Phone: 02 6232 8679
Fax: 02 6232 8785

Part 3–Post-market

Section 21. Changes to ARTG Inclusions

This section to be drafted.

Section 22. Post-market vigilance and monitoring requirements

Overview

Once a medical device has been included in the ARTG the device must continue to meet all the regulatory, safety and performance requirements and standards that were required for the approval.

The TGA, along with several international partners in the GHTF, have developed agreements and documents to promote a harmonised approach to medical device regulation around the world. The GHTF has produced a guidance document *Medical Devices Post-market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices*, which is available from the GHTF website at <http://www.ghtf.org>.

The TGA has mandatory requirements for all manufacturers and sponsors of medical devices. These requirements are intended to monitor information about medical devices so that appropriate action can be taken. The requirements facilitate the systematic investigation of failures and/or deviations in the way a device performs, in an attempt to prevent an adverse event occurring again. For information about the corrective actions that may be taken, please see Section 23. Recalls, suspensions, cancellations and tampering of medical devices.

There are four key stakeholders involved in improving outcomes for users of medical devices:

- sponsors—who are responsible for the legal supply of the device in Australia
- manufacturers as defined in section 41BG of the *Therapeutic Goods Act 1989* (the Act)
- the TGA—the Regulator
- users—consumers and health practitioners who by voluntarily reporting concerns with devices enable issues to be identified and corrective action to be taken

The TGA has a comprehensive strategy for ongoing monitoring and vigilance for medical devices, which includes four major components:

- sponsor's ongoing responsibilities
- manufacturer's ongoing obligations
- ongoing monitoring
- vigilance—adverse-event management

Sponsor's ongoing responsibilities

In accordance section 41FD of the Act, in applying to include a device in the ARTG, the sponsor has certified that:

- the products is a medical device
- its intended purpose as stated in the application form has been ascertained from the manufacturer's instructions from use, advertising material, technical documentation, and/or project label(s)
- the device is correctly classified
- the information included with the application is complete and correct

- the device complies with the Essential Principles and the manufacturer has available sufficient information to substantiate that compliance with the Essential Principles or have procedures in place, including a written agreement, to ensure that such information can be obtained from the manufacturer within 20 working days
- an appropriate conformity assessment procedure has been applied to the device
- the sponsor has available sufficient information to substantiate the application of those conformity assessment procedures or have procedures in place to ensure that such information can be obtained from the manufacturer within 20 working days
- any advertising material relating to the medical device complies with the TGA requirements—for more information see Advertising in Section 12. Information about a medical device.
- the device does not contain substances that are prohibited imports under the Customs Act
- the device is not an excluded device

The sponsor has ongoing responsibilities once a device has been included in the ARTG.

The Act requires that the sponsor will:

Requirement	Example(s)	Legislative reference
Allow entry and inspections of premises	• allowing a person authorised by the TGA to enter and inspect any premises, including outside Australia, where the devices are manufactured or located • while on the premises, to inspect the premises and medical devices on the premises • to take samples of medical devices from the premises	section 41FN(1) of the Act
Deliver samples upon request	• providing samples of the medical device to the TGA upon request	section 41FN(2) of the Act
Availability of information	• access to the technical documentation that demonstrates compliance with the Essential Principles • access to the evidence that appropriate conformity assessment procedures have been applied • on request, provide this information to the TGA within specified timeframes	section 41FN(3) of the Act
Advertising material	• ensuring any advertising material relating to the medical device complies with the TGA requirements	section 41FN(5) of the Act
Report details of certain incidents and performance issues to the TGA	• reports events in accordance with the requirements laid out in the *Therapeutic Goods Act 1989* and the *Medical Devices Regulations 2002* and this guidance document	section 41FN(3)(d) of the Act
Report any overseas regulatory actions to the TGA if the product involved is from the same batch or product run that was supplied Australia	an adverse event has occurred with a product in another country and the ensuing investigation by the manufacturer determines that a batch of the product should be recalled. If the batch is supplied in Australia the sponsor should notify the TGA of the overseas action to determine if the same action should occur in Australia	section 41FN of the Act
Report results of investigations undertaken the manufacturer to the TGA	• Relay the results to the TGA of an investigation into a returned sample associated with an adverse event report	section 41FN of the Act
Assist the TGA and the manufacturer in investigations if an incident occurs	• Pass information to the TGA and the manufacturer during an investigation of an adverse event • Assist in the gathering of information and samples from the user	section 41FN of the Act

Requirement	Example(s)	Legislative reference
Take corrective action when necessary	• recall medical devices • inform the public about medical devices that do not comply with requirements	section 41KA of the Act
Maintain distribution records for product supplied in or exported from Australia	• Regulation 8.1(b) • records of delivery to: – distribution warehouses – manufacturing sites – retails outlets	section 41FO of the Act
Conditions imposed when medical devices are included in the ARTG	• For Class III, Class AIMD, and Class IIb implantable devices to provide annual reports for first three years that the device is available in Australia	section 41FO(2) of the Act

Distribution records

Under section 41FO of the Act sponsors of medical devices supplied in and exported from Australia are required to keep distribution records of the medical devices to:

- expedite any recalls of batches of the medical devices
- identify the manufacturer of each batch of devices

Sponsors are not required to maintain records of the individual users of medical devices, however the sponsor should have records of distribution centres, hospitals and export countries the device has been supplied to.

Each sponsor is required to retain the distribution records for their medical devices for:

- 10 years for Class AIMD, Class III, and Class IIb implantable devices
- five years for all other devices

after the last product has been distributed. These records, or copies of the records, must be provided when requested by the TGA.

The Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use, available on the TGA website, sets out appropriate procedures for wholesalers and/or distributors to ensure that there is effective, efficient and safe handling, storage and distribution of products. It is in the sponsor's interest to encourage their wholesalers to follow this code.

Annual reports on problems—Class III, Class AIMD and implantable Class IIb medical devices

In addition to the penalties for failing to notify adverse events under sections 41MP, 41MPA,41MPB, 41MQ, 41MR of the Act the vigilance provisions, it is a condition of inclusion in the ARTG (section 41FN) that the sponsor of a medical device that is:

- an AIMD
- Class III
- implantable Class IIb

provides three consecutive annual reports to the TGA following inclusion of the device in the ARTG (as specified in 5.8 of the Regulations).

Annual reports are due on 1 October each year. Reports should be for the period 1 July to 30 June.

The first report following the date of inclusion in the ARTG must be for a period of at least six months but no longer than 18 months. If the information is limited to the time the device has been on the Australian market because it hasn't been supplied elsewhere, this should be stated in the report. Subsequent reports are to be provided on 1 October for a further 2 years.

The annual report must include all complaints received by the manufacturer relating to problems with the use of the device that have been received by them over the year.

Complaints received by the manufacturer relating to the use of the device, including its supply under a different name, in other countries where the device is available must also be included.

These reports are reviewed by the TGA and any issues arising will be discussed with the sponsor.

Note: Sponsors of products that have been transitioned to an inclusion, which were previously registered and were on the ARTG for three years prior to transitioning will have already submitted Annual Reports for these devices as it was a condition of registration. Annual Reports will not be required for products that meet this criterion. This should however be noted in Annual Reports to pre-empt enquiries from the TGA.

If the device is included in the ARTG	then an annual report
before 1 April	is due in October of that year for information from 1 July of the preceding year to 30 June
after 1 April	will not be required until 1 October the following year

Examples—annual reports of problems with high-risk devices

A Class IIb implantable device is approved for inclusion in the ARTG on 10 March 2007. The first annual report will be due on 1 October 2007 and should cover the details for the device for the period 1 July 2006 to 30 June 2007. Even though the device has only been available in Australia since 10 March, if the device has been available in other countries prior to 10 March the report must include details of any problems reported to the manufacturer for the period 1 July 2006 to 30 June 2007. The second and third reports are due on 1 October 2008 and 2009 respectively.

A Class III medical device is approved for inclusion in the ARTG on 10 May 2008. The first annual report will be due on 1 October 2009 and should cover the details for the device for the period 10 May 2008 to 30 June 2009. The second and third reports are due on 1 October 2010 and 2011 respectively.

What the sponsor should include in the annual report

- ARTG no
- Product name
- Model no(s)
- Number supplied in Australia
- Number supplied world wide (Numbers should include devices that are the same but supplied under a different name in another jurisdiction)
- Number of complaints in Australia
- Number of complaints world wide
- Number of adverse events and incident rates in Australia (Rate= No. of events/ No. Sup[illegible]d x 100 = Rate%)
- Number of adverse events and incident rates world wide
- A list of the more common complaints and all of the adverse events
- Device Incident Report (DIR) number of those adverse events reported to [illegible]TG[illegible]
- Regulatory/corrective action/notification by manufacturer

An example of how this might be presented is shown below:

ARTG #	Product name	Model #	# supplied [illegible] Aus	# [illegible]ied [illegible]orld Wide	# of complaints Aus WW		# of Adverse Events Aus WW	
123456	Knee prosthesis—femoral component	ABC 123	200	8000	32		2	

Type of complaints	Number	Percentage in Australia	Percentage world Wide	TGA DIR #	Regulatory action
Adverse events					
loosening	2	0.025%		DIR 12234	Nil

Re[illegible]s sh[illegible]d be submitted to <iris@tga.gov.au> where possible. Otherwise, they may be sent to:

Annual Reports
The Coordinator
Medical Device Incident Report Investigation Scheme (IRIS)
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Facsimile: 02 6203 1713
Telephone: 1800 809 361

Manufacturer's ongoing obligations

Manufacturers have ongoing legal obligations for medical devices that they manufacture that are supplied in Australia. These obligations are outlined in full in the therapeutic goods legislation.

As part of the approval process to market a medical device in Australia a manufacturer must sign an Australian Declaration of Conformity. The Australian Declaration of Conformity states which conformity assessment procedures the manufacturer has chosen to use to demonstrate that their medical device meets the Essential Principles. The ongoing obligations for a manufacturer vary depending on which conformity assessment procedures they have used. Full details of the ongoing obligations for each of the conformity assessment procedures are in Schedule 3 of the *Therapeutic Goods Regulations (Medical Devices) 2002* (the Regulations). These surveillance activities are a critical part of the manufacturer's overall quality manufacturing system.

Requirement	Example(s)	Legislative reference
Manufacturer must maintain appropriate records	• technical documentation that demonstrates the conformity of their devices with the Essential Principles • evidence that an appropriate conformity assessment procedure has been applied • the Australian Declaration of Conformity • details of any post-market activities undertaken after the device was supplied in Australia • details of any changes or variations to the device and/or quality management system—for more information, please see Section 21. Changes to ARTG notifications. • any notice, report, certificate or other document in relation to the quality management system issued to the manufacturer by the TGA • for all devices that are not Class I non-sterile and non-measuring: • details of the manufacturer's quality management system • the design, production process and intended performance of the medical device These records must be kept for a minimum of 5 years after the manufacture of the last medical device. On request from the TGA, the manufacturer must make the records available to the TGA	Schedule 3 of the Regulations
implement appropriate measures to apply any necessary corrective action in relation to the design or production of a device	• unless covered by the exemption rules, notify the TGA or the sponsor, as soon as practicable after becoming aware of: - information relating to ▪ any malfunction or deterioration in the characteristics or performance of the device ▪ any inadequacy in the design, production, labelling or *Instructions for Use* of the device ▪ any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device that might lead, or might have led, to the death of a patient	Schedule 3 of the Regulations

Requirement	Example(s)	Legislative reference
	or a user of the device in Australia, or to a serious deterioration or serious injury to his or her state of health. For more information, please refer to Vigilance in this section - information relating to any technical or medical reason for a malfunction or deterioration that has led the manufacturer to take steps to recover devices that have been distributed - systematically review information gained after the device was supplied in Australia. Information can come from many sources, for example: ▪ Expert user groups ▪ Customer surveys ▪ Customer complaints and warranty claims ▪ Service and repair information ▪ Literature reviews ▪ User feedback other than complaints ▪ Device tracking and registration records ▪ User reactions during training programs ▪ Adverse event reports from users provided by the TGA	

Please note: Even though a certified quality system is not required for manufacturers of Class I medical devices (non-sterile or non-measuring), the manufacturer is still required to have an ongoing surveillance system established, in accordance with clause 6.5 of Schedule 3 of the Therapeutic Goods Regulations (Medical Devices) 2002.

Manufacturers must also notify the TGA of substantial changes to the design, intended performance or quality management system of the device. For more information on changes, please see Section 21. Changes to ARTG Inclusions.

Ongoing monitoring of compliance by the TGA

Ongoing monitoring by the TGA is a series of activities carried out to ensure that regulatory compliance and safety of the medical devices continues after supply to the Australian market.

Monitoring activities may include:

- reviews of technical and clinical information to ensure that compliance with the Essential Principles and conformity assessment procedures is demonstrated
- testing to confirm compliance with the Essential Principles
- inspections of manufacturer's or sponsor's records and documentation
- on-site testing of medical devices or taking samples for off-site testing
- audits of distribution records
- audits of the traceability of raw materials used in the manufacture of therapeutic goods and tracking of component parts
- trend analysis and reporting to sponsors

The TGA may take corrective action in accordance with the legislation if problems are found, such as:

- sponsors and/or manufacturers not fulfilling their regulatory responsibilities
- safety concerns about a medical device
- certifications made in the device application are incorrect or no longer correct

For more information, please see Section 23. Recalls, suspensions, cancellations and tampering of medical devices.

Post-market reviews for medical devices

Post-market reviews support the inclusion in the ARTG process for medical devices, which includes both random, flagged, and targeted reviews.

There are three levels of post-market reviews for medical devices:

Level	Reason for the Review	Scope	Objectives of the Review
Flagged (Class I)	restricted word used in online eBS application	GMDN Intended Purpose of the device as specified by the manufacturer Classification	• check accuracy and consistency of ARTG information • check appropriate classification
Targeted (All Classes)	Targeted based on: • outcomes of Flagged review • recurrent breaches of advertising code • repeated device test failures • overseas regulatory activity/advice • trends from problem reports • random reviews • unresolved/repeated recalls • manufacturer audit reports • notice from manufacturer/sponsor • implant registry • particular words in the intended purpose • complaints	Flagged, Random + any or all: • Manufacturer audit reports • TGA laboratory testing • Manufacturer audit • clinical evidence • Manufacturer's Evidence • technical file • sterilisation validation evidence (where appropriate) • matters certified in the device application	• check accuracy and consistency of ARTG information • check appropriate classification • review available documentation for potential or real risks of safety and performance issues certifications in device application remain correct • sponsor is meeting the conditions of inclusion • manufacturer shows compliance with the Essential Principles
Random (Class II)	Random on ARTG inclusion	Flagged • labels • Instructions for Use • Australian Declaration of Conformity • manufacturer's advertising material	• check accuracy and consistency of ARTG information • check classification appropriate
Please note: it is important to be aware that any advertising material submitted is not assessed for compliance with the advertising requirements, but is only used to assist with clarifying the manufacturer's intended purpose for the device			

If an application is inconsistent with the definition of a Class I device:

- for Flagged reviews, sponsors will be sent a section 41JA letter requesting the Australian Declaration of Conformity, which will be reviewed and either accepted or
  - the sponsor will be issued with a proposal to cancel letter with 10 days to respond

Vigilance

The purpose of medical device vigilance is to improve the health and safety of patients, users, and others by reducing the likelihood of adverse events being repeated. This can be achieved by:

- evaluating reported adverse events
- disseminating information that could be used to prevent or minimise the consequences of adverse events, where appropriate
- modifying the medical device
- removing the medical device from the market

Action is undertaken by the TGA and the sponsor and/or manufacturer after a problem becomes aware of information about a medical device supplied in Australia, such as:

- adverse event reports
- malfunctions
- results of testing
- any other information

The manufacturer and sponsor must inform the TGA of all reportable adverse events, within the appropriate timeframes. They must also ensure timely and appropriate action is taken.

To improve the monitoring of the performance of medical devices supplied in Australia, the TGA encourages the reporting of adverse events by users of devices.

Vigilance exchange

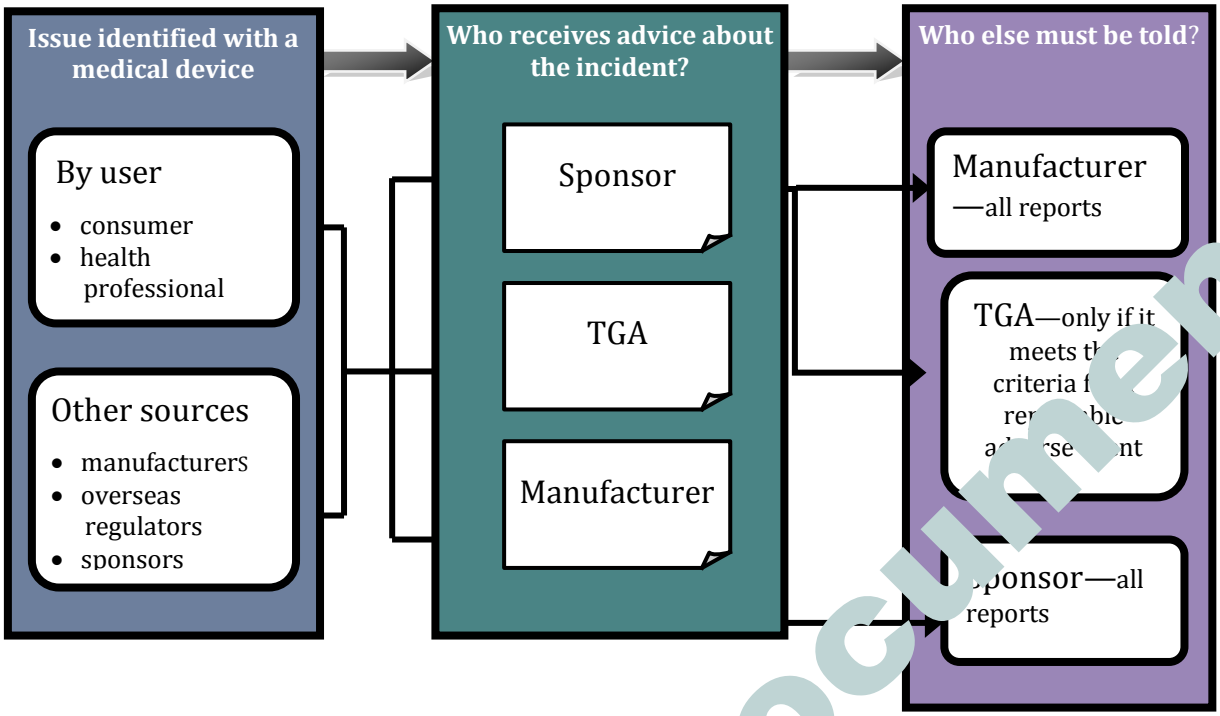
Through various Mutual Recognition Agreements for medical device regulation and its participation in the Global Harmonization Task Force (GHTF), the TGA has an obligation to exchange vigilance information with overseas regulatory agencies. Information will be exchanged on incidents and events where:

- corrective action, including a recall, is to be taken
- there is a serious risk to the safety of patients or other users, but where the corrective action is still being determined.

The TGA will consult the sponsor when preparing a vigilance report to be sent to other regulatory agencies. It is the responsibility of the sponsor to ensure that the manufacturer is aware of the TGA vigilance report, and that any comments that are made by the manufacturer are passed on to the TGA for consideration. The TGA will only consider changes that address inaccuracies in the report.

Regulatory agencies generally use discretion where a manufacturer takes corrective action that is not considered to be essential to protect the safety of patients or others. Examples of this are minor improvements to current devices and updates of user information. In the case of doubt, however, a regulatory agency will generally disseminate information.

Who is notified when there is an issue with a medical device?



The sponsor is legally responsible for the supply of the dev in a, including the receipt and handling of complaints and adverse events. The sponsor may receive e eports from users, the TGA, the manufacturer or other sources, e.g., literature, consumer bodies, profession bo s. The sponsor must forward copies of all reports to the manufacturer and copies of all reportable adv event reports to the TGA.

The manufacturer must maintain records of any pr ems/incidents that occur involving a medical device that they manufacture that is supplied in Australia. e m ufacturer must inform the sponsor of any reports from users or other information that indicates th i ssible problem with a device supplied in Australia.

The TGA must be notified of any incide chat ur in Australia and that are considered adverse events (please see below for an explanation of what con ered an adverse event). The TGA will forward details of incident and the device in the reports fro se. e sponsor of the device.

Reportable adve se vents

Any event that meets th ee sic reporting criteria, even if it does not involve a patient or user, should be reported to the T A

- an adverse eve e occurred
- th ma f er's medical device is associated with the adverse event
- he nt led to or might lead to (often referred to as a near adverse event) death or serious injury, or might d to eath or serious injury if it were to occur again

An adverse event is an event that led to:

- death
- a serious injury or serious deterioration to a patient, user or other person, including
  - a life-threatening illness or injury
  - permanent impairment of a body function
  - permanent damage to a body structure
  - a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure

A 'near adverse event' is an event that might have led to a death or serious injury. It may be that due to the timely intervention of a healthcare practitioner a death or serious injury did not occur. For an event to be defined as a near adverse event, it is sufficient that:

- an event associated with the device happened
- if the event occurred again, it might lead to death or serious injury
- testing or examination of the device or the information supplied with the device, or scientific literature indicated some factor that could lead to a death or serious injury.

Typical adverse events are as follows:

Event or cause of an adverse event	Description
Malfunction or deterioration in the characteristics or performance of a medical device	Failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions *Please note: intended purpose means the intended use according to the data supplied by the manufacturer on the labelling, in the* Instructions for Use *and/or in advertising materials*
Inadequate design or manufacture of a device	Design or manufacturing of a device is found deficient
Inaccuracy in the labelling, *Instructions for Use* and/or promotional materials	Inaccuracies include omissions and deficiencies Omissions do not include the absence of information that should generally be known by the intended users
Significant public health concern	Can include an event that is of significant and unexpected nature that becomes a potential public health hazard, for example, human immunodeficiency virus (HIV) or Creutzfeldt–Jacob Disease (CJD) the TGA, the sponsor, or the manufacturer may identify these concerns
Other information becoming available	Can include: • information from the literature or other scientific documentation • the results of testing performed by the manufacturer on its products • reports from the user prior to the device being used on the patient

Reporting incidents with medical devices

The act of reporting a problem is not an admission of manufacturer, sponsor, user, or patient liability for the event or its consequences.

Only adverse events that occur in Australia are required to be reported to the TGA. Adverse events that occur overseas for devices supplied in Australia do not need to be reported to the TGA. However, records of these events should be available if requested. Also, any remedial action that arises overseas for devices supplied in Australia should be reported. For more information, please see Section 23. Recalls, suspensions, cancellations and tampering of medical devices.

The reporting requirements for sponsors are conditions on the inclusion of medical devices in the ARTG. Breaching conditions of inclusion may lead to suspension or cancellation of the device from the ARTG (section 41G of the Act), as well as constituting a criminal and civil offence (section 41MN of the Act).

The sponsor is responsible for forwarding reports of all incidents to the manufacturer for assessment under manufacturer's surveillance system.

Please note: There are exceptions to the requirement to report, which are outlined over the following pages.

It is possible that the sponsor will not have enough information to decide if the problem should be reported to the TGA. This judgement may be difficult when there are multiple devices involved. The sponsor should make reasonable efforts to obtain additional information to assist in making this decision. In assessing the link between the device and the event, the sponsor should take into account:

- the opinion, based on available information, from a health professional
- information concerning previous, similar events
- other information held by the sponsor

In complex situations, it should be assumed that the device was associated with the event. If there is any doubt about whether a report should be submitted, the report should be submitted.

Where possible, the manufacturer should consult with the user and/or medical practitioners or other healthcare professionals involved, and do their utmost to retrieve the particular device.

Please note: Although it is the manufacturer who must assess an incident, the sponsor will be held accountable for forwarding information concerning events to the manufacturer and then for forwarding the results of any analysis to the TGA. The manufacturer must advise the sponsor but can also advise the TGA directly.

Reporting of events or near events by users is voluntary. The TGA promotes and encourages users to report but cannot enforce reporting by users. Device users are encouraged to report events associated with the use of a medical device to either the sponsor or the TGA.

Examples of reportable adverse events

- The premature revision of an orthopaedic implant due to loosening or fracture
- An infusion pump stops, due to a malfunction, but fails to give an alarm. The patient receives an under-infusion of needed fluids
- During the use of an external defibrillator on a patient, the defibrillator failed to deliver the programmed level of energy due to a malfunction
- An intravenous set separates and the comatose patient's blood leaks onto the floor, resulting in significa blood loss

Examples of reportable adverse events involving public health concerns

- Fatigue testing performed on a commercialised heart valve bioprosthesis demonstrates prem e fa re, which would indicate that a risk to public health could occur
- After delivery of an orthopaedic implant, errors were discovered in heat treatment rec raising questions about the effectiveness of the implant's materials that would create a risk to public h th
- A manufacturer provides insufficient details on cleaning methods for reusable su al instruments used in brain surgery, despite the obvious risk of transmission of CJD

Please note: A definition of what represents a serious threat to public hea can be found in Part 5, Division 5.2, Regulation 5.7 (2) of the Therapeutic Goods (Medical Devi) Re lations 2002.

Exemptions from reporting adverse events to the T

There are eight exemption rules that can apply (see table e xe ption rules overleaf). However, these rules do not apply when:

- a device, event or issue specifically identified by e TGA as an issue that requires close monitoring—sponsors of devices that are affected will b tifi by the TGA when this occurs
- an adverse event normally subject to a rep ting exemption, where a change in trend (usually an increase in frequency) or pattern is identified
- adverse events associated wi use or, as the TGA may use this data to identify trends with similar products that may lead to co endations for:
- corrective action for the de e
- revising the labelli or *structions for Use*
- identifying a d for increased user education.

If a manufa ur elieves an exemption rule applies to reporting an adverse event, the reasons for not reporting the ev t sh d documented.

Exemption Rules from reporting adverse events to the TGA

Rule No.	Exemption Rule	Examples of adverse events exempt from reporting
1	**Deficiency of a new device found by the user prior to its use** Regardless of the existence of provisions in the Instruction for Use provided by the manufacturer, deficiencies of devices that will be always detected by the user and where no serious injury has occurred, do not need to be reported. *Please note: If the device is used the exemption does not apply—the event must be reported.*	• A user performs an inflation test (standard procedure) prior to inserting the balloon catheter in the patient as required in the *instructions for use* accompanying the device. Malfunction on inflation is identified. Another balloon is used. Patient is not injured. • Sterile single-use device packaging is labelled with the caution 'do not use if package is opened or damaged'. Open package seals are discovered prior to use, device is not used. • An intravenous administration set tip protector has fallen off the set during distribution resulting in a non-sterile fluid pathway. The intravenous administration set was not used.
2	**Adverse event caused solely by patient conditions** When the manufacturer has information that the root cause of the adverse event is due to patient condition, the event does not need to be reported. These conditions could be pre-existing or occurring during device use. To justify not reporting, the manufacturer should have information available to conclude that the device performed as intended and did not cause or contribute to a death or serious injury. A person qualified to make a medical judgement would accept the same conclusion.	• An orthopaedic surgeon implants a hip joint and warns against sports-related use. Patient chooses to go water skiing and subsequently requires premature revision. • The early revision of an orthopaedic implant due to loosening caused by the patient developing osteoporosis. • A patient died after dialysis treatment. The patient had end-stage-renal disease and died of renal failure.
3	**Service life of the medical device** The service life is defined as 'the time of usage that a device is intended to remain functional after it is manufactured, placed into use, and maintained as specified'. The service life must be specified by the device manufacturer and included in the master record (technical file). When the only cause for the adverse event was that the device exceeded its service life and the malfunction is not unusual, the adverse event does not need to be	• Loss of sensing after a pacemaker has reached its end of life. The elective replacement indicator has shown up in due time according to the device specification. Surgical explanation of pacemaker is required. • A drill bit was used beyond the end of its specified life. It fractured during invasive operation. Operation time was prolonged due to the difficulty to retrieve the broken parts.

Rule No.	Exemption Rule	Examples of adverse events exempt from reporting
	reported. Assessment of whether an event is exempt from reporting under this rule must be based on the information in the master record, on the label or in *Instructions for Use* for the device.	
4	**Protection against a fault functioned correctly** Adverse events that did not lead to serious injury or death, because a design feature protected against a fault becoming a hazardous situation (in accordance with relevant standards or documented design inputs) do not need to be reported.	• An infusion pump stops, due to a malfunction, but gives an appropriate alarm (for example, in compliance with relevant standards) and there was no injury to the patient. Microprocessor-controlled radiant warmers malfunction and provide an audible appropriate alarm, in compliance with relevant standards and there was no injury to the patient. • During radiation treatment, the automatic exposure control is engaged and the treatment stops. Although the patient receives less than an optimal dose, the patient is not exposed to excess radiation.
5	**Remote likelihood of occurrence of death or serious injury** Adverse events that could lead, but have not yet led, to death or serious injury, but have a remote likelihood of causing death or serious injury and which have been established and documented as acceptable after risk assessment do not need to be reported. If an adverse event resulting in death or serious injury occurs, the adverse event is reportable and a reassessment of the risk is necessary. If reassessment determines that the risk remains remote, previous reports of near incidents of the same type do not need to be reported retrospectively. Decisions not to report subsequent failures of the same type must be documented. Please note: A change in the trend (usually an increase in frequency) of these non-serious outcomes must be reported.	The manufacturer of a pacemaker supplied to the market identified a software bug and determined that the likelihood of occurrence of a serious injury with a particular setting is remote. No patients experienced any adverse health effects. The manufacturer of blood donor sets obtains repeated complaints of minor leaks of blood from these sets. No patient injuries from blood loss or infections of staff have been reported. The chance of infection or blood loss has been re-evaluated by manufacturer and deemed remote.
6	**Expected and foreseeable side effects that are documented in manufacturer's Instructions for use labelling**	A patient receives a second-degree burn during the use of an external defibrillator in an emergency. The risk assessment

Rule No.	Exemption Rule	Examples of adverse events exempt from reporting
	Side effects that are clearly identified in the manufacturer's labelling or are clinically well known as being foreseeable and having a certain functional or numerical predicability when the device was used as intended need not be reported. Some of these events are well known in the medical, scientific, or technology fields. Others may have been clearly identified during clinical investigation and labelled by the manufacturer. Documentation, including the risk assessment, for the particular side effect should be available in the device master record prior to the occurrence of adverse events. The manufacturer cannot conclude in the face of events that they are foreseeable unless there is prior supporting information.	documents that such a burn has been accepted in view of the potential patient benefit and a warning is provided in the *Instructions for Use*. The frequency of burns is occurring within range specified in the device master record. A patient has an undesirable tissue reaction that is previously known and documented in the device master record. A patient who has a mechanical heart valve developed endocarditis ten years after implantation and then died. Placement of central line catheter results in an anxiety reaction and shortness of breath. Both reactions are known and labelled side effects.
7	**Adverse events described in an advisory notice** Adverse events that occur after the manufacturer has issued an advisory notice need not be reported individually if they are specified in the notice. Advisory notices include removals from the market, corrective actions and product recalls. The manufacturer should provide a summary report, the content and frequency of which should be agreed with the TGA.	A manufacturer issued an advisory notice and undertook a recall of a coronary stent that migrated due to inadequate inflation of an attached balloon mechanism. Subsequent examples of stent migration were summarised in quarterly reports required for the recall action and individual adverse events did not have to be reported.
8	**Reporting exemptions granted by the TGA** Upon request by the sponsor, common and well documented events may be exempted by the TGA from reporting or changed to periodic reporting on a case by case basis.	

Timeframes for submitting adverse event reports to the TGA

The reporting requirements are conditions on the inclusion of medical devices in the ARTG. Breaching conditions of inclusion may lead to suspension or cancellation of the entry from the ARTG as well as constituting a criminal offence and/or resulting in a civil penalty.

From the *Therapeutic Goods Act 1989*...

5.7 Conditions applying automatically — period for giving information about adverse events etc (Act s 41FN)

For paragraph 41FN (3) (d) of the Act, the period in which a person in relation to whom a kind of medical device is included in the Register must give information of a kind mentioned in subsection 41MP (2) of the Act to the Secretary is:

a. if the information relates to an event or other occurrence that represents a serious threat to public health — 48 hours after the person becomes aware of the event or occurrence; and

b. if the information relates to an event or other occurrence that led to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person — 10 days after the person becomes aware of the event or occurrence; and

c. if the information relates to an event or other occurrence a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person — 30 days after the person becomes aware of the event or occurrence.

Details to be included in an adverse event report

There are two report forms available on the TGA website:

- Medical device adverse event reporting by medical device users—for use by medical device users (clinicians, patients or their relatives, etc) to report any suspected problems with a medical device that has or may present a health hazard. Typical problems include deficiencies in labelling, *Instructions for Use* or packaging, defective components, performance failures, poor construction or design

- Medical device adverse event reporting by medical device manufacturers and sponsors—to be used by medical device sponsors, manufacturers or their authorised representatives for mandatory reporting of adverse events associated with a medical device

The report should not be unduly delayed if the information is incomplete. It is important to get this process underway as additional information can always be provided later. It may also include a statement to the effect that the report is made by the manufacturer and sponsor without prejudice and does not imply any admission of liability for the incident or its consequences.

If a person is not able to access the forms on the TGA website, they should ensure that the report includes the following details:

- the sponsor's:
  - name
  - address
  - contact person
  - telephone number
  - fax number
- the date when the incident came to the knowledge of the:
  - manufacturer
  - sponsor
- information about the device including the:
  - kind of medical device
  - commercial name
  - catalogue number
  - ARTG number
  - model number
  - serial number
  - batch number
  - lot number
  - software version (if applicable)
- if implantable, date of implant and if applicable, date of explant
- any associated devices and/or accessories involved in the incident
- the known details of the event, including the date and patient or user outcome
- the current known location of the medical device involved in the event
- the contact point of the user where the event occurred. The patient's full identity should not be reported. The contact point need not necessarily be a person who actually witnessed the event. It is recommended that health care facilities have a contact person for all reported events
- any manufacturer and sponsor comments
- the action taken or proposed action and timeframe
- a statement of whether the manufacturer and sponsor are aware of the same type of events having an impact on the current report. This statement should include the:
  - names of any other regulatory authorities to which these events have been reported
  - date of the reports
  - number of similar events
  - number of devices supplied
  - type of similar events, if available
  - any other countries in which the medical device is known to be on sale or supplied

Reports should be submitted to <iris@tga.gov.au> where possible. Otherwise, they may be sent to:

The Coordinator
Medical Device Incident Report Investigation Scheme (IRIS)
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Email: <iris@tga.gov.au>
Facsimile: 02 6203 1713
Telephone: 1800 809 361

Access to medical devices involved in adverse events

Where possible, a manufacturer, through a sponsor should consult with the medical device user ... the event before a report is submitted to the TGA. The manufacturer may also wish to have access to ... edical device involved in the event to help decide whether the event should be reported to the TGA. S... acce...s would be at the discretion of the user or healthcare facility concerned, but they are encouraged t... sist... e manufacturer to determine the root cause of the incident.

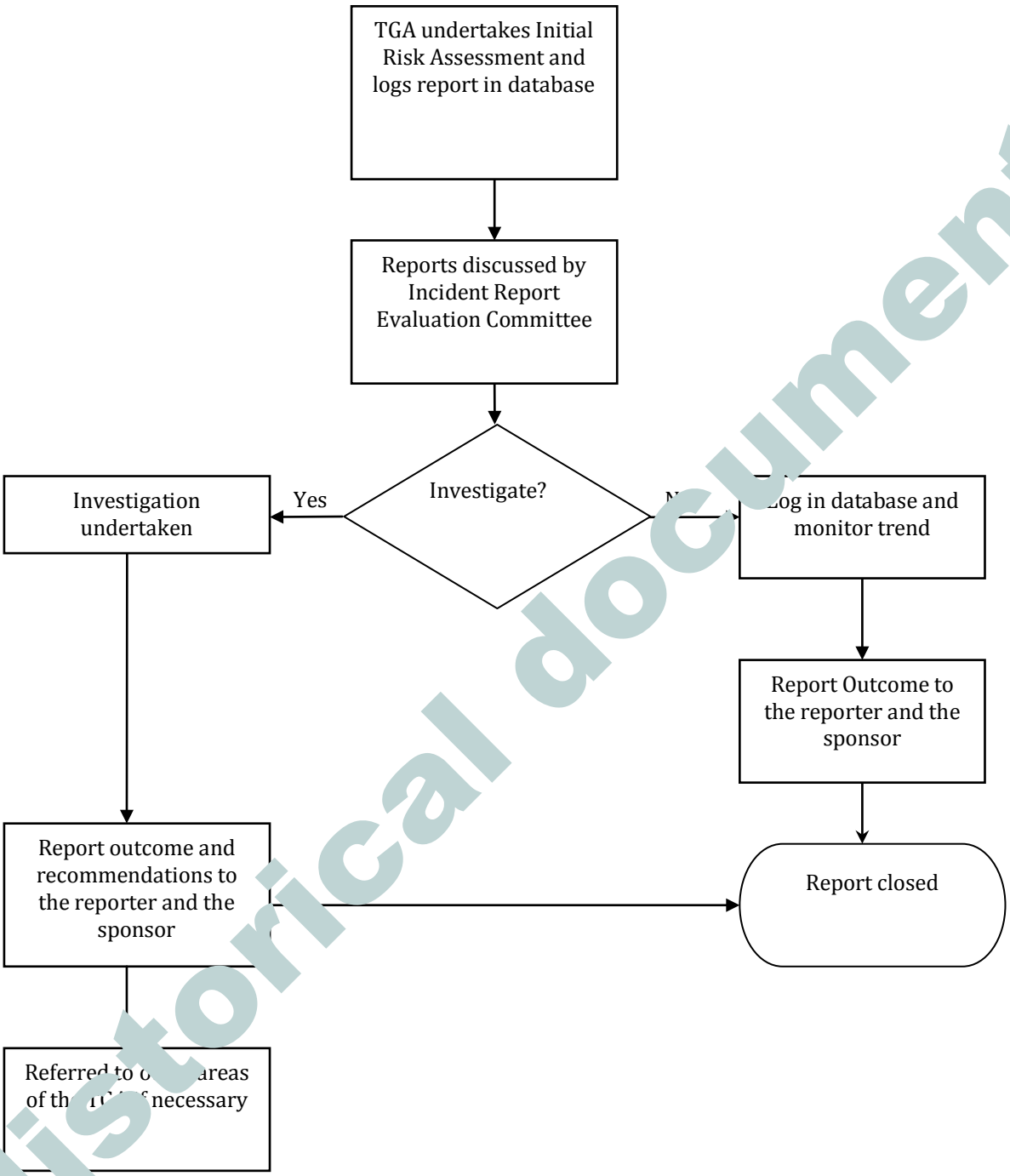
If the manufacturer has access to the medical device, and the initial assessmen... cl...ing or decontamination process will involve altering the device in a way that may affect subsequen... analy..., the manufacturer should, through the sponsor, inform the TGA before proceeding.

Where the healthcare facility sends the medical device directly to th... GA, ...e device will be inspected and its condition recorded and described. The TGA will not carry out any ...est...ctive testing without consulting both the:

- manufacturer, through the sponsor, of the medical de...e
- healthcare facility or reporter.

On completion of the examination the medical devic... ill generally be sent to the manufacturer, again through the sponsor, for their analysis provided the h...a... re facility consents. The TGA encourages release of the medical device to the manufacturer so that the... ca... complete their analysis.

What the TGA does when it receives an adverse event report



The following is a summary of the key components of the TGA's strategy for investigating incident reports:

- Urgent, serious reports are reviewed and addressed as soon as possible by the TGA.
- A panel of scientific, engineering, and clinical experts assesses all reports. The panel determines what level of investigation will take place
- Isolated incidents or problems with a very low clinical risk and no impact on device performance are not usually investigated
- When a report is investigated the person who is investigating will contact the company responsible for t device and work with them to resolve issues
- Reporters' details are treated as confidential. Both the reporter and the supplier are informed of th outcome of the investigation
- All reports are entered into a database so that a trend analysis can be conducted and are eas ef enced in the future

The outcome of an investigation may include one or more:

- referral to other areas of TGA for regulatory actions, such as auditing of the manu ure
- recall of the devices to:
- remove the devices from supply in Australia
- allow correction at the user's site
- the issue of a Safety Alert where there is a need to reinf rce t ma ufacturer's *Instructions for Use* to those responsible for the use of the device or those affected b p m
- product improvement for problems that are not safet lat - carried out by the manufacturer
- report in the TGA News, on the TGA website d/or appropriate journals

For more information on these actions, please Sec n 23. Recalls, suspensions, cancellations and tampering of medical devices.

TGA testing of devices

Medical devices involved in an vers ver may be sent to the TGA for testing. The TGA accepts devices that are contaminated. The TGA can t or visually inspect all medical devices, although there are some devices for which the TGA cannot do a co plete amination as the equipment available for some of the tests is specific to the device manufacturer. The A will, however, test or examine the device as much as it is able, and, if granted permission by the repo e evice will be sent to the manufacturer for further testing. Analysis of the manufacturer's testing red red by the TGA as part of its investigation of the adverse-event report.

It is important th sers keep the device after submitting a report, until the TGA has contacted them to advise whether the d ice s d be sent to the TGA or the sponsor/manufacturer.

Pleas efe TGA website <http://www.tga.gov.au> for instructions on how to send a medical device to the TGA—S ples testing - *Protocol for sending medical devices to the TGA for testing*.

Section 23. Recalls, suspensions, cancellations, and tampering of medical devices

Overview

Once a medical device has been approved for supply in Australia the device must continue to meet all the regulatory, safety and performance requirements and any applicable standards.

If there is a problem with a medical device or the way in which it is being used, the sponsor and manufacturer will first conduct an analysis and make a decision on the appropriate action. One of these actions may require notifying or obtaining further advice from the TGA. Some actions that may need to be taken could include to:

- follow corrective actions / preventive actions procedures under the sponsor/manufacturer's quality management system or for Class 1 devices follow the post-market requirements under Part 6.5, Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*
- inform the users of the device
- make corrections to the device
- remove the device from the market

As a regulator, the TGA has established procedures for the ongoing monitoring and vigilance for medical devices supplied in Australia. This includes a range of penalties for the inappropriate supply of medical devices.

Recalls of medical devices

If the sponsor or manufacturer is intending any of the following:

- correcting product on the market
- removing product from the market, or
- advising users of a risk with a medical device

contact the Australian Recall Coordinator at the TGA via 02 6232 8636 or email <recalls@tga.gov.au> for advice.

When the need for a recall of a medical device supplied in or exported from Australia has been established, the sponsor of the affected device is responsible for the recovery of the devices. There are two key types of recalls:

- correction, which may involve temporary removal from the market or from use
- permanent removal of deficient medical devices from the market or from use

Most recalls are conducted on a voluntary basis. Where recall is refused, or is not carried out satisfactorily, the TGA may order a mandatory recall. Failure to comply with such an order may result in substantial fines.

The *Therapeutic Goods Act 1989* (the Act), in conjunction with the *Trade Practices Act 1974,* provides the legislative basis for recalls of therapeutic goods. Recall provisions can be applied under section 41KA of the Act when:

- the medical device does not meet the Essential Principles
- conformity assessment procedures have not been applied to the medical device

- the medical device has been illegally supplied
- the medical device has been cancelled or suspended from the ARTG.

In addition, in accordance with section 42V of the Act a recall may be conducted where therapeutic goods have been or could possibly be, subject to actual or potential tampering.

The Uniform Recall Procedure for Therapeutic Goods (URPTG), available on the TGA website, provides detailed information about the action to be taken by health authorities and sponsors when medical devices available in Australia are to be removed from supply or use, or are subject to corrective action

The sponsor has the prime responsibility for implementing recall action, and for ensuring compliance with the recall procedure at its various stages. However, no recall, regardless of level, should be undertaken without consultation with the Australian Recall Coordinator and without agreement on the recall strategy.

The role of the TGA is to assist the sponsor by:

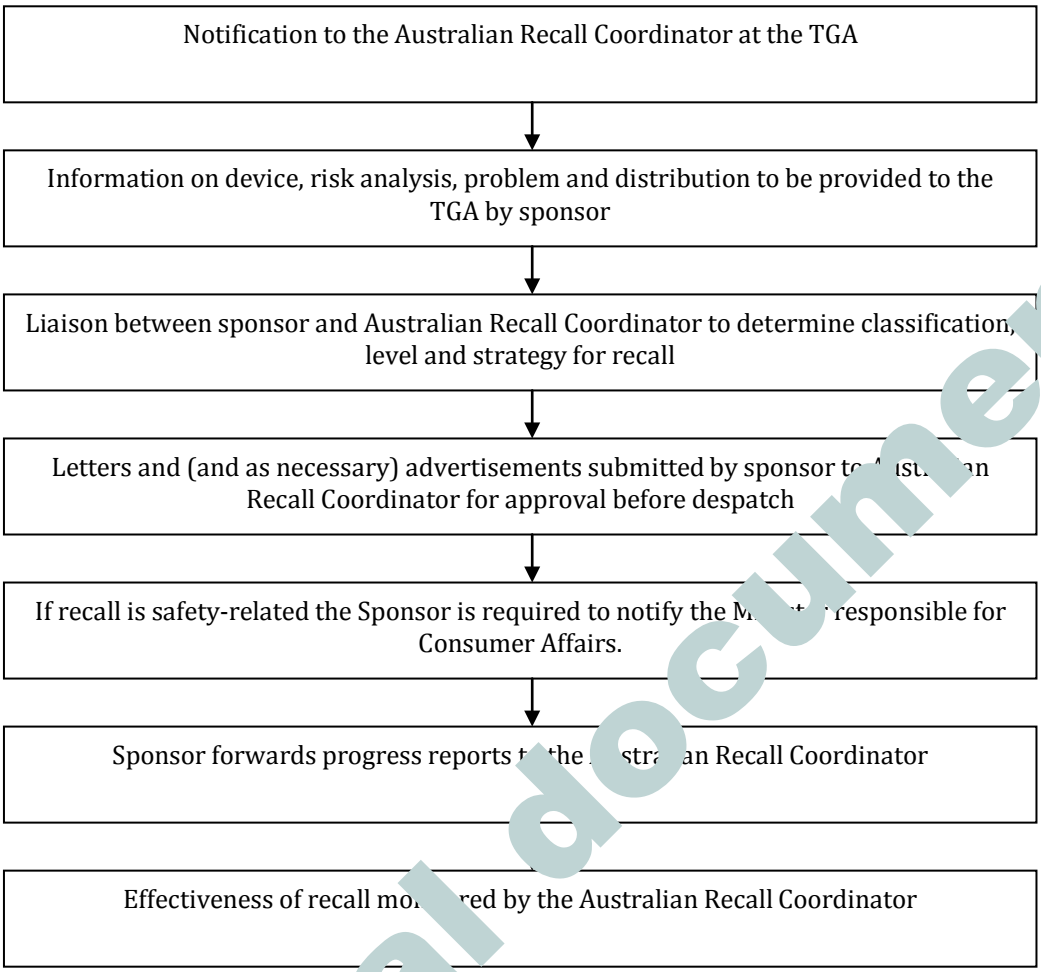
- advising the sponsor immediately of problem reports with medical devices that may necessitate recall
- where there may be a hazard to the user, providing expert advice on the classification and level of recalls. More information on classifications and levels of recalls in Australia is provided later in this section
- providing advice and assistance in relation to letters, advertisements and recall strategies
- notifying agreed third parties, such as state/territory health departments, as well as regulatory agencies, the Australian Competition and Consumer Commission
- monitoring the overall action
- considering and reaching agreement with the sponsors recall procedures or in serious situations to mandate a recall. Appeal provisions will apply with a mandated recall and should be provided

Please note: A Hazard Alert may be issued by the sponsor for implantable medical devices where it has been proven that there is no stock to be recalled and all affected devices are already implanted. The appropriate action to be taken for a device that has been implanted in a patient should be discussed with the Australian Recall Coordinator, as the risk of surgery to replace the implantable device must be balanced against the risk of a problem occurring with the device

Please note: A Hazard Alert as defined in URPTG is issued by the sponsor for implanted medical devices as part of a recall action

A Safety Alert as defined in URPTG is not related to a recall and is intended only to provide information on the safe use of a medical device where the issue was related to the inappropriate use of the device. A Safety Alert is issued by the sponsor or manufacturer not the TGA

Stages of a recall



Recall classifications

Recalls are classified as follows:

Classification	Description	Examples
Class I (Safety related)	Product defects are potentially life-threatening or could cause permanent debilitating health issues	• Hot/cold gel packs that contain a toxic substance that could be ingested accidentally by a young child • A software error in a CT scanner that could cause the g... to rotate in an unintended direction and cause an injury ... or the death of a patient • Implantable pacemakers with a defect that results ... loss of pacing output, which for pacemaker-dep... patients may result in death or serious injury • A false result on an IVD test for a me... with a narrow therapeutic index that could lead ... overdose, causing permanent injury
Class II (Safety related)	Product defects could cause illness or mistreatment and the recovery of the patient is likely	• Microbial contamination ... gical lubricant • A software error in ... radi...tion treatment planning tool that could lead to thera... be... g miscalculated and incorrectly administered • The *In... ct... ... Use* for a catheter omits a precaution for certa... p... edures that could cause complications in its remo... The incorrect combination of metal femoral heads and ...ers has been supplied to surgeons. If implanted then t...ere is a high risk of accelerated wear and tear An IVD test kit that could identify the wrong strain of micro-organism and lead to inappropriate treatment
Class III (Non-Safety related)	Product ...ct ... may not po... sign...icant hazard t... ...alth ...out withdrawal ... ...e initiated for ...her reasons	• A disinfectant has been mislabelled with an expiry date that predates the actual expiry date • The outer packaging of a consumable medical device indicates a different size to that which is actually in the supplied in the box. It would be obvious to the clinician that the consumable was the incorrect size • An IVD reagent is causing calibration failures towards the end of its shelf life. There is no effect on patient results

...s I or Class II recalls are considered to be urgent safety-related recalls. Class III recalls are considered to be ro...ine non safety-related recalls

Recall levels

The sponsor determines the applicable outlets in accordance with the URPTG.

There are four levels of recall in Australia:

Level	Outlets
Wholesale	• medicine and medical device wholesalers • State purchasing authorities
Hospital	Outlets at the wholesale level and where applicable any of the following: • nursing homes, hostels and other institutions • clinical investigators and the institutions in which clinical investigations are performed • hospital pharmacists, blood banks, pathology laboratories, operating facilities • fractionators, human tissue banks and personnel in other hospital departments • Ambulance Services, Flying Doctor Services
Retail	Outlets at the wholesale and hospital levels and where applicable any of the following: • retail pharmacists • medical, dental and other health care practitioners • other retail outlets, e.g., supermarkets and health food stores
Consumer	Outlets at the wholesale, hospital and retail levels and where applicable patients and other consumers

More information about recalls

For further information on recalls of medical devices, please refer to the Uniform Recall Procedure for Therapeutic Goods available on the TGA website or contact the:

Australian Recall Coordinator
Office of Product Review
Therapeutic Goods Administration
MDP 122
PO Box 100
WODEN ACT 2606

Telephone: 02 6232 8636

Non-recall actions for medical devices

Where the sponsor is unsure of the appropriate action to be taken, and particularly in cases where patient safety may be a consideration, the issues involved should be discussed with the Australian Recall Coordinator.

Other action may be taken by a sponsor voluntarily that is not considered to be a recall:

Action	Description
Safety Alert	• intended to provide information on safe use of devices, as distinct from recall action, which addresses product deficiencies • are issued to provide additional advice to health professionals in situations where the device, although meeting all specifications and therapeutic indications, its use could present an unreasonable risk of substantial harm if certain specified precautions or advice are not observed. For example, specific precautions about the longevity of an implanted medical device
Product Notification	• issue of precautionary information about a device in a situation that is unlikely to involve significant adverse health consequences
Product Withdrawal	• sponsor's removal from supply or use of devices for reasons not related to their quality, safety or performance
Product Recovery	• the sponsor recovers devices that have been manufactured or imported but not yet supplied to the market. For example, recovery of devices in a warehouse
User information	• generally conducted by the sponsor in response to issues with the use of a medical device • includes in-house sessions, seminars and improved educational materials such as posters

Please note: Terms such as upgrade notice, market correction, field safety correction that are commonly used by overseas manufacturers and, or regulators may be considered a recall in Australia.

If a sponsor is uncertain of the interpretation of these terms please contact the Australian Recalls Co-coordinator for advice.

Suspending medical devices from the ARTG

The *Therapeutic Goods Act 1989* provides the TGA with the power to suspend a medical device from the ARTG, as follows:

Legislative reference	Description
Section 41GA—Suspension of kinds of medical devices from the register Section 41GB—Notice of proposed suspension must be given in certain cases Section 41GC—Duration of suspension Section 41GD—Revocation of suspension Section 41GE—Treating applications for revocation as having been refused	• the TGA Delegate may by written notice suspend a device from the ARTG if: – there is a potential risk of death, serious illness or serious injury if the device continues to be included in the ARTG and – it is likely that the sponsor and/or the manufacturer will within period of the suspension, be able to take the action necessary to ensure that the kind of device would not cause a potential risk of death, serious illness or serious injury if it were to continue to be included in the ARTG; or – that it is likely that there are grounds for cancelling the entry under division 2 – the suspension may be limited to one or more medical devices of that kind covered by the ARTG inclusion • the TGA will: – inform the sponsor by written notice of the proposed suspension and set out the reasons for it – give the sponsor an opportunity to make submissions to the TGA in relation to the proposed suspension – consider any submissions the sponsor makes before making a decision relating to the proposed suspension • the period of the initial suspension will not exceed 6 months, but may be extended by up to another 6 months • the suspension may be revoked if the grounds for the suspension no longer apply, for example, if the corrective action is implemented within the timeframe. The suspension can be revoked on the written request of the sponsor or on the TGA's own initiative. • if the suspension is not revoked by the TGA Delegate before the end of the suspension period (for example, the corrective action has not been implemented in the timeframe), the device is automatically cancelled from the ARTG • does not affect the powers to cancel an entry
Section 41HE—Suspensions of kinds of medical devices from the register	• the TGA may by written notice suspend a device from the ARTG if a conformity assessment certificate (either issued in Australia or by an overseas regulatory agency) is suspended • the suspension in place until revoked by TGA Delegate

The TGA must publish in the Gazette, as soon as practicable, a notice setting out the suspension, any extensions to the suspension, and the revocation of the suspension.

Cancellation of medical devices from the ARTG

The TGA will cancel devices from the ARTG under Part 4-6 of the Act in cases where there has been a breach of the legislation or safety or performance issues associated with the use of the device that has or could lead to risk of death, serious illness or injury. If the devices are cancelled from the ARTG, the sponsor may be required to recall any affected devices. There are four legislative provisions for cancelling medical devices from the ARTG:

Legislative reference	Description
Section 41GK—Automatic cancellation of medical devices from the ARTG	The TGA must cancel a device from the ARTG if: • the device has been suspended from the ARTG under section 41GA of the Act and the period applying to the suspension expires before the suspension is revoked under section 41GD; or • a TGA Conformity Assessment Certificate applying to that device is revoked under Part 4-4 of the Act. The TGA will provide written notice of the cancellation to the sponsor of the device.
Section 41GL—Immediate cancellation of devices from the ARTG	The TGA may, by written notice given to the sponsor, cancel the entry of a device from the ARTG if: • the TGA Delegate is satisfied that there would be an imminent risk of death, serious illness or serious injury if the device continues to be included in the ARTG; or • devices of that kind are no longer therapeutic goods; or • devices of that kind are no longer medical devices; or • the sponsor requests in writing the cancellation of the entry of the kind of device from the ARTG; or • the TGA Delegate is satisfied that a statement made in or in connection with the: – application for including the device in the ARTG – the certification or purported certification under section 41FD of the Act relating to the application; was false or misleading; or • the annual charge is not paid within 20 working days after it becomes payable; or the sponsor does not comply with the direction or requirement to ensure that advertising complies with the Therapeutic Goods Advertising Code; or there is a serious breach involving the device, of the requirements relating to advertising applicable under Part 5-1 or under the Regulations, and the TGA Delegate is satisfied that the breach is significant and the presentation of the devices is misleading to a significant extent.
Section 41GM—Cancellation of devices from the ARTG after section 41JA notice	The TGA may, by written notice given to the sponsor cancel the entry of a device from the ARTG if: • the TGA gives the sponsor a notice under section 41JA requiring them to give the TGA information or documents relating to the device and – the notice is given for the purposes of ascertaining whether the device should have been included in the ARTG – the sponsor fails to comply with the notice within a further 10 working days from the day specified in that notice

Legislative reference	Description
	• the TGA gives the sponsor a notice under section 41JA requiring them to give the TGA information or documents relating to whether medical devices are being: – supplied in Australia – imported into Australia – exported from Australia and either the: – information or documents given are to the effect that medical devices of that kind are not being supplied in Australia, imported into Australia or exported from Australia; or – sponsor fails to comply with the notice within a further 10 working days from the day specified in that notice.
Section 41GN—Cancellation of entries of devices from the ARTG after notice of proposed cancellation	Before cancelling the device from the ARTG under this section, the Act, the TGA must: • inform the sponsor in writing of the proposed cancellation and set out the reasons for it; and • give the sponsor a reasonable opportunity to make submissions to the TGA in relation to the proposed cancellation. The TGA will not make a decision relating to the proposed cancellation until any submissions from the sponsor have been considered. Examples of when the TGA may, by written notice to the sponsor, cancel a device from the ARTG are if: • a medical device has changed since inclusion on the ARTG so that device is no longer a device of the same kind • the sponsor refuses or fails to comply with a condition to which that inclusion is subject • the sponsor does not comply with a request for information under section 41JA of the Act • the sponsor does not notify the TGA of adverse events within the required timeframes • the TGA is satisfied that the safety or performance of the device is unacceptable the TGA is satisfied that certification in relation to the application for inclusion of the device in the ARTG is incorrect, or is no longer correct. This includes: – compliance with the Essential Principles – application of conformity assessment procedures – compliance with advertising requirements.

The TGA must arrange for a notice to be published in the Gazette setting out particulars of the cancellation, as soon as practicable, after cancelling an entry from the ARTG.

Date of effect of cancellation of medical devices from the ARTG

If the TGA cancels a medical device from the ARTG the cancellation has effect:

- if the cancellation is under section 41GK or 41GL—on the day on which the notice of cancellation is given to the sponsor
- in any other case, on the date specified in the notice but not earlier than 20 working days after the notice is given to the sponsor

Product tampering

Any and all reports of actual or potential tampering with a medical device will be taken seriously and investigated, and should be immediately reported to the Australian Recall Coordinator. There is also a legal obligation for the sponsor under Section 42T of the Act to report such matters to the TGA within 2 days of becoming aware.

The Australian Recall Coordinator will convene a Crisis Reference Group (CRG) that will coordinate the activities required to resolve the crisis. For any tampering crisis, the CRG will comprise:

- Australian Recall Coordinator
- State or Territory Health Department Recall Co-ordinator
- appropriate State Police officers nominated for this purpose by the Police Ministerial Council
- senior personnel of the company concerned

The following documents have been developed as joint industry-government initiatives with the aim of assisting managers in responding to a product contamination and/or extortion event directed at the therapeutic goods industry:

- *Product Contamination & Extortion - A Protocol for the Therapeutic Goods Industry*
- *Crisis Management Guidelines - For the management of actual, potential or threatened tampering of medicines, complementary healthcare products and medical devices*

In order to maintain the usefulness of these documents, their availability is being limited to legitimate therapeutic goods industry stakeholders. These documents are available to sponsors from therapeutic goods industry associations or the TGA. Where a sponsor is a member of an industry association, access should be sought through that association in the first instance.

Where a sponsor of therapeutic goods is not a member of an industry association, a written request for a copy of the documents can be forwarded to the TGA. Such a request should be signed by a duly authorised person occupying a senior position within the sponsor's company.

Written requests should be forwarded to the:

Australian Recall Coordinator
Office of Product Review
Therapeutic Goods Administration
MDP 122
PO Box 100
WODEN ACT 2606

Telephone: 02 6232 8636

Any requests for a copy of the documents by persons who are not sponsors of therapeutic goods will be considered on a case-by-case basis and may be referred to an expert committee for advice on whether release would be in the best interests of the therapeutic goods industry.

Part 4–Navigation and Reference

Section 24. Bibliography

Legislation

Therapeutic Goods Act 1989

Act Compilation: C2010C00430

Amendments up to Act No. 54 of 2010

Prepared by the Office of Legislative Drafting and Publishing

<http://www.comlaw.gov.au/>

Therapeutic Goods (Medical Devices) Regulations 2002

Legislative Instrument Compilation: F2010C00749

Incorporating amendments up to SLI 2010 No. 267

Prepared by the Office of Legislative Drafting and Publishing

<http://www.comlaw.gov.au/>

Therapeutic Goods Regulations 1990

Legislative Instrument Compilation: F2010C00737

Incorporating amendments up to SLI 2010 No. 2

Prepared by the Office of Legislative Drafting and Publishing

<http://www.comlaw.gov.au/>

Section 25. Contact Details

Medical Devices Information Line

Phone

Free call (within Australia): 1800 141 144

Email

<devices@tga.gov.au>

Postal Address

Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

or

Courier Deliver

Office of Devices Au ation
Therapeutic Goo Ad istration
136 Na bu h Lane
SY NSTO ACT 2609

Adverse Events

Reports should be submitted to <iris@tga.gov.au> where ssi Otherwise, they may be sent to:

The Coordi or
Medical Device Incident ort Investigation Scheme (IRIS)
Thera e Goods Administration
PO Box 100
WODEN ACT 2606

Email: <iris@tga.gov.au>
Facsimile: 02 6203 1713
Telephone: 1800 809 361

Recall

Australian Recall Coordinator
Office of Product Review
Therapeutic Goods Administration
MDP 122
PO Box 100
WODEN ACT 2606

Telephone: 02 6232 8636

Device Inclusions and Application Audits

Postal Address		Courier Delivery
Devices Application Section	or	Devices Application Section
Office of Devices Authorisation		Office of Devices Authorisation
Therapeutic Goods Administration		Therapeutic Goods Administration
PO Box 100		136 Narrabundah Lane
WODEN ACT 2606		SYMONSTON ACT 2609

Conformity Assessment Certifications

Postal Address		Courier Deli[illegible]
Devices Conformity Assessment Section	or	Devices Conformity [illegible]ssessment Section
Office of Devices Authorisation		Office of D[illegible]es [illegible]horisation
Therapeutic Goods Administration		Therape[illegible]c Goods Administration
PO Box 100		1[illegible] N[illegible]rabundah Lane
WODEN ACT 2606		[illegible]MONSTON ACT 2609

Advertising

Complaints about advertisements appearing in [illegible] media

Complaints about advertisements appearing [illegible] media are considered by the Complaints Resolution Panel; they should be submitted on forms available at <http://www.tgacrp.com.au>. The forms can be submitted electronically on line or sent to

The Executive Officer
Complaints Resolution Panel
PO Box 764
NORTH SYDNEY NSW 2059

Complaints about other forms of medical device advertisements (such as, labels, leaflets, flyers)

These complaints should be sent to:

Recalls & Advertising Section
Office of Product Review
Therapeutic Goods Administration
MDP 122
PO Box 100
WODEN ACT 2606

Clinical Trial Notification (CTN) Scheme

Postal Address		Courier Delivery
The Business Management Unit	or	The Business Management Unit
Therapeutic Goods Administration		Therapeutic Goods Administration
PO Box 100		136 Narrabundah Lane
WODEN ACT 2606		SYMONSTON ACT 2609
Australia		Australia

Clinical Trial Adverse Event Reports

For reports to the TGA, the report should be clearly marked 'Clinical Trial Incident' and ser

Postal Address		Courier Delivery
Clinical Section	or	Clinical Section
Office of Devices Authorisation		Office of Devices Authorisation
Therapeutic Goods Administration		Therapeutic Goods Administration
PO Box 100		136 Narrabundah Lane
WODEN ACT 2606		SYMONSTON ACT 2609
Australia		Australia

Comments Regarding the ARGMD

The TGA welcomes comments and suggestions about the ARGMD; these should be directed to:

Email:

<ODAConsult@tga.gov.au>

Post:

Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Section 26. Glossary

Declaration of Conformity (DoC)

The DoC is a document that the manufacturer signs to say that it is compliant with all the essential components of legislation and requirements applicable to the device. Australia requires manufacturers to hold a DoC for every device they manufacture.

An Australian Declaration of Conformity is distinct, though similar, to an EU Declaration of Conformity.

EC Certificate

The *EC Certificate* is a European (EU) equivalent to Australia's Conformity Assessment certificate. EC certificates, in general, define what type of devices the manufacturer may manufacture. As with Australia, high-risk devices additionally require the manufacturer to obtain an *EC Design-Examination* or *EC Type-Examination* certificate.

Manufacturers' Evidence

Manufacturers' Evidence (ME) is the substantive evidence of the manufacturer's Quality System that supports the scope of manufacture. It is usually in the form of an EC or TGA Certificate (or certificates) and is submitted to the TGA in order to support a later device inclusion application.

For systems and procedure packs (e.g. joint replacement systems, first-aid kits, and surgical procedure packs), a specially formed Declaration of Conformity (with supporting evidence) can also be considered to be the manufacturer's evidence. This occurs under the Special Conformity Assessment Procedure (Clause 5 of Schedule 3 of the Regulations).

Time Frames

Application time frames are given in working days and start from the date the e-Business application fee is paid. See also *Working day* in this Glossary.

Vital Physiological Process/Parameter

of a patient, means a process that is necessary to sustain life and the indicators of which may include any one or more of the following:

a. respiration
b. heart rate
c. cerebral function
d. blood gases
e. blood pressure
f. body temperature

Working day

A working day is any day other than a weekend, a public holiday in the Australian Capital Territory, or when the TGA is waiting on information requested of the applicant or waiting for payment of fees. Refer to subsection 3(1) of the Act for the definition of working day. See also *Time Frames* in this Glossary.

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Therapeutic Goods Administration

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www.tga.gov.au

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