Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian regulatory guidelines for medical devices (ARGMD)

Part 1–Introduction

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

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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]y 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]or supply in Australia.

Scope of the ARGMD

The ARGMD is a consolidated reference document c[illegible]ain[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] guid[illegible]e[illegible] other therapeutic devices that are listed or registered is not included. The *Australian[illegible]edical 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]s
- [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 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 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.

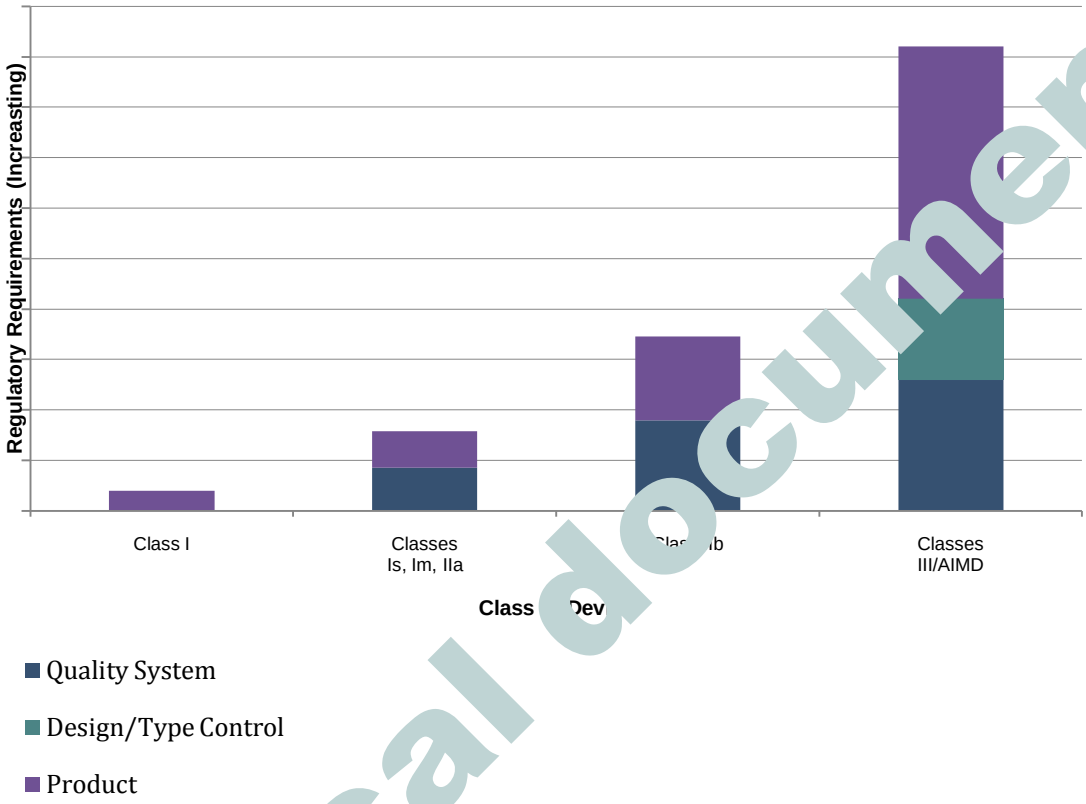
Before a new medical device can be supplied to the market in Australia, the TGA needs to be involved. The TGA's regulatory requirements vary, depending on what the device is and how it is to be used. The TGA is involved in most of the stages in the life cycle of a medical device.

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 while 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

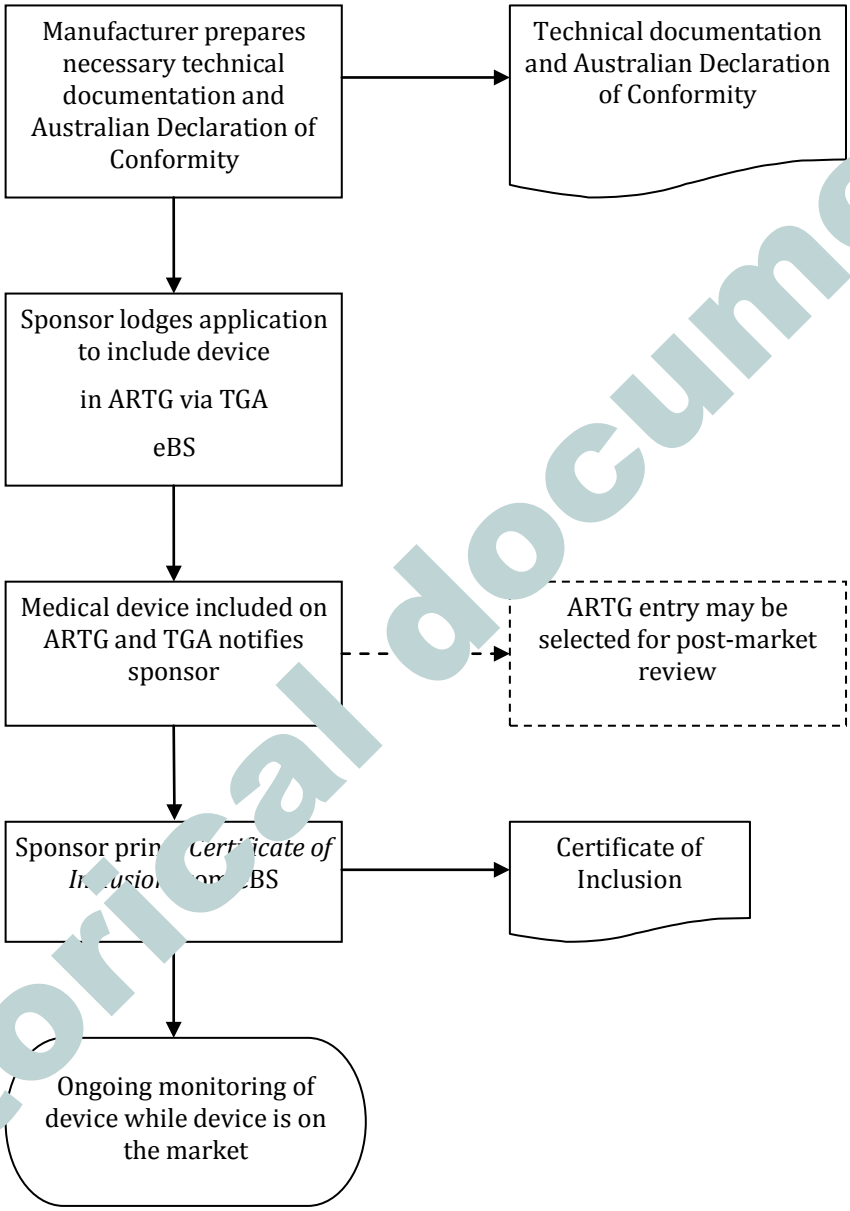
The legislation requires that there are different processes that must be followed to be able to supply medical devices for sale in Australia.

These processes have been summarised as follows:

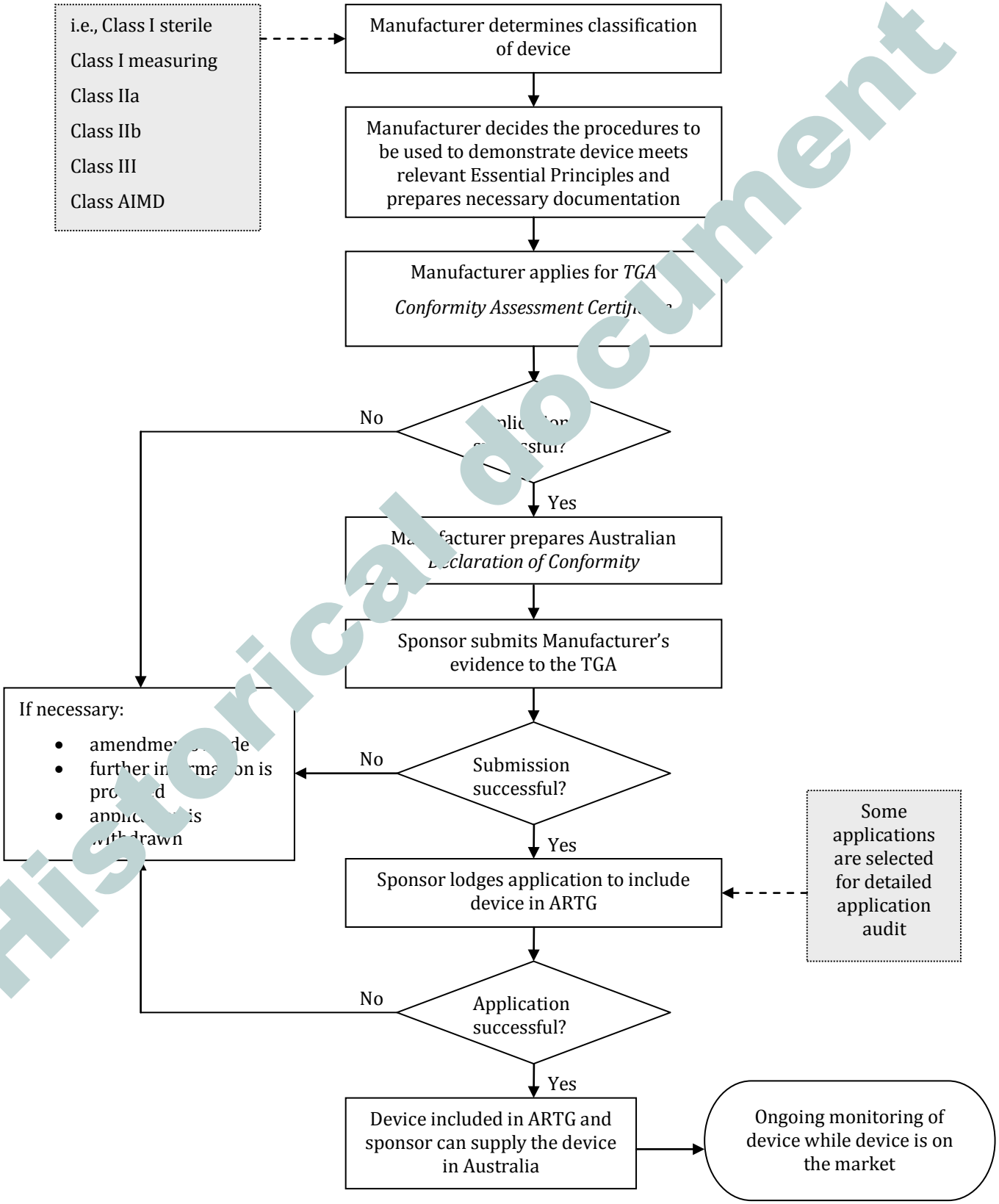
- Process to supply a medical device in Australia—all Class I non-sterile and non-measuring devices

- 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

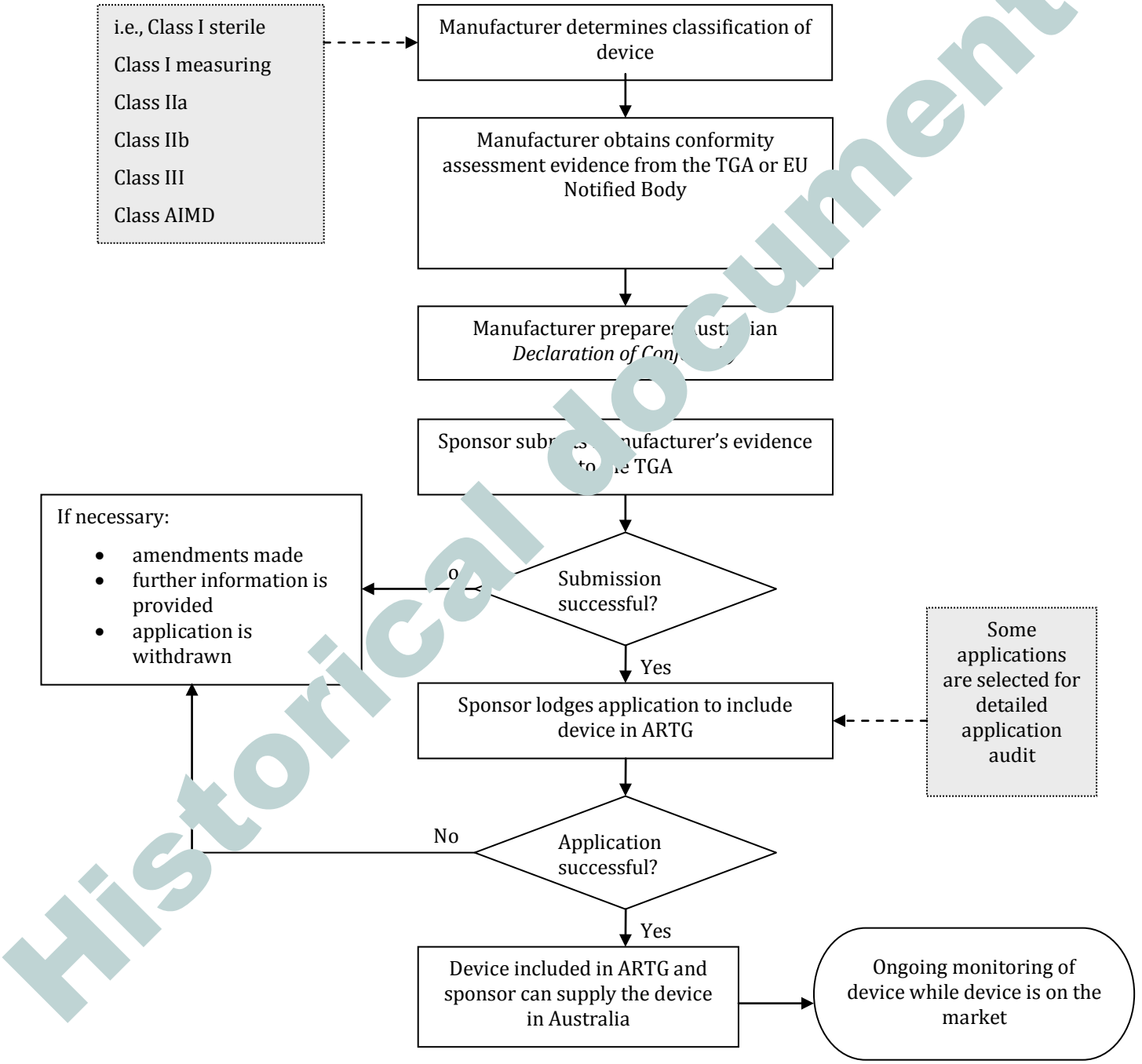
Process to supply a medical device in Australia—all Class I non-sterile and non-measuring devices



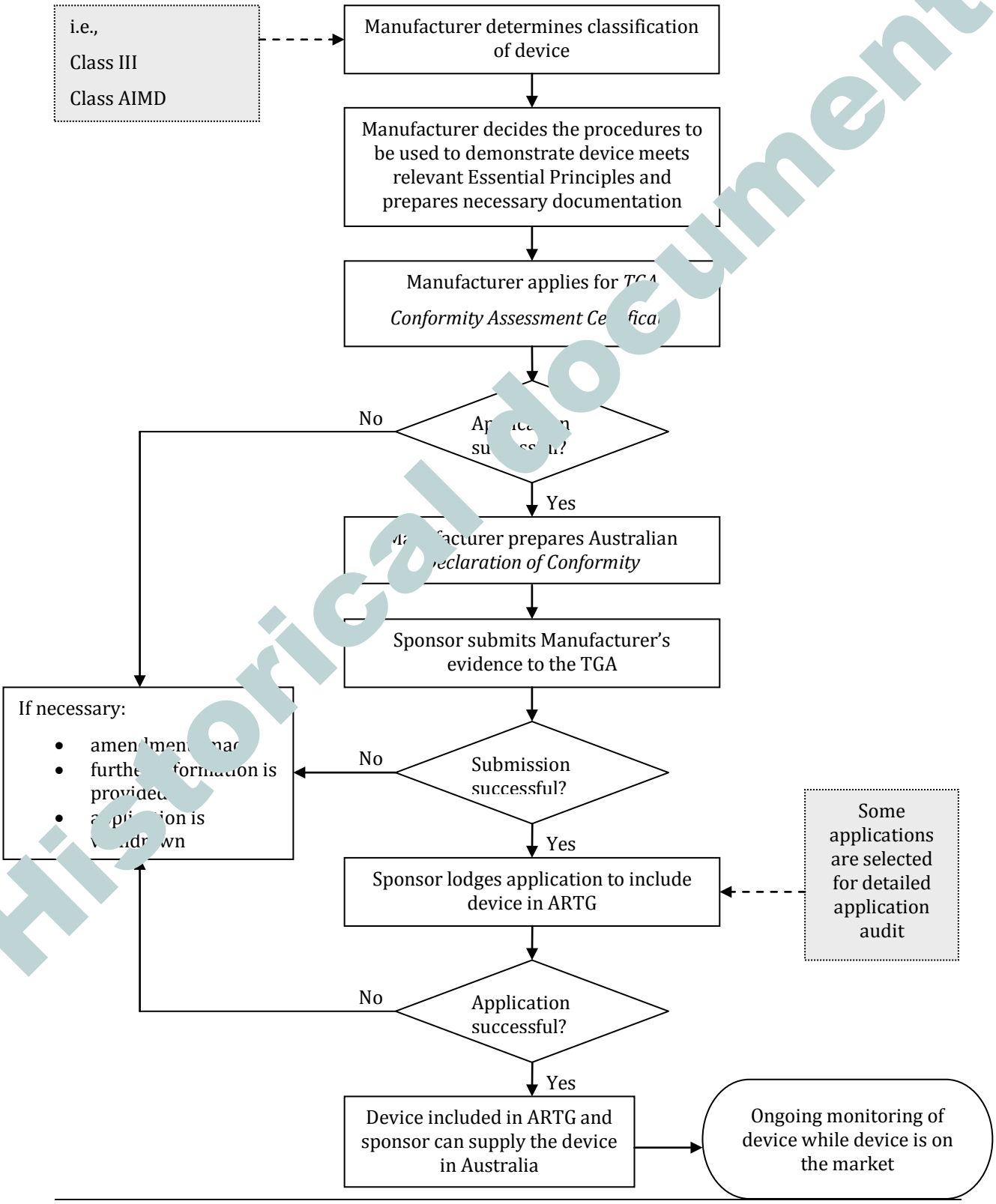
Process to supply a medical device in Australia—if the medical device is manufactured in Australia



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 all or 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 AIM 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

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

A new 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.

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 an assessment 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 *Corporations 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 recertification 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 AFTA-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 regulatory procedures and labelling etc. • More 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 a manufacturer	• The issue of a TGA Conformity Assessment

Conformity assessment fees are payable for:	Description of fees
	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 the audit team in and outside Australia are payable
changes to a TGA Conformity Assessment Certificate	• Fees vary depending on the procedure 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 audit 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 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 9.5 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, 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]son, when the device is used on a patient under the conditions [illegible]d fo[illegible]e [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]ng; 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]a 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 [illegible]cur by using the device and compare these with a well-reasoned and documented analysis o[illegible]ne[illegible]nefits that would be provided for the patient or user of the medical device. These analyses have to [illegible]ecog[illegible]a t[illegible]t a patient or user's safety is paramount.

The work undert[illegible]b[illegible]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:
    a. perform in the way intended by the manufacturer; and
    b. 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

   a. the device is used within the period, indicated by the manufacturer, in which the device can be safely used; and
   b. the device is not subjected to stresses that are outside the stresses that can occur during normal conditions of use; and
   c. 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:

a. the chemical and physical properties of the materials used in the device; and
b. 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 into 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:

- a 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 the p duction process must implement validated methods of elimina or activation, in relation to viruses and other transmissible agent

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

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

- evidence the v ous controls, supervisory procedures, records and processing requirements
  - for animal sources Conformity Assessment Standards Order No. 2 and ISO 22442[5] can provide further guidance on this, but are not mandatory standards that must be used
- viding 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 should 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.

11.4 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

12.4 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 of 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 for[illegible]ble noise emitted by the device, either intentional or unintentional
- evidence of appropriate testing to confirm the design and production[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 indication on the device must be clearly specified on the device.
5. If the instructions for the operation of a 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 [illegible]ith a[illegible]edical device:
   a. information identifying the device;
   b. information identifying the [illegible]anu[illegible]tur[illegible] of the device;
   c. information explaining how [illegible]se [illegible]evice safely;

   having regard to the training and k[illegible]owl[illegible]e of potential users of the device.
2. In particular:
   a. the information re[illegible]ired by clause 13.3 must be provided with a medical device; and
   b. if *instructions for* [illegible]of the device are required under subclause 13.4, the information [illegible]e[illegible]ified in subclause 13.4 (3) must be provided in those instruct[illegible]s.
3. The i[illegible]form[illegible]tion
   a. m[illegible] be p[illegible]ovided in English; and
   b. [illegible]ay [illegible] be provided in any other language.
4. Th[illegible]rmat, content and location of the information must be appropriate for [illegible]de[illegible]ice and its intended purpose.

   A[illegible]y 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.[illegible] 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

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 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.

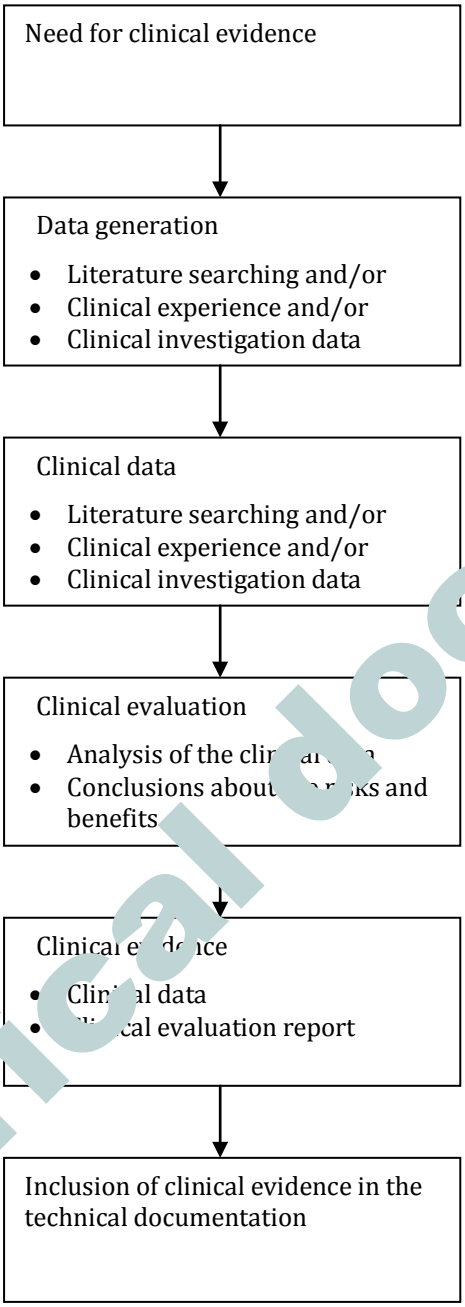
How should the clinical evaluation be conducted

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

Identical 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 an 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		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 Australia 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.

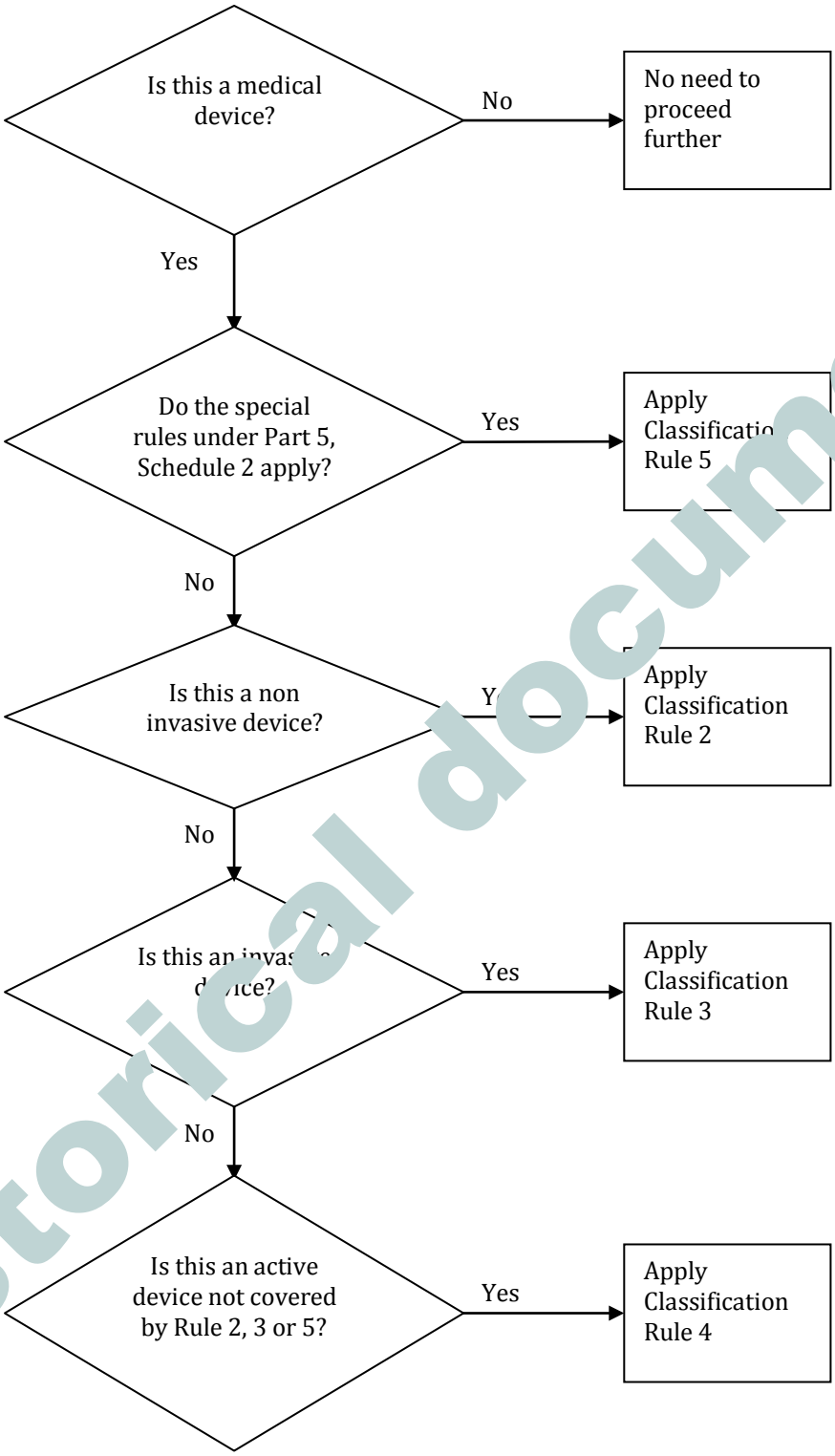
The *Medical Device Standards Order (Standards for Medical Devices Required to be Sterile) 2* available at <http://www.tga.gov.au>, is not mandatory but is one way to establish compliance with Principles. This Order references the following standards:

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 l ood	5.6—these devices are Class IIb	blood bags (including those containing or coated with an anticoagulant).
i ive 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.

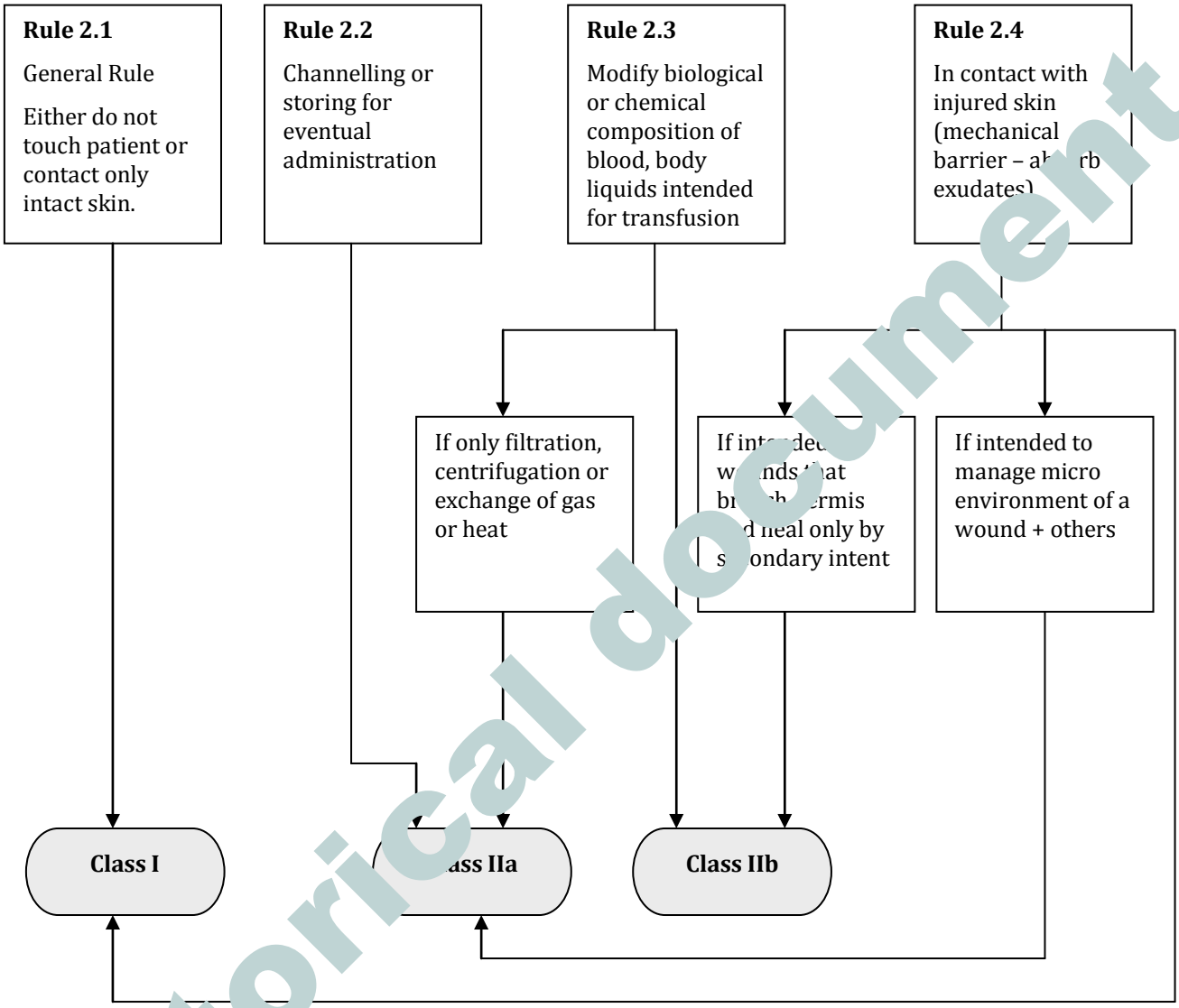
Classification Rule 1—Transient, short-term, and long-term use

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, adm[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

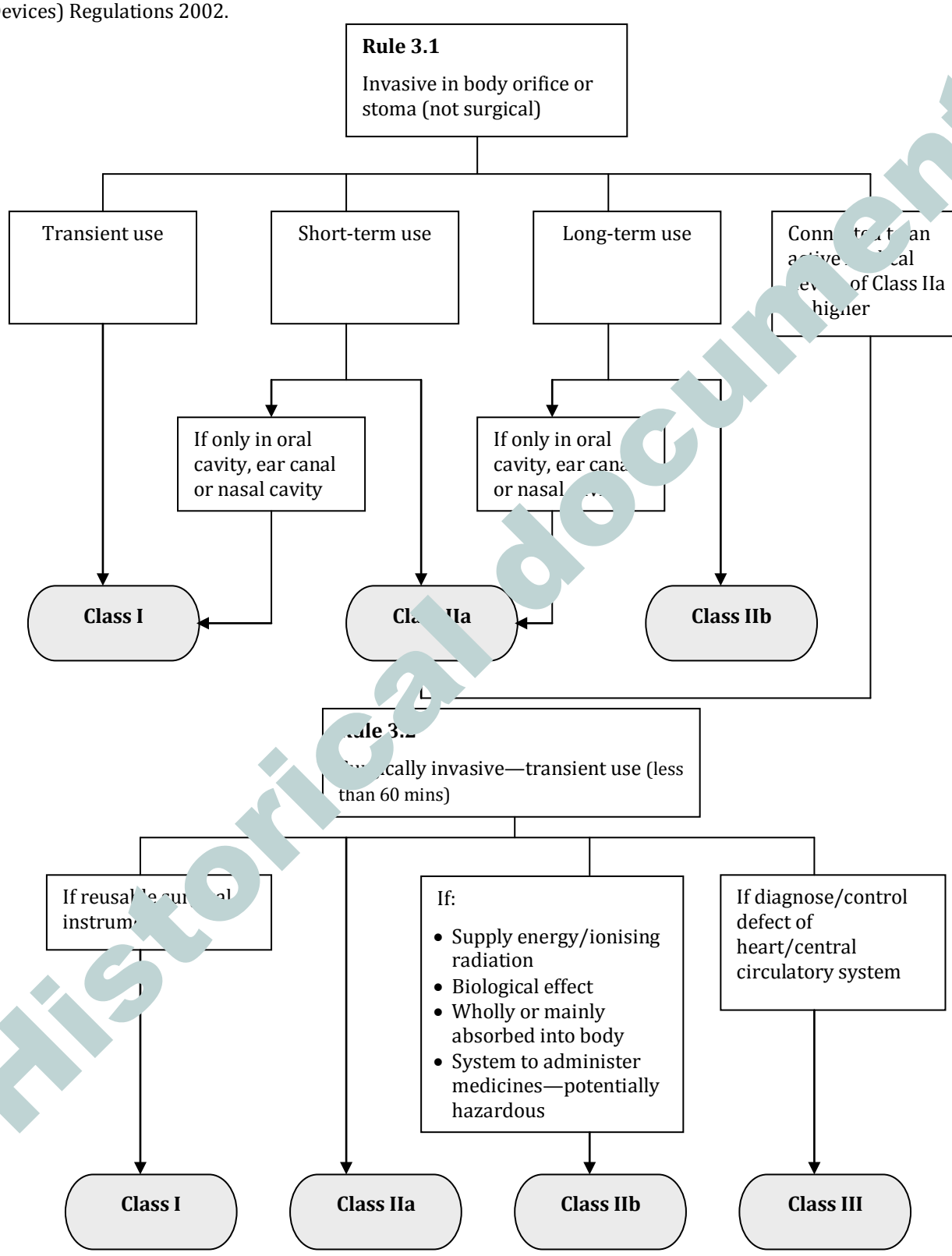
This rule covers wound dressings without consideration of the wound d th. e technology associated with these devices is well understood and they are not considered potentially dous to the patient.

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

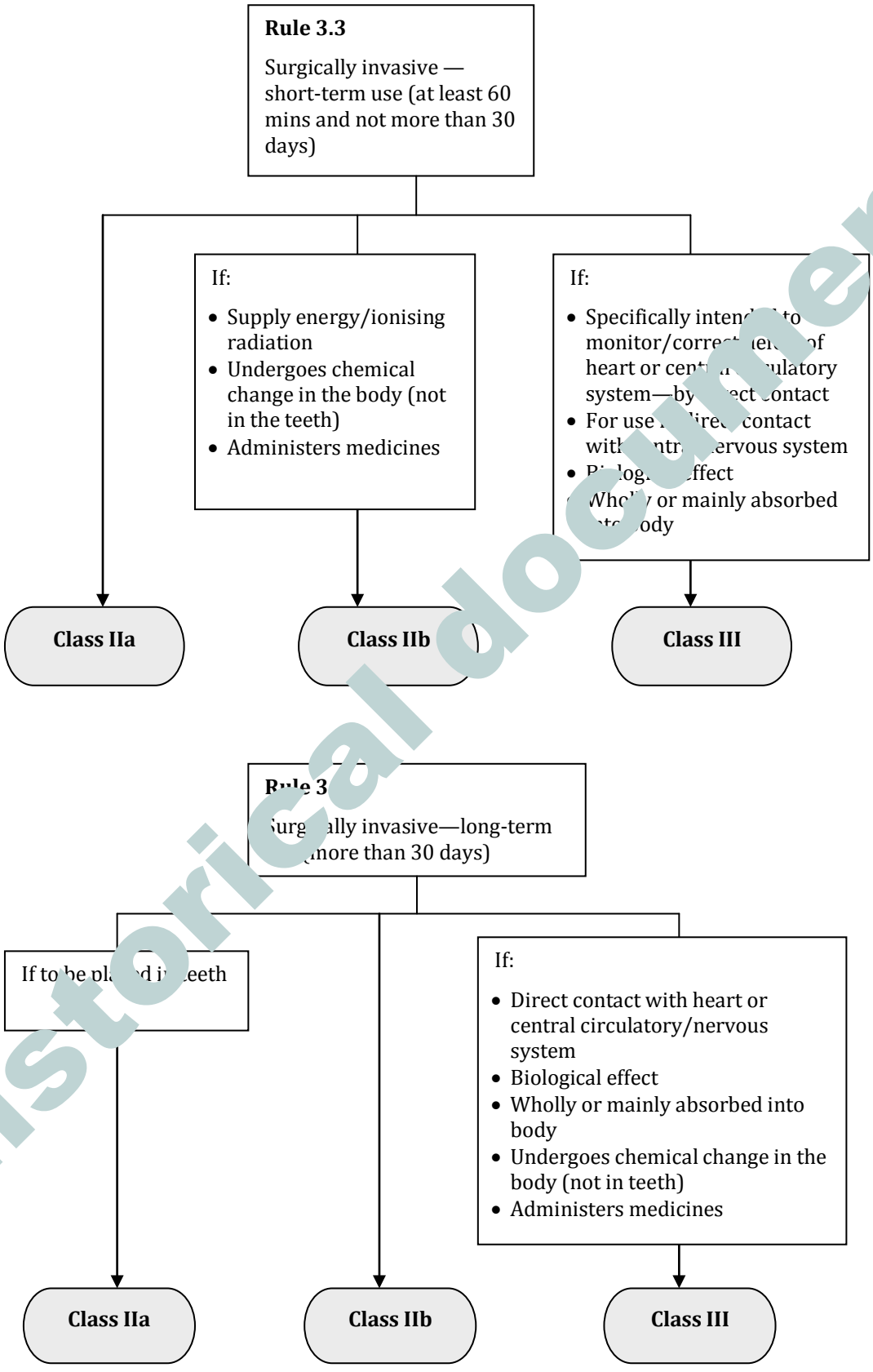
Classification Rules 3.1 and 3.2—Invasive Medical Devices—flowchart

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, fissures 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 the 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.	Examples: int 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 at system, through direct contact with these pa of 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 ect 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

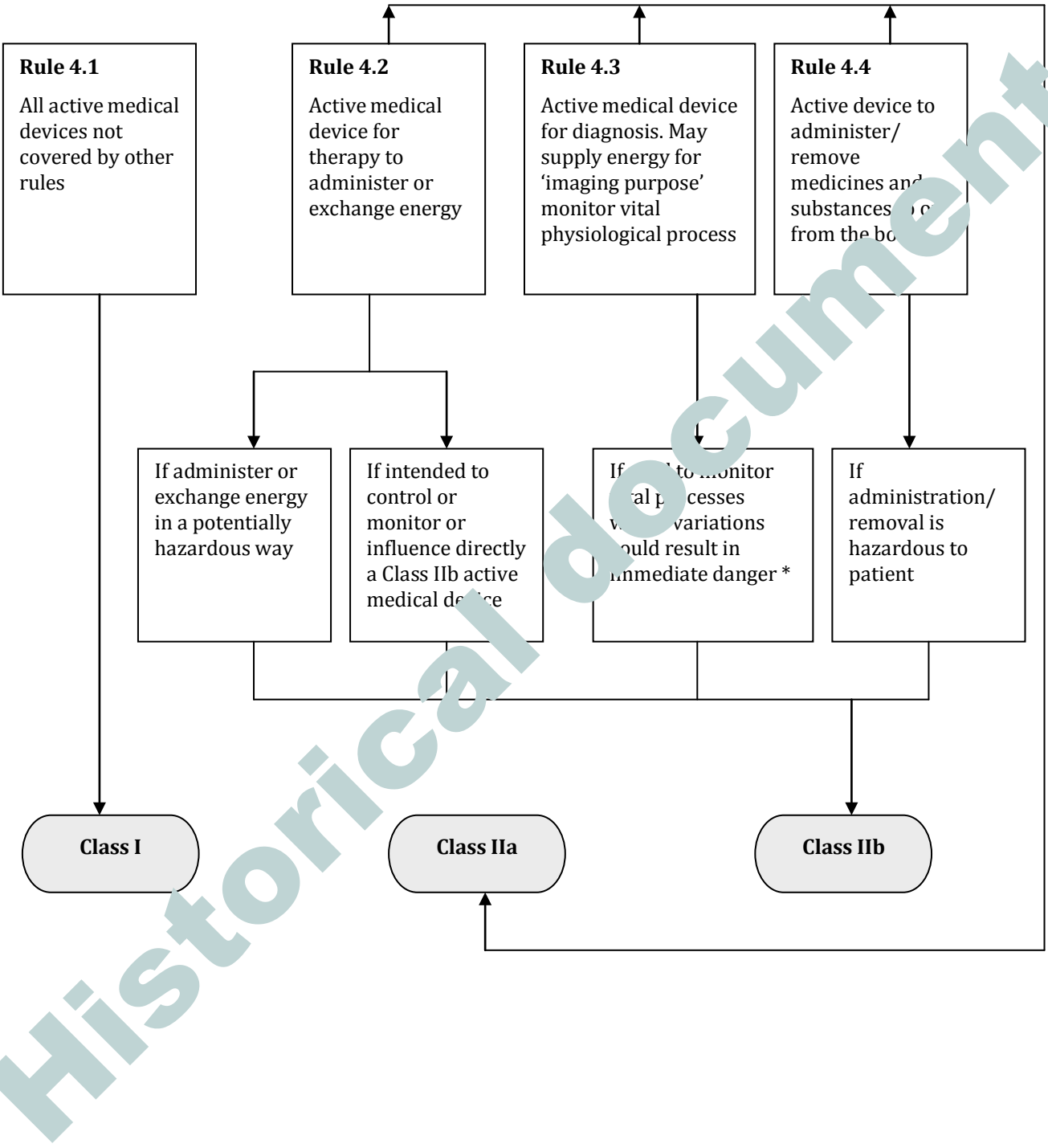
Devices covered by this rule include implants used in orthopaedic, dental, ophthalmic and [illegible]ovascular fields. In addition, soft tissue implants used in plastic surgery are covered by this rule.

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]lly 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 diagnosis and adaptive 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 to be 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 after loading controls systems.

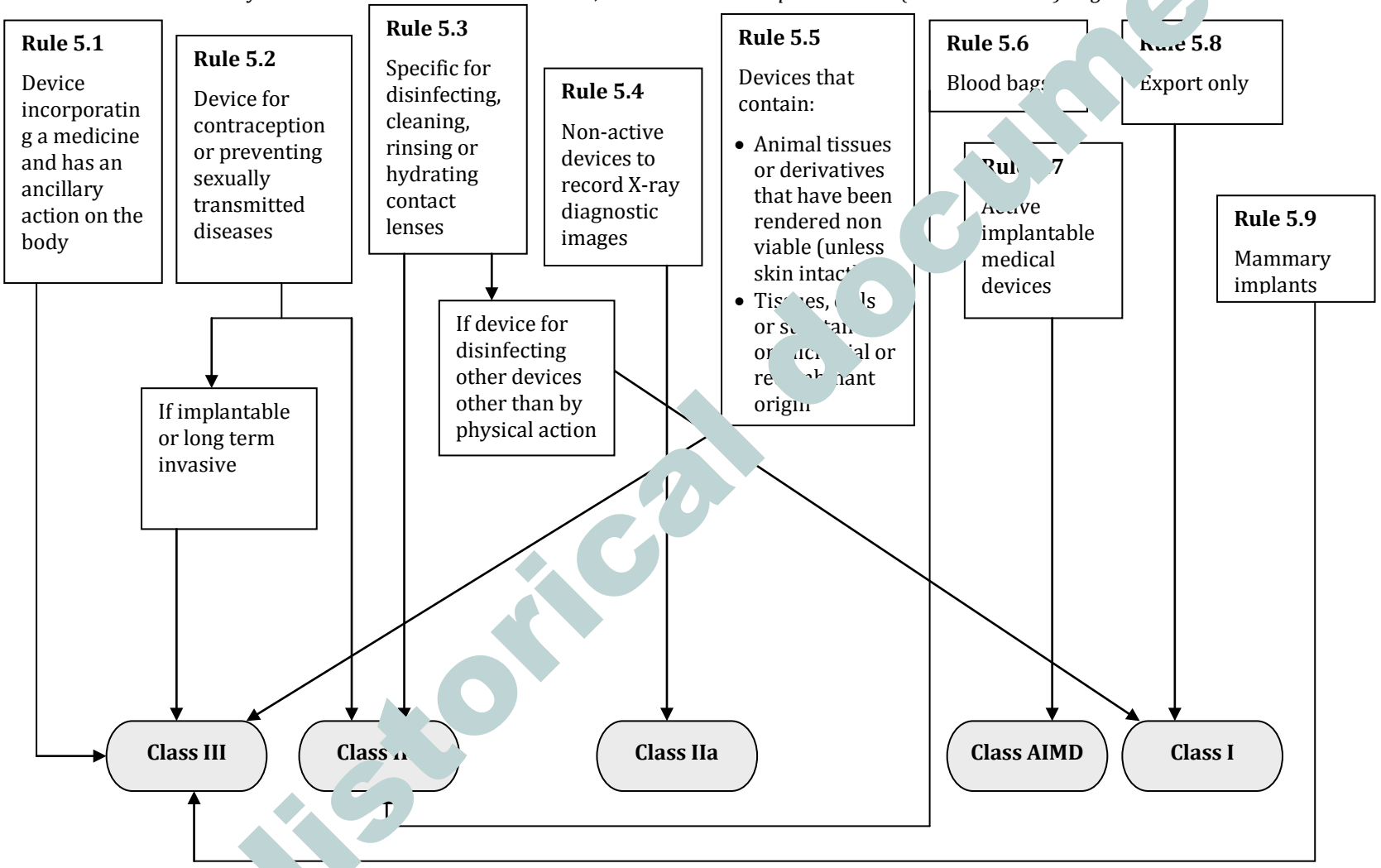
Rule 4.4 Active medical devices intended to administer or remove medicine from a patient's body

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 b. P ote: this clause does not apply to a medical evic at 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 *plan 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(2)	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 (ster
Adhesive dressing strip—with silver	Has silver (microbial agent) to assist in healing. The silver is a medicine	Rule 5.1 (2)	
Compression bandage used for sprains	Used for compression to assist in injury management	Rule 2.4(3)	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 (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-mi bial 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 ma ia biological origin	Rule 5.5(1)(a)	Class III
A non-sterile, trauma covering used to mai in the stability of rn patient en route t hospital. D ssi is coat in taining a esth ic	Contains medicine	Rule 5.1(2)	Class III
on erile, trauma vering used to maintain t 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)	Class I
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	Rule 3.3(4)(d)	Class III
Fixation screw that has direct contact with central circulatory or central nervous systems	Location in body—direct co with high-risk areas (central circulat or ntral 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 as having 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 process is voluntary 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.

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 that information on the certificate remains current and valid.

The manufacturer must also prepare an Australian Declaration of Conformity that includes 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 required 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 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 a[illegible] ongoing requirements are met (for example, reporting adverse events, regular quality systems audit[illegible] Fo[illegible]ore information on these requirements please see Section 22. Post-market vigilance and monitoring [illegible]qu[illegible]nts.

The manufacturer is responsible for obtaining the conform[illegible]y a[illegible]sment evidence and ensuring the information on the certificate remains current and valid.

The manufacturer must also prepare an Australia[illegible]eclaration of Conformity that includes all the manufacturing details for the medical device.

The legislation requires that the TGA must b[illegible]d in writing by the appropriate legal representative, within 3 months of the event occurring, if the manufact[illegible]:

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

A manufacturer may al[illegible] be[illegible]e Australian sponsor.

For some manuf[illegible]rers, the TGA can only accept TGA Conformity Assessment Certificates. These manufacturers are [illegible]ed 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 manufacture
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 claus[illegible]and arrange for the quality [illegible]nag[illegible]e[illegible] system to be audited by the T[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]ay
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 procedures
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 E[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]n 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 [illegible]nal inspection and testing of the device.

- For Class AIMD, Class III, or Class IIb devices that are su[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 / [illegible]DD 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 proce[illegible]es

This part requires the [illegible]A o[illegible]EU Notified Body to assess the production records for each Class I, Class IIa, Class IIb, Class III, or C[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]ufacturers 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: Section 16. Systems and procedure packs

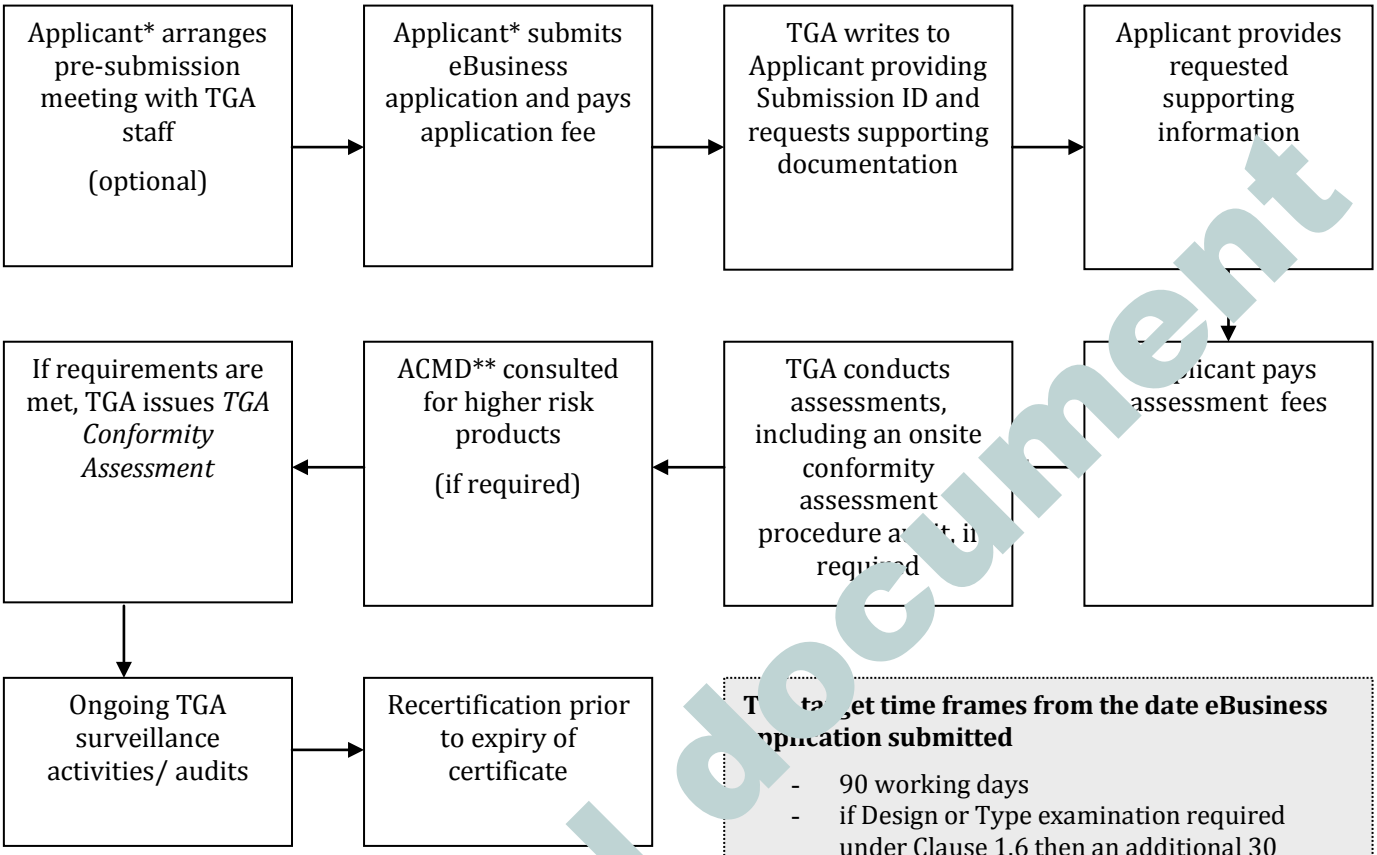
Please note: The requirements for custom made medical devices are similar to the EU MDD Annex VIII and AIMDD Annex VI requirements.
The requirements for systems and procedure packs are similar to the EU MDD Article 12 requirements.

Part 8 Clinical Evaluation procedure

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 suppli
  - Latest version of the quality manual
  - Procedure for a feedback system
  - Procedure for the issue and implementation of advisory notices and notifi 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 e 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 documenta w lways include the following:

- clinical evide nce
- risk manage r cords (see ISO 14971 for details)
- Essenti P iples compliance summary (e.g., Essential Principle checklist or similar). For more i ma on the Essential Principles see Section 3. The Essential Principles.
- ide to support compliance with any standards or test methods utilised for compliance (for example, e eports or assessment reports, labels and *Instructions for Use*)

lass I medical devices assessed under Part 6, the manufacturer self-assesses the technical documentation for 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 Essenti 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 Pri p While it is not mandatory for manufacturers to adhere to all the requirements outlined in the STED, it p ides 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 der ives, animal, microbial, or recombinant origin; or medicinal substances

Manufacturers of devices containing materials of human blood or plasma derivatives, mal, microbial or recombinant origin or medicinal substances should be aware that these devices a lass ed as Class III in Australia. The manufacturer is required to obtain two certificates from the TG with

- Full Quality Assurance certificate (Part 1) + Design Examination certi ate (Clause 1.6), or
- Production Quality Assurance certificate (Part 4) + Type Examinatio ficate (Part 2)

Only one conformity assessment application is required to btain both rtificates.

If these manufacturers hold a current EC Certificate under t DD 93/42/EEC, the TGA may, upon review of the documentation generated by the EU Notified Body, condu n a dged assessment of the manufacturer's quality system and technical documentation. In s me cases GA may waive conducting an on-site audit.

For devices that contain:

- animal-derived waxes
- heparin
- gelatin

and conform to pharmacopeial tan rds, a manufacturer may submit a MRA certificate of conformity to the TGA as support for a conformity a ssme t application. This may result in the TGA conducting an abridged conformity assessment.

However, the TGA rese es t right to conduct a full assessment if the TGA is not fully satisfied with the evidence of com ce p ided. If an abridged assessment is considered sufficient for the application, the TGA may reduce the a p le assessment fees.

At a minim n TGA requires evidence to support the quality and safety of animal derived material, in accor a ce wit e TGA approach to minimising the risk of exposure to Transmissible Spongiform E phal thies (TSEs) through medicines and medical devices, available on the TGA website. For more inf tion please see Section 15. Medical devices containing materials of animal, microbial or recombinant in.

Please note: The Australian requirements for devices that contain materials of microbial or recombinant origin 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

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 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 unacceptable.
- 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 possible 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' MS assessment is required
- where the applicant provides EU Notified Body reports of similar assessments 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 the 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
- the quality system audit (if conducted) is closed out—all non-conformities are resolved
- 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 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.

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 device 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 systems
- 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 11. Changes to ARTG Inclusions.

4. Payment of fees

Any prescribed fees for a device with 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.

The 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 such 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 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 over 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 provisions 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 syste Surveillance activities may also be associated with product compliance monitoring activities, such as monitori of non-standard conditions on the certificate or follow-up of post-approval recommendations and agree

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 evide a thorough and comprehensive assessment, the TGA may abridge the surveillance activities and c duced fees. However, the TGA reserves the right to conduct its own surveillance irrespective of su

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 c te in Australia, they need to apply for recertification prior to the expiry date.

An application to re-issue an existing TGA Conformity Assessment Certi ll need to be submitted to the TGA, allowing sufficient time for processing prior to the current c te expiring. Recertification applications are lodged via the same process utilised for new applicatio See pli ation for certificates earlier in this Section.

An application fee and assessment fee are payable for the ert cation. Assessment fees are levied according to the level of assessment required.

Recertification will normally be associated with an ite quality management system audit, dependent on the timing of the last TGA surveillance audit.

The manufacturer will be asked to provide a co p hensive concise summary of:

- all design, production, and labelli cha ges implemented since the certificate was issued
- clarification of the current cr al s pliers
- sterilisation arrangeme or eac sterile product
- country of origin; s tissue or cell or derivative; and production arrangements for all animal-, microbial-, a d re bi nt- origin materials
- details of all cinal substances and their production arrangements, including the current Australian GMP status if evant
- post ma ket erformance data for each device including adverse events, recalls, and alerts since the erti te was issued
- y 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 found in Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 are available at <http://www.[illegible].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 procedures 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 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
- 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 EU, the conformity assessment procedure requirements may be different in Australia. The manufacturer may be required to obtain additional conformity assessment evidence. Where the manufacturer is not able to obtain the appropriate additional conformity assessment evidence from their EU Notified Body, they may need to obtain a TGA Conformity Assessment Certificate. For more information, please see Section 8. Difference between the Australian and European Union medical device regulatory requirements.

The TGA will make the final determination as to whether the evidence is acceptable.

Conformity assessment evidence not accepted by the TGA

The TGA does not accept the following certificates as evidence that the Australian regulatory requirements have been met:

- certificates from any countries outside Australia, the EU and EFTA
- a certificate 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 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.

[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 V[illegible] (MDD only)
Schedule 3 Part 6—Declaration of conformity procedures	[illegible]nex V[illegible] (MDD only)
Schedule 3 Part 7—Procedures for medical devices used for a spe[illegible] purpose	[illegible]nex VIII & Article 12 (MDD only)

TGA Conformity Assessment Certificates

The TGA accepts TGA Conformity Assessment Certificates as [illegible]nformity 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 conform[illegible]ssessment.

For some manufacturers, the TGA can only a[illegible]t [illegible]A Conformity Assessment Certificates. These manufacturers are detailed in Section 5. Conformity assessm[illegible]verview.

MRA certificates of c[illegible]nformity accepted by the TGA

Australia has signed a Mutual [illegible]ecog[illegible]on 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 internat[illegible]greements that are in place see Section 9. International agreements.

Several Europea[illegible] Notif[illegible]d Bodies have been designated by the European Commission as competent to assess medical devices [illegible]nufactured 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 apply 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 Devices 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 on 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 [illegible] conducted once the sponsor lodges an Application for Inclusion on the ARTG with the TGA. The applic[illegible]n a[illegible]it is to confirm that the manufacturer of a medical device has carried out conformity assessment proc[illegible]ure appropriate to the classification of the medical device. For more information, please see Section [illegible] pplication audits of medical device applications. The following table outlines the EU MDD and Annex optio[illegible]

Classification	Options	EU Directive
Class I Measuring	Annex II.3 Annex V Annex IV for non-sterile devices where specific bat[illegible]es ar[illegible] 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-st[illegible]ile [illegible]ces where specific batches are included on the [illegible]rtifi[illegible]te Annex VI fo[illegible]n-s[illegible]ile devices	93/42/EEC (MDD)
Class IIb	Annex II. A[illegible]nex [illegible]+ III An[illegible]IV for non-sterile devices where specific batches are [illegible]luded on the certificate Annex VI + III for non-sterile devices	93/42/EEC (MDD)
C[illegible]s 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 resells another manufacturer's medical device that has CE certification.

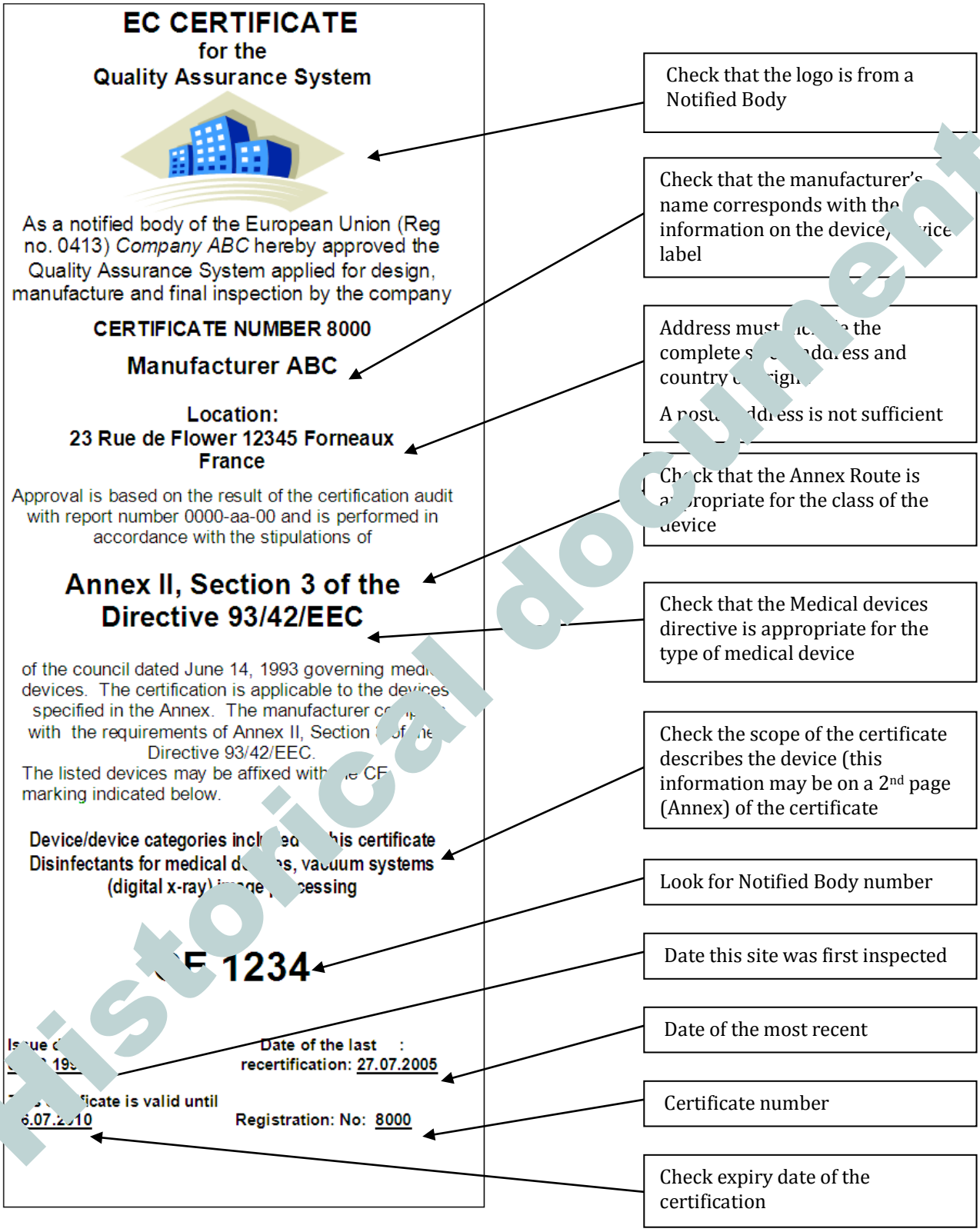
The TGA will accept CE certificates for 'Own Brand Labelling' as conformity assessment evidence, without requiring additional information, provided:

- 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

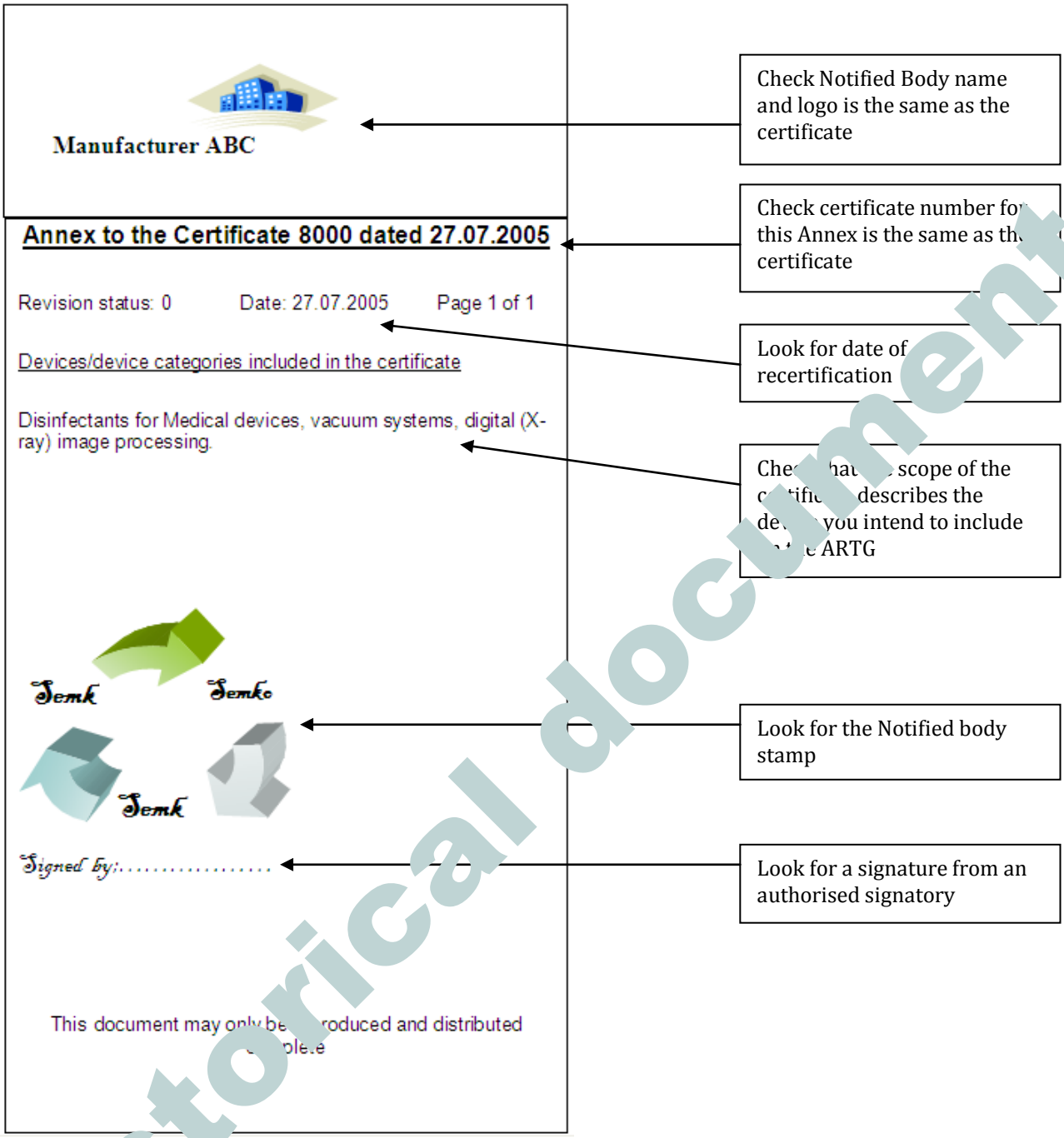
An example of an EC certificate is provided on the next page highlighting some of the key details that should be checked.

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



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**	**Allowable 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 AIMDD/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 application 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 certificates 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 was 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 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 in 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 have 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 sponsors 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 Device Identifier for each Class III and AIMD device

Australian Register of Therapeutic Goods (ARTG) and CE marking

The ARTG is a 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. CE 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 table database. For further information regarding GMDN, please see Section 10. Including medical devices in the ARTG.

Retention of records

In Australia, the manufacturer must keep all manufacturing records for at least 5 years from the last date of manufacture or the lifetime of the device, whichever is longer. However, distribution records relating to Class AIMD, Class III or implantable Class IIb medical devices must be retained by the sponsor for inspection by the TGA for 10 years.

Similarly, the EU directives require the retention of manufacturing records for 5 years from the last date of manufacture or the lifetime of the device, whichever is longer. However, for implantable devices, records must be kept for at least 15 years from the last date of manufacture.

Please note: Directive 2007/47/EC introduces the requirement that manufacturing records of implantable devices must be kept for at least 15 years from the last date of manufacture.

Differences between Australian Essential Principles and EU Essential Requirements

The Australian Essential Principles are specified in Schedule 1 of the Regulations. The analogous requirements in the EU are referred to as the Essential Requirements and are specified in Annex I of the MDD. The following table compares the Australian Essential Principles with the EU Essential Requirements.

Despite the differences, and with the exception of some medical device manufacturers who require a TGA Conformity Assessment Certificate, CE certificates can be submitted in support of an application to include medical devices in the ARTG. This will continue once the amended MDD (due to Directive 2007/47/EC) becomes fully effective.

For more details on TGA 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 removal 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 administer and/or remove medicines, body liquids or

Australian Essential Principles (EPs)	EU Essential Requirements (ERs)
above).	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 labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging a device containing phthalates. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the *instructions for use*, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.'
EP 8.2—Control of animal, microbial, or recombinant tissues, cells, and other substances.	ER 8.2 Please see section 15. Medical devices containing materials of animal, microbial or recombinant origin [illegible] details.
EP 10—Medical devices with a measuring function. The Australian EP 10.1(3) requires that measurements must be expressed in Australian legal units of measurement; or; if the device measures a quantity that is not prescribed under the *National Measurement Act 1960*, the units used are to 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 development lifecycle is not explicitly addressed in the Australian EPs. EP 12.1 addresses other requirements for medical devices incorporating electronic programmable systems. See Section 13 Active medical devices for more details on medical 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.'
EP 13—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 the information to be legible and at least 1 millimetre high.	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 supplied by the manufacturer of medical devices.

Australian Essential Principles (EPs)	EU Essential Requirements (ERs)
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 by date (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 requirement under ER 9.1 any restrictions on use, in relation to other devices or equipment, must be indicated on the 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) that is incorporated, or is intended to be incorporated, into the device as an integral part of the device	ER 13.3 EU ER 13.3 requires that devices incorporating human blood derivative must indicate this on the label. Including this information in separate *instructions for use* is sufficient in the EU.
EP 14 Australian EP 14 requires that every medical device have clinical evidence, appropriate for the use/ classification of the device, demonstrating that the device complies with the applicable 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 the Regulations).

EU Directive 2005/50/EC of 11 August 2005 changed the classification of implantable component parts of total hip, knee and shoulder replacements from Class IIb to Class III. Hip, knee and shoulder joint replacements that have followed the Annex II conformity assessment procedures must undergo a design dossier examination (Annex II.4) to be placed on the EU market after 1 September 2009. Devices currently approved under Annex VI in conjunction with Annex III have until 1 September 2010 to upgrade the Annex VI conformity assessment certificate to Annex IV or Annex V of the MDD (Annex VI is not acceptable for Class III devices).

In order to maintain CE Certification for these devices, manufacturers may need to upgrade their conformity assessment certification. If the CE Certification lapses they may not have appropriate evidence to support ARTG inclusions for hip, knee and shoulder joint replacements as Class IIb devices in Australia. 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 the Australian Class IIb devices
- Obtain a TGA Conformity Assessment Certificate
- Support Australian health professionals to consider special access arrangements as described in Section 20. Access to unapproved medical devices in Australia

Please note: The IIb classification of hip, knee, and shoulder replacements in Australia is subject to change pending the outcome of the public consultation that closed in December 2009. Further information and the consultation paper is available on the TGA website.

Devices intended for direct contact with the central nervous system

In the EU, all devices intended specifically for use in direct contact with the central nervous system are Class III (Annex IX, Rule 6, 7, 8 of the MDD). 'Central nervous system' is defined as the system in a human being that comprises the brain, meninges and spinal cord.

In Australia, devices intended for transient use in direct contact with the central nervous system may be classified as Class IIa, Class IIb, or Class IIb (Schedule 2, Part 3.2 of the Regulations). Devices intended for short-term, long-term or implantable use in direct contact with the central nervous system are classified as Class III or Class AIMD (Schedule 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 iliac 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 4.1 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 Class III (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 covered 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 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 Act. 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, Part 3, 3(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 to be used 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, scientific, 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 conside not placed on the market when purpose-built for a hospital. Medical gases stored in gas cylinders are also classified as medicines in the EU. The international standard *ISO 7396—Medical gas pipeline systems* is harmonised under the MDD. Requirements for medical gases stored in gas cylinders are given in Europ standards. The requirements for labelling, colour coding, and connections for medical gas system for medical gases stored in cylinders will be different to those of Australia, and may vary depending on the country.

Devices with radio-communication transmitters and/or that connect to telecommunications networks

Medical devices intended for connection to Australian telecommunication networks or that use Australian radio communication spectrum are required to be compatible with these systems (see Essential Principle 9.1).

In Australia, medical devices that connect to a public telecommunications network must comply with the Australian Communications and Media Authority (ACMA) A-Tick requirements. Medical devices with radio communication transmitters (for example, Bluetooth devices) must comply with the ACMA spectrum licensing and C-Tick requirements. Further details are available in Section 13. Active medical devices.

The EU radio spectrum and telecommunications requirements (for example, Radio & Telecommunications Terminal Equipment(R&TTE) Directive 1999/5/EC) are different to those in Australia.

Medical devices that connect to public mains electricity networks

Medical devices intended for connection to Australian public mains electricity networks are required to be compatible with these systems (see Essential Principle 9.1).

The Australian mains electricity supply operates at 230 volts, 50 Hz. All electrical equipment, including medical devices, connect to the mains electricity supply using a plug with active and neutral pins partially insulated and with Australia-specific pin configuration as required by *AS/NZS 3112—Approval and test specification—Plugs and socket-outlets*.

For more details, please see Section 13. Active medical devices.

In the EU, the mains connection requirements will be different to that of Australia and will vary depending on the country.

Medical devices incorporating a medicinal substance

In Australia, medicinal substances that are incorporated or intended to be incorporated in the device must meet the Australian regulatory requirements for medicines. Manufacturers of these devices must obtain a TGA Conformity Assessment Certificate. See Section 14. Medical devices incorporating a medicine for more details.

In the EU for devices incorporating a medicinal substance, the Notified Body has to consult with one of the Competent 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 ovine. Catgut sutures are no longer supplied in the EU. In Australia, catgut sutures are classified as Class III medical devices because they contain substances of animal origin. Animal material must only be sourced from countries that have not reported indigenous cases of Bovine Spongiform Encephalopathy (BSE), unless it can be justified otherwise.

As manufacturers of catgut sutures are not able to obtain valid CE certification, the TGA assessment of the conformity assessment procedures cannot be abridged and an on-site audit of the manufacturing facilities will be required.

Medical devices containing gelatine and collagen

There are differences between the EU and Australia in terms of requirements for bovine-bone derived gelatine and collagen used with medical devices.

In the EU, collagen and gelatine used for the manufacturing of medical devices shall meet at least the requirements as fit for human consumption (Article 1.3, TSE Directive 2003/32/EC).

In Australia, bovine-derived gelatine and collagen raw material (BGCRM) must not be sourced from high-risk countries. See Supplementary requirements for therapeutic goods for minimising the risk of TSEs on the TGA website for more details.

Medical devices containing tissues, cells, and substances of microbial or recombinant origin

In Australia, medical devices containing tissues, cells, and substances of microbial or recombinant origin are Class III (Schedule 2, Part 5.5 of the Regulations). Manufacturers of these devices must obtain a TGA Conformity Assessment Certificate.

There is currently no distinction in the EU regarding such devices and they are classified according to the other rules on the basis of the intended purpose. This means that some devices classified as Class III in Australia will have a lower classification in the EU. Generally, implantable or long-term surgically invasive devices will be Class IIb and transient or short-term surgically invasive devices will be Class IIa, but some devices that are Class I in the EU may contain substances of microbial or recombinant origin.

Medical devices containing mercury

In Australia, the medical devices regulatory framework does not impose any additional requirements for medical devices containing mercury.

In the EU, Directive 2007/51/EC imposes restrictions on the marketing of certain measuring devices containing mercury. Mercury-In-Glass fever thermometers may no longer be placed on the market. Mercury sphygmomanometers may no longer be placed on the market for sale to the general public, but may still be available for healthcare professionals.

Medical 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 an 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 reproce 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 regu requirements of the destination country, such as the countries of the EU. These devices sti d to be included on the ARTG, but are treated as Class I, regardless of other rules. This provides basic co ls 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 ma as other devices.

Special/particular procedure for systems and procedure packs

In the EU, the 'particular procedure' defined under Article 12 of the MDD an b applied for systems and procedure packs, if all products making up the system or procedure pac the CE mark, including medical devices, medicines, and non-therapeutic goods.

In Australia, the special procedure requirements (Schedule lau for products making up a system or procedure pack are different from the EU. The special pro can be applied if the manufacturer can meet the following requirements for the products included in th ys m or procedure pack:

- medicines, or other therapeutic goods, must e an appropriate ARTG entry
- medical devices must have undergone an op e conformity assessment procedure
- non-therapeutic goods are not required to av undergone conformity assessment

There are also other requirements for pply g the Australian special procedure. For more details, please see Section 16. Systems and proced ro pa

Certification of sterilisati pr iders

In Australia, there are no requi ents for certification of sterilisation providers under the regulatory framework.

Directive 2007/ C a ued Article 12 of the MDD so that sterilisation providers, who sterilise CE-marked medical devices i ded to be sterilised before use in the EU are limited to use conformity assessment procedures u er Annex II or V.

Section 9. International agreements

Overview

The TGA's participation in international forums helps ensure Australia aligns its policies, regulatory frameworks 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 Blood 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 what 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/acc t 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 followin international agreement between the two countri r ex mple, WTO Agreement on Technical Barriers on Trad
Memoranda of Understanding (MoUs)	• terms of the MoU are not usually legally forc le • MoUs are generally used where the ties wish to formalise the arrangements between them but d not sh to create any legally binding obligations
Memoranda of Intention (MoIs), Records of Understanding (RoUs) and others	• generally described as ement' between two agencies or governments • terms are n usually legally enforceable • very similar to oU, however, in some countries a MoU (as translat be taken to mean a legally binding agreement

Current international agreements

The details of the MRAs nd Us with leading international regulatory agencies are available on the TGA website. As a March 2011, there are agreements in place with:

- Canada
- Euro
- Singapo
- ze and
- e United States of America (USA)

e 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 into 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 6. 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 29 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

Agreement	Key features
	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 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 as a result, will prevent duplicate assessments of 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>.

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 02 6232 8444 Fax: 02 6232 8605
www.tga.gov.au

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