



Australian Government

Department of Health and Ageing  
Therapeutic Goods Administration

# Australian regulatory guidelines for medical devices (ARGMD) Part 2—Pre-market

Version 1.1, May 2011

**TGA** Health Safety  
Regulation



## About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- 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.

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## Version history

Version	Description of change	Effective date
V1.0	Initial publication	28/04/10
V1.1	<ul style="list-style-type: none"> <li>Updated references and contact details to reflect TGA's new organisational structure post TGA21</li> <li>Made multiple amendments and additions in Section 3. Essential Principles, Principle 14—Clinical Evidence.</li> <li>Made multiple amendments in Section 22. Post-market vigilance and monitoring requirements.</li> <li>Added a fourth part titled 'Navigation and Reference' that includes: <ul style="list-style-type: none"> <li>a bibliography</li> <li>consolidated contact details</li> <li>an index</li> <li>a glossary of terms</li> </ul> </li> <li>Made various punctuation and grammar amendments</li> <li>Reformatted for compliance with a new TGA style manual</li> </ul>	04/05/11

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## Part 2–Pre-market

Historical document

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# Section 10. Including medical devices in the ARTG

## Overview

The ARTG is a register of therapeutic goods accepted for importation into, supply for use in, or exportation from Australia. The ARTG can be viewed from the TGA eBusiness Services (eBS) at <<http://www.ebs.tga.gov.au>>

Medical devices cannot generally be imported, supplied in, or exported from Australia unless they are included in the ARTG.

Only an Australian sponsor can apply to include a medical device in the ARTG. For more information please see [Section 7. What a sponsor needs to know about conformity assessment](#)

The exceptions to this requirement are devices that are supplied through one of the four mechanisms for supplying medical devices in Australia not included in the ARTG:

- clinical trials in Australia
- authorised prescribers
- Special Access Scheme
- personal importation
- custom-made medical devices

For more information on the first four mechanisms, please see [Section 20. Access to unapproved medical devices in Australia](#).

For more information on custom-made medical devices, please see [Section 18. Custom-made medical devices](#).

A sponsor can apply to include a medical device in the ARTG if:

- the device complies with the Essential Principles
- appropriate conformity assessment procedures have been applied to the device

There are also other requirements that must be complied with that are outlined in this section.

All inclusions in the ARTG are subject to automatic conditions and further conditions may be imposed by the TGA where it is appropriate.

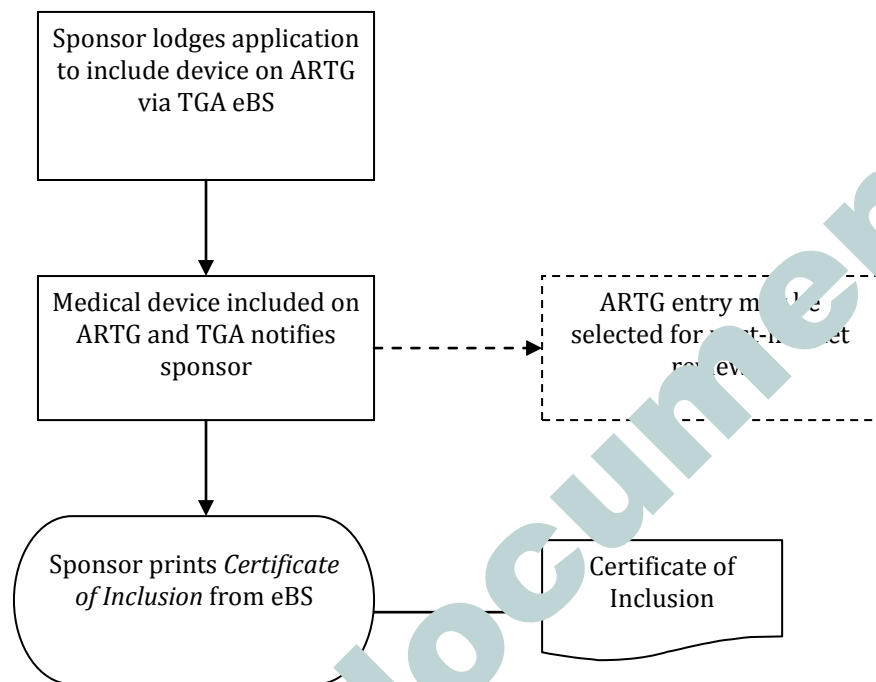
There are three slightly different processes for including medical devices in the ARTG. There are processes for:

- Class I medical devices
- Export-only medical devices
- Medical devices other than Class I.

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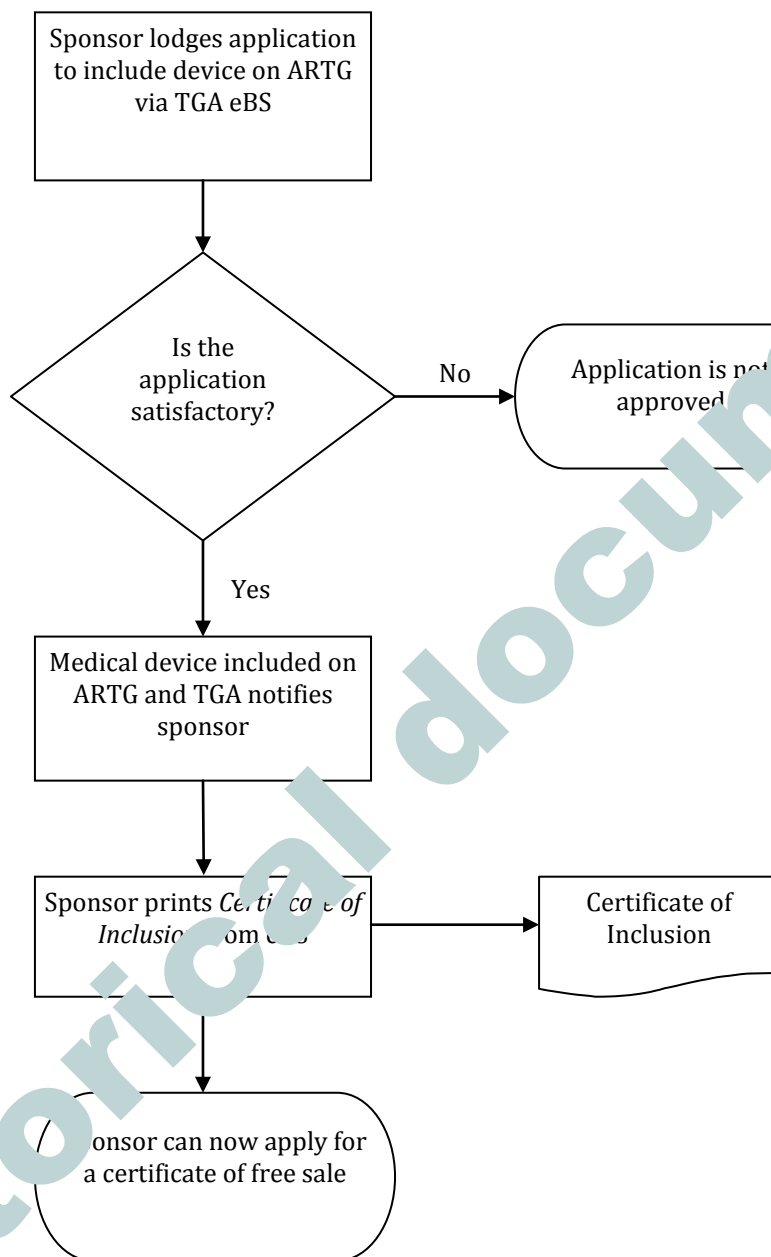
## Process for including Class I devices in the ARTG

The following flowchart summarises the process for including Class I medical devices in the ARTG. For Class I measuring and Class I devices that are supplied sterile sponsors should refer to Medical devices other than Class I for supply in Australia.



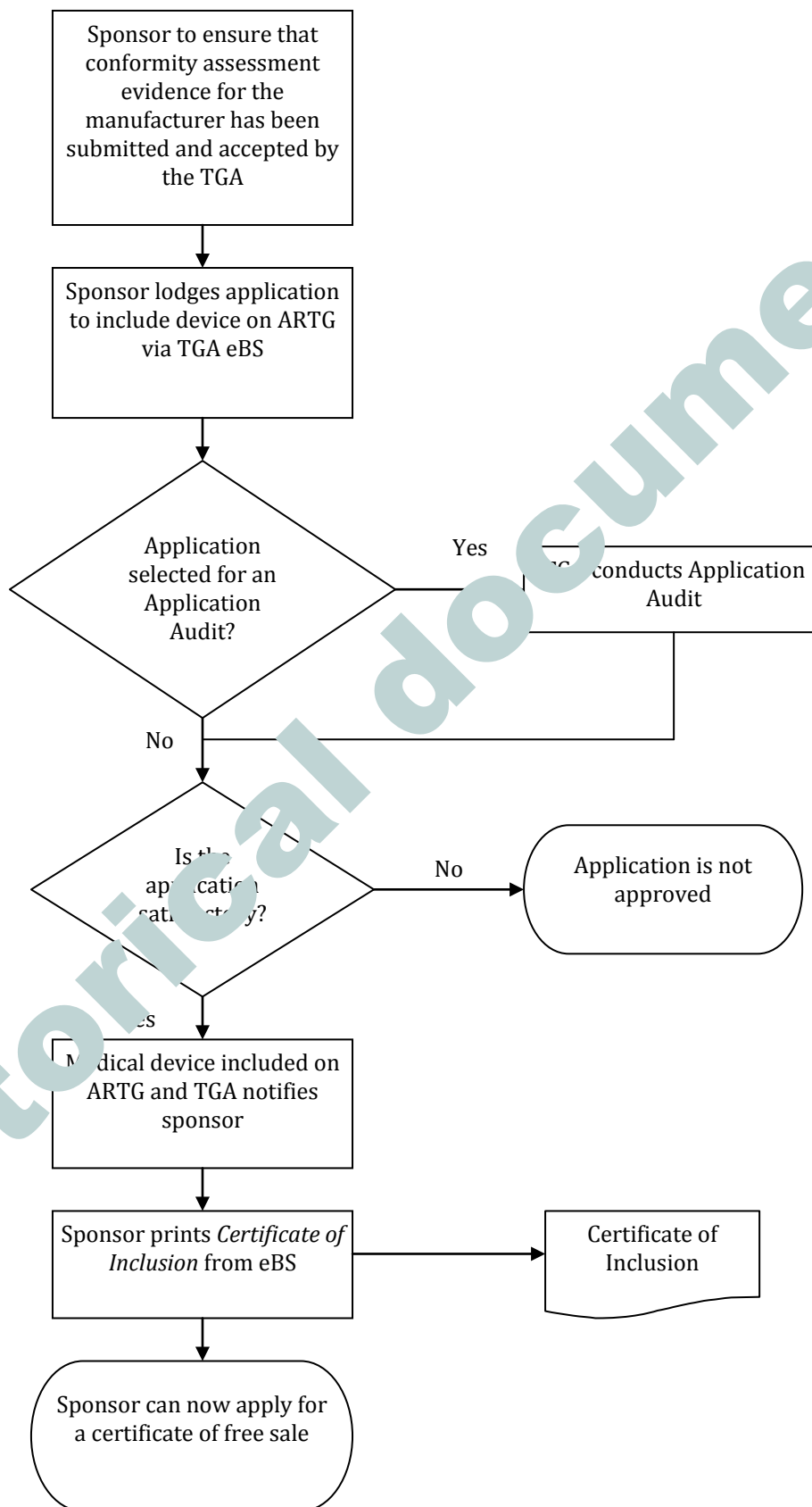
## Process for including export-only devices in the ARTG

Export only medical devices are either manufactured in Australia for export only or are imported into Australia for export only. Export only medical devices are not supplied to users in Australia. The following flowchart summarises the process for including an export only medical device in the ARTG:



## Process for including medical devices (other than Class I) in the ARTG

The following flowchart summarises the process for including a medical device that is to be supplied in Australia, other than Class I devices, in the ARTG:



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## Applications for inclusion in the ARTG

The Australian sponsor must lodge an application to include the devices in the ARTG using the eBS.

Manufacturers of Class I devices must apply a conformity assessment procedure and prepare an Australian Declaration of Conformity, however, it does not need to be submitted to the TGA prior to submitting a device application. However, once included on the ARTG, the sponsor must provide the evidence to the TGA upon request.

Manufacturer's Evidence is required for all other classifications of medical device. Before lodging an application, sponsors must submit and receive notification that the conformity assessment evidence has been accepted by the TGA. For more information on how to do this, please see [Section 7. What a sponsor needs to know about conformity assessment](#).

In order to lodge an application, the sponsor must in accordance with section 41FC of the Act:

- complete the appropriate application form
- submit the completed application to the TGA
- pay the prescribed application fee
- ensure that if conformity assessment evidence is required for the device that appropriate evidence has been obtained
- ensure that the application does not contain information that is false or misleading

When lodging an application, the sponsor must certify in accordance with section 41FD of the Act that:

- the devices are medical devices
- the devices are intended for a specified purpose
- the devices are correctly classified according to the medical device classifications
- the devices comply with the Essential Principles
- they have:
  - available sufficient information to substantiate compliance with the Essential Principles or
  - procedures in place, including a written agreement with the manufacturer of the devices to ensure that this information can be obtained from the manufacturer within the period required by the TGA
- an appropriate conformity assessment procedure has been applied to the devices
- they have:
  - available sufficient information to substantiate the application of those conformity assessment procedures or
  - procedures in place, including a written agreement with the manufacturer of the device/ to ensure that this information can be obtained from the manufacturer within the period required by the TGA
- the devices comply with every requirement (if any) relating to advertising
- the devices do not contain substances that are prohibited imports for the purposes of the *Customs Act 1901*
- the information included in or with the application is complete and correct

Successful Class I (non measuring, non-sterile) applications, lodged in eBS will result in an 'automatic' inclusion in the ARTG. This means that there will not be any further assessment of the application by the TGA prior to the device being included in the ARTG.

However, all other applications may be selected for an application audit, which involves checking some or all aspects of the application and certifications.

Section 41FH of the *Therapeutic Goods Act 1989* (the Act) specifies that:

- applications to include certain higher risk medical devices in the ARTG must be selected for an application audit and an assessment fee will be charged. However, if the conformity assessment evidence is:
  - a TGA Conformity Assessment Certificate
  - for Class III devices—a certificate of conformity issued under the Australia – European Community or Australia – European Free Trade Association Mutual Recognition Agreement (MRA)
  - an audit will not be conducted as the necessary assessments are considered to have already been conducted
- the TGA may select any other applications for inclusion to undergo an application audit. An application audit assessment fee will not be charged for these audits.

For more information on Application Audits, see [Section 11. Application audits of medical device applications](#).

If	then	and
an application to include a device in the ARTG is successful	the TGA will notify the sponsor that the application has been successful	the sponsor can provide a Certificate of Incorporation on eBS.
an application to include a device in the ARTG is not successful	the TGA will notify the sponsor in writing that the application has not been successful	the sponsor should ensure that they have addressed any deficiencies in the information provided to the TGA before they re-apply.

## Kinds of medical devices

An inclusion in the ARTG is for a kind of medical device. This means that an entry in the ARTG may cover a range of products that are of the same kind rather than individual devices.

From the *Therapeutic Goods Act 1989*...

41BE

1. For the purposes of this Chapter, a medical device is taken to be of the same kind as another medical device if they:
  - a. have the same sponsor; and
  - b. have the same manufacturer; and
  - c. have the same device nomenclature system code (see subsection (3)); and
  - d. have the same medical device classification; and
  - e. are the same in relation to such other characteristics as the Regulations prescribe, either generally or in relation to medical devices of the kind in question.





1.6 Kinds of medical devices — other common characteristics

For paragraph 41BE (1) (e) of the Act, in relation to a Class III medical device, or Class AIMD medical device, a characteristic is the unique product identifier given to the device by its manufacturer to identify the device and any variants.

In the case of Class I, Class I sterile, Class I measuring, Class IIa, and Class IIb medical devices, one medical device is considered to be of the 'same kind' as another medical device, if both devices:

- have the same manufacturer and
- have the same sponsor and
- are the same classification and
- have the same GMDN code

Provided these criteria are met, a single entry in the ARTG may encompass multiple devices. There is no record kept in the ARTG of the product family name, model numbers, or catalogue number for these classes of device.

For Class III and Class AIMD medical devices a further requirement is added to the definition of same kind of medical device—they must have the same Unique Product Identifier (UPI).

An example of a *kind of medical device* is described below:

Manufacturer 'Acacia Pty Ltd' manufactures nylon sutures intended for general purpose wound closure applications. The sutures come in a variety of different colours, lengths, and thickness. The manufacturer has classified them as Class IIb medical devices.

Sponsor 'Waratah Pty Ltd' wishes to import the full range of sutures and supply them in Australia. Before the sponsor imports the sutures they obtain the manufacturer's Australian Declaration of Conformity and discover that they are classified as Class IIb medical devices, and categorised using GMDN code '13905 Suture, nylon'. The range of nylon sutures therefore have:

- the same manufacturer (Acacia Pty Ltd)
- the same classification (Class IIb)
- the same GMDN code (13905 Suture, nylon)

Because the difference in suture colour, length, and thickness do not result in a change to any of the above parameters, there is no need to have multiple ARTG entries, even though the sutures may have different trade names (for example, 'Acacia Blue Sutures', 'Acacia Red Sutures', etc.). The trade name of the product does not appear on the ARTG, and is not considered part of the definition of a kind of medical device. Therefore, sponsor Waratah Pty Ltd submits an application to the TGA to include the full range of nylon sutures under a single entry on the ARTG.

Sponsor 'Grevillea Pty Ltd' also wishes to supply the same range of nylon sutures in Australia, and they discover that Acacia Pty Ltd already has an ARTG entry for the products. However, because they are not the same sponsor as identified in the existing ARTG entry, they will need to apply to the TGA to have the same range of nylon sutures included on the ARTG under their name before they import the sutures.

This is an example of where different sponsors supply the same products in Australia and, hence, why separate ARTG entries are required to cover the different kinds of medical devices.

## Unique Product Identifiers (UPIs)

As specified in Regulation 1.6, of the *Therapeutic Goods (Medical Devices) Regulations 2002*, the UPI is the combination of words, numbers, symbols, or letters assigned by the manufacturer to uniquely identify the device and any of its variants.

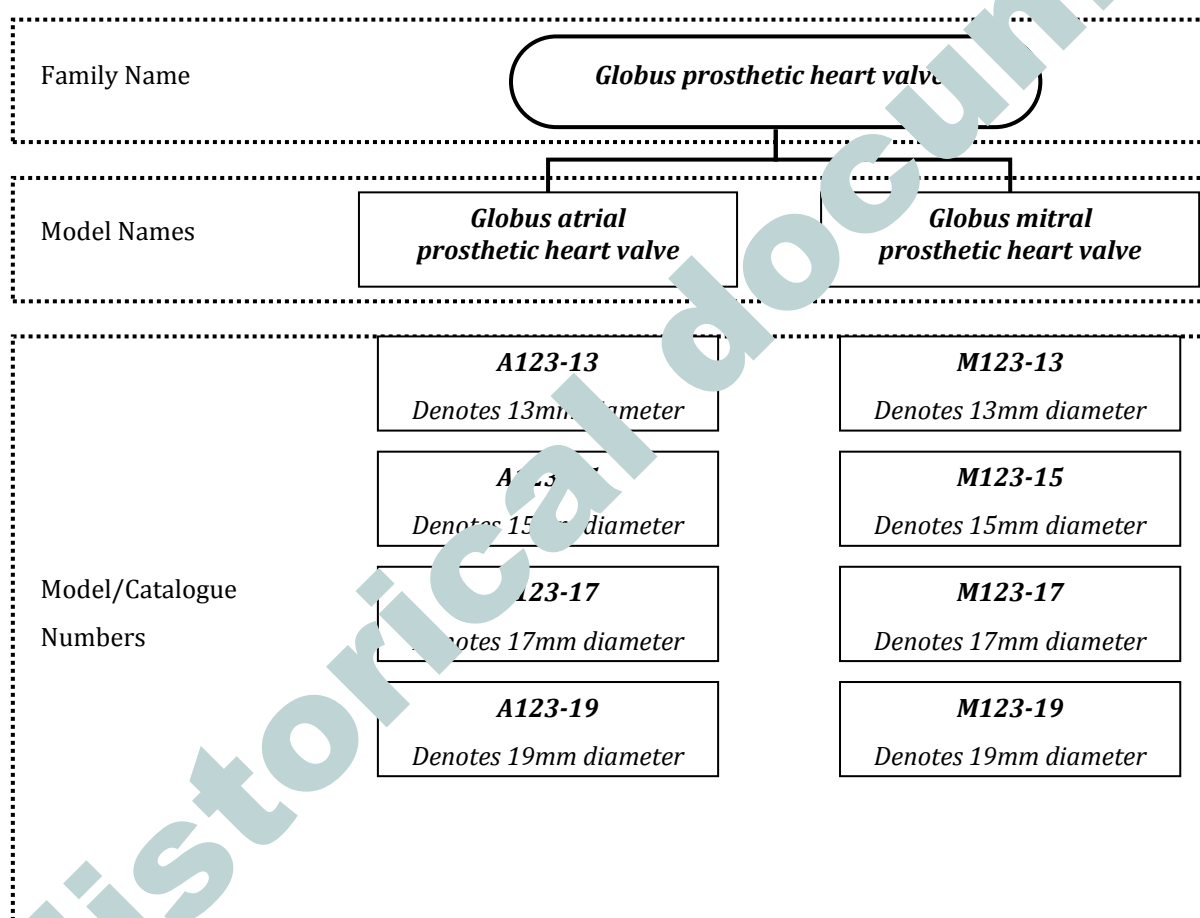
This is generally different to the catalogue or stock unit identifier assigned to the device.

Often, the family name, model names, and model/catalogue numbers will form a hierarchy in identifying the device.

Different manufacturers identify their product lines in different ways such as:

- using family names to identify a range of similar devices
- uniquely identifying each device with a model number
- a combination of both these approaches

For example, a family of prosthetic heart valves may be represented as follows:



In this example, the family name does not uniquely identify all of the device models in the product range. Therefore, the term 'Globus prosthetic heart valves' is not considered a UPI, because it does not distinguish between the different intended purposes of each model in the product range—atrial- versus mitral- valve replacement.

However, the model names:

- Globus atrial prosthetic heart valve
- Globus mitral prosthetic heart valve

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are considered UPIs. This is because the model/catalogue numbers are only variations of the diameter of the device that do not change its intended purpose.

## Global Medical Device Nomenclature (GMDN) Codes

GMDN codes are used by regional or national regulatory bodies to consistently describe medical devices. GMDN codes are used to assist in the:

- consistent assessment of devices before they are approved for supply
- ongoing monitoring of devices once they are available for supply

The GMDN database is a collection of terms that use a unique 5-digit code to describe particular devices. The database is maintained by a not-for-profit company based in the United Kingdom.

International regulatory authorities, including the TGA, liaise with the GMDN Agency to request amendments to existing codes and the creation of new codes. Other GMDN users may also make applications to the GMDN Agency. For more information please see the GMDN Agency website at <http://www.gmdnagency.org>.

When lodging an application to include a device in the ARTG, the sponsor must specify the GMDN code that best describes the devices that they want to include in the ARTG.

The manufacturer is responsible for determining the appropriate GMDN code for a device or range of devices, as manufacturers are best placed to determine the correct GMDN code. Sponsors are urged to seek the advice of the manufacturer and the manufacturer's Declaration of Conformity in order to verify the GMDN code before submitting an application to the TGA.

GMDN codes are available as a look-up table within eBS. Some GMDN codes within the TGA database may differ from GMDN codes in the GMDN Agency database. Sponsors should contact the TGA if there is a discrepancy that requires attention.

*Please note: Where there is no clear GMDN term for a particular medical device, the GMDN term that most closely matches the product should be used by the sponsor for the purposes of including the medical device in the ARTG. This may mean that the GMDN 'description' associated with the GMDN 'term' may not be strictly accurate. To enable sponsors and manufacturers to include medical devices in the ARTG without the need to have new GMDN codes created, the TGA focuses on ensuring that the GMDN term and intended purpose are consistent, rather than the GMDN description. Any discrepancy between the GMDN description and the intended purpose of the device will not affect the validity of the ARTG entry, as the GMDN description does not appear on the ARTG certificate or the ARTG record.*

## GMDN structure

Each GMDN code is linked to a category and term(s). The GMDN structure consists of the following:

Level	Description	Examples												
Device category	<ul style="list-style-type: none"><li>14 categories</li><li>broad break down of the entire medical device market</li></ul>	<ul style="list-style-type: none"><li>dental devices</li><li>single-use devices</li><li>reusable devices</li><li>anaesthetic and respiratory devices</li><li>in vitro diagnostic devices</li></ul>												
Template terms	broad names that group similar preferred terms	forceps												
Preferred terms	represent a type of device that has the same or similar intended purpose or common technology	<ul style="list-style-type: none"><li>forceps bone</li><li>forceps biopsy</li><li>forceps lung</li></ul>												
Synonym and multi-linked synonym terms	From a previous coding system—eBS will default to the appropriate cross-referenced code	<table><thead><tr><th>Code</th><th>Term</th><th>Synonym</th><th>Definition</th></tr></thead><tbody><tr><td>31814</td><td>Forceps, dental dressing</td><td>0</td><td>Hand held dental instrument .....used to grasp a dressing which is being applied orally</td></tr><tr><td>39187</td><td>Forcep dressing dental</td><td>31814</td><td>No definition</td></tr></tbody></table>	Code	Term	Synonym	Definition	31814	Forceps, dental dressing	0	Hand held dental instrument .....used to grasp a dressing which is being applied orally	39187	Forcep dressing dental	31814	No definition
Code	Term	Synonym	Definition											
31814	Forceps, dental dressing	0	Hand held dental instrument .....used to grasp a dressing which is being applied orally											
39187	Forcep dressing dental	31814	No definition											
Device name	UPI—Not specified by the GMDN code database - the manufacturer must provide enough information to enable a specific product to be identified	May include make and/or model number. For more information please see Unique Product Identifiers.												

The data required for each classification is:

	GMDN category	GMDN template term	GMDN preferred term	Device type (UPI)
Example	Reusable devices	scissors	scissors suture	
Class I	√	√	optional	n/a
Class I sterile	√	n/a	√	n/a
Class I measuring				
Class IIa				
Class IIb				
Class III	√	n/a	√	√



---

## Variants for Class III and AIMD devices



From the *Therapeutic Goods (Medical Devices) Regulations 2002 – Dictionary...*

*Variant* means a medical device the design of which has been varied to accommodate different patient anatomical requirements (for example, relating to the shape, size, length, diameter or gauge of the device), or any other variation approved by the Secretary for the purposes of this definition, if the variation does not change the intended purpose of the device.

The regulatory framework for medical devices recognises that many devices are provided in various configurations, or with varying characteristics, such as size and length, while the intended purpose of each device is exactly the same. For example, a cardiovascular stent may be supplied in four different diameters and six different lengths. These variations are only to accommodate differing vessel diameters and occlusion lengths for different patients.

Class III and Class AIMD devices can have one or more variants associated with a single ARTG entry. This minimises the number of entries required in the ARTG, but still provides a sufficient level of identification of the products.

The list of currently allowable variants is available on the TGA website. In addition, the eBS electronic application form provides a drop-down list of variants that the TGA allows, which a sponsor will access when entering an application for a Class III or Class AIMD device.

Examples of the currently allowable variants are:

- Diameter (mm)
- Gauge (cm)
- Shape (of tip)
- Suture, no. of strands
- Volume (mL)

### Adding new allowable variants

The TGA is responsible for considering a number of factors when deciding whether a variant is acceptable for identifying a medical device for the purpose of entry onto the ARTG:

- Are the devices the same classification?
- Do they have the same GMDN codes?
- Are the intended purposes of each of the devices the same?
- Do the devices operate or function in the same way?
- Are the physical design and construction the same or very similar?
- Are the devices made of the same material(s)?
- Are the risk profiles for each of the devices the same?

*Please note: The intended purpose is determined from all sources of information that accompany the device. This includes information on the label, the Instructions for Use, and any other advertising*

*information or product literature for the device. If there is evidence in the accompanying information to suggest that the intended purpose of a device is more specific than what has been nominated in the eBS application, the more specific intended purpose will be used for assessment purposes.*

If a sponsor considers a device to have a characteristic that is not listed in the current allowable variants list, but that fits within the concept and definition of a variant, they are encouraged to contact the TGA via email at [<devices@tga.gov.au>](mailto:devices@tga.gov.au).

The sponsor will need to provide a detailed written rationale supporting inclusion of the variant type in the list of allowable variants, and supporting documentation such as labelling, *Instructions for Use* and advertising material.

Additions to the allowable variants list must be approved by the Delegate to the Secretary before they can be included as an allowable variant in the eBS application form.

## Medical device variant examples

### Globus prosthetic heart valves

Using the example on Page 177 of the heart valve, a separate application for inclusion and subsequent entry in the ARTG would be required for both the Globus atrial prosthetic heart valve and the Globus mitral prosthetic heart valve. This is due to the difference in intended purpose and UPI of the two devices.

However, each of the heart valves is available in multiple diameters. This is an acceptable variant because the diameter of the heart valve is considered an allowable variant. These devices are supplied in differing diameters to accommodate the variation in size of the natural orifice within the heart between different patients. For example, patient A may be physically larger and so might need a larger diameter valve than patient B.

When entering variant details in the eBS application, the variant type would be 'Diameter (mm)', and the variant range would be: 13–19mm

### Angiography Catheter Curve Styles

Angiography catheters are intended to inject contrast media into blood vessels of the cerebral, visceral, or peripheral vasculature for visualisation of the vascular system of a targeted area of the body. Patients undergoing this procedure vary greatly in the size and orientation of their vasculature. Angiography catheters are often supplied in a variety of different 'curve styles' to accommodate for this natural variation between patients.

Common catheter curve styles include:

- Amplatz
- Femoral
- Brachial
- Internal Mammary
- Ventricular Pigtail

For the purposes of this example, the delivery system for each curve style is identical and each curve style of the device has the same intended purpose, which is to inject contrast media for the visualisation of the vascular system. Each device has similar physical construction and is manufactured using the same process.

It is therefore acceptable to consider the 'curve style' of the catheter a variant.

Provided the devices can be covered by the same UPI, and the classification and GMDN code do not change as a result of the curve style, only one entry in the ARTG would be required.

When entering variant details in the eBS application, the variant type would be 'Shape (of tip)', and the variant range would include: Amplatz, Femoral, Brachial, Internal Mammary, and Ventricular Pigtail.

### Catheter Delivery Systems



Cardiovascular catheters are directed to the central circulatory system using a pre-positioned guidewire. As an example, two differing designs can be used to locate the catheter using the guidewire either:

- inserting the catheter over and encasing the entire guidewire within the catheter
- constructing the catheter such that only a relatively small portion of the distal end of the catheter is hollow to encase the guidewire, allowing the catheter to be located at the treatment site within the central circulatory system

The intended purpose of both catheters is the same, however, for each of the catheters there are differences in the:

- construction of the catheters
- some or all of the materials used
- physical construction
- clinical use

As a consequence, the risk profile presented by each of the devices is also different, and separate entries in the ARTG are required for each device.

### Sutures

Sutures generally follow the model of describing different variants of sutures using a family name approach. The intended purpose of all types is to approximate the edges of an incision to assist in healing. They are also provided with:

- varying configurations
- with and without varying types of needles
- in different
  - lengths
  - pack sizes

They may be supplied constructed using either:

- a single filament of suture material – monofilament
- multiple filaments of material – multifilament

Provided the sutures all carry the same family name, and the relevant variants are listed in the eBS application, it is acceptable to have a single ARTG entry to cover all products within the family.

For example:

Unique Product Name: VIOLEXAN sutures

Possible variants:

Variant type	Variant range
Suture gauge	0.7 mm – 4.0 mm
Suture length (cm)	60–90
Suture, colour	undyed, violet
Suture, no. of strands	monofilament, multifilament
Suture, needle, physical attributes	curved, straight, blunt, cutting

Variant type	Variant range
Quantity/pack	1–10 sutures per pack

### Isotope Activity Level

Small implantable seeds of the radioactive isotope Iodine125 are used in brachytherapy procedures to treat cancerous lesions in the body. The seeds are all of a consistent design and construction, but are available in different activity levels. The treating clinician selects the appropriate activity level of the isotope based on factors such as size and location of the lesion, to optimise treatment, while at the same time, minimising exposure to unnecessarily high levels of radiation.

It is appropriate that such a range of activity levels be considered a variant. Therefore, only a single entry in the ARTG is required, with 'Isotope, activity level' nominated as a variant type in the eBS application.

However, should the radioisotope embedded in the seed be different to Iodine125, the construction, design, and possibly the intended purpose of the implant could not be considered the same. A separate entry in the ARTG would be required in this instance.

### Method of Tissue Fixation

Manufacturers of prosthetic heart valves fabricated from porcine or other animal tissue use a fixation process to stabilise and render the tissue non-viable as part of the manufacturing process.

In recent years, a number of changes to the manufacturing techniques and processes have been used to minimise calcification build up on the valve once implanted. Where a change in the process is implemented:

If	and	then
the manufacturer has the change assessed and implemented as part of process refinement	chooses not to change the product name	a new entry in the ARTG is not required.  <i>Please note: the changed manufacturing process must be assessed and accepted by the TGA.</i>
the manufacturer has the change assessed and implemented	adopts a new product name for valves produced using the new process, to differentiate the 'new' product from the 'old'	a new entry in the ARTG is required as the UPI of the device has changed.

## Conditions on inclusion in the ARTG

All inclusion of medical devices in the ARTG are subject to conditions. There are:

- automatic conditions imposed when a device is included in the ARTG
- other conditions that may be imposed by the TGA when a device is included in the ARTG
- conditions imposed after devices are included in the ARTG

## Automatic conditions on inclusion in the ARTG

In accordance with section 41FN of the Act, the following conditions on inclusion apply automatically:

Type of condition	Description
Entry and inspection powers	An authorised person be allowed to: <ul style="list-style-type: none"><li>• enter and carry out inspections of premises where devices are dealt with</li><li>• take samples</li><li>• obtain and copy documents</li></ul>
Delivery for samples	If requested by the TGA, the sponsor will deliver a reasonable number of samples of a device
Availability of information about a device	<p>The TGA may request information at any time while a device is included in the ARTG:</p> <ul style="list-style-type: none"><li>• substantiating compliance with the Essential Principles</li><li>• substantiating that conformity assessment procedures have been applied to the medical device</li><li>• relating to changes to the:<ul style="list-style-type: none"><li>– medical device</li><li>– product range</li><li>– quality management system of the manufacturer of the device.</li></ul></li></ul> <p>The sponsor must have procedures in place, including a written agreement with the manufacturer of the device, to ensure that information required by the Regulations can be obtained from the manufacturer within 20 working days.</p> <p>The sponsor must also report adverse events to the TGA within the mandatory timeframes and assist in their investigation. For more information please see <a href="#">Section 22. Post-market vigilance and monitoring requirements</a></p>
Advertising materials	Advertising material relating to the medical device is consistent with the intended purpose as certified in the application for inclusion in the ARTG.

## Conditions that may be imposed on inclusion in the ARTG

In accordance with section 41FO of the Act, the TGA may impose additional conditions when including the kind of device in the ARTG. These conditions may be imposed to address any specific concerns regarding the manufacture, storage or disposal of products, keeping records and tracking devices, or any other issues relating to quality, safety, and/or performance.

## Conditions imposed after devices are included in the ARTG

In accordance with section 41FP of the Act, the TGA may by written notice to the sponsor:

- impose new conditions on including the kind of device in the ARTG
- vary or remove existing conditions.

If the notice states that the action is necessary to prevent imminent risk of death, serious illness or serious injury, the new conditions or variation of a condition take effect on the day on which the notice is given to the person

In any other case, the new conditions or variation of a condition take effect on the day specified in the notice, not earlier than 20 working days after the notice is given to the sponsor.

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## Certificates of Inclusion

Sponsors will be notified by the TGA if their application for inclusion in the ARTG has been successful. The notification will include instructions for printing the Certificate of Inclusion from eBS.

## Applications for amendments to entries in the ARTG

If a sponsor needs to amend the details of a medical device that is already included in the ARTG, they should access eBS and complete the appropriate form. For more information on changes to entries on the ARTG please see [Section 21. Changes to ARTG Inclusions](#).

Historical document

# Section 11. Application audits of medical device applications

## Overview

The *Therapeutic Goods Act 1989* (the Act) and *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations) specify that:

- applications to include certain medical devices in the ARTG must be selected for an application audit—an application audit assessment fee will be charged
- the TGA may also select any other application for inclusion for an application audit—an audit assessment fee will not be charged for these audits

If an application audit is to be conducted the TGA will write to the sponsor who submitted the application to include the medical device on the ARTG advising:

- that the application has been selected for an application audit
- the documentation that the TGA requires the sponsor to provide
- if applicable, the fee that is payable. The TGA will send a separate invoice formally requesting the payment. The invoice will provide the payment options and the due date for payment

Section 41FI of the Act specifies that there are two aspects of an application that the TGA can consider when conducting an application audit, whether:

- the application complies with the requirements of the Act and the Regulations
- matters that the sponsor has certified in including the application are correct

The TGA has established two levels of application audit, Level 1 and Level 2.

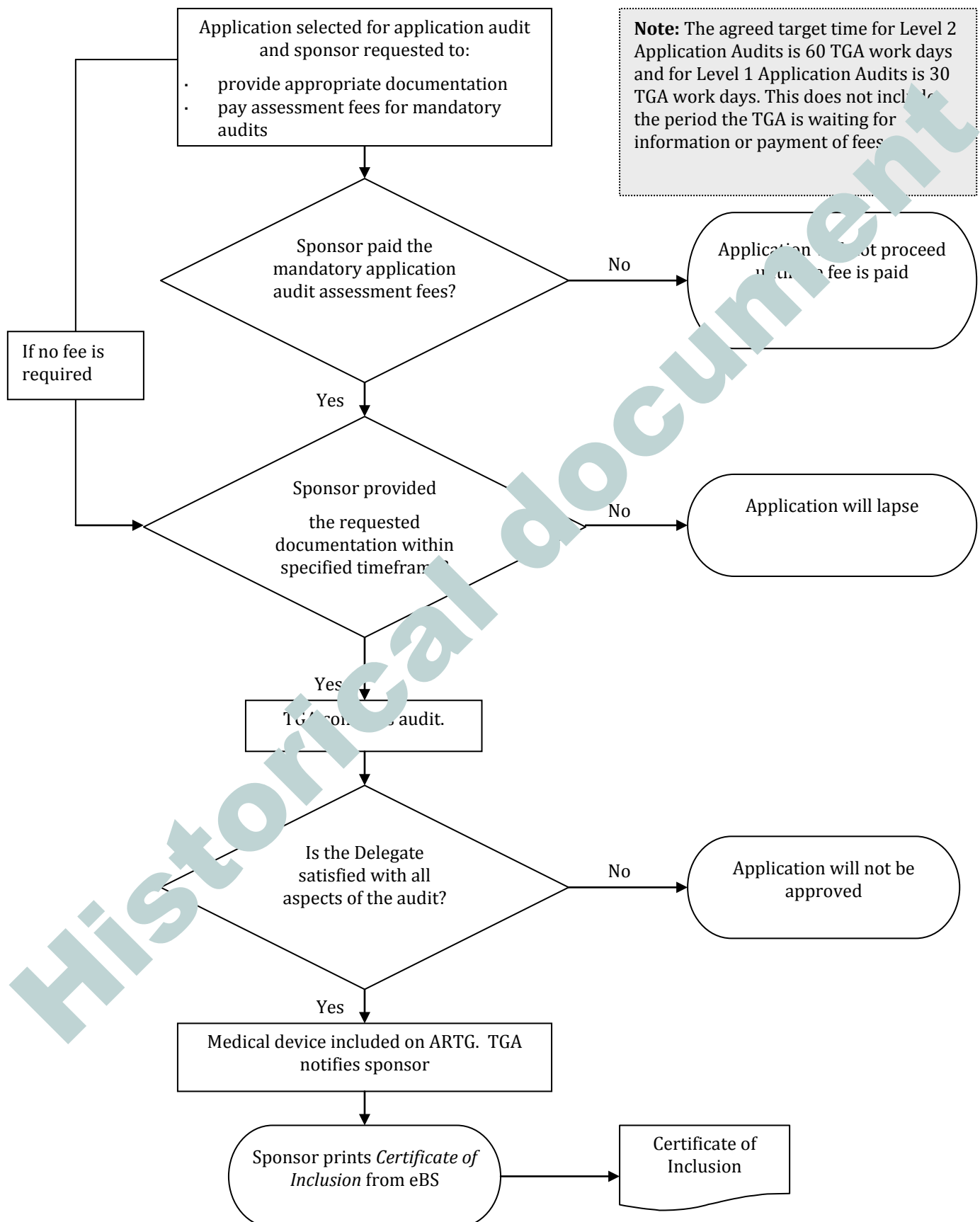
If an application audit is to be conducted the TGA will determine what level of application audit is appropriate for each application. There are different fees for each level of application audit. Details of the fees currently applicable are available on the TGA website at <<http://www.tga.gov.au>>.

The possible outcomes of an application audit are:

If the application audit	then	and
is successful and the sponsor has paid the appropriate fees	the TGA will notify the sponsor that the application for inclusion in the ARTG has been successful	the sponsor can print the Certificate of Inclusion on eBS.
is not successful	the sponsor will need to re-apply to include the device in the ARTG	pay any associated fees again.
is not successful	the TGA will notify the sponsor that the application has not been successful and the reasons for the decision	the sponsor should ensure that any deficiencies in the information provided to the TGA have been addressed before an application to re-apply to include the device in the ARTG is made

## Application audit process

The following flowchart summarises the process for the conduct of an application audit:



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## Applications that must be selected for an application audit

Regulation 5.3 of the Regulations specifies the medical devices that must be selected for an application audit. Where the conformity assessment evidence is a current TGA Conformity Assessment Certificate an application audit is not required.

The following devices will be selected for an application audit:

- a medical device (other than a condom) that is a barrier indicated for contraception or prevention of the transmission of disease in the course of penile penetration during sexual intercourse
- a medical device that is an implantable contraceptive device
- a medical device that is an implantable breast prosthesis containing material of fluid consistency (other than water only or a saline solution only)
- a medical device that is intended by the manufacturer to be used for disinfecting another medical device
- a Class AIMD medical device
- a medical device that is a prosthetic heart valve
- a medical device that is an implantable intra ocular lens
- a medical device that is an intra ocular visco elastic fluid
- a Class III medical device that has not been assessed under the EC Mutual Recognition Agreement or the EFTA Mutual Recognition Agreement
- Class III procedure packs using a declaration of conformity made under clause 7.5 of Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002*

All of these applications will undergo a Level 2 application audit, with the exception of a medical device that is an implantable Poly methyl methacrylate (PMMA) intra ocular lens, which will usually undergo a Level 1 audit.



## Information requested for an application audit

The TGA will write to the sponsor requesting the information that is required to conduct the application audit. The TGA may ask for any documentation relating to the device and/or manufacturer.

### Minimum documentation required for each level of application audit

Level	Documentation required
Level 1	Original or correctly notarised copy of the manufacturer's Australian Declaration of Conformity
	Copy of the latest and current conformity assessment evidence for the medical device and/or manufacturer
	Information about the device, including copies of the: <ul style="list-style-type: none"><li>• label</li><li>• <i>Instructions for Use</i></li><li>• advertising material such as brochures, web pages, advertisements</li></ul>
Level 2	All the documentation listed above for a Level 1 audit
	Risk management report
	Clinical evaluation report
	Efficacy and performance data for medical devices that disinfect including sterilisation of other medical devices

## Documents the sponsor is requested to provide

Document	Description	Legislative reference/guidance	Please note:
Original or correctly notarised copy of the manufacturer's Australian Declaration of Conformity	As part of the conformity assessment procedures, the manufacturer of a medical device is required to make a Declaration of Conformity that declares that the device complies with the Australian legislative requirements.	<ul style="list-style-type: none"> <li>Schedule 3 of the Regulations</li> <li><a href="#">Section 6. What a manufacturer needs to know about conformity assessment</a></li> </ul>	The Declaration of Conformity must be for the Australian requirements. A European declaration of conformity is not acceptable.
Copy of the latest and current conformity assessment evidence for the medical device and/or manufacturer	<p>Conformity assessment evidence is the certificate(s) issued by the TGA or Notified Body that demonstrates:</p> <ul style="list-style-type: none"> <li>a manufacturer has been assessed and has the appropriate systems in place to manufacture the devices</li> <li>the design of the device has been assessed where required by the conformity assessment procedure</li> </ul>	<ul style="list-style-type: none"> <li>Conformity assessment procedure, Schedule 3 of the Regulations</li> <li><a href="#">Section 6. What a manufacturer needs to know about conformity assessment overview</a></li> <li><a href="#">Section 6. What a manufacturer needs to know about conformity assessment</a></li> <li><a href="#">Section 7. What a sponsor needs to know about conformity assessment</a></li> </ul>	<p>Includes:</p> <ul style="list-style-type: none"> <li>quality assurance certificates</li> <li>design examination certificates</li> <li>type examination certificates</li> </ul> <p>that apply to the classification of the medical device.</p> <p>If the manufacturer has applied the conformity assessment procedure for system or procedure packs under Schedule 3, Clause 7.5 of the Regulations, the sponsor may be requested to provide copies of the manufacturer's certification for each Class III or AIMD device in the system or procedure pack.</p> <p>Certificates issued for an ISO standard (such as ISO13485 or ISO9001) or by the US FDA, are not considered to be suitable evidence.</p>

Document	Description	Legislative reference/guidance	Please note:
Information about the device, including copies of the:  label  <i>Instructions for Use</i>  advertising material such as brochures, web pages, advertisements	Information that is supplied with the device or used to promote the use of the device in Australia.	<ul style="list-style-type: none"> <li>Essential Principle 13, Schedule 1 of the Regulations</li> <li><a href="#">Section 12. Information about a medical device</a></li> </ul>	<ul style="list-style-type: none"> <li>all information must be provided in English</li> <li>labelling and <i>Instructions for Use</i> are not necessarily required for every model or variant, unless there are significant differences in content. The copies provided must be representative</li> <li>include a document that lists the addresses where the device is available on the Internet.</li> </ul>
Risk Management Report	The Essential Principles require a manufacturer to conduct a risk analysis to evaluate the known and foreseeable risks of using a device and ensuring that any undesirable side-effects are minimised and acceptable, when weighed against the benefits of the intended performance of the device	<ul style="list-style-type: none"> <li>Essential Principle 14, Schedule 1 of the Regulations</li> <li><a href="#">Section 3. The Essential Principles</a></li> </ul>	The Risk Management Report required by the current accepted version of ISO14971 is acceptable.
Clinical evaluation report	A report that contains a comprehensive analysis of the clinical data relating to the device. The report should be objective and be prepared by an expert in the field relevant to the intended use of the device.	<ul style="list-style-type: none"> <li>Essential Principle 14, Schedule 1 of the Regulations</li> <li>Part 8, Schedule 3 of the Regulations</li> <li><a href="#">Section 3. The Essential Principles</a></li> </ul>	Evidence to support the clinical competence of the author must be provided, such as a short curriculum vitae
Efficacy and performance data for medical devices intended by the manufacturer to be used for disinfecting including sterilisation	Data that provides evidence that the devices meet relevant efficacy and performance requirements	<ul style="list-style-type: none"> <li>Essential Principles, Schedule 1 of the Regulations</li> <li><a href="#">Section 3. The</a></li> </ul>	TGO 54 <i>Therapeutic Goods Order No. 54—Standard for Disinfectants and Sterilants</i> is a standard that may be used to demonstrate compliance with the relevant Essential Principles but it is not a mandatory standard

Document	Description	Legislative reference/guidance	Please note:
another medical device (for example, instrument grade disinfectants, bench top sterilisers)		<a href="#">Essential Principles</a>	

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## General requirements for the information to be supplied

The TGA requires all the requested information to be provided as a complete stand-alone submission. Cross-referencing to information submitted in support of previous applications that are already included in the ARTG or are still being processed is not acceptable.

One hard copy of the documentation is required.

When compiling the application it is recommended that:

- The supporting information is supplied in loose-leaf binders. Plastic sleeves or stapled material should not be submitted
- The information is sectioned for ease of reference, and a table of contents provided that details the content of the binder(s)
- There is appropriately named tab identifiers. For example, the Labelling information should be separated from the other documents by a tab identifier named Labelling Information
- Standard A4 paper is used for all submissions. Text and tables should be prepared using margins that allow the document to be printed on A4 paper. The left hand margin should be sufficiently large so that information is not obscured through binding
- Font sizes for text and tables are of a style and size that are large enough to be easily legible, even after photocopying or when provided electronically.
- Information supporting an application is in English and legible. Where material is not originally in English a full translation must be submitted, the accuracy of which is the responsibility of the sponsor
- Metric units are used. Units generally accepted in clinical practice may also be used (e.g. mmHg)
- All text and drawings are legible and drawings are clearly labelled

## Timeframe for the provision of information

The Act and Regulations require that the sponsor either hold documentation to substantiate compliance with the Essential Principles, or have in place procedures to obtain that documentation from the manufacturer within 20 work days. The sponsor is required to certify that they have procedures in place to address these requirements when they submit the application to include a medical device in the ARTG.

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## Where to send the information:

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

## What does an application audit involve?

Section 41FI of the Act specifies that there are two aspects of an application that the TGA will consider when conducting an application audit, whether:

- the application complies with the requirements of the Act and the Regulations
- matters that the sponsor has certified in submitting the application are correct.

Examples of what the TGA will consider when conducting an application audit are:

- Is the product a medical device as defined by section 41BD of the Act?
- Are the variant and Unique Product Identifier (UPI) details valid in the device application?
- Is the GMDN term in the device application appropriate for the device?
- Based on the manufacturer's intended purpose, the details in the application form, and the information provided by the sponsor, has the device been correctly classified in the Australian Declaration of Conformity and the device application?
- Is there any evidence of non-compliance with any of the Essential Principles in Schedule 1 of the Regulations?
- Is the manufacturer's Australian Declaration of Conformity in compliance with the requirements of Schedule 3 of the Regulations, and is it provided as an original or properly notarised copy?
- Is the conformity assessment procedure appropriate for the classification of the device?
- Has representative labelling and *Instructions for Use* been provided, and do they demonstrate compliance with Essential Principle 3?
- Has a risk management report been submitted and is it applicable to the medical device?
- Does the submitted clinical data meet the requirements of:
  - Essential Principle 14, Schedule 1 of the Regulations
  - Part 3, Schedule 3 of the Regulations?

During an application audit the TGA will not undertake any assessment or activity that would normally be performed as part of a conformity assessment procedure.

If there are any deficiencies identified during the application audit, the TGA may request the sponsor to provide information within the specified period to address the deficiencies prior to making a final decision.

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## When does an application selected for an application audit lapse?

In accordance with section 41FK of the Act, an application that has been selected for an application audit will lapse if:

- the sponsor does not provide the information requested by the TGA
- the sponsor does not provide a reasonable number of samples of the device, if they have been requested
- the information provided by the sponsor in support of an application is false or misleading
- the sponsor fails to pay the application audit assessment fee after being notified of the decision

## Application audit assessment fees

An assessment fee is payable for each application audit that is required by the therapeutic goods legislation. For more information on the devices that are required to have an application audit please see [section 41FK of the Act](#).



[Applications that must be selected for an application](#) audit. Fees are not payable for other application audits that the TGA conducts.

There are different fees for Level 1 and Level 2 application audits. Details of the fees currently applicable are available on the TGA website at <<http://www.tga.gov.au>>.

Level 2 application audit assessment fees can be reduced where a sponsor has more than one medical device application able to be grouped with other similar device applications (within the TGA called 'a submission'). The below rules must be followed by applicants to ensure reduced fees are applied. If these rules are not followed by default, the TGA will undertake assessment of an application at the full prescribed fee.

Applications will be eligible to be considered for a reduced assessment fee if:

- All the effective applications for inclusion are received on the same day (that is, the application fees are paid on the same day)
- All the applications are for the same medical device classification (that is, all Class III or all Class II (MID))
- A written request from the sponsor for reduced fees is electronically attached to each of the applications by the applicant. In particular, the written request must include:
  - A reference to each of the relevant application ID numbers to be considered for abridged assessment fees.
  - A statement from the sponsor that the standard supporting information package normally required for application audits is entirely common for all of the applications and will allow an abridged assessment to be performed (except for labelling, instructions for use, or promotional material).
- The Manufacturer's Evidence used to support each of the device applications must be the same (that is, the devices in each application must be covered by the same CE Quality Assurance certificate and the same Design or Type Examination certificate).
- Applications are selected for a mandatory pre-market application audit as per section 41FH of the Act, and Regulation 5.3 of the *Medical Devices Regulations 2001*.

If all of the above conditions have been met, then:

- A full scheduled Level 2 application audit assessment fee will apply to the first application in the group.
- A reduced assessment fee equivalent to 30% of the scheduled Level 2 audit assessment fee will be recommended to the Secretary for each of the other applications in the same group.
- Based on the information in each of the applications, and the written request for reduced fees from the sponsor, the delegate of the Secretary under Regulation 9.7 will make a decision whether to reduce the amount of the assessment fees.
- The sponsor will be notified of the outcome of this decision at the time the supporting information is requested for the application audit. A statement of reasons shall be provided where the decision is not to reduce the assessment fees.
- An invoice for the total assessment fees to be paid shall be issued to the sponsor under separate cover.

*Please note: Application audit assessment fees will not be reduced on the basis of similarity to effective applications received on a different day, or medical devices already included on the ARTG.*

*The amount of the reduced assessment fee is not negotiable*

For more information on fees and charges please see [Section 2. Fees and charges for medical devices](#).

# Section 12. Information about a medical device

## Overview

Users of medical devices must be provided with information about the medical device. Users of medical devices could be considered to be:

- an institution such as a hospital (and its employees)
- a healthcare professional in private practice
- a member of the public
- the patient or carer

It should be noted that for many devices there may be more than one user, depending on circumstances. For example, when used in the hospital setting a urinary catheter is used by a healthcare professional in the course of treating the patient, but when used at home for self catheterisation the user may be the patient or the patient's carer.

The Australian regulatory requirements for medical devices are specified in the therapeutic goods legislation. In particular, the detailed requirements for information to be provided with medical devices are outlined in:

- Essential Principle 13, Schedule 1, Part 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations)
- the *Therapeutic Goods Advertising Code* (TGAC)

Summary as follows:

Type of information	Description	Legislative reference
Label	Printed information supplied on or with the device or packaging. Where this is not practicable, other appropriate means may be used.  Includes information:  • identifying the: device manufacturer explaining how to use the device safely	Essential Principle 13.1, 13.2, 13.3, Schedule 1, Part 2, of the Regulations
Sponsor Details	Sponsor's name and address provided with the device so that a user of the device can identify the sponsor.	Regulation 10.2 of the Regulations
Instructions for Use	Information that must be provided with a device unless the device:	Essential Principle 13.1, 13.2, 13.4, Schedule 1, Part 2, of the Regulations

Type of information	Description	Legislative reference
	<ul style="list-style-type: none"> <li>is Class I or Class IIa and</li> <li>can be used safely for the manufacturer 's intended purpose without instructions.</li> <li>Appropriate electronic media may be used instead of printed information.</li> </ul>	
Advertising	<ul style="list-style-type: none"> <li>any: <ul style="list-style-type: none"> <li>statement</li> <li>pictorial representation</li> <li>design</li> </ul> </li> <li>however made, that is intended whether directly or indirectly to promote the use or supply of a medical device</li> <li>promotional samples</li> <li>promotional seminars demonstrations and displays</li> </ul>	<p>Divisions 3 and 4, and 5.1 of the <i>Therapeutic Goods Act 1989</i> (the Act)</p> <p>Part 2 of the <i>Therapeutic Goods Regulations 1990</i></p> <p>Section 58(5) of the Act</p> <p>GAC</p>

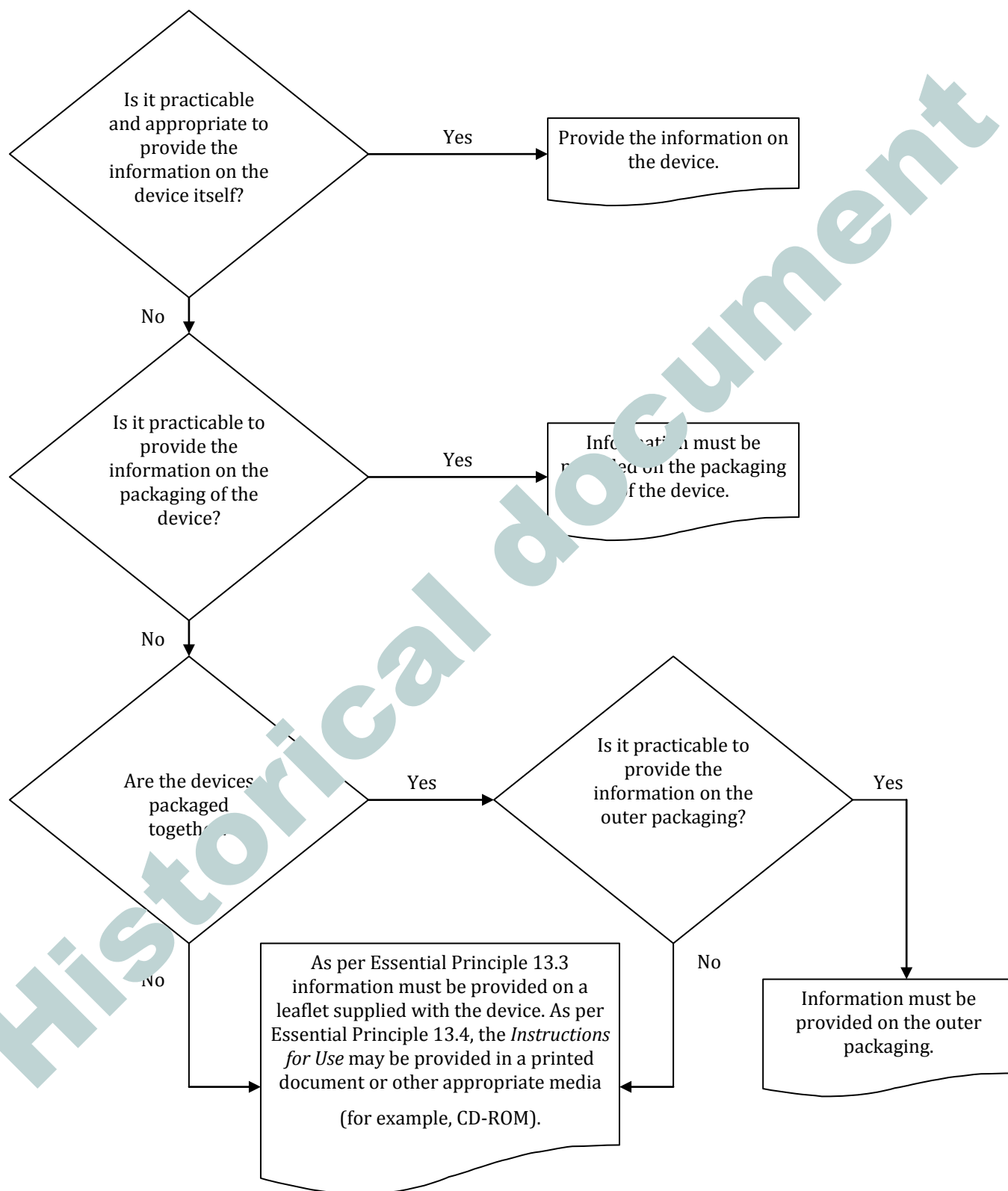
*Please note: Electronic media such as information on websites and CDs may also be used to provide information about medical devices. Where a manufacturer chooses to use a media other than the printed form, they must also be able to supply the information in printed form if requested by the user.*

*Providing the instructions for use through a website identified on the product labelling only, is not sufficient to comply with Essential Principle 12.*

*These forms of media must comply with the requirements for printed materials.*

## Location of information

In recognition of the large range of medical devices and the variations in physical size, Essential Principle 13.2, Schedule 1, Part 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002* outlines where the information must be located:



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This flexibility allows a manufacturer to vary the location of where the information is provided to accommodate the physical and other constraints of the device.

Where label space is limited, a manufacturer may choose to put some of the information on the individual packaging for the device. This information should include information to enable a user to identify the device and any critical warning statements. Other information such as the storage conditions and *Instructions for Use* may be provided on the outer carton in which multiple devices are supplied.

For example, it is not practical to include information on a suture, a hypodermic needle or winged infusion set. In such circumstances the required information would usually be contained on the individual packaging of each device.

It is expected that where there is sufficient surface area on a piece of equipment that all the information could be incorporated on the device. Examples of these devices are an infusion pump, cardiac monitor or x-ray machine. This information may be repeated on the packaging, leaflet and/or *Instructions for Use*.

### Size of Text

In accordance with Essential Principles 13.1(5) and 13.1, Schedule 1, Part 2 of the Regulations, any:

- number
- letter
- symbol
- letter or number in a symbol

used in the information must be legible and at least one millimetre high.

### Language

In accordance with Essential Principle 13.1(3), Schedule 1, Part 2 of the Regulations, the information provided with the device and the *Instructions for Use* must be in English. To assist in the use of 'international' labelling by manufacturers, the information may also be provided in any other language.

### Use of Symbols

Essential Principle 13.1, Schedule 1, Part 2 of the Regulations outlines the general requirements for information to be provided with medical devices. Many manufacturers use symbols on labelling to convey information about the device. The most commonly used symbols are defined in the international standard ISO 15223-1:2007—Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied—Part 1: General requirements. This standard identifies requirements for the development and use of symbols that may be used to convey information for the safe and effective use of medical devices. It also lists symbols applicable to a broad spectrum of devices that satisfy the requirements of the standard. These symbols may be used on the device itself, the package or in the associated documentation.

Manufacturers should note that to date this standard has not been adopted by the TGA in a Medical Device Standards Order. Accordingly, the meaning of all symbols or colour coding used in labelling or *Instructions for Use* must be explained in the information provided with the device.

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## Labelling

A medical device label is important as it communicates information including:

- identification of the
  - device
  - manufacturer of the device
- information explaining how to use the device safely

The Australian medical device labelling requirements adopt the Global Harmonisation Task Force (GHTF) principles for labelling practices.

The requirements adopt a risk based approach to the content and level of detail that must be provided on a label. In general the level of information required increases with the classification of a medical device. More complex and higher risk devices require more information to be provided to facilitate the safe use of the device.

The Australian labelling requirements are specified in Essential Principle 13.1, 13.2 and 13.3 of the regulations. Essential Principle 13.3 details the particular requirements for information to be provided with medical devices.

### Information to be provided with medical devices—particular requirements



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

- 13.3      **Information to be provided with medical devices — particular requirements**
- The information mentioned in the following table must be provided with a medical device.

### Contact details to be provided with a medical device

Both the manufacturer's and Australian sponsor's name and addresses must be provided with a medical device. The address is interpreted by the TGA to be the physical location with sufficient detail to enable the physical location of the manufacturer and sponsor to be determined by the end user of the device. A post office box address alone is not sufficient. Internet and email addresses are not considered to be physical locations.

Regulation 10.2 of the *Therapeutic Goods (Medical Devices) Regulations*; implemented on 4 October 2007 requires the name and address of the sponsor of a medical device to be provided in a manner that allows the sponsor to be readily identified by a user of the device. This is so that users of the device have a person in Australia who they can contact with any queries or problems with the device.

As required by Essential Principle 13.2 the contact details must be provided on the device itself, unless it is not practicable to do so. The sponsor's name and address may only be included in a leaflet supplied with the device if it is not practicable for those details to be provided on the device or on the device's packaging.

For more information, please see [Location of information](#).

*For example: 'Not practicable' does not include reasons of increased cost associated with providing the sponsor's details with the device. Reasons that would be considered genuinely not practicable include, but are not limited to:*

- *too small to be able to provide the sponsor's details on the device itself*
- *in a sterile pouch and cannot be opened to place the sponsor's details on the device or in the pouch*

The sponsor must determine how compliance will be achieved, but common examples are the:

- manufacturer incorporating the name of the sponsor in labelling provided with the device
- sponsor applying a label to the device, such as with large devices like diagnostic imaging devices, monitoring and diagnostic electro-medical equipment and infusion therapy equipment
- sponsor applying a label to the packaging of the device, or devices when packed in multiples, or the *Instructions for Use* for the device
- sponsor providing a supplementary leaflet with the device

If the sponsor arranges for a label to be attached to the device with their contact details, the label must not in any way adulterate the device or obscure the information provided with the device by the manufacturer.

## Examples relating to sponsor contact details supplied on medical devices

### Devices that are pre-packaged

For devices that are supplied pre-packaged from the manufacturer, there should be adequate space to affix the sponsor's details to the device package or outer packaging.

### Devices supplied to consumers

Devices supplied to consumers must have the sponsor's contact details on or with the device in the following descending order:

- on the device itself, or if that is not practicable, then
- on the product label, or if this is not practicable, then
- on the packaging of the devices, or if this is not practicable, then
- on the outer packaging, or if this is not practicable, then
- on the leaflet or *instructions for use* supplied with the device

It would not be considered sufficient to provide the sponsor's details on the invoice for the place of purchase because the consumer of the device would not be able to identify the sponsor.

### Devices supplied without packaging or a label

For devices that are supplied without packaging and require processing prior to use, for example, reusable surgical instruments supplied to a healthcare facility, it may be impracticable to place a label on the device or packaging as no label or packaging exists. In this case a leaflet or invoice supplied with the device could be an appropriate method of supplying the sponsor's details.

## Guidance on how to apply Regulation 10.2 (Information about sponsor)

The following table is intended as a general guide to assist sponsors to meet the requirements of Regulation 10.2

Methods for supplying information about the sponsor must be considered in the following order:	Possible legitimate rationale for not using a particular method:
1. Can the sponsor's name and address be applied to the product without adulterating the device or obscuring information provided by the manufacturer?  If NO, sponsor must consider method 2.	<ul style="list-style-type: none"><li>• the device is too small</li><li>• labels cannot be stuck to the surface of the device due to an unusual shape or material</li><li>• the device is pre-packaged (e.g., a sterile pouch) and cannot be opened prior to use</li><li>• The device has to be processed or sterilised before use and any labelling on the device would be rendered unreadable</li></ul>

Methods for supplying information about the sponsor must be considered in the following order:	Possible legitimate rationale for not using a particular method:
	<ul style="list-style-type: none"> <li>The process of applying a label by the sponsor may compromise the performance of the device</li> </ul>
<p>2. Can the sponsor's name and address be included on the packaging of the device (or the outer packaging of a group of devices) without obscuring information provided by the manufacturer?</p> <p>If NO, sponsor must use method 3.</p>	<ul style="list-style-type: none"> <li>insufficient free space on the packaging</li> <li>the packaging is too small</li> </ul>
<p>3. Can the sponsor's name and address be supplied on a leaflet with the device? A leaflet is taken to be <i>instructions for use</i> or labelling supplied with the device.</p>	<ul style="list-style-type: none"> <li>Instructions are not supplied with the device because the device can be safely used without instructions.</li> </ul>
<p>4. If methods 1, 2 and 3 are not practicable or appropriate, the sponsor's name and address must be supplied on a printed document supplied with the device.</p> <p>A printed document may be in the form of a packaging slip or invoice.</p>	<ul style="list-style-type: none"> <li>This option is only available to the sponsor where they can demonstrate that Method 1, 2 or 3 is not practicable or appropriate</li> <li>For example, this option might be appropriate for a single device that is supplied without any packaging or instructions.</li> </ul>

*Please note: It is the sponsor's responsibility to meet Regulation 10.2*

*The sponsor may instruct another party to include their details on the device on their behalf (e.g. the sponsor may arrange for a distributor of the device to affix a label to the packaging of the device prior to shipment to the user).*

*Affixing the sponsor's contact details to a medical device to comply with Regulation 10.2 does not constitute a step in manufacture, and does not invalidate the manufacturer's certification or the manufacturer's Australian Declaration of Conformity*

*Although the manufacturer may choose to print the Australian sponsor's details on the labelling of the device, it is not a requirement of the manufacturer to do so under the Conformity Assessment Procedures or Regulation 10.2*

*If the sponsor uses method 3 above, the leaflet should be in a form that is physically supplied as close as possible to the medical device itself. For example, a leaflet placed in the box of a device would be considered more appropriate than an invoice supplied to the user independently from the device.*

## Implanted Devices

The user of an implanted device may be considered to be both the:

- recipient of the device—the person who has the device implanted in his or her body
- the health professional that implants the device

Essential Principle 13.4 (19) requires information about any risks associated with implantation of an implantable medical device to be provided with the device. Hence, it is recommended that the following information be provided for devices that are implanted:



Type of device	Information recommended	Examples
All implantable devices	<p>Manufacturers should, wherever practical, provide information to the recipient about:</p> <ul style="list-style-type: none"> <li>the materials the device is made from</li> <li>the model and manufacturer</li> <li>if the device might trigger security screening machines (for example at airports)</li> <li>whether there will be safety issues if a MRI machine is used on the recipient</li> </ul> <p><i>Please note: because of the simple nature of devices such as sutures, staples and tissue adhesive, and the way in that they are dispensed and used, it may not be necessary to provide any form of detailed information to the recipient or patient.</i></p>	<ul style="list-style-type: none"> <li>bone plates</li> <li>bone screws</li> <li>staples</li> <li>tissue adhesives</li> <li>sutures</li> </ul>
Devices with an electronic or mechanical action	In addition to the recommendations for all implantable devices outlined above, manufacturers should provide device restrictions cards or similar documentation to the recipient, providing information about the implant, the manufacturer and the sponsor	<ul style="list-style-type: none"> <li>active implantable medical devices</li> <li>major orthopaedic implants</li> <li>heart valves</li> </ul>
Devices that contain a medicine	<p>In addition to the recommendations for all implantable devices outlined above, manufacturers should provide details of the medicine, in case of:</p> <ul style="list-style-type: none"> <li>hazard alerts</li> <li>adverse drug interactions between drugs in/on the device and other medicines the recipient may be taking or need to take</li> <li>Any contraindications, warnings, restrictions, or precautions that may apply in relation to use of the device</li> </ul>	<ul style="list-style-type: none"> <li>drug-eluting stents and leads</li> </ul>

In accordance with Essential Principle 2(2) the manufacturers and sponsors should undertake a documented benefit/risk assessment where there is a question about the practicalities of supplying the required information to the patient. The assessment should take into account the requirement of Essential Principle 13.1(1) to have regard to the training and knowledge of potential users of the device when preparing the information to be provided with a device. This assessment must be available for review by the TGA if requested.

### Instructions for Use

Essential Principle 13.4 of the Regulations details the Australian requirements for *Instructions for Use*. The Essential Principle is provided below.

*Instructions for Use* are not required or may be abbreviated if the device

- is Class I or Class IIa and
- can be used safely for the manufacturer's intended purpose without instructions

*Instructions for Use* may be provided on the device itself; however, it is generally not practical to include all the required information because of size constraints. The *Instructions for Use* are usually provided:

- 
- where there is sufficient space:
  - if the device is supplied individually on the packaging for the device
  - when multiple devices are packaged together, on the packaging for the devices
  - separately with the device in printed form, or using other appropriate media such as CD, DVD, or other electronic media

*Please note: Where a manufacturer chooses to use a media other than the printed form, such as information on websites and CDs they must also be able to supply the information in printed form if requested by the user. Providing the instructions for use through a website identified on the product labelling only is not sufficient to comply with Essential Principle 13.*

Historical document

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

**13.4 Instructions for use**

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

Item	Information to be provided
1	The manufacturer's name, or trading name, and address
2	The intended purpose of the device, the intended user of the device, and the kind of patient or person to 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 medical 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 contraindications, warnings, restrictions, or precautions that may apply in relation to use of the device
6	Sufficient information to enable a user to identify the device, and, if relevant, the contents of packaging
7	Any particular handling or storage requirements applying to the device
8	If applicable, an indication that the device is intended for a single use only
9	If applicable, an indication that the device has been custom-made for a particular individual and is intended for use only by that individual or health professional
10	If applicable, an indication that the device is intended to be used only for clinical or performance investigations before being supplied <ol style="list-style-type: none"><li>a) if the device is a medical device other than an IVD medical device — the device is intended for pre-market clinical investigation; or</li><li>b) if the device is an IVD medical device — the device is intended for performance evaluation only</li></ol>
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 reuse of the device (including information about cleaning, disinfection, packaging and, if appropriate, resterilisation of the device); and
  - b. an indication of the number of times the device may be safely reused
- 21 For a medical device that is intended by the manufacturer to emit radiation for medical purposes — details of the nature, type, intensity and distribution of the radiation emitted
- 22 Information about precautions that should be taken by a patient and the user if the performance of the device changes
- 23 Information about precautions that should be taken by a patient and the user if it is reasonably foreseeable that use of the device will result in the patient or user being exposed to adverse environmental conditions

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- 24 Adequate information about any medicinal product that the device is designed to administer, including any limitations on the substances that may be administered using the device
- 25 Information about any medicine (including any stable derivative of human blood or blood plasma) that is incorporated, or is intended to be incorporated, into the device as an integral part of the device
- 25A For a medical device, other than an IVD medical device, information about any tissues, tissue derivatives, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin that are included in the device
- 26 Information about precautions that should be taken by patient and the user if there are special or 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 preservation;
  - 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
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# Advertising



From the *Therapeutic Goods Act 1989*...

**advertisement**, in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.

This includes:

- product labels
- pamphlets
- *Instructions for Use*
- promotional samples
- promotional seminars, demonstrations and displays
- advertorials
- advertisements for health services or treatments that identify a medical device

## Regulation of advertising

Advertisements for therapeutic goods, including medical devices, that are directed to consumers are required to comply with:

- Chapter 5 of the Act
- Divisions 3 and 4, Part 2 of the *Therapeutic Goods Regulations 1990*
- *Therapeutic Goods Advertising Code* (TGAC)

The advertising of therapeutic goods, including medical devices, is regulated in Australia under a co-regulatory arrangement and involves:

- the TGA
- the therapeutic goods industry
- healthcare professionals
- consumers
- the advertising industry
- the Australian Competition & Consumer Commission (ACCC),
- the Medicines Division in New Zealand
- the media

The Therapeutic Goods Advertising Code Council (the Code Council) consists of 15 members and 6 observers. The Code Council is the principal body responsible for considering the requirements for advertising and making recommendations to the Minister on advertising issues, including amendments to the advertising requirements in the legislation and the TGAC.

Unlike medicines, advertisements for medical devices do not have to be approved prior to publication or broadcast, however, the advertisements must comply with:

- conditions of inclusion on the ARTG detailed in section 41FN(5) of the Act
- Division 3 and 4, Part 2 of the *Therapeutic Goods Regulations 1990*
- the TGAC

*Please note: It is a condition of inclusion under section 4FN(5) that advertising material relating to medical devices of that kind is consistent with the intended purpose as certified in the device application. The ARTG inclusion and the stated intended purpose for Class I, IIa and IIb medical devices is representative of a kind of device that can cover several different models with varying intended purpose. The intended purpose of each specific model of device is provided in the product label or instructions for use that accompanies the device.*

## Therapeutic Goods Advertising Code (TGAC)

The object of the TGAC is to ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer.

The TGAC is based on a set of principles and when interpreting the code the total presentation and context of the advertisement is taken into consideration.

The TGAC is updated on a regular basis and therefore it is important to ensure that the current version is referred to. A copy of the code can be accessed via the TGACC website at <http://www.tgacc.com.au>.

Section 4 of the TGAC states that advertisements for therapeutic goods must:

- comply with the statute and common law of the Commonwealth, States and Territories
- contain correct and balanced statements only and claim that the sponsor has already verified

The principles for advertising as per Section 4 of the TGAC state that therapeutic goods must not:

- be likely to arouse unwarranted and unrealistic expectations of product effectiveness
- be likely to lead to consumers self-diagnosing or inappropriately treating potentially serious diseases
- mislead, or be likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions
- abuse the trust or exploit the lack of knowledge of consumers or contain language that could bring about fear or distress
- contain any matter that is likely to lead persons to believe:
  - that they are suffering from a serious ailment
  - that harmful consequences may result from the therapeutic good not being used- except for sunscreen preparations if the claims made in the advertisement are consistent with current public health messages
- encourage or be likely to encourage, inappropriate or excessive use
- contain any claim, statement or implication that:
  - it is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure
  - it is effective in all cases of a condition
  - the goods are safe or that their use cannot cause harm or that they have no adverse effects
- be directed to minors, except the goods listed in Appendix 5 of the TGAC. Examples include:
  - condoms and personal lubricants
  - bandages and dressings
  - devices for management of chronic conditions under medical supervision

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## Restricted representations

Restricted representations refer to claims made in relation to serious:

- diseases
- conditions
- ailments
- defects

In the context of advertising therapeutic goods, the term serious means a form of those diseases, conditions, ailments or defects that are generally accepted

- not to be appropriate to be diagnosed and/or treated without consulting a suitably qualified healthcare professional
- to be beyond the ability of the average consumer to evaluate accurately and to treat safely without regular supervision by a qualified healthcare professional.

The complete list of restricted representations are listed in Appendix 6 of the TGAC. Examples include:

- cardiovascular diseases
- dental and periodontal diseases
- diseases of joint, bone, collagen, and rheumatic disease
- diseases of the eye or ear likely to lead to blindness or deafness
- diseases of the liver, biliary system or pancreas
- endocrine diseases and conditions including diabetes and prostate disease
- gastrointestinal diseases or disorders
- haematological diseases
- infectious diseases
- immunological diseases
- mental disturbances
- metabolic disorders
- musculo-skeletal diseases
- nervous system diseases
- poisoning, venomous bites and stings
- renal disease
- respiratory diseases
- skin diseases
- substance dependence
- urogenital diseases and conditions

If a person wants to make reference to a restricted representation in an advertisement directed to consumers, they must first obtain an exemption from this section of the Code.

To obtain an exemption to use a restricted representation in an advertisement directed to consumers for a medical device, including labels, the advertiser must apply to the Head of the Office of Devices Authorisation



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(ODA) of the TGA. The Application for approval to use a restricted representation in advertising form is available from the TGA website. The website also has guidance on submitting an application.

To facilitate the consideration of an application, applicants are encouraged to include:

- a copy of the proposed advertisement or advertising campaign
- product information such as product label and *Instructions for Use* to assist in establishing the manufacturer's intended purpose
- any clinical data or evidence to support the use of the device for the serious disease condition, ailment or defect

The decision to approve or refuse to approve an application is made by the TGA Delegate. The Delegate may, in most cases, seek advice from the Code Council.

The decisions to grant or revoke an exemption are published on the TGA website.

### **Prohibited representations**

Prohibited representations are described in Part 1, Appendix 6 of the TGAC and are prohibited to be used in advertisements directed to consumers and there are no provisions under the legislation to apply for an exemption.

Prohibited representations include any representation relating to abortifacient action or any representation regarding the treatment, cure or prevention of the following:

- neoplastic disease (for example, cancer, tumours, malignancies)
- sexually transmitted diseases (STDs)
- HIV AIDS and/or HCV
- mental illness

The exceptions are claims about the:

- prevention of skin cancer through the use of sunscreens
- devices used in contraception or in the prevention of transmission of disease between persons

These claims are restricted and an exemption must be granted prior to using the representation in an advertisement to consumers.

### **Complaints**

Anyone can lodge a complaint about an advertisement for therapeutic goods and all complaints are treated in confidence. Anonymous complaints are also accepted.

When lodging a complaint, please include where possible:

- a copy of the advertisement
- the name of the publication and the date published (if applicable)
- details of what it is about the advertisement that is unacceptable

Complaints in relation to advertisements for devices appearing in:

- radio
- television
- consumer magazines
- newspapers
- billboards

- 
- cinema
  - the Internet

are considered by the Complaints Resolution Panel.

Complaints about advertisements appearing in these types of media should be submitted on forms available at <<http://www.tgacrp.com.au>>. The forms can be submitted electronically on line or sent to

The Executive Officer  
Complaints Resolution Panel  
PO Box 764  
NORTH SYDNEY NSW 2059

The determinations of the Complaints Resolution Panel are published on their website at <<http://www.tgacrp.com.au/index.cfm?pageID=13>>

The Advertising Unit of the TGA considers complaints about other forms of medical device advertisements (such as labels, leaflets, flyers, and promotional brochures) and recommendations are made to the sponsor.

These complaints should be sent to:

Recalls & Advertising Section  
Office of Product Review  
Therapeutic Goods Administration  
MDP 122  
PO Box 100  
WODEN ACT 2606

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# Section 13. Active medical devices

## Overview

An active medical device is a device that uses and converts energy in a significant way in order to operate. An active device may use any form of energy except for gravitational or direct human energies.

Active devices may run from internal or external power sources.

Some example active devices include:

- pacemakers (electrical energy)
- electric hospital beds (electrical energy)
- gas-powered suction pumps (pressure energy)
- software (electrical energy—software is a controlling agent for an electrical device)
- active warming blankets (electrical and thermal energies)
- X-ray machines (electrical and ionising electromagnetic radiation energies)
- surgical lasers (electrical and electromagnetic radiation energies)
- lung ventilators (electrical and pressure energies)
- ultrasound machines (electrical and acoustic energies)

Devices that are powered by gravity or directly by a human being are not active devices. Examples of these devices include:

- gravity fed intravenous infusion sets
- traction systems
- hand-operated bag/valve mask respirators/resuscitators
- hand-powered drills

Some devices are intended by their manufacturer to transmit energy, a substance, or another element between an active medical device and a human being without any significant change occurring to the element being transmitted. These devices are not active. For example:

- electroencephalograph (EEG) leads (purely passive reduction in electrical signal)
- tubing sets (reduction in transferred pressure along the tubing).

## What is an active medical device?

From the *Therapeutic Goods (Medical Devices) Regulations 2002*...

**active medical device:**

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

Manufacturers of active medical devices must consider all classification rules and must meet all of the relevant Essential Principles. The following Essential Principles and classification rules are specific to active medical devices:

The requirements are outlined in	which is located in the	and
Essential Principle 9.2—Minimisation of risks associated with use of medical devices	Essential Principles, Schedule 1, <i>Therapeutic Goods (Medical Devices) Regulations 2002</i>	outlines requirements for the risk of reciprocal interference involving other devices
Essential Principle 12—Medical devices connected to or equipped with an energy source	Essential Principles, Schedule 1, <i>Therapeutic Goods (Medical Devices) Regulations 2002</i>	outlines requirements for the safety and performance of active devices.
Part 4 Special rules for active medical devices	Classification rules, Schedule 2, <i>Therapeutic Goods (Medical Devices) Regulations 2002</i>	provides information for determining the classification of an active device.
Part 5.7 Special rules relating to active implantable medical devices	Classification rules, Schedule 2, <i>Therapeutic Goods (Medical Devices) Regulations 2002</i>	provides information for determining the classification of active implantable medical devices and associated medical devices.

## Different forms of energy

The following table describes different forms of energy in order to help the reader determine if his or her device is active or not.

Form	Description	Comments	Medical Device Examples
Chemical energy	Stored in batteries, liquids, gases, fuel, etc.		Chemical hot/cold packs
Elastic energy	Energy is stored when something is stretched, squashed, etc.	Includes clockwork-powered devices, spring-powered devices, elastomeric-powered devices, etc.  Although human power is often applied to these devices in order to elastically deform, compress or stretch them, the energy of operation is a transformation of the stored potential energy into kinetic energy.	Spring-loaded syringe drivers Bellows drains
Electric energy	Electrical energy is used to drive the action of the device, for example, turn a motor, emit heat, emit light, or emit electrical signals.	Mainly (230V grid) power and batteries are the primary sources of electrical energy, although there are other methods of generating electric energy.	Blood gas analysers (which measure electric potential relating to concentrations of gases in blood)  Electric devices such as drills  All electronic devices and computers  Software (used to control a computer)
Radioactivity	Stored in the nuclei of atoms where energy is released from the nucleus rather than via the release of the electrons (see Electric energy above).	The decay of isotopes is used for medical imaging and for cancer treatments (radiation oncology).	Radioactive seeds/beads
Magnetic energy	Magnetic potential energy is closely related to electric potential energy (see above). A magnetic field can also impart energy to a	Electric motors operate from magnetic fields interacting with electric currents in order to rotate. An alternator or electric generator	Magnetic Resonance Imaging (MRI) machines use a magnetic field (and also radio waves) to excite particles within

Form	Description	Comments	Medical Device Examples
	particle within it.	works in the reverse: a (motor) generator is externally rotated, resulting in the generation of an electrical current.	biological tissues Electric dentist drills
Electromagnetic radiation	Electromagnetic radiation is a flow of electromagnetic energy waves ranging from very long-wavelength radio waves to microwave, infrared, visible, ultraviolet, and x-rays, through to very short-wavelength gamma rays.	Electromagnetic radiation is microscopic kinetic (movement) energy.	UV phototherapy cabinets (for treating psoriasis); and x-ray imaging and therapy devices
Thermal energy	Thermal (or heat) energy is microscopic movement energy. It is often realised as infrared waves.	Hot water packs and no-wave devices as there is no change in the form of energy.	Electric warming blankets; Respiratory humidifiers Chemical heat packs.
Pressure energy	Pressure is stored as potential energy and is often converted to kinetic (movement energy) via conversion of a high-pressure source to a low pressure one.	The conversion is then from an amount of potential energy to an amount of kinetic energy and a smaller remaining amount of potential energy.	Air turbine- powered dentist drill — a flow of released compressed air (potential pressure energy) pushes on the blades of the turbine (this is a conversion of potential to kinetic energy) and transfers some of this airflow into rotation of the turbine shaft
Sound/Acoustic/ Sonic	Sound or acoustic energy is a form of kinetic energy, realised as sound/pressure waves.	Many of these devices derive their primary power from an electrical source.	Ultrasound imagers; Hearing aids; Ultrasonic nebulisers; Tinnitus maskers; and Lithotripters.

## Electromedical safety standards

Electromedical devices are powered by electricity—mains, battery and low-powered devices. Examples are pacemakers, pulse oximeters, and blood-pressure monitors.

There are potential safety risks to the patient and/or user if the medical device:

- causes the patient and/or user unintended exposure to electrical currents
- interferes with or affects another electromedical device—Electromagnetic Compatibility (EMC).

To ensure that manufacturers of electromedical devices have considered these risks they must demonstrate compliance with:

- Essential Principle 9.2—Minimisation of risks associated with use of medical devices
- Essential Principle 12—Medical devices connected to or equipped with an energy source.

The most common way to demonstrate compliance is to meet a standard published by an Australian or international standards agency, or a similar standard. If the manufacturer chooses to use other voluntary standards they must provide evidence that the chosen standard is applicable to the manufacturer's device and that its application satisfies the requirements of the Regulations. The use of such standards is not mandatory.

Standards that are commonly used to demonstrate compliance include:

Standard	Description
IEC 60601: General requirements for basic safety and essential performance of medical equipment and any applicable sub-parts	Applies to the basic safety and essential performance of all general medical electrical equipment such as defibrillators, electrical beds, ECG machines
AS/NZ 3200.1.0: Medical electrical equipment—General requirements for safety	Australian standard equivalent to the international standard IEC 60601-1
IEC 60601-1-2: Collateral standard for electromagnetic compatibility (EMC) of medical equipment	Specifies general requirements and tests for EMC of medical equipment. Collateral standards serve as the basis for specific standards by applying additional requirements to those prescribed in the associated general standard(s).
AS/NZ 3200.1.2: Collateral standard for electromagnetic compatibility (EMC) of medical equipment	Australian standard equivalent to the international standard IEC 60601-1-2
IEC 61010.1: General requirements for safety of electrical equipment for Measurement, Control, and Laboratory use (e.g., IVD equipment, sterilisers, etc.)	This international standard is applicable for some medical devices that are not in direct contact with patients. Example include bench-top sterilisers and ex vivo tissue-processing equipment

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## Medical devices that connect to the public mains electricity supply

In Australia, the public mains electricity supply is 230 volts, 50 Hz. In accordance with *AS/NZS 3112—Approval and test specification—Plugs and socket-outlets*, electrical equipment must be connected to a mains electricity supply using a plug with active and neutral pins partially insulated and with Australian-specific pin configuration.

In addition, *AS/NZS 3551—Technical management programs for medical devices* requires that a transparent cover should be used if the plugs are re-wireable. For moulded plugs, it is preferable that the plug cover is transparent but this requirement is not mandatory.

## Electromagnetic Compatibility (EMC)

EMC and the influence of the expected environment should be considered when determining the risks associated with the use of a medical device. Environments include domestic, clinical, and critical-care. EMC requirements also apply to battery-powered devices.

The first step in determining compliance with EMC requirements is to perform a thorough risk analysis. Ideally, such an analysis should be undertaken as part of an overall risk management process as defined in ISO 14971. The risk analysis must form the basis for specifying EMC test requirements.

Manufacturers should consider the highest potential-risk environment to determine the amount and type of testing required. The standards provide guidance for the type and amount of testing required. Manufacturers may also need to consider specialised aspects not covered by a standard. It is generally expected that EMC testing be conducted by an accredited test laboratory due to the highly specialised nature of the testing.

The manufacturer should include testing for:

- protection of the public mains network—IEC 60601-1-2, clause 6.1.3 (AS/NZS 3200.1.2 clause 36.201.3). Mains network testing is not applicable to battery-powered devices unless a battery charger forms part of the device
- emissions—IEC 60601-1-2, clause 6.1 (AS/NZS 3200.1.2 clause 36.201)
- immunity—IEC 60601-1-2, clause 6.2 (AS/NZS 3200.1.2 clause 36.202)

Life-supporting equipment used in a clinical environment normally require full compliance with the IEC 60601-1-2 standard, including more stringent requirements imposed by an IEC 60601 part 2 standard, since higher levels of immunity are necessary in order to establish a broader safety margin. For example, the part 2 standard, IEC 60601-2-31, imposes additional EMC requirements for external pacemakers.

Less stringent requirements normally apply to non-life-supporting equipment used in a clinical environment (for example, suction pump). IEC 60601-1-2 makes allowance for waiving immunity testing, provided the manufacturer can justify essential performance via the risk analysis. As per Essential Principle 13.4 of the *Therapeutic Goods (Medical Devices) Regulations 2002*, the *Instructions for Use* for the device must also provide information to allow the user to manage the electromagnetic environment in the clinical setting.

Low-risk devices used exclusively in a non-clinical setting, such as a massager for domestic use, and that are clearly labelled as ‘not for use in a clinical setting’ or ‘for domestic use only’ may not require full compliance with IEC 60601-1-2. EMC compliance may be demonstrated by justifying essential performance via the risk analysis indicated in IEC 60601-1-2. If such an analysis demonstrates that the device does not pose any inherent hazards, either alone or in connection with other equipment, then the following minimum EMC requirements may apply:

- Labelling or *Instructions for Use* that indicate that the device was not tested to clinical EMC requirements
- Evidence to support the Australian Communications and Media Authority (ACMA) EMC C-Tick (however, the C-Tick may not be required on the label).

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<sup>1</sup> These clauses are from the 2007-03 edition of IEC 60601-1-2, and 2005 edition of AS/NZ 3200.1.2.



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Medical devices are exempt from the ACMA EMC C-Tick labelling requirement as they must comply with the more stringent requirements described by the Essential Principles, except for those incorporating radio-communications transmitters (see below).

## Telecommunications and Radio-Communications Transmitters

The Australian Communications and Media Authority (ACMA) is responsible for the regulation of broadcasting, the Internet, radio-communications, and telecommunications. The ACMA administers regulatory systems relating to a device's compliance with:

- Australian telecommunications (A-Tick)
- electromagnetic compatibility requirements and radio-communications standards (C-Tick).

Medical devices with telecommunications ports must comply with ACMA A-Tick requirements, for example, in-home patient-monitoring devices that have modem ports.

Medical devices with radio-communications transmitters must comply with ACMA C-Tick requirements for radio-communications standards, for example, wrist-worn sphygmomanometers that connect to a mobile phone using Bluetooth.

However, electrically-powered medical devices do not require C-Tick marking in relation to electromagnetic compatibility. They must comply with the more stringent requirements described in the Essential Principles.

Active implantable medical devices (AIMDs) that utilise radio communications and the associated external radio transceiver such as an external programmer or data-logger, must also comply with ACMA radio spectrum licensing and C-Tick requirements. The ACMA Radiocommunications Class Licence (Low Interference Potential Devices) 2000 (also known as the LIPD Class Licence) makes specific allowance for some kinds of low-power radio communications for AIMDs, including those using Medical Implant Communications Systems (MICS), under specific conditions.

Further details are available on the ACMA website: <<http://www.acma.gov.au>>.

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## Radioactive medical devices

All medical devices that are radioactive are active medical devices. If radioactive medical devices are implantable they are classified as Class AIMD.

Radioactive medical devices are radioactive products that do not have a pharmacological, immunological, or metabolic action, or that are administered locally rather than systemically, for example:

- brachytherapy spheres are active implantable medical devices. Their primary mode of action is radiation, and the basis for the therapeutic claims for the product are that the radiation affects the tissue irradiated. The mechanism of such action on the tissue is physical in nature. The only way that such an action can take place is via an energy conversion at the tissue interface—the precise nature of the energy conversion may vary from temperature effects to denaturing of cellular molecules, or other physical interaction that leads to tumour cell death.
- in vivo imaging agents (such as barium meals) are regulated in Australia as medicinal products.

The TGA regulates the supply of radioactive medical devices in Australia.

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), and state and territory authorities, regulate the use of radioactive materials. More information is available on the ARPANSA website at <http://www.arpansa.gov.au>. The TGA uses the expertise of ARPANSA when assessing radioactive devices.

## Radiating medical devices

The manufacturers of radiating medical devices must comply with Essential Principle 11. Examples of radiating medical devices include:

- medical lasers
- phototherapy devices
- X-ray machines
- dental curing lamps

Radiating beauty therapy products such as:

- solariums
- laser combs
- dermal abrasion devices (or dermal abrasion products that apply energy to the patient)
- skin rejuvenation devices (or skin rejuvenation products that apply energy to the patient)
- hair removal products that apply energy to the patient
- are not medical devices unless:
  - therapeutic claims are made or
  - the product is:
    - surgically invasive
    - invasive via a body orifice

The TGA regulates the supply of radiating medical devices in Australia.

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), and state and territory authorities regulate the use of radiating medical devices and the use of radiating beauty therapy products on human beings. More information is available on the ARPANSA website at <<http://www.arpansa.gov.au>>. The TGA uses the expertise of ARPANSA when assessing radioactive medical devices.

## Software

Software operates as a controlling agent for an electronic device, e.g., a microcontroller or computer.

Software is regulated in different ways depending on the manufacturer's intended purpose for the software and how it is supplied:

Type of software	How is it regulated?	Examples
Software that is part of a device and is supplied with a medical device	Part of the device	Pacemaker firmware Embedded patient monitoring software
Software or an accessory to a device that is a device in its own right if it is supplied separately from the related device	A separate medical device	Image-processing software for use with an X-ray machine Pacemaker programmer and controller for use on a personal computer or laptop
Software that is used as a diagnostic or therapeutic tool	A separate medical device	One-stop image-processing tool Radiation planning/treatment Software
Upgrades to software supplied separately	A separate medical device	Upgrade to image-processing software to add artificial colouring of images Upgrade to ultrasound equipment to allow 4-dimensional images
Corrections to software errors that have been supplied with a device  Please note: must be a replacement part with no additional functionality. This may be a product correction under the Uniform Recall Procedure or a Therapeutic Goods Recall. More information available from < <a href="http://www.tga.gov.au">http://www.tga.gov.au</a> >.	Not a medical device	Bug fix to stop infusion pump indicating incorrect drug administration values Stability fix to image processing tool to reduce incidence of crashing or freezing
Software used in combination with other equipment for handling general patient-related information	Not a medical device	Patient record management system (admission dates, case notes, contact details) Conversion, compression, and encryption functionality/tool Clinical Information System (CIS) without diagnostic or therapeutic functionality

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The legislation applies to all forms of medical device software including software that is embedded (for example, firmware in hardware) such as:

- field-programmable gate arrays (FPGAs)
- electronic programmable read only memory (EPROM)
- flash memory
- static or dynamic random access memory (RAM)

Software often forms an integral part of an electronic device, for example, in a pacemaker or patient monitor. In these cases, the software is a part of the device and is not considered to be a separate or distinct device.

Software that fits the definition of a medical device in its own right requires separate entry on the ARTG, which means that the sponsor must lodge an application with the TGA to include the device in the ARTG.

Some devices have more than one type of software residing within them. For example, an infusion pump and monitor system may have software:

- to control the infusion parameters—Class IIb
- for the logging of patient data—Class I

If the device is supplied as a complete unit, the classification of the complete device is the highest classification—Class IIb. If the software is supplied separately, the individual classification of each device applies.

The international standard *IEC 62304 Medical device software—Software life cycle processes* addresses requirements that are specific to software, while the *IEC 62366 Medical devices—Application of usability engineering to medical devices* standard addresses usability engineering requirements to all devices, including those that are wholly or partially software-based. The TGA considers these standards as representing the state-of-the-art for medical device software.

The labelling requirements apply to medical device software, regardless of whether it is:

- downloaded from the Internet
- installed from a CD
- pre-installed on a device

Manufacturers need to ensure that their product information, such as the graphical user interface, screenshots, CD labels, and product demos meet the requirements of Essential Principle 13.

# Section 14. Medical devices incorporating a medicine

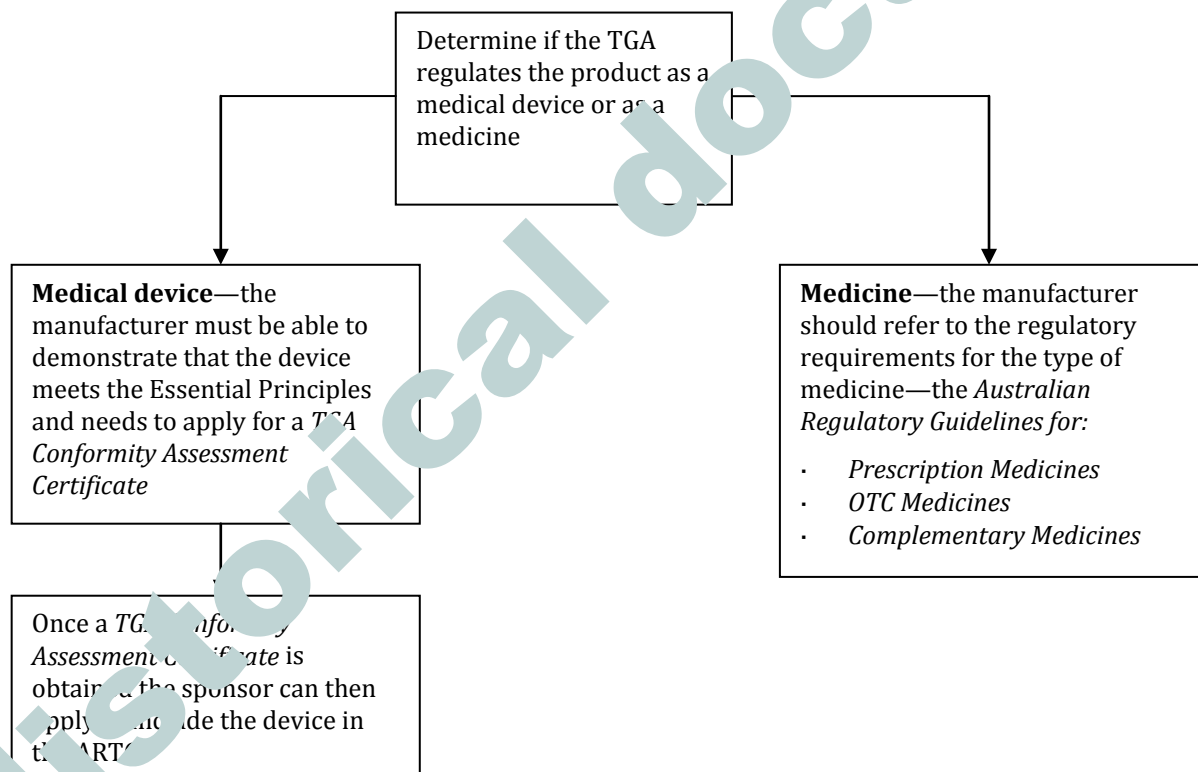
## Overview

There are therapeutic goods that have both a medicine and a medical device component and it is the combination of the two components that deliver the desired therapeutic effect. In deciding how these products are regulated, the TGA considers:

- the primary intended purpose
- the mode of action of the product

as they relate to the definition of a medicine and a medical device.

The diagram below illustrates the two assessment pathways possible for such combination products:



Please note: Applicants are strongly encouraged to email the TGA <[devices@tga.gov.au](mailto:devices@tga.gov.au)> prior to submitting an application for a TGA Conformity Assessment Certificate to discuss the characteristics and intended use of their product and to ascertain the TGA's requirements for the medicinal component in relation to these characteristics.

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Examples of devices that this guidance applies to include (but are not limited to):

- catheters coated with an anticoagulant or an antibiotic agent
- medicine-coated coronary artery stents (drug-eluting stents)
- bone cements containing antibiotics
- sponge impregnated with antibiotics
- intraocular viscous solution with anaesthetic
- medicated root canal sealant
- silver impregnated dressings
- Surgical adhesive of collagen (medical device) and thrombin (medicine) packaged as two components that are not applied to patient until mixed together and 'intended to incorporate an ancillary medicine'

System or procedure packs that include at least one medical device and may contain a medicine are regulated as medical devices. The medicine must be entered onto the ARTG in its own right before an application for the system and procedure pack can be lodged. For more information on system and procedure packs, please see [Section 16. Systems and procedure packs](#).

This guidance does not apply to:

- chemicals that are not medicinal in nature
- contact lens solutions that contain an antimicrobial substance where the purpose of the substance is solely to preserve the solution and not intended to confer antiseptic properties to the eye
- products such as pre-filled syringes where the syringe serves as the container for the medicine, as these products are regulated as medicines

For a product considered to be:

- a medical device, an application must be submitted to the Office of Devices Authorisation and the product will be assessed by the medical device program with input from the relevant Office for medicines regulation
- a medicine, an application must be submitted to the relevant Office for medicines regulation and the product will be assessed by the medicines program, with input from the Office of Devices Authorisation

The decision on approval and issuance of the relevant certificates will be issued by the Office to which the application is submitted.

If the decision for the product to be regulated as a medicine or a medical device is not obvious from consideration of the intended purpose and the mode of action, the matter should be referred to the TGA to determine the most appropriate Office. Direct queries through the medical devices email service at [devices@tga.gov.au](mailto:devices@tga.gov.au).

A list of some products that contain both a medical device and a medicine component, where the TGA has previously made a determination in relation to whether the type of product is to be regulated as a medical device or a medicine, is available on the TGA website: Medical device – medicine boundary products.

Even though the manufacturer may have an overseas issued conformity assessment certificate, this can not be used as the basis for inclusion in the ARTG for these devices. An application must be made for a TGA Conformity Assessment Certificate; please see [Section 5. Conformity assessment overview](#).

Essential Principle 7.4 of Schedule 1 of the Regulations requires that:

- the safety and quality of the medicinal substance be verified in accordance with the requirements for medicines
- the ancillary action of the substance be verified having regard to the intended purpose of the device

Classification Rule 5.1 of Schedule 2 of the Regulations indicates that medical devices are Class III if they incorporate, or are intended to incorporate, as an integral part, a substance that:

- 
- if used separately would be a medicine; and
  - is liable to act on the patient's body with an action ancillary to that of the device.

For information on the classification of medical devices, please see [Section 4. Classification of medical devices](#).

Where an application is made for a medical device incorporating a medicinal component, the relevant parts of the Design Dossier are referred to the appropriate area of the TGA by the Office of Devices Authorisation for evaluation of the medicinal component. The medicinal assessment is undertaken in parallel with the assessment of the medical device and the relevant fees for the assessment of the medicine component will also apply. The manufacturer should ensure that they have included data for the medicinal substance as part of the Design Dossier in submissions. The medicinal component documentation may be supplied directly to the TGA if there are proprietary information considerations; authorisations from the medicine supplier must be supplied to the TGA in relation to the specific medical device submission. Refer to the TGA website for the Letter of Access for the DMF/CEP template.

Some medical devices contain substances that are scheduled in the Standard for Uniform Scheduling of Drugs and Poisons (SUSDP). This includes medical devices incorporating medicinal substances. Entries in the SUSDP refer to all salts and derivatives of the substance unless specifically exempted. The TGA refers new chemical entities in medical devices incorporating medicinal substances to the National Drugs and Poisons Schedule Committee (NDPSC). Medical devices containing substances that are scheduled in the SUSDP must comply with any labelling requirements specified in the SUSDP.

Many, but not all, substances scheduled by the SUSDP are considered as medicines. Note that medical devices that contain substances cited in the SUSDP, but not considered to be a medicine are not addressed by Classification Rule 5.1.

Medical devices classified as Class III because they contain a medicine that acts in a manner ancillary to the device are generally exempted from the requirements of the SUSDP.

However, the following five groups of products, irrespective of their device classification, must comply with the labelling requirements of the SUSDP:

- injectable tissue reconstructive, augmentation and restoration materials, including collagen
- medical devices that include anticoagulants
- artificial tears
- urinary catheters
- intra-articular fluids

Further information on the NDPSC is available on the TGA website.


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## What is a medical device incorporating a medicine?

There are three definitions from the therapeutic goods legislation that must be considered when determining whether a product that has both a medicine and a medical device component is to be regulated as a medicine or a medical device.

### From the *Therapeutic Goods Act 1989*...


#### Section 41DB What is a medical device

- 
1. A medical device is:
    - a. any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person to whom it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:
      - i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
      - ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;
      - iii. investigation, replacement or modification of the anatomy or of a physiological process;
      - iv. control of conception;and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or
    - aa. any instrument, apparatus, appliance, material or other article specified under subsection (1A); or
    - ab. any instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection (2B); or
    - b. an accessory to such an instrument, apparatus, appliance, material or other article covered by paragraph (a), (aa) or (ab).

### From the *Therapeutic Goods Act 1989*...

#### Section 41(1)

*medicine* means:

- 
- a. therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human; and
  - b. any other therapeutic goods declared by the Secretary, for the purpose of the definition of **therapeutic device**, not to be therapeutic devices.



### From the *Therapeutic Goods (Medical Devices) Regulations 2002...*

#### **Medical devices incorporating a medicine:**



means a medical device of any kind that incorporates, or is intended to incorporate, as an integral part, a substance that:

- i. if used separately, would be a medicine; and
- ii. is liable to act on a patient's body with action ancillary to that of the device

## Data requirements for medicinal substances

A wide range of medicinal substances may be incorporated into medical devices. In recognition that the regulatory status and evaluation history of the medicinal component may vary considerably, the data requirements will be considered on a case-by-case basis. In general, the amount of data required depends on whether the:

- the medicinal substance is already available for supply in Australia (for example, as an API)
- the medicine is already on the ARTG
- the clinical indications and or presentation are the same or different
- the medicinal substance originates from a manufacturer who has been satisfactorily audited for the manufacture of that substance and has current TGA-issued GMP certification or has a TGA GMP Clearance based on other evidence accepted by TGA
- the incorporation of the medicine within the device is consistent with its approved use, and whether it poses any concerns in relation to, for example:
  - local toxicity/tolerability
  - changes to the physico-chemical properties of the substance as a result of its incorporation into the device, including kinetics of release of the substance from the device.

The manufacturer must submit an additional component of the Design Dossier specifically dealing with the medicinal substance.

Detailed guidance on the Australian regulatory requirements for medicines is available on the TGA website. Regulatory requirements vary depending on the type of medicine and relative risk/benefit to the user. The following table provides a summary of each type of medicine—for full details, please refer to the appropriate regulatory guidance as shown in the table below that are available on the TGA website:

Type of medicine	Description	Guidelines
Prescription	Generally, a prescription is needed to buy from a pharmacist. Otherwise, only authorised health care professionals can supply them, such as in a hospital setting.  Examples include contraceptive pills, antibiotics, and strong painkillers	Australian Regulatory Guidelines for Prescription Medicines
OTC	Consumers can buy over-the-counter (OTC) medicines for self-treatment from pharmacies, with selected products also available in supermarkets, health food stores and other retailers.  Examples include cough and cold remedies, anti-fungal	Australian Regulatory Guidelines for OTC Medicines

Type of medicine	Description	Guidelines
	treatments, sunscreens, non-prescription analgesics such as aspirin and paracetamol	
Complementary	<p>Substances also known as 'traditional' or 'alternative' medicines.</p> <p>Examples include vitamins, minerals, nutritional supplements; and herbal, aromatherapy, and homoeopathic products</p>	Australian Regulatory Guidelines for Complementary Medicines

If a medicine is considered to be a new chemical entity (NCE) in Australia the medicine is also required to undergo the approval processes for a NCE; this includes forwarding data relating to the medicinal component of the device to the Office of Prescription Medicines within the TGA for review, and to the Australian Drug Evaluation Committee (ADEC) in addition to the submission of the composite medicinal device combination to the Advisory Committee on Medical Devices (ACMD).

For prescription medicines, the data provided with the application should be presented in the format outlined in the Common Technical Document (CTD) format, which is available on the TGA website.

The following table is intended as a general guide to the TGA data requirements for the medicinal component of medical devices in which the medicinal substance would normally be a prescription medicine. Equivalent procedures may apply to OTC or complementary medicines. For example, Certificate of Suitability (CEP) may be acceptable for an OTC or complementary medicines:

Data Description	Medicine not in ARTG	Medicine in ARTG with different manufacturer	Changes to ingredients for medicine in ARTG with same manufacturer	Medicine in ARTG with same manufacturer
Chemical and pharmaceutical data				
<p>Drug master files (DMF) for the substance—data may be provided as DMF or as part of the dossier for the medicine</p> <p>If a DMF change can alter anything about the medicine that is being used in the medical device, then the medical device manufacturer must have a formal arrangement in their supplier agreement to ensure they (the manufacturer) are aware of the change so that they can conduct a risk analysis to determine if there is any ‘substantial’ change to the medical device. If there is a substantial change, then the medical device manufacturer must notify the TGA (section 41EJ of the Act ).</p> <p><i>Please note: If the DMF is already lodged with the TGA, the medical device manufacturer may be able to provide written permission from the manufacturer of medicinal substances authorising the TGA access the DMF (that is, provide DMF File Reference Number in support of the device application</i></p> <p>A template letter of access for the DMF/CEP is available on the TGA website.</p>	Yes	Yes	Not normally required, but helpful if application includes overall description of manufacturing process	Not normally required, but helpful if application includes overall description of manufacturing process
<p>Method of incorporation of medicine with the device. Includes:</p> <ul style="list-style-type: none"> <li>description of the medicinal substance and the amount incorporated into each device</li> <li>results of studies examining whether the medicinal substance is modified during its incorporation onto the device (process</li> </ul>	Yes	Yes	Yes	Yes

Data Description	Medicine not in ARTG	Medicine in ARTG with different manufacturer	Changes to indication of medicine in ARTG with same manufacturer	Medicine in ARTG with same manufacturer
<p>treatments, effect of sterilisation, etc.)</p> <ul style="list-style-type: none"> <li>controls of starting materials—the specification of the medicinal substance and any excipients used</li> <li>control tests: <ul style="list-style-type: none"> <li>carried out at intermediate stages of manufacture</li> <li>on finished product</li> </ul> </li> </ul>				
Stability—includes data to demonstrate the stability of the active medicinal substance in the medical device (potency, purity, release rate) throughout the defined shelf-life of the device under the manufacturer's recommended storage conditions	Yes	Yes	Yes	Yes
Labelling	Yes	Yes	Yes	Yes
Performance data				
Studies to address intended action of the medicine in the context of its incorporation into the device	Yes	Yes	Yes	Yes
Data in relation to its release from the device at the site of action and the subsequent distribution and elimination	Yes	Yes	Yes	Yes
Non-clinical studies conducted				
Full toxicity profile	Yes	May be required if substance is a	Local tolerance studies relevant to	Local tolerance studies relevant to

Data Description	Medicine not in ARTG	Medicine in ARTG with different manufacturer	Changes to indication of medicine in ARTG with same manufacturer	Medicine in ARTG with same manufacturer
		product of fermentation or other variable manufacturing process, and whose properties and degradation products have been shown to be different	the site of implantation of the medical device need to be included. Additional information may be requested by the TGA.	the site of implantation of the medical device need to be included. Additional information may be requested by the TGA.
Full pharmacology and pharmacokinetic profile	Yes	No	No	No
Data to address intended action of the medicine in the context of its incorporation into the device; and in relation to its release from the device at the site of action and the subsequent distribution and elimination	Yes, however if a full pharmacology and pharmacokinetic profile is conducted that allows corollary to the use in the medical device then may not be required	Yes	Yes	Yes
Clinical studies				
Human pharmacology including pharmacodynamics and pharmacokinetics	Yes	No	No	No
Data to address intended action of the medicine in the context of its incorporation into the device; and in relation to its release from the device at the site of action and the subsequent distribution and elimination, as a minimum	Not required if full human pharmacology is provided (see	Yes	Yes	Yes

Data Description	Medicine not in ARTG	Medicine in ARTG with different manufacturer	Changes to indication of medicine in ARTG with same manufacturer	Medicine in ARTG with same manufacturer
	previous item)			
Efficacy and safety studies, including adequately powered study to demonstrate performance and safety of the medical device	Yes	Yes—unless justification for not requiring clinical evidence is accepted	Yes—unless justification for not requiring clinical evidence is accepted	Yes—unless justification for not requiring clinical evidence is accepted

## Quality control for manufacturing medicinal substances incorporated into medical devices

The manufacturing of a medicinal substance or Active Pharmaceutical Ingredient (API) that is incorporated into a medical device must be undertaken in accordance with an appropriate system for managing quality and is required to be in compliance with Good Manufacturing Practice (GMP), where appropriate.

To ensure that the incorporated medicinal substances are consistently produced and controlled to the quality standards appropriate to their indications, applicants for a TGA Conformity Assessment Certificate must provide the following evidence:

Medicinal substance	Overseas	Australian
Prescription medicine	<p>A TGA GMP Clearance. Sponsors must ensure that the currency of the evidence is maintained for as long as the device remains on the ARTG</p> <p>or</p> <p>TGA issued GMP certification if the TGA has conducted an on-site audit</p>	TGA GMP Licence unless exempt under Schedule 7 of the <i>Therapeutic Goods Regulations 1990</i>
OTC and complementary medicines	<p>Not normally required, however, the TGA reserves the right to request evidence and to audit the medicinal substance production facilities if there are questions concerning the acceptability of the manufacturing and quality control procedures.</p> <p>Further information on what is acceptable and what is not acceptable is available on the TGA website in the document <i>Guidance on the GMP clearance of overseas medicine manufacturers</i>.</p> <p>In these circumstances the medicinal substance manufacturer may:</p> <ul style="list-style-type: none"> <li>• apply for TGA GMP licence (if located in Australian)</li> <li>• apply for a GMP Clearance supported by acceptable evidence of GMP, issued by an overseas assessment body (if located overseas)</li> </ul> <p>Manufacturers may also be audited by the TGA as part of the medical device manufacturer's application for a TGA Conformity Assessment Certificate.</p>	

# Section 15. Medical devices containing materials of animal, microbial or recombinant origin

## Overview

Some medical devices contain materials that are of non-viable animal, microbial, or recombinant origin.

Medical devices incorporating these materials pose a special risk for both patients and healthcare providers due to, for instance, the potential for pathogen transmission to humans.

**Please note: Products containing viable animal materials or that are viable animals are currently regulated under Chapter 3 of the Therapeutic Goods Act 1989 as therapeutic devices—see Australian Device Requirements Version 4 (DR4).**

There is particular concern with regard to the possible transmission of Transmissible Spongiform Encephalopathies (TSEs) associated with materials originating from some animal species.

If a medical device or the cell-culture media used for microbial cell-culture contain animal-derived material, the TGA requires manufacturers to comply with the requirements outlined in the TGA approach to minimising the risk of exposure to Transmissible Spongiform Encephalopathies (TSEs) through medicines and medical devices, which is available on the TGA website.

### Descriptions of the kinds of materials and some examples

Origin	Description	Examples
Animal	An invertebrate or vertebrate member of the animal kingdom	<ul style="list-style-type: none"><li>• Bovine, porcine, lapine, etc</li><li>• Crustacean</li><li>• Coral</li></ul>
Microbial	Micro-organisms	<ul style="list-style-type: none"><li>• Bacteria</li><li>• Yeast</li></ul>
Recombinant	Genetically modified (GMO) biological organisms	<ul style="list-style-type: none"><li>• Microbial cells</li><li>• Animals</li><li>• Plants</li></ul>



### Examples of medical devices containing these materials

Medical devices	Materials
Biological heart valves	Porcine valve, valves made of bovine or equine pericardium
Wound dressings	Gelatin or collagen from porcine skins; recombinant plant expressing human collagen genes
Collagen corneal shields	Collagen from porcine skins
Vascular grafts	Coated with porcine collagen or gelatin
Catgut sutures	Bovine or ovine animal intestine
<ul style="list-style-type: none"><li>• Intra-ocular fluids</li><li>• Meniscus joint fluid replacement</li><li>• Anti-adhesion barriers</li><li>• Tissue augmentation</li><li>• Catheters with 'lubricious' coating</li></ul>	Hyaluronic acid extracted from rooster combs or harvested from a microbial cell line
Blood cell separation devices	Monoclonal antibody derived from microbial cell line expressing human gene

## Requirements for medical devices containing these materials

Requirement	Legislative reference	Description
Classification	Rule 5.5, Part 5, Schedule 2 of the Regulations	Medical device is Class III unless it: <ul style="list-style-type: none"> <li>only contains materials of animal origin that have been rendered non-viable AND</li> <li>is intended by the manufacturer to only come into contact with intact skin.</li> </ul>
TGA Conformity Assessment Certificate	Section 41EA of the <i>Therapeutic Goods Act 1989</i> Regulation 4.1, Part 4 of the Regulations	A TGA Conformity Assessment Certificate must be issued before a valid application can be made to include the medical device in the Australian Register of Therapeutic Goods (ARTG).
Essential Principles	Essential Principle 8.2, Schedule 1 of the <i>Therapeutic Goods (Medical Devices) Regulations 2002</i> (the Regulations)	Designs requirements for risk management, control measures including sourcing, selecting, harvesting, processing and validation methods for elimination/inactivation of viral or TSE agents.

All medical devices require classification to determine the relevant applicable conformity assessment procedures, and all medical devices are required to comply with all applicable Essential Principles. Some requirements apply specifically to medical devices containing materials of animal, microbial or recombinant origin.

The risk analysis that a manufacturer is required to perform to show compliance with the Essential Principles must take into account the presence or potential contamination by the materials of animal, microbial, or recombinant origin. A risk management report for the medical devices containing materials of animal, microbial, or recombinant origin must be included in the Design Dossier for the medical device.

## Medical devices included in Classification Rule 5.5

From the *Therapeutic Goods (Medical Devices) Regulations 2002 — Schedule 2...*

### 5.5 Medical devices containing non viable animal tissues, cells or other substances, or microbial or recombinant tissues, cells or other substances

1. This clause applies to a medical device if the device contains:
  - a. tissues, cells or substances of animal origin that have been rendered non viable, or tissues, cells or substances of microbial or recombinant origin; or
  - b. a combination of tissues, cells or substances of the kind described in paragraph (a).
2. The device is classified as Class III, unless:
  - a. the device contains only tissues, cells or substances of animal origin that have been rendered non viable; and
  - b. the device is intended by the manufacturer to come into contact with intact skin only.

*Please note A medical device that conforms to the description in paragraphs (2) (a) and (b) is classified as Class I under clause 2.1 of this Schedule*

*Please note: The TGA defines 'rendered non viable' as referring to tissues and cells that have been processed to a point such that no further inherent capacity for cellular metabolic activity exists.*

*Products containing substances of microbial or recombinant origin are not captured in the EU by a special rule. For further information please see [Section 8. Differences between the Australian and European Union medical device regulatory requirements](#)*

Classification Rule 5.5 includes medical devices:

- in which the animal tissues, cells and their derivatives are used as:
  - raw and starting materials (for example, collagen, hyaluronate, gelatin)
  - active substances (for example, heparin)
  - excipients in the device (for example, bovine serum albumin)
  - reagents used in production (for example, porcine pepsin, albumin, meat broth etc used in the culture of microbial cell lines)
- that contain tissues, cells or substances of:
  - microbial origin (production processes for example, biofermentation, harvested from microbial cell-culture; or in the finished product itself)
  - recombinant origin (for example, from any category of genetically modified organism and may be either during manufacture or in the finished product)

For further assistance, contact the Devices Conformity Assessment Area of the TGA at <[devices@tga.gov.au](mailto:devices@tga.gov.au)> or on 1800 141 144.

If the medical device is captured by classification rule 5.5 then a TGA Conformity Assessment Certificate is required.

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## Medical devices containing materials of animal origin not classified under Classification Rule 5.5

The TGA has determined that Classification Rule 5.5 does not apply to:

- the following tissue or cellular derivatives:
  - bovine milk
  - silk
  - beeswax
  - hair
  - lanolin
  - sintered hydroxyapatite (process must be validated to demonstrate no evidence of organic material)
  - tallow or tallow derivatives
  - alcohols
  - simple sugars or salts fermented from cultures that do not have any animal reagents
  - microbial sourced enzyme cleaners
- a medical device that contains tissues, cells, or substances of animal origin that have been rendered non-viable where the device is intended by the manufacturer to come into contact with intact skin only (for example, leather straps associated with limb prostheses).

The TGA has determined that honey is not considered to be an animal-derived substance.

### **Self assessment for animal components where the device is not classified under Classification Rule 5.5 and conformity assessment by the TGA is not required**

If a device contains materials of animal origin and the device is not considered class III by Classification Rule 5.5, the manufacturer is still required to comply with the TGA Supplementary requirements and conduct a self assessment for TSE risk.

Self assessment is described in more detail in the TGA Supplementary requirements for therapeutic goods for minimising the risk of transmitting transmissible spongiform encephalopathies (TSEs) (December 2004), available on the TGA website. This document includes the processing requirements for tallow and tallow derivatives. The document takes into account the requirements of the European Union Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (EMEA/410/01 Rev. 1 October 2003).

Records are required to be kept and maintained by the manufacturer for those animal origin components, as referred to in the TGA approach to minimising the risk of exposure to Transmissible Spongiform Encephalopathies (TSEs) through medicines and medical devices.

Manufacturers of medical devices containing ingredients identified as having animal origin must comply with the requirements for each of the animal-derived ingredients, in accordance with Essential Principle 8.2 of Schedule 1 of the Regulation.

Appropriate control measures must be implemented regarding animal material sourcing, selection, harvesting, and processing.

# Conformity assessment procedures for medical devices that contain materials of animal, microbial or recombinant origin

Regulation 4.1 requires manufacturers of medical devices containing:

- tissues of animal origin that have been rendered non-viable (Sub-regulation 4.1(2)(a)), or
- tissues, cells, or substances of microbial or recombinant origin (Sub-regulation 4.1(2)(b)),

to obtain a TGA Conformity Assessment Certificate prior to applying to include the medical device in the ARTG.

Essential Principle 8.2, part of Essential Principle 8—Infection and microbial contamination, is particularly relevant to medical devices that contain materials of animal, microbial, or recombinant origin.

## From the *Therapeutic Goods (Medical Devices) Regulations 2002*—Schedule 2

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

1. This clause applies in relation to a medical device that contains:
  - a. tissues, tissue derivatives, cells or substances of animal origin that have been rendered non viable; and
  - b. tissues, tissue derivatives, cells or substances of microbial or recombinant origin.
2. If the tissues, tissue derivatives, cells or substances originated from animals, the animals must have been subjected to appropriate veterinary controls and supervision having regard to the intended use of the tissues, cells or substances.
3. If the medical device contains tissues, 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, tissue derivatives, cells or substances originated.
4. The processing, preservation, testing and handling of tissues, tissue derivatives, cells or substances of animal, microbial or recombinant origin must be carried out in a way that ensures the highest standards of safety for a patient, the user of the device, and any other person.
  - a. In particular, the production process must implement validated methods of elimination, or inactivation, in relation to viruses and other transmissible agents.

When a manufacturer conducts a risk analysis during the design process for a medical device, the presence or possible presence of animal origin material in the finished medical device must be taken into consideration. This analysis must be undertaken, regardless of whether Classification Rule 5.5 is applicable to the medical device or not.

For medical devices constructed of recombinant or microbial origin material, or animal origin material that has been rendered non-viable, this analysis along with details of risk mitigation steps undertaken, must be provided when a design dossier is submitted to the TGA in support of an application for a TGA Conformity Assessment Certificate.

For medical devices not requiring a TGA Conformity Assessment Certificate, this analysis along with details of risk mitigation steps undertaken, must be maintained in the Technical File held by the manufacturer, and be made available to the TGA on request. Changes to the Technical File, in this case, do not require notification to the TGA unless this is specifically requested.

Incidental contact with various substances of animal, microbial, or recombinant sources material during manufacture must be considered when deciding whether a TGA Conformity Assessment Certificate is required. Note that lubricants and cleaning agents of animal or microbial sources used solely during manufacturing and

that do not end up in the finished medical device are not considered in the decision of whether a TGA Conformity Assessment Certificate is required.

The manufacturer must apply to the TGA for assessment prior to implementing a change to the design materials or manufacturing processes for medical devices for which the TGA has issued a TGA Conformity Assessment Certificate. Changes to the supplier of animal material are notifiable and assessable changes. The manufacturer needs to undertake a risk analysis to determine whether changes to sourcing, collection or handling have reduced the safety of the product. The manufacturer also needs to consider whether this change affects the validation of the inactivation or elimination of viruses or TSE agents.

After this risk analysis and conclusions has been documented, notify the medical devices conformity assessment area of the TGA on 1800 141 144 for confirmation of whether the proposed change(s) require TGA approval.

For more information please see:

- Conformity Assessment Standards Order No 2—Conformity assessment standards for quality assurance techniques for animal tissues and their derivatives utilised in the manufacture of medical devices (CASO No 2), which is available on the TGA website.
- Section 21. Changes to ARTG Inclusions

### **Specific requirements for animal-origin components**

There are special requirements for:

- medical devices incorporating tissues, their derivatives, or other substances originating from animals
- materials of animal origin that are used or that come into contact with medical devices during production processes where the materials are not included in the final device

The TGA has adopted EN 12442: 2000 Animal tissues and their derivatives utilised in the manufacture of medical devices – Part 1, Part 2 and Part 3 as conformity assessment standards (CASO No 2). Compliance with these standards is not mandatory. However if a manufacturer chooses to follow a different approach, its relevance and adequacy in achieving a satisfactory level of safety must be demonstrated. The TGA will also accept compliance to ISO 22442: 2007.

These standards specify relevant quality assurance techniques for the analysis and management of risk in the manufacture of medical devices, such as sourcing, collecting, handling of animal materials and their derivatives, viral and transmissible agent elimination and inactivation.

Documented compliance with these standards can form the evidence to demonstrate compliance with elements of Essential Principle 8.2.

Details of rigorous manufacturing processes for various materials are outlined in TGA Supplementary requirements for therapeutic goods for minimising the risk of transmitting transmissible spongiform encephalopathies (TSE) (September 2004).

The quality systems implemented by manufacturers of medical devices containing materials of animal origin must also ensure that the following are in place:

- quality control processes and procedures to prevent contamination with potential infectious/transmissible agents including TSEs and disinfection/decontamination procedures in the event of contamination; this includes adequate evidence of segregation between animal species in abattoirs or tissue supplier facilities
- a documented system for animal and tissue traceability
- procedures for the selection, review, and auditing of tissue suppliers
- records of audit reports for the supplier of animal tissue by the device manufacturer
- name and address for the supplier of any animal materials. The TGA treats animal-tissue material suppliers as key suppliers and the details of these suppliers are entered or referenced on the TGA Conformity Assessment Certificate

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## Specific requirements for microbial origin components

For medical devices containing components of microbial origin, manufacturers are also required to provide the following additional information:

- microbial species
  - identification
  - cell bank qualification to demonstrate that it has been fully characterised and tested for the absence of viruses
- composition of fermentation or growth media,
  - identification of all components
  - origin of components: animal, microbial, or plant
  - suppliers, specifications, and certificates of analysis of the components.

## Specific requirements for recombinant origin components

For medical devices containing components of recombinant origin, manufacturers are also required to provide the following additional information:

- identification and source of nucleotide sequence coding
- source of expression construct or host animals
- composition of fermentation or growth media, including:
  - identification of all components
  - origin of components: animal, microbial, or plant
  - suppliers, specifications, and certificates of analysis of the components

In addition, there may be further requirements as specified by the Office of Gene Technology Regulator (OGTR). More information is available at <<http://www.ogtr.gov.au>>

## SUSDP Considerations

Some medical devices incorporate substances of animal or microbial origin where that substance is scheduled in the Standard for Uniform Scheduling of Drugs and Poisons (SUSDP). Entries in the SUSDP refer to all salts and derivatives of the named substance unless specifically exempted. Some special clinical uses of collagen, hyaluronic acid and lactic acid render that medical device subject to scheduling requirements- see Schedule 4 of the SUSDP. Medical devices containing substances that are scheduled in the SUSDP must comply with any labelling requirements specified in the SUSDP.

## Options for conformity assessment certification for medical devices containing animal origin material

A manufacturer must apply to the TGA for conformity assessment certification for medical devices containing animal origin material.

However, if a medical device contains:

- tissues of animal origin that contact intact skin only
- refined derivatives of animal derived waxes
- sintered hydroxyapatite
- heparin that conforms to pharmacopoeial standards
- gelatin that conforms to pharmacopoeial standards

The TGA may consider an EC–Australia and EFTA–Australia MRA certificate to support the application to the TGA for conformity assessment certification.

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*Please note: An MRA certificate cannot be used as the sole basis for manufacturer's certification for inclusion in the ARTG*

Applicants must contact the TGA prior to submitting an application using certificates issued under the MRA to determine the requirements. The eligibility requirements under the MRA do not completely align with the criteria under classification rule 5.5 previously described in this section.

For more information please see the Australia – European Community Mutual Recognition Agreement, which is available on the TGA website.

## Import Permits

An AQIS import certificate is generally required for biological substances. More detail is provided at <http://www.daff.gov.au/aqis/import/biological/therapeutic-foods-dietary>.

Whether the item intended for importation contains material from a protected species must also be checked. For further information see <http://www.cites.org>.



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# Section 16. Systems and procedure packs


## Overview

'System or procedure pack' is a term used in the legislation to identify products that are packaged together for a specific intended purpose. Such a package must include at least one medical device but it can also contain medicines, other therapeutic goods (OTGs), and non-therapeutic goods. A group of products packaged together that meets the definition of 'system or procedure pack' is considered to be a medical device for the purposes of the Act.

Other groupings of therapeutic products, such as therapeutic kits and composite packs, are also discussed in this section.

### From the *Therapeutic Goods Act 1989*...

#### 41BF System or procedure packs

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1. A package and therapeutic goods in the package are a system or procedure pack if:
    - a. the package and the therapeutic goods are for use as a unit, either in combination as a system or in a medical or surgical procedure; and
    - b. the package contains at least one medical device; and
    - c. the package and the therapeutic goods do not constitute a composite pack.
  2. To avoid doubt, a system or procedure pack is a medical device.

The term 'system' and the term 'procedure pack' are used in order to accommodate different types of packages that contain medical devices. Additionally, some manufacturers might use the term 'procedure pack' for a particular collection or combination of products (for example, a collection of therapeutic goods for an appendectomy surgical procedure) while other manufacturers might refer to the same collection of therapeutic goods as a system. Nevertheless, no regulatory distinction is made between the two terms. The regulatory requirements are the same regardless of whether the package of goods meets the definition of 'system' or meets the definition of 'procedure pack' or meets the definitions of both.

The term 'component' is used to describe an individual item in a system or a procedure pack.

A system or procedure pack does not consist of:

- an individual item only

A collection of miscellaneous items that are not intended by the manufacturer to be used for a specific purpose

- Bulk packs of one or more items

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## Regulatory and legislative requirements

The legislative requirements for systems and procedure packs are set out in the:

- *Therapeutic Goods Act 1989* (the Act)—41BF
- Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations)—Regulation 3.10 (3) and Part 7 of Schedule 3

The regulatory requirements for systems and procedure packs are the same as for other medical devices. Manufacturers of all medical devices must:

- ensure that their medical devices meet the Essential Principles
- apply appropriate conformity assessment procedures
- comply with the clinical evidence requirements
- undertake adequate post-market surveillance activities for all medical devices

regardless of whether they manufacture a system or procedure pack.

However, there are additional provisions in the legislation for systems and procedure packs. Manufacturers of systems and procedure packs:

- must ensure that any applicable regulatory requirements are met for each individual component in the system or procedure pack
- must ensure that all components are mutually compatible with the intended purpose of the system or procedure pack and:
  - the intended purpose of each device
  - the approved indications for medicines and OTGs

Manufacturers wishing to utilise the conformity assessment procedure already undertaken by the component manufacturers may be eligible to use the specific conformity assessment procedures under Clause 7.5, Schedule 3 of the Regulations. This procedure is available so that manufacturers of a system or procedure pack may not need to hold conformity assessment certification for the assembly of that system or procedure pack.

Systems and procedure packs are treated as medical devices in their own right and, unless they are exempt (for example, custom-made medical devices), must be included on the ARTG separately from the individual items in the system or procedure pack.

If individual or replacement component items in a system or procedure pack are supplied for use separately from the system or procedure pack, they require separate entry on the ARTG from the system or procedure pack.

Systems and procedure packs that are supplied on loan (for example, instrumentation for orthopaedic implant surgery) are registered as medical devices and require inclusion in the ARTG.

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## Different therapeutic goods packages

### Systems

Systems are comprised of components, including at least one medical device, that are intended by the manufacturer to be used in combination as a unit. A manufacturer will often supply one or more components of a system in a number of sizes in order to accommodate differences in patient anatomy. Some example systems include:

- orthopaedic drill system, incorporating
  - drill
  - drill bits
  - burs
  - cables
  - a foot pedal
- knee joint- replacement system, incorporating
  - a femoral component
  - an articulating surface
  - a stemmed tibial plate
  - wedges
  - pins
  - screws
- patient monitoring system, incorporating
  - a monitor
  - ECG leads
  - blood-pressure cuff with cable
  - an infusion pump with tubing set

### Procedure packs

Procedure packs are comprised of components that are packaged together, including at least one medical device, and intended by the manufacturer to be used in a medical, surgical, or diagnostic procedure. Examples include:

- appendectomy surgical procedure pack incorporating:
  - clamps
  - drapes
  - sutures
  - needles
  - forceps
  - scalpels
  - gauze
  - swabs
  - kidney stones
- first aid-kit, incorporating:
  - bandages
  - antiseptic ointment
  - tweezers
  - pain-relief tablets
  - adhesive strips
  - cotton buds
  - swabs

## Boundary products and articles that are not medical devices

The *Therapeutic Goods (Articles that are not Medical Devices) Order No. 1 of 2004* is a declaration of those articles that are not, for the purposes of the Act, medical devices. The order includes:

- c) an article that is intended to administer a medicine in such a way that the medicine and the article form a single integral product that is intended exclusively for use in the given combination and that is not reusable (may be multi-dose);

Requirement	Legislative reference	Description
Classification	Rule 5.5, Part 5, Schedule 2 of the Regulations	Medical device is Class III unless it: <ul style="list-style-type: none"><li>only contains materials of animal origin that have been rendered non-viable</li></ul> AND <ul style="list-style-type: none"><li>is intended by the manufacturer to only come into contact with intact skin</li></ul>
TGA Conformity Assessment Certificate	Section 41EA of the <i>Therapeutic Goods Act 1989</i> Regulation 4.1, Part 4 of the Regulations	A TGA Conformity Assessment Certificate must be issued before a valid application can be made to include the medical device in the Australian Register of Therapeutic Goods (ARTG)
Essential Principles	Essential Principle 8.2, Schedule 1 of the <i>Therapeutic Goods (Medical Devices) Regulations 2002</i> (the Regulations)	Describe requirements for risk-management, control measures including sourcing, selecting, harvesting, processing and validation methods for elimination/inactivation of viral or TSE agents.

Examples include:

- a tube of cream with a specifically designed applicator to attach to the tube to deliver the required amount of cream
- eye or nasal medication with a dropper that is specifically designed to attach or be attached to the medicine container to deliver the measured eye or nasal drops
- a syringe pre-filled with medicine

Therapeutic Goods Orders can be found on the TGA Internet site.

For further information, please see Guidance Document 35: Device–Medicine Boundary Products on the TGA Internet site.

## Composite packs

Composite packs only contain medicines and their containers. They are entered on to the ARTG as medicines or other therapeutic goods (OTGs). Composite packs are used for a single treatment or for a single course of treatment. The components must either be combined before administration or be administered in a particular sequence. Examples include:

- vials of medicines administered in a sequence
- a powdered medicine for injection supplied with a diluting agent housed in a vial
- day and night cold and flu medicine

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Composite packs cannot contain any medical devices as, by definition, a collection of goods that includes at least one medical device is defined to be a system or procedure pack.

The definition of composite packs is in Section 7B(2) of the Act.

### Therapeutic kits

Therapeutic kits comprise a collection of medicines, other therapeutic goods (OTGs), and non-therapeutic goods, for example, a multi-vitamin pack supplied with fish oil capsules and iron tablets.

Kits are listed on the ARTG as medicines or as OTGs. Kits cannot contain any medical devices as, by definition, a collection of goods that includes at least one medical device is defined to be a system or procedure pack.

The legislative requirements for therapeutic kits are set out in the:

- *Therapeutic Goods Act 1989* (the Act) — Chapter 1, Section 7B(1)
- *Therapeutic Goods Regulations 1990* — Regulation 10 (Schedule 4, Part 1, Items 11–12)

The term ‘kit’ in the legislation has a specific meaning. Although some products use the word in their name, they may not meet the definition of kit according to the Act. For example, first-aid-kits meet the definition of procedure pack under the legislation but do not meet the definition of ‘therapeutic kit’.

### Custom-made medical devices

Some systems and procedure packs fit the definition of ‘custom-made medical devices’. Custom-made medical devices are exempt from inclusion in the ARTG.

A system or procedure pack that contains one or more custom-made medical devices and no other kinds of therapeutic goods is also a custom-made medical device, and therefore exempt from inclusion on the ARTG. However, a system or procedure pack that contains one or more custom-made medical devices, as well as medicines, OTGs, or non-custom-made medical devices, is not a custom-made medical device and must be included on the ARTG.

For more information, please see [Section 18. Custom-made medical devices](#).

## Classification of systems and procedure packs

When classifying a system or procedure pack, the manufacturer should note that:

- The medical device component with the highest classification determines the overall classification for the system or procedure pack. For example, a procedure pack containing a Class III device will also be classified as Class III
- The highest classification rule is applied when two or more classification rules could be applied
- A system or procedure pack intended to be used in combination with another medical device is classified separately to that other medical device
- Any accessories to a system or procedure pack are classified separately
- The component manufacturer's intended purpose and classification applies. By changing the component manufacturer's intended purpose or classification, the system or procedure pack manufacturer assumes responsibility for the revised intended purpose for the component device
- The software used to drive or control a system has the same classification as the system
- Class I systems or procedure packs that are supplied sterile are included on the ARTG as ‘Class I (supplied sterile)’
- Class I systems or procedure packs that are not supplied sterile but that contain a component that is supplied sterile are included on the ARTG as ‘Class I’ (non-sterile)
- Class I systems or procedure packs that contain a device with a measuring function are included on the ARTG as ‘Class I (with a measuring function)’

- Systems and procedure packs are classified without considering any component medicines or other therapeutic goods (OTGs)

For more information on determining the appropriate classification of a medical device please see [Section 4. Classification of medical devices](#).

## Conformity assessment procedure options

Manufacturers of medical devices demonstrate that their devices conform to the Essential Principles by applying conformity assessment procedures.

Manufacturers of systems or procedure packs have two options:

- obtaining conformity assessment evidence for the entire system or procedure pack as a single kind of medical device, or
- using the special conformity assessment procedures for systems and procedure packs outlined in clause 7.5 of Schedule 3 of the Regulations

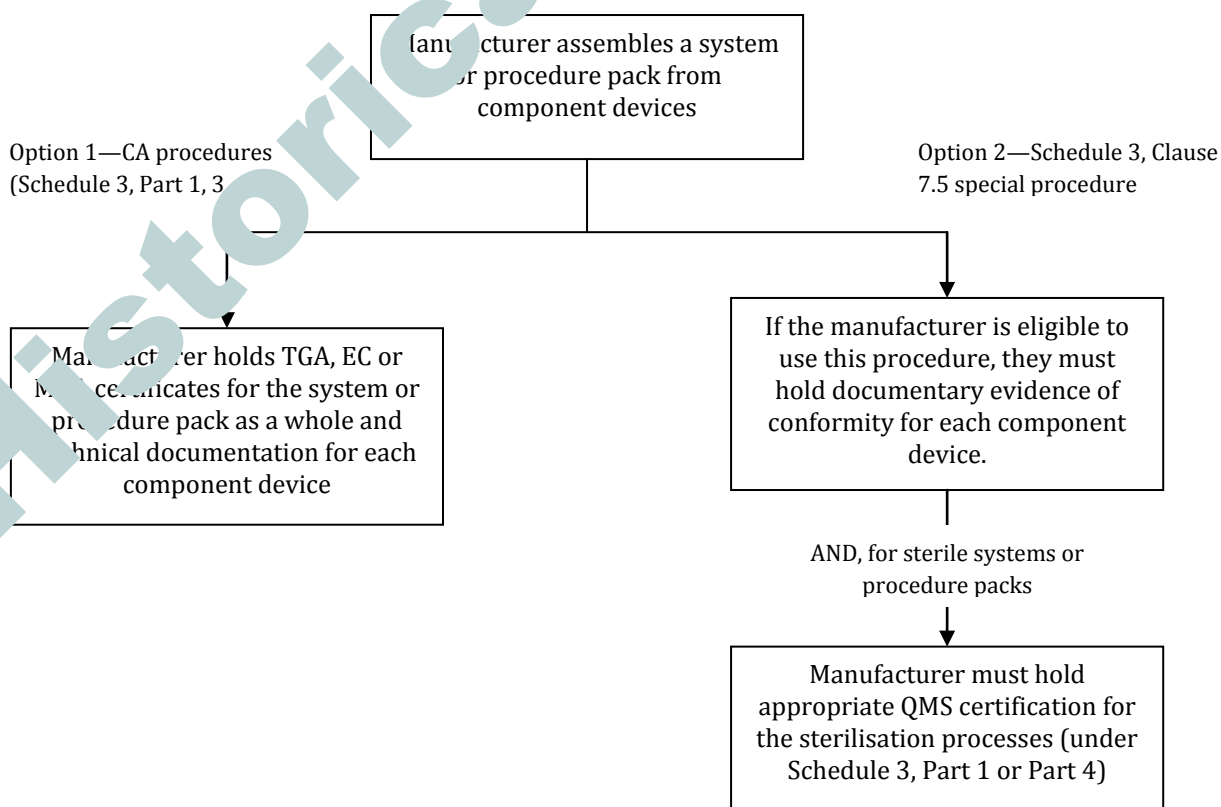
Some manufacturers assemble procedure packs or systems from devices and other therapeutic goods that are manufactured by other (component) manufacturers. These system or procedure pack manufacturers either need to:

- apply for and obtain conformity assessment evidence for the entire system or procedure pack from the TGA or from an EU Notified Body. For more information please see [Section 4.2. Conformity assessment overview](#)

or

- keep adequate documentary evidence of conformity for each of the component devices and prepare an Australian Declaration of Conformity in accordance with clause 7.5. The documentary evidence requirements are outlined later in this document in the sub-section [Documentary evidence for manufacturers using the special procedure](#).

### Conformity assessment procedure option



## Clause 7.5 special conformity assessment procedure

The special conformity assessment procedure allows manufacturers to assemble systems or procedure packs without being considered to be the manufacturer of each of the component devices (the component manufacturer); however, system or procedure pack manufacturers must keep adequate documentary evidence for each of the component devices.

For example, if a manufacturer assembles a surgical procedure pack that incorporates gauze, needles, sutures, scalpels, forceps, and some clamps, each supplied by different component manufacturers, they may use the Clause 7.5 special conformity assessment procedure if they can obtain documentary evidence for each component device within the pack from each of the component manufacturers.

An application to include a system or procedure pack in the ARTG that uses the Clause 7.5 special conformity assessment procedure is based on a Declaration of Conformity and does not require a conformity assessment certificate to be held by the manufacturer of the system or procedure pack, unless the system or procedure pack is supplied sterile. In this case, the system or procedure pack manufacturer must obtain certification for the sterilisation processes.

### Eligibility for the special conformity assessment procedure

The Clause 7.5 special conformity assessment procedures can be used for systems and procedure packs if the manufacturer can meet the requirements of Regulation 3.10, Subsection (3) 'Medical devices used for a special purpose'; systems and procedure packs:

Item	Requirement
Medical device	The system or procedure pack manufacturer must have documentary evidence (outlined in the next table) to demonstrate that each of the medical device components have: <ul style="list-style-type: none"><li>met the Essential Principles</li><li>had the relevant conformity assessment procedures applied to them</li></ul>
Medicine	Medicines in the systems or procedure pack must be listed or registered on the ARTG, unless the medicine is exempt
Other therapeutic goods (OTGs)	OTGs in the system or procedure pack must be listed or registered on the ARTG, unless the OTG is exempt
All component devices, medicines, and OTGs.	All components must be mutually compatible with the intended purpose of the system or procedure pack and: <ul style="list-style-type: none"><li>the intended purpose of each device</li><li>the approved indications for medicines and OTGs</li></ul>
Declaration of conformity	The system or procedure pack manufacturer must make an Australian Declaration of Conformity for the system or procedure pack in accordance with Schedule 3, Clause 7.5

If the criteria for the special conformity assessment procedures cannot be met, the system or procedure pack manufacturer must apply the general conformity assessment procedures. For more information, please see [Section 5. Conformity assessment overview](#).

## Documentary evidence for manufacturers using the special procedure

Item	Requirement
For each component device	<p>the system or procedure pack manufacturer must hold at least one of the following:</p> <ul style="list-style-type: none"> <li>• an Australian Declaration of Conformity from the component manufacturer</li> <li>• a TGA Conformity Assessment Certificate from the component manufacturer</li> <li>• a CE certificate from the component manufacturer AND agreement with the component manufacturer to supply technical documentation to the TGA on request</li> <li>• an ARTG inclusion certificate from the component sponsor AND agreement with the component sponsor to supply technical documentation to the TGA on request</li> </ul>
For each component medicine	The system or procedure pack manufacturer must hold a copy of the ARTG listing/registration certificate for that component, unless the medicine is exempt.
For each component OTG	The system or procedure pack manufacturer must hold a copy of the ARTG listing/registration certificate for that component, unless the OTG is exempt.
For each component including any non-therapeutic goods	The system or procedure pack manufacturer must hold evidence to demonstrate that the goods work together to achieve the intended purpose and are compatible with the other goods in the system or pack
For sterile systems or procedure packs	The system or procedure pack manufacturer must hold appropriate conformity assessment evidence of the sterilisation processes for the system or procedure pack as a whole. This does not apply to systems or procedure packs that are non-sterile but include sterile component devices
For every component for the lifetime of the device and at least 5 years after manufacture of the last device	<p>The manufacturer must have access to technical documentation, including:</p> <ul style="list-style-type: none"> <li>• the component manufacturer's Australian Declaration of Conformity</li> <li>• certification and technical documentation.</li> </ul> <p>The system or procedure pack manufacturer must either hold or be able to arrange for these to be provided to the TGA on request.</p>
For each sub-pack kind of system or procedure pack	The system or procedure pack manufacturer must provide a list of the contents.



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## Choosing to use the special procedure

The following examples describe when a system or procedure pack manufacturer may choose to use one of the usual conformity assessment procedure routes or to use the special procedure for systems and procedure packs:

### Example: packs where evidence is not held for any of the component devices

Australian manufacturer *Gumtree Medical Manufacturing Pty Ltd* assembles Class IIa first-aid-kits from components it manufactures itself. The first-aid-kit includes some sterile device components but the first-aid-kit itself (as a whole) is not supplied sterile. The manufacturer does not hold the required documentary evidence for any of the component devices and consequently is not eligible for the Clause 7.5 special conformity assessment procedure for systems and procedure packs.

The manufacturer must apply for a TGA Conformity Assessment Certificate to cover:

- each of the component devices inside the first-aid-kit and thereby become eligible for the Clause 7.5 special conformity assessment procedure. The manufacturer would need to submit a change application any time they wanted to introduce a new component not included within the scope of the certificate. The certificate could also be used to support inclusions in the ARTG for the separate supply of the individual components of the first-aid-kit.

and/or

- the first-aid-kit as a whole. The manufacturer would need to submit a change application any time they wanted to introduce a new first-aid-kit not included within the scope of the certificate. The certificate could not be used to support inclusions in the ARTG for the separate supply of the individual components of the first-aid-kit.

### Example: packs where evidence is held for some of the component devices

Manufacturer *Dryandra Medical Manufacturing Pty Ltd* assembles and sterilises surgical tubing procedure packs and wants to apply the Clause 7.5 special procedure for systems and procedure packs.

Some of the component devices purchased by Dryandra Medical are supplied to it sterile while others are supplied non-sterile. Some of the component devices are purchased from overseas suppliers and some from suppliers in Australia.

Dryandra Medical looks at the eligibility requirements for meeting the special procedure and finds that it is eligible to apply it to all of its component devices except for the tubing and gauze, as the component manufacturers of these devices do not hold the appropriate documentary evidence. Dryandra Medical therefore chooses to take on the role of the (component) manufacturer just for those components, and assembles appropriate technical files accordingly.

Dryandra Medical then applies for a TGA Conformity Assessment Certificate for:

- terminal sterilisation of surgical tubing procedure packs; and
- the component devices where it is assuming the role of component manufacturer.

Once the TGA Conformity Assessment Certificate is issued, Dryandra Medical applies the Clause 7.5 special procedure for systems and procedure packs for the entire procedure pack.

The sponsor then submits the Australian Declaration of Conformity that Dryandra Medical has completed in accordance with Clause 7.5 as the Manufacturer's Evidence.

## Additional requirements of the special procedure

Item	Requirement
Labelling and <i>Instructions for Use</i>	<p>Clause 7.5 requires that in addition to the requirements of Essential Principle 13, Part 2, Schedule 1 of the Regulations, the <i>Instructions for Use</i> must be included for each component item in a system or procedure pack whenever it is provided by the component manufacturer.</p> <p>The Aust L or Aust R number for all component medicines included in the system or procedure pack must be included on the labelling of the system or procedure pack.</p> <p>For more information please see <a href="#">Section 12. Information about a medical device</a>.</p> <p><i>Please Note: As per Essential Principle 13.3(3), manufacturers must provide a list of the contents of the system or procedure pack with the product.</i></p>
Declarations of Conformity to Clause 7.5	<p>System and procedure pack manufacturers using the special procedure should ensure that the Declaration of Conformity is prepared in accordance with Clause 7.5 of Schedule 3 of the Regulations. Declarations of conformity made to the European special procedure for systems and procedure packs (Article 12.2) are not acceptable.</p> <p>Manufacturers must identify each item in the package, regardless of whether they are medical devices, medicines, OTGs, or non-therapeutic goods.</p> <p>When making an Australian Declaration of Conformity in accordance with Clause 7.5, system and procedure pack manufacturers must list the ARTG numbers for all medicines and OTGs in the pack; however, there is no requirement to list ARTG inclusion numbers or GMDN codes for the medical device components.</p> <p>Each medical device component in a system or procedure pack must be used for the intended purpose indicated by the component manufacturer. For example, a blood-collection container cannot be used as a container for a povidone iodine solution. A person who wants to change the intended purpose of a medical device becomes the manufacturer of that medical device and must apply appropriate conformity assessment procedures accordingly.</p>
Manufacturer's evidence	<p>Manufacturer's evidence for manufacturers using the special procedure consists of the manufacturer's Australian Declaration of Conformity to Clause 7.5.</p> <p>For systems or procedure packs that are supplied sterile the system or procedure pack manufacturer must hold appropriate QMS certification for the sterilisation processes, for example a Part 4 or MDD Annex V certificate for 'the sterilisation of surgical tubing procedure packs'. Manufacturer's Evidence in this case consists of an Australian Declaration of Conformity to Clause 7.5 as well as the Part 4 certificate for the sterilisation processes.</p>
Post-market requirements	<p>Clause 7.5(3) of the special procedure for systems and procedure packs requires the manufacturer to establish a post-market surveillance system to:</p> <ul style="list-style-type: none"> <li>• systematically review experiences gained after the device is supplied in Australia</li> <li>• implement any necessary corrective action in relation to the production of the device</li> <li>• notify the TGA of adverse events and near miss events</li> <li>• notify the TGA as soon as practicable about information relating to malfunction or deterioration of its device</li> <li>• notify the TGA as soon as practicable about any inadequacy in the production, labelling, <i>instructions for use</i>, or advertising materials of its device</li> </ul>

Item	Requirement
	<ul style="list-style-type: none"> <li>· notify the TGA as soon as practicable about any use the device that might lead to, or might have led to, the death or serious deterioration of the health of a patient or user of the device</li> <li>· notify the TGA as soon as practicable about any information relating to technical or medical reasons that have led the manufacturer to recover the device for any of the reasons outlined above.</li> </ul> <p>For more information about these requirements, please see <a href="#">Section 22. Post-market vigilance and monitoring requirements</a>.</p>

## Specific types of systems and procedure packs

Case	Description
Subsets of systems or procedure packs	<p>If a system or procedure pack contains a large number of items, sponsors can supply systems or procedure packs that contain a subset of these items without additional ARTG inclusions, provided that the subsets of the system or procedure pack are of the same kind of medical device, that is, the same sponsor, manufacturer, GMDN, and Class.</p>
Sterile systems or procedure packs	<p>If a system or procedure pack is to be supplied sterile, the manufacturer must obtain a TGA Conformity Assessment Certificate from the TGA or CE Certification from an EU Notified Body.</p> <p>For further information, please see <a href="#">Section 6. What a manufacturer needs to know about conformity assessment</a>.</p> <p>The sterilisation process must be appropriate for all medicines, RTGs and medical devices in the system or procedure pack. This has particular significance where a sterile system or procedure pack contains a pre-sterilised component.</p>
Class III and AIMD systems or procedure packs	<p>If a system or procedure pack is classified as Class III or Class AIMD, each model of the system or procedure pack needs to be included in the ARTG at the Unique Product Identifier level.</p> <p>In accordance with Regulation 5 of the Regulations, Class III/AIMD systems and procedure packs will be selected for a mandatory pre-market application audit unless a TGA Conformity Assessment Certificate or MRA Certificate has been issued for the entire system or procedure pack. If a TGA Conformity Assessment Certificate has only been issued for sterilisation activities then a mandatory application audit will be conducted.</p> <p>For more information, please see:</p> <ul style="list-style-type: none"> <li>• <a href="#">Section 11. Application audits of medical device applications</a></li> <li>• <a href="#">Section 10. Including medical devices in the ARTG</a></li> </ul>
Single-use system or procedure pack	<p>A single-use system or procedure pack should not be reprocessed for reuse.</p> <p>If a manufacturer of a system or procedure pack has provided instructions for reprocessing of unused components then unused components can be reprocessed according to those instructions.</p> <p>For further information, please see <a href="#">Section 19. Single-use devices (SUDs)</a></p>
Reusable system or procedure pack	<p>A reusable system or procedure pack can be reprocessed for reuse if the manufacturer has declared that it can be reused. Any reprocessing should be done in accordance with the manufacturer's instructions.</p>
Medical devices containing materials of animal, microbial, or recombinant origin and medical devices incorporating a medicinal substance	<p>A TGA Conformity Assessment Certificate is required for medical devices that incorporate a medicinal substance or that contain materials of animal, microbial, or recombinant origin. For systems and procedure packs that include such Class III components, the manufacturer may either obtain the TGA Conformity Assessment Certificate for:</p>

Case	Description
	<ul style="list-style-type: none"> <li>the system or procedure pack as a whole</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>the relevant Class III component only—and then apply the special procedure for the system or procedure pack as a whole. The manufacturer's Clause 7.5 declaration of conformity would then be lodged as manufacturer's Evidence in order to include the system or procedure pack on the ARTG.</li> </ul> <p>For more information, please see:</p> <ul style="list-style-type: none"> <li><a href="#">Section 15. Medical devices containing materials of animal, microbial or recombinant origin</a></li> <li><a href="#">Section 14. Medical devices incorporating a medicine</a></li> </ul>
<p>Component medicine(s) and systems or procedure packs that incorporate other therapeutic goods (OTGs)</p>	<p>Systems and procedure packs are classified without considering any medicine or OTG components. However, component medicines or OTGs that are incorporated into a system or a procedure pack must meet the regulatory requirements for the medicine or OTG. The system or procedure pack containing the medicine must also satisfy the labelling requirements for the medicine.</p> <p>Where a sterilisation process is used to sterilise a system or procedure pack, the method must be appropriate for all medicines, OTGs, and medical devices in the system or procedure pack. The additional sterilisation process must be in accordance with the initial approval for Registration of the medicine on the ARTG, that is, an assessment must have been made to determine if the sterilisation process will affect the quality, safety, or efficacy of the medicine.</p> <p>For further information, please see <a href="#">Section 14. Medical devices incorporating a medicine</a>.</p>

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## Changes to contents

If the contents in a system or procedure pack change, the system or procedure pack manufacturer needs to

- reassess:
  - the classification
  - the GMDN
  - the UPI (applicable to Class III and AIMD only)
  - whether the change is covered by the scope of the existing conformity assessment evidence
  - eligibility for the Clause 7.5 special conformity assessment procedures (if applicable), and then
- apply appropriate conformity assessment procedures
- update documentation, including the Australian Declaration of Conformity

If the changes result in a new GMDN and/or classification then a new application to include the system or procedure pack in the ARTG will be required.

For further information on changes and variations, please see [Section 21. Changes to ARTG Inclusions](#).

## Accessories

If an accessory to a system or procedure pack is a medical device as defined under Section 41BD of the Act, and it is supplied separately from the system or procedure pack, it will need a separate ARTG inclusion from that of the system or procedure pack.

If the accessory has a different GMDN or Classification to the system or procedure pack, or in the case of Class III/AIMD a different UPI, it is considered to be a different kind of medical device (under Section 41BE of the Act) to the system or procedure pack and hence requires a separate inclusion in the ARTG.

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# Section 17. Medical devices for export

## Overview

Sponsors wanting to export medical devices from Australia must meet certain regulatory requirements set out in the *Therapeutic Goods Act 1989* (the Act) and the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Before a sponsor can export a medical device from Australia, the device must:

- be included in the ARTG for supply in Australia, or
- be included in the ARTG as an export only medical device, or
- be exempt under Item 1.2, Part 1, Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002*

When exporting medical devices from Australia, the sponsor will need to comply with the regulatory requirements of the importing country and should contact the relevant Embassy, High Commission or Consulate for advice on their importation requirements. These regulatory requirements could include conformity assessment procedures for the importing country. If additional certification is required by the importing country, medical device sponsors can apply to the TGA for an Export Certificate or a Certificate of Free Sale.

## Included medical devices for supply in Australia

Sponsors of medical devices that are included in the ARTG for supply in Australia are also able to export these devices from Australia under the existing ARTG inclusion number. With the exception of class III and Active implantable medical devices (AIMDs), an inclusion in the ARTG is for a kind of medical device that can cover a range of individual models of that kind. This means that an inclusion in the ARTG only records the kind of device and not the individual device models.

If the importing country requires an Export Certificate or Certificate of Free Sale with an attached schedule of devices covered by the ARTG inclusion, there will be insufficient information on the ARTG inclusion for the TGA to certify the individual models of devices covered by the Inclusion.

In this situation the sponsor may submit an application for an export only inclusion and provide a list, on page 2a of the application, of all the devices of that kind to be exported under the ARTG inclusion.

## Included medical devices for export only

Export only medical devices are either manufactured in Australia for export only or are imported into Australia for export only and cannot be supplied to the Australian market.

Export only medical devices are still subject to:

- the classification rules
- the Essential Principles for safety and performance
- the Conformity Assessment Procedures; and
- inclusion in the Australian Register of Therapeutic Goods (ARTG), unless the exemption under Item 1.2, Part 1, Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002* applies

**From the *Therapeutic Goods (Medical Devices) Regulations 2002* —  
*Schedule 2...***



*Classification Rules Part 5 Special rule for particular types of medical devices*

**5.8 Medical devices intended for export only**

Despite any other classification in this Schedule, a medical device that is intended by the manufacturer to be for export only is classified as Class I.

Medical devices that are intended by the manufacturer to only be exported from Australia are classified as Class I for entry in the ARTG. However, the products themselves would need to meet the classification and conformity assessment requirements of the importing country. For example, a cardiac catheter may be classified as a Class III in the importing country but would be included in the ARTG as a Class I “export only” device.

The minimum mandatory Conformity Assessment Procedure to be undertaken by the manufacturer for export only medical devices is described in Part 6, Declaration of Conformity, (not requiring assessment by the TGA) procedures in Schedule 3, the *Therapeutic Goods (Medical Devices) Regulations 2002*. It is recommended that sponsors check with the relevant Embassy, High Commission or Consulate for advice regarding the Conformity Assessment Procedures required by the importing country.

An application for an export only inclusion differs from an inclusion for sale in Australia in that the export only application:

- enables sponsors to provide a list the names of the export devices on Page 2a of the application form and consequently for an approved application, the export only devices will form part of the ARTG inclusion and
- is not subject to post-market review

## Export-only devices exempt from inclusion in the ARTG

**From the *Therapeutic Goods Act 1989*...**



*Schedule 4 Exemption devices, Part 1 General exemptions*

item 2 Medical device that is exported from Australia and:

- a. is not intended for commercial supply; and
- b. does not contain a substance, the export of which is prohibited under the *Customs Act 1901*; and
- c. is not intended for experimental purposes on humans

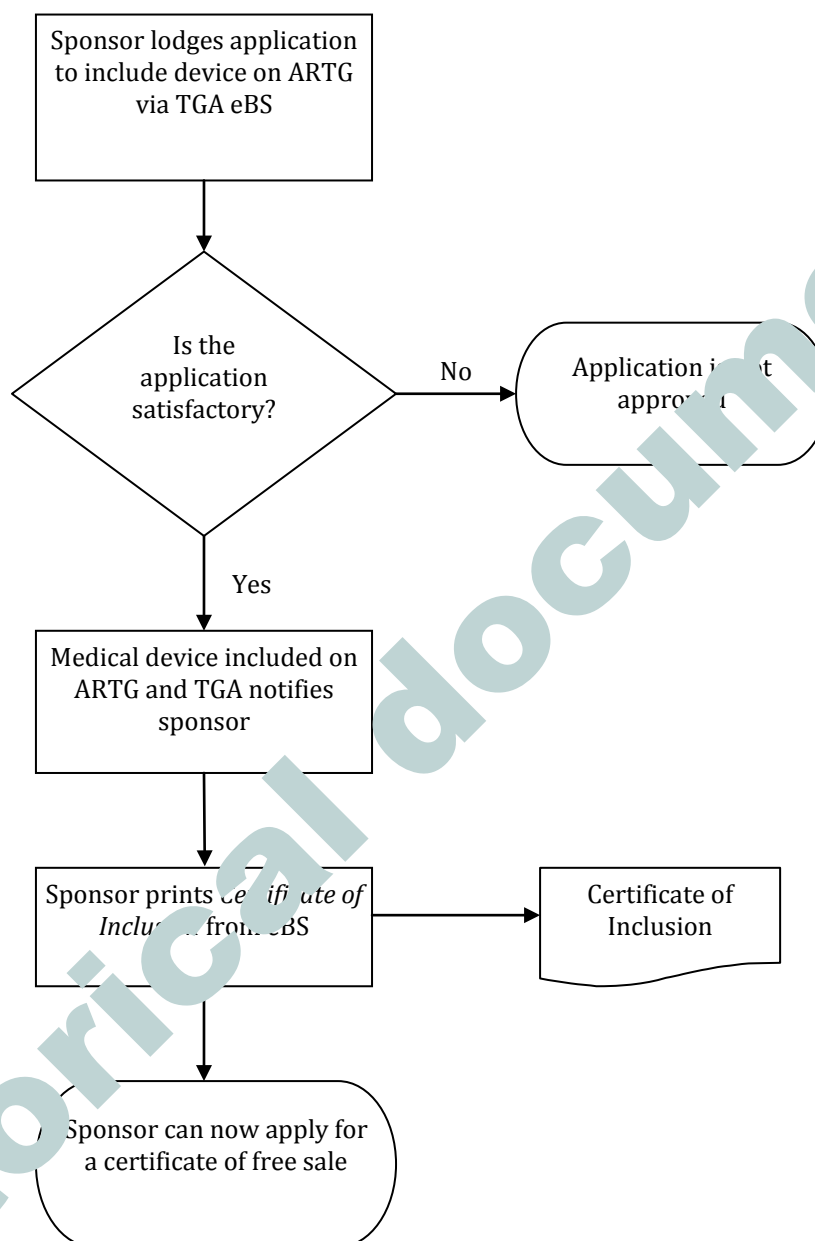
Medical devices that are exported from Australia for non-commercial supply and that do not contain a substance that is prohibited under the *Customs Act 1901*, are exempt from inclusion in the ARTG.

If a Certificate of Free Sale is required, the sponsor submits to the TGA a statement of exemption that contains a detailed explanation of the circumstances or purposes of the export and the products to be exported including the export destinations.



## Process for including export only devices on the ARTG

The following flowchart summarises the process for including an export-only medical device on the ARTG via the TGA eBusiness Services (eBS):



For more information on how to include a medical device in the ARTG, please see [Section 10. Including medical devices in the ARTG](#).

Once the medical device is included in the ARTG, or the exemption under Schedule 4 applies, the sponsor may apply for a Certificate of Free Sale, if it is required by the importing country.

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## Export Certificates

An Export Certificate is issued by the TGA for medical devices that are included in the ARTG for supply in Australia and the manufacturer has been issued with a TGA Conformity Assessment Certification.

An Export Certificate remains valid as long as the devices covered by the certificate remain unchanged and current on the ARTG.

## Certificates of Free Sale

A Certificate of Free Sale is issued by the TGA for included medical devices or medical devices exempt under item 1.2, Part 1, Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002* in situations where the TGA has not issued or reviewed the manufacturer's Conformity Assessment Certification.

A Certificate of Free Sale also remains valid as long as the devices covered by the certificate remain unchanged and current on the ARTG or the exemption under Schedule 4 remains unchanged.

## Application for an Export Certificate or a Certificate of Free Sale

### From the *Therapeutic Goods Act 1989*...

#### Chapter 7 Miscellaneous Section 58

#### 58 Export certifications

1. The Secretary may issue an export certification for goods for therapeutic use in humans, including certifications for the purposes of the World Health Organisation Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.
2. A State or Territory must not issue export certifications for goods for therapeutic use in humans.
3. Such fee as is prescribed is payable in respect of:
  - (a) an application for a certification under this section; and
  - (b) where an inspection of manufacturing premises is necessary for the purposes of the issue of a certification under this section—the inspection of those premises.

The application form for a Certificate of Free Sale or an Export Certificate is available on the TGA website at <<http://www.tga.gov.au>>. The TGA aims to process applications for a Certificate of Free Sale or an Export Certificate within 10 TGA work days.

Sponsors should ensure that the information provided in their application for a Certificate of Free Sale or Export Certificate is consistent with their eBS and ARTG records. Any inconsistencies in information currently in the ARTG or eBS client details should be rectified before making an application.

Some importing countries also require a schedule of information to be attached to the certificate. The information provided in the schedule must also be consistent with the ARTG record. A single certificate may be issued to cover multiple inclusions on the ARTG provided these entries have the same sponsor and the same manufacturer.

A fee is payable for applications for a Certificate of Free Sale or Export Certificate. Details of the fees currently applicable are available on the TGA website at <<http://www.tga.gov.au>>. For more information on fees and charges, please see [Section 2. Fees and charges for medical devices](#).

The Certificate of Free Sale or Export Certificate issued by the TGA may also need to be endorsed by the Department of Foreign Affairs and Trade, and authorised by the Embassy, High Commission, or Consulate of the importing country. This is the responsibility of the applicant, not the Therapeutic Goods Administration.

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## Section 18. Custom-made medical devices

This section to be drafted.

Historical document

# Section 19. Single-use devices (SUDs) and the reuse of SUDs

## Overview

If a device is for:	The manufacturer's intention is that the device:
single use	can only be used once and should then be disposed of
single patient use	can be used multiple times on one patient. Single patient use devices are able to be reprocessed and reused on the same patient in accordance with the manufacturer's instructions

It is the responsibility of the manufacturer to determine whether a device should only be for single use or single patient use. If the device is only intended to be for single use this must be clearly stated on the device, the label or the *Instructions for Use* in accordance with Essential Principle 13.4, Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

If a SUD (for example, an orthopaedic plate or screw) is trialled during the surgical/medical procedure and comes in contact with blood, tissue or bodily fluids during the surgical/medical procedure it is regarded as used.

The TGA will include the device in the ARTG based on the manufacturer's intended purpose. Therefore, the TGA does not conduct any pre-market assessments to determine if a device can be reused if the manufacturer states that the device is for single use or single patient use.

There may be several reasons why a medical device is for single use or single patient use, including that the:

- materials used in the manufacture of the device may not withstand repeated reprocessing
- design of the device may not facilitate adequate cleaning and sterilisation
- device may not perform as intended by the manufacturer if it is reused

The reuse of SUDs may lead to:

- Potential risks of cross infection/contamination associated with using inadequately cleaned and sterilised devices
- Failure of the device to perform as intended
- Material degradation
- Incompatibility issues
- Endotoxic reactions caused by the residues from reprocessing

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## SUDs that are opened but unused

The regulation of the remanufacture of SUDs does not include those SUDs that are opened but unused.

‘Opened but unused’ is the term used to refer to a SUD whose packaging has been opened but the device was not used and did not come in contact with blood, tissue or bodily fluids.

The TGA regards opened but unused as having the same meaning as packaging that is damaged. In the case of a sterile device the original manufacturer is required under Essential Principle 13.4, Item 12 to provide advice on what to do when the packaging is damaged.

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



**13.4**      *Instructions for use*

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

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

Users of sterile medical devices are expected to follow these instructions when the package is opened but the device is not used.

The *Instructions for Use* may be considered by the TGA if the manufacturer under goes a pre-market assessment before the device is included on the Australian Register of Therapeutic Goods (ARTG).

The TGA will assess the *Instructions for Use* against the Medical Device Standards Order (Standards for Medical Devices Required to be Sterile) 2008 that maps Essential Principle 13.4 Item 12 to the international standard *ISO 17664: 2004 Sterilization of medical devices—Information to be provided by the manufacturer for the processing of re-sterilisable medical devices*.

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## Reusing SUDs

When a SUD is reused, the TGA considers that the device has been remanufactured as the:

- intended purpose and design specifications for the device are altered from single use to reusable
- device may undergo manufacturing processes, such as sterilisation
- device may need to have components replaced so that it can be reused
- original manufacturer can no longer be considered responsible for the safety and performance of the device

The person responsible for undertaking these remanufacturing activities is considered to be a manufacturer under section 41BG(2) of the *Therapeutic Goods Act 1989* and must comply with the therapeutic goods legislation relating to the manufacture of medical devices.

### From the *Therapeutic Goods Act 1989*...

#### 41BG Manufacturers of medical devices

1. The manufacturer of a medical device is the 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 action of the device.

Once a medical device has been re-processed, the original manufacturer no longer has any regulatory responsibility under the therapeutic goods legislation for the reprocessed device. This includes:

- maintaining distribution records
- issuing safety or hazard alerts
- recall actions

People, including health professionals and health-care facilities, who want to reprocess SUDs may:

- become a manufacturer
- need to find a manufacturer to undertake the remanufacture of the SUDs

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### **Reuse of SUDs for personal use**

The TGA does not regulate the practice where people clean and reuse products such as single use enteral feeding tubes, urinary catheters, etc as long as it is for their own use.

### **Health professionals who give advice on reusing SUDs**

Healthcare professionals often advise their patients about the reuse of the SUDs. They are not undertaking any work but are providing advice on how the device may be cleaned for reuse. The healthcare professional may be professionally liable if the information provided contradicts the information provided in the manufacturer's *Instructions for Use*.

Historical document

## Regulatory requirements for remanufacturing SUDs

The Australian regulatory framework for medical devices is designed to ensure that the reprocessing of devices that were not originally intended for reprocessing does not compromise the safety and effectiveness of the device. Under these regulatory controls, the reprocessing facility is regulated as a manufacturer and is required to demonstrate that the reprocessed device is equivalent to the original and will continue to perform without additional risk to the patient.

People wanting to remanufacture SUDs in Australia must be familiar with the Australian legislative requirements. The steps required to obtain approval to remanufacture SUDs are as follows:

Action	Relevant section of the ARGMD to refer to for more information
Determine the classification of the SUDs to be remanufactured	<a href="#">Section 4. Classification of medical devices</a>
Select appropriate conformity assessment procedures  <i>Please note: most require a manufacturer to develop and implement a quality management system</i>	<a href="#">Section 5. Conformity assessment overview</a> <a href="#">Section 6. What a manufacturer needs to know about conformity assessment</a>
Ensure compliance with the Essential Principles and that the necessary evidence to demonstrate this compliance is held, including: <ul style="list-style-type: none"> <li>• a risk-analysis identifying all possible risks and the associated risk mitigation strategies</li> <li>• technical documentation about the device</li> <li>• appropriate clinical evidence</li> </ul>	<a href="#">Section 3. The Essential Principles</a>
For all devices except for Class I non-sterile non-measuring, apply for a TGA Conformity Assessment Certificate	<a href="#">Section 6. What a manufacturer needs to know about conformity assessment</a>
Decide who is to be the sponsor (the person legally responsible for the supply of the device in Australia) for the remanufactured SUDs.  The sponsor then needs to apply to the TGA to include the remanufactured devices in the ARTG	<a href="#">Section 7. What a sponsor needs to know about conformity assessment</a>  <a href="#">Section 10. Including medical devices in the ARTG</a>
Establish and maintain compliance with the post-market requirements, including: <ul style="list-style-type: none"> <li>• tracking the number of times the device is remanufactured and reused</li> <li>• tracing the device to the batch/serial number of the original device</li> <li>• recording who they supply the device to in case of recall or other regulatory action</li> <li>• reporting adverse events associated with the use of the device to the TGA</li> </ul>	<a href="#">Section 22. Post-market vigilance and monitoring requirements</a>



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The manufacturer must ensure that the technical documentation addresses the following issues that are relevant to the remanufacturing process, that:

- the materials used to make the original device and the biocompatibility of those materials is not affected
- the cleaning and disinfection processes are validated as effective, including appropriate viral inactivation studies
- prion/TSE hazards are suitably mitigated and controlled
- the sterilisation processes have been validated to demonstrate the achievement of a sterility assurance level of at least  $10^{-6}$
- endotoxins do not exceed the allowable limit for medical devices
- the device will continue to perform as originally intended without additional risk to the patient or user

## Costs of remanufacturing SUDs

Before making a decision to reprocess SUDs, it is recommended that an analysis be undertaken of the costs involved in opting for a single use policy compared to reusing devices. These costs may include, but not be limited to:

- reprocessing the devices—staff, equipment, materials
- developing and maintaining a quality management system
- demonstrating compliance with the Australian Essential Principles

This analysis should also take into account the fees payable to the TGA for:

- if applicable, an application for a TGA Conformity Assessment Certificate and the associated assessments of the documentation provided
- applications to include the remanufactured devices in the ARTG
- ongoing annual charges for each kind of device that is in the ARTG

Please refer [Section 2. Fees and charges for medical devices](#) for more information on fees and charges payable to the TGA.

## Case studies

### Single-use implants for use in orthopaedic procedures

It is common practice for manufacturers to supply orthopaedic implants for restocking implant sets prior to sterilisation for use in orthopaedic procedures. Examples of these implants are screws, hooks, rods, plates, cages, discs, washers, nuts and associated spinal and trauma implants.

The manufacturer provides instructions on how to process and sterilise these implants prior to use and although they are intended to be used once, those unused implants have been designed and manufactured to undergo re-sterilisation in accordance with the manufacturer's instructions.

When the sterilised set of implants is opened in the operating suite, the unused implants within the set are regarded as 'opened but unused single-use medical devices'. The subsequent re-sterilisation of the unused implants must be undertaken in accordance with the manufacturer's instructions. The intended use for the device has not been changed, there is no reuse occurring and the reprocessing and re-sterilisation is in accordance with the manufacturer's original instructions.

However, if one of these single use devices is used or comes into contact with blood, tissue, or bodily fluids, the device is taken to be used and cannot be remanufactured for reuse on another person unless the remanufacturing is undertaken in a TGA-certified manufacturing facility. The remanufacturer must have demonstrated to the TGA through scientific and clinical evidence that the remanufactured device performs as

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intended and meets the Essential Principles. To be able to clean and sterilise the device and reuse it in another patient the TGA must have issued a:

- TGA Conformity Assessment Certificate to the new manufacturer who is responsible for the sterilisation
- certificate of inclusion in the ARTG to the sponsor for that device.

### External fixation devices

External fixation devices either encircle or lie adjacent to the head or a limb, and are attached to the skeleton by pins, fine tensioned wires or screws. They are used to treat fractures or reconstruct bones and joints that are deformed or damaged.

External fixation devices may be initially supplied as part of a system pack, which comprises component parts that are intended by the manufacturer to be used in combination as a unit.

The component with the highest risk classification determines the overall classification for the system pack. For example, the Ilizarov external fixation system contains sterile pins that secure the external frame to the patient's bones. These would usually be considered Class IIb medical devices and as a consequence the entire system pack is classified as Class IIb.

However, there are occasions where it may be appropriate to supply individual components of a system separately. In these circumstances each device that is individually supplied is classified separately and requires a separate entry in the ARTG. The manufacturer will classify the individual device using the classification rules and then apply the appropriate conformity assessment procedures to each of the individual types of device.

The non-sterile external components of the external fixation systems, when supplied separately to the system, are Class I medical devices. For example, the frame used in an external fixation system is non-invasive, is not active and none of the special classification rules apply, so it is Class I. The reprocessing of these non-sterile external components may be within the capability of some reprocessing supply departments.

Prior to the facility reprocessing and reusing the Class I external fixation frame labelled as single use, they will need to:

- prepare a Declaration of Conformity—for more information, please see [Section 6. What a manufacturer needs to know about conformity assessment](#)
- apply to the TGA to have the reprocessed device included in the ARTG.

There is no TGA inspection of the reprocessing facility or pre-market assessment of the reprocessed device as it is a Class I device. This is only the case for Class I reprocessed devices. The only regulatory cost is an annual charge to maintain the entry in the ARTG. The TGA will monitor the safety and performance of the device as part of its post-market vigilance and monitoring program.

The regulatory controls also require that the reprocessing facility reports to the TGA any serious incidents or adverse events associated with the use of the reprocessed device.

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# Section 20. Access to unapproved medical devices in Australia

## Overview

Medical devices are therapeutic goods. The TGA regulatory framework exempts some therapeutic goods from the need for inclusion in the Australian Register of Therapeutic Goods (ARTG) prior to supply in Australia, in certain circumstances.

This means that medical devices that have not been assessed by the TGA for quality, safety and performance and included in the ARTG may still be accessed in certain legitimate circumstances via specific exemptions in the therapeutic goods legislation. Such exempt medical devices are also typically referred to as 'unapproved medical devices' or 'unapproved therapeutic goods'.

There are four main mechanisms for legally accessing unapproved medical devices not included on the ARTG. These are:

- the Clinical Trial exemptions
- the Authorised Prescriber Scheme
- the Special Access Scheme (SAS)
- personal importation

This guidance document provides information on each of these mechanisms in relation to medical devices. If more information is required a comprehensive document Access to unapproved therapeutic goods in Australia is available on the TGA website, which outlines the Australian regulatory requirements for accessing medicines and medical devices that are not in the ARTG.

### Substances subject to additional controls

Some substances are prohibited under the *Custom (Prohibited Imports) Regulations 1956*. Further information on prohibited imports can be obtained from the Australian Customs and Border Protection Service website at <<http://www.customs.gov.au>>.

Prior quarantine clearance must be obtained to import any material of biological origin (human, animal, plant or bacterial). The importer should contact the Australian Quarantine & Inspection Service (AQIS) to see if an import permit is required. Further information can be obtained from the AQIS website <<http://www.aqis.gov.au>>.

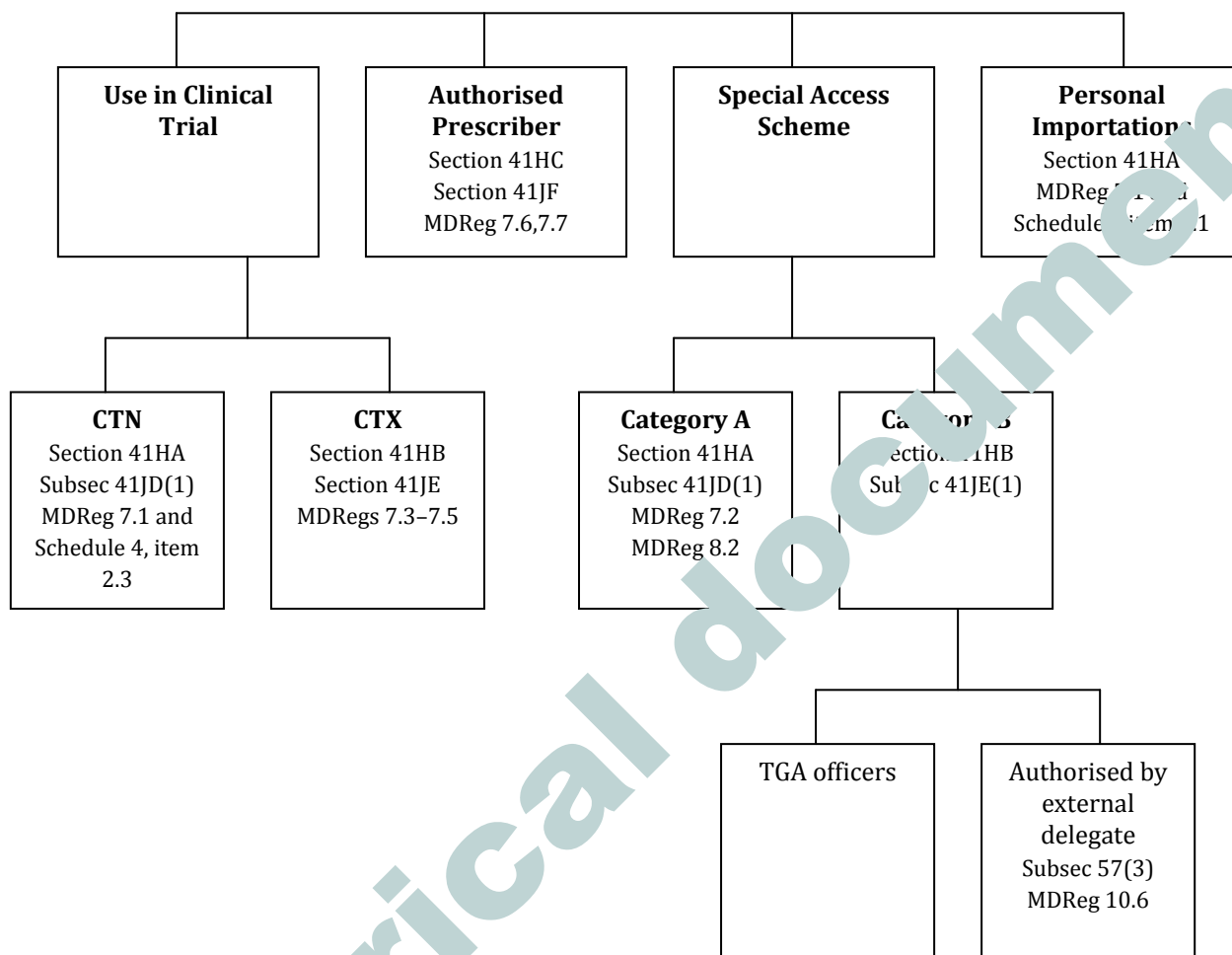
The import or export of substances containing parts of animals and plants listed as endangered species required a permit issued under the *Wildlife Protection (Regulation of Exports and Imports) Act 1982*. Further information can be obtained from the Environment Australia website <<http://www.biodiversity.environment.gov.au/wildlife>>.

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## Legislative basis for access to unapproved medical devices

The following table outlines the legislative basis for each of the mechanisms for accessing unapproved medical devices. References to:

- Sections and Subsections refer to the *Therapeutic Goods Act 1989* (the Act)
- MDReg refer to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations).



In considering requests for unapproved medical devices that have not been included in the ARTG, the TGA has a responsibility to maintain a flexible and efficient means of ensuring individuals are able to gain timely access to important new therapeutic developments without jeopardising the broader community interest in ensuring that devices available in Australia are evaluated for quality, safety and performance.

Under the Special Authorised Prescribers Schemes the TGA also has a responsibility to encourage at all times the availability of included devices in the ARTG. The various mechanisms for accessing unapproved devices are intended to be temporary measures pending inclusion of the device in the ARTG. There are some circumstances, however, when unapproved medical devices may be required for a prolonged period. For example, devices not available in Australia for whatever reason, yet fulfilling a legitimate clinical need. The TGA requires that applications to access unapproved devices clinically justify why available approved devices are not suitable for use, focussing on quality, safety and performance issues. Practitioner preference or cost issues are not acceptable as clinical justifications to support an application for access to an unapproved medical device.

### Release of information

Information provided to the TGA concerning the use of unapproved medical devices will be treated as confidential within the constraints of:

- Section 61 of the Act, which prescribes certain circumstances in which information may be released

- Section 27 of the *Freedom of Information Act 1982* requires that consultation occur between the TGA and the owner of the information prior to release of that documentation
- the *Privacy Act 1988* places limits on the disclosure of personal information by parties in possession or control of records. Such parties cannot disclose personal information about an individual to a person, body or agency other than the individual concerned except under certain circumstances. These circumstances include situations where the:
  - individual concerned has consented to the disclosure or is reasonably likely to have been aware that information of that kind is usually passed to that person or agency
  - holder of the record has reasonable grounds to believe that disclosure is necessary to prevent or lessen a serious, imminent threat to life or health of the person concerned
  - disclosure is required or authorised by or under law
  - disclosure is reasonably necessary for the enforcement of criminal law or of a law imposing criminal penalty, or for the protection of the public revenue.

Under the Act, the TGA is able to release information concerning the use of unapproved therapeutic goods to State and Territory authorities. This may allow States and Territories to have information for action on matters under their jurisdiction, such as medical or pharmacy practice. The circumstances under which this may occur include, but are not limited to:

- the TGA becoming aware that a medical practitioner is using notification mechanisms (for example, Category A SAS or the CTN Scheme) inappropriately so as to avoid having to obtain permission from the TGA for supply of an unapproved therapeutic good
- where audit of use of unapproved products establishes issues of negligence or unprofessional behaviour.

Doctors and sponsors reporting adverse events to the TGA associated with use of unapproved products should be familiar with and meet obligations in relation to the collection, storage and disclosure of personal information in accordance with the National Privacy Principles based on the *Privacy Act 1988*. These obligations are set out in the *Guidelines on Privacy in the Private Health Sector, Office of the Federal Privacy Commissioner, November 2001*.

The information required to report an adverse event is dependent on whether the person reporting the event is:

- a sponsor
- the user of the device

There are two separate forms available on the TGA website.

The information provided to the TGA is to identify the event rather than the patient. The TGA's requirement for information should not include data that could identify the patient; however the TGA may request details such as the patient's:

- age
- weight
- height
- common name
- medications they are currently taking

If disclosure of the patient's identity to the TGA is required, the patient's or relative's explicit consent to the release of the information must be sought.

## Clinical trials in Australia

A clinical trial or clinical investigation is an experiment conducted in humans in order to assess the effects, efficacy and/or safety of a medicine, medical device or procedure/intervention. Clinical trials of medical devices are undertaken to answer questions about their performance and safety. The trial should be designed to collect the information necessary to provide evidence to answer the questions posed and should advance scientific

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knowledge. It is therefore necessary that the trial be conducted using appropriate experimental designs to obtain valid data without exposing people to unnecessary risks.

The responsibility for monitoring a clinical trial rests with the:

- sponsor
- institution in which the trial is being conducted
- ethics committee
- investigator

Clinical trials must be approved by a Human Research Ethics Committee (HREC). The committee must be constituted and operating in accordance with the NHMRC's National Statement on Ethical Conduct in Human Research. With respect to the conduct of a trial at a specific site, approval of the trial is required from an HREC with jurisdiction at that site.

It is important to distinguish between clinical trials and use of a device in an individual patient as part of clinical practice. Use of unapproved medical devices in individual patients as part of clinical practice should be done using the provisions of the Authorised Prescriber or Special Access Scheme and not as a clinical trial.

A person must not intentionally or recklessly make a claim, by any means, that they or another person can arrange the supply of unapproved devices. This is an offence under Section 41(1)(M) of Chapter 4 of the Act and carries a financial penalty.

There are two schemes under which clinical trials involving medical devices may be conducted:

- the Clinical Trial Notification (CTN) Scheme
- the Clinical Trial Exemption (CTX) Scheme

These schemes are used for clinical trials involving:

- any device not included in the ARTG
- use of a device in a clinical trial beyond the conditions of its marketing approval

It is a decision of the clinical trial sponsor with respect to which scheme they wish to use. The two schemes are described in detail later in this document, but essentially the:

- CTN process involves a notification only to the TGA with a nominal notification fee (no approval or decision is made by the TGA)
- CTX process comprises an assessment by the TGA of summary data and usage guidelines for a proposed clinical development programme, and if approval is granted the subsequent trials must be carried out under the terms of the approval and be notified to the TGA

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The assessment of a CTX application is fully cost-recovered, and the TGA has a timeframe of up to 50 working days to make a decision on the application. Reasons for deciding upon a CTX approval are varied, but might include the medical device:

- being a completely novel treatment method and thus an application could assist in the evaluation of pre-clinical and clinical data and the identification of any deficiencies prior to commencement of trials in Australia and potentially overseas
- incorporates biological substances for which specific pre-clinical data may be required and clinical trial sponsors may wish to have confidence that current data is sufficient to address pre-clinical concerns

Clinical trials in which medical devices are used within the conditions of their marketing approval are not subject to CTN or CTX requirements but still need to be approved by a HREC before the trial may commence.

All CTN and CTX trials must have an Australian clinical trial sponsor. The clinical trial sponsor is that person, body, organisation or institution that takes overall responsibility for the conduct of the trial and signs the relevant page of either the CTN form or the CTX form. The clinical trial sponsor usually initiates, manages and supports a clinical study and carries the medical and legal responsibility associated with the conduct of the trial. Examples of possible clinical trial sponsors are:

- medical practitioners
- hospitals
- non-government organisations
- clinical research organisations
- medical device manufacturers

### **Clinical Trial Notification (CTN) Scheme**

All material relating to the proposed trial is submitted directly to the HREC by the researcher at the request of the clinical trial sponsor. This would usually include:

- the trial protocol
- the investigator's brochure
- related patient information
- supporting data
- the Notification of intent to supply unapproved therapeutic goods under the clinical trial notification (CTN) scheme. This is available from the TGA website: <<http://www.tga.gov.au>>.

For more information on the CTN application please see *Access to Unapproved Therapeutic Goods—Clinical Trials in Australia*, which is available from the TGA website: <<http://www.tga.gov.au>>.

HRECs usually have their own standard format for applications to conduct a clinical trial at their institution. The TGA does not review any data relating to a clinical trial prior to notification under the CTN Scheme, although key documents may be subsequently requested and reviewed.

The HREC is responsible for assessing the:

- scientific validity of the trial design
- safety and performance of the device
- ethical acceptability of the trial process

The HREC is also responsible for approval of the trial protocol.

The institution or organisation at which the trial will be conducted, referred to as the 'Approving Authority', gives the final approval for the conduct of the trial at the site, having due regard to advice from the HREC.

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The Notification of intent to supply unapproved therapeutic goods under the clinical trial notification (CTN) scheme form must be signed by the:

- clinical trial sponsor
- principal investigator
- Chairman of the HREC
- person responsible from the Approving Authority

*Please note: Once the original CTN has been approved, each additional trial site(s) will require another CTN notification to the TGA.*

CTN trials cannot commence until the Notification of intent to supply unapproved therapeutic goods under the clinical trial notification (CTN) scheme form is submitted to the TGA with the notification fee. The TGA will send the clinical trial sponsor an acknowledgement letter, providing the form has been appropriately completed. However notification of the CTN Form with the appropriate fee automatically creates the exemption necessary to allow lawful supply of the unapproved medical devices for the clinical trial.

The completed Notification of intent to supply unapproved therapeutic goods under the clinical trial notification (CTN) scheme form and a cheque for the notification fee should be forwarded to:

Postal Address	or	Courier Delivery
The Business Management Unit		The Business Management Unit
Therapeutic Goods Administration		Therapeutic Goods Administration
PO Box 100		136 Narrabundah Lane
WODEN ACT 2606		SYMONSTON ACT 2609
Australia		Australia

### Clinical Trial Exemption (CTX) Scheme

The CTX Scheme is an approval process.

A clinical trial sponsor must submit a supply of Unapproved Therapeutic Goods under the Clinical Trial Exemption (CTX) Scheme form (available from the TGA website) to the TGA for evaluation and comment. Submission of clinical devices/medical devices under the CTX scheme must comply with ISO 14155<sup>2</sup>.

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<sup>2</sup> ISO 14155: *Clinical investigation of medical devices for human subjects* defines procedures for the conduct and performance of clinical investigations of medical devices.



A CTX application for medical devices should be presented in 7 parts. Two copies of the complete application are required to allow simultaneous evaluation in different sections of TGA.

Part	Contents
Part 1	Administrative information and information complementary to the summaries of scientific information.
Part 2	Summary report of risk analysis documentation
Part 3	Summary report of the design dossier, including concept
Part 4	Summary report of manufacturing and materials
Part 5	Summary report of preclinical and/or clinical documentation
Part 6	Documentation on all fatal or life-threatening adverse events that have been associated with the use of the device prior to the date of the application
Part 7	Information for Human Research Ethics Committees

For more information on the contents of each part of the CTX application please see *Access to Unapproved Therapeutic Goods—Clinical Trials in Australia* available from the TGA website.

It is important to note that the application submitted to the TGA does not need to include the clinical trial protocol(s). The primary responsibility of the TGA is to review the safety of the device and the HREC is responsible for considering the scientific and ethical issues of the proposed clinical trial protocols.

The completed Supply of Unapproved Therapeutic Goods under the Clinical Trial Exemption Scheme, Part 1—the CTX Application form and a cheque for the evaluation fee should be forwarded to:

**Postal Address**

The Business Management Unit  
or  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2606  
Australia

**Courier Delivery**

The Business Management Unit  
Therapeutic Goods Administration  
136 Narrabundah Lane  
SYMONSTON ACT 2609  
Australia

A copy of the form and accompanying data should be forwarded to:

**Postal Address**

Clinical Section  
or  
Office of Devices Authorisation  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2606  
Australia

**Courier Delivery**

Clinical Section  
Office of Devices Authorisation  
Therapeutic Goods Administration  
136 Narrabundah Lane  
SYMONSTON ACT 2609  
Australia

The TGA will send a formal acknowledgment of the application. A 50 working day period applies for CTX applications for medical devices. The evaluation time commences from the date of acceptance of the application or receipt of the appropriate fee; whichever is the later day. If the TGA seeks more information from the clinical trial sponsor, the evaluation time is suspended until the information is provided.

The TGA evaluates the safety of the device and considers the proposed Usage Guidelines for the device. If the data supplied with the CTX application is not complete, the application may be returned unevaluated.

The TGA decides whether or not to object to the proposed Usage Guidelines for the device. If an objection is raised, trials may not proceed until the objection has been addressed to the Delegate's satisfaction. Further information may be requested from the clinical trial sponsor, which will interrupt the 50 day evaluation period. If the sponsor can not respond within 30 working days they should contact the TGA or the application may lapse.

If the application is acceptable, the clinical trial sponsor will be formally advised in writing that there are no objections to the supply of the device under the CTX Scheme.

If the TGA decides to reject the application, this decision may be appealed under Section 60 of the Act. Applications may be rejected due to:

- insufficient pre-clinical data
- inappropriate Usage Guidelines

If no objection is raised, the clinical trial sponsor may conduct any number of clinical trials under the approved CTX, provided use of the device in the trials fall within the original approved Usage Guidelines. This would involve notification of such trials to the TGA in a similar manner to the CTX scheme, but on a different form making it clear they are being conducted under an approved CTX.

*Please note: Once a CTX application has been approved, this is only an approval based on review of the summary information provided and the proposed usage guidelines for the product. Each actual trial conducted under a CTX must be notified to the TGA as described above on the appropriate notification form, which is available on the TGA website: <<http://www.tga.gov.au>>.*

The clinical trial sponsor must seek approval from the HREC and Approving Authority for each trial conducted under a CTX approval, in a similar manner to the CTN Scheme. The TGA must be notified by the clinical trial sponsor if an HREC objects to a trial, and if other HRECs have previously considered, or have approved, a protocol for a substantially similar trial the sponsor should inform an assessing HREC of this fact and the decision made by that HREC.

A clinical trial sponsor cannot commence a CTX trial until:

- written advice has been received from the TGA stating the application has been approved
- approval for the conduct of the trial has been obtained from:
  - a HREC
  - the institution at which the trial will be conducted.

The trial can commence on receipt by the TGA of the Supply of Unapproved Therapeutic Goods under the Clinical Trial Exemption (CTX) Scheme—Part 2 Notification of the Conduct of a Trial Under the CTX Scheme. There is no fee for notification of trials under the CTX scheme.

## TGA fees for clinical trials

The fees for applications for clinical trials under the CTX scheme are higher than notifications under the CTN due to the increased work required by TGA to evaluate the data provided.

There is a single fee for the CTX application.

For the CTN there is a notification fee.

Notification	Fee
all sites notified at same time (including composite sites)	single notification fee
each site notified individually	notification fee for each separate notification
sites notified in groups	notification fee for notification of each group

The current fees for clinical trials for included devices are available on the TGA website.

## Completion of clinical trials

The TGA maintains a record of each clinical trial and each trial site conducting a trial. To maintain the record for each trial, the TGA should be notified of the:

- date the trial was completed (That is, the last date of completion at all sites. It is not necessary to notify completion dates for individual sites.)
- reason the trial ceased (for example, concluded normal, insufficient recruits).

The clinical trial sponsor should complete the Clinical Trial Completion Advice—CTN and CTX Schemes form, which requests this information, and which is available from the TGA website.

## Responsibilities of the clinical trial sponsor

The general responsibilities of sponsors of clinical trials are set out in section 5 of the CPMP/ICH Note for Guidance on Good Clinical Practice (CPMP/ICH, 35/95) available from the TGA website. The clinical trial sponsor must also fulfil all regulatory requirements of the TGA and comply with state and territory legislation in relation to the supply of therapeutic goods.

The clinical trial sponsor is also responsible for establishing legal and financial agreements between the clinical trial sponsor, investigators and participating institutions/organisations. These should address issues such as indemnity of the parties involved in the trial and compensation and treatment of trial participants in the case of injury or death.

The TGA does not require protocol amendments to be notified by clinical trial sponsors where the amendments clarify the use of, and the monitoring of treatment. However a new notification to the TGA may be required if there is a major change to the protocol and the HREC requires a change to the conditions of their approval, such as:

- introduction of new devices
- changes in addresses of sites where the clinical trial is conducted
- expansion of indications being treated
- changes to the treatment population being targeted

## Adverse event reporting requirements for clinical trials

Reporter	What needs to be reported	Who to report to	In what format?	Timeframe
Sponsor of trial	Serious and unexpected adverse device events	TGA	Medical Device Incident Report form	<ul style="list-style-type: none"> <li>fatal or life-threatening adverse device events—initial report within 24 calendar days of first knowledge. Complete report within 10 calendar days.</li> <li>other serious unanticipated device events, full report no later than 15 calendar days of first knowledge.</li> </ul>
	Other adverse device events and adverse events	TGA	Submission/Line listing	On request by TGA
Clinical investigator	Adverse device events and adverse events	HREC	As required by HREC	As required by HREC
		Sponsor of trial	As required by study protocol	As required by study protocol

For reports to the TGA, the report should be clearly marked 'Clinical Trial Incident' and sent to:

**Postal Address**  
 Clinical Section  
 Office of Devices Authorisation  
 Therapeutic Goods Administration  
 PO Box 100  
 WODEN ACT 2606  
 Australia

**Courier Delivery**  
 Clinical Section  
 Office of Devices Authorisation  
 Therapeutic Goods Administration  
 136 Narrabundah Lane  
 SYMONSTON ACT 2609  
 Australia

The Medical Device Incident Report form is available on the TGA website: <<http://www.tga.gov.au>>.

### More information

More information on conducting clinical trials in Australia, including the forms to be completed, is available on the TGA website: <<http://www.tga.gov.au>>.

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## Authorised prescribers

The TGA is able to grant certain medical practitioners authority to prescribe a specified unapproved medical device or kind of medical device to recipients who have a particular medical condition. The medical practitioner becomes an 'Authorised Prescriber' and can prescribe that product for that condition to individual patients in their immediate care without further approval from the TGA.

The TGA cannot vouch for the quality, safety or performance of an unapproved device, therefore the use must be regarded as experimental. The granting of this authority does not render the Commonwealth or the TGA liable to a person in respect of loss, damage, or injury of any kind suffered by the person as a result of, or arising out of, the use of the device by that person or another person.

The authorisation only allows the Authorised Prescriber to supply the device directly to specified patients and not to other practitioners who are not authorised to prescribe/administer the device to patients.

The basis for providing the approval is that the authorised medical practitioner has training and experience appropriate for the condition being treated and the proposed use of the device and that the Authorised Prescriber is able to best determine the needs of the patient and to monitor the outcome of the therapy.

Authorised Prescribers can supply individual patients with unapproved therapeutic goods under a range of circumstances, such as when devices:

- were provided initially to patients through a clinical trial while an application for inclusion on the ARTG is being considered
- are available overseas but not in Australia.
- no suitable alternative approved device is available in Australia

Patients who may access unapproved medical devices prescribed by an Authorised Prescriber are those suffering from an illness or condition that is either:

- life-threatening, or
- serious, being generally accepted as not being appropriate to be diagnosed or evaluated and treated safely without consulting a health practitioner

## Applications to be an Authorised Prescriber

The following information is required by the TGA as part of an application to become an Authorised Prescriber:

Recipients	
Indication	Disease/condition to be treated
Clinical justification	An outline of the seriousness of the condition, and, if other approved treatments are available, justification for the use of the unapproved device in preference to the treatments
Medical Device	
Product details	Name of device, supplier
Performance/safety data	Performance and safety data sufficient to support the proposed use of the device. A copy of the reference articles from which the data have been obtained should be included
Prescriber	
Details	Name, postal address, phone number, fax number
Ethics committee Endorsement	Evidence of endorsement from an ethics committee must be submitted
Agreement to Treatment Directions	A completed and signed Agreement to Treatment Directions form must accompany the application <i>Please note: this form is available on the TGA website: &lt;<a href="http://www.tga.gov.au">http://www.tga.gov.au</a>&gt;</i>

Applications should be sent to:

Chief Clinical Advisor  
Clinical Section  
Office of Devices Authorisation  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2606

Phone: 02 6232 8615  
Fax: 02 6232 8785

Once the TGA Delegate has considered the application, the applicant will be sent a letter advising that the application has been:

- accepted
- rejected, or
- more information is required

If an application is rejected there are various appeal mechanisms that can be considered. For more information please, refer to *Access to unapproved therapeutic goods—Authorised prescribers* available on the TGA website.

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## Endorsement from an ethics committee

Medical practitioners seeking to become Authorised Prescribers require endorsement from an ethics committee as follows:

- for a medical practitioner engaged in clinical practice in a hospital, endorsement from the ethics committee of that hospital
- for a medical practitioner treating patients outside a hospital setting, endorsement from an appropriate ethics committee

A special exemption exists for medical practitioners who can demonstrate that they do not have access to an ethics committee to get endorsement from an appropriate specialist college. Appropriate specialist colleges are listed in Schedule 4 to the *Health Insurance Regulations 1975*.

It is recommended that the letter of endorsement from the ethics committee should include:

- a clear statement that endorsement is being given for the purpose of the medical practitioner becoming an Authorised Prescriber
- the name of the medical practitioner being endorsed
- the device and the intended purpose for which endorsement has been given
- the sites at which use is covered by the endorsement
- any conditions the ethics committee has imposed on the endorsement
- the signature of the chairman of the ethics committee over his or her official title

*Please note: Under the Act, an ethics committee must be constituted and operating in accordance with NHMRC guidelines and have notified its existence to the Australian Health Ethics Committee. Endorsement from ethics committees that do not satisfy these requirements will not be accepted by the TGA.*

## Once approval is given by the TGA

If the medical device is available from a supplier in Australia, the Authorised Prescriber should contact the supplier/sponsor to organise supply.

The supplier will require authorisation to lawfully release the device. A copy of the letter of Authorisation must be forwarded to the supplier.

If the device is not available from an Australian sponsor, the requesting doctor will need to find an overseas source. The device will need to be imported from that supplier. This can be done by the doctor, a pharmacist, hospital, by the patient or by a licensed importer. Similarly, the overseas supplier will likely require a copy of the letter of authorisation. Please note that import controls may also apply to some devices, in particular those of animal origin or containing prohibited substances.

The doctor is responsible for reporting the number of patients treated on a six-monthly basis.

It is a condition of the approval that the treating doctor reports the details of any actual or suspected adverse events to the TGA. For more information, please see [Adverse event reporting requirements for clinical devices](#) in this section.

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## Responsibilities of the patient

It is a condition of the approval to supply an unapproved therapeutic good for use in Australia that the patient or the patient's legal guardian must be in a position to make an informed decision regarding treatment. Informed consent should be in writing unless there are good reasons to the contrary. Informed consent should be freely given and includes an adequate knowledge of the condition and its consequences, an adequate knowledge of the treatment options, the likelihood of recovery and the long-term prognosis. Additional consent is required where the device contains products derived from biological tissue including human blood or plasma. Patients should complete the Authorisation of Supply Under S19(5) or Section 41HC *Therapeutic Goods Act 1989—Consent to Treatment and Indemnity for Use of Products Derived from Biological Tissue Including Human Blood or Plasma* form available on the TGA website.

A patient should be specifically informed of the following:

- that the device is not included on the ARTG for the intended purpose
- possible benefits of treatment and any risks and side effects that are known
- the possibility of unknown risks and late side-effects
- any alternative treatments using approved devices that are available.

## Responsibilities of the supplier/sponsor

A company is under no obligation to supply an unapproved product just because it has been prescribed by an Authorised Prescriber. Applicants should ensure companies are willing to supply the device before making an application.

The supplier/sponsor is required to:

- provide the TGA with six-monthly reports detailing the supply of unapproved devices to Authorised Prescribers
- consider whether to submit an application to the TGA if long-term supply of their device is expected
- monitor the use of their devices
- report to the TGA all those serious unanticipated device related adverse events of which they have been informed. For more information, please see [Adverse event reporting requirements for clinical trials](#).
- communicate rapidly to the TGA information that has an important bearing on the benefit–risk assessment of the device, particularly any information that may lead changes to the usage of the device by Authorised Prescribers



## Adverse event reporting requirements for Authorised Prescribers

Reporter	What needs to be reported	Who to report to	In what format?	Timeframe
Authorised Prescriber	Any adverse device event	TGA	Medical Device Incident Report form	As promptly as possible, to reach TGA within 15 days
		Sponsor	As required by sponsor	As required by sponsor
		HREC (if applicable)	As required by HREC	As required by HREC
Sponsor	Serious unanticipated adverse device related events	TGA	Medical Device Incident Report form	<ul style="list-style-type: none"> <li>fatal or life-threatening adverse device events, initial report within 7 calendar days of first knowledge. Complete report within 8 additional calendar days</li> <li>other serious unanticipated device events, full report no later than 15 calendar days of first knowledge</li> </ul>
	Other adverse device events	TGA	Tabular form/ List	On request by TGA

For reports to the TGA, the report should be clearly marked 'Authorised Prescriber Incident' and sent to:

The Medical Officer  
Clinical Section  
Office of Devices Authorisation  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2606  
Australia

The Medical Device Incident Report form is available on the TGA website: <<http://www.tga.gov.au>>.

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## Circumstances under which the TGA may revoke an authorisation

The TGA may give notice of revocation of an Authorisation at any time if:

- the ethics committee responsible for endorsement of the Authorised Prescriber has withdrawn its endorsement
- the Authorised Prescriber has failed to comply with conditions for Authorisation contained within the letter of authorisation
- a device similar to the unapproved device is evaluated and approved for treatment of the specified indication and included on the ARTG
- the TGA becomes aware of information from other use in Australia or from overseas that indicates major safety concerns with the use of the device

### More information

More information on Authorised Prescribers, including the forms to be completed, is available on the TGA website.

## Special Access Scheme (SAS)

The SAS is a mechanism to provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis. Applications are made by registered medical practitioners.

The SAS allows individual patients, with the support of their medical practitioner, access to unapproved devices in a range of circumstances, such as when:

- early access for terminally ill patients to almost any device, including experimental and investigational devices is needed (see Category A)
- devices were provided initially to patients through a clinical trial while a marketing application is being considered
- devices are available overseas but not in Australia

Final responsibility for the use of an unapproved device within an institution always rests with that institution. Medical practitioners working in an institution may also need approval from the institution's Ethics Committee or Drug and Therapeutics Committee prior to using a particular device.

There are two categories of patients who may use the SAS:

- Category A patients—medical practitioners can supply unapproved devices to some very seriously ill patients without the approval of the TGA as long as the medical practitioner notifies the TGA within 28 days.
- Category A patients are defined in the Therapeutic Goods legislation as 'persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment'.
- Category B patients—all other patients. Approval of an application to supply an unapproved device is required from a delegate in the TGA. Approval by the TGA is given on a patient by patient basis to reflect the needs of different patients.

The choice of classification of each patient lies with the treating medical practitioner. However, TGA is able to review, seek clarification and request information regarding the classification of patients under Category A.

### Category A patients

Prior approval from the TGA is not required for the use of an unapproved device in a Category A patient. The treating registered medical practitioner is the approving authority in that he/she is prepared to use the device in question.

The practitioner is required to complete the Category A Form Special Access Scheme available from the TGA website, and send it to the sponsor of the device. This provides the sponsor with the legal authority to supply the device.

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The practitioner must send a copy of the Category A Form Special Access Scheme to the TGA within 4 weeks of the date of signature on the form. Failure to do so is an offence that carries a financial penalty. The form should be faxed to 02 6232 8785.

The form requires the medical practitioner to certify that they:

- have determined that the patient is Category A
- are prepared to use the medical device requested
- have obtained the informed consent of the patient, or the patient's legal representative to the proposed treatment

A patient should be specifically informed of the following:

- that the device is not included on the ARTG for the intended purpose
- possible benefits of treatment and any risks and side-effects that are known
- the possibility of unknown risks and late side-effects
- any alternative treatments using approved devices that are available

Although the way in which a doctor prescribes a treatment for an individual in a particular clinical setting is a matter of medical practice and the TGA does not regulate medical practice, the TGA has responsibilities in relation to the safety of therapeutic goods supplied in Australia.

When the TGA identifies use of a device for an indication that is considered to fall outside the scope of the Category A definition, the TGA will inform the sponsor.

The TGA has the authority to review and seek clarification of the Category A classification of patients. This will occur on a case by case basis only if it is believed that the Category A provision is inappropriate for the particular clinical use. The TGA is also able to release such information to state and territory authorities, such as a Medical Board and/or Medical Complaints Units that are principally involved in the regulation of medical practice.

### **Category B patients**

Approval from the TGA is required prior to the device being supplied. Applicants should complete the Category B Form Special Access Scheme.

Applications need to address criteria relating to the patient, the device and the prescriber. Applicants can also provide any other information they consider important. In considering whether to grant approval, the TGA Delegate will generally consider the quality and extent of the information provided in the application.

Applications should be sent to:

The Medical Officer, SAS  
Clinical Section  
Office of Devices Authorisation  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2606

Phone: 02 6232 8679  
Fax: 02 6232 8785

Phone requests may be made where there is an urgent medical need for access to the device.

*Please note: The TGA can give no guarantee as to the quality, safety, or performance of devices containing biologically derived products, particularly in relation to any prion or viral inactivation. In view of the potential risks associated with the use of biological tissue-derived products, requests should not be made for non-essential uses of these devices. In addition, a specific consent form must be used when supplying biological products under the SAS Scheme, available on the TGA website.*

If the application is approved, certain conditions may be placed on the medical practitioner, including:

- the quantity of a medical device that can be supplied
- that should treatment be discontinued before the end of the treatment period approved, the TGA must be notified of the reasons for discontinuation within 6 weeks of the treatment being discontinued
- the use of an unapproved device should be regarded as an experimental use. The principles set out in the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research should be observed
- the doctor and patient, or patient's guardian, accept responsibility for any adverse consequence of treatment. The Commonwealth accepts no responsibility for any defects in the device whatsoever, including defects related to manufacture, distribution and *instructions for use*
- on completion of the treatment all remaining supplies of the device should be returned to the supplier
- any special conditions appropriate to the specific patient and device
- the period for which the approval is valid, particularly in cases where importation is required. For example, for up to 18 months from the date of the decision
- that the total quantity imported and supplied is not to exceed that required for the treatment of the particular patient
- the approval is for supply for use only by the particular patient

If the TGA Delegate approves the application, the medical practitioner will be sent a letter outlining the conditions of the approval, which will include an approval number.

If an application is rejected there are various appeal mechanisms that can be considered. For more information, please refer to *Access to unapproved therapeutic goods—Special Access Scheme* available on the TGA website.

### **Once approval is given by the TGA**

If the medical device is available from a supplier in Australia, the medical practitioner should contact the supplier/sponsor to obtain the supply.

The supplier will require authorisation to lawfully release the device. For a Category A patient, the completed Category A Form Special Access Scheme form acts as the authorisation. For Category B patients, the approval number issued by the TGA must be quoted in all correspondence with the sponsor.

If the device is not available from an Australian sponsor, the requesting doctor will need to find an overseas supplier. The device will then need to be imported from that supplier. This can be done by the doctor, a pharmacist, hospital, by the patient, or by a licensed importer.

### **Responsibilities of the patient**

It is a condition of the approval to supply an unapproved therapeutic good for use in Australia that the patient or the patient's legal guardian must be in a position to make an informed decision regarding treatment. Informed consent should be in writing unless there are good reasons to the contrary. Informed consent should be freely given and includes an adequate knowledge of the condition and its consequences, an adequate knowledge of the treatment options, the likelihood of recovery and the long-term prognosis. Additional consent is required where the device contains products derived from biological tissue including human blood or plasma. Patients should complete the Authorisation of Supply Under S19(5) or Section 41HC *Therapeutic Goods Act 1989—Consent to*

*Treatment and Indemnity for Use of Products Derived from Biological Tissue Including Human Blood or Plasma* form available on the TGA website.

A patient should be specifically informed of the following:

- that the device is not generally available in Australia
- possible benefits of treatment and any risks and side-effects that are known
- the possibility of unknown risks and late side-effects
- any alternative treatments using approved devices that are available

### Responsibilities of the supplier/sponsor

A company is under no obligation to supply an unapproved device just because it has been approved under the SAS. Applicants should ensure companies are willing to supply the device before making an application.

The supplier/sponsor is required to:

- provide the TGA with six monthly reports detailing the supply of unapproved devices under the SAS
- consider whether to submit an application to the TGA if long-term supply of their device is expected
- monitor the use of their devices continually and record the safety of the device and the balance of its benefit and risk
  - report to the TGA all those serious unanticipated device related adverse events of which they have been informed. For more information please see Adverse event reporting requirements.
- communicate rapidly to the TGA information that has an important bearing on the benefit/risk assessment of the device

### Adverse-event reporting requirements for devices supplied under the SAS

Reporter	What needs to be reported	Who to report to	In what format?	Timeframe
Treating Doctor	Any adverse device event	TGA	Medical Device Incident Report form	As promptly as possible, to reach TGA within 15 days
		Sponsor	As required by sponsor	As required by sponsor
		HREC (if applicable)	As required by HREC	As required by HREC
Sponsor	Serious unanticipated adverse device related events	TGA	Medical Device Incident Report form	<ul style="list-style-type: none"> <li>• fatal or life-threatening adverse device events—initial report within 7 calendar days of first knowledge. Complete report within 8 additional calendar days.</li> <li>• other serious unanticipated device events, full report no later than 15 calendar days of first knowledge.</li> </ul>
	Other adverse device events	TGA	Tabulation/Line listing	On request by TGA

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For reports to the TGA, the report should be clearly marked 'SAS Incident' and sent to:

The Medical Officer  
Clinical Section  
Office of Devices Authorisation  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2606  
Australia

The Medical Device Incident Report form is available on the TGA website <<http://www.tga.gov.au>>.

### More information

More information on the Special Access Scheme, including the forms to be completed, is available on the TGA website.

## Personal importation

Personal importation occurs when an individual:

- brings a medical device into Australia on their person
- arranges from within Australia for a device to be sent to them from a overseas supplier

The goods must be used by that individual or a member of their immediate family and must not be sold or supplied to any other person.

Individuals wishing to import unapproved devices for their personal use should be aware that in many cases the quality, safety and performance of the device may be unknown and they must therefore be prepared to accept any risks associated with the use of the device. If an individual suffers adverse consequences from using such devices, information about the goods and redress may be difficult to obtain.

Where the device is classified as low-medium risk (class IIa) or higher, the quantity imported must not exceed the amount required to deliver three months' treatment using the device according to a treating medical practitioner's directions. The total quantity imported per year must not exceed 15 months treatment using the device according to a treating medical practitioner's directions. These supply restrictions do not apply to devices used for long-term treatment, such as a hip implant.

Individuals may import medical devices without the goods being included in the ARTG where:

- the goods are either imported by the importer or a member of the importer's immediate family
- the goods do not contain a substance that is a prohibited import under the *Customs (Prohibited Imports) Regulations 1957*
- the device is not manufactured using tissues, cells or substances of animal origin that have been rendered non-viable or tissues, cells or substances of bacterial or recombinant origin
- the device either does not incorporate or is not intended to incorporate derivatives of human blood or blood products

In the case of a medical device that:

- is subject to Schedule 4—Prescription only medicines or Schedule 8—Controlled drugs, of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)
- incorporates or is intended to incorporate a substance that is subject to either of those Schedules, the device is acknowledged in writing by a State/Territory registered medical practitioner to be appropriate treatment for the importer

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**More information**

More information on personal importation is available on the TGA website or contact the TGA:

The Medical Officer, SAS  
Clinical Section  
Office of Devices Authorisation  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2606

Phone: 02 6232 8679  
Fax: 02 6232 8785

Historical document

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Historical document

**Therapeutic Goods Administration**

PO Box 100 Woden ACT 2606 Australia  
Email: [info@tga.gov.au](mailto:info@tga.gov.au) Phone: 02 6232 8444 Fax: 02 6232 8605  
[www.tga.gov.au](http://www.tga.gov.au)

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