



White paper:

How to register a medical device in Australia

The Australian medical device industry is constantly growing. Who regulates medical devices? What is the process for registering medical devices? This white paper highlights the key requirements for registering medical devices in Australia.



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What is a medical device?

The Therapeutic Goods Act 1989 defines a medical device as any instrument, apparatus, appliance, material or other article (whether used alone or in combination, including any applicable software) intended by the person under whose name it is to be supplied, to be used for:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception.

A medical device is further defined as any instrument, apparatus, appliance, material or other article (whether used alone or in combination, including any applicable software) 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.

A medical device can also be an accessory to such an instrument, apparatus, appliance, material or other article.

The range of medical devices runs from the simplicity of a tongue depressor right up to the intricacy of a surgically inserted pacemaker. Given such an array of products that impact human health and quality of life, it is vital that there is a regulatory body to supervise the medical device industry. The Australian Therapeutic Goods Administration (TGA) is primarily responsible for regulating this industry in Australia.

Australia's Medical Device Regulatory System

The TGA medical devices regulatory system:

- classifies medical devices based on the level of risk the devices pose to patient health or safety.
- sets out a number of Essential Principles which are the requirements for safety, performance and quality and must be fulfilled before products enter the market and while on the market.
- allows manufacturers to select the appropriate Conformity Assessment process for their product's risk profile, to demonstrate compliance with the Essential Principles.
- recognises international medical device reference standards and allows manufacturers to cite such standards in demonstrating compliance with the Essential Principles.
- implements regulatory controls for manufacturing processes.

The system also allows for the:

- periodic monitoring of available medical devices within the market.
- implementation of post-market surveillance systems, adverse incident reporting programs and vigilance activities.
- application of penalties for infringement of medical device regulatory requirements.

Who are the key players in the Australian regulatory system?

Who?	Roles	Responsibilities
Manufacturers	<p>Manufacturers perform design, production, packaging, refurbishment and labeling of the device.</p> <p>Note: Manufacturers are not persons who adapt a device for an individual patient that does not modify intended purpose, via labeling, instructions for use or technical documentation.</p>	<p>Determines classification, intended purpose, suitable Global Medical Device Nomenclature (GMDN) code</p> <p>Ensures compliance with the Essential Principles and documents the evidence of compliance in the technical file</p> <p>Selects suitable Conformity Assessment procedure</p> <p>Prepares Declaration of Conformity</p> <p>Notifies the assessment body of substantial changes to design, production or intended purpose</p>
Sponsors	<p>A sponsor imports, exports, or manufactures medical devices in Australia. (The Sponsor can be an Australian manufacturer.)</p> <p>Note: A sponsor is not a person who imports, exports or manufactures medical devices on behalf of another Australian resident.</p>	<p>Obtains requested information from the manufacturer for the TGA</p> <p>Submits Conformity Assessment evidence to the TGA</p> <p>Applies for inclusion of device in ARTG</p> <p>Submits samples to the TGA upon request</p> <p>Allows the TGA to enter and inspect premises</p> <p>Reports adverse events to the TGA</p>
Therapeutic Goods Administration (TGA)	Government body that regulates therapeutic goods including medical devices	
Agents	Persons (i.e. PharmOut) acting on behalf of manufacturers or sponsors, to include medical devices on the Australian Register of Therapeutic Goods	

Elements of the regulatory system

Intended Purpose

Manufacturers are required to determine the intended purpose of their medical devices. The intended purpose determines the classification, which in turn determines the assessment process.

Classification

Medical devices are classified into five levels based on the level of risk and the intended purpose of the device, in accordance with:

- the Therapeutic Goods (Medical Devices) Regulations 2002, Regulation 3.2 and Schedule 2, and
- the Therapeutic Goods Act 1989, section 41BD.

The level of risk determines the required regulatory control for the medical device.

Class	Level of Risk	Device Examples
I	Low	Scalpels, compression bandages, dental kits
IIa	Low-medium	Hearing aids, masks for providing anaesthesia,
IIb	Medium-high	Condoms, blood bags, infusion pumps,
III	High	Cardio-vascular stents, joint prostheses, heart valves
AIMD (Active Implantable Medical Device)	High	Pacemakers, implantable defibrillators

Essential Principles

The TGA's Essential Principles set out the requirements relating to the safety and performance characteristics of medical devices. The Essential Principles require that the:

- use of a medical device must not compromise health and safety.
- design and construction of a medical device must conform with safety principles.
- medical device is appropriate for its intended purpose.
- long term safety of user has been ensured.
- benefits of a medical device outweigh any side effects.

These Essential Principles apply to all medical devices, regardless of intended purpose or classification. There are also a number of more specific Essential Principles may or may not apply to a particular device, depending upon its design, intended purpose and manufacture. They include requirements for biological safety, electrical safety, sterilisation, materials of biological origin, mechanical and radiation safety, and labelling requirements.

Demonstrating compliance with the Essential Principles

A manufacturer's can demonstrate compliance with the Essential Principles by providing evidence that may include:

- a documented risk analysis;
- the documentation for the manufacturer's testing results;
- copies of labels, packaging and Instructions for Use that indicate compliance with relevant requirements and standards.
- clinical evidence, from clinical trials and/or a documented review of appropriate published literature, drawn together by a relevant clinical expert;

The manufacturer will document the evidence of compliance in the Technical File for the device; for Class III or AIMD devices, the technical file is presented to the regulatory body in the form of a design dossier.

Standards

Medical device manufacturers may choose to use relevant standards as the means of demonstrating compliance with the Essential Principles for medical devices. Whilst standards are not mandatory, the TGA has identified a number which, if applied correctly to a medical device which is in scope of the standard, may be used as evidence of compliance with one or more Essential Principles. Examples of these regulatory standards are:

- ISO 14971 - Application of risk management to medical devices
- ISO 13485 - Quality management systems - Requirements for regulatory purposes
- ISO 11137 - Sterilization of health care products - Radiation, Parts 1-3

The manufacturer should identify the relevant standards and document testing to show compliance in a device's technical files.

Conformity Assessment

Conformity Assessment is the systematic and ongoing examination of evidence and procedures to ensure that a medical device complies with the Essential Principles. The manufacturer should select appropriate Conformity Assessment procedures based on the classification of the medical device.

Issuance of Conformity Assessment certificate

A Conformity Assessment certificate is issued by a regulatory body as evidence that a manufacturer has been assessed and has established appropriate systems to manufacture the medical devices.

The Conformity Assessment:

- confirms that the Conformity Assessment procedures are appropriate for the classification of the device.
- covers a systematic examination of the technical documentation, including risk analysis, clinical evidence, the manufacturing processes and ongoing monitoring undertaken by the manufacturer.
- conducts re-certification of the Conformity Assessment evidence that is due to expire.

A conformity assessment certificate issued by TGA is required for:

- Australian manufacturers (other than manufacturers of Class I devices);
- Overseas manufacturers of devices which
 - incorporate a medicinal substance with action ancillary to that of the device;
 - contain tissues of animal origin;
 - contain tissues, cells or substances of microbial or recombinant origin intended for use in or on the body; or
 - incorporate stable derivatives of blood or human plasma that are liable to act on the body in a manner ancillary to the device.

In other cases, a conformity assessment certificate issued by a European Notified Body in accordance with the requirements of the European Medical Devices Directive or the Active Implantable Medical Device Directive (an EC certificate) is acceptable. The TGA has recently announced that it will also accept certificates issued under the Medical Device Single Audit Program (MDSAP) pilot, in which the TGA participates, together with Brazil's Agência Nacional de Vigilância Sanitária (ANVISA), Health Canada, and the US Food and Drug Administration.

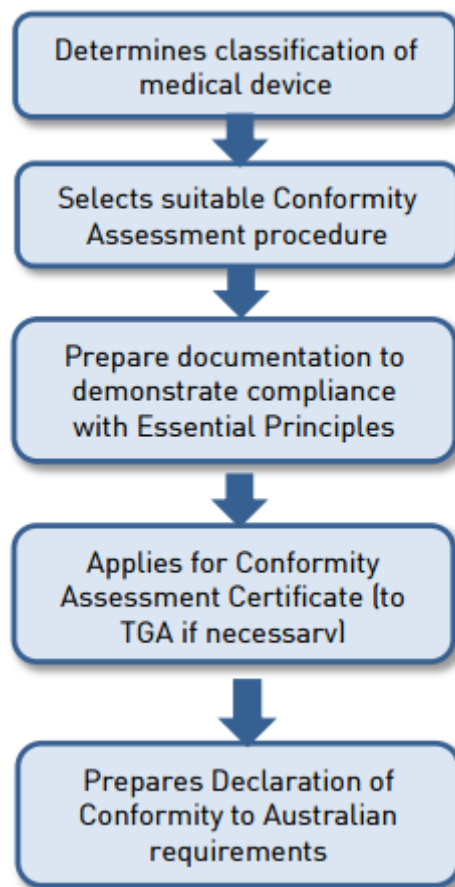
For Class III and AIMD devices for which the application is based on a European certificate, the TGA will conduct an Application Audit (now referred to as an Application Inspection Assessment). This process requires the sponsor to submit for assessment the key documents from the technical file, such as the Risk Management Report, the Clinical Evidence Report, copies of labels and instructions for use, and original copies of the European certification and the Australian Declaration of Conformity. There is a fee for this assessment. The TGA may

conduct an Application Audit on any other application, but as the Audit is not mandatory, no fee applies.

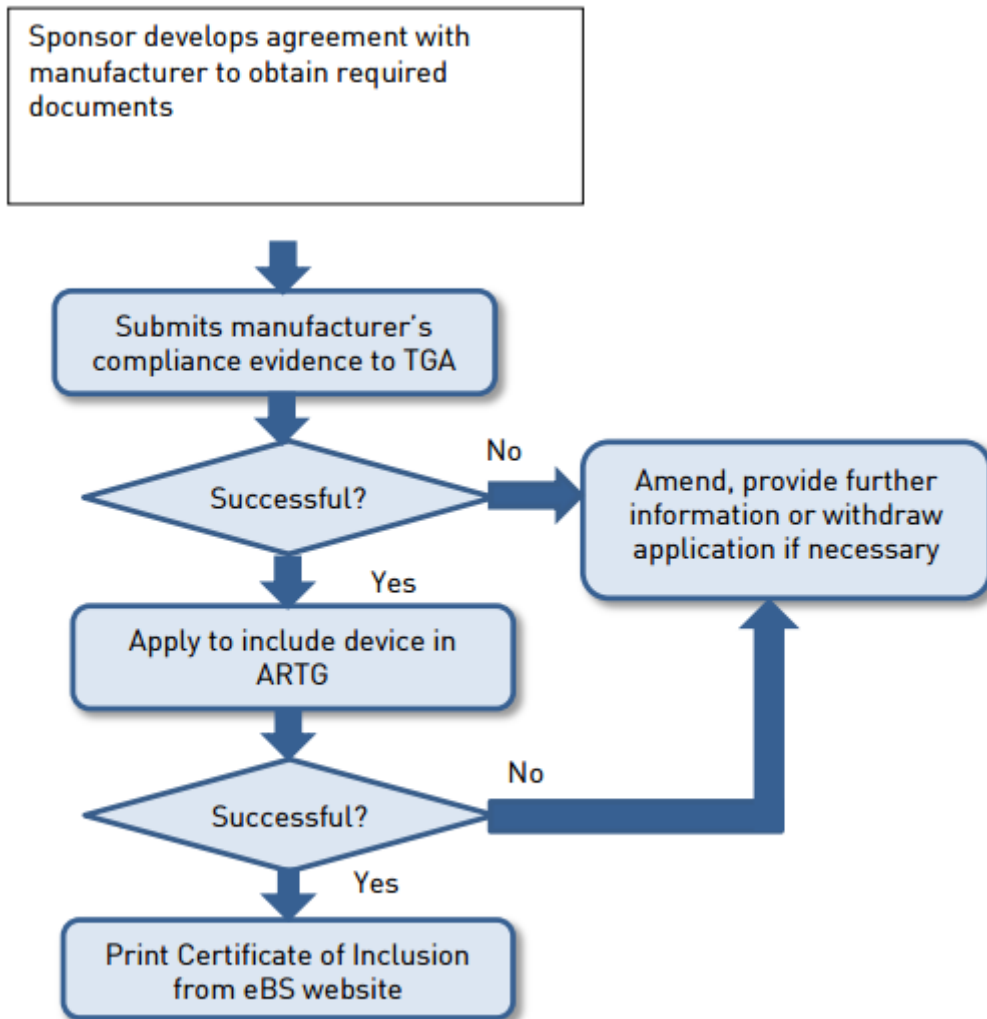
Overview of processes to supply medical devices in Australia

The overview of processes to supply medical devices in Australia is depicted below. There might be variations to these processes, depending on the different classifications of medical devices and the locations of manufacturing sites.

Manufacturer



Sponsor



Conformity Assessment procedures based on classification

	Conformity Assessment procedure	Manufacturer's requirements
I	Part 6 (Declaration of Conformity, not requiring assessment by the Secretary)	Documentation to show conformity with Essential Principles.
I (measuring) & IIa (non-sterile)	Part 6 (Declaration of Conformity, not requiring assessment by the Secretary) Part 5 (Product quality management system)	Documentation to show conformity with Essential Principles. Implement product quality management system for final inspection and testing for audits. Note: Submission of Declaration of Conformity is not required for Class I (non-measuring and non-sterile) but should be available upon request by the TGA.
I (sterile) & IIa (sterile)	Part 6 (Declaration of Conformity, not requiring assessment by the Secretary) Part 4 (Production Quality Assurance)	Documentation to show conformity with Essential Principles. Implement quality management system that excludes design element, based on ISO 13485.
IIb	Part 1 (Full Quality Assurance) excluding Clause 1.6 (Examination of design)	Implement full quality management system including design, production, labelling, packaging and final inspection based on ISO 13485. Excludes design dossier.
III & AIMD	Part 1 (Full Quality Assurance) including Clause 1.6 (Examination of design)	Implement full quality management system including design, production, labelling, packaging and final inspection based on ISO 13485. Design dossier in accordance with Essential Principles.

	Conformity Assessment procedure	Manufacturer's requirements
Systems or Procedure Packs	Part 7 (Procedures for Medical Devices Used for a Special Purpose)	Essential Principles. Conformity Assessment procedure. Clinical evidence for individual component in system or pack.

There are two other Conformity Assessment Procedures available, but which are not often used. These are Part 2, Type Examination and Part 3, Verification Procedures. These pathways involve testing of the "type" of a device to determine compliance with a standard or other specification (Part 2), and then confirmation that each batch conforms to the "type" (Part 3).

These procedures are expensive and not recommended, unless perhaps the device is a large piece of capital equipment that is not mass-produced. Part 2 may be combined with Part 4, rather than Part 3.

Declaration of Conformity (DoC)

Once a manufacturer has obtained Conformity Assessment evidence, an Australian DoC must be generated to declare that the medical device complies with:

- the applicable provisions of the Essential Principles;
- the classification rules; and
- an appropriate Conformity Assessment procedure.

The DoC must be maintained, and updated when appropriate. A European Declaration of Conformity is not accepted.

Mutual Recognition Agreements

Australia has agreements with the following countries and regions:

- **Europe:** Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between Australia and the European Community or the European Free Trade Association. This agreement allows designated European Conformity Assessment Bodies to assess devices manufactured in Europe to Australian requirements and the TGA to assess devices manufactured in Australia to European requirements. The Agreement means that a device with a MRA certificate may be included on the ARTG without further assessment. Certain product exclusions apply.
- **USA:** Co-operative agreement between the TGA and the Federal Drugs Administration (FDA) to exchange regulatory information
- **New Zealand:** Memorandum of Understanding between the TGA and MedSafe.

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- Canada: A Memorandum of Understanding (MoU) has been signed between the TGA and Health Canada regarding recognition of the quality management system certificates issued by approved Canadian Registrars.
- Switzerland: Established Memorandum of Understanding (MoU) to exchange information about regulatory decisions and post-market monitoring of therapeutic products
- The Medical Device Single Audit Program (MDSAP) pilot will be in place from January 2014. This Program involves the TGA, Brazil's Agência Nacional de Vigilância Sanitária (ANVISA), Health Canada, and the US Food and Drug Administration. The TGA will use an MDSAP audit report as part of the evidence that is assessed for compliance with medical device market authorisation requirements.

How do you register a medical device using the eBS system?

In order to register a medical device, you need to create an e-business account for the e-Business (eBS) system on www.ebs.tga.gov.au.

Click on the eBS Access Forms section of the page and download the following forms:

- Client Details Form – only to be completed if, as a sponsor, you do not already have a client identification number. For first-time sponsors, the form needs to be completed for both the sponsor and the overseas manufacturer
- eBS Access Request Form – download and complete it to establish an e-business account with the TGA. Either fax it to the TGA on 02-62328581, or post it to the TGA address listed on the eBS website.

In order to complete an eBS application for inclusion of a medical device on the ARTG, you need to:

- submit copies of the manufacturer's Conformity Assessment Certificate (Manufacturer's Evidence); and
- once you have received a Manufacturer's Evidence Number, you submit an application to register a medical device on the ARTG. The application will not be processed until the applicable fee is paid.

If an Application Audit is required, the TGA will notify you in writing, listing the documentation required and the applicable fees, if any.

The lodgment and acceptance of the Manufacturer's Evidence generally takes 5 to 10 business days and no fees are payable for this lodgment process. The processing time for the entire application may take from 3 to 8 weeks, or longer, depending on the completeness of the application. If an Application Audit is required, the time-frame will be 3 – 6 months.

Fees and charges for medical devices

The TGA fees for medical devices comprise: application fees, Conformity Assessment fees and Application Audit fees.

Application fees	Conformity Assessment fees	Application audit fees
TGA Conformity Assessment	TGA Conformity Assessment (QMS certification)	Consists of Level 1 and 2 audits
A change or recertification of a TGA Conformity Assessment Certificate	Recertification when a TGA Conformity Assessment Certificate is due to expire	-
Inclusion of a medical device in ARTG	Assessment of Essential Principles documentation for initial application and recertification (Design Examination) – applies to Class III	-
Change incorrect ARTG entry	QMS certification for European Community – Mutual Recognition Agreement	-
Certificate of Free Sale or Export Certificate	TGA surveillance audits for Conformity Assessment	-
Application for importing, supplying or exporting a device that does not conform to Essential Principles requirements	Amendments to TGA Conformity Assessment Certificate	-
Application for Clinical Trial Exemption Scheme	Testing of medical devices by the TGA (in the context of an application for Conformity Assessment via the Type Examination or Verification routes)	-
Application for Clinical Trial Notification Scheme	-	-

Refer to the TGA website (www.tga.gov.au) for current TGA fees and charges for medical devices.

References

TGA eBusiness Services

www.ebs.tga.gov.au

Australian Regulatory Guidelines for Medical Devices (Version 1.1, May 2011)

www.tga.gov.au

www.ghtf.org

www.imdrf.org

<http://www.gmdnagency.org/>

Therapeutic Goods Act 1989

[http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/72D440E51DF66177CA257375000E52B1/\\$file/TherapeuticGoods1989_WD02_Version2.pdf](http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/72D440E51DF66177CA257375000E52B1/$file/TherapeuticGoods1989_WD02_Version2.pdf)

Therapeutic Goods (Medical Devices) Regulations 2002

<http://www.comlaw.gov.au/Series/F2002B00237>

Sources

Links used within this document are prone to change. Please refer to the appropriate source for the most recent information. We endeavour to keep an up-to-date record of information at

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