



White Paper

How to Register a Medical Device in Australia

The Australian medical device industry is constantly growing. It is currently worth more than \$4.6 billion dollars and consists of more than 25,000 devices, 1100 companies and employs more than 10 000 people¹. Who regulates medical devices? What is the process for medical device registration? This white paper highlights the key requirements to register medical devices in Australia.

¹ See <http://www.industry.gov.au/assets/documents/itrinternet/AMDIFinalReport20051102150005.pdf>
<http://www.ausbiotech.org/content.asp?pageid=109>

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, and including the software necessary for its proper application) intended by the person under whose name it is to be supplied, to be used for human beings for the purposes of one or more of the following:

- 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,

and does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means; or an accessory to such an instrument, apparatus, appliance, material or other article.”

Australia’s Medical Device Regulatory System

The Therapeutic Goods Administration (TGA) is the government body that regulates therapeutic goods, including medical devices, in Australia.

Australia’s regulatory framework is based upon the recommendations of the Global Harmonization Task Force (GHTF). The GHTF is a voluntary group of international regulatory affairs experts for medical devices that was established to harmonise the regulation of medical devices internationally².

The Australian regulatory system has the following features:

- a classification scheme based on the level of risk
- compliance with a set of essential principles to ensure that only safe, effective and quality medical devices are supplied
- implementation of conformity assessment procedures, depending on the class of the medical device to demonstrate compliance with the essential principles including an implemented quality management system in accordance to ISO 13485:2003
- a recognition of international medical device reference standards in order to demonstrate compliance to the essential principles e.g. IEC 60601-1
- implementation of regulatory controls for manufacturing processes
- inclusion on the Australian Register of Therapeutic Goods (ARTG)
- implementation of post market surveillance systems, adverse incident reporting programs and vigilance activities.

² See www.gh tf.org

Who are the key players in the Australian regulatory system?

There are 4 key players in the Australian regulatory system:

Who?	Role
Manufacturers	To manufacture medical devices in Australia or overseas
Sponsors	To import, export, or manufacture medical devices. An Australian manufacturer may also act as a sponsor.
Therapeutic Goods Administration (TGA)	Government body that has regulatory control of therapeutic goods (including medical devices) in Australia
Agents	Consultants, such as PharmOut, that act on behalf of manufacturers or sponsors, to register their medical devices in Australia

Medical Device Requirements for inclusion on the ARTG

In order for a medical device to be included on to the ARTG³ the following criteria must be met:

- the product must be a medical device
- the device must have an intended purpose
- the device must be correctly classified i.e. in accordance to the classification rules
- there must be evidence provided to demonstrate that the device complies with the applicable essential principles
- there must be evidence of selection of an appropriate conformity assessment procedure and the rationale for the use of the conformity assessment procedure needs to be substantiated
- the advertising for the device must comply with all legal requirements
- the device must not contain any prohibited imports
- the information included in or with the application is complete and correct.

³ There is public access to the ARTG at the following link.:

<https://www.tgasime.health.gov.au/SIME/ARTG/ARTGPublicWeb.nsf?OpenDatabase>

Who is responsible for registering the medical device on the ARTG?

The sponsor or his designated agent registers (“includes”) the device on the ARTG after receiving the following information from the manufacturer:

- class of the device
- intended purpose of the device
- GMDN code and term
- conformity assessment certification
- Australian declaration of conformity

Classification:

Medical devices are classified in to 5 classes based on the level of risk and the intended purpose of the device, in accordance to a set of 22 classification rules. The higher the class, the more regulatory control is required. The manufacturer is responsible for classifying the device. TGA guidance on classification can be found at the following link: <http://www.tga.gov.au/docs/pdf/devguid25.pdf>

Class	Level of Risk	Device Example
I	Low	Scalpel
IIa	Low-medium	Hearing aids
IIb	Medium-high	Condoms
III	High	Vascular stents
AIMD	High	Pacemakers

Intended purpose:

The *Therapeutic Goods (Medical Devices) Regulations 2002* defines “intended purpose” as:

“...means the purpose for which the manufacturer of the device intends it to be used, as stated in:

- (a) the information provided with the device; or
- (b) the instructions for use of the device; or
- (c) any advertising material applying to the device.”

For example, the intended purpose of an adhesive wound dressing may be to cover and protect wounds and/or to hold together the skin edges of a wound, or, the intended purpose of a stethoscope is to project the sounds associated with the heart, arteries, and veins and other internal organs.

GMDN Code and Term:

The Global Medical Device Nomenclature (GMDN) code is a collection of terms, each with a unique code number, to describe and catalogue medical devices.

The GMDN was developed according to the internationally recognised standard EN ISO 15225, and consists of 3 levels.

1. *Device Category*: This is a broad categorization. Currently there are 14 categories including: single use devices, dental devices, and in vitro diagnostic devices.
2. *Generic Device Group*: This level consists of the codes and the terms that define devices. This level is further broken down into preferred terms, template terms and synonym terms. Template terms can be recognised as having the word, "specify" written after them. Template terms can be used to classify class I (non-measuring and/or non-sterile) medical devices only. Higher classes need to use preferred terms. Preferred terms consist of devices that have similar intended purposes or common technology. Synonym terms are terms that relate to a previous nomenclature. The synonym terms are linked back to the corresponding template and preferred terms.
3. *Device Type*: This is a unique product identification provided by the manufacturer for the purpose of declaration of conformity, product type registration and traceability. It includes the make, model, serial numbers of a device that would enable the manufacturer to identify the device.

On the DEAL website there is a GMDN help button on the home page which enables manufacturers to look up suitable GMDN codes for their device.

The table below summarises the TGA's requirements for the type of GMDN code required, according to Class.

Class	Type of GMDN code required
I	Template term
IIa, IIb	Preferred Term
III/AIMD	Preferred term + unique product identifier

There is a GMDN fact sheet available at: http://www.tga.gov.au/devices/fs_gmdn.htm or for further information see <http://www.gmdnagency.com/>

Essential principles

The Essential Principles are a set of guiding requirements that specify characteristics to assist the manufacturer in producing safe, quality and effective medical devices. The Essential Principles are divided into 2 sections:

Part 1: General Principles

- use of medical devices not to compromise health and safety
- design and construction of medical devices to conform with safety principles
- medical devices to be suitable for intended purpose
- long term safety
- medical devices not to be adversely affected by transport or storage
- benefits of medical devices to outweigh any side effects.

Part 2: Principles about design and construction

- chemical, physical and biological properties
- infection and microbial contamination
- construction and environmental properties
- medical devices with a measuring function
- protection against radiation
- medical devices connected to or equipped with an energy source
- information to be provided with medical devices
- clinical evidence.

For further information check the following TGA guidance document
<http://www.tga.gov.au/docs/pdf/devguid22.pdf>.

Conformity Assessment Certification

The Conformity Assessment Certification is a certificate that is awarded by the TGA or another regulatory body to the manufacturer to demonstrate that a conformity assessment procedure has been adequately applied to the device and that the device complies with the essential principles. The manufacturer selects the conformity assessment procedure according to the classification of the device. The higher the class, the more TGA involvement is necessary. A conformity assessment procedure consists of:

- implementation, ongoing surveillance and certification of the manufacturer's quality management system
- demonstration of compliance with the essential principles
- declaration of conformity
- technical documentation including specifications, labeling
- design inputs
- design outputs
- implementation of change control procedures
- record keeping
- risk management
- clinical evidence
- performance monitoring
- implementation of a post market monitoring system
- implementation of procedures for reporting adverse incidents and recalls to the TGA.

For more information on Conformity Assessment procedures see:

<http://www.tga.gov.au/docs/pdf/devguid3.pdf> and
<http://www.tga.gov.au/docs/pdf/devguid26.pdf>

Mutual Recognition Agreements

Australia has a mutual recognition agreement with the European Union (EU). This means that the conformity assessment certificate that is awarded by the TGA is mutually recognised by the EU, and vice versa with the CE certification. The TGA can award a CE certification for an additional cost so that a device can be sold in Europe provided that the Australian manufacturer has a local European representative.

Australia has other agreements with the following countries:

- *New Zealand:* The Australian and New Zealand Governments have signed an agreement to establish a joint regulatory scheme for therapeutic products however, this is currently on hold.
- *Canada:* Memorandum of Understanding has been signed regarding recognition of the Quality Management System certificates
- *Switzerland:* Memorandum of Understanding has been signed in order to exchange information about regulatory decisions and post market monitoring of therapeutic products
- *Singapore:* Mutual recognition agreement for conformity assessment certification.

Declaration of Conformity

The declaration of conformity is a document that states that the manufacturer of a medical device:

- complies with the essential principles
- has been classified according to the classification rules
- complies with the conformity assessment procedures selected (although no conformity assessment certification is required for class I (non-sterile and /or non-measuring medical devices).

The Declaration of Conformity must be written to Australian Standards and must be provided by all manufacturers.

The TGA has a guidance document with templates for the Declaration of Conformity, <http://www.tga.gov.au/docs/pdf/devguid5.pdf>

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

In order to register a medical device you need to create an e-business account for the DEAL (Device Electronic Application Lodgement) system. New users will need to complete a client details form and an e-business access form. When you have your user name and password, you can enter the TGA online website and the DEAL home page. From here you will need to submit the manufacturer's evidence before completing the medical device application.

In order to submit the **manufacturer's evidence** you need the following information:

- client reference and details
- conformity assessment certification including the certificates details and if there are any restrictions on the scope
- class of the device
- conformity assessment procedure
- conformity assessment body
- manufacturer's details including name and address
- GMDN code

Once a manufacturer's evidence has been submitted you can view it from the DEAL homepage. Manufacturer's evidence currently takes between 5-10 days to be accepted by the TGA. A medical device application can be created once the manufacturer's evidence has been accepted by the TGA.

In order to submit the **medical device application** you will need the following information:

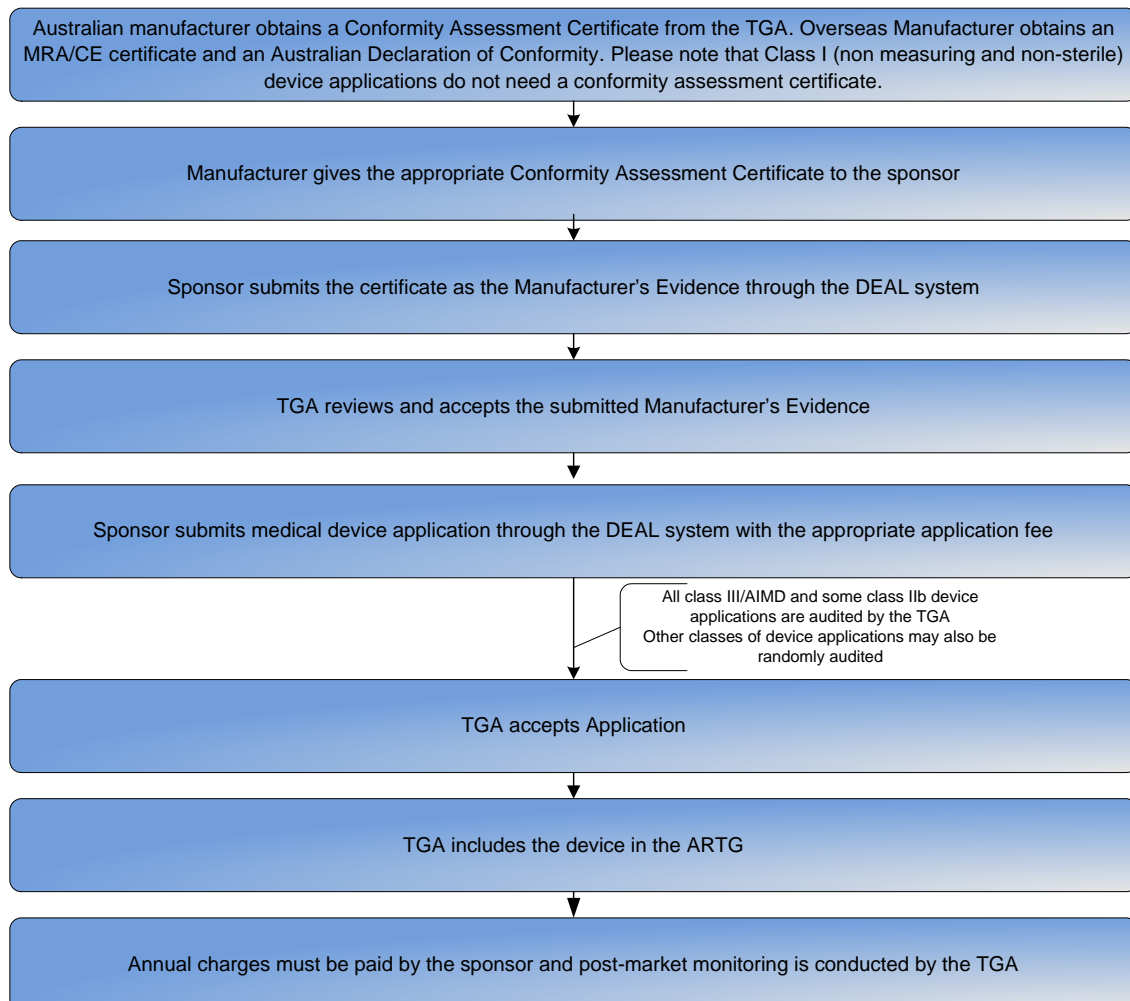
- client reference and details
- conformity assessment certification including the certificates details and if there are any restrictions on the scope
- class of the device
- conformity assessment procedure
- conformity assessment body
- manufacturer's details including name and address
- GMDN code.

Once the manufacturer's evidence has been accepted by the TGA, you need to enter the DEAL system and enter the following information:

- sponsor's reference and details
- class of the device
- intended purpose of the device
- manufacturer's details including name and address
- GMDN code
- ingredient details if the device is medicated or formulated
- indicate payment method of fees
- indicate whether to cancel current Registered/Listed ARTG Numbers that the device inclusion will be replacing.

Once a device application form has been submitted you can view it from the DEAL homepage. Devices will currently take between 6-10 weeks to be approved by the TGA.

Overview of the Medical Device regulatory process



How much does it cost to register a medical device in Australia⁴?

The current⁵ application and annual fees for including a medical device on the ARTG are:

Class	Application Fee (\$AUD)	Annual Fee (\$AUD)
I	0	60.00
I measuring	730.00	480.00
I sterile	730.00	480.00
IIa	730.00	730.00
IIb	730.00	730.00
III	960.00	960.00
AIMD	960.00	960.00

The current⁶ conformity assessment fees for including a medical device on the ARTG are:

Conformity Assessment Procedure	Initial Assessment (\$AUD)	Changes (\$AUD)	Surveillance Audits (\$AUD)
Schedule 3, Part 1- Full Quality Management System Audit;	21,400.00	12,900.00	6,250.00
Schedule 3, clause 1.6 - Design Examination;	42,400.00	25,500.00	
Schedule 3, Part 2 - Type Examination (including management of testing, analysis, and reporting on examination of the type);	29,500.00	17,800.00	
Schedule 3, Part 3 - Verification (including management of testing, analysis, and reporting on verification tests);	20,700.00		
Schedule 3, Part 4 - Production Quality Management System Audit;	18,800.00	11,300.00	6,250.00
Schedule 3, Part 5 - Product Quality Management System Audit	16,100.00	9,710.00	6,250.00

⁴ Additional TGA fees can be found at the link: <http://www.tga.gov.au/fees/fees07.htm>

⁵ As at November 2007

⁶ As at November 2007

Glossary

Term	Meaning
Australian Register of Therapeutic Goods (ARTG).	The ARTG is a list of therapeutic goods that have been included on the Register. Australian manufactured goods are evaluated for quality, safety and efficacy by the TGA except non sterile or non-measuring class I devices.
CE Mark/EC certification	The CE mark must be applied to all medical devices sold within the EU to demonstrate that the device conforms to the essential requirements of the MDD. Note the TGA refers to the CE certificate as an EC certificate or European Community Certificate.
Conformity Assessment	Conformity Assessment is a series of procedures that manufacturers are obligated to meet that check that the medical devices measure up to the specifications of a relevant standard in order for them to be placed on the markets in regulated countries (e.g Australia, Europe, United States of America, Japan, Canada, etc).
DEAL -Device Electronic Application Lodgment	This is an online regulatory submission process for registering medical devices on the Australian Register of Therapeutic Goods (ARTG).
Essential Principles	A list of principles that are performance standards for medical devices to comply with in order to demonstrate that they are safe, effective and quality devices.
Global Medical Device Nomenclature (GMDN)	The Global Medical Device Nomenclature (GMDN) system is an international coding system used to catalogue medical devices
Intended Purpose	The use for which the device is intended according to the data supplied by the manufacturer on the labeling, in the instructions for use/or in promotional material.
ISO 13485:2003	ISO 13485: 2003 is an international standard that specifies what is required for a quality management system where an organisation needs to provide medical devices and associated services that consistently meets customer's needs and global regulatory requirements.
Mutual Recognition Agreement (MRA)	Where each country that is a party to an international agreement recognises another country's regulatory assessment and approval of a medical device. The purpose of mutual recognition is to promote economic integration and increased trade between participants. It is one of a number of regulatory techniques available to governments to reduce regulatory impediments to the movement of

Term	Meaning
	goods and provision of services across jurisdictions
Technical Documentation/Technical File	<p>Information on each device relating to: classification, description, intended use— including use with other devices, performance characteristics, evidence that all safety and effectiveness requirements for the various regulatory jurisdictions have been satisfied, harmonized standards used, key documents that demonstrate product conformance, risk analysis, clinical data, quality management system approval, product approvals and all associated documents. The TGA may do a random audit on a sponsor so you must be able to present the technical documentation within 20 days of TGA notification</p>
Therapeutic goods	<p>Goods that are used for therapeutic use, includes medicines and medical devices.</p> <p>“Therapeutic use” means use in or in connection with:</p> <ul style="list-style-type: none"> • preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury; • influencing inhibiting or modifying a physiological process; • testing the susceptibility of persons to a disease or ailment; • influencing, controlling or preventing conception; • testing for pregnancy; or • replacement or modification of parts of the anatomy.
Therapeutic Goods Administration (TGA)	The current Australian therapeutic goods regulator.

References

www.tga.gov.au

www.tgasime.health.gov.au

www.ghtf.org

www.gmdnagency.com

<http://www.industry.gov.au/assets/documents/itrinternet/AMDIFinalReport20051102150005.pdf>

<http://www.ausbiotech.org/content.asp?pageid=109>

Therapeutic Goods (Medical Devices) Regulations 2002

[http://www.comlaw.gov.au/comlaw/legislation/legislativeinstrumentcompilation1.nsf/0/61E6D00DA6BF451BCA2571C70019405A/\\$file/TherapeutGoodMedDevic2002.pdf](http://www.comlaw.gov.au/comlaw/legislation/legislativeinstrumentcompilation1.nsf/0/61E6D00DA6BF451BCA2571C70019405A/$file/TherapeutGoodMedDevic2002.pdf)

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)

About PharmOut

PharmOut is a boutique consultancy to the Pharmaceutical, Medical Device, and Veterinary drug industries.

PharmOut specialises in GMP compliance, validation and continuous improvement consulting and training.

Some of the company's customers include ASTRAZENECA, Bernafon, CSL, Fonterra, GSK, Hospira, Invetech, Intertek Caleb Brett, Mayne Pharma, Pharmatel Fresenius Kabi and Probe Analytical Laboratories.

How PharmOut can help

We offer a range of services that will assist you in all regulatory, scientific and quality matters in the areas of medical device registration in Australia including:

- device classification:
- preparation of technical files/documentation
- quality audits in accordance to ISO 13485, 21 CFR 820
- risk assessments
- product development
- CE Marking: Australia has a mutual recognition agreement with the EU. Why not apply to affix the CE mark to your device and increase your market potential.

In all these areas mentioned above we can make sure that everything is in order before a TGA audit in order to save you time and money. Get it done right the first time.

