Australian Government
Department of Health
Therapeutic Goods Administration

Overview of medical devices and IVD regulation

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This information is provided to assist you if you are new to engaging with the TGA and Australia's regulatory framework for medical devices, including in vitro diagnostics (IVD) medical devices. It will introduce you to some of the concepts and terminology used in medical device regulation.

This information should be used as a guide only. If you would like further information, please refer to the Australian Regulatory Guidelines for Medical Devices (ARGMD) (//www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd) or contact the TGA (//www.tga.gov.au/contact-tga). For specific advice on the application of therapeutic goods legislation in particular cases, you may need to seek your own independent advice.

Introduction

Our risk-based approach to regulating therapeutic goods is designed to ensure that the level of regulation matches the risks posed by particular therapeutic goods.

Medical devices including IVD medical devices are assessed against the Essential Principles and in line with their intended purpose and risk-based classification. The regulatory framework for medical devices spans the life of the device and includes:

- **pre-market assessment:** conformity assessment
- **market authorisation:** inclusion in the ARTG
- **post-market monitoring:** continuing compliance with all regulatory, safety and performance requirements and standards.

Supplying medical devices

Medical devices must be entered on the ARTG before they can be lawfully:

- supplied in Australia
- imported into Australia
- exported from Australia.

A person or company who is legally responsible for supplying a device in Australia is called a sponsor.

What is a medical device?

Medical devices are defined by section 41BD of the *Therapeutic Goods Act 1989* (https://www.legislation.gov.au/Series/C2004A03952) (the Act), and further informed by the *Therapeutic Goods (Articles that are Medical Devices) Specification 2014* (https://www.legislation.gov.au/Details/F2014L01741). You should refer to this definition for any regulatory purpose, including preparing your application.

In summary, medical devices:

- are used for humans
- are intended to diagnose, prevent, monitor, treat or alleviate a disease or injury, or modify or monitor anatomy or physiological functions of the body
- generally achieve their purpose by a physical, mechanical or chemical action.

For example, implantable prostheses are medical devices due to their function to replace and/or modify the human anatomy and/or a physiological process.

IVD medical devices are also regulated in Australia as a subset of medical devices.

You may wish to check if your product is a medical device using the SME Assist tool (//www.tga.gov.au/my-product-medical-device) .

What is an IVD medical device?

IVD medical devices are defined in the *Therapeutic Goods (Medical Devices) Regulations 2002* (https://www.legislation.gov.au/Series/F2002B00237) (the MD Regulations). You should refer to this definition for any regulatory purpose, including preparing your application.

Typically, IVD medical devices are pathology tests (and related instrumentation) used to carry out testing on human samples where the results are intended to assist in clinical diagnosis or in making decisions concerning clinical management. IVD medical devices can also be intended for use by a health professional at the point of care or for use by lay persons for self-testing (note, certain IVD medical devices for self-testing are currently prohibited from supply in Australia (https://www.legislation.gov.au/Series/F2010L01889)).

Kind of device

Under the Act, a 'kind of medical device (//www.tga.gov.au/kind-medical-device)' must be included in the ARTG prior to supply in Australia unless an exemption applies. For example, custom-made medical devices, which are regulated under the Act, are exempt from the requirement to include them in the ARTG.

What makes a kind of medical device?

The criteria for a kind of medical device depend on its classification:

- **High risk devices**

For high risk devices (Class III and AIMD, and most Class 4 IVD medical devices), a 'kind of device' is a fairly narrow grouping restricted to a single Unique Product Identifier (UPI), typically covering design variations of a single device such as devices with different length, width, shape, etc. (defined in the MD Regulations as variants).

- **Lower risk devices**
  For lower classifications, a 'kind of medical device' is a broader concept and covers a range of similar products which have the same sponsor, manufacturer, classification, and are described by the term of the same Global Medical Device Nomenclature (GMDN) code.
  For example, a single ARTG entry may cover a range of different models or brands of similar devices, such as the multiple variations of intravenous infusion sets from the same manufacturer and sponsor.

How it works in practice

New products which are devices of the same kind may be supplied under an appropriate existing ARTG entry without further clearance by, or notification to, the TGA (unless required under conditions of ARTG inclusion, or when information entered on the ARTG in relation to the device should be corrected).

However, any new device which fits within the 'kind' must meet the requirements of the conformity assessment procedures implemented by the manufacturer in relation to that kind of device (and in line with the risk of the device will be assessed or monitored via ongoing certification by either TGA or a comparable overseas regulator).

Classification of medical devices

The intended purpose and the risk management approach underpin the classification system for medical devices, and it's the manufacturer who is responsible for classifying their medical device(s).

The higher the classification level of a device, the higher the requirements for the conformity assessment procedures that manufacturers must apply to their device.

> Multiple classification rules may apply for any given medical device. The device will be classified **at the highest applicable classification**.
>
> The classification rules for medical devices are prescribed in Schedule 2 and Schedule 2A of the MD Regulations (https://www.legislation.gov.au/Series/F2002B00237) and outlined in the ARGMD.

Classification of medical devices (not IVD medical devices)

Medical devices, other than IVD medical devices, are classified with regard to their intended purpose. In particular, the classification rules take into account the degree of invasiveness in the human body, the duration and location of use, and whether the device relies on a source of energy other than the body or gravity.

Examples of devices with different classifications are summarised in the following table.

Class	Risk	Examples
Class I	Low	Surgical retractors, tongue depressors
Class I - supplied sterile Class I - incorporating a measuring function Class IIa	Low-medium	Hypodermic needles, suction unit Medicine cup with specific units of measurement Digital or infrared thermometers
Class IIb	Medium-high	Lung ventilator, blood bags, condoms
Class III	High	Heart valves, major joint replacement implants, devices containing medicines or tissues, cells or substances of animal, biological or microbiological origin
AIMD (Active Implantable Medical Devices)	High	Implantable defibrillator

More information on the classification of medical devices (not IVD medical devices) can be found in Schedule 2 of the MD Regulations. You can also refer to Section 4 of the ARGMD (//www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd).

Classification of IVD medical devices

The classification of IVD medical devices is based on their intended purpose and the public health risk or personal risk that may arise from an incorrect result.

The higher the potential risk an incorrect result would pose, the higher the classification.

Examples of IVD medical devices with different classifications are summarised in the following table.

Class	Risk level/description	Examples
Class 1 IVD	No public health risk or low personal risk	• Sample collection container • Microbiological culture media
Class 2 IVD	Low public health risk or moderate personal risk	• Pregnancy and fertility self-testing kits • Cholesterol test

Class	Risk level/description	Examples
Class 3 IVD	Moderate public health risk or high personal risk	• Tests to detect a sexually transmitted disease (e.g., chlamydia, gonorrhoea) • Human genetic tests
Class 4 IVD	High public health risk	• Blood donor screening tests for HIV • Test for Ebola

More information about the classification of IVD medical devices can be found in Schedule 2A of the MD Regulations and Classification of IVD medical devices (//www.tga.gov.au/book-page/classifying-ivds).

Essential Principles

The Essential Principles set out the fundamental design and manufacturing requirements for medical devices.

Medical devices must comply with the Essential Principles (//www.tga.gov.au/form/essential-principles-checklist-medical-devices), and the manufacturer must apply appropriate conformity assessment procedures to ensure compliance of their devices with the Essential Principles.

Among other things, before a medical device can be supplied in Australia, the sponsor must ensure (and be able to demonstrate) that the device meets all applicable Essential Principles so it is safe and performs as intended.

There are six general Essential Principles that apply to all devices (relating to health and safety, including long-term safety, with benefits outweighing the risks), and a further nine Essential Principles about design and construction that apply to devices on a case-by-case basis.

This principles-based regulatory framework caters for technological advances and changes in the development of new medical devices and provides flexibility for manufacturers. It does not mandate the means by which a manufacturer must prove that they have met the Essential Principles.

More information on the Essential Principles can be found in Schedule 1 of the MD Regulations and Section 3 of the ARGMD.

Pre-market assessment: conformity assessment of medical devices

Conformity assessment is the systematic and ongoing examination by the manufacturer of evidence and procedures to determine that the safety of a medical device is acceptable and the device performs as intended and, therefore, conforms to the Essential Principles.

The applicant must be able to demonstrate that the appropriate conformity assessment procedure has been applied to their device in order to apply for inclusion of the medical device in the ARTG.

This should be demonstrated by providing appropriate certification issued to the manufacturer by an appropriate assessment body (e.g. the TGA or a comparable overseas regulator (//www.tga.gov.au/comparable-overseas-regulators-medical-device-applications)).

> The level of conformity assessment required must match the level and nature of the risks associated with the use of the device, ranging from manufacturer self-assessment for low risk devices through to an assessment of the manufacturer's quality management system and examination of the design of the specific device by a conformity assessment body for the highest risk devices.

What type of conformity assessment certification does the manufacturer need?

Specific high risk medical devices

Manufacturers must hold a conformity assessment certificate issued by the TGA in relation to medical devices that contain medicines or tissues, cells or substances of animal, biological or microbiological origin; or if it is a Class 4 IVD medical device.

Other medical devices

For other medical devices, conformity assessment should be demonstrated by providing appropriate certification issued to the manufacturer by an appropriate assessment body (e.g. the TGA or a comparable overseas regulator (//www.tga.gov.au/comparable-overseas-regulators-medical-device-applications)).

More information about conformity assessment can be found in Section 5 of the ARGMD (//www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd).

> **Medical device reforms**
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> Please note that the TGA is currently considering a range of changes to the medical devices regulatory framework, including classification rules, essential principles and conformity assessment procedures.
>
> For more information on changes being considered is available at: MMDR: Medical devices regulatory reforms (//www.tga.gov.au/hubs/mmdr/mmdr-medical-devices-regulatory-reforms)

Market authorisation: inclusion of medical devices, including IVD medical devices, in the ARTG

Inclusion of lower risk devices in the ARTG

Class 1 IVD medical devices that are not intended to be used for self-testing or point-of care, can be 'included' in the ARTG via a self-declaration process. Sponsors of these devices must fill in and submit an electronic application (Medical Device Application) to the TGA and pay the application fee; however, they are not required to submit any other documents to the TGA at the time of ARTG inclusion.

The sponsors of Class I medical devices that do not have a measuring function and are not intended to be supplied sterile ,must submit a copy of the manufacturer's Declaration of Conformity (//www.tga.gov.au/form/declaration-conformity-templates-medical-devices) for the device with the application to include the device in the ARTG (//www.tga.gov.au/book-page/step-4-submitting-application-tbs-class-i-non-sterile-non-measuring-and-class-1-ivd-medical-devices) . Sponsors of these devices must also be able to provide other documentation relevant to the device (e.g. labelling, instruction for use, advertising material, and evidence of the performance of the device) to the TGA on request.

For all other devices, before you apply

For any other device, before an application to include the medical device in the ARTG can be made, the applicant should submit a copy of the conformity assessment certification issued to the manufacturer by an appropriate conformity assessment body or a declaration of conformity made by the manufacturer (if relevant).

This document should be submitted to (and accepted by) the TGA as Manufacturer's Evidence before an application for inclusion of the device in the ARTG can be made.

Sponsors should be in Australia, and are usually an Australian importer of overseas manufactured medical devices. Applicants must have a relationship with the manufacturer to enable them to fulfil their regulatory obligations, including obtaining information requested by the TGA from the manufacturer.

Preliminary assessment of applications for ARTG inclusion

Any application for inclusion of a medical device in the ARTG must include certain information as required in the application form, including conformity assessment certification from TGA or comparable overseas regulators and possibly evidence of product assessment (depending on the classification of the device). If not provided the application will not pass preliminary assessment and it will be refused. More information on preliminary assessment of applications for ARTG inclusion of medical devices is available at: Application requirements for medical devices - preliminary assessment (//www.tga.gov.au/application-requirements-medical-devices-preliminary-assessment).

TGA assessment of applications for ARTG inclusion

The degree of rigour of the TGA's assessment of applications for inclusion of medical devices in the ARTG depends on the intended purpose and risk classification of the device, and the source of the conformity assessment certification.

The TGA may approve the inclusion of a device in the ARTG based on the information provided in the application received, or TGA may select an application for audit assessment. The audit of the application may involve a desktop review of information such as the labelling, instructions for use, technical documentation and advertising materials for the device, clinical evidence, risk management documentation for the device, reports from the notified bodies, or microbiology assessment.

The scope of any audit will depend largely on the issues identified by the TGA as requiring further scrutiny.

Applications for devices, such as Class III, AIMDs and selected Class IIb medical devices, must be selected for audit (mandatory application audits) where the manufacturer's conformity assessment certification was issued by a comparable overseas regulator (//www.tga.gov.au/comparable-overseas-regulators-medical-device-applications).

Applications for certain IVD medical devices (e.g. those intended for self-testing or use at the point of care; or applications for Class 3 IVD medical devices supported only by an ISO 13485 certificate) must also be selected for audit.

Post-market assessment of medical devices

Maintenance of conformity assessment

Once a device is approved, manufacturers are expected to continue to monitor the performance and safety of their devices and ensure continued compliance with the Essential Principles. This surveillance program is part of the quality management system aspect of their conformity assessment, and will be periodically checked by the certifying body (whether this is the TGA or a European notified body). These surveillance programs should be appropriate to the intended purpose and risks of the device.

The data generated from safety and adverse event reports and complaints, newly identified risks, literature, any updated or new clinical investigations, significant regulatory actions and formal surveillance activities such as registries should be used by the manufacturer to review the performance, safety and benefit-risk assessment of the device.

TGA post-market vigilance and monitoring

The medical device regulatory framework includes provision for post-market monitoring by the TGA, including:

- risk assessment and investigation of medical device adverse event and complaint reports
- checking evidence of conformity against the Essential Principles
- conducting periodic inspections of manufacturers' quality management systems and technical documentation
- imposing specific requirements for manufacturers and sponsors to report, within specified timeframes, adverse incidents and other information involving their medical devices.

Post-market monitoring by the TGA is carried out to ensure the ongoing regulatory compliance and safety of medical devices supplied to the Australian market.

Sponsor responsibilities

In support of the TGA's post-market monitoring activities, the sponsor of a medical device has ongoing responsibilities once a device has been included in the ARTG. These statutory responsibilities include that the sponsor must report to the TGA:

- adverse incidents

- overseas regulatory actions
- the results of investigations undertaken by the manufacturer, such as further clinical studies and reviews of adverse events.

The sponsor must also obtain requested information from the manufacturer and maintain distribution records.

All adverse event reports or complaints received by the TGA are entered into a database, and a risk assessment undertaken by a panel of clinicians and scientists within the TGA to determine if investigation is required. Expert advice may be sought during an investigation.

The outcomes of TGA's investigations may result in:

- product recovery (recalls)
- hazard and safety alerts
- product modification/improvement by a manufacturer
- surveillance audits of manufacturing sites.

Further information

For more information on any of the sections above, please refer to the Australian Regulatory Guidelines on Medical Devices (//www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd) (ARGMD).

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