Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Australian regulatory guidelines for medical devices (ARGMD)

The Australian Regulatory Guidelines for Medical Devices (ARGMD) provides information on the import into, export from and supply of medical devices within Australia.

Last updated:
19 August 2022

PLEASE NOTE

We are currently in the process of reviewing and updating the Australian Regulatory Guidelines for Medical Devices (ARGMD).

• For information on our regulation of medical devices go to Medical devices (https://www.tga.gov.au/products/medical-devices)
• For information on obtaining market authorisation go to Supply a medical device. (https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device)
• For information on medical device manufacture go to Manufacture a medical device (https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device).
• For information on medical device reforms go to Medical device reforms (https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/medical-devices-reforms).

The previous version of the ARGMD (https://www.tga.gov.au/node/285201) can be found on our archived site.

If you:

- would like to nominate an area of guidance that has not yet been covered or provide feedback on the guidance that appears here; or

- you notice erroneous/missing information, broken links, etc please Email us (https://www.tga.gov.au/get-in-touch) .

Frequently requested information about medical devices

The following pages represent the most frequently requested information about medical devices:

- Medical device inclusion process (https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/medical-device-inclusion-process)
- Declaration of conformity templates (medical devices) (https://www.tga.gov.au/node/288300)
- What classification is my device? (https://www.tga.gov.au/resources/what-classification-my-medical-device)
- Global Medical Device Nomenclature (GMDN) Terms (https://www.tga.gov.au/node/288140)
- Comparable overseas regulators for medical device applications (https://www.tga.gov.au/node/289428)
- Varying entries in the ARTG - medical devices and IVDs (https://www.tga.gov.au/node/285148)
- Changing the sponsor/transferring therapeutic goods (https://www.tga.gov.au/node/285756)
- Clinical evidence guidelines: Medical devices (https://www.tga.gov.au/node/289565)
- Personalised medical devices (including 3D-printed devices) (https://www.tga.gov.au/node/289584)
- Search the ARTG for all current inclusions (https://www.tga.gov.au/resources/artg)
- Search for products that have been cancelled from the ARTG at the sponsor's request (https://www.tga.gov.au/node/123)
- Fees and charges (https://www.tga.gov.au/node/287173)
- Regulatory affairs consultants (https://www.tga.gov.au/node/289230)
- Adverse event reporting (https://www.tga.gov.au/node/289466)
- Annual charge exemption (ACE) scheme (https://www.tga.gov.au/node/289327)

Essential principles

Meet safety, performance and quality requirements for medical device manufacturers.

This guidance is currently under construction. More information and links to further guidance will be added when available.

The Essential Principles (the Principles) are legislative requirements relating to safety and performance characteristics of medical devices, including in vitro diagnostic (IVD) devices. The Principles are in Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002 (https://www.legislation.gov.au/Series/F2002B00237)* (the Regulations).

- Meet safety, performance and quality requirements for medical device manufacturers (https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/meet-safety-performance-and-quality-requirements-medical-device-manufacturers) (The Essential Principles)
- Principle 1 - Use of medical devices not to compromise health and safety (https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/meet-safety-performance-and-quality-requirements-medical-device-manufacturers/principle-1-use-medical-devices-not-compromise-health-and-safety)
- Principle 2 - Design and construction of medical devices to conform with safety principles (https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/meet-safety-performance-and-quality-requirements-medical-device-manufacturers/principle-2-design-and-construction-medical-devices-conform-safety-principles)
- Principle 9 - Construction and environmental properties (https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/meet-safety-performance-and-quality-requirements-medical-device-manufacturers/principle-9-construction-and-environmental-properties)
- Demonstrating compliance with the Essential Principles (https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/meet-safety-performance-and-quality-requirements-medical-device-manufacturers/demonstrating-compliance-essential-principles)
- Essential principles checklist (medical devices) (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices)

Conformity assessment

Conformity assessment (https://www.tga.gov.au/node/287644) is the systematic and ongoing examination of evidence and procedures to ensure that a medical device (including IVD medical devices) complies with the essential principles (https://www.tga.gov.au/node/287377). Manufacturers of all medical devices (including IVD medical devices) manufactured and/or supplied in Australia should ensure that they have:

- appropriate conformity assessment procedures in place for the device; and
- appropriate documentation demonstrating compliance of the device with the essential principles.

Evidence that a device has undergone an appropriate conformity assessment procedure must be held before a device can be included in the Australian Register of Therapeutic Goods (ARTG). For more information about acceptable documentation and the submission of a valid application for inclusion of a medical device (including IVDs) in the ARTG, please see:

- Manufacturer evidence for medical devices and IVD medical devices (https://www.tga.gov.au/node/287913)
- Medical device (including IVD devices) inclusion process (https://www.tga.gov.au/node/285202)

On 23 July 2021 the Government repealed Regulation 4.1 and amended Regulation 5.3 of the *Therapeutic Goods (Medical Devices) Regulations 2002 (https://www.legislation.gov.au/Series/F2002B00237)* (the Regulations). This means that from 28 July 2021, devices that were previously described under regulation 4.1 (those that contain medicines or materials of animal, microbial, recombinant or human origin, and Class 4 IVDs) no longer require mandatory TGA conformity assessment certification.

For such devices (those that contain medicines or materials of animal, microbial, recombinant or human origin, and Class 4 IVDs), we will accept conformity assessment evidence issued by the TGA, EU notified bodies and Australian conformity assessment bodies (https://www.tga.gov.au/node/288103). More information is available on the web page: Conformity assessment certificates, changes to requirements for certain medical devices (https://www.tga.gov.au/node/289667).

The following pages contain information and guidance for manufacturers who intend to submit an application for TGA-issued conformity assessment certificate:

- Conformity assessment overview (https://www.tga.gov.au/node/287644)
- Application for conformity assessment certificates (https://www.tga.gov.au/node/288307)
- Substantial changes affecting a TGA conformity assessment certificate and transfers of certificates (https://www.tga.gov.au/node/289361)
- Reduction of assessment fees for medical devices (https://www.tga.gov.au/node/285108)
- Essential principles checklist (medical devices) (https://www.tga.gov.au/node/288302)
- Fees and charges (https://www.tga.gov.au/node/287173)
- Manufacturer statutory declarations (https://www.tga.gov.au/node/288304)
- What a manufacturer needs to know about conformity assessment and declarations of conformity for IVDs (https://www.tga.gov.au/node/285106)

- Conformity assessment overview (IVDs) (https://www.tga.gov.au/node/285100)
- Conformity assessment procedures for IHRs (https://www.tga.gov.au/node/285101)
- Declaration of conformity templates (medical devices) (https://www.tga.gov.au/node/288300)

Other information relevant to submitting evidence to support the application for TGA-issued conformity assessment certificate:

- Standard orders and medical devices (https://www.tga.gov.au/node/289274)
- Medical devices notices & standards orders (https://www.tga.gov.au/node/287259)
- Device medicine boundary products (https://www.tga.gov.au/node/285132)
- In vitro fertilisation (IVF) solutions (https://www.tga.gov.au/node/289273)
- Requirements for the assessment of medical devices containing animal material (https://www.tga.gov.au/node/285109)
- Transmissible Spongiform Encephalopathies (TSE): TGA approach to minimising the risk of exposure (https://www.tga.gov.au/node/285109)
- Electronic Instructions for Use - eIFU (https://www.tga.gov.au/node/285180)
- Patient implant cards and consumer device information leaflets (https://www.tga.gov.au/node/287797)
- Medical device patient information leaflets and implant cards (https://www.tga.gov.au/node/151129)
- The Poisons Standard and medical devices (https://www.tga.gov.au/node/289390)
- Clinical evidence guidelines: Medical devices (https://www.tga.gov.au/node/289565)
- Guidelines for sterility testing of therapeutic goods (https://www.tga.gov.au/node/285119)
- Regulation of Software as a Medical Device (https://www.tga.gov.au/node/289271)
- Systems or procedure packs (https://www.tga.gov.au/resources/resource/guidance/system-or-procedure-packs)
- Custom made medical devices (https://www.tga.gov.au/node/289270)
- Declaration of conformity templates (medical devices) (https://www.tga.gov.au/node/288300)
- What classification is my device? (https://www.tga.gov.au/node/287640)
- Reclassification of surgical mesh devices (https://www.tga.gov.au/node/285188)
- Defining joint replacement medical devices and ancillary medical devices (https://www.tga.gov.au/node/285132)
- Manufacturer of medical devices: Quality management (https://www.tga.gov.au/node/287377)

- Clinical evidence guidelines: Medical devices (https://www.tga.gov.au/node/289390)
- Overview of the Regulatory Framework for IVDs (https://www.tga.gov.au/node/290017)
- HIV testing in Australia (https://www.tga.gov.au/node/289330)
- Classification of IVD medical devices (https://www.tga.gov.au/node/285099)
- The use of GMDN codes for IVD medical devices in Australia (https://www.tga.gov.au/node/285104)
- Clinical performance requirements and risk mitigation strategies for HIV tests (https://www.tga.gov.au/node/285104)
- The TGA's approach to delays in medical device conformity assessment recertification (https://www.tga.gov.au/node/289557)

Medical device inclusion

- Medical device inclusion process (https://www.tga.gov.au/node/285202)
- Manufacturer evidence (https://www.tga.gov.au/node/287913)
- Declaration of conformity templates (medical devices) (https://www.tga.gov.au/node/288300)
- What classification is my device? (https://www.tga.gov.au/node/287640)
- Global Medical Device Nomenclature (GMDN) Terms (https://www.tga.gov.au/node/288140)
- Comparable overseas regulators for medical device applications (https://www.tga.gov.au/node/289428)
- Essential principles checklist (medical devices) (https://www.tga.gov.au/node/288302)
- Fees and charges (https://www.tga.gov.au/node/287173)
- Clinical evidence guidelines: Medical devices (https://www.tga.gov.au/node/289565)
- Defining joint replacement medical devices and ancillary medical devices (https://www.tga.gov.au/node/285132)

Post market

Once a medical device has been included in the ARTG the device must continue to meet all the regulatory, safety and performance requirements and standards that were required for the approval.

The TGA has mandatory requirements and ongoing responsibilities for all manufacturers and sponsors of medical devices. These requirements facilitate the monitoring of device performance and ensure systematic investigation of failures and/or deviations in the way a device performs, in an attempt to prevent an adverse event occurring again.

Information received by the TGA once a device is included in the ARTG informs actions including:

- Corrective actions including, but not limited to, changes to device design, construction and information accompanying the device;
- Suspension and/or cancellation of the product;
- Recall actions including safety alerts; and
- Educational resources including website notifications.

The following pages contain information relating to ongoing post-market responsibilities and activities for sponsors and manufacturers:

- Sponsor's ongoing responsibilities (https://www.tga.gov.au/node/286564)
- Distribution records (https://www.tga.gov.au/node/287915)
- Manufacturer's ongoing responsibilities (https://www.tga.gov.au/node/287916)
- Adverse event reporting - sponsors (https://www.tga.gov.au/node/289466)
- Report an adverse event - health professionals and consumers (https://www.tga.gov.au/node/289286)
- Adverse event reporting form - sponsors (https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx)
- Post market reviews (https://www.tga.gov.au/node/287917)
- Post market review compliance dashboard (https://www.tga.gov.au/node/289715)
- Annual reports (https://www.tga.gov.au/node/289465)
- Changing the sponsor/transferring therapeutic goods (https://www.tga.gov.au/node/285756)
- Recalls (https://www.tga.gov.au/node/289281)

Reporting an adverse event

If you are a consumer or health care provider and you wish to report an adverse event, you can do so at Medical device incident reporting & investigation scheme (IRIS) (https://www.tga.gov.au/node/289286).

Topics:

Medical devices (https://www.tga.gov.au/products/medical-devices)

In Vitro Diagnostic medical devices (IVDs) (https://www.tga.gov.au/vitro-diagnostic-medical-devices-ivds)