Legal

Legal framework: Yes


National Regulatory Authority

National Regulatory Authority present: Yes


Note: The Office of Devices Authorization is responsible for pre-market regulation, while the Office of Product Review is in charge of post-market regulation. ARGMD, p. 20.

Responsibilities of the NRA: N/A

Medical device definition

Medical device defined: Yes

Text: 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 under whose name 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;
   v. 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 (2A); 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).

Therapeutic Good Act 1989, 41BD.

In vitro diagnostic medical device (IVD) defined: Yes

Text: Defined Separately.

Medical device classification

Classification: Yes

Categories: Class I, I-supplied sterile, I-incorporating a measuring function, IIa, IIb, III, and active implantable medical devices

Therapeutic Good Act 1989, 41BD

Classification rules: Yes

Classification rules details: Classification rules are based on the
- manufacturer’s intended use of the device
- the level of risk to users, patients, and other
- degree of invasiveness
- duration of use

ARGMD, p. 74.

Essential principles

Essential principles: Yes

Details: Therapeutic Good Act 1989, Art. 41C.

Conformity assessment

Conformity assessment bodies: Yes

Details: YES - TGA or a European Union notified body ARGMD, p. 106


Pre-marketing / procedure: As a general matter, a manufacturer must demonstrate safety, minimization of risk, and sufficient protections against risks. Guidelines, Principle 7, p. 45 - 62.

The Australian conformity assessment procedure is based on the GHTF yet differs from the EU. AGRMD, p. 107.
Reliance
Reliance: Yes
Details: Australian regulatory guidelines for medical devices (ARGMD), 2011, p.160
Jurisdictions: EU (so long as the device fits within the Australian definition of a medical device)
ARGMD, p. 107-08, Canada, Singapore, Switzerland, US

Clinical investigation
Clinical investigation controls: N/A
Details: There is no requirement that clinical trials be done in Australia. ARGMD, at. 70.
Where a clinical trial is conducted in Australia, it must be done so in accordance with Australian requirements and ethical standards. ARGMD, at 71.

Registration and listing
Registration of establishment: Yes
Listing of medical devices: Yes
Details: The Australian Therapeutic Good Register (ARGT) captures all medical devices accepted for importation, supplied for use in or exportation from Australia. A medical device may generally not be imported into Australia unless it is in the ARTG. ARGMD, p. 164. and Australian Medical Device Requirements Version 4 under the Therapeutic Goods Act 1989 https://www.tga.gov.au/sites/default/files/dr4-v1-s3.pdf

Import controls
Import controls: Yes
Details: N/A

Post market controls
Post Market Surveillance: Yes
Details: A manufacturer or sponsor is responsible for ongoing market surveillance and it is subject to periodic surveillance audits by the TGA or notified body. ARGMD, pp. 240, 123.

Inspection (QMS): Yes
Details: The manufacturer, in a TGA Conformity Assessment Certificate, must attest to proper inspection of its products. Further, receipt of the certificate is conditioned on allowing an authorized person to inspect premises, even outside of Australia, and to take samples/perform tests. ARGMD, pp. 120, 131. Inspections can be performed by single inspectors or inspection teams. https://www.tga.gov.au/book/inspection-process

Enforcement: Yes
Details: There are criminal and civil penalties available for violations of regulatory requirements. ARGMD.

Adverse event reporting: Yes
Details: The TGA, manufacturer, or sponsor must notify those other entities when it receives information on an adverse event associated with the manufacturer’s device that has caused injury or led to death. ARGMD, p. 299-300. The sponsor must notify of any adverse events as well as issue annual reports. The TGA and sponsor/manufacturer may take action after any party becomes aware of an adverse event within Australia. ARGMD, p. 298. The TGA also shares information with other entities through its participation in the GHTF. ARGMD, p. 298.

Field safety corrective action monitoring: Yes
Details: The sponsor is required to take necessary corrective actions pursuant to the Therapeutic Goods Act (1989), 41K. If a manufacturer or sponsor contemplates taking a corrective action (such as recalling from market or advising users of an issue with the device), it must notify the Australian Recall Coordinator at the TGA. ARGMD, p. 311.

Advertising: Yes
Details: Advertisements for medical devices may not be misleading, and there are certain categories of restricted representations for which one must obtain a grant to advertise from the Office of Devices Authorization. Therapeutic Goods Act 1989; Therapeutic Goods Advertising Code

Labelling: Yes

Limitations: these data reflect a limited view and do not capture what may currently occur within Member States or how they implemented the data. Complete verification of the data may not be immediately possible and inaccuracies may linger. Mis-categorization or non-capture of a country’s regulatory framework is possible due to translation and interpretation.