Australian regulatory guidelines for medical devices
(ARGMD) Part 4–Navigation and Reference

Version 1.1, May 2011
About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.

- TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk-management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety, and efficacy (performance), when necessary.

- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.

- The TGA relies on the public, healthcare professionals, and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.

- To report a problem with a medicine or medical device, please see the information on the TGA website.
## Version history

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<tr>
<th>Version</th>
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<tr>
<td>V1.0</td>
<td>Initial publication</td>
<td>28/04/10</td>
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<tr>
<td>V1.1</td>
<td>Updated references and contact details to reflect TGA’s new organisational structure post TGA21</td>
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<td>Made multiple amendments and additions in Section 3, Essential Principles, Principle 14—Clinical Evidence.</td>
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<td>Made multiple amendments in Section 22, Post-market vigilance and monitoring requirements.</td>
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<td>Added a fourth part titled ‘Navigation and Reference’ that includes:</td>
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<td>Made various punctuation and grammar amendments</td>
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Legislation

*Therapeutic Goods Act 1989*
Act Compilation: C2010C00430
Amendments up to Act No. 54 of 2010
Prepared by the Office of Legislative Drafting and Publishing

*Therapeutic Goods (Medical Devices) Regulations 2002*
Legislative Instrument Compilation: F2010C00749
Incorporating amendments up to SLI 2010 No. 267
Prepared by the Office of Legislative Drafting and Publishing

*Therapeutic Goods Regulations 1990*
Legislative Instrument Compilation: F2010C00737
Incorporating amendments up to SLI 2010 No. 266
Prepared by the Office of Legislative Drafting and Publishing
Section 25. Contact Details

Medical Devices Information Line

Phone
Free call (within Australia): 1800 141 144

Email
<devices@tga.gov.au>

Postal Address
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Courier Delivery
Office of Devices Authorisation
Therapeutic Goods Administration
136 Narrabundah Lane
SYMONSTON ACT 2609

Adverse Events

Reports should be submitted to <iris@tga.gov.au> where possible. Otherwise, they may be sent to:

The Coordinator
Medical Device Incident Report Investigation Scheme (IRIS)
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Email: <iris@tga.gov.au>
Facsimile: 02 6203 1713
Telephone: 1800 809 361

Recalls

Australian Recall Coordinator
Office of Product Review
Therapeutic Goods Administration
MDP 122
PO Box 100
WODEN ACT 2606

Telephone: 02 6232 8636
Device Inclusions and Application Audits

Postal Address
Devices Application Section
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

or

Courier Delivery
Office of Devices Authorisation
Therapeutic Goods Administration
136 Narrabundah Lane
SYMONSTON ACT 2609

Conformity Assessment Certifications

Postal Address
Devices Conformity Assessment Section
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

or

Courier Delivery
Office of Devices Authorisation
Therapeutic Goods Administration
136 Narrabundah Lane
SYMONSTON ACT 2609

Advertising

Complaints about advertisements appearing in the media
Complaints about advertisements appearing in the media are considered by the Complaints Resolution Panel; they should be submitted on forms available at <http://www.tgacrp.com.au>. The forms can be submitted electronically on line or sent to

The Executive Officer
Complaints Resolution Panel
PO Box 764
NORTH SYDNEY NSW 2059

Complaints about other forms of medical device advertisements (such as, labels, leaflets, flyers)
These complaints should be sent to:

Recalls & Advertising Section
Office of Product Review
Therapeutic Goods Administration
MDP 122
PO Box 100
WODEN ACT 2606
Clinical Trial Notification (CTN) Scheme

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<td>The Business Management Unit</td>
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Clinical Trial Adverse Event Reports

For reports to the TGA, the report should be clearly marked 'Clinical Trial Incident' and sent to:

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Comments Regarding the ARGMD

The TGA welcomes comments and suggestions about the ARGMD; these should be directed to:

Email: <ODAConsult@tga.gov.au>

Post:

Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
Section 26. Glossary

Declaration of Conformity (DoC)

The DoC is a document that the manufacturer signs to say that it is compliant with all the essential components of legislation and requirements applicable to the device. Australia requires manufacturers to hold a DoC for every device they manufacture.

An Australian Declaration of Conformity is distinct, though similar, to an EU Declaration of Conformity.

EC Certificate

The EC Certificate is a European (EU) equivalent to Australia’s Conformity Assessment certificate. EC certificates, in general, define what type of devices the manufacturer may manufacture. As with Australia, high-risk devices additionally require the manufacturer to obtain an EC Design-Examination or EC Type-Examination certificate.

Manufacturers’ Evidence

Manufacturers’ Evidence (ME) is the substantive evidence of the manufacturer’s Quality System that supports the scope of manufacture. It is usually in the form of an EC or TGA Certificate (or certificates) and is submitted to the TGA in order to support a later device inclusion application.

For systems and procedure packs (e.g., joint replacement systems, first-aid kits, and surgical procedure packs), a specially formed Declaration of Conformity (with supporting evidence) can also be considered to be the manufacturer’s Evidence. This occurs under the Special Conformity Assessment Procedure (Clause 7.5 of Schedule 3 of the Regulations).

Time Frames

Application time frames are given in working days and start from the date the e-Business application fee is paid. See also Working day in this Glossary.

Vital Physiological Process/Parameter

of a patient, means a process that is necessary to sustain life and the indicators of which may include any one or more of the following:

- a. respiration
- b. heart rate
- c. cerebral function
- d. blood gases
- e. blood pressure
- f. body temperature
**Working day**

A working day is any day other than a weekend, a public holiday in the Australian Capital Territory, or when the TGA is waiting on information requested of the applicant or waiting for payment of fees. Refer to subsection 3(1) of the Act for the definition of working day. See also *Time Frames* in this Glossary.
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