



Australian Government  
Department of Health and Ageing  
Therapeutic Goods Administration

# Australian regulatory guidelines for medical devices

## (ARGMD) Part 4—Navigation and Reference

Version 1.1, May 2011

**TGA** Health Safety  
Regulation



## 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, 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.

Historical document

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## Version history

Version	Description of change	Effective date
V1.0	Initial publication	28/04/10
V1.1	<ul style="list-style-type: none"> <li>• Updated references and contact details to reflect TGA's new organisational structure post TGA21</li> <li>• Made multiple amendments and additions in Section 3. Essential Principles, Principle 14—Clinical Evidence.</li> <li>• Made multiple amendments in Section 22. Post-market vigilance and monitoring requirements.</li> <li>• Added a fourth part titled 'Navigation and Reference' that includes: <ul style="list-style-type: none"> <li>– a bibliography</li> <li>– consolidated contact details</li> <li>– an index</li> <li>– a glossary of terms</li> </ul> </li> <li>• Made various punctuation and grammar amendments</li> <li>• Reformatted for compatibility with the new TGA style manual</li> </ul>	04/05/11

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# Part 4—Navigation and Reference

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# Section 24. Bibliography

## 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

<<http://www.comlaw.gov.au/>>

*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

<<http://www.comlaw.gov.au/>>

*Therapeutic Goods Regulations 1990*

Legislative Instrument Compilation: F2010C00737

Incorporating amendments up to SLI 2010 No. 267

Prepared by the Office of Legislative Drafting and Publishing

<<http://www.comlaw.gov.au/>>

# Section 25. Contact Details

## Medical Devices Information Line

### Phone

Free call (within Australia): 1800 141 144

### Email

[<devices@tga.gov.au>](mailto:devices@tga.gov.au)

### Postal Address

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

or

### Courier Deliver

Office of Devices Authorisation  
Therapeutic Goods Administration  
136 Narrabundah Lane  
SYNTHONIC, ACT 2609

## Adverse Events

Reports should be submitted to [<iris@tga.gov.au>](mailto: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>](mailto:iris@tga.gov.au)

Facsimile: 02 6203 1713

Telephone: 1800 809 361

## Recall

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	or	Courier Delivery
Devices Application Section		Devices Application Section
Office of Devices Authorisation		Office of Devices Authorisation
Therapeutic Goods Administration		Therapeutic Goods Administration
PO Box 100		136 Narrabundah Lane
WODEN ACT 2606		SYMONSTON ACT 2609

## Conformity Assessment Certifications

Postal Address	or	Courier Delivery
Devices Conformity Assessment Section		Devices Conformity Assessment Section
Office of Devices Authorisation		Office of Devices Authorisation
Therapeutic Goods Administration		Therapeutic Goods Administration
PO Box 100		136 Narrabundah Lane
WODEN ACT 2606		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

<b>Postal Address</b>	<b>Courier Delivery</b>	
The Business Management Unit Therapeutic Goods Administration PO Box 100 WODEN ACT 2606 Australia	or	The Business Management Unit Therapeutic Goods Administration 136 Narrabundah Lane SYMONSTON ACT 2609 Australia

## Clinical Trial Adverse Event Reports

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

<b>Postal Address</b>	<b>Courier Delivery</b>	
Clinical Section Office of Devices Authorisation Therapeutic Goods Administration PO Box 100 WODEN ACT 2606 Australia	or	Clinical Section Office of Devices Authorisation Therapeutic Goods Administration 136 Narrabundah Lane SYMONSTON ACT 2609 Australia

## Comments Regarding the ARGMD

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

**Email:**

[<ODAConsult@tga.gov.au>](mailto: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 can 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 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 is filed. See also *Working day* in this Glossary.

## Vital Physiological Process/Parameter

For 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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**Therapeutic Goods Administration**

PO Box 100 Woden ACT 2606 Australia  
Email: [info@tga.gov.au](mailto:info@tga.gov.au) Phone: 02 6232 8444 Fax: 02 6232 8605  
**[www.tga.gov.au](http://www.tga.gov.au)**