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, 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

<table>
<thead>
<tr>
<th>Version</th>
<th>Description of change</th>
<th>Effective date</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1.0</td>
<td>Initial publication</td>
<td>28/04/10</td>
</tr>
</tbody>
</table>
| V1.1    | - Updated references and contact details to reflect TGA’s new organisational structure post TGA21  
- Made multiple amendments in Section 22. Post-market vigilance and monitoring requirements.  
- Added a fourth part titled ‘Navigation and Reference’ that includes:  
  - a bibliography  
  - consolidated contact details  
  - an index  
  - a glossary of terms  
- Made various punctuation and grammar amendments  
- Reformatted for compliance with new TGA style manual | 04/05/11   |
Contents

Part 4–Navigation and Reference 327

Section 24. Bibliography 328

Legislation 328

Section 25. Contact Details 329

Medical Devices Information Line 329
Adverse Events 329
Recalls 329
Device Inclusions and Application Audits 330
Conformity Assessment Certifications 330
Advertising 330
Clinical Trial Notification (CTN) Service 331
Clinical Trial Adverse Event Reports 331
Comments Regarding the ARGMD 331

Section 26. Glossary 332

Declaration of Conformity (DoC) 332
EC Certificate 332
Manufacturers’ Evidence 332
Time Frames 332
Vital Physiological Process/Parameter 332
Working day 333

Index 334
Part 4–Navigation and Reference
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

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
or
Office of Devices Authorisation
Therapeutic Goods Administration
136 Narrabundah Lane
SYDNEY 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

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

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

Courier Delivery

or

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

Courier Delivery

or

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 online 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

Postal Address
The Business Management Unit
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
Australia

or

Courier Delivery
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:

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

or

Courier Delivery
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 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.
Index

A
Accessories
- EU Directive, 145
- Systems and procedure packs, 258
ACMD. See Advisory Committee on Medical Devices, See Advisory Committee on Medical Devices
Active implantable medical devices, 64
Advisory Committee on Medical Devices (ACMD)
- Function, 19, 230
ARTG
- Cancellation of medical devices from, 324
- Suspension of medical devices from, 323

C
Cancellation of medical devices from the ARTG, 324
CASOs. See • Conformity Assessment Standards Orders
Classification of medical devices
- Overview, 77
Composite packs
- Definition, 248
Conformity Assessment Standards Orders
- Overview, 18

D
Declaration of Conformity
- Glossary entry, 332

E
EC Certificate
- Glossary entry, 332
Essential Principles
- Overview, 39
- Risk management, 41
- Use of Standards Orders, 41
Export of medical devices
- Applications, 262
- Certificate of Free Sale, 262
- Export certificates, 262
- Overview, 259
- Process for including on the ARTG, 261

F
Fees and charges
- Annual charges, 34
- Application audit fees, 37
- Application fees, 35
- Conformity assessment fees, 36
- Fee reductions, 37
- Low-value turnover, 35
Overview, 34
Payment of fees by instalments, 38

G
Global Medical Device Nomenclature Codes
Overview, 178
GMDN. See Global Medical Device Nomenclature Codes

I
Instructions for use, 69

K
Kits
Definition, 249

M
Manufacturer
Conformity assessment requirements, 116
Definition, 25
Responsibilities, 25
Manufacturers’ Evidence
Glossary entry, 332
MDSOs. See • Medical Device Standards Orders
Medical Device
Definition, 19
Medical Device Standards Orders (MDSOs)
Overview, 18
Medical Devices
Examples of, 20
Life-cycle approach to the regulation of,

N
National Coordinating Committee on Therapeutic Goods
Function, 19
NCCTG. See National Coordinating Committee on Therapeutic Goods

P
Procedure packs, 37
Product tampering, 326
Recalls of medical devices, 317
Classifications, 320
Stages of a recall, 319
Recalls, suspensions, cancellations, and tampering
Overview, 317

S
Single-use devices
Case studies, 269
Overview, 264
Reusing, 266
Systems and procedure packs, 256

Sponsor
Definition, 26
Responsibilities, 27


Suspending medical devices from the ARTG, 323
Systems, 247

Systems and procedure packs
Accessories to, 258
Changes to, 258
Classification of, 249
Clause 7.5 special conformity assessment procedure, 251
Conformity assessment procedure options, 250
Overview, 245
Regulatory and legislative requirements, 246
Specific types, 256
Class AIMD, 256
Class III, 256
Containing a component medicine, 257
Containing a medicinal substance, 256
Containing materials of animal, microbial, or recombinant origin, 256
Containing other therapeutic goods (OTGs), 257
Reusable, 256
Single-use, 256
Sterile, 256
Subsets, 256

T

TGC. See Therapeutic Goods Committee
Therapeutic Goods Committee (TGC)
Function, 19
Time Frames
Glossary entry, 332

V

Vital Physiological Process/Parameter
Glossary entry, 332

W

Working Day
Glossary entry, 333