Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Supporting documentation for inclusion of a medical device

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Depending on the classification and kind of device (including IVDs) a sponsor is seeking to include in the Australian Register of Therapeutic Goods (ARTG), a range of documents may be required to:

- complete a valid application,
- undergo an application audit, or
- fulfil sponsor responsibilities once a device is included in the Register.

The following guidance aims to help sponsors identify the relevant documentation that will assist them throughout the application, inclusion and post-market processes associated with maintaining a device inclusion in the ARTG.

Associated guidance

This information should be read in tandem with:

- Application for inclusion process (https://www.tga.gov.au/node/286556)
- Auditing of medical device applications (https://www.tga.gov.au/node/289469)
- Manufacturer Evidence for Medical Devices (including IVDs) (https://www.tga.gov.au/node/287913)
- Comparable overseas regulators for medical device applications (https://www.tga.gov.au/node/289428)
- Declaration of conformity templates (medical devices) (https://www.tga.gov.au/node/288300)

The guidance below outlines the following:

- Information that must be attached to your application for inclusion for it to pass preliminary assessment
- Information that the sponsor must have access to in order to satisfy TGA request for information under section 41FH and section 41JA.

Information that must be attached to your application for inclusion for it to pass preliminary assessment

Depending on the classification of your medical device, you will need to attach documentation to your device application in TBS in order to pass preliminary assessment. This information must be provided in addition to the Manufacturer Evidence for Medical Devices (including IVDs) (https://www.tga.gov.au/node/287913) that you submitted to the TGA prior to commencing your device application. The specific documents that you are required to attach are outlined in the final column "Documentation to be provided with the application (Evidence of product assessment)" of Table 2 in the Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices (including IVDs) (https://www.tga.gov.au/node/285179).

Information that the sponsor must have access to in order to satisfy TGA request for information under section 41FH and section 41JA

Declaration of Conformity (DoC)

This document is a declaration made by the manufacturer in accordance with Schedule 3 of the Regulations that demonstrates that the manufacturer complies with regulatory requirements of Australia.

The DoC must be appropriate for the conformity assessment procedure that has been applied to the kind of medical device and made according to the Australian requirements. For example a DoC to the requirements of the European Medical Devices Directive is not acceptable.

For guidance and templates regarding the DoC refer to the Declaration of conformity templates (medical devices) (https://www.tga.gov.au/node/288300) and Declaration of conformity templates (IVD medical devices) (https://www.tga.gov.au/node/288299) web page.

Conformity assessment document issued for the kind of medical device

A document providing evidence of the application of appropriate conformity assessment procedures for the kind of medical device is required under Schedule 3 of the Regulations.

An appropriate conformity assessment document referencing an appropriate conformity assessment procedure for the kind of medical device may be one of the following:

- A TGA Conformity Assessment Certificate.

- Overseas market authorisation evidence from a comparable overseas regulator (https://www.tga.gov.au/node/289428) including an EC Certificate issued by a recognised Notified Body.
- Declaration of Conformity to clause 7.5 of Schedule 3 of the Regulations for a system or procedure pack. For guidance and templates regarding the Declaration of Conformity refer to the Declaration of conformity templates (medical devices) (https://www.tga.gov.au/node/288300) webpage.
- A Certificate issued under an MRA (Mutual Recognition Agreement) in accordance with Schedule 3 of the Regulations by a recognised Notified Body.

> **Note**
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> Certificates issued under MRAs may no longer be acceptable for some higher risk devices including Class III and AIMDs

The conformity assessment document must demonstrate:

- that the manufacturer has been assessed and has the appropriate quality management system in place to manufacture device of that kind; and
- where applicable, appropriate evidence of product assessment is available.

> **Note**
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> Ensure you have any required documentation as outlined in the final column "Documentation to be provided with the application (Evidence of product assessment)" of Table 2 in the Use of market authorisation evidence from comparable overseas regulators/assessment bodies for medical devices (including IVDs (https://www.tga.gov.au/node/285179)) as you will need to attach these documents to your application in order to pass preliminary assessment.

Systems or procedure packs where clause 7.5 of Schedule 3 of the Regulations has been applied to the kind of medical device

For a system or procedure pack where the special conformity assessment procedure under regulation 3.10 and clause 7.5 of Schedule 3 of the Regulations has been applied to the kind of medical device, the following is required:

- a declaration of conformity in accordance with clause 7.5 of Schedule 3 of the Regulations;

- a certificate for the sterilisation of the system or procedure pack issued under Part 4 of Schedule 3 of the Regulations if the system or procedure pack is sterile and a special conformity assessment procedure under regulation 3.10 and clause 7.5 Schedule 3 of the Regulations has been applied to the kind of medical device; and
- documentary evidence of compliance of the system or procedure pack with the requirements of regulation 3.10 and clause 7.5 of Schedule 3 of the Regulations.

> **Note**
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> A certificate issued under Part 4 of Schedule 3 of the Regulations for the sterilisation of a system or procedure pack where the the special conformity assessment procedure under regulation 3.10 and clause 7.5 Schedule 3 of the Regulations has been applied to the kind of medical device is not a Conformity Assessment Certificate issued in relation to a kind of medical device (i.e not issued in relation to the system or procedure pack itself), this certificate is issued in relation to the sterilisation of the system or procedure pack only.

Product information to be provided with the medical device and used to supply the medical device in Australia

Information provided with the medical device, including IVD medical devices, and used to supply the medical device in Australia is documentation that identifies the kind of medical device, describes the manufacturer's intended purpose and mechanism of action of the device, and provides information about the unique product identifier (UPI) and variants relevant to devices of that kind.

All information must be clear, legible and provided in English.

Labelling and instructions for use are not necessarily required for every model or variant, unless there are significant differences in content.

> **Note**
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> Advertising material relating to medical devices must be limited to the approved intended purpose of the device under the ARTG inclusion. It is an offence to advertise by any means a device for any other purpose.

Related information and guidance

Medical Device Inclusion including IVD Medical Devices (https://www.tga.gov.au/node/286556) (includes information on kind of medical device, GMDN codes, UPI and variants)

Essential principle 13 of Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (https://www.legislation.gov.au/Series/F2002B00237) (the Regulations) specifies the requirements for the information that must be provided with the device, the location of this information, and the requirements for the instructions for use for the device.

Essential Principle 13A provides information in relation to the patient implant cards and patient information leaflets for implantable devices (https://www.tga.gov.au/node/287797).

Regulation 10.2 of the Regulations (https://www.legislation.gov.au/Series/F2002B00237) specifies the information about the sponsor that must be provided with the medical device.

Advertising therapeutic goods (https://www.tga.gov.au/node/137882)

Advertisements for medical devices that are directed to consumers are required to comply with the following:

- *Therapeutic Goods Act 1989* (https://www.legislation.gov.au/Series/C2004A03952) (Chapter 5 - Part 5-1 - Division 1, 3, 3A, 4)
- *Therapeutic Goods Regulations 1990* (https://www.legislation.gov.au/Series/F1996B00406) (Part 2 - Division 1, 3, 4, 5)
- *Therapeutic Goods Advertising Code 2018 (No. 2)* (https://www.tga.gov.au/node/288202)

Clinical evidence

Clinical evidence is required to substantiate compliance of the kind of medical device with the essential principles, including requirements set out under Schedule 1 and Part 8 of Schedule 3 of the Regulations (https://www.legislation.gov.au/Series/F2002B00237).

All medical devices supplied in Australia must comply with relevant legislative provisions. One of these is compliance with the Essential Principles that are set out in Schedule 1 of the Regulations (https://www.legislation.gov.au/Series/F2002B00237).

Subregulation 3.11(1) of the Regulations (https://www.legislation.gov.au/Series/F2002B00237) stipulates that in addition to the conformity assessment procedures that are applied for a medical device, clinical evaluation procedures must also be applied to the device, for the purpose of demonstrating that the device complies with the applicable provisions of the essential principles, in particular:

- Essential Principle 1 - Use of medical device not to compromise health and safety

- Essential Principle 3 - Medical devices to be suitable for intended purpose
- Essential Principle 6 - Benefits of the medical devices to outweigh undesirable effects.
- Essential Principle 14 - Clinical evidence

Part 8 of Schedule 3 of the Regulations (https://www.legislation.gov.au/Series/F2002B00237) provides requirements for the clinical data that the manufacturer of a kind of medical device must obtain and evaluate in relation to the kind of device.

To demonstrate compliance with the above mentioned requirements you need to do the following:

- Obtain the clinical data
- Obtain the Clinical expert report and the full curriculum vitae for the clinical expert
- Complete the Clinical evidence report (CER)checklist
- For further information refer to the related information and guidance below

Related information and guidance

For information on clinical evidence and presentation of clinical evidence refer to Clinical evidence guidelines: Medical devices (https://www.tga.gov.au/node/289565).

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch	October 2019

Topics:

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