Australian Government
Department of Health
Therapeutic Goods Administration

Guidance – manufacturer's declaration of conformity for Class I and Class 1 IVD medical devices, export-only Class I and Class 1 IVD medical devices, and Class I and Class 1 IVD system or procedure packs

Version 1.2, November 2021

TGA Health Safety Regulation

Contents

About this guidance

This guidance applies to the manufacturer's declaration of conformity procedures for:

- Class I (non-sterile, non-measuring) medical devices
- export-only Class I medical devices
- Class 1 in vitro diagnostic (IVD) medical devices
- export-only Class 1 IVD medical devices
- Class I (non-sterile, non-measuring) system or procedure packs
- Class 1 IVD system or procedure packs.

This document is designed to assist manufacturers in completing the relevant declaration of conformity and to assist sponsors confirming that documentation prepared by the manufacturer is complete.

Sponsors must obtain a declaration of conformity from the manufacturer to upload as part of their application for inclusion in the ARTG for any medical device with a classification listed above.

This guidance is not legislative in nature and is subject to the requirements of therapeutic goods legislation. The Therapeutic Goods Administration (TGA) will continue to update this guidance as required.

Definitions

This guidance refers to the following:

- Medical devices
- In vitro diagnostic (IVD) devices
- Manufacturers
- Sponsors
- Medicines
- Biologicals
- Other therapeutic goods

For more information on the regulation of medical devices and the responsibilities of sponsors and manufacturers refer to Overview of medical devices and IVD regulation and the Australian regulatory guidelines for medical devices (ARGMD).

Declaration of conformity

When applying for inclusion in the Australian Register of Therapeutic Goods (ARTG), different classes of medical device require different levels of evidence under Australian law.

The declaration of conformity provides sponsors and the TGA with information about medical devices to ensure compliance with the Essential Principles, the classification rules and the appropriate conformity procedures, as provided under Australian legislation.

The declaration of conformity must be completed by the manufacturer or an authorised representative of the manufacturer. Manufacturers and sponsors have different responsibilities. A person or entity may be both the sponsor and manufacturer, provided they satisfy the relevant legal requirements and are aware of their ongoing responsibilities.

For more information refer to TGA Business Services: getting started with the TGA.

The declaration of conformity must be maintained and updated by the manufacturer. The manufacturer may hold a declaration of conformity made under the legislative provisions of other jurisdictions, however the TGA requires a copy of a declaration of conformity that satisfies the Australian legislative requirements.

For more information refer to:

- *Therapeutic Goods Act 1989*
- *Therapeutic Goods (Medical Devices) Regulations 2002*
- *Therapeutic Goods Regulations 1990*

Who needs to complete the form

The declaration of conformity must be:

- completed and signed by the manufacturer (or an authorised representative of the manufacturer)
- completed in English.

The sponsor will require a copy of the completed declaration of conformity from the manufacturer to complete their application for inclusion in the ARTG for any medical device with a classification listed above.

Templates

The relevant Australian declaration of conformity templates that provide the required information under Schedule 3 of the Regulations, as specified in Part 6, clause 6.6, and Part 7, clause 7.5 (Systems and procedure packs) respectively, are available at Declaration of conformity templates (medical devices).

Details to include in the declaration of conformity

Manufacturer's details

Manufacturer's name

The name of the company or individual responsible for manufacturing the device (the person signing this form must be authorised by the manufacturer). The name of the manufacturer has to be written on the declaration the same as it appears on the labelling of the device and must also match the manufacturer's name on the application for inclusion in the ARTG.

For example: ABC Pty Ltd

Business address

This address is the primary business address of the company or person responsible for manufacturing the device.

This address must be:

- the physical location of the manufacturer's operations – websites and email addresses are not acceptable.
- a street address – post office box numbers are not acceptable
- the address of the manufacturer as it appears on the label of the device and in the application for inclusion in the ARTG.

For example: Level 1, 123 Smith St, Sydney NSW 2000

The TGA will use this address to contact the manufacturer if required.

The manufacturer's name and address must be on the outer label of the device to enable the end user to identify who the manufacturer is and their location.

Classification

It is the responsibility of the manufacturer to specify the appropriate classification for the medical device.

For example: Class I non-sterile, non-measuring device

For more information on the different classifications, refer to Schedules 2 and 2A of the *Therapeutic Goods (Medical Devices) Regulations 2002*. You may also find the What classification is my medical device useful.

GMDN code and term

Global Medical Device Nomenclature (GMDN) Terms are an international naming and grouping convention used to identify and consistently describe medical devices. In Australia, GMDN Terms are a key factor in determining a 'kind' of medical device'.

It is the manufacturer's responsibility to select the most appropriate GMDN Term for the medical device including system or procedure pack (SOPP) they manufacture. There may be multiple GMDN Terms that could apply to a kind of device and the manufacturer should carefully consider all available GMDN Terms to ensure they apply the most appropriate GMDN Term for the medical device (or closest fit) based on what type of device it is, and how it is intended to be used.

For example: GMDN 14066 – Depressor, tongue, a single use instrument intended to displace the tongue to facilitate examination

The GMDN Terms and codes are a system of internationally agreed generic descriptors that are used to identify all medical device products. GMDN codes are generated by the GMDN Agency.

Class 1 IVD medical devices require the use of a level 1 collective term (CT). Refer to guidance regarding an appropriate CT for this kind of device: The use of GMDN codes for IVD medical devices in Australia.

The GMDN code tables are available via the GMDN Agency website.

Standards applied to the device(s)

There are many different standards that may apply to the design and manufacturing of a medical device, depending on the type of device and factors such as the materials used in its construction. Identifying relevant standards that have been used in the manufacture of the device helps manufacturers demonstrate compliance with the Essential Principles.

List any standards used in the manufacturing of the device, including, where appropriate:

- International Standards (ISO)
- Australian Standards (AS)
- Conformity Assessment Standard Orders (CASO)
- Medical Device Standard Orders (MDSO)

For example: ISO 7153-1:2016 Surgical instruments — Materials — Part 1: Metals

Note

If no standards have been applied to the device, leave this field blank.

Identification of the Class I or Class 1 IVD system or procedure pack

The manufacturer of the SOPP assigns the overall name of the SOPP. State the name of the SOPP and sufficient information to identify the SOPP.

Where multiple configurations of SOPPs are to be included, please add a schedule to the end of the declaration, specifying the information required in the box (for example, see attached Schedule A – Identification of the system or procedure packs).

Kind of medical device

Medical devices, including Class I or Class 1 IVD medical devices, are included in the ARTG as a 'kind of medical device'. An application for inclusion of a medical device in the ARTG must be made for a 'kind of medical device'.

Devices are taken to be of the same kind if they have all of the following:

- the same sponsor
- the same manufacturer
- the same classification
- the same GMDN code.

Contents of the system or procedure pack

Include a list of all the items (including medical devices, medicines, biologicals and any other therapeutic goods) in the SOPP.

List all Class I or Class 1 IVD medical devices that are intended for supply under the ARTG entry. Model numbers or variants are not required for Class I or Class 1 IVD medical devices.

For example: Wooden tongue depressor, plastic tongue depressor, bamboo tongue depressor, flavoured tongue depressor.

Where multiple items are to be included in different configurations of SOPPs, please add a schedule to the end of the declaration (for example, Schedule B – Items within the system or procedure packs), specifying the following details:

- All items included within the SOPP.
- Specify if there have been any modifications to any device that is included in the SOPP, or its packaging. For each component medical device or IVD medical device on your declaration:
    - Select 'not applicable' if the medical device has not been modified and neither has its packaging. This means the original packaging of the component medical device has not been opened, removed and the medical device is supplied as originally intended by its manufacturer.
    - Select 'yes' if the device or its packaging has been modified, and the modification has been done in accordance with its manufacturer's instructions. This means the original packaging of the component medical device has been opened or removed, and it is repackaged with the consent of the component manufacturer as per their instructions.
    - Select 'no' if the device or its packaging has been modified, but this modification has not been done in accordance with its manufacturer's instructions. This means the original packaging of the component medical device has been opened or removed and it is repackaged without the consent of the component manufacturer; that is, not in accordance with their instructions.
    - The manufacturer of the system or procedure pack becomes the manufacturer of the component device and must ensure that the modification does not affect the quality, safety or performance of the medical device or IVD medical device, as modified.
- State the ARTG number for any medical device or IVD medical device that is included in the SOPP and also supplied independently of the SOPP in Australia.
- State the ARTG number for any medicine included in the SOPP. This is mandatory for all medicines supplied in a SOPP.
- State the ARTG number for any biological included in the SOPP. This is mandatory for all biologicals supplied in a SOPP.
- State the ARTG number for any other therapeutic good that is included in the SOPP and supplied independently of the SOPP in Australia. Specify any other therapeutic good that is included in the SOPP and is exempt from inclusion in the ARTG. Refer to guidance on Other therapeutic goods for information on other therapeutic goods that are exempt from this requirement.

Essential Principles

The Essential Principles are legislative requirements relating to safety and performance characteristics of medical devices, including IVD devices.

There are 15 Essential Principles listed in Schedule 1 of the Regulations, including:

- six general Essential Principles that apply to all devices

- seven Essential Principles relating to design and construction that apply to some devices on a case-by-case basis
- one Essential Principle relating specifically to IVD medical devices
- one Essential Principle relating to information that is to be provided with medical devices that applies to all medical devices.

It is the manufacturer's responsibility to demonstrate compliance with the Essential Principles for their medical devices. The Essential Principles checklist will help identify which principles are relevant to the device and demonstrate that they have been met.

The declaration requires confirmation that all relevant Essential Principles have been met.

Technical documentation

Technical documentation provides evidence the TGA may consider when assessing the safety, quality and performance of the device. The TGA may request any technical documentation that provides information about the device at any time.

The following information and undertakings applicable to the device must be available in writing:

- Details of each manufacturing site where these conformity assessment procedures have been applied.
- A general description of the device.
- Diagrams and drawings of the design of the device including any components, sub-assemblies or circuits, and descriptions or explanations that allow the diagrams and drawings to be properly understood.
- Documentation demonstrating that your device complies with the applicable Essential Principles and conformity assessment procedures (such as certification or demonstrated compliance with medical device or conformity assessment standards).
- Results of any design calculations, risk analyses, investigations, technical tests, analytical or clinical studies or any other tests carried out in relation to the device.
- Evidence – if your device is intended to be connected to another device – showing that the device will continue to comply with the relevant Essential Principles when it is connected to the other device and both devices are being used for their intended purpose.
- A copy of the clinical evidence in relation to the device as required by the clinical evaluation procedures described in Schedule 3 (Part 8) of the Regulations.
- A copy of information to be provided with the device including labelling, packaging and instructions for use (Essential Principle 13).
- Additionally, for Class I or Class 1 IVD SOPPs:
    - documentation demonstrating that your device complies with the applicable Essential Principles and conformity assessment procedures such as:
        - a declaration of conformity made under clause 6.6 of Schedule 3 of the Regulations to demonstrate that the relevant conformity assessment procedures have been applied by the manufacturer of the Class 1 or Class 1 IVD medical device(s) in the SOPP

- a statement under subclause 7.2(2) of Schedule 3 of the Regulations to demonstrate that the relevant conformity assessment procedures have been applied by the manufacturer of the custom-made medical device(s) in the SOPP

- documentary evidence that demonstrates how the SOPP manufacturer has verified the mutual compatibility of the components placed in the SOPP in accordance with the component manufacturer's instructions and approved indications
- documentary evidence to show that, for any modification to any component device or the packaging of any component device placed in the SOPP:
  - the modification has not affected the quality, safety or performance of that device
  - the modification has been done in accordance with the component manufacturer's instructions for use (such as a written agreement from the component manufacturer).

Refer to specific guidance on system or procedure packs.

Post-market monitoring, reporting and corrective system

The manufacturer must have a post-market monitoring system in place for the medical device that:

- systematically reviews experience gained in the post-production phase of the device
- implements corrective action in relation to the design or production of the device when required
- reports to the TGA:
  - adverse events or incidents, including malfunctions or deteriorations in the performance of the device
  - inadequacies in the design, production, labelling, instructions for use, or advertising materials
  - any use of the device that might lead, or might have led, to the death of a patient or user of the device, or to a serious deterioration in their state of health
  - any recall actions that have been taken due to the previous points.

Declaration

The declaration of conformity is a legally binding declaration made by the manufacturer. Providing information in this document that is false or misleading is a serious offence subject to criminal penalties.

Before signing this declaration, manufacturers must:

- Review the declaration of conformity procedures under either clause 6.6 or clause 7.5 of Schedule 3 of the Regulations before signing the declaration.
- Confirm that the device complies with the applicable provisions.
- Confirm that the device complies with the Essential Principles.
- Confirm that the appropriate classification rules have been applied to the device.

Signature

- The manufacturer (or an authorised representative of the manufacture) must sign and date the declaration of conformity.
- If the sponsor is also the manufacturer, they are responsible for signing and dating the declaration of conformity.
- The sponsor cannot sign the declaration of conformity on behalf of the manufacturer.
- Signatories must sign their name and print their name in block letters.
- Signatories must state their title and date the document.
- Handwritten copies which have been scanned are acceptable.
- Electronic signatures are acceptable.

For information or assistance contact the Medical Devices Information Unit on 1800 14 11 44 or at devices@tga.gov.au.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Surveillance Branch	December 2020
V1.1	Update to include text 'Class I Medical Device (Export Only) and Class 1 IVD Medical Device (Export Only)'	Medical Devices Surveillance Branch	May 2021
V1.2	Update to include guidance relating to requirements for system or procedure packs	Medical Devices Authorisation Branch	November 2021

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au
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