Australian Government
Department of Health
Therapeutic Goods Administration

Guidance – manufacturer's declaration of conformity for system or procedure packs (other than Class I or Class 1 IVD system or procedure packs)

Version 1.0, November 2021

TGA Health Safety Regulation

Contents

About this guidance

This guidance applies to manufacturers of medical devices that are regulated as 'system or procedure packs' and supplied using the special conformity assessment procedure regulatory pathway. In order to supply via the special conformity assessment procedure set out in clause 7.5 of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations), the criteria set out in Regulation 3.10 defining 'medical devices used for a special purpose' must be met. Refer to guidance on 'system or procedure packs' for more information.

This document is to assist manufacturers of system or procedure packs in completing the declaration of conformity made under clause 7.5 for system or procedure packs (other than a Class I or Class 1 IVD system or procedure pack). Separate guidance is available to assist manufacturers of Class I or Class 1 IVD system or procedure packs to make this declaration using a different template.

Sponsors must obtain a copy of a declaration of conformity, made under clause 7.5 of Schedule 3 of the Regulations by the manufacturer of the system or procedure pack, to make a Manufacturer's Evidence application. Once this application has been accepted by the TGA, the sponsor can use the manufacturer's evidence to apply for the system or procedure pack's inclusion in the Australian Register of Therapeutic Goods (ARTG) as a medical device. The sponsor of a system or procedure pack may also be its manufacturer.

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

The declaration of conformity must be completed and signed by the manufacturer of the system or procedure pack (SOPP), or the manufacturer's authorised representative who supplies the SOPP under their name in the Australian market. A person or entity may be both the manufacturer and sponsor of the SOPP, 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 and must satisfy the Australian legislative requirements. 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) of the SOPP
- provided in English.

Templates

The relevant Australian declaration of conformity templates are available at Declaration of conformity templates (medical devices).

The SOPP manufacturer must complete:

- Clause 7.5 template for Class I or Class 1 IVD system or procedure packs
- Clause 7.5 template for SOPPs other than a Class I or Class 1 IVD SOPPs (subject of this guidance)

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 manufacturer's name has to be written on the declaration 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

Manufacturer's business address:

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 the manufacturer and their location.

Classification of the SOPP

It is the responsibility of the manufacturer to determine the appropriate classification of their SOPP. Manufacturers must consider all the classification rules when classifying their medical device.

When determining the classification of a SOPP, its manufacturer must consider the following elements:

- The overall classification of the SOPP is determined by the medical device with the highest classification of those included in the SOPP. This means that other than medical devices, the overall classification does not consider any medicines, biologicals, or other therapeutic goods, if any are included. For example, if a SOPP contains a Class IIb device, a Class IIa device and an over-the-counter-medicine, its overall classification is Class IIb.
- If the SOPP contains an IVD medical device and a non-IVD medical device with equivalent classifications, the overall classification of the SOPP is determined according to its primary intended purpose. That is, the SOPP's classification is the same as the device whose intended purpose is most closely aligned with that of the SOPP.
- Where the SOPP manufacturer purchases medical devices in a finished state (that is, market-ready devices that have undergone all manufacturing processes including packaging and sterilisation, if applicable), the original component manufacturer's intended purpose and classification applies to this purchased medical device. If the SOPP manufacturer changes the original component manufacturer's intended purpose or its classification, the SOPP manufacturer assumes responsibility as manufacturer of the medical device.

For more information on how to determine the appropriate classification of a medical device, refer to Schedules 2 and 2A of the Regulations, or try our online decision-support tool, What classification is my medical device?

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. 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.

An IVD medical device, other than an immunohematology reagent that is a Class 4 IVD medical device, requires the use of a GMDN collective term (CT). The classification of the IVD medical device will determine the level of collective term required. For example, a Class 2 IVD medical device requires the use of a Level 2 CT, while for a Class 3 IVD medical device, there is no existing Level 3 CT and a Level 2 CT can be used. For guidance on using the appropriate CT for IVD medical devices, see: The use of GMDN codes for IVD medical devices in Australia.

It is the manufacturer's responsibility to select the most appropriate GMDN Term (or collective term for an IVD medical device) for the 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 SOPP (or closest fit) based on what type of device it is, and how it is intended to be used.

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

Identification of the system or procedure pack

The manufacturer of the SOPP assigns the overall name and identification of the SOPP. State the name and identification (including Unique Product Identifier (UPI), where applicable) of the SOPP and sufficient information to identify the SOPP.

Where multiple configurations of system or procedure packs 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 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.

Another characteristic that determines a kind of medical device for Class III medical devices, AIMD and Class 4 IVD medical devices (other than an immunohematology reagent that is a Class 4 IVD medical device) is the UPI assigned to the device by its manufacturer to uniquely identify individual devices and define the products supplied in the global marketplace.

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.

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 criteria in the box, including the following details.

- All items included within the SOPP.
- For each medical device and IVD medical device that is included in the SOPP:
  - The name or identification (including Unique Product Identifier, model numbers) of the medical device as assigned by its manufacturer. For example:

    Male stress urinary incontinence surgical mesh (UPI: ABC Male Sling).

  - The classification of the medical device as determined by the manufacturer. For example:

    Class III (ABC Male Sling)

  - Details of the conformity assessment document issued by the TGA or a comparable overseas regulator for the medical device (other than a Class I, Class 1 IVD medical device or custom-made medical device). For example:

    ABC Male Sling:

    QMS Certificate: Annex IX of EU Regulation 2017/745 issued by NB Snowman (NB 006), Certificate No. ABC345, expiry date: 20-08-2026

    Design examination certificate: Annex IX of EU Regulation 2017/745 issued by NB Snowman (NB 006), Certificate No. ABC345, expiry date: 20-08-2026

  - State the ARTG number for any medical device in the SOPP that is supplied separately to the SOPP.

    For example: ARTG 12345 (ABC Male Sling).

- For any medical device (other than a Class I, Class 1 IVD or custom-made device) included in the SOPP, select 'yes' or 'no' to indicate if there has been any modification to the medical device or its packaging after it was obtained from its manufacturer. If 'yes' is selected:
  - Select 'yes' or 'no' to indicate whether the modification was done in accordance with the medical device's instructions for use, as specified by its manufacturer. Selecting 'yes' means there have been modifications to the medical device, or the packaging of any medical device included within the SOPP, and this modification was done in accordance with the medical device's instructions for use as specified by its manufacturer. The SOPP manufacturer has documentary evidence to demonstrate the modification was done in accordance with the medical device's instructions for use as specified by its manufacturer.
  - If 'no' is selected, this means there have been modifications to the medical device or the packaging of any medical device included within the SOPP, but the modification **has not** been done in accordance with the instructions for use of the medical device as specified by its manufacturer. The SOPP manufacturer does not have documentary evidence to demonstrate that modification been done in accordance with the instructions for use of the medical device as specified by its manufacturer. The manufacturer of the system or procedure pack becomes the manufacturer of this component device and must ensure that the modification does not affect the quality, safety or performance of the medical device, as modified. If 'no' is selected, indicate whether the modified device is a 'Class I or Class 1 IVD', 'Custom-made' or 'other' device after its modification.
  - If 'other' is selected, this means the modified device is a medical device (that is not a Class I non-measuring, non-sterile device, Class 1 IVD or custom-made device), such as a Class I sterile device. Specify the details of the conformity assessment document issued by the TGA or a comparable overseas regulator or assessment body for the modified medical device. For example:

Hypodermic needles / Class I sterile:

MDSAP Certificate: Scope: Design, manufacturer and sterilisation of hypodermic needles, Certificate No. ABC345, expiry date: 20-08-2026

- 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 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.

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 documentation that provides information about the device at any time. This may include:

- Documentation demonstrating that your device complies with the applicable Essential Principles and that conformity assessment procedures have been applied to the device, including evidence such as:
    - certification issued by the TGA or documentation issued by a comparable overseas regulator or assessment body to the manufacturer for the medical device included in the SOPP
    - certification issued by the TGA or documentation issued by a comparable overseas regulator or assessment body to the SOPP manufacturer for undertaking sterilisation of the SOPP (where the SOPP is intended to be supplied in a sterile state).
- Documentary evidence produced by the SOPP manufacturer that demonstrates verification of 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).
- 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 of the Regulations).

Refer to guidance on 'System or Procedure Packs' for more information.

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 of the SOPP. Providing false or misleading information in this document is a serious offence subject to criminal penalties.

Before signing this declaration, manufacturers must review the declaration of conformity procedures under Part 7 of Schedule 3 of the Regulations and declare that the SOPP complies with the applicable provisions of those procedures.

Signature

- Review the declaration of conformity procedures under Part 7 of Schedule 3 of the Regulations and declare that the SOPP complies with the applicable provisions of those procedures.
- 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@health.gov.au

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	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
Reference/Publication #