Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

System or procedure packs

Guidance for sponsors, manufacturers and charities

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Contents

About this guidance

From **25 November 2021**, new regulatory requirements apply to medical devices that meet the definition of 'system or procedure packs' and are supplied using the special conformity assessment procedure regulatory pathway. System or procedure packs are regulated by the Therapeutic Goods Administration (TGA) as single medical devices in their own right and therefore must be included in the Australian Register of Therapeutic Goods (ARTG).

For inclusion in the ARTG, manufacturers have two options to apply conformity assessment procedures to system or procedure packs. This relates to aspects of the manufacturing process and demonstrating that medical devices produced by it are safe and perform as intended. The manufacturer of a system or procedure pack may obtain market authorisation evidence, issued by an independent assessment body or regulator for the system or procedure pack; or use the special conformity assessment procedure set out in clause 7.5 of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the 'Regulations') if they meet the eligibility criteria for 'medical devices used for a special purpose' defined in Regulation 3.10.

The new regulations only apply to system or procedure packs that are supplied using the special conformity assessment procedure. This guidance aims to assist sponsors and manufacturers of these medical devices, by explaining their obligations under the new regulations and transitional arrangements for any of these medical devices included in the ARTG before 25 November 2021.

This guidance also describes the various regulatory mechanisms that are in place to support the supply of various types of system or procedure packs by charities and other organisations (such as schools). Refer to Appendix 1 of this guidance for more information.

Background

The regulatory changes aim to clarify how the medical device regulations apply to devices that are system or procedure packs, and follow a public consultation conducted by the TGA in October 2019 and a number of targeted consultations with stakeholders. The changes support the Australian Government's commitment, in its response to the Review of Medicines and Medical Devices Regulation, to align Australian medical device regulations with the European Union framework where possible and appropriate.

In relation to packs supplied by charities and other organisations, the TGA held a stakeholder workshop with charities and state education department on 1 July 2021, to discuss the range of packages these organisations currently supply and understand any limitations on their supply. The participants discussed specific examples of the packs supplied by their organisations and different viewpoints relating to their supply. The outcomes from that workshop and further re-engagements with these stakeholders have been used to inform Appendix 1 of this guidance.

Definition of 'system or procedure packs'

System or procedure packs (SOPPs), defined in section 41BF of the *Therapeutic Goods Act 1989* (the 'Act'), are medical devices that are intended to be used in a medical or surgical procedure, containing a combination of two or more goods where:

- at least one of the goods is a medical device (which may be an in vitro diagnostic (IVD) medical device); and
- all of the goods are packaged together; or are to be interconnected or combined for use.

Section 41BF 'System or procedure packs'

Two or more goods (including at least one medical device) are a *system or procedure pack* if:

(a) all of the goods are to be interconnected or combined for use in a medical or surgical procedure; or

(b) all of the goods are packaged together for use in a medical or surgical procedure.

A SOPP must include a medical device (or an IVD medical device), and depending on its intended purpose, may also include:

- medicines
- biologicals
- other therapeutic goods, or
- other goods that are not considered to be therapeutic goods.

SOPPs are medical devices in their own right and must be included in the ARTG. If individual medical devices in the SOPP are also supplied separately from the SOPP, these devices must be included in the ARTG separately from the SOPP.

IMPORTANT: Other regulatory pathways for combinations of goods

A wide range of products are assembled using a combination of goods that includes at least one therapeutic good. They are regulated in different ways, depending on the specific combination of goods contained in the package.

- some of these products, like medicine kits and composite packs, are not regulated as medical devices
- surgical loan kits are regulated as medical devices, but they do not meet the definition of a SOPP
- some products are exempt from inclusion in the ARTG, such as packages containing tampons, etc. supplied free of charge by charities to homeless or disadvantaged women (including adolescent women) (see Appendix 1)
- others are excluded goods and therefore are not regulated by the TGA. Some excluded goods, however, are regulated by state or territory government bodies. These include packages containing medical devices for the prevention of blood-borne and sexually transmissible diseases (e.g. HIV self-tests), supplied by charities or other organisations.

For more information, refer to **Appendix 1** of this guidance.

Examples of SOPPs

Systems that are SOPPs

Implantable ventricular circulatory assist system

A portable assembly of components intended to provide mechanical assistance to a heart ventricle, typically by pumping blood from the left ventricle to the aorta through an extra-cardiac circuit. The system includes: an implantable pump; an implantable connecting cannula and/or grafts; a percutaneous electrical lead; and external electronic components (such as a battery pack or controller). It is typically intended to be used as a bridge to heart transplantation.

Blood glucose monitoring system

A non-continuous blood glucose monitoring system is an IVD medical device intended to be used for monitoring blood glucose levels in patients with diabetes. A blood glucose monitoring system could comprise of a blood glucose meter that connects to a smart phone, a software app, blood glucose test strips, blood glucose controls, and lancets.

Systems that are medical devices

Systems comprise components that are intended by the manufacturer to be used together, in combination, to achieve a particular medical purpose.

Not all systems meet the definition of SOPP, as some systems don't include a component that is a medical device in its own right.

Procedure packs

First aid kits

First aid kits are medical devices that are put together as a unit and contain a collection of equipment and materials intended to be used in an emergency for the rapid, initial treatment of an injury. They are intended for use by emergency medical service officers, first aid officers in schools and other institutions, consumers at home, in motor vehicles or in other public settings.

Refer to our guidance on first aid kits for further information.

Sterile surgical procedure packs

Sterile surgical procedure packs are medical devices intended for use in hospitals by healthcare professionals. The packs are put together as a unit and contain some or all the necessary materials to perform a surgical procedure. As these packs are to be used in sterile surgical settings, it is essential that the sterility of the entire pack and its components are assured. Sterile surgical procedure packs may contain (but are not limited to) the following contents: clamps, drapes, sutures, needles, forceps, scalpels, gauze and dressings.

Severe acute respiratory syndrome-associated coronavirus (SARS-CoV) antigen test kit

The tests are IVD medical devices that are intended to be used in antigen testing to provide information about infection with or exposure to SARS-CoV. These test kits contain a rapid antigen test (IVD medical device) and a nasal swab (non-IVD medical device) that may be used at the point of care by trained health professionals and for self-testing by consumers.

Classification of SOPPs

Like any medical device, the classification rules that apply to each device in the system or procedure pack are those set out in Schedule 2 of the Regulations. The classification rules are applied according to the device's intended purpose, as determined by its manufacturer, and various aspects of the device's design including but not limited the degree of invasiveness in the human body, the duration and location of use, and whether the device relies on a source of energy other than the body or gravity. Manufacturers must consider all the classification rules when classifying their medical device. Where more than one rule applies, the device must be classified at the highest applicable level.

When determining the classification of a SOPP, the SOPP 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 paracetamol, its overall classification is Class IIb.
- If the SOPP contains an IVD medical device and a non-IVD medical device with equivalent classifications[1], 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 the interactive classification tool on the TGA website.

Updated requirements for SOPPs supplied using the special conformity assessment procedure

Before including any medical device in the ARTG, including a SOPP, a manufacturer must:

[1] For example, a Class 3 IVD device such as a COVID-19 rapid antigen self-test is equivalent in classification to a Class IIb non-IVD medical device.

- apply the relevant conformity assessment procedures or procedures comparable to conformity assessment[2]
- meet the essential principles for safety and performance
- meet on-going post-market and record-keeping requirements.

Some SOPPs are eligible for supply via the special conformity assessment procedure set out in clause 7.5 of Schedule 3 of the Regulations. To be eligible, the SOPP must meet the criteria set out in Regulation 3.10 defining 'medical devices used for a special purpose', including sub-regulations 3.10(3) and 3.10(4), which apply specifically to SOPPs.

There are two regulatory pathways that are available to manufacturers for applying conformity assessment procedures to their SOPPs (see **Figure 1**). The two pathways are described below.

Option 1:

The manufacturer obtains market authorisation evidence (a conformity assessment document), issued either by the TGA, or a comparable overseas regulator/assessment body. This demonstrates that the manufacturer has applied appropriate conformity assessment procedures or met requirements comparable to the Australian conformity assessment procedures appropriate to the SOPP. The sponsor (who may also be the manufacturer) uses this conformity assessment document as evidence to make an application for inclusion in the ARTG.

Option 2:

The manufacturer decides to apply the special conformity assessment procedure, as they meet the eligibility criteria specified in Regulation 3.10 and **complies with all elements of clause 7.5 of Schedule 3 of the Regulations**. This means they make a declaration of conformity that includes all required information about their procedures and evidence regarding the manufacturing the SOPP, the goods it contains, how it is to be supplied to users and information that is to be supplied with it. The sponsor (who may also be the manufacturer) uses this declaration as market authorisation evidence to make an application for inclusion in the ARTG.

Changes to the special conformity assessment procedure take effect on 25 November 2021, along with refinements to the eligibility criteria for the procedure, which are found in Regulation 3.10 of the Regulations.

These regulatory changes only apply to SOPPs that are supplied using the special conformity assessment procedure (Option 2). They do not affect SOPPs (other than Class I or Class 1 IVD SOPPs) supplied using conformity assessment documents issued by the TGA, or a comparable overseas regulator or assessment body (Option 1).

The intent of the special conformity assessment procedure is to allow multiple products, all of which individually comply with the relevant regulatory requirements, to be supplied as a single product that is intended for use in a medical or surgical procedure. This means that a SOPP can be included in the ARTG as a single entry and a separate ARTG entry is not always required for each medical device placed in a SOPP. However, if a medical device placed in a SOPP is supplied separately from the SOPP, it must have its own separate ARTG entry.

[2] The concept of 'procedures comparable to conformity assessment' was introduced to allow recognition of market authorisation approvals made by comparable overseas regulators. Further information on marketing approvals from comparable overseas regulators that are recognised by the TGA can be found in our guidance on Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices (including IVDs).

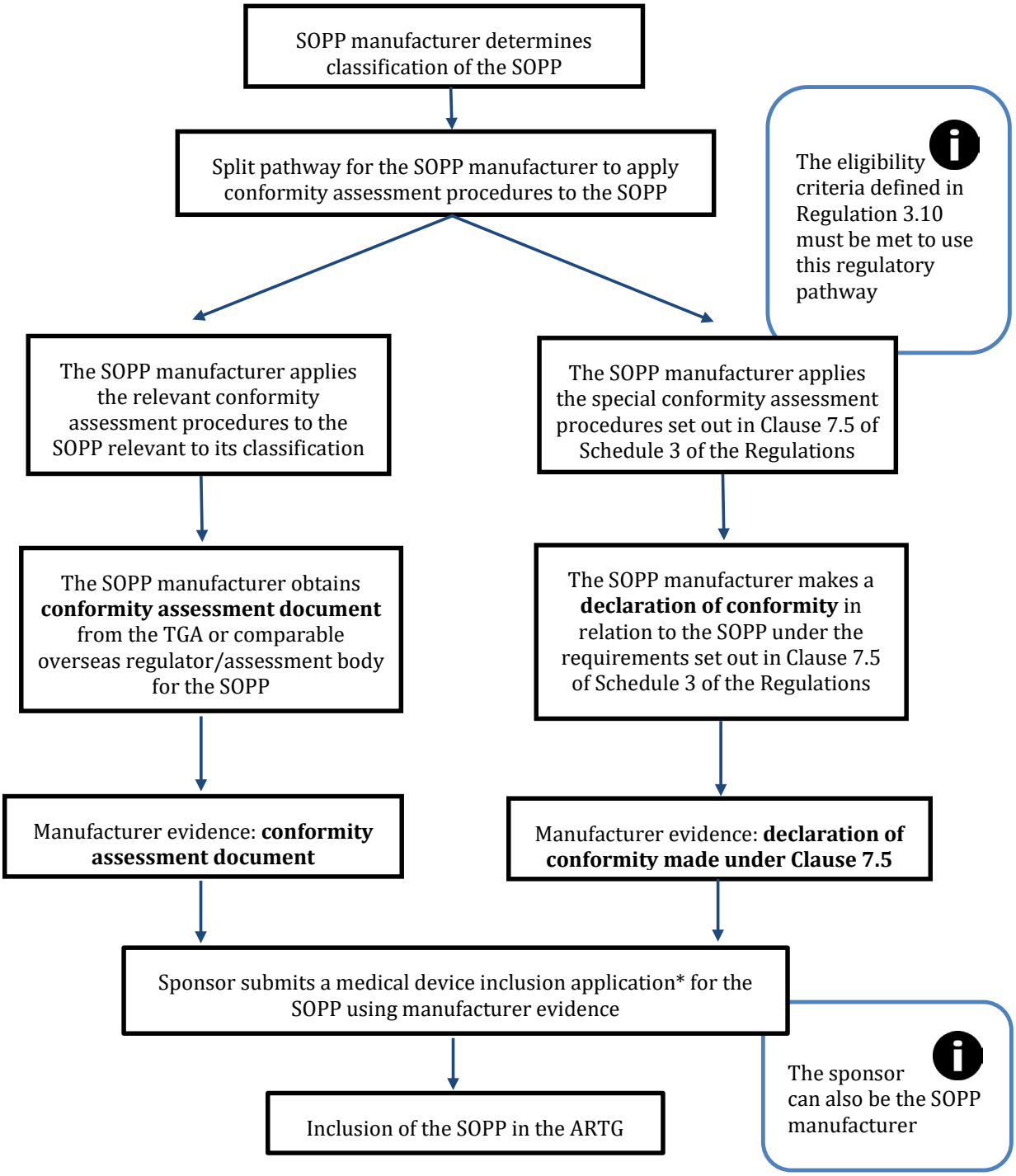

Figure 1: Split conformity assessment pathways for SOPP manufacturers[3]

[3] Asterisk (*) indicates that the application must be successful for inclusion of the SOPP in the ARTG.

Note:

Conformity assessment document means:

(a) a conformity assessment certificate; or

(b) an Australian conformity assessment body certificate; or

(c) an overseas regulator conformity assessment document.

The comparable overseas regulators for medical devices that are recognised by the TGA include:

- European notified bodies
- Canada
- Japan
- United States of America
- Certificates and reports issued under the Medical Device Single Audit Program

The specific market authorisation evidence (i.e. conformity assessment documents), recognised by the TGA that is required for inclusion of each medical device in the ARTG based on the device's classification is detailed in Table 2 of the guidance: Use of market authorisation evidence from comparable overseas regulators/ assessment bodies for medical devices (including IVDs).

What are the requirements?

Amended eligibility criteria for supply via the special conformity assessment procedure

For SOPP manufacturers to be eligible to apply the special conformity assessment procedure (Option 2 on p. 9) to their SOPP, they must meet the criteria described in Regulation 3.10 which define 'medical devices used for a special purpose' – including sub-regulations 3.10(3) and 3.10(4), which apply specifically to SOPPs.

These criteria relate to the combination of therapeutic goods placed in the SOPP. The kinds of goods that can be included in a SOPP to meet the amended eligibility requirements in Regulation 3.10 are detailed below.

Inclusion of kinds of goods in the SOPP to meet eligibility under Regulation 3.10

Requirements related to medical devices

- The SOPP must only include medical devices to which the relevant conformity assessment procedures have been applied.
- The SOPP manufacturer must hold market authorisation evidence in the form of a conformity assessment document (unless the device is Class I, Class 1 IVD, or custom-made) issued by the TGA or a comparable overseas regulator or assessment body to demonstrate that relevant conformity assessment procedures have been applied to each medical device by the component manufacturer.

Requirements related to medicines or biologicals

- The SOPP must only include medicines or biologicals that are listed or registered in the ARTG.
- There must not be any modification to any included medicine or biological or its packaging.

Requirements related to other therapeutic goods

- The SOPP may only include other therapeutic goods that are listed or registered in the ARTG, unless these goods are exempt from inclusion in the ARTG (e.g., tampons, menstrual cups and certain disinfectants).
- There must not be any modifications to any other therapeutic goods or their packaging.

General requirements related to all of the above

- The SOPP must have been assembled in accordance with the intended purpose of each medical device and the approved indications of any medicine, biological or other therapeutic good.
- The SOPP must have been assembled with goods that are mutually compatible when combined, with regard to the intended purpose of each medical device and the approved indications of any medicine, biological or other therapeutic good in the SOPP.

To supply a SOPP in Australia using the special conformity assessment procedure, its manufacturer must meet all elements specified above. If the SOPP manufacturer is intending to supply the SOPP in a sterile state, they must meet additional requirements.

Requirements related to SOPPs supplied sterile

- The manufacturer must apply either the production quality assurance procedures or full quality assurance procedures (other than those in clause 1.6 of Schedule 3 of the Regulations) to the SOPP, in relation to the manufacturing process for maintaining its sterility.
- The SOPP manufacturer must have either Production Quality Assurance or Full Quality Assurance certification, or equivalent certification (refer to 'Questions and Answers' in this guidance) for maintaining sterility of the SOPP, including

undertaking sterilisation in accordance with the component manufacturer's instructions and approved indications for each component placed in the SOPP.

Self-declaring compliance for Class I and Class 1 IVD medical devices and Class I and Class 1 IVD SOPPs

Manufacturers self-declare compliance for:

- Class I (non-measuring, not supplied sterile) and Class 1 IVD medical devices
- Class I or Class 1 IVD system or procedure packs that are not supplied sterile and meet the criteria for 'medical devices used for a special purpose'.

These medical devices are not required to be assessed by an independent assessment body or regulator.

The special conformity assessment procedure

If the eligibility criteria described in Regulation 3.10 are met, the SOPP manufacturer can use the special conformity assessment procedure and make a declaration that complies with clause 7.5 of Schedule 3 of the Regulations.

The SOPP manufacturer's declaration must cover certain information about the individual items placed in the SOPP, related documentation and the manufacturing process, including:

- identifying each item placed in the SOPP, including all therapeutic goods
- providing instructions for use, as supplied by the component manufacturer, for each item in the SOPP
- having evidence that demonstrates the application of relevant conformity assessment procedures or procedures comparable to conformity assessment to each medical device by its manufacturer
- having evidence that each medical device in the SOPP complies with the relevant essential principles
- ensuring that the intended use of any medicine, biological or other therapeutic good included in the SOPP is in accordance with its original intended purpose or the approved indications specified by its manufacturer
- manufacturing the SOPP in accordance with the instructions for use provided by the manufacturer of each component device and the approved indications of any medicine, biological or other therapeutic good in the SOPP
- verifying the mutual compatibility of each medical device, medicine, biological or other therapeutic good and any other goods placed in the SOPP, in accordance with the component manufacturer's instructions and approved indications
- that where the SOPP is intended to be supplied sterile, the minimum requirements are met to ensure sterilisation is undertaken in accordance with the component manufacturer's instructions.

Mutual compatibility

Mutual compatibility is demonstrated by documentary evidence, which the SOPP manufacturer is expected to produce, showing how they have verified the mutual compatibility of the components placed in the SOPP. This evidence must demonstrate that the combined components in the SOPP can perform as intended without any conflict or interference being caused by their combination.

Here, the word 'compatibility' means[4]:

The ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose, to:

(a) perform without losing or compromising the ability to perform as intended, and/or

(b) integrate and/or operate without the need for modification or adaption of any part of the combined devices, and/or

(c) be used together without conflict/interference or adverse reaction.

[4] The meaning of the term 'compatibility' is closely aligned with the definition in the EU Regulation on medical devices 2017/745.

Refinements to the requirements under the special conformity assessment procedure from 25 November 2021

The changes to the special conformity assessment procedure apply to applications for ARTG inclusion made on or after 25 November 2021. These changes require declaration of conformity made under clause 7.5 of Schedule 3 of the Regulations to include several new elements, requiring the SOPP manufacturer to declare on the following matters:

- **has a conformity assessment document** either issued by the TGA or a comparable overseas regulator/assessment body for each medical device (other than Class I, Class 1 IVD or custom-made) placed in the SOPP to demonstrate that the relevant conformity assessment procedures have been applied to each medical device by its component manufacturer
- **has a declaration of conformity** made by the component manufacturer (under clause 6.6 of Schedule 3 of the Regulations) for each Class I or Class 1 IVD device in the SOPP
- **has a statement** made by the component manufacturer under subclause 7.2(2) of Schedule 3 of the Regulations for each custom-made device in the SOPP
- has – where the SOPP is intended to be supplied sterile – applied the full quality assurance procedures (other than those in clause 1.6 of Schedule 3), or the production quality assurance procedures (other than those in clause 4.7 of Schedule 3) to the SOPP in accordance with the manufacturer's instructions for use of each medical device and the approved indications of any medicine included in the SOPP (such as holding relevant third-party certification for undertaking sterilisation of the SOPP, refer to 'Questions and Answers')
- has 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)
    - the SOPP manufacturer assumes responsibility for the modified component if the modification has not been done in accordance with the component manufacturer's instructions for use. The SOPP manufacturer must have evidence that demonstrates the medical device, as affected by the modification, complies with the applicable provisions of the essential principles and must do one of the following that is applicable:
        - obtain a conformity assessment document (as described above) for any component device (other than Class I, Class 1 IVD or custom-made) that is affected by the modification

- make a declaration of conformity under clause 6.6 of Schedule 3 for any component affected by the modification that is a Class I or Class 1 IVD device
- make a statement under subclause 7.2(2) of Schedule 3 for any component custom-made device that is affected by the modification.

Custom-made medical devices

From 25 February 2021, a new definition of custom-made medical device commenced as part of the new framework for regulating personalised medical devices. Devices that meet the amended definition of a custom-made medical device (defined in Regulation 1.3 of the Regulations) are exempt from inclusion in the ARTG.

The new regulations for SOPP allow custom-made medical devices to be placed in SOPPs that meet the definition of 'medical devices used for a special purpose' and are consequently eligible for the special conformity assessment procedure. All custom-made medical devices placed in the SOPP must be supplied with a written statement for the device prepared in accordance with subclause 7.2(2) of Schedule 3 of the Regulations by the manufacturer of the custom-made device.

For more information on custom-made medical devices including information that should be provided in the statement under subclause 7.2(2) of Schedule 3 by the manufacturer of the custom-made device are detailed in Custom-made medical devices guidance.

Record retention requirements

Manufacturers

The manufacturer of a medical device must retain records of its manufacture for either 5 or 15 years, depending on whether it is an implantable medical device.

Since the overall classification of a SOPP is the same as its highest-classified medical device that it includes, the manufacturer of a SOPP supplied using the special conformity assessment procedure is required to retain all records from the date of its manufacture for:

- 5 years if the SOPP does not contain an implantable medical device
- 15 years if the SOPP contains an implantable medical device.

The manufacturer of the SOPP must be able to provide these records, or copies of the records, to the TGA when requested.

Sponsors

There are no changes to the record retention requirements applying to sponsors of SOPPs. Sponsors must retain their records for ten or five years after the last product has been distributed, depending on the classification of the devices as detailed in: Distribution records guidance. These records, or copies of the records, must be provided when requested by the TGA.

Other requirements under the special conformity assessment procedure

Information to be provided with the SOPP

Essential principle (EP) 13 of Schedule 1 of the Regulations sets out the requirements for the information that must be provided with any medical device.

Information about the SOPP Manufacturer

EP 13.3, EP 13.4 and EP 13A.2 sets out the requirements for the information to be provided on the label, the instructions for use and the patient implant card. The required information includes the manufacturer's details, in particular, the manufacturer's name, or trading name, and the address.

Please note:
For SOPPs, the "manufacturer" should be understood to be the SOPP manufacturer[5], whose details must be provided on the labels, the IFU and the patient implant card to demonstrate compliance with the EPs.

Instructions for use

In the declaration made under clause 7.5 by the SOPP manufacturer, they must:

- state that the information supplied with the SOPP for the use of the SOPP includes instructions for use (IFU) provided by the manufacturer of each item in the SOPP.

EP 13.4(1) and (2) states that the instructions for the use of a medical device must be provided with the device unless the device is a Class I, Class 1 IVD or Class IIa medical device; and the device can be used safely for its intended purpose without instructions. EP 13.4(3) prescribes specific information that must be included in the IFU for the purposes of supply of medical devices in Australia. EP 13.4(3), Item 6 applies to a medical device that is a SOPP, and states that the information to be provided with the SOPP must include:

- Sufficient information to enable a user to identify the device, or if relevant, the contents of packaging

As such, the SOPP manufacturer must provide with the SOPP:

- sufficient information to enable a user to identify the SOPP including contents of the items placed in the SOPP; and
- IFU for each item placed in the SOPP as provided by the original manufacturer of each item.

If the SOPP manufacturer modifies the original IFU provided by the component manufacturer for the component included in the SOPP (for example, changing the intended purpose of the component device), then the SOPP manufacturer would assume responsibility as the manufacturer of the component for which the IFU was modified and would need to apply the

[5] The meaning of 'SOPP manufacturer' is closely aligned with the 'System or Procedure Pack Producer referred to in the EU Regulation on medical devices 2017/745 and the EU guidance on procedure packs.

relevant conformity assessment procedures or procedures comparable to conformity assessment to that component device. This includes having conformity assessment document for the component device (other than a Class I, Class 1 IVD or custom-made device).

Note: Provision of electronic IFU with SOPPs intended for use by professional users

Essential principle 13.2 of the Regulations allows the use of a printed document or other appropriate media for the provision of IFU, when it is not practicable to comply with the requirement for providing these directly on the device, or directly on the device packaging. The TGA considers that 'other appropriate media' for providing the IFU to professional users, such as surgeons, could include online publication or by other electronic means. The provision of electronic IFUs is not permitted for SOPPs that are intended for supply to the public, such as first aid kits.

For example, implantable medical devices included in a SOPP that it is intended for use by professionals users, where the IFU is provided electronically, the SOPP should include a printed document that makes professional users aware of how to access the electronic IFU (eIFU). This should clearly explain how to find the correct version on the manufacturer's website.

The eIFU must be a complete representation of all information required to be included, as specified in essential principle 13.4. For further information, refer to guidance on 'Electronic Instructions for Use – eIFU: For professional users of medical devices'.

Patient implant cards and patient information leaflets

From 1 December 2021, all implantable medical devices are required to have patient information materials available in the form of both patient implant cards and patient information leaflets. Information that must be contained in the patient information materials are set out in EP 13A of the Regulations. For any implantable or active implantable medical device placed in the SOPP (other than a suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip, connector or similar article), the SOPP must be provided together with the patient information materials (both patient information leaflet and patient information card) produced by the manufacturer of the implantable component medical device.

Note: Provision of electronic patient information leaflets and patient information card with SOPPs

From 29 October 2021, sponsors and manufacturers have greater flexibility in how they provide patient information materials for implantable medical devices. This means that sponsors and manufacturers of SOPPs that includes an implantable or active implantable medical device have the option to provide the patient information materials in a printed or electronic form with the SOPP. This includes providing the:

- patient information leaflet, either in the form of a leaflet or an electronic form that is readily accessible by the patient
- patient information card, either in the form of a card or an electronic form that is readily accessible by the patient.

For further information, refer to guidance on 'Medical device patient information leaflets and implant cards'

Obligations for SOPP manufacturers

The changes commencing on 25 November 2021 are only applicable to manufacturers of SOPPs that are supplied using the special conformity assessment procedure, the use of which itself requires they meet the eligibility criteria for 'medical devices used for a special purpose' in Regulation 3.10. Transition arrangements apply to SOPPs that are already included in the ARTG or the subject of applications for inclusion in the ARTG made before 25 November 2021.

Manufacturers of medical devices (as defined in 41BG of the Act) that are SOPPs that do not meet the eligibility criteria for 'medical devices used for a special purpose' will not be able to supply their SOPP using the special conformity assessment procedure. These manufacturers will be required, however, to obtain certification and approvals from the TGA or a comparable overseas regulator or assessment body, for the SOPP as a whole, relevant to its classification.

Section 41BG Manufacturers of medical devices

(1) The *manufacturer* of a medical device is the person who is responsible for the design, production, packaging and labelling of the device before it is supplied under the person's name, whether or not it is the person, or another person acting on the person's behalf, who carries out those operations.

(2) If subsection (1) does not apply to a medical device, the *manufacturer* of the device is the person who, with a view to supplying the device under the person's name, does one or more of the following using ready made products:

(d) assembles the device;

(e) packages the device;

(f) processes the device;

(g) fully refurbishes the device;

(h) labels the device;

(i) assigns to the device its purpose by means of information supplied, by the person, on or in any one or more of the following:

(a) the labelling on the device;

(b) the instructions for using the device;

(c) any advertising material relating to the device;

(d) technical documentation describing the mechanism of action of the device.

Obligations for SOPP sponsors

The sponsor (defined in Chapter 1 of the Act) is the person or company responsible for the importation of medical devices into Australia; and/or the supply of medical devices in Australia; and/or the export of medical devices from Australia; and for applying to the TGA to have their device included in the ARTG. The sponsor must be a resident of Australia, or be an incorporated body in Australia that is conducting business in Australia and has a representative residing in Australia.

Like any medical device sponsor, the sponsor of a SOPP has various responsibilities including being responsible for:

- ✓ making an application to include the SOPP in the ARTG
- ✓ ensuring they have available sufficient information to demonstrate that their device complies with the essential principles (including requirements for patient information materials), or have procedures in place to obtain relevant information

from the manufacturer to demonstrate compliance with the requirements in the essential principles

- ✓ ensuring that the appropriate market authorisation evidence supporting the ARTG entry is provided when requested by the TGA and remains valid while the device is supplied in Australia
- ✓ complying with labelling requirements detailed in Regulation 10.2 of the Regulations that require sponsor information to be provided with the SOPP (refer to guidance on medical device labelling obligations)
- ✓ complying with post-market monitoring, surveillance, adverse events reporting and record-keeping obligations following inclusion of the SOPP in the ARTG.

What you need to do as the SOPP sponsor

If you are a sponsor of a SOPP that is supplied using the special conformity assessment procedure, the actions you will need to take to comply with the new requirements will depend on the status of your product as at 25 November 2021.

- Transition arrangements apply for SOPPs included in the ARTG or those with an application to include SOPPs in the ARTG is made before 25 November 2021.
- All applications to include SOPPs in the ARTG on or after 25 November 2021 must meet the new requirements.

Sponsors of SOPPs that are not supplied using the special conformity assessment procedure are not affected by the new regulations and do not need to take any action. Sponsors of these SOPPs will still require a valid conformity assessment document for inclusion in the ARTG and demonstrate ongoing compliance following its inclusion.

Transition arrangements for SOPPs that are included in the ARTG or the subject of an application for inclusion made before 25 November 2021

If you have a SOPP included in the ARTG as a result of an application made before 25 November 2021, your SOPP is automatically eligible for the transition period. This means you can continue to supply your device without meeting the new requirements until 25 November 2025.

From 25 November 2025, the ARTG entry for the SOPP is expected to be supported by manufacturer's evidence using the updated template for making a declaration of conformity under Part 7, clause 7.5 of Schedule 3 of the Regulations to demonstrate compliance with the new requirements.

You may consider updating the manufacturer evidence using the new template for the ARTG entry during recertification.

Applications to include SOPPs in the ARTG on or after 25 November 2021

Any new application for inclusion of a SOPP using the special conformity assessment procedure that is submitted to the TGA on or after 25 November 2021 must be submitted using the updated template for making a declaration of conformity under Part 7, clause 7.5 of Schedule 3 of the Regulations.

For more information, refer to guidance on:

- Manufacturer evidence for medical devices and IVD medical devices
- Guidance for declaration of conformity

Appendix 1

Products that are not medical devices or SOPPs

Composite packs

Composite packs (defined in subsection 7B(2) of the Act) contain:

- two or more therapeutic goods and must not any contain medical devices.
- therapeutic goods that must be combined before administration or be administered in a particular sequence, for administration as a single treatment or course of treatment.
- therapeutic goods, where each good do not require individual registration or listing in the ARTG, unless they are supplied separately.

Composite packs do not contain any medical devices and therefore are not regulated as medical devices or as SOPPs. Depending on the indications of composite packs and their contents, they are regulated as medicines or biologicals.

Examples of composite packs include:

- 'Cold and Flu Day and Night medication' which consists of tablets that are required to be taken in a particular order.
- A vial of a lyophilised biological or powdered medicine that is packaged with an ampoule or vial containing a diluent for administration of the medication in a sequence.

Kits

Kits (defined in subsection 7B of the Act):

- contain one or more goods that are supplied in a single package for use as a unit, where one of these goods must be a therapeutic good
- must not contain any medical devices
- must not meet the definition of a composite pack; that is, the individual goods in a kit can be used independently and do not need to be combined before administration or be administered in a particular sequence, as part of a single treatment or course of treatment
- contain therapeutic goods such as medicines, biologicals or other therapeutic goods, where each therapeutic good must be separately registered or listed in the ARTG unless exempt from the requirement to be registered or listed in the ARTG.

Kits, by definition in the Act, do not contain any medical devices. Depending on the indications of a kit and its contents, it may be regulated as a medicine, biological, or other therapeutic good.

Examples of kits include:

- medicine kits, such as a sunscreen lotion and lip balm supplied in a single package
- other therapeutic goods kits, like a menstrual cup and a pack of tampons supplied in a single package.

Although the term 'kit' has a specific meaning in the Australian legislation, some products that are regulated as medical devices include the word kit in their name and include at least one medical device, for example:

- first-aid kits, which can contain medical devices, and/or medicines
- SARS-CoV antigen test kits, which only contain medical devices (including IVD medical devices)
- surgical loan kits, which could contain only medical devices
- a hair-lice kit with a comb (a medical device) and a hair-lice solution (a medicine).

Articles that are not medical devices

The *Therapeutic Goods (Articles that are not Medical Devices) Order No. 1 of 2010* declares a number of articles not to be medical devices (as defined in subsection 41BD(3) of the Act).

This includes an article that is intended to administer a medicine in such a way that the medicine and the article form a single integral product that is intended exclusively for use in the given combination and is not reusable (but may be multi-dose).

Products that fall into the above category are not regulated as medical devices and are regulated as medicines. Examples of these products that are not medical devices include:

- nasal spray medicine co-packaged with dropper that is specifically designed to attach or be attached to the medicine container to deliver the measured eye or nasal drops
- a syringe pre-filled with a medicine
- vaginal tablets that are co-packaged with a vaginal applicator. The applicator is specifically used for the insertion of the tablets into the vagina and is used at the same time as each of the tablets from the package is administered.

Products that are medical devices but are not SOPPs that are exempt from inclusion in the ARTG

Surgical loan kits

Surgical loan kits are supplied on loan to Australian hospitals for use in a particular surgical procedure and generally comprise collections of reusable surgical instruments. They may also include implantable medical devices and other medical devices. All goods in a loan kit are medical devices and each medical device in the kit must be included in the ARTG.

While SOPPs can contain therapeutic goods other than medical devices (such as medicines, other therapeutic goods or biologicals), surgical loan kits must not contain any therapeutic goods other than medical devices.

Further, unlike SOPPs, loan kits include a set of transport cases and containers that can contain instrumentation, trays and implantable medical devices; the goods in the kit may not all be

packaged together and must not be intended to be interconnected or combined for use in a surgical procedure.

As such, surgical loan kits are not regarded as SOPPs. Loan kits are regarded as medical devices, however, and are subject to certain regulatory obligations, such as compliance with the essential principles and adverse event reporting, like any other medical device supplied in Australia. As all goods in a loan kit must be included in the ARTG, surgical loan kits are exempt from inclusion in the ARTG from 25 November 2021. For further information, refer to guidance on 'Surgical loan kits'.

Packs that are exempt from inclusion in the ARTG

Packages containing tampons, etc supplied free of charge by charities to homeless or disadvantaged women (including adolescent women)

Item 14 of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the 'Regulations') provides that 'packs' (i.e. packages) that are supplied free of charge by charities to homeless or disadvantaged women are **exempt** from inclusion in the ARTG in certain circumstances.

In order to meet the exemption when supplying packs, charities must meet all of the following:

- supply the packs free of charge to homeless or disadvantaged women - this includes women who are not able to fully support themselves including adolescent females;
- in circumstances where all of the following criteria are met:
- The packs contain tampons or menstrual cups - and any other therapeutic goods (other than tampons or menstrual cups) in the packs are individually included in the ARTG.
- The packaging of any individually packaged medical device or medicine placed in the pack is intact.
- The packs do not contain any medical device that is classified as Class IIa or higher.
- The packs do not contain any IVD medical device or in-house IVD medical device that is classified as Class 2 or higher.
- The packs do not contain any biologicals or prescription medicines.

Examples

Examples of packs supplied free of charge by charities to homeless or disadvantaged women that meet the exemption include:

- packages containing tampons or menstrual cups, iodine, toothbrush, soap and a blanket, supplied by benevolent charities
- care packages containing tampons or menstrual cups and band-aids supplied by health promotion charities for adolescent females in schools
- sanitary packages containing tampons and menstrual cups supplied by benevolent or health promotion charities.

Other matters

It is important to note that although tampons may be individually packaged inside the box, the individual tampons cannot be supplied separately to the box they are contained in. This is

because the box contains information such as the expiry date and instructions for use that are critical to ensuring safe use of the tampons.

Further, tampons being supplied in Australia are still required to meet the requirements under the applicable standard for tampons.

Importantly, although these type of packs, supplied free of charge by charities to homeless or disadvantaged women including adolescent women in schools, are exempt from inclusion in the ARTG, charities will still need to act consistently with advertising requirements in the *Therapeutic Goods Act 1989* (the 'Act') and the Therapeutic Goods Advertising Code, and be able to recall the goods or take other appropriate action in the event that the goods do not meet the requirements under applicable standards.

Although assembling the packs involves a manufacturing step, charities are exempt from the requirements in the Act relating to manufacturers (item 7 of Schedule 8 to the Regulations).

Supply of individual female hygiene products by schools or charities (i.e. not in packs)

Schools and charities can also supply female hygiene products such as:

- menstrual cups
- tampons
- menstrual pads

as an individual product, i.e. not in the type of 'pack' referred to in Schedule 5A.

Menstrual cups and tampons, as individual products, are exempt from inclusion in the ARTG (Schedule 5). Exempt goods are still regulated by the TGA and must meet relevant standards. When sourcing these goods from the sponsor, schools and charities should seek assurance from the sponsor that they meet relevant standards.

Menstrual pads are excluded goods that are not regulated by the TGA. They may be regulated as a consumer good or by State or Territory government bodies.

Packs that are excluded goods

Some products are excluded from the therapeutic goods/medical device regulatory framework. The *Therapeutic Goods (Excluded Goods) Determination 2018* ('the Excluded Goods Determination') refers. These goods may be regulated as a consumer good or by State or Territory government bodies.

Examples of excluded goods include:

- ear candles
- menstrual pads
- packages containing medical devices for the prevention of blood borne and sexually transmissible diseases (which can be supplied by charities or other organisations)

when, amongst other requirements, presented as a part of a Government endorsed health promotion program

Packages containing medical devices for the prevention of blood borne and sexually transmissible diseases supplied by charities or other organisations

Schedule 2 to the Excluded Goods Determination provides for certain goods to be excluded from the therapeutic goods legislation when used, advertised or presented for supply in a particular way.

Relevant 'packs and kits' (i.e. packages) presented for supply as a part of a government-endorsed health promotion program, having been authorised by that government as part of that program, are excluded goods (item 7 of Schedule 2 refers) and, therefore, are not regulated by the TGA, provided they meet all of the following criteria:

- The packs or kits contain medical devices that are intended for the prevention of blood borne and sexually transmissible diseases.
- Each individual therapeutic good placed in the packs or kits is included in the ARTG.
- Charities have evidence or supporting material (in writing) that indicates state, territory or Commonwealth government authorisation (or permission or support) for supply of the packs or kits as a part of the government endorsed health promotion program.

To meet the above criteria and be an excluded good, it is not a requirement for packs or kits supplied as a part of a government-endorsed health promotion program to be funded by that government - even though government funding would normally be expected to be an indicator that there may be government support for at least some of an organisation's activities. However, it is a requirement for charities or other organisations to have written evidence or supporting documentation that demonstrates state, territory or Commonwealth government support of both the health promotion program and the supply of the packs or kits as a part of that program.

Examples of packages containing medical devices for the prevention of bloodborne and sexually transmissible diseases supplied as a part of a government endorsed health promotion program include:

- packs of safe-sex supplies such as condoms and water-based lubricant supplied by health promotion or benevolent charities or schools, through a government-supported program
- packages containing a sterile needle and syringe supplied by health promotion charities, through a government-supported program
- HIV self-testing kits for home use supplied by health promotion charities through a government-supported program.

As noted, the relevant government-supported program must support both the program and the supply of the packs or kits under the program.

Supply of individual HIV self-tests by charities or other organisations (i.e. not in packs or kits)

Charities and other businesses, organisations and institutions that work with HIV at-risk communities can also supply HIV self-tests as an individual product, i.e. not in the type of packs or kits referred to in the Excluded Goods Determination.

In these circumstances, HIV self-tests must be included in the ARTG and provided with the instructions for use that are included with the device - so that the user knows how to perform the test and interpret the results correctly.

For more information, refer to our guidance on 'HIV testing in Australia'.

Questions and Answers

1. What is the difference between a SOPP manufacturer and a component manufacturer?

Component manufacturer

The component manufacturer is the original owner of the component, or has an agent acting on their behalf who is responsible for designing, producing, packaging and labelling the component, including assigning its intended purpose before it is supplied under the person's name.

In order to supply the component in the Australian market, the component manufacturer must be independently assessed and certified by the TGA or a comparable overseas regulator/assessment body, for any component device other than a Class I, Class 1 IVD or custom-made device. Here, the component manufacturer is required to generate technical documentation to demonstrate that the component device manufactured is safe and performs as intended and meets the applicable provisions of essential principles.

SOPP manufacturer

The SOPP manufacturer is the owner of the SOPP, or has an agent acting on their behalf who is responsible for assembling, packaging, labelling and – if applicable – sterilisation of the SOPP, using a combination of ready-made products produced by the component manufacturers. The SOPP manufacturer must also ensure that in combination, the products are mutually compatible, having regard to the original intended purpose of each component assigned by the component manufacturer.

The SOPP manufacturer has the option to use the special conformity assessment procedure to supply their SOPP, provided it meets the eligibility criteria in Regulation 3.10. This pathway recognises that the risk mitigation has been applied to all components of the pack by the component manufacturers, and that each component is intended to be placed in the pack in its original, market-ready, finished state, as if it was being supplied under its own individual ARTG entry.

Where the SOPP does not comply with the eligibility criteria for the special conformity assessment procedure, the SOPP manufacturer is required to apply the relevant conformity assessment procedures to the SOPP or procedures comparable to conformity assessment, as appropriate to its classification, and obtain certification/approval either by the TGA or a comparable overseas regulator or assessment body for the entire SOPP.

2. The manufacturer of SOPP opens the box (secondary carton) of 10 sterile syringes that are individually packaged with no breach of primary sterile packaging and then placing individually packaged sterile syringe in the SOPP. What evidence is required to be held by the SOPP manufacturer?

Opening of the secondary carton is not considered to be a modification, as long as this activity does not compromise the sterile integrity/barrier of the individually packaged sterile syringes and it has been done in accordance with the syringe manufacturer's instructions. As such, the SOPP manufacturer is required to hold conformity assessment certification issued by the TGA or a conformity assessment document issued by a comparable overseas regulator or assessment body to the component manufacturer for the syringes that are placed in the SOPP. The information to be provided with the sterile individually packaged syringe as required by Essential Principle 13 and supplied by the manufacturer of the syringe, must be provided with the SOPP.

3. I am the manufacturer of a SOPP and intend to assemble a package containing non-therapeutic goods and medical devices that are purchased from different component manufacturers. All items in the package will be supplied in its finished, market-ready form (as supplied by the component manufacturer) except for a component device. For the component device, I have a written agreement from the component manufacturer to remove the finished device's original sterile packaging and re-sterilises it according to the component manufacturer's instructions. As the SOPP manufacturer, can I make a declaration of conformity under clause 7.5 to supply the SOPP in Australia?

TGA views activities including removing the finished device's original sterile packaging and undertaking re-sterilisation of the component device, performed by the SOPP manufacturer as modification to the component device and its packaging.

Yes, the SOPP manufacturer can make a declaration of conformity under clause 7.5 to supply the SOPP if all of the criteria are met:

- the SOPP manufacturer has documentary evidence (such as written agreement) that demonstrates that the removal of the original sterile packaging and re-sterilisation of the component device has been done in accordance with the component manufacturer's instructions
- the removal of sterile packaging and undertaking re-sterilisation does not impact the quality, safety and performance of the component device including documentary evidence to demonstrate this is the case.
- the SOPP manufacturer has conformity assessment document (obtained from the component manufacturer) either issued by the TGA or a comparable overseas regulator or assessment body for the component device.
- the SOPP manufacturer has Production Quality Assurance certificate or equivalent certification (refer to Question 5) that is issued to the SOPP manufacturer for undertaking sterilisation activities including bioburden or endotoxin testing where applicable (for example, if the modified device is in contact with a person's cardiovascular system).
- For all other component devices placed in the SOPP, the SOPP manufacturer has conformity assessment certification issued by the TGA or an equivalent conformity assessment document issued by a comparable overseas regulator or assessment body to the component manufacturer for the component device.
- the SOPP manufacturer has evidence that demonstrates how they have verified the mutual compatibility of the components placed in the SOPP in accordance with the component manufacturer's instructions and approved indications.

If the SOPP manufacturer does not have documentary evidence (such as written agreement) that demonstrates that the removal of the original sterile packaging and re-sterilisation of the component device has been done in accordance with the component manufacturer's instructions or Production Quality Assurance certificate or equivalent certification for undertaking sterilisation activities; the SOPP manufacturer assumes responsibility for the modified component device and must obtain conformity assessment certification issued by the TGA or a conformity assessment document issued by a comparable overseas regulator or assessment body for the modified device for it to be placed in a SOPP in order to supply the SOPP via the special conformity assessment procedure pathway.

4. I am the manufacturer of a SOPP and intend to assemble the package containing medical devices in unfinished form that are purchased in bulk from different manufacturers. I will sterilise these medical devices for supply. Can I still supply the SOPP using the special conformity assessment procedure?

No. The manufacturer of the SOPP cannot apply the special conformity assessment procedures to medical devices purchased in bulk unfinished form (not market-ready). They will need to obtain conformity assessment certification issued by the TGA or a conformity assessment document issued by a comparable overseas regulator for the entire SOPP unless the SOPP is Class I or Class 1 IVD in which case the SOPP manufacturer is required to self-declare compliance and the SOPP is not required to be assessed by an independent assessment body or regulator.

5. I am the manufacturer of a SOPP and intend to include several finished, ready-made medical devices in my SOPP. I have purchased the medical devices in their sterile state from a sponsor, who is not the manufacturer of those items. I have not modified them in any way including not making any changes to packaging or undertaking any sterilisation activities before placing them in the SOPP. What kind of evidence should I hold as the SOPP manufacturer?

The SOPP manufacturer must hold the following evidence and provide this to the TGA when requested:

- a copy of the conformity assessment document relevant to each medical device (other than Class I, Class 1 IVD or custom-made) included in the SOPP. The document issued by the TGA or a comparable overseas regulator/assessment body is evidence to demonstrate that the relevant conformity assessment procedures have been applied to each medical device by its component manufacturer
- a copy of the declaration of conformity made by the component manufacturer (under clause 6.6 of Schedule 3 of the Regulations) for each Class I or Class 1 IVD device in the SOPP
- a copy of the statement made by the component manufacturer under subclause 7.2(2) of Schedule 3 of the Regulations for each custom-made device in the SOPP
- evidence that each medical device in the SOPP complies with the relevant essential principles
- evidence that shows how the SOPP manufacturer has verified the mutual compatibility of the components placed in the SOPP, in accordance with the component manufacturer's instructions. This includes evidence that demonstrates that the combined components in the SOPP can perform as intended without any conflict or interference being caused by their combination.

The SOPP manufacturer must assemble the SOPP in a way that ensures each device included in the SOPP is presented and will be used accordance with the original component manufacturer's instructions.

6. For a SOPP that is supplied using the clause 7.5 pathway, in a sterile state, what types of conformity assessment documents issued by the TGA and comparable overseas regulators are SOPP manufacturers required to have?

The SOPP manufacturer is required to have either of the following certification issued by the TGA, a comparable overseas regulator or recognised auditing organisation for a SOPP that is intended to be supplied in a sterile state:

- Certification issued by the TGA:
- Part 1, Full quality assurance procedures (excluding clause 1.6); or
- Part 4, Production quality assurance procedures
- Certification issued by the EU NB under the following EU Directive:
- Full quality assurance system certificate or other document issued under Annex II of 93/42/EEC (Medical Devices) Directive, excluding section 4; or
- Production quality assurance certificate or other document issued under Annex V of 93/42/EEC (Medical Devices) Directive
- Certification issued by the EU NB under the following EU Directive:
- Complete quality assurance system certificate or other document issued under section 3 of Annex 2 of 90/385/EEC (Active implantable medical devices) Directive; or
- An Assurance of production quality certificate or other document issued under Annex 5 of 90/385/EEC (Active implantable medical devices) Directive.
- Certification issued by the EU NB under the EU Medical Devices Regulation (MDR):
- Quality management system certificate issued under Chapter I of Annex IX of the EU MDR; or
- Production quality assurance certificate issued under Part A of Annex XI of the EU MDR
- Certification issued by the recognised auditing organisation
- Certificates issued under the Medical Device Single Audit Program (MDSAP)

7. I am intending to manufacture a Class IIb SOPP and intend to place in it the following ready-made devices in finished form, from different manufacturers:

- Sterile Class IIb implantable device, which is supported by EU certification, manufactured by Company A.
- Class 1 sterile gloves with MDSAP certification, manufactured by Company B.
- Class IIa suction unit with MDSAP certification and Health Canada Medical Device Licence, manufactured by Company C.

Can I declare compliance under clause 7.5 to supply the SOPP, noting the various overseas conformity assessment documents issued to each component manufacturer?

Yes, provided the SOPP manufacturer meets the eligibility criteria defined in Regulation 3.10 of the Regulation, the SOPP manufacturer will be able to assemble the SOPP and declare compliance with the requirements set in clause 7.5 of the Regulations.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Authorisation Branch	November 2021
V1.1	Added clarification about SOPP manufacturer and System or Procedure Pack Producer under “Information about the SOPP Manufacturer”	Medical Devices Authorisation Branch	January 2024

Therapeutic Goods Administration

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

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