Australian Government
Department of Health
Therapeutic Goods Administration

# First aid kits that contain medical devices and/or medicines

## Guidance for sponsors and manufacturers

Version 1.0, November 2021

TGA Health Safety Regulation

# Contents

# About this guidance

From **25 November 2021**, new regulatory requirements apply to medical devices regulated as system or procedure packs and supplied using the special conformity assessment procedure. First aid kits are regulated by the Therapeutic Goods Administration (TGA) as medical devices that are system or procedure packs, as they contain a combination of two or more goods including at least one medical device, which are all packaged together for convenient use in an emergency and for rapid, initial treatment of injuries. This means that like other system or procedure packs, first aid kits are regulated as single medical devices in their own right and therefore must also be included in the Australian Register of Therapeutic Goods (ARTG). Accordingly, unlike 'kits' (as defined in section 7B of the *Therapeutic Goods Act 1989*) that do not contain any medical devices and, depending on their contents, are regulated as medicines, biologicals or other therapeutic goods, first aid kits always contain at least one medical device, and therefore are regulated as medical devices.

For inclusion in the ARTG, manufacturers of first aid kits (and other types of system or procedure packs) have two options to apply conformity assessment procedures to demonstrate that the medical device produced is safe and performs as intended. They may obtain market authorisation evidence, issued by an independent assessment body or regulator for the first aid kit; or use the special conformity assessment procedure if they meet the criteria related to 'medical devices used for a special purpose'. The revised regulations only apply to first aid kits that are supplied using the special conformity assessment procedure.

This guidance aims to assist sponsors and manufacturers of **first aid kits supplied using the special conformity assessment procedure** by explaining their obligations under the regulations and transitional arrangements for devices registered prior to 25 November 2021.

# What are first aid kits?

A first aid kit is generally a collection of equipment and materials that are packaged together for convenient use in an emergency and for rapid, initial treatment of an injury.

**First aid kits are in a category of medical devices called 'system or procedure packs'**, which is defined in section 41BF of the *Therapeutic Goods Act 1989* (the Act). They are system or procedure packs as they contain two or more goods, one of which is a medical device or in vitro diagnostic (IVD) medical device, all of which are packaged together for the end user, for use in a medical procedure (or procedures). Refer to guidance on system or procedure packs for more information.

Under this legal definition, a first aid kit includes at least one medical device. Depending on its intended purpose, it may also include:

- medicines
- IVD medical devices (e.g. a self-test for COVID-19)
- other goods that are not considered to be therapeutic goods.

First aid kits are assembled for use in public settings such as homes, schools and institutions, or in emergency medical services and hospital settings.

**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.

# First aid kit classification and examples

First aid kits, like all medical devices, are classified according to the risks they may pose to patients and users. A higher degree of risk leads to a higher classification, which in turn leads to a higher level of regulatory scrutiny.

The classification rules that apply to all medical devices are set out in Schedule 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations). The overall classification of a first aid kit is determined by the medical device with the highest classification that is included. 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 first aid kit contains a Class IIb device, a Class IIa device and an over-the-counter medicine, its overall classification is Class IIb. If two or more classification rules apply, the higher level of classification applies. If an IVD medical device is included in the first aid kit, then the classification rules in Schedule 2A of the Regulations will also need to be considered. Some examples are below.

## Low risk: Class I[1]

### Workplace first aid kits

Intended to be used by trained first aid officers, these may include items like burn gel, sterile eye pads, sterile gauze, antiseptic solution, scissors, tweezers, bandages, disposable gloves, disposable safety pins, forceps, notebooks, pens and disposable ice packs.

### Snake and spider bite first aid kits

Intended to be used by general consumers, these may include items like snake bite bandages with indicators, splints, snake bite markers, instant ice packs, swabs and snake bite leaflets.

[1] Class I first aid kits that are not supplied in a sterile state but contain a component that is supplied sterile are included in the ARTG as 'Class I (non-sterile)'. Class I first aid kits that contain a component device with a measuring function are included in the ARTG as 'Class I (with a measuring function)'.

# Low–medium risk: Class IIa

## Home or residential first aid kits

Intended to be used by general consumers, these may include items like sodium chloride ampoules, mouth piece, digital thermometers, dressings, bandages, scissors, first aid quick reference guides, gloves, eye pads, antiseptic liquid, cleaning wipes, burn gel and reusable hot or cold packs.

# Medium–high risk: Class IIb (intended for use by healthcare professionals)

## Oxygen resuscitation kits

Intended to be used by trained medical personnel, these may include items like suction hoses, suction units, oxygen cylinders, ventilators, Ventolin nebules, facemasks, resuscitation masks, syringes and shears.

## Paramedic response first aid kits

Intended to be used by trained paramedics, these may include items like COVID-19 rapid antigen self-test[2], cervical collars, sharps containers, IV access and drug kits, morphine, multi-layer wound bandages, IV fluids and giving sets, splints, vacuum pumps, sphygmomanometers, stethoscopes, glucometer kits, insulin, anaesthetics, pumps, chest needles, space blankets, multi-trauma dressings, shears, infectious waste bags and bandages.

# High risk: Class III (intended for use by healthcare professionals)

## Advanced paramedic kits

Intended for use by trained paramedics or medical officers, these may include items that may be included in a paramedic response kit, like the examples listed above, advanced paramedic kits may include devices containing medicines, such as syringes containing sodium chloride.

[2]A COVID-19 rapid antigen self-test is a Class 3 IVD medical device; this classification is equivalent to a Class IIb non-IVD medical device. This means the first aid kit's overall classification would still be Class IIb, according to its primary intended purpose. Note, if an HIV self-test was to be included in this first aid kit, its classification would be Class 4 IVD.

**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:

- (a) assembles the device;
- (b) packages the device;
- (c) processes the device;
- (d) fully refurbishes the device;
- (e) labels the device;
- (f) assigns to the device its purpose by means of information supplied, by the person, on or in any one or more of the following:
  - (i) the labelling on the device;
  - (ii) the instructions for using the device;
  - (iii) any advertising material relating to the device;
  - (iv) technical documentation describing the mechanism of action of the device.

# Obligations for first aid kit manufacturers

Like any medical device, the manufacturer of the first aid kit (as defined in section 41BG of the Act) must:

- ✓ determine the classification of the first aid kit
- ✓ apply the minimum conformity assessment procedures related to the manufacture of the first aid kit that are appropriate to its overall classification
- ✓ have evidence that demonstrates compliance of their first aid kit with the relevant essential principles for safety and performance
- ✓ comply with post-market monitoring, surveillance, adverse-event reporting and record keeping obligations following inclusion of the first aid kit in the ARTG.

In addition, essential principle (EP) 13 specifies information that must be provided with medical devices. Together with EP 13.3 and EP 13.4 (in the Regulations, Schedule 1) this requires first aid kit manufacturers to:

- provide a list of the first aid kit's contents along with the kit, and include the instructions for use for each item the kit contains
- ensure the first aid kit's label includes the ARTG registration or listing number for any medicine it includes.

First aid kit manufacturers must make a declaration of conformity which includes the details of relevant compliance evidence, in accordance with **clause 7.5** of Schedule 3 of the Regulations.

Manufacturers may apply the special conformity assessment procedure to their first aid kits if they meet the criteria related to '**medical devices used for a special purpose'**. The two options to apply conformity assessment procedures to the first aid kit are discussed below.

# Two options for applying conformity assessment procedures to first aid kits

Manufacturers of first aid kits (and other system or procedure packs) have two options to apply conformity assessment procedures relating to the manufacture of their device. The regulatory pathway selected determines which kind of market authorisation evidence is used to include it in the ARTG for supply.

Option 1:

The manufacturer gets market authorisation evidence (a conformity assessment document), issued either by the TGA or a recognised comparable overseas regulator/assessment body. This demonstrates that the manufacturer has applied relevant conformity assessment procedures or met requirements comparable to the Australian conformity assessment procedures appropriate to the first aid kit based on its classification. 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 related to '**medical devices used for a special purpose'** 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 for manufacturing the first aid kit, 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.

**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)

Changes to the special conformity assessment procedure take effect **from 25 November 2021.** These regulatory changes only apply to first aid kits supplied using the special conformity assessment procedure (Option 2 on p. 8 of this guidance). They do not affect first aid kits supplied using conformity assessment documents from the TGA or a recognised comparable overseas regulator/assessment body (Option 1 on p. 8). Manufacturers of first aid kits that do not meet the eligibility criteria 'medical devices used for a special purpose' (as described below) will not be able to supply using the special conformity assessment procedure and will be required to obtain certification and approvals from the TGA or a recognised comparable overseas regulator/assessment body, for the first aid kit as a whole relevant to its classification.

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 procedure. This means that a first aid kit 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 first aid kit. However, if a medical device placed in a first aid kit is supplied separately from the kit, it must have its own separate ARTG entry.

**Note:**

Unless the medical device is a Class I (that does not have a measuring function and is supplied non-sterile) or Class 1 IVD medical device, a conformity assessment document from the TGA or a recognised comparable overseas regulator/assessment body is required for ARTG inclusion. This demonstrates that the device has been assessed by an independent assessment body or a regulator.

Manufacturers self-declare regulatory compliance for Class I, Class 1 IVD and Class I or Class 1 IVD system or procedure packs supplied using the special conformity assessment procedure. As such, these do not need to be assessed by an independent assessment body or a regulator.

## Updates to the eligibility criteria for supply via the special conformity assessment procedure

To supply a first aid kit via the special conformity assessment procedure (Option 2 on p. 8), the manufacturer must ensure it complies with all the criteria related to '**medical devices used for a special purpose'**, which are set out in Regulation 3.10. These eligibility criteria have been amended for clarity and include the following elements:

(a) A first aid kit that is a 'medical device used for a special purpose':

- includes two or more goods where at least one is a medical device, and for any device it includes (other than a Class I or Class 1 IVD medical device), relevant conformity assessment procedures have been applied by its component manufacturer, demonstrating that the medical device has market authorisation evidence from the TGA or a comparable overseas regulator/an assessment body
- may include medicines, however any medicine it includes must be registered or listed in the ARTG and no modifications to a medicine or its packaging are permitted
- has been assembled in accordance with the intended purpose of each medical device and the approved indications of any medicine it includes
- includes goods that are all compatible, with respect to the intended purpose of each medical device and the approved indications of any medicine it includes.

(b) If the entire first aid kit is intended to be supplied in a sterile state, the conformity assessment procedures – either the production quality assurance procedures or full quality assurance procedures (other than those in clause 1.6 of Schedule 3 of the Regulations) – must be applied by the first aid kit manufacturer to the kit to ensure its sterility.

First aid kit manufacturers must meet all elements of criterion (a) before they can use the special conformity assessment procedure to supply their first aid kit in the Australian market (Option 2 on p. 8). They must also comply with criterion (b) if they are intending to supply the kit in a sterile state via the special conformity assessment procedure.

# Refinements to the special conformity assessment procedure

If the eligibility criteria defined in Regulation 3.10 (and described above) are met, the first aid kit manufacturer can use the special conformity assessment procedure and make a declaration under **clause 7.5** of Schedule 3 of the Regulations.

In their declaration for the special conformity assessment procedure, the manufacturer must do all of the following:

- **Identify** each item in the first aid kit.
- **State that they have** a conformity assessment document that has been issued to the component manufacturer for each included medical device, either by the TGA or a recognised comparable overseas regulator/assessment body, unless it is a Class I medical device with a non-measuring function or that is not supplied sterile or it is a Class 1 IVD medical device.
- **State that they have** a declaration of conformity (under **clause 6.6** of Schedule 3 of the Regulations) for any included Class I medical device with a non-measuring function or that is not supplied sterile or a Class 1 IVD medical device.
- **State that they have** evidence that each included medical device complies with the relevant essential principles for safety and performance.
- **Include** any medicine that has been registered or listed in the ARTG (the registration or listing ARTG number starts with 'AUST' and is followed by an 'R', 'L' or 'L(A)').
- **State** that each included medical device is intended to be used for its original intended purpose specified by its manufacturer.
- **State** that any included medicine is only intended to be used within the approved indications specified by its manufacturer.
- **State** that the mutual compatibility of each included medical device and any included medicine has been verified, in accordance with the instructions for use provided by the manufacturer of the component device and the approved indications of the medicine.
- **State** that the first aid kit has been manufactured in accordance with the instructions for use provided by the manufacturer of each component device and the approved indications of any medicine it includes.
- **State** that the full quality assurance procedures (other than those in clause 1.6 of Schedule 3 of the Regulations) or the production quality assurance procedures have been applied to the first aid kit, if it is intended to be supplied sterile, in accordance with the instructions for use of each included medical device and the approved indications of any included medicine.
- **State** that the information supplied with the first aid kit includes instructions for use provided by the manufacturer of each item in the package.
- **State** that any modification by the first aid kit manufacturer of any included device, or the packaging of any included device, has not affected the quality, safety or performance of the device.
- **State** that for any included medical device classified above Class I (or Class 1 for an IVD medical device), which has been modified in a way that is not in accordance with the instructions for use provided by its original component manufacturer, they have a conformity assessment document for the device, as modified.

- **State** that for any included Class I or Class 1 IVD medical device that has been modified, they have a declaration of conformity (made by the component manufacturer under **clause 6.6** of Schedule 3 of the Regulations) for the device, as modified, and evidence that it still complies with the applicable provisions of the essential principles following modification.

## Record retention requirements

**Manufacturers**

The manufacturer of any medical device must retain all records of the device's manufacturing for either 5 or 15 years, depending on whether it is an implantable medical device. First aid kits do not generally contain any implantable medical devices.

Therefore, a first aid kit manufacturer supplying their kit using the special conformity assessment procedure must retain all records from the date of its manufacture for **5 years if** the kit does not include an implantable medical device.

The manufacturer of the first aid kit must be able to provide these records (or copies of them) to the TGA when requested.

**Sponsors**

The record retention obligations that apply to sponsors of first aid kits do not change on 25 November 2021.

Sponsors must retain their records for either 5 or 10 years after the last product has been distributed, depending on the classification of the relevant device, as detailed in our guidance on distribution records. These records, or copies of them, must be provided if requested by the TGA.

# New obligations for first aid kit manufacturers

From 25 November 2021, manufacturers of first aid kits supplied using the special conformity assessment procedure will need to:

- ✓ have a conformity assessment document either issued by the TGA or a recognised comparable overseas regulator/assessment body to the component manufacturer for any included medical device other than a Class I or Class 1 IVD medical device
- ✓ have a declaration of conformity made under **clause 6.6** of Schedule 3 of the Regulations by the component manufacturer of any Class I or Class 1 IVD medical device that is placed in the first aid kit
- ✓ ensure that, if the first aid kit is intended to be supplied sterile, sterilisation has been undertaken in accordance with the instructions for use of each medical device and the approved indications of any medicine it includes
- ✓ apply the minimum conformity assessment procedures – 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 first aid kit
- ✓ declare any modifications that have been made to any device or the packaging of any device in the first aid kit.

If an included device or a device's packaging has been modified, the manufacturer of the first aid kit must:

- ✓ declare that the modification has not affected the quality, safety or performance of the device along with evidence to support this declaration
- ✓ have documentary evidence (e.g. written agreement from the component manufacturer) that demonstrates that the **modification** made to any device or the packaging of any device in the first aid kit has been **done in accordance with the instructions** for use of the component device, provided by its original manufacturer
- ✓ have a conformity assessment document for the device, as modified, and evidence that it still complies with the essential principles, as modified, if it is classified higher than Class I where the **modification is not in accordance with the instructions** for use of the component device, provided by its original manufacturer
- ✓ have a declaration of conformity (made under **clause 6.6** of Schedule 3 of the Regulations) by the component manufacturer for the device, as modified, and evidence that it still complies with the essential principles, as modified, if it is Class I or Class 1 IVD medical device where the modification is not in accordance with the instructions for use provided by the device's original manufacturer
- ✓ retain records for five years after the manufacture of a first aid kit supplied using the special conformity assessment procedure and does not include any implantable medical devices.

These changes are only applicable to manufacturers of first aid kits that are supplied using the special conformity assessment procedure.

Manufacturers of first aid kits need to meet the eligibility criteria in Regulation 3.10 to supply kits using the special conformity assessment procedure. They would therefore need to obtain conformity assessment certification from the TGA, or an equivalent conformity assessment document from a recognised comparable overseas regulator or assessment body, for the first aid kit as a whole (Option 1 on p. 7).

# Obligations for first aid kit sponsors

The sponsor (defined in Chapter 1 of the Act) of a medical device is the person or company responsible for applying to the TGA to have it included in the ARTG, as well as for its importation into Australia, its supply in Australia, and/or its export from Australia.

The sponsor must be a resident of Australia; or an incorporated body that is conducting business in Australia and has a representative residing in Australia.

Like any medical device sponsor, the sponsor of a first aid kit has a range of ongoing responsibilities, and they are responsible for:

- ✓ making an application to include the first aid kit in the ARTG
- ✓ ensuring they have available sufficient information to demonstrate that their device complies with the essential principles; or have procedures in place to ensure that such information can be provided to the TGA by the manufacturer within 20 working days, if requested
- ✓ ensuring the appropriate conformity assessment procedures have been applied to the device and that the market authorisation evidence supporting its ARTG entry remains valid while the device is supplied in Australia

- ✓ complying with the labelling requirements detailed in Regulation 10.2, which require sponsor information to be provided with the first aid kit (refer to our guidance on medical device labelling obligations)
- ✓ complying with post-market monitoring, surveillance, adverse-event reporting and record keeping obligations following inclusion of the first aid kit in the ARTG.

# What first aid kit sponsors need to do

If you are a sponsor of a first aid kit that is supplied (or to be supplied) **using the special conformity assessment procedure**, the actions you need to take to comply with the new regulatory requirements depend on the first aid kit's registration status on 25 November 2021.

- Transition arrangements apply to those that are included in the ARTG and those for which an application for inclusion in the ARTG is made **before 25 November 2021**.
- The new requirements apply to all applications to include first aid kits in the ARTG, using the special conformity assessment procedure, made **on or after 25 November 2021**.

Sponsors of **first aid kits that do not use the special conformity assessment procedure** do not need to take any action to comply with the new regulations from 25 November 2021. These first aid kits will still require valid conformity assessment documents for inclusion in the ARTG and their sponsors must be able to demonstrate ongoing compliance following inclusion.

## Transition arrangements

A first aid kit that is included in the ARTG as a result of an application made before 25 November 2021 is automatically eligible for the transition period. The sponsor can continue to supply their device without meeting the new requirements **until 25 November 2025**.

**From 25 November 2025**, the ARTG entry for the first aid kit is expected to be supported by manufacturer evidence, using the updated template for making a declaration of conformity under 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 for ARTG inclusion on or after 25 November 2021

Any new application for inclusion of a first aid kit 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 clause 7.5 of Schedule 3 of the Regulations.

For more information refer to our guidance on manufacturer evidence for medical devices and IVD medical devices.

# Questions and answers

**1. I am a manufacturer of a first aid kit. When I assemble the package, I intend to include non-therapeutic goods and medical devices that are purchased from different manufacturers. I have modified one of the medical devices included in the first aid kit. Can I still supply the kit using the special conformity assessment procedure?**

Modification in this context may include opening or removing primary packaging or sterile packaging, repackaging, further processing such as re-sterilisation of a medical device. You may use the special conformity assessment procedure, provided that:

- the purchased medical devices are in finished form (that is, they are ready to use);
- the first aid kit manufacturer has conformity assessment documentation (issued to the component manufacturer) for each medical device in the package;
- the first aid kit manufacturer has evidence to demonstrate that all goods placed in the first aid kit are compatible (that is, the combined goods in the first aid kit can perform as intended without any conflict or interference being caused by its combination) having regard to the intended purpose of each medical device in the package;
- the modification is performed in accordance with the original manufacturer's instructions for use and does not impact the quality, safety or performance of the device;
- this includes having documentary evidence (such as written agreement from the component manufacturer) that demonstrates that the modification made to any medical device, or the packaging of any medical device in the first aid kit, has been done in accordance with the component manufacturer's instructions for use along with evidence that demonstrates that the quality, safety or performance of the device is not impacted by its modification; and
- if the modification including re-sterilisation of the component device has been done in accordance with the component manufacturer's instructions for use, the first aid kit manufacturer has Production Quality Assurance certificate or equivalent certification (refer to Question 5) that is issued to the first aid kit manufacturer for undertaking sterilisation activities.

Refer to Figure 1 on p. 18.

**2. I am a manufacturer of a first aid kit. When I assemble the package, I intend to include 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 kit using the special conformity assessment procedure?**

No. The manufacturer of the first aid kit cannot use the special conformity assessment procedure for medical devices in unfinished form that are purchased in bulk. You will need to obtain conformity assessment certification issued by the TGA or an equivalent conformity assessment document issued by a comparable overseas regulator or an assessment body for the entire first aid kit.

Refer to Figure 1 on p.18.

**3. I am the manufacturer and the sponsor of a first aid kit that is supplied non-sterile and included in the ARTG using a declaration of conformity made under Clause 7.5 of Schedule 3 of the Regulations. What is the impact of replacing one or more components in this kit with another component from a different manufacturer?**

The first aid kit manufacturer (who is also the sponsor in this example) is required to assess whether the replacement of one or more components included in the kit has resulted in a change

to the 'kind of medical device' that is included in the ARTG. The criteria for a kind of medical device is defined in section 41BE of the Act.

If the replacement of the component(s) in the first aid kit does not result in a change to a 'kind of medical device' included in the ARTG, the manufacturer of the first aid kit is required to update the declaration of conformity made under Clause 7.5 of Schedule 3 of the Regulations, provided they still meet the eligibility criteria defined in Regulation 3.10; and:

- have evidence to demonstrate that each medical device in the first aid kit complies with the relevant essential principles
- have conformity assessment certification issued by the TGA, or an equivalent conformity assessment document issued to the component manufacturer by a recognised comparable overseas regulator or assessment body for each medical device that is not a Class I or Class 1 IVD medical device, included in the first aid kit
- have evidence that demonstrates how they have verified the mutual compatibility of the components placed in the first aid kit in accordance with the component manufacturer's instructions and approved indications
- provide instructions for use, as supplied by the component manufacturer, for each item in the first aid kit.

If requested, the manufacturer or sponsor of the first aid kit must be able to provide the above technical documentation to the TGA.

The sponsor of the first aid kit is required to vary their manufacturer's evidence, attach the updated declaration of conformity and, once this has been accepted, request the TGA to vary the respective ARTG entry if the information included in the ARTG for the first aid kit (for example, the GMDN code) has changed as a result of the replacement of one or more components included in the first aid kit.

**4. I am the sponsor of a first aid kit and the manufacturer of some of the component devices placed in the first aid kit. All the medical devices are included in the ARTG. Is holding evidence in the form of an ARTG certificate sufficient?**

No. The sponsor of the first aid kit must be able to provide the TGA, on request, with either conformity assessment certification issued by the TGA or an equivalent conformity assessment document issued by a comparable overseas regulator or assessment body, for each medical device in the first aid kit, unless the medical device is Class I, in which case they must hold a declaration of conformity (made under **clause 6.6** of Schedule 3 of the Regulations) for each Class I medical device they manufacture.

**5. I am the manufacturer of a Class IIb first aid kit. When I assemble the package, I intend to include the following ready-made devices, which come from different manufacturers, in finished form:**

- **Class IIb sterile wound dressing, which is supported by EU certification, manufactured by Company A**
- **Class I sterile adhesive bandage with MDSAP certification, manufactured by Company B**
- **Class IIa sterile gauze pad with MDSAP certification and Health Canada Medical Device Licence, manufactured by Company C.**

**Will I, as the first aid kit manufacturer, be able to declare compliance with clause 7.5 to supply the kit, noting the various overseas conformity assessment documents issued to each of the component manufacturers?**

Yes, provided you meet the eligibility criteria defined in Regulation 3.10 and the requirements set out in the special conformity assessment procedure detailed on clause 7.5, you as the first kit manufacturer can assemble the first aid kit and declare compliance with the requirements set out in clause 7.5 of Schedule 3 of the Regulations.

**6. For a first aid kit that is supplied using the clause 7.5 pathway and in a sterile state, what types of conformity assessment documents is the manufacturer required to have?**

The manufacturer of a first aid kit that is intended to be supplied in a sterile state is required to have either of the following forms of certification, either issued by the TGA, a recognised comparable overseas regulator or an assessment body:

- 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 Directives:
    - Full quality assurance system certificate or other document issued under Annex II of Directive 93/42/EEC (Medical Devices), excluding section 4; or
    - Production quality assurance certificate or other document issued under Annex V of Directive 93/42/EEC (Medical Devices).
- Certification issued by the EU NB under the following EU Directives:
    - Complete quality assurance system certificate or other document issued under section 3 of Annex 2 of Directive 90/385/EEC (Active implantable medical devices); or
    - An Assurance of production quality certificate or other document issued under Annex 5 of Directive 90/385/EEC (Active implantable medical devices).
- 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 a recognised auditing organisation
    - Certificates issued under the Medical Device Single Audit Program (MDSAP).

**7. The manufacturer of a first aid kit opens a box (secondary carton) of 10 sterile syringes that are individually packaged and then placing an individually packaged sterile syringe in the first aid kit. There is no modification or breach of the primary sterile packaging. What evidence is the first aid kit manufacturer required to hold?**

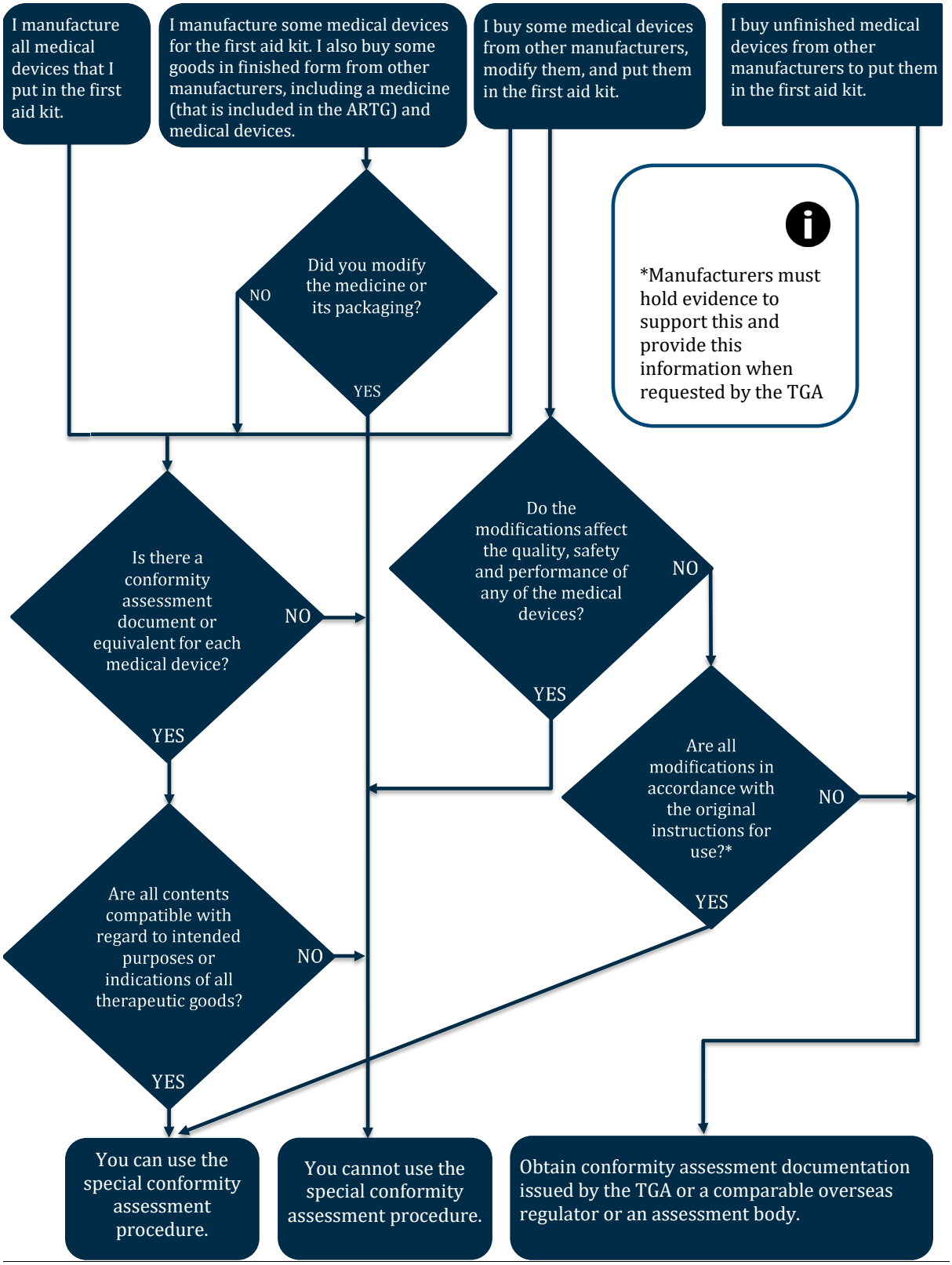
Opening the secondary carton is not considered to be a modification, as long as this activity does not compromise the sterility of the individually packaged sterile syringes and it has been done in accordance with the syringe manufacturer's instructions. As such, the first aid manufacturer is required to hold conformity assessment certification issued by the TGA, or an equivalent conformity assessment document issued to the syringe manufacturer by a recognised comparable overseas regulator or assessment body, for the syringes that are placed in the first aid kit. 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 first aid kit.

# First aid kit assembly

The manufacturer of the first aid kit may choose to assemble them in several ways.

**Figure 1: Manufacturers of the first aid kits have the option to use the special conformity assessment procedure pathway, depending on their contents and manufacturing processes.**



# Version history

| Version | Description of change | Author | Effective date |
|---|---|---|---|
| V1.0 | Original publication | Medical Device Authorisation Branch | November 2021 |

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