Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

# Custom-made medical devices

## Information for manufacturers, sponsors and health professionals

Version 4.1, October 2022

# Contents

### The way that custom-made medical devices are regulated has changed

On 25 February 2021 a new framework for regulating personalised medical devices commenced. The framework includes a new definition for custom-made medical devices. The impact of the new definition is the majority of devices previously supplied under the exemption for custom-made medical devices **no longer meet the definition of a custom-made medical device and will need to be included in the Australian Register of Therapeutic Goods (ARTG) if they are being supplied in volumes of more than five (5) per financial year.**

For more information about the new personalised medical devices framework, including information about the changes to how custom-made medical devices are regulated, frequently asked questions, go to medical devices reforms: personalised medical devices.

You can also send an email to devices@health.gov.au with 'SUBSCRIBE PMD' in the subject line to receive:

- notification when guidance documents and other information resources are published;
- updates about the new framework; and
- details about webinars and workshops.

# Notifying the TGA of custom-made medical devices

You must notify the TGA if you are:

- the Australian manufacturer of a custom-made medical device; or
- the Australian sponsor (supplier) of a custom-made medical device that was manufactured overseas.

You are required to notify the TGA within two (2) months of manufacture or initial supply of the custom-made medical device. You will need to be a client of the TGA with access to the TBS online portal before you can complete a notification form for a custom-made medical device.

There are instructions on the TGA website for becoming a client of the TGA.

Notifications must be submitted using the TGA online form – further details below.

There are penalties associated with failing to notify the TGA.

## Completing the online notification form

You will need the following information to complete your online notification form:

- manufacturer details (name and address);
- GMDN Code for the device(s);
- classification of the device(s); and
- a description of the device(s).

Important things to note:

- If you are an Australian-based manufacturer, you will also be the sponsor of any custom-made medical devices that you produce. When completing the form you should select 'Australian manufacturer of a custom-made medical device'.
- You must supply one online notification form for each 'kind' of medical device.

# Definition of a custom-made medical device

A custom-made medical device is defined in the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations) as a medical device that:

a. is intended by the manufacturer to be for:

   i. the sole use of a particular patient (the ***intended recipient***); or

   ii. the sole use of a particular health professional (the ***intended recipient***) in the course of the health professional's practice; and

b. is manufactured by the manufacturer in accordance with a written request of a health professional (the ***requesting health professional***) and with particular design characteristics specified by that health professional in the request (even if the design is developed in consultation with the manufacturer), where those design characteristics are intended to address:

   i. either or both of the anatomical and physiological features of the intended recipient; or

   ii. a pathological condition of the intended recipient; and

c. the requesting health professional has determined is necessary to address the matters covered by paragraph (b) because there is no kind of medical device included in the Register to address those matters or to address those matters to an appropriate level.

**However, a custom-made medical device does not include a patient-matched medical device, an adaptable medical device or other mass-produced medical device.**

More information is available in the guidance document Personalised medical devices (including 3D-printed devices).

**Note**

A product is unlikely to meet the definition of a custom-made medical device if:

- there are professional, clinical and/or technical standards that describe how it should be designed or produced; or
- you use consistent design methodology, raw materials and manufacturing methods to make the device(s); or
- the instructions for use for your devices are a standard document supplied with each device of that 'kind' that you supply.

# How are custom-made medical devices regulated?

Custom-made medical devices are exempt from inclusion in the ARTG, **but they are not exempt from regulation by TGA.**

**Sponsors and manufacturers of custom-made medical devices must:**

- notify the TGA they are manufacturing and/or importing custom-made medical devices;
- adhere to the conditions of exemption relating to inspection and review;
- adhere to the record keeping requirements;
- supply their devices with all relevant information required;
- provide an annual report to the TGA between 1 July and 1 October each year for the preceding year; and
- meet TGA advertising requirements.

Further detail on these requirements is provided in the sections below.

Additionally, sponsors and manufacturers of custom-made medical devices need to comply with standard regulatory requirements including:

- ensure the custom-made medical devices they supply conform to all applicable Essential Principles;
- meet the ongoing responsibilities of a sponsor including ensuring advertising compliance and reporting adverse events; and
- comply with all other relevant regulatory requirements (for example, providing patient information leaflets and implant cards for all implantable medical devices).

More information is available in the Australian Regulatory Guidelines for Medical Devices (ARGMD).

## Inspection and review

The TGA has the legal authority to request the production of certain information from manufacturers and sponsors of custom-made medical devices, and to request access by authorised officers to inspect premises that form part of the supply chain of a custom-made medical device.

**Table 1. Obligations of manufacturers and sponsors of custom-made medical devices relevant to inspections**

| Obligation | This means that |
|---|---|
| Allow entry and inspection of premises | An authorised person (a delegated departmental officer) may:<br>• enter at any reasonable time any premises – including premises outside of Australia – that is a part of the supply chain for the custom-made medical device and:<br>– inspect those premises;<br>– inspect the device or anything on the premises that relates to the device including:<br>▪ examining;<br>▪ taking measurements; or<br>▪ conducting tests on, or requiring tests to be conducted, on the device or any aspect of the manufacturing facility for the device; and<br>– make any still or moving image or any recording of those premises of any things on those premises. |
| Produce documentation | An authorised person (a delegated TGA officer) may request documentation of any kind relating to the custom-made medical device including, but not limited to:<br>• a copy of the original health professional's request for the device;<br>– in cases where the health professional is the manufacturer, this could be a document outlining the clinical notes taken to inform design of the device.<br>• any information supplied with the device; and<br>• evidence of conformity assessment documentation. |

**Note**

Inspections are generally initiated in relation to adverse events associated with the device. The TGA will typically provide at least two (2) weeks' notice of routine domestic inspections, and four (4) weeks' notice of routine international inspections. Notice periods may differ where inspections are being performed as part of serious compliance investigations.

## Record-keeping requirements

Manufacturers and sponsors of custom-made medical devices must maintain records relating to the devices they have supplied in Australia for:

- a minimum of **5 years** after the date of manufacture if the device is **non-implantable**; or
- a minimum of **15 years** after the date of manufacture if the device is **implantable**.

If you are not sure whether a device you manufacture or supply is implantable, please review the definition in the dictionary section of the Regulations.

At a minimum, manufacturers and sponsors of custom-made medical devices should maintain:

- a copy of the statement described in **Information to be supplied with your device** below;
- annual reports relevant to the device;
- evidence that the device conforms to the Essential Principles; and
- any other documentation that they determine is needed to comply with the conditions outlined in the **Inspection and review** section of this document.

## Information to be supplied with a device

Manufacturers of custom-made medical devices must supply written statements prepared in relation to each of the custom-made medical devices they manufacture. The statements must include, at minimum, the following information:

- the name and business address of the manufacturer;
- information identifying the device or, where relevant, the contents of the packaging;
- a statement to the effect the device is intended to be used only in relation to a particular individual (who may be a health professional);
- the name of the individual to whom the device is intended to be used;
- the name and business address of the health professional who provided the specifications for the device;
- the particular design characteristics or construction of the device as specified by the health professional who provided the specifications; and
- a statement to the effect the device complies with the applicable provisions of the Essential Principles. If the device does not comply with all applicable provisions, then a

statement must be included explaining which provisions it does not comply with and the reasons why.

The statement must be signed and dated by a person authorised by the manufacturer of the device, and include details of the person's name and position. It is the legal manufacturer of the device under section 41BD of the Act who must compile the statement, including where manufacturing steps are outsourced.

Manufacturers may choose to use the statement template included as Appendix 2 to the guidance document Personalised Medical Devices (including 3D-printed devices). Manufacturers may choose to supply the statement digitally, provided sufficient information is provided with both the statement and the device to allow the user to correctly match the two.

**Note**

Manufacturers should note that the requirement to supply these statements is ***in addition to*** existing requirements for information to be supplied with a device under Essential Principle 13 of Schedule 1 of the Regulations including:

- instructions for use; and
- a patient implant card (PIC) or patient information leaflet (PIL) for implantable devices.
  - The manufacturer may choose to include the required PIC/PIL information in the statement to be supplied with the device. More information on PICs and PILs can be found on our website.

## What level of information should be provided in the statement?

The level of information supplied in the statement will differ between devices, but it must be sufficient to allow the intended recipient(s) (in many cases, this will be both the patient and any health professional involved in their healthcare, both now and in the future) to make informed decisions that will:

- ensure the device continues to perform as intended;
- ensure the device can be maintained and used safely for the length of its intended life; and
- ensure risks associated with the device can be managed.

Manufacturers of custom-made medical devices should consider, but not limit their thinking to, the following:

- Will the intended user need to see a health professional other than the health professional that requested the device about their presenting issue, or a related issue, in the future?
- What kind of information might be needed to safely perform a revision procedure, or a re-fit, or a modification of the device?
- What kind of information might be needed to safely maintain the device?
- What is the expected clinical course for this patient, and what other kinds of health professionals might be involved in their care? What might they need to know?

## Annual reports

Manufacturers and sponsors of custom-made medical devices must supply an annual report detailing all of the custom-made medical devices they have manufactured and/or supplied within the preceding 1 July – 30 June financial year. The report must be submitted in the approved format by 1 October of the following financial year.

To submit an annual report:

2. Download the custom-made medical device annual report spreadsheet template from the TGA website; and
3. Submit the completed report to the TGA using the online form: Annual Reporting Form – Custom-made medical devices

**Note**

You do not need to submit an annual report if your device meets the definition of a patient-matched medical device and has been registered for transition.

# Information for health professionals

## What are the responsibilities of health professionals prescribing custom-made devices?

The health professional prescribing the custom-made device is responsible for specifying its design characteristics or construction. If they are also the manufacturer or sponsor of the medical device, then they must also meet the relevant regulatory responsibilities outlined in the section for sponsors and manufacturers above.

## Can health professionals import custom-made medical devices?

Health professionals can import custom-made medical devices from overseas, but in doing so they meet the definition of a sponsor and are subject to the regulatory obligations outlined in the section **How are custom-made medical devices regulated?**

## Are health professionals obliged to tell patients if a custom-made device is manufactured overseas?

All custom-made medical devices must meet the Essential Principles. Essential Principle 13.1 requires devices to be supplied with information identifying the manufacturer of the device.

## What do I do if I find a suspect medical device?

If you are concerned that a custom-made medical device is not being supplied in accordance with what is outlined above, you are encouraged to submit a report via the TGA website.

If you have concerns about the safety or performance of a custom-made medical device, you are encouraged to submit a report to the TGA. The act of reporting an event is not an admission of liability for the event or its consequences.

This can be done online via the TGA website, or the forms can be posted to:

Medical Devices Surveillance Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

# Version history

| Version | Description of change | Author | Effective date |
|---|---|---|---|
| V1.0 | Original publication | Medical Devices Surveillance Branch | January 2020 |
| V1.1 | Minor updates | Medical Devices Surveillance Branch | April 2021 |
| V2.0 | Updated to include links to annual reporting template and provide up-to-date information | Medical Devices Surveillance Branch | July 2021 |
| V3.0 | Updated to reflect regulation changes under the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* | Medical Devices Surveillance Branch | November 2021 |
| V3.1 | Updated to remove obsolete information about advertising and change information and links to redirect to the new custom-made medical devices database in PMR | Medical Devices Surveillance Branch | June 2022 |
| V4.0 | Updated to remove obsolete information about nominated email address details no longer applicable with the new custom-made medical devices database | Medical Devices Surveillance Branch | July 2022 |
| V4.1 | Updated to reflect close of the patient-matched medical devices transition notification period and changes to advertising rules | Medical Devices Surveillance Branch | October 2022 |

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Reference/Publication #