Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Understanding regulation of custom-made medical devices

Information for manufacturers, sponsors and health professionals on the definition of a custom-made medical device and how we regulate them.

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Purpose

This guidance outlines the legal obligations of manufacturers and sponsors of custom-made medical devices.

Regulation

Custom-made medical devices are exempt from inclusion in the ARTG. They are not exempt from regulation by us.

Manufacturers and sponsors of custom-made medical devices must:

1. notify us of their custom-made medical devices
2. follow inspection and review conditions
3. maintain records
4. supply written statements with their device
5. provide an annual report to us, and
6. meet our advertising requirements.

Definition of a custom-made medical device

A custom-made medical device is one that's made for a particular person.

Other qualifying factors include:

- it is made at the request of a health professional
- it is made to fit anatomical, physiological, or pathological features of the patient
- there is no other kind of medical device included in the Australian Register of Therapeutic Goods (ARTG) like it.

Custom-made medical device is defined in the Therapeutic Goods (Medical Devices) Regulations 2002.

> It is unlikely a product meets this definition if:
>
> - professional, clinical, or technical standards describe how it is made
> - you use consistent raw materials, manufacturing methods, and design methodologies, or
> - each device of that 'kind' that you supply comes with standard instructions for use.

Legislation

Therapeutic Goods (Medical Devices) Regulations 2002

Notify us

Within 2 months of manufacturing or initial supply, you need to notify us of:

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

Failure to notify us can result in penalties.

To notify us you will need to be a client of the TGA with access to the TGA Business Services (TBS) online portal.

Notifications must be submitted using the online form.

Please note:

- one form is required per 'kind of medical device'
- 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'.

Please see the step-by-step guide to submitting a custom-made medical device notification.

Inspection and review

We can legally ask for information from manufacturers and sponsors.

We might also ask to inspect the location of where the custom-made medical device is made.

Relevant obligations of manufacturers and sponsors of custom-made medical devices

Obligation	Meaning

Allow entry and inspection of premises	An authorised person (a delegated TGA officer) may:
	• enter at any reasonable time any premises. This includes those outside of Australia - that are part of the supply chain. The authorised person can:
	  ○ inspect the premises
	  ○ inspect the device or anything that relates to the device including:
	  ○ examining
	  ○ taking measurements; or
	  ○ conducting tests on, or requiring tests; and

Obligation	Meaning
	◦ make any still or moving image or any recording of those premises of any things on those premises.
Produce documentation	The TGA officer can request documentation related to the custom-made medical device including, but not limited to: • a copy of the original health professional's request for the device ◦ where the health professional is the manufacturer, a document that outlines the clinical notes used to inform device design • any information supplied with the device • evidence of conformity assessment documentation.

Adverse events usually trigger inspections.

We will usually provide:

- at least two (2) weeks' notice of routine domestic inspections
- four (4) weeks' notice of routine international inspections.

Notice periods may vary where inspections are being performed as part of serious compliance investigations.

Record-keeping requirements

Medical device manufacturers and sponsors in Australia must keep records for:

- at least 5 years after the date of manufacture if the device is non-implantable; or at least 15 years after the date of manufacture if the device is implantable
- a copy of the written statement
- annual reports relevant to the device
- evidence that the device conforms to the Essential Principles, and
- any other documents needed to follow the Inspection and Review section.

Look at the dictionary section of the Regulations to see if your device is implantable.

Written statements

Manufacturers must supply written statements for each custom-made medical device.

The statements must include:

- name and business address of the manufacturer
- information identifying the device or, where relevant, the contents of the packaging
- a statement that the device is intended to be used only for a particular person (may be a health professional)

- name of the person using the device
- name and business address of the health professional who provided the specifications
- specified design characteristics or construction of the device by the health professional
- an explanation of how the device complies with the Essential Principles. If the device does not comply, a statement should explain why it doesn't and the reasons why
- instructions for use, and
- a patient implant card (PIC) or patient information leaflet (PIL) for implantable devices.

A person authorised by the manufacturer must date and sign the statement. It should also include details of the person's name and position.

The manufacturer of the device must compile this statement, including outsourced manufacturing activities. See section 41BD of the *Therapeutic Goods Act 1989*.

Manufacturers can use the statement template included in Appendix 2 of Personalised Medical Devices (including 3D-printed devices).

When compiling your written statement, you might want to consider:

- will the intended user need to see another health professional about their presenting issue, or a related issue, in the future?
- what kind of information is needed to safely perform a revision procedure, or a re-fit, or a modification of the device?
- how can the device be maintained safely?
- what is the expected clinical course for this patient, and who else might be involved in their continuing care?

Annual reports

Manufacturers and sponsors of custom-made medical devices must supply an annual report. The report must be submitted by 1 October of that year.

You need to:

1. provide details about all custom-made medical devices manufactured and/or supplied within the last financial year
2. populate and submit your annual report using the Annual Reporting Form - Custom-made medical devices.

You can submit a nil report if you have not manufactured or supplied a custom-made device in the last financial year.

You do not need to submit an annual report if your device is a patient-matched medical device and a notification for transition to the ARTG has been submitted.

Advertising rules

Manufacturers and sponsors of custom-made medical devices must meet all our advertising requirements.

Information for health professionals

When prescribing custom-made devices, health professionals are responsible for:

- specifying design characteristics or construction
- meeting relevant regulatory responsibilities if they are the manufacturer or sponsor
- making sure the device comes with information such as the manufacturers name, address.

Health professionals can import custom-made medical devices from overseas. In doing so, they become a sponsor and have regulatory obligations.

We encourage you to report concerns about custom-made medical devices. Reporting an event isn't admitting liability for it or its consequences.

Related links

Medical devices reforms: Personalised medical devices

Topics: Advertising Australian Register of Therapeutic Goods (ARTG) Manufacturing

Page history

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Major content and structural refresh.