Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Understanding regulation of custom-made medical devices

Guidance for manufacturers and sponsors (including health professionals) on how we define and regulate custom-made medical devices (CMMDs).

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Contents

Purpose

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

Legislation

Therapeutic Goods (Medical Devices) Regulations 2002

Definition of a custom-made medical device

A CMMD is made for a particular person. Also, a CMMD is so *rare and unique* that the manufacturer cannot adequately or fully validate the design or production processes used.

Other qualifying factors include:

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

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

> It is unlikely your 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.
>
> Most devices made for a particular person are patient-matched medical devices, not CMMDs. Use this decision tree to help you decide if we define your device as custom-made or patient-matched.

Regulation overview

CMMDs are exempt from inclusion in the ARTG. They are not exempt from regulation by the TGA.

Manufacturers and sponsors of CMMDs must:

1. ensure their device meets the Essential Principles.

2. apply CMMD conformity assessment procedures. These are:
    - supply written statements with their device
    - keep records
    - report adverse events
3. notify us of their CMMDs
4. provide an annual report to us
5. meet our advertising requirements; and
6. follow inspection and review conditions.

> **Note.** If you make a CMMD in Australia, you are both the manufacturer and sponsor, unless you arrange for someone else to assume the sponsor responsibility. If you import a CMMD from overseas, you are the sponsor. You will need to work with the overseas manufacturer to ensure the CMMD complies with our regulations.

Written statements

Manufacturers must supply written statements with their CMMDs.

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 (can be a health professional)
- name of the person using the device
- name and business address of the health professional who provided the specifications
- the 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 how it doesn't and the reasons why
- instructions for use, and
- 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.

You can use this written statement template:

> **Statement template for custom-made medical devices** [Word, 17.36 KB]

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

- will the patient need to see another health professional about the issue they are being treated for, 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?

Record-keeping requirements

Manufacturers and sponsors in Australia must keep:

- a copy of the written statement
- annual reports relevant to the device
- evidence that the device conforms to the Essential Principles
- information about the device's design, production and intended performance; and
- a copy of the health professional's request for the device.

Records must be kept 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.

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

Notify us

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

- manufacturer and sponsor name and address
- GMDN Code for the device
- classification of the device
- device description.

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 Australia-based manufacturer, you will also be the sponsor of any CMMDs that you produce, unless you arrange for someone else to assume the sponsor responsibility. 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.

Annual reports

Manufacturers and sponsors of CMMDs must provide an annual report to us, for the period 1 July-30 June, each year. The report must be submitted before 1 October following the end of the financial year reporting period.

You need to:

1. provide details about CMMDs 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 CMMD in the last financial year.

Advertising rules

Manufacturers and sponsors of CMMDs must meet all our advertising requirements.

Adverse event reporting

Manufacturers and sponsors of CMMDs must report adverse events to us as soon as possible.

Inspection and review

We can legally ask for information from manufacturers and sponsors.

Relevant obligations of manufacturers and sponsors of CMMDs

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 - 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 CMMD 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.

We might also ask to inspect the location where the CMMD is made.

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.

Information for health professionals

When prescribing CMMDs, health professionals are responsible for:

- specifying design characteristics or construction
- ensuring the device comes with information such as the manufacturer’s name and address
- determining whether they are the manufacturer or sponsor. If so, they must meet the regulatory obligations.

Health professionals can import CMMDs from overseas. In doing so, they become a sponsor and must meet the regulatory obligations.

We encourage you to report concerns about CMMDs. Reporting an event isn't admitting liability for it or its consequences.

More information

Personalised medical devices

Information about how we regulate personalised medical devices.

Topics Manufacturing Therapeutic goods regulation

Page history

7 May 2025

Rearranged section order to improve flow. Expanded definition section and added further details to Regulation overview, Record-keeping, Adverse event reporting.

4 October 2024

Title changed from 'Custom-made medical devices' to 'Understanding regulation of custom-made medical devices' as part of migration to new 'Guidance' content type:

- Consistent ‘Purpose’ heading.
- ‘Legislation’ section to clearly show which laws the Guidance relates to.
- ‘Page history’ section replaces document version history.
- New page navigation features.
- Updated page summaries.
- Complex images include long descriptions.
- New ‘Save as PDF’ feature.

31 May 2024

Major content and structural refresh.
