Australian Government
Department of Health
Therapeutic Goods Administration

Custom made medical devices

Information for sponsors, health professionals and manufacturers

Definitions

What are custom made medical devices?

Custom made medical devices are defined in the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations) as medical devices that are:

- made specifically in accordance with a request by a health professional specifying its design characteristics or construction.
- intended to be used only in relation to a particular individual, or by a health professional to meet special needs arising in the course of his or her practice.

Are medical devices that are adapted for an individual considered to be custom made?

Custom made medical devices do not include medical devices that have been adapted or modified to accommodate an individual patient. However, the device that requires modification is also required to be included on the Australian Register of Therapeutic Goods (ARTG) before it is supplied.

It is important to note that the person who adapts a medical device for an individual patient is not considered to be a manufacturer of a medical device if the adaptation does not alter its intended purpose. This exclusion is covered under subsection 41BG(3) of the *Therapeutic Goods Act 1989* (the Act).

Regulation—general

How are custom made devices regulated?

Manufacturing of custom made devices must at a minimum, meet conformity assessment procedures regulated by the TGA. These include conformity assessment procedures prescribed under Part 7, Schedule 3 of the Regulations that comply with the relevant Essential Principles in Schedule 1 of the Regulations.

Custom made devices are not required to undergo premarket assessment by the TGA or to be included on the ARTG before supply. This is because of the relatively low risk associated with the use of custom made devices such as prescription glasses and dental crowns, as well as the impracticalities of the TGA assessing such devices.

Can the TGA prevent custom made devices from being imported?

The TGA regulates the supply and exportation of medical devices to ensure they meet required standards of quality, safety and performance. So long as a custom made medical device meets these requirements, the TGA will not prevent their importation.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8444 Fax: 02 6232 8605 Email: info@tga.gov.au www.tga.gov.au

Examples of custom made medical devices

- dental appliances such as crowns, bridges and dentures
- prosthetic or glass eyes
- orthopaedic or pedorthic footwear
- prosthetic limbs
- prescription glasses

Requirements for sponsors

What or who is the sponsor of custom made medical devices?

A sponsor is the person or organisation that imports or supplies medical devices in Australia, or exports medical devices from Australia. The sponsor can be the manufacturer, a health professional, or someone else.

For example where a manufacturer in Australia also supplies their custom made devices directly to the market rather than through a third party, they will also be a sponsor under the Regulations.

Or if a health professional obtains custom made devices directly from the manufacturer for supply to his or her patients, then they will be a sponsor under the Regulations.

What are the requirements for sponsors of custom made medical devices?

The sponsor:

- must ensure that the manufacturer is aware of their responsibilities for manufacturer custom made devices under the therapeutic goods legislation
- have the same reporting obligations as the manufacturer (see below).
- must notify the TGA under section 41MP of the Act of the following:
    - any malfunction or deterioration in the characteristics or performance of the device
    - any inadequacy in the design, production, labelling, instructions for use or advertising material for the device
    - any use of the device that has led to, or potentially may lead to, the death or serious deterioration in the health of the patient or user of the custom made device
    - any information relating to technical or medical reason for a malfunction or deterioration of a custom made device that has led the manufacturer to recover the device
    - any information that indicates the device does not comply with the essential principles.

It is mandatory for medical device sponsors and manufacturers to report adverse events associated with a medical device. If there is any doubt about whether an adverse event report should be submitted, then the report should be submitted.

Requirements 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 responsibilities.

Can health professionals import custom made medical devices?

Health professionals can import custom made medical devices from overseas, but in doing so they become the sponsor and are subject to the sponsor's obligations as outlined above.

Are health professionals obliged to tell patients if custom made device are manufactured overseas?

This is a matter for the health professional to decide and is not covered by therapeutic goods legislation.

Requirements for manufacturers

What are the requirements for manufacturers of custom made medical devices?

Manufacturers of custom made medical devices are required to apply appropriate conformity assessment procedures and should refer to the Australian regulatory guidelines for medical devices (ARGMD). In addition to this, the TGA provides the Essential principles checklist to assist manufacturers to ensure that any custom made devices meet safety and performance requirements.

What must be reported to the TGA?

Manufacturers are required to notify the TGA about:

- malfunctions or deteriorations in the characteristics or performance of the device
- any problems with the design, production, labelling or instructions for use of the device that has led to, or potentially may lead to, the death or a serious deterioration in the health of the user of the custom made device
- information relating to the technical or medical reason for a malfunction or deterioration of custom made devices that has led to the recovery of that device.

These reporting requirements are detailed in Schedule 3, Part 7(7.5)(4)(c) of the Therapeutic Goods (Medical Devices) Regulations 2002.

Suspect devices

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

If you have concerns about the safety or performance of a custom made medical device, you can 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 via the TGA Internet site, or the forms can be posted to:

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