Australian Government
Department of Health
Therapeutic Goods Administration

Custom-made medical devices

Information for the dental industry

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ADIA industry briefing 12-13 July 2016

TGA Health Safety Regulation

Discussion topics

- Legislative framework
- What is custom-made?
- Notifying TGA
- Regulatory obligations
  - pre-market
  - post-market

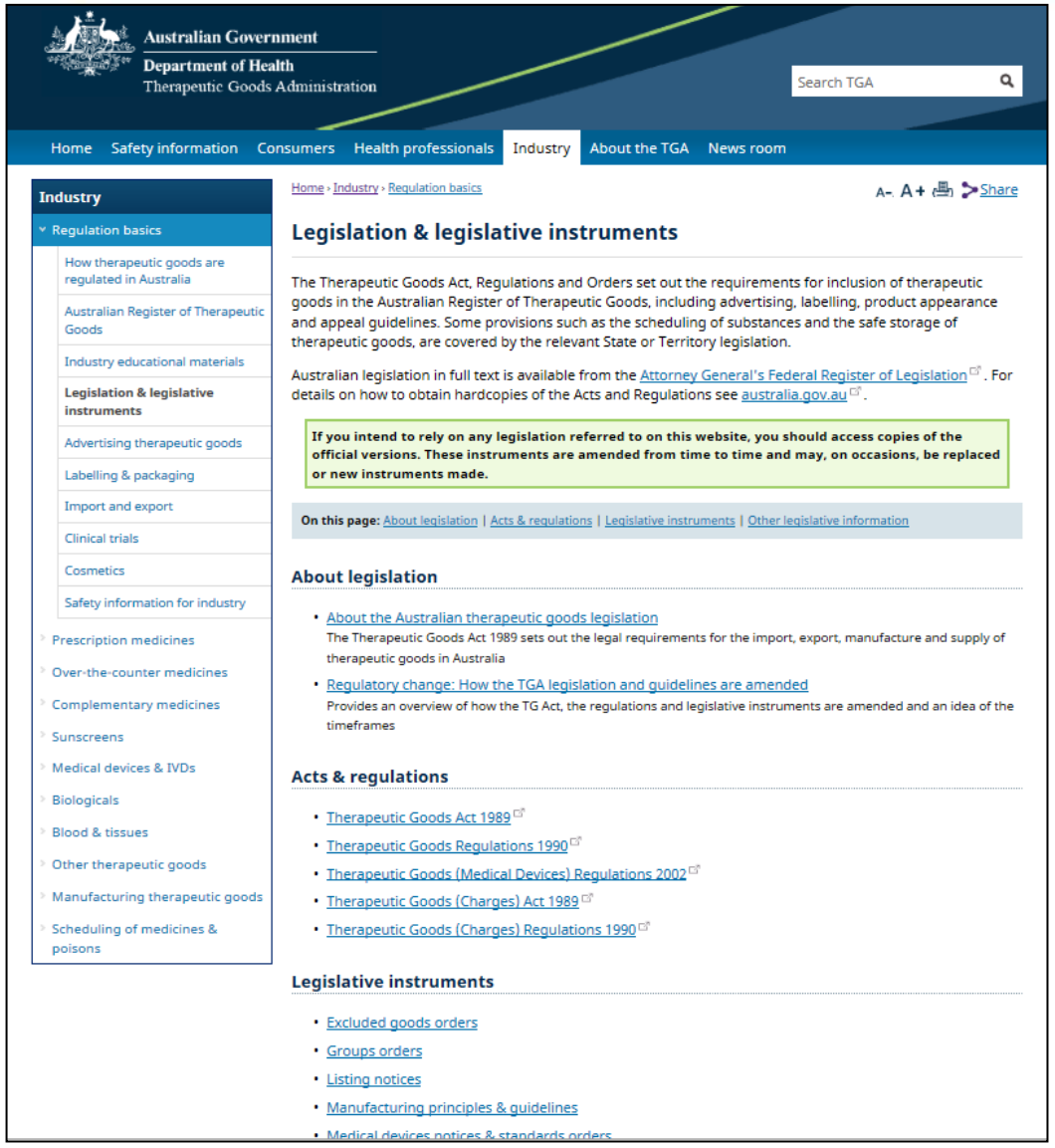
Regulatory framework

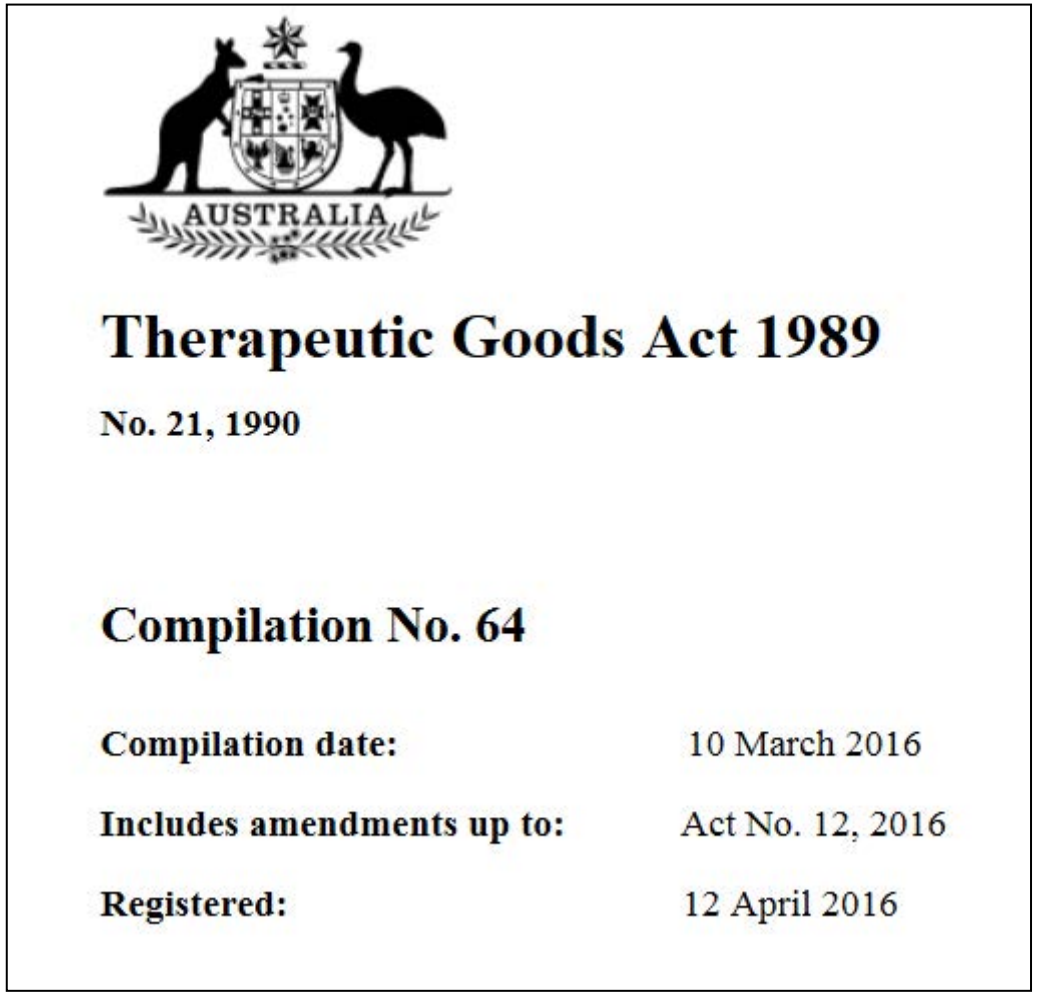
Commonwealth legislation

- *Therapeutic Goods Act 1989*
  especially Chapter 4 Medical Devices

- Therapeutic Goods (Medical Devices) Regulations 2002

- https://www.tga.gov.au/legislation-legislative-instruments





- Chapter 4—Medical devices
  - Part 4-1—Introduction
  - Part 4-2—Essential principles and medical device standards
  - Part 4-3—Conformity assessment procedures
  - Part 4-4—Conformity assessment certificates
  - Part 4-5—Including medical devices in the Register
  - Part 4-6—Suspension and cancellation from the Register
  - Part 4-6A—Exempting medical devices to deal with emergencies
  - Part 4-7—Other exemptions from including medical devices in the Register
  - Part 4-8—Obtaining information
  - Part 4-9—Public notification and recovery of medical devices
  - Part 4-10—Assessment fees
  - Part 4-11—Offences and civil penalty provisions relating to medical devices

https://www.legislation.gov.au/Series/C2004A03952

Therapeutic Goods (Medical Devices) Regulations 2002

Statutory Rules No. 236, 2002

made under the

Therapeutic Goods Act 1989

Compilation No. 30

Compilation date:	16 February 2016
Includes amendments up to:	F2016L00109
Registered:	22 February 2016

https://www.legislation.gov.au/Series/F2002B00237

Definitions

Medical device

- s41BD of the Act defines a medical device as …

41BD What is a *medical device*

(1) A ***medical device*** is:

(a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;

(iii) investigation, replacement or modification of the anatomy or of a physiological process;

(iv) control of conception;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or

(aa) any instrument, apparatus, appliance, material or other article specified under subsection (2A); or

(ab) any instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection (2B); or

(b) an accessory to an instrument, apparatus, appliance, material or other article covered by paragraph (a), (aa) or (ab).

Definitions

Custom-made medical device

- the Regulations define a custom-made medical device as ….

- examples relevant to the dental industry may include:
  - crowns
  - bridges
  - dentures
  - specialised instruments

custom–made medical device means a medical device that:

(a) is made specifically in accordance with a request by a health professional specifying the design characteristics or construction of the medical device; and

(b) is intended:

(i) to be used only in relation to a particular individual; or

(ii) to be used by the health professional to meet special needs arising in the course of his or her practice.

‘Customised’ does not equal a custom-made medical device

- an existing medical device that is adapted, altered, fashioned, modified or ‘customised’ to fit a patient is NOT a custom-made medical device

- for example, a preformed permanent dental crown that may require minimal fashioning in situ during restorative work is not a custom-made medical device

- devices already included on the ARTG that are combined and adapted for an individual (provided the devices are used as intended by the manufacturer/IFUs) are not custom-made medical devices (orthodontic braces)

Definitions

Manufacturer

- s41BG of the Act defines a manufacturer as …

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.

(3) However, a person is not the manufacturer of a medical device if:

(a) the person assembles or adapts the device for an individual patient; and

(b) the device has already been supplied by another person; and

(c) the assembly or adaptation does not change the purpose intended for the device by means of information supplied by that other 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.

(4) A person is not the manufacturer of a medical device if the person is included in a class of persons prescribed by the regulations for the purposes of this subsection.

Definitions

Sponsor

- s3 of the Act defines a sponsor as …

- sometimes the sponsor and the manufacturer are the same entity e.g. a dental laboratory that supplies their products directly to dental professionals

- dentists and allied oral healthcare providers can import custom-made devices from overseas, but in doing so they become the sponsor and acquire obligations

sponsor, in relation to therapeutic goods, means:

(a) a person who exports, or arranges the exportation of, the goods from Australia; or

(b) a person who imports, or arranges the importation of, the goods into Australia; or

(c) a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere);

but does not include a person who:

(d) exports, imports or manufactures the goods; or

(e) arranges the exportation, importation or manufacture of the goods;

on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia.

Definitions

Kinds of devices

- s41BE of the Act defines kinds of medical devices as …
- TGA needs to be notified of each kind of device
- TGA does not need to be notified about each individual device being made for individual patients

41BE Kinds of medical devices

General

(1) For the purposes of this Chapter, a medical device is taken to be of the same kind as another medical device if they:

(a) have the same sponsor; and

(b) have the same manufacturer; and

(c) have the same device nomenclature system code (see subsection (3)); and

(d) have the same medical device classification; and

(e) are the same in relation to such other characteristics as the regulations prescribe, either generally or in relation to medical devices of the kind in question.

Unique medical devices

(2) If a medical device is not of the same kind as any other medical device:

(a) this Chapter applies in relation to the device as if it were a kind of medical device; and

(b) references in this Chapter to delivering a reasonable number of samples of the kind of device are taken to be references to delivering the device.

Device nomenclature codes

(3) The Minister may, by legislative instrument, determine device nomenclature codes for medical devices.

Kinds of medical devices - examples

Example 1

Dentist (sponsor) imports polymer dental bridges manufactured by Manufacturer A in China:

- same sponsor
- same manufacturer
- same GMDN code
- same classification

Therefore **same kind of medical device** and only **one notification** to TGA required.

Do not need to notify TGA for each patient receiving a custom-made medical device of this kind.

Example 2

Dentist (sponsor) imports polymer dental bridges manufactured by Manufacturer A in China and Manufacturer B in Germany:

- same sponsor
- different manufacturers
- same GMDN code
- same classification

Therefore **not the same kind of medical device** and separate **notifications required for each kind**.

Again, do not need to notify TGA for each patient, only the kind of device.

Regulatory obligations

Who has obligations?

- both the manufacturer and the sponsor have obligations
- requirements to:
  - meet the essential principles (EPs) - this demonstrates the quality, safety and performance of the device
  - apply a conformity assessment procedure - this generates evidence that the device complies with the EPs
  - notify the TGA
  - comply with advertising requirements
  - report adverse events

But aren't custom-made devices 'exempt'?

- exempt from ARTG inclusion only
- all other obligations still apply

Requirement to notify TGA

- since 2002, Australian manufacturers and sponsors importing custom-made medical devices into Australia have been required to notify TGA about certain details, e.g. name and business address, description of the 'kind of device'
- in February 2016 the regulations were amended to introduce a two month timeframe for notification to the TGA
- details in Regulation 10.3

10.3 Custom–made medical devices—information about manufacturer

(1) The manufacturer of a custom–made medical device that is manufactured in Australia must, within 2 months after the medical device is first manufactured in Australia, give the following information about the device to the Secretary:

(a) the manufacturer's name and business address;

(b) a description of the kinds of medical devices being custom–made by the manufacturer (including the device nomenclature system code for any such devices).

Penalty: 10 penalty units.

(2) The sponsor of a custom–made medical device that is imported into Australia must, within 2 months after the medical device is first imported into Australia, give the following information about the device to the Secretary:

(a) the sponsor's name and address;

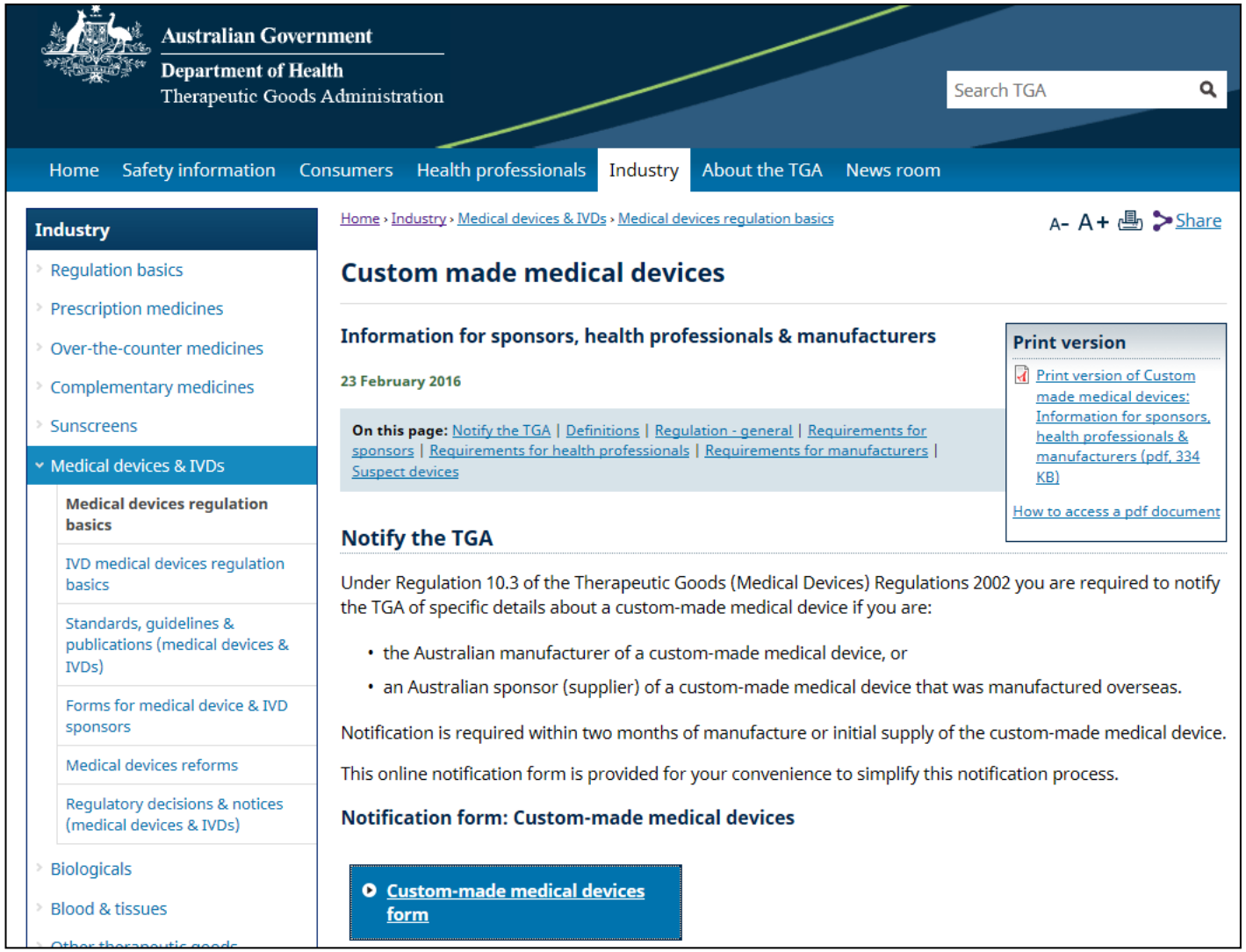
(b) the manufacturer's name and business address;

(c) a description of the kinds of medical devices being custom–made by the manufacturer (including the device nomenclature system code for any such devices).

How to notify …

- simple web-based notification form
- quick and easy to complete and submit
- some fields mandatory
- within 2 months of the device being manufactured in Australia or first imported into Australia

www.tga.gov.au/custom-made-medical-devices



Australian Government
Department of Health
Therapeutic Goods Administration

Need Help

Tracking Code: CUSTOM-MADE-MEDICAL--659

Save For Later

Custom-made medical devices

*Fields marked with * are required*

Under Regulation 10.3 of the Therapeutic Goods (Medical Devices) Regulations 2002 you are required to notify the TGA of specific details if you are:

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

Notification is required within two months of manufacture or initial supply of the custom-made medical device.

These forms are provided for your convenience to simplify this notification process.

I am the: *

- ○ Australian manufacturer of a custom-made medical device
- ○ Sponsor of a custom-made medical device

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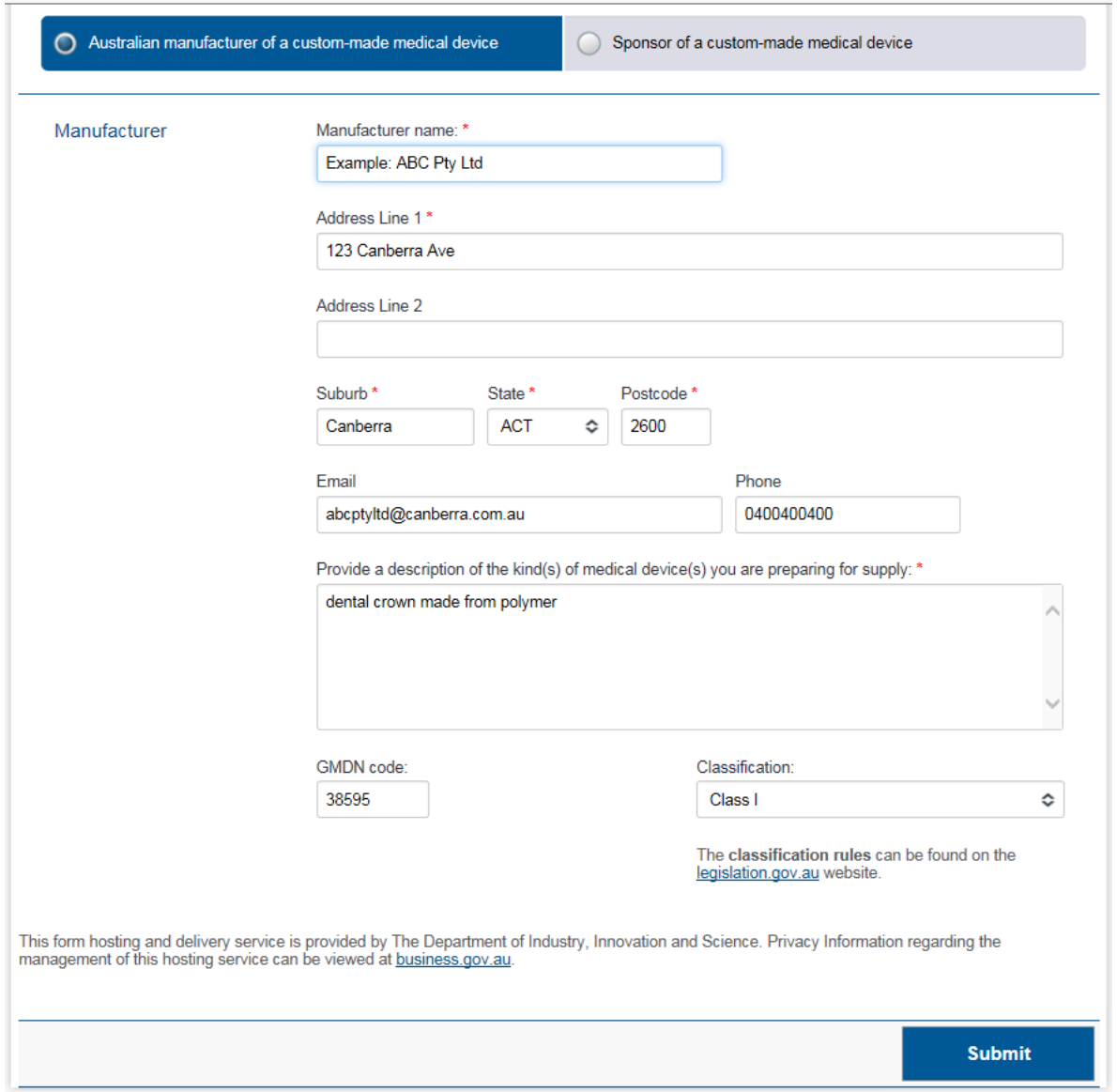
Submit


Australian manufacturer of a custom-made medical device
Sponsor of a custom-made medical device
Manufacturer
Manufacturer name: *
Example: ABC Pty Ltd
Address Line 1 *
123 Canberra Ave
Address Line 2
Suburb *
State *
Postcode *
Canberra
ACT
2600
Email
Phone
abcptyltd@canberra.com.au
0400400400
Provide a description of the kind(s) of medical device(s) you are preparing for supply: *
dental crown made from polymer
GMDN code:
38595
Classification:
Class I
The classification rules can be found on the legislation.gov.au website.
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Submit

Submission Complete - Custom-made medical devices

Thank you

Your form has been submitted for processing

Submitted: 11:06 AM, Thursday 23 June 2016

Your form tracking code is:

CUSTOM-MADE-MEDICAL--659

Submission Enquiries:

For technical assistance email tga.website@tga.gov.au or call 1800 020 653 and ask to speak to a member of the website team. Enquiries about your notification should be directed to the TGA's medical devices information team at devices@tga.gov.au or call 1800 141 144.

To keep a copy of the completed form:

- Download the form and receipt; and/or
- Email a copy to:

abcptyltd@canberra.com.au Email form

Service Provided By

Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Administration - Department of Health

Phone: 18 0002 0653

Email: tga.website@tga.gov.au

Form Receipt - (Automated Notification) - Therapeutic Goods Administration - Department of Health - Message (HTML)

File | Message | Adobe PDF

Ignore | Junk | Delete | Reply | Reply All | Forward | Meeting | IM | More | Close & File | Save Attachments | Create an appoint... | To Manager | Reply & Delete | Forward | Team E-mail | Create New | Move to folder | Done | Move | Rules | OneNote | Actions | Mark Unread | Categorize | Follow Up | Translate | Find | Related | Select | Zoom

Delete | Respond | Filing | Quick Steps | Move | Tags | Editing | Zoom

If there are problems with how this message is displayed, click here to view it in a web browser.

From: noreply@industry.gov.au

Sent: Thu 23/06/2016 11:18 AM

To: MERCER, Valerie

Cc:

Subject: Form Receipt - (Automated Notification) - Therapeutic Goods Administration - Department of Health

Message | custom-made-medical--659.pdf (146 KB)

Form Submitted

You submitted a form called: **Custom-made medical devices.**

Your form tracking code is: **CUSTOM-MADE-MEDICAL--659**

Your submission reference number is: **custom-made-medical--659**

To check the progress of your submission and/or confirm it has been received you should contact the agency that provides the form. Where available these details may be displayed below. Alternatively the agency name is usually displayed on the front page of the form or as part of the form logo.

Please see the attached PDF for a copy of your form submission.

Please do not reply to this email as it has been sent from an automated system and replies are routed to an unmonitored mailbox. For further information regarding your form please contact the relevant Government Agency:

Agency Name: Therapeutic Goods Administration - Department of Health

Phone: 18 0002 0653

Email: tga.website@tga.gov.au

Australian Government
Department of Health
Therapeutic Goods Administration

Custom-made medical devices

Tracking Code: **CUSTOM-MADE-MEDICAL--659**

Custom-made medical devices

Under Regulation 10.3 of the Therapeutic Goods (Medical Devices) Regulations 2002 you are required to notify the TGA of specific details if you are:

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

Notification is required within two months of manufacture or initial supply of the custom-made medical device.

These forms are provided for your convenience to simplify this notification process.

I am the: *

(•) Australian manufacturer of a custom-made medical device ( ) Sponsor of a custom-made medical device

Manufacturer

Manufacturer name: *
Example: ABC Pty Ltd

Address Line 1 *
123 Canberra Ave

Address Line 2

Suburb * | State * | Postcode *
Canberra | ACT | 2600

Email | Phone
abcptyltd@canberra.com.au | 04 0040 0400

Provide a description of the kind(s) of medical device(s) you are preparing for supply: *
dental crown made from polymer

GMDN code:
38595

Classification:
Class I

The **classification rules** can be found on the legislation.gov.au website.

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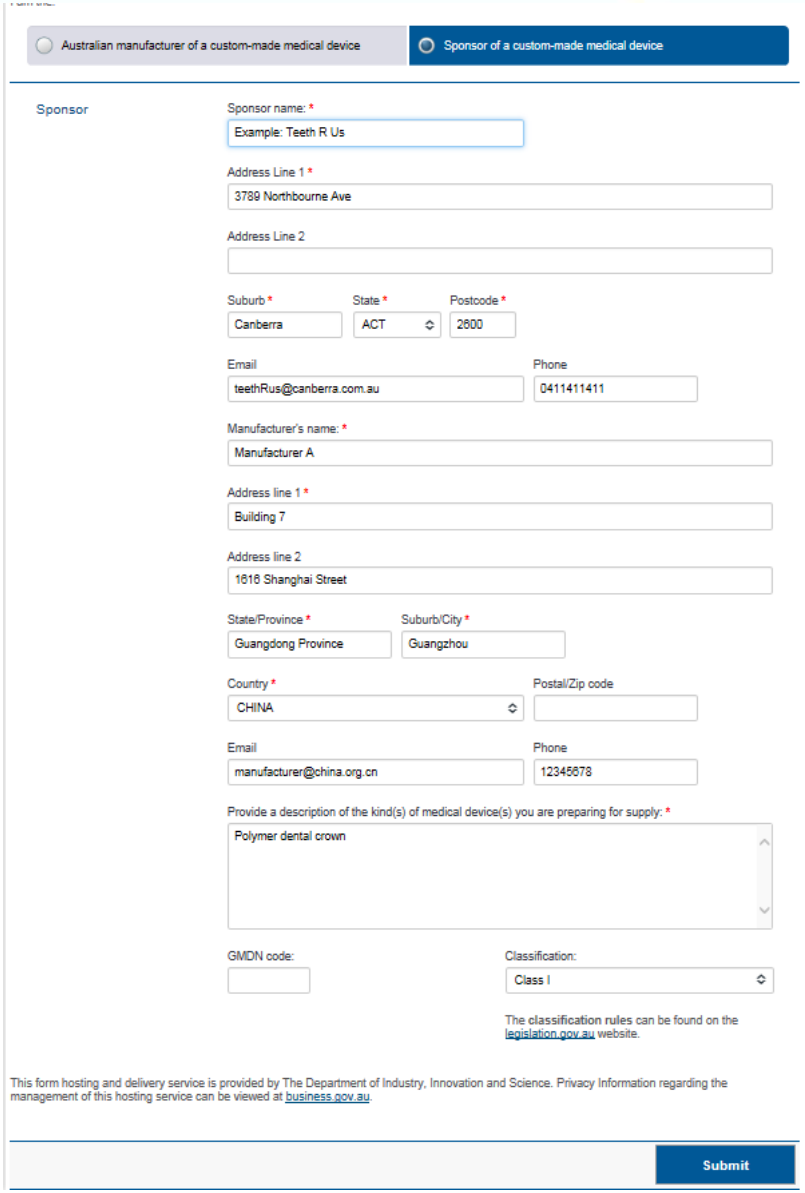

Australian manufacturer of a custom-made medical device

Sponsor of a custom-made medical device

Sponsor

Sponsor name: *
Example: Teeth R Us

Address Line 1 *
3789 Northbourne Ave

Address Line 2

Suburb *
Canberra

State *
ACT

Postcode *
2600

Email
teethRus@canberra.com.au

Phone
0411411411

Manufacturer's name: *
Manufacturer A

Address line 1 *
Building 7

Address line 2
1616 Shanghai Street

State/Province *
Guangdong Province

Suburb/City *
Guangzhou

Country *
CHINA

Postal/Zip code

Email
manufacturer@china.org.cn

Phone
12345678

Provide a description of the kind(s) of medical device(s) you are preparing for supply: *
Polymer dental crown

GMDN code:

Classification:
Class I

The classification rules can be found on the legislation.gov.au website.

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Submit

Other regulatory obligations

Essential Principles

- Regulations Schedule 1, Part 1 (general principles) and Part 2 (principles about design and construction)
- manufacturer must meet the applicable essential principles
- sponsor must ensure device meets applicable essential principles
- some EPs may not apply to the device (e.g. if the custom-made medical device is not supplied in a sterile state, the essential principles regarding sterility are not relevant and will not need to be met)
- some essential principles apply only to custom-made medical devices:
  - *information that must be provided with a medical device* - an indication that the device has been custom-made for a particular individual or health professional and is intended for use only by that individual or health professional must be provided with a custom-made medical device
  - *instructions for use* (if required) must include an indication that the device has been custom-made for a particular individual or health professional and is intended for use only by that individual or health professional
- there is an 'essential principles checklist' on TGA's website which may be helpful (not mandatory)

Other regulatory obligations

Conformity assessment procedures

The manufacturer is required to:

- prepare and sign a written statement containing specific information (detailed in the Regs sched 3 item 7.2)
- prepare documentation relating to the design, production and intended performance of the device (and keep the documentation up-to-date)
- take all measures necessary to ensure that the manufacturing process results in the device complying with the documentation mentioned above
- notify the TGA as soon as practicable of certain events that might lead (or might have led) to the death or serious deterioration of the state of health of the patient or user, or caused the manufacturer to recover a device that has been distributed. Examples of these events include malfunction, deterioration and inadequacy in the design, production, labelling or instructions for use.

The sponsor is required to ensure that the manufacturer has applied the conformity assessment procedures.

About the ‘statement’

Details to be included:

- name and business address of manufacturer
- information to identify the device
- statement that manufacturer intends device to be used only for a particular individual or health professional
- name of the individual or health professional
- name and business address of health professional that provided device specifications
- particular design characteristics or construction provided by health professional
- a statement that the device complies with the applicable essential principles, or a statement explaining which essential principles it does not comply with and reasons for the non-compliance

Statement to be signed and dated by an authorised person (from the manufacturer) and kept up-to-date

Therapeutic Goods Advertising Code 2015

General Principles

Section 4 sets out the key requirements including that therapeutic good advertisements **"must not"**:

- Mislead or be likely to mislead
- Arouse unrealistic expectations of product effectiveness
- Lead consumers to self-diagnosing, inappropriately treating or believing they have a serious disease
- Abuse consumers' trust or exploit their lack of knowledge
- Encourage inappropriate or excessive use
- Claim that a good is guaranteed, certain, sure cure or that the goods are completely safe or harmless
- Be directed to minors (subject to exceptions)

https://www.legislation.gov.au/Details/F2015L01787

Adverse events

What to report

What to report? Please report adverse events, as well as near misses

The TGA encourages the reporting of any suspected adverse event or potential adverse event relating to a medical device. Adverse events can involve actual harm to a patient or caregiver, or a near miss that may have resulted in harm.

Some issues relating to medical devices that may lead to adverse events and prompt you to report include:

- mechanical or material failure
- design issues
- labelling, packaging or manufacturing deficiencies
- software deficiencies
- device interactions
- user/systemic errors.

Suspected adverse events or near misses can be reported directly to the TGA:

- **online** at Report a problem
- **by emailing** iris@tga.gov.au
- **by mail** to IRIS, TGA, PO Box 100, Woden ACT 2606
- **by fax** to 02 6203 1713.

For more information about reporting, visit www.tga.gov.au or contact the TGA's Medical Devices Branch on 1800 809 361.

Summary

- Both manufacturers and sponsors/suppliers of custom-made medical devices have obligations
- ‘Custom-made’ has a specific meaning and is defined in the regulatory framework (not customised/adapted)
- Custom-made devices have specific requirements for information to be supplied with the device
- Custom-made devices are exempt from ARTG inclusion, but other obligations still apply
- Timeframe for notifying TGA of custom-made devices is 2 months
  - from initial manufacture (if manufactured in Australia)
  - from initial importation/supply in Australia (if manufactured overseas)
- Notifying TGA is only one obligation – others include:
  - device must meet essential principles
  - device must have had conformity assessment procedure applied
  - adverse events must be reported to TGA

Australian Government

Department of Health

Therapeutic Goods Administration