Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Frequently asked questions

Regulatory framework for personalised medical devices

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Contents

Introduction

The Therapeutic Goods Administration (TGA) has compiled these frequently asked questions to provide further clarity on the regulatory framework for personalised medical devices. This document should be read in conjunction with the guidance document Personalised medical devices (including 3D-printed devices): Regulatory changes for custom-made medical devices.

It is important that you read both the guidance document and the frequently asked questions before contacting the TGA with further enquiries.

General

What is and is not a medical device?

The definition of a medical device as set out in section 41BD of the *Therapeutic Goods Act 1989* (the Act) as follows:

> *(1) A **medical device** is:*
>
> *(a) any instrument, apparatus, appliance, software, implant, reagent, 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, prediction, prognosis, 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 or pathological process or state;*
>
> *(iv) control or support of conception;*
>
> *(v) in vitro examination of a specimen derived from the human body for a specific medical purpose;*
>
> *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, software, implant, reagent, material or other article specified under subsection (2A); or*
>
> *(ab) any instrument, apparatus, appliance, software, implant, reagent, material or other article that is included in a class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles specified under subsection (2B); or*
>
> *(b) an accessory to an instrument, apparatus, appliance, software, implant, reagent, material or other article covered by paragraph (a), (aa) or (ab); or*
>
> *(c) a system or procedure pack.*
>
> *Note: Declarations under subsection (3) exclude articles from the scope of this definition. Declarations under section 7 can also have this effect: see subsection 7(4).*

If a product you manufacture, import or supply meets the definition of a medical device, you are regulated by the TGA and have obligations that you will need to meet.

The information in this document specifically pertains to *personalised* medical devices.

What is a personalised medical device?

Personalised medical devices are medical devices that are devices that are specifically designed and manufactured, or adapted/modified, to meet the needs of an individual. The TGA uses three (3) specific terms to describe personalised medical devices:

- ***Patient-matched*** medical devices;
- ***Adaptable*** medical devices; and
- ***Custom-made*** medical devices.

Both patient-matched and custom-made medical devices are personalised *before* they are manufactured. Dental aligners, for example, are a patient-matched medical device that are designed in a software suite to suit a specific person **before** they are manufactured.

Adaptable medical devices are personalised *after* they are manufactured. A limb prosthesis, for example, is assembled using pre-manufactured components to meet the needs of a specific person.

It is important to understand what these definitions mean. Please refer to Personalised medical devices (including 3D-printed devices): Regulatory changes for custom-made medical devices for more information.

Who is the manufacturer, and what is a sponsor?

The definition of a ***manufacturer of a medical device*** can be found in section 41BG of the Act. You are strongly encouraged to read the definition to ensure you understand whether or not you are a manufacturer of a medical device.

Generally, the legal manufacturer is the person or entity who:

1. Takes responsibility for ensuring that a device is safe and fit for its intended purpose; and
2. Supplies the device as a medical device under their name.

This can include parties who:

- Produce medical devices themselves;
- Outsource production of medical devices to other parties; or
- Assemble, refurbish, package, label or assign the intended purpose to ready-made products produced by another party.

Please note: You ***will not*** meet the definition of a manufacturer if you assemble or adapt an already-supplied medical device to suit a particular patient, providing your assembly or adaptation does not change the intended purpose of the device that was assigned by the original manufacturer.

The definition of a ***sponsor*** as set out in Chapter 1, Section 3 of the Act is as follows:

> ***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.*

In short, the sponsor is the Australian-based legal entity who is responsible for ensuring that a device is legally imported into, exported from or manufactured and supplied within Australia. This includes healthcare practitioners who manufacture a medical device as a part of their clinical practice.

In most cases, an Australian manufacturer will also be the sponsor of their devices as they will be the first point of supply within Australia.

Devices imported from overseas must have an Australian-based sponsor. If you procure devices directly from an overseas manufacturer, then you meet the definition of a sponsor.

Sponsors are required to meet regulatory obligations associated with the supply of a medical device both before and after the device is imported and/or supplied including:

- Ensuring the device is included in the ARTG;
- Reporting adverse events associated with the device to the TGA; and
- Meeting advertising requirements.

A full list of the ongoing responsibilities for a medical device sponsor is available on the TGA website.

Custom-made medical devices

My devices are made for each individual patient. Doesn't that mean they are, by definition, custom-made?

No. Patient-matched devices are also designed and manufactured for individual patients. A custom-made medical device is a device that is made using manufacturing methods that cannot be validated, verified or reproduced, and which is produced only in rare circumstances where no other suitable patient-matched alternatives are available. If you are making a kind of device many times over using similar materials and methods, it is likely your device will meet the definition of 'patient-matched' and will require inclusion in the ARTG.

I make my device by hand. Doesn't that automatically mean it is custom-made?

No. Many mass-produced medical devices are also made or finished by hand (for example, porcine heart valves). If you are making a kind of device many times over using similar materials and methods, it is likely your device will meet the definition of 'patient-matched' and will require inclusion in the ARTG, even if it is made by hand.

Are there any devices that are always custom-made?

No. This is because the definition of a custom-made medical device is not determined by what kind of device it is.

Since when have I had to notify the TGA that I manufacture or supply custom-made medical devices?

The requirement under regulation 10.3 of the Regulations for Australian-based manufacturers and sponsors to inform the TGA that they are supplying a kind of custom-made medical device has been a requirement since 2002.

I still think my devices are custom-made. What happens if I don't apply to include them in the ARTG?

If your medical device does not meet the definition of a custom-made medical device, you must include it in the ARTG. If you are manufacturing, importing or supplying a medical device within, or exporting a medical device from, Australia without a valid inclusion in the ARTG, you may be subject to civil or criminal penalties (see section 41MI of the Act).

If you would like to discuss your specific circumstances, please contact personaliseddevices@health.gov.au.

Patient-matched medical devices

What is a specified design envelope?

The specified design envelope is the limits of design a manufacturer can be confident (with the support of objective evidence) will result in a medical device that is safe, and will meet the intended recipient's requirements (i.e. design validation). Factors that inform the specified design envelope could include:

- Industry standards;
- Clinical practice guidelines;
- Specialist training;
- Specifications for materials;
- Dimensions; and
- Tolerances.

Please note: objective evidence includes information given to you through tertiary study or during on-the-job training. While you may not have access to the specific clinical data that underpins the design and manufacture of the devices produced in your profession, as a professional in the field you are using an evidence-based approach to the design and manufacture of the devices you are producing.

What does process validation or verification mean? What about reproducibility?

Information about the meanings of the terms 'production validation' and 'verification' relevant to medical devices is provided in the guidance document for personalised medical devices. There are also other resources that may assist you including the Global Harmonisation Task Force document Quality Management Systems – Process Validation.

How do I know if I'm using raw materials to produce a patient-matched device or if I'm using an adaptable medical device?

There is confusion around when a person is manufacturing a patient-matched medical device using a raw material and when they are using an adaptable medical device.

The product is likely to be an **adaptable** medical device if:

- The product meets the definition of a medical device in the form that it is supplied, and only requires:
  - assembly or adaptation to suit the patient at the point of care; or
  - a final preparatory step is required because the intended purpose of the device means it cannot be supplied in a finished form (amalgam for a filling or bone cement, for example); and
- The manufacturer:
  - has included the product you are using in the ARTG; **and**
  - has included the product at the same classification as the device you are intending to produce; **and**
  - has stated that the intended purpose of the product is consistent with your intentions to assemble or adapt the device.

If **any** of the above conditions are not met, then the product is likely a raw material that you are using to produce a patient-matched medical device. If you are unsure, you should contact the manufacturer of the product to confirm whether or not it is their intention the product be an adaptable medical device or a raw material.

The raw material/component I'm using is included in the ARTG. Does this mean I don't have any regulatory obligations?

On 20 August 2021, refinements were made to the personalised medical devices framework, including a legislative instrument known as the *Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Personalised Medical Devices) Instrument 2021* came into effect. The instrument specifies some raw materials and components to be a medical device when they are intended to be used by a healthcare practitioner, or by someone who is working to instructions/directions provided by a healthcare practitioner.

If you are a healthcare practitioner, or someone who is working to instructions/directions received from a healthcare practitioner and you are using materials or components named in this instrument that have been included in the ARTG, the device you make will be **exempt from inclusion in the ARTG.**

You will still need to meet all other regulatory requirements for your medical device including:

- ensuring it meets all relevant Essential Principles (including supplying the devices with adequate labelling and instructions for use);
- reporting adverse events to the TGA; and
- meeting the advertising requirements for therapeutic goods under the TGA legislation including the Therapeutic Goods Advertising Code.

Find out more information about this instrument.

Medical Device Production Systems (MDPSs)

When can I apply to the TGA to include my Medical Device Production System (MDPS) in the ARTG?

While the definition of an MDPS has been included in the Regulations from 25 February 2021, this **will not take effect** until a subsequent legislative instrument declaring an MDPS to be a medical device is in place. This subsequent legislative instrument is likely to be drafted following work currently underway with the International Medical Device Regulators Forum (IMDRF) and the TGA has established regulatory structures to appropriately assess and evaluate these systems.

More information can be found in the guidance document on personalised medical devices. We will include further information and guidance about MDPSs at personalised medical devices as it is developed.

Can anyone use an MDPS?

No. MDPSs are only for healthcare professionals (or other suitably qualified people) working within a healthcare facility.

Can I use my MDPS to manufacture a custom-made or adaptable device?

No. MDPSs are only for the manufacture of a patient-matched medical device.

The ARTG inclusion process

How do I have my device approved by the TGA and included in the ARTG?

Comprehensive guidance on the process of having a device approved by the TGA for inclusion in the ARTG can be found on the TGA website. If you have any questions after reading the guidance you can contact the Medical Devices Information Unit between the hours of 8:30am-5:00pm Monday to Friday via devices@tga.gov.au or by phoning 1800 141 144.

What paperwork will I need?

The paperwork needed depends on:

1. The classification of the medical device; and
2. The conformity assessment procedures that need to be applied.

Additional information and resources will be published on our website as they are produced. Resources that may assist you include:

- The online classification tool;
- Declaration of conformity templates; and
- Guidance for meeting the evidence requirements for market authorisation.

Are there advantages to including my device in the ARTG?

Yes. Inclusion in the ARTG is the legal basis of supply for medical devices in Australia. ARTG inclusion can also be a requirement for eligibility to apply for tenders with healthcare facilities such as hospitals and, if the device is an implantable medical device, potential reimbursement through private health funds.

Do I have to include every individual device that I supply in the ARTG?

Inclusions in the ARTG are for a kind of medical device. A sponsor can supply multiple devices under the one ARTG entry if the devices are of the same kind.

Devices are considered to be of the same kind if they have the following characteristics:

- the same Sponsor;
- the same Manufacturer;
- the same Classification;
- the same Global Medical Device Nomenclature System Code (GMDN code); and
- for Class III, Class AIMD medical devices and Class 4 IVD medical devices (other than an immunohaematology reagent that is a Class 4 IVD medical device), the same unique product identifier (UPI).

For example, a sponsor can have an ARTG entry for a dental needle (Class IIa, GMDN 12740). The sponsor can supply dental needles of different lengths, widths, shapes, etc., as long as they share the same manufacturer, classification and GMDN code.

I work in a health service. Who needs to do the ARTG inclusion – each individual worker, or the business?

Applications for inclusions in the ARTG must be submitted by an Australian-based legal entity. Each business must decide the most appropriate entity to submit an application for inclusion in the ARTG based on their own unique structure and business model. Sponsors have regulatory obligations they must fulfil both before a device is included in the ARTG, and afterwards including:

- Ensuring the device is included in the ARTG;
- Reporting adverse events associated with the device to the TGA; and
- Meeting advertising requirements.

A full list of a sponsor's ongoing responsibilities once a device has been included is available..

I produce devices using TGA-approved materials. Do I need to include the devices I produce using these materials in the ARTG?

If you are:

- A relevant health professional practicing within Australia; or
- A relevant technical professional operating in Australia, at the direction of a relevant health professional practicing within Australia; and
- You are producing a patient-matched medical device using materials that have been included in the ARTG by the person who supplied them to you; and
- The ARTG-inclusion states that the materials are for use by a member of your profession, for the purposes you are using them for; then

You are exempt from needing to include the resultant patient-matched medical devices in the ARTG. **Please note that when a device is *exempt from inclusion in the ARTG*, it does not mean the device is exempt from TGA regulation entirely.** Manufacturers and sponsors of custom-made medical devices still have regulatory obligations that they must meet under TGA legislation, including ensuring that their devices comply with the Essential Principles, and that they have applied the relevant conformity assessment procedures to their products.

What are GMDN codes and terms?

The Global Medical Device Nomenclature (GMDN) is a list of generic names used to identify medical device product; including products used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans. GMDN Codes and Terms allow medical devices with similar features to be identified and are used by the TGA to assist in the:

- consistent assessment of medical devices before they are approved for supply;
- ongoing monitoring of medical devices once they are available for supply; and
- exchange of post market vigilance information between regulatory bodies.

All medical devices included in the ARTG have an associated GMDN Code and Term.

You can access the list of GMDN Codes and Terms by registering with the GMDN Agency.

How much does it cost to have my device approved by the TGA and included in the ARTG?

There are three (3) main costs associated with regulatory approval and inclusion in the ARTG:

- Costs associated with the conformity assessment procedures (including certification) that need to be applied to your device. Please note that if:
  - You are importing a medical device from a manufacturer who has obtained market authorisation for the device in a comparable overseas jurisdiction recognised by the TGA; and
  - The device is not a kind of medical device that is specified in regulation 4.1 of the Regulations, you may not need to undergo (and pay for) conformity assessment certification.
- The cost of an application to the TGA for inclusion in the ARTG , which is based on the classification of the kind of medical device; and
- The annual charge associated with maintaining an inclusion in the ARTG.

Once you have determined the classification of your device and what kind of assessment you require, you can review the information about fees and charges.

Please note: While the TGA can provide you with advice to help you navigate the regulatory requirements and understand your regulatory obligations, you are responsible for ensuring your device is correctly classified and meets all relevant regulatory obligations. The TGA is unable to provide definitive advice about the classification of a device outside of a formal application or investigation process.

I have read through this FAQ document and the guidance document and I still don't understand what I have to do. Where can I go for more advice?

TGA will continue to liaise with stakeholders and produce guidance and information to support stakeholders who are transitioning their devices to ARTG inclusion. You can find these resources at personalised medical devices or you can subscribe to receive this information directly by sending an email to devices@tga.gov.au with 'SUBSCRIBE PMD' in the subject line.

The TGA has engaged with more than 100 professional bodies across the health and technology sectors to develop and provide targeted information for each sector. You can find these resources at personalised medical devices, but you may also like to contact your peak body directly for assistance. If your professional body has not been contacted by the TGA,

they can request further information to support their membership by contacting PersonalisedDevices@health.gov.au.

SME assist is a dedicated service that TGA offers to help small to medium enterprises (SMEs), researchers, start-ups and those unfamiliar with regulation to understand their regulatory and legislative obligations. The SME website contains a range of resources to assist people who have not had dealings with the TGA before.

Regulatory affairs consultants offer services, including advice, on regulatory matters and can provide explicit advice about your specific devices.

Advertising personalised medical devices

Can I advertise personalised medical devices to consumers? Do the advertising rules apply?

Yes. You can advertise personalised medical devices to consumers, but you will need to make sure you meet all legal requirements for advertising medical devices. You can generally advertise to consumers as long as your medical device is:

- included in the ARTG; or
- exempt from ARTG inclusion because it is custom-made, or
- a patient-matched medical device that is not included in the ARTG, providing you have submitted a transition notification.

There are legal requirements around what you can say in advertisements. For further guidance on advertising requirements and links to other resources, see general requirements for advertising personalised medical devices to consumers and the TGA advertising hub.

My device is a ‘patient-matched’ or ‘adaptable’ medical device. Can I use the term ‘custom-made’ in advertising for my product?

Yes. You can use the term ‘Custom-made’ to describe a device, even if it meets the TGA definition of a ‘patient-matched’ device. ‘Custom-made’ has a recognised meaning in everyday language that is different from the definition used in regulations. Generally, you can use the term ‘custom-made’ to indicate that a device is designed and manufactured to suit an individual. You may also choose to avoid the term and use a similar term such as ‘custom’, ‘patient-specific’ or ‘fit-to-you’.

What types of testimonials and endorsements can I include in advertising for my product?

Check our guidance for using testimonials and endorsements in advertising for more information.

What kinds of comparisons can I use in advertisements?

Advertising must not contain any statement, image or design that, either expressly or by implication, compares the advertised medical device with other competing medical devices, where the comparison states or implies that the other medical devices are **harmful** or **ineffectual**.

For example, aligners and braces are both used to treat misaligned teeth. Comparisons can be made between aligners and braces in advertising, but the comparisons cannot express or imply that the other medical device is harmful or ineffectual.

Examples of statements that **could be used** when comparing aligners and braces:

- Is your child resisting traditional braces? They may prefer using aligners…

- On vacation? Forgotten your aligners? Should've gone with braces!
- aligners achieve faster results than traditional braces (when used as directed by your dentist)
    - This claim includes a qualifier in brackets and avoids a blanket statement. Blanket statements can mislead consumers
    - This comparison could be used if the advertisement includes references to robust scientific studies that support this claim
- braces can correct more extensive misalignments in your smile compared to aligners (by exerting more physical force than aligners)
    - This comparison could be used if the advertisement includes references to robust scientific studies that support this claim
- unlike braces, aligners allow you to enjoy your favourite crunchy foods!
    - This statement is factual and does not express or imply that the other medical device is harmful or ineffectual
- 90% of customers say they prefer aligners over braces
    - This comparison could be used if the advertisement includes references to robust scientific studies that support this claim

Examples of statements that **should not be used** when comparing aligners and braces:

- Braces are ineffective at straightening teeth compared to aligners
    - Comparisons cannot express or imply that other medical devices are ineffective
- Aligners are better than braces
    - This statement is unsubstantiated and could be considered misleading for implying that braces are ineffective compared to aligners
- Braces take forever to straighten teeth compared to aligners
    - This statement could be considered to be misleading and exaggerate how long it takes braces to straighten teeth, implying that braces are ineffectual

Can I advertise to other Health Professionals?

Yes. You can provide more information in advertising aimed at Health Professionals. This only applies if you take steps to ensure consumers cannot access this material. The requirements for advertising accessible to consumers are outlined in the Code and in Chapter 5 of the Act. Please see our guidance on advertising to health professionals for further information.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Devices Emerging Technology & Diagnostics Section	February 2021
V2.0	Updated to reflect user feedback, and to incorporate changes to the transition arrangements for patient-matched medical devices	Devices Emerging Technology & Diagnostics Section	March 2021
V3.0	Updated to reflect recent updates to the Regulations	Devices Emerging Technology & Diagnostics Section	July 2021
V4.0	Updated to reflect currency of the Framework after the close of the registration period for transitioning devices, and the publication of the Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020	Devices Emerging Technology & Diagnostics Section	August 2021
V5.0	Updated to include FAQs for advertising personalised medical devices	Devices Emerging Technology & Diagnostics Section	August 2022
V5.1	Updated to fix broken weblinks and update the link for advertising personalised medical devices to consumers	Devices Emerging Technology & Diagnostics Section	May 2023

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