Australian Government
Department of Health
Therapeutic Goods Administration

Personalised medical devices (including 3D-printed devices)

Regulatory changes for custom-made medical devices

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TGA Health Safety Regulation

Contents

Background and overview

On 25 February 2021, a new regulatory framework commenced changing the way the Therapeutic Goods Administration (TGA) regulates medical devices that are designed, manufactured, assembled or adapted to meet the particular needs of an individual person. The changes are collectively referred to as the personalised medical devices framework (the Framework).

Prior to the commencement of the Framework, most personalised medical devices were supplied in Australia as ***custom-made medical devices.*** Custom-made medical devices are exempt from the requirement to be approved by the TGA and included in the Australian Register of Therapeutic Goods (ARTG) before they are supplied, but are not exempt from other regulatory requirements for medical devices.

When a device is ***exempt from inclusion in the ARTG***, it does not mean the device is exempt from regulation. The exemption for custom-made medical devices is a *conditional exemption*. This means custom-made medical devices are exempt from inclusion in the ARTG before they are supplied providing they meet all other Australian regulatory requirements for medical devices.

Information about the regulatory requirements for custom-made medical devices is available in the Custom-made medical devices: Information for sponsors, health professionals & manufacturers guidance.

The exemption for custom-made medical devices was included in the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations) when they commenced in 2002. The definition at that time included any medical device designed and manufactured specifically for a particular patient or healthcare professional. At the time, custom-made devices were mainly low risk devices, usually supplied in lower volumes, and generally manufactured by accredited professionals who had received training and qualifications in medical device design and production. Other comparable regulators such as the US Food & Drug Administration and the European Commission included similar definitions of custom-made medical devices in their own frameworks.

Over the last two decades, the personalised medical device market has changed significantly. Access to low-cost materials, manufacturing equipment and the ability to produce and transmit digital patient data has resulted in an increase in the availability of personalised medical devices, and has meant that manufacturing in this sector is no longer limited to trained and accredited professionals.

Regulation of this sector has not kept pace with technological change. The challenge of appropriate regulation of these devices to ensure they are safe and fit for their intended purpose, and that independent oversight of their manufacture aligns with the public's expectations, is a global issue. Following extensive consultation and liaison with industry representatives from across the health and technology sectors and other regulators, the Australian Government introduced the Framework to meet these challenges. The Framework also aligns with guidance produced by International Medical Device Regulators Forum (IMDRF).

The Framework introduces new requirements for manufacturers and suppliers of personalised medical devices to ensure an appropriate level of safety and performance.

The Framework introduced the following:

- new definitions for types of personalised medical devices, greatly reducing the number of devices that can be supplied under the custom-made medical device exemption;
- new conditions of exemption for custom-made medical devices, in the form of requirements to:
  - submit an annual report detailing all custom-made medical devices supplied in the previous financial year;
  - allow the TGA to inspect production facilities;
  - retain documentation about custom-made medical devices for 5 years (for non-implantable devices) or 15 years (for implantable devices); and
  - provide information about each custom-made medical device to the intended recipient.
- the new concept of a Medical Device Production System (MDPS) which, once fully implemented, will provide options to healthcare providers wishing to produce personalised devices for treating their patients; and
- updates to the classification rule for medical devices that record diagnostic images to include a broader range of technology now used for the purposes of recording patient anatomy for diagnosis and investigation, including anatomical models.

This document provides information and examples to help you understand the Framework and meet your regulatory obligations. The intention of the examples is not to tell you how every device is regulated, but to provide information to help you identify the boundaries of concepts in the Framework so you can apply these concepts to your own circumstances.

Note

A decision tree has been included at Appendix 1 to help manufacturers and sponsors of medical devices identify how their personalised medical devices will be regulated under the Framework.

Other resources

The TGA understands that many manufacturers and suppliers of personalised medical devices are engaging with our organisation for the first time. There are a number of resources available to assist you including:

- Frequently asked questions (FAQ): answers to frequently asked questions raised by stakeholders about the Framework.
- The Australian Regulatory Guidelines for Medical Devices: a range of information relevant to anyone who manufactures, imports, exports or otherwise supplies medical devices in Australia.
- The medical device inclusion process guidance: a step-by-step guide to applying to the TGA for regulatory approval of a medical device.
- SME Assist: a dedicated service that the TGA offers to help small-to-medium enterprises (SMEs), researchers, start-ups and those unfamiliar with regulation to understand their legal

obligations. The SME Assist website contains a range of resources to assist people who have not had dealings with the TGA before, including an overview of medical device regulation.

- The Medical Devices Information Unit (MDIU) are available to assist you with specific enquiries Monday to Friday, 8:30am – 5:00pm (AEST). You can contact the MDIU on 1800 141 144 or via devices@tga.gov.au.

Part 1: New definitions for personalised medical devices

Personalised medical devices typically fall into one of two categories:

1. those that are commonly used in clinical practice, but for which it is ideal to either produce or adapt/modify/assemble on a case-by-case basis to suit the anatomy or physiology of the patient (for example orthotics, dental crowns or sockets for prosthetic limbs); and
2. those that are produced in circumstances where an individual's needs are so rare and unique that they cannot be catered to by any mass-produced medical devices.

Previously, most of these devices met the definition of a ***custom-made medical device*** and they were regulated in the exact same way, though they are clearly different. Devices that fall into the first category can be produced in greater quantities, allowing them to be studied, refined and standardised while devices in the latter category cannot. The Framework introduces new definitions for types of personalised medical devices that distinguishes between these two different scenarios and regulates them accordingly.

1.1 Patient-matched medical devices

Overview

The definition of a patient-matched medical device is:

> ***patient-matched medical device*** means a medical device that:
>
> (a) is manufactured by the manufacturer, within a specified design envelope, to match:
>
> (i) either or both of the anatomical and physiological features of a particular individual; or
>
> (ii) a pathological condition of a particular individual; and
>
> (b) is designed by the manufacturer (even if the design is developed in consultation with a health professional); and
>
> (c) is manufactured using production processes that are capable of being:
>
> (iii) either or both validated and verified; and
>
> (iv) reproduced.

Almost all of the devices that were previously supplied under exemption as custom-made medical devices will now meet the definition of a patient-matched medical device.

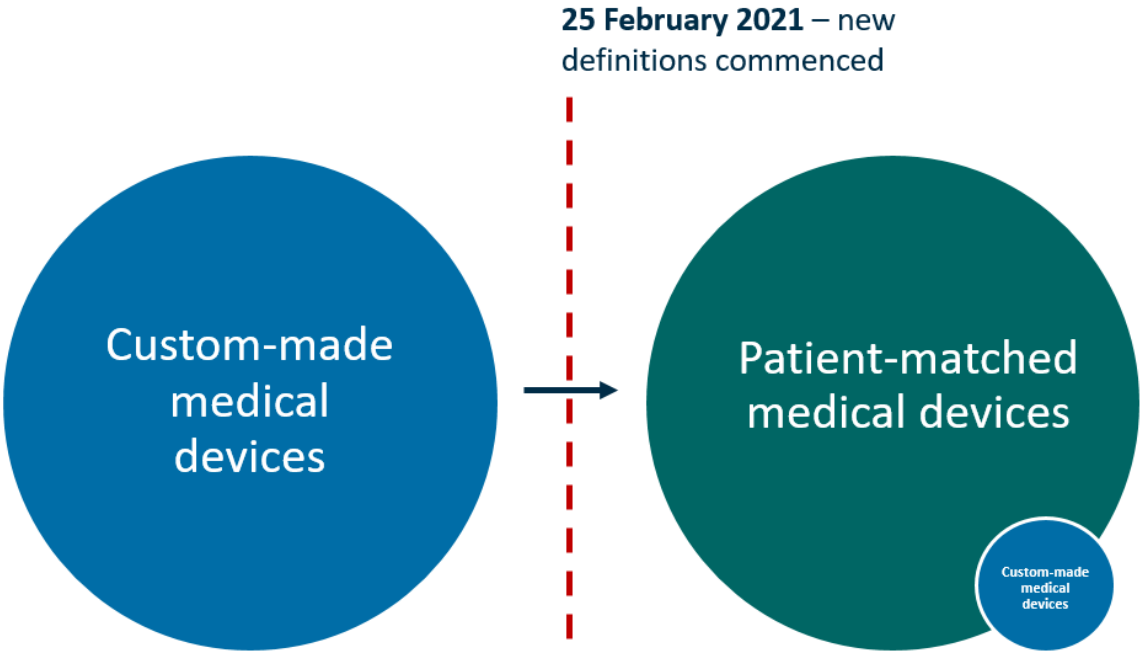


Figure 1. Under the Framework, almost all of the medical devices that previously met the definition of 'custom-made' will now meet the definition of 'patient-matched'. Only a small number of devices will continue to meet the definition of custom-made.

Patient-matched medical devices will need to be included in the ARTG before they can be supplied. There are transition arrangements in place that will allow manufacturers and sponsors of these devices time to come into compliance with the Framework. Accessing the transition arrangements will allow you to continue to supply your device until your application for inclusion in the ARTG is finalised. More information can be found in What you need to do.

Note

You will only need one ARTG entry per 'kind' of medical device that you manufacture or supply.

Specified design envelope

The definition of a specified design envelope, taken from the Regulations, is as follows:

> ***specified design envelope*** means minimum and maximum dimensions, performance limits or other relevant factors that:
>
> (a) characterise a medical device for production purposes; and
>
> (b) may be based on a standard device template.

The specified design envelope is the limits of design that 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).

A design envelope may include a number of factors, such as:

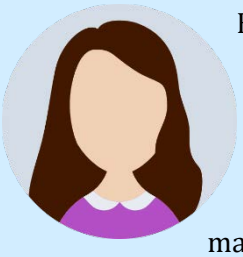
- minimum and maximum dimensions;

- performance limits;
- allowable environmental limits for operation; and
- specifications for materials and their properties.

Things that inform the specified design envelope could include:

- clinical research;
- industry standards;
- clinical practice guidelines;
- specialist education or training; and
- on-the-job experience producing and using medical devices.

Example – Specified design envelope



Eleanor is a podiatrist who produces patient-matched therapeutic insoles for her patients. As part of her technical documentation, Eleanor establishes a specified design envelope for these devices.

Eleanor considers the following:

- The range of pathologies she knows she can treat using her patient-matched insoles, based on her training and professional experience and supported by knowledge held by her profession more broadly;
- What design features she knows are suitable for use in treating each pathology (e.g. forefoot valgus wedge for treating plantar fasciitis);
- What materials she knows she can and cannot use for each kind of insole she produces; and
- The foot sizes she knows her equipment can and cannot accommodate.

While documenting this information, Eleanor notes that her specified design envelope is quite broad and consequently she is able to accommodate almost any patient who presents to her. This is because her devices and their use in clinical practice are very well-characterised within her industry. As a result, Eleanor is unlikely to ever need to produce a custom-made insole.

Production processes that can be validated and/or verified, and reproduced

Process validation, product verification and reproducibility are key concepts in medical device production.

Process validation refers to establishing by objective evidence that a process consistently produces a product meeting predetermined requirements. When used in the medical device context, process validation means a process has been subject to such scrutiny it can be virtually guaranteed to produce devices of a consistent quality. Both automated and manual processes can be validated.

Validation is particularly important if the predetermined requirements of the product can only be assured by destructive testing. Factors such as production volume and number of

manufacturing steps per unit may influence how process validation is undertaken. Manufacturers can, and should, seek out and select technology-specific guidance and applicable technical standards on applying process validation to their particular situation.

Verification refers to confirmation by objective examination of a product that the predetermined requirements of the product have been met. For example, measuring a device to ensure it has the required dimensions is an example of a verification procedure.

When process validation and product verification are applied, they result in production processes that will consistently produce devices that have similar characteristics, are of a similar quality and perform in a uniformly reliable manner. In other words, the outcome from the process is reproducible.

Note

It is important to note that the manufacture of some medical devices, including those manufactured using additive or subtractive methods require humans to be involved in the production process – providing hand finishing and verification activities, for example. The involvement of a human factor in a manufacturing process does not mean that a manufacturing process cannot be validated and/or verified and reproduced.

More information

Other resources that may assist you to better understand these concepts, include:

- the Global Harmonisation Task Force (GHTF) document Quality Management Systems - Process Validation; and
- ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes.

Example – Patient-matched medical device

Dean's company manufactures mass-produced orthopaedic implants, but has also developed a capability to personalise certain devices in their catalogue where necessary. Dean is contacted by an orthopaedic surgeon who needs a personalised acetabular cage and cup manufactured for Dorcas, an 81-year-old female patient who needs to undergo a revision procedure complicated by complete loss of the anterior column and marked bone loss through the remaining acetabulum.

Dean reviews the information sent through by the surgeon including Dorcas' age, height and weight, and determines that the design and production considerations for her device fall well within what his company knows it can produce (i.e. their design envelope). The surgeon sends through CT imaging data to help inform the design of the device, and consults with Dean's company on certain features such as how the device should attach to the bone. Dean employs the same production and verification methods to produce Dorcas' implant as he has dozens of other personalised devices.

In this example, the device meets the definition of a ***patient-matched medical device*** because it:

- has been designed by the manufacturer within a specified design envelope to fit the particular anatomy and physiology of a particular individual; and
- has been produced using a process capable of being validated and/or verified and reproduced.

Counter example

Dean is contacted again by the orthopaedic surgeon, this time to manufacture an acetabular for Jake. Jake is a 43-year-old male patient who is 2.26 metres tall and weighs 160 kilos. Dean has never made an implant for someone so tall or heavy, and Dean determines that the dimensions and tolerances of the implant required for Jake fall well outside the design envelope that his company has validated. The surgeon has spoken to several producers, and finds that Jake's requirements are not catered to by the design envelope of any patient-matched acetabular cage.

Dean uses the technical and design files to inform a modified device to meet Jake's requirements. He uses computer modelling to perform an engineering assessment to ensure the device he is producing will withstand the forces reasonably expected to be exerted during normal use, but does not have the capacity to conduct a full clinical assessment or evaluation for what will be a one-off design. Dean communicates with Jake's surgeon, who uses his expertise and clinical judgement to inform the design of the device. Jake is made aware that his device is truly unique and informed about the risks associated with its use.

Dean employs the same production and verification methods to produce Jake's implant as he has dozens of other personalised devices.

The resultant device meets the definition of a ***custom-made medical device*** because the device:

- is intended for the **sole use** of the intended recipient (Jake);
- has been made at the **request of a healthcare professional (the orthopaedic surgeon)**;

- who has **determined that there are no alternative devices available** on the ARTG to address the specific needs of this patient to an appropriate level; and
- does not meet the definition of a patient-matched or adaptable medical device.

In this case, while the manufacturing process can (and has) been validated, the device is being produced outside the design envelope. The resultant product therefore meets the definition of a custom-made device and will continue to be exempt from inclusion in the ARTG subject to the conditions outlined previously.

What you need to do

There is a transition period available that will allow you to continue to supply the device while you apply for an inclusion in the ARTG. To access the transition period, you will need to register with the TGA. If you access the transitional arrangements, the deadline for ARTG inclusion will be extended to **1 November 2024**.

To register for transition, ensure you have submitted and submit the online transition form **before 25 August 2021**.

Once you have submitted the form you will have until **1 November 2024** to undertake the appropriate conformity assessment procedures relevant to the classification of the device and submit an application for your device to be included in the ARTG.

Please note

If you do not notify the TGA of your devices **before 25 August 2021**, you must **cease supplying them from 25 August 2021** and not resume supply until you have an inclusion in the ARTG.

If you notify the TGA **before 25 August 2021** that you have a custom-made medical device that must transition to a patient-matched medical device, you will need to **submit an application** for inclusion **before 1 November 2024**.

If you then **do not submit your application by 1 November 2024**, you must **cease supply** on or before this date and not recommence until you hold an appropriate inclusion in the ARTG.

If your application for inclusion is rejected you are no longer eligible for the transition arrangements and must cease supplying your device immediately until such time as you have made a successful application.

Example – Transitioning manufacturer

Sakura's laboratory is based in Australia and makes retainers based on dental impressions supplied by dentists from around Australia. Under the new personalised medical devices framework, Sakura's dental retainers meet the definition of a patient-matched device and require inclusion in the ARTG before they can be supplied.

Sakura will need to:

- check the information on the TGA website to determine how many 'kinds' of medical device her retainers are (noting that, in her case, all of the retainers produced by her laboratory are one 'kind' of device);
- confirm the classification of her dental retainers using the online classification tool;
- register for transition using the online form **before 25 August 2021** so that she can continue to supply after this date;
- review the Essential Principles checklist and ensure she holds appropriate evidence to demonstrate that her dental retainers meet *all relevant Essential Principles*;
- apply the appropriate conformity assessment procedures relevant to the classification of her dental retainers, including making a declaration of conformity;
- make an application for an inclusion of the retainers in the ARTG **before 1 November 2024**; and
- pay the relevant application fee (Sakura has determined that her device is a Class I non-sterile, non-measuring device. Current fees and charges for medical devices indicate the application fee will be $550 with an ongoing annual charge of $90 to maintain the inclusion in the ARTG).

Sakura uses the medical device inclusion process guidance to help her navigate the process of including her device in the ARTG and to learn what her ongoing responsibilities will be.

Example – Transitioning sponsor

Muhammed is a dentist who chooses to source retainers for his patients directly from an overseas supplier. Muhammed meets the legal definition of a sponsor (the Australian legal entity responsible for meeting all relevant requirements associated with the devices) and will need to work with his overseas supplier to follow the exact same process as Sakura.

If you do not register for the transition period

If you do not register to access the transition period by 25 August 2021, you will not be able to manufacture or supply patient-matched medical devices until you hold a valid ARTG inclusion for the devices.

A guide to the medical device inclusion process is available on the TGA website.

1.2 Adaptable medical devices

Overview

From **25 February 2021**, the following definition of an adaptable medical device commenced in the Regulations:

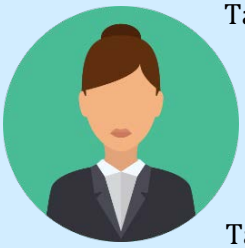
> ***adaptable medical device*** means a mass produced medical device that is intended by the manufacturer to be assembled or adapted after it has been supplied, in accordance with the manufacturer's instructions, to:
>
> (a) address either or both of the anatomical and physiological features of a particular individual; or
>
> (b) address a pathological condition of a particular individual; or
>
> (c) otherwise perform as intended by the manufacturer.

The definition has been included in the Regulations for the sake of clarity but there is no change to the way devices that meet this definition are regulated. Adaptable medical devices continue to be regulated through inclusion in the ARTG under an appropriate classification.

Information to be supplied with an adaptable medical device

Essential Principle 13.4(3 – item 30) applies to adaptable medical devices and requires manufacturers of these devices to ensure that any adaptable medical device that they produce is supplied with instructions for assembling or adapting the device that, if followed by intended users, will ensure the device continues to comply with all relevant Essential Principles.

Example – Adaptable medical device



Tamara's company supplies a mass-produced polymer surgical implant for cranial reconstruction that is:

- supplied in a sterile state; and
- intended to be thermoformed during the cranial reconstruction procedure to suit the individual patient's anatomical features.

Tamara's implant meets the definition of an ***adaptable medical device*** because it is:

- mass-produced; and
- intended by the manufacturer to be assembled or adapted after it has been supplied in order to address an anatomical feature of the intended recipient.

Under the new personalised medical devices framework this product will continue to require an inclusion in the ARTG before it can be supplied. It will also need to be supplied with instructions for use that will allow the surgeon using it to safely heat and shape the polymer to suit the patient's anatomy, ensuring the device continues to be safe and fit for its intended purpose after it has been adapted.

Counter example – not a manufacturer

Brett is a rehabilitation engineer. During a consultation, a patient who wears an off-the-shelf ankle-foot orthosis (AFO) asks for Brett's help as she is finding the AFO painful to wear. Brett reviews the AFO, and determines some minor adjustments can be made, such as the addition of some padding, to address this issue for the patient.

Brett wants to understand if he will become the manufacturer of an AFO if he makes these adjustments.

Brett reviews the information available on the TGA website and notes that under section 41BG(3) of the Act, a person does not meet the definition of a manufacturer 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.

Brett determines that the modifications he has made, while not necessarily intended by the manufacturer of the AFO, does not make him the manufacturer because the modifications do not change any of the features listed under (c) above.

Counter example – not an adaptable medical device

Peter is a dentist who sources an adaptable medical device system consisting of a dental implant, abutment and crown from a commercial supplier. While these components are able to be supplied separately, they are intended only to be used in conjunction with each other.

At a conference, Peter meets Tim, a local manufacturer of dental devices. Tim tells Peter that while he doesn't supply dental implants, he can produce abutments and crowns for the dental implants that Peter uses for far cheaper than Peter's current supplier. Peter checks the Instructions for Use for the implants he buys and notes it specifically states that they are not to be used with abutments and crowns sourced from other suppliers.

If Peter decides to source his abutments and crowns from Tim, he will be changing the intended purpose of the implants. Peter will therefore meet the definition of a manufacturer under section 41BG(3)(c)(iv) of the Act.

As a result, if Peter sources his abutments and crowns from Tim:

- Peter will meet the legal definition of a manufacturer of **all devices in the system, including the dental implant**;
- He will need to ensure he has appropriate conformity assessment certification (including clinical data) demonstrating the devices meet the Essential Principles when used together; and

He will need to include the devices in the ARTG under his own name.

What you need to do

If you are the manufacturer or sponsor of an adaptable medical device, you will need to:

- continue to include your devices in the ARTG prior to supply; and
- ensure the information supplied with the device conforms to the updated Essential Principle 13.4(3 – 30).

1.3 Custom-made medical devices

Overview

From **25 February 2021**, the definition of a custom-made medical device has changed.

> ***custom made medical device*** means a medical device that:
>
> (a) is intended by the manufacturer to be for:
>
> (i) the sole use of a particular patient (the ***intended recipient***); or
>
> (ii) the sole use of a particular health professional (the ***intended recipient***) in the course of the health professional's practice; and
>
> (b) is manufactured by the manufacturer in accordance with a written request of a health professional (the ***requesting health professional***) and with particular design characteristics specified by that health professional in the request (even if the design is developed in consultation with the manufacturer), where those design characteristics are intended to address:
>
> (i) either or both of the anatomical and physiological features of the intended recipient; or
>
> (ii) a pathological condition of the intended recipient; and
>
> (c) the requesting health professional has determined is necessary to address the matters covered by paragraph (b) because there is no kind of medical device included in the Register to address those matters or to address those matters to an appropriate level.
>
> However, a custom made medical device does not include a patient matched medical device, an adaptable medical device or other mass produced medical device.

Almost all of the devices that were previously supplied under exemption as custom-made medical devices will not meet the above definition, as they will instead meet the definition of a patient-matched medical device.

Both custom-made and patient-matched devices are designed and produced for a particular individual. The key difference between these definitions is that a custom-made device is so rare and unique that there is no way that the manufacturer can adequately validate the design of the device, or adequately validate and/or verify the production process, at the time it is requested. Custom-made medical devices can only be produced and supplied where a patient's particular circumstances mean that there is no other suitable device available in the ARTG for use in their treatment.

Table 1. Overview of some distinguishing features between custom-made and patient-matched medical devices

Type of personalised medical device	Designed and produced for the sole use of a particular individual?	Routinely-made by the manufacturer?	Is it feasible to collect objective evidence of the safety and performance of the device?
Custom-made	✓	✗	✗
Patient-matched	✓	✓	✓

Wherever possible, patients and health professionals should access medical devices that are supported by evidence of their quality, safety and performance. The custom-made medical devices exemption addresses the rare circumstances where the rarity of the clinical presentation and needs of the end-user limit the availability of evidence.

In circumstances where a device does meet the new definition of a custom-made medical device, there are new ***conditions of exemption*** that manufacturers and sponsors must meet in order to remain eligible to supply under the exemption. If the conditions are not met, the exemption will be revoked and the supply of the device without a valid inclusion in the ARTG will amount to illegal supply.

The conditions of exemption for custom-made medical devices relate to:

- information to be supplied with the device;
- record keeping requirements;
- annual reporting; and
- inspection and review.

Note

A custom-made medical device is only exempt from the requirements to be included in the ARTG provided all of the conditions of the exemption are met. If the conditions of the exemption are not met (the custom-made device is supplied without the patient statement, for example) then the exemption is automatically revoked, and the supply of the device will be an offence under 41MI of the *Therapeutic Goods Act 1989* (the Act). Penalties apply.

Examples – Custom-made medical device for a patient

Samara is an orthopaedic surgeon. Samara is asked to review a patient who presented to the emergency department with loss of elbow function and severe pain following a traumatic fall. CT imaging demonstrates significant injury to the radial head, with loss of viable bone throughout the proximal portion of the radius. Samara determines the radial head will need to be replaced in order to restore functionality to the elbow; however, the loss of bone in the proximal portion of the radius is significant.

Samara determines there is no device included in the ARTG that could be used to reconstruct the radial bone. She approaches a manufacturer of orthopaedic devices to request they produce a proximal replacement radius for the patient, making use of the patient's own bone to form part of both the matrix and reinforcement component of the replacement implant. Samara uses her knowledge and experience as an orthopaedic surgeon to determine key design characteristics (including the angle of the radial head to the stem and the composition of materials) that should provide the best outcome for the patient.

Samara provides these characteristics and the patient's CT scanning data to the manufacturer to help inform part of the design. The manufacturer designs and produces a proximal radial implant for the patient based on the information supplied by Samara.

In this example, the proximal radial implant is a ***custom-made medical device*** because the device:

- is intended for the **sole use** of the intended recipient;
- is **designed with particular design characteristics (e.g. the angle of the radial head to the stem) specified by a health professional (Samara)** to address the **anatomical features** of the intended recipient;
- was manufactured because there were **no alternative devices available** on the ARTG to address the intended recipient's needs to an appropriate level, owing to the degree of injury and its rarity;
- **does not meet the definition of a patient-matched medical device** because although the manufacturer has experience with these types of device, the degree of bone loss means they have had to design this device well outside the parameters of their specified design envelope; and
- **does not meet the definition of an adaptable medical device** because the device is not mass produced, and is not intended to be adapted after supply.

Example – custom-made medical device for a health professional

Tony is a gastroenterologist who has lost some dexterity as a result of nerve damage sustained during an accident. He employs a biomedical engineer to design and manufacture a modified steering mechanism for an endoscope to help him manage the loss of dexterity, thereby allowing him to continue operating the endoscope safely. Tony dictates the design characteristics that he will need for the steering mechanism including the level of responsiveness needed.

The engineer devises a solution to fit. In this example, the steering mechanism will meet the definition of a **custom-made medical device** because the device:

- is intended for the **sole use** of the intended recipient (the gastroenterologist);
- is **designed by a health professional (Tony)** to address the **physiological features of the intended recipient**;
- was manufactured because there were **no alternative devices available** in the ARTG to address the intended recipient's needs;
- **does not meet the definition of a patient-matched medical device** because it has been produced outside of the manufacturer's specified design envelope as a one-off for Tony; and
- **does not meet the definition of an adaptable medical device** because it is not being mass-produced, and it is not intended to be adapted after supply.

Counter example – not a custom-made medical device

Sharni's company produces personalised maxillofacial plates that can be manufactured to suit a patient's unique anatomy. DICOM files are sent to Sharni by each referring surgeon. Sharni imports the DICOM file data to her computer-aided design and manufacture (CAD/CAM) program and designs a plate to fit the patient's specific defect.

Sharni confirms the design with each requesting surgeon before commencing production of the final device.

Sharni's maxillofacial plates will not meet the definition of a custom-made medical device because they are manufactured:

- within a specified design envelope; and
- using production processes that can be validated and/or verified, and reproduced.

Sharni's plates meet the definition of a ***patient-matched medical device*** and Sharni will need to either:

- include the devices in the ARTG before they are supplied; **or**
- register the devices for transition to ARTG inclusion by 25 August 2021 and submit an application for inclusion by 1 November 2024.

Information to be supplied with your device

Since 2002, manufacturers of custom-made medical devices have been required to prepare written statements in relation to each of the custom-made devices they manufacture. **Under the new Framework, these statements must be supplied with the devices.**

The statements must include at minimum the following information:

- the name and business address of the manufacturer;
- information to allow the intended user and/or their health professional to identify the device or, where relevant, the contents of the packaging;
- the name of the individual who is the intended user of the device;

- a statement to the effect that the device is intended to be used only in relation to the particular intended user;
- the particular design and/or construction characteristics that the health professional specified;
- the name and business address of the health professional who provided the specifications for the device; and
- a statement to the effect the device complies with the *applicable* provisions of the Essential Principles. If the device does not comply with all *applicable* provisions, then a statement must be included explaining which provisions it does not comply with and the reasons why.

The statement must be signed and dated by a person authorised by the manufacturer, and include details of the person's name and position. Manufacturers may choose to use the statement template developed by the TGA and included as Appendix 2 to this document in order to meet these requirements. Manufacturers may choose to supply the statement digitally, provided sufficient information is provided with both the statement and the device to allow the user to correctly match the two.

Note

Manufacturers should note that the requirement to supply these statements is in addition to the requirements of all medical device manufacturers to supply particular information with their devices under Essential Principle 13 of Schedule 1 of the Regulations.

If the device is of a kind that is required under Essential Principle 13A to be supplied with a patient implant card (PIC) or patient information leaflet (PIL), the manufacturer may choose to include the required PIC/PIL information in the statement to be supplied with the device. More information on PICs and PILs can be found on our website.

What level of information should be provided in the statement?

The level of information that will need to be supplied in the statement will differ between devices, but it must be sufficient to allow the patient, the requesting health professional and any other person who may be involved in the patient's care (both now and in the future) to make informed decisions that will:

- ensure the device continues to perform as intended;
- ensure the device can be maintained and used safely for the length of its intended life; and
- ensure risks associated with the use of the device can be appropriately managed.

Manufacturers of custom-made medical devices should consider, but not limit their thinking to, the following:

- Will the intended user need to see a health professional other than the health professional that requested the device about their presenting issue, or a related issue, in the future?
- What kind of information might be needed to safely perform a revision procedure, re-fit, or a modification of the device?
- What kind of information might be needed to safely maintain the device?

- What is the expected clinical course for this patient, and what other kinds of health professionals might be involved in their care? What might they need to know?

Record-keeping requirements

Manufacturers and sponsors of custom-made medical devices must maintain records relating to the devices they have supplied in Australia for:

- a minimum of **5 years** after the date of manufacture if the device is **non-implantable**; or
- a minimum of **15 years** after the date of manufacture if the device is **implantable**.

If you are not sure whether a device you manufacture or supply is implantable, please review the definition in the dictionary section of the Regulations.

What information must be kept on record?

At a minimum, manufacturers and sponsors of custom-made medical devices should maintain:

- a copy of the statement described in 3.2 Information to be supplied with your device;
- annual reports relevant to the device;
- evidence that the device conforms to the Essential Principles; and
- any other documentation that they determine is needed to show that the conditions of the exemption have been met when each device was supplied.

Annual reports

Manufacturers and sponsors of custom-made medical devices must supply an annual report detailing all of the custom-made medical devices they have manufactured and/or supplied within the past financial year (1 July – 30 June). The annual report will be submitted via an online form that will be available on the TGA website.

Annual reports must include:

- the date you notified the TGA you are manufacturing/supplying a custom-made medical device through the online reporting form;
- the number of devices supplied in the financial year you are reporting; and
- a declaration that you have reported adverse events associated with the use of your devices to the TGA through the online reporting system.

Note

There are penalties associated with failing to provide an annual report to the TGA.

Inspection and review

The TGA has the legal authority to demand that manufacturers and sponsors of custom-made medical devices produce certain information, and allow authorised officers to inspect premises that form part of the supply chain of a custom-made medical device.

Table 1. Obligations of manufacturers and sponsors of custom-made medical devices relevant to inspections

Obligation	This means that
Allow entry and inspection of premises	An authorised person (a delegated departmental officer) may: • enter at any reasonable time any premises – including premises outside of Australia – that is a part of the supply chain for the custom-made medical device and: – inspect those premises; – inspect the device or anything on the premises that relates to the device including: ▪ examining; ▪ taking measurements; or ▪ conducting tests on, or requiring tests to be conducted, on the device or any aspect of the manufacturing facility for the device; and – make any still or moving image or any recording of those premises of any things on those premises.
Produce documentation	An authorised person (a delegated TGA officer) may request documentation of any kind relating to the custom-made medical device including, but not limited to: • a copy of the original health professional's request for the device; – in cases where the health professional is the manufacturer, this could be a document outlining the clinical notes taken to inform design of the device. • any information supplied with the device; and • evidence of conformity assessment documentation.

Note

Inspections are typically initiated in relation to adverse events associated with the device. The TGA will typically provide at least two (2) weeks' notice of routine domestic inspections, and four (4) weeks' notice of routine international inspections. Notice periods may differ where inspections are being performed as part of serious compliance investigations.

What you need to do

Manufacturers and sponsors of custom-made medical devices must:

- notify the TGA within two (2) months' of first manufacturing or supplying a 'kind' of custom-made medical device using the online reporting form;
- ensure statements are supplied with each device;
- retain records about the device(s) supplied by you for five (5) or fifteen (15) years, depending on whether or not the device is implantable;
- if requested, allow an officer of the TGA to enter the premises where the device was manufactured for the purposes of inspection, or supply any requested documents relating to the device; and
- supply an annual report to the TGA at the conclusion of the financial year (reports are due by **1 October**).

1.4 Medical Device Production Systems (MDPS)

Overview

Please note

Medical Device Production Systems (MDPS) are a new regulatory concept, designed to provide options to healthcare facilities wanting to produce patient-matched device in-house for treating their patients.

The TGA is currently working with a number of stakeholders, including the IMDRF, to ensure appropriate procedures and processes are in place to enable the safe introduction of this new concept.

For this reason, while the definition of an MDPS has been included in the Regulations from 25 February 2021**, this facility is not currently available and an MDPS cannot be approved by the TGA or included in the ARTG at this time.**

If you are a health professional currently using a system to produce patient-matched medical devices, you currently meet the definition of a manufacturer under section41BG of the Act and will need to ensure you are meeting your regulatory obligations by registering for transition.

If you would like to be notified when MDPS can be approved, please subscribe to the Medical Devices Information email list.

The definition of a Medical Device Production System (MDPS) in the Regulations is:

> ***medical device production system*** means a system that consists of raw materials and main production equipment (whether or not the system also consists of software), **where the system is intended by the manufacturer to be used** (whether or not with ancillary inputs or equipment) by a health professional, or suitably qualified person within a healthcare facility, **to produce a particular medical device** for use in relation to a patient of the health professional or healthcare facility.

An MDPS is a validated, multi-component design and production system intended to produce a patient-matched medical device within a healthcare facility.

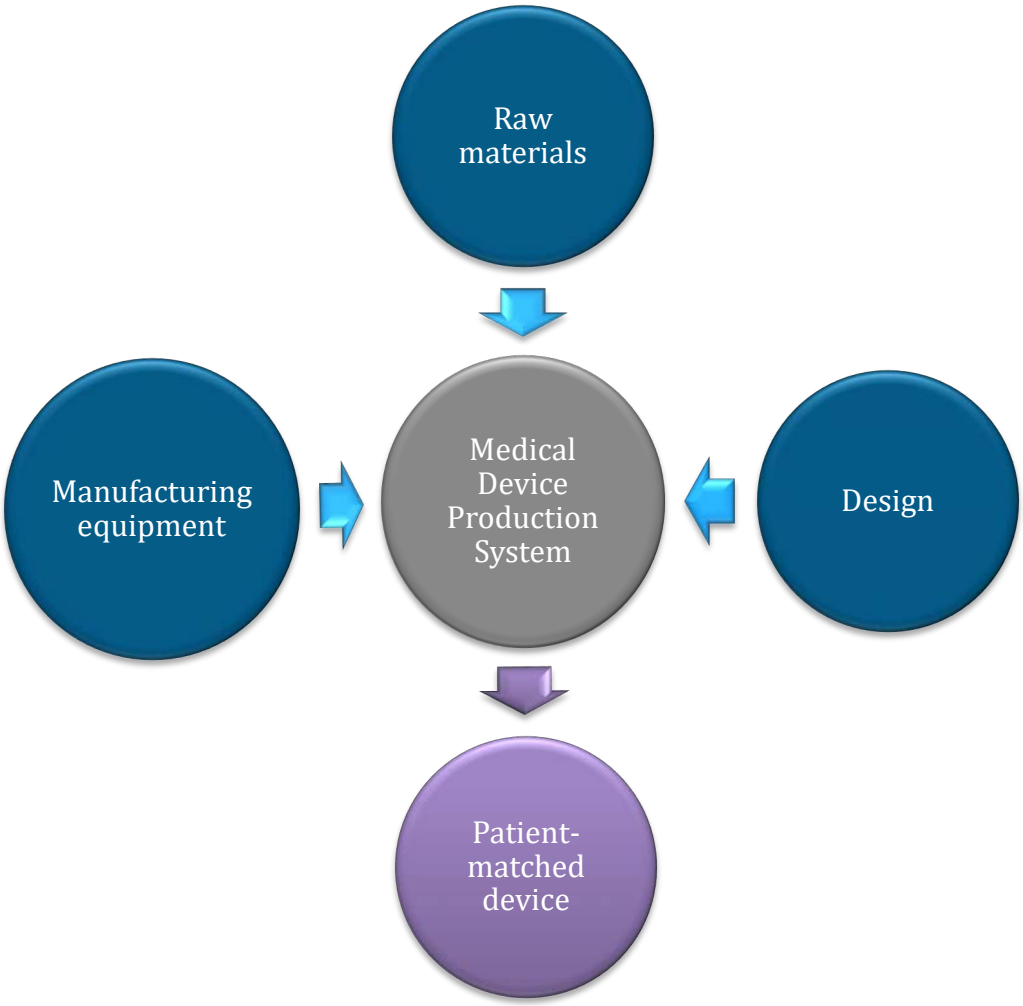


Figure 2. A Medical Device Production System (MDPS) consists of all the required components to produce a patient-matched medical device, from raw materials to production equipment.

Where a manufacturer includes an MDPS in the ARTG, the conformity assessment process for the MDPS will include the resultant devices. When a healthcare professional or suitably qualified person within a healthcare facility within a healthcare facility uses an MDPS that has been included in the ARTG to manufacture a patient-matched medical device, they will not be required to:

- undergo a conformity assessment for the patient-matched device they are manufacturing; or
- include the device they are manufacturing in the ARTG.

Users of MDPS

Once the MDPS facility is available, if you are a health professional or suitably qualified person within a healthcare facility who produces patient-matched medical devices, you will be able to supply devices providing:

- you purchase and use an MDPS that has been included in the ARTG; **and**

- you only use the MDPS to produce devices in accordance with the intended purpose and instructions for use as stated by the manufacturer.

Note

If you:

- manufacture medical devices from a production system **not included in the ARTG as an MDPS; OR**
- use an ARTG-included MDPS to produce a medical device **other than the kind of medical device intended by the manufacturer of the MDPS**;

then you will need to meet all regulatory requirements associated with the manufacture and supply of a medical device.

By using an ARTG-included MDPS in accordance with the manufacturer's instructions, you will not need to:

- apply the relevant conformity assessment procedure yourself to the patient-matched devices produced by the MDPS; or
- include the patient-matched medical devices produced by the MDPS in the ARTG before you supply them to a patient.

Examples – Medical Device Production System (MDPS)

Example 1 – Using an MDPS to produce devices as intended by the MDPS manufacturer

Kate has developed a ceramic milling system that she intends to include in the ARTG and supply to dentists, who can use the system to produce patient-matched dental crowns for adult patients. These crowns are to be used with standard dental implants and abutments from a line that Kate's company also supplies. The system incorporates:

- ceramic blocks;
- a ceramic milling machine;
- a furnace for firing;
- post-machining finishing equipment; and
- CAD/CAM proprietary software that:
  - reads files generated from intraoral scans;
  - designs a patient-matched dental crown for a particular patient according to the scans; and
  - controls the production equipment.

Kate intends to restrict use of the MDPS to dentists, dental nurses and dental technicians in accredited practices that have attended a training course in how to safely use and maintain the MDPS.

This system meets the definition of an MDPS because:

- Kate has specifically intended for it to be an MDPS;
- it includes raw materials and main production equipment intended to be used together as a system;
- the system is intended by the manufacturer to be used by dentists in their capacity as health professionals; and
- the system is intended to produce personalised medical devices for patients of the dental clinic.

Example 2 – Using an MDPS to produce a device other than intended

Achara is a dentist who wants to buy an MDPS from Kate for use in her practice. Achara has previously used a supplier in China to procure zirconia blocks for far cheaper than what Kate is offering to sell them for as part of the MDPS. Achara wants to know if she can swap out Kate's blocks for the ones she imports herself.

If Achara uses materials other than those supplied by Kate's company, she will meet the definition of a manufacturer because she is not using the MDPS in accordance with Kate's Instructions for Use, as validated through the conformity assessment process.

Kate's company cannot account for the composition of non-genuine materials, and so cannot accept responsibility for ensuring that any devices produced using it are safe and fit for their intended purpose. **Given also that the crown is not used in isolation but as part of a system with the dental implant and abutment, the use of non-genuine materials would mean that Achara becomes the legal manufacturer of these components as well.** Achara

would therefore become the legal manufacturer of all three of these components, and would need to meet all of the relevant regulatory obligations as the manufacturer of a medical device, including undergoing an appropriate conformity assessment certification process through a third party (noting that a dental implant is a Class IIb medical device *at minimum*).

Counter example – A production system that is not an MDPS

A team of medical physicists working in a hospital radiation oncology department have put together a system for producing 3D-printed, patient-matched (medical device) boluses in-house for their patients. The physicists have put the system together themselves, selecting raw materials, design and production equipment based on their expertise. The team does not plan to commercialise its system to sell on to other hospitals.

✘ The team members *are not* using an MDPS because the system has not been supplied to them by a third party as a complete system, they have put it together themselves; and

✘ The physicists *are not* the manufacturers of an MDPS because they do not intend to supply the system.

✓ The physicists *are* manufacturers of *patient-matched medical devices* and will need to submit an application for inclusion of their boluses in the ARTG.

Who is a health professional or a suitably qualified person within a healthcare facility?

The Regulations define a health professional as:

> ***health professional*** includes a person who is:
>
> (a) a medical practitioner, a dentist or any other kind of health care worker registered under a law of a State or Territory; or
>
> (b) a biomedical engineer, chiropractor, optometrist, orthodontist, osteopath, pharmacist, physiotherapist, podiatrist, prosthetist or rehabilitation engineer.

It is recognised that professionals not listed in the definition above may also work in healthcare facilities and:

- provide healthcare services; or
- support health professionals to deliver healthcare services.

This includes, but is not limited to:

- allied health assistants;
- speech pathologists
- medical physicists;
- clinical scientists;
- orthotists;
- occupational therapists;

- medical and dental laboratory technicians or technical officers;
- prosthetic subspecialties (e.g. ocularists, anaplastologists); and
- dental technicians.

The degree to which any user is 'suitably qualified' to operate an MDPS will depend upon the device to be produced, the complexity and needs of the system, and the training and experience held by, or available, to them. **The manufacturer of an MDPS will be required to state in the instructions for use the requirements they have of a 'suitably qualified' user.** This could include minimum qualifications and experience, job title or classification, accreditation by a third party and/or attendance at training courses run by the manufacturer.

Note

If the manufacturer's explicit instructions regarding who should be operating the MDPS are not followed, then the MDPS is not being used in accordance with the manufacturer's instructions. As a result, the user of the system would be responsible for all relevant regulatory obligations as a manufacturer and sponsor of a patient-matched medical device.

Supplying devices without an ARTG inclusion is a breach of the Act. Civil and criminal penalties apply.

Manufacturers and sponsors of an MDPS

If you are the manufacturer or supplier of a Medical Device Production System (MDPS), you will need to ensure that:

- the appropriate conformity assessment procedures have been applied to the MDPS relevant to its classification, demonstrating it, and all devices it produces, meet all relevant Essential Principles; and
- the MDPS is included in the ARTG with the same classification as the highest class of device it is intended to produce.

The TGA recognises that the concept of an MDPS is new, and that manufacturers and sponsors may need assistance to ensure they comply with the Regulations. You may wish to contact PersonalisedDevices@health.gov.au to discuss your specific circumstances.

Example – Medical Device Production System (MDPS)

Zane leads a research team that has developed a system for the production of patient-matched, 3D-printed splints for use in immobilising patients' arms while broken bones heal. Zane intends to commercialise the system and sell it to hospitals as an MDPS, allowing orthopaedic departments to produce patient-matched 3D-printed splints in-house.

The system is comprised of some components manufactured by Zane and some sourced from other manufacturers. The system consists of:

- CAD/CAM software that provides instructions to the system;
- a 3D printer;
- raw materials; and
- tools for finishing the devices produced (e.g. sandpaper for sanding down support struts leftover from the printing process).

Before they can apply to the TGA to have their MDPS approved and included in the ARTG, Zane and his team will need to apply the appropriate conformity assessment procedures and ensure that all of the relevant Essential Principles are met both for the MDPS and the devices it produces.

Zane will need to take into consideration a number of factors including:

- ***Who is the manufacturer?*** Even though Zane's team only produces certain components of the system, they will be the legal manufacturer of the MDPS under section 41BG(2) of the Act because they will be responsible for assigning to the system its purpose through labelling, Instructions for Use, advertising material and technical documentation.

  Zane will need to review the information about manufacturing medical devices available on the TGA website and ensure he understands the obligations he and his team will now have. He will need to manage third-party suppliers (including the producers of the components) under his quality management system to ensure they continue to provide components / raw materials of sufficient specified quality, as well as holding, and being able to provide him with, suitable documentation as required by the Regulations.

- ***What must be supplied as part of the system, and what can be recommended?*** The splint functions best when it is sufficiently rigid so as to immobilise the fracture site, but not so stiff that it will crack when reasonably anticipated force is exerted on it (for example, if the patient were to fall or hit the splint on a door accidentally). Zane determines that the performance of the device is heavily dependent on the properties of the raw material from which it is produced. Zane selects a supplier to work with who can provide ongoing assurance that the raw materials supplied are of sufficient and consistent quality to be used in the production of the splints produced by the MDPS.

  Zane will supply the system to his customers with the raw material from this specific supplier, and will clearly state in the system's Instructions for Use that only the specific material from the specific supplier he specifies is to be used. If one of Zane's customers sources the same material from a different supplier and uses it to produce devices, they will be operating the system outside of the Instructions for Use and it is the user, and not Zane, who will assume all regulatory responsibility for the devices that are manufactured.

  Unlike the raw materials, the sandpaper for finishing the devices does not have any characteristics integral to the safety or performance of the end device. Zane's team can

choose to supply sandpaper with the system, or recommend a grade of sandpaper suitable for this purpose and allow the user of the MDPS to source their own sandpaper.

- ***Who is a suitable user?*** Zane and his team consider knowledge and skills necessary to both operate and maintain the MDPS to ensure it, and the devices it produces, continue to conform to the Essential Principles once the MDPS has been supplied. Zane and his team mandate minimum qualifications for the users of the MDPS, and put together a two-week training course that must be completed before the MDPS is used. Zane and his team enforce the user requirements by providing those who complete the training course with a unique passcode they must input into the MDPS before they use it. If the individualised passcode is not used, the MDPS will not start.
- ***How will the quality assurance procedures for the system be carried out and ensured?*** If the MDPS is not checked and calibrated at specified intervals, Zane and his team cannot guarantee the MDPS will continue to conform to the Essential Principles. In addition to the training course, Zane and his team decide they will automate as much of the quality assurance and quality control (QA/QC) processes as possible.

  They also plan to install safeguards into the system such as:

  – reminder notices to perform routine QA/QC tasks;

  – an automated feature that will shut down the MDPS if QA/QC is not carried out, is carried out inappropriately or if the pre-imposed limits are exceeded.

  Zane and his team will also commit to performing routine check-ins with their customers by visiting them on-site, using these visits to perform manufacturer-specific maintenance activities and to ensure trained users continue to use the MDPS as intended.

Information to be supplied with an MDPS

Essential Principle 13.4(3) includes a specific requirement for information to be supplied with an MDPS. Manufacturers of MDPSs must ensure they supply their systems with instructions to allow the end-user to produce a medical device that meets the Essential Principles.

These instructions should contain an explicit statement notifying the health professional or suitably qualified person within a healthcare facility using the MDPS that failure to follow the instructions for the system:

- could result in a device not meeting the Essential Principles, which means it may not be safe and fit for its intended purpose; and
- means they will be responsible for meeting all relevant regulatory obligations for manufacturers and sponsors of patient-matched medical devices.

Note

If an individual:

- produces a device not included in the manufacturer's intended purpose for the system; or
- modifies, changes or adapts the system outside the manufacturer's Instructions for Use; or

- fails to follow the manufacturer's Instructions for Use when using the system;

the individual will be responsible for meeting all relevant regulatory requirements associated with being a manufacturer and sponsor.

What you need to do

If you are the manufacturer or sponsor of a system that you intend to market in Australia as an MDPS, you should contact PersonalisedDevices@health.gov.au.

Part 2: Classification of diagnostic images and anatomical models

Overview

From **25 February 2021,** classification rule 5.4 has been updated to capture a broader range of technologies being used to record patient images.

(1) If:

(a) a medical device is intended by the manufacturer to be used to record patient images that are to be used for either or both of the following:

(i) the diagnosis or monitoring of a disease, injury or disability;

(ii) the investigation of the anatomy or of a physiological process; and

(b) the images are to be acquired through a method that relies on energy outside the visible spectrum;

the device is classified as Class IIa.

(2) A medical device that is an anatomical model (whether physical or virtual) that is intended by the manufacturer to be used for either or both of the following:

(a) the diagnosis or monitoring of a disease, injury or disability;

(b) the investigation of the anatomy or of a physiological process;

is classified as Class IIa.

(3) A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to generate a virtual anatomical model that is to be used for either or both of the following:

(a) the diagnosis or monitoring of a disease, injury or disability;

(b) the investigation of the anatomy or of a physiological process;

is classified as Class IIa.

There are transition arrangements available for manufacturers and sponsors of Class I, ARTG-included medical devices that meet the descriptions of devices in the classification rule. Information about the transition arrangements can be found in what you need to do. The transition arrangements will extend the deadline for updating an existing Class I ARTG entry to **1 November 2024**.

Note

A number of devices that record patient images from technologies such as CT, MRI and ultrasound are already classified as Class IIa or IIb via other classification rules. The classification of these devices will not change following the amendment to classification rule 5.4. If multiple rules apply to a device, then the device takes the highest classification that it is given by any applicable rule.

Example – Device that records patient-images using a method that relies on energy outside the visible spectrum

Viet manufactures intraoral scanners. The intraoral scanners are supplied as units consisting of a wand that uses near-infrared light to capture and record images of patient's mouths, connected to a wheeled unit that houses hardware and software that records the imaging data. Viet's devices are currently included in the ARTG under a Class I entry, but will be regulated as Class IIa devices from 25 February because:

- an intraoral scanner meets the definition of a medical device under section 41BD of the Act;
- the scanner unit records patient images used to investigate the anatomy; and
- the images are acquired through a method that relies on energy in the near-infrared region of the spectrum, including outside of the visible spectrum.

Example – Virtual anatomical model

Nicola has developed a photogrammetry app that can be installed on a smartphone. The app is intended to be used by an orthotist to help gauge the effectiveness of cranial orthoses in the treatment of plagiocephaly. The orthotist takes photos of an infant patient's head from different angles, and the app uses the photos to produce a 3D model of the patient's head.

Nicola's app will be regulated as a Class IIa device because it:

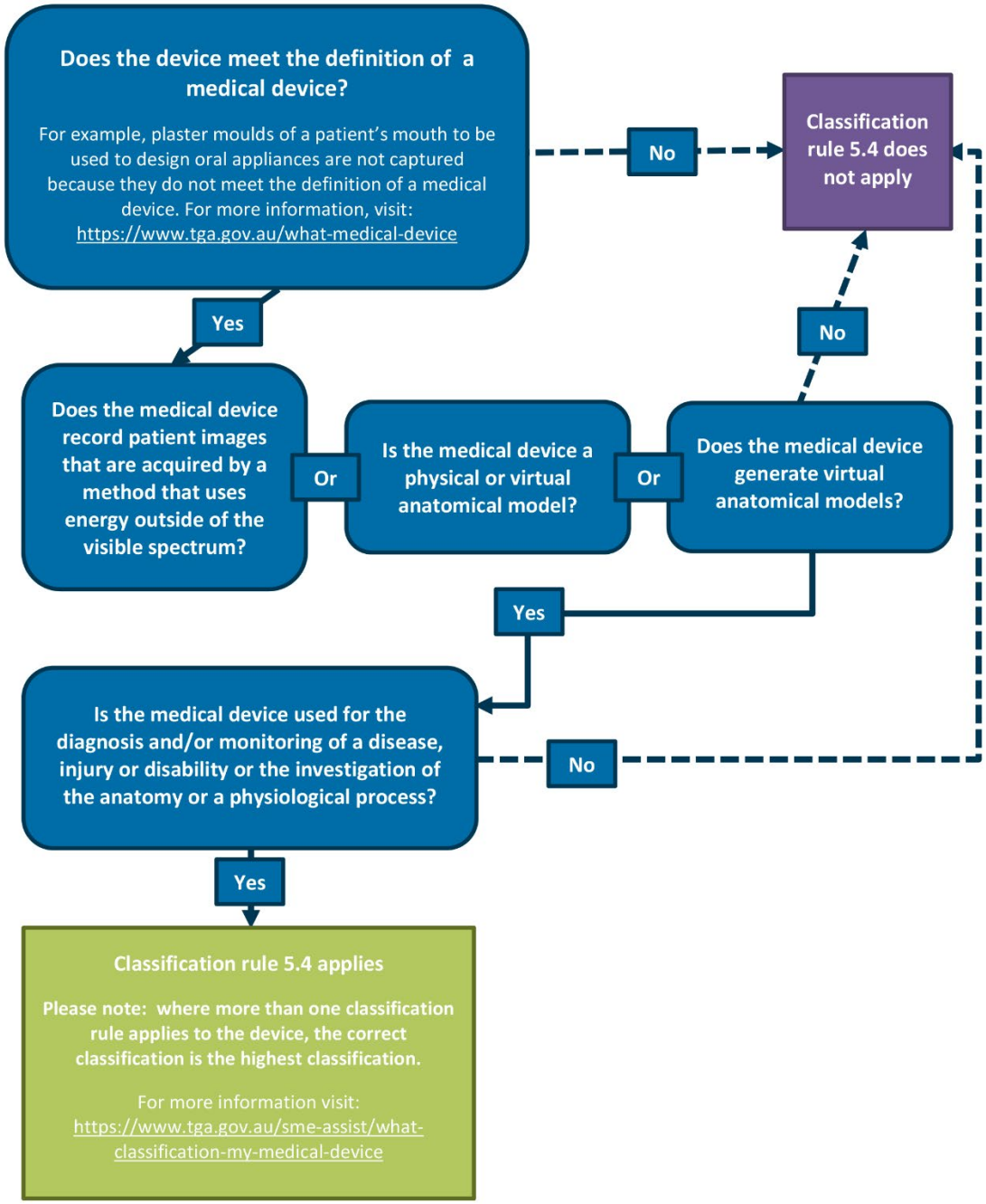
- meets the definition of a medical device under section 41BD of the Act (it is intended to be used for investigation of anatomy and physiology); and
- is intended by the manufacturer to be used to generate a virtual anatomical model that is to be used for the investigation of a physiological process as per Rule 5.4(2)(b).

Counter example – Camera

A health professional buys an off-the-shelf digital camera from a camera store and uses it to take photographs of patients with pectus carinatum to assess chest shape change. The camera is not impacted by these regulatory changes because:

- the camera does not meet the definition of a medical device under section 41BD of the Act; and
- the camera does not produce photographs using a method that relies on energy outside the visible spectrum.

Does classification rule 5.4 apply to my device?



Note

If a physical or virtual anatomical model is produced using a programmed or programmable medical device, or software that is a medical device, that is:

- already included in the ARTG; and
- is intended by the manufacturer to be used to produce that kind of anatomical model;

then the model itself **does not need to be included in the ARTG**.

What you need to do

The action you will need to take depends on whether or not the medical device was included in the ARTG before the Framework commenced on 25 February 2021.

For devices included as Class I in the ARTG before 25 February 2021

Transition arrangements are in place to ensure you can continue to supply your device while you apply for it to be included in the ARTG as a Class IIa medical device. Accessing the transitional arrangements will extend the deadline for updating an existing ARTG entry to **1 November 2024**.

If you would like to continue to supply your device under the transitional arrangements you must:

- register for transition using the **online form** **before 25 August 2021**;
- obtain the appropriate evidence of conformity assessment, as outlined in Table 2 above; and
- submit an application for your device to be included in the ARTG as a Class IIa medical device **before 1 November 2024**.

Note

If you do not intend to continue supplying the device beyond **25 August 2021**, you must cease supply, and should consider cancelling your inclusion.

If you **notify** the TGA of your devices **before 25 August 2021** but you do not **submit an application** for a Class IIa inclusion in the ARTG **before 1 November 2024**, you must cease supply your device from **1 November 2024** and consider cancelling your inclusion.

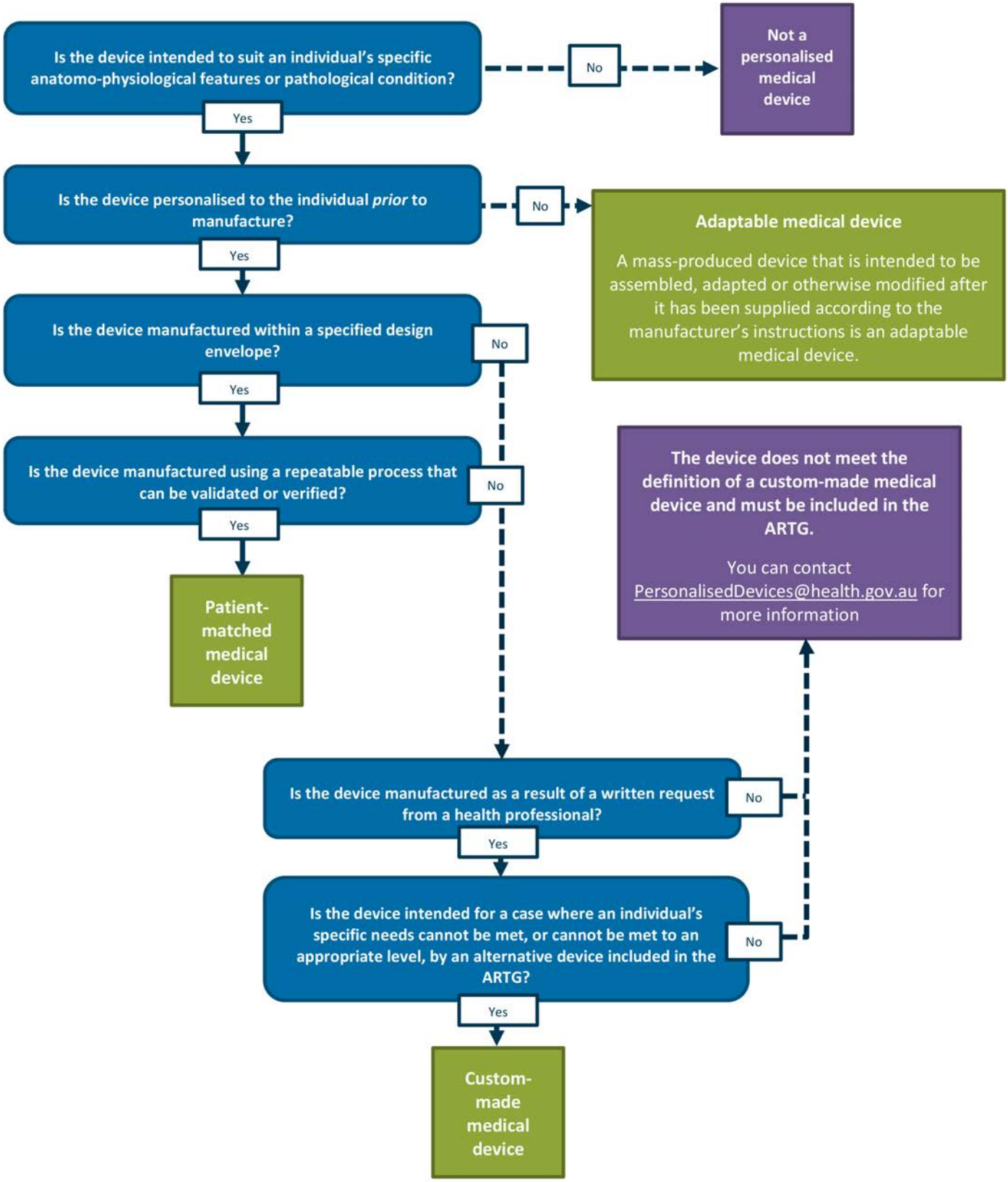
For devices supplied as custom-made medical devices before 25 February 2021

If you were manufacturing or supplying patient-matched anatomical models under the custom-made exemption before 25 February 2021, you will need to follow the instructions set out in the patient-matched medical devices section of this document.

For devices *not* included in the ARTG or supplied as a custom made medical device prior to 25 February 2021

If you are bringing a device to market after the Framework has commenced, you will need to apply to the TGA for approval and inclusion in the ARTG of your medical device at a classification of Class IIa. A guide to the medical device inclusion process is available on the TGA website.

Appendix 1: Personalised medical devices decision tree



Appendix 2: Statement template for custom-made medical devices

This statement is being supplied with a custom-made medical device in accordance with subclause 7.2(3A) of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations).

This custom-made medical device was manufactured by **[insert name and legal address of manufacturer]**. The device is a **[insert a brief description of the device, e.g., transtibial prosthetic sleeve]** that can be identified by the following features-

- ***Briefly outline any identifying features of the device e.g. any branding it may carry, the colour of the material, the size of the device etc.***

The device is packaged **alone/along with the following-**

- ***List all other contents of the packaging***

The device was custom-made for- and intended only to be used in relation to- **[insert the name of the individual to whom the device is intended to be used]**, according to specifications provided by **[insert the name and business address of the health professional who provided the specifications for the device]**.

The following **design and/or construction** characteristics of the device were specified by **[insert the name of health professional who provided the specifications for the device]** when they requested the device be manufactured:

Characteristic	Specifications
E.g. length	*15mm*

[Insert the name of the manufacturer] certifies that the device **complies/does not comply** with the applicable provisions of the Essential Principles of Schedule 1 of the Regulations.

If the device does not comply with any of the applicable provisions of the Essential Principles:

The device does not comply with essential principle/s ***[insert the numbers of the applicable Essential Principles that the device does not conform to]*** because ***[insert the reason for non-compliance]***.

This statement will be kept on file by [insert the name of the manufacturer] for **5 years [if the device is non-implantable]/15 years [if the device is implantable]**, in accordance with subclause 7.6(2) of Schedule 3 of the Regulations.

This statement was compiled by the person named below, in accordance with the requirements of subclause 7.2(2) of Schedule 3 the Regulations.

Name and position			
Signature		Date	

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Surveillance Branch	November 2020
V2.0	Updated to fix formatting issues	Medical Devices Surveillance Branch	December 2020
V3.0	Updated to reflect commencement of the Framework and updates to the legislation	Medical Devices Surveillance Branch	June 2021

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