Personalised medical devices (including 3D-printed devices)

Regulatory changes for custom-made medical devices

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Background and overview

Under the current medical devices regulatory framework custom-made medical devices are exempt from the requirement to be included in the Australian Register of Therapeutic Goods (ARTG). Since the introduction of the exemption in 2002, the technology and manufacturing processes used to produce medical devices have changed dramatically. Higher risk custom-made medical devices, including orthopaedic implants, are now available and their continued supply under the custom made medical devices exemption requires independent oversight.

The Therapeutic Goods Administration (TGA) has conducted extensive consultation and liaison with members of industry and other global regulators, designing a new framework for medical devices that are designed and manufactured for individual patients. Collectively these changes are known as the “personalised medical devices framework”. The framework has been introduced by the Australian Government to ensure an appropriate level of regulation is applied to personalised medical devices in order to manage the risks associated with their use.

Under the new framework, regulatory requirements which apply from 25 February 2021, will:

- introduce **new definitions for personalised medical devices**, thereby reducing the scope of the existing definition of a custom-made medical device;
- change the conditions of exemption for custom-made medical devices to:
  - require annual reporting of custom-made devices supplied in the previous financial year;
  - allow the TGA to inspect production facilities;
  - require documentation about the device to be retained for 5 years (for non-implantable devices) or 15 years (for implantable devices); and
  - require manufacturers to provide information about each custom-made medical device to the intended recipient.
- introduce the new concept of a Medical Device Production System (MDPS) and a framework for regulating these systems to allow healthcare providers to produce personalised devices for treating their patients, without the need for manufacturing certification; and
- **update 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.
1. New definitions for personalised medical devices

On 25 February 2021, changes to the Therapeutic Goods (Medical Devices) Regulations 2002 (‘the Regulations’) commence to introduce new definitions and regulatory requirements for therapeutic goods currently known as custom-made medical devices.

The impact of these changes is that the majority of the devices currently supplied under the custom-made medical device exemption will no longer be eligible for supply in this way. Personalised medical devices will be regulated in different ways depending on which of the definitions they meet.

- **Custom-made medical device**: the definition of a custom-made medical device will change to exclude devices that meet the new definitions of patient matched medical device or an adaptable medical device. While medical devices that meet the new definition of a custom-made medical device will continue to be exempt from inclusion in the ARTG, there will be new **conditions of exemption** that sponsors and manufacturers of these devices must meet from 25 February 2021.

  **Note**: Under the new personalised medical devices framework the majority of currently supplied custom-made medical devices will now meet the definition of a **patient-matched device**. Patient-matched medical devices will require inclusion in the ARTG before they can be legally manufactured, imported or supplied in Australia.

- **Patient-matched medical devices**: a patient matched medical device is a medical device that is designed and manufactured within a specified design envelope to match:
  - anatomical and/or physiological features of a particular individual; or
  - a pathological condition of a particular individual.
A patient-matched device is manufactured using production processes capable of being validated and/or verified, and reproduced. Manufacturers and sponsors of devices currently supplied in Australia under the custom-made medical device exemption that will become patient-matched under the new definition will be eligible for a transition period that will extend the deadline for inclusion from **25 February 2021** to **1 November 2024**.

New patient-matched devices that have not been supplied in Australia as a custom-made medical device prior to 25 February 2021 will not be eligible for the transition arrangements. See **3.2.2 For devices not supplied as custom-made before 25 February 2021** for more information.

**Note:** Under the new personalised medical devices framework the majority of currently supplied custom-made medical devices will now meet the definition of a patient-matched device and will require inclusion in the ARTG (by 1 November 2024 for those eligible for the transition arrangements).

- **Devices produced using a Medical Device Production System:** a Medical Device Production System (MDPS) is a complete system supplied to a health professional or healthcare facility so that personalised medical devices can be manufactured by a health professional (or other suitably qualified person within the healthcare facility). A unique feature of MDPSs is that it is the *manufacturer of the system and not the user of the system* (health professional or other suitably qualified person within the healthcare facility) that is the legal manufacturer of any devices produced using the system, providing the system is used in accordance with the manufacturer’s instructions for use.

- **Adaptable medical devices:** a mass-produced medical device intended by the manufacturer to be assembled or adapted after it is supplied, in accordance with the manufacturer’s instructions, to:
  - address either or both of the anatomical and physiological features of a particular individual; or
  - address a pathological condition of a particular individual; or
  - otherwise perform as intended by the manufacturer.

Adaptable medical devices will continue to need to be included in the ARTG and meet all relevant Australian regulations before they can be supplied.

A decision tree has been included as **Appendix 1** to this guidance document to assist manufacturers and sponsors of medical devices to identify how their personalised medical devices will be regulated under the new framework.

Whether a medical device is custom-made, patient-matched, produced using an MDPS or adaptable will not change:

- the classification of the device; or
- the requirement for manufacturers to hold evidence that the devices they manufacture meet the Essential Principles.

More examples and clarifying information can be found in the following pages, which provide guidance outlining the impact of the changes on the regulation of personalised medical devices:

- **custom-made medical devices**;
- **patient-matched medical devices**;
- **Medical Device Production Systems (MDPS)**; and
- **adaptable medical devices**.
There are also changes to the classification of certain diagnostic imaging and modelling technologies that are described in the section Diagnostic images and anatomical models.

You can contact PersonalisedDevices@health.gov.au to discuss your specific circumstances.

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**Case study example: one product, many ways to produce**

**Jilpa**'s dental laboratory produces retainers designed to fit specific individuals. Orthodontists send scans of their patients' teeth to Jilpa, and Jilpa uploads the scans into her design and production system. The system uses the scanning data to design and produce the retainer within specified parameters such as minimum thickness of the plastic. Once the retainer has been produced by the system, Jilpa and her team check the retainers manually for flaws, finishing the retainers by hand.

Jilpa’s production process and the materials used for the retainers does not change, and she has put in place standard operating procedures to ensure that the manual finishing steps are conducted consistently between staff—the only variable is the patient’s dimensions, taken from the scan supplied by the orthodontist. These products were previously exempt from inclusion in the ARTG via the custom-made medical device exemption pathway. After 25 February 2021, Jilpa’s products will meet the definition of patient-matched medical devices and Jilpa will need to submit an application for inclusion in the ARTG as the manufacturer of patient-matched retainers (by 1 November 2024 if eligible for the transition period).

**Jay** offers a service to produce retainers for patients with complex needs who cannot be catered to by any ARTG-included, patient-matched devices. For example, patients may be referred to Jay because they have allergies to standard materials used in retainers, or because their physical dimensions are well outside of the normal range owing to a condition they have. Jay is sufficiently trained and experienced to be able to make informed assumptions about the performance and safety of these devices, but he will make so few, generally less than five each year, that he cannot generate or maintain robust evidence to validate his processes or verify the end products. After 25 February 2021, Jay's specialist devices will meet the definition of custom-made medical devices.

After 25 February 2021, Jay’s products will continue to be regulated as custom-made medical devices. Jay will not need to include these devices in the ARTG, but he has new obligations he must meet if he wants to continue to supply his products.
Nitin is a dentist who occasionally needs to have a dental retainer made for one of his patients. In the past he has sourced these products from overseas but they sometimes take a long time to arrive and he would like to produce them himself. If Nitin decides to buy components and piece together a system to manufacture the retainers himself, his products will meet the definition of a patient-matched medical device and he will be subject to the same regulatory requirements as Jilpa.

If he decides to purchase a medical device production system (MDPS) that has been included in the ARTG, he will no longer meet the definition of a manufacturer providing he only produces retainers in accordance with the manufacturer’s instructions.

Charlie’s company produces a dental retainer-like device made of thermoforming plastic intended to be modified by a dentist or orthodontist to fit their patient as an initial treatment for temporomandibular joint disorders.

Charlie’s company holds conformity assessment evidence in accordance with Australian regulatory requirements and the device is included in the ARTG. While there is no material change to the regulation of Charlie’s product, which is now defined as an adaptable medical device, the Essential Principles now includes a specific requirement for adaptable medical devices to include explicit instructions for the safe adaptation of the device when it is supplied.

Charlie must continue to comply with the Australian regulatory requirements for her devices, including meeting all relevant Essential Principles.

Note
A decision tree has been included as Appendix 1 to this guidance document to assist manufacturers and sponsors of medical devices to identify how their personalised medical devices will be regulated under the new framework.
2. Custom-made medical devices

2.1 Overview

From 25 February 2021, a new definition of a custom-made medical device will come into legal effect:

**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.

The impact of this change is that the majority of devices currently being supplied using the custom-made medical device exemption will not meet this definition and will need to transition to inclusion in the ARTG as patient-matched medical devices by 1 November 2024 (if eligible for the transition period).

Both custom-made and patient-matched devices require the provision of patient information or data in the form of specifications from the health professional and/or scans and imagery to be supplied to the manufacturer for the purposes of designing and constructing a suitable device for the individual patient. The design of the custom-made device may also be informed by the technical and design files for an already existing patient-matched medical device.

Devices that meet the new definition of a custom-made medical device will be rare, one-off, bespoke pieces that are designed and manufactured for patients whose treating health professional has determined that the patient’s anatomical or physiological features, or pathological condition, make them unsuitable candidates for patient-matched or adaptable medical devices that are included in the ARTG.

The intention of the custom-made medical devices exemption is to allow these kinds of devices to continue to be supplied while ensuring that, wherever possible, patients are accessing devices supported by appropriate conformity assessment evidence and appropriate third-party oversight.
There are new **conditions of exemption** for sponsors and manufacturers of medical devices that meet the new definition of a custom-made medical device including:

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

The following guidance provides more information about the new regulatory requirements for custom-made medical devices and a checklist for action that manufacturers and sponsors must take from **25 February 2021**.

**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- for example, the custom-made device is supplied without the required information- 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). Civil penalties apply.

**Examples - Custom-made medical devices**

**Example 1**

Samara is an orthopaedic surgeon. Samara is asked to review a patient who presented to a hospital 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 and approaches a manufacturer of orthopaedic devices to 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 design characteristics (including the angle of the radial head to the stem and the composition of materials) to 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 patient-matched medical device. In this example, the device does not meet the definition of a patient-matched medical device because the production method required to produce a device to address a presentation of such clinical rarity means there is no clinical evidence available to demonstrate the production process can be either validated or verified; and

• does not meet the definition of an adaptable medical device. In this example, the device does not meet the definition of an adaptable medical device because it is not mass produced. It also is not intended to be adapted after supply.

Example 2

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 (including both patient matched and adaptable medical devices);

• does not meet the definition of a patient-matched medical device. In this example, the device does not meet the definition of a patient-matched medical device as it has been manufactured outside of a specified design envelope because the manufacturer is producing it as a one-off; and

• does not meet the definition of an adaptable medical device. In this example, the device does not meet the definition of an adaptable medical device because it is not mass-produced (the manufacturer is producing it as a one-off).

Counter example

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 *patient-matched medical devices* and will need to be included in the ARTG before they can be supplied (or by 1 November 2024 if eligible for the transition period).

### 2.2 Information to be supplied with your device

A requirement under the current exemption is that manufacturers of custom-made medical devices must prepare written statements in relation to each of the devices they manufacture. From **25 February 2021**, these statements must be provided with the devices. The statements must include the following information:

- the name and business address of the manufacturer;
- information identifying the device or, where relevant, the contents of the packaging;
- a statement to the effect that the device is intended to be used only in relation to a particular individual (who may be a health professional);
- the name of the individual to whom the device is intended to be used;
- the name and business address of the health professional who provided the specifications for the device;
- the particular design characteristics or construction of the device as specified by the health professional who provided the specifications; 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 of the device, and include details of the person's name and position. It is the legal manufacturer of the device under section 41BD of the Act who must compile the statement, including where manufacturing steps are outsourced. 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 existing requirements for information to be supplied with a device 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.

### 2.2.1 What level of information should be provided in the statement?

The level of information supplied in the statement will differ between devices, but it must be sufficient to allow the intended recipient(s) (in many cases, this will be both the patient and any
health professional involved in their healthcare, 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 device can be 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, or a 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?

### 2.3 Record-keeping requirements

Manufacturers and sponsors of custom-made medical devices must hold evidence demonstrating the devices they manufacture comply with all relevant Essential Principles as described in Schedule 1 of the Regulations. The Essential Principles checklist may assist manufacturers and sponsors with establishing documentation demonstrating compliance.

If you are the manufacturer of a custom-made medical device, from **25 February 2021** you must keep a copy of the statement supplied with the device and any other documentation associated with the device, including annual reports and documentation relevant to the conformity assessment procedures prescribed under Part 7.2 of Schedule 3 of the Regulations, 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.

Please note that the definition for implantable medical devices can be found in the dictionary section of the Regulations.

### 2.4 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 1 July – 30 June financial year. The report must be filled in using the annual reporting template and submitted to the TGA before **1 October of each year**.

This means if you are a manufacturer or a sponsor of a custom-made medical device, from **25 February 2021** you will have to provide your first annual report to the TGA before **1 October 2021**. One annual report is required to match the statement of supply previously provided to the TGA.
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;
- confirmation you have reported adverse events associated with your devices to the TGA through the online reporting system;
- the device Incident Report (DIR) number(s) for those adverse events reported to the TGA; and
- details of any regulatory/corrective action/notification taken by the manufacturer (if applicable).

**Note**

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

The TGA intends to incorporate annual reporting for custom-made medical devices in the online annual reporting facility we are currently developing. More information will be published on our website as this facility develops. Custom-made medical device manufacturers and sponsors who have provided valid email address when they notified the TGA that they were manufacturing/supplying a custom-made medical device through our online reporting form will receive an email when this system becomes available.

### 2.5 Inspection and review

If you are the manufacturer or the sponsor of a custom-made medical device, you must have the following available at all times:

- sufficient information to substantiate the conformity assessment procedures prescribed under Part 7.2 of Schedule 3 of the Regulations have been applied to the device; and
- information relating to the design and manufacture of the device and any changes made to the device.

This information must be supplied to the TGA on request. Manufacturers and sponsors also have obligations under the regulatory amendments relevant to inspection; as outlined in Table 1 below.
Table 1. Obligations of manufacturers and sponsors of custom-made medical devices relevant to inspections

<table>
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| 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.
2.6 What you need to do

If you are a manufacturer or sponsor intending to manufacture or supply a custom-made medical device on or after 25 February 2021, you will need to ensure you undertake the following:

- notify the TGA within two (2) months of manufacture / supply using the online reporting form;
- prepare a statement for supply with the device;
- retain a record of 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).

Figure 2. Timeline of key dates relevant to the changes to the regulatory requirements of manufacturers and sponsors of custom-made medical devices.
Example – Reporting for a custom-made medical device

Jay produces custom-made dental retainers designed to fit specific individuals with complex needs that cannot be catered to by patient-matched retainers. From **25 February 2021**, Jay will need to take the following actions to be able to lawfully supply his custom-made medical devices:

- Jay will need to provide the TGA with one statement using the [online reporting form](#) indicating he is making custom-made retainers. As the retainers all have the same GMDN code and classification, one statement will cover all of the retainers Jay manufactures and supplies.

- Jay will need to review the [Essential Principles checklist](#) and the conformity assessment procedures for custom-made medical devices outlined in clause 7.2 of Part 7 of the [Regulations](#) to ensure he has all relevant documentation available on file.

- Jay will need to keep records for each device that he manufactures, including the original health professional’s request for manufacture, a copy of the statement he supplied with the device and any other information he feels is pertinent (including any design or materials documentation that are unique to each device).

- Jay will need to [report all adverse events](#) he is notified of associated with his devices to the TGA.

- Jay will need to submit an annual report for the 01 July – 30 June financial year to the TGA by 01 October each year.
3. Patient-matched medical devices

3.1 Overview

From **25 February 2021**, the definition of a patient-matched medical device will come into legal effect:

A **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:
   
   (i) either or both validated and verified; and
   
   (ii) reproduced.

3.1.1 Specified design envelope

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

A **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 term ‘specified design envelope’ means the limits within which production and operation of the device has been validated. 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.

Any factors determining limits or boundaries of effective design transfer (design for transfer to production) will, in part, characterise the specified design envelope.

In the case of a dental retainer, for example, if the limit of the polymer pour is a diameter of 100mm, the specified design envelope would include a dimensional limit for the retainer of a 100mm maximum diameter.
3.1.2 Production processes that can be validated and/or verified, and reproduced

Process validation, product verification and reproducibility are key concepts that define whether a medical device meets the patient-matched definition.

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. Further information is available in ISO 9001 and ISO 13485.

Validation is particularly important if the predetermined requirements of the product can only be assured by destructive testing (for example, the required strength of the device). 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 to the specified requirements.

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, for instance, in providing hand finishing and verification activities. 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.

Examples – Patient-matched medical device

Dean’s company manufactures mass-produced orthopaedic implants, but can personalise certain devices in their catalogue to meet the particular needs of a patient. 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’s age, height and weight, and determines the design envelope and production processes used by his company for these devices have been sufficiently validated and can reliably produce a high-quality product for treating the surgeon’s patient. 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.
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 by the orthopaedic surgeon to manufacture an implant for Jake, a 43-year-old male patient who is 2.26 metres tall and weighs 160 kilos. Dean determines that the size and dimensions of the implant required for Jake fall outside the design envelope that has been validated.

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.

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.

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**If a device that you manufacture or supply meets the definition of a patient-matched medical device, from 25 February 2021 it will no longer be exempt from inclusion in the Australian Register of Therapeutic Goods (ARTG) under the regulatory provisions for custom-made medical devices.**

Patient-matched medical devices will need to be **included in the ARTG** before they can be supplied. Inclusions in the ARTG are for a “kind” of medical device. This means only one inclusion in the ARTG is required providing the devices all have the following characteristics:

- the same **sponsor**;
- the same **manufacturer**;
- the same **classification**;
- the same [Global Medical Device Nomenclature System (GMDN) code](https://www.gmdn.org); and
- **for Class III, Class AIMD medical devices only:** the same unique product identifier (UPI).
There are transitional arrangements available for manufacturers and sponsors of custom-made medical devices that will meet the definition of patient-matched under the new framework. The transitional arrangements, which will allow you to continue to supply your device until your application for inclusion in the ARTG is finalised, are outlined in the section What you need to do.

**Examples – Patient-matched medical device**

Muhammed is a dentist who takes an impression of his patient’s teeth and sends the impression away so that a retainer can be made in a dental laboratory. At the laboratory a technician makes a plaster model of the patient’s teeth using the dental impression supplied by Muhammed. A heated polymer is poured over the model, creating the beginnings of a retainer.

The technician must then trim the excess polymer from the retainer and polish the device to ensure a smooth fit for the patient, a process that is completed by hand.

Previously this kind of device would have met the definition of a custom-made medical device. While the retainer would have been excluded from inclusion in the ARTG, it would still have needed to meet all relevant Australian regulatory requirements including meeting the Essential Principles, including being accompanied by instructions for use and appropriate labelling when supplied.

Under the new personalised medical devices framework the retainer meets the definition of a patient-matched medical device because it has been:

- manufactured within a specified design envelope (for example, the limits of the polymer pour);
- to match the anatomical features of a particular individual; and
- manufactured using production processes that are capable of being validated, verified and reproduced.

If the dental laboratory is based in Australia, the laboratory will meet the legal definition of a sponsor (in addition to manufacturer) under the relevant legislation (Australian manufacturers are automatically also sponsors). This means that the laboratory will be responsible for:

- ensuring it has implemented the appropriate conformity assessment procedures and documenting evidence demonstrating the devices meet the Essential Principles (requirements relating to factors of the device including design, construction and information to be supplied with the device); and
- including the kind of medical device in the ARTG, thereby allowing devices to be legally supplied within, or exported from, Australia.
### 3.2 What you need to do

If you are currently manufacturing or supplying a custom made medical device that will meet the new definition of a patient-matched medical device, and you intend to continue supplying the device, you will need to submit a notification of transition **before 25 August 2021**.

**Figure 3. Timeline of key dates relevant to the changes to the regulatory requirements of manufacturers and sponsors of patient-matched medical devices.**

#### Examples – Transition to patient-matched medical device

Sakura’s laboratory is based in Australia and makes retainers based on dental impressions supplied by dentists from around Australia. Sakura had previously notified the TGA the laboratory was producing custom-made medical devices. 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:

- notify the TGA using the [online reporting form](#) **before 25 August 2021** that she intends to access the transition period;

- check the classification of her dental retainers using the [online classification tool](#);

- obtain a copy of the [Essential Principles checklist](#) and ensure her dental retainers meet all relevant Essential Principles;

- apply the appropriate conformity assessment procedures including making a [declaration of conformity](#);

- make one [application for an inclusion in the ARTG](#) (Sakura’s retainers are all the same ‘kind of medical device’ and so, in this instance, Sakura or her laboratory will only require **one** inclusion in the ARTG for all the dental retainers she/it manufactures and supplies) 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.

**Note:** If Muhammed, the dentist from the previous example, chooses to source his retainers from an overseas laboratory, Muhammed will meet the legal definition of a sponsor (the Australian legal entity responsible for meeting all relevant requirements associated with the devices) and will need to:

• ensure his manufacturer has appropriate conformity assessment evidence for the devices;
• include the devices in the ARTG; and
• meet all relevant ongoing responsibilities as the sponsor of the devices.

### 3.2.1 If you are already supplying patient-matched devices

If you are currently supplying devices under the custom-made exemption but those devices will meet the definition of a patient-matched device from 25 February 2021, transitional arrangements are in place to ensure you can continue to supply your device while you apply for an inclusion in the ARTG. If you access the transitional arrangements, the deadline for ARTG inclusion will be extended to 1 November 2024.

Accessing the transition period is a two-step process. To be eligible, you must:

• have been supplying your custom-made medical device **prior to 25 February 2021** (ensuring you have met your regulatory obligation under Regulation 10.3 and have notified the TGA within two months of any medical devices you have manufactured or supplied under the custom-made exemption is acceptable evidence of supply); and
• notify the TGA **before 25 August 2021 via the transition notification form** that you have a device you wish to access the transition period.

Once you have completed both of these steps, you will have until **1 November 2024** to obtain the appropriate evidence of conformity assessment 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.
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.

3.2.2 For devices not supplied as custom-made before 25 February 2021

If a device meets the definition of patient-matched but has not been manufactured or supplied in Australia as a custom-made medical device before **25 February 2021**, it will not be eligible for the transitional arrangements. From **25 February 2021**, these devices must be included in the ARTG before they can be supplied in Australia. A noted exception is in the circumstance where:

- a health professional makes a written request for a device that will meet the definition of a patient-matched medical device; **AND**
- the request is dated **before 25 February 2021**; **AND**
- the kind of device has not been manufactured or supplied before this date.

In this circumstance, the specific device requested by the health professional can still be manufactured or supplied under the custom-made exemption. The **kind of device**, however, **will not be eligible** for the transition period and must be included in the ARTG before it is further manufactured or supplied in Australia.

A [guide to the medical device inclusion process](#) is available on the TGA website.
4. Medical Device Production Systems (MDPS)

4.1 Overview

Please note

Medical Device Production Systems (MDPS) are a new concept in regulation designed to enable the production of patient-matched medical devices for individual patients by health professionals or suitably qualified persons within healthcare facilities. The TGA is currently working with stakeholders, including the IMDRF, to ensure appropriate procedures and processes are in place to enable the introduction of this new concept.

For this reason, while the definition of an MDPS will be included in the Regulations from 25 February 2021, the definition will not take effect until a legislative instrument is in place to declare an MDPS to be a medical device.

To receive notification when the legislative instrument is signed giving effect to the definition of an MDPS, please subscribe to the Medical Devices Information email list.

The definition of a Medical Device Production System (MDPS) 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 that a manufacturer can supply to health professionals and healthcare facilities, in order for them to produce a specific type of patient-matched medical device. Depending on the complexity of the system, conditions of supply may include requirements for operators to participate in a training program, and/or agreements in relation to:

- the maintenance and servicing requirements for the MDPS (the system);
- operational requirements including restricting access to the system; and
- the source of materials used in the system and/or spare parts.
Figure 4. A Medical Device Production System (MDPS) consists of all the required components to make a medical device, from raw materials to production equipment.

**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 intended to be supplied as a complete solution to dentists, who can use the system to produce patient-matched dental crowns for adult patients. The system incorporates:

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

The full system is supplied as a product by Kate. A dental clinic purchases the system for use by their dentists and dental technicians.

The system meets the definition of an MDPS because:

- 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 buys an MDPS from Kate for use in her practice. Achara can use the MDPS to produce patient-matched dental crowns in accordance with the instructions for use provided with the MDPS.

If Achara uses the MDPS for any purpose other than that intended by Kate as explained in the instructions for use, she will meet the definition of a manufacturer.

For example if Achara:

• uses the system to produce crowns using raw materials other than those supplied by the manufacturer; or

• allows a member of staff who does not meet the definition of a health professional or suitably qualified person in a healthcare facility – for example, a receptionist – to operate the system; or

• uses the system to produce devices that are not dental crowns; or

• uses the system to produce dental crowns for paediatric patients (as the system is intended for adult patients only),

Then she would need to comply with all relevant regulatory requirements that apply to manufacturers.

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.

If in the future the physicists wanted to supply the system to other healthcare facilities as a turnkey solution, then they would first need to include the system as an MDPS in the ARTG.
4.2 Users of MDPS

If you are a health professional or suitably qualified person within a healthcare facility who produces personalised medical devices, you will no longer meet the definition of a manufacturer under the Act providing the following two points are met:

- 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.

This means:

- you will not need to meet the regulatory requirements for a manufacturer for the MDPS or any of the devices produced by the MDPS;
- you will not need to undertake an appropriate conformity assessment procedure for the devices produced by the MDPS; and
- you will not need to include devices produced by the MDPS in the ARTG before you supply them to a patient.

Note

You will meet the definition of a manufacturer of medical devices under section 41BG of the Act and will need to ensure you meet all relevant Australian regulatory requirements, including having a current inclusion in the ARTG for any patient-matched you are manufacturing and supplying if you are a health professional, or suitably qualified person within a healthcare facility, who:

- is manufacturing patient-matched medical devices from a production system not included in the ARTG; OR
- is manufacturing an MDPS for supply to a third party; OR
- is using an MDPS to produce a medical device other than the kind of medical device intended by the manufacturer of the MDPS.

4.2.1 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 expect a (suitably qualified) user to hold. 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, the MDPS will not be being used in accordance with the manufacturer’s requirements and so the end user will become the manufacturer of any patient-matched medical devices produced by the system and will be required to hold an inclusion in the ARTG for the kind(s) of device they are supplying. Supplying devices without an ARTG inclusion is a breach of the Act. Civil and criminal penalties apply.

### 4.3 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 meets all relevant Essential Principles;
- the MDPS is included in the ARTG with the same classification as the highest class of device it produces.
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.

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**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 market their MDPS, Zane and his team will need to apply the appropriate conformity assessment procedures and ensure that all of the relevant Essential Principles of Schedule 3 of the Regulations are met.

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 as to immobilise the broken region, 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 be the legal manufacturer of any devices produced.

Were this scenario to occur, the user would need to meet the relevant regulatory obligations, such as including the devices in the ARTG before they are supplied.

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.

- **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, and 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.

### 4.3 Information to be supplied with an MDPS

Essential Principle 13.4(3) will be amended to include 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 fail to follow the instructions for the system:

- could result in a device not meeting the Essential Principles and may not be safe and fit for its intended purpose; and

- means they will meet the definition of a manufacturer for the purposes of regulation under the Act and will need to meet all relevant regulatory obligations for manufacturers of either a custom-made or patient-matched medical device.
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 meet the definition of a manufacturer and will need to meet all relevant regulatory requirements associated with being a manufacturer.

4.4 What you need to do

If you are the manufacturer or sponsor of a system that meets the definition of an MDPS, once the legislative instrument is in place to declare these kinds of systems to be a medical device, you will need to apply to have the system included in the ARTG before it can be supplied in Australia. A guide to the medical device inclusion process is available on the TGA website. You may wish to contact PersonalisedDevices@health.gov.au to discuss your specific circumstances.

Figure 5. Timeline of key dates relevant to Medical Device Production Systems.
5. Adaptable medical devices

5.1 Overview

From 25 February 2021, the following definition of an adaptable medical device will come into legal effect:

**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.

Adaptable medical devices continue to be regulated through inclusion in the ARTG under an appropriate classification.

5.2 Information to be supplied with an adaptable medical device

From 25 February 2021, essential principle 13.4(3) will specifically consider information that must be supplied with adaptable medical devices. The effect of this addition to the regulatory requirements is, that if you are the manufacturer of an adaptable medical device, you will need to ensure that your product 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 to 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

Brett works in a hospital orthotics department. A patient who wears an off-the-shelf ankle-foot orthosis (AFO) has presented to the department for 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.

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.

The modification Brett 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.
5.3 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

• from 25 February 2021, ensure the information supplied with the device conforms to the updated essential principle 13.4(3).

Figure 6. Timeline of key dates relevant to the changes to the regulatory requirements of manufacturers and sponsors of adaptable medical devices.
6. Diagnostic images and anatomical models

6.1 Overview

Clause 5.4 (also called classification rule 5.4) of Schedule 2 of the Regulations currently provides that a non-active medical device intended by its manufacturer to be used to record X-ray diagnostic images is classified as Class IIa.

From 25 February 2021 classification rule 5.4 will capture a broader range of technologies being used to record diagnostic images:

1. If:
   - 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:
     - the diagnosis or monitoring of a disease, injury or disability;
     - the investigation of the anatomy or of a physiological process; and
   - the images are to be acquired through a method that relies on energy outside the visible spectrum;
   then 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:
   - the diagnosis or monitoring of a disease, injury or disability;
   - 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:
   - the diagnosis or monitoring of a disease, injury or disability;
   - the investigation of the anatomy or of a physiological process;
   is classified as Class IIa.

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 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 does not need to be included in the ARTG.

There are transitional arrangements available for manufacturers and sponsors of these devices as outlined in what you need to do. The transitional arrangements will extend the deadline for updating an existing ARTG entry to 1 November 2024.

Examples – Devices captured by classification rule 5.4

Example 1 – Intraoral scanner

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 is 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 2 – Virtual anatomical model

Nicola has developed a photogrammetry app that can be installed on a smartphone intended to be used to help gauge the effectiveness of cranial orthoses in the treatment of plagiocephaly. The app is intended to be used by an orthotist, who takes photos of an infant patient’s head from different angles. 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, as it is intended to be used for investigation of anatomy and physiology (section 41BD(1)(a)(iii) of the Act); 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

An off the shelf digital camera used to take photographs of a patient with pectus carinatum to assess chest shape change is not impacted by these regulatory changes because:
• the camera does not meet the definition of a medical device as it is not intended by the manufacturer for a purpose that aligns with section 41BD of the Act; and
• the camera does not produce photographs using a method that relies on energy outside the visible spectrum.
6.2 Will my device be captured under classification rule 5.4?

Does the device meet the definition of a medical device?
For example, plaster moulds of a patient’s mouth to be used to design oral appliances are not captured because they do not meet the definition of a medical device. For more information, visit: https://www.tga.gov.au/what-medical-device

Does the medical device record patient images that are acquired by a method that uses energy outside of the visible spectrum?

Is the medical device a physical or virtual anatomical model?

Does the medical device generate virtual anatomical models?

Is the medical device used for the diagnosis and/or monitoring of a disease, injury or disability or the investigation of the anatomy or a physiological process?

Classification rule 5.4 applies

Please note: where more than one classification rule applies to the device, the correct classification is the highest classification.

For more information visit: https://www.tga.gov.au/sme-assist/what-classification-my-medical-device
6.3 Conformity assessment procedures for Class IIa devices

Many of the devices now captured by classification rule 5.4 are currently included as Class I medical devices in the ARTG. The change in classification means the manufacturers of these devices will have increased conformity assessment requirements from 25 February 2021. There are transitional arrangements in place for kinds of devices already included in the ARTG, provided manufacturers or sponsors notify the TGA by 25 August 2021 they wish to access the arrangements; see what you need to do.

Table 2 provides an overview of the differences between acceptable conformity assessment procedures for manufacturers of Class I and Class IIa devices.

Table 2. Comparison of the conformity assessment procedures for Class I and Class IIa devices.

<table>
<thead>
<tr>
<th>Class of medical device</th>
<th>Conformity assessment procedure required under Schedule 3 of the Regulations</th>
<th>Directive 93/42/EEC on Medical Devices – European Union equivalent</th>
<th>Declaration of conformity required under Schedule 3 of the Regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I (non-measure, non-sterile)</td>
<td>Part 6 (Declaration of conformity procedures)</td>
<td>Nil</td>
<td>Schedule 3, Part 6, clause 6.6</td>
</tr>
<tr>
<td>Class I (measuring)</td>
<td>Part 1 excluding clause 1.6 (Full quality assurance procedures) OR Part 6 (Declaration of conformity procedures)</td>
<td>Annex II.3 OR nil + Annex IV or Annex V or Annex VI</td>
<td>Schedule 3, Part 1, clause 1.8 OR Schedule 3, Part 6, clause 6.6</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class of medical device</td>
<td>Conformity assessment procedure required under Schedule 3 of the Regulations</td>
<td>Directive 93/42/EEC on Medical Devices – European Union equivalent</td>
<td>Declaration of conformity required under Schedule 3 of the Regulations</td>
</tr>
<tr>
<td>-------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------</td>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td>Class I (sterile)</td>
<td>Part 1 excluding clause 1.6 (Full quality assurance procedures) OR Part 6 (Declaration of conformity procedures) + Part 4 (Production quality assurance procedures)</td>
<td>Annex II.3 ORNil + Annex V</td>
<td>Schedule 3, Part 1, clause 1.8 OR Schedule 3, Part 6, clause 6.6</td>
</tr>
<tr>
<td>Class IIa</td>
<td>(Full Quality Assurance Procedures) Part 1 excluding clause 1.6 OR Part 6 (Declaration of conformity procedures) + Part 3 (Verification procedures) or Part 4 (Production quality assurance procedures) or Part 5 (Product quality assurance procedures)</td>
<td>Annex II.3 ORNil + Annex IV or Annex V or Annex VI</td>
<td>Schedule 3, Part 1, clause 1.8 OR Schedule 3, Part 6, clause 6.6</td>
</tr>
</tbody>
</table>
6.4 What you need to do

If you are a manufacturer or sponsor intending to manufacture or supply a kind of device now captured by the amended classification rule 5.4 on or after 25 February 2021, the action you need to take to comply with the amended Regulations will depend on whether or not the device is currently included in the ARTG.

Figure 7. Timeline of key dates relevant to the changes to the regulatory requirements of manufacturers and sponsors of devices captured by the updated classification rule 5.4.

6.4.1 For Class I devices included in the ARTG and custom made medical devices supplied before 25 February 2021

Transitional 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:

- notify the TGA before 25 August 2021 that you have an inclusion to be reclassified using the transition notification reporting form;
- 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.
6.4.2 For devices *not* included in the ARTG or supplied as a custom made medical device prior to 25 February 2021

Any [application for inclusion](#) made on or after 25 February 2021 must be submitted as an application for a Class IIa medical device (unless subject to the transition arrangements detailed previously). A [guide to the medical device inclusion process](#) is available on the TGA website.

<table>
<thead>
<tr>
<th>Date</th>
<th>Requirements</th>
</tr>
</thead>
</table>
| Before 25 August 2021 | • Notify the TGA; OR
                     | • cease supply on that date, until such time as you hold a Class IIa entry. |
| Before 1 November 2024 | • Obtain appropriate evidence of conformity assessment; AND
                     | • submit a Class IIa application for inclusion.                           |
| After 1 November 2024 | • Continue to supply under a Class IIa ARTG entry; OR
                     | • cease supply if an application for inclusion is rejected, lapsed, or not made before 1 November 2024.; OR
                     | • obtain an entry in the ARTG.                                             |
Appendix 1: Personalised medical devices decision tree

Is the device intended to suit an individual’s specific anatomo-physiological features or pathological condition?

Yes

Is the device personalised to the individual prior to manufacture?

Yes

Adaptable medical device
A mass-produced device that is intended to be assembled, adapted or otherwise modified after it has been supplied according to the manufacturer’s instructions is an adaptable medical device.

No

Is the device manufactured within a specified design envelope?

Yes

Patient-matched medical device

No

Is the device manufactured using a repeatable process that can be validated or verified?

Yes

No

Is the device manufactured as a result of a written request from a health professional?

Yes

Is the device intended for a case where an individual’s specific needs cannot be met, or cannot be met to an appropriate level, by an alternative device included in the ARTG?

Yes

Custom-made medical device

No
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:

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>E.g. length</td>
<td>15mm</td>
</tr>
</tbody>
</table>

[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

<table>
<thead>
<tr>
<th>Version</th>
<th>Description of change</th>
<th>Author</th>
<th>Effective date</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1.0</td>
<td>Original publication</td>
<td>Medical Devices Authorisations Branch</td>
<td>November 2020</td>
</tr>
<tr>
<td>V2.0</td>
<td>Improvements to clarity of key information and editorial changes</td>
<td>Medical Devices Authorisations Branch</td>
<td>December 2020</td>
</tr>
</tbody>
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