Australian Government
Department of Health
Therapeutic Goods Administration

Consultation: Proposed refinements to the regulation of personalised medical devices

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TGA Health Safety Regulation

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Contents

Introduction

The Australian Government is undertaking a significant program of reform to the regulation of therapeutic goods in Australia. As part of the Australian Government Department of Health, the Therapeutic Goods Administration (TGA) regulates therapeutic goods, and is responsible for implementing the Government's reforms. The TGA has issued this consultation paper as part of the Government's reform program.

Background

On **25 February 2021**, changes to the *Therapeutic Goods (Medical Devices) Regulations 2002* ('the Regulations') commenced to introduce a new framework (the Framework) for the regulation of medical devices that are designed and manufactured for individual patients (otherwise known as personalised medical devices). The Framework includes new definitions and regulatory requirements for personalised medical devices including custom-made medical devices.

The definition of medical device in the *Therapeutic Goods Act 1989* (the Act) (Appendix 1) states that a medical device is any instrument, apparatus, appliance, material or other article intended to be used for:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of a disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state; or
- control and support of conception.

The manufacturer assigns the **intended purpose** of the medical device. The intended purpose is reflected in the labelling, instructions for use or any advertising material (including website advertising) provided with or for the device. For regulatory purposes, the intended purpose will determine the **classification of the device** and minimum **conformity assessment** procedures that the manufacturer must comply with for inclusion in the Australian Register of Therapeutic Goods (ARTG). Medical devices must be included in the ARTG before import, export or supply, unless an exemption (such as being a custom-made device) applies.

Conformity assessment procedures are requirements placed on the manufacturer of a medical device. They include controls around manufacture (design and construction) of medical devices, keeping and maintaining records, and managing complaints and recalls. The minimum conformity assessment procedures that apply are determined by the classification of the device. The procedures are followed by the manufacturer in order to demonstrate conformity with safety and performance principles (the essential principles of safety and performance). This principles-based approach provides flexibility for manufacturers of medical devices on how to demonstrate compliance and supports different technologies and technological advances over time.

The degree of oversight by TGA varies according to the classification of the device and the manufacturer's intended purpose for the device. There is a four-tier classification system for medical devices:

- Class I non-sterile, non-measuring (lowest classification);

- Class IIa, Class I sterile and Class I measuring (low-medium risk);
- Class IIb (medium-high risk); and
- Class III and Active Implantable Medical Devices (AIMD) (highest classification).

The higher the classification of the device the higher the level of regulatory scrutiny. Manufacturers of all medical devices supplied in Australia must:

- meet the minimum conformity assessment certification requirements appropriate to the level of classification of devices being manufactured; and
- have evidence that demonstrates compliance of their medical devices with the relevant essential principles.

Class I non-sterile, non-measuring medical devices are self-certified and the majority of applications for inclusion in the ARTG are processed with no further assessment undertaken by the TGA. Manufacturers of all devices other than Class I non-sterile, non-measuring medical devices must obtain conformity assessment certification from an independent body (e.g, from a European notified body) or from the TGA prior to an application being made for inclusion in the ARTG. Manufacturers of Class III medical devices are also required to have the design of each individual device examined by the conformity assessment body.

Consultation on the regulation of personalised medical devices

Prior to 25 February 2021 most Personalised Medical Devices (PMD) met the definition of 'custom-made'. While devices that met the definition of custom-made were exempt from inclusion in the ARTG, they were still required to meet all other regulatory obligations for devices including:

- Ensuring the Essential Principles were met including;
    - Designing and producing the device in a way that does not compromised health and safety;
    - Having evidence demonstrating the long term safety of the device;
    - Meeting packaging and labelling requirements;
    - Supplying the device with Instructions for Use to ensure it could be safely used and maintained by the end user; and
- Reporting adverse events associate with the device to the TGA.

Manufacturers and sponsors of custom-made medical devices were also required to notify the TGA of the manufacture/supply of a custom-made medical device within two (2) months of initial manufacture/supply.

This exemption had been in place since 2002. At that time the majority of custom-made medical devices were relatively low in risk, and usually manufactured by trained, accredited professionals. Examples include:

- prescription spectacles from optometrists;
- occlusal splints made by dental technicians;
- dentures manufactured by dental prostetists;
- prosthetic eyes made by occularists; and
- a range of products made by occupational therapists.

Over the past two decades, rapid advances in computing technology and materials science have resulted in significant changes to medical imaging technology, manufacturing technology and, as a result, medical device technology. Newer methods of manufacture such as 3D-printing allow more complex and, in some cases, higher-risk medical devices to be personalised for an individual patient and supplied under the custom-made medical device exemption. For lower risk devices these advances resulted in new manufacturers, who are not always trained or accredited, entering the market.

The TGA conducted workshops, targeted discussions and two public consultations relating to personalised medical devices:

- 2017: Proposed regulatory changes related to personalised and 3D printed medical devices.
- 2019: Proposed regulatory scheme for personalised medical devices, including 3D-printed devices.

Regulatory changes were made by the government decisions following these consultation on 12 December 2019. The majority of the new requirements became effective from 25 February 2021 but include a transition period for eligible manufacturers and sponsors until 1 November 2024. A summary of the changes can be found on the TGA website here.

Further, more detailed guidance will also be informed by the current consultation process, and will be published on the Medical devices reforms: Personalised medical devices landing page.

Summary of the changes

The main changes introduced under the Framework are:

1. The majority of medical devices that previously met the definition of a custom-made medical device (which are exempt from inclusion in the ARTG) will now meet the definition of a **patient-matched medical device and will require inclusion in the ARTG.**

2. **Changes to the conditions of exemption for medical devices** that continue to meet the definition of a custom-made medical device;

3. The **introduction of "Medical Device Production Systems"** wherein an end-to-end system for the manufacture of patient-matched medical devices can be included in the ARTG, thereby allowing medical devices to be manufactured within healthcare facilities without the need to undergo full conformity assessment and application for inclusion in the ARTG.

4. New classification rules including the reclassification of **anatomical models** (physical or virtual) for the diagnosis and/or monitoring of a disease, injury or disability or the investigation of a physiological process as Class IIa medical devices.

Sponsors of affected medical devices will need to include their products in the ARTG at the correct classification level prior to 1 November 2024. Manufacturers of impacted devices will need to ensure they have third party certification to demonstrate conformity assessment before the sponsor of the device can submit a valid application for inclusion.

Feedback following the introduction of the framework

We have received a range of feedback and information during the course of introducing the Framework including concerns from some sectors about the impact of the changes. Manufacturers and sponsors of patient-matched medical devices includes the following healthcare professionals who produce or import devices for treating their patients:

- Dentists, prosthodontists and orthodontists
- Dental technicians
- Dental prosthetists
- Orthotists
- Rehabilitation engineers producing custom wheelchair assemblies
- Radiation therapists
- Audiologists
- Hand therapists
- Prosthetists
- Osteopaths.

In some cases it was claimed that the regulatory requirements were:

- a duplication of existing regulation already provided by professional accrediting bodies or other regulatory bodies;
- the requirements for some devices were excessive compared with the actual risk posed by the device; and/or
- the regulatory burden imposed by the introduction of the Framework is unreasonable.

During the introduction of the framework we have also received information and evidence demonstrating that manufacturers and sponsors of devices that met the custom-made definition were not aware of, and therefore not complying with, their existing regulatory requirements.

We are now seeking feedback on potential refinements to the Framework that could be considered to ensure risks associated with personalised medical devices are appropriately mitigated without imposing unnecessary administrative and regulatory burden.

This consultation

In considering what could be refined, we propose the following principles:

- Reduction or removal of unnecessary regulatory burden by:
    - not regulating products where there is no risk to safety (a no-harm principle); or
    - not regulating twice (that is, where suitable frameworks for product or system oversight are already in place).
- Applying an appropriate level of oversight which is commensurate with the risk of the device.
- Ensuring the Australian regulatory requirements for medical devices are met, thereby ensuring devices are safe and fit for their intended purpose.

Basing the proposed refinements on these principles ensures the Framework meets the Australian Government's commitment to ensuring a patient-focused, transparent regulatory system thereby meeting consumer expectations and increasing public confidence.

Mechanisms for refinement of the Framework

There are three main mechanisms available to refine the regulatory approach for personalised medical devices:

1. Exclusion
2. Exemption
3. Inclusion in the ARTG through an alternative conformity assessment procedure.

Exclusion

An **exclusion** means that the specified products are **not subject to regulation by the TGA.**

Specified products may be excluded for all uses or, alternatively, only when used, advertised, or supplied in a specified manner for a particular purpose.

Excluded products would not be:

- able to be included in the ARTG;
- required to be assessed in any way by the TGA before they are made available in Australia; or
- monitored for ongoing safety by the TGA after they are made available.

Suppliers of excluded products would also not be required to report adverse events associated with their product and the TGA would be unable to take regulatory action such as conducting a recall or issuing a hazard alert if there is a problem with the product. Advertising of excluded goods is also not subject to TGA legislation, including the Therapeutic Goods Advertising Code.

Before making a determination to exclude goods from the regulatory scheme, the Minister must have regard to:

- whether it is likely that the specified product, if not regulated under the Act, might harm the health of members of the public;
- whether it is appropriate in all the circumstances to apply the national system of controls relating to the quality, safety, efficacy and performance of therapeutic goods established by TGA legislation to regulate the specified product; and
- whether the kinds of risks from the specified product to which members of the public might be exposed could be more appropriately dealt with under another regulatory scheme or mechanisms of oversight.

Note

Excluded products are still subject to other regulatory requirements, including relevant consumer laws.

Exemption

Exempt products are not required to be included in the ARTG (and thus an application relating to the product does not have to be submitted to TGA for review) but must meet all other

Australian regulatory requirements associated with the manufacture and supply of a medical device including:

- meeting all relevant Essential Principles including;
    - Designing and producing the device in a way that does not compromised health and safety;
    - Having evidence demonstrating the long term safety of the device;
    - Meeting packaging and labelling requirements;
    - Supplying the device with Instructions for Use to ensure it could be safely used and maintained by the end user;
- keeping records of supply; and
- reporting adverse events associated with the medical device to the TGA.

The TGA maintains all relevant regulatory powers with respect to the device including the capacity to:

- undertake a post-market review of the device to ensure it meets all relevant regulatory requirements;
- request relevant information relating to the device including, but not limited to;
    - samples of the device for testing;
    - examples of the packaging, labelling or advertising material for the device;
    - supply records for the device;
- suspend manufacture or supply of the device; and
- conduct a recall activity in relation to the device including issuing a hazard alert if there is a problem with the product.

The TGA is also able to take regulatory action if the device is advertised in contravention of the advertising requirements under Therapeutic Goods legislation.

An exemption can either be made for a product without conditions or be made subject to conditions that can be prescribed in the Regulations (e.g., exemption for a specified product when manufactured by a particular professional or when supplied to a certain type of facility or for a specified purpose).

Special conformity assessment procedures for inclusion in ARTG

An alternative conformity assessment procedure could be made for inclusion of certain patient-matched medical devices in the ARTG. This would only be considered if there are already adequate alternative mechanisms of oversight in place so that the risks associated with their use and performance can be appropriately mitigated. Such a procedure could replace the need for a manufacturer to obtain quality management system certification prior to applying for inclusion of their device in the ARTG.

Proposed principles for consideration of potential refinements to the Framework

In Australia the risk posed by a medical device is established through key factors including duration of use and level of invasiveness. The level of regulation imposed under each mechanism for refinement varies, and we are therefore proposing to apply the mechanisms available according to the following principles:

Mechanism	Application
Exclusion from regulation	Products that: • do not meet the definition of a medical device (for the sake of clarity); • meet the definition of an accessory that do not pose significant harm to the individual (including due to inappropriate use of the product); and • meet the definition of a medical device but are predominantly used for cosmetic purposes and do not present a risk of harm.
Exemption from inclusion in the ARTG	Class I non-sterile, non-measuring patient-matched medical devices where there are alternative mechanisms of oversight for the manufacture and use of the device.
Alternative conformity assessment procedure	Class IIa patient-matched devices where: • there are alternative mechanisms of oversight for the manufacture and an alternative use of the device; and • the manufacturer undertakes a self-assessment and declaration that they meet the regulatory requirements.

1. Products that could potentially be excluded from regulation

Given exclusion from regulation will remove the requirement for manufacturers of products to meet the Australian regulatory requirements for medical devices, it is proposed this would be limited to products that:

- do not meet the definition of a medical device and the product's regulatory status requires clarification; or
- meet the definition of a medical device, or an accessory to a medical device, but the level of risk posed by the devices is considered to be very low.

Examples of products that could be excluded from regulation are:

- Physical impressions of a patient's anatomy and models cast from these
- Anatomical models manufactured for educational purposes
- Plastic moulds used to anchor a hearing aid in the ear canal
- Orthodontic appliance positioning tray
- Mouthguards for sports purposes
- Spectacle frames

- Bleaching trays
- Eyeball prosthesis
- Denture repair kits
- Polymers and resins used in the manufacture of a medical device
- Cosmetic finishing components for orthoses

Impact of the proposal

The impact of this exclusion is that these kinds of products will not need to meet any of the regulatory obligations associated with the manufacture or supply of a medical device including:

- demonstrating that they meet the Essential Principles; and
- reporting adverse events to the TGA; and
- meeting the advertising requirements for therapeutic goods under the TGA legislation including the Therapeutic Goods Advertising Code.

These products would be subject to consumer protection laws administered by the Australian Competition and Consumer Commission (ACCC) as well as state or territory consumer protection laws.

2. Patient-matched medical devices that could potentially be exempt from inclusion in the ARTG

Class I non-sterile, non-measuring patient-matched medical devices represent a low risk to end users that is currently managed through:

- self-declaration by the manufacturer that they have met Australian regulatory requirements; and
- inclusion of the device in the ARTG.

It is proposed some Class I patient-matched medical devices could be exempted from inclusion in the ARTG where it can be demonstrated the risks associated with the manufacture and use of the device can be adequately managed:

1. the device is manufactured by a trained, accredited professional; or
2. other third-party mechanisms of oversight are in place that are suitable to manage the low risk that may be posed by the device.

It is considered that where a medical device has been "prescribed" by a registered health professional and is manufactured by a qualified or accredited professional according to the specifications provided by the healthcare practitioner, risks can be adequately mitigated.

Examples where Class I (low-risk) patient-matched medical devices could be exempted are where they are being manufactured:

- Within a healthcare facility accredited against the National Safety and Quality Health Service (NSQHS) Standards by a body recognised by the Australian Commission on Safety and Quality in Health Care (ASCQHC); **or**
- By a provider who has been registered with the National Disability Insurance Scheme Quality and Safeguards Commission (NDISQSC), and the scope of their registration encompasses the patient-matched medical devices that they are producing; **or**
- By a health professional registered with the Australian Health Practitioner Regulation Agency (AHPRA) under the *Health Practitioner Regulation National Law Act 2009,* and whose scope of practice encompasses production of the patient-matched medical devices that they are producing; **and**

The devices they produce are intended to be used by a patient of the healthcare facility, registered provider or AHPRA-registered health professional.

- By a dental technician who holds a recognised qualification under the Australian Qualifications Framework **and**
  The devices they produce are intended to be used by a patient of a healthcare facility, registered provider or AHPRA-registered health professional.
- By a dental laboratory accredited by the Oral Health Professional Association **and**
  The devices they produce are intended to be used by a patient of a healthcare facility, registered provider or AHPRA-registered health professional.
- By an orthotist or prosthetist who is a full member of the Australian Orthotic Prosthetic Association.

Examples of devices that could potentially be exempt include:

Profession	Examples of Class I non-sterile non-measuring patient-matched medical devices
Dental prosthetists	• Dentures (including complete and partial), • Occlusal splints • Aligners • Palate prosthesis
Dental technicians	• Dentures (including complete and partial) • Occlusal splints • Aligners • Palate prosthesis
Orthotists and prosthetists	Non-invasive orthoses and prostheses including: • Hand splints (with or without outrigger) • Shoulder orthosis • Ankle-foot orthosis • Orthopaedic shoes • Orthotics
Osteopaths	Plagiocephaly helmets

Impact of the proposal

The impact of this exemption is that any Class I non-sterile, non-measuring patient-matched medical devices manufactured by a party that falls into any of the above categories would not need to be included in the ARTG. The manufacturer and sponsor would still need to meet all other regulatory requirements for medical devices including:

- ensuring their device(s) meet all relevant Essential Principles, including supplying the devices with adequate labelling and instructions for use;

- documenting evidence of conformity assessment (holding a declaration of conformity for the devices); and
- reporting adverse events associated with the use of their device(s).

A further impact of exempting these kinds of devices from inclusion in the ARTG is that they would not be able to be advertised to consumers.

Note

This proposal would not apply to higher risk devices (i.e., Class IIa, IIb or III patient-matched medical devices).

3. Inclusion of patient-matched medical devices in the ARTG using an alternative conformity assessment procedure

Class IIa medical devices represent low-medium levels of risk to patients. Currently the minimum conformity assessment procedures for inclusion of a Class IIa medical device in the ARTG requires the manufacture have a quality management system that has been certified by the TGA or another third party conformity assessment body. Manufacturers are also required to hold evidence that their devices comply with the Essential Principles.

Examples of Class IIa patient-matched devices include:

- Dental devices that are intended to remain in the oral cavity for more than 30 days continuously; and
- Orthoses that are intended to penetrate the skin and be anchored within the body.

The risks posed by Class IIa devices include the potential for significant harm if the device integrity cannot be assured. Failure of Class IIa fixed dental prostheses such as a crown or bridge can include biological complications such as secondary caries and tooth or root fractures, and technical complications such as device fractures, problems with marginal integrity and loss of retention[1].

For invasive orthoses the risk of failure is directly linked to the stability of the device structure, which can have significant patient impacts including nerve and tissue damage if not managed through appropriate design and construction.

Given the risk posed by these kinds of devices, and that most Class IIa patient-matched medical devices cannot be removed without the assistance of a healthcare professional, it is considered inappropriate to exclude or exempt these devices.

It is proposed that Class IIa patient-matched medical devices should still be included in the ARTG but an alternative conformity assessment procedure could be considered where it can be demonstrated the risks associated with the manufacture and use of the device can be adequately managed:

1. the device is manufactured by a trained, accredited professional; or

[1] Examples of reports in the literature include http://www.aae.org/specialty/wp-content/uploads/sites/2/2017/06/jada_dangers_of_dental_devices.pdf and https://www.researchgate.net/publication/341352795_ADVERSE_EVENTS_IN_DENTAL_PRACTICE_AND_HOW_TO_PREVENT_IT

2. other third-party mechanisms of oversight are in place that are suitable to manage the low risk that may be posed by the device.

The alternative procedure would also require the manufacturer to perform a self-assessment and make declaration that they meet the regulatory requirements, including that the device(s) comply with the Essential Principles. The TGA would develop a self-assessment template for use for this purpose. The completed template and declaration could then be submitted to the TGA in support of an application for inclusion in the ARTG. Inclusion in the ARTG would be required before the device could be legally supplied.

This proposal still requires the manufacturer to:

(a) prepare and hold technical documentation in relation to the kind of device to enable assessment of the device; and
(b) hold evidence that the device meets the Essential Principles; and
(c) establish and keep up-to-date a post-market monitoring, reporting and corrective action system.

This proposal removes the requirement for a manufacture to obtain certification for their quality management system from the TGA (or another body) and significantly reduces the regulatory burden associated with including a Class IIa device in the ARTG while maintaining an appropriate level of regulation oversight.

Examples where Class IIa (low-medium risk) patient-matched medical devices could be subject to alternative conformity assessment procedures are if they are being manufactured:

- Within a healthcare facility accredited against the National Safety and Quality Health Service (NSQHS) Standards by a body recognised by the Australian Commission on Safety and Quality in Health Care (ASCQHC); **or**
- By a provider who has been registered with the National Disability Insurance Scheme Quality and Safeguards Commission (NDISQSC), and the scope of their registration encompasses the patient-matched medical devices that they are producing; **or**
- By a health professional registered with the Australian Health Practitioner Regulation Agency (AHPRA) under the *Health Practitioner Regulation National Law Act 2009,* and whose scope of practice encompasses production of the patient-matched medical devices that they are producing; **and**
  The devices they produce are intended to be used by a patient of the healthcare facility, registered provider or AHPRA-registered health professional.
- By a dental technician who holds a recognised qualification under the Australian Qualifications Framework **and**
  The devices they produce are intended to be used by a patient of the healthcare facility, registered provider or AHPRA-registered health professional.
- By a dental laboratory accredited by the Oral Health Professional Association **and**
  The devices they produce are intended to be used by a patient of the healthcare facility, registered provider or AHPRA-registered health professional.
- By an orthotist or prosthetist who is a full member of the Australian Orthotic Prosthetic Association.

The kinds of Class IIa medical devices that could be exempted under such a proposal may include:

Profession	Examples of Class IIa patient-matched medical devices
Dental technicians	• Crowns • Veneers • Bridges • Bonded retainers • Palate expanding devices
Orthotists and prosthetists	Invasive (that penetrate the skin for the purposes of stabilisation) orthoses and prostheses including splints.
All professions and facilities subject to the alternative conformity assessment procedures	Anatomical models (virtual and physical)

Note

This proposal would not apply to Class IIb or Class III patient-matched medical devices.

What we invite you to do

In your submission, we ask you to consider and respond to the questions below, and to provide comments on the issues outlined in this consultation paper.

Questions

Exclusions

1. **Do you agree with the rationale for the proposed exclusion of products? If not, why not?**
2. **Are the risks posed by the products adequately managed if they are excluded from regulation by the TGA? Please explain your response, including by providing examples that illustrate and/or support your position.**

3. **Are there further products that meet the principles proposed for exclusion? What are they and why should they be excluded?**

   Please provide an explanation for why:

   - **the product represents no, or insignificant levels, of risk; or**
   - **the product does not meet the definition of a medical device.**

Exemptions

4. **Do you agree with the rationale for the proposed exemption of Class I non-sterile, non-measuring patient-matched devices when produced under the circumstances listed in this consultation paper? If not, why not?**
5. **Can the risks posed by the Class I non-sterile, non-measuring patient-matched medical devices when produced under the circumstances listed in this consultation paper be adequately managed if they are exempted from inclusion in the ARTG? Please explain your response, including by providing examples that illustrate and/or support your position.**
6. **Are there further circumstances where Class I non-sterile, non-measuring patient-matched devices could be exempt? If so, what measures are in place to manage the risks associated with the devices?**

   Please provide details:

   - **describe the specific circumstances that are in place (such as qualifications, accreditation, certification, etc) to ensure that the risks associated with the manufacture of the devices have been managed and the Australian regulatory requirements for medical devices have been met before they are supplied.**

Inclusion in ARTG using alternative conformity assessment procedures

7. **Do you agree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched devices when produced under the circumstances listed in this consultation paper? If not, why not?**
8. **Do you agree that the risks associated with the proposed Class IIa patient-matched devices when produced under the circumstances listed in this consultation paper could be adequately managed through the proposed alternative conformity assessment procedure? Please explain your response, including by providing examples that illustrate and/or support your position.**
9. **Are there further circumstances where an alternative conformity assessment procedure for Class IIa patient-matched devices would be appropriate? If so, what measures are in place to manage the risks associated with the devices?**
10. **Are there any Class IIa patient-matched devices that should not be subject to an alternative conformity assessment procedure? What are they and why not?**

General question

11. **Are there alternative mechanisms for reducing the regulatory burden for patient-matched medical devices without compromising patient health and safety that you would like to propose?**

How to submit your response

Responses are to be provided electronically using the online response form: Complete the online consultation response form:
https://consultations.health.gov.au/tga/proposed-refinements-to-the-regulation-of-pmd

Enquiries

Please direct any questions or queries relating to the consultation to:
personaliseddevices@tga.gov.au.

Please note

Before providing feedback, it is important to read the explanatory material that follows.

Next steps

Following closure of this consultation the TGA will review the feedback received on:

1. what types of products could potentially be excluded from regulation, if appropriate;
2. what types of patient-matched medical devices should be exempt from inclusion in the ARTG, if appropriate; and
3. what types of patient-matched medical devices should be included in the ARTG subject to an alternative conformity assessment procedure, if appropriate.

Consideration also needs to be given to how consumers would view the prospect of using medical devices that are either not regulated by the TGA, or are not regulated at the same standard as devices of an equivalent classification.

Before a Ministerial decision can be made to either exclude or exempt a product, or establish an alternative conformity assessment procedure for a particular kind of patient-matched medical device, there is a need to consider whether there are any policies, standards, regulatory frameworks or accreditation systems already in place that would negate the need for the TGA to regulate the product or device to the full extent currently required.

Appendix 1 – The legal definition of a medical device

41BD What is a *medical device*

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

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

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

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

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

(iv) control or support of conception;

(v) in vitro examination of a specimen derived from the human body for a specific medical purpose;

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

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

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

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

(c) a system or procedure pack.

Note: Declarations under subsection (3) exclude articles from the scope of this definition. Declarations under section 7 can also have this effect: see subsection 7(4).

(2) For the purposes of paragraph (1)(a), the purpose for which an instrument, apparatus, appliance, software, implant, reagent, material or other article (the ***main equipment***) is to be used is to be ascertained from the information supplied, by the person under whose name the main equipment is or is to be supplied, on or in any one or more of the following:

(a) the labelling on the main equipment;

(b) the instructions for using the main equipment;

(c) any advertising material relating to the main equipment;

(d) technical documentation describing the mechanism of action of the main equipment.

(2A) The Secretary may, by notice published in the *Gazette* or on the Department's website, specify a particular instrument, apparatus, appliance, software, implant, reagent, material or other article for the purposes of paragraph (1)(aa). The notice is not a legislative instrument.

(2B) The Secretary may, by legislative instrument, specify a particular class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles for the purposes of paragraph (1)(ab).

(3) The Secretary may, by order published in the *Gazette* or on the Department's website, declare that a particular instrument, apparatus, appliance, software, implant, reagent, material or other article, or that a particular class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles, are not, for the purposes of this Act, medical devices.

Note: A declaration under this section does not stop articles from being therapeutic goods.

(4) A declaration under this section takes effect on the day on which the declaration is published in the *Gazette* or on the Department's website or on such later day as is specified in the order.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Devices Emerging Technology and Diagnostics Section	June 2021

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