Australian Government
Department of Health
Therapeutic Goods Administration

Personalised medical device framework

ATSA Independent Living Expo 2022

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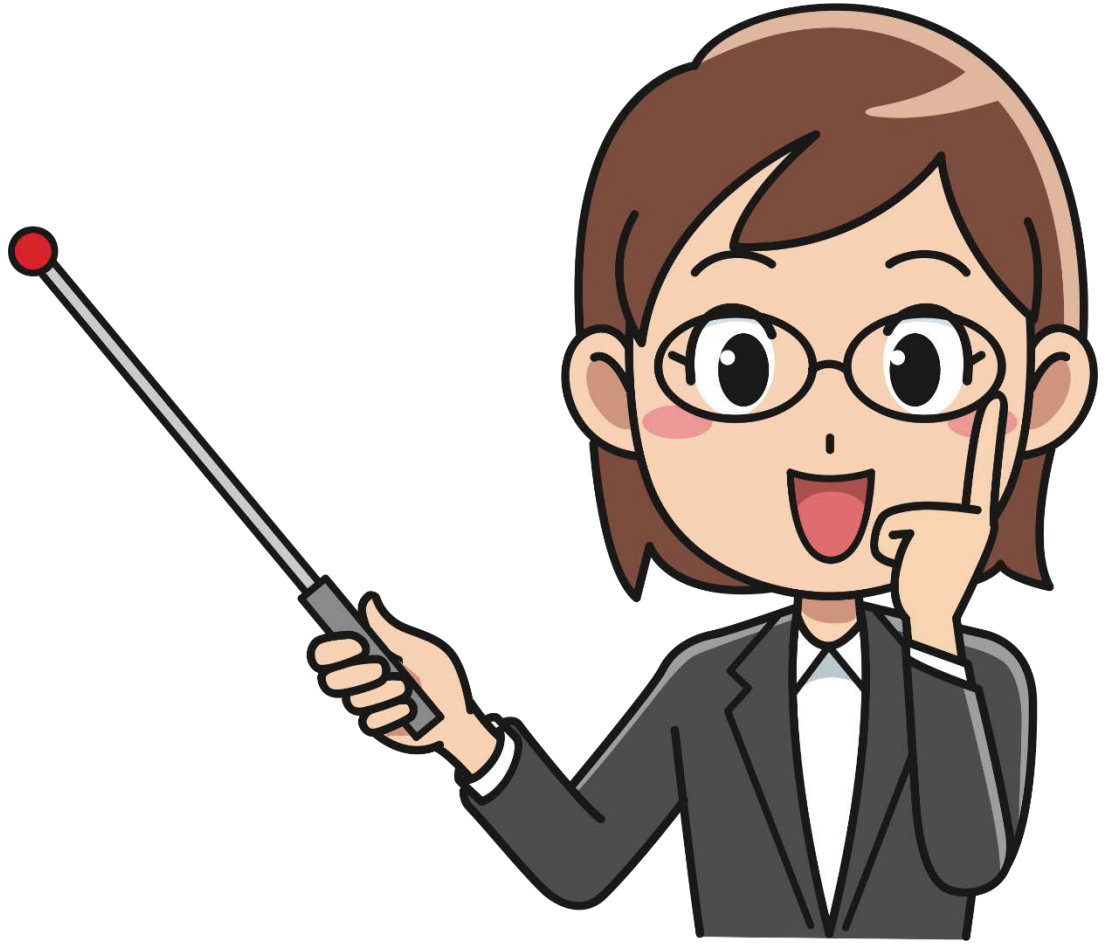
TGA Health Safety Regulation

Today's presentation

- Housekeeping
  - Caretaker mode
  - Productivity Commission – Right to repair
- Overview of medical device regulation
  - What is a medical device?
  - Who is regulated?
- Regulation basics
- Excluded goods
- Proposed changes for assistive technology
- Personalised medical devices
- Looking ahead/what to do next



Overview of medical device regulation

Therapeutic Goods Administration regulates the import, export and supply of therapeutic goods, including medical devices

Medical devices must be included in the Australian Register of Therapeutic Goods (ARTG), unless they are **EXEMPT** or **EXCLUDED**

EXEMPT devices do not have to be included in the ARTG but must meet all other regulatory requirements

EXCLUDED devices do not need to meet any regulatory requirements set by the TGA

What is a medical device?

- **Section 41BD in the *Therapeutic Goods Act 1989* defines in law 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;

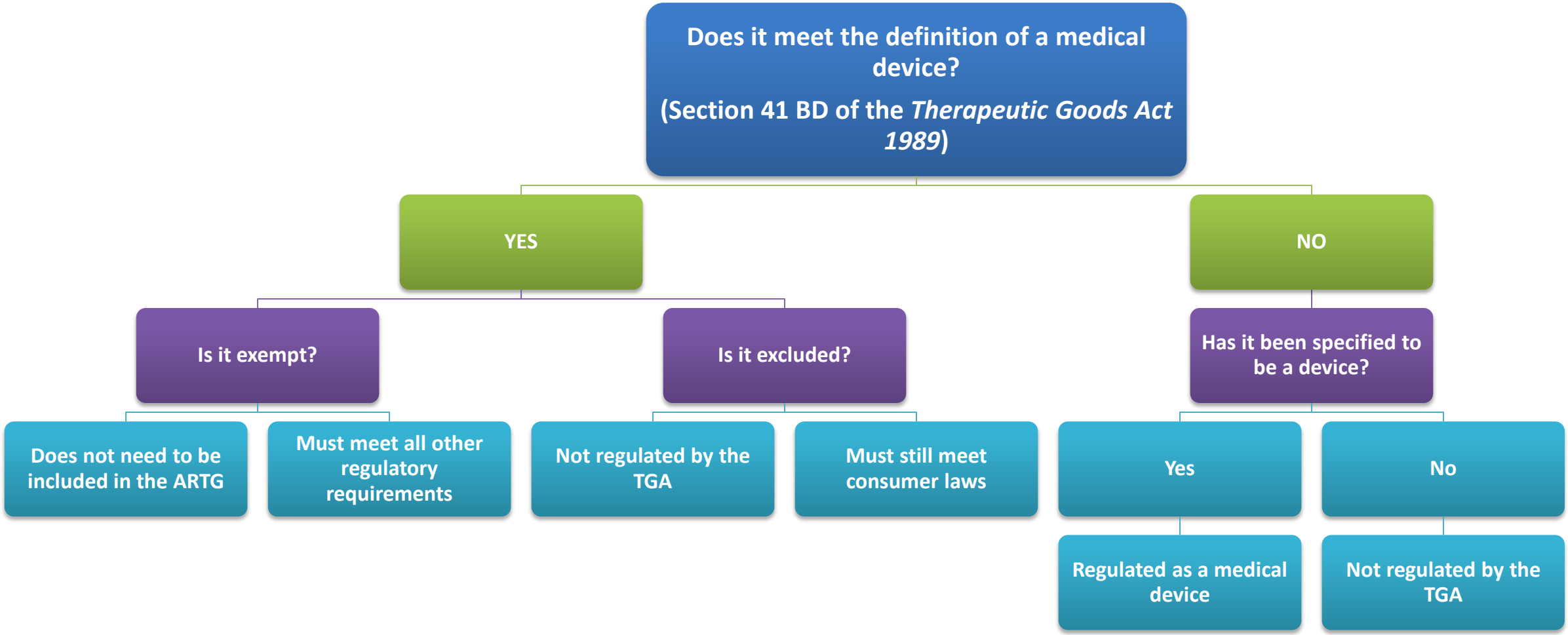
(iii) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;

(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

Is it regulated?



Who is regulated?

Manufacturer – Conformity Assessment	Sponsor – ARTG inclusion
Defined in Section 41BG of the *Therapeutic Goods Act 1989*	Described in the *Therapeutic Goods Act 1989*
Defines the intended purpose of the device	An Australian-based legal entity who is importing or manufacturing
Ensures the device meets the Essential Principles	Includes the device in the ARTG and takes responsibility for: - Meeting advertising requirements - Reporting adverse events - Maintaining records of supply
Responsible for certification / declaration of conformity	

Am I regulated?

You will be regulated* if you are:

- Importing products that meet the definition of a medical device
- Manufacturing and supplying or using products that meet the definition of a medical device

** Unless your device is excluded.*

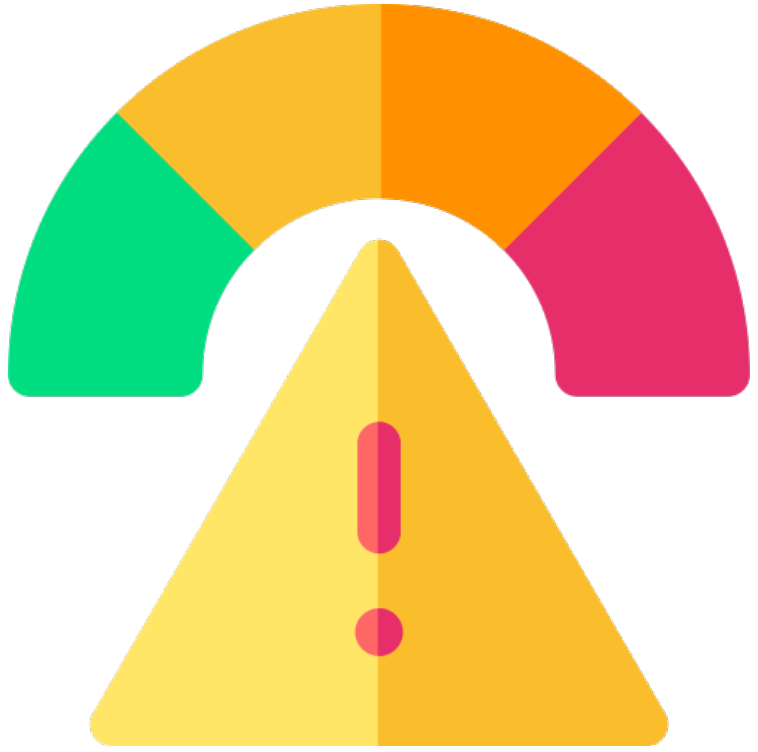
Common misconceptions

 You don’t need to register medical devices you make for your own clients	 The TGA regulates all medical devices, regardless who is making/importing them
 You don’t have to include a medical device in the ARTG if it has been made using ARTG-included components	 Some raw materials and components have been specified to be devices – you may be exempt but you will **not be excluded** if you use these products to manufacture a device
 You can import devices for use in your practice or on your clients under the “personal importation scheme”	 Medical devices imported under the personal importation scheme are for use on you and your family members **only,** not patients/clients

Medical device regulation continued

Regulation in Australia is a **risk-based** and **principles-based** approach

- Medical devices must meet the Essential Principles
  - Legislative requirements relating to safety and performance characteristics
  - Includes design, construction, materials and information supplied with the device
  - 6 general Principles that relate to all devices
  - 9 Principles relating to design and construction that apply on a case-by-case basis
  - There are many ways to demonstrate compliance

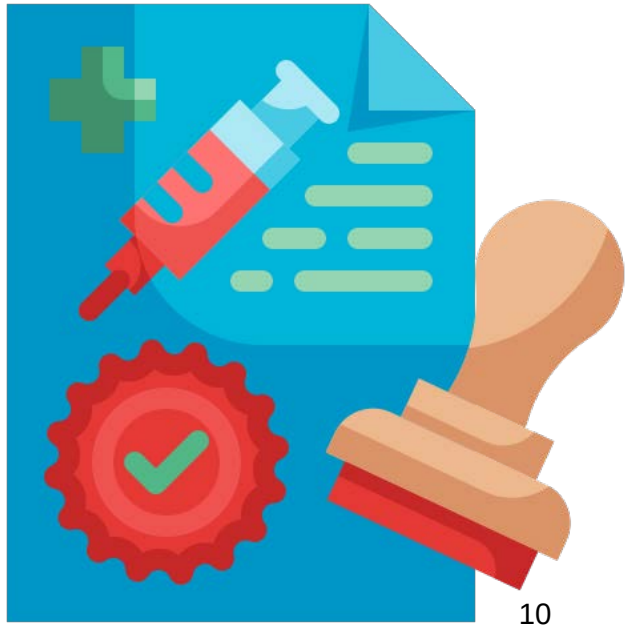


Essential Principles

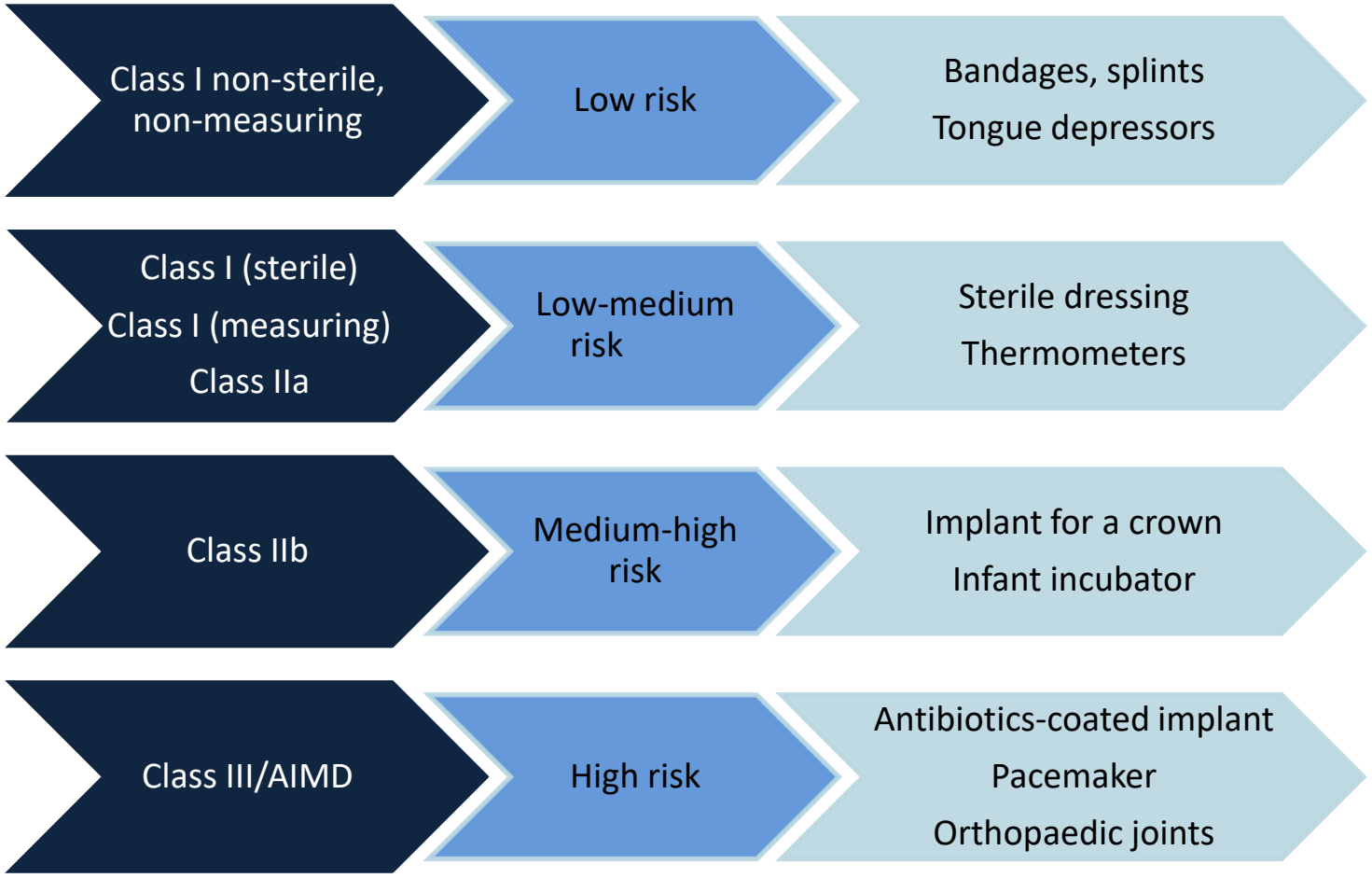
General Principles	Design and Construction
Use of medical devices not to compromise health and safety	Chemical, physical and biological properties
Design and construction of medical devices to conform with safety principles	Infection and microbial contamination
Medical devices to be suitable for intended purpose	Construction and environmental properties
Long-term safety	Medical devices with a measuring function
The device is not to be adversely affected by transport or storage	Protection against radiation
Benefits of medical devices to outweigh any undesirable effects	Medical devices connected to or equipped with an energy source
	Information to be provided with medical devices
	Clinical evidence
	Principles applying to IVD medical devices only

Classification levels

- Classification rules are contained in Schedule 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002*
- TGA has an online classification tool to assist you
- Devices are classified according to risk
  - Length of use
  - Invasiveness
  - Other features (active, programmable, kind of device, etc)
- The classification of the device determines what kind of evidence of compliance with the Essential Principles you will need before you can apply to include your device in the ARTG.



Classification examples



ARTG inclusion

- Must have evidence of conformity assessment (demonstrate that you have met the Essential Principles)
  - Class I non-sterile, non-measuring (self declaration)
  - All other classes (third party certification)
- ARTG inclusions are for a “kind” of medical device.
  - Global Medical Device Nomenclature (GMDN) code
  - Classification
  - Sponsor
  - Manufacturer
  - Unique Product Identifier (Class III, AIMD)

Excluded goods

Some products are excluded from the therapeutic goods regulatory system

- Primarily under the *Therapeutic Goods (Excluded Goods) Determination 2018*

Current exclusion:

- household and personal aids, or furniture and utensils, for people with disabilities

Proposed changes for assistive technology

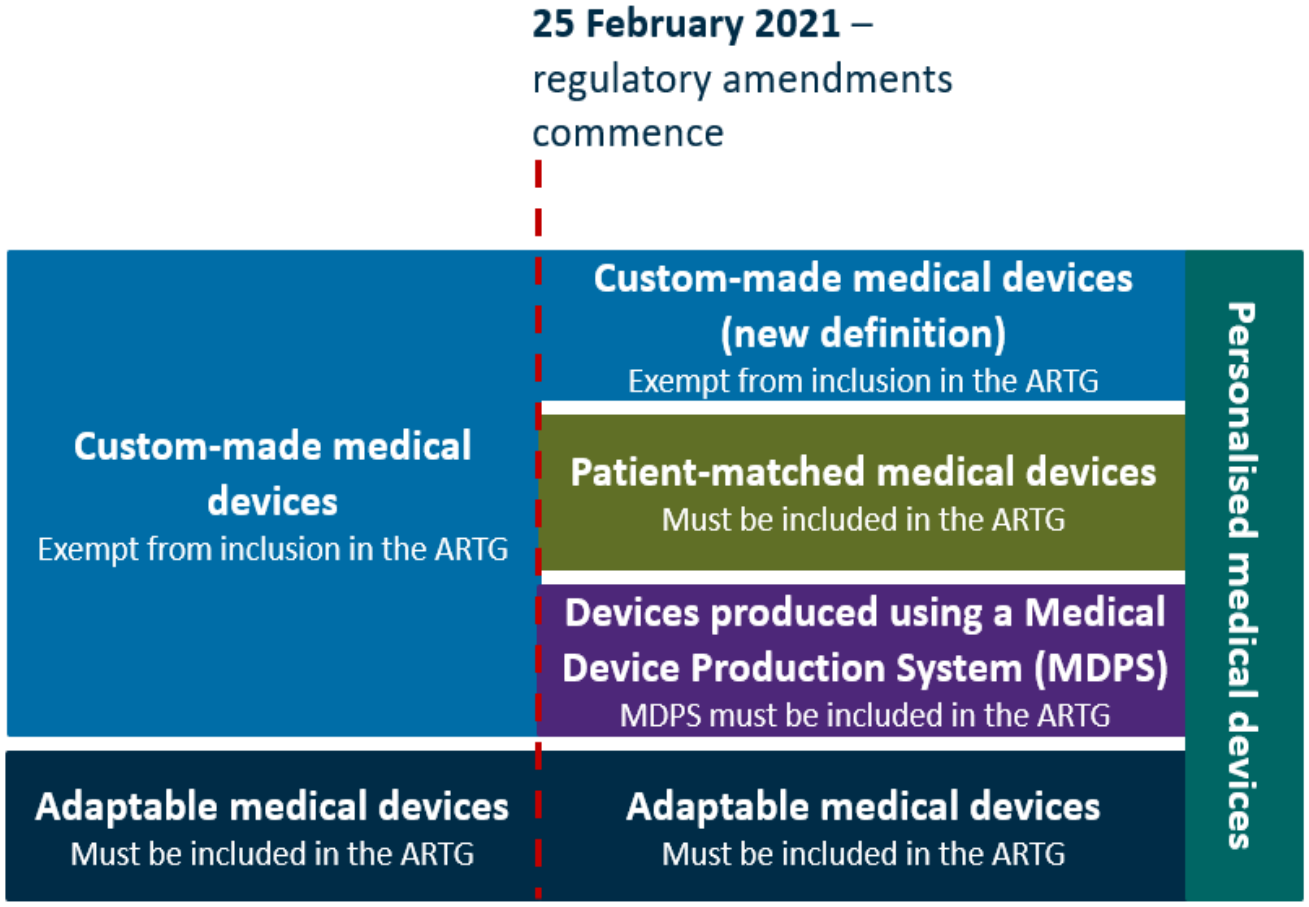
Proposed change:

- Assistive technology products intended by the manufacturer to maintain or improve functional capacity of persons with disability to undertake activities of daily living in settings other than health care settings.
- Must be:
  - Low risk (Class I, non-sterile, non-measuring)
  - would not pose a risk of harm that requires medical attention in circumstances where it malfunctions or deteriorates when used as intended

    Example - not weight bearing (falls can cause significant injury)

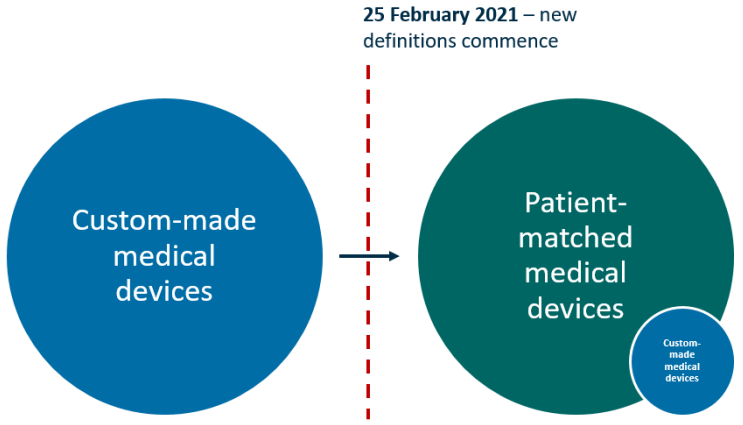
Overview of the changes

- Traditionally custom-made devices were low risk, and manufactured by trained and accredited professionals
- Rapid advances in technology have changed the regulatory environment
- Two years of public consultation and collaboration through the International Medical Device Regulator's Forum
- A new regulatory framework for personalised medical devices commenced on **25 February 2021**



Patient-matched medical devices

- Manufactured within a “design envelope”
- Production processes can be validated, verified or reproduced
- No longer exempt – must be included in the ARTG
- Notify the TGA by **25 August 2022** to access transition arrangements
- Submit an application for inclusion **before 1 November 2024**
- **The majority of medical devices previously supplied as custom-made will now meet the patient-matched definition**



Adaptable medical device

- A new definition for an existing concept
- Mass-produced and designed to be modified at the point of care to suit a particular patient.
- Definition introduced to provide clarity
- Adaptable medical devices **continue** to require inclusion in the ARTG before they can be supplied.
- Essential principle 13.4(3) will specifically require adaptable medical devices are supplied with instructions to allow safe modification/assembly at the point of care.

Point-of-care manufacturing

- Collaboration ahead with:
  - Ahpra
  - Australian Commission on Safety and Quality in Health Care
  - NDIS Commission
  - State/territory governments
  - Private hospitals
  - Healthcare practitioners/clinicians

- To:
  - Ensure regulation is appropriate (by whom, to manage what risks)
  - Establish clear boundaries
  - Communicate those boundaries effectively
  - Ensure devices are safe and accessible

Resources and contacts

- Australian Regulatory Guidelines for Medical Devices
- Medical device inclusion process guidance
- Medical devices information unit
  - 1800 14 11 44
  - devices@tga.gov.au
- SME Assist
- Subscribe to the PMD newsletter (send an email to devices@tga.gov.au with “SUBSCRIBE PMD” in the subject line)

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