Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Understanding specified articles and excluded products in personalised medical devices regulation

Guidance for manufacturers and sponsors of personalised medical devices, including health professionals. Learn what we mean by ‘specified articles’ and the difference between exempt vs excluded products.

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Purpose

This guidance helps health professionals and those working to instructions by health professionals understand the specified articles exemption for medical devices. It also lists relevant products excluded from TGA regulation.

Legislation

Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020

Therapeutic Goods (Excluded Goods) Determination 2018

Therapeutic Goods (Medical Devices) Regulations 2002

Specified articles exemption

An exemption means that a medical device does not need to be included in the Australian Register of Therapeutic Goods (ARTG).

> Certain medical devices, including some patient-matched medical devices (PMMDs) are exempt under the **specified articles exemption**.
>
> If you are:
>
> - A health professional, who makes the following as part of your clinical practice:
> - direct or indirect tooth restorations
> - non-implantable dental devices
> - externally applied orthopaedic devices; or
> - A person making these devices to a health professional's written instructions,
>
> **and** you make them **exclusively** from ARTG-included materials or components, you do not have to include your finished devices in the ARTG.

Note:

Exempt devices are exempt from inclusion in the ARTG. **They are not exempt from regulation**. If you make or supply an exempt medical device, you still have to comply with TGA regulations, such as:

- Meeting all relevant Essential Principles. This includes supplying the device with adequate labelling and instructions for use;
- Meeting advertising requirements for therapeutic goods.

A ‘health professional’ as defined in the *Regulations* includes someone who is:

- a medical practitioner, or a dentist or any other kind of health care worker registered under a law of a State or Territory; or
- a biomedical engineer, chiropractor, optometrist, orthodontist, osteopath, pharmacist, physiotherapist, podiatrist, prosthetist or rehabilitation engineer.

Specified articles

The Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020 declares certain products to be a medical device. This includes some starting materials and components used in the manufacture of specific medical devices.

The following products (‘specified articles’), mostly used in the dental and allied health sectors, are regulated as medical devices. They must be included in the ARTG.

- Materials for direct tooth restoration, including but not limited to:
  - amalgam;
  - composite resins and respective bonding systems;
  - core build-up materials;
  - crown forms;
  - fibre or metal preformed posts;
  - fibre reinforcement materials;
  - fissure sealants;
  - glass ionomers;
  - liners and bases;
  - resin-modified glass ionomers; and
  - temporary crown or bridge materials.
- Materials and articles used for indirect tooth restorations, like:
  - ceramic;
  - crown forms;
  - metal alloy; and
  - temporary crown or bridge materials.
- Materials and other articles to be supplied or used by a relevant practitioner in the manufacture of externally applied orthopaedic devices. This includes, but is not limited to:
  - fibreglass bandages used to make splints or orthoses;
  - software; and
  - thermoplastic sheeting to make splints or orthoses.

- Materials and other articles to be supplied or used by a relevant practitioner to manufacture non-implantable dental appliances. This includes, but is not limited to:
    - acrylic;
    - denture repair or reline materials;
    - metal alloy used in casting;
    - orthodontic components; for example bands, brackets, chains, elastics, ligature ties, separators, and wire;
    - palate expanders;
    - preformed acrylic teeth;
    - preformed clasps;
    - software;
    - thermoplastic; and
    - wrought wire used in the manufacture of clasps or retainers.
- Materials and other articles used by a relevant practitioner to obtain dental impressions.

Medical device inclusion process

Steps to include a medical device (including IVD medical devices) in the Australian Register of Therapeutic Goods (ARTG).

Excluded products

An excluded product means a product that it is not regulated by the TGA. This is **different from exemption**.

If you make or supply a product that is excluded, TGA requirements do not apply.

For example, you don't need to include it in the ARTG, meet the Essential Principles, or report adverse events to the TGA.

Excluded products are still subject to other regulatory requirements. These include the Australian Competition and Consumer Commission (ACCC) consumer protection laws and state or territory consumer protection laws.

The Therapeutic Goods (Excluded Goods) Determination 2018 excludes:

- Anatomical models intended to be used for educational or record-keeping purposes.
- Cosmetic finishing components for orthoses and prostheses.
- Craniofacial prostheses that are
    - spectacle-retained
    - adhesive-retained
- Dental impression trays.
- Ear moulds intended by the manufacturer to anchor hearing aids.
- Medicament trays intended by the manufacturer to hold medicaments.
- Mouthguards that protect teeth from external forces, including contact sports mouthguards.
- Ocular prostheses intended by the manufacturer to be used for cosmetic purposes.
- Physical impressions of anatomy, and models cast from such impressions.
- Spectacle frames.

No action is required if you have already included a product in the ARTG that is mentioned in the Therapeutic Goods (Excluded Goods) Determination 2018.

More information

Personalised medical devices

Information about how we regulate personalised medical devices.

Topics Manufacturing Therapeutic goods regulation

Page history

7 May 2025

- Reformatted into new guidance template. Content was previously titled 'Refinements to the Personalised Medical Device Framework'.
- Added details about the specified articles exemption.

5 November 2024

- Updated to indicate the transition notification period has ended.

17 October 2024

- Updated transition eligibility content.

5 December 2023

- Updated to reflect the extension of the patient-matched transition notification period and deadline and provides links to point-of-care manufacturing of medical devices work.

5 September 2022

- Updated to reflect the closure of the patient-matched transition notification period.

2 August 2021

- Original publication.
  Originally titled 'Refinements to the Personalised Medical Device Framework'.