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

Meeting 3D printing (additive manufacturing) rules for medical devices

Guidance for manufacturers to help you manage risks and meet regulatory requirements.

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Purpose

This page provides information for manufacturers to help address the risks of three-dimensional (3D) printing and meet the Australian regulatory requirements for medical devices.

3D printing is a process where a digital model is created using computer-aided-design (CAD) software or via a 3D scanner, and then used to build an object through a layer-by-layer approach. This method, also known as additive manufacturing, is increasingly used to make medical devices and their parts. While it offers many benefits, it also comes with specific risks that manufacturers must address to ensure the products are safe and perform as intended.

Legislation

Therapeutic Goods (Medical Devices) Regulations 2002

Therapeutic Goods (Conformity Assessment Standard for Quality Management Systems) Order 2019

How we regulate 3D-printed medical devices

We regulate 3D-printed medical devices in the same way as non-3D-printed medical devices. This is because medical devices are regulated based on the type of device, rather than how they are made. This means they have the same regulatory requirements as non-3D-printed medical devices.

We do not independently regulate the 3D printing technology.

Medical devices overview
Information about how we regulate medical devices and how to get your medical device approved for use in Australia.

Personalised medical devices
Information about patient-matched, custom-made, and adaptable medical devices.

3D printers

3D printers intended to manufacture medical devices are **not independently regulated** by us but are considered as part of the overall manufacturing process. 3D printers are considered manufacturing equipment and do not meet the definition of a medical device.

There are many 3D printing methods and processing steps that can be used to create medical devices. No specific brand of 3D printer is required for this purpose.

Overview of 3D printing

3D printing is a type of additive manufacturing. It enables the manufacture of complex 3D objects, shapes and textures. It uses raw materials such as polymers, resin, ceramics or metals in a layer-by-layer process. 3D printing is often used to produce personalised medical devices, for example:

- patient-matched models for pre-operative planning
- surgical guides
- patient-matched permanent implants

The 3D printing workflow generally involves these main stages:

- Image acquisition or modelling
- Generating an STL (stereolithography) file
- Slicing
- Printing
- Post-processing

Risk management

Medical devices should be designed and manufactured to reduce risk. Manufacturers of 3D-printed medical devices must understand and describe material properties and processing requirements to minimise risks to users or patients.

Manufacturers must be able to show:

- how they mitigate any risks associated with the manufacture of a medical device; and
- that the medical device complies with all relevant Essential Principles.

Key considerations

Starting materials

Starting (raw) materials or components used in the manufacture of a medical device generally do not meet the definition of a medical device. Therefore, they do not need to be included in the Australia Register of Therapeutic Goods (ARTG) before they are supplied.

The exception is if a starting material meets our definition of a **specified article**. In this case, it is regulated as a medical device and **must be included in the ARTG** before it can be used in the manufacture of a medical device.

Examples of specified articles include materials used in non-implantable dental appliances, materials used in externally applied orthopaedic devices.

Understanding specified articles and excluded products in personalised medical devices regulation

Starting materials may undergo significant physical or chemical changes during manufacture. Changes can affect the success of the printing process and the final device. Manufacturers should monitor the consistency and suitability of raw materials used.

Manufacturers must document manufacturing processes and material specifications as part of a quality management system.

When determining the suitability of a starting material, a manufacturer should consider:

- the material's supplier, specification, and certificate of analysis
- the physical properties of the material (e.g. viscosity, melting temperature, purity)
- its biocompatibility with the human body
- the use of additives, crosslinkers, rheology modifiers or processing aids
- the degradability and leachables
- suitable post-printing processes.

Note. Biocompatibility is the ability of a material to perform safely within the human body without causing adverse reactions. One option for demonstrating it is using ISO 10993.

Cleaning the medical device

If your medical device is supplied non-sterile, it should be cleaned through a validated process before it is packaged for supply.

Cleaning can involve removing:

- physical,
- chemical, and
- microbial residue.

Sterilisation

If the device is intended to be sterilised, the manufacturer should include at least one validated cleaning procedure, and one validated sterilisation procedure in the Instructions for Use (IFU).

If your 3D-printed medical device is designed to be sterile, the sterilisation process must be validated.

Sterilisation standards can be found in:

- Therapeutic Goods (Conformity Assessment Standard for Quality Management Systems) Order 2019
  Lists sterilisation standards that can be used.

> **Note:**
> - 3D printing can result in air bubbles or pockets being present in the body of the device. As these air bubbles or pockets could be non-sterile, this poses a problem for sterilisation.
> - Microbiological risks can arise if a sterile implantable device with air bubbles or pockets breaks or degrades.

You will need to describe how you mitigated the risk of this outcome in your documentation.

3D bioprinting

3D biological printing or 'bioprinting' is an advanced form of 3D printing. It uses biological materials, including living cells, to create tissue-like structures. These cells can come from animals or humans, and can be primary cell lines or stem cells. The printed scaffold eventually degrades, leaving behind functional tissue in the desired shape and location.

Bioprinted implants meet the definition of a medical device containing biological materials. For TGA approval, such implants are submitted as a medical device.

More information

US FDA - Technical Considerations for Additive Manufactured Medical Devices - Guidance for Industry and Food and Drug Administration Staff

Personalised medical devices
Information about patient-matched, custom-made, and adaptable medical devices.

Topics Manufacturing

Page history

20 August 2025

Added more background information on 3D printing and details about how the TGA regulates 3D-printed devices. Edits for readability. Added links to the personalised medical devices and specified articles pages.

23 September 2024

Title changed from '3-D printing (additive manufacturing) of medical devices' to 'Meeting 3-D printing (additive manufacturing) rules for medical devices' as part of migration to new 'Guidance' content type.

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