



Australian Government
Department of Health
Therapeutic Goods Administration



Current Regulatory Landscape for Medical Device 3D-Printing

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TGA Health Safety
Regulation



Medical device 3D printing - This talk

- Scope
- Overview of medical device regulation—including mass produced 3D-printed devices
- Current regulation of 3D-printed medical devices made for a particular patient
- Consultation for regulatory reforms
- International harmonisation
- Next steps



Medical Device 3D-Printing - Scope

Test beds for Medicine Preclinical Testing and Research

Medicines

Anatomical Models for Teaching

ü Anatomical Models for Investigation of a Patient's Anatomy

ü Externally Applied Medical Devices

ü Invasive Medical Devices

ü Implantable Medical Devices



Medical device regulatory framework in Australia (including mass-produced 3D-printed devices)



Regulatory requirements for medical devices

- Does it Fit the Definition of a Medical Device?
- Apply the Classification Rules
- Evidence of Safety, Performance and Quality
- Regulatory Review of Evidence (if device is above Class I)
- Manufacturing Certification (if device is above Class I)
- Inclusion in the ARTG
- Post-Market Requirements
 - Monitor Post-Market Performance
 - Report Problems to the TGA
 - Annual Manufacturing Inspections



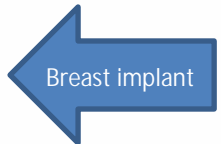
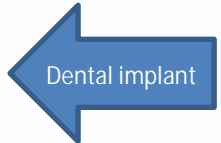
What is a medical device?

Defined in s41BD of the *Therapeutic Goods Act 1989*

Any instrument, apparatus, appliance, material or other article intended to be used for human beings for the purpose of one or more of the following

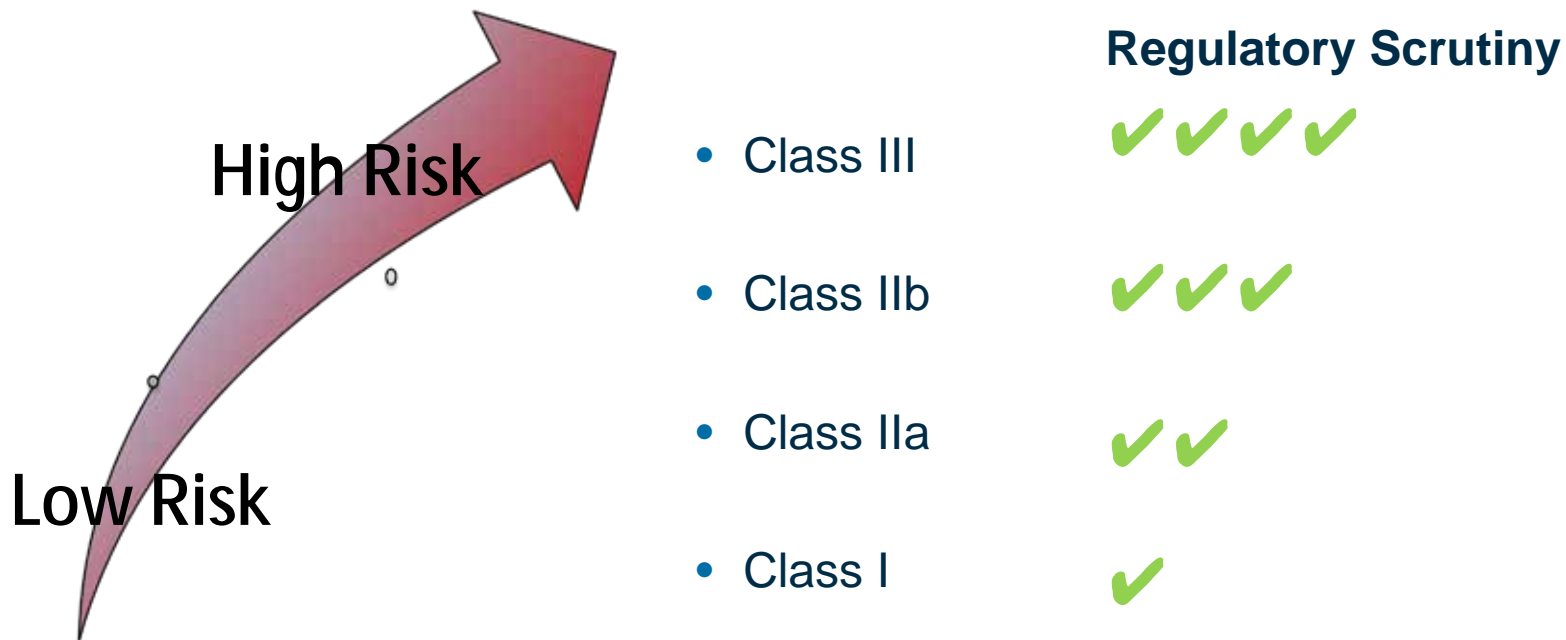
- (i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
- (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability
- (iii) investigation, replacement or modification of the anatomy or of a physiological process
- (iv) control of conception;

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





Regulatory oversight increases with risk category





Some Exceptions

Special Access Scheme for Unapproved Goods

Experimental Product Exemptions

Custom-Made Medical Devices

In-House In Vitro Diagnostic Devices



Medical device regulatory framework in Australia (3D-printed devices - excluding mass-produced)



Custom-made medical device

- the Regulations define a custom-made medical device as ...

custom-made medical device means a medical device that:

- (a) is made specifically in accordance with a request by a health professional specifying the design characteristics or construction of the medical device; and
- (b) is intended:
 - (i) to be used only in relation to a particular individual; or
 - (ii) to be used by the health professional to meet special needs arising in the course of his or her practice.



Custom-made medical devices

Exempt from Inclusion in the Australian Register of Therapeutic Goods

Sponsors and/or Manufacturers must notify the TGA that they are supplying devices in Australia

No third-party oversight of manufacturing or device EP compliance evidence



Are consumers protected under these requirements?

- Custom-made implants are **not currently subject to third-party pre-market review of safety, quality and performance**
- Historically, custom-made medical devices were **considered to comprise low-risk products, or be very limited in number**
- **High-risk devices**, e.g., implants, that are manufactured conventionally are subject to rigorous regulatory oversight of design and manufacture
- **There are some novice players with limited awareness of QMS and regulatory requirements** involved in 3D-printed device development



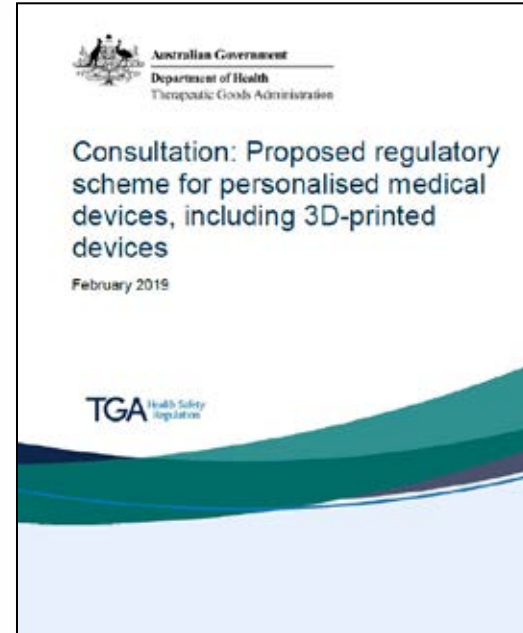
Regulatory reform ahead



Public consultation

- Same proposals previously consulted at the end of 2017
- Includes further detail to clarify proposals
- Seeks to understand impact on stakeholders

<https://www.tga.gov.au/consultations-reviews>





Current consultation proposals

Proposal 1—Introduce new definitions

- Personalised medical device
- Patient-matched medical device
- Adaptable medical device

Proposal 2—Change the requirements for supplying custom-made medical devices

- Annual reporting to the TGA
- Provide information about the device to patients
- Allow the TGA to inspect manufacturing sites

Proposal 3—Introduce a ‘medical device production system’

- Allow healthcare providers to produce lower-risk personalised devices for treating their patients, without the need for manufacturing certification



Current consultation proposals

Proposal 4—Update the classification rule for medical devices that record diagnostic images

- Includes any device for this purpose and not just X-rays, for example, 3D-printed models of patient anatomy

Proposal 5—Regulate medical devices with a human-origin component, for example, a 3D-printed implant incorporating cells from the patient, as medical devices with a biological component rather than as pure biologicals

Proposal 6—Clarify that any modifications or adaptations, to personalise a medical device that has already been supplied, must have been intended by the original manufacturer of the device.



International harmonisation



International Medical Device Regulators Forum (IMDRF)

- Global harmonisation initiative established in 2011
- Current members are:
 - Australia*
 - Brazil,*
 - Canada,*
 - China,
 - the European Union,
 - Japan,*
 - Russia,
 - Singapore,
 - South Korea,
 - the United States*

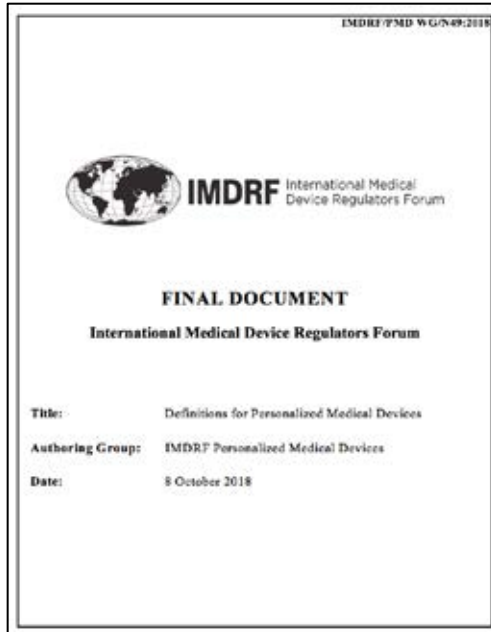
* Founding members

Personalised Medical Devices Working Group

- Established 2017
- Australia is Chair



IMDRF documents from the PMD working group





Next steps in Australia

Use of 3D-printing for patient specific applications is increasing, but does our existing regulatory framework adequately mitigate risk for patients?

What's next...

- Analyse results of current consultation
- Seek government approval for regulatory changes based on consultation proposals and responses
- Implement changes following an appropriate transition period



Further information

TGA website

- Medical devices (<https://www.tga.gov.au/medical-devices-ivds>)
- SME Assist (<https://www.tga.gov.au/sme-assist>)
- News, consultations, guidance, subscribe to updates

IMDRF website

- International Medical Device Regulators' Forum (<http://imdrf.org>)

Contact the TGA Medical Devices Branch

- devices@tga.gov.au ph.: 1800 141 144



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