



# TGA REGULATORY UPDATE

## December 2020



# New and Upcoming Reforms

- Software as a Medical Device (SaMD)
- Personalised Medical Devices (PMD) and Medical Device Production Systems (MDPS)
- Reclassification of Surgical Mesh
- Reclassification of devices
- Unique Device Identification (AusUDID)
- Patient Implant Cards and Leaflets (PIC/PIL)
- IVD Companion Diagnostics

# Software as a Medical Device (SaMD)



- Commencing: 25 Feb 2021 (new inclusions)
- Changes
  - New classification rules
  - EP 12.1 and 13.2(3) amended
  - New EP 13B introduced
- <https://www.tga.gov.au/regulation-software-medical-device>



# Personalised Medical Devices (PMD)



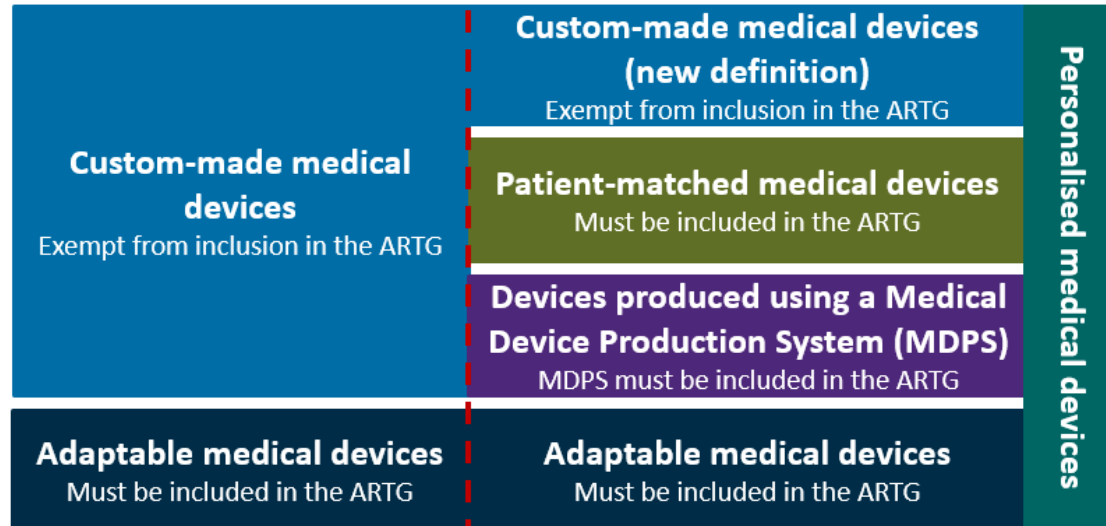
- Commencing: 25 Feb 2021 (new inclusions)
- Changes:
  - Reduced scope of custom made devices, r excludes patient matched devices
  - New concept of Medical Device Production System (MDPS)
  - Update to classification rule 5.4
- <https://www.tga.gov.au/resource/personalised-medical-devices-including-3d-printed-devices>



# PMD – Overview of changes



25 February 2021 –  
regulatory amendments  
commence



# PMD - Patient-matched medical devices



- Production processes can be validated, verified or reproduced
- Manufactured within a “design envelope”
- No longer exempt – must be included in the ARTG
- Notify the TGA by 25 August 2021 to access transition arrangements
- Submit an application for inclusion before 1 November 2024

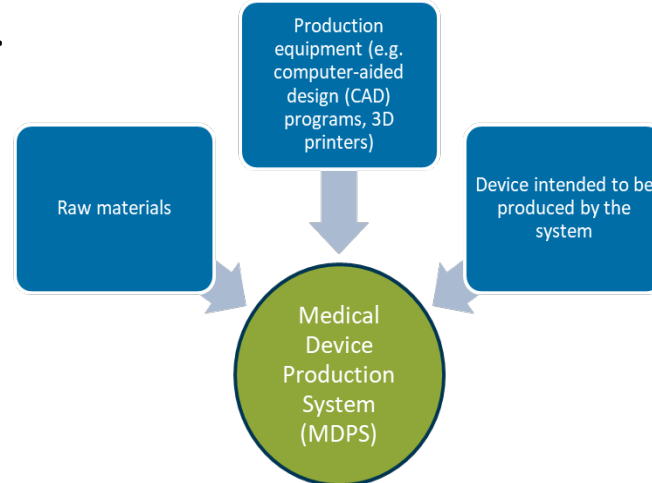




# MDPS



- TGA is the first regulator to introduce the concept
- A validated, multi-component design and production system that a manufacturer can supply to health professionals and healthcare facilities, to produce a specific type of personalised medical device in-house.





# MDPS



- Health professionals (or a suitably qualified person within a healthcare facility) who use an MDPS to produce a medical device will not meet the definition of a manufacturer.
- The MDPS must:
  - be included in the ARTG;
  - classified at the same level as the device it produces; and
  - be supplied with comprehensive instructions to allow the healthcare professional (or qualified person) to safely produce a device commensurate with the intended purpose of the MDPS.



# Reclassification of Surgical Mesh



- Commencement:
  - Existing urogynaecological mesh entries require Class III application by 1 Dec 2020
  - Other surgical mesh entries require Class III application by 1 Dec 2021
- Changes
  - Reclassification from Class IIb to Class III
- <https://www.tga.gov.au/publication/reclassification-on-surgical-mesh-devices>



# Reclassification of devices



- Commencing: Delayed to 25 Nov 2021
- Changes:
  - Generally changed to align with the EU MDR's.
  - Includes 6 categories of medical devices, for example:
    - spinal implantable medical devices (some to Class III)
    - medical devices that administer medicines or biologicals by inhalation (to Class IIa or IIb)
    - medical devices that are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system (to Class III)
- <https://www.tga.gov.au/therapeutic-goods-legislation-amendment-2019-measures-no1-regulations-2019>

# Unique Device Identification (UDI)



- Second consultation period closed 2 Dec 2020
- Changes:
  - Proposal for both sponsor and manufacturer to have legislated UDI responsibilities
  - Proposal for TGA managed data base (AusUDID) linked to the ARTG.
  - <https://www.tga.gov.au/medical-device-reforms-establishment-unique-device-identification-system>

# Patient Implant Cards and Leaflets (PIC/PIL)



- Transition Dec 2018 -Dec 2021
- Changes:
  - Changes have already been added to the MDSAP Audit Approach
  - EP 13A added to MD Regulations
- <https://www.tga.gov.au/book-page/patient-implant-cards>

# IVD Companion Diagnostics



- Transition: 1<sup>st</sup> Feb 2020 – 30<sup>th</sup> June 2022
- Changes:
  - new definition of the term 'IVD companion diagnostic' was introduced into the Therapeutic Goods (Medical Devices) Regulations 2002
  - Australia's definition of IVD companion diagnostic and the regulatory requirements are now aligned with the U.S. Food & Drug Administration and the European Union Regulations
  - Generally classified as Class 3 IVD's or Class 3 in-house IVD's.
  - <https://www.tga.gov.au/publication/ivd-companion-diagnostics>



**MDSAP**  
MEDICAL DEVICE SINGLE AUDIT PROGRAM