



**IMDRF** International Medical  
Device Regulators Forum

# **Regulatory and Policy Update**

Therapeutic Goods Administration  
Australian Department of Health

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## Overview

- Recent regulatory reforms
- Consultations for regulatory reforms
- Recently published guidance
- Other activities



## Recent regulatory reforms

Effective 1 December 2018:

- Up-classification of surgical mesh
- Patient implant cards / patient information leaflets

	Up-classification	Device info leaflet	Patient implant card
<b>Urogynaecological mesh</b>			
New devices	1 Dec 2018	1 Dec 2018	1 Dec 2018
Existing devices	1 Dec 2020	1 Dec 2019	1 Dec 2019
<b>Surgical mesh</b>			
New devices	1 Dec 2018	1 Dec 2018	1 Dec 2020
Existing devices	1 Dec 2021	1 Dec 2021	1 Dec 2021
<b>Implantable devices (other than those exempted)</b>			
New devices	NA	1 Dec 2018	1 Dec 2020
Existing devices	NA	1 Dec 2021	1 Dec 2021



## Consultations for regulatory reforms

### Current consultations

#### **Closing 31 March 2019:**

- Personalized medical devices (including 3D printed devices)
  - Incorporates IMDRF Definitions for personalized medical devices
- Software including software as a medical device
  - Incorporates IMDRF SaMD concepts
- Spinal implantable medical devices

#### **Closing 29 April 2019:**

- Medical devices that administer medicines or biologicals by inhalation
- Active implantable medical devices and their accessories
- Human cells, tissues and organs storage solutions and IVF media
- Substances introduced into the body via a body orifice or applied to the skin
- Medical devices used in direct contact with the heart, central circulatory or central nervous systems



# Consultations for regulatory reforms

## Recently closed consultations

### **Closed 7 January 2019:**

- Changes to a number of definitions and the scope of the medical device regulatory framework in Australia
- Potential reclassification of active medical devices for closed-loop diagnosis and patient therapy
- Proposal to introduce a Unique Device Identification (UDI) system

### **Closed 20 December 2018:**

- Medical device cyber security – Guidance for manufacturers and users
- Changes to the regulation of IVD companion diagnostics



## Consultations for regulatory reforms

### Upcoming consultations

- Reclassification of devices containing nanomaterials
- Systems and procedure packs
- Essential Principles / General safety and performance requirements
- Conformity assessment procedures
- Post market, including:
  - Periodic Safety Update Reporting – changing from Annual Reporting
  - Electronic reporting of adverse events as the only way to report events
- Excluded Goods Determination – items that are not medical devices



## Consultations for regulatory reforms

### Where to find information on the consultation documents

Visit the TGA webpage to view the consultations:

- **Current consultations:** <https://www.tga.gov.au/open-consultations>  
- Instructions on how to submit is provided in each consultation paper
- **Recently closed consultations:** <https://www.tga.gov.au/medical-devices-ivds-closed-consultations-reviews> - Submissions to the consultations will be published on these pages
- To know more about TGA's consultation in general see <https://www.tga.gov.au/about-consultations>



## Recently published guidance

- **The Poisons Standard and medical devices**  
10 September 2018  
<https://www.tga.gov.au/poisons-standard-and-medical-devices>  
Information for medical device manufactures and sponsors on complying with Australia's Poisons Standard
- **Medical device patient cards and leaflets**  
15 October 2018  
<https://www.tga.gov.au/publication/medical-device-patient-cards-and-leaflets>  
Information for manufacturers and sponsors on new requirements for patient cards and leaflets for implantable medical devices
- **Reclassification of surgical mesh devices**  
27 November 2018  
<https://www.tga.gov.au/publication/reclassification-surgical-mesh-devices>  
Guidance for sponsors of surgical mesh medical devices, which have been reclassified as Class III with transitional arrangements from 1 December 2018.





## Recently published guidance

- **Regulation of Software as a Medical Device**  
11 December 2018  
<https://www.tga.gov.au/regulation-software-medical-device>  
Guidance on the regulation that applies to software and apps that meet the legislated definition of a medical device in Australia
- **How to determine if your product should be included in the ARTG**  
14 January 2019  
<https://www.tga.gov.au/how-determine-if-your-product-should-be-included-artg>  
Assistance for sponsors to decide if products are required to be included in the ARTG, and action for incorrectly included products
- **Conditions of approval on the ARTG for HIV POCT**  
30 January 2019  
<https://www.tga.gov.au/conditions-approval-artg-hiv-poct>  
Text of condition of marketing approval for HIV point of care testing



## Other activities

- **Update on Breast Implant Associated ALCL**  
Expert Working Group meeting on 30 Jan 2019  
21 December 2018 update to TGA statement on BIA ALCL  
<https://www.tga.gov.au/breast-implant-associated-cancer-or-bia-alccl>
- **ISO 13485**  
1 March 2019  
TGA released a statement on the end of the period for transition to ISO 13485:2016 and implications for manufacturers <https://www.tga.gov.au/iso-134852016-transition-period-ending>
- **Brexit**  
6 March 2019  
TGA released a statement on implications of the UK's withdrawal from the EU for the supply of medical devices in Australia  
<https://www.tga.gov.au/brexit-implications-therapeutic-goods-australia>



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Thank you