IMDRF International Medical Device Regulators Forum

Regulatory update from TGA Australia

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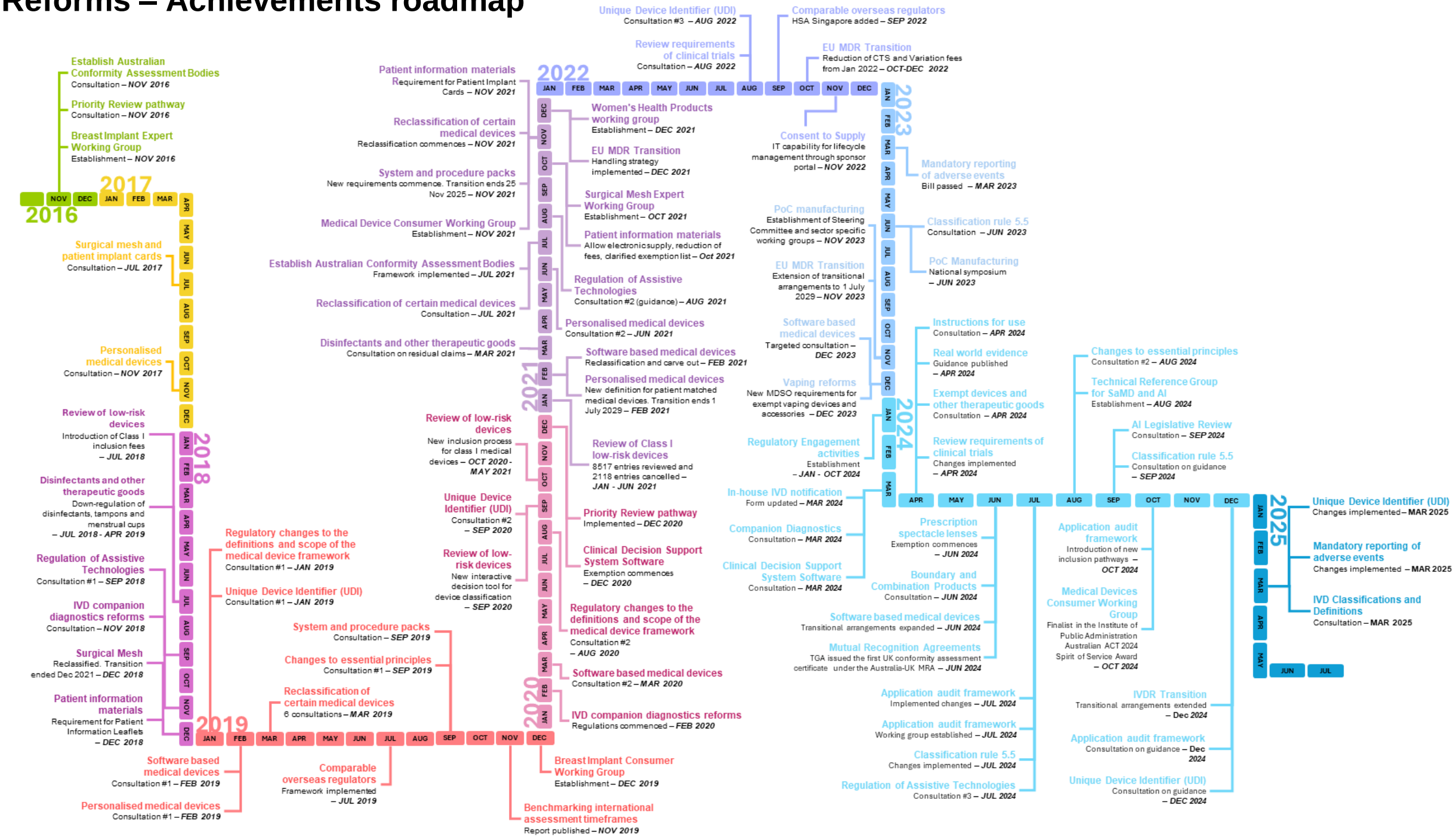
Australia's Adoption of IMDRF Guidance

Fully implemented	Partially implemented	Not implemented
Adverse event terminology		Machine learning-enabled medical devices
Unique device identification – system and guidance		
IVD classification		
Clinical evidence, investigation and evaluation		
Medical device single audit program – requirements for recognition, competence and training, assessment and decision process, and reports		
Good regulatory review practices – Essential principles, Guidance on Regulatory review reports, Requirements for Regulatory Authority Recognition of CABs, Regulatory Authority Assessment Method for Recognition and Surveillance of CABs, Competence and Training Requirements for Regulatory Authority Assessors of CABs,	Good regulatory review practices - Competence, training and conduct requirements, recognition and assessment of conformity assessment bodies, labelling	
Software as a medical device – risk framework, clinical evaluation, and QMS	Software as a medical device – definitions and principles and practices for software bill of materials	
Personalised medical devices - definitions	Personalised medical devices – regulatory pathways, production verification and validation	
Cybersecurity principles and practices	Cybersecurity - Principles and Practices for Software Bill of Materials	Cybersecurity for legacy devices
Regulated product submission – Common data elements for medical device identification		Regulated product submission – Non-IVD and IVD market authorisation table of contents, assembly and technical guide
	Optimizing standards for regulatory use	

Reforms – Achievements roadmap



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165+ GUIDANCE PUBLICATIONS AND UPDATES

410+ PRESENTATIONS AT CONFERENCES & FORUMS

STAKEHOLDER ENGAGEMENT

880+

WORKSHOPS ▪ WEBINARS
MEETINGS ▪ ENGAGEMENTS

680+ MEETINGS

85+ WEBINARS

115+ WORKSHOPS

75+ NEW GUIDANCE & FACT SHEETS

85+ UPDATES TO GUIDANCE & FACT SHEETS TO COMMUNICATE CHANGES

70+ PUBLIC CONSULTATIONS SINCE 2019

STAKEHOLDER GROUPS

INDUSTRY WORK GROUPS ▪ INDUSTRY ASSOCIATIONS ▪ ADVISORY GROUPS ▪ SPONSORS ▪ MANUFACTURERS ▪ PEAK BODIES ▪ CONSUMERS ▪ RESEARCH ORGANISATIONS ▪ STATE AND TERRITORY GOVERNMENT ▪ HEALTH PROFESSIONALS ▪ REGULATORY GROUPS

UDI implementation – Cleared for launch!

Labelling

A unique identifier **for each model of device** to be on the device labelling and all higher levels of packaging

Unique identifier to be issued by a TGA recognised issuing agency

Australian UDI Database

The UDI Device Identifier (UDI-DI) and related device data to be in the UDI database

Within 30 days after the device is first supplied into Australia

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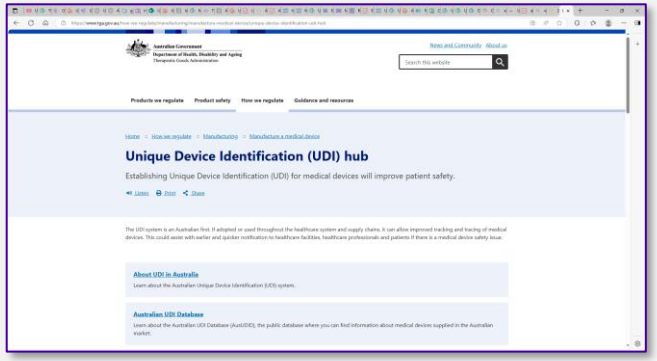
UDI implementation – Support for industry

Unique Device Identification (UDI) hub

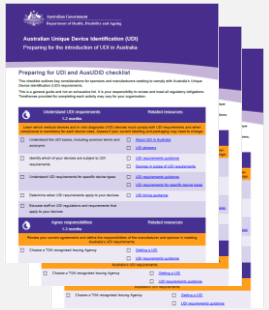


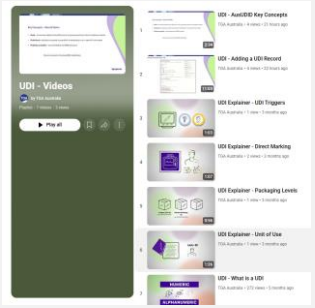
Guidance

Complying with the Unique Device Identification requirements for medical devices

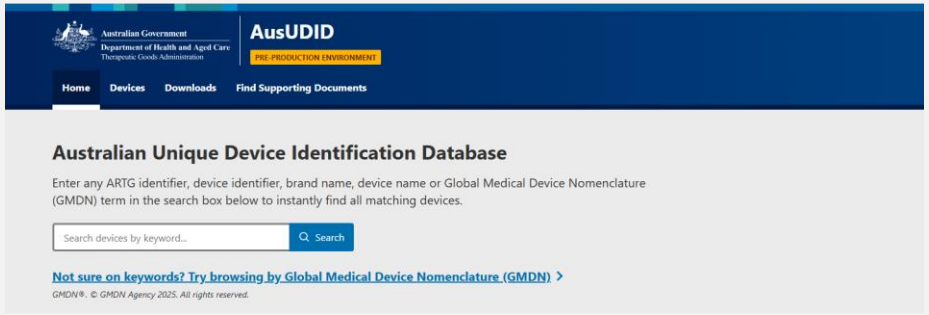
Complying with the Unique Device Identification timeframes for medical devices

Quick Reference Guides, Videos and Flowcharts





Pre-Production



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UDI implementation – Compliance timeframes

Requirement	Medical Devices				In vitro diagnostic devices			
	Class III	Class IIb	Class IIa	Class Is	Class 4	Class 3	Class 2	Class 1
UDI on the label	1 July 2026		1 July 2027	1 July 2028	1 July 2028		1 July 2029	
Data submitted	1 July 2026		1 July 2027	1 July 2028	1 July 2028		1 July 2029	
Direct Marked	1 Jan 2028	1 Jan 2029	1 Jan 2029	1 Jan 2029	1 July 2029		1 July 2030	

Existing devices

Meet UDI requirements for existing Class III and Class IIb

All other classes manufactured and labelled prior to their UDI compliance date are exempt for the lifetime of the device

EU transition

Devices supplied under an MDD or IVDD certificate have extended timeframes for compliance

Once compliant under MDR/IVDR. must meet Australian UDI requirements

For more information, refer to the UDI – Timing Flowchart and the Timing Guidance.

TGA AI review – Outcomes report published

14 key findings, grouped into five strategic priority areas

Priority Area 1 **Supporting stakeholders**	Providing clear information and guidance explaining regulatory requirements to support compliance.
Priority Area 2 **Robust regulation**	Refining regulation to ensure risks associated with therapeutic goods continue to be appropriately mitigated throughout their lifecycle
Priority Area 3 **Reinforce roles & responsibilities**	Ensuring language in our legislative framework (the Act) captures responsibility appropriately
Priority Area 4 **Improve transparency of AI use**	Facilitating access to information and support for stakeholders to understand how AI is used in the goods they access and how it is regulated.
Priority Area 5 **Conducting compliance**	Pragmatic and timely compliance activities to ensure the policy outcomes

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Expanding pre-market reliance

Our Comparable Overseas Regulators Framework

Oct 2018:

Recognised the following CORs:

- EU Notified bodies
- Health Canada
- Japan PMDA, MHLW
- MDSAP Auditing Organisations
- US FDA

Jul 2021:

Expanded reliance for previously ‘specified’ medical devices

Sep 2022:

Recognised Singapore HSA as a COR

Jul 2024:

Mandatory audits limited to high-risk devices

Oct 2024:

Expanded reliance pathways:

- Class III devices: MDSAP Certification + USFDA 510(K) clearance
- Class IIa devices exempt from USFDA regulation: MDSAP Certification + evidence of exemption from USFDA 510(K) regulation

Discussions underway

UK MHRA

Brazil ANVISA

Impact of EU MDR/IVDR continues…..

- Challenges with Australia implementing some requirements ahead of Europe
  - Reclassifications reforms
  - Software based medical devices
- Increase in non-EU reliance
  - In 2020, 90% of approvals were supported by EU certification
  - In 2025, 78% of approvals were supported by EU certification
  - Increasing reliance on MDSAP, HSA Singapore and US FDA approvals

Application audit framework – our audit/review is risk based

- Co-designed with industry
- Key features
  - Dynamic risk-based selection criteria for application audits
  - Case management for applications selected for audit
  - Target timeframes

Medical device reforms – What's next?

Reform	Next steps
Application Audit Framework	Publication of selection criteria and case management guidance documents
Electronic IFU	Regulatory amendments to allow eIFU
Boundary products	Regulatory instruments to clarify regulatory categories
IVD classification and definitions	Consultation submissions are being reviewed
Essential Principles	Review of submissions received during public consultation
Conformity Assessment Procedures	Upcoming public consultation on international alignment
Adverse event reporting exemption rules	Review existing framework
Medical Devices Vigilance Program	Finalise evaluation of 12-month pilot
Excluded Software Review including CDSS	Review and consultation on potential amendments
Improving software sector compliance	Leveraging legislative powers to support ongoing education

Upcoming public consultations

Consultation Topic	Consultation Intent
IVD definitions and classifications	Review Australia's alignment with the EU classification system and definitions for IVD medical devices.
Conformity Assessment Procedures	Review the Australian Conformity Assessment Procedures including where appropriate, alignment with the EU.
Disinfectants	Review and refine the current framework for therapeutic disinfectant goods and to align more closely with international risk classifications
Adverse event exemption rules	Follow up consultation on implementation options
Patient-matched medical devices (PMMD)	Proposed refinements to the current arrangements for the regulation of personalised medical devices framework, specifically for PMMD, including those manufactured at the point-of-care and personalised medical device production systems.
Clinical trials	Pending review of additional requirements implemented in 2024, we may propose further refinements to the current arrangements for the clinical trials requirements
Software and Artificial Intelligence (AI)	Proposed refinements to the current arrangements for the regulation of software and AI.

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Thank you/Questions

Therapeutic Goods Administration – TGA
Australia