



**IMDRF** International Medical Device  
Regulators Forum

# 29<sup>th</sup> IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 10 March 2026



# Regulatory update from Australia

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**Therapeutic Goods Administration**



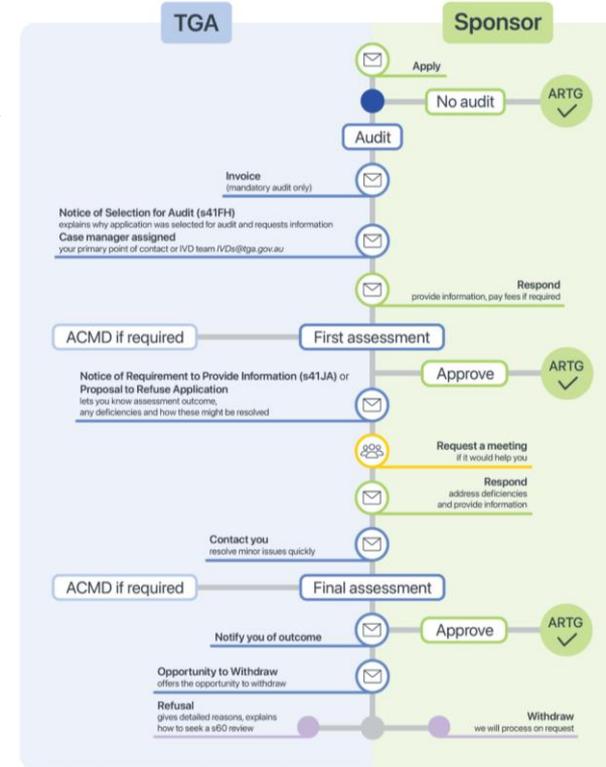
# Reliance – Supported by Application Audit (Review) Framework

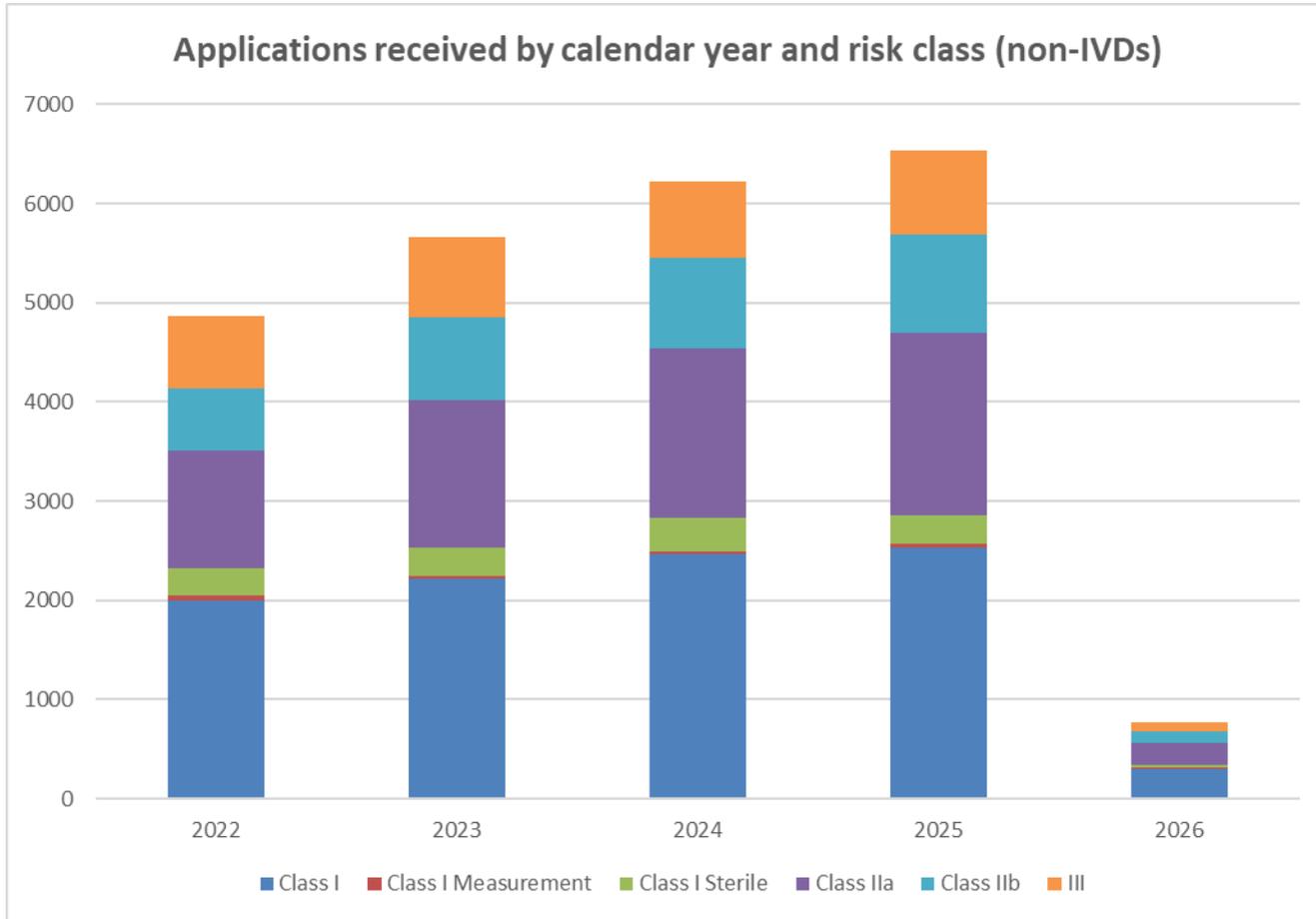
- Draft introduced in July 2024 – final version published 2025
- For applications that use reliance on comparable overseas regulator certification/approvals
- Dynamic risk-based selection criteria for application audits
  - [Criterion 1: Aspects related to the application and the device](#)
  - [Criterion 2: Kinds of devices subject to regulatory reforms](#)
  - [Criterion 3: Post market signals](#)
  - [Criterion 4: Factors related to the sponsor or manufacturer](#)
- Case management for applications selected for audit

## Primary drivers for application audits

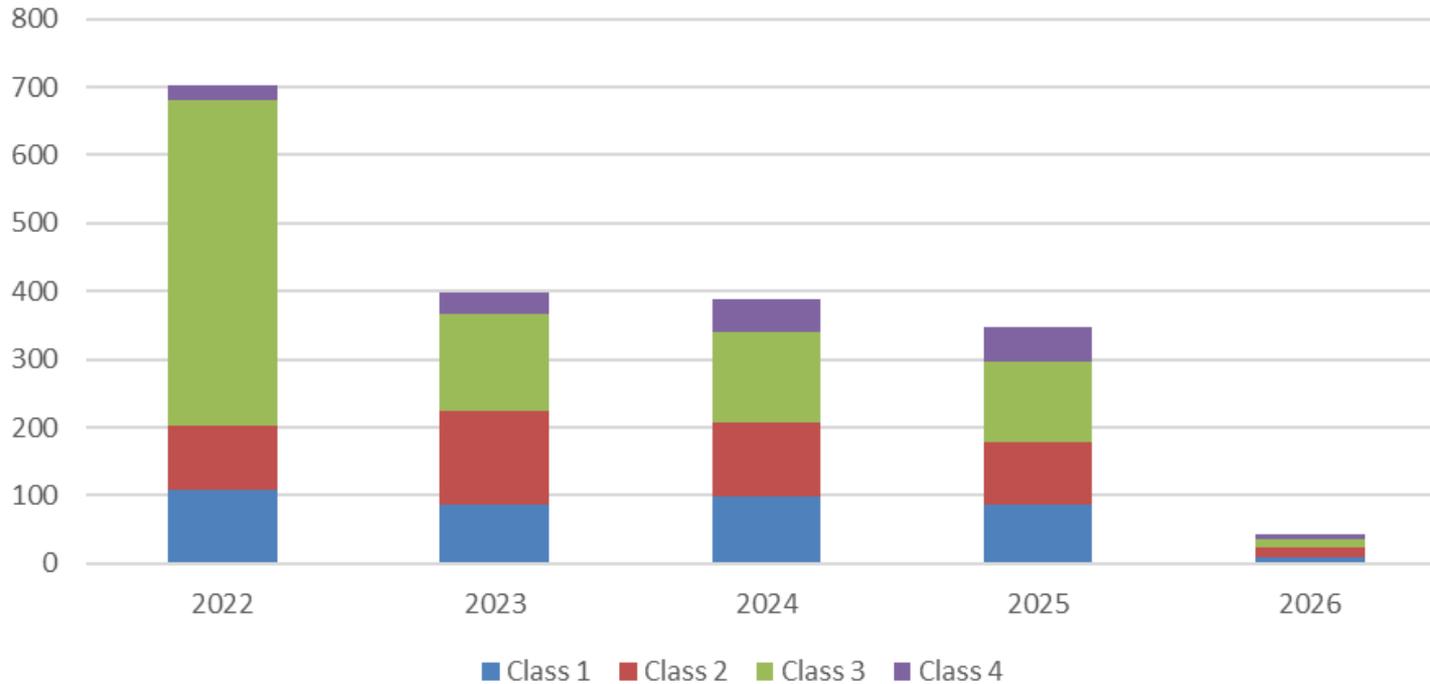
- Clarification of information in the application (79%)
- Medical device software and artificial intelligence (AI) (13%)

### Case management process

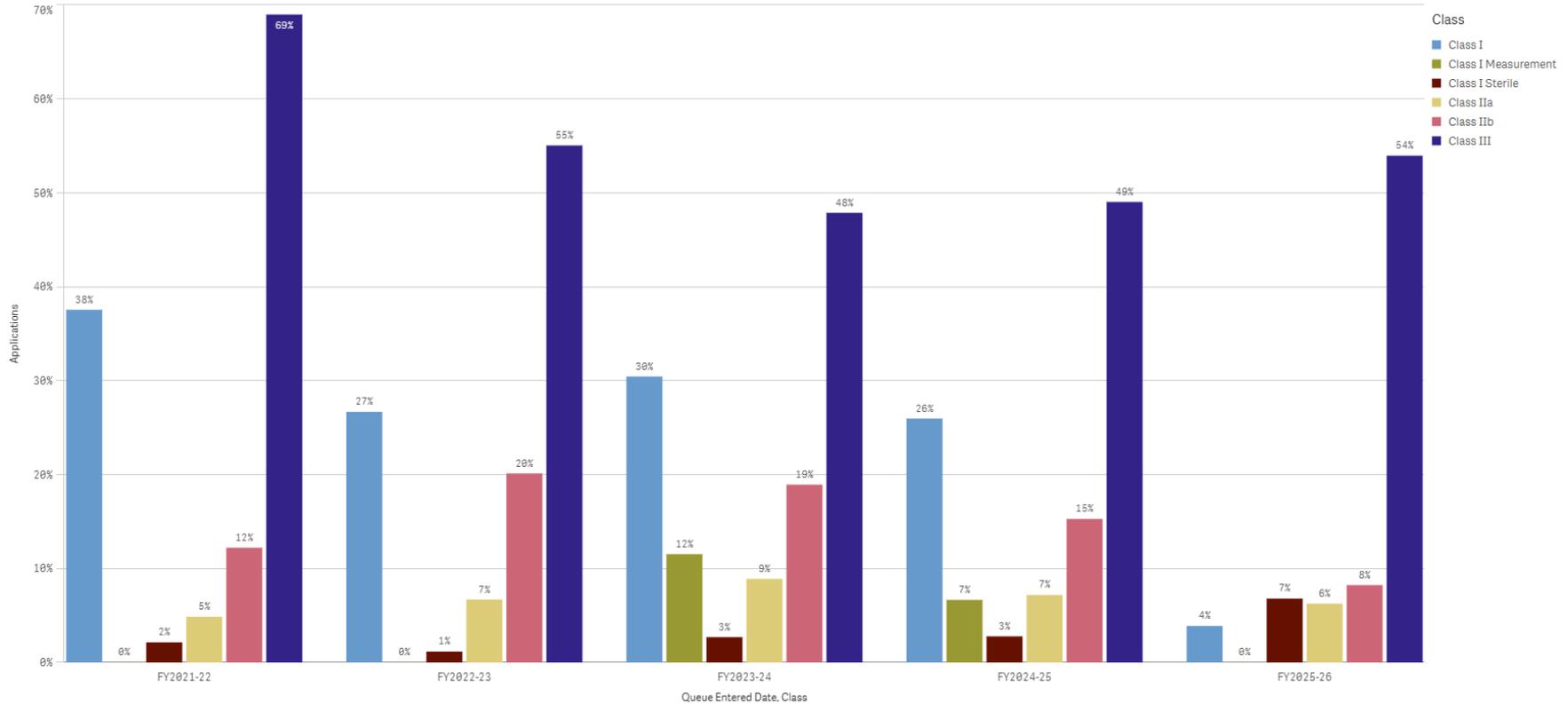




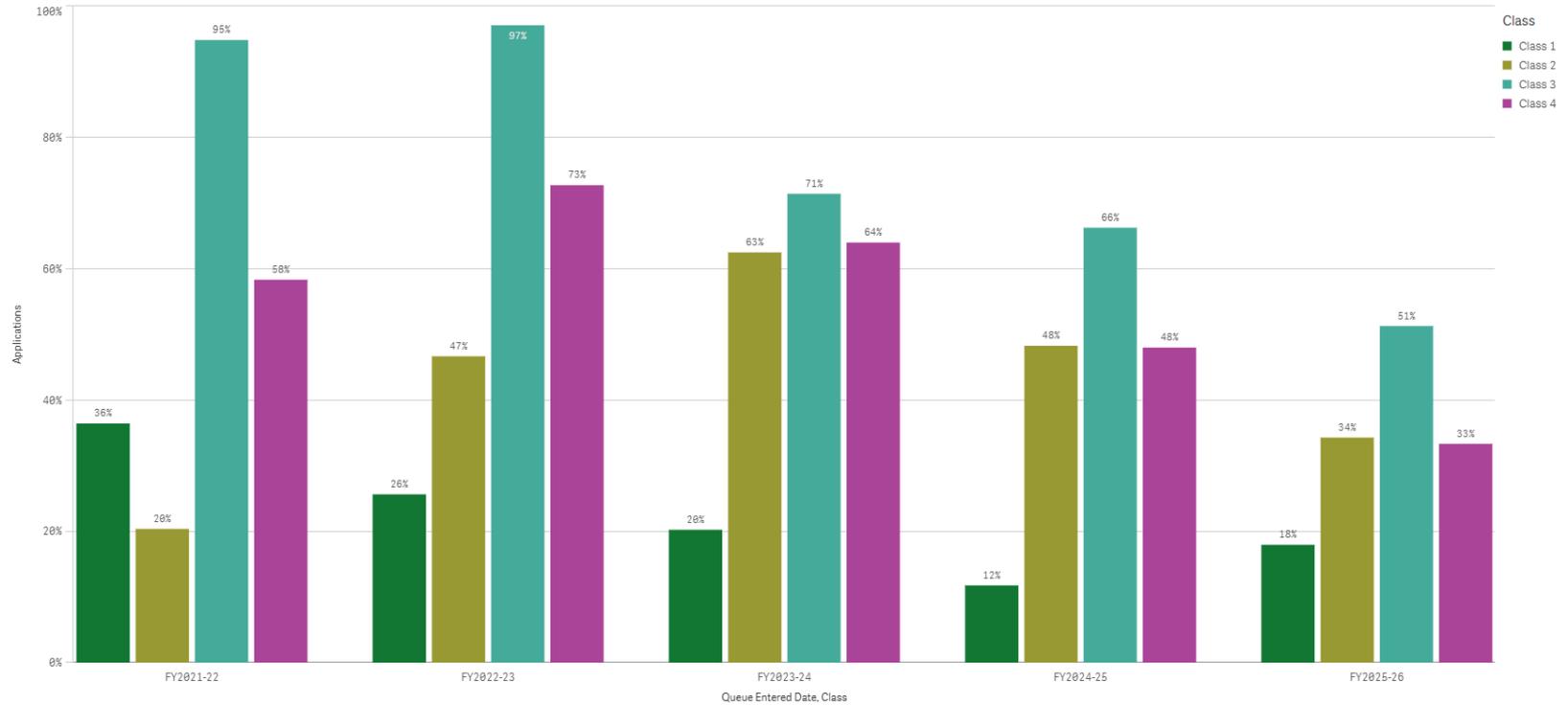
Applications received by calendar year and risk class (IVDs)



# How many applications do we audit (ie: review) - non-IVDs?

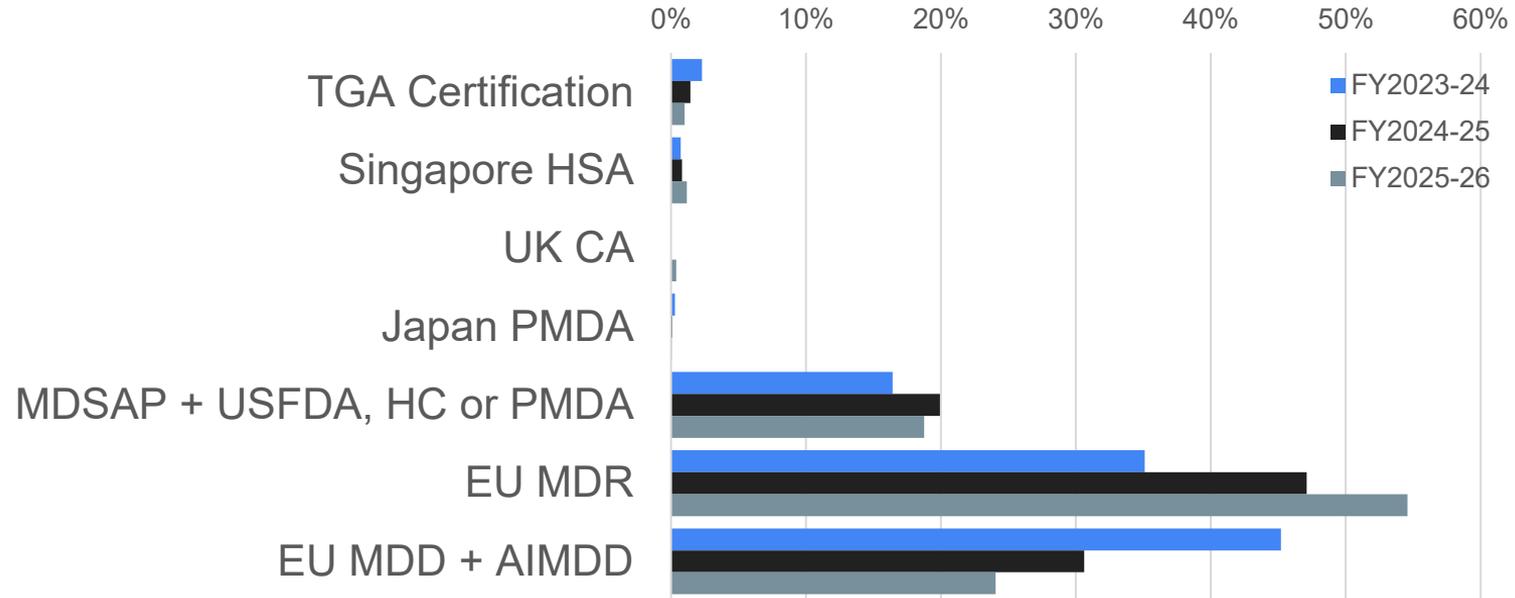


# How many applications do we audit (ie: review) - IVDs?



# Applications for market approval – medical devices – using reliance

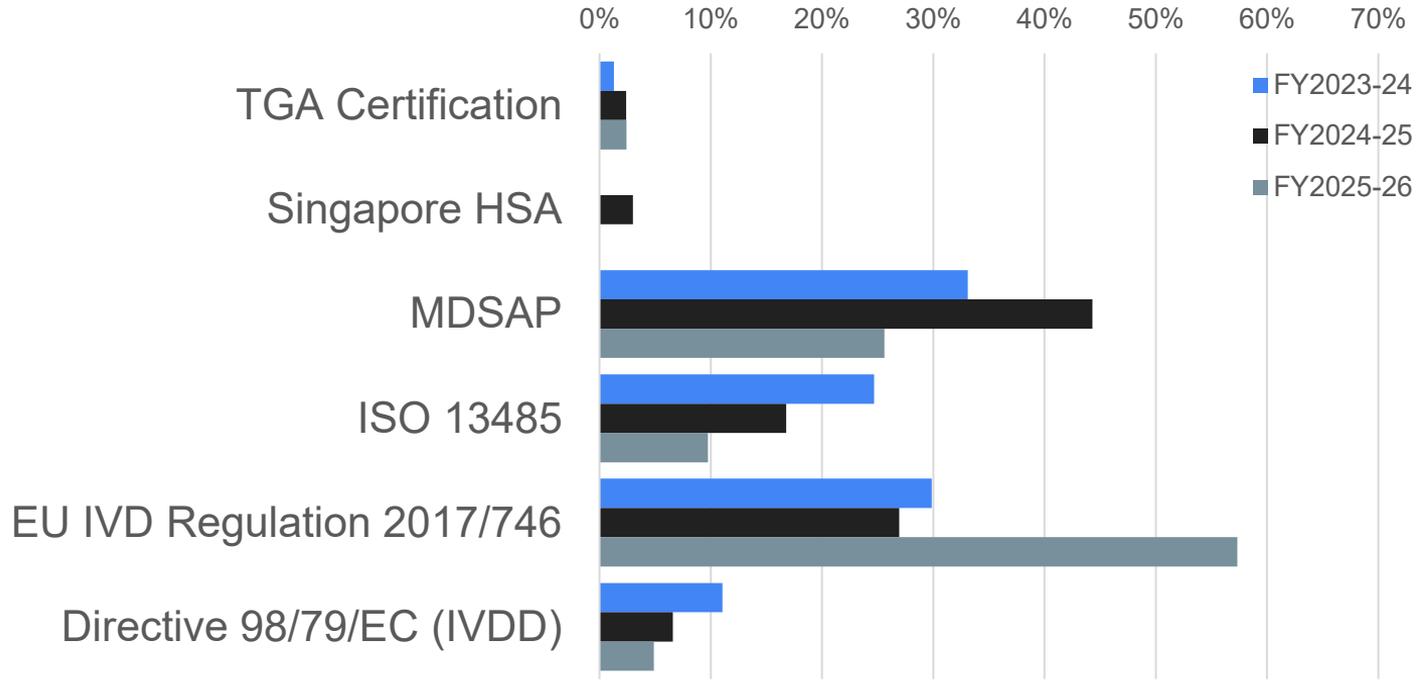
## Application Pathways



Note: FY2025/2026 covers the period July 2025 - Jan 2026

# Applications for market approval – IVDs – using reliance

## Application Pathways



Note: FY2025/2026 covers the period July 2025 - Jan 2026

## TGA Standards Activities – Laboratories



**STANDARDS**  
Australia

The logo for Standards Australia, featuring a stylized graphic of a yellow and orange wave or ribbon shape above the text 'STANDARDS Australia'.

### Standards Participation

#### ISO

- ISO/TC 150 on Implants for surgery

#### ASTM

- Committee F04 on Medical and Surgical Materials and Devices
- Committee F23 on Personal Protective Clothing and Equipment
- Committee D37 on Cannabis (including vape devices)

#### Standards Australia

- Committee HE-012 on Implants for Surgery
- Committee HE-013 on Medical and Surgical Apparel
- Committee SF-010 on Occupational Respiratory Protection



## Australia's contribution to standards development

### Participation in standards committees – other examples

IEC	<a href="#"><u>IEC/TC 62</u></a>	Electrical equipment in medical practice Medical equipment, software, and systems
ISO	<a href="#"><u>ISO/TC 121</u></a>	Anaesthetic and respiratory equipment
ISO	<a href="#"><u>ISO/TC 150</u></a>	Implants for surgery
ISO	<a href="#"><u>ISO/TC 194</u></a>	Biological evaluation of medical devices
ISO	<a href="#"><u>ISO/TC 210</u></a>	Quality management and corresponding general aspects for medical devices
ISO	<a href="#"><u>ISO/TC 212</u></a>	Clinical laboratory testing and in vitro diagnostic test systems
ASTM	E61	Radiation Processing
ASTM	F02	Primary Barrier Packaging
ASTM	F04	Medical and Surgical Materials and Devices
ASTM	F23	Personal Protective Clothing and Equipment



## MARKET RESEARCH - Consumer facing health software

### THEME

### KEY FINDINGS

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#### Consumer Use

34% use SaMD; high reliance (43%); used for diagnosis, chronic conditions, mental health

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#### Risk Perception

75% see benefits outweigh risks; 62% perceive no risk

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#### Assumptions of Oversight

69% assume regulatory review; 79% trust health professional recommendations; 61% trust app stores

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#### Developer Barriers

Lack of regulatory awareness; difficulty interpreting requirements; fear of getting on TGA's radar; resource and viability concerns

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#### Market Characteristics

High product turnover; broad developer base; limited AU-specific data



## Digital Scribes – Compliance Review – Goals

### Education



#### Clarify the rules

When digital scribes become medical devices

Advertising code and medical devices

### Scoping



#### Market research

Identify current suppliers

Identify current functionality

### Compliance - for medical device digital scribes



#### Voluntary compliance

Remove or disable functionality  
OR  
cease supply



#### Enforced compliance

Interrupt supply of non-compliant products through regulatory powers.



#### Review applications for inclusion

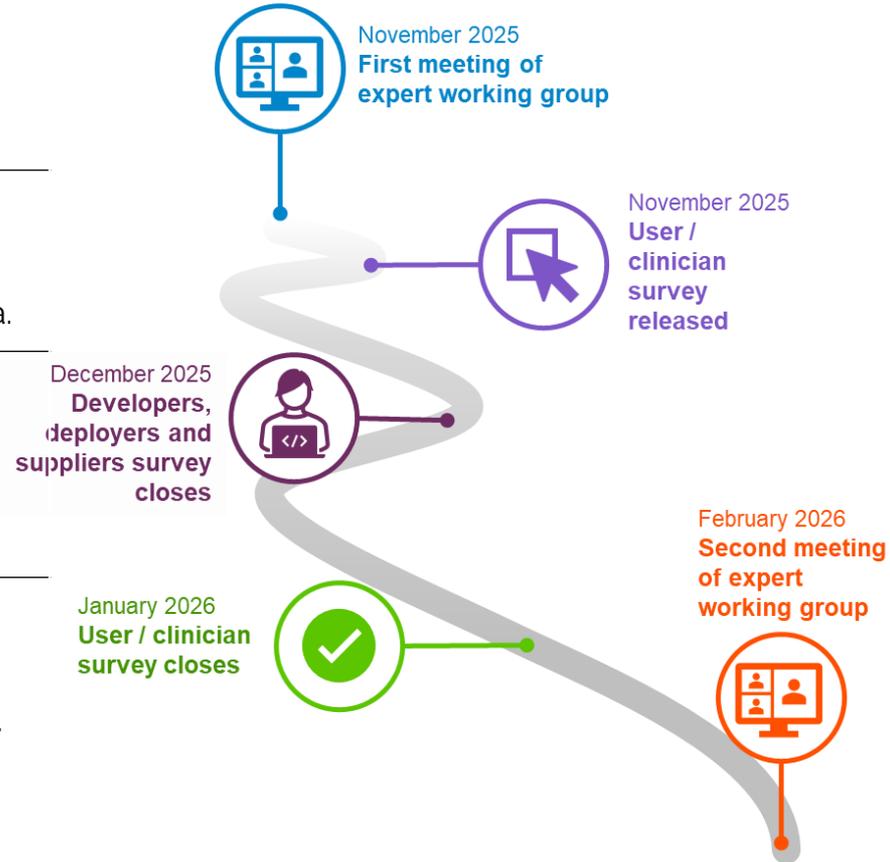
Ensure products with medical device functionality are included in the Register and comply with regulatory requirements.

## Digital Scribes – Compliance Review – Timelines



## Digital Mental Health Tools (DMHT) – Key issues and Review

<b>What are DMHTs?</b>	Digital services, web-based tools, and apps for screening, assessment, diagnosis, or therapy; used with or without clinical oversight.
<b>Current Position</b>	Conditionally excluded from TGA regulation if based on established, reviewable clinical guidelines; no tools identified as meeting criteria.
<b>Why Review Now?</b>	Growing functionality (analytics, AI), increased consumer use without oversight, and 62% of stakeholders say exclusion is no longer appropriate.
<b>What We Are Doing</b>	Surveys of developers, clinicians, and users; Expert Advisory Group; data analysis, consultation, and advice to Government in 2026.



## Recent, Current and Upcoming Reforms

Reform	Recent Update
Application Audit Framework	Risk selection criteria – commenced 25 Sep 2025
Boundary products	Regulatory instruments – commenced 1 Jan 2026
Mandatory Adverse Event Reporting by hospitals	Commences 21 March 2026 (over 600 hospitals)
Conformity Assessment Procedures	Public consultation on international alignment closes on 31 March 2026
UDI implementation	Compliance commences July 2026 (high risk and implanted devices)
Electronic IFU	Regulatory amendments to allow eIFU – mid 2026
IVD classification and definitions	Drafting of regulatory amendments underway
Improving software sector compliance	Leveraging legislative powers to support ongoing education
Adverse event reporting exemption rules	Pilot underway to evaluate proposed changes
Medical Devices Vigilance Program	Finalising evaluation of 12-month pilot
Excluded Software Review including CDSS	Review and consultation on potential amendments
Essential Principles	Finalising proposed amendments for Government decision



## Upcoming public consultations 2026

Consultation Topic	Intent
<b>Exempt Devices and Other Therapeutic Goods</b>	To refine the regulatory requirements for medical devices and other therapeutic goods that are exempt from certain premarket requirements
<b>Boundary Products</b>	Clarifying the regulatory categories of certain boundary products, and guidance
<b>Assistive Technologies</b>	Refining the regulatory framework for assistive technologies
<b>Patient-matched medical devices</b>	Refinements to the regulation of personalised medical devices, specifically for patient-matched medical devices including those manufactured at the point-of-care.
<b>Conformity Assessment Procedures</b>	Clarifying post-market requirements under conformity assessment procedures
<b>Adverse Event reporting requirements</b>	Requirements for updated adverse event reporting codes in submissions to align with comparable overseas regulators
<b>Digital mental health tools</b>	Appropriateness of the current exclusion of certain low-risk digital mental health tools
<b>Regulatory pathways for innovative medical devices</b>	Options for improving the regulatory pathway for innovative medical devices, including the priority pathway
<b>In-house IVD arrangements</b>	Seeking feedback on the appropriateness of regulatory framework for in-house IVDs
<b>Disinfectants</b>	Refining the regulation of disinfectant products to align more closely with international risk classifications
<b>Medical device vigilance program</b>	Options to implement an ongoing medical device vigilance program
<b>Software and Artificial Intelligence</b>	Proposed refinements to the current arrangements for the regulation of software and AI.



# Thank You!

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Australia

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