Regulatory update from the Medical Devices Authorisation Branch

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- EU MDR & IVD transitions
- Recent budget measures for the TGA
- COVID-19 tests
- Upcoming premarket public consultations

Short update on current and planned activities

EU MDR transition extension

The European Parliament agreed the following key elements:

- extend the transition for qualifying medical devices from 26 May 2024 to:
  - 26 May 2026 for class III implantable custom-made devices
  - 31 December 2027 for class III and implantable class IIb devices
  - 31 December 2028 for non-implantable class IIb and lower risk devices
- remove the “sell-off” deadline of 25 May 2025 from the MDR and IVDR.

Australian approach – extended validity for MDD certificates

Until 26 May 2024	Accept MDD certificates that have not expired
Until 26 September 2024	Accept MDD certificates accompanied by evidence of applying with NB for MDR
Until 31 December 2027	Class III and implantable Class IIb – evidence of contract with NB for MDR
Until 31 December 2028	All other medical devices – evidence of contract with NB for MDR

IVD manufacturer evidence transitions

Manufacturer evidence	TGA cut-off dates
No new ISO 13485 certificates	Not accepted after 26 May 2023
EU IVDD certificate	Class 4 IVD until 26 May 2025 Class 3 IVD until 26 May 2026 Class 2 IVD until 26 May 2027
ISO 13485 certificate (with EU IVDD Declaration of Conformity issued before 26 May 2022)	Class 3 IVD until 26 May 2026 Class 2 IVD until 26 May 2027

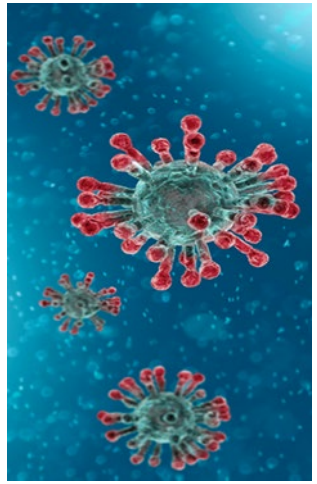
The following IVDs will need new evidence

Before ISO 13485 expires	Replace with: MDSAP, IVDR, TGA-CA, etc.
Before 26 May 2025	Class 4 IVDs supported by IVDD evidence
Before 26 May 2026	Class 3 IVDs supported by IVDD evidence
Before 26 May 2027	Class 2 IVDs supported by IVDD evidence

Recent budget measures for the TGA

- $61 million over 4 years for public good activities
  - Compliance and enforcement of unregulated products and entities
  - Management of device and medicine shortages
  - Consumer and healthcare professional enquiries and public education
  - Assistance to industry and applicants particularly emerging technologies
    - Expanded support to sponsors bringing new products to market, restoring staff to evaluation areas, expanding capacity for engagement with industry, other regulators or standards bodies (collaboration, alignment)
- $10 million for medicines repurposing function
- Stronger vaping controls (devices and pods)

Reflection – COVID-19 tests



What happened

- Unlike most other countries, we required full premarket approval
- Over 1000 COVID-19 test applications
- Over 900 completed – 64% unsuccessful
- Less than 100 remain on-hand - ⅔ are rapid antigen tests (RATs)
- Over 110 COVID-19 RATs approved - self-tests & Point of Care (PoC)
- Also approved several combination COVID-19 + respiratory virus RATs
- Also PCR lab, other PoC tests, multiplex tests, serology tests, etc.
- Returning to business-as-usual operations

What helped

For users:	We published IFUs and performance information to build confidence
For sponsors:	We published detailed guidance & checklists
	A dedicated inquiries team, status updates helped but challenged us
Processes:	We established a limit of 2 information requests
	Offered assessment fee refunds where assessment had not started
	We moved staff internally while we recruited

Upcoming premarket medical device consultations

- Medical devices with substances of animal, microbial or recombinant origin
  - Exempt specific low-risk substances from class III (eg Xanthum gum)?
  - Align with the EU classification for microbial or recombinant origin?
  - Accept more comparable overseas regulators (eg US FDA)?
- Application audit framework
  - Criteria for selecting applications for non-mandatory audit
  - Review categories for mandatory audit (limit to high risk)
  - Supporting information for audit selection (IFU, clinical evidence)
  - Stronger recognition of US FDA approval?
  - Process and timeframes

Website references

TGA website	www.tga.gov.au
EU MDR transition extension	www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/eu-mdr-transition/eu-mdr-transition-extension
Phase out of ISO 13485 certificates for IVD medical devices	www.tga.gov.au/news/news/phase-out-iso-13485-certificates-ivd-medical-devices
Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices (including IVDs)	www.tga.gov.au/resources/publication/publications/use-market-authorisation-evidence-comparable-overseas-regulators-assessment-bodies-medical-devices-including-ivds
Budget Paper No. 2: Budget Measures	budget.gov.au/content/bp2/download/bp2_2023-24.pdf
COVID-19 tests	www.tga.gov.au/products/covid-19/covid-19-tests
TGA consultations	www.tga.gov.au/resources/consultation

Therapeutic Goods Administration (TGA)

Exhibition booth **No.1**

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Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration