Australian Government
Department of Health
Therapeutic Goods Administration

Post Market Surveillance of Medical Devices

Considerations for medical device sponsors

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TGA Health Safety Regulation

Post-market obligations

- Market authorisation is just the beginning
- Post-market performance is monitored for trends or issues not previously known
- Devices are subject to conditions of inclusion such as annual reports for higher classes of device
- Devices can be subjected to post market review or investigations at any time

The TGA has authority to:

- Ask questions of sponsors and manufacturers
  - there are penalties for providing false and misleading information and not providing all information in the time frame specified
- Ask for samples of the medical device for testing
- Seize products and inspect premises
- Cancel/suspend products from supply
  - immediate if there is a potential risk of death or serious injury
  - failure to respond to a letter requiring information
  - not reporting an adverse event
  - safety or performance is unacceptable
- Mandate a recall of a therapeutic product
- Issue infringement notices

Tools used in post-market monitoring

For higher risk devices: an AIMD, Class III or implantable Class IIb device

Three consecutive annual reports to the TGA required

Adverse event reporting

Post-market reviews

Environmental scanning

(confidential advice from other regulators and review of medical literature, regulatory news, media and other sources)

Aus UDI voluntary compliance Jan 2023

Sponsor timeframes for reporting to the TGA

Adverse events

Sponsors must report the details of events associated with their devices that have resulted, or could have resulted, in serious injury or death.

- Within **two days** of becoming aware of an issue of serious public health threat or concern that will require prompt action to reduce the hazard.
- Within **ten days** of becoming aware of a death or serious injury.
- Within **thirty days** of becoming aware of an event that might have led to serious injury or death.

Annual reports

- By 1 Oct for supply, adverse event and complaint data from previous financial year, being 1 July of the previous year to 30 June of that year

Conformity assessment

- Within **sixty days** of becoming aware of information relating to a lapsed or revoked conformity assessment certificate.

Revised TGA risk assessment process

Criteria for the assessment of adverse event reports and complaints

Screening: Cases where current evidence indicated no need for further investigation. This outcome typically assigned to isolated incidents, likely to result in no harm to patients/users or well know risks associated with a particular type of device.

Level 1 Investigation: Cases where available evidence indicated the need for investigation and/or follow-up.

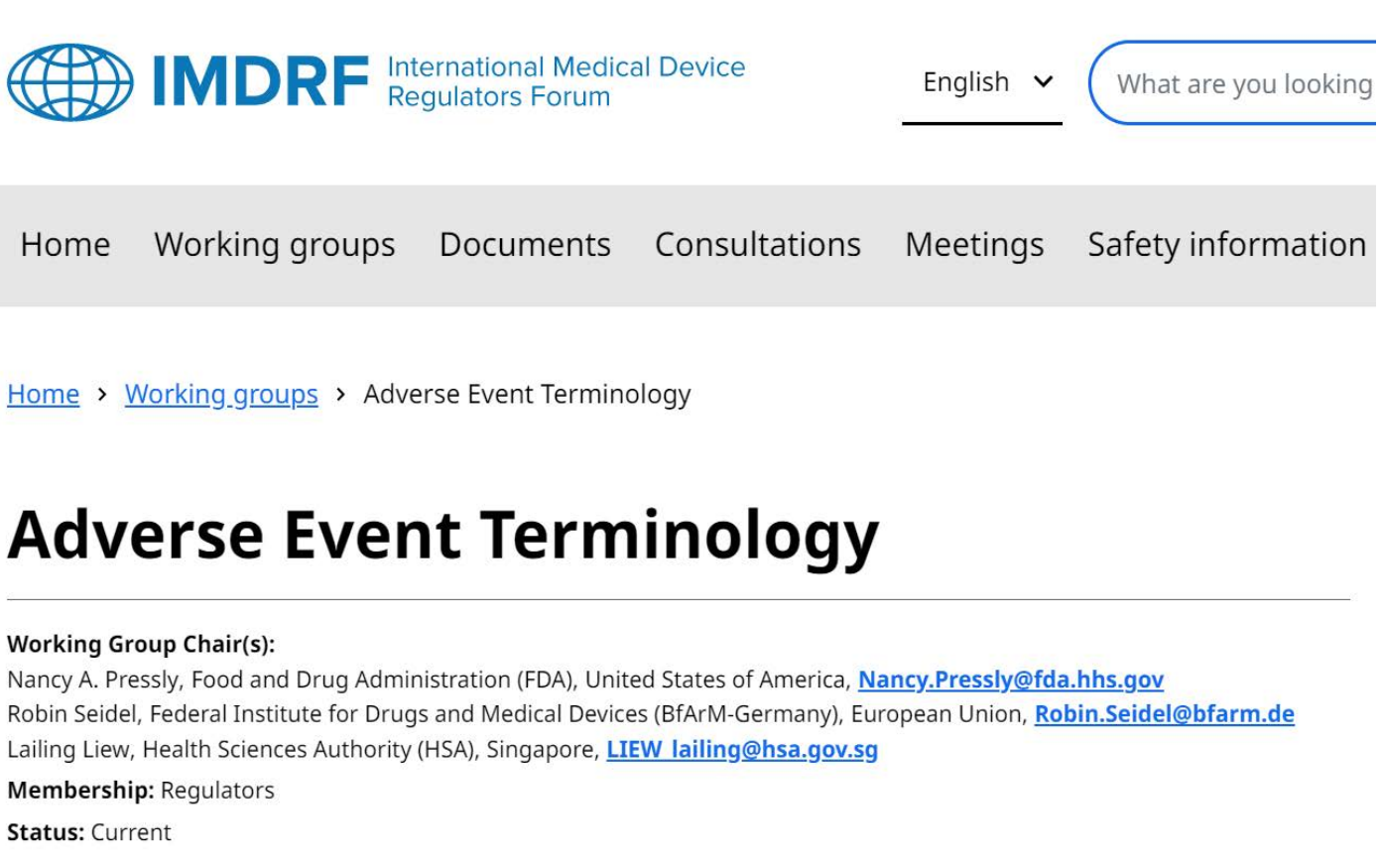
Level 2 Investigation: Cases where available evidence indicated the need for a single incident investigation requiring full examination of the reported incident.

Level 3 Investigation: Cases where available evidence indicated the need for a multiple incident or device investigation requiring examination of a potential cluster of events (including the current incident).

Future of adverse event surveillance

- The TGA received ~300 reports annually when first implemented market surveillance activities
  - a risk assessment of each report was a realistic goal
- In 2021, TGA received ~6,900 reports through the triage system - a risk assessment of each report becoming unsustainable
- **How do we effectively manage risk to patients and users in the face of increased reporting?**
  - data analytics and trending
  - analysis of adverse event outcome experience
  - focused risk assessment on specific report source or risk criteria
  - focus on non-compliance (e.g. lack of reports)
  - decreased manual risk assessment and increased investigation

IMDRF AE Working Group



Seven annexes to code incident reports:

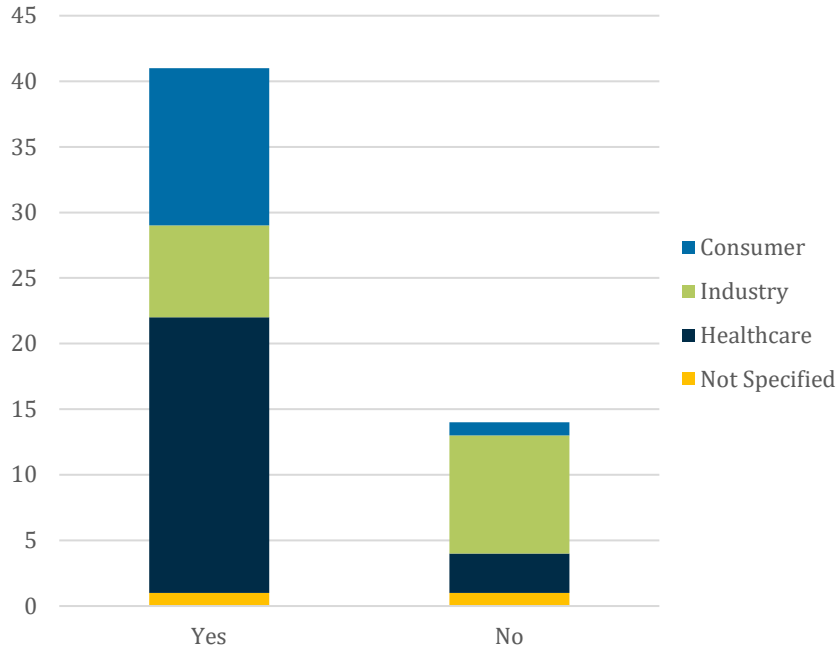
- Medical device problem
- Type of investigation
- Investigation findings
- Investigation conclusions
- Clinical signs and symptoms or conditions
- Health impact
- Medical device component

Minimum reporting data set

Proposed mandatory reporting of medical device adverse events by healthcare facilities

- Early 2021: Targeted discussions with a range of Australian hospitals, peak bodies, state and territory governments and the Australian Commission on Safety and Quality in Health Care, along with a number of international regulators to inform on a Discussion Paper.
- October – December 2021: Public feedback sought on Discussion Paper
- 56 responses received – submissions published
- The TGA will work closely with the Australian Commission on Safety and Quality in Health Care (ACSQHC), state and territory health departments, and private and day hospitals to progress this project.

Should Australia introduce mandatory reporting for medical device related adverse events by healthcare facilities?



Proposed Enhancements to Adverse Event Reporting for Medical Devices

- The TGA published a public consultation paper seeking feedback on five proposals to enhance adverse event reporting of medical devices.
- The consultation was published on the Department of Health Consultation Hub from 23 September to 24 December 2020.

1	Proposal 1 – make changes to the current adverse event reporting exemptions
2	Proposal 2 - strengthen reporting requirements for medical device adverse events
3	Proposal 3 - implement a program of TGA inspections and audits of sponsor activities and premises
4	Proposal 4 – review post-market definitions in the Medical Device Regulations
5	Proposal 5 - find ways to enhance communication between the TGA and the consumers of medical devices

Next Steps

- The summary analysis of feedback and individual submissions has been published on the Department of Health Consultation Hub and the TGA website
  - https://www.tga.gov.au/consultation/consultation-proposed-enhancements-adverse-event-reporting-medical-devices

The TGA has:

- undertaken further targeted consultations with non-industry stakeholders
- made changes to the legislation for final adverse event reports
- begun developing a program for the inspection of sponsors premises

Post-market monitoring

Why are post-market reviews conducted

Safety or performance signals from (not an exhaustive list):

- Trends from IRIS
- Recurrent advertising breaches
- Unresolved/repeated recalls
- Information from stakeholders, organisations, or other regulatory agencies
- ARTG anomalies

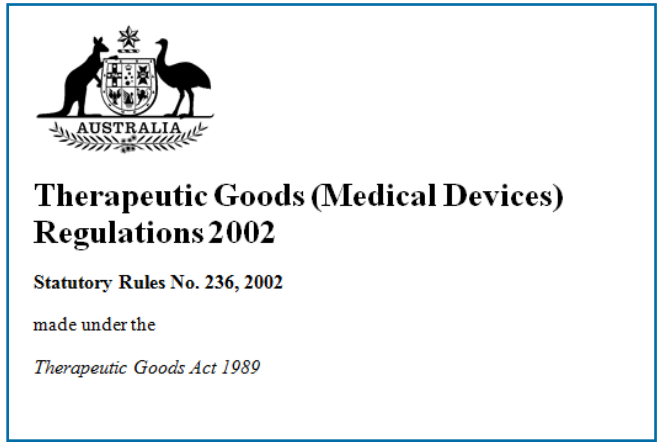
Who or what is reviewed:

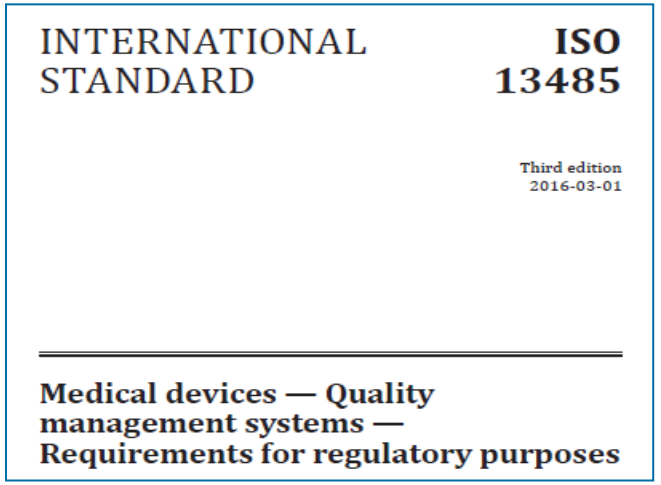
- Sponsor
- Manufacturer
- Ingredient
- Product
- Kind of device

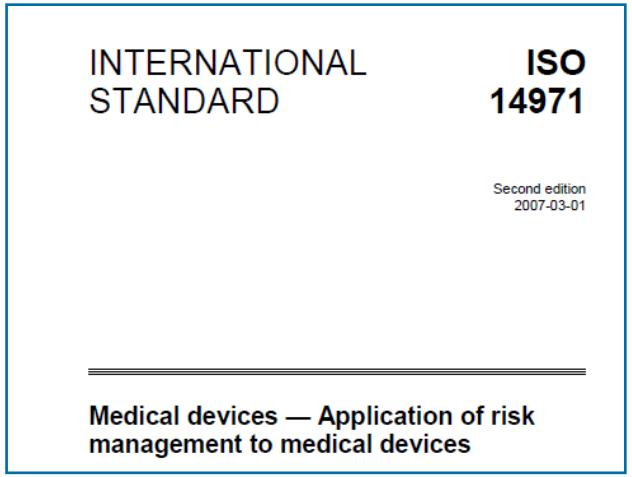
When:

- At any point in the product's life-cycle.

Post-market review: evidence







Post-market review outcomes

- Closure of review
  - Not in scope
  - Sufficient and satisfactory evidence provided
- Amendment to Instructions for Use
- Recall of devices or safety notice
- Additional conditions of inclusion (s41 FP)

- Suspension (s41 GA & GF)
- Cancellation (s41 GK, GL, GM, & GN)
- Infringement notices
- Referral to:
  - Advertising Compliance (s42 DL) or
  - Regulatory Compliance

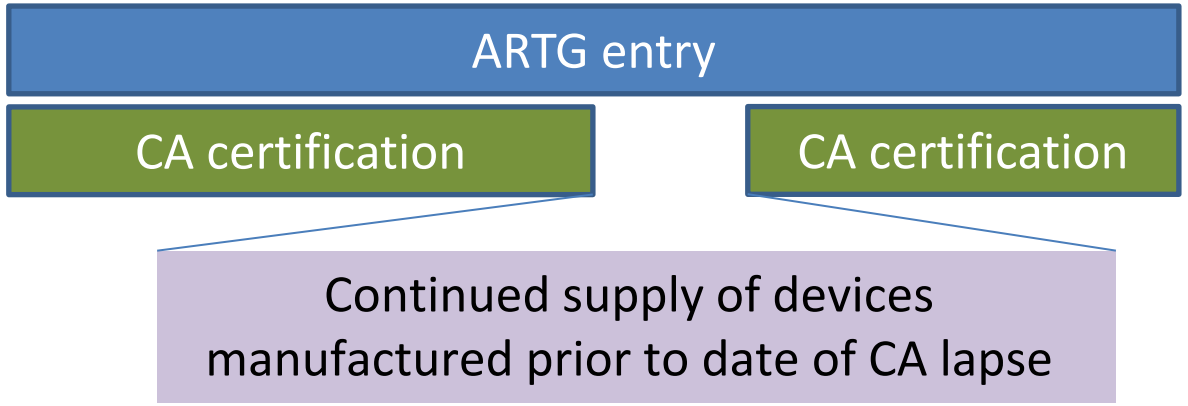
Uniform Recall Procedure for Therapeutic Goods (https://https://www.tga.gov.au/sites/default/files/uniform-recall-procedure-therapeutic-goods-urptg.pdf)

Consent to supply medical devices non-compliant with EPs

- In Dec 2021, modernised process from paper form to online form
- Applications made through TBS portal
- Multiple ARTG entries can be included in a single application if the application relates to non-compliance with the same Eps
- On 29 October 2021, amendment to legislation to allow reduced fees for applications relating to non-compliant patient information materials

Lapse in conformity assessment

- Notify TGA within 60 days when conformity assessment certification is restricted, suspended, revoked, or is no longer in effect
- For delays in recertification - continued supply of devices manufactured prior to CA lapse is permissible
- For suspended or revoked CA certification – suspension of supply is required



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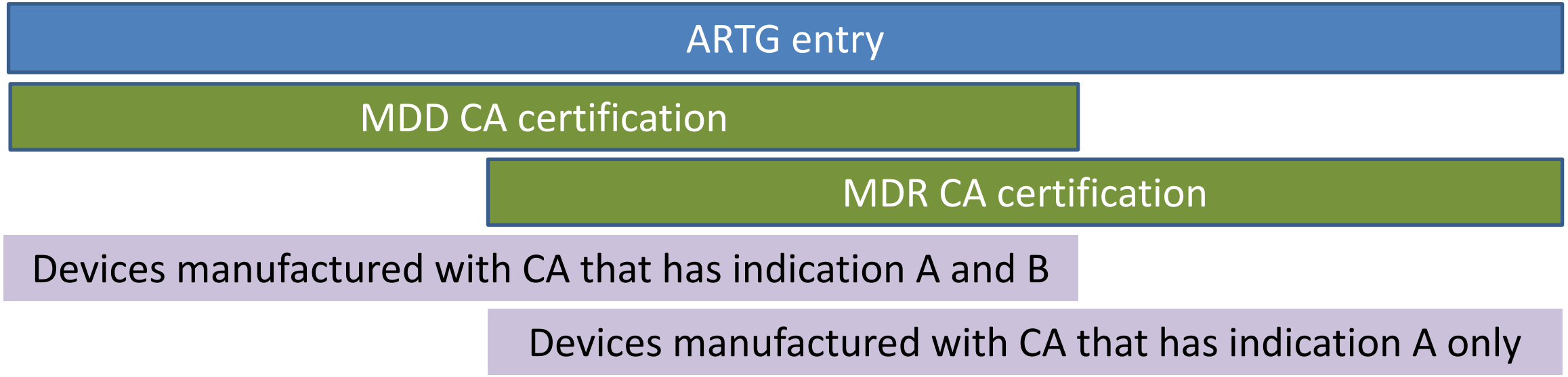
The TGA's approach to delays in medical device conformity assessment recertification

Due to COVID-19 pandemic and delays in EU MDR implementation

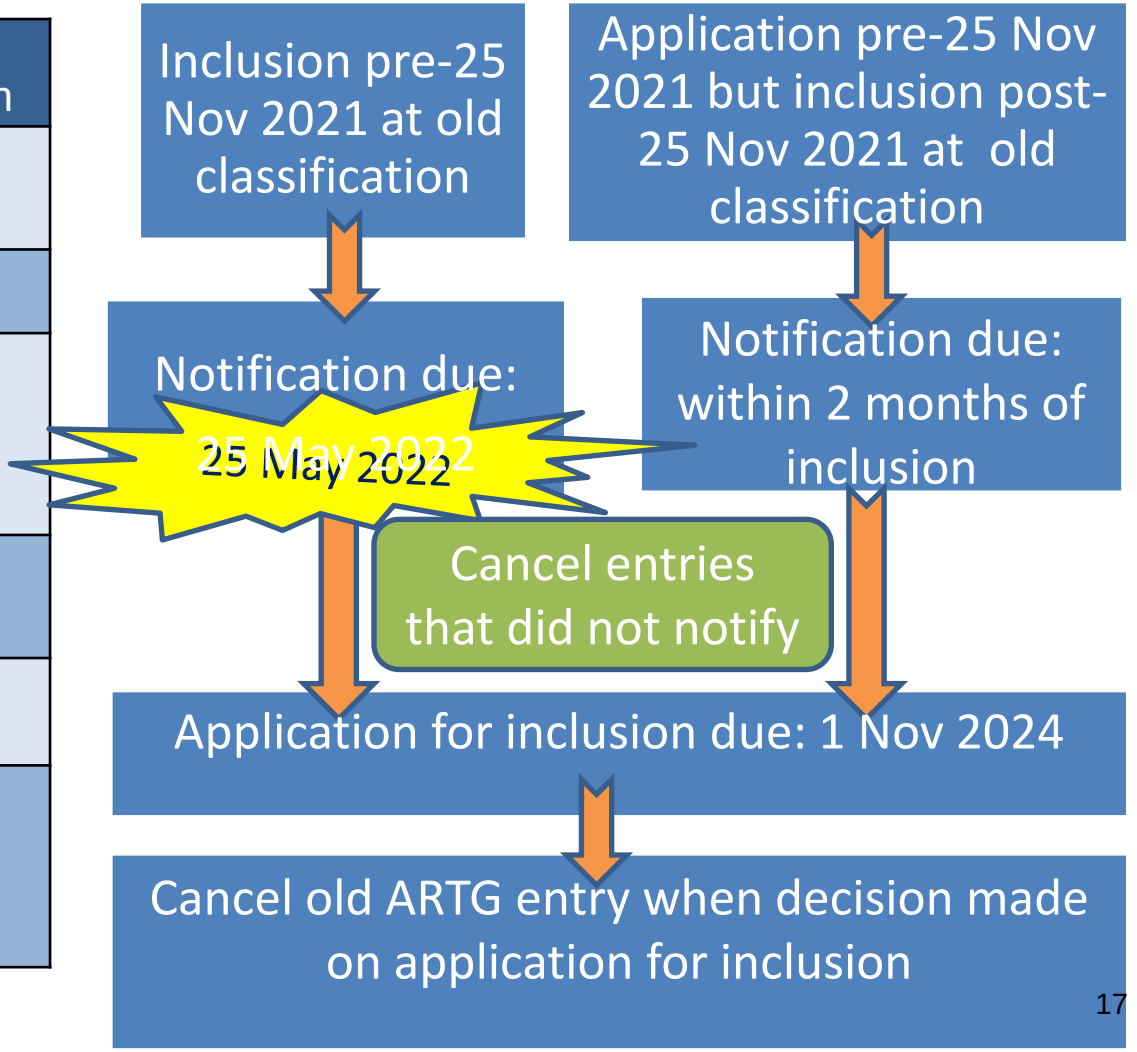
Overlap in conformity assessment

- Notify TGA within 60 days when conformity assessment certification is restricted, suspended, revoked, or is no longer in effect
- For overlap in certification - continued supply of devices manufactured with MDD CA certification is permissible, if CA remains valid; manufacturer is still required to hold evidence of compliance with EPs
  - for a reduction in indications, consider if consent is needed if there is a lack of evidence to demonstrate compliance with EPs



Reclassification of some medical devices

Reform	Old classification	Revised classification
Active medical devices for therapy with diagnostic function	IIa or IIb	III
Spinal implantable medical devices	IIb	IIb or III
Devices used in direct contact with the heart, central circulatory system (CCS), or central nervous system	IIa	III
Medical devices that administer medicines or biologicals by inhalation	I or IIa	IIa or IIb
Active implantable medical devices (AIMD)	AIMD	III
Medical devices that are substances introduced into the body via body orifice or applied to the skin	I or IIa	IIa, IIb or III



If in doubt – contact us

- Devices contact team
  - devices@health.gov.au
  - 1800 141 144
- Reforms
  - devicereforms@health.gov.au

- Incident reporting
  - IRIS@health.gov.au
  - 1800 809 361
- Post-market reviews
  - postmarketdevices@health.gov.au

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