Lapses in conformity assessment

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Medical devices supplied in Australia are required to be supported by valid conformity assessment certification

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

What is not changing under our framework

- Notify the TGA within 60 days of EU MDD certification no longer being ‘in force’.
- Possible compliance measures for expired Manufacturer Evidence

Lapse in conformity assessment

ARTG entry

CA certification

CA certification

Continued supply of devices manufactured prior to date of CA lapse

Australian Government
Department of Health
Therapeutic Goods Administration

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

ARTG entry

MDD CA certification

MDR CA certification

Devices manufactured with CA that has indication A and B

Devices manufactured with CA that has indication A only

If in doubt – contact us:

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Questions?

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Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration