Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

EU MDR Transition – Manufacturer evidence

Case studies and scenarios

Version 2.1, January 2024

Contents

Introduction

This guidance provides case studies and scenarios about manufacturer evidence for sponsors transitioning their ARTG entries to EU MDR certification.

This guidance is to be read in conjunction with the guidance EU MDR Transition – Overview and management under the Australian regulatory framework - guidance for manufacturers and sponsors available on the TGA website.

You may also find the following related guidance useful:

- EU MDR Transition – Online assessment tool and notification form - user guide
- EU MDR Transition – DCRs and variations – case studies and scenarios
- EU MDR Transition – Recalls and market notifications - case studies and scenarios
  EU MDR Transition - Conformity assessment, Essential Principles and consent to supply - case studies and scenarios

EU MDR Transition Extension

On 15 March 2023, the European Union extended the EU MDR transition periods- external site for devices transitioning to the EU MDR 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
- 31 December 2028, for class I devices that are a higher class under the MDR.

MDD notified bodies will not re-issue MDD certificates with extended expiry dates. Rather, the EU MDR unilaterally extends the validity of current MDD certificates if certain criteria are met. To qualify for the EU MDR transition extension, manufacturers must:

- apply for MDR certification with an MDR notified body by 26 May 2024 and before their MDD certificate expires, and
- have a contract in place with an MDR notified body before 26 September 2024.

MDD notified bodies will continue to be responsible for ongoing oversight of manufacturers they have certified, until the manufacturer transitions to an MDR notified body.

The TGA will now accept MDD certificates that have been extended in the EU, as new or revised Manufacturer Evidence, as detailed below:

- until 26 May 2024, we will continue to accept MDD certificates that have not expired
- we recognise that the expiry date on MDD certificates will not be updated
- until 26 September 2024, we will accept MDD certificates that are accompanied by evidence that the manufacturer has applied with a notified body for MDR certification of the device
- after 26 September 2024, we will accept MDD certificates that are accompanied by evidence that the manufacturer has a contract with a notified body for MDR certification of the device:
  - until 31 December 2027, for class III and implantable class IIb devices
  - until 31 December 2028, for non-implantable class IIb and lower risk devices.

For new applications that rely on an MDD certificate, submitted after the expiry date listed on the certificate, the sponsor will need to provide evidence that the manufacturer is eligible for extended validity under the EU MDR.

Evidence of extended validity for expired MDD certificates

The TGA is aligning with the EU and will recognise and accept EU MDD certificates with extended validity in the EU.

To qualify for extended validity, the manufacturer must have engaged an MDR notified body for conformity assessment of the device, or for a device intended to substitute that device.

The TGA will accept the following as evidence of extended validity for MDD certificates:

1. The manufacturer's self-declaration confirming that the conditions for the extension are fulfilled, stating the end date of the transition period. The self-declaration should clearly identify the devices covered by the extension and certificates concerned.

   The TGA may undertake post market sampling and request for evidence that the manufacturer has applied for MDR certification with a Notified Body by 26 May 2024 and before their old certification expires and has a contract in place with a Notified Body before 26 September 2024. **It is important to note that there are criminal (and civil) penalties of up to 5 years imprisonment for making a false or misleading statement.**

2. A signed written agreement between the manufacturer and the notified body in respect of the device covered by the expired certificate.

3. A confirmation letter issued by the notified body stating the receipt of the manufacturer's application for conformity assessment and the conclusion of a written agreement. Such confirmation should clearly identify the devices covered by the extension and certificates concerned. Where a manufacturer has been unable to engage an MDR notified body, a competent authority of a Member State may grant a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) of this Regulation or has required the manufacturer, in accordance with Article 97(1) of this Regulation, to carry out the applicable conformity assessment procedure. In this case, the TGA will also accept the following evidence:

- Article 97 decision letter confirming the validity of the extension, with the manufacturer details clearly stated. The manufacturer details should match the current MDD certificate. If the original letter is not in English, a translated copy must be provided.

NOTE – When submitting expired MDD certificates with extended validity in TGA's eBS portal, select the expiry date should match the applicable extended validity.

Case studies

Case studies - Manufacturer name and address change

1

Green Pty Ltd is a sponsor supplying MRI machines with EU MDD certification. The manufacturer Yellow Co decided to move their factory to a new location but has retained their existing QMS. The legal entity remains the same and the only change made is the manufacturing site address which is the address present in the ARTG certificate.

Green Pty Ltd can submit a Manufacturer evidence variation application followed by a DCR application so that their ARTG entry is up to date.

2

Orange Pty Ltd is a sponsor supplying hip implants under EU MDD certification. Peach Ltd, the manufacturer of Orange Pty Ltd's hip implants, is undergoing a rebranding to consolidate their portfolios, and plan on transitioning to a new trading name Pink Ltd when undergoing EU MDR certification. The change from Peach Ltd to Pink Ltd is a name change only and the legal entity remains the same, with no change to QMS or corporate structure.

Orange Pty Ltd can submit a Manufacturer evidence variation application followed by a DCR application so that their ARTG entry is up to date.

3

Blue Pty Ltd is a sponsor supplying thermometers under EU MDD certification. Cold Ltd, the manufacturer of Blue Pty Ltd's thermometers, is being acquired by a global conglomerate Hot Pty Ltd, alongside many other medical device manufacturers. Hot Pty Ltd has an established QMS, which will be applied to the production of Cold Ltd's thermometers.

Blue Pty Ltd will need to submit a new application of inclusion for their thermometers, as the manufacturer is now Hot Pty Ltd, which is a different legal entity to Cold Ltd.

Scenarios

Is it possible to have one ARTG linked to two different manufacturers evidence?

No, this is not an option. An ARTG entry can only be linked to one Manufacturer Evidence. It is highly encouraged that you associate the ME that is most relevant to the ARTG entry, and hold evidence of any other ME as necessary, and be able to provide that to the TGA upon request.

I have an ARTG entry and I would like to add additional devices of the same kind, but which are supported by a different manufacturer evidence. What do I need to do?

An ARTG entry can only be linked to one Manufacturer Evidence. It is highly encouraged that you associate the ME that is most relevant to the ARTG entry, and hold evidence of any other ME as necessary, and be able to provide that to the TGA upon request. Please note that the additional devices must be of the same kind, and must meet requirements

outlined in the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018*

I currently supply a system or procedure pack (SOPP) that is transitioning to EU MDR, when should I submit an ME variation?

Manufacturers have two options to apply conformity assessment procedures to system or procedure packs.

Option 1: The manufacturer of a system or procedure pack may obtain market authorisation evidence, issued by an independent assessment body or regulator for the system or procedure pack; or

Option 2: use the special conformity assessment procedure set out in clause 7.5 of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the 'Regulations') if they meet the eligibility criteria defined in Regulation 3.10.

When transitioning to MDR, you may use either option 1 or 2.

If using option 1, you should submit an ME variation when all components have transitioned with acceptable CA evidence.

If using option 2, you must ensure that all relevant conformity assessment procedures are applied to the individual components and if applicable, the sterility aspect of the SOPP, and ensure that other requirements stipulated in the Regulation 3.10 are met. If there are staggered MDR certification of the individual components, whereby there are changes to the kit configurations and hence changes to the UPI and /or variant information, a DCR/variation application would be required.

When do we need to notify the TGA if we have one MDD full quality assurance certificate that supports several ARTG entries?

Each individual ARTG entry requires valid conformity assessment evidence. The sponsor should use some form of business tool to track each ARTG entry and the type of conformity assessment documents that support the ARTG entry.

- Each ARTG entry (kind of device) should be sufficiently similar to be supported by the same Quality Manufacturing System (QMS) evidence.
- You must hold or be able to obtain the manufacturer's valid conformity assessment documents for each ARTG entry for that kind of device and provide to the TGA when requested.
- You may choose to wait and take action to coincide with the MDD certificate expiry noting you can continue to use existing MDD certificates up until the extended transition period or the certificate expiry (whichever occurs first). MDR transition provisions are outlined under the amended Article 120.
- If a new medical device application is required due to the reclassification of the current device in line with Schedule 2 of the Regulations - Classification rules in the ARTG, you will need to cancel that ARTG entry as it is no longer correct.

What if the MDR changes result in two or more products previously listed under one ARTG entry as the same "kind of device", as now being subject to different requirements under the EU MDR?

- Introduction of MDR Nomenclature and definitions may cause such circumstances. It is important to note that under the Australian regulatory framework, devices of the same kind can be grouped under one ARTG entry. Therefore, for products under one ARTG

entry which are now being subject to different requirements under the EU MDR, sponsors will need to determine if there are any implications for the products under the Australian regulatory framework. If the changes result in the devices being of a different kind, then new applications for inclusion will be required for the new kinds of devices.

- Each individual ARTG entry containing the same kind of device requires valid conformity assessment evidence that supports the device with the same design/intended purpose/indications. The sponsor should use some form of datasheet tool to track each entry and the type of documents that support the ARTG entry.
- If not all the devices of the kind that are being supplied under one ARTG entry receive MDR certification and/or other appropriate conformity assessment evidence, the sponsor can no longer supply that model of device in Australia. Where the ARTG entry is Class III or AIMD the sponsor may submit a variation application and request to remove the devices that are no longer within scope of the conformity assessment evidence.
- Sponsors must notify the TGA within 60 days of becoming aware of the lapsing, revocation, suspension or cancellation of conformity assessment certification using the Lapses in Conformity Assessment Notification Form. The TGA will review the relevant ARTG entries on a case-by case basis and decide whether the entries should be suspended or cancelled in accordance with the Act. There are criminal and civil penalty sanctions if a sponsor fails to notify the TGA within 60 days of becoming aware that a conformity assessment document (other than a conformity assessment certificate issued by the TGA) has been restricted, suspended, revoked or is no longer in effect.

What if the scope of the new EU MDR certificate has changed and the change no longer covers a device that is supplied under the ARTG entry?

Where the scope of the manufacturer evidence certificate has changed and no longer supports the kind of device included in the ARTG, the sponsor must submit a request to the TGA to cancel the ARTG entry(s).

My Manufacturer Evidence is linked to multiple ARTGs, and the time that each device family transitions to the EU MDR is different and staggered up until 2024. When should I lodge my ME Variation(s)?

Sponsors can choose to update their Manufacturer Evidence when all related ARTG entries have transitioned to the EU MDR, or to update the Manufacturer Evidence as and when certain ARTG entry(s) transition to the EU MDR. This is a decision for the sponsor based on how they would like to manage their ARTG entries.

My MDD Manufacturer Evidence is expired in the TGA system, however I am eligible for extension of this certificate, can I submit a new application using this certificate?

You can still submit a new application that is linked to an expired certificate. The TGA will request evidence that supports the certificate is eligible for extension of validity and that this still covers the kind of device you wish to include in the ARTG.

Version history

V1.0	Draft publication for feedback	Medical Devices Authorisation Branch	16 June 2022
V1.1	Publication for beta release	Medical Devices Authorisation Branch	29 June 2022
V1.2	Publication for stakeholder review	Medical Devices Authorisation Branch	31 Oct 2022
V2.0	Publication for final release	Medical Devices Authorisation Branch	1 Dec 2022
V2.1	Amendments based on the EU MDR transition extension	Medical Devices Authorisation Branch	February 2024

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Reference/Publication #