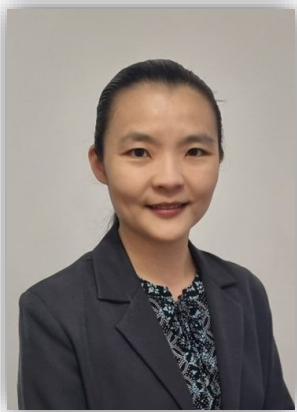


EU MDR Transition – Webinar 2

Manufacturer Evidence and Variations to the ARTG



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Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past, present and emerging.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

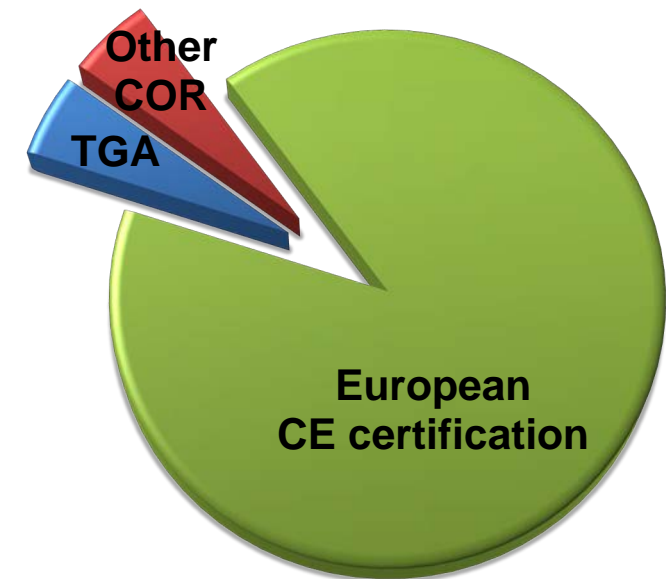
Agenda



- Background
- Manufacturer Evidence (ME) – new and variation
- Device change requests (DCR) – change types
- Variations – change types
- Updates to application forms
- Resources available
- Q&A

Background

- Majority of medical device ARTG inclusions are supported by European certification.
- Medical device regulation in Europe is undergoing transition to replace the existing Medical Device Directive (MDD) (93/42/EEC) and the Active Implantable Medical Device Directive (90/385/EEC) (AIMDD) with the new Medical Device Regulation (MDR) (2017/745/ EU).
- To continue supply, these devices will need to transition by 26 May 2024 to the new certification under the European Union Medical Device Regulation (EU MDR).



Implications for medical device ARTG inclusions

- Regulatory actions may include
 - Updates to manufacturer evidence (conformity assessment documents)
 - New applications for inclusion due to changes in device classification
 - Variation to ARTG entries
 - Recall action
 - Market notifications
 - Consent to supply

Manufacturer Evidence
(Conformity Assessment)

Variations to the ARTG
(DCR/Variations)

EU MDR Transition – Guidance

Guidance on our website:

- Overview and management under the Australian regulatory framework
- Online assessment tool and notification form – User guide for sponsors and agents
- **Manufacturer Evidence – Example scenarios and FAQs**
- **DCRs and variations – Example scenarios and FAQs**
- **Recalls and market notifications - Example scenarios and FAQs**
- **Conformity Assessment, Essential Principles and Consent to Supply - Example scenarios and FAQs**

The screenshot shows the Australian Government Therapeutic Goods Administration website. The page title is "EU MDR Transition" and the sub-heading is "Overview and management under the Australian regulatory framework". The main text explains that this guidance is to assist manufacturers, Australian sponsors, and agents of medical devices (excluding in vitro diagnostic (IVD) medical devices) included in the Australian Register of Therapeutic Goods (ARTG), where the conformity assessment certification that supports the inclusion in the ARTG is transitioning to the new certification issued under the European Union Medical Device Regulations (EU MDR). This guidance will assist sponsors to understand and meet their obligations under the Australian regulatory framework.

Note on IVDD to IVDR transition: This guidance relates to non-IVD medical devices only and does not cover the transition of IVD medical devices to the EU IVD Regulation (IVDR). Separate guidance will be provided for the transition of IVD medical devices to the EU IVDR.

Below the note are links for Listen, Print, and Share.

What is changing

The transition from the EU MDD to EU MDR has introduced a range of changes for medical device manufacturers such as:

- More stringent requirements to demonstrate medical device safety for patients and users including requirements for clinical evidence
- Additional requirements for the manufacturer's quality management systems
- Detailed technical document requirements
- Changes to classification rules for medical devices

Most medical devices included in the ARTG are supported by EU MDD certification and may need to transition to the new EU MDR to continue to be supplied in Australia.

The Therapeutic Goods Administration (TGA) recognises that some manufacturers are facing delays in...

On the right side of the page, there is a navigation menu with a search bar at the top. The menu items are: Products we regulate, Product safety, How we regulate, and Guidance and resources. The "Guidance and resources" item is selected. Below the menu, there is a search bar with the text "Search this website" and a magnifying glass icon. The "EU MDR Transition" item is highlighted in a purple box, and a dropdown menu is open showing the following items: Manufacturer evidence, Device Change Request (DCR) and variations, Conformity assessment, Essential Principles and consent to supply, Recalls and market notifications, and Online assessment tool and online notification form.

Online Assessment Tool

Overview

This tool is for sponsors or agents of non-IVD medical devices included in the ARTG with a need to transition from the EU MDD to the new EU MDR to allow medical devices to continue to be supplied in Australia.

This tool will assist you to determine what actions you may or may not need to take as a result of changes to conformity assessment documents relevant to your medical devices as a result of the implementation of the European Union Medical Device Regulations (EU MDR).

Background

Most medical devices included on the ARTG are supported by EU MDD certification and will need to transition to the new EU MDR to allow medical devices to continue to be supplied in Australia.

Changes

- Intended purpose
- GMDN code and term
- Linking the EU MDR document to an existing ARTG inclusion
- Manufacturer details (name or address)

Regulatory action

ME variation or new ME

Changes to device classification

New application

Changes to any of the following (for all classifications):

- Intended purpose
- GMDN code and term
- Linking the EU MDR document to an existing ARTG inclusion
- Manufacturer details (name or address)

Changes to any of the following (for class III/AIMD):

- Total number of devices
- Variant list
- UPI (Unique Product Identifier)
- Functional Description

Changes to any of the following:

- Indications in IFU
- Class of persons for which the device is suitable for
- Reduction in scope of intended purpose
- Functional description
- Addition of a warning for a newly identified safety issue or contraindication
- Addition of adverse event information which would change patient management recommendations

Non-compliant with the Essential Principles

Consent to Supply

Change	Regulatory action
New MDR certification	ME variation or new ME
Changes to device classification	New application
Changes to any of the following (for all classifications): <ul style="list-style-type: none"> • Intended purpose • GMDN code and term • Linking the EU MDR document to an existing ARTG inclusion • Manufacturer details (name or address) 	DCR
Changes to any of the following (for class III/AIMD): <ul style="list-style-type: none"> • Total number of devices • Variant list • UPI (Unique Product Identifier) • Functional Description 	Variation
Changes to any of the following: <ul style="list-style-type: none"> • Indications in IFU • Class of persons for which the device is suitable for • Reduction in scope of intended purpose • Functional description • Addition of a warning for a newly identified safety issue or contraindication • Addition of adverse event information which would change patient management recommendations 	Recalls or Market notifications
Non-compliant with the Essential Principles	Consent to Supply

s41BE Kinds of medical devices

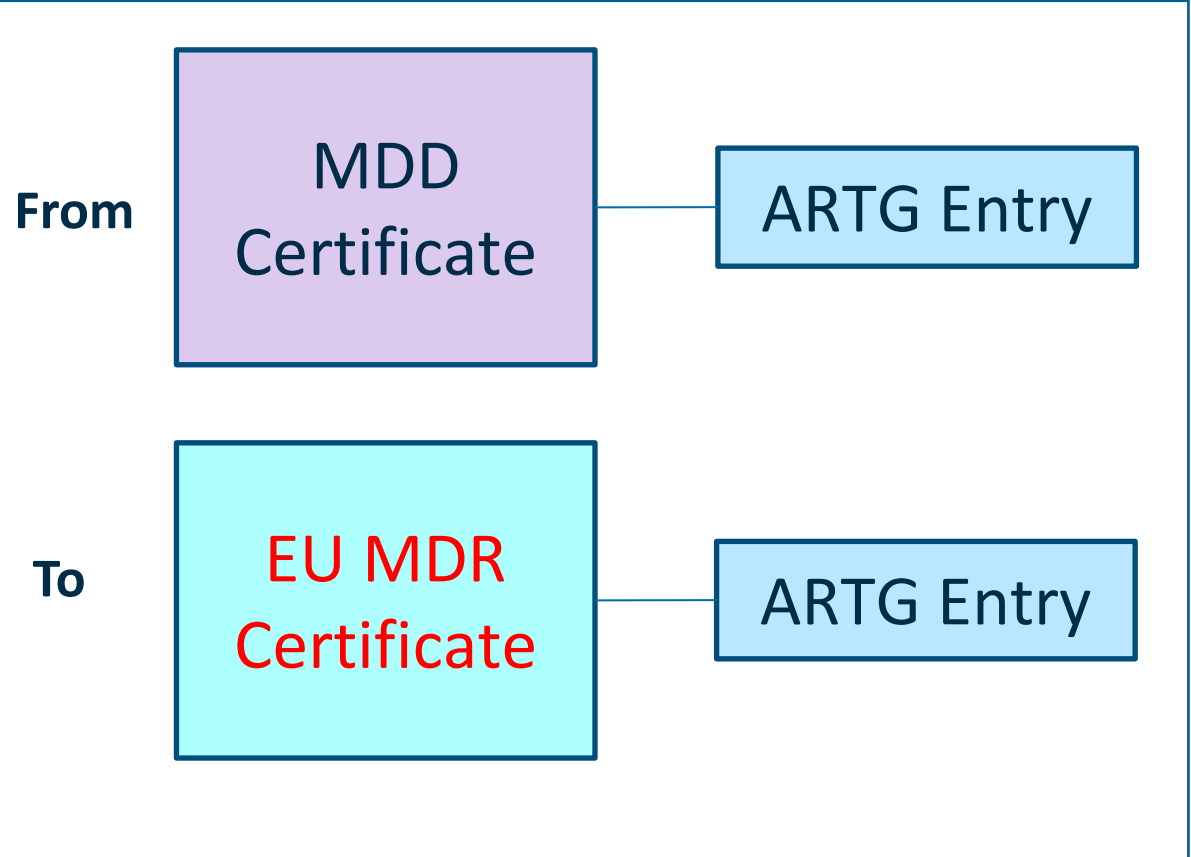
(1) For the purposes of this Chapter, a medical device is taken to be of the same kind as another medical device if they:

- (a) have the same **sponsor**; and
- (b) have the same **manufacturer**; and
- (c) have the same **device nomenclature system code** (see subsection (3)); and
- (d) have the same **medical device classification**; and
- (e) are the same in relation to such **other characteristics as the regulations prescribe**, either generally or in relation to medical devices of the kind in question.

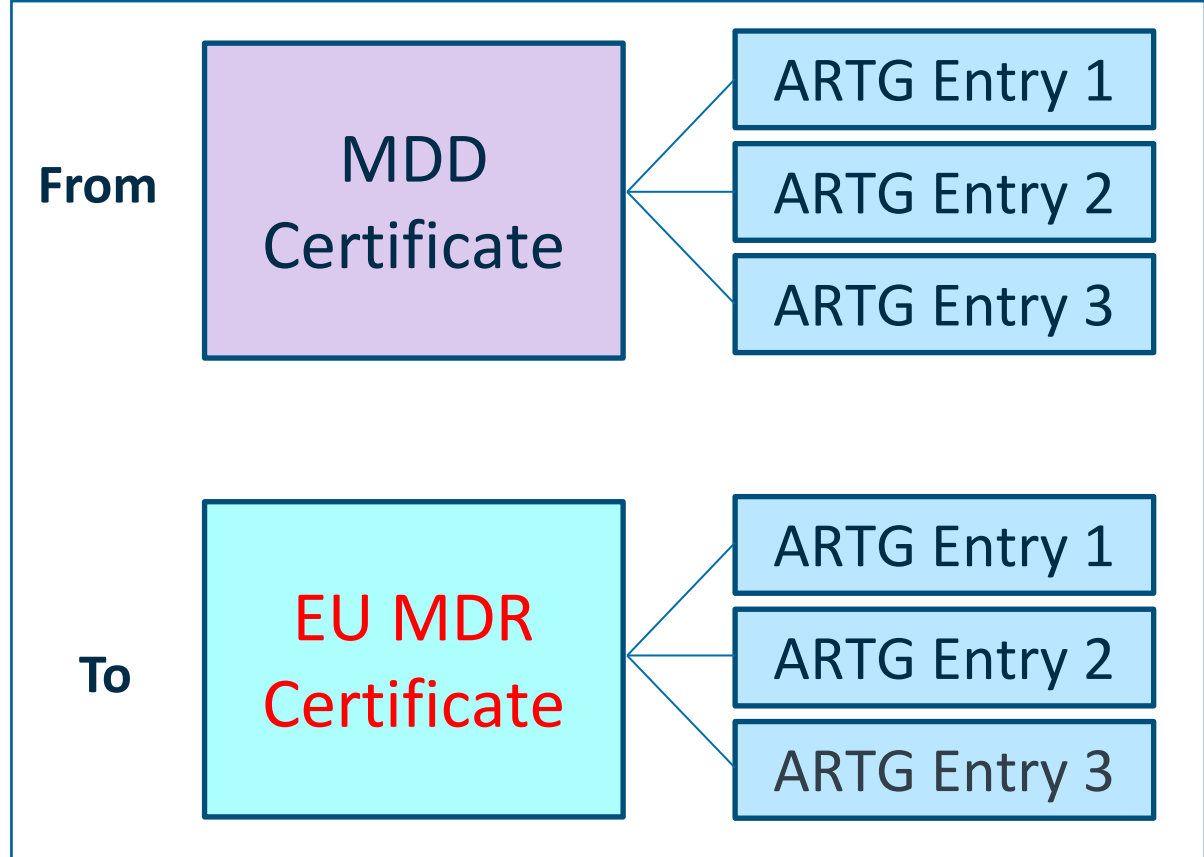
Reg1.6 prescribes that for a Class III medical device, a characteristic is the **unique product identifier** of the device

Example 1: Update all ARTG entries with new EU MDR certification

Single entry

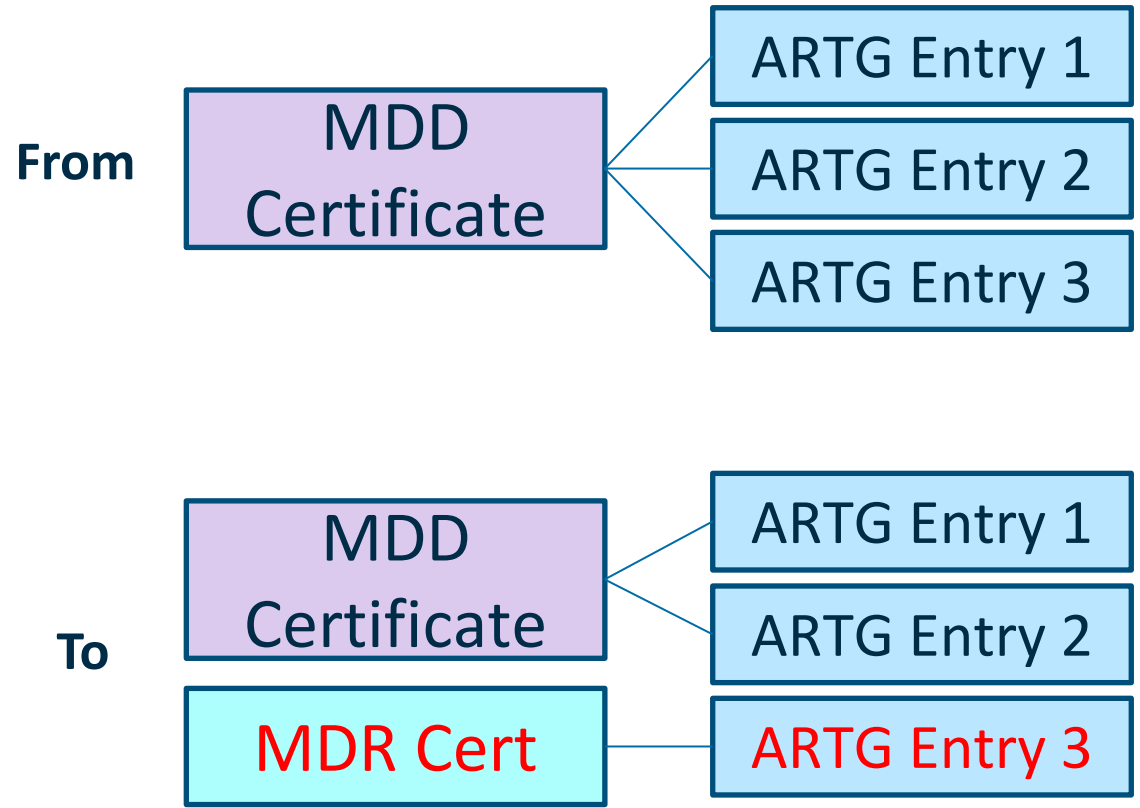


Multiple entries



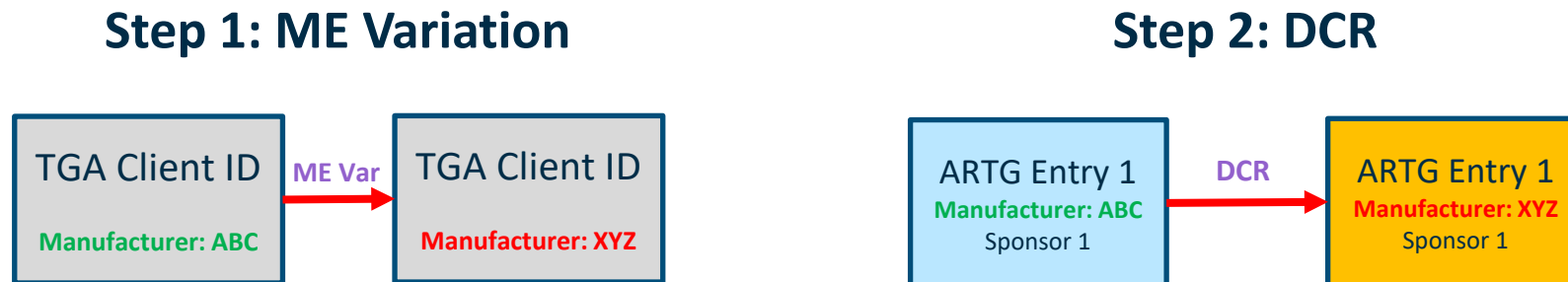
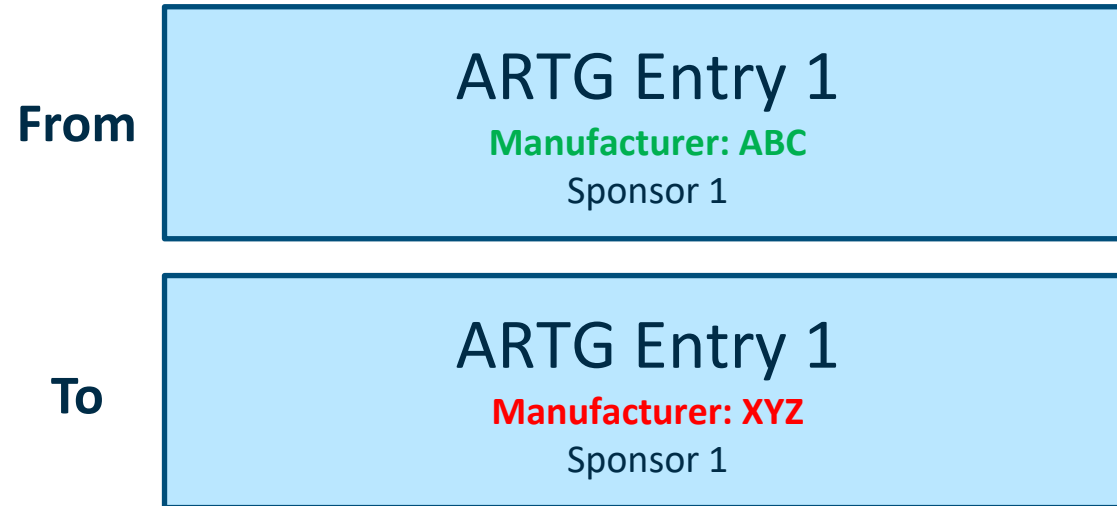
Pathway: Manufacturer Evidence (ME) Variation application

Example 2: Update a subset of ARTG entries with new EU MDR certificate



Pathway: New ME application, then DCR to delink/relink your ME identifier

Example 3: Update manufacturer details (same legal entity)



**Pathway: ME Variation application,
then DCR to update ARTG entry**

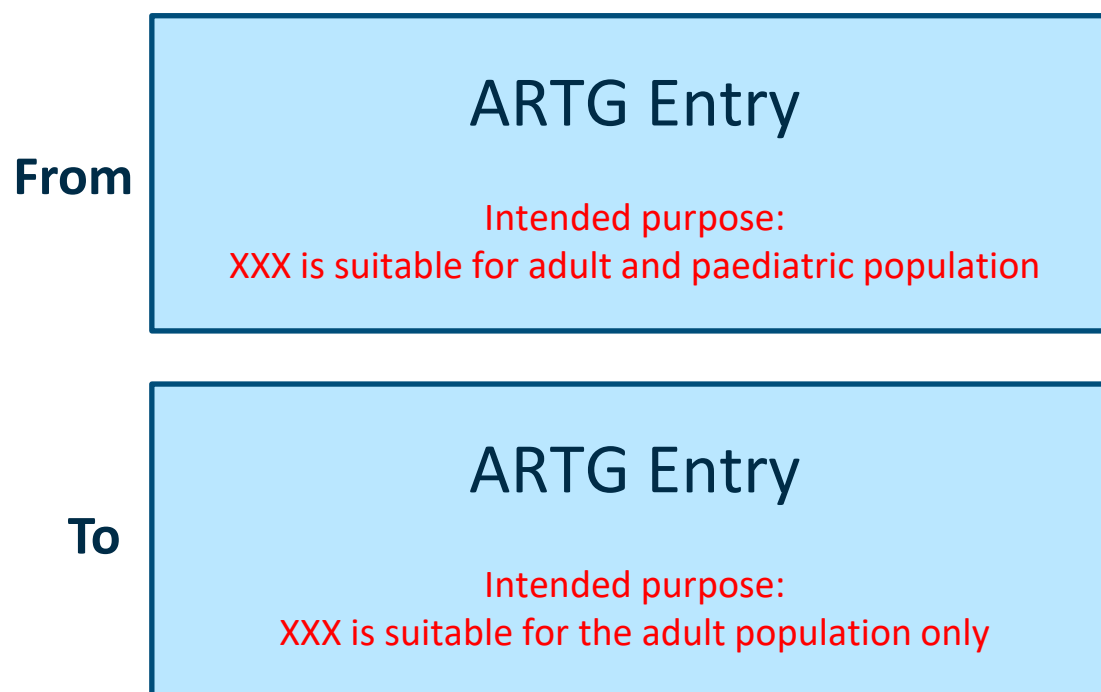
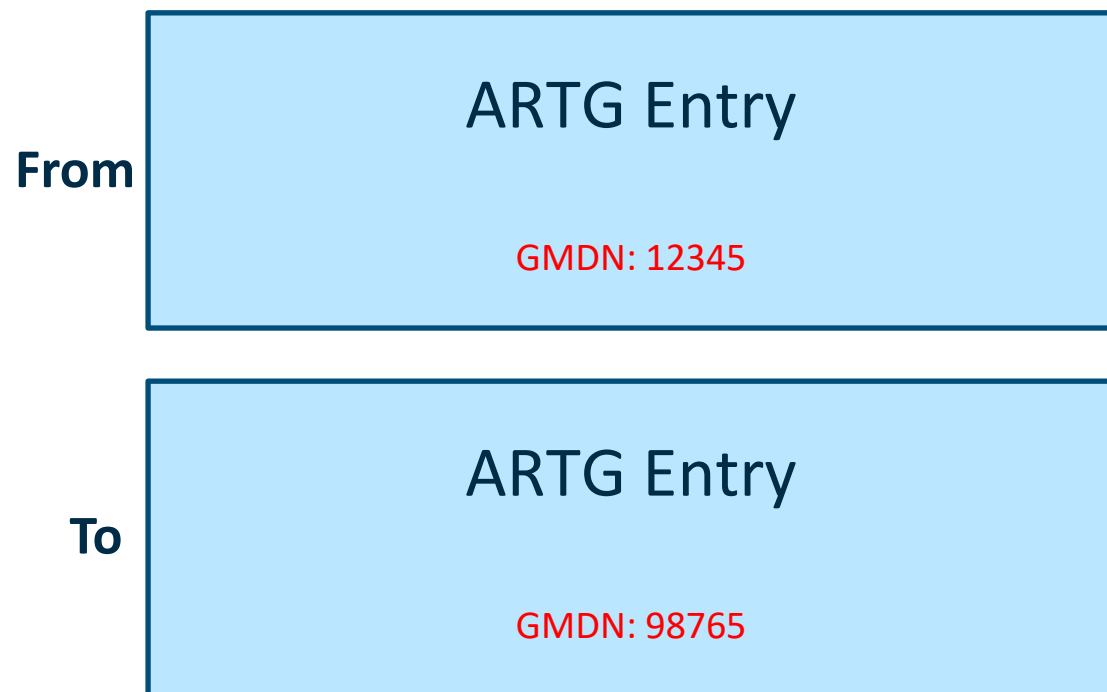
Example 4: Updating Sponsor name and/or address



Pathway: complete the *Notification: Change of sponsor name form* and return it to ebs@health.gov.au

Note: This form is only to be used if the Australian Business Number (ABN) or Australian Company Number (ACN) remains unchanged. The change in the TGA client database will update all ARTG entries associated with this sponsor.

Example 5: Updating GMDN or intended purpose



Pathway: DCR application

Note: If the new GMDN code changes the kind of device included in the ARTG, a **new application for inclusion** is required.

Example 6: Changes specific to class III devices

Change to the functional description:

From	ARTG Entry XXX approved for MRI 1.5T environment
To	ARTG Entry XXX approved for MRI 3T environment

Pathway

Variation to Class III/AIMD application

Additional information to support change:

- Evidence of Product Assessment,
- Clinical Evaluation Report which is specific to the change in MR conditional capabilities
- Patient Information Card (PIC) and Patient Information Leaflet (PIL)
- Instructions for Use (IFU)
- Device Label

Change in total number of devices, or variants:

From	ARTG Entry Total number: 5	ARTG Entry Total variants: 12
To	ARTG Entry Total number : 8	ARTG Entry Total variants: 10

Pathway

Variation to Class III/AIMD application

Additional information to support change:

- Design Examination (DE) certificate (or equivalent document)
- Declaration of Conformity (DoC)
- Product Catalogue

Change in device Unique Product Identifier (UPI):

From	ARTG Entry UPI: XXX
To	ARTG Entry UPI: XXX - XXX

Pathway

Variation to Class III/AIMD application

Additional information to support change:

- Design Examination (DE) certificate (or equivalent document)
- Declaration of Conformity (DoC)
- Instructions for Use (IFU)
- Justification

Case Study A: Manufacturer name/address change (rebranding)



- 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 the quality management system or corporate structure.

Orange Pty Ltd can submit a **Manufacturer evidence variation application**, and then a **Device Change Request application**, so that their ARTG entry is up to date.

Case Study B: Manufacturer name/address change (acquisition)



- 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 quality management system**, 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.

Case Study C: Changes to intended purpose



- Red Pty Ltd. is the sponsor of a patient monitor intended to be used for monitoring physiological parameters in adult patients.
- As part of the MDR certification, the target patient group was expanded to include paediatric and neonatal patients.

Red Pty Ltd. needs to submit a **DCR application**.

Case Study D: Classification change



- Tobias is the sponsor of a vascular guidewire which was intended to be used in the central circulatory system (CCS) under the MDD certification.
- As part of the MDR certification the intended purpose was revised to exclude the CCS.

Tobias needs to submit a **new application for inclusion** as the guidewire is a new 'kind' of device with a different risk classification.

Updates to the Device Change Request (DCR) form

TGA eBusiness Services **Device Change Request**

Close Save Print Help

Sponsor Details
Applicant address:
Sponsor name:
Contact name:
Email address:
Phone number:

Change Request
Change type:
 Variation to ARTG Listed Entry (OTG Disinfectants)
 Variation to ARTG Registered Entry (Legacy Disinfectants)
 Variation to ARTG Included Entry (Medical Devices and IVDs)

The variation application is to be based on an existing entry by searching the ARTG, selecting a number and then "cloning" to populate the application form. Once cloned the ARTG can not be changed and the Change Type selection will be locked.

Search Clone

ARTG number:

Payment Details
Fee \$430.00

Close Save Print

Code Picker - ARTG ID

Search for... Go! Reset

< < > >

Updates to the Device Change Request (DCR) form

TGA eBusiness Services **Device Change Request**

[Previous](#) [Next](#) [Close](#) [Save](#) [Validate](#) [Submit](#) [Print](#)

Page 2 of 3

ARTG number: [REDACTED]

* Are you making the same change across multiple ARTG entries? Yes No

* Are you changing to an EU MDR/IVDR certification? Yes No

* Are you changing manufacturer details (i.e. name and/or address)? Name Address Both Neither

* Are you seeking to link your ARTG entries to a new approved notification of Manufacturer Evidence (ME)? Yes No

* Are you varying the intended purpose? Yes No

* Are you varying the GMDN code and description? Yes No

Payment Details

Fee [REDACTED]

[Previous](#) [Next](#) [Close](#) [Save](#) [Validate](#) [Submit](#) [Print](#)


Updates to the Device Change Request (DCR) form

* Are you making the same change across multiple ARTG entries? Yes No

* Choose up to 9 additional ARTG entries for which you're making the same change:

* Choose up to 9 additional ARTG entries for which you're making the same change:

* Are you changing to an EU MDR/IVDR certification? Yes No

* Date of effect for EU MDR/IVDR changes: 

* Are you changing manufacturer details (i.e. name and/or address)? Name Address Both Neither

* Where is your evidence supporting this change? In approved Manufacturer Evidence (ME) In supporting evidence to be supplied later

Updates to the Device Change Request (DCR) form

* Are you seeking to link your ARTG entries to a new approved notification of Manufacturer Evidence (ME)? Yes No

* Choose Manufacturer Evidence: **-- Please Select --**


* Are you varying the intended purpose? Yes No

Existing intended purpose: Galeo Focus (Hydro) coronary guide wires are indicated to facilitate the placement of interventional cardiology catheters with compatible guide wire lumen during interventional procedure.

* New intended purpose: Galeo Focus (Hydro) coronary guide wires are indicated to facilitate the placement of interventional cardiology catheters with compatible guide wire lumen during interventional procedure.

* Is there any change in scope to the intended purpose?
 Yes, reduction in scope
 Yes, expansion in scope
 No change

* Are you varying the GMDN code and description? Yes No

* GMDN code and description:  **Search**

* Does this GMDN code change the kind of device? Yes No



Updates to the Device Change Request (DCR) form

Page 3 of 3

ARTG number:

* Are there any other changes you are seeking which have not been identified above? Yes No

* **Please describe changes:**

TGA identifiers for recently submitted DCR or Variation applications covering similar changes to other medical devices

Microsoft Edge

ceptance.tga.gov.au/ebs/Devices/DWebFileU...

DV-2022-CR-00778-1

-- Please Select --

Choose File No file chosen

Add

Please complete:

- The Document Type
- Select the File to be submitted.

Attach / Add Supporting Information

This function allows the attachment of supporting documentation for the application.
Class I non-sterile, non-measuring, Class 1 IVD, Class I export only, and Class 1 IVD export only: Applications must have a signed copy of the [Declaration of Conformity](#) attached.
All other classes: The application must be accompanied by supporting information appropriate to the class of device in the [Use of market authorisation evidence from comparable overseas regulatory bodies for medical devices](#) guidance document.

Add No Attachments

Updates to the Device Change Request (DCR) form

Declaration:

The applicant certifies:

1. For changes to manufacturer details, the legal entity has not changed and the QMS remains the same.
2. The manufacturer holds appropriate evidence of product assessment, for all the devices of that kind (if applicable).
"Evidence of product assessment must be able to be provided if requested for the kind of device to verify the device meets all the regulatory requirements."
[Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices \(including IVDs\)](#)
3. The information included in or with the application is complete and correct.

PLEASE NOTE: A false declaration will result in the device entry being removed/cancelled from the ARTG.

I agree Yes No

Payment Details

Fee



[Previous](#) [Close](#) [Save](#) [Validate](#) [Submit](#) [Print](#)



Updates to the Variation form

TGA eBusiness Services Variation of Device Application

[Previous](#) [Next](#) [Close](#) [Save](#) [View Entire App](#) [Validate](#)

Page 2

The variation application is for ARTG entry [REDACTED]

* Are you changing to an EU MDR certification? Yes No

* Are you varying the intended purpose? Yes No

[Previous](#) [Next](#) [Close](#) [Save](#) [View Entire App](#) [Validate](#)

* Are you varying the intended purpose? Yes No

Existing intended purpose The [REDACTED] is for treatment of supraventricular/ ventricular tachycardia rhythm disturbances or AV node re-entry tachycardia by rf ablation. This includes WPW syndrome; atrial flutter; atrial fibrillation; atrial tachycardia; ventricular tachycardia; ablation of the bundle of His or the atrioventricular node in the case of therapy resistant tachycardia atrial fibrillation (as palliative measure); and pulmonary vein isolation in the case of left atrial fibrillation and flutter.

* Proposed intended purpose The [REDACTED] is for treatment of supraventricular/ ventricular tachycardia rhythm disturbances or AV node re-entry tachycardia by rf ablation. This includes WPW syndrome; atrial flutter; atrial fibrillation; atrial tachycardia; ventricular tachycardia; ablation of the bundle of His or the atrioventricular node in the case of therapy resistant tachycardia atrial fibrillation (as palliative measure); and pulmonary vein isolation in the case of left atrial fibrillation and flutter.

* Is there any change in scope to the intended purpose? Yes, reduction in scope Yes, expansion in scope No change

Common Manufacturer Evidence and DCR or Variation issues

Some examples of common ME and DCR/Var issues

- Not attaching supporting evidence of manufacturer detail changes.
- Documents supplied do not clearly state whether the quality management system or legal entity of the manufacturer have changed.
- Sponsor asks to amend manufacturer name or address in ARTG when the legal entity and quality management system have changed due to an acquisition.
- Manufacturer or Notified Body letter and sponsor clarification to support manufacturer name or address change do not provide sufficient evidence for the change requested.
- Scope of the certificate has changed, and the sponsor has indicated that it has not changed.

Fees and charges

- New ME or ME Variation
 - No charge
- DCR/Variations
 - De/relink manufacturer evidence identifier only – **PROPOSED** reduced fee (\$190 to relink up to 10 ARTG entries to the **same** manufacturer evidence identifier)
 - Any other change – full fee (\$482)

Upcoming Webinars

Webinar Topic	Date	Time (GMT+11)
#3 EU MDR Transition - Consent to Supply, market notifications	Tuesday 13 December	1-2pm

Website and link references

EU MDR guidance material	www.tga.gov.au/how-we-regulate/supply-therapeutic-good-0/supply-medical-device/eu-mdr-transition
Online Assessment Tool	https://consultations.tga.gov.au/tga/tool-sponsor-obligations-for-medical-devices-tran/
Online Notification Form	https://consultations.tga.gov.au/tga/form-sponsor-notification-for-medical-devices-tra/
EU MDR web publication service	www.tga.gov.au/how-we-regulate/supply-therapeutic-good-0/supply-medical-device/eu-mdr-transition/eu-mdr-transition-web-publication-service
Consent to supply	www.tga.gov.au/resources/resource/forms/essential-principles-consent-non-compliance
Lapses in Conformity Assessment Notification Form	consultations.tga.gov.au/tga/notification-form-lapses-in-conformity-assessment/
Recalls	www.tga.gov.au/safety/product-recalls
Schedule of fees and charges	https://www.tga.gov.au/schedule-fees-and-charges
TGA business services	https://www.tga.gov.au/tga-business-services

Contact us

EU MDR Transition Team

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Questions




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More information



	TGA website	https://www.tga.gov.au
	TGA Facebook	https://www.facebook.com/TGAgovau/
	TGA Twitter	https://twitter.com/TGAgovau
	TGA YouTube	https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw
	TGA topics blog	https://www.tga.gov.au/blogs/tga-topics
	TGA LinkedIn	https://www.linkedin.com/company/therapeutic-goods-administration/
	TGA Instagram	https://www.instagram.com/tgagovau/?hl=en

Contact us

EU MDR Transition Team

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Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration