EU MDR Transition – Webinar 2

Manufacturer Evidence and Variations to the ARTG

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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

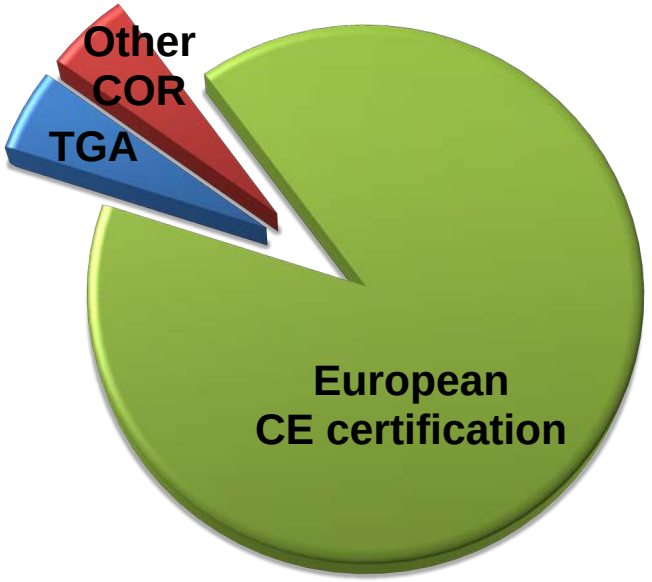
- Background
- Manufacturer Evidence (ME) – new and variation
- Device change requests (DCR) – change types
- Variations – change types
- Updates to application forms
- Resources available
- Q&A

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

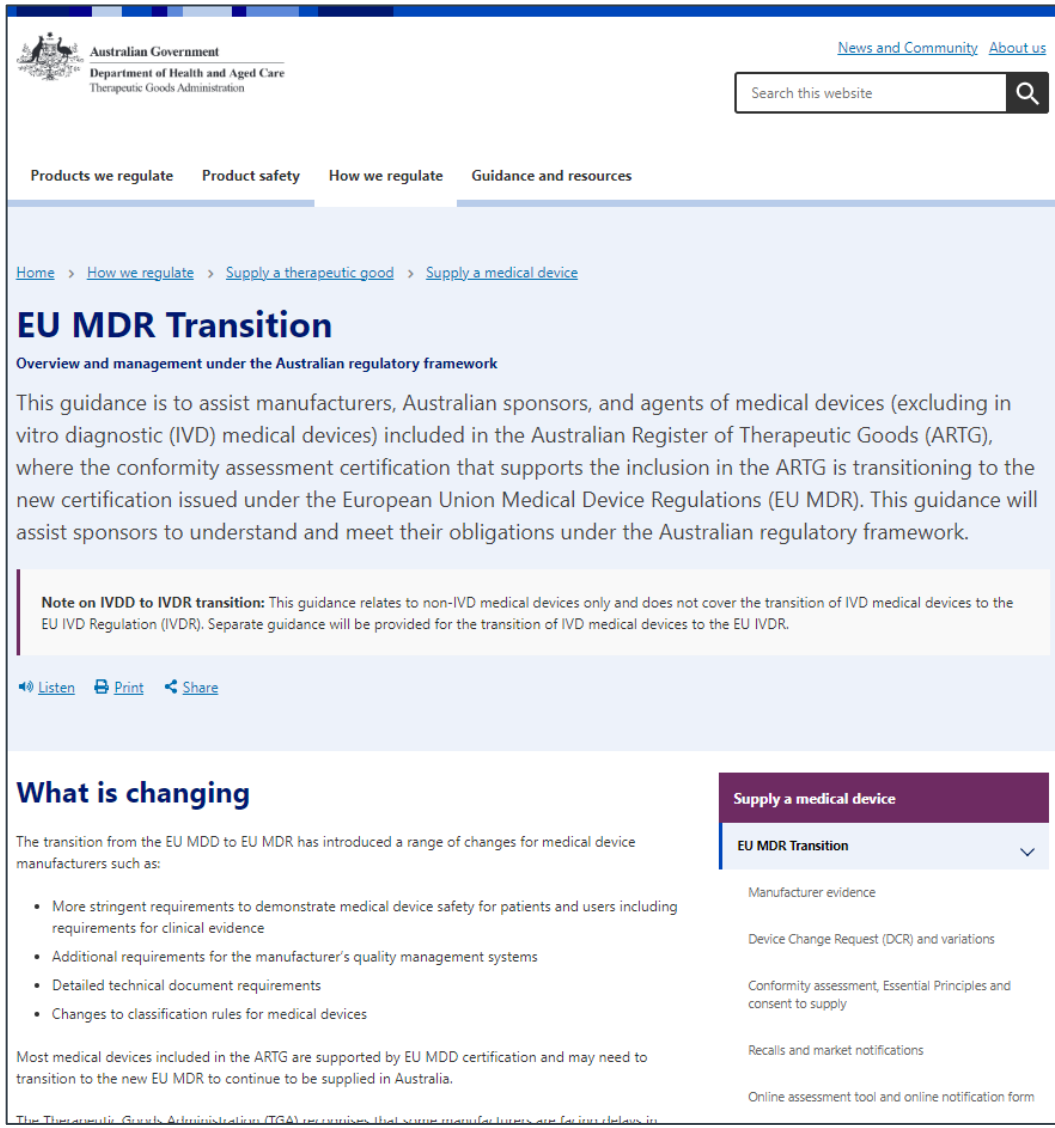
Manufacturer Evidence (Conformity Assessment)

Variations to the ARTG (DCR/Variations)

EU MDR Transition – Guidance

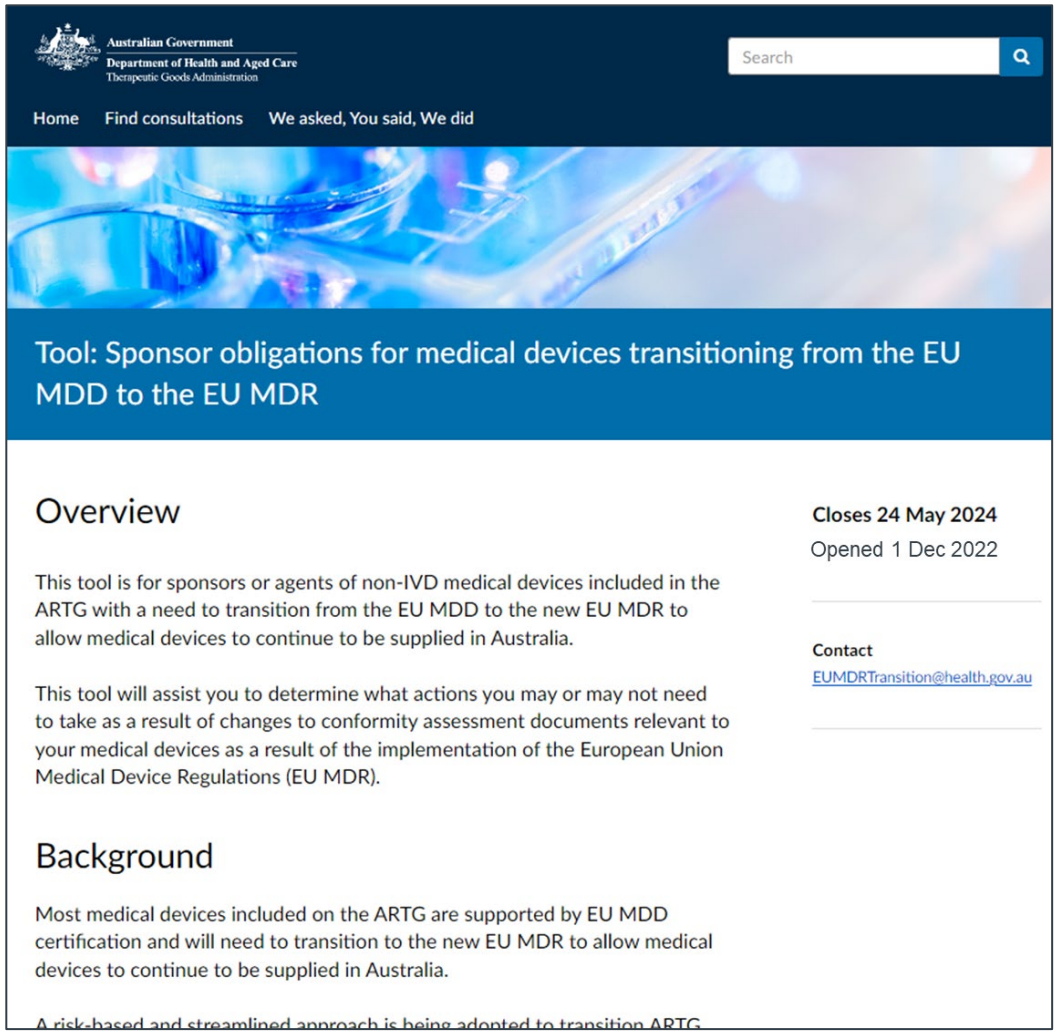
Guidance on our website:

- 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



https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good-0/supply-medical-device/eu-mdr-transition

Online Assessment Tool



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): •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): •Total number of devices •Variant list •UPI (Unique Product Identifier) •Functional Description	Variation
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	Recalls or Market notifications
Non-compliant with the Essential Principles	Consent to Supply

https://consultations.tga.gov.au/tga/tool-sponsor-obligations-for-medical-devices-tran/

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

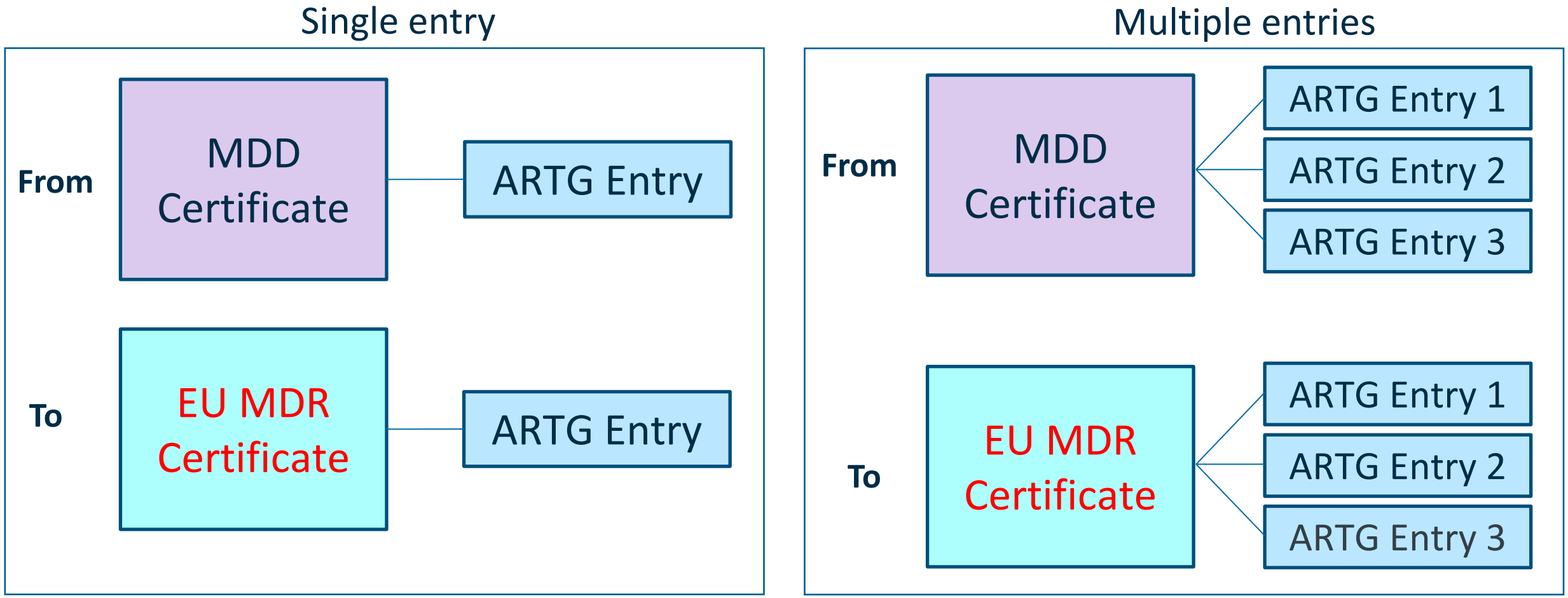
(c) have the same **device nomenclature system code (**see subsection (3)); and

(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.

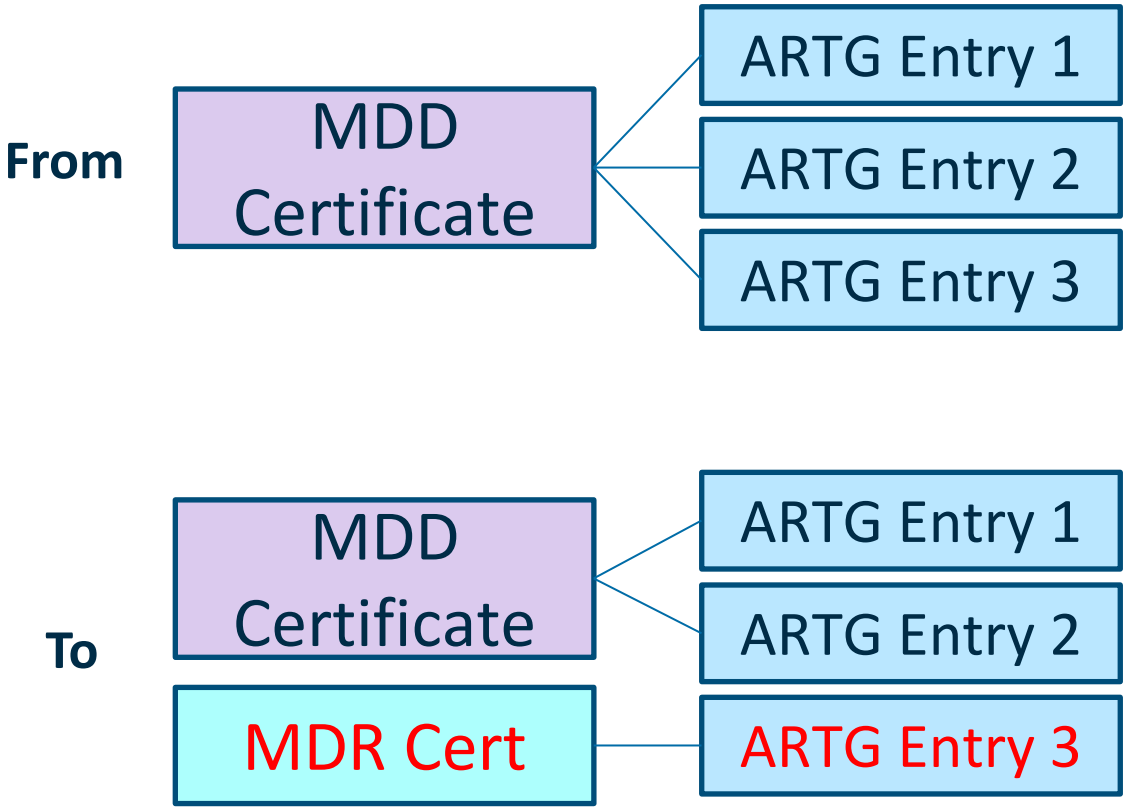
Reg1.6 prescribes that for a Class III medical device, a characteristic is the **unique product identifier** of the device

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



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)

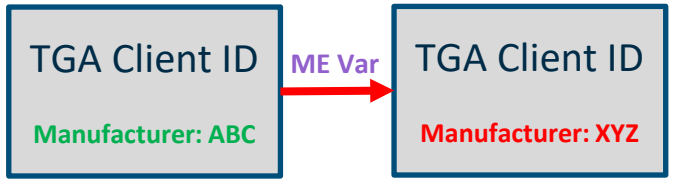
From

ARTG Entry 1
Manufacturer: ABC
Sponsor 1

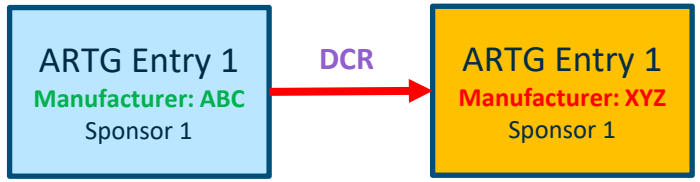
To

ARTG Entry 1
Manufacturer: XYZ
Sponsor 1

Step 1: ME Variation



Step 2: DCR



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

Example 4: Updating Sponsor name and/or address

From

ARTG Entry

Sponsor: ABC

To

ARTG Entry

Sponsor: XYZ

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.

https://www.tga.gov.au/sites/default/files/notification-change-of-sponsor-name.pdf

Example 5: Updating GMDN or intended purpose

From

ARTG Entry

GMDN: 12345

To

ARTG Entry

GMDN: 98765

From

ARTG Entry

Intended purpose:
XXX is suitable for adult and paediatric population

To

ARTG Entry

Intended purpose:
XXX is suitable for the adult population only

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

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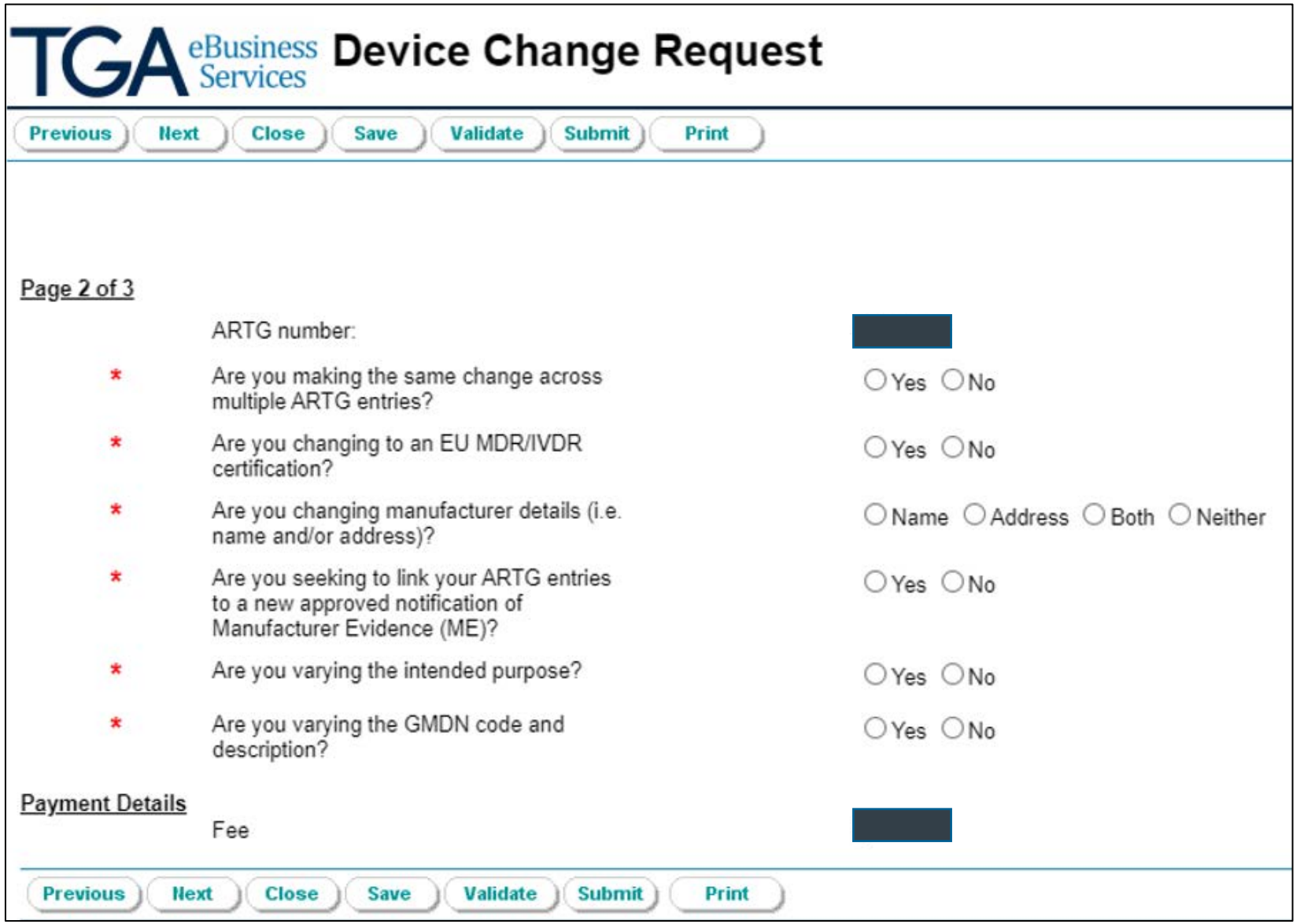

TGA eBusiness Services **Device Change Request**

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	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]

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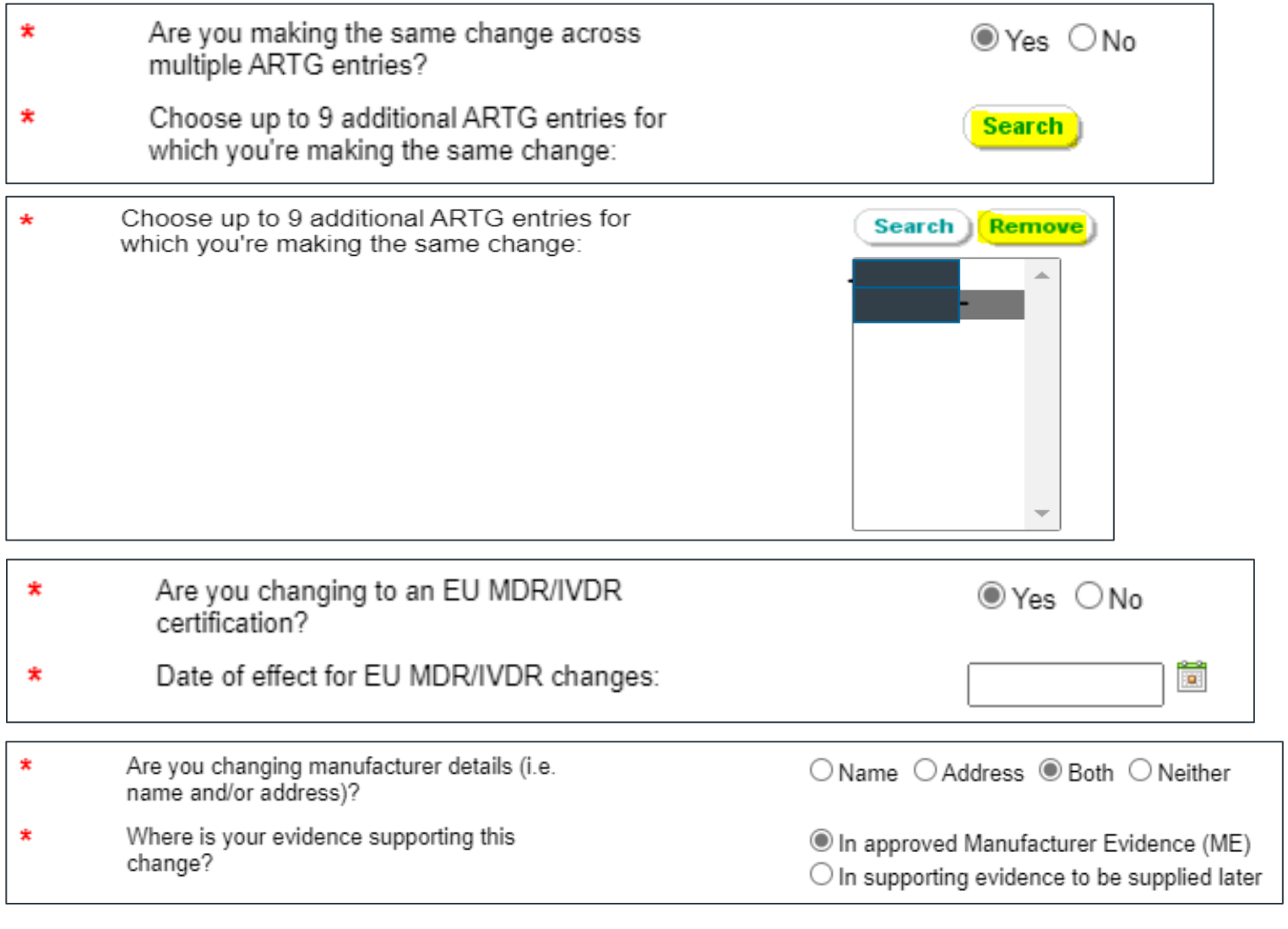
Updates to the Device Change Request (DCR) form



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.

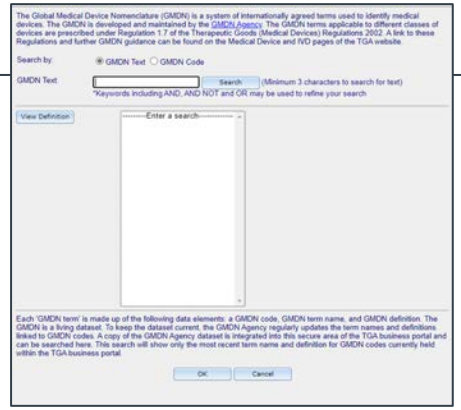
* New intended purpose: Galeo Focus (Hydro) coronary guide wires are indicated to facilitate the placement of interventional cardiology catheters with compatible guide wire lumen during interventional procedure.

* 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

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ARTG number: [redacted]

* 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

icrosoft Edge

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

DV-2022-CR-00778-1

-- Please Select --

Choose File No file chosen

Add

Please complete:

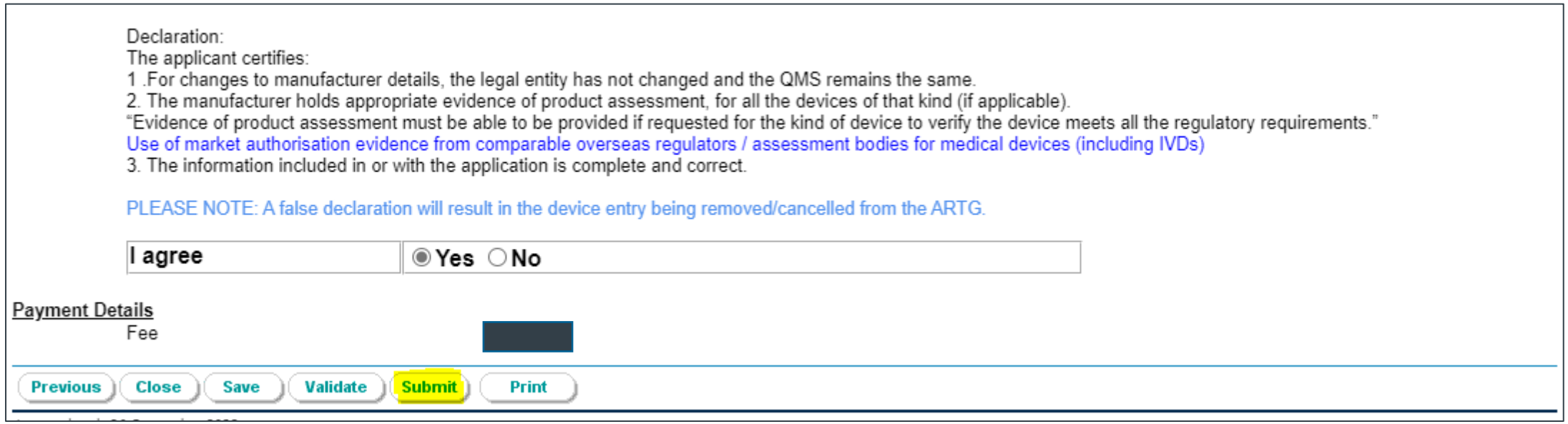
- The Document Type
- Select the File to be submitted.

Attach / Add Supporting Information

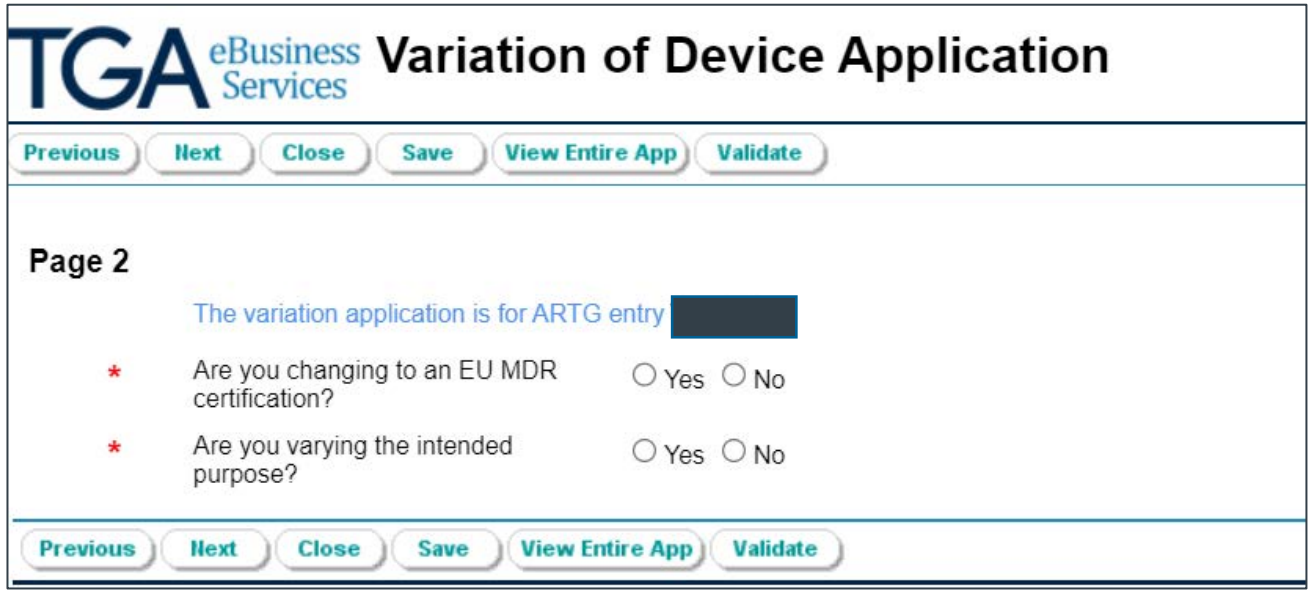
This function allows the attachment of supporting documentation for the application.
Class I non-sterile, non-measuring, Class 1 IVD, Class I export only, and Class 1 IVD export only: Applications must have a signed copy of the Declaration of Conformity attached.
All other classes: The application must 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



Updates to the Variation form



TGA eBusiness Services **Variation of Device Application**

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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

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* 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

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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

EUMDRTransition@health.gov.au

Questions

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Therapeutic Goods Administration (TGA)

Q&A

More information

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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

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Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration