Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Reclassification of medical devices in direct contact with the heart, central circulatory and central nervous systems

Guidance on the transitional arrangements and obligations

Version 1.3, August 2023

The purpose of this guidance is to help sponsors and manufacturers comply with the requirements of the therapeutic goods legislation.

This is a guide only, and sponsors and manufacturers are encouraged to familiarise themselves with the legislative and regulatory requirements in Australia. If necessary, seek professional advice as it is the responsibility of each sponsor and/or manufacturer to understand and comply with these requirements.

This document will evolve over time and updates and clarifications will be included as required. Feedback on the guidance is always welcome.

Contents

About this guidance

This guidance aims to assist sponsors of medical devices intended to be used in direct contact with the heart, central circulatory system (CCS) or the central nervous system (CNS) with meeting their obligations and outlines transitional arrangements to help comply with new regulations.

From 25 November 2021 medical devices intended to be used in direct contact with the heart, central circulatory system (CCS) or the central nervous system (CNS)will be required to meet regulatory requirements demonstrating the safety and performance for Class III medical devices.

Background

In early 2019 the Therapeutic Goods Administration (TGA) conducted a public consultation seeking feedback on a proposal to reclassify medical devices intended to be used in direct contact with the heart, central circulatory system (CCS) or the central nervous system (CNS). The proposed regulatory changes supported the commitment made in the Australian Government Response to the Review of Medicines and Medical Devices Regulation to align Australian medical device regulations, where possible and appropriate, with the European Union framework.

Stakeholders who responded to the public consultation were broadly supportive of the proposed changes and the *Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019* was made on 12 December 2019.

The amendments include the reclassification of all surgically invasive medical devices intended to be used in direct contact with the heart, CCS or CNS from Class IIa (low-medium risk) to Class III (high risk), effective from 25 November 2021.

Further regulatory refinements were made on 29 October 2021 to provide greater clarity around the regulation of these products.

Requirements for reclassification

The requirements include:

- more detailed assessment of the manufacturer's quality management systems and assessment of technical documentation related to each device
- conformity assessment documents demonstrating procedures appropriate for a Class III device
- mandatory audit assessment by the TGA for device inclusion applications, including assessment of clinical evidence.

Medical devices in direct contact with the heart, CCS or CNS

Medical devices in direct contact with the heart, CCS or CNS will be reclassified to Class III, regardless of the duration of action of the device (transient, short-term or long-term). This means that:

- medical devices used in direct contact with the **heart and CCS** which are intended for **transient or short-term use** will be reclassified from Class IIa (low-medium risk) to Class III (high risk)
- medical devices used in direct contact with the **CNS** which are intended for **transient use** will be reclassified from Class IIa to Class III.

Medical devices in direct contact with the heart, CCS or CNS that are intended for **long-term use** are **already classified as Class III** and there are no changes to the classification for these devices.

From 25 November 2021, the following amendments to the classification rules will apply:

Subclause 3.2(3A) of Schedule 2:

(3A) If the device is not a reusable surgical instrument and the device is intended by the manufacturer specifically to be used in direct contact with the heart, the central circulatory system or the central nervous system of a patient, the device is classified as Class III.

Paragraph 3.3(4)(b) of Schedule 2:

If the device is intended by the manufacturer:

…(b) specifically to be used in direct contact with the heart, the central circulatory system or the central nervous system of a patient;

…the device is classified as Class III

Examples of devices to be reclassified to Class III

Some examples of transient and short-term surgically invasive medical devices used in direct contact with the **heart and/or CCS** include:

- self-expanding valve prosthesis
- post-dilatation balloon catheter
- cardiac vent catheter
- central venous catheterisation kit
- cardiopulmonary cannulae.

Some examples of transient-use surgically invasive medical devices used in direct contact with the **CNS** include:

- flexible fibreoptic neuroscope
- rigid neuroscope
- automatic cranial perforator
- spinal needle.

What you need to do

If you are a sponsor of a medical device that is used in direct contact with the heart, CCS or CNS, the action you will need to take to comply with the new regulations will depend on the status of your product:

- Medical devices included in the ARTG prior to 25 November 2021
- Applications to include a medical device in the ARTG lodged before 25 November 2021
- Applications to include a new medical device in the ARTG on or after 25 November 2021

Medical devices included in the ARTG prior to 25 November 2021

If you have a medical device inclusion in the ARTG that will be reclassified, with a start date before 25 November 2021, transitional arrangements are in place to ensure that you can continue to supply your device while you apply for it to be included in the ARTG as a Class III medical device.

To continue to supply your device you must:

- Notify the TGA **before 25 May 2022** that you have an inclusion that will need to be reclassified
- Submit a reclass application for your device to be included in the ARTG as a Class III medical device **before the transition deadline**.

Please note

If you do not intend to continue supplying the device, you should cancel your ARTG inclusion **before 25 May 2022**.

If you **notif**y the TGA of your devices **before 25 May 2022** but you do not **submit an application** for a Class III inclusion **before the transition deadline**, you must cease supplying your device from the day of the transition deadline and cancel your inclusion.

Applications to include a medical device in the ARTG lodged before 25 November 2021

If you have submitted an application for inclusion in the ARTG for a Class IIa device before 25 November 2021, your application will be assessed and the device will be included in the ARTG as a Class IIa device under the old classification rules.

To be eligible for the transitional arrangements to reclassify your device as a Class III device, you will need to:

- Notify the TGA that you have an inclusion that will need to be reclassified by whichever is the later date:
  - **Before 25 May 2022**
  - **Within 2 months of the start date of your ARTG entry**
- Submit a reclass application for your device to be included in the ARTG as a Class III device **before the transition deadline**.

Cancelling your ARTG inclusion

If you **do not notify** the TGA before 25 May 2022 or within two months of the start date for your ARTG entry (whichever is the later date) of your intention to apply for the device to be included in the ARTG as a Class III device you will no longer be eligible for the transitional arrangements. You should:

- cease supply of your device from 25 May 2022 and
- cancel your ARTG inclusion.

If you **notify** the TGA of your device before the due date, but you **do not submit an application** for a Class III inclusion **before the transition deadline**, you must:

- cease supply of your device from the day of the transition deadline and
- cancel your ARTG inclusion.

Applications to include a new medical device on or after 25 November 2021

Any application for inclusion of a new device, that is not yet included in the ARTG, submitted to the TGA **on or after 25 November 2021** must be submitted as an application for a Class III medical device.

For more information refer to the Medical device ARTG inclusion process.

See below for information about the differences between a Class IIa and a Class III medical device.

Notifying the TGA

To notify the TGA that you have an ARTG inclusion for a device that needs to be reclassified, you will need to fill in the online form on our Consultation Hub:

https://consultations.health.gov.au/tga/reclass-md-direct-contact-heart-ccs-cns

The form will be available until 24 May 2022.

The information you will need to provide includes the existing ARTG number and for devices that will be newly classified as Class III medical devices, you will also need to provide UPIs for each device and/or variant.

Reclassifying an ARTG inclusion as a Class III device

Kind of device: Class IIa vs Class III

The application requirements for inclusion of a Class III device in the ARTG are different from the requirements for a Class IIa device.

Only devices of the same kind can be supplied under one ARTG entry.

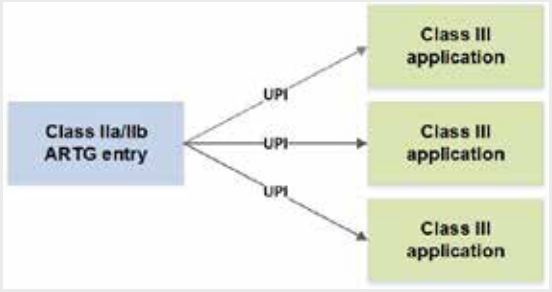
Class IIa devices are considered to be of the same 'kind' and can be included in one ARTG entry when they have the same:

- sponsor
- manufacturer
- classification
- Global Medical Device Nomenclature (GMDN) System Code.

Class III devices must additionally have the same Unique Product Identifier (UPI) in order to be considered of the same "kind".

Please note

The devices included in your current Class IIa ARTG entry may have different UPIs. **You will require a separate Class III application for inclusion in the ARTG for each UPI.**



A Class III ARTG entry may still cover more than one device, but **only if** the:

- devices have the same UPI
- variation in the design of the devices is only to accommodate different patient anatomical requirements
- variation does not change the intended purpose of the device.

For more information about acceptable variants refer to Kind of medical device.

Timeframes for ARTG inclusion applications as Class III medical devices

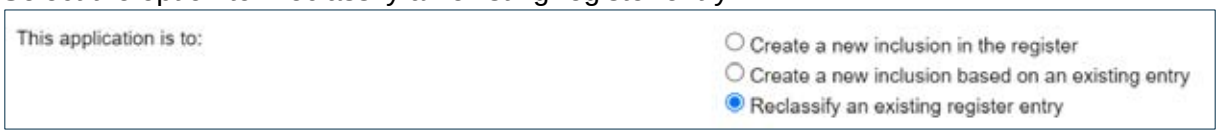
In order to continue supplying your devices, you must submit your reclassification application for a Class III inclusion in the ARTG **before the transition deadline.** In July 2023, the Government agreed that regulatory amendments should be drafted to extend this transition deadline to 1 July 2029. The regulatory amendments are underway and are expected to be in place before December 2023. Once the amendments are made, the transition deadline would be **1 July 2029**. More information about the proposed regulatory amendment can be found at https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/eu-mdr-transition/eu-mdr-transition-extension.

If you have submitted your application before this date, but it has not yet been finalised by the TGA, you are able to continue to supply your devices using your Class IIa or IIb ARTG entry until a decision is made about your Class III application.

How to submit a reclassification application

1. Create a 'New Device Application' from the menu in the eBS Portal
2. Select "Medical Device - Included" from the first drop-down list provided

3. Select the option to 'Reclassify an existing register entry'



4. Search for the ARTG Number to be reclassified: eg. 130099 (example only)

5. Select the "Clone" button.
6. Allow the system to clone the information associated with the ARTG entry into the application
7. Select **Class III** from the drop down provided for the "New classification" question.

Please note

If the GMDN code in the existing entry has been made obsolete or has been updated, the sponsor is responsible for selecting the most appropriate and current code available in the GMDN agency database.

If you are required to select a new GMDN code that is different to the cloned ARTG entry, you will not be able to validate and submit the application.

Please save the draft application and email TGA Devices info line at devices@tga.gov.au for assistance.

If there is a change of manufacturer, you must submit a new application (*i.e.* select "Create a new inclusion in the register" instead of "Reclassify an existing register entry" in the Step 3 shown above) and provide information about the existing ARTG entry in the application form or in a supporting document attached with the form.

What to include in your application

To pass preliminary assessment, Class III applications for ARTG inclusion must be accompanied by conformity assessment documentation as outlined in supporting documentation for inclusion of a medical device.

The required documents are outlined in the final column 'Documentation to be provided with the application (Evidence of product assessment)' of Table 2 in the Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices (including IVDs). This information must be provided in addition to the manufacturer evidence.

Please ensure you allow sufficient time to obtain your conformity assessment documentation in order to submit your documents with your application.

If you do **not pass preliminary assessment**, your application **will be refused** and you will **not be able to transition** your device to the new classification.

Mandatory Audits

If your Class III application is not supported by MDR, TGA or AU CAB certification, your application will be selected for a compulsory application audit. Compulsory application audits attract an **audit assessment fee** and require submission of additional information, which may include, clinical evidence to support the safety and performance of the device

The Clinical Evidence Guidelines outline the level of evidence expected for medical devices to be included on the ARTG.

Audit assessment fees are listed in the TGA's Schedule of fees and charges.

A step-by-step guide to the medical device ARTG inclusion process can be found on the TGA website.

Fees

You will need to pay the relevant application fee and audit assessment fee.

You can request abridgement and reduction of the assessment fee of the audit assessment (including requests to abridge the level of audit if appropriate).

If your inclusion application is not successful

If your inclusion application to transition your device to the new classification is not successful, you will be notified of the decision in writing and you will be provided the reasons for the decision.

If you are not satisfied with this decision, you may request reconsideration of this initial decision under section 60 of the *Therapeutic Goods Act 1989* within **90 days** of the decision.

If you are not satisfied with the reconsideration (reviewable decision), you may apply to the Administrative Appeals Tribunal or the court.

When to cease supply using your old ARTG entry

If you do not meet your obligations under the transitional arrangements, you will need to cease supply of your device. The following table outlines the circumstances and timeframes:

When to cease supply using an old ARTG entry

Circumstance	Timeframes
You have **not notified** the TGA that your device needs to be reclassified before 25 May 2022, or within two months of inclusion of your device under the old classification rules (whichever is the later date).	**Cease supply** of your devices **from 25 May 2022** or the date that is **2 months after the start date of your ARTG entry (whichever is the later date)**.
You have **not submitted an application for inclusion** in the ARTG to transition your device to the correct classification **before the transition deadline**.	**Cease supply** of your devices **from the day of the transition deadline.**
Your application for inclusion of your device in the ARTG with the correct classification is unsuccessful.	**Cease supply** of your device from the time that you are **notified of the outcome** of your application.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Authorisation Branch	August 2021
V1.1	Update due to regulatory refinements	Medical Devices Authorisation Branch	November 2021
V1.2	Addition of steps for reclassification application	Medical Devices Authorisation Branch	December 2022
V1.3	Update the transition deadline, weblink and some minor edits	Medical Devices Authorisation Branch	August 2023

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