Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Reclassification of active medical devices for therapy with a diagnostic function

Guidance on the transitional arrangements and obligations

Version 1.3, December 2023

Contents

About this guidance

This guidance aims to assist sponsors of active medical devices for therapy with a diagnostic function with meeting their obligations and outlines transitional arrangements to help comply with new regulations.

From 25 November 2021 active medical devices for therapy with a diagnostic function 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 active medical devices for therapy with a diagnostic function that significantly determines patient management. 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 active medical devices for therapy with a diagnostic function that determines the patient management from Class IIa (low-medium risk)/Class IIb (medium-high risk) to Class III (high risk), effective from 25 November 2021.

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.

Active medical devices for therapy with a diagnostic function

Definition of an active medical device for therapy, from the *Therapeutic Goods (Medical Devices) Regulations 2002*:

Active medical device for therapy means an active medical device that is intended by the manufacturer to be used on a human being, either alone or in combination with another medical device, to support, modify, replace or restore biological functions or structures for the purpose of treating or alleviating an illness, injury or handicap. From 25 November 2021, the following classification rule will apply:

Subclause 4.2(4) of Schedule 2:

(4) An active medical device for therapy that includes a diagnostic function the purpose of which is to significantly determine patient management by the device is classified as Class III.

Example: An automated external defibrillator

Active medical devices for therapy that includes a diagnostic function that significantly determines patient management includes, but is not limited to, devices such as fully or semi-automated external defibrillators and closed loop systems. These devices may undertake activities such as examining, monitoring and/or analysing a patient's condition or state and determining the patient management based on these diagnostic results (for example, the device itself may adjust the therapy or deliver the treatment based on the diagnostic function of the device).

Examples of devices to be reclassified to Class III

Active medical devices for therapy with a diagnostic function that will need to be reclassified to Class III include:

- automated external defibrillators
- closed loop systems
- external pacemakers
- intravascular heating/cooling system control units
- hyperthermia systems
- temperature mapping units
- intraperitoneal-circulation hypothermia system control units
- mechanical bloodstream indicator injectors.

Example: An automated external defibrillator (AED), when attached to a patient, will assess a patient's heartbeat and if the AED detects a life-threatening fibrillation, will deliver a high energy electric shock designed to cease the abnormal cardiac activity and return the heart to its normal working state. An AED is an example of an active medical device that includes a diagnostic function to determine the patient's management.

Continuous positive airway pressure devices will not be reclassified

Continuous positive airway pressure (CPAP) devices are considered medium-risk devices due to the nature of the therapy these devices provide to patients. They are not considered to significantly determine patient management. When used for treatment of obstructive sleep apnoea in spontaneously breathing patients, the automatic adjustment of pressure delivery within set limits is intended to improve patient comfort and does not serve any diagnostic function. Therefore, they are not considered to be within scope of this new classification rule.

On **25 February 2021** changes to the Regulations commenced to introduce new classification rules for programmed and programmable medical devices, and medical devices that are software. This includes all software-based medical devices.

Please ensure that you review those classification rules, in conjunction with this new rule, to ensure that you select the correct classification for your device.

If your device is subject to more than one classification rule, then your device should be classified at the highest classification of the applicable rules.

What you need to do

If you are a sponsor of an active medical device for patient therapy that has a diagnostic function that determines patient management, the actions 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 Class IIa or IIb medical device inclusion in the ARTG 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**.

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

If you **notify** 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 or Class IIb device before 25 November 2021, your application will be assessed and the device will be included in the ARTG as a Class IIa or Class IIb device under the old classification rules.

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

- 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. As soon as possible after those dates you must:

- cease supply of your device
- cancel your 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 supplying your device from the day of the transition deadline
- cancel your 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 inclusion process.

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

Notifying the TGA

To notify the TGA about an ARTG inclusion for a Class IIa or Class IIb active medical device for therapy with a diagnostic function that needs to be reclassified, you will need to fill in an online form at https://consultations.health.gov.au/tga/reclass-active-md-therapy-with-diagnostic-function

The information you will need to provide includes the existing ARTG number, current classification, and new classification. 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/Class IIb vs Class III

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

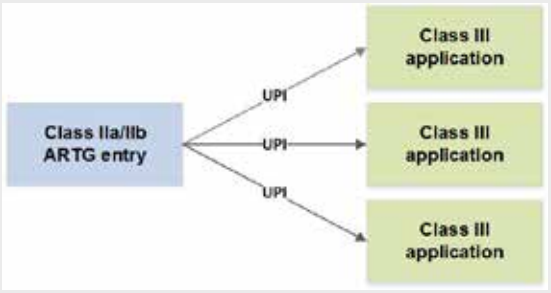
Only devices of the same kind can be supplied under one ARTG entry.

Class IIa and Class IIb devices are 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) to be considered of the same 'kind'.

The devices included in your current Class IIa or Class IIb 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 requirement
- 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

To continue supplying your devices, you must submit your reclassification application for a Class III inclusion in the ARTG **before the transition deadline.** In November 2023, regulatory amendments have been made to extend the transition deadline for some transitional devices. The updated transitional deadline for active medical devices for therapy with diagnostic function is **1 July 2029**. More information about the TGA's strategy in response to EU MDR transition extension 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. 

4. Select the option to ‘Reclassify an existing register entry’.
5. 

6. Search for the ARTG Number to be reclassified: eg. 130099 (example only).
7. 

8. Select the "Clone" button.
9. Allow the system to clone the information associated with the ARTG entry into the application.
10. Select **Class III** from the drop down provided for the “New classification” question.
11. 

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

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 old ARTG entry

Circumstance	What to do
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 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	December 2020
V1.1	Addition of steps for reclassification application	Medical Devices Authorisation Branch	December 2022
V1.2	Update the transition deadline, weblink and some minor edits	Medical Devices Authorisation Branch	August 2023
V1.3	Update the transition deadline	Medical Devices Authorisation Branch	December 2023

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