Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Reclassification of active implantable medical devices (AIMD)

Guidance on the transitional arrangements and obligations

Version 1.5, May 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.

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About this guidance

This guidance aims to assist sponsors of **active implantable medical devices (AIMD)** with meeting their obligations and outlines transitional arrangements to help comply with new regulations.

From **25 November 2021** active implantable medical devices will be required to be reclassified **from Class AIMD to Class III**.

Background

In early 2019 the Therapeutic Goods Administration (TGA) conducted a public consultation seeking feedback on a proposal to reclassify active implantable medical devices and their accessories. 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 aligning the Australian medical devices framework with the EU framework; however, there were diverse views regarding the proposal to reclassify accessories to active implantable medical devices.

The proposal was refined based on the feedback provided by stakeholders and the *Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019* was made on 12 December 2019.

The amendments simplify and reclassify active implantable medical devices from Class AIMD to Class III, effective from 25 November 2021.

Please note

The conformity assessment procedures applied to Class III medical devices are the same as for Class AIMD medical devices. Therefore, there will be no change to the level of the regulatory requirements or the level of scrutiny for these devices.

Active implantable medical devices

Active implantable medical device is defined in the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations):

Active implantable medical device or **AIMD** means an active medical device, other than an implantable medical device, that is intended by the manufacturer:

(a) either:

(i) to be, by surgical or medical intervention, introduced wholly, or partially, into the body of a human being; or

(ii) to be, by medical intervention, introduced into a natural orifice in the body of a human being; and

(b) to remain in place after the procedure.

From 25 November 2021, the following classification rule will apply:

Subclause 5.7(1) of Schedule 2:

(1) An active implantable medical device is classified as Class III.

Examples of devices to be reclassified to Class III

Active implantable medical devices that will need to be reclassified to Class III include:

- implantable cardiac pacemakers (for example, single-chamber and dual-chamber pacemakers)
- implantable cardioverter-defibrillators (ICD)
- biventricular pacemaker/defibrillators
- implantable cardiac monitor
- cochlear implants
- brain electrical stimulation systems
- spinal cord stimulation systems.

What you need to do

If you are a sponsor of an active implantable medical device, 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 an active implantable medical device 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.

If you would like 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; and
- Submit an application for your device to be included in the ARTG as a Class III medical device before 1 November 2024.

Please note

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 1 November 2024, you must cease supplying your device from 1 November 2024 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 AIMD device before 25 November 2021, your application will be assessed and the device will be included in the ARTG as a Class AIMD 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 an application for your device to be included in the ARTG as a Class III device **before 1 November 2024**.

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 1 November 2024**, you must:

- cease supplying your device from 1 November 2024
- cancel your inclusion

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

Any application for inclusion of a new active implantable medical 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.

Annual Reporting Requirements

Regulation 5.11 of the *Therapeutic Goods (Medical Devices) Regulations 2002* specifies conditions applying automatically to a new ARTG inclusion and includes annual reporting requirements for the first 3 years of inclusion in the ARTG.

Amendments were made to Regulation 5.11 in July 2020. These amendments specify that the annual reporting period is based on the original inclusion date for the medical device. The amendments apply only to medical devices that were previously subject to annual reporting requirements **and** are subject to (reclassification) transitional arrangements.

For example, a Class AIMD device that is already included in the ARTG for greater than three years and is transitioning to a Class III ARTG inclusion is excluded from 3 year annual reporting requirement. However, for devices that are at a lower classification (e.g. Class IIa) that are transitioning to Class III, and have not previously been subjected to the 3 years of annual reporting, then these devices would be subject to the 3 years of annual reporting.

Notifying the TGA

To notify the TGA of your active implantable medical devices that need to be reclassified to Class III, you will need to fill in an online form at https://consultations.tga.gov.au/tga/reclass-active-implantable-md

The form will be available until 24 May 2022.

The information you will need to provide includes the existing ARTG number and UPIs for each device and/or variant.

Class III applications for ARTG inclusion

To continue supplying your devices, you must submit your application for a Class III inclusion in the ARTG **before 1 November 2024**. 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 AIMD entry until a decision is made about your Class III application.

Please note

You must submit a Class III application electronically through TGA Business Services using the Class III device application form. If you submit your application using any other form (for example, another classification form) your application will fail and your application fee will not be refunded.

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

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

2. Search for the ARTG Number to be reclassified: e.g. 130099 (example only)

3. Select the "Clone" button.
4. Allow the system to clone the information associated with the ARTG entry into the application
5. Select the new classification from the drop down provided for the “Reclassification” 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.

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. This information must be provided in addition to the manufacturer evidence.

The specific documents that you are required to attach 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).

Please ensure you allow sufficient time to obtain your conformity assessment documentation in order to submit your documents with your application. For example, it is acceptable to

attach valid evidence of design examination for the device issued under Annex 2.4 of EU 90/385/EEC.

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.

Please note

Class III applications for ARTG inclusion to reclassify active implantable medical devices will not be subject to mandatory audit.

However, TGA will select applications for non-mandatory audit if there are any concerns with the application (e.g., post market signals) or if there are minor changes in the submitted reclassification application. For example, if the information in the new application is not consistent with the information in the current ARTG entry (such as a rewording of the intended purpose).

If there is a change of manufacturer, you must submit a new application.

Fees and charges

The Class III application fee will be waived and will not be applicable to Class III applications submitted during the first year of the transition period (25 November 2021 to 24 November 2022 inclusive).

However, the Class III application fee will be payable from the second year of the transition period (25 November 2022) to the end of the transition period (before 1 November 2024).

If the device is included in the ARTG as a Class III medical device, then Class III annual charges will apply. However, if at any time during a charge year, the same medical device is included in the ARTG as a Class AIMD and a Class III medical device, then the Class III annual charge is nil.

For more information refer to the TGA's Schedule of fees and charges.

Amendments to Prostheses List

Some surgically implantable prostheses and other eligible devices are listed on the Prostheses List. The Prostheses List contains information about the device, including the ARTG entry.

If your Class III ARTG inclusion application with the TGA is successful and a new ARTG number is assigned, you should apply for your Prostheses List billing code to be amended to ensure the information entered on the Prostheses List is accurate.

Failure to maintain the currency of your Prostheses List billing codes' details may result in discrepancies between private hospital records and the Prostheses List, and consequently may cause delays and inaccuracy in benefits paid by private health insurers.

To update the Prostheses List with your new ARTG numbers, you will need to submit an Amendment Application using the Prostheses List Management System (PLMS) for each of the affected billing codes. When submitting an Amendment Application, please ensure you clearly explain the reason for the change and include relevant supporting documentation.

Examples of supporting documentation include:

- new ARTG certificate
- catalogue or product brochure that provide relevant information about the devices affected by the change.

For any further queries about the Prostheses List, please email prostheses@health.gov.au.

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 1 November 2024**.	**Cease supply** of your devices **from 1 November 2024.**
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	April 2021
V1.1	Addition of paragraph related to annual reporting requirements	Medical Devices Authorisation Branch	March 2022
V1.2	Addition of application instructions	Medical Devices Authorisation Branch	June 2022
V1.3	Addition of reclassification instructions	Medical Devices Authorisation Branch	December 2022
V1.4	Clarification of annual charges	Medical Devices Authorisation Branch	April 2023
V1.5	Clarification of annual charges	Medical Devices Authorisation Branch	May 2023

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