Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

# Regulatory changes for medical devices containing medicinal substances or materials of animal, microbial or recombinant origin

## Guidance on the new regulatory requirements and transition arrangements

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# About this guidance

This guidance explains the new regulatory requirements for medical devices containing medicinal, microbial, recombinant, or animal origin substances effective from 1 July 2024. It helps sponsors interpret the new classification rule, conformity assessment requirements and transition arrangements.

This guidance covers the background, highlights key changes, and outlines the steps for sponsors and manufacturers to comply with the new requirements. Additionally, it provides examples to demonstrate how to apply the requirements in practice.

# Background

In June 2023, the Therapeutic Goods Administration (TGA) conducted a public consultation seeking feedback on potential changes to the regulatory requirements for non-IVD medical devices that contain tissues, cells, or substances of animal, microbial or recombinant origin. The proposed changes aimed to ensure that Australia's regulatory requirements for medical devices remain risk-based, align with the European Union (EU) requirements where possible, and to reduce unnecessary regulatory burdens, allowing timely access to safe medical devices in Australia.

Stakeholders who responded to the consultation were broadly supportive of the proposed changes. On 14 June 2024, the Government amended the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations).This removed "microbial or recombinant origin substances" and some low risk animal origin substances from classification rule 5.5 of Schedule 2 of the Regulations. It also changed the labelling requirements for those devices. The amendments took effect on 1 July 2024.

Additionally, changes were made to the Therapeutic Goods (Medical Devices— Information that Must Accompany Application for Inclusion) Determination 2018 (the 2018 Determination). These changes repealed special conformity assessment requirements for a category of class III medical devices known as "specified medical devices". This category included medical devices containing medicinal, microbial, recombinant, or animal origin substances. The reform now allows the TGA to recognise a broader range of overseas regulator approvals for these types of devices.

These changes coincided with other amendments to reduce the types of medical device applications the TGA must select for mandatory audit. In particular, the TGA no longer needs to select applications for class III medical devices supported by approvals from a broader range of comparable overseas regulators for mandatory audit.

# Changes to classification rule 5.5

From 1 July 2024, classification rule 5.5 was amended to:

> 5.5 Medical devices containing non-viable animal tissues, cells or their derivatives
>
> (1) Subject to subclause (2), this clause applies to a medical device if the device contains any of the following;
>
> > (a) non-viable tissues, cells, of animal origin (other than tissues or cells from hair or wool);
> >
> > (b) derivatives of tissues or cells covered by paragraph (a) (other than sintered hydroxyapatite or tallow derivatives).
>
> (2) This clause does not apply to a medical device if the device is intended by the manufacturer to come into contact with intact skin only.
>
> (3) A device to which this clause applies is classified as Class III.

Classification rule 5.5 no longer applies to medical devices that contain:

- Tissues, cells, or substances of microbial or recombinant origin.
- Tissues or cells from hair or wool, or sintered hydroxyapatite, or tallow derivatives.
- Materials produced by animals that are not animal tissues or cells or their derivatives (such as milk, honey, beeswax, or silk).
- A combination of the above.

Classification rule 5.5 does not apply to devices intended only to contact intact skin. These devices must be classified according to any other relevant classification rules.

As a result of these changes, some devices have been reclassified to a lower class, while others remain Class III. Table 1 provides examples of devices that were previously Class III under the old rule 5.5, along with their new classification under the updated rule.

**Table 1 - Examples to illustrate the change to classification rule 5.5.**

| Devices that were Class III under old rule 5.5 | Class after change |
|---|---|
| Contact lens solution or eye lubricant containing microbially derived hyaluronic acid | Class IIb as per rule 5.3(1) |
| Intraocular lens containing microbially derived hyaluronic acid | Class IIb as per rule 3.4(2) |
| Non-medicated wound dressings containing microbially derived hyaluronic acid | Class IIa or IIb as per rule 2.4 |
| Devices containing hyaluronic acid of animal origin | Still Class III as per rule 5.5 |
| Cardiopulmonary bypass devices coated with substances of microbial origin | Still Class III as per rule 3.4(4)(a) |
| Bioabsorbable reconstructive materials | Still Class III as per rule 3.4(4)(c) |
| Surgical mesh | Still Class III as per rule 3.4(4A) |
| Subcutaneous glucose sensor containing glucose oxidase of microbial origin (and no medicinal substances) | Class IIb as per rule 3.3(3)(b) |
| Subcutaneous glucose sensor containing glucose oxidase of microbial origin and one or more medicinal substance (e.g. human blood derivative) | Still Class III as per rule 5.1 |
| Surgical sealant containing recombinant human serum albumin (recombinant human serum albumin is regulated as a biological medicine) | Still Class III as per rule 5.1 |
| Medicated wound dressings | Still Class III as per rule 5.1 |
| Bovine or porcine derived heart valve replacement devices | Still Class III as per rule 5.5 |
| Non-absorbable intranasal splint containing chitosan | Still Class III as per rule 5.5 |
| Bovine Pericardial Patch | Still Class III as per rule 5.5 |
| Internal wound dressing containing porcine derived gelatin | Still Class III as per rule 5.5 |

# Changes to labelling requirements

All medical devices supplied in Australia must include information like labels and instructions for use (IFU). The Regulations outline these requirements in more detail.

If a medical device includes non-viable tissues or cells of animal origin or their derivatives, the IFU must provide information about these materials (item 25A, clause 13.4 of the Regulations). The changes on 1 July 2024, updated this item to limit this to materials captured under rule 5.5. It is no longer necessary to include information about substances of microbial or recombinant origin in the IFU unless this is important for the safe use of the device, such as to control the risk of incompatibility, contraindication or allergy.

Some medical devices contain substances of animal or microbial origin that are scheduled in the Poisons Standard (SUSMP). Entries in the Poisons Standard refer to all salts and derivatives of the named substance unless otherwise exempted. Medical devices that incorporate scheduled substances for specified clinical uses, such as collagen, hyaluronic acid, or lactic acid, must comply with any related labelling requirements in the Poisons Standard.

# Compliance with essential principle 8.2

Essential principle 8.2 sets out specific requirements in relation to the control of animal, microbial or recombinant tissues, tissue derivatives, cells and other substances. It describes requirements for risk management and control measures, including sourcing, selecting, harvesting, processing and validation methods for elimination or inactivation of viral or transmissible agents. This requirement remains unchanged and applies to all medical devices that contain:

- tissues, tissue derivatives, cells or substances of animal origin that have been rendered non-viable; or
- tissues, tissue derivatives, cells or substances of microbial or recombinant origin.

Documented compliance with the state-of-art standards such as International Standard *ISO 22442: Medical devices utilizing animal tissues and their derivatives*, or the *European Pharmacopoeia* can form the evidence to demonstrate compliance. Refer to Essential Principle 8: Infection and microbial contamination for further information.

# Critical supplier changes

The TGA previously considered suppliers of raw materials of microbial or recombinant origin as critical suppliers and identified them on TGA conformity assessment certificates. As part of the changes, the TGA will no longer list these suppliers on its conformity assessment certificates.

Manufacturers still need to analyse the risks of any changes to these suppliers and update their quality management system and risk management documentation accordingly. These documents must also be available for the TGA to review upon request.

However, this change means that manufacturers will no longer need to advise the TGA of changes involving these suppliers.

# Changes for ‘specified medical devices’

The 2018 Determination specifies the documents sponsors need to apply to include a medical device in the Australian Register of Therapeutic Goods (ARTG). It lists the approvals and assessments from comparable overseas regulators that sponsors can use for each device class. Previously, applications for ‘specified medical devices’ could only be supported by TGA or European Union (EU) certification.

Effective from 1 July 2024, the 2018 Determination no longer references ‘specified medical devices’. This means that devices containing medicinal, microbial, recombinant, or animal origin substances

can now be supported by approvals from a broader range of comparable overseas regulators – the same range that applies to all other class III medical devices.

Table 2 provides examples of the changes for medical devices that contain materials of animal, microbial or recombinant origin.

**Table 2 - Examples of the changes**

| | Before 1 July 2024 | After 1 July 2024 |
|---|---|---|
| Contact lens solution with microbial derived hyaluronic acid | Class III | Class IIb |
| Animal derived aortic heart valve | Class III | Class III |
| Evidence options | TGA Conformity Assessment certificate<br>EU Medical Devices Directive certificate<br>EU Medical Devices Regulation certificate | TGA Conformity Assessment certificate<br>EU Medical Devices Directive certificate<br>EU Medical Devices Regulation certificate<br>United States Food and Drug Administration approval<br>Health Canada medical device licence<br>Japanese Pharmaceuticals and Medical Devices Agency approval<br>Singapore Health Sciences Authority medical device registration |
| Application audit | Mandatory audit, with fee, if EU Medical Devices Directive certificate<br>May be selected for non-mandatory audit, with no fee, if other evidence types | |

# What you need to do

If you are a sponsor of a medical device that contains materials of animal, microbial or recombinant origin, what you need to do will depend on the status of your product:

- Medical devices in the ARTG before 1 July 2024
- Applications lodged before 1 July 2024
- Applications lodged after 1 July 2024.

## Medical devices in the ARTG before 1 July 2024

If you had a medical device in the ARTG before 1 July 2024 that is now reclassified, transition arrangements allow you to continue to supply that device while you reapply under the new classification.

To continue to supply your medical device you must:

- Submit a reclass application to include your medical device in the ARTG under the new classification **before 1 July 2026**.

Table 3 provides an example and two scenarios that could apply in this situation.

**Table 3 – Transition scenarios for an existing reclassified device**

| **A sponsor has a class III ARTG entry for a non-medicated wound dressing containing microbial derived hyaluronic acid. From 1 July 2024, the medical device will be reclassified to class IIb.** |
|---|
| • **Scenario 1** – The manufacturer has TGA conformity assessment certificates covering the medical device as Class III, and comparable overseas regulator evidence covering the medical device that is appropriate to support a Class IIb application.<br><br>What the sponsor needs to do: You must apply to include the product in the ARTG as a class IIb medical device before 1 July 2026. You may use either the TGA quality management system certificate or the appropriate comparable overseas regulator evidence to support your application. After the application is approved, please email the TGA at devices@tga.gov.au to revoke the TGA design examination certificate. You may also ask us to revoke the TGA quality management system certificate if you no longer need it. |
| • **Scenario 2** - The manufacturer has TGA conformity assessment certificates covering the medical device as Class III and does not have any appropriate comparable overseas regulator approval.<br><br>What the sponsor needs to do: You must apply to include the product in the ARTG as a class IIb medical device before 1 July 2026, using the TGA quality management system certificate to support your application. After the application is approved, please email the TGA at devices@tga.gov.au to revoke the TGA design examination certificate. |

Through the lifetime of your ARTG inclusion, you must maintain your evidence of conformity assessment and keep it up to date. You must notify the TGA of any changes, suspensions, revocations, or lapses of your conformity certificates.

# Applications lodged before 1 July 2024

If you submitted an application to include a Class III medical device in the ARTG before 1 July 2024 and that device is no longer Class III because of the amendment to Rule 5.5, your application will continue as usual. If your application is successful, you may supply the device until 1 July 2026. However, to supply the device after 1 July 2026 you must:

- Submit a reclass application to include your medical device in the ARTG under the correct classification **before 1 July 2026**.

If you submitted a TGA conformity assessment application for a Class III medical device before 1 July 2024, and that device is no longer Class III because of the amendment to Rule 5.5, your application will continue as usual. If the requirements are met, the TGA will issue a quality management system certificate but will not issue a Design Examination certificate. This will allow you to then apply to include the device in the ARTG at the correct classification.

If you have a comparable overseas regulator approval that covers the medical device and is appropriate for the new medical device class, you may choose to use that approval to support an ARTG inclusion application without waiting for the outcome of the TGA conformity assessment application.

## Applications lodged after 1 July 2024

Any new application submitted to the TGA **on or after 1 July 2024** must be submitted as an application at the correct classification, based on the updated classification rules.

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

# Reclassifying existing ARTG inclusions

## Kind of medical device

ARTG applications are for a kind of medical device. This allows low to medium risk medical devices to be grouped under one ARTG entry if they have the same sponsor, manufacturer, classification, and Global Medical Device Nomenclature (GMDN).

The Unique Product Identifier (UPI) also determines the 'kind of medical device' for class III devices, but the UPI does not apply to lower class medical devices. Sponsors making multiple reclassification applications may be able to group them into one application if the devices remain the same 'kind of medical device'. If there is a change of manufacturer, you must submit a new 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 **the new classification that is current** from the drop down provided for the "New classification" question.

The reclassification application form may not work well when certain changes are needed. For example,

- 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 there is a change of manufacturer, or

- if you would like to reclassify a few Class III ARTG entries into one lower class.

In these cases, you may wish to 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.

*Note:* If you submit a new application (*i.e.* select “Create a new inclusion in the register” instead of “Reclassify an existing register entry”, following the approval of the new application, you will need to cancel the inclusion of your old ARTG entries.

## Fees and application audits

Reclassification applicants will need to pay the application fee, but no assessment fee will apply.

We will not select reclassification applications that are due to the classification rule 5.5 change for mandatory audit. However, we may select applications for non-mandatory audit if we have concerns with the application (e.g. post market signals) or if there are major changes in the submitted 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 your application is not successful

If your application to transition your medical device to the new classification is not successful, we will notify you of the decision in writing and provide you 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, 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 the requirements under the transition arrangements, you will need to cease supply of your medical device. The following table outlines the circumstances and timeframes:

| Circumstance | Timeframes |
|---|---|
| You do **not submit an ARTG application** to transition your medical device to the new classification **before 1 July 2026**. | Cease supply of your medical device from **1 July 2026** and cancel your inclusion. |
| Your ARTG application to transition your medical device to the new classification is unsuccessful. | **Cease supply** of your medical 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 | September 2024 |

**Therapeutic Goods Administration**

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
Web: tga.gov.au