Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

How to submit a custom-made medical device / patient-matched medical device notification

Step-by-step guide

Version 2.0, December 2023

TGA Health Safety Regulation

Contents

Introduction

The following guide is designed to assist you with completing and submitting a:

- Custom-Made Medical Device (CMMD) notification; and
- Patient-Matched Medical Device (PMMD) transition notification.

Both notifications can be submitted using the CMMD notification form.

Completing a notification form will take approximately ten minutes for each "kind" of device you manufacture/supply.

Our new database replaces the two separate databases previously used to notify the TGA of CMMD or PMMD(s).

Any notifications you have made previously will remain valid but there is **no cross-linking** functionality for notifications submitted via the old database with the new database. Notifications to the old databases ceased in August 2022 and the content has been archived.

Even if you have previously submitted a CMMD notification on the business.gov.au website or a PMMD notification on the Citizen Space platform, we **strongly recommend you resubmit your notifications to the new database as we will not be using information from the previous database to contact you**.

Resubmitting your notifications using the new database will allow you to view, modify and withdraw your organisation's notifications, and enable us to better engage and support you with updates and information that may impact you and/or your products.

Who needs to submit a CMMD notification

Manufacturers and sponsors who:

- manufacture, supply or import a kind of CMMD

You are required to notify the TGA within two (2) months of manufacture or initial supply of the CMMD.

Who needs to submit a PMMD notification

Manufacturers and sponsors who are making or supplying a PMMD:

- that was supplied on or before 25 February 2021
- and intend to access the transition arrangement for a PMMD that needs to transition to inclusion in the Australian Register of Therapeutic Goods (ARTG)

If you provide a transition notification for your eligible PMMD before 1 November 2024, you can continue supplying your devices without an ARTG inclusion until 1 July 2029.

If no transition notification is made for an eligible PMMD it must be included in the ARTG prior to import or supply (unless exempt or excluded).

If your PMMD entered the market after 25 February 2021, it will not qualify for transition and must be included in the ARTG before it can be supplied.

Please note that if you are supplying a kind of PMMD in quantities of five (5) or less per financial year, you are exempt from requiring an ARTG inclusion.

More detail about the extended transition period for PMMDs is provided under the Transition plan section.

Step 1: Getting started with the TGA

Before you can make a CMMD or PMMD notification you will need a client identification number (Client ID) and also apply to access to our secure online TGA Business Services (TBS).

The resources on the TGA website will help you get started and guide you on using our online services. Access will allow you to make both a CMMD notification and a PMMD transition notification.

Step 2: Access to the notification form

Once you are a TGA client and have a TBS account, you can access the notification form in two pathways:

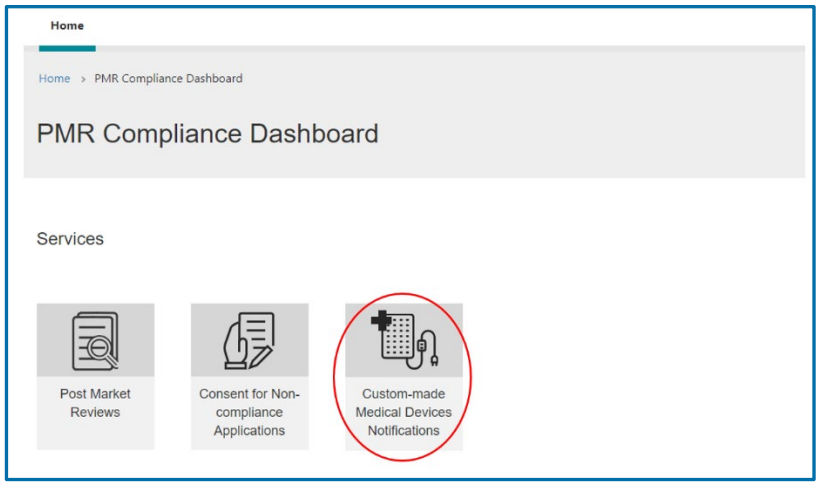
1. Directly via the PMR compliance Dashboard, or
2. From the TGA Business Services (TBS) Portal Homepage

Pathway 1: Accessing the form directly

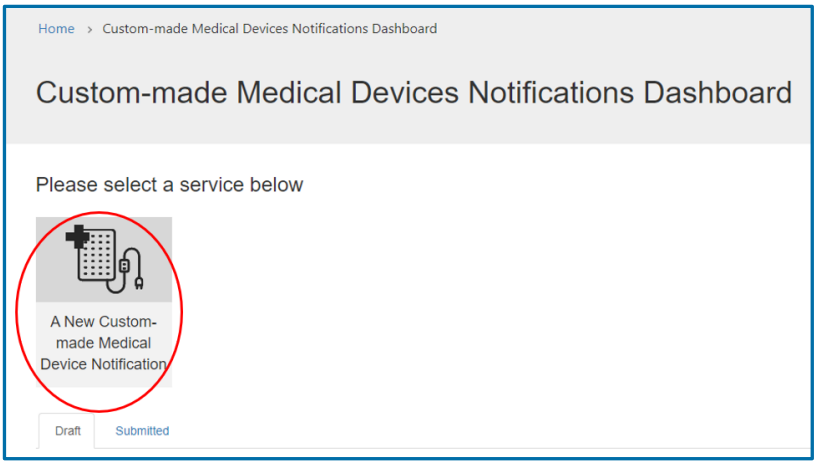
Login to your account via the URL: https://compliance.health.gov.au/pmr-compliance/

To access the CMMD notifications form:

1. select the Custom-made Medical Devices Notifications tile from the PMR Compliance Dashboard



2. select the tile for a New Custom-made Medical Device Notification from the Custom-made Medical Devices Notifications Dashboard

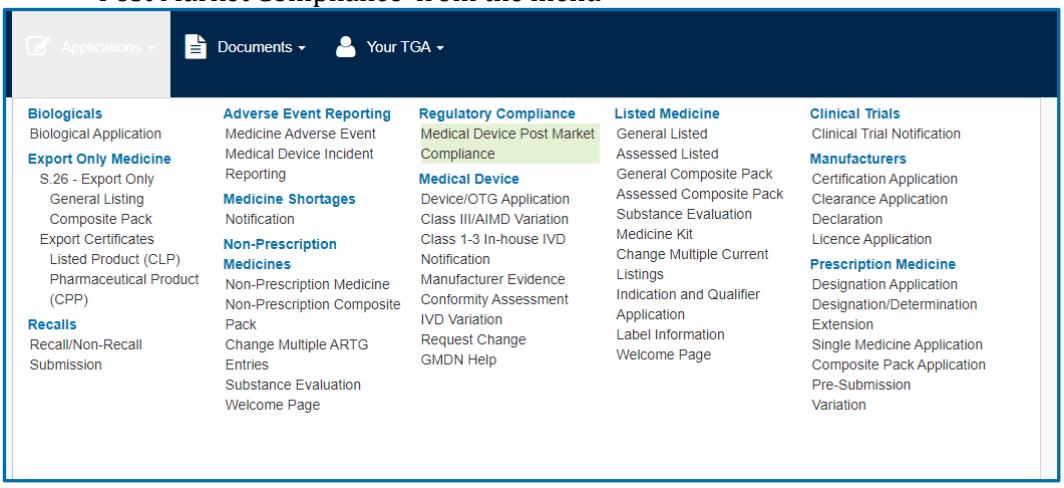


Pathway 2: Accessing the form from the TBS portal homepage

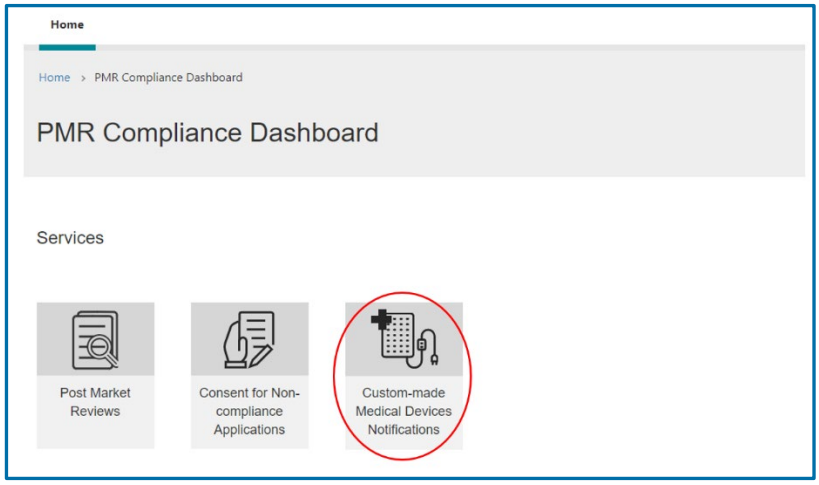
Log into your account from TGA Business Services (TBS) Portal Homepage https://www.ebs.tga.gov.au.

To access the CMMD notifications form:

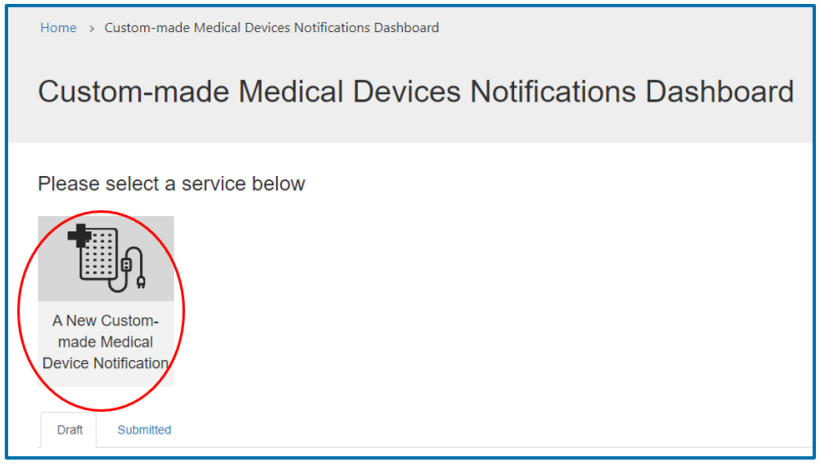
1. Click on the 'Applications' dropdown menu on the homepage and select 'Medical Device Post Market Compliance' from the menu



2. You will be redirected to the PMR Compliance Dashboard, select the Custom-made Medical Devices Notifications tile



3. Select the tile for a New Custom-made Medical Device Notification from the Custom-made Medical Devices Notifications Dashboard



Step 3: Submitting your CMMD Notification

All fields in the form are mandatory and will need to be completed for your notification to be submitted successfully.

About the submitter

You can submit this form as either the manufacturer or the sponsor.

If you submit the form as the Australian-based manufacturer, you will not have to submit the form a second time as the sponsor. In this situation we assume that Australian-based manufacturers are also the sponsor of their device.

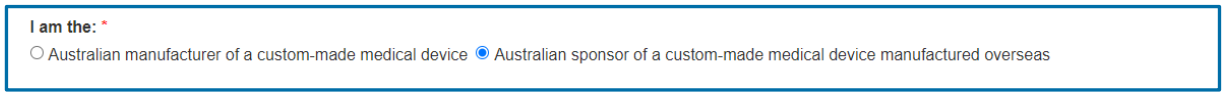
Manufacturer

If you are the **Australian-based manufacturer** of the device, select the first option by clicking on the radio button titled 'Australian manufacturer of a custom-made medical device'.

Your organisation name (either your own name, or the name of your organisation) will be automatically displayed. This will be the same organisation name you had used to apply for a client account to access the TBS Portal.

Sponsor

If you are the **sponsor** of the device, select the second radio button titled 'Australian sponsor of a custom-made medical device manufactured overseas'.

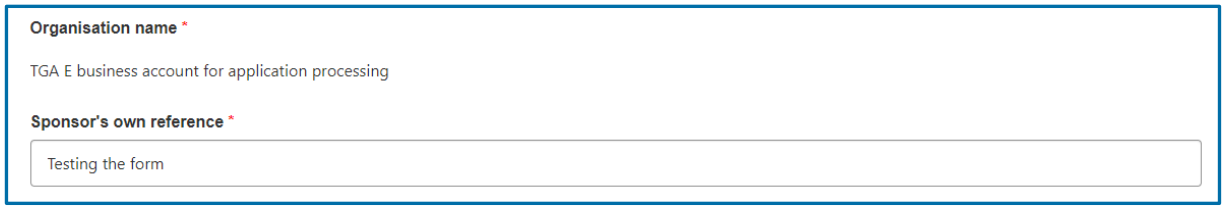


Your organisation name (either your own name, or the name of your organisation) will be automatically displayed. This will be the same organisation name you had used to apply for a client account to access the TBS Portal.

Sponsors own reference field

The 'Sponsor's own reference' field is for your own reference. You can use this field for tracking information about the specific device you are completing the form for. This could be a model or series number, a project name, or a record or file number.

Your 'Sponsor's own reference' can be edited later, if needed.

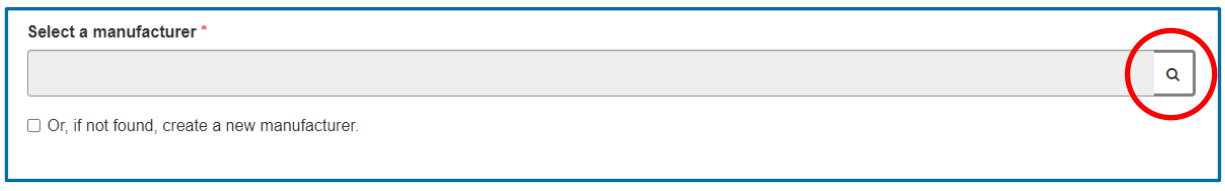


Manufacturer details

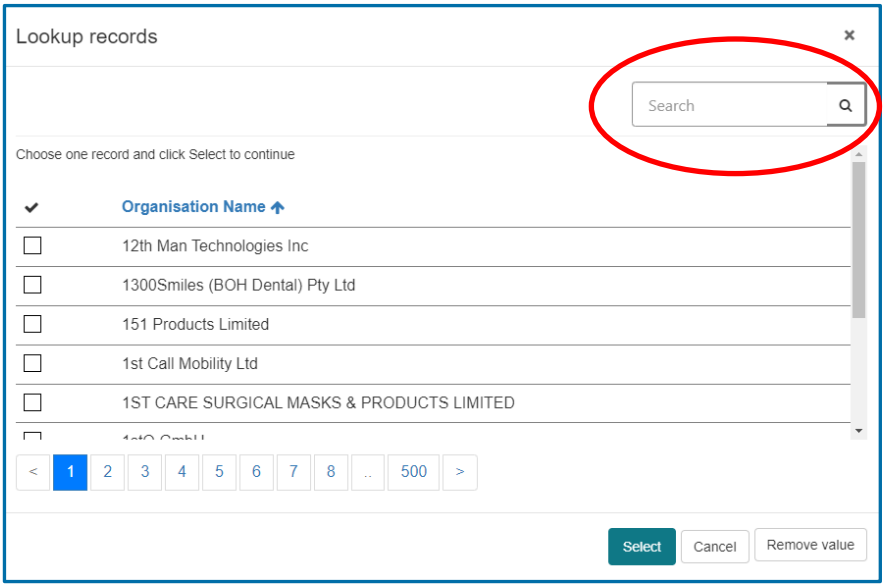
If you are completing the notification as a sponsor, you will be asked to provide details of the manufacturer of your device.

This field will not display if you are completing the notification as a manufacturer.

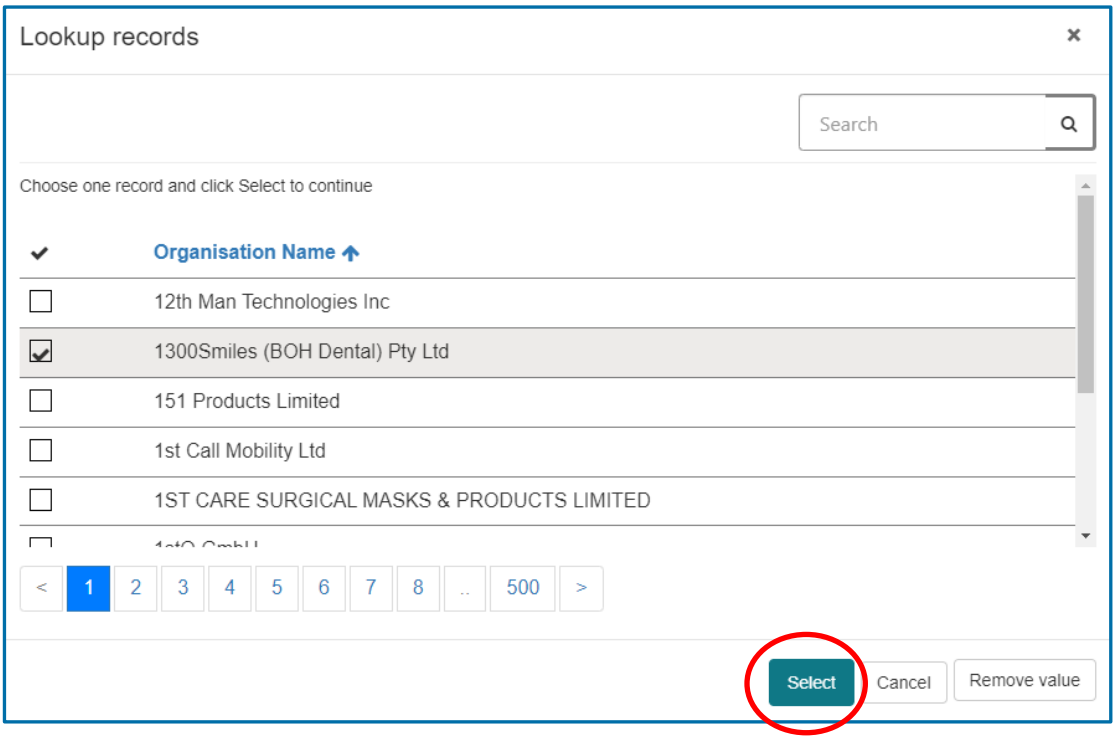
Do not type the manufacturer's name directly into the search field as it will not work. You will need to click on the magnifying glass icon to select your manufacturer from a list. The magnifying glass icon is circled in red in the screenshot.



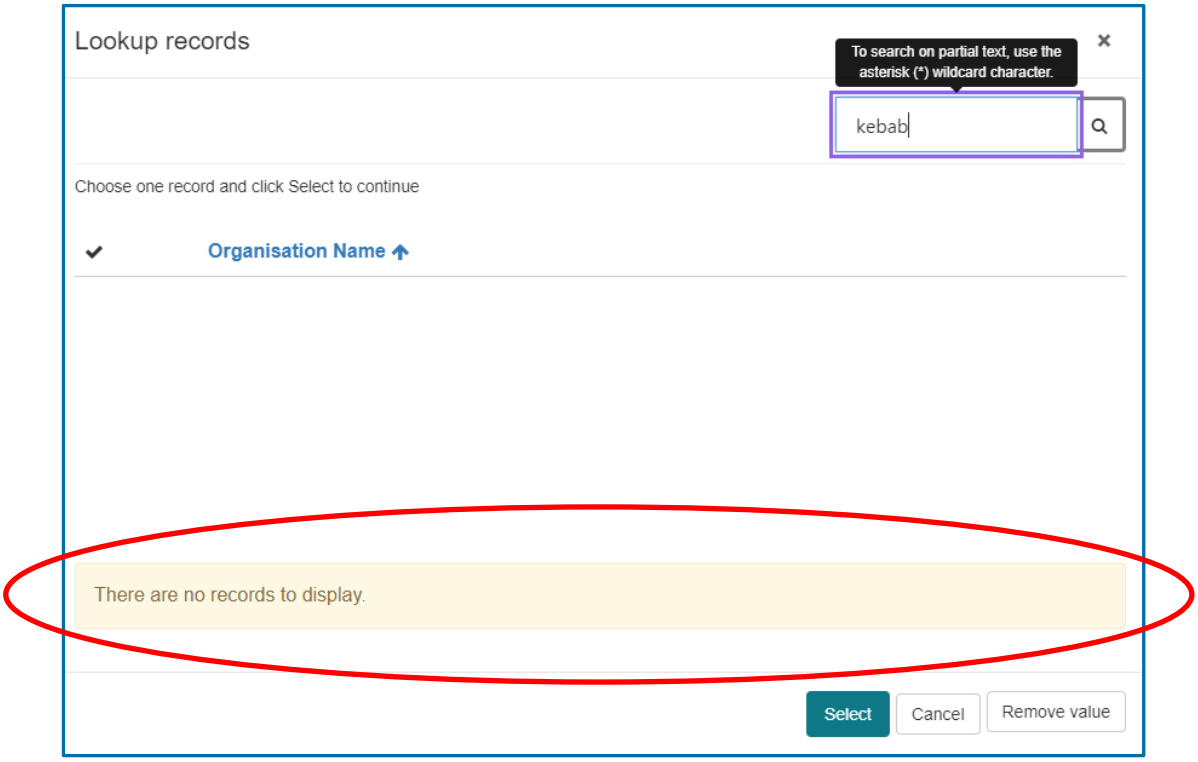
The manufacturer list will appear in a new look-up window. You can search for the manufacturer by typing their name in the search field and clicking on the magnifying glass icon again circled in red.



Select your manufacturer by ticking the checkbox that corresponds to their name and then click on the green 'Select' button at the bottom right of the pop-up window.

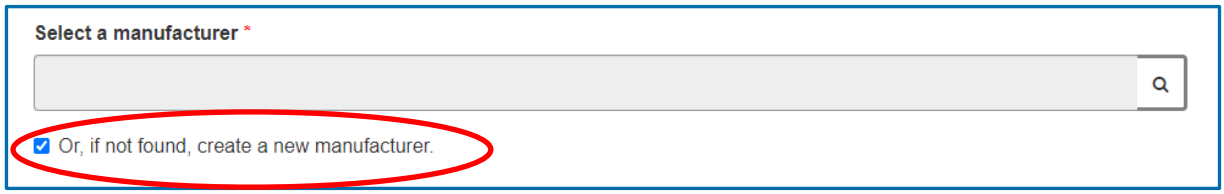


If the name of the manufacturer you are searching for is not on the list, a yellow error message will appear as shown in the screenshot.



Manufacturer details not found in the look-up window list

If you can't find the manufacturer in the look-up window, please tick the checkbox to create a new manufacturer.

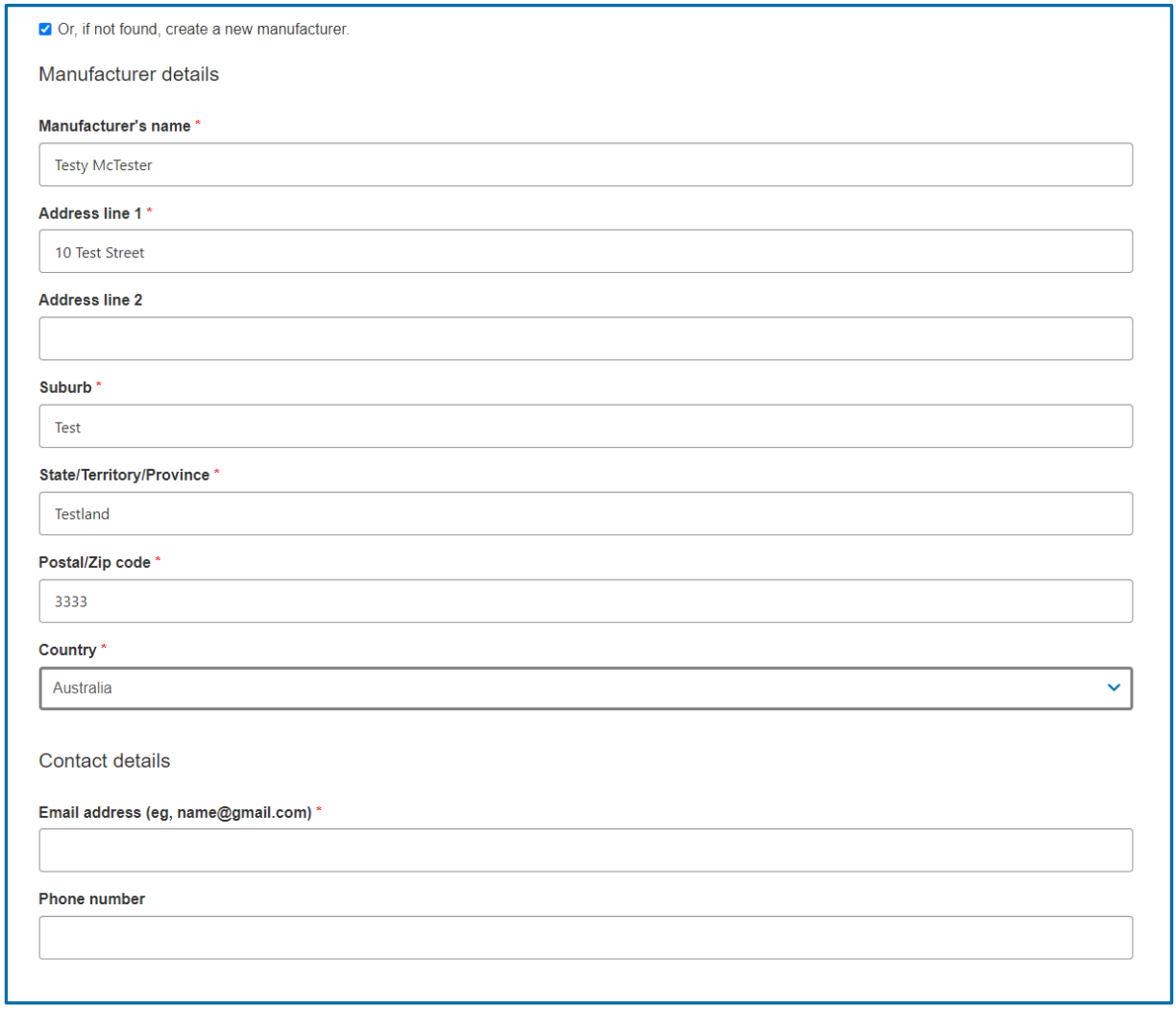


Check that the manufacturer does not already exist in the manufacturer list in the look-up window before creating a new entry. Otherwise a new manufacturer record will subsequently be added to the TGA Master manufacturer list.

After the ticking the checkbox, the 'Manufacturer details' fields will appear. Enter the appropriate details in each of the corresponding fields.

When entering the manufacturer's address details, **ensure you enter a physical address, not a post office box or locked bag**. It is acceptable to provide the manufacturer's head office address instead of the address of the specific factory, lab or other location used to manufacture the device.

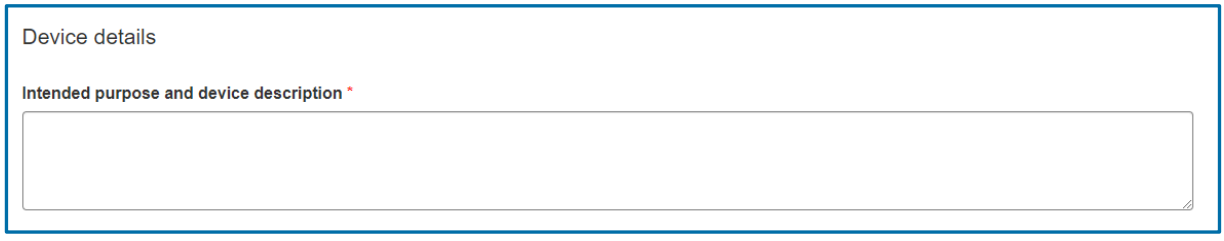
Under the 'Contact details' section, enter the manufacturer's email address and phone number.



Device details

Intended purpose and device description

Enter the intended purpose and device description in the dialog box. This is your own description of what the device is and what it is intended to do.



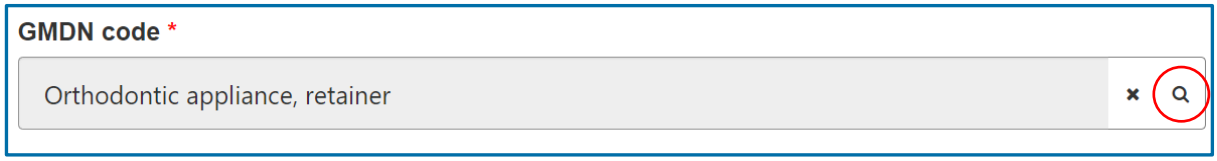
Global Medical Device Nomenclature (GMDN) Terms

GMDN Terms are an international naming and grouping convention used to identify and consistently describe medical devices. In Australia, GMDN Terms are a key factor in determining a 'kind' of medical device.

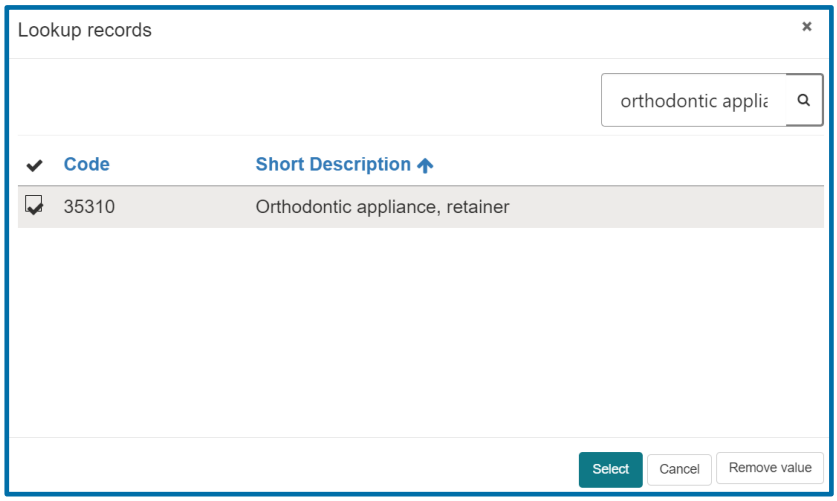
You will need to select an appropriate GMDN for your device.

Do not type the manufacturer's name in the search field as it will not work. To find the correct code for your device, select the magnifying glass icon as shown below to launch the GMDN code list.

Type a description for your device's intended purpose (for example 'retainer') and search the code list.



Select the correct GMDN code and linked description from the list available.

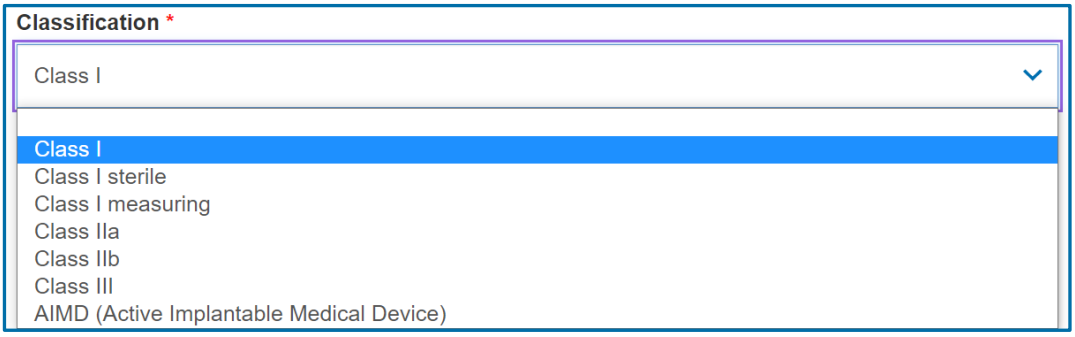


If your GMDN Code changes or is made obsolete after you have submitted your form, you will still be able to continue supplying the device. However, you may be unable to submit subsequent applications for the device using the obsolete GMDN Code.

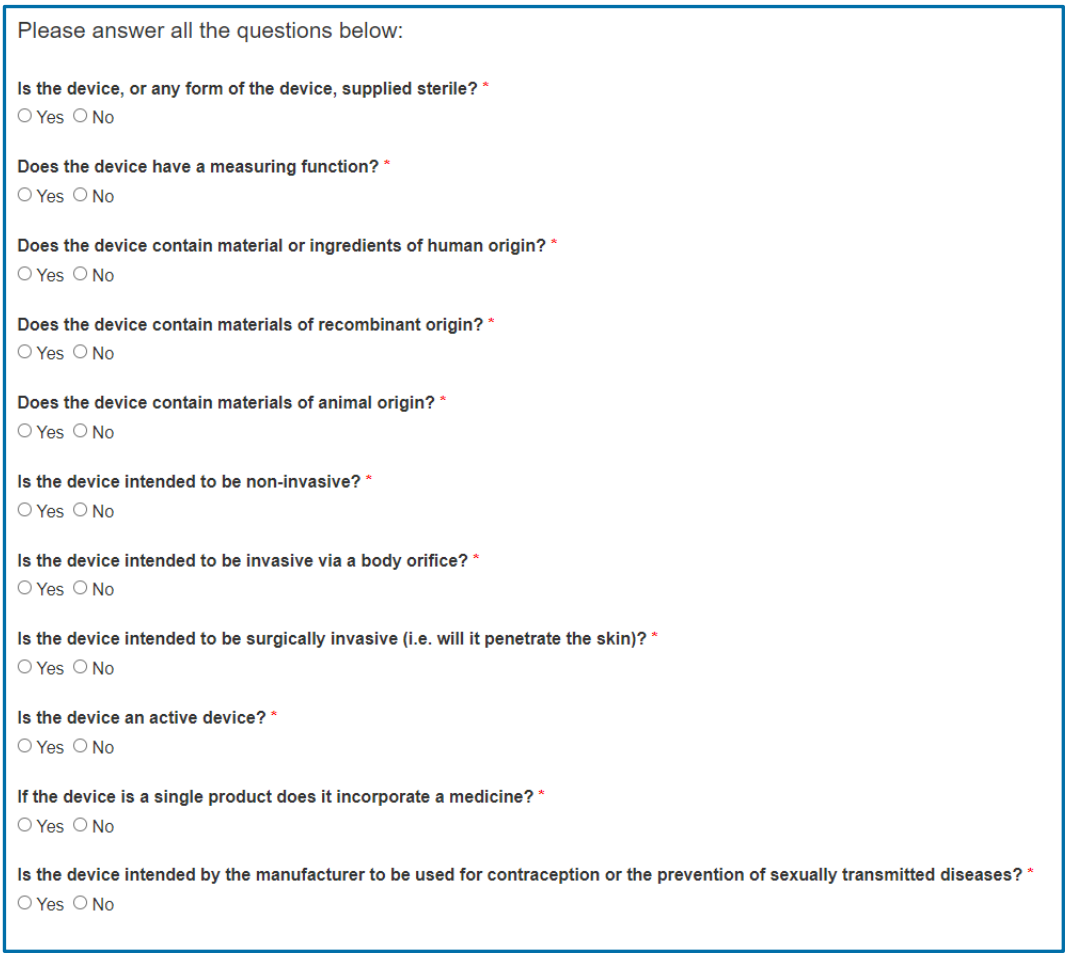
Device Classification

The classification of your medical device will depend on several factors, including how long the device is intended to be used for, and how invasive it is. You can check the classification of your medical device by using the online classification tool or by reading through the classification rules, which can be found in Schedule 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

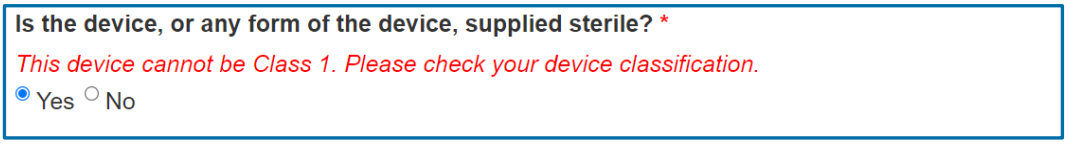
Use the drop-down menu to select the device classification.



Based on the classification level you select, a series of questions about the device will be presented, prompting you to select yes or no for each question.



A warning in red text appear if a selected response conflicts with the selected classification level of the device.



Transition plan details

Custom-made medical devices that meet the definition of a patient-matched medical device

Under the Australian regulatory framework for medical devices, 'custom-made' medical devices are exempt from the requirement to be included in the ARTG. However, they are **not exempt from regulation**. Manufacturers and sponsors of custom-made medical devices still need to comply with TGA regulatory requirements including:

- ensuring that the device(s) meets all relevant Essential Principles, including supplying the device(s) with adequate labelling and instructions for use
- ensuring advertising complies with the advertising requirements
- submitting annual reports, and
- reporting adverse events

New definitions for medical devices that are personalised to suit an individual patient or health professional commenced on **25 February 2021**. Under these changes most devices that would previously have met the definition of a custom-made medical device will now meet the definition of a patient-matched medical device.

Medical devices that meet the new definition of patient-matched are **no longer exempt from inclusion in the ARTG**.

You can check our guidance on whether your custom-made medical device meets the definition of a patient-matched medical device.

Patient-matched medical devices supplied in low volumes (five or less per financial year) are exempt devices and are therefore not required to notify for transition or be included in the ARTG.

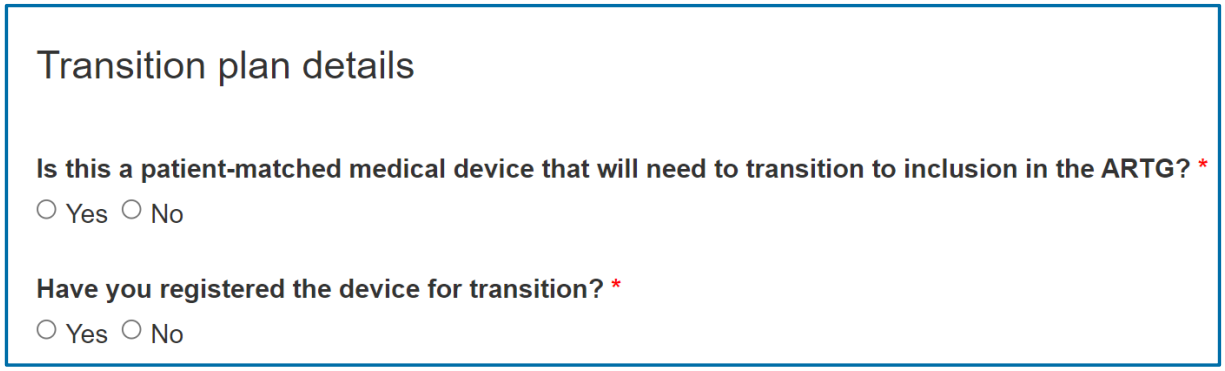
Transition notification period for patient-matched medical devices

The transition notification period for eligible PMMDs open until 1 November 2024.

If you are manufacturing or supplying an eligible PMMD there are arrangements in place to ensure you can continue to supply your device while you apply for ARTG inclusion. You must submit a valid application for inclusion in the ARTG by **1 July 2029**.

You can make a transition notification for your eligible PMMD by indicating in the form that your device meets the definition of a PMMD. By checking 'Yes' you are notifying your PMMD for transition.

You can also let us know if you have previously submitted a notification.



Once the form is submitted, you will have until **1 July 2029** to complete an application for inclusion in the ARTG. More information about the medical device inclusion process can be found on our website.

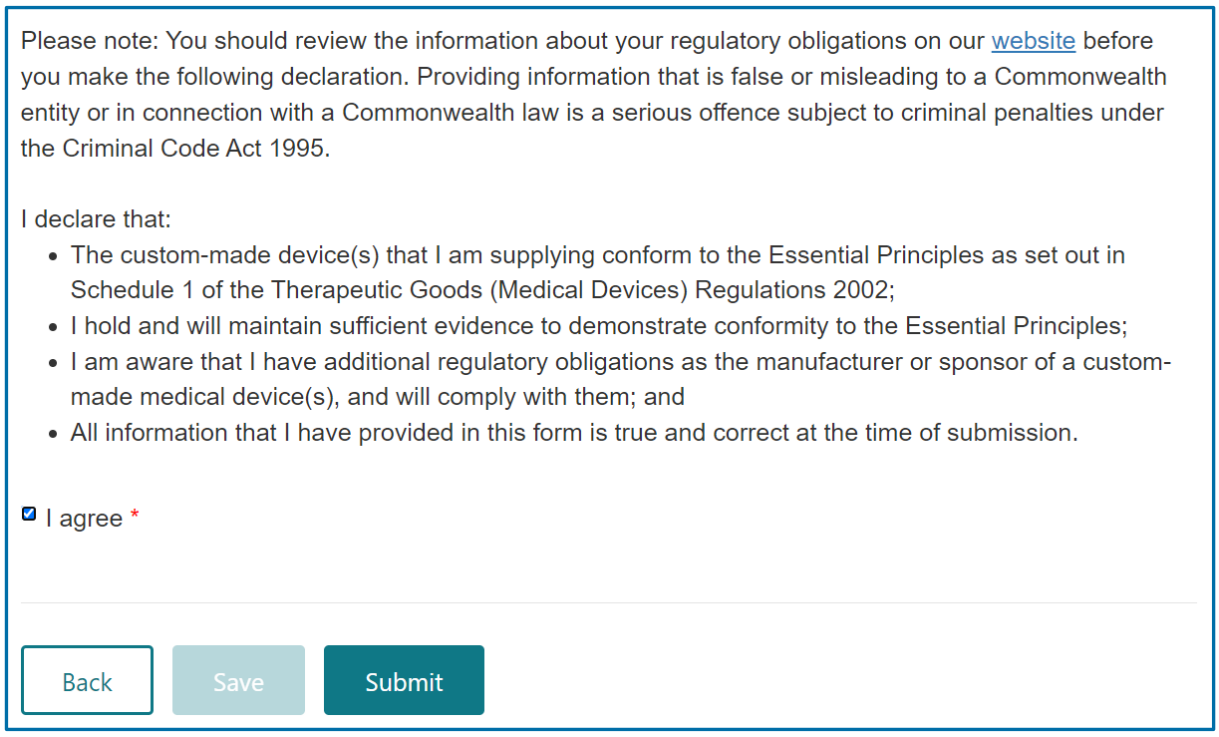
Declaration and submission of the notification

When you finalise the form and submit it to the TGA, you will need to indicate that all information is true and correct by selecting 'I agree' before your form is submitted.

You can go back and amend any information using the 'Save' button at the bottom of the form. Your form will then be saved as a 'Draft' and you are able to return to the same notification from the 'Draft' tab on your dashboard and edit the information in your notification at any time.

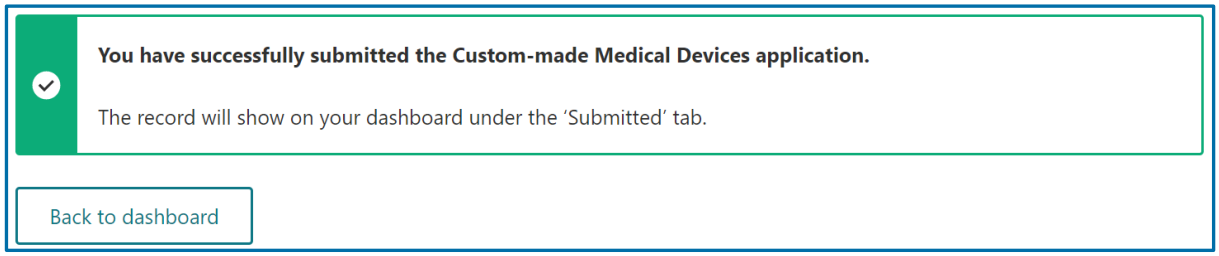
Once you select 'Submit', your information will be sent to the TGA. By selecting 'I agree' and submitting the form to the TGA, you are making a formal declaration under Australian law.

Please do not click 'Back' or 'Refresh' on your web browser at any time while the notification is being processed, as your notification may be duplicated.

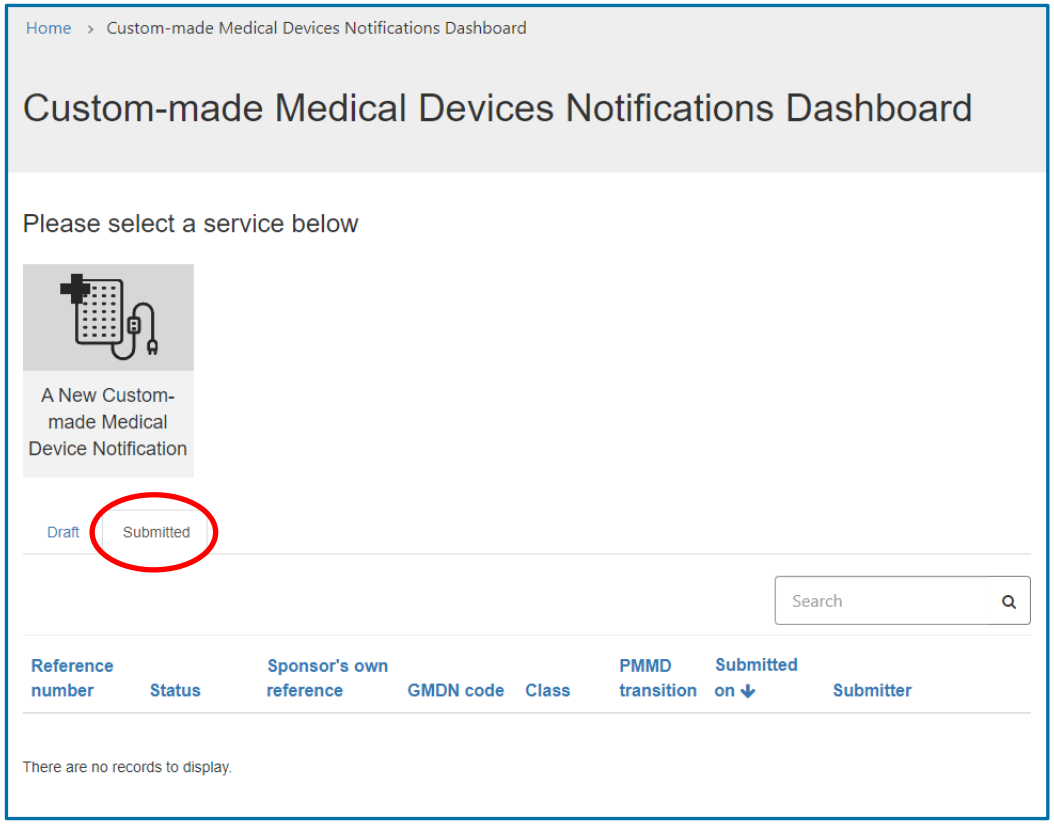


Step 4: After you have submitted a notification

Once you have submitted your notification you will be sent to a page on your screen that will look like this:



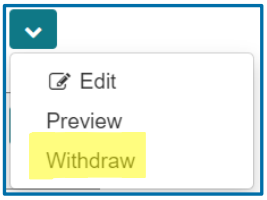
From this page you may return to the dashboard, where you can view your submitted notifications under the 'Submitted' tab. A screenshot of the dashboard opened on the 'Submitted' is shown below:



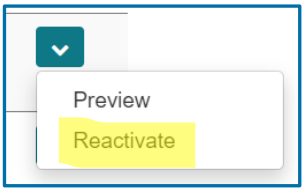
Withdrawing a notification

You can withdraw notifications that are no longer in use or no longer contain the correct information by navigating to the 'Submitted' tab on your dashboard.

Locate the notification you wish to withdraw and click on the arrow on the far right. Select 'Withdraw':



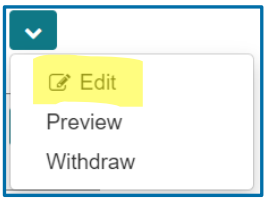
You can reactivate your withdrawn notification at any time:



Please note that withdrawn notifications will not be deleted and will be archived for auditing purposes.

Modifying a notification

If you need to make any updates to your notification, you can do so by locating your notification on the 'Submitted' tab on your dashboard. Click the arrow on the far right and select 'Edit':



Please note that once you select 'Submit', your information will be resubmitted to the TGA. By selecting 'I agree' and submitting the form to the TGA, you are making a formal declaration under Australian law. All changes you make to your notification after it has been submitted will be tracked for auditing purposes by the TGA.

Further information and resources

The following resources and additional information may be of assistance:

- Guidance on regulation of personalised medical devices
- Frequently asked questions on personalised medical devices
- Overview of refinements to regulation of personalised medical devices made in August 2021

For general advice and information about the regulation of medical devices, please contact the Medical Devices Information Unit at devices@tga.gov.au.

If you have any questions or require any further assistance with the submission of your notification, please don't hesitate to contact us at PersonalisedDevices@health.gov.au

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Surveillance Branch	August 2022
V.20	Updated to reflect the extension of the transition notification period and ARTG inclusion deadline	Medical Devices Surveillance Branch	December 2023

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Reference/Publication #