



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Submitting a custom-made medical device / patient-matched medical device transition notification

Guidance

Version 1.0, August 2022

TGA Health Safety
Regulation

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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 are able to be submitted using a **single form** called the CMMD notification form.

Completing a notification form will take approximately ten minutes for each [“kind” of device](#) you manufacture/supply.



Note

If you have previously submitted notification(s) using one of the old databases, we **strongly recommend you resubmit your notifications into the new database**. Using the new database will allow you to keep your information up-to-date, and us to support you with updates and information that will impact you.

Resubmitting your notifications into the new form will also allow you to view, modify and withdraw your organisation's notifications.

There is **no cross-linking** of notifications submitted to the old databases and the new database, and the old databases will be archived.

TGA Business Services (TBS) Access

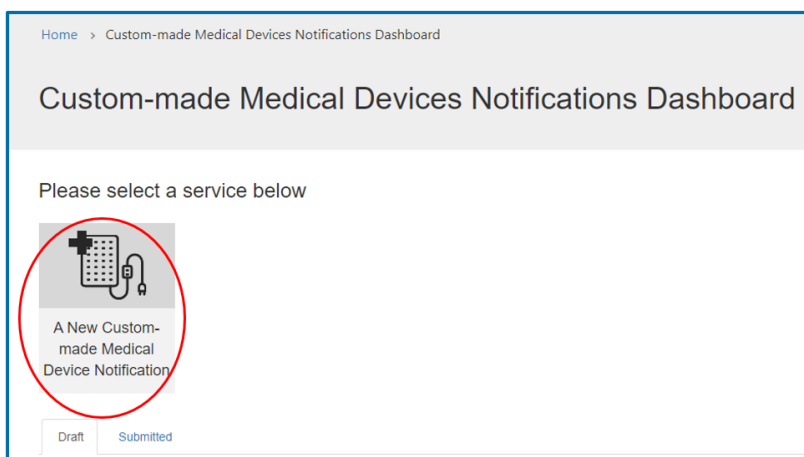
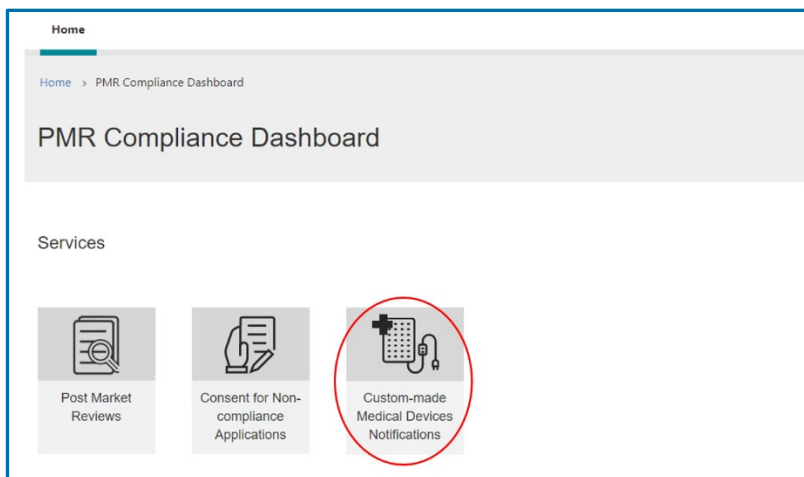
You, or your organisation, will need to be a client of the TGA with access to the TBS online portal before you can complete a notification form for a CMMD.

There are [instructions on the TGA website](#) to assist you with becoming a client of the TGA.

Once you have a TBS client account, login to your account via the URL:

<https://compliance.health.gov.au/pmr-compliance/>

To access the CMMD notification form, select the tile as displayed below:

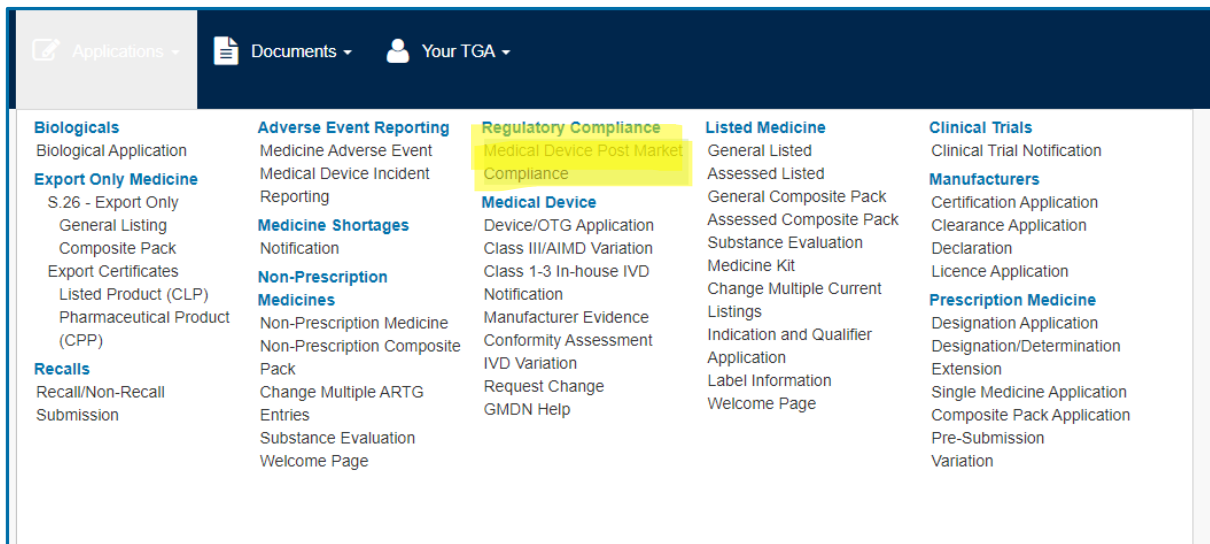


Accessing the form from the TBS portal

You can also access the CMMD database from the TGA Business Services (TBS) Portal Homepage <https://www.ebs.tga.gov.au>.

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

You will be redirected to the 'PMR Compliance Dashboard' as shown above.



Submitting your CMMD Notification form

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 an Australian manufacturer or an Australian sponsor.



Note

If you submit the form as the manufacturer of the device, you will not have to submit the form a second time as the sponsor – it is assumed that Australian-based manufacturers are also the sponsor of their device.

Manufacturer

If you are the **Australian-based manufacturer and supplier** of the device, select the first option by clicking on the radio button.

I am the: *

Australian manufacturer of a custom-made medical device 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 name as your TBS client account. .

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:

Organisation name *
TGA E business account for application processing

Sponsor's own reference *

Sponsor

If you are the **sponsor** of the device (the importer and supplier of a device manufactured overseas), select the second radio button:

I am the: *

Australian manufacturer of a custom-made medical device 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 name as your TBS client account. .

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:

Organisation name *
TGA E business account for application processing

Sponsor's own reference *

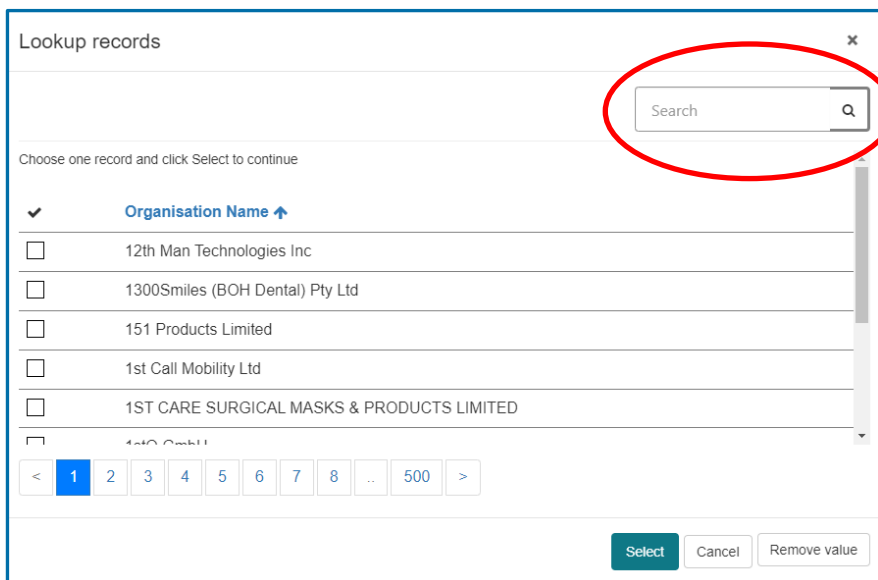
You will also be asked to provide details of the manufacturer of your device. Select the manufacturer by clicking on the magnifying glass icon. The magnifying glass icon is circled in red in the screenshot below:

Select a manufacturer *

Or, if not found, create a new manufacturer.

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. See screenshot of search field and magnifying glass icon below:



Lookup records

Search

Choose one record and click Select to continue

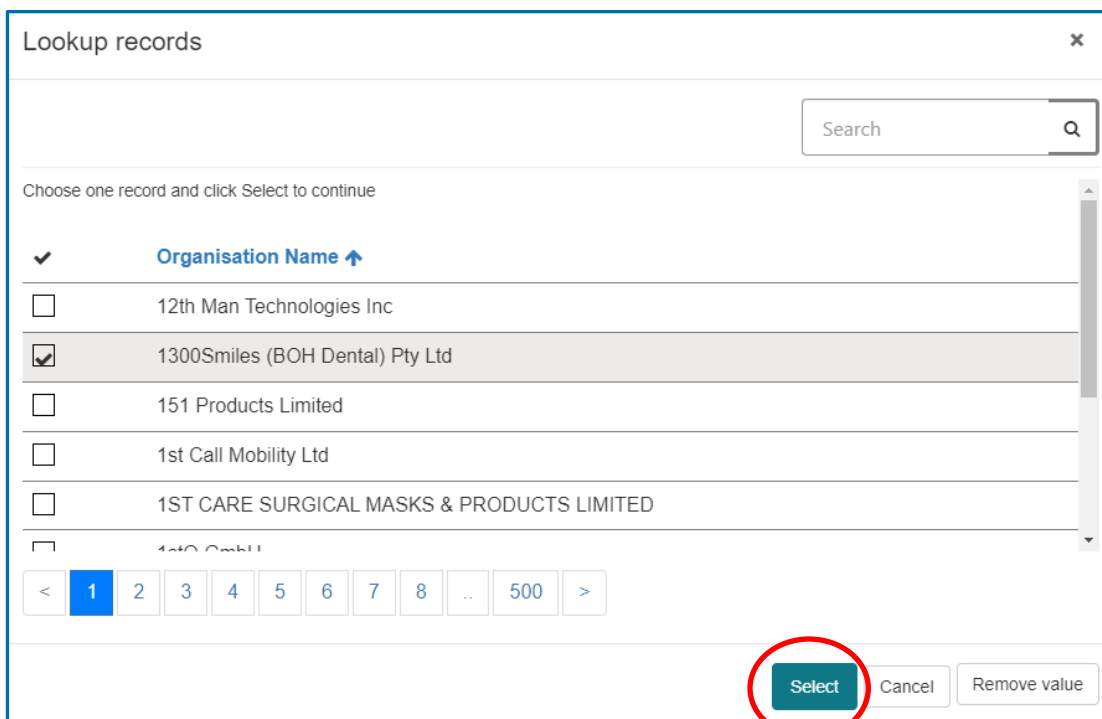
✓ Organisation Name ↑

<input type="checkbox"/>	12th Man Technologies Inc
<input type="checkbox"/>	1300Smiles (BOH Dental) Pty Ltd
<input type="checkbox"/>	151 Products Limited
<input type="checkbox"/>	1st Call Mobility Ltd
<input type="checkbox"/>	1ST CARE SURGICAL MASKS & PRODUCTS LIMITED
<input type="checkbox"/>	1st Call Mobility

< 1 2 3 4 5 6 7 8 .. 500 >

Select Cancel Remove value

Select your manufacturer by ticking the checkbox that corresponds to their name and then click on the green 'Select' button:



Lookup records

Search

Choose one record and click Select to continue

✓ Organisation Name ↑

<input type="checkbox"/>	12th Man Technologies Inc
<input checked="" type="checkbox"/>	1300Smiles (BOH Dental) Pty Ltd
<input type="checkbox"/>	151 Products Limited
<input type="checkbox"/>	1st Call Mobility Ltd
<input type="checkbox"/>	1ST CARE SURGICAL MASKS & PRODUCTS LIMITED
<input type="checkbox"/>	1st Call Mobility

< 1 2 3 4 5 6 7 8 .. 500 >

Select Cancel Remove value

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 below:

Lookup records

To search on partial text, use the asterisk (*) wildcard character.

kebab

Choose one record and click Select to continue

✓ Organisation Name ↑

There are no records to display.

Select Cancel Remove value

What if I can't find the manufacturer 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:

Select a manufacturer *

Or, if not found, create a new manufacturer.



Note

Please ensure the manufacturer does not already exist in the manufacturer list in the look-up window before creating a new entry, as this new record will be subsequently added to the TGA Master manufacturer list.

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

Or, if not found, create a new manufacturer.

Manufacturer details

Manufacturer's name *

Address line 1 *


Address line 2

Suburb *

State/Territory/Province *

Postal/Zip code *

Country *

Contact details

Email address (eg, name@gmail.com) *

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.

Device details

Intended purpose and device description *

Global Medical Device Number (GMDN)

You will be required to select an appropriate [GMDN](#) for your device. 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 (such as 'retainer') and search the code list:

GMDN code *

Orthodontic appliance, retainer ✕ 🔍

Select the correct GMDN code and linked description from the list available, as shown in the example below:

Lookup records

orthodontic appli 🔍

Code	Short Description ↑
35310	Orthodontic appliance, retainer

Select Cancel Remove value



Note

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:

Classification *

Class I ▼

- Class I
- Class I sterile
- Class I measuring
- Class IIa
- Class IIb
- Class III
- AIMD (Active Implantable Medical Device)

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.

Please answer all the questions below:

Is the device, or any form of the device, supplied sterile? *

Yes No

Does the device have a measuring function? *

Yes No

Does the device contain material or ingredients of human origin? *

Yes No

Does the device contain materials of recombinant origin? *

Yes No

Does the device contain materials of animal origin? *

Yes No

Is the device intended to be non-invasive? *

Yes No

Is the device intended to be invasive via a body orifice? *

Yes No

Is the device intended to be surgically invasive (i.e. will it penetrate the skin)? *

Yes No

Is the device an active device? *

Yes No

If the device is a single product does it incorporate a medicine? *

Yes No

Is the device intended by the manufacturer to be used for contraception or the prevention of sexually transmitted diseases? *

Yes No

You will see a warning in red text appear if a selected response conflicts with the selected classification level of the device. See screenshot below:

Is the device, or any form of the device, supplied sterile? *

This device cannot be Class 1. Please check your device classification.

Yes No

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](#)
- [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 the majority of 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 if your custom-made medical device meets the definition of a patient-matched medical device [here](#).



Note

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

How do I access transitional arrangements?

If you are manufacturing or supplying a device that needs to transition to inclusion in the ARTG there are arrangements in place to ensure you can continue to supply your device while you apply for it to be included in the ARTG until **1 November 2024**.

You can register for transition by indicating in the form that your device meets the definition of a patient-matched device. By checking 'Yes' you are registering your patient-matched medical device for transition.

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

Transition plan details

Is this a patient-matched medical device that will need to transition to inclusion in the ARTG on 1 November 2024? *

Yes No

Have you registered the device for transition? *

Yes No

Once the form is submitted, you will have until the **1 November 2024** to complete an application for inclusion in the ARTG. More information about the inclusion process can be found on our website: <https://www.tga.gov.au/publication/medical-device-inclusion-process>.

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.

Please note: You should review the information about your regulatory obligations on our [website](#) before you make the following declaration. Providing information that is false or misleading to a Commonwealth entity or in connection with a Commonwealth law is a serious offence subject to criminal penalties under the Criminal Code Act 1995.

I declare that:

- The custom-made device(s) that I am supplying conform to the Essential Principles as set out in Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002;
- I hold and will maintain sufficient evidence to demonstrate conformity to the Essential Principles;
- I am aware that I have additional regulatory obligations as the manufacturer or sponsor of a custom-made medical device(s), and will comply with them; and
- All information that I have provided in this form is true and correct at the time of submission.

I agree *


Back

Save

Submit

After you have submitted your notification

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

 **You have successfully submitted the Custom-made Medical Devices application.**

The record will show on your dashboard under the 'Submitted' tab.


[Back to dashboard](#)

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:

Home > Custom-made Medical Devices Notifications Dashboard

Custom-made Medical Devices Notifications Dashboard

Please select a service below



A New Custom-made Medical Device Notification

Draft Submitted

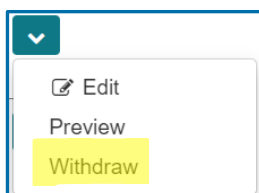
Search

Reference number	Status	Sponsor's own reference	GMDN code	Class	PMMD transition	Submitted on ↓	Submitter
There are no records to display.							

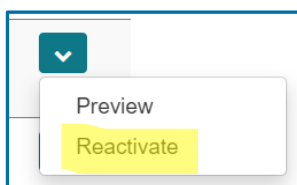
Withdrawing your notification

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':



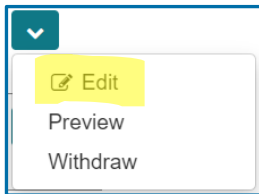
You can reactivate your withdrawn notification at any time:



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

Modifying your 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

Overview of the changes to the regulation of personalised medical devices:

<https://www.tga.gov.au/resource/personalised-medical-devices-including-3d-printed-devices>

Frequently asked questions: <https://www.tga.gov.au/regulatory-framework-personalised-medical-devices-frequently-asked-questions>

Overview of further changes made in August 2021:

<https://www.tga.gov.au/resource/refinements-personalised-medical-device-framework>

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

Therapeutic Goods Administration

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Reference/Publication #