Frequently Asked Questions

Why is there a new custom-made medical device database?

The new database responds to feedback from stakeholders asking for improvements. We've introduced new functions to support our clients, which means you will be able to:

- view all of your previously submitted notifications
- edit or modify information about your devices
- withdraw notifications that are no longer in use so you don't have to submit annual reports
- grant access to others in your organisation so they can also see, modify or withdraw notifications (depending on the role assigned to them by you in your client account)
- in-built support to help ensure you have correctly classified your medical device before submitting your notification.

These new functions enable you to keep your records up-to-date, support business continuity and provide us with better information about your devices in order to help us support you with the right information at the right time.

What if I have already submitted a notification(s) on the old databases?

If you have previously submitted a notification(s) on one of the old databases, you are not legally required to re-submit the same notification in the new database, but you should be mindful that we will be archiving the information previously submitted and it will no longer be used.

We therefore **strongly recommend you resubmit notifications into the new database**, so that you can keep your information up-to-date, and we can support you with updates and information that will impact you.

How do I access this new database and submit my notification?

Guidance for how to submit your notification is attached to this email. Please note, you will need to become a client of the TGA with access to the TBS online portal before you can access the database. There are instructions on the TGA website for becoming a client of the TGA.

If your organisation is already a client of the TGA, please contact the Administrator of your organisation's account and ask them to provide you with access to your organisation's account.

How much does it cost?

There are no costs associated with becoming a client of the TGA, submitting or varying notifications using this form.

Can I submit annual reports for custom-made medical devices using this new database?

The new custom-made medical device database cannot be used to submit annual reports for custom-made medical devices. To submit an annual report, you will still need to:

1. Download the custom-made medical device annual report spreadsheet template: Annual Reporting Form - Custom-made medical devices (Excel,13kb)
2. Submit the report using the online form: Annual Reporting Form - Custom-made medical devices(link is external)

Please note: You do not need to submit an annual report if your device meets the definition of a patient-matched medical device and has been registered for transition.

Does my custom-made medical device meet the new definition of a patient-matched medical device?

Custom-made medical devices are exempt from inclusion in the ARTG, but 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 meets the Essential Principles 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 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.

Custom-made medical devices that meet the new definition of patient-matched will **no longer be exempt from inclusion in the ARTG**. Transitional arrangements are in place to allow manufacturers and sponsors to continue supplying custom-made devices that meet the new patient-matched definition and are not included on the ARTG until **1 November 2024**.

You can check if your custom-made medical device meets the new definition for a patient-matched medical device here.

How do I notify the TGA and access the transition arrangements for my patient-matched medical device?

To notify the TGA, use the form for the new custom-made medical device database.

Once the form is submitted, you will have until the **1 November 2024** to submit 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.

Where can I get more information?

More information about the Personalised Medical Devices framework is available on our website.

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