Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Application for priority review designation – medical devices

- To apply for priority review designation for your medical device(s), you must complete and provide this application form along with sufficient supporting information which addresses the relevant eligibility criteria.
- Before submitting your application, please refer to the Priority review designations medical devices (including IVDs) guidance. This guidance will outline the application process, the criteria your device must meet to be eligible for designation, and how to pay your application fee.
- Please refer to Fees and charges for the current fee.

Section 1 – Applicant details

Name	
Client ID	
Postal address	
Billing email address	

Primary contact

Name	
Phone	
Email	

Secondary contact (optional)

Name	
Phone	
Email	

Section 2 – Application scope

This designation application is for a:

- ☐ Medical device
- ☐ In vitro diagnostic medical device (IVD)

And to seek priority review of an application for:

- ☐ TGA conformity assessment
- ☐ ARTG Inclusion

Do you have overseas approval for this kind of device? ☐ Yes ☐ No

If yes, please provide details:

Has an overseas regulatory agency refused to approve the medical device (for the above intended purpose) for a reason related to its safety or performance? ☐ Yes ☐ No

If yes, please provide details:

Section 3 – Product details

Name of the device (unique product identifier)	
Intended purpose	
GMDN code and term	
Classification	
Manufacturer	
Client ID of manufacturer	
Address of manufacturer	

Is the medical device for…?

☐ Prevention

☐ Diagnosis

☐ Treatment

Is the device intended to be used together with any other therapeutic good?

☐ Yes ☐ No

If yes, provide details.

Section 4 – Supporting information

The criteria for Priority Assessment of certain novel medical devices are that they must:

- be intended to treat serious conditions, **and**
- address an unmet clinical need in Australian patients, **and**
- represents a breakthrough in technology, or a clinical advantage, or provides a major public health benefit.

Your supporting information must make a concise, persuasive argument against **all three** eligibility criteria. See the Priority review designations medical devices (including IVDs) guidance for further information.

Section 5 – Planning details

When do you plan to submit an application for TGA conformity assessment or ARTG inclusion?

Section 6 – Related applications

As per the standard medical devices registration process, you may submit multiple applications as part of your submission for either TGA conformity assessment or ARTG inclusion. However, in order to access the Priority Review pathway, **all applications within your submission must have valid and relevant designations**.

If this application is related to any other application currently under evaluation by the TGA **OR** is related to a lapsed Priority Review Designation(s), please provide relevant details for each submission:

Submission #	Relationship to this application

If there are additional submissions, please add them as an attachment to the form.

Declaration and Signature

Please note

Under section 137.1 of the *Criminal Code Act 1995*, it is an offence to knowingly provide information to a Commonwealth entity that is false or misleading in a material particular, or to omit any information without which the information is misleading in a material particular.

Penalty: 12 months imprisonment

I declare that the information I have provided in the application is true and correct:

Signature		Date	
Full name		Email	
Position		Phone	