Australian Government
Department of Health and Aged Care
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 applicant determination – medical devices

- This is an application for EITHER a conformity assessment (priority applicant) determination OR a medical devices (priority applicant) determination. Please indicate your selection at Section 2 below.
- You only need to apply for **one type** of priority applicant determination.
- Before submitting your application, please refer to the Priority applicant guidelines for medical devices (including IVDs). This guideline outlines the two types of priority applicant determinations for medical devices, the eligibility criteria and the application and assessment process.
- To apply for a priority applicant determination for your medical device, you must complete and provide this application form to the TGA along with sufficient supporting information that addresses the relevant eligibility criteria.
- 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 details and background

This application is for a (tick one only):

☐ Conformity assessment (priority applicant) determination – this applies if you are seeking priority consideration of an application for a TGA-issued conformity assessment certificate.

☐ Medical devices (priority applicant) determination – this applies if you are seeking priority consideration of an application for ARTG inclusion.

This application relates to a (tick **one** only):

☐ Medical device (non-IVD)

☐ In vitro diagnostic medical device (IVD)

Do you have overseas regulatory approval for this device?

Yes ☐ No ☐

If yes, provide details:

Has an overseas regulatory agency refused to approve the medical device for a reason related to its safety or performance?

Yes ☐ No ☐

If yes, provide details:

Section 3 – Device details

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

Section 4 – Addressing the criteria/ supporting information

Please refer to the Priority applicant guidelines for medical devices (including IVDs) for guidance on addressing the criteria and supporting information, when completing this section. There are 3 criteria that must be satisfied. Criterion 2 and 3 allow for alternatives to be met.

1. Is the intended purpose of the medical device for the monitoring, treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition?

   Yes ☐ No ☐

2. Tick **one** of the following only:

   ☐ There are no medical devices with that intended purpose included in the Australian Register of Therapeutic Goods (ARTG).

   ☐ The medical device provides a significant improvement in terms of safety or performance compared to existing devices already included in the ARTG for that intended purpose.

3. Tick one (or more) of the following as applicable:

   ☐ The medical device is a breakthrough technology offering a major clinical advantage over existing technology.

   ☐ The medical device offers a major clinical advantage over existing alternatives included in the ARTG.

   ☐ The medical device is an IVD medical device and its early availability in Australia will result in a major public health benefit.

In order to be eligible for a priority applicant determination, you will need to demonstrate that all 3 criteria are satisfied, that is that the matters referred to in 1, 2, and 3 (above) are satisfied. This should be done by way of a supporting document addressing the criteria and supported by evidence including epidemiological and clinical evidence.

Please attach your supporting information, including:

- your document addressing the criteria, and
- other supporting information or documents.

Your supporting information should be attached to your email along with this application form.

Section 5 – Corresponding application

Have you already submitted a corresponding application for TGA conformity assessment or ARTG inclusion?

Yes ☐ No ☐

If yes, provide details including the application ID.

If not, when do you plan to submit an application for TGA conformity assessment or ARTG inclusion? (Note: if an application is not submitted within 6 months of a priority applicant determination being made, then the priority applicant determination will cease to be in force.)

Section 6 – Related devices

Are there any related devices (predicate devices or devices from within the same system) that you also wish to be subject to priority consideration?

Yes ☐ No ☐

If yes, provide any relevant details of such devices (device name, application number/s, date of submission, expected date of submission). Generally, such devices will require separate applications for priority applicant determination.

Are there other related devices that are currently ARTG-listed, the subject of a TGA application, planned for TGA application, or subject to other Department of Health processes that you would like the TGA to note? (Optional)

Yes ☐ No ☐

If yes, provide any relevant details of such related devices (device name, application number(s), date of submission, expected date of submission).

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, including the supporting information, is true and correct:

Signature		Date	
Full name		Email	
Position		Phone	