



Australian Government
Department of Health
Therapeutic Goods Administration



Home

Safety information

Consumers

Health professionals

Industry

About the TGA

News room

[Home](#) > [Industry](#) > [Medical devices & IVDs](#) > [Standards, guidelines & publications \(medical devices & IVDs\)](#)

[Share](#)

Class 4 in-house IVDs: using the online application form

12 September 2016

This guidance is for sponsors who are applying to include class 4 in-house IVDs on the ARTG.

On this page: [TGA Business Services](#) | [Manufacturer evidence](#) | [The dashboard](#) | [Starting a new Class 4 in-house IVD application](#) | [Completing the form](#) | [Submitting your application](#) | [Version history](#)

TGA Business Services

The online application form is in TGA Business Services.

- Before your organisation uses TGA Business Services for the first time, you need to apply for a [client identification number](#).
- For help with using TGA Business Services, including resetting your password, go to [TGA Business Services - how to use this site](#).

Manufacturer evidence

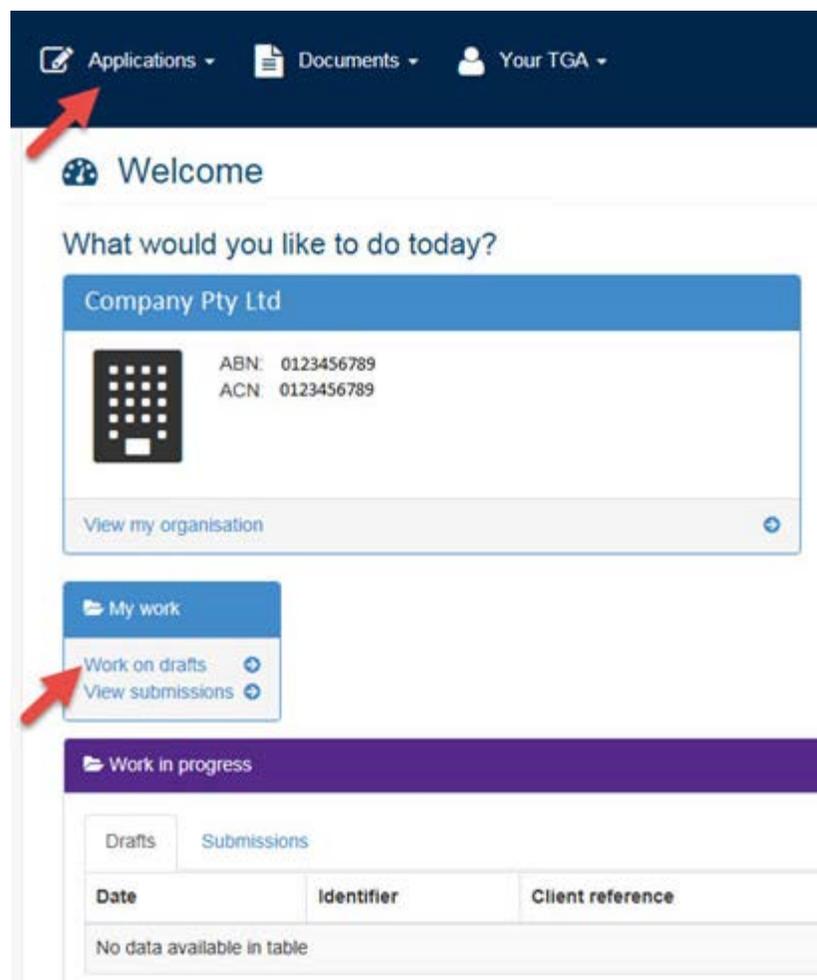
Before you can apply for a Class 4 in-house IVD, you need to have submitted your [manufacturer evidence](#) to the TGA, and we need to have accepted it.

The dashboard

First, log in to [TGA Business Services](#).

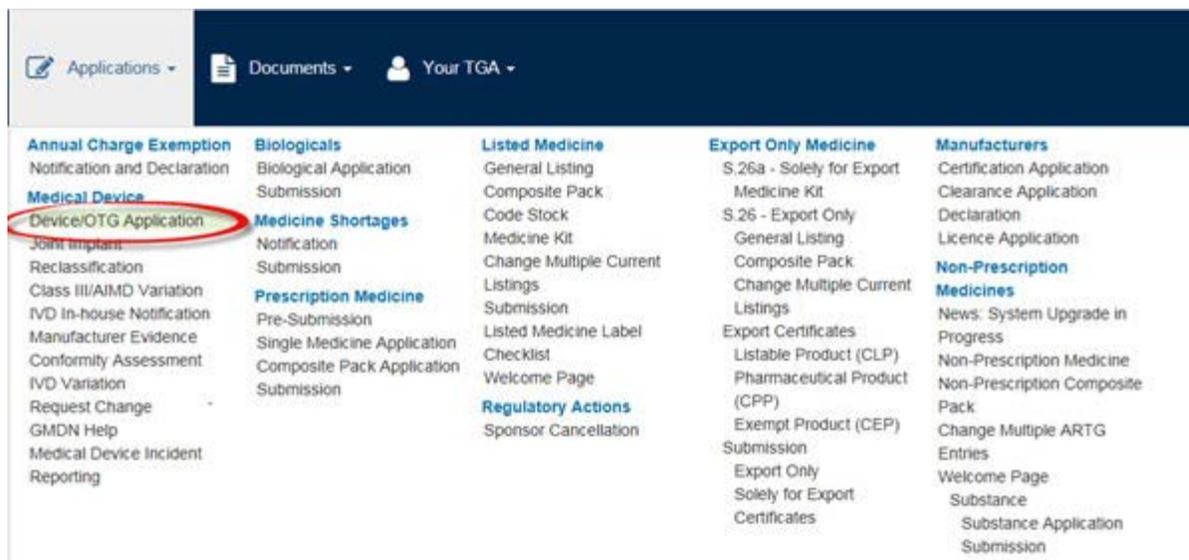
Across the top of the dashboard there are three main menus: **Applications**; **Documents**; and **Your TGA**. If you have the financial role, there is an additional **Financials** menu.

- To begin a new application, select the **Applications** menu.
- If you want to open an existing draft form, select **Work on drafts** from the **My work** menu.



Starting a new Class 4 in-house IVD application

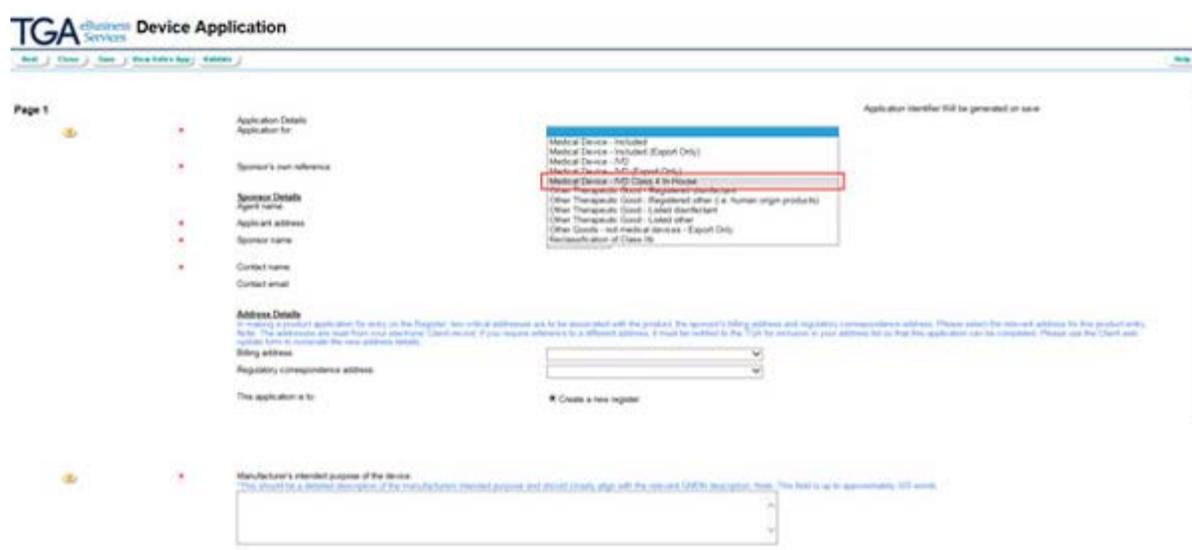
1. Select Applications from the top menu. This will open a list of application types.
2. Select **Device/OTG Application**.



A blank Device application form is then displayed, starting with the **Application** page 1.

Note that Help texts are available throughout the form using the yellow '?' buttons on the left.

- To change your device application into an IVD device application, select **'Medical Device - IVD Class 4 In-House'** from the drop down menu at **Application for**.



Completing the form

At any stage you can save the application form to your drafts by clicking the **Save** button on the bottom of your screen.

Once you selected **'Medical Device - IVD Class 4 In-House'**, sponsor, address and application class details will auto-populate from your client details.

- Verify the auto-populated details and when necessary, change them using the drop down menus.

5. Provide a detailed description (up to 350 words) of the intended purpose of the device that closely aligns with the relevant [GMDN description](#).

The screenshot shows the 'Page 1' of the 'TGA eBusiness Services IVD Device Application' form. The application identifier is 'DV-2016-NM-00000-1'. The form is divided into several sections: 'Application Details' (Application for: Medical Device - IVD Class 4 In-House), 'Sponsor Details' (Agent name, Applicant address, Sponsor name, Contact name, Contact email), 'Address Details' (Billing address, Regulatory correspondence address), and 'Application Class Details' (Class: Class 4, Fee: \$160.00). A red oval highlights the 'Manufacturer's intended purpose of the device' field, which is intended for a detailed description of the device's purpose.

6. Click the **Next** button at the bottom of the page.
7. Select the **Manufacturer for Evidence** from the drop down menu on page 2.

The screenshot shows 'Page 2 - Manufacturing Details (Class 4)' of the application form. The application identifier is 'DV-2016-NM-00000-1'. The form includes sections: 'Select Manufacturer for Evidence' (with a red oval around the 'Manufacturer for Evidence' dropdown menu), 'Product Details' (Does this application include Immunohaematology Reagents? (QRD): Yes/No, GMDN Code and Description), and 'Functional Description' (Total Number of IVD Medical Devices covered, Variant Type, Variant Range). A 'Search' button is located below the 'Product Details' section.

This drop down menu only shows manufacturers with accepted manufacturer's evidence that covers the type and class 'IVD class 4 in-house'. If the intended manufacturer is not shown, make sure that you have submitted the [manufacturer's evidence](#), and that we have accepted it.

8. Select the **Evidence number** from the drop down menu that pops up after you have selected the manufacturer and indicate the authority that issued the evidence.

The screenshot shows the 'Page 2 - Manufacturing Details (Class 4)' form. It includes a navigation bar at the top with 'TGA eBusiness Services IVD Device Application' and a breadcrumb trail: 'Home > Add > Class > Add > View Entry > Add > Validate'. The main content area is divided into several sections:

- Select Manufacturer for Evidence:** Includes instructions and a dropdown menu for 'Example' with a red circle around it.
- Product Details:** Includes a search button and a dropdown menu for 'GMDN Code' with a red circle around it.
- IVD Name (Unique Product Identifier):** Includes a text input field for 'Example' and a dropdown menu for 'Example'.

9. Indicate whether the device includes immunohaematology reagents.

If 'yes' is selected, the form will no longer display the IVD name (Unique Product Identifier), because this is not applicable to immunohaematology reagent IVD applications.

10. Use the search button to take you to the GMDN code search screen. Enter a search term and select the GMDN code for the application. Click the **OK** button.

Note: If the application is for an immunohaematology reagent, only [GMDN codes for immunohaematology reagents](#) will be displayed.

The screenshot shows the 'GMDN Code Search' screen. The search results list various GMDN codes, and a 'View Definition' window is open for the selected code: 'GMDN Definition : HIV1HIV2 antigen/antibody IVD, control[48449]'. The definition text reads: 'A material which is used to verify the performance of an assay intended to be used for the qualitative and/or quantitative detection of antigens from and antibodies to human immunodeficiency virus 1 and 2 (HIV1/HIV2) in a clinical specimen.' The 'View Definition' window also shows the 'Primary Code and Term' as '48449 - HIV1HIV2 antigen/antibody IVD, control' and a 'Close Window' button.

11. If your IVD is not an immunohaematology reagent, enter the [Unique Product Identifier](#). This text will be used as the 'product name' for the ARTG entry.

12. For the **Functional Description**, enter a description of how the device achieves its intended

purpose.

13. For the **total number** of IVD medical device variants covered:
 - Enter '1' if the IVD is not an immunohaematology reagent
 - Specify the total number of variants that you are applying for, if the IVD is an immunohaematology reagent.
14. **Variant type** is only applicable to immunohaematology reagents. For immunohaematology reagents:
 - Select as the type 'Immunohaematology reagents'
 - Provide details in the free text **Variant range** field. Click the **Add** button to confirm.
15. Click the **Next** button at the bottom of the screen.

Submitting your application

16. Click the **Add** button on top of page 3 to upload [supporting documentation](#).
17. Select the **Document Type** from the drop down menu and select **Browse** to search for files. Then, select the file to be submitted and click the **Add** button once more to confirm.

The screenshot shows a 'File Upload' form. At the top left, there is a label 'Application/Certificate Id:' with the value 'DV-2016-IVH-00000-1'. Below it is a label 'Document Type:' with a dropdown menu showing '-- Please Select --'. To the right of the dropdown is a 'Browse...' button. Below the dropdown menu, a red arrow points to the expanded list of options: 'National Association of Testing Authorities accreditation to ISO 15189', 'TGA Conformity Assessment Certification (IVDs)', and 'TGA Good Manufacturing Practice Licence'. On the left side of the form, there is an 'Add' button and a section titled 'Please complete:' with two bullet points: 'The Document Type' and 'Select the File to be submitted.'

18. Read the **Declaration** and agree or decline.



You have to agree to the declaration in order to submit your application.

19. Click the **Validate** button at the bottom of the screen to run a check whether all mandatory questions have been answered.

Once the validation is complete:

20. If you only have drafter rights, click the **Save** button at the bottom of the screen. Ask a person in your organisation that has submitter rights to verify the application and submit.

If you do not have the submitter role, there will be no **Submit** button at the bottom of your screen.

21. Only someone with the submitter role can submit the application. Use the **Submit** button at the bottom of the screen.
22. We will only process your application once we have received payment. When you submit the application, an invoice will be automatically generated and will be visible if you have the financial role. Please note, we will not send you a paper copy of the invoice by post.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch with the Regulatory Guidance Team	September 2016

Category: Medical devices/IVDs

Tags: regulatory guidance

URL: <https://www.tga.gov.au/node/730873>

[Copyright](#) | [Privacy](#) | [Disclaimer](#) | [Security](#) | [Acronyms & glossary](#) | [Sitemap](#) | [A-Z guide](#)

| [Contact the TGA](#) | [Freedom of Information](#)

Sitemap Navigation

www.australia.gov.au  | www.health.gov.au  | www.odc.gov.au 

The Therapeutic Goods Administration is part of the Health Products Regulation Group