Australian Government
Department of Health
Therapeutic Goods Administration

Class 4 in-house IVD application

Using the online application form

Version 1.0, September 2016

TGA Health Safety Regulation

Contents

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

TGA Business Services

The online notification form is in TGA Business Services.

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

Manufacturer's evidence

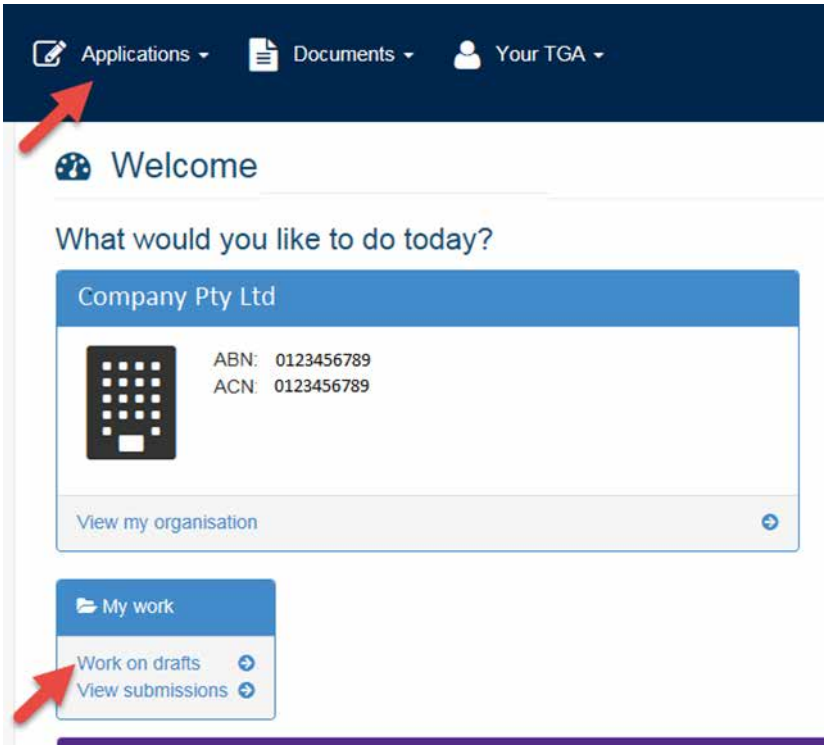
Before you can apply for a Class 4 in-house IVD, you need to have submitted your manufacturer's evidence to the TGA, and we need to have accepted it.

The Dashboard

First, log in to TGA Business Services.

Across the top of the dashboard, there are three main menus: **Application**; **Documents**; and **Your TGA**. If you have a 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

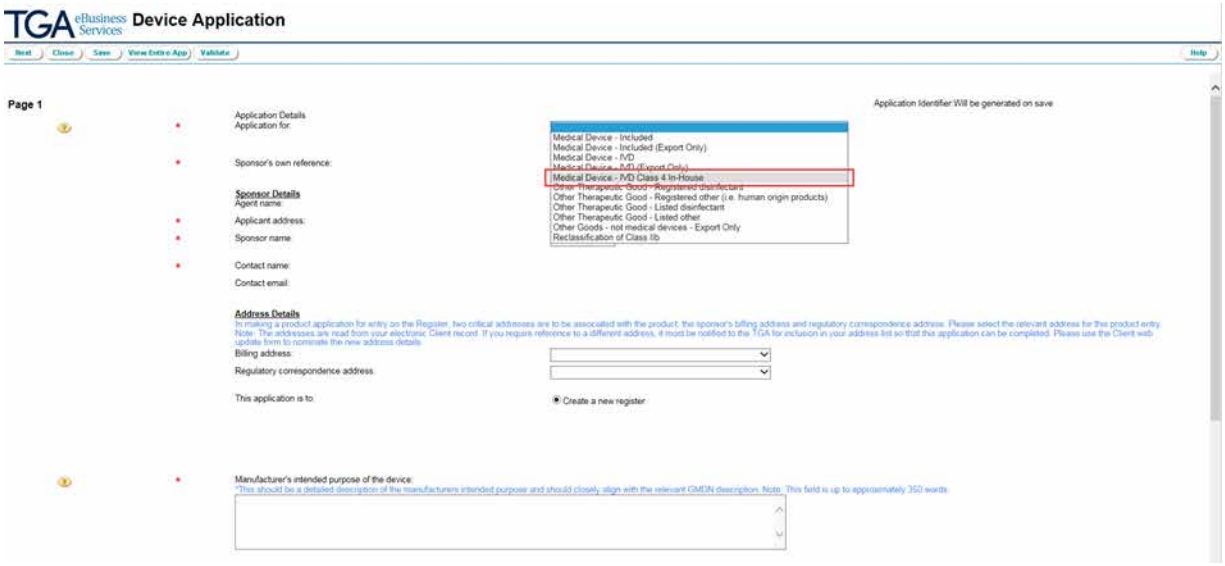
1. Select **Applications** from the top menu. This will open a list of application types.

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.

3. 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**.



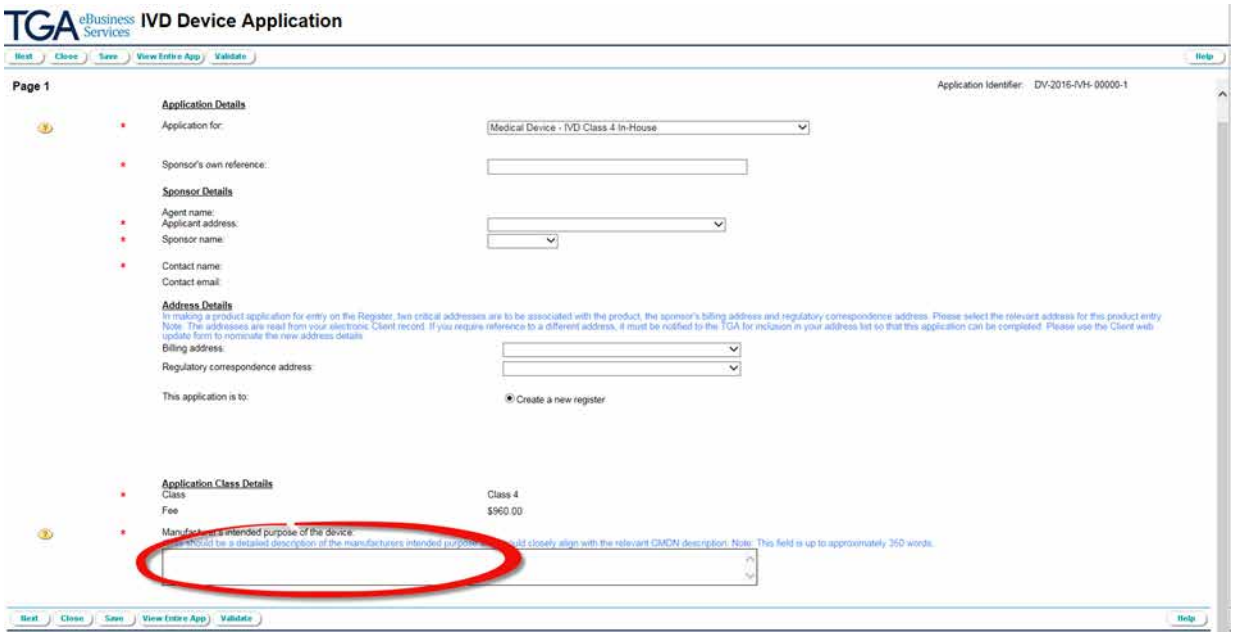
Completing the form

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.

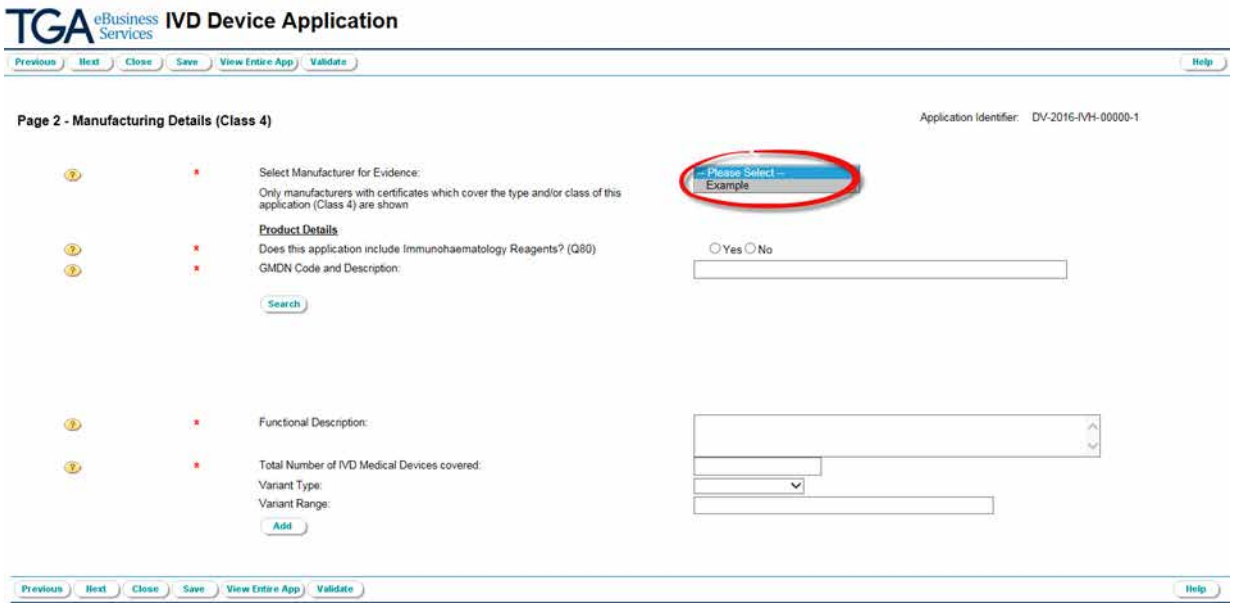
4. Verify the auto-populated details and when necessary, change them using the drop down menus.

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



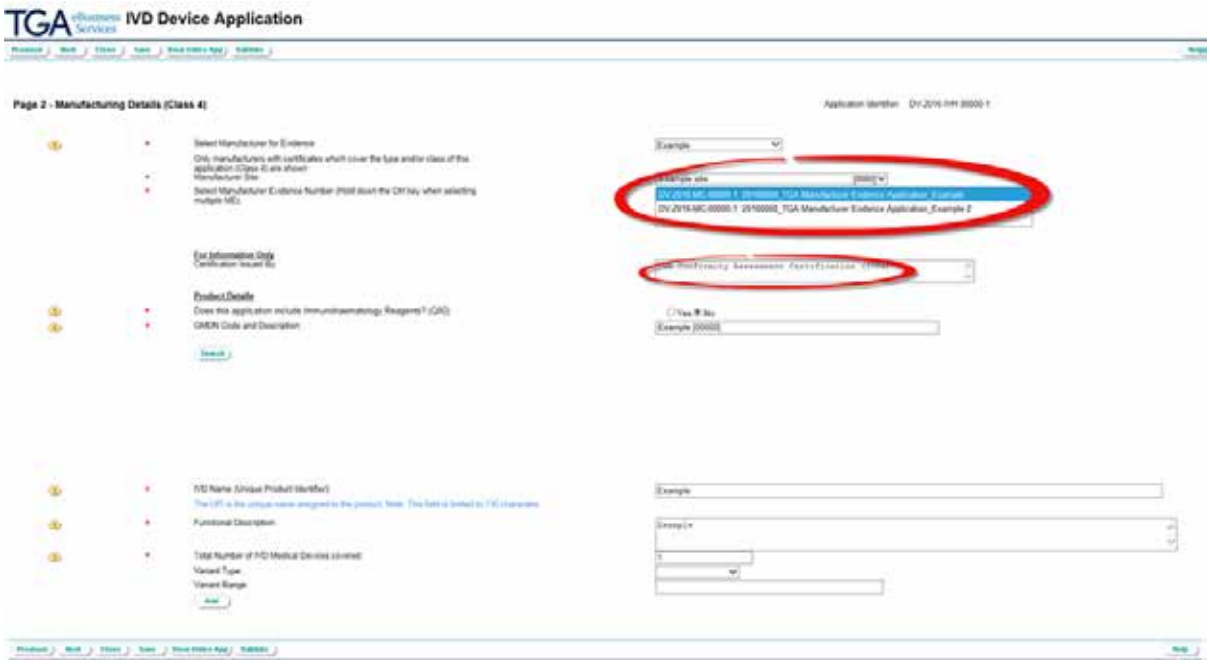
6. Click the **Next** button at the bottom of the page.

7. Select the **Manufacturer for Evidence** from the drop down menu on page 2.



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.

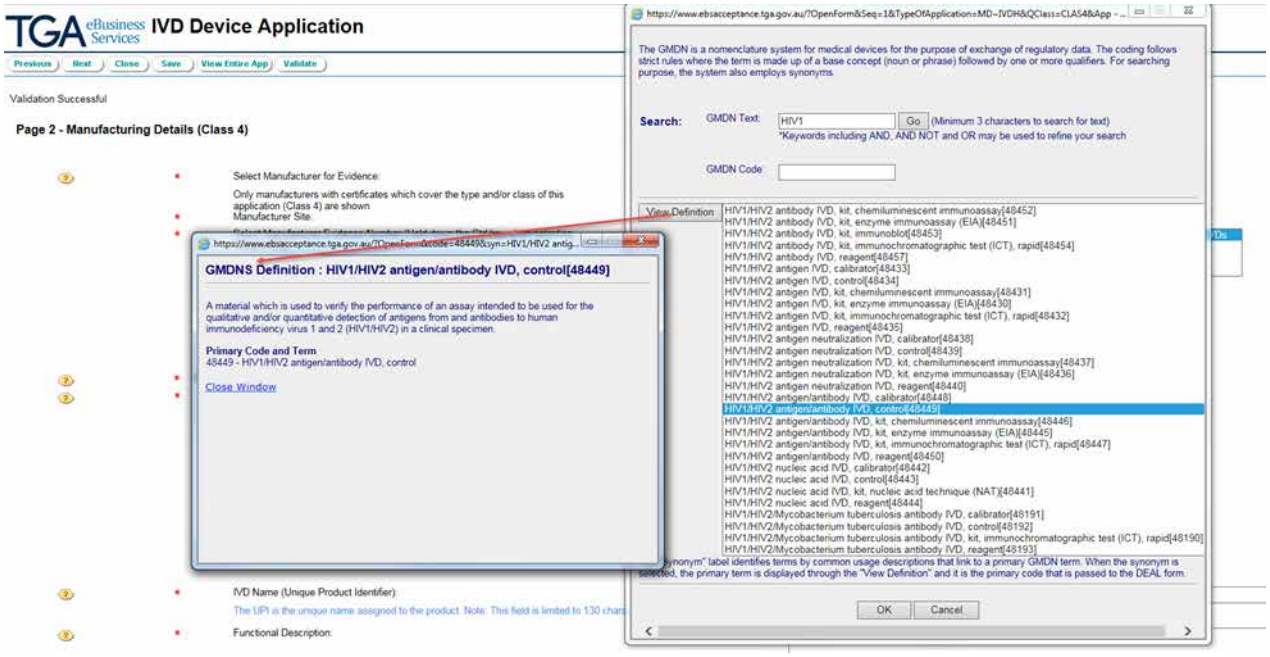


9. Indicate whether the device includes immunohaematology reagents.

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.

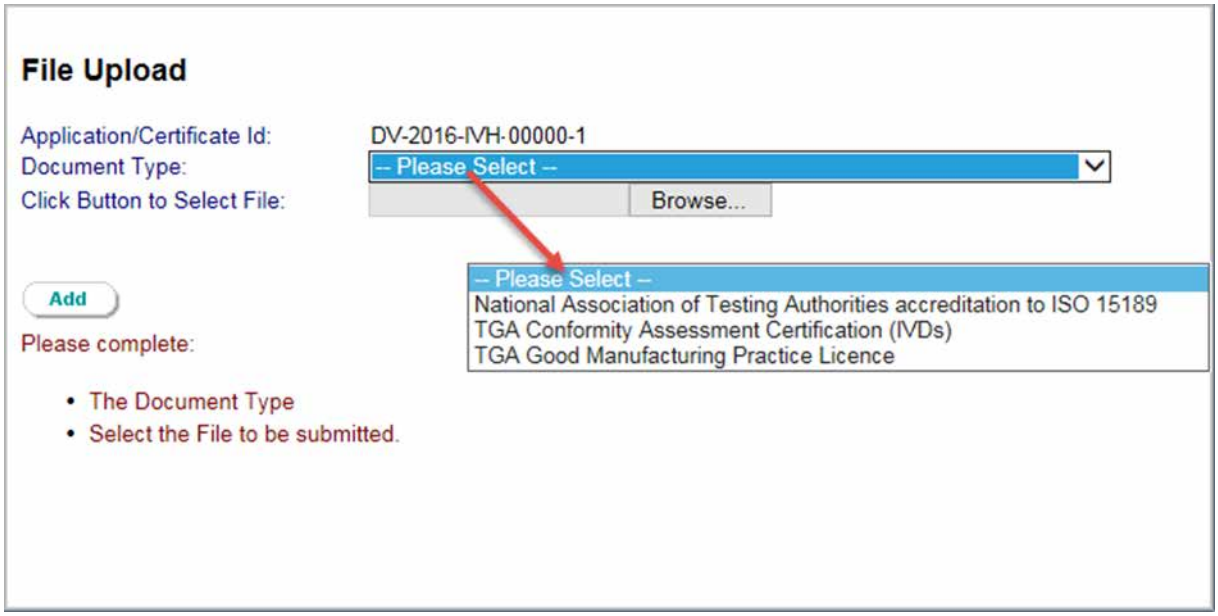
Note: If the application is for an immunohaematology reagent, only GMDN codes for immunohaematology reagents will be displayed.



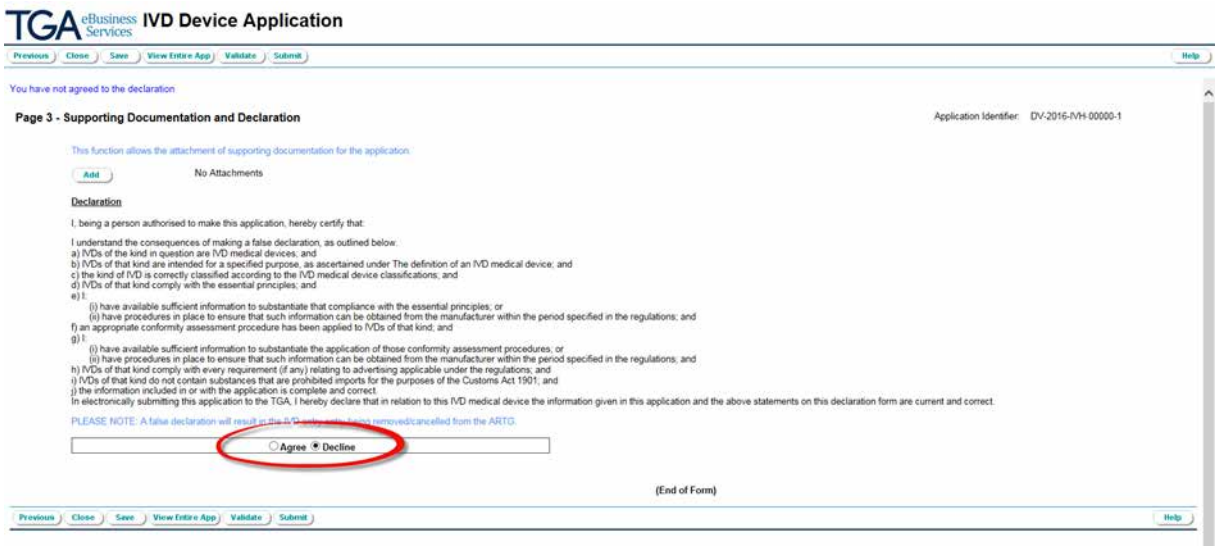
11. If your IVD is not an immunohaematology reagent, enter the Unique Product Identifier. This text will be used as the 'product name' for the ARTG entry.
12. For the **Functional Description**, enter a description of how the device achieves its intended purpose.
13. For the **total number** of IVD medical 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.



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

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Reference/Publication #