Australian Government
Department of Health
Therapeutic Goods Administration

Class 1-3 in-house IVD notification

Using the online application form

Version 1.2, June 2017

TGA Health Safety Regulation

Contents

This guidance is for sponsors who are providing their initial notification to the TGA of their Class 1-3 in-house IVDs.

TGA Business Services

The online notification form is available in TGA Business Services.

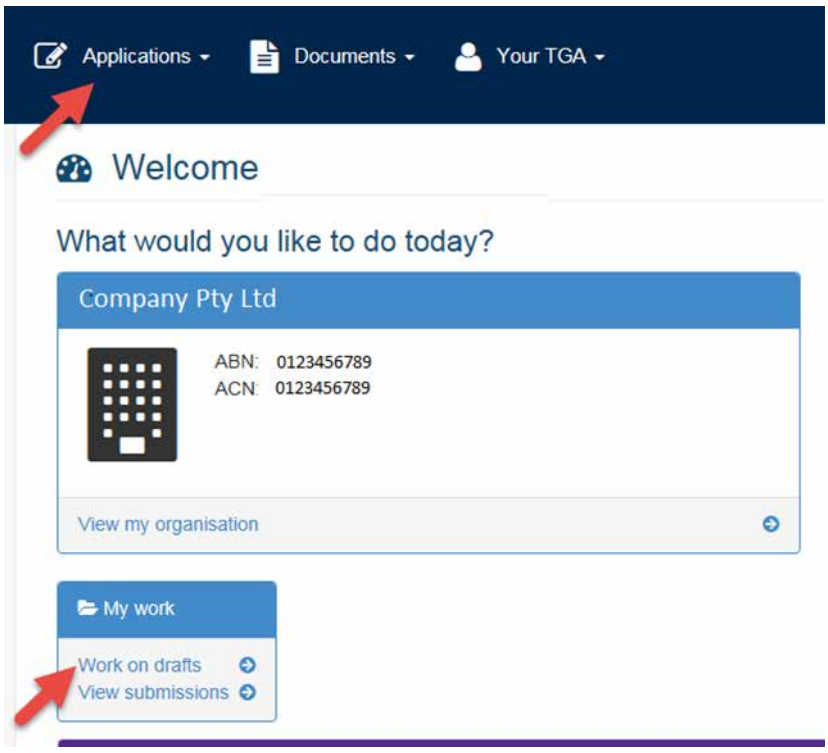
- Before your organisation uses TGA Business Services (TBS) for the first time, you need to apply for a client identification number. Complete the 'Organisation details form' and send it to ebs@health.gov.au. Once the form has been processed, you will be sent an email with the Organisation ID and an administrator guide.
- For help using the TGA Business Services, including resetting your password, go to TGA Business Services – how to use this site.
- If you are experiencing issues with TGA Business Services site, please email ebs@health.gov.au or contact them on 1800 010 624.

The Dashboard

First, log in to TGA Business Services, with the user name provided to you by the TBS. When you first go to login, you will need to set your password by clicking on 'Forgotten your password' and following the instructions.

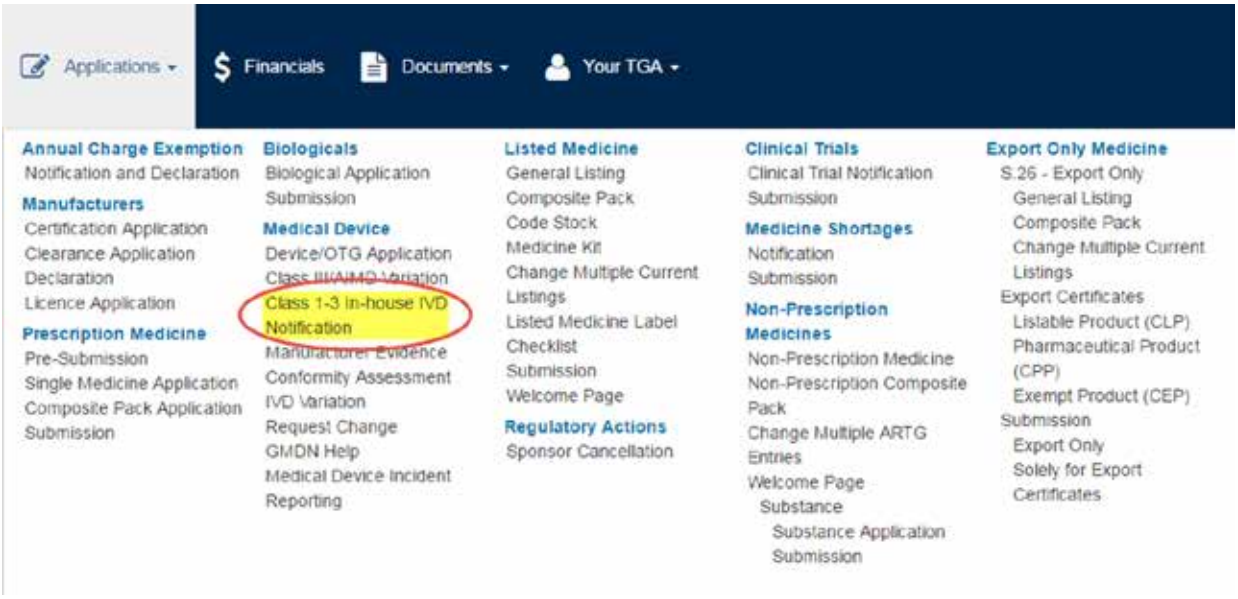
Across the top of the dashboard, there are three main menus: **Application**; **Documents**; and **Your TGA**. If you have a financial role, there is an additional **Financials menu**.

- 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**.

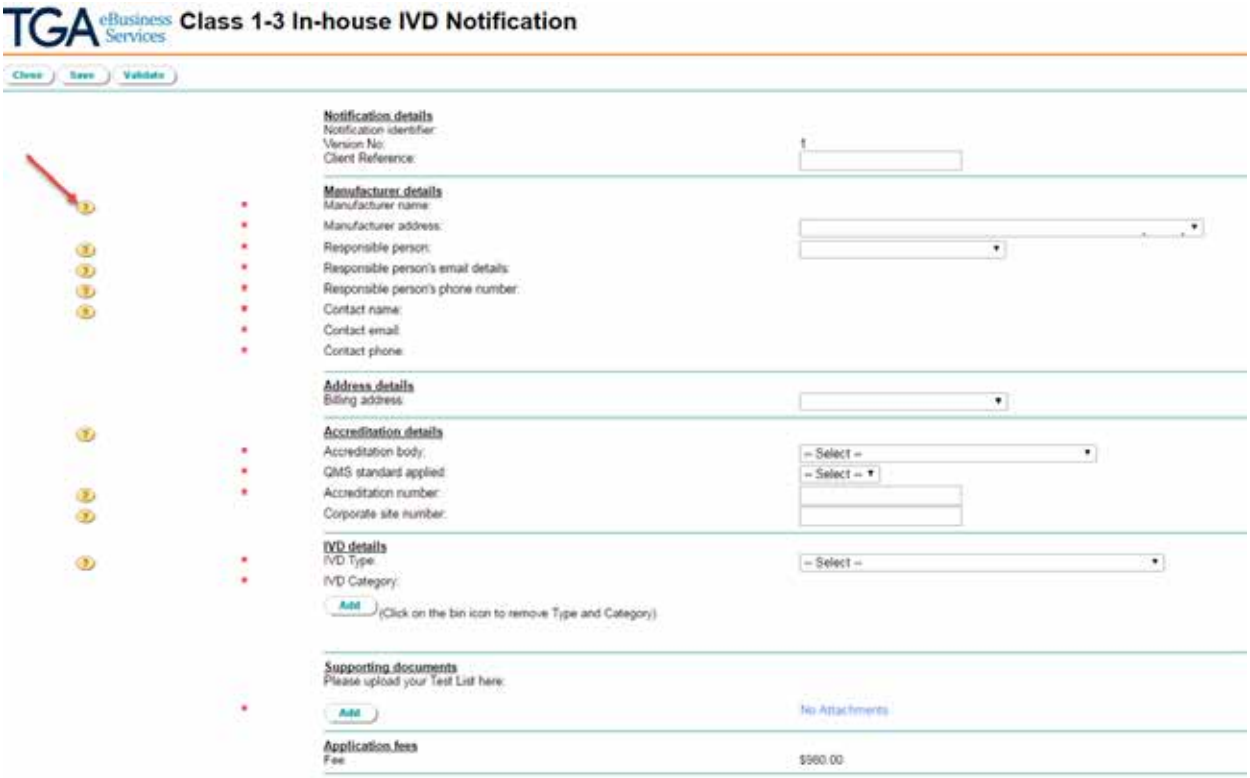


Starting a new Class 1-3 in-house IVD notification

1. Select **Applications** from the top menu. This will open a list of application types.
2. Select **Class 1-3 In-house IVD Notification**.



A new IVD Notification form, like the image below, is then displayed.



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

Verifying Manufacturer and Address details

At any stage you can save the notification form to your drafts by clicking the Save button at either the top or the bottom of the page.

The form will auto-populate **Manufacturer** and **Address details**, including **Contact Details** from your own client details.

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

4. Using the drop down menu, select the **Responsible Person** details from the options available. Only persons with portal access will appear within the drop down menu.

5. If you want, you can enter in your own Client reference title into the free text box at the top of the page. This reference is for your own use to assist in identifying your notification, rather than trying to recall the assigned notification identifier.

Selecting Accreditation body and QMS standard

Under this portion of the notification form, enter your laboratory's accreditation details.

Note that only one notification form needs to be submitted if multiple laboratories are accredited as a laboratory network under the one Corporate Accreditation number (i.e. the laboratories all operate under the one quality management system).

If your laboratories operate under the one quality management system, but you don't have a Corporate Accreditation number, please enter one of your laboratory accreditation numbers in the form and then list the remaining accreditation numbers for your individual laboratories in a separate document and upload this along with your test list at Step 12.

Although, each laboratory can submit their own notification should they choose to do so. However, each notification will incur its own application fee.

If multiple laboratories are to be included under the one notification, it is recommended that each site has access to the TBS portal, so that they too can view the completed notification.

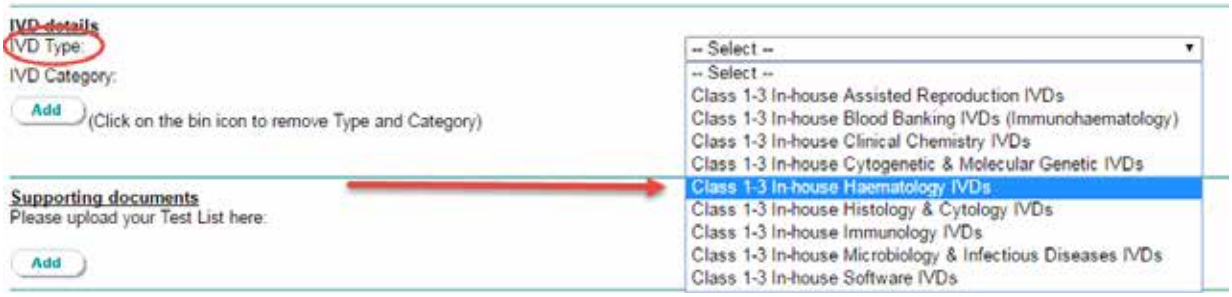
6. Select the **Accreditation body** from the drop down menu and then the **QMS standard applied** from the following drop down.

Both drop down menus only show accepted **Accreditation bodies** and **QMS standards** that cover Class 1-3 in-house IVDs.

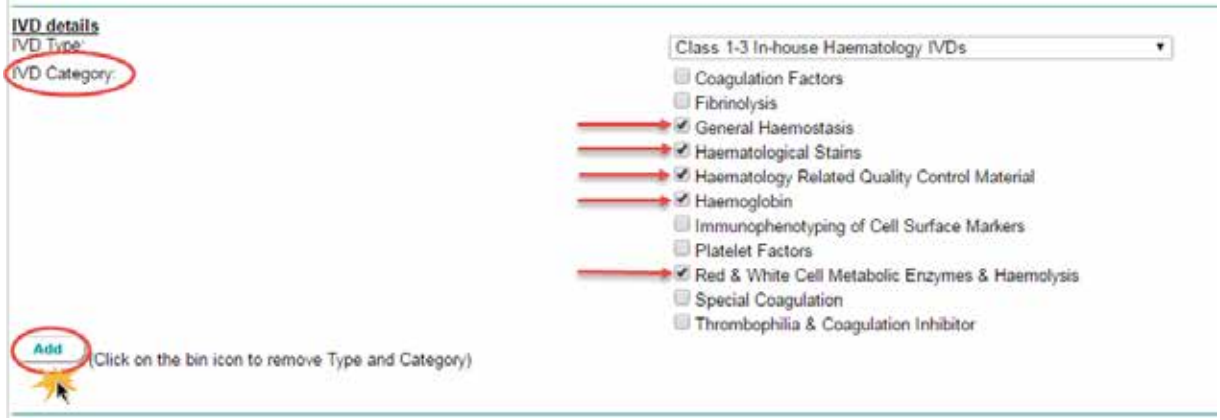
7. Enter the **Accreditation number** as listed on the certification and if available, the **Corporate site number**.

Selecting IVD Type and IVD Categories

8. From the drop down menu, select the **IVD Type**.



9. Once **IVD type** has been selected, a list of **IVD Categories** for that **IVD Type** will appear. Click the relevant check boxes for which the in-house IVDs fall under.



10. Click the **Add** button to populate your selection within the form.

Incorrect **IVD types** and their related categories can be removed by selecting the bin icon.

If you have missed an **IVD category**, you must delete the type and re-add it with the correct categories. The form allows you to sequentially add as many of the nine **IVD Types** you require.

11. Repeat Steps 6 to 8 until all your Class 1-3 in-house IVDs have been included under the relevant **IVD Type** and **Category**.

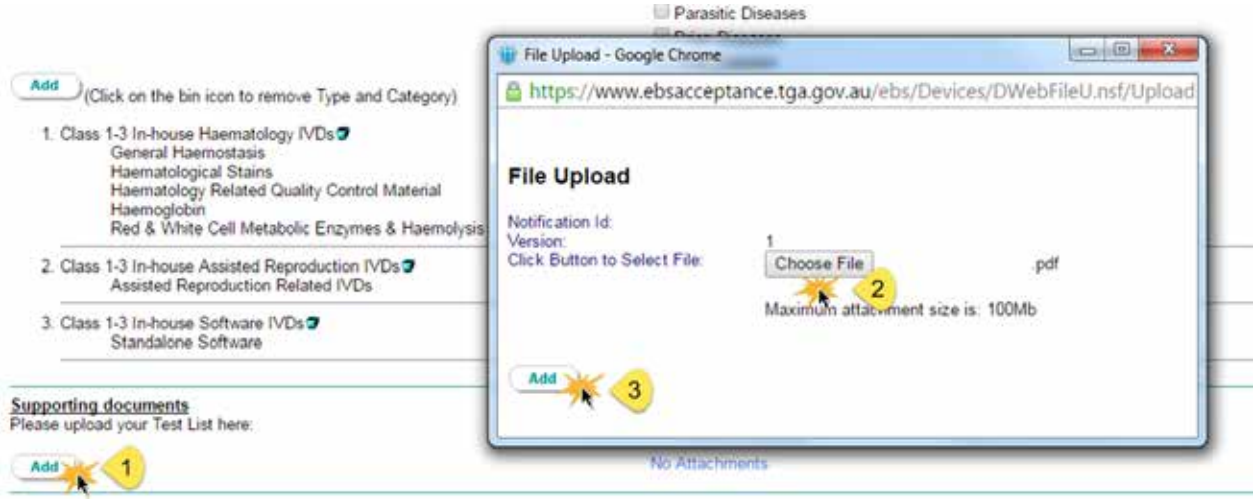
Supporting documents and In-house IVD test lists

The Supporting documents portion of the form is where you upload your NATA test list or any other alternative document which details your in-house IVDs. If your NATA accreditation supports more than one corporate site, you may wish to upload separate lists for each site. The form supports word, excel, pdf and other common file types. The preference of most laboratories has been to upload their NATA test list or a filtered version of this, but laboratories can create and upload a separate list if this is preferred. These test lists will not be made publicly available.

Within your test list, please attempt to classify your Class 1-3 in-house IVDs but note that your notification will not necessarily be refused if you don't get these entirely correct. For more information on the classification rules, please refer to the Classification of IVD medical devices guidance document.

As mentioned above, if you have more than one laboratory operating under the same quality management system, but do not hold corporate accreditation which covers all sites, please upload documentation stating each laboratory and corresponding accreditation number.

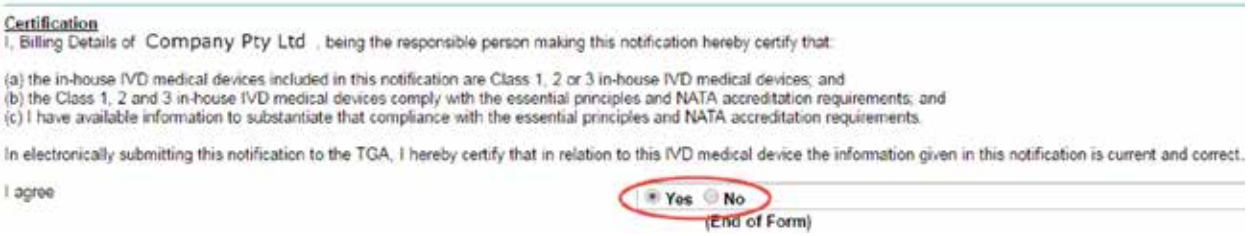
12. Click the **Add** button to upload your supporting documents. A pop-up window should appear.



13. Within this window, select **Browser** to search for your **Test List** files. Select the file to be submitted and click the **Add** button once more to confirm. The file will appear under the **Supporting documents** heading. Repeat this step until all documents have been uploaded.

Submitting your notification

14. Read the **Certification** at the end of page and select **Yes** if you agree.



You will have to agree to the certification in order to submit your notification.

Note: Compliance with the NPAAC standard, Requirements for the development and use of in-house in vitro diagnostic medical devices (IVDs), will be taken as compliance with the relevant essential principles for the safety and performance of a Class 1-3 in-house IVD medical device.

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

Once the validation is complete only someone with the submitter role can submit the application:

16. If you only have drafter rights there will be no **Submit** button at either the top or bottom of your screen. Click the **Save** button at either the top or bottom of the screen. Ask a person in your organisation that has submitter rights to verify the application and submit.

17. If you do have a submitter role click on the **Submit** button at either the top or the bottom of the screen.

18. We will only process your notification once we have received payment. When you submit the notification, 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	November 2016
V1.1	Additional information included to clarify steps	Medical Device Branch	March 2017
V1.2	Additional step included (Step 4) due to IT upgrade. Additional information included to clarify steps.	Medical Devices Branch	June 2017

Therapeutic Goods Administration

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Reference/Publication #