Australian Government
Department of Health
Therapeutic Goods Administration

Varying entries in the ARTG

Medical devices and IVDs

Version 1.0, November 2016

TGA Health Safety Regulation

Contents

Introduction

It is important that information included in the ARTG is kept up-to-date and is correct from a public health, regulatory and transparency point of view. When any information included in the ARTG has changed, the sponsor should consider if they need to request the TGA to vary the respective ARTG entry.

There are many reasons why sponsors may require variation of their ARTG entries, for example the:

- information entered on the ARTG is not correct or no longer correct
- manufacturer's details (e.g. name and/or address) have changed
- GMDN code was made obsolete and the manufacturer decided to change to a current relevant GMDN code*
- intended purpose of the device was changed by the manufacturer
- manufacturer has added variants
- manufacturer's evidence identifier was changed (e.g. split or combine certificates or new ID following sponsors transfer**)
- manufacturer amended the Unique Product Identifier (UPI) and/or number of devices of the kind
- sponsor wants to vary the list of IVD devices included in ARTG entry

* The GMDN code must be current at the time when an application for ARTG inclusion of a kind of medical device is submitted to the TGA, and the code is expected to remain the same for the whole life of ARTG entry. TGA does not require the sponsor to amend the GMDN code if it becomes obsolete. However if the manufacturer decides to vary the GMDN code because it was made obsolete by the GMDN Agency, the sponsor may require the TGA to vary this information on the ARTG by submitting an application to the TGA.

** This guidance does not cover sponsor transfers and/or change of sponsor's name. For requirements related to the sponsors transfers refer to Regulation 10F of the Therapeutic Goods Regulations 1990, and our guidance on Sponsor transfer and change of sponsor name amendments.

Decisions about variation of ARTG entries are made under Section 9D of the Therapeutic Goods Act 1989.

We will always vary the ARTG entry if the sponsor requests a variation that:

- reduces the class of persons for whom the kind of medical device is suitable, **or**
- adds a warning, restriction or precaution.

We will not accept a request for variation if:

- the result of the proposed variation would be that the device is no longer a device of the same kind, **or**
- the proposed variation indicates any reduction in the quality, safety or performance of the medical device for the purposes for which it is to be used.

Fee and forms for varying entries in the ARTG

Fee

Schedule 9, Part 2 Item 2A(g) of the Therapeutic Goods Regulations 1990 sets out the fee to vary one ARTG entry. The fee is the same regardless of which variation application form you use, i.e.:

> **One Variation form or Device Change Request (DCR) form for one ARTG entry = one invoice and one fee.**

If you submit multiple Variation or DCR forms, you will receive an invoice with a fee for each form. Please remember that fees are **non-refundable**.

The TGA does not charge any evaluation fee for varying ARTG entries, even when assessment of the information (e.g. clinical evidence) is required for the TGA to be satisfied that the requested variation does not indicate any reduction in the quality, safety or performance of the medical device.

Forms

The variation request forms are within the TGA Business Services (TBS) online portal, and there are three application forms available:

- Medical Device Application (Variation) for Class III and AIMD
- IVD Application (Variation)
- Device Change Request (DCR).

Guidance on selecting and completing these forms is available from page 8: How do I request a variation of my ARTG entry?

Class III/AIMD Variation and IVD Variation

These forms are designed to request variation of the information included in the ARTG for specific characteristics related to the device of the kind (UPI, number of devices, functional description, and variant list).

We generally ask sponsors to provide information that demonstrates that the variation does not indicate any reduction in the quality, safety or performance of the medical device.

In cases where the design of the device has changed, sponsors are asked to demonstrate that this variation neither indicates any significant change of the intended purpose of the devices of the kind, nor results in the device no longer being the device of the same kind. You can attach additional information with this application to explain the required change if you wish (maximum 1 page).

Request Change (Device Change Request)

A Device Change Request (DCR) is the most frequently used form. It is a very simple form where the sponsor can briefly describe the required variation in a free text field.

When a DCR is received, the TGA will send you a letter requesting that you describe in detail the required change (section 41JA Notice). You may also be asked to provide other information as specified to support the requested variation.

Generally, sponsors should submit one DCR per ARTG entry.

Same change to multiple ARTG entries

Sometimes we may decide to vary some ARTG entries on our own initiative (could be based on a request to vary one ARTG entry). In these cases, sponsors are not required to submit multiple DCRs.

Examples of this could be a change of the:

- manufacturer's name and/or address
- Manufacturer Evidence ID.

To check your eligibility, work through the questions below. If you answer 'YES' to all of the questions in either Group A or Group B, you may be eligible to submit one DCR to make the same change to a number of ARTG entries:

Eligibility

Group A

1. Do you have more than one ARTG entry for the devices manufactured by the same manufacturer, the name and/or address of which has/have changed?
2. Is the classification of your devices lower than Class III/AIMD or Class 4 IVD?
3. Are all ARTG entries linked to the same Manufacturer Evidence ID?

Group B

4. Does your change only relate to the variation of the Manufacturer Evidence ID stated on your ARTG Certificate (re-linking)?
5. Is this Manufacturer Evidence ID linked to a number of ARTG entries (re-linking)?

Go to Requesting the same change to multiple ARTG entries for the process to follow.

The manufacturer of the device must not change

When considering requests for variation of the manufacturer's address and/or name, we will assess whether the person responsible for the design, production, packaging, and labelling of the device is still the same.

If the manufacturing quality system and control over the design and production have changed, we will not accept the DCR and will require the sponsor to submit a new application for inclusion of the kind of device in the ARTG.

Conformity assessment certification

Any change(s) proposed by the manufacturer must be assessed and approved by the body that issued the conformity assessment certification in relation to the kind of device (either TGA conformity assessment certificate or EC Certificate issued by a European NB).

If the change(s) is approved, a revised certificate may or may not be issued, depending on whether the information appearing on the certificate requires updating.

This process must be completed **prior** to seeking a variation of your ARTG entry.

How do I request a variation of my ARTG entry?

Using the correct form

Answer the following questions to decide which application form you need to use:

1. Is your device a Class III or AIMD device, and are you requesting to vary information relating to any of the following:
   - UPI
   - total number of devices
   - functional description
   - variant list

   YES – use the Class III/AIMD Variation Application form.

2. Is your device an IVD device, and do you need to vary your list of devices of the kind entered on ARTG entry?

   YES - use the IVD Variation Application form.

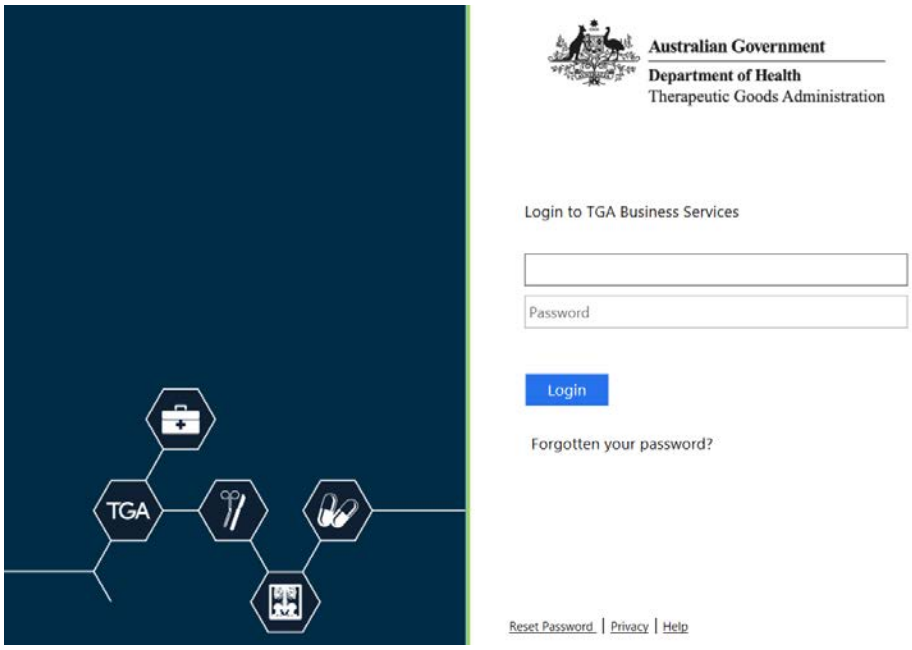
In ALL other cases, use the Request Change (Device Change Request) form.

Getting started

You need to login into your TGA Business Services (TBS) account to access the application forms. If you don't have an account/access, follow the instructions at TGA Business services: getting started with the TGA.

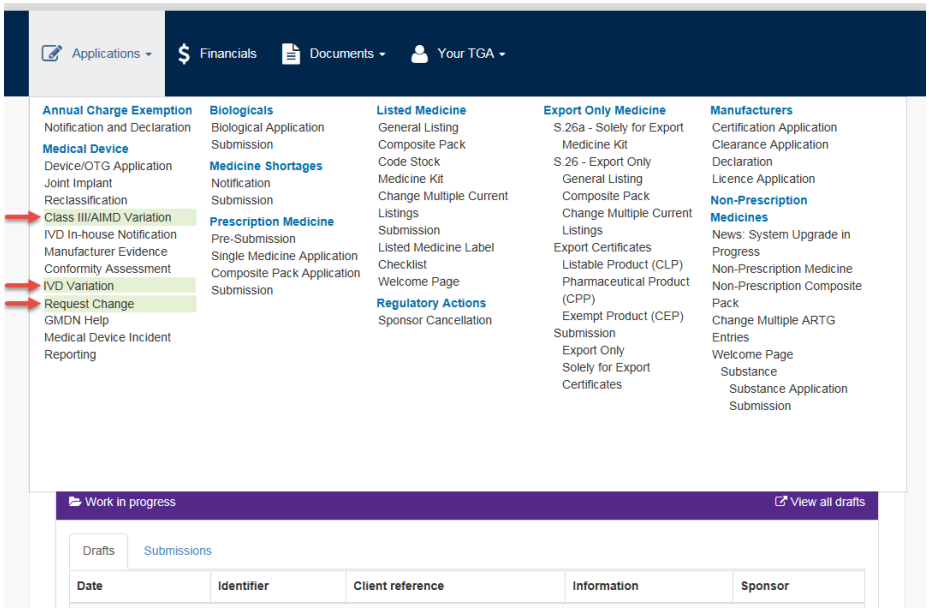
Step 1 - Login to TGA Business Services

Enter your user name and password.



Step 2 - Select the relevant variation type

From the Applications menu, under the Medical Device list, select the relevant variation type. Indications for the use of each form are detailed above in 'Types of Variation Applications'.



Step 3 - Submit required information

The form requirements for each variation type are different, and we have outlined these in three sections:

- Class III/AIMD
- IVD variation
- Request change (Device change request)

Step 4 - Payment of fee

Once the sponsor has paid the invoice, the application joins the queue for the assessment.

Step 5 - TGA assessment

The application is reviewed by an assessor who makes a recommendation to the Delegate.

The TGA may request further information under section 41JA of the Act to make an informed decision on whether the requested change is acceptable and does not change the kind of device in the Register.

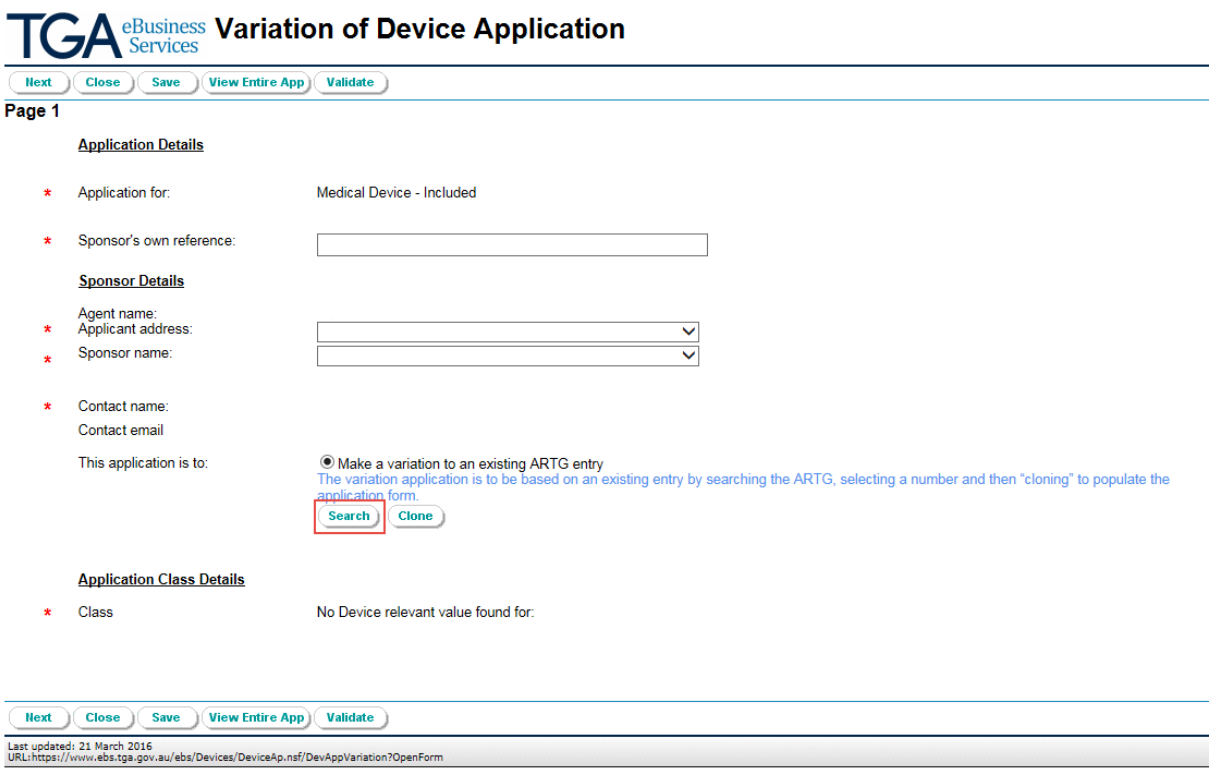
Step 6 - Decision and notification

The TGA Delegate makes a decision under section 9D of the Act to:

- accept the variation application, vary the ARTG entry (or entries). The sponsor will be notified via email about this outcome, **or**
- reject the variation and notify the sponsor via email with a statement of reasons.

Class III/AIMD Variation

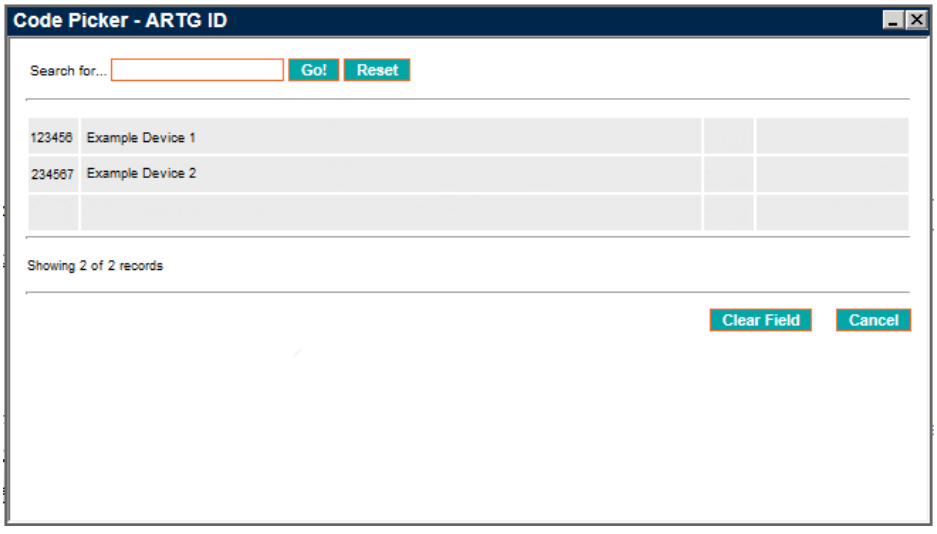
The ***Sponsor Details*** will be pre-populated with your information, but correct these if necessary. There is a field under the ***Application Details*** for a *Sponsor's own reference*, but this will be populated later in the process.



You need to search for the ARTG entry you wish to vary, and selecting the Search button on page 1 of the form will open a new search window titled Code Picker – ARTG ID.

This will list all of the ARTG entries you have for Class III and AIMD medical devices. If the list is long (e.g. multiple pages), you can search by key words in the ***Search for...*** field to narrow the list.

To choose the entry you want to vary, select it directly from the list. Once selected, the Code Picker window will close.

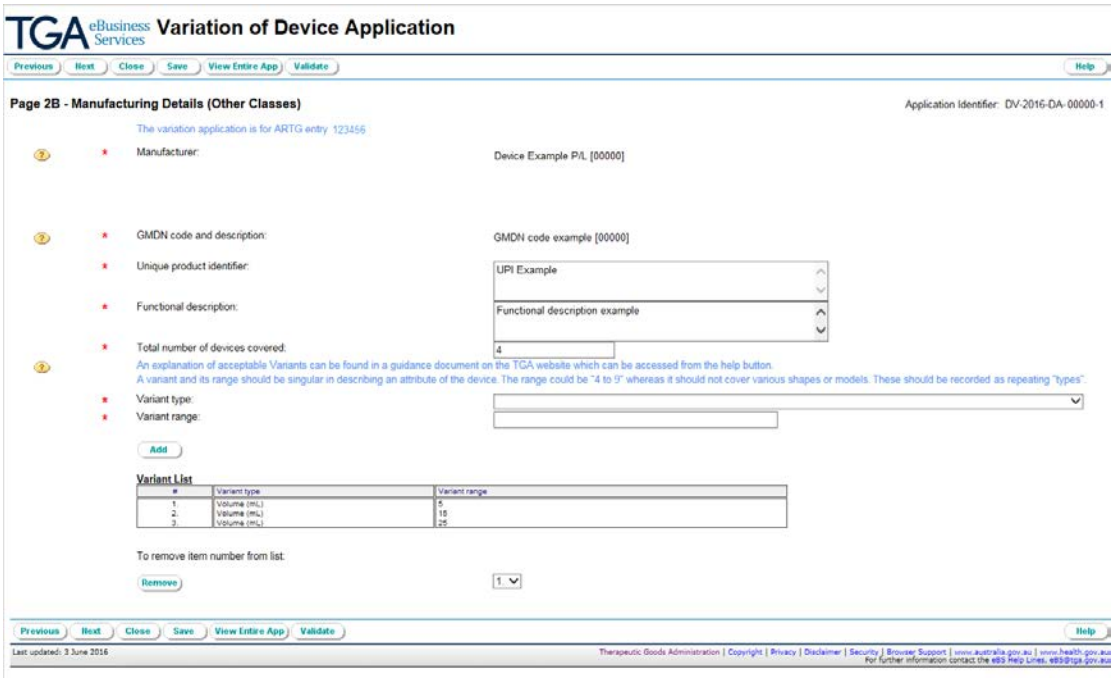


Once you have chosen the correct entry, its ARTG number will appear on page 1 of the form. To continue, select the ***Clone*** button on the form which will copy all the details from the selected ARTG entry for use in the new application to vary.

Page 1 of the application form will then show the ARTG entry to be varied within the ***Sponsor's own reference*** field.

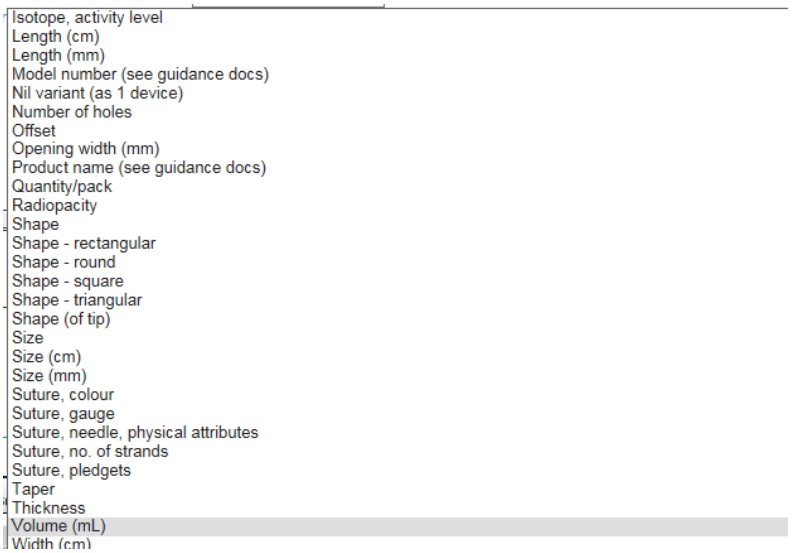
Select ***Next*** to continue.

You'll then go to the next page of the form, where you'll make the variation(s) to the ARTG entry. All the details you see initially are the same as the original device you selected to change.



You can modify the details for the ***Unique Product Identifier***, the ***Functional description***, and the ***Total number of devices covered***.

To add an entry to the ***Variant List***, first select the relevant ***Variant type*** (in this example, mL) from the drop-down list.

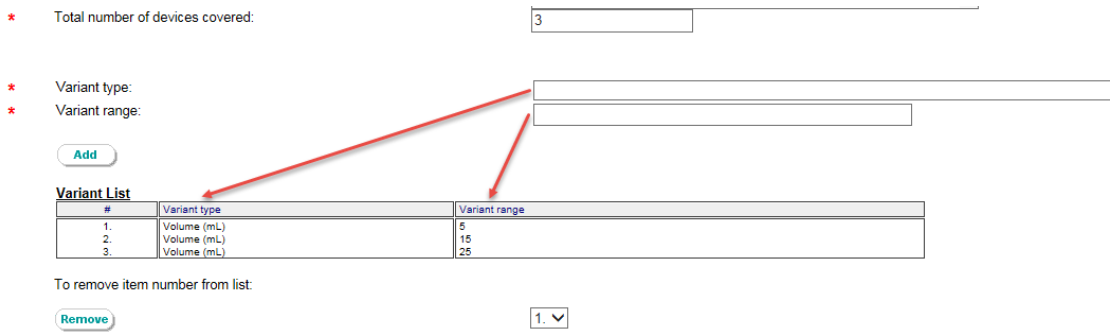


Then include the new amount for the ***Variant range***, and select ***Add***. The ***Variant List*** will then be updated. You can only add one entry at a time.

Note

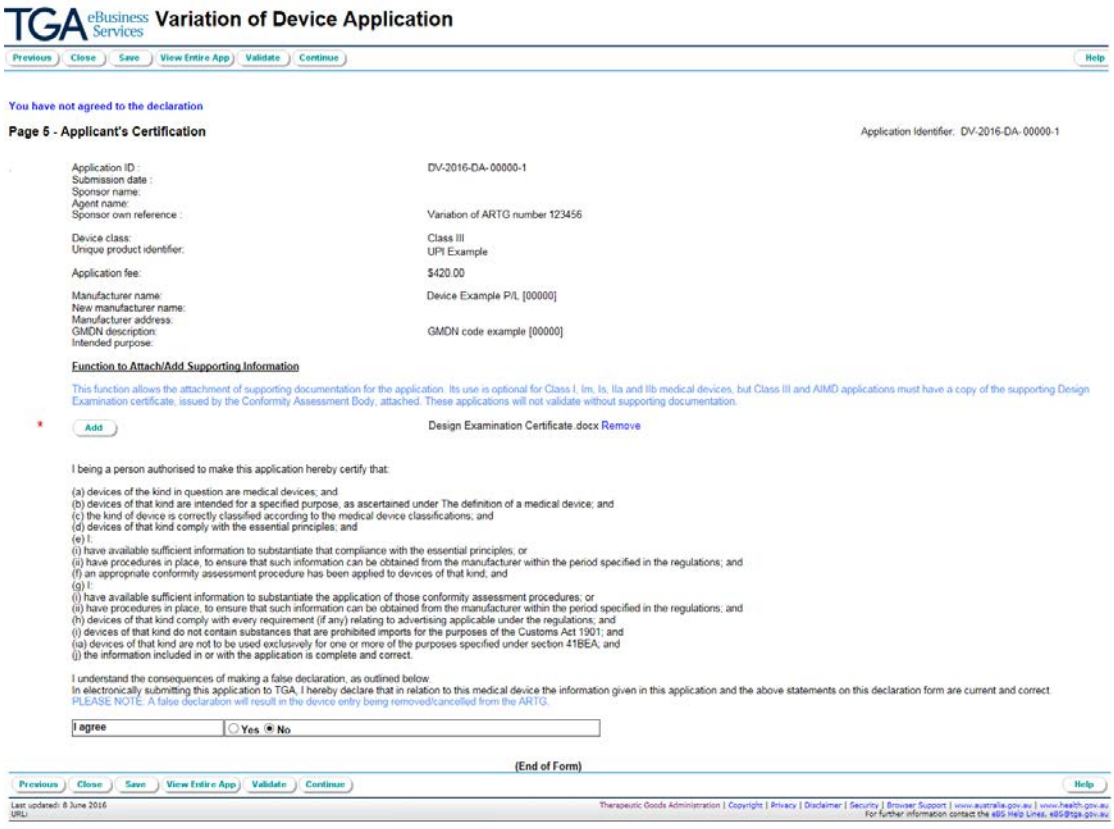
A value in the variant range must only relate to **one** physical characteristic of the device, e.g. diameter.

Different sizes of a variant type can be listed individually in the variant list or, for example, listed once with a variant range of "4 to 9", as long as that range doesn't also cover other physical characteristics of the device.



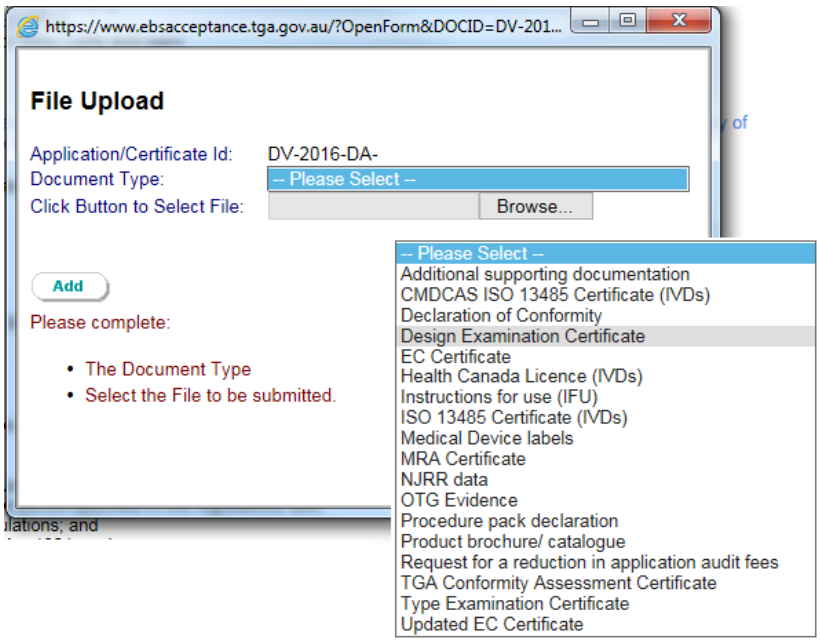
To remove an entry from the ***Variant List***, select the entry number (***#***) you want to delete using the small dropdown menu located directly below the list. Then select the ***Delete*** button. You can only delete one entry at a time.

Once you've finished modifying on this page, select the ***Next*** button to proceed.



The final page of the form allows you to review information, and attach supporting information.

To add an attachment, select the ***Add*** button which opens the ***File Upload*** box.



You will need to select the ***Document type*** (in this case, a Design Examination Certificate), and then select the ***Browse*** button to search for the document. Once complete, select the ***Add*** button to attach the document to your application.

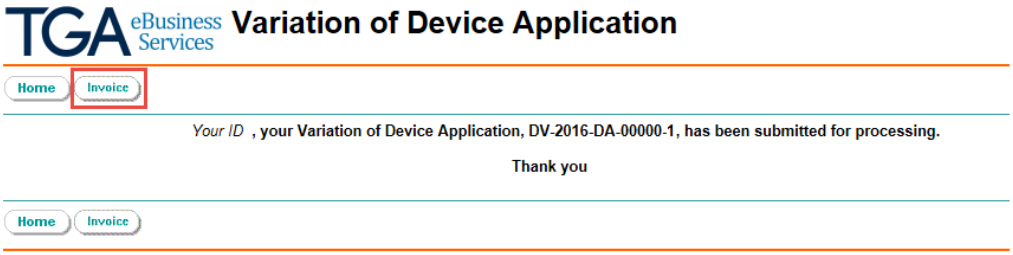
Please agree with the terms of the declaration, and select the ***Validate*** button.

If there are any validation errors, they will appear in 'blue bold' text in the top left hand corner of the form. You need to correct any of these to proceed.

Once you have successfully validated the application, select the ***Continue*** button to submit it.

Note

The fee for this change does not appear on the application form. We will email a tax invoice to you, or you can access one by selecting the Invoice button on the confirmation screen.



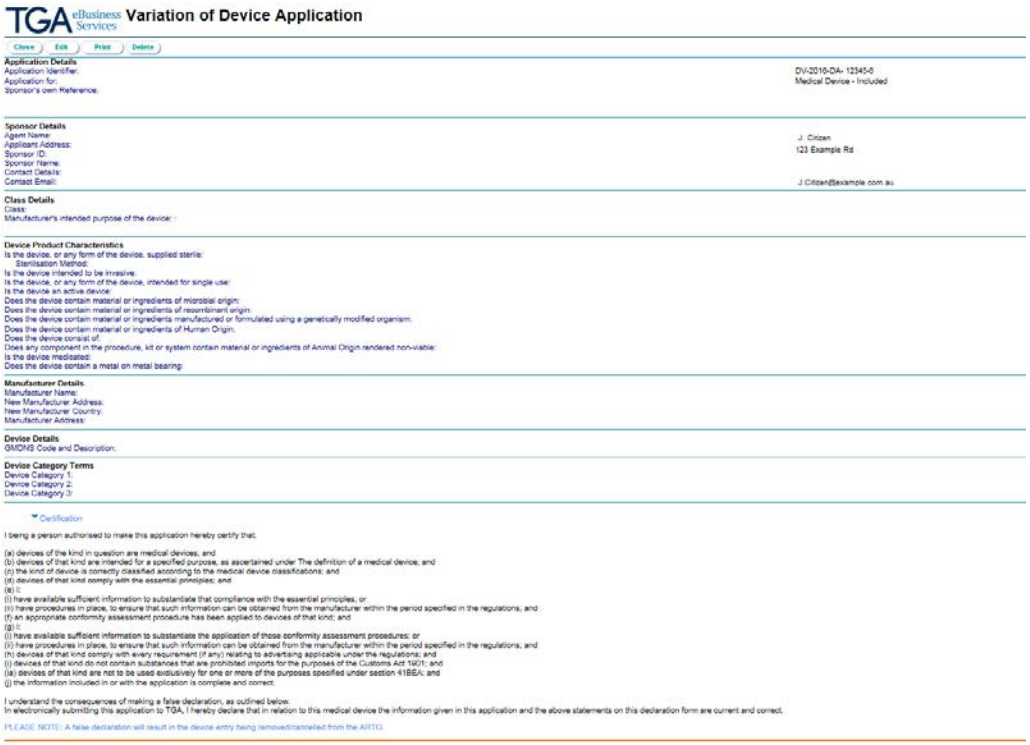
Reviewing the entire application before you submit

To do this, select the ***View Entire App*** button.

If you want to go back and change anything (or if you are happy to submit the application), select the Edit button to continue.

Note

If you select ***Close***, the application will be saved in your Drafts list.

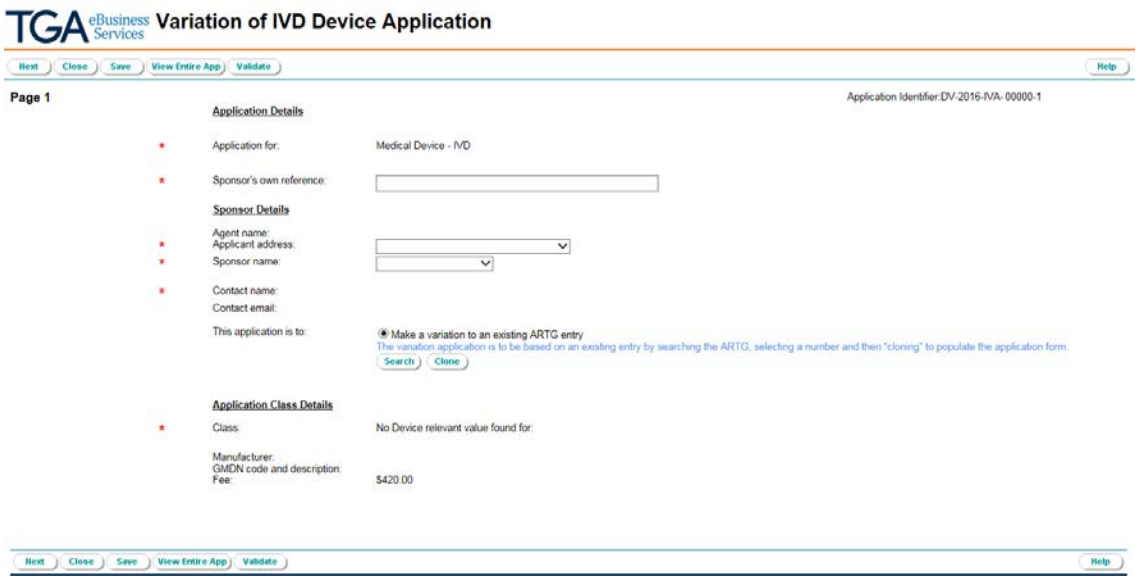


Note

The fee for this change does not appear on the application form; however a tax invoice is emailed to the sponsor.

IVD variation

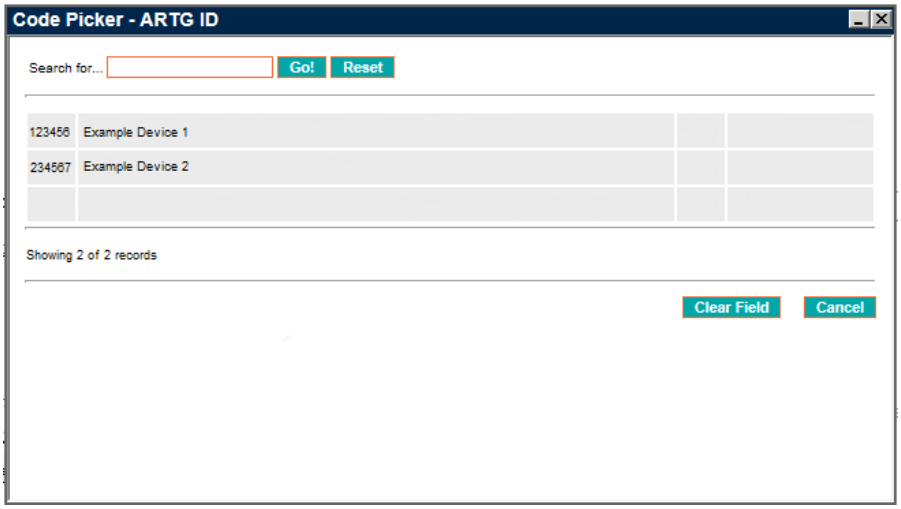
An application to vary an IVD entry is similar to the Class III/AIMD process, however the first page displays as ***Variation of IVD Device Application***.



You need to search for the ARTG entry you wish to vary, and selecting the Search button on page 1 of the form will open a new search window titled ***Code Picker – ARTG ID***.

This will list all of the ARTG entries you have for IVD medical devices. If the list is long (e.g. multiple pages), you can search by key words in the ***Search for...*** field to narrow the list.

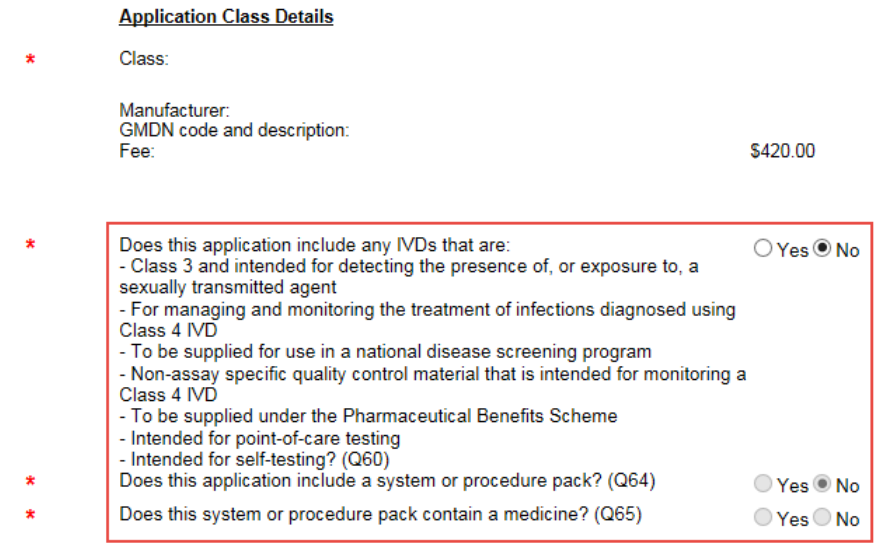
To choose the entry you want to vary, select it directly from the list. Once selected, the Code Picker window will close.



Once you have chosen the correct entry, its ARTG number will appear on page 1 of the form. To continue, select the ***Clone*** button on the form which will copy all the details from the selected ARTG entry for use in the new application to vary.

Page 1 of the application form will then show the ARTG entry to be varied within the ***Sponsor's own reference*** field.

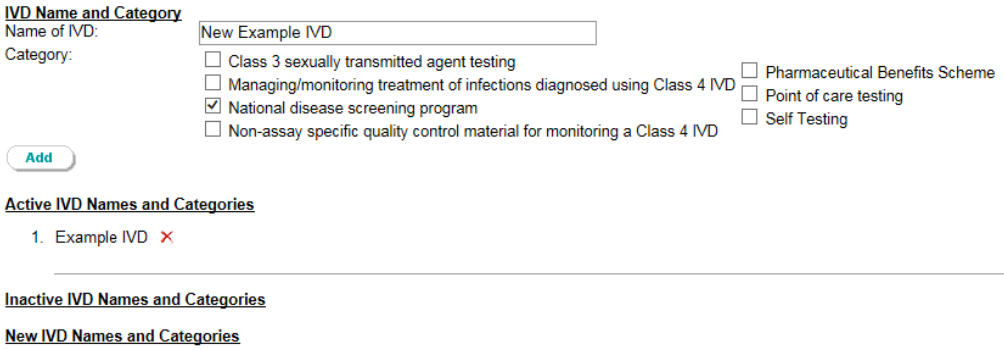
Additional questions will also appear under the Application Class Details heading, and these need to be completed before you can continue.



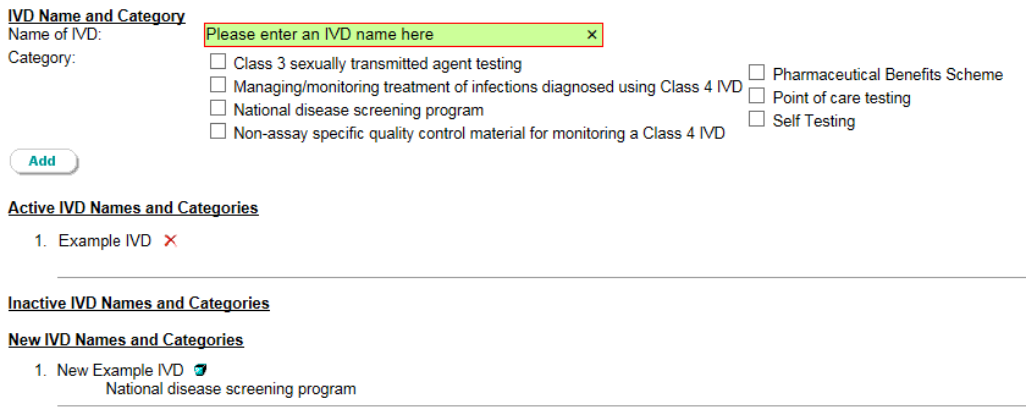
Selecting ***Yes*** to the first question opens additional fields to complete.

Caution

Please be aware that pressing the red cross immediately next to any entries in the ***Active IVD Names and Categories*** list will render that entry inactive, and remove it from the ARTG certificate.



Complete the relevant fields, and select the ***Add*** button to include the additional IVD on the ***New IVD Names and Categories*** list. Once you have added the extra details, select the ***Next*** button to continue.



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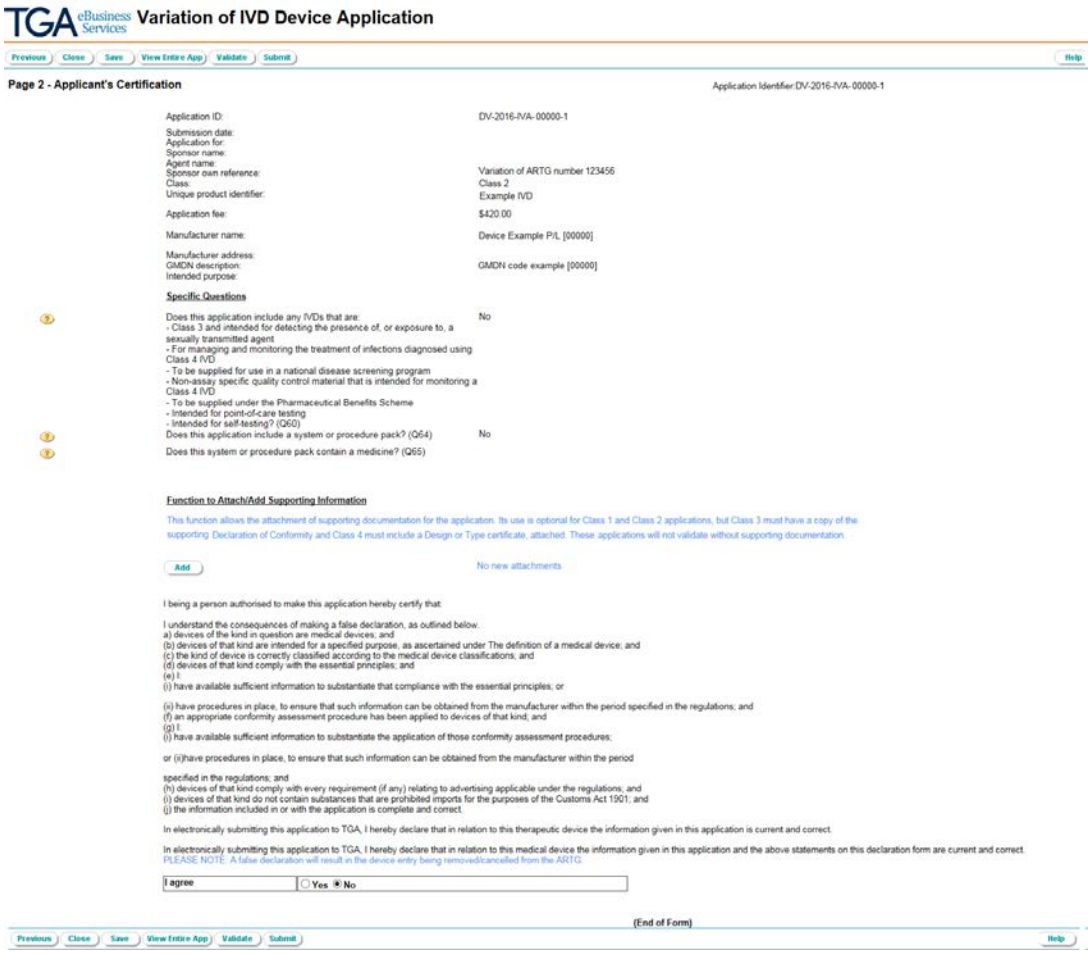
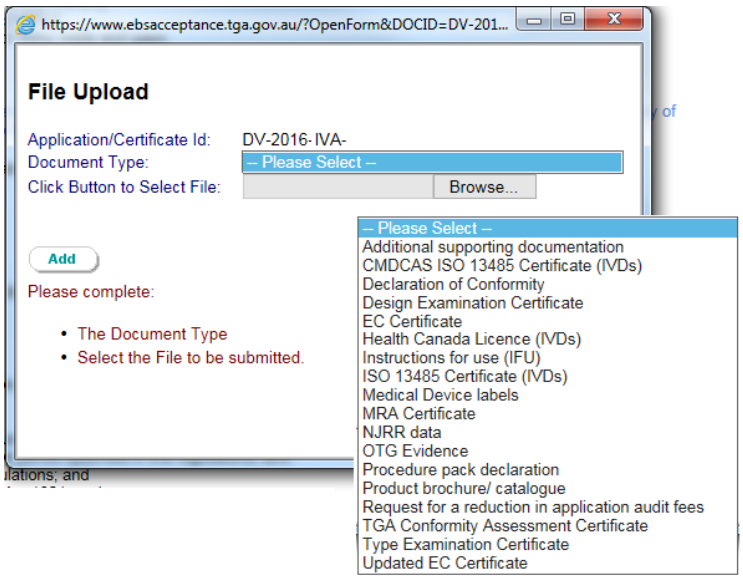


To attach supporting information, select the ***Add*** button which opens the ***File Upload*** box.

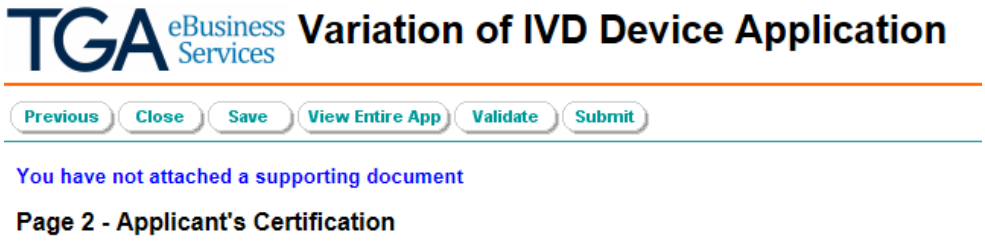


You will need to select ***Document type***, and then select the ***Browse*** button to search for the document. Once complete, select the ***Add*** button to attach the document to your application.

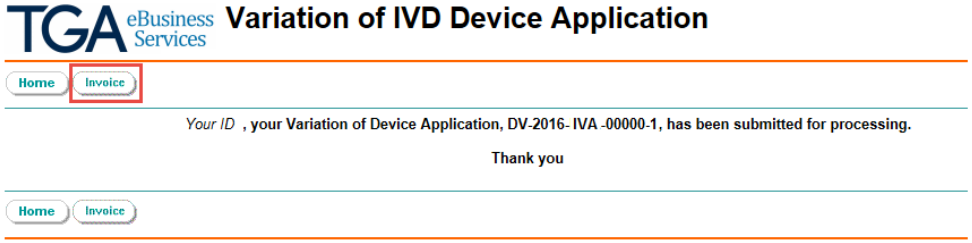
Please agree with the terms of the declaration, and select the ***Validate*** button.

If there are any validation errors, they will appear in 'blue bold' text in the top left hand corner of the form. You need to correct any of these to proceed.

Once you have successfully validated the application, select the ***Submit*** button.

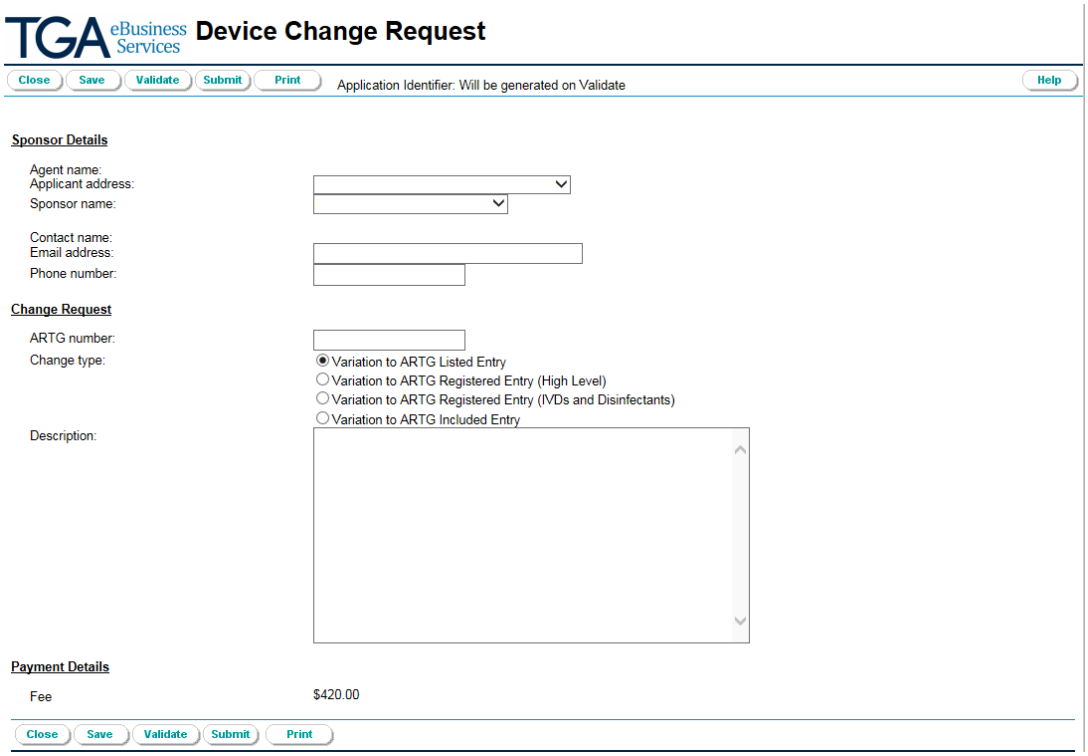


The fee for this change does not appear on the application form. We will email a tax invoice to you, or you can access it by selecting the ***Invoice*** button on the confirmation screen.



Request Change

There is only one page for this form. Confirm the Sponsor details before proceeding.



Enter the ARTG number you wish to change, select from the ***Change type*** options, and then provide a description of the requested change.

Once finished, select ***Validate***. If there are no validation errors, select ***Submit***.

Requesting the same change to multiple ARTG entries

Process

- If eligible, select one ARTG entry and submit one DCR form.
- Inform us that the same change impacts a number of ARTG entries (use the free text box in the DCR form to list all the affected ARTG entries you would like to vary).
- If we approve the DCR for the first ARTG entry, we will then make a decision about varying the other affected ARTG entries on our own initiative (i.e. no further DCRs or fees are required).

  This is only applicable if we decide that the same information to be assessed in the same way applies to all affected ARTG entries.
- You will receive one invoice for one fee.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch	30/11/2016

Therapeutic Goods Administration

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