



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

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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.

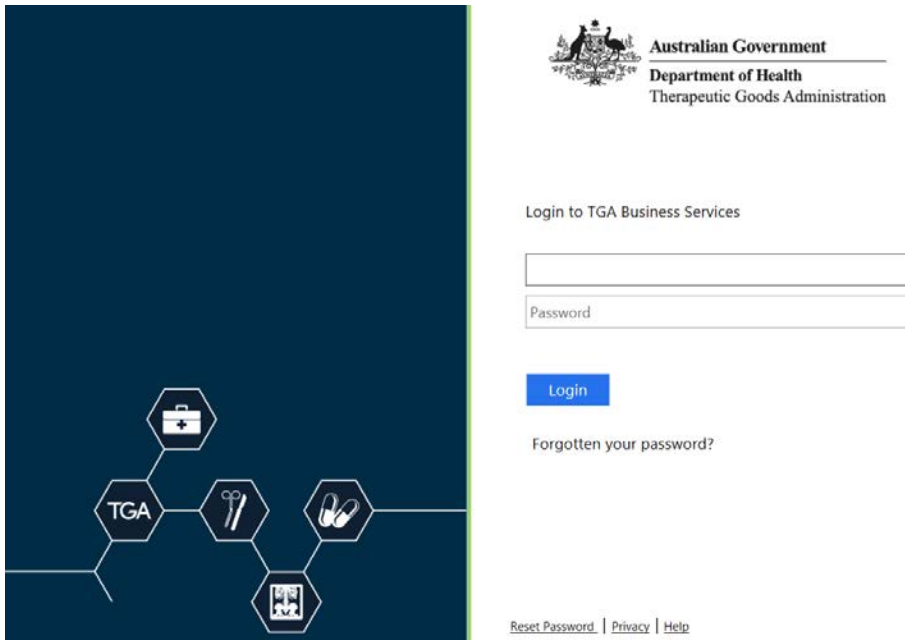
In ALL other cases, use the [Request Change](#) (Device Change Request) form.

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](#).

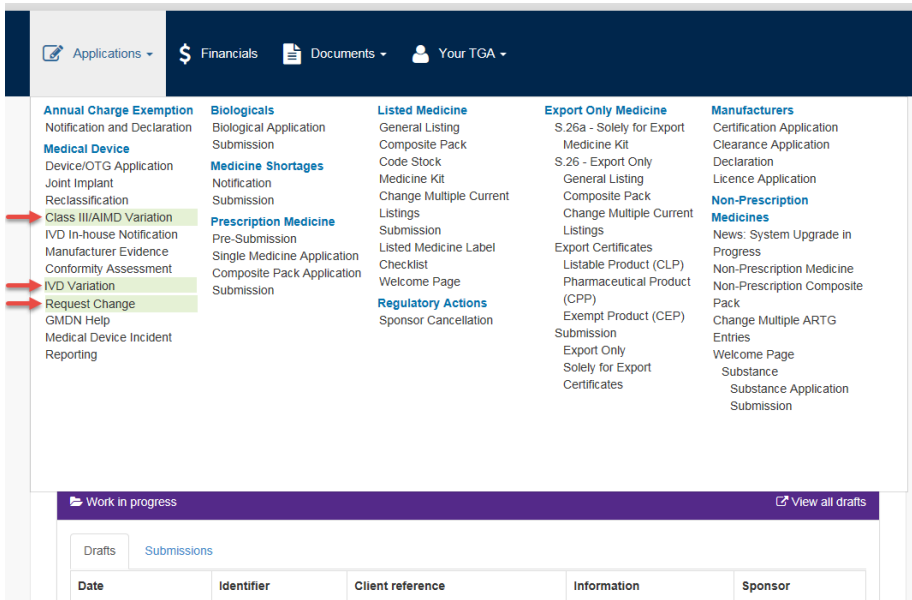
Step 1 - Login to TGA Business Services

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.

TGA eBusiness Services Variation of Device Application

Next Close Save View Entire App Validate

Page 1

Application Details

* Application for: Medical Device - Included

* Sponsor's own reference:

Sponsor Details

* Agent name:

* Applicant address:

* Sponsor name:

* Contact name:

Contact email

This application is to:

Make a variation to an existing ARTG entry

The variation application is to be based on an existing entry by searching the ARTG, selecting a number and then "cloning" to populate the application form.

Application Class Details

* Class No Device relevant value found for.

Next Close Save View Entire App Validate

Last updated: 21 March 2016
URL: <https://www.ebs.tga.gov.au/ebs/Devices/DeviceAp.nsf/DevAppVariation?OpenForm>

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.

ARTG ID	Device Name		
123458	Example Device 1		
234567	Example Device 2		

Showing 2 of 2 records

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.

TGA eBusiness Services Variation of Device Application

Page 2B - Manufacturing Details (Other Classes) Application Identifier: DV-2016-DA-00000-1

The variation application is for ARTG entry 123456

Manufacturer: Device Example P/L [00000]

GMDN code and description: GMDN code example [00000]

Unique product identifier: UPI Example

Functional description: Functional description example

Total number of devices covered: 4

Variant type: [Dropdown menu]

Variant range: [Text input]

Variant List

#	Variant type	Variant range
1	Volume (mL)	5
2	Volume (mL)	15
3	Volume (mL)	25

To remove item number from list: [Dropdown menu]

Remove [1]

Footer: Last updated: 3 June 2016 | Therapeutic Goods Administration | Copyright | Privacy | Disclaimer | Security | Browser Support | www.australia.gov.au | www.health.gov.au | For further information contact the eBS Help Lines: eBS@tga.gov.au

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.

- Isotope, activity level
- Length (cm)
- Length (mm)
- Model number (see guidance docs)
- Nil variant (as 1 device)
- Number of holes
- Offset
- Opening width (mm)
- Product name (see guidance docs)
- Quantity/pack
- Radiopacity
- Shape
- Shape - rectangular
- Shape - round
- Shape - square
- Shape - triangular
- Shape (of tip)
- Size
- Size (cm)
- Size (mm)
- Suture, colour
- Suture, gauge
- Suture, needle, physical attributes
- Suture, no. of strands
- Suture, pledgets
- Taper
- Thickness
- Volume (mL)
- Width (cm)

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.

* Total number of devices covered:

* Variant type:

* Variant range:

[Add](#)

Variant List

#	Variant type	Variant range
1.	Volume (mL)	5
2.	Volume (mL)	15
3.	Volume (mL)	25

To remove item number from list:

[Remove](#)

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.

TGA eBusiness Services Variation of Device Application

[Previous](#) [Close](#) [Save](#) [View Entire App](#) [Validate](#) [Continue](#) [Help](#)

You have not agreed to the declaration

Page 5 - Applicant's Certification Application Identifier: DV-2016-DA-00000-1

Application ID: DV-2016-DA-00000-1

Submission date:

Sponsor name:

Agent name:

Sponsor own reference: Variation of ARTG number 123456

Device class: Class III

Unique product identifier: UPI Example

Application fee: \$420.00

Manufacturer name: Device Example P/L [000000]

New manufacturer name:

Manufacturer address:

GMDN description: GMDN code example [00000]

Intended purpose:

Function to Attach/Add Supporting Information

This function allows the attachment of supporting documentation for the application. Its use is optional for Class I, Im, Is, Ila and Iib medical devices, but Class III and AIMD applications must have a copy of the supporting Design Examination certificate, issued by the Conformity Assessment Body, attached. These applications will not validate without supporting documentation.

* [Add](#) [Design Examination Certificate.docx](#) [Remove](#)

I being a person authorised to make this application hereby certify that:

(a) devices of the kind in question are medical devices; and
 (b) devices of that kind are intended for a specified purpose, as ascertained under the Definition of a medical device; and
 (c) the kind of device is correctly classified according to the medical device classifications; and
 (d) devices of that kind comply with the essential principles; and
 (e) I:
 (i) have available sufficient information to substantiate that compliance with the essential principles, or
 (ii) have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
 (f) an appropriate conformity assessment procedure has been applied to devices of that kind; and
 (g) I:
 (i) have available sufficient information to substantiate the application of those conformity assessment procedures; or
 (ii) have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
 (h) devices of that kind comply with every requirement (if any) relating to advertising applicable under the regulations; and
 (i) devices of that kind do not contain substances that are prohibited imports for the purposes of the Customs Act 1901; and
 (j) devices of that kind are not to be used exclusively for one or more of the purposes specified under section 41BEA, and
 (k) the information included in or with the application is complete and correct.

I understand the consequences of making a false declaration, as outlined below.
 In electronically submitting this application to TGA, I hereby declare that in relation to this medical device the information given in this application and the above statements on this declaration form are current and correct.
PLEASE NOTE: A false declaration will result in the device entry being removed/cancelled from the ARTG.

agree Yes No

(End of Form)

[Previous](#) [Close](#) [Save](#) [View Entire App](#) [Validate](#) [Continue](#) [Help](#)

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 For further information contact the eBS Help Line: 480928282

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.

You have not attached a supporting document

Page 5 - Applicant's Certification

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.

TGA eBusiness Services Variation of Device Application

[Home](#) [Invoice](#)

Your ID , your Variation of Device Application, DV-2016-DA-00000-1, has been submitted for processing.

Thank you

[Home](#) [Invoice](#)

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.

TGA eBusiness Services Variation of Device Application

[Close](#) [Edit](#) [Print](#) [Delete](#)

Application Details	
Application Identifier:	DV-2016-DA-12345-0
Application for:	Medical Device - Included
Sponsor's own Reference:	
Sponsor Details	
Agent Name:	J. Citizen
Applicant Address:	123 Example Rd
Sponsor ID:	
Sponsor Name:	
Contact Details:	
Contact Email:	J.Citizen@example.com.au
Class Details	
Class:	
Manufacturer's intended purpose of the device:	
Device Product Characteristics	
Is the device, or any form of the device, supplied sterile:	
Sterilisation Method:	
Is the device intended to be invasive:	
Is the device, or any form of the device, intended for single use:	
Is the device an active device:	
Does the device contain material or ingredients of microbial origin:	
Does the device contain material or ingredients of microbial origin:	
Does the device contain material or ingredients manufactured or formulated using a genetically modified organism:	
Does the device contain material or ingredients of Human Origin:	
Does the device consist of:	
Does any component in the procedure, kit or system contain material or ingredients of Animal Origin rendered non-viable:	
Is the device medicated:	
Does the device contain a metal on metal bearing:	
Manufacturer Details	
Manufacturer Name:	
Head Manufacturer Address:	
Head Manufacturer Country:	
Manufacturer Address:	
Device Details	
GMDS Code and Description:	
Device Category Terms	
Device Category 1:	
Device Category 2:	
Device Category 3:	
Declaration	
I being a person authorised to make this application hereby certify that:	
(a) devices of the kind in question are medical devices; and	
(b) devices of that kind are intended for a specified purpose, as ascertained under The definition of a medical device; and	
(c) the kind of device is correctly classified according to the medical device classifications; and	
(d) devices of that kind comply with the essential principles; and	
(e) I have available sufficient information to substantiate that compliance with the essential principles; or	
(f) I have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and	
(g) an appropriate conformity assessment procedure has been applied to devices of that kind; and	
(h) I have available sufficient information to substantiate the application of those conformity assessment procedures; or	
(i) I have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and	
(j) devices of that kind comply with every requirement (if any) relating to advertising applicable under the regulations; and	
(k) devices of that kind do not contain substances that are prohibited imports for the purposes of the Customs Act 1901; and	
(l) devices of that kind are not to be used exclusively for one or more of the purposes specified under section 41BE(1); and	
(m) the information included in or with the application is complete and correct.	
I understand the consequences of making a false declaration, as outlined below.	
In electronically submitting this application to TGA, I hereby declare that in relation to this medical device the information given in this application and the above statements on this declaration form are current and correct.	
PLEASE NOTE: A false declaration will result in the device entry being removed/cancelled from the ARTG.	



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**.

TGA eBusiness Services Variation of IVD Device Application

Page 1 Application Identifier: DV-2016-IVA-00000-1

Application Details

- * Application for: Medical Device - IVD
- * Sponsor's own reference:

Sponsor Details

- * Agent name:
- * Applicant address:
- * Sponsor name:
- * Contact name:
- * Contact email:

This application is to: Make a variation to an existing ARTG entry
The variation application is to be based on an existing entry by searching the ARTG, selecting a number and then "cloning" to populate the application form.

Application Class Details

- * Class: No Device relevant value found:
- Manufacturer: GMDIN code and description: \$420.00
- Fee: \$420.00

Navigation:

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.

Code Picker - ARTG ID

Search for...

123456	Example Device 1		
234567	Example Device 2		

Showing 2 of 2 records

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.

Application Class Details

* Class:

Manufacturer:
GMDN code and description:
Fee: \$420.00

* Does this application include any IVDs that are: Yes No

- Class 3 and intended for detecting the presence of, or exposure to, a sexually transmitted agent
- For managing and monitoring the treatment of infections diagnosed using Class 4 IVD
- To be supplied for use in a national disease screening program
- Non-assay specific quality control material that is intended for monitoring a Class 4 IVD
- To be supplied under the Pharmaceutical Benefits Scheme
- Intended for point-of-care testing
- Intended for self-testing? (Q60)

* Does this application include a system or procedure pack? (Q64) Yes No

* Does this system or procedure pack contain a medicine? (Q65) Yes No

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.

IVD Name and Category

Name of IVD:

Category:

<input type="checkbox"/> Class 3 sexually transmitted agent testing	<input type="checkbox"/> Pharmaceutical Benefits Scheme
<input type="checkbox"/> Managing/monitoring treatment of infections diagnosed using Class 4 IVD	<input type="checkbox"/> Point of care testing
<input checked="" type="checkbox"/> National disease screening program	<input type="checkbox"/> Self Testing
<input type="checkbox"/> Non-assay specific quality control material for monitoring a Class 4 IVD	

Active IVD Names and Categories

1. Example IVD

Inactive IVD Names and Categories

New IVD Names and Categories

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.

IVD Name and Category

Name of IVD:

Please enter an IVD name here

Category:

- Class 3 sexually transmitted agent testing
- Managing/monitoring treatment of infections diagnosed using Class 4 IVD
- National disease screening program
- Non-assay specific quality control material for monitoring a Class 4 IVD
- Pharmaceutical Benefits Scheme
- Point of care testing
- Self Testing

Add

Active IVD Names and Categories

- 1. Example IVD

Inactive IVD Names and Categories

New IVD Names and Categories

- 1. New Example IVD National disease screening program

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

TGA eBusiness Services

Variation of IVD Device Application

Previous Close Save View Entire App Validate Submit
Help

Page 2 - Applicant's Certification
Application Identifier: DV-2016-IVA-00000-1

Application ID: Submission date: Application for: Sponsor name: Agent name: Sponsor own reference: Class: Unique product identifier: Application fee: Manufacturer name: Manufacturer address: GMDN description: Intended purpose:	DV-2016-IVA-00000-1 Variation of ARTG number 123456 Class 2 Example IVD \$420.00 Device Example P/L, [000000] GMDN code example [00000]
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Specific Questions

1 Does this application include any IVDs that are:
 - Class 3 and intended for detecting the presence of, or exposure to, a sexually transmitted agent
 - For managing and monitoring the treatment of infections diagnosed using Class 4 IVD
 - To be supplied for use in a national disease screening program
 - Non-assay specific quality control material that is intended for monitoring a Class 4 IVD
 - To be supplied under the Pharmaceutical Benefits Scheme
 - Intended for point-of-care testing
 - Intended for self-testing? (Q63) No

2 Does this application include a system or procedure pack? (Q64) No

2 Does this system or procedure pack contain a medicine? (Q65)

Function to Attach/Add Supporting Information

This function allows the attachment of supporting documentation for the application. Its use is optional for Class 1 and Class 2 applications, but Class 3 must have a copy of the supporting Declaration of Conformity and Class 4 must include a Design or Type certificate, attached. These applications will not validate without supporting documentation.

Add No new attachments

I being a person authorised to make this application hereby certify that:

I understand the consequences of making a false declaration, as outlined below:

(a) devices of the kind in question are medical devices; and
 (b) devices of that kind are intended for a specified purpose, as ascertained under The definition of a medical device; and
 (c) the kind of device is correctly classified according to the medical device classifications; and
 (d) devices of that kind comply with the essential principles; and
 (e) I
 (i) have available sufficient information to substantiate that compliance with the essential principles; or
 (ii) have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
 (f) an appropriate conformity assessment procedure has been applied to devices of that kind; and
 (g) I
 (i) have available sufficient information to substantiate the application of those conformity assessment procedures; or
 (ii) have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
 (h) devices of that kind comply with every requirement (if any) relating to advertising applicable under the regulations; and
 (i) devices of that kind do not contain substances that are prohibited imports for the purposes of the Customs Act 1901; and
 (j) the information included in or with the application is complete and correct.

In electronically submitting this application to TGA, I hereby declare that in relation to this therapeutic device the information given in this application is current and correct.

In electronically submitting this application to TGA, I hereby declare that in relation to this medical device the information given in this application and the above statements on this declaration form are current and correct.

PLEASE NOTE: A false declaration will result in the device entry being removed/cancelled from the ARTG.

I agree Yes No

Previous Close Save View Entire App Validate Submit
(End of Form)
Help

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

https://www.ebsacceptance.tga.gov.au/?OpenForm&DOCID=DV-201...

File Upload

Application/Certificate Id: DV-2016-IVA-
 Document Type: -- Please Select --
 Click Button to Select File:

Please complete:

- The Document Type
- Select the File to be submitted.

-- Please Select --
 Additional supporting documentation
 CMDCAS ISO 13485 Certificate (IVDs)
 Declaration of Conformity
 Design Examination Certificate
 EC Certificate
 Health Canada Licence (IVDs)
 Instructions for use (IFU)
 ISO 13485 Certificate (IVDs)
 Medical Device labels
 MRA Certificate
 NJRR data
 OTG Evidence
 Procedure pack declaration
 Product brochure/ catalogue
 Request for a reduction in application audit fees
 TGA Conformity Assessment Certificate
 Type Examination Certificate
 Updated EC Certificate

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.

TGA eBusiness Services Variation of IVD Device Application

You have not attached a supporting document

Page 2 - Applicant's Certification

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.


TGA eBusiness Services Variation of IVD Device Application

Your ID , your Variation of Device Application, DV-2016-IVA-00000-1, has been submitted for processing.

Thank you

Request Change

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



Device Change Request

Application Identifier: Will be generated on Validate
Help

Sponsor Details

Agent name:

Applicant address:

Sponsor name:

Contact name:

Email address:

Phone number:

Change Request

ARTG number:

Change type:

- Variation to ARTG Listed Entry
- Variation to ARTG Registered Entry (High Level)
- Variation to ARTG Registered Entry (IVDs and Disinfectants)
- Variation to ARTG Included Entry

Description:

Payment Details

Fee: \$420.00

Close
Save
Validate
Submit
Print

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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<https://www.tga.gov.au>

Reference/Publication # [R16/917484](#)