Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Guidance for completing an application for consent to import, supply, or export a medical device that does not comply with the Essential Principles

Guidance for the consent application form on the TGA Business Services (TBS) portal

Version 2.1, July 2023

Contents

Introduction

This document provides guidance on how to successfully complete and submit an application for consent to import, supply, or export a medical device that does not comply with the Essential Principles (EPs).

The TGA has modernised the consent application process, moving from a paper form to an online form. The new form, hosted in the TGA Business Services (TBS) portal, streamlines the application process and allows for greater functionality, including the ability for sponsors to view their current and previous applications for consent.

There are criminal offences under section 41MA and civil penalties under section 41MAA of the *Therapeutic Goods Act 1989* (the Act), for importing, supplying, or exporting medical devices that do not meet the Essential Principles (EPs) for safety and performance, unless consent has been granted by the Secretary of the Department of Health and Aged Care.

The TGA expects compliance with the EPs, however there may be some extenuating circumstances preventing compliance to one or more parts of an Essential Principle for a limited period of time.

NOTE: If your non-compliant device(s) is currently part of an application to vary the device or manufacturer's evidence or is part of an Application for Inclusion in the Australian Register of Therapeutic Goods (ARTG), you still need to apply for consent to be able to import, supply, or export the device(s) if they are non-compliant with the EPs.

In seeking consent an authorised representative of the sponsor needs to:

- complete and submit the application for 'consent to import, supply, or export a medical device that does not comply with the Essential Principles' through the TBS sponsor portal;
- upload all relevant documents as part of this application; and
- pay the applicable processing fees in full.

Multiple devices included in one application

An application for consent can include entries included in the ARTG or medical devices that are currently part of an Application for Inclusion in the ARTG that do not comply with the same EPs. Each application form can accommodate multiple ARTG entries or Applications for Inclusion.

Note

One application form can be used for requesting consent to import, supply, or export multiple medical devices that do not comply with same Essential Principle(s).

Application / Processing Fees

Processing fees apply to **each** ARTG entry/Application for Inclusion included in the application.

The fee paid for the application is not refundable.**Consent for devices that are non-compliant solely with EP 13**

On 29 September 2022, amendments to the Therapeutic Goods (Medical Device) Regulations 2002 came into effect to introduce fee concessions to reduce the regulatory costs for sponsors of ARTG entry(s) supported by EU MDD/IVDD certifications who are transitioning to the EU MDR/IVDR and seeking consent to import, supply or export their devices where they do not have compliant information to be provided with their medical devices (EP13).

The application fee for consent has been reduced to a flat fee per ARTG entry where the application is made solely in relation to non-compliance with EP 13 (information supplied by the manufacturer) due to transitioning from EU MDD/IVDD to EU MDR/IVDR certification.

Consent for devices that are non-compliant solely with EP 13A

On 29 October 2021, amendments the Therapeutic Goods (Medical Device) Regulations 2002 came into effect providing for reduced fees for applications for consent to import, supply or export medical devices that are non-compliant with Essential Principles related to patient information material.

The application fee for consent has been reduced to a flat fee per ARTG entry / Application for Inclusion where the application is made solely in relation to non-compliance with EP 13A (patient information materials).

How do I calculate my fees?

Fees are calculated using the total number of ARTG entries/Applications for Inclusion in the consent application.

For example (this may not reflect the current fees), if your application for consent pertains to 220 ARTG entries which are non-compliant with EPs other than, or in addition to, EP 13A, the fees are calculated as $500 for the first ARTG entry plus $100 for each of the remaining 219 ARTG entries [that is: ($500 x 1) + ($100 x 219) = $22,400].

If your application for consent pertains to 220 ARTG entries which are non-compliant solely with EP 13A, the fees are calculated as $30 x 220 ARTG entries [that is: 220 x 30= $6,600].

How to pay

There are two ways to pay the processing fees for the consent application.

1. **IMMEDIATE PAYMENT** – You can pay the processing fees for your consent application immediately after completing and submitting the application. To do this:
    a. Calculate the total fees for your application based on the number of ARTG entries or Applications for Inclusion, as per the example above.
    b. Go to the TGA payment page (https://www.bpoint.com.au/payments/TGA)
    c. In the Biller Code field choose option 9 – “Exemption under S41MA device”
    d. Enter your client ID number in the box provided.
    e. Enter the consent application ID/ reference number (provided on submission) in the “ARTG No.” field to link the payment to your application.
    f. Enter the total amount of fees to be paid in AUD.
    g. Select the payment method.
    h. Follow the instructions to complete the credit card payment.

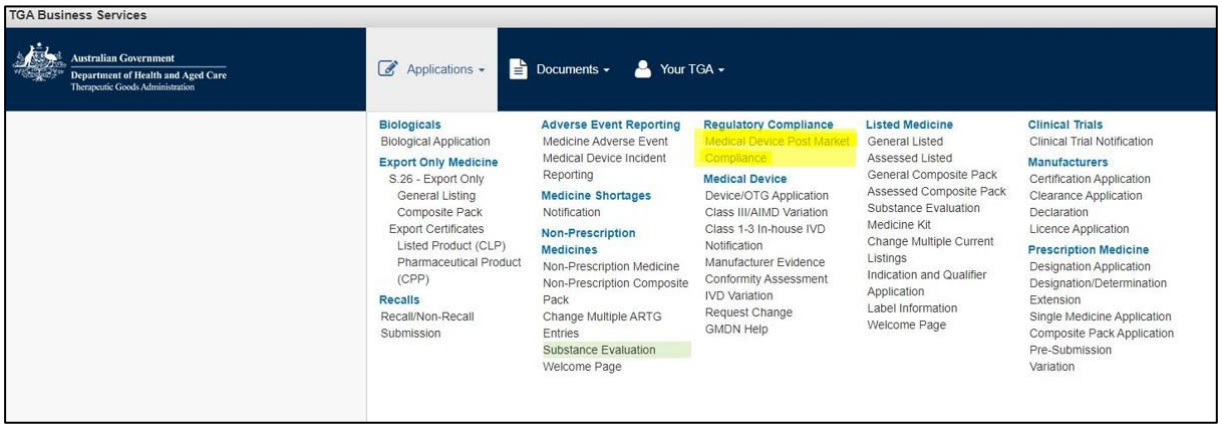
Your application and payment will be linked during processing using the TBS Client ID number and the consent application ID provided in the payment details.

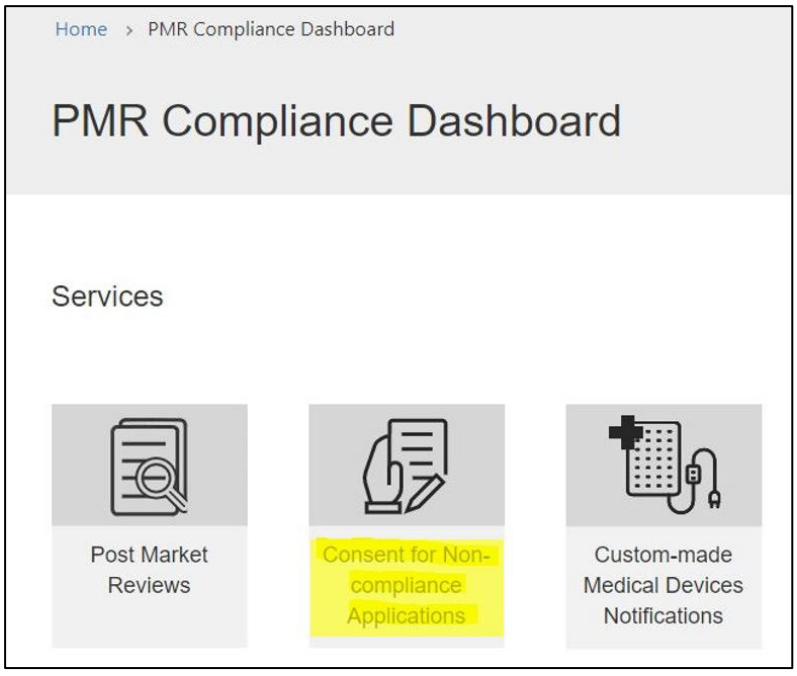
2. **PAYMENT AGAINST INVOICE** - If you require the TGA to raise an invoice for payment, simply complete and submit your application for consent, and the TGA will raise and send the submitter an invoice for the processing fees.

NOTE: Applications for consent will only be processed once the application fees have been paid in full.

The application form

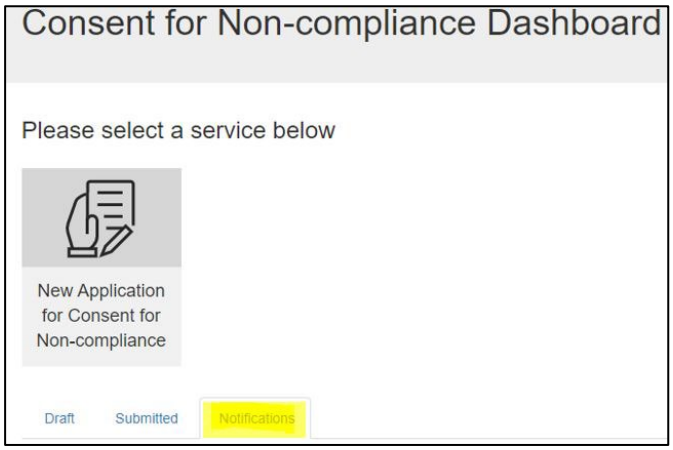
Once you log-in to the TBS portal, in the 'Applications' drop-down menu, select the 'Medical Device Post Market Compliance' option under the 'Regulatory Compliance' heading. Doing so will take you to the 'PMR Compliance Dashboard' where you can select the 'Consent for Non-compliance Applications' tile to access the next dashboard and start a new application, edit an existing application or view your previous applications.





On the 'Consent for Non-compliance Dashboard', you will find options to view 'Draft' consent applications, 'Submitted' consent applications, and 'Notifications' related to consent applications.

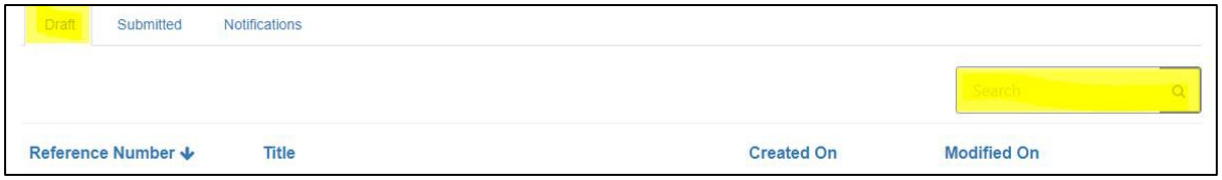
You can choose the 'Draft' tab to review or edit consent applications that are in draft and not yet submitted by your organisation. You can choose the 'Submitted' tab to view details of consent applications previously submitted by your organisation. The 'Notifications' tab is to view any notifications related to devices that are part of an approved consent application.



Please note that you will not be able to edit an application once it is submitted and you will need to contact the TGA if you wish to make any amendments to a submitted application. Your request will be considered on a case-by-case basis. You may, however, withdraw an application after it has been submitted. More information can be found in the 'Withdrawing an application' section of this guidance document.

You can search for a submitted application using the search box (indicated by the magnifying glass symbol) by the name (title) of the application, reference number, or who submitted it. The search function will also allow for partial text searches by typing an asterisk (*) at the beginning of the search as the wildcard character. You can also sort the table by clicking on the column heading to change the order of the reference number, title, date the application was created/modified on, and the submitter of the application.

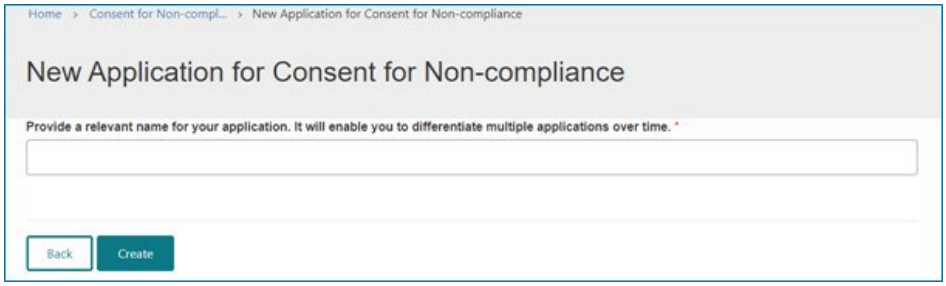
Similarly, you can search for a draft application using the search box (indicated by the magnifying glass symbol) by the name (title) of the application or reference number. The search function will also allow for partial text searches by typing an asterisk (*) as the wildcard character. You can also sort the table by clicking on the column heading to change the order of the reference number, title, or the date the application was created or modified.



Start a new application

On the dashboard, select the ‘New Application’ tile to start a new consent application.

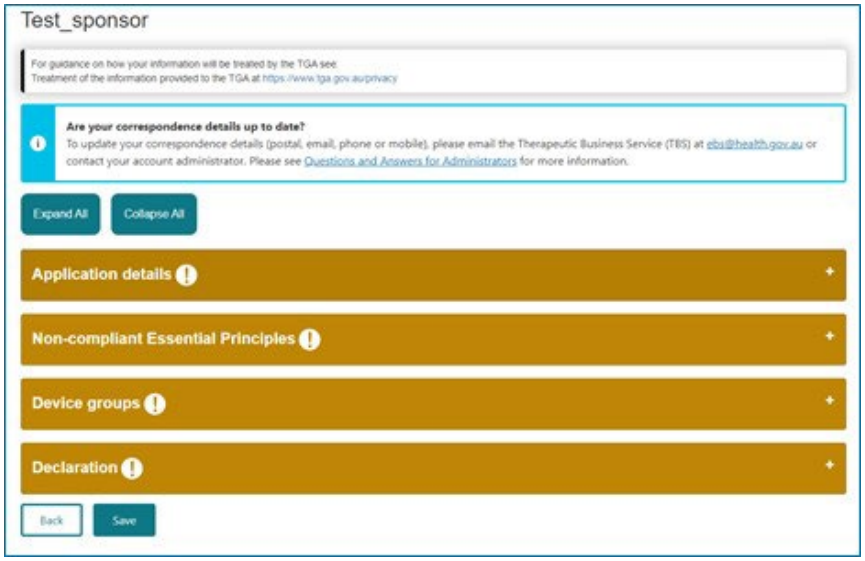
A window will open in the current view, where you will be prompted to provide a name for the application.



You can name the application anything that you think is relevant or meaningful to your organisation. Providing a relevant name will enable you to differentiate applications over time. Once you type in the name of the application, select the ‘Create’ button.

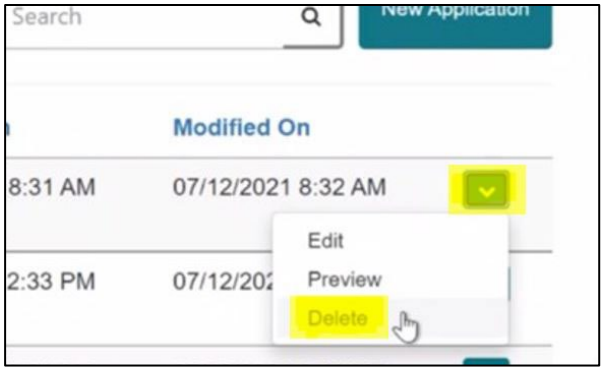
Your new application will be created, ready for you to complete the different sections of the application. The name of your application will appear at the top of the page. An application reference number (consent application ID) is also generated at this point. This consent application ID is quoted in any communication with the TGA regarding this application and is also used in the payment process if the immediate payment option is chosen for the payment of application fees. The consent application ID can be found in the ‘Application details’ section of the form.

If you want to save the application to complete at another time, press the ‘Save’ button at the bottom of the page.

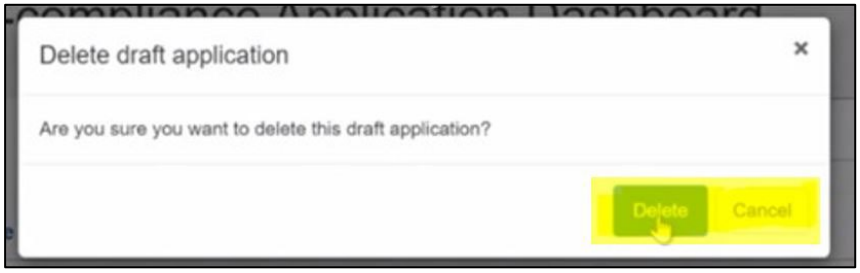


The newly created application will be available to view on the ‘Draft’ tab of the dashboard.

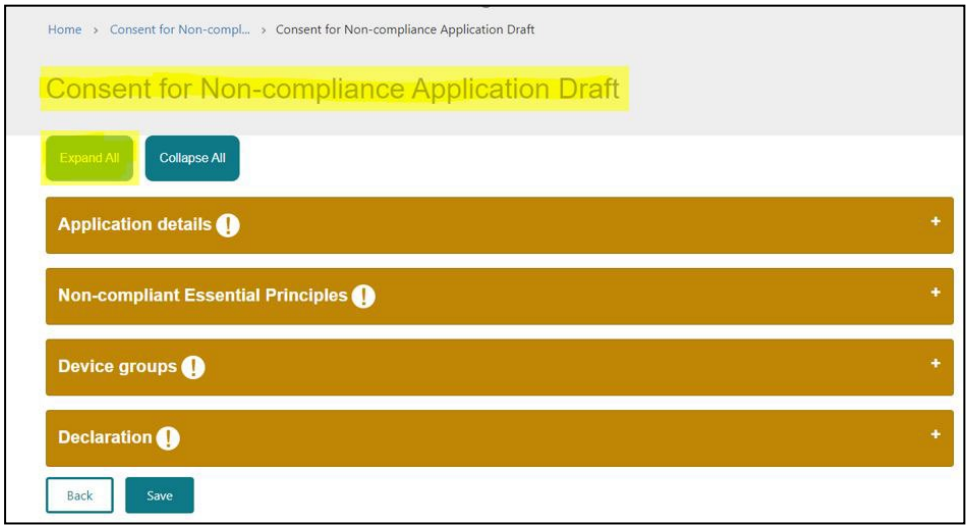
Applications on the 'Draft Consent Applications' view can be deleted permanently. To do so, click the down-arrow on the right side of the relevant application and select 'Delete'.



If you select 'Delete' a prompt will appear to confirm your action. Select 'Delete' if you wish to permanently delete the application or 'Cancel' if you do not wish to delete.



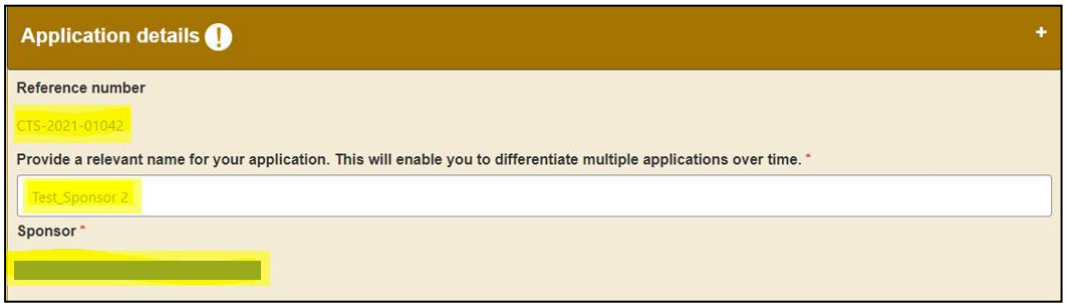
To continue with the application, click the down-arrow on the right side of the application details and select 'Edit'. This will take you to the landing page 'Consent for Non-compliance Application Draft', where you can select and complete different sections of the application form.



There is an option to 'Expand All' sections at once or you can expand one section at a time. Start the application by clicking on the 'Application details' section.

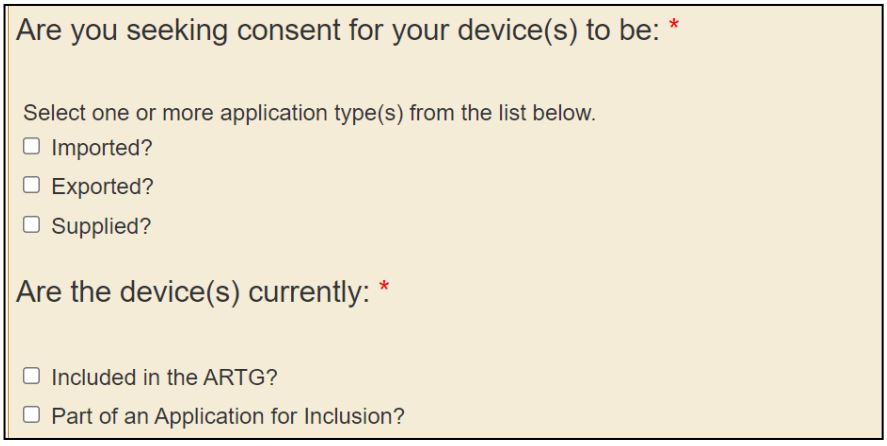
At this stage, the sections will be amber in colour, to reflect mandatory information is required before the application can be submitted. When all the mandatory information in a section is completed, the section will change colour to green. The mandatory fields are indicated with a red asterisk (*)

Application details section

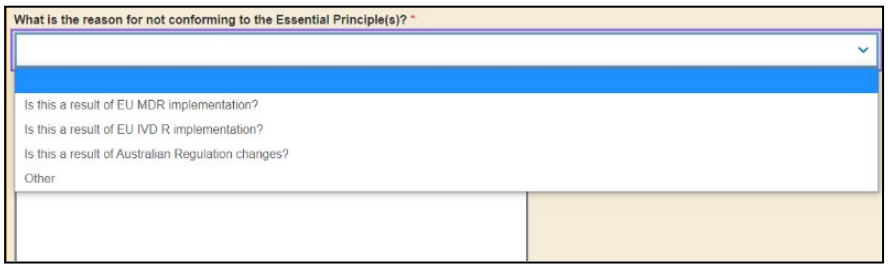


At the top of this section, you will find the application reference number (consent application ID), which can be quoted in communication with the TGA regarding this application. The fields with the application name and the sponsor's name will be auto-populated. You can change the name of the application by typing the revised name in the field provided.
Next, select whether you are seeking consent for the non-compliant device(s) to be imported, exported, or supplied. You can select one or multiple options. This is a mandatory field and at least one option must be selected.

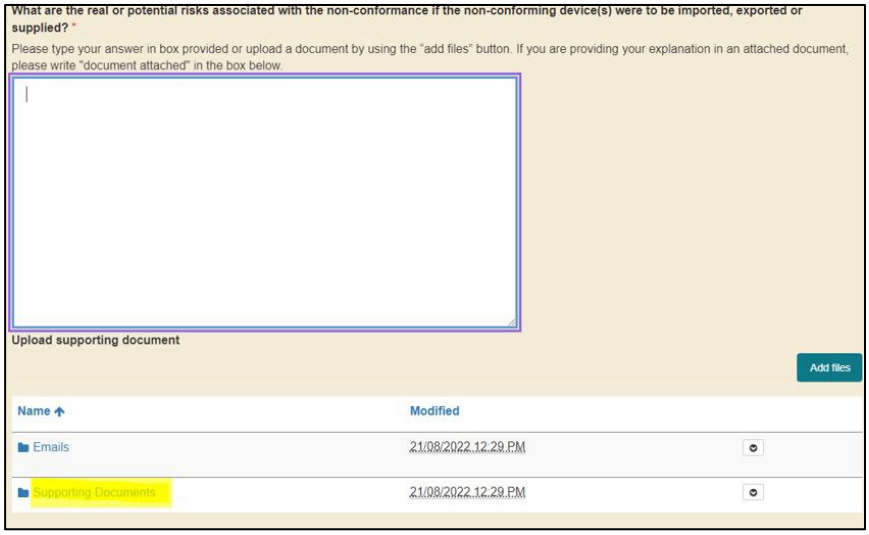
Next, you can select whether this application is in relation to device(s) that are already included in the ARTG and/or if the device(s) are a part of an Application for Inclusion in the ARTG. One application for consent can be submitted for both, provided the devices are non-compliant with same EPs. This is a mandatory field and at least one option must be selected.



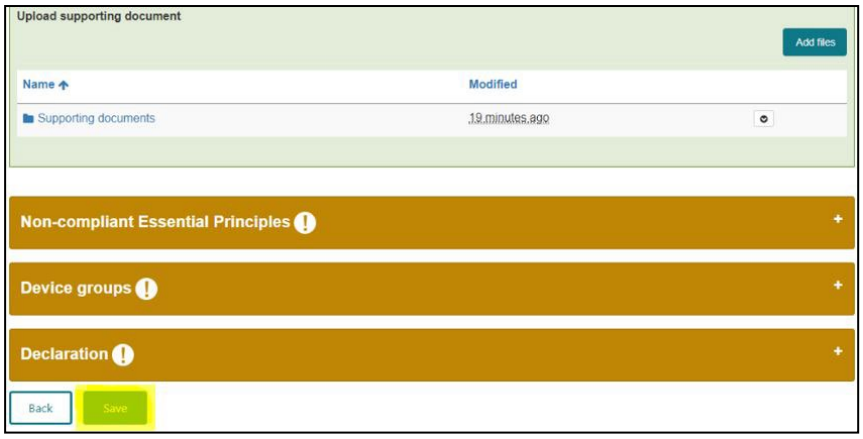
Next, you can specify the reason for non-conformance to the EP(s). You may select one of the provided options in the drop-down menu or select ‘Other’ if a suitable option is not available. If you select ‘Other’, a free text box will appear where you must provide an explanation for the non-conformance. This is a mandatory field and at least one option must be selected.

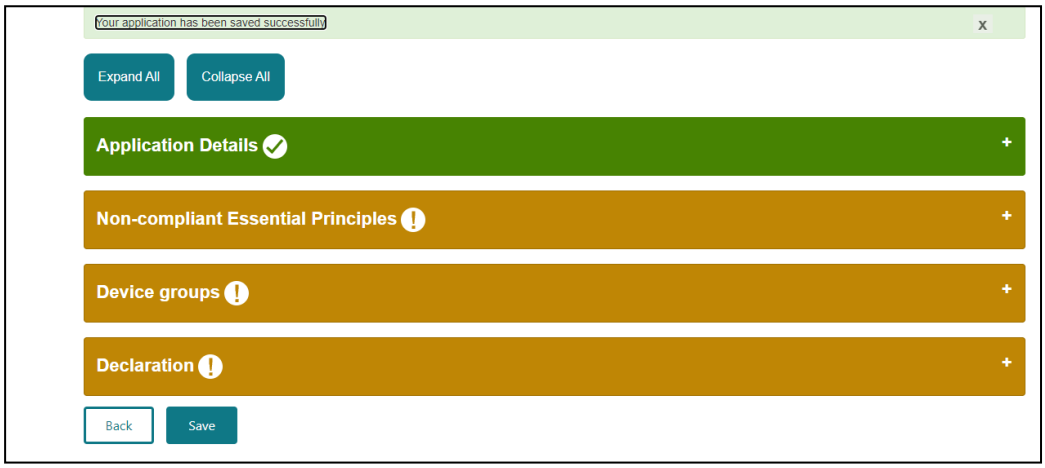


Next, you must provide an explanation of the real or potential risks associated with the non-conformance, if the non-conforming device(s) were to be imported, exported, or supplied. You may provide your response by typing in the text box, or by uploading document(s). To upload a document, click on the ‘Supporting Documents’ folder link and then press the ‘Add files’ button. Microsoft Word, Excel, and Adobe Acrobat documents, with a file size of up to 50MB, can be uploaded. As this is a text box is a mandatory field, if you are uploading a document, please type ‘document attached’, or a similar description, in the text box provided.

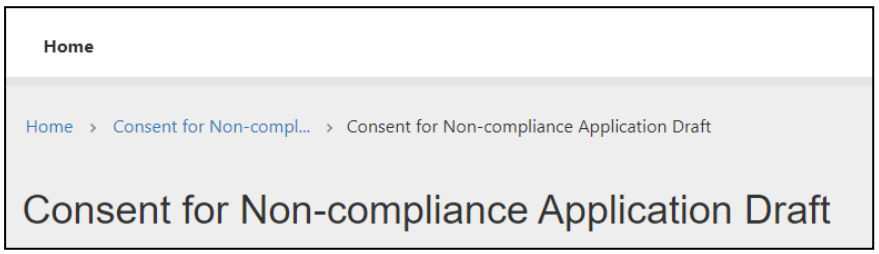


Once you have completed the information in the mandatory fields for this section, the section colour will change from amber to green to reflect that the section is now complete. Click the ‘Save’ button at the bottom of the page to save the information entered so far. You may save the information at any time, but if the mandatory fields are not completed the section will remain amber in colour.





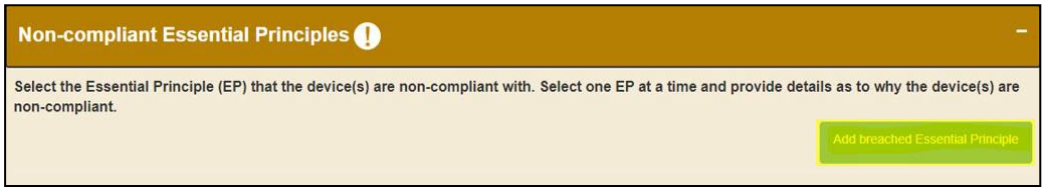
From here on, you can either click on another section to continue filling in the application, or you can select the ‘Back’ button at the bottom of the page or click on the ‘Consent for Non-compl…’ link in the breadcrumb at the top of the page to return to the dashboard.



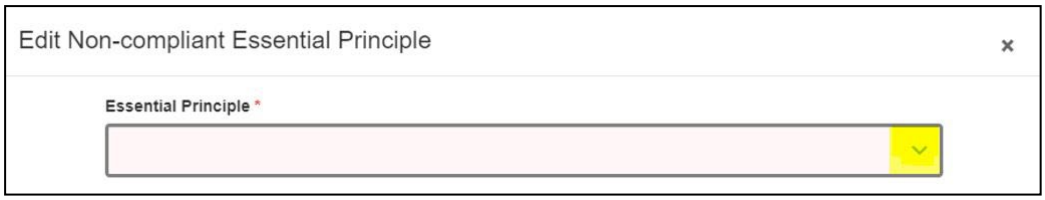
Non-compliant Essential Principles

In the Non-compliant Essential Principles section, you can select all the EPs that the device(s) are non-compliant with. Select one EP at a time and provide details as to why the device(s) is non-compliant with that EP.

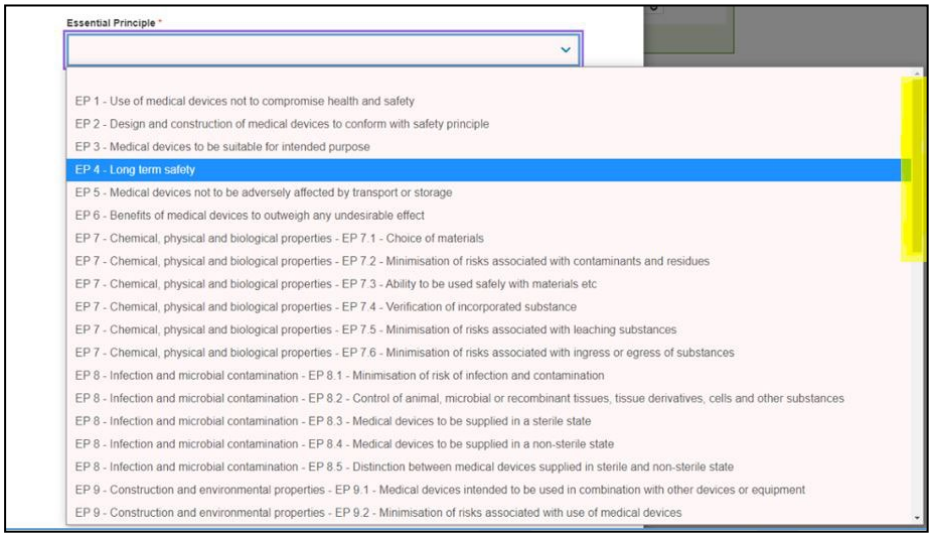
To select an EP, click on the ‘Add breached Essential Principle’ button.



This will open a window ‘Edit Non-compliant Essential Principle’ within the current view. Click on the down-arrow on the right to select the relevant EP that the device(s) are non-compliant with. You can only select one EP at a time from the drop-down list.

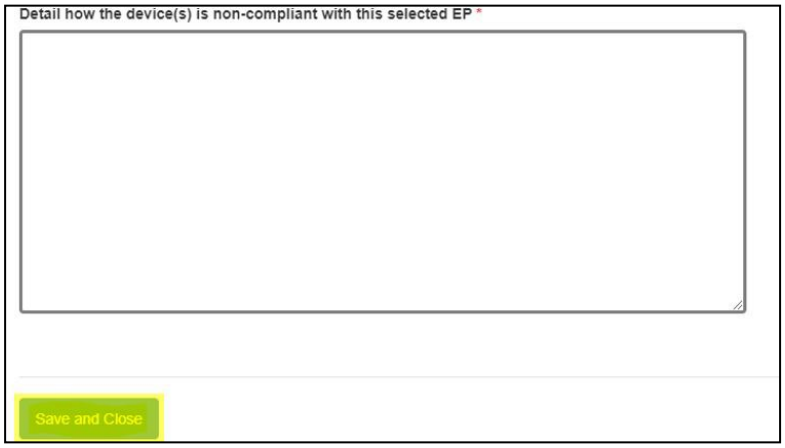


The EPs are listed in numerical order, so you may have to scroll down the list to find the relevant EP, such as EP13A. This is a mandatory field and at least one EP must be selected.

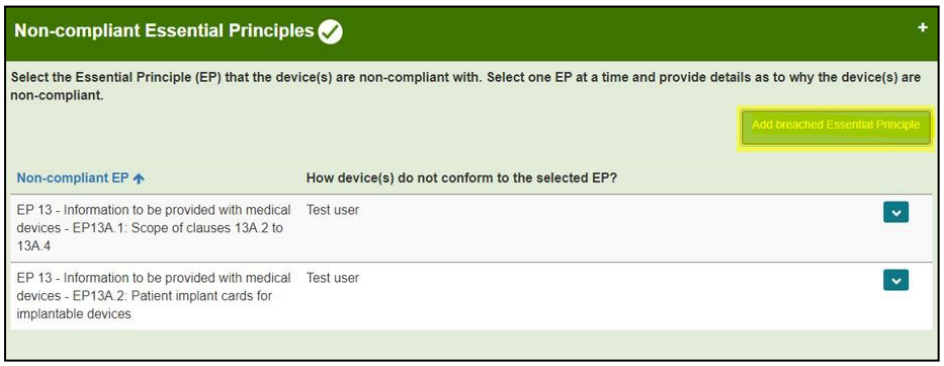


Next, you must provide an explanation on how the device(s) are non-compliant with the selected EP in the free text box provided. This is a mandatory field.

Once you have selected the relevant EP and provided an explanation on how the device(s) are non-compliant with the selected EP, click the ‘Save and Close’ button at the bottom of this window to save the information.

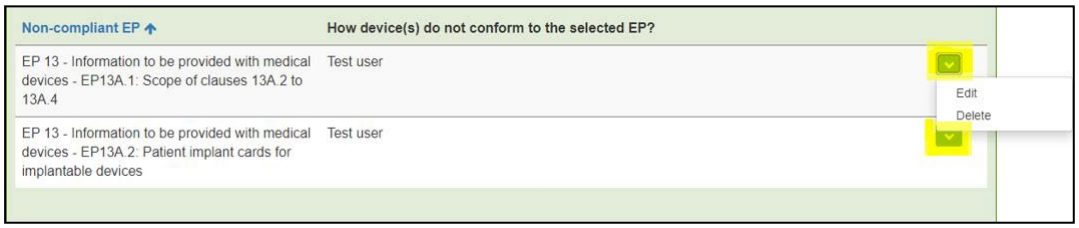


You may select another EP that the devices are non-compliant with using the ‘Add breached Essential Principle’ button again and repeat the process of selecting the EP, providing the reason for non-compliance to the selected EP, and clicking ‘Save and Close’ button.

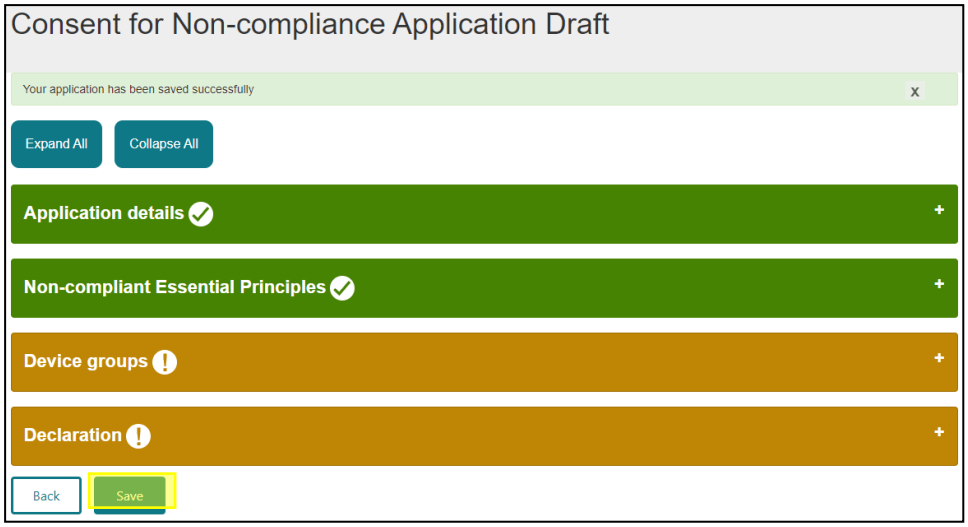


The ‘Non-compliant Essential Principles’ section will turn green, indicating that the mandatory information has been provided as soon as the first EP has been selected and the reason for non-compliance has been provided.

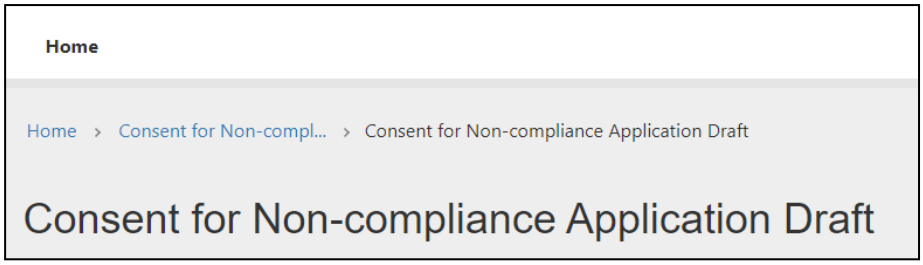
You can use the down-arrow on the right to edit or delete the EPs that you have added.



Once you have selected all the relevant non-compliant EPs for this application, click the 'Save' button to save the information entered so far.



From here on, you can either click on the next section to continue filling in the application, or you can select the 'Back' button at the bottom of the page, or the 'Consent for Non-compl…' in the breadcrumb at the top of the page, to return to the dashboard.



Device groups

You can provide information on the non-compliant medical device(s) in the Device groups section. Here you can create a group for all the devices that have same proposed start and end dates of consent, and the same Implementation Plan.

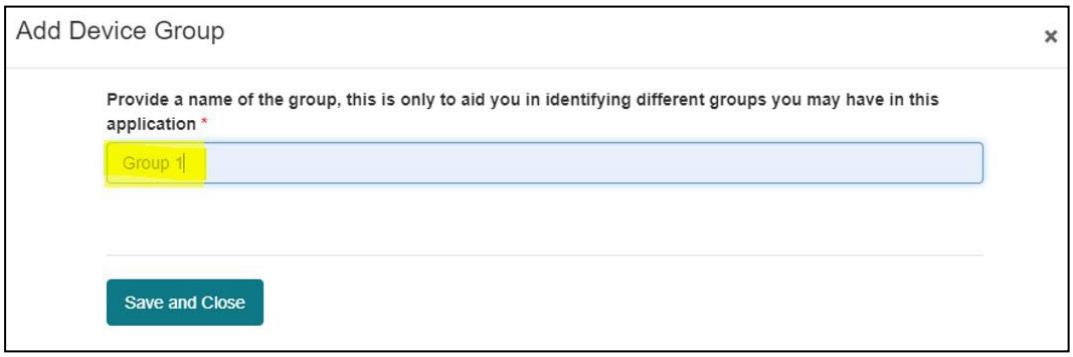
For example, if you have 20 devices (comprising of existing ARTG entries or devices included in an Application for Inclusion in the ARTG), of which five devices have same proposed start date of consent period (for example 28/12/2021), proposed end date of consent period (for example 28/12/2023), and the same Implementation Plan to rectify the non-compliance, then these five devices can be included in one group. Similarly, the remaining 15 devices can also be grouped based on matching proposed start and end dates of consent, and Implementation Plans.

If a singular device does not have the same proposed start and end date of consent, and Implementation Plan as other devices in the application, then you can create a separate group for this one device.

There is no limit on the number of device groups you can create, but you must create at least one group, and each group can must have at least one device included in it. The same device cannot be included in multiple groups.

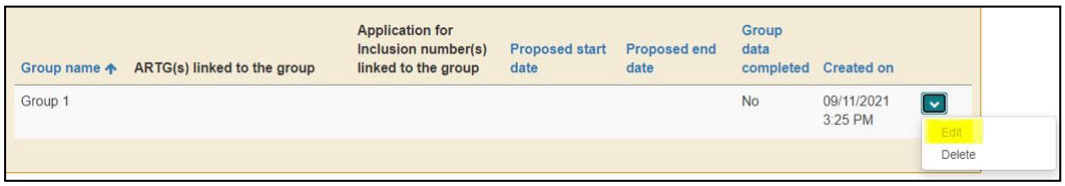
To create a device group, click on the ‘Add Device group’ button on the ‘Device groups’ section. This will open a window within the current view.

Provide a relevant name for the device group, so you can identify different groups within the application. Click ‘Save and Close’ after you enter the device group name.



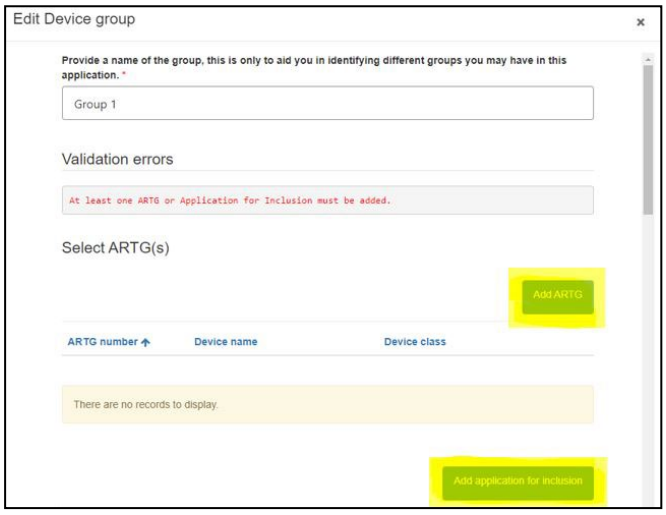
Once you save the new device group you will be taken back to the ‘Device groups’ section, where you will see the newly added group and you will be able to select the group for editing.

Click on the down-arrow on the right side of the device group to be able to select ‘Edit’ to provide details for this device group or select ‘Delete’ to delete the group if it was made in error.



If you select ‘Edit’ a window will open within the current view. This is where you can add devices to this group.

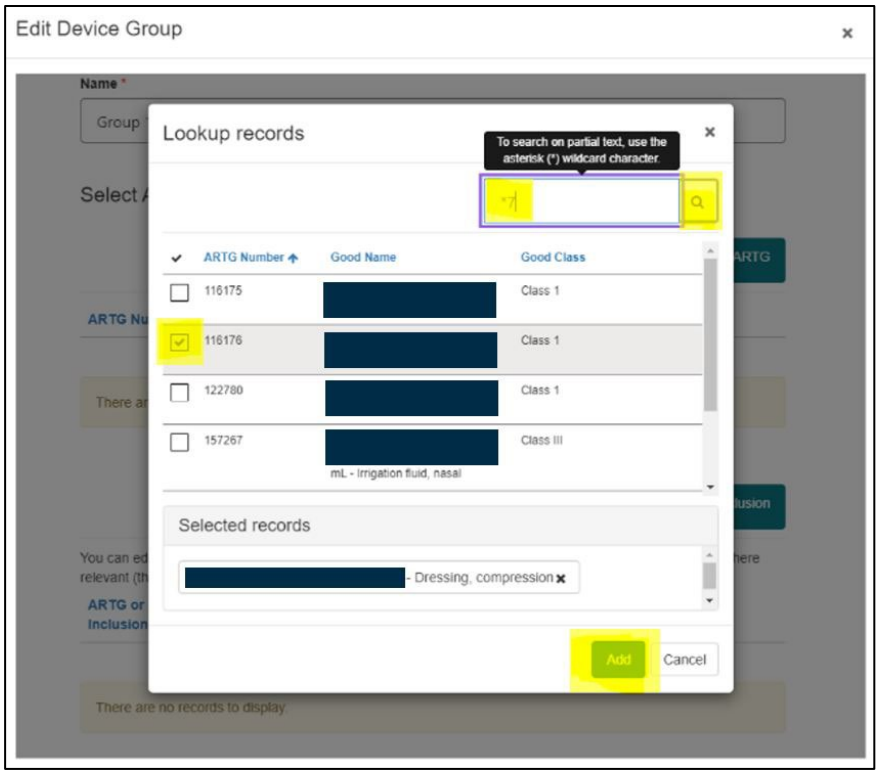
Using the ‘Add ARTG’ button you can include device(s) that are currently in the ARTG to this group. Similarly, by using the ‘Add Application for Inclusion’ button, you can include device(s) that are currently part of an Application for Inclusion to this group.



To add ARTG entries to this group, click on the ‘Add ARTG’ button to open a window within the current view. Here you will see a list of active medical device ARTG entries related to your organisation.

There is a search box (indicated by the magnifying glass symbol) which you can use to search for devices by name or ARTG number; you can search for partial text by typing an asterisk (*) as the wildcard character. You can also sort the table by clicking on the column heading to change the order of the ARTG entries, the name of the device, or the device class.

You can select a single or multiple devices from the list at a time by clicking in the box on the left-hand side of the ARTG Number. A tick in the box will indicate that the ARTG has been selected.

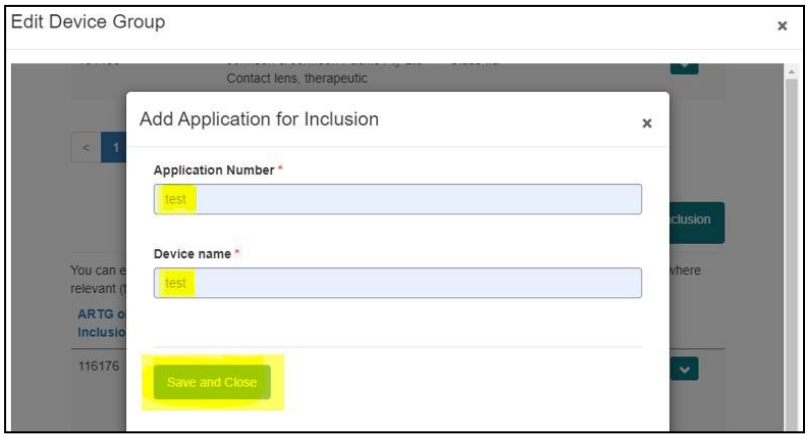


After you have selected all the ARTG entries you want to add to this group, click on the ‘Add’ button at the bottom of this window. Doing so will add all the selected ARTG entries to the group. You can go back in to the ‘Lookup records’ to select additional ARTG entries by clicking on the ‘Add ARTG’ button again.

NOTE: An ARTG entry can only be included in one device group; an ARTG entry cannot be included in multiple device groups.

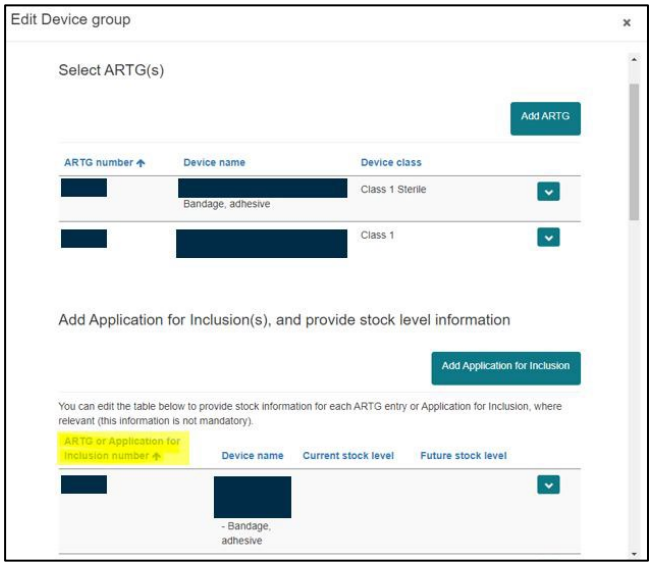
To add devices that are part of an Application for Inclusion, click on the ‘Add Application for Inclusion’ button. This will open a window within the current view. Here you can type in the Application for Inclusion number and the device name. Both fields are mandatory. Once you type this information, click on the ‘Save and Close’ button to add this device to the group.

You can add additional Applications for Inclusion devices by clicking on the ‘Add Application for Inclusion’ button again.

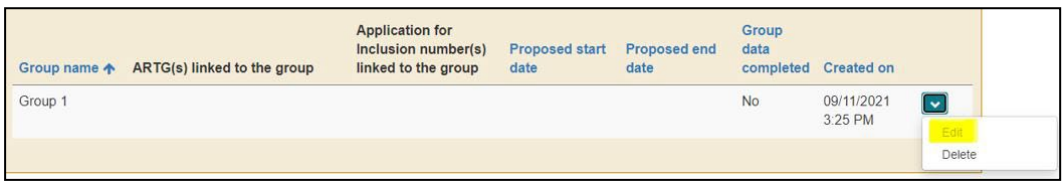


A list of all the devices that you have included in this group, both those included in the ARTG and the Applications for Inclusion, will be displayed in a table that allows you to provide stock information. You can edit the table to provide stock information for each ARTG entry or Application for Inclusion, where relevant. This information is not mandatory.

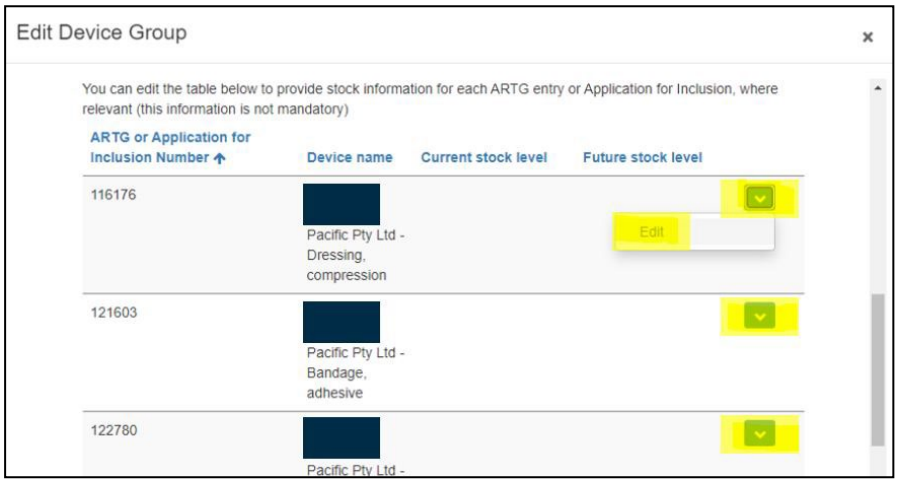
NOTE: If your device group only contains ARTGs (and no devices that a part of an Application for Inclusion), the devices will not appear in the stock information table until the form is refreshed. To do this please click on the column header ‘ARTG or Application for Inclusion number’. This will refresh the form and the ARTGs should appear in the table.



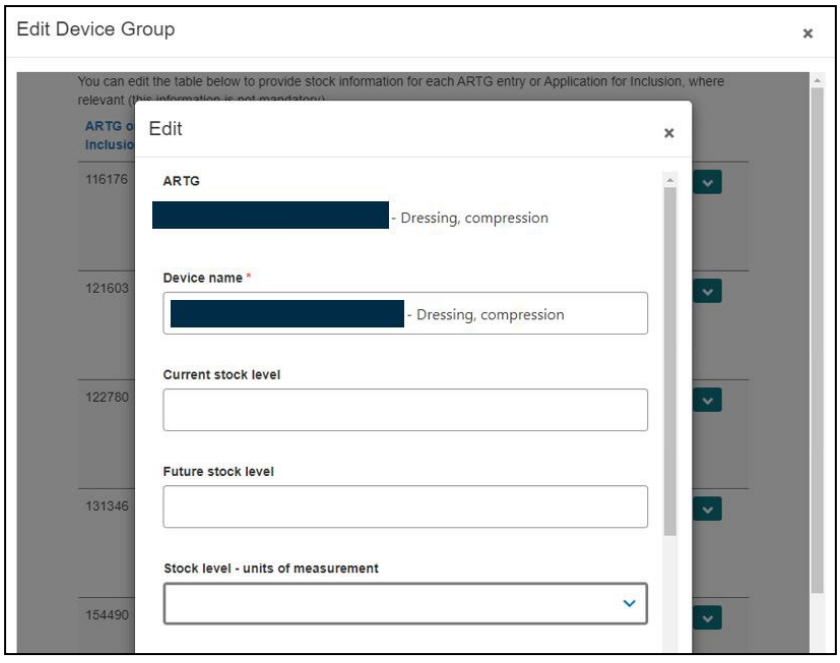
To get back to editing the device group click on the down-arrow on the right side of the relevant device group, and you will be able to select ‘Edit’ to provide the remaining details for this device group.



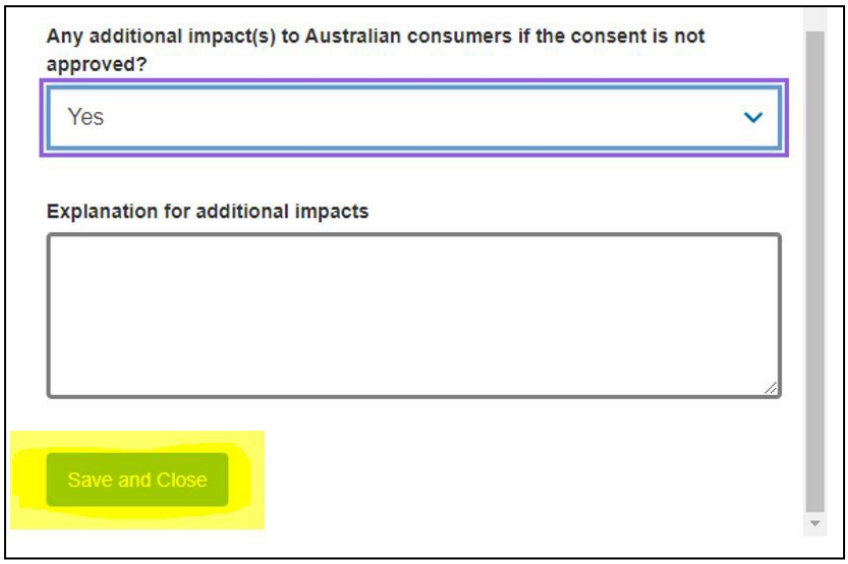
All the devices in this device group will appear in the stock information table- you can add stock information for the devices in this group.



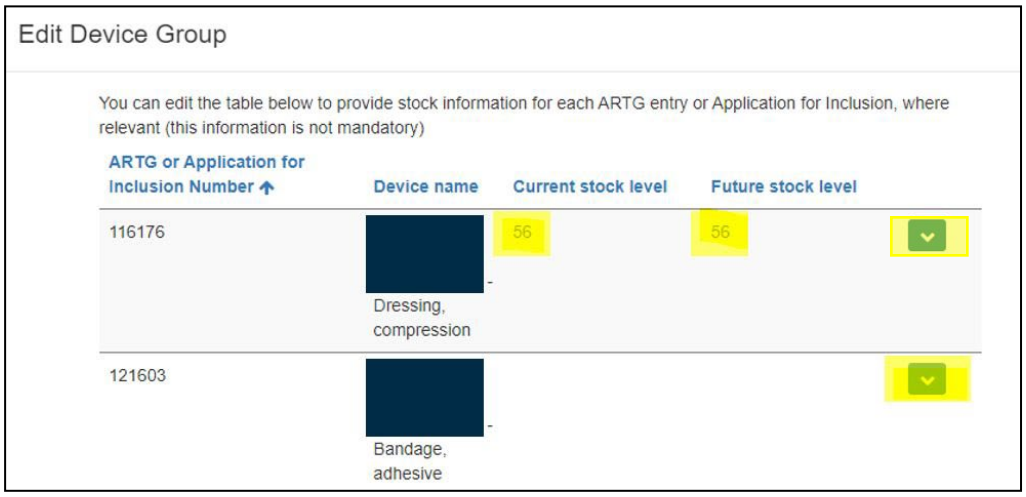
To add information on each device, click the down-arrow on the right side of the window against the device, and select ‘Edit’. Doing so will open a new window within the current view.



Here you can enter stock information for this device, the expected date of stock depletion, and if there will be any additional impact(s) to consumers if consent is not granted. These are non-mandatory fields.



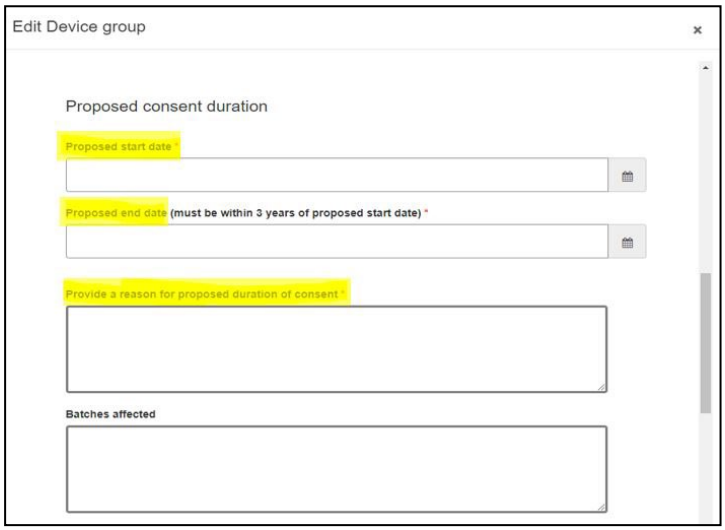
You can provide this information for the remaining devices related to this group by clicking the down-arrow on the right side of the device and selecting ‘Edit’. Any stock related information you have provided for each device will appear in the table, in ‘Edit Device Group’ view.



Next, you must provide the proposed start and end date for the consent, relevant to this group of device(s). The ‘Proposed end date’ must be within 3 years of ‘Proposed start date’ of the consent. You must also provide a reason for the proposed duration of consent in the text box provided. These fields are mandatory.

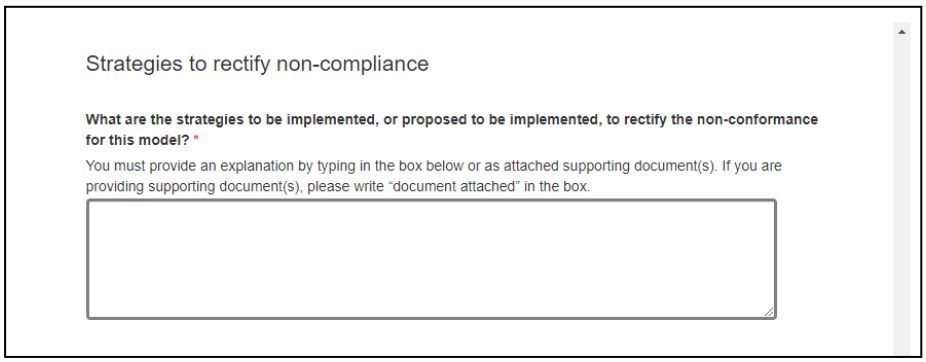
NOTE: If your device(s) is non-compliant with EP13A, and the proposed consent period for the Patent Implant Card (PICs) is different to that of the Patient Information Leaflet (PIL), you can still have these devices in the same device group by nominating the proposed end date as the later date when the device(s) will become compliant for both PIC and PIL.

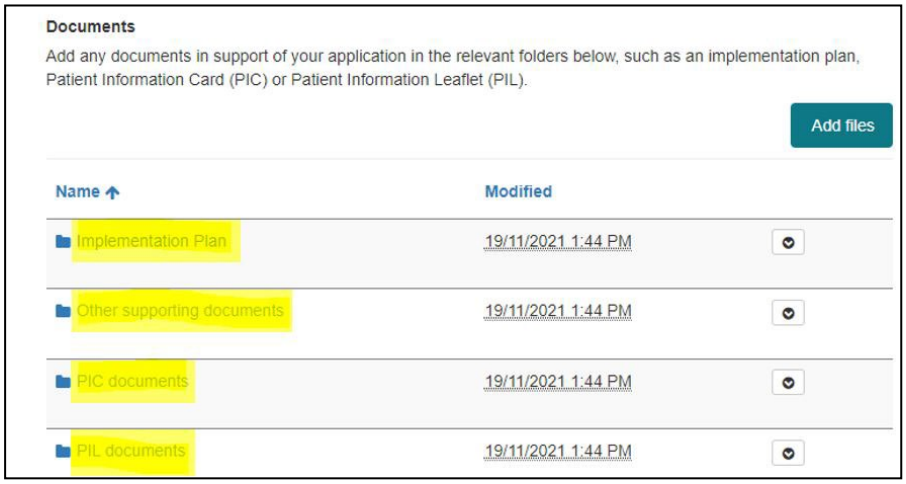
You can also provide details on the batches affected if relevant. This is a non-mandatory field.



Next, you must provide information on the strategies to be implemented to rectify the non-conformance for all the devices that are included in this group. You can do so by typing an explanation in the free text box provided, or by uploading documents in the relevant folders under the 'Documents' section below the text box. Microsoft Word, Excel, and Adobe Acrobat documents with a file size of up to 50MB can be uploaded. This is a mandatory field; therefore, if

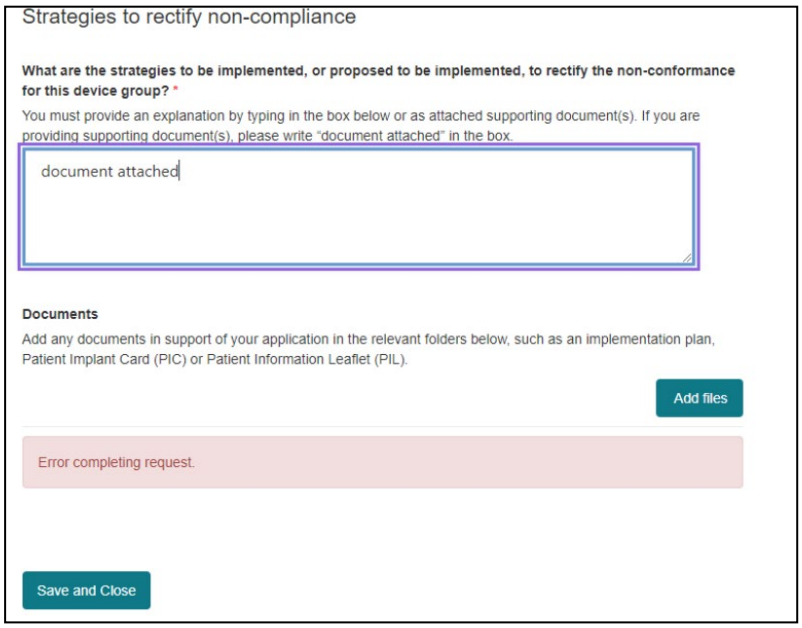
you are uploading the information in a document, please type 'document attached', or a similar descriptor, in the text box provided.



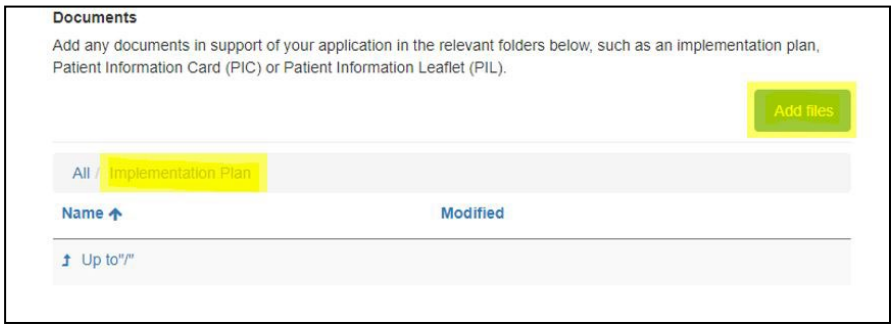


NOTE: If the devices are non-compliant with EP13A, you can upload a copy of the interim PIC(s)/PIL(s) and your Implementation Plan here. You may also upload any additional documents to support your application.

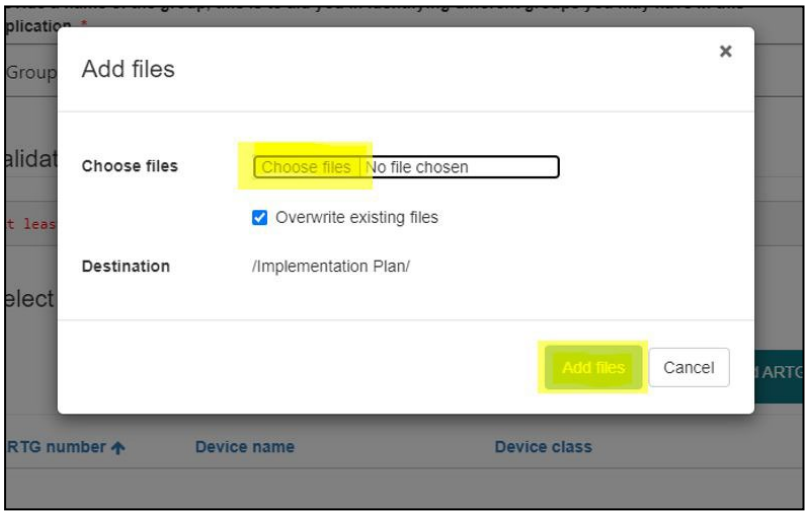
If the document folders do not appear below the ‘Add files’ button, and/or you see an error message where the folders should be, there may be a delay in the SharePoint folders appearing on screen. To overcome this issue, simply select ‘Save and Close’ under the error message, and then reopen the ‘Device Groups’ section and the folders should appear, ready for you to upload your documents.



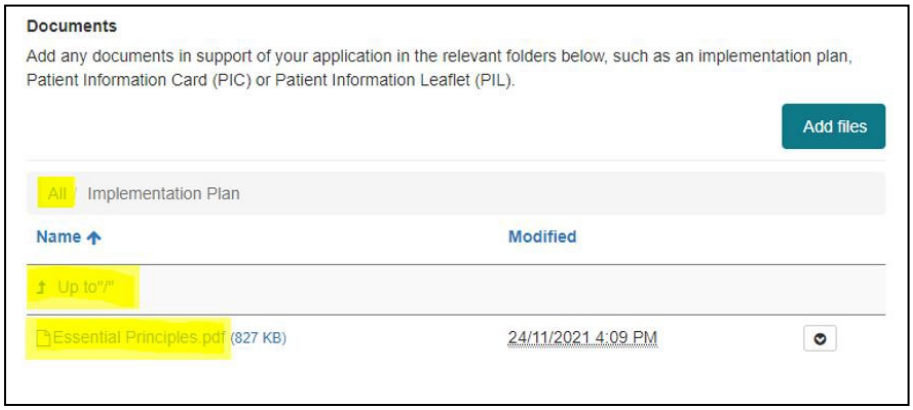
To upload a document, select the relevant folder by clicking on the name of the folder. Then click on the ‘Add files’ button. Doing so will open a window within the current view.



Using the ‘Choose files’ option on this window, you can upload a document saved on your computer. Select the relevant document that you wish to upload and click ‘Add files’ at the bottom of this window to add the selected file to this folder.



You will see the name and size of the document that has been uploaded to this folder. Click on the 'All' option or the ' Up to "/"' option to select other folders for uploading other documents if required. You can delete any files by clicking on the downward arrow on the right-hand side of the document name.



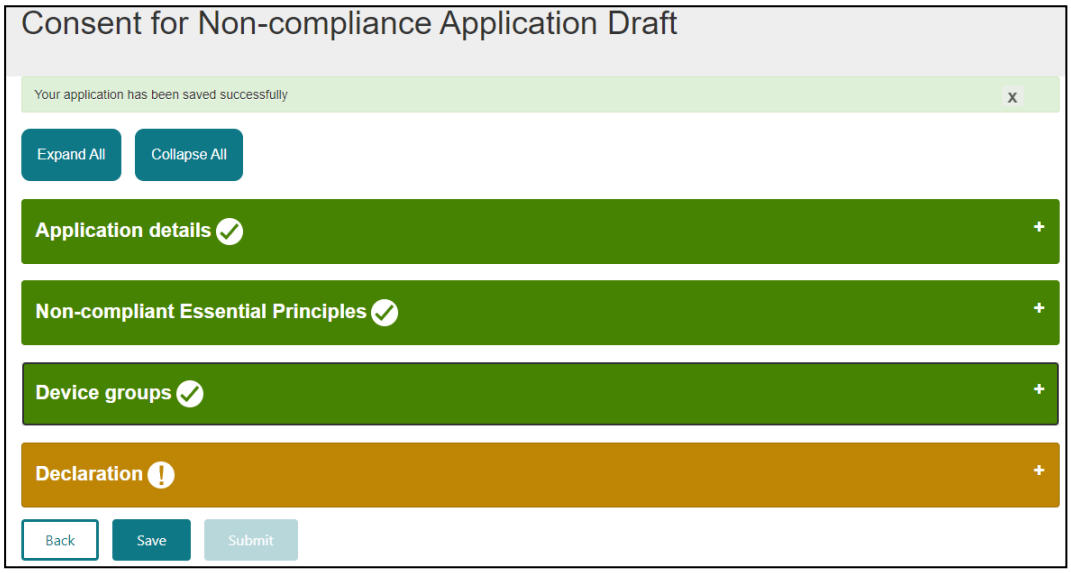
Once you have completed all required information for your device group, click the 'Save and Close' button at the bottom of this window. Doing so will save the information that you have provided. The system will display an error message if any of the required information is missing or incorrectly added.

Once all the mandatory fields are completed the 'Device groups' section will turn green, reflecting that it is now complete.

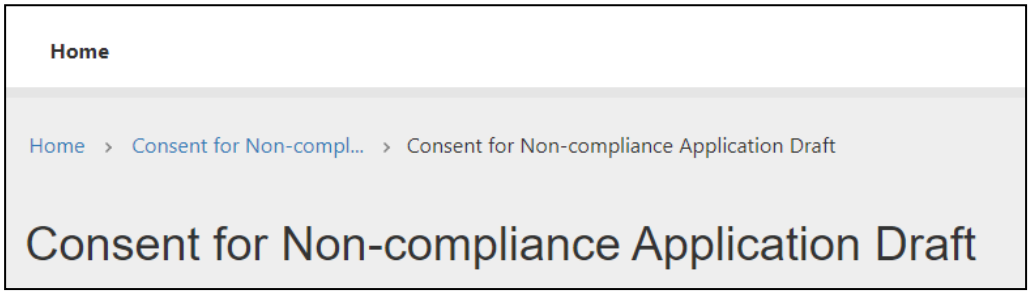
You can add another device group by using the 'Add Device group' button on the 'Device groups' section.

The table on the Device groups section will summarise the device group names, devices included in those groups, the proposed start and end dates for the consent period, and the date when device group was created.

If the required information related to a device group is complete, you will see a 'Yes' under the 'Group data completed' field. If the 'Device groups' section is amber in colour and the 'Group data complete' field displays a 'No' this reflects that the mandatory data for this group is incomplete, and you will be unable to submit this application until this information is provided.



From here you can either click on another section to continue filling in the application, or you can select the ‘Back’ button at the bottom of the page, or the ‘Consent for Non-compl…’ in the breadcrumb at the top of the page, to return to the dashboard.

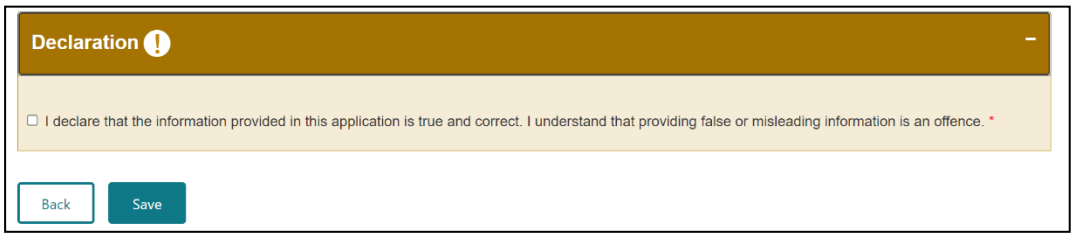


Declaration

To submit the application, you must complete the ‘Declaration’ section.

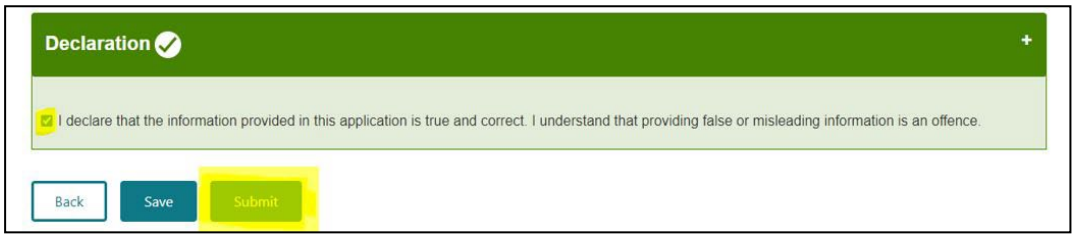
If any of the mandatory fields in the other sections are not completed, the ‘Declaration’ section will not display the ‘Submit’ button.

Additionally, the form can only be submitted by an authorised user, with submitter access for the TBS sponsor portal. Users with drafter access can only draft and save an application and are not authorised to submit an application through the TBS portal. As such, users with drafter access will not see the ‘Submit’ button.



Please ensure that all the mandatory form fields in the other sections are complete.

Read the declaration statement and if you agree, check the tick box under the declaration section to provide your declaration. Once ticked, the colour of the ‘Declaration’ section will change to green, which will trigger the ‘Submit’ button to appear.



From here, you can either submit the application by clicking the 'Submit' button or you can click on the 'Save' button and it will remain in draft for you to submit at a later time.

NOTE: If you have drafter access then you will only be able to save the application once you have unchecked the declarations tick box.

Once submitted, the application will move from the 'Draft' view to the 'Submitted' view, which can be accessed through the 'Consent for Non-compliance Application Dashboard'.

Viewing the status of submitted applications

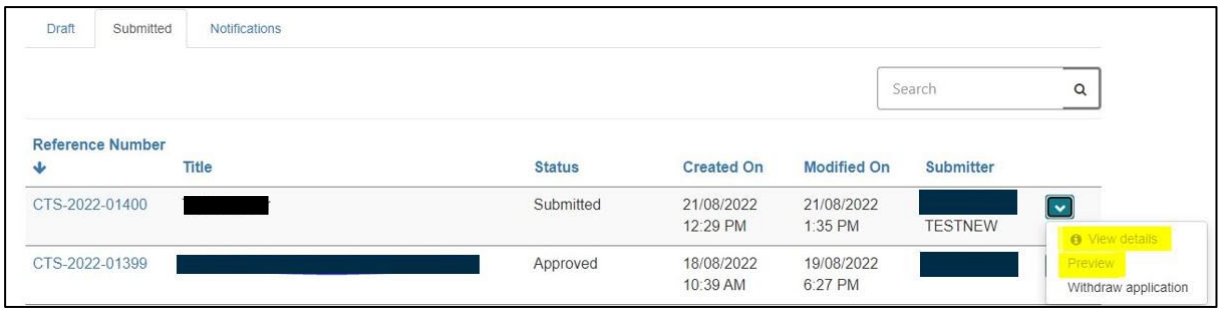
You can view the status of submitted applications on the 'Submitted' tab.

You will be able to see the following application statuses:

- Submitted: The application has been submitted, but not yet under review.
- Review: The application has been paid and is under review.
- Approved: The application has been approved, and consent has been granted.
- Not Approved: The application was not approved, and consent has not been granted.
- Revoked: An approved consent has been revoked.
- Expired: The consent period for this application has expired.
- Withdrawn: The application has been withdrawn by the sponsor.

Viewing and printing submitted applications

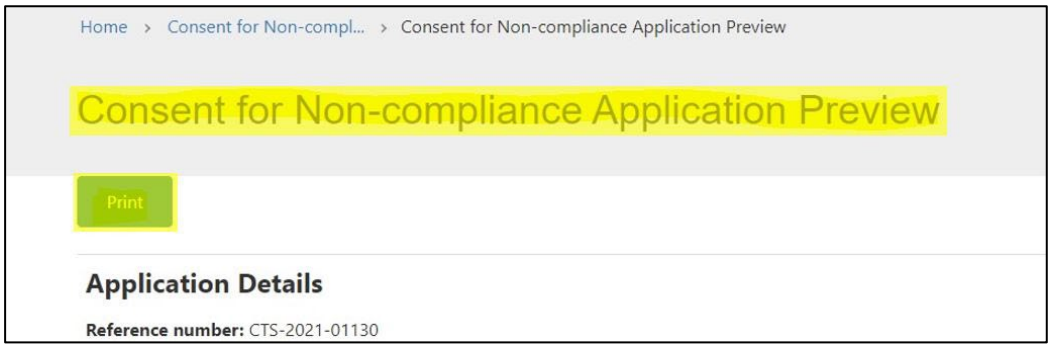
You can view and/or print a submitted application by clicking on the arrow down button along the application in 'Submitted' view.



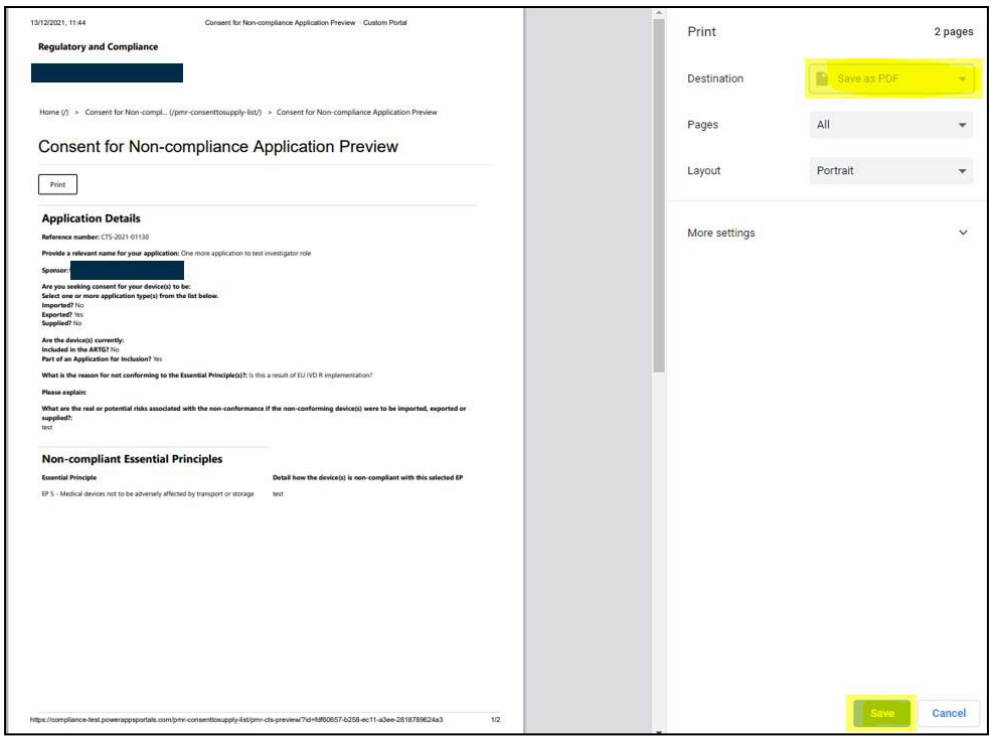
Here you will see three options, 'View details', 'Preview' and 'Withdraw application'.

Click on 'View details' option to view the application information provided, including any documents that were uploaded as part of the application.

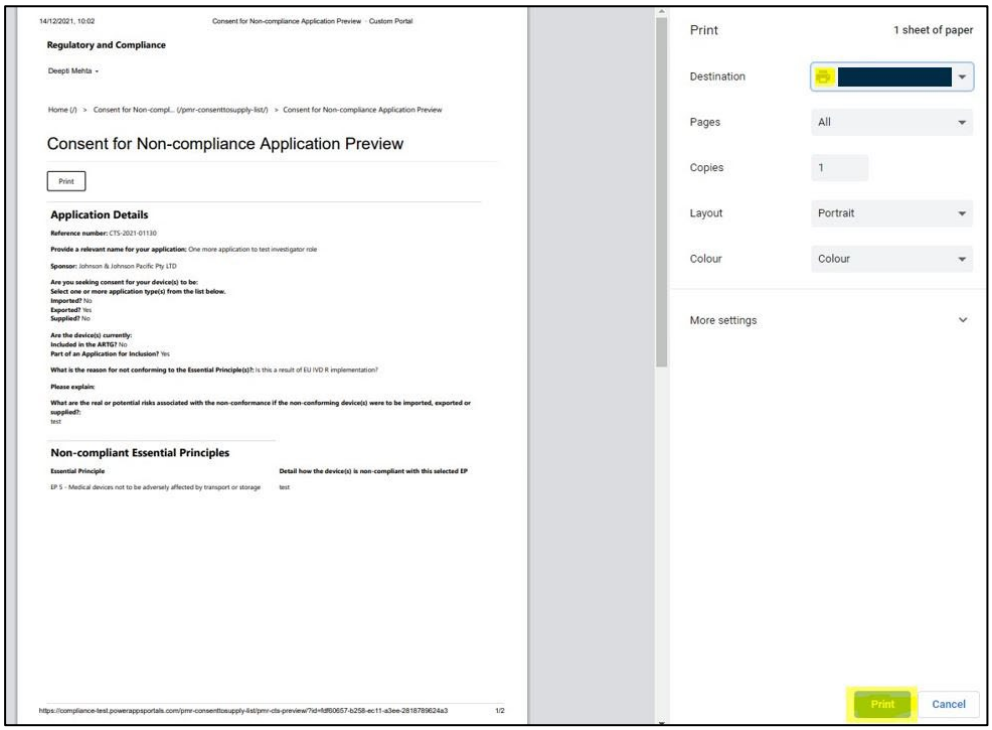
Click on 'Preview' option to preview and print the application form.



On the ‘Consent for Non-compliance Application Preview’ view, click on the ‘Print’ button, this will open a window within the current view to save or print a copy of this application.



To save the application, in the ‘Destination’ section on this window, select ‘Save as PDF’ and click ‘Save’ at the bottom of the window. This will give you the option to save the document to a desired folder on your computer.

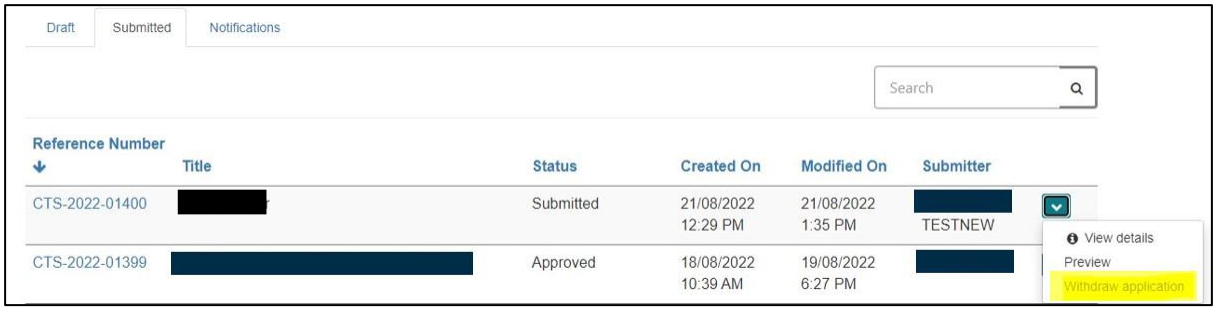


To print the application, in the ‘Destination’ section of the window, select the appropriate printer and click the ‘Print’ button at the bottom of the window.

Withdrawing an application

An application for consent can be withdrawn by the sponsor after it has been submitted or when it is under review by the TGA. It is important to note however that once an application is withdrawn, it cannot be reactivated, and any application fees paid by the sponsor cannot be refunded. If consent is required for the same devices at a later date, a new application will be required.

To withdraw an application go to the ‘Submitted’ tab and on the application you wish to withdraw, click on the arrow down button on the right-hand side and select the ‘Withdraw application’ option.

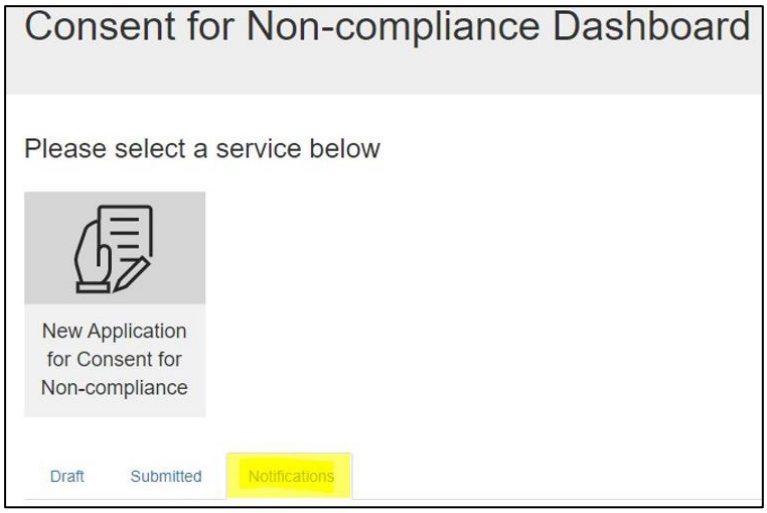


This will open a new window in the current view where you must provide an explanantion for the withdrawal of the application. This is a mandatory field. Then click on the ‘Withdraw’ button to withdraw the application.

A pop-up warning message will appear explaining that once an application is withdrawn, it cannot be reactivated. To continue with the withdrawal, press ‘OK’ to finalise or ‘Cancel’ to cancel the withdrawal request. A withdrawal notification will be sent to you confirming the withdrawal of the application and this notification will be available to view from the ‘Notifications’ tab.

Notifications related to a consent application

All notifications regarding a submitted consent application can be viewed on the ‘Notifications’ tab of the dashboard.



Notifications may include letters regarding the outcome of the application review (consent approved or not approved), application withdrawal confirmation, consent expiry or consent revocation notifications as well as an informal request for more information related to a submitted application or regulatory letters related to devices that are part of an approved consent application.

For guidance on how to view and respond to notifications related to a consent application please see guidance document on the TGA website “Guidance for viewing and responding to notifications on the Consent for Non-compliance Dashboard”.

Questions and answers

For more questions and answers related to applying for consent to import, supply, and export a medical device that does not comply with the Essential Principles, please see the TGA website https://www.tga.gov.au/consent-non-compliant-medical-devices-frequently-asked-questions

Q1. Can a device group have a single ARTG entry or device included in an Application for Inclusion?

A: Yes, a device group can consist of a single device, as long as the device is not included in another device group in the application.

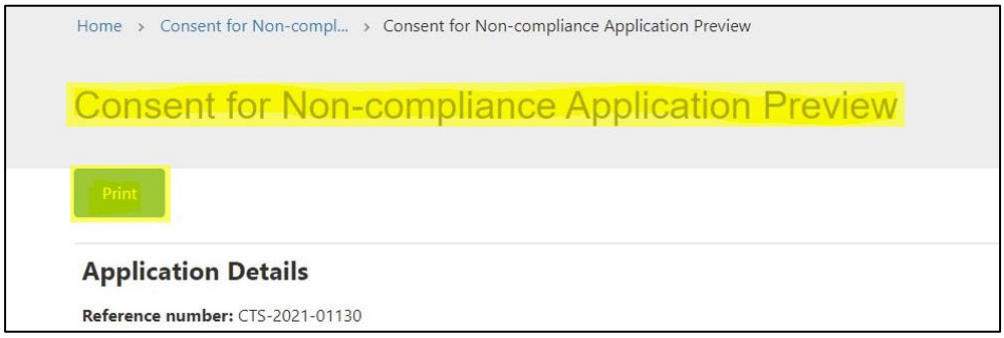
Q2. I have completed all the mandatory fields, why am I not able to save my response on the 'Declarations' section?

A: You must check whether you have submitter access or drafter access to the TBS sponsor portal. Only users with submitter access will be able to save their response on the 'Declaration' section and submit the application.

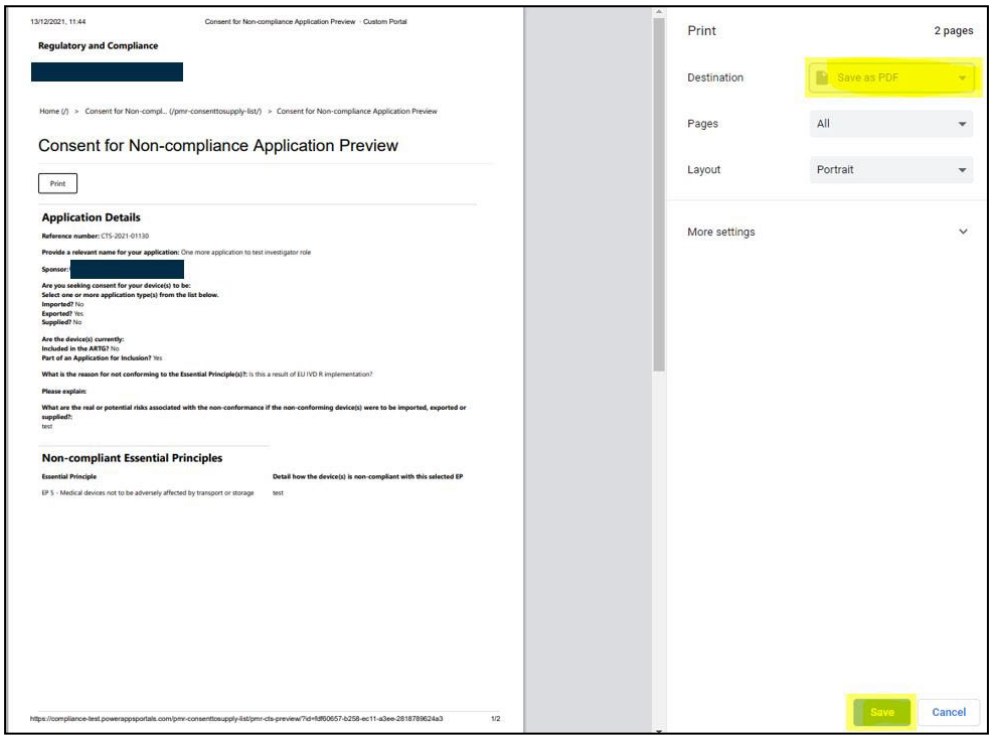
If you wish to change the type of access to the TBS sponsor portal, please contact the TBS Service Desk: eBS@health.gov.au

Q3. Can I download or print a copy of the submitted application form?

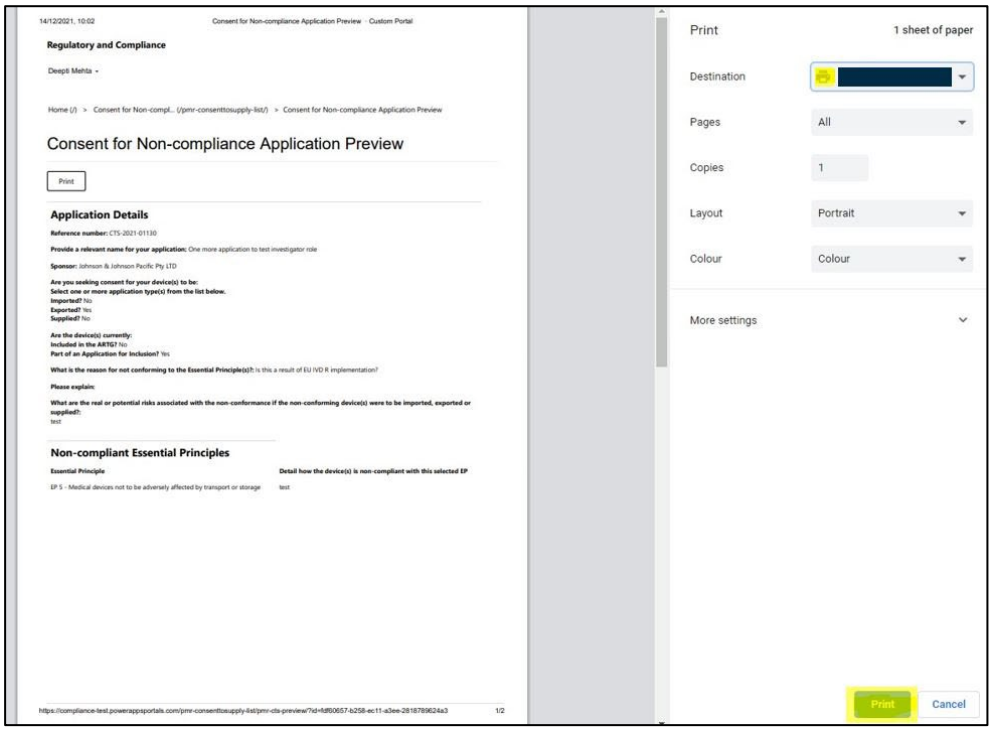
A: Yes, you can download and / or print a copy of an application that you have submitted. Click on the application reference number (consent application ID) or the 'Preview' option located within the drop-down arrow function along the application row, in the 'Submitted Consent Applications' view. Here you will find a 'Print' button, click on this option to print the application form.



A window will open in the current view. In the 'Destination' section on this window, you can select 'Save as PDF' and click 'Save' at the bottom of the window. Doing so will give you the option to save the document to a desired folder on your computer.



To print the application, in the ‘Destination’ section of the window, select the appropriate printer and click the ‘Print’ button at the bottom of the window.



For more information on how to submit your application, please contact mdconsent@health.gov.au or call us on 1800 141 144. To provide feedback on this application form, please complete the survey available on the TGA Consultation Hub.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication for new form in TBS	Medical Devices Surveillance Branch	December 2021
V1.1	Updated to include information on print function and status columns in submitted dashboard	Medical Devices Surveillance Branch	December 2021
V1.2	Updated to include information on withdrawn status	Medical Devices Surveillance Branch	January 2022
V2.0	Updated to reflect change in dashboard and additional features with Release 2.0	Medical Devices Surveillance Branch	September 2022
V2.1	Updated to remove reference to the amount of the fee associated with the application and provide a link to the current fees web page.	Medical Devices Surveillance Branch	July 2023

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference/Publication #