Australian Government
Department of Health
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 non-compliance with patient information requirements only

TGA Consultation Hub

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TGA Health Safety Regulation

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Introduction

This is a guidance document to provide advice on how to successfully submit an application for consent to import, supply, or export a medical device that does not comply with the Essential Principles (EPs); specifically, non-compliance with EP 13A.

The TGA is currently undertaking a project to modernise the consent application process, moving from a paper form to an online, electronic digital form. The new form will streamline the application process and allow for greater functionality, including the ability for sponsors to view their current and previous applications for consent. The transition to the new form will occur in two phases, with the first phase complete and now ready to use. This interim electronic application form is currently located on the TGA's Consultation Hub and is the form that this guidance document refers to.

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.

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.

Please note that if your non-compliant device(s) is currently part of an application to vary the device or manufacturer's evidence, or have an Application for Inclusion in the ARTG, you will 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';
- attach all relevant documentation; and
- pay the applicable processing fees in full.

Multiple devices included in one application

An application for consent can include entries included in the Australian Register of Therapeutic Goods (ARTG) or medical devices that are currently part of an Application for Inclusion in the ARTG that do not comply with the EPs.

Each application form can accommodate up to 100 ARTG entries or Applications for Inclusion. If you are seeking consent for more than 100 ARTG entries or 100 Applications for Inclusion, you will be required to complete multiple forms to complete your application. **Alternatively, you can upload a Microsoft Excel spreadsheet with a list of all the affected ARTG number(s) on the 'Information on non-compliance' page.** The list can only contain one ARTG number in each cell, in a single column working down the rows. Do not enter more than one ARTG number in any cell or across multiple columns. Do not repeat the ARTG number(s). Information other than ARTG number(s) will not be considered.

Similarly, you can upload a Microsoft Excel spreadsheet with a list of all the affected Application for Inclusion number(s) on the 'Information on non-compliance' page. Please note this needs to be a separate spreadsheet to the list of ARTG number(s).

For example, if your application for consent is for 220 ARTG entries, you can either:

- Complete three forms, entering the ARTG number(s) in the boxes provided on the 'ARTG entry/entries for which consent is requested' page. The first two forms will have 100 ARTG entries per form and the third form will have the remaining 20 entries. These three forms will be considered as one application for the purpose of fees; or
- You can upload a Microsoft Excel spreadsheet, listing the 220 ARTG entries, on the 'Information on non-compliance' page. If you do this, you are not required to enter the ARTG number(s) into the boxes provided on the ARTG entry/entries for which consent is requested' page.

For those entering the ARTG number(s) or Application for Inclusion number(s) into the form manually, and are completing multiple forms, please note that these forms will be considered part of the same application and will be linked during processing using the response ID generated for each form. The response ID is sent in the receipt email upon completion and submission of the form.

Application for consent for other than non-compliant patient information materials.

If you are a sponsor of a device seeking consent to import, supply, or export medical devices for any reason other than non-compliant patient information materials, there is a general application form for this purpose. Please refer to the TGA Webpage for more information.

Application / Processing Fees

Reduced consent application fees for devices with non-compliant patient information materials

On 29 October 2021, amendments to the Therapeutic Goods (Medical Devices) Regulations 2002 came into effect to introduce a fee concession for sponsors of implantable devices seeking consent to import, supply, or export their devices where they do not have compliant patient information materials. The application fee has been reduced to a flat fee of $30 for each ARTG entry and Application for Inclusion where the application is made solely in relation to non-compliance with EP 13A.2 and/or 13A.3.

The TGA will apply this fee concession retrospectively, refunding the difference in fees to eligible sponsors with consent in place on or after 1 January 2021. Sponsors with a consent in place who believe they are eligible for a fee refund should contact the TGA at mdconsent@health.gov.au identifying the relevant consent application. If the refund request is validated, it will be forwarded to the Product Billing and Industry Assistance team who will contact you regarding the refund.

NOTE: For consent applications related to other Essential Principles (different or in addition to EP 13A.2 and/or 13A.3), the normal processing fees of $500 for the first and $100 for each subsequent ARTG entry/Application for Inclusion applies.

How do I calculate my fees?

Fees are calculated using the total number of ARTG entries/Applications for Inclusion in the consent application, regardless of the number of forms submitted as part of the application. For example, if your application for consent pertains to 220 ARTG entries, you will need to complete three forms as part of the application (100 ARTG entries on the first and second forms, and 20 ARTG entries on the third form). The fees are calculated as $30 per ARTG entry / Application for Inclusion [that is: ($30 x 220) = $6,600].

If you are submitting multiple forms due to having more than 100 ARTG entries/Applications for Inclusion, please submit all forms within 24 hours so that all forms are linked as one application and payment can be easily tracked

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 **one** ARTG or Application for Inclusion number from your application in the box provided.
    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.

NOTE: if you choose this payment option please ensure that you only pay the fees after the submission of your final form in the application. If you pay the fees prior to the submission of the final form in your application, any subsequent form submission may be charged as a new application.

Your application and payment will be linked during processing using the TBS Client ID number and the ARTG entry or Application for Inclusion 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 not be processed until all applicable fees have been paid in full.

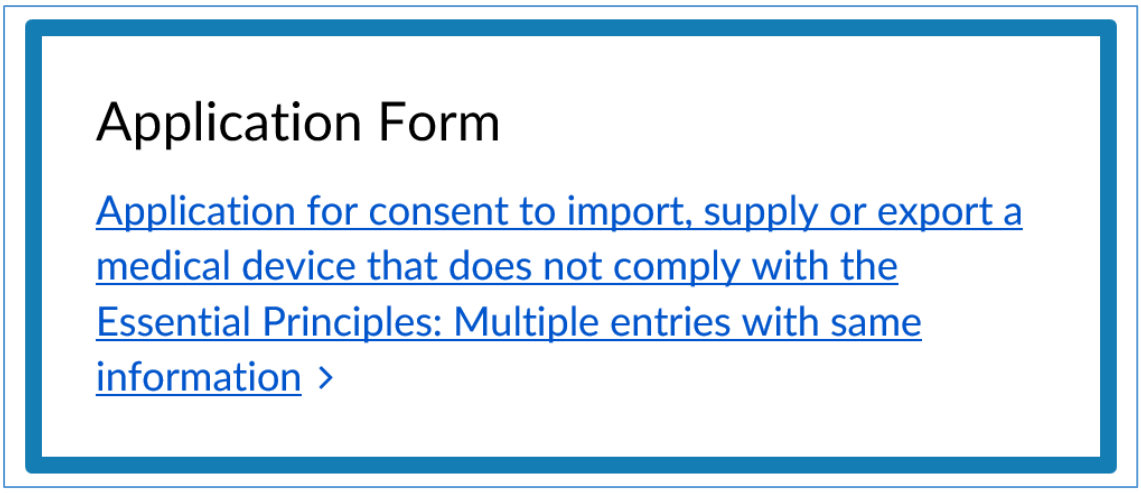
The application form

Overview Page

The overview page provides you with an overview of the consent to import, supply, or export medical devices that do not comply with the EP13A.

The page also points out that whilst this application form is being hosted on a consultation platform the information that is provided in the form will **not** be published. The information will be classified as 'For official use only'. For further information you can read Treatment of information provided to the TGA**.**

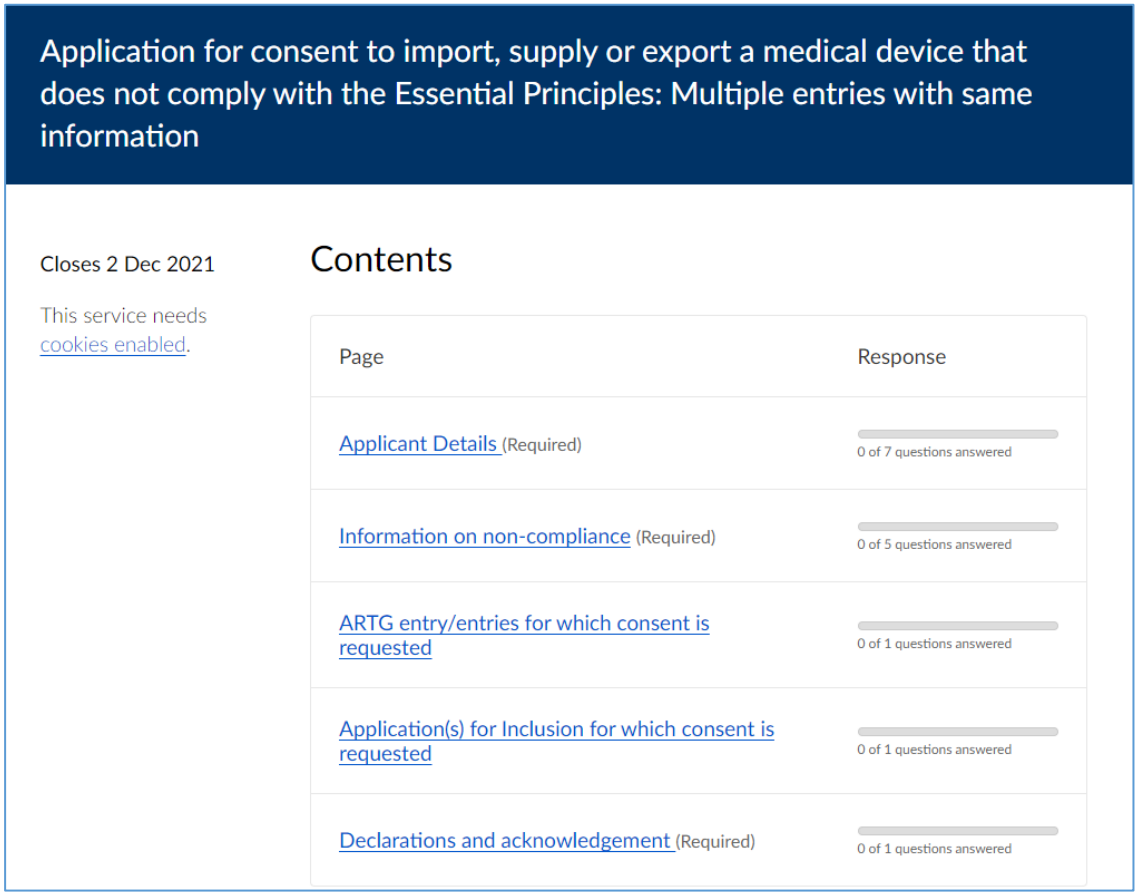
Step 1: At the bottom of the 'Overview' page, click on the link 'Application for consent to import, supply or export a medical device that does not comply with the Essential Principles' to start the application. This will take you to the 'Contents' page.



Contents Page

The Contents page contains links to all the different sections or 'pages' of the application form that you are required to complete as part of the application. When you complete a page, you will be returned the Contents page where you can select the next page to complete.

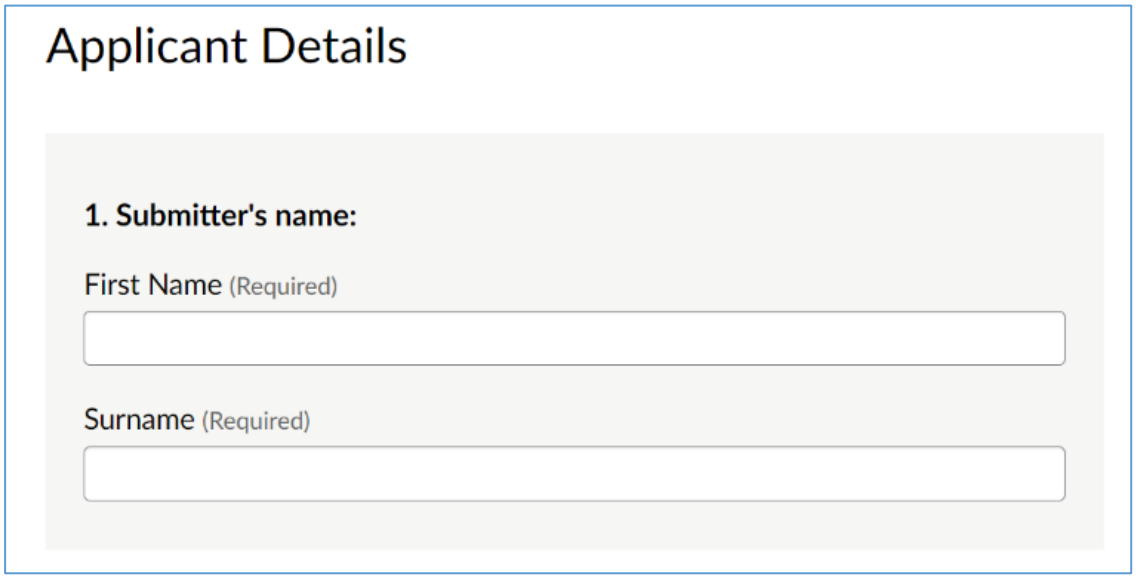
Click on the link 'Applicant Details' to start the application.



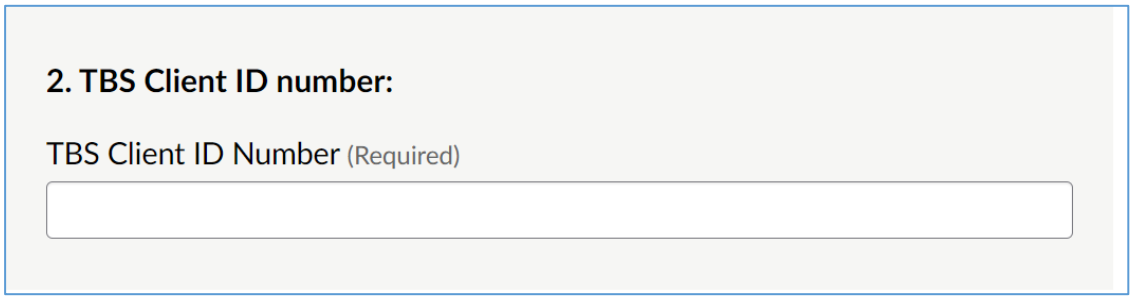
Applicant Details

This section of the form contains mandatory fields.

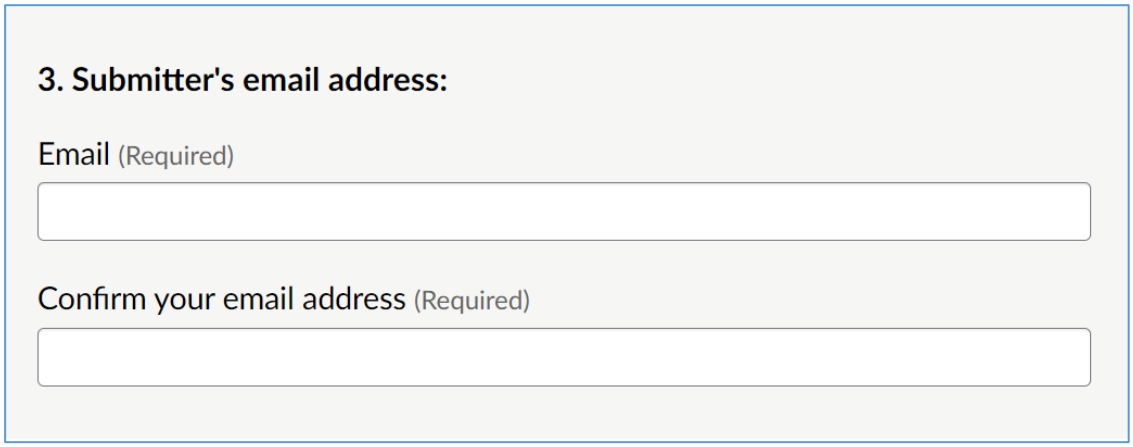
1 -Submitter's name: Fill in your first name and surname in the respective boxes. Only authorised representatives of the Sponsor should complete the application for consent form.



2 -TBS Client ID Number: provide your TGA electronic business systems (tBS) Client ID Number in the box provided.



3 -Submitter's email address: provide and confirm your email address in the boxes provided. This email address will be used to send a receipt and PDF copy of the application once it is submitted.



4-Role of submitter: select the option that best describes your role in relation to the medical device(s) for which the application for consent is being submitted. You can only select one option.

4. Which of the following best describes your role in relation to the medical device(s) for which this application for consent to supply is being submitted?

Please select most applicable option.

(Required)

- ○ Sponsor
- ○ Sponsor and Manufacturer
- ○ Agent

5-Sponsor details: provide the sponsor details in the boxes provided including name, postal address, email address and phone number. When filling out the phone number, please ensure there are no spaces between numbers and do not include brackets.

5. Sponsor details:

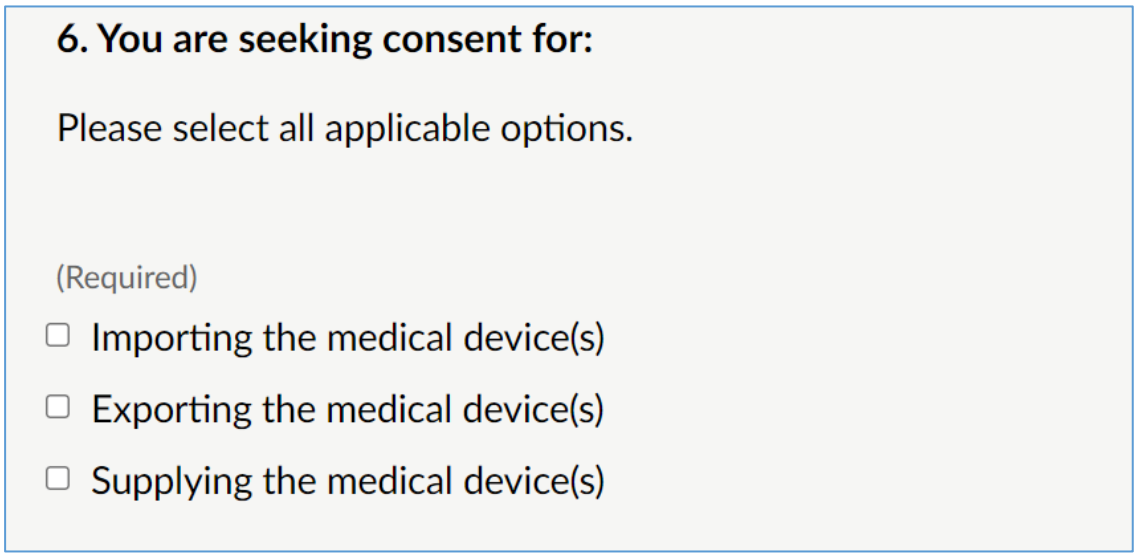
Sponsor's Name (Required)

Sponsor's Postal Address (Required)

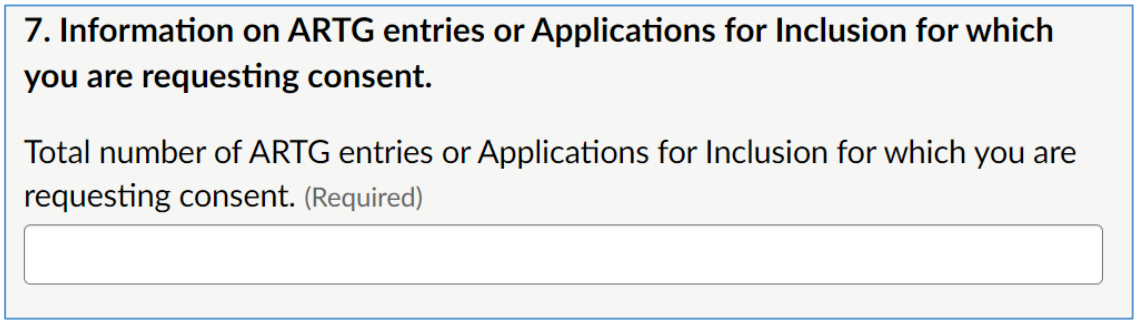
Sponsor's Email Address (Required)

Sponsor's Phone Number (Required)

6-Consent (Import, export, Supply): select the options for which you are seeking consent for in this application. You can select more than one option.

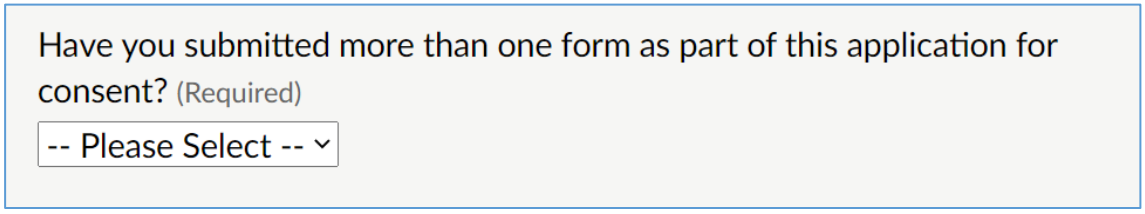


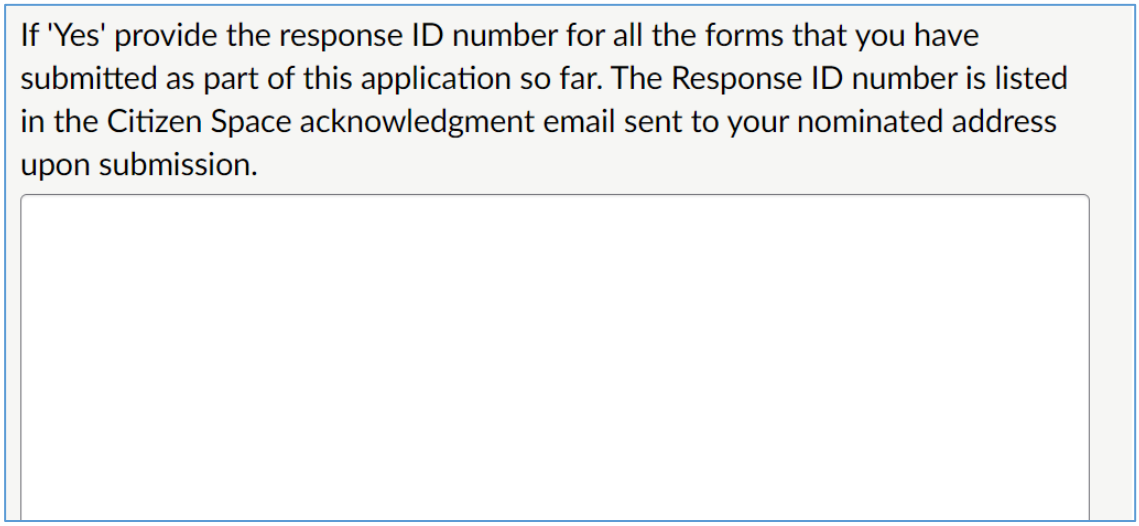
7-ARTG entries / Applications for Inclusion information: provide the total number of ARTG entries or applications for inclusion in the ARTG for which you are requesting consent. This must be a whole number.



If you are seeking consent for more than 100 ARTG entries or applications for inclusion you will be required to complete more than one form as each form can accommodate up to 100 ARTG entries or applications for inclusion in the ARTG. However, please include the total number of ARTG entries and applications for inclusion in the ARTG above, and not just how many will be in this form.

If this is the first form you have filled out as part of the application, please answer 'No' the question below. If this is the second or subsequent form you have filled out as part of the one application, please answer 'Yes' and then provide response IDs for the other forms you have submitted so far as part of your application. If this is the first form you have completed or your application is for 100 or less ARTG entries or Applications for Inclusion, select 'No'.





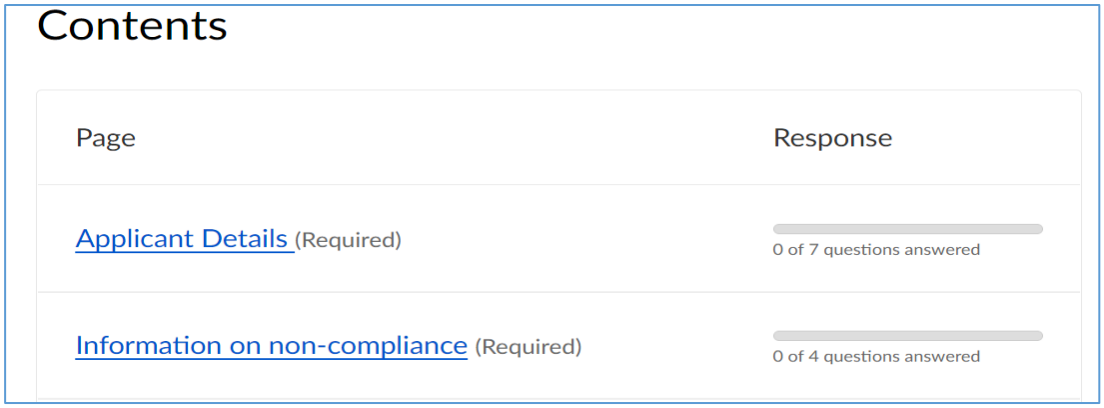
Note: You can upload a Microsoft Excel spreadsheet with a list of all the affected ARTG number(s) on the 'Information on non-compliance' page. The list can only contain one ARTG number in each cell, in a single column working down the rows. Do not enter more than one ARTG number in any cell or across multiple columns. Do not repeat the ARTG number(s). Information other than ARTG number(s) will not be considered.

Similarly, you can upload a Microsoft Excel spreadsheet with a list of all the affected Application for Inclusion number(s) on the 'Information on non-compliance' page. Please note this will need to be a separate spreadsheet to the ARTG number(s) list.

Next page: once you have completed this information you can either press 'save and come back later' to complete the rest of the application at another time, or you can press 'continue' to keep filling out the application.

If you select the 'Save and come back later' button you will be directed to a page that requires you to enter an email address. A link to the form with progress so far will be sent to that email address; to resume completing the form, click on the link.

If you select 'Continue', you will be returned the 'Contents' page where you can select the link 'Information on non-compliance' to continue the application.



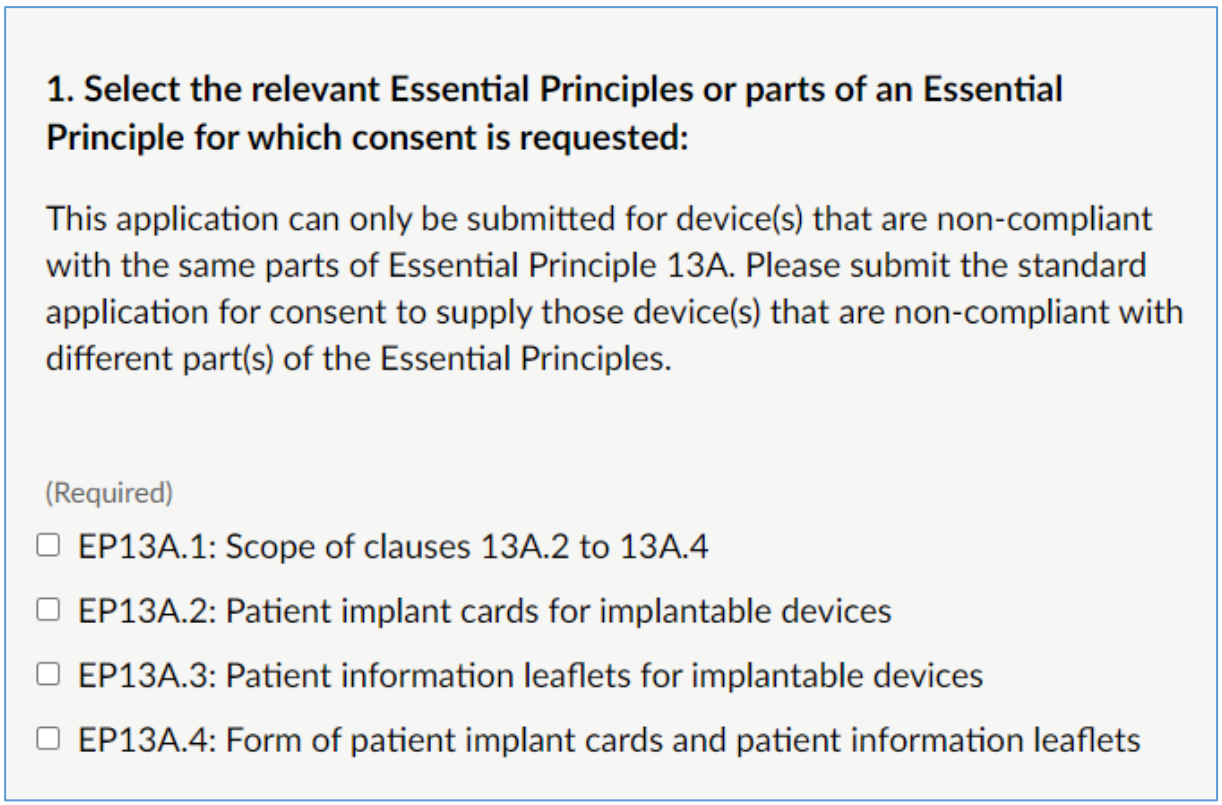
Information on non-compliance to the Essential Principles

The fields on this page are mandatory.

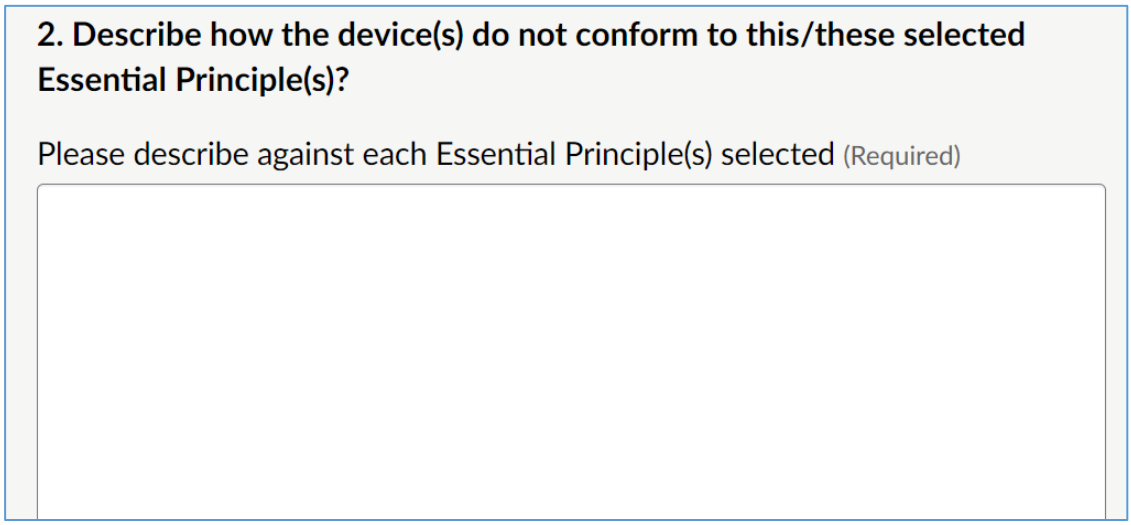
This page is where you need to select the EPs that the devices are non-compliant with, provide descriptions of how the devices do not comply to each of the selected EPs and sub-EPs, explain why they are non-compliant, and detail what risks are associated with the non-conformance.

1-Select the relevant Essential Principles or parts of an Essential Principle for which consent is requested: select the sub-EPs that the device(s) are non-compliant with. More than one of the sub EPs can be selected.

If your application for consent does not relate to non-compliance with EP13A you need to complete the general application form for consent, which can also be found on the TGA Consultation Hub.

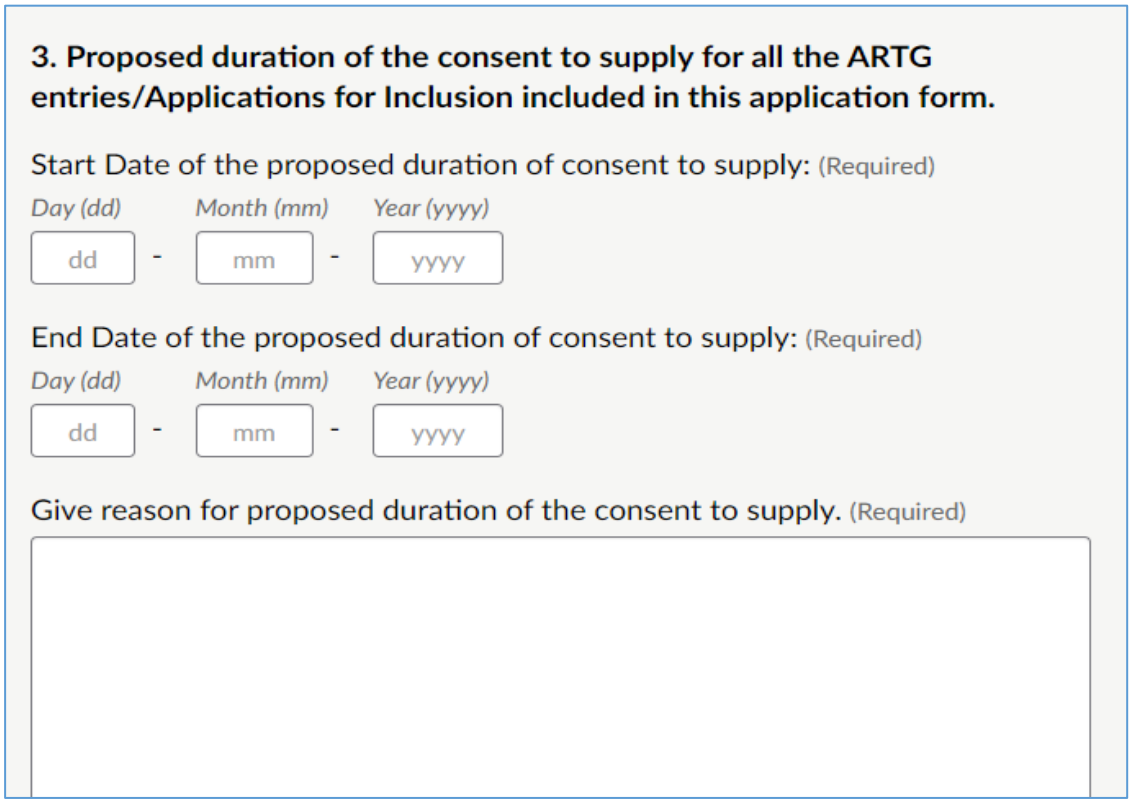


2-Describe how the device(s) do not conform to this/these selected Essential Principle(s)?: in the box provided, describe the particular aspect of how the device does not conform to each of the selected EPs. For example, if the Patient Implant Card does not contain the model of the device, this should be specified, rather than just stating that the Patient Implant Card is non-compliant with EP 13A.2.

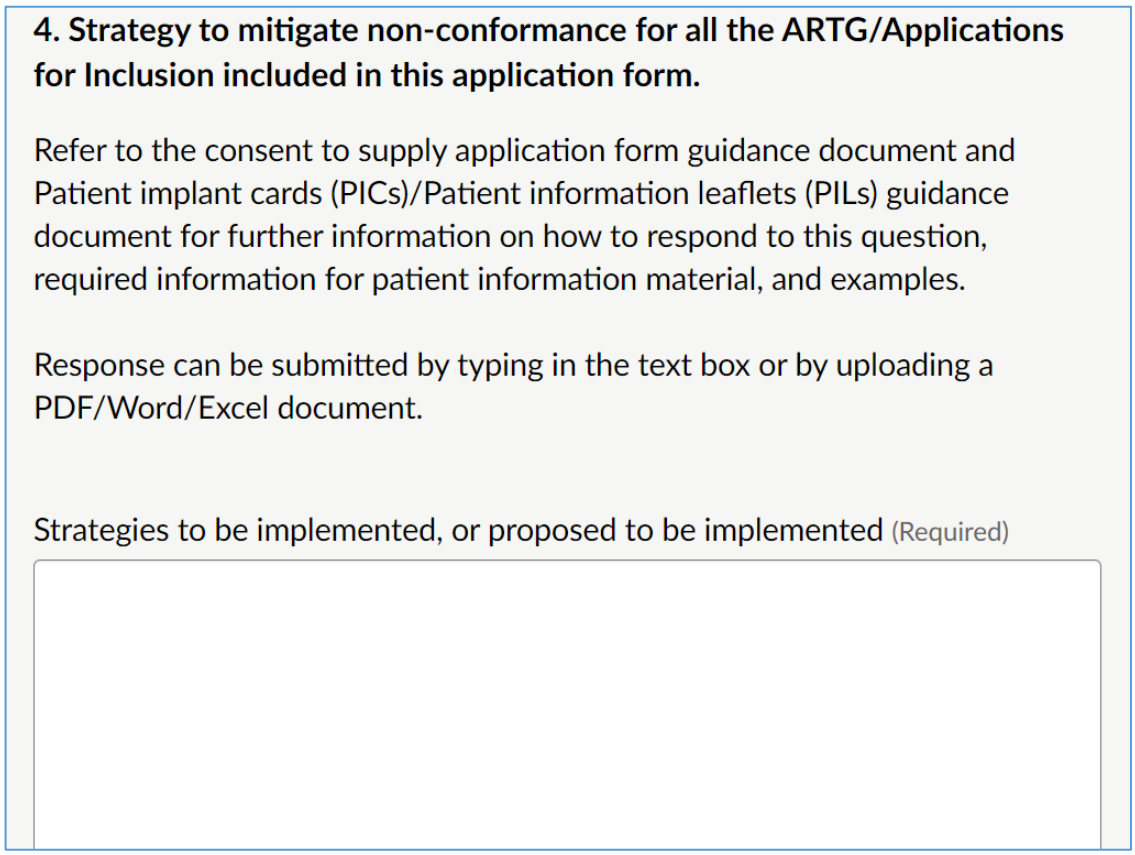


3- Proposed duration of the consent to supply for this ARTG/Application for Inclusion: select a proposed start and end date for consent and include a reason in the text box provided for why those dates have been selected.

For example, if you are seeking consent for device(s) with non-compliant Patient Information Cards (PICs) or Patient Information Leaflets (PILs) due to manufacturers implementing changes in line with European regulations, you may choose to enter your start date as 01-12-2021 and the end date as 25-05-2024.

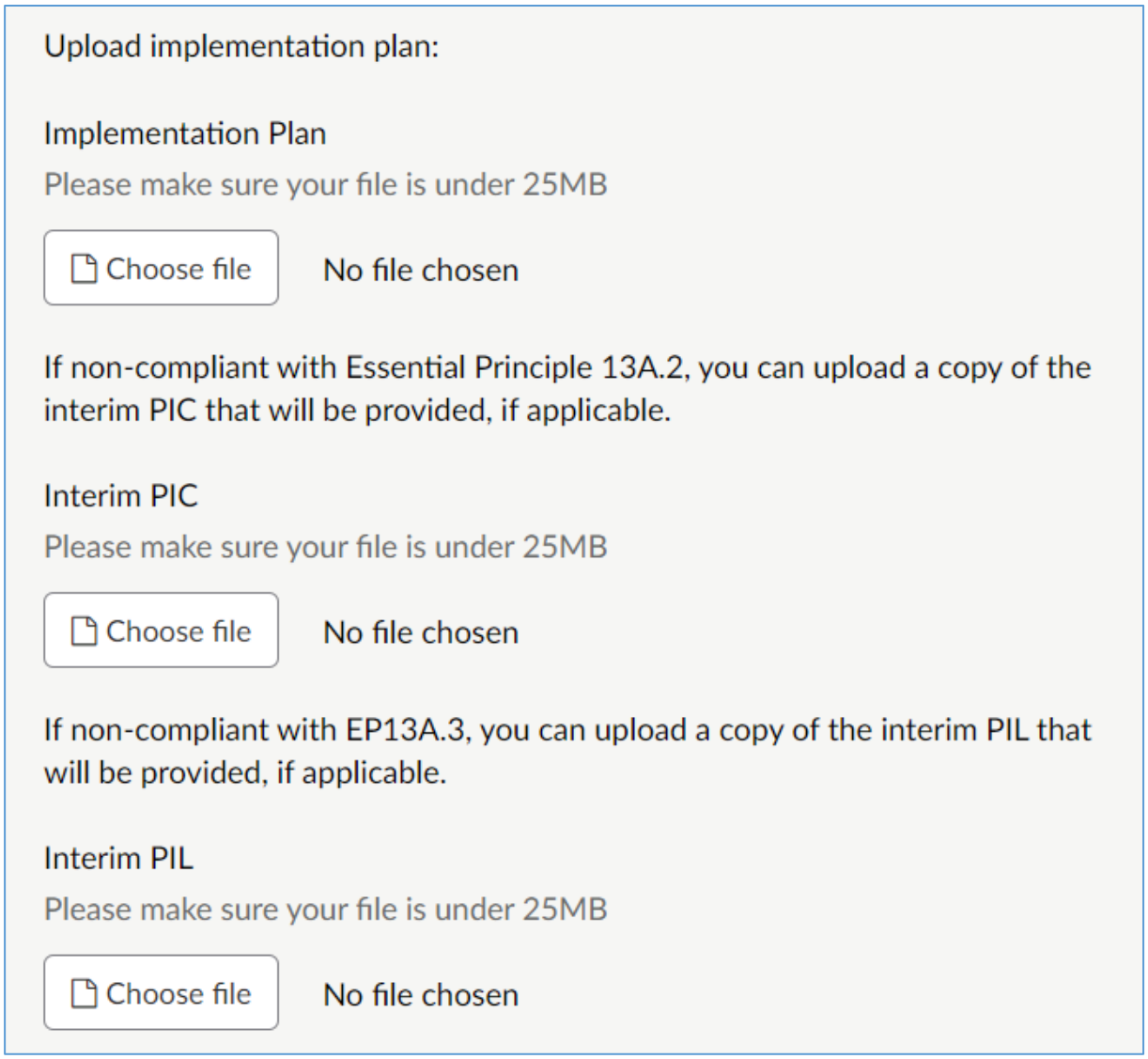


4-Strategy to mitigate non-conformance for all ARTG entries/Application for Inclusion?: Information on how the non-conformance is being mitigated can be provided here as free text or by uploading documents. If you are only uploading a document, then in the free text box please name the uploaded documents.



Documents uploaded may include an implementation plan, which should include information such as the proposed risk mitigation strategy, how it will be implemented, and when the mitigation will commence. The documents and information provided should relate to all the ARTG entries and Applications for Inclusion included in this consent form. If some of the ARTG entries or Applications for Inclusion have different implementation plan(s), interim PICs/PILs or proposed consent dates, you must submit a separate consent application form for those device(s).

There are fields to upload the interim non-compliant patient information to support the information provided in the implementation plan. Please ensure the documents uploaded are either in Adobe PDF, Microsoft Word or Excel formats. Further information on the requirements for patient implant cards and patient information leaflets can be found in the guidance https://www.tga.gov.au/book-page/patient-implant-cards.



Implementation Plans

Example 1 – Non-compliant Patient Implant Card (PIC)

If the consent relates to non-compliant patient implant cards due to missing device information, it would be expected that the implementation plan would include:

- what information is missing from the card (i.e. the card is missing the device model and batch number);
- how the missing information is going to be provided to the patient or healthcare facility and when will this be provided (e.g., there are stickers provided with the device that can be adhered to the card);
- how the non-compliant card will be provided to the patient or healthcare facility and when will this be provided (e.g., a template card will be provided in bulk prior to device being supplied or with the device. Extra cards can be requested from the sponsor or downloaded from the manufacturer's web site);
- what the expectation is of the healthcare facility (if any) to facilitate the convergence of the missing information with the non-compliant card (e.g., the healthcare facility will need to adhere the device sticker on the template card);

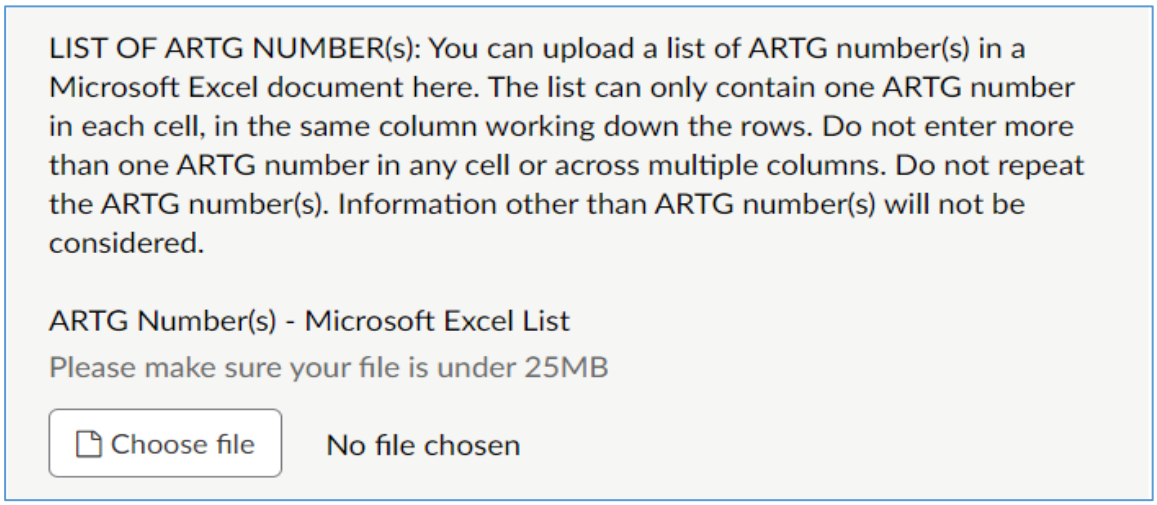
- will there be education sessions provided to the healthcare facility or patient, and if so, when will these be provided (e.g., the sponsor will provide support to the healthcare facilities when products are ordered or supplied); and
- when can the healthcare facility or patient expect to receive a compliant patient implant card and how will this change be relayed (e.g., the compliant cards will be introduced for products manufactured from 20 May 2022. Healthcare facilities will be advised by email when the new cards are being included with the device and they are no longer required to add stickers to template cards).
- Copy of interim non-compliant card.

Electronic Patient Information Cards and Leaflets

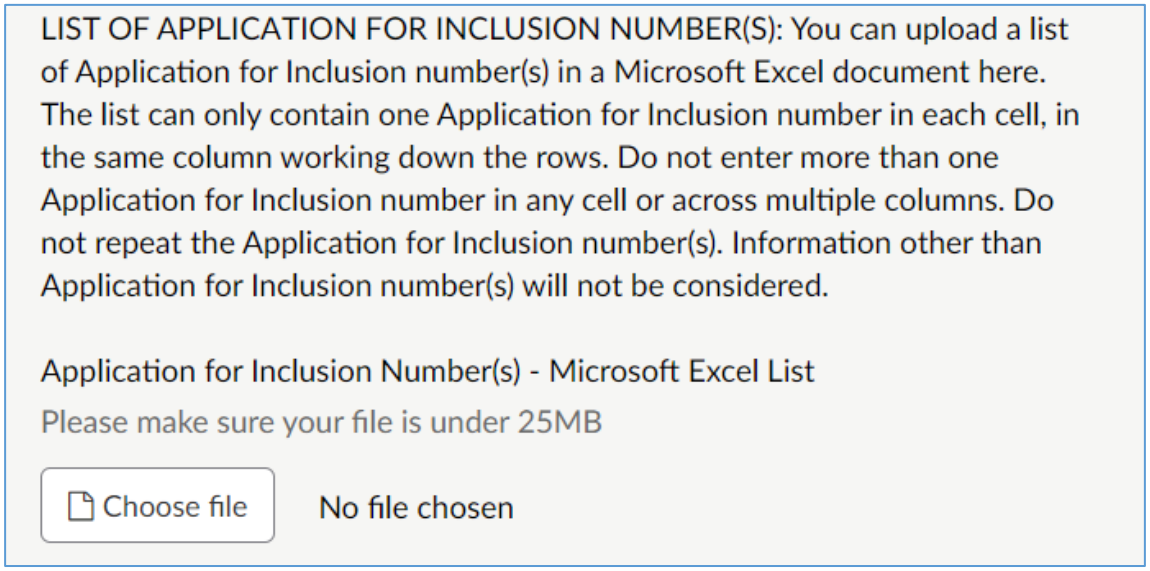
On 29 October 2021, amendments to the Therapeutic Goods (Medical Devices) Regulations 2002 came into effect to allow patient information materials for implantable and active implantable devices to be supplied in more flexible (principally electronic) formats. The Regulation changes mean that patient information cards and patient information leaflets can be supplied electronically rather than in hard copy format, as long as they contain all required information and are made available in a way that is readily accessible by the patient concerned. Where this is the case, electronic PICs and/or PILs made available in a way that is readily accessible by the patient concerned will be considered compliant and consent will not be required for these devices.

Uploading a list of non-compliant devices

You can upload a Microsoft Excel spreadsheet with a list of all affected ARTG number(s) on this page. The list can only contain one ARTG number in each cell, in a single column working down the rows. Do not enter more than one ARTG number in any cell or across multiple columns. Do not repeat the ARTG number(s). Information other than ARTG number(s) will not be considered.



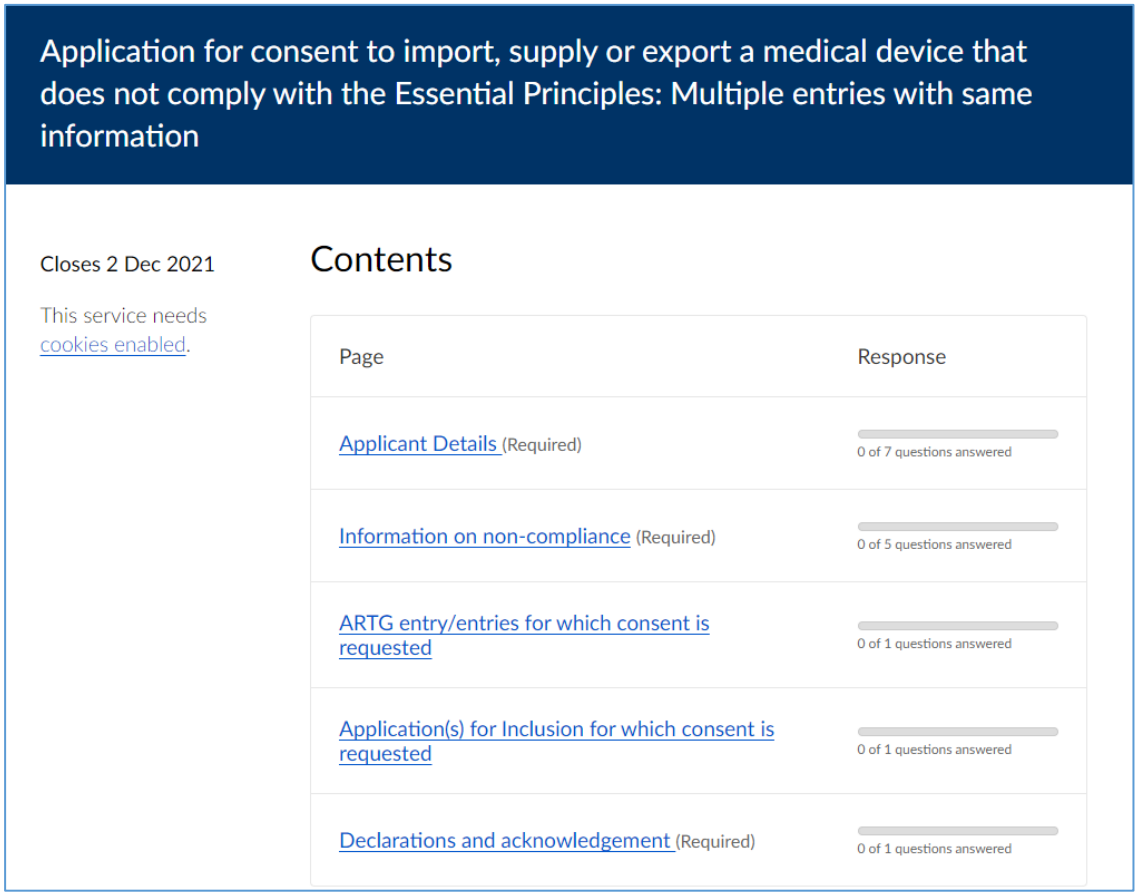
Similarly, you can upload a Microsoft Excel spreadsheet with a list of all the affected Application for Inclusion number(s) on this page, Please note this needs to be a separate spreadsheet to the ARTG number(s) list.



Next page: once you have completed this information you can either press 'save and come back later' to complete the rest of the application at another time, or you can press 'continue' to keep filling out the application.

If you select the 'Save and come back later' button you will be directed to a page that will require you to enter an email address. A link to the form with progress so far will be sent to that email address; to resume completing the form, click on the link.

If you select 'Continue', you will be returned the 'Contents' page where you can select the link 'ARTG entry/entries for which consent is request' if you have ARTG entries to be included in the consent application or 'Application(s) for Inclusion for which consent is requested' if you only have Applications for Inclusion to be included in this consent application.



Application for consent to import, supply or export a medical device that does not comply with the Essential Principles: Multiple entries with same information

Closes 2 Dec 2021

This service needs cookies enabled.

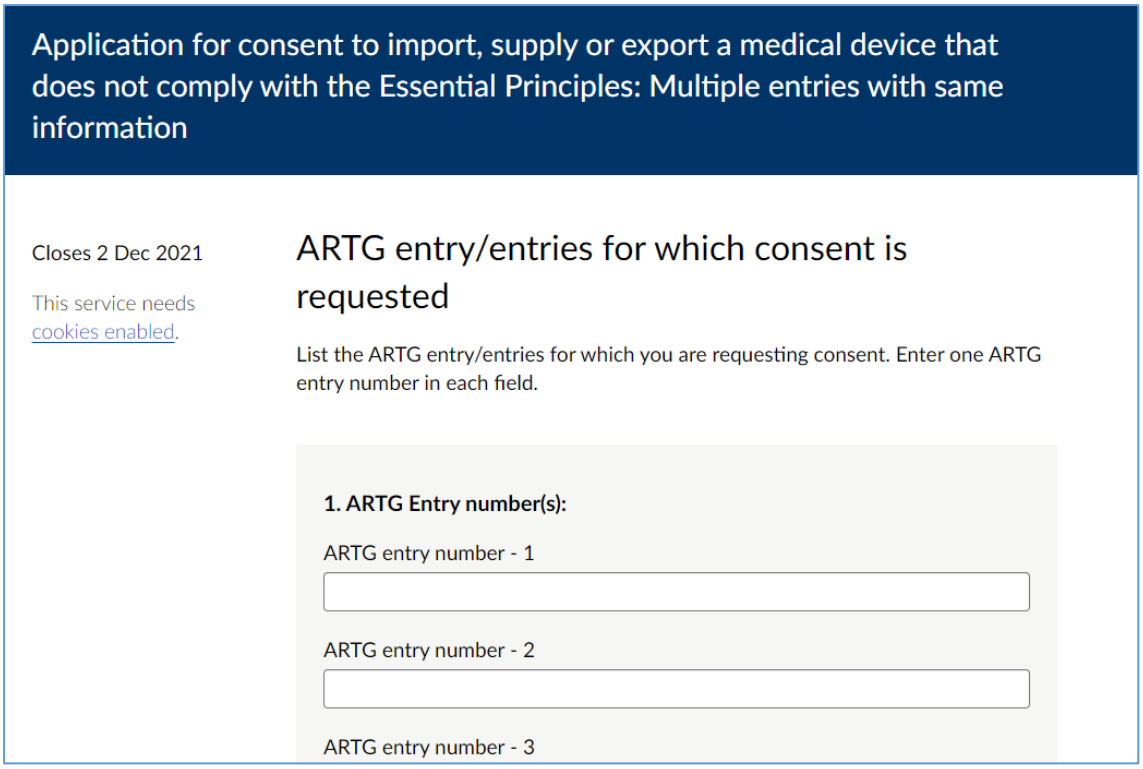
Contents

Page	Response
Applicant Details (Required)	0 of 7 questions answered
Information on non-compliance (Required)	0 of 5 questions answered
ARTG entry/entries for which consent is requested	0 of 1 questions answered
Application(s) for Inclusion for which consent is requested	0 of 1 questions answered
Declarations and acknowledgement (Required)	0 of 1 questions answered

ARTG entry/entries for which consent is requested

This is where you can manually enter ARTG entries that you want included in this consent application. This page has 100 fields for ARTG entries; if you have more than 100 ARTG entries that require consent for non-compliance with EP13A you will need to complete an additional form. The multiple forms will be linked during processing using the response ID generated for each form. The response ID is sent in the receipt email upon completion and submission of the form. Alternatively, **you can upload a Microsoft Excel spreadsheet with a list of all the affected ARTG number(s) on the 'Information on non-compliance' page.**

If your application for consent is only for devices that are part of an Application for Inclusion in the ARTG, you do not need to complete this section.

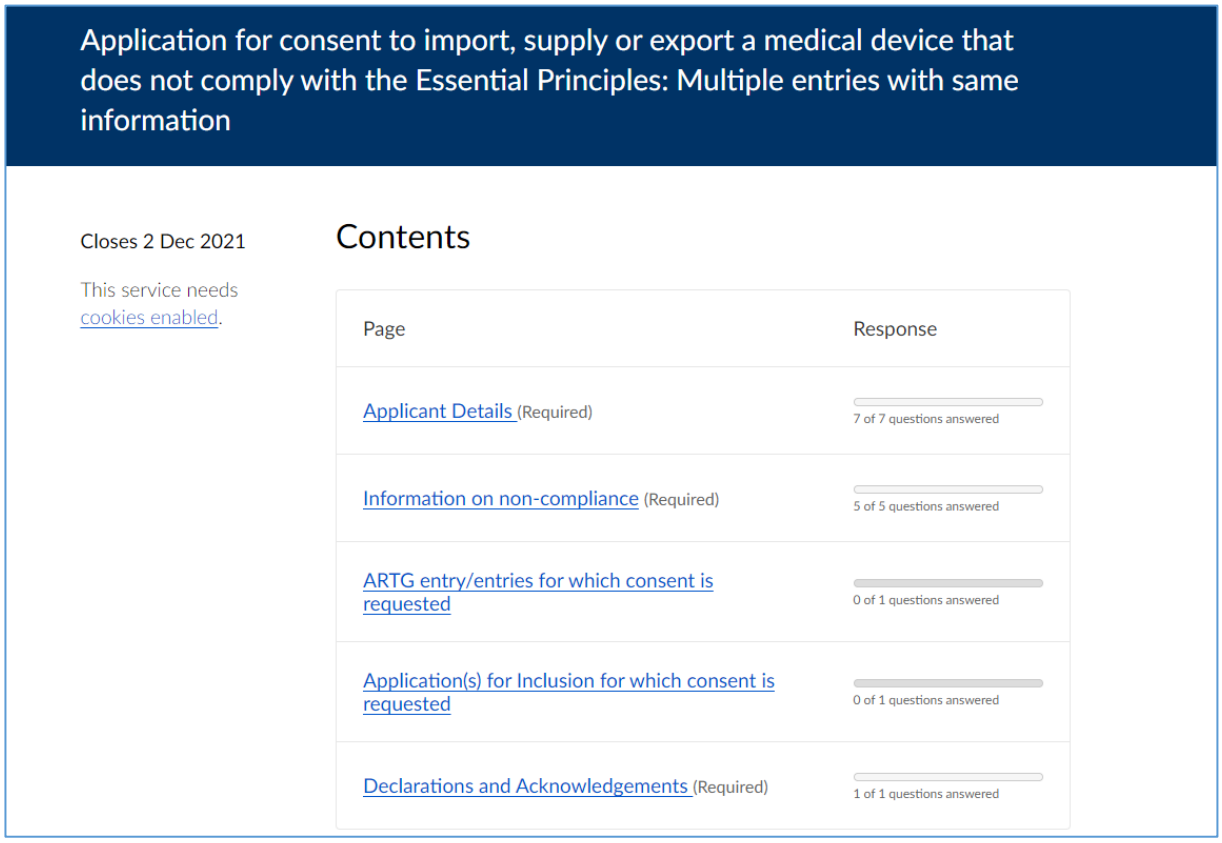


Next page: once you have completed this information you can either press 'save and come back later' to complete the rest of the application at another time, or you can press 'continue' to keep filling out the application.

If you select the 'Save and come back later' button you will be directed to a page that will require you to enter an email address. A link to the form with progress so far will be sent to that email address; to resume completing the form, click on the link.

If you select 'Continue', you will be returned the 'Contents' page where you can select the link 'Application for Inclusion for which consent is requested' if you have Applications for Inclusion in the ARTG to be included in this consent application.

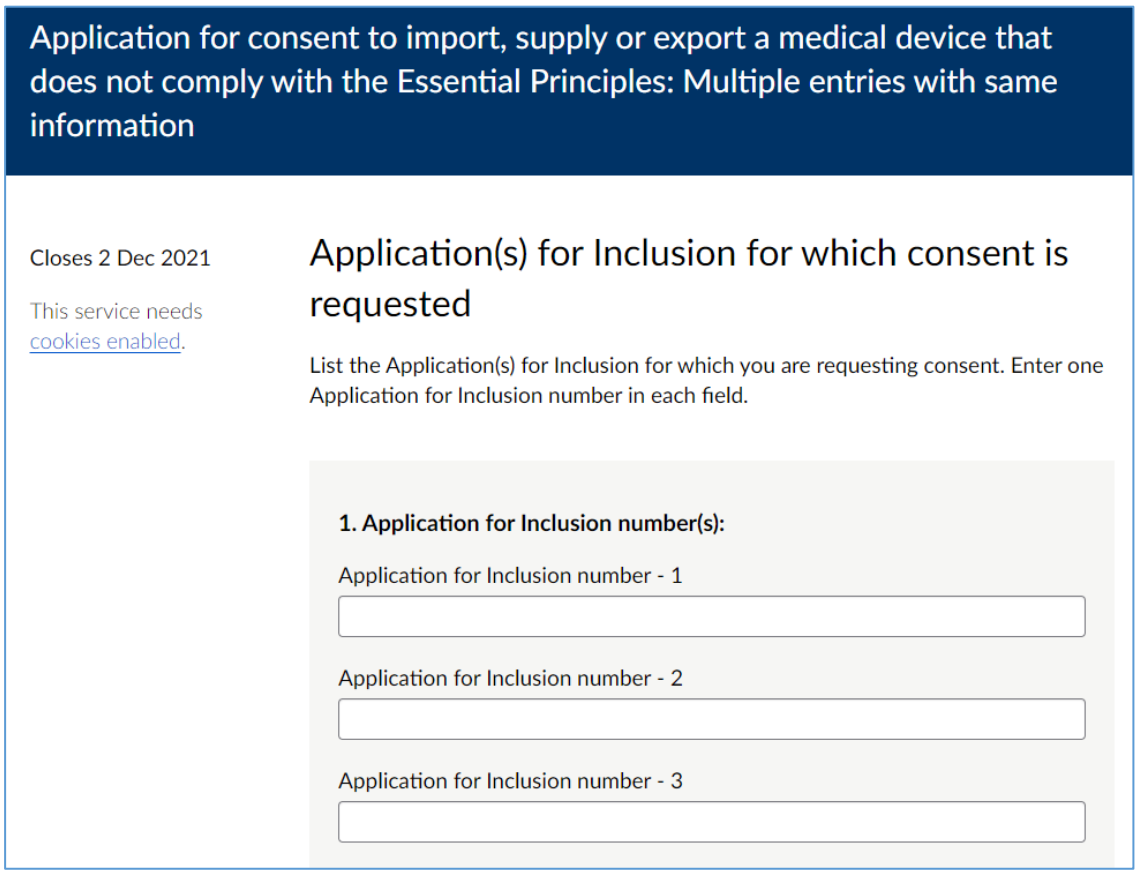
If you do not have any Applications for Inclusion in the ARTG, the you can select the link 'Declarations and Acknowledgements' to finalise and submit the application.



Application(s) for Inclusion for which consent is requested

This is where you can manually enter Application for Inclusion number(s). This page has 100 fields for Applications for Inclusion number(s); if you have more than 100 Applications for Inclusion that require consent for non-compliance with EP13A you will need to complete an additional form. The multiple forms will be linked during processing using the response ID generated for each form. The response ID is sent in the receipt email upon completion and submission of the form. Alternatively, you can upload a Microsoft Excel spreadsheet with a list of all the affected Application for Inclusion number(s) on the 'Information on non-compliance' page.

If your application for consent is only for current ARTG entries, you do not need to complete this section.



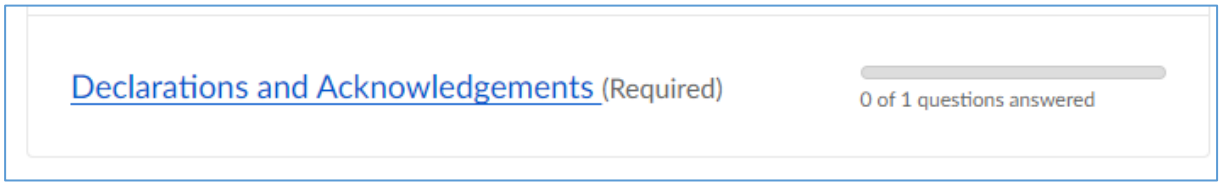
Next page: once you have completed this information you can either press 'save and come back later' to complete the rest of the application at another time, or you can press 'continue' to keep filling out the application.

If you select the 'Save and come back later' button you will be directed to a page that will require you to enter an email address. A link to the form with progress so far will be sent to that email address; to resume completing the form, click on the link.

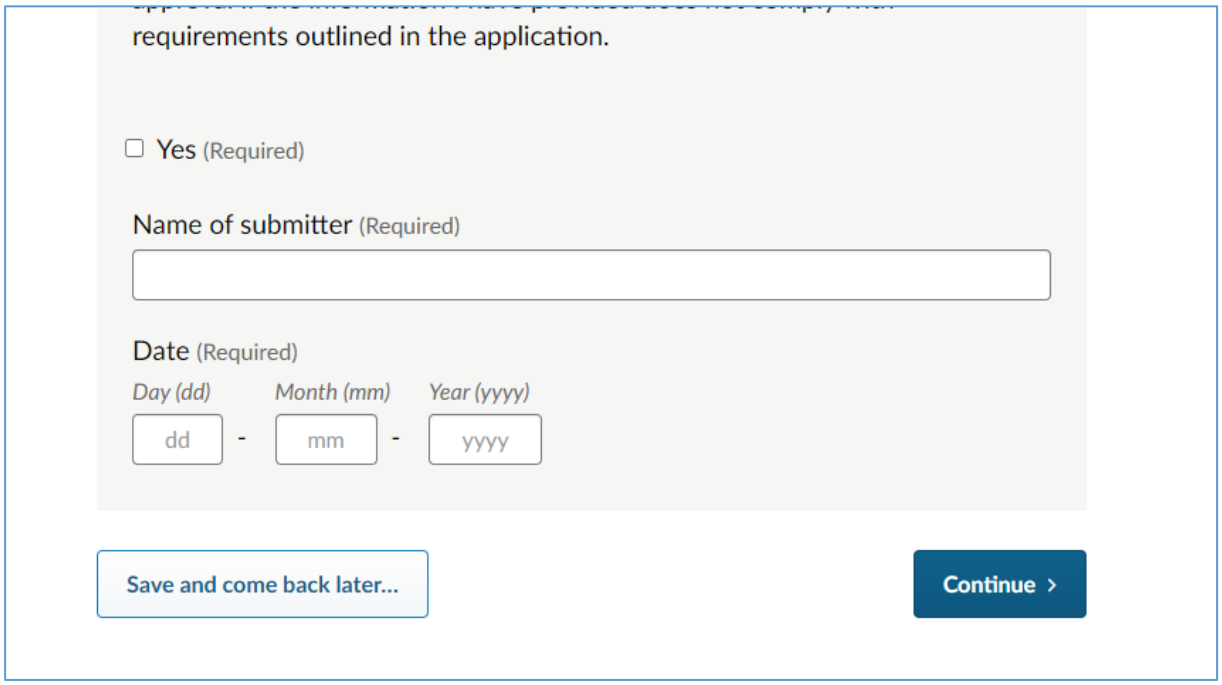
If you select 'Continue', you will be returned the 'Contents' page where you can select the link 'Declarations and Acknowledgements' to finalise and submit the application.

Declarations and Acknowledgements

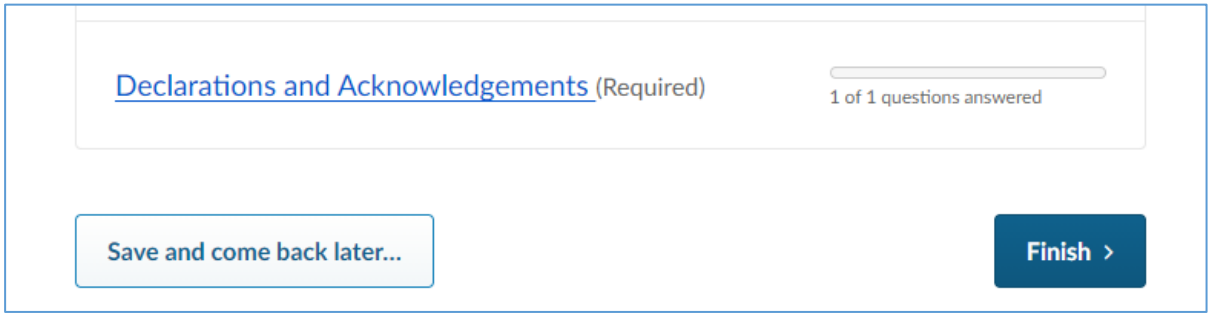
Once you have finished entering details of all or up to 100 ARTG entries or Application for Inclusions, select the 'Declarations and Acknowledgements page'. All fields on this page are mandatory.



At the bottom of this page, check the 'Yes' box, to approve the declarations and acknowledgements, enter your name and date in the spaces provided.

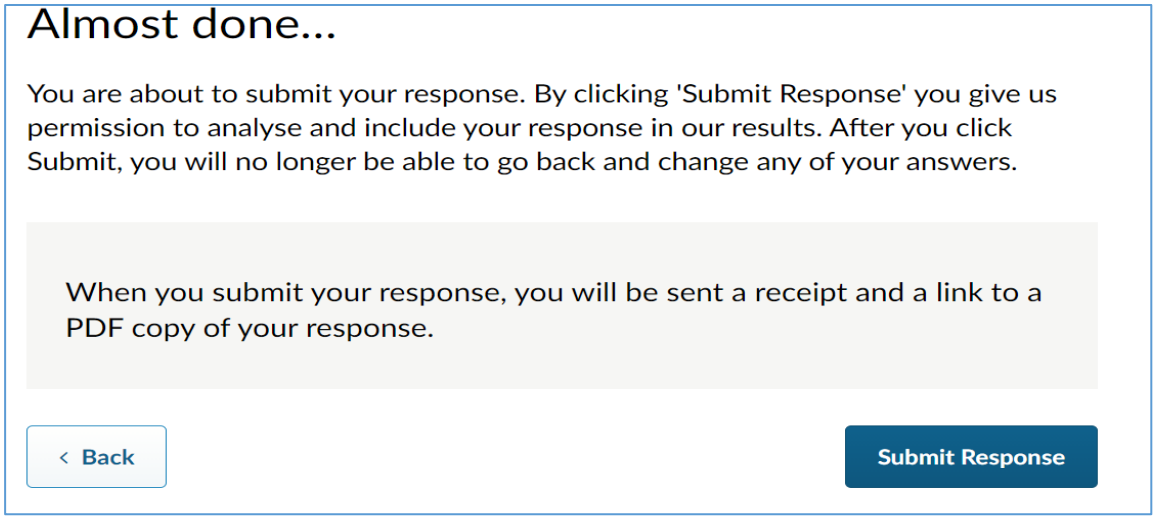


Once you have completed this information you can either press 'Save and come back later' to complete the rest of the application at another time, or you can press 'Continue' to keep filling out the application. Selecting 'Continue' will take you to the 'Contents' page, where you can select 'Finish', located at the bottom of the page, to submit your application.



Final Step

After you select 'Finish' you will be directed to the 'Almost done…' page. On this page you can select 'Submit Response' to submit the application or select 'Back' to amend the application. Selecting 'Back' will take you to the 'Contents' page.



After you submit the application, an acknowledgement email will be sent to your nominated email address with a copy of your submission, including the response ID number of this application form. Please ensure that you keep a record of this response ID for future reference.

If you are seeking consent for more than 100 ARTG entries / Applications for Inclusion, you will need to complete a new form(s) for the additional devices.

Frequently Asked Questions

How long will the application form take to complete?

Typically, the form takes 15-30 minutes to complete depending on how many ARTG entries or Application for Inclusions you are including in your application.

Is it mandatory to answer all the sections of the form?

Most of the questions on the 'Applicant Details' page, 'Information on non-compliance' page and 'Declarations and Acknowledgements' page are mandatory to respond. Some questions on 'ARTG entry/entries for which consent is requested' page and 'Application(s) for Inclusion for which consent is requested' page are mandatory to respond. Please answer the required questions to allow you to submit this application.

Are there any special considerations that I should keep in mind while answering a question?

Please follow the instructions while answering a question (e.g. *'If you selected 'New information to be entered', please respond to the questions below. Otherwise, skip to question 4*.). This is important for processing your application.
Some questions will have additional elements or sub questions (e.g. '*Please specify'*). Please answer those elements wherever possible, as it will give you an opportunity to provide further information.

What should I do after I finish answering all questions on the page?

Once you finish answering questions on a page, please click on the 'Continue' button located at the bottom of that page. Doing so will take you to the next page of the form.

Can I partially complete form and come back to it later?

If you are not able to complete the form in one sitting, you can click the 'Save and come back later' button. This will save your progress and allow you to complete the form later (before the due date). Doing so will direct you to a page that will require you to enter an email address. A link to the form with progress so far will be sent to that email address. Please click on the link provided to resume the form.

Why am I seeing an error message when I click 'Continue' after answering all the questions?

The error message indicates that you have submitted a response in a format that is not acceptable for that question.

For example:

Can I copy and paste text into the form?

You can copy and paste text into the form wherever the form permits free text answers.

Can I attach a supporting document to the form?

You can attach a supporting document into the form wherever the format allows you to do so.

What should I do to save my progress on each page?

To save the progress on a page, you need to click a button such as 'Continue', 'Save and come back later', 'Finish' located at the end of the page. This ensures that the data you have entered will be saved. You will lose your progress if you navigate away without clicking on a button.

The portal does not receive and register the data entered on a page unless you click on a button.

Can I make changes to my response after I have submitted the form?

Your responses cannot be edited once you have clicked the 'Submit Response' button. However, a request to make changes to the application can be considered by the TGA on a case-by case basis by email mdconsent@health.gov.au and quoting the response ID number.

Further information:

For more information or further question on how to submit your application online, please contact mdconsent@health.gov.au or call us on 1800 141 144.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Surveillance Branch	October 2021
V1.1	Updated to include information on fee reduction for sponsors seeking consent for non-compliant patient information, and regulation changes for electronic patient information materials	Medical Devices Surveillance Branch	October 2021

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Reference/Publication #