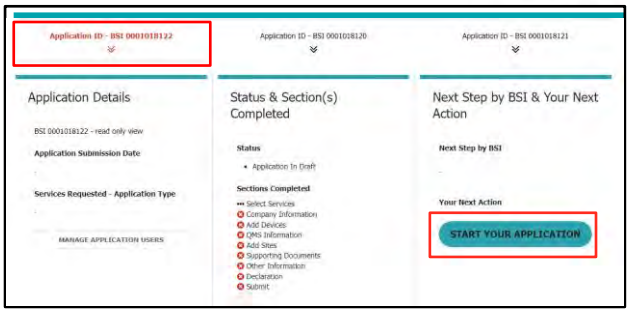
Completing an application

Starting the application

Select the application on your portal homepage that you'd like to complete. If you only have one Application it will be automatically selected.

In the Next Step & Next Action(s) section, Click START YOUR APPLICATION.

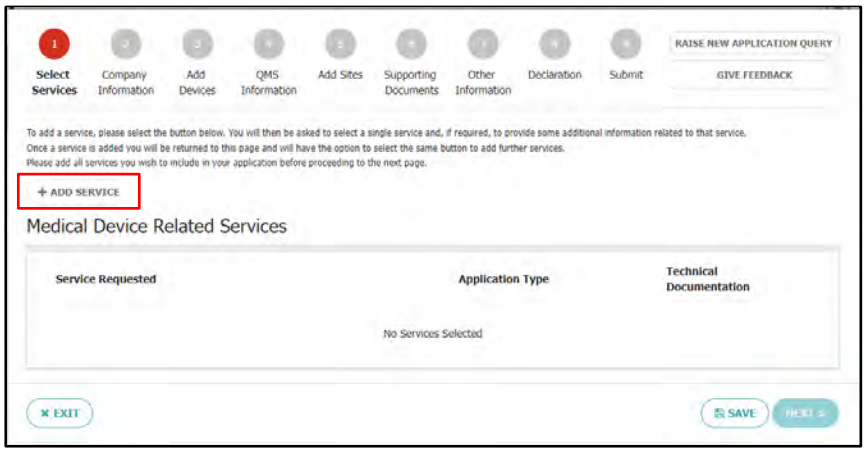


Tip: Throughout the process, the Application Owner will receive automated email notifications as the application progresses or changes are made.

Step 1 → Adding services

The first section will allow you to choose what services you would like to apply for. You can add more than one service, but you'll need to add each service individually using the ADD SERVICE button.

Click ADD SERVICE.

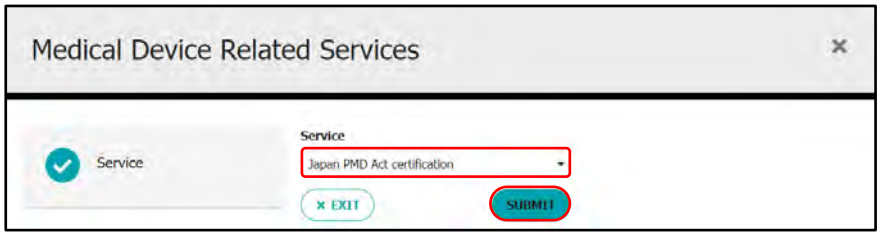


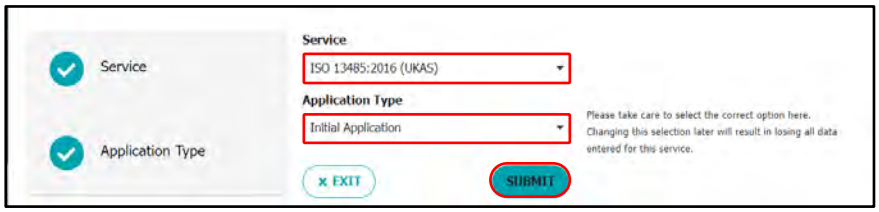
The Service Selection page displays.

Enter the following details:

Service: select the required service from the drop-down list.

Tip: Additional options display depending on the type of service you select (three examples are shown on the right).

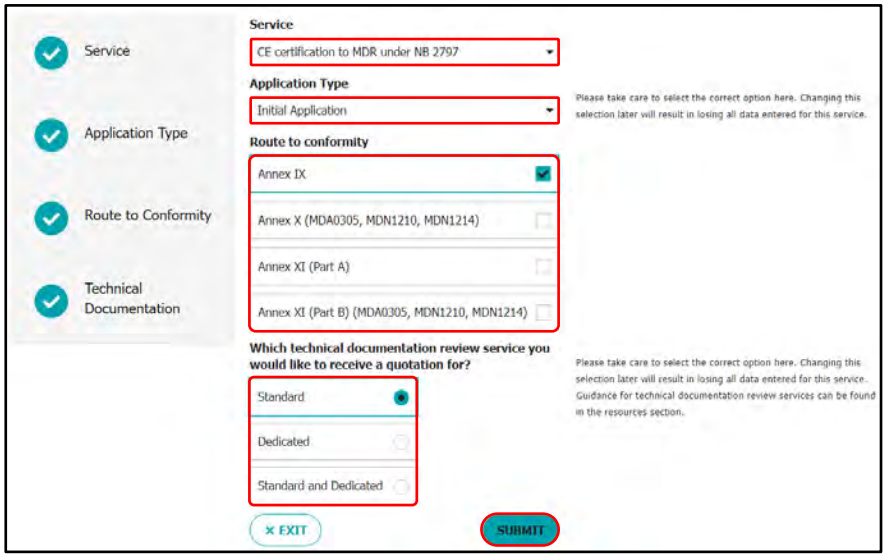




Application Type: select from the drop-down list the services that have been requested in this application.

Route to conformity: select one or more annex.

Which technical document review service you would like to receive a quotation for?: select the level of technical documentation review service, Standard, Dedicated or Standard and Dedicated.



Click SUBMIT.

Completing an application

Step 1 → Adding services (continued)

The selected service(s) displays on the Select Services page.

You can select ADD SERVICE again to add any additional services.

If you wish to amend any service details other than the service itself, click the Pencil Edit symbol.

If a service is no longer required, or you would like to replace it with another click the X next to any service to remove it.

Click Next.

Step 2 → Updating your company information

Your legal company name and address are imported into the application, but there are other details that you will need to fill in about your company.

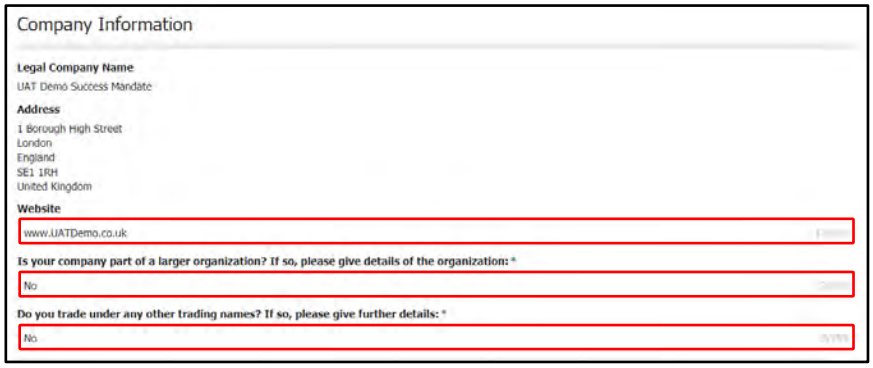
Enter the following details:

Tip: you can update your legal company name and address from the portal landing page at any stage in the application process.

Website: enter your company's website address.

Is your company part of a larger organization? If so, please give details of the organization: Enter N/A or the name of the larger organisation your company is part of.

Do you trade under any other trading names? If so, please give further details: Enter No or any other trading names of your company.

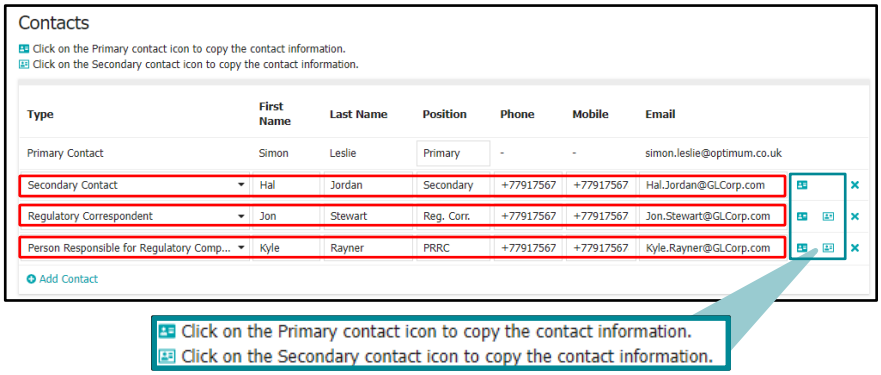


Scroll down to the Contacts section.

Your primary contact details are the same as your application owner and already populated.

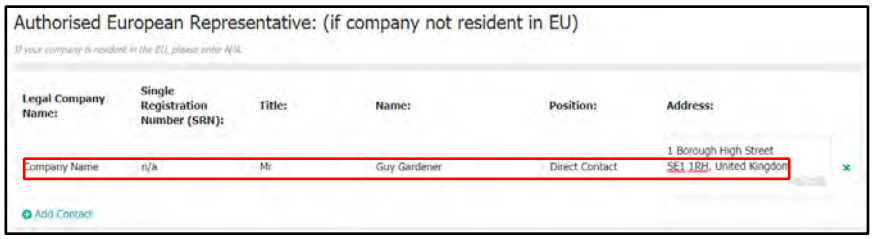
Enter the details of your secondary contact, regulatory correspondent and person responsible for regulatory compliance here.

You can click the Primary or Secondary contact icons right of the details to copy existing contact information.



Scroll down to the Authorised European Representative section.

Enter the details of your authorised European representative if your company is not resident in the European Union. Otherwise, if your company is resident in the EU, enter N/A.



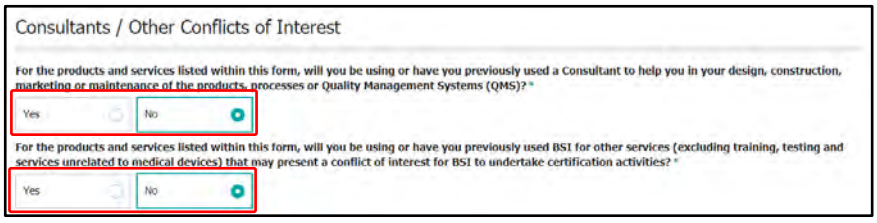
Completing an application

Step 2 → Updating your company information (continued)

Scroll down to the Consultants / Other Conflicts of Interest section.

Select Yes or No to indicate if there any consultants associated with the application or any potential conflicts of interest.

If Yes is selected for either option, additional fields display to enter more information.



Once all of the Company information is captured, click NEXT in the bottom right.

Sections differ based on Services

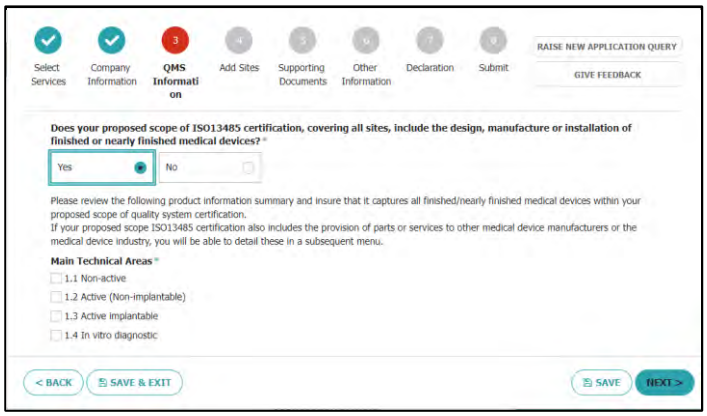
For a QMS Service:

Step 3a → QMS Information

The QMS Information section of the application is specific to applications including QMS services.

The first question "Does your proposed scope of ISO13485 certification, covering all sites, include the design, manufacture or installation of finished or nearly **finished medical devices?"**

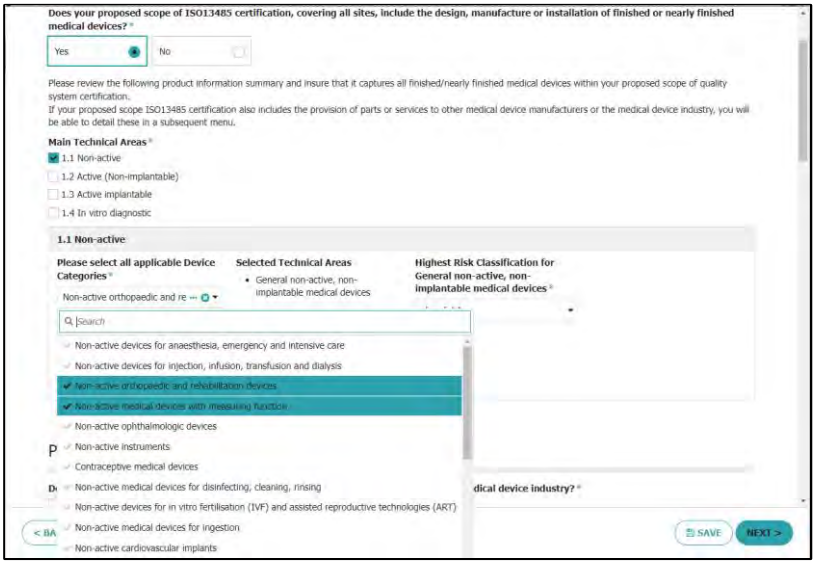
Will give you four Main Technical Areas to choose from if you answer yes. You can select as many as needed with the check boxes to the left of the areas.



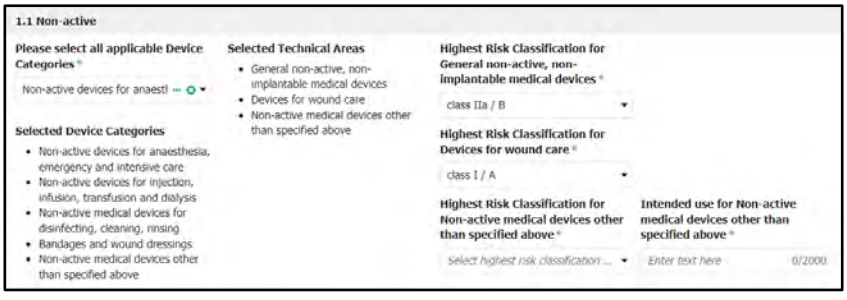
When you select a Main Technical Area a details section for that area will appear below. Each technical area selected will have it's own detail section.

By using the dropdown menu under **"Please select all applicable Device Categories"** you can select as many device categories as needed by clicking the category.

This will highlight the category and they will appear below **"Selected Device Categories"** in a bullet pointed list.



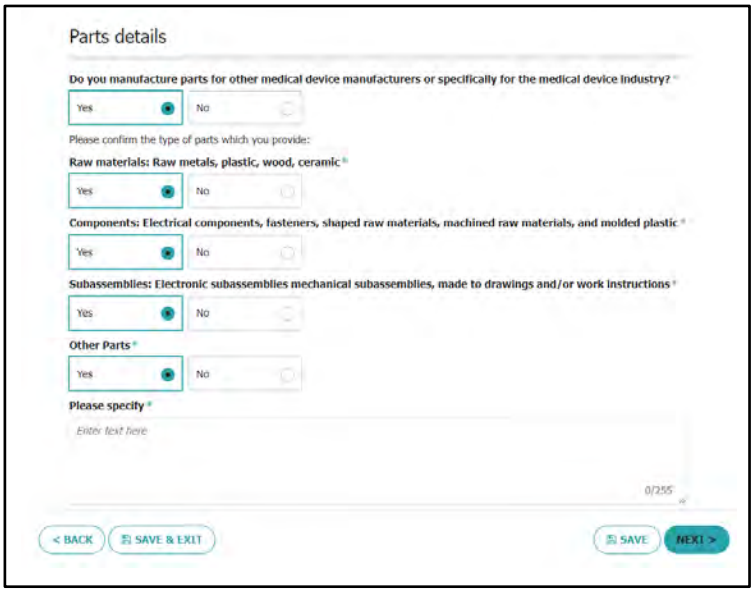
The "Selected Technical Areas" and "Highest Risk Classification" are automatically filled based on the "Selected Device Categories" unless an "other than specified above" device category is chosen.



Completing an application

Step 3a → QMS Information (continued)

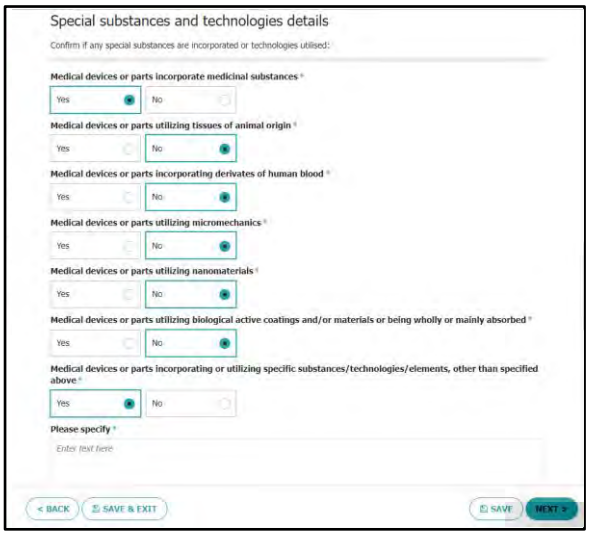
Scroll down to the Parts Details section. If you answer yes to "Do you manufacture parts for other medical device manufacturers or specifically **for the medical device industry?"** there will be follow up questions. Select yes for all types of parts you provide.



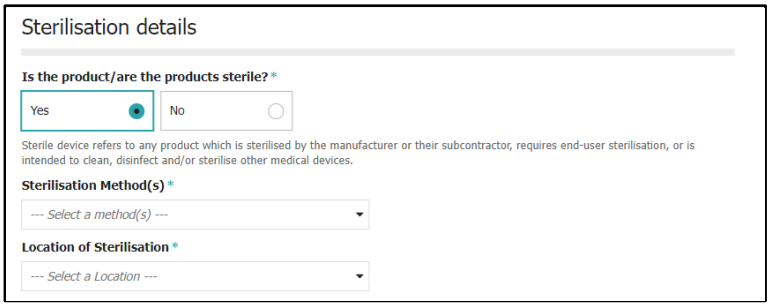
Tip: If you have answered yes to "Does your proposed scope of ISO13485 certification, covering all sites, include the design, manufacture or installation of finished or **nearly finished medical devices?"** there will also be follow up questions in the Parts Details section.

Scroll down to the Special substances and technologies details section. Here you will answer if there are any special substances or technologies used in your devices or parts.

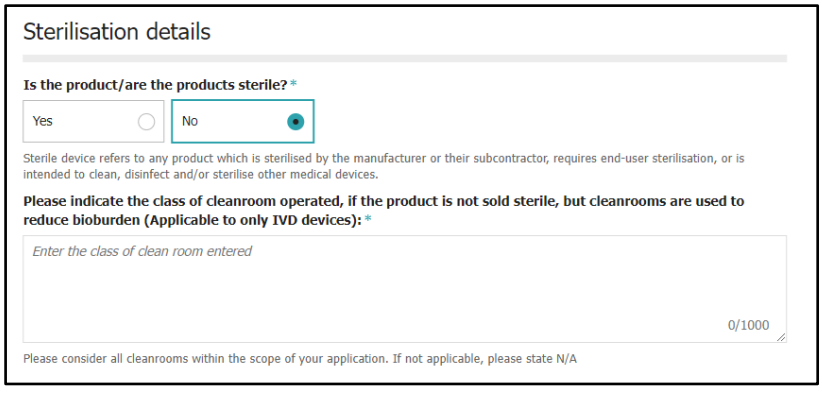
You will need to answer yes or no for each question specifying types of special substances or technologies. If you use a substance or technology is not covered by the specific questions the last question in this section is for "other than specified above" and will allow you to fill in a free text box if answered yes.



Next is the Sterilisation details section. If you answer yes to **"Is the product/are the products sterile?"** you will have follow up questions in the form of drop downs to indicate the method(s) and location(s) of sterilization. You can select more than one option from each drop down by clicking on multiple options. The selected methods or locations will be highlighted in the dropdown menus.



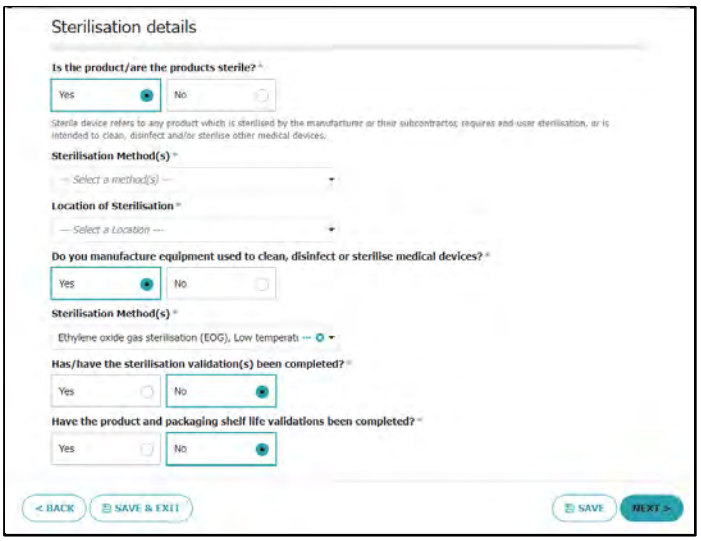
If you answer no to the same question there is a follow up question for IVD devices about cleanroom use. If you do not have IVD devices or cleanrooms are not used please answer N/A in the free text box.



Completing an application

Step 3a → QMS Information (continued)

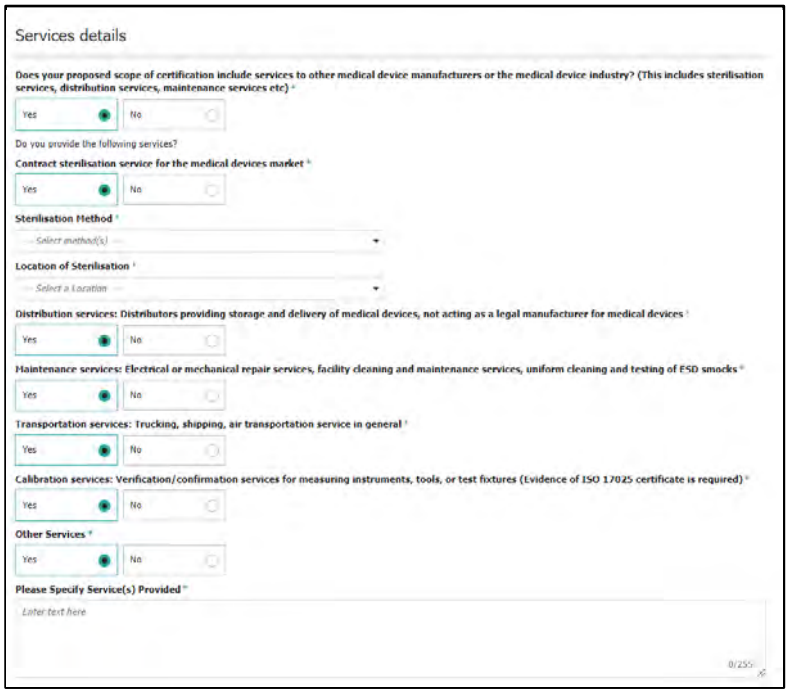
Continuing with the Sterilisation details section, if you answer yes to **"Do** you manufacture equipment used to clean, disinfect or sterilise **medical devices?"** you will be asked to select at least one sterilisation method from the dropdown menu. You can select more than one method by clicking on them in the dropdown menu which will highlight the selected method(s).



You will also be asked two questions about the validations for your products, please answer yes or no.

> Tip: You can remove a selected location or method by either reopening the dropdown and clicking the highlighted selection again, or by selecting the teal X next to the selected methods or locations. Reopening the dropdown will allow you to remove one selection at a time, while the X next to the list of selections will remove all selections.

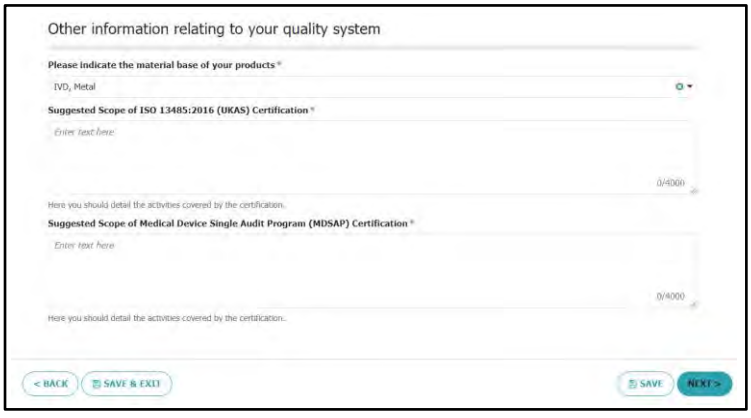
Scroll down to the Services details section. If you answer yes to "Does your proposed scope of certification include services to other medical device manufacturers or the medical device industry? (This includes sterilisation services, distribution services, maintenance services etc)" you will have follow up questions to answer afterwards.



You will need to answer yes or no for each question. If you answer yes to providing a contract sterilisation service you will also need to provide the sterilisation method(s) and location(s). As noted for previous sections you can select multiple options for both of these dropdowns.

There will also be a free text box for you to specify other services provided if you answer yes to providing other services not listed.

Scroll down to the Other information relating to your quality system section. You will be asked to select the base material of your product(s) from a drop down menu. You may select as many materials as needed from the list.



Each QMS certification you are applying for will have a free text box for you to outline the suggested scope of the certification. Please provide a detailed list of the activities you wish to have the certificate cover.

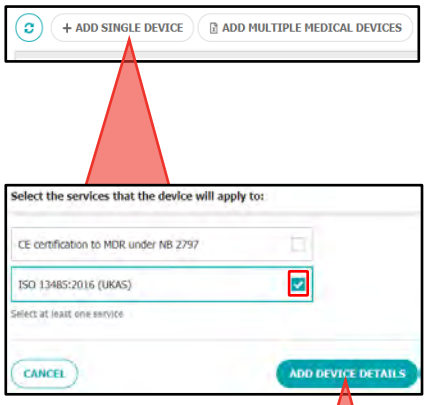
Once you have finished select NEXT> in the bottom right to complete the QMS Information page.

Completing an application

Step 3b → Adding devices

The Add Devices section of the application allows you to add to the details of devices if your application includes the ISO 13485 (Optional), CE Marking (Mandatory), UKCA (Mandatory) or Medical Device Single Audit Program (MDSAP) (Optional).

To add multiple medical devices, refer to the *Managing applications with multiple devices* quick card.



To add an individual device (and you can repeat these steps for up to five devices):

Click ADD SINGLE DEVICE.

The Select Services for Device page displays.

Select one or more service(s) that apply to the new device and click ADD DEVICE DETAILS.

Depending on the service(s) you select, there will different information requested for the device. The information requested for the ISO 13485:2016 (UKAS) service will be shown in detail and an example of a device under the CE Certification to MDR under NB 2797 service will be summarised.

A Device Details page displays. Enter the following details:

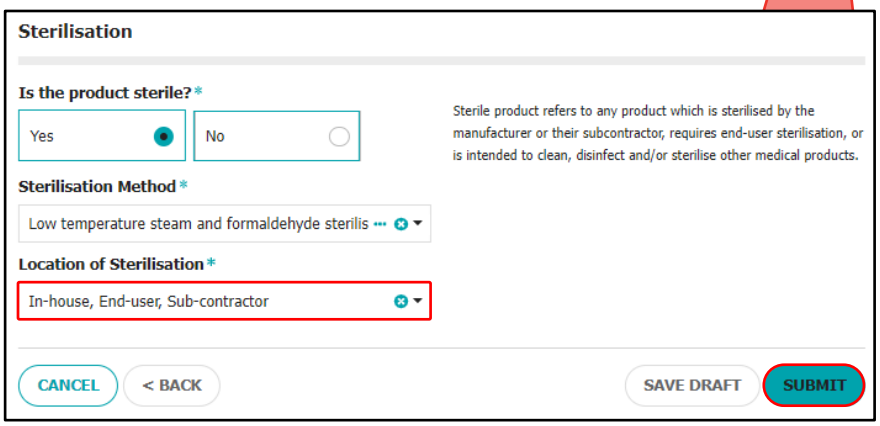
Product Name: enter the product name, including the brand name.

Product Description/Intended Use: enter the description of the product and how it is intended to be used.

Click NEXT.

The Materials & Sterilisation page for the device displays.

Enter the following details:



Is the product sterile?: select Yes or No. If you select Yes the remaining two options display.

Sterilisation Method: select one or more sterilisation method. If Other is selected, an additional text box displays for you to specify the method.

Location of Sterilisation: select one or more of the location options.

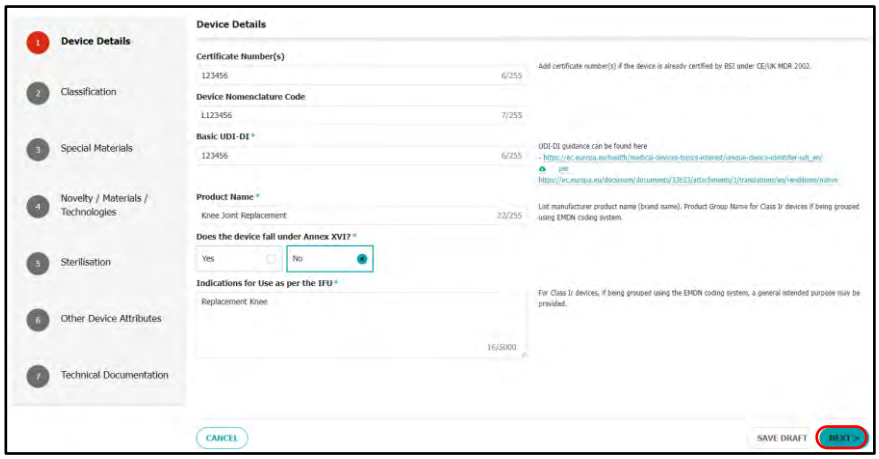
Completing an application

Step 3b → Adding devices (continued)

A device that is associated with a service such as the CE Certificate to MDR under NB 2797 has more required information requested. This quick card will summarise an example of this instance.

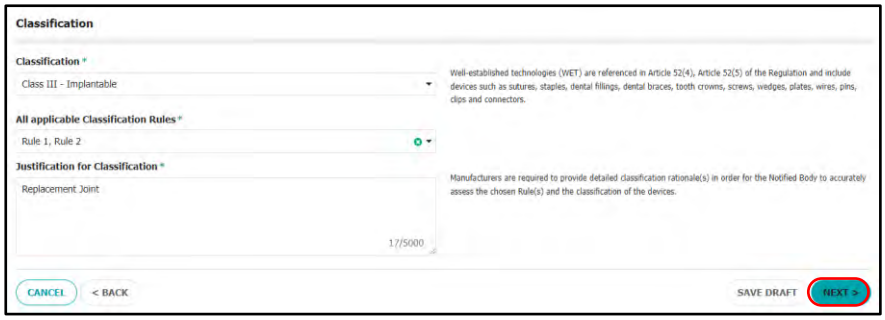
Initially, Device Details must be entered, including certificate number(s), the device 's nomenclature code, basic UDI-DI, Product Name, whether the device falls under Annex XVI and Indications for use.

Click NEXT.



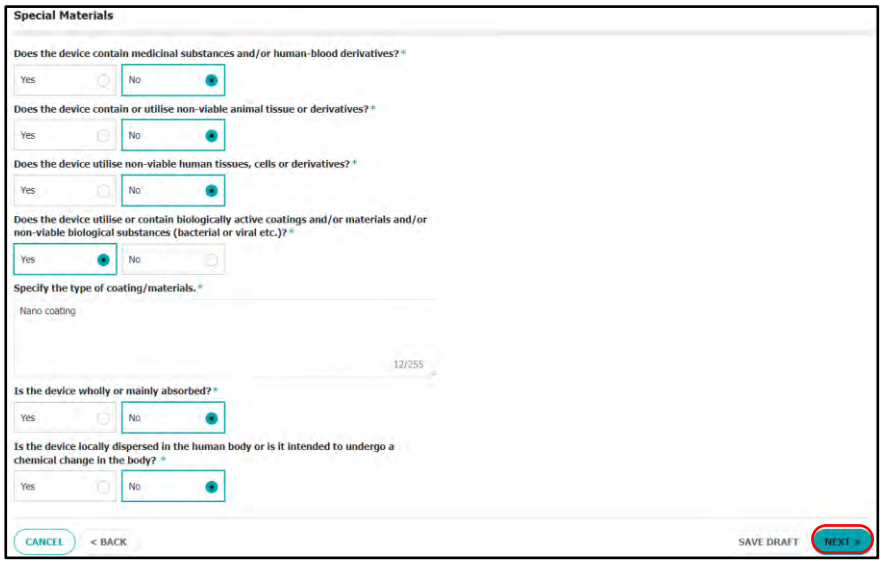
Classification details are entered, including selecting the classification, applicable classification rules and the justification for classification.

Click NEXT.



Special Materials details are entered, with follow up questions requesting more details if any questions are answered Yes.

Click NEXT.



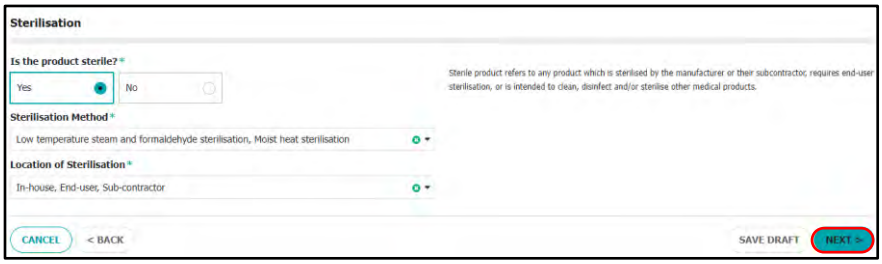
Novelty / Materials / Technologies related questions must then be entered to indicate in the device is a new development, if it features an novel features in terms of material, technology or intended use and the primary material base or technology used in the product.

Click NEXT.

Completing an application

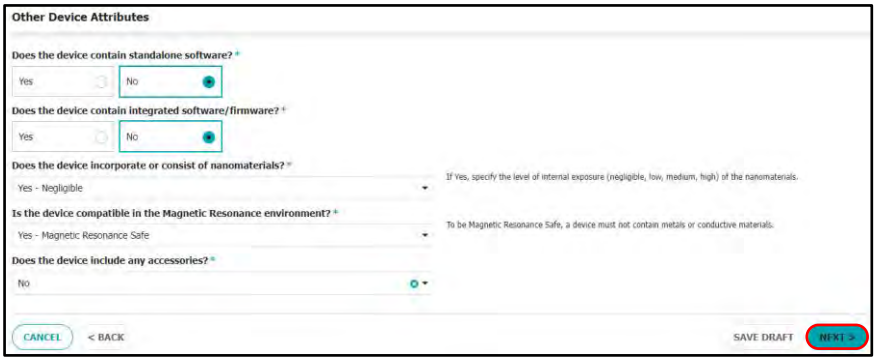
Step 3b → Adding devices (continued)

Sterilisation related questions are entered and cover the same sterilisation questions demonstrate earlier in step 5.



Click NEXT.

Other Device Attributes related questions are asked, including whether the device contains any standalone or integrated software, whether the device incorporate or consists of nanomaterials, if the device is compatible in the Magnetic Resonance environment and if the device includes any accessories.



Click NEXT.

Technical Documentation related questions are asked, include a set month for the date for submission of technical document and the technical documentation file reference number(s).

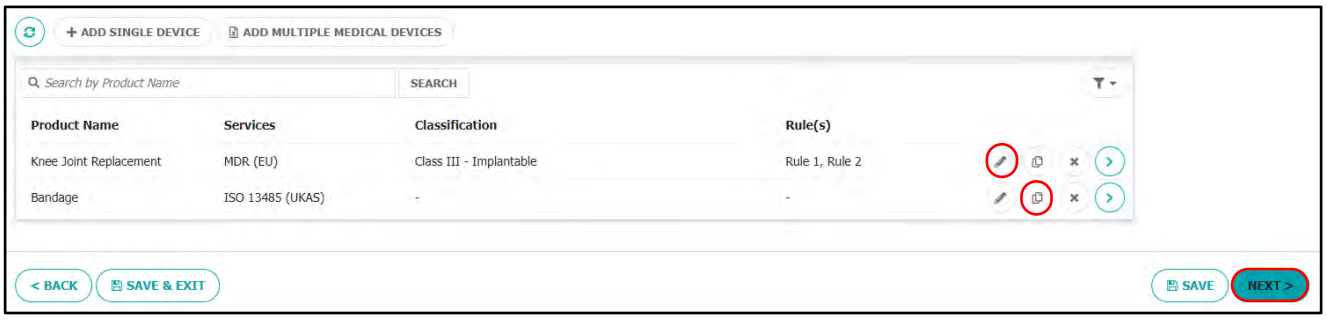
Click SUBMIT.

The Add Devices page displays with the new device(s).

To add more devices, repeat the previous steps.

If you are adding a similar device, click the Clone Device symbol. This will recreate the same device with the exception of the Product Name which must be different.

Once all devices have been recorded, click NEXT.



Completing an application

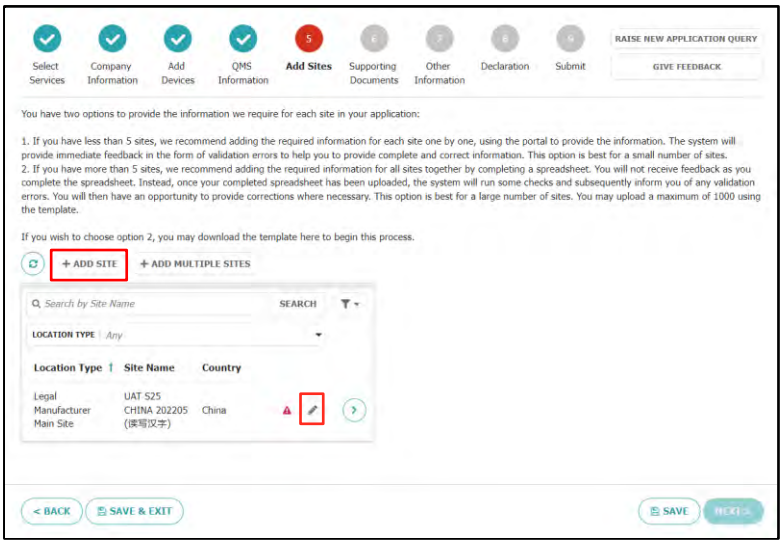
Step 4 →

The Add Sites section of the application allows you to add to the details of your main site as well as record details of any additional sites.

It is recommend if you have 5-10 sites or less to individually enter them on the portal. You can do so by using the +ADD SITE button with detailed steps below.

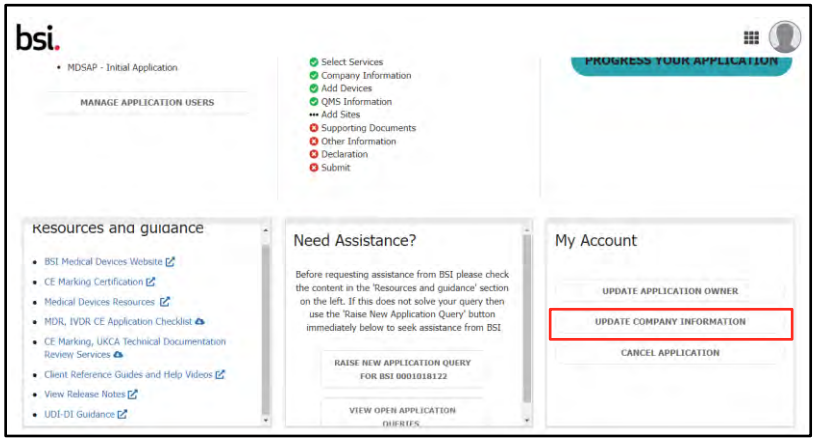
Alternatively, clicking +ADD MULTIPLE SITES will lead you to the download for the bulk site template. Refer to the *Managing applications with multiple sites* quick card for more information.

Your first site is automatically added to the application. This is your Legal Manufacturer Main Site. Click the Edit (pencil) symbol for the Main site to fill in the rest of the information needed.



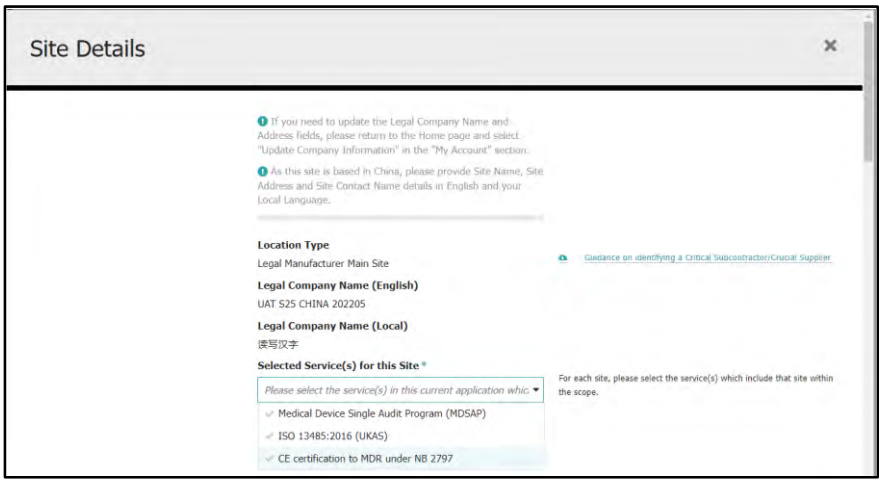
Tip: If you need to change the address or name of the Legal Manufacturer main site you will need to Save & Exit the application and request a Company Information update from the landing page of the application. This can be found in the My Account section of the landing page in the bottom right corner.

Please note that while a Company Information update is being processed the application will be paused and unavailable for editing.



Continuing with the editing of the Legal Manufacturer Main Site. When the edit symbol to the right of the site listing is selected the Site Details page displays.

The main site will already have some details filled in, such as the address, but will require other details to be added.



Selected service(s) for this site: select from the previously identified services that include this site within the scope. You can select multiple services from the dropdown. Be aware you must update this field if services are added or removed in the future.

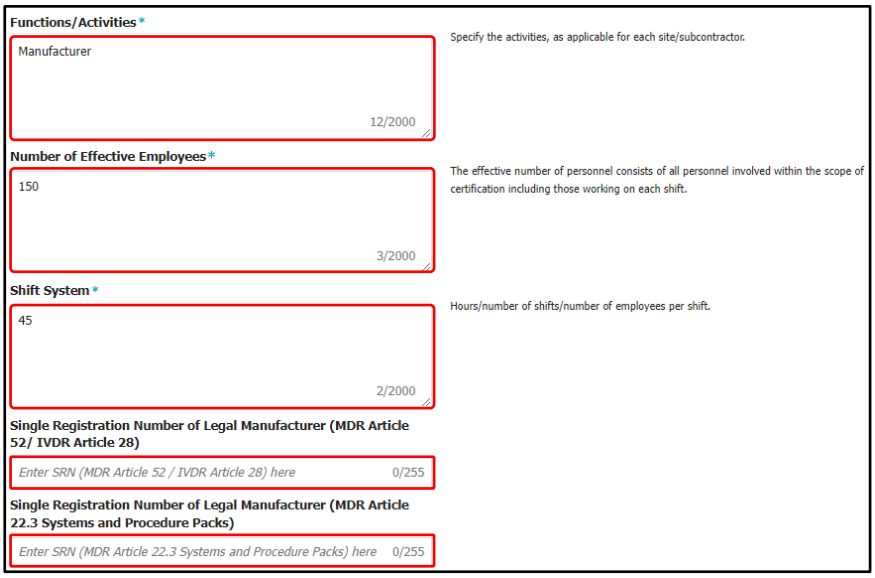
Completing an application

Step 4 → Adding sites (continued)

Scroll to the Functions/Activities section.

Enter the following details for the site:

Functions/Activities: enter the typical functions and activities for the site.
Number of Effective Employees: enter the number of effective employees on site.
Shift System: enter the number of hours per employee, per shift on the site.
Single Registration Number of Legal Manufacturer (MDR Article 52 / IVDR Article 28): enter the Single Registration Number, if required.
Single Registration Number of Legal Manufacturer (MDR Article 22.3 Systems and Procedure Packs): enter the Single Registration Number, if required.



Scroll to the Contact section.

Enter the contact details for the responsible individual on-site.

Name: enter the name of the contact for the site.
Name (Local): if the company is based in China, a localised version of the contact's name should be entered.
Email address: enter the site contact's email address.
Phone Number: enter the site contact's phone number.

Completing an application

Step 4 → Adding sites (continued)

Scroll to the Existing Registration(s)/ Certification(s) held section.

Click Add Site Certificate Info.

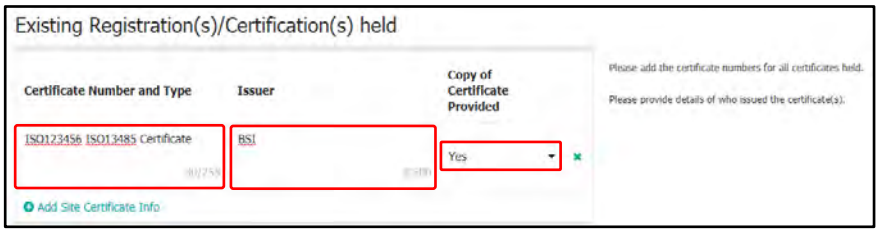
Enter the following details for any certificates:

Tip: if you holds a BSI-issued certificate, you do NOT need to upload a copy to this section.

Certificate Number and Type: enter the number and type of the certificate for the site.

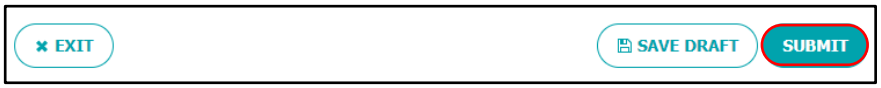
Issuer: enter the name of the issuer of the certificate.

Copy of Certificate Provided: select either Yes, No or N/A to indicate if a copy of the certificate is available. If it has been provided it will be uploaded to the portal later in the process.



Repeat these steps for any additional certificates for the site.

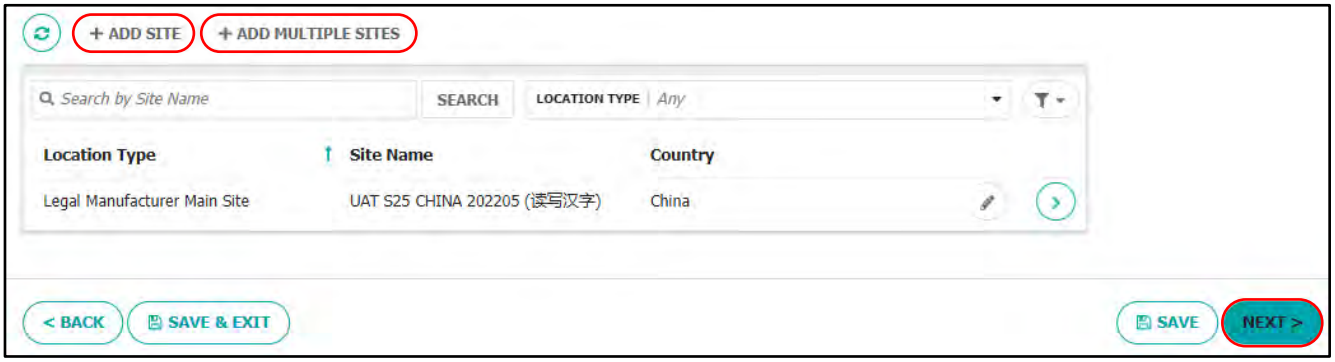
Click Submit to save the amended site details.



You are returned to the Add Sites page.

For any additional sites. Click ADD SITE and repeat the process for any remaining sites.

To add multiple sites devices, click ADD MULTIPLE SITES and refer to the *Managing applications with multiple sites* quick card for more information.



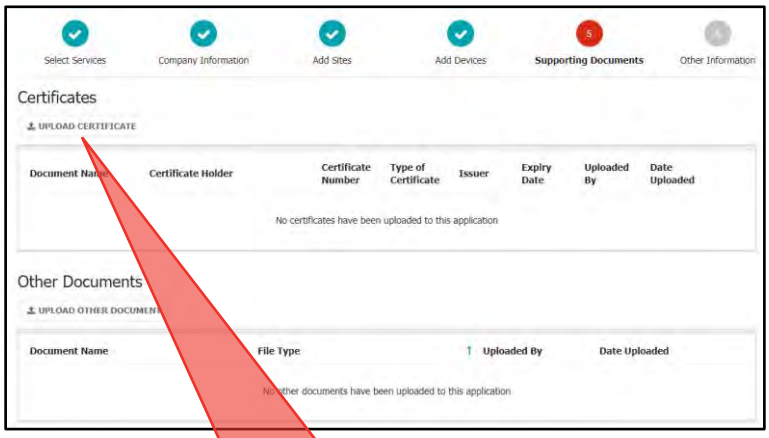
Once all your sites have been recorded, click NEXT.

Completing an application

Step 5 → Adding supporting documents

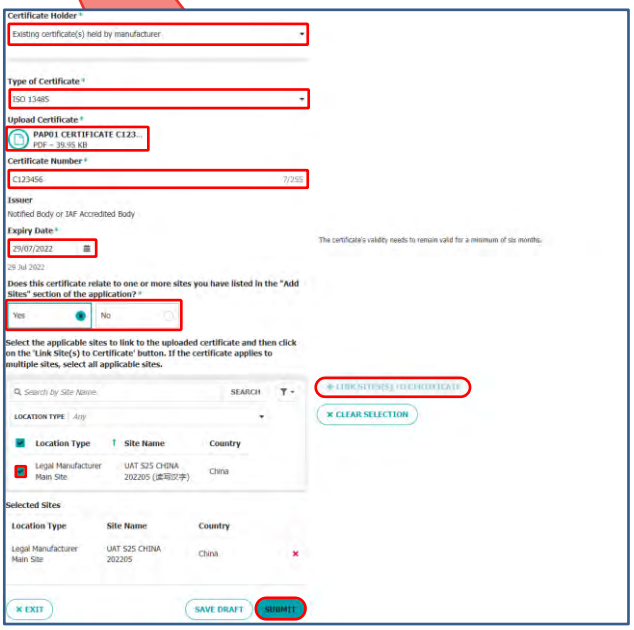
The Supporting Documents section of the application allows you to upload certificates as well as any other documents supporting the application such as Instructions for Use or contract details.

For any certificates, click UPLOAD CERTIFICATE.



The Add Certificate to Application page displays.

Enter the following details:



Certificate Holder: select if the certificate is held by the manufacturer or by suppliers/ subcontractors.
Type of Certificate: select the type of certificate from the drop-down list.
Upload Certificate: Click Upload and select the certificate through a file dialog box or drag and drop the file directly.
Certificate Number: enter the certificate number.
Issuer: this field auto-populates based on the content of the certificate you upload.
Expiry Date: enter the expiry date of the certificate. The certificate's validity should be at least twelve months.
Does this certificate relate to one or more sites you have listed in the "Add Sites" section of the application?: select Yes if the certificate is related to a specific site in your application.

If you selected Yes, select the checkbox of the site relevant to the certificate, click LINK SITE(S) TO CERTIFICATE.

Click SUBMIT.

The Supporting Documents page displays with the uploaded certificate.

It can be re-downloaded or, if it is in PDF format, previewed by clicking VIEW PDF.

Completing an application

Step 5 → Adding supporting documents (continued)

Scroll to the Other Documents section.

Click UPLOAD OTHER DOCUMENT for any additional documents supporting the application.

The Add Other Document to Application page displays.

Enter the following details:

Document Type: select the type of supporting document from the drop-down list.

Upload Document: click Upload and select the document through a file dialog box or drag and drop the file directly.

Click SUBMIT.

The Other Documents section displays with the uploaded supporting document. The uploaded document can be re-download or, if it is a PDF format, previewed by clicking VIEW PDF.

Repeat this step for any additional documents.

Once all supporting documents are stored on the portal, click NEXT.

Completing an application

Step 6 → Entering Other information

The Other Information section of the application allows you to enter additional details in your application related to readiness for assessment, language requirements, additional details to help progress the quotation process and any scope suggestions.

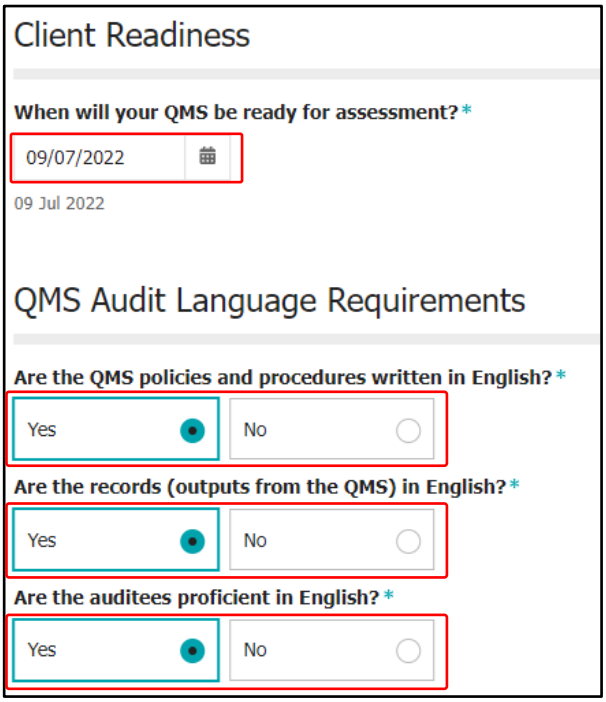
Enter the following details:

When will your QMS be ready for assessment?: enter the date your QMS will be ready for assessment.

Are the QMS policies and procedures written in English?: select Yes or No to indicate if your policies and procedures are written in English.

Are the records (outputs from the QMS) in English?: select Yes or No to indicate if your records are written in English.

Are the auditees proficient in English?: select Yes or No to indicate if your auditees are fluent in English.



Completing an application

Step 6 → Entering Other information (continued)

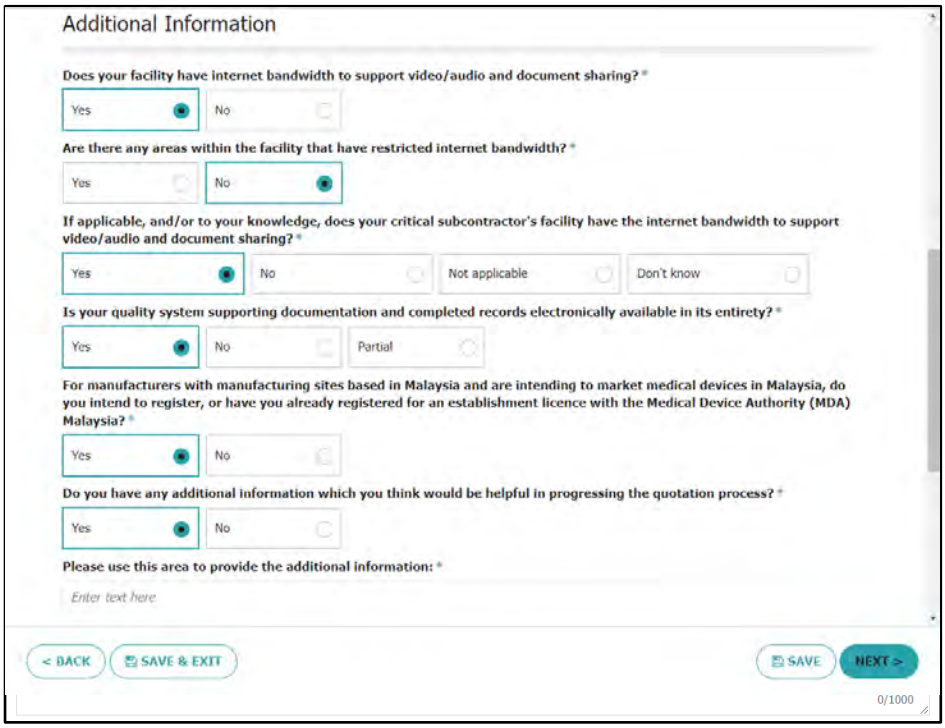
Additional Information Section: enter details for hybrid audits, Malaysia manufacturing and any additional information that may be needed for your quotation.

Internet bandwidth: Answer the three questions related to internet bandwidth by selecting Yes or No. Not applicable or Don't Know are also available for the third question.

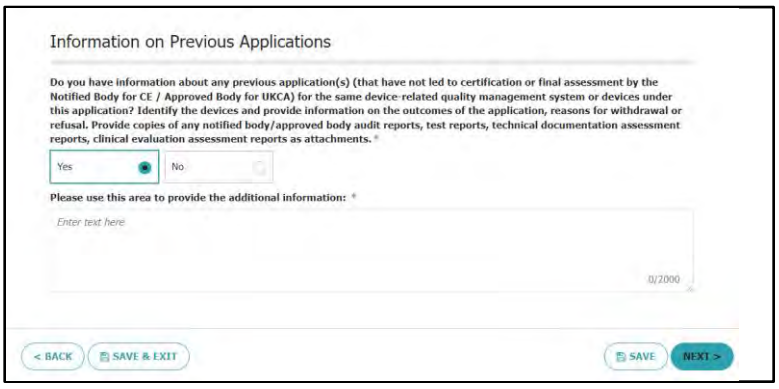
Is your quality system supporting documentation available electronically in **it's** entirety?: select Yes, No.

Malaysia Medical Device Authority manufacturing and marketing details: select Yes or No in answer to the full question.

Additional Information: select Yes to enter any additional details to the application, such as specifying the audit language requirements. An additional text box displays if Yes is selected.



Scroll down to the Information on Previous Applications section. If you have applied for these certifications before please yes and provide additional information. If you have documents to upload for this question you can select BACK in the bottom left and add them to Other Supporting Documents.



Once all questions in the Other Information section is recorded you will have one of two options. If you are the Application Owner, click NEXT and you will be taken to the Declaration section.

If you are an Application Editor you will see SUBMIT TO APPLICATION OWNER instead of NEXT. This will allow the Application Owner to review the application, fill out the Declaration and Submit the application to BSI.

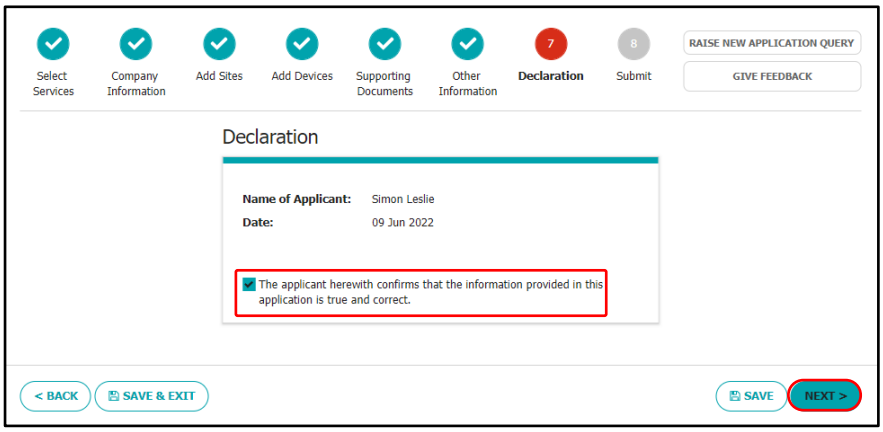
Completing an application

Step 7 → Signing the Declaration

The Declaration section of the application allows the Application Owner to effectively sign and date the application to confirm that the information provided is true and correct. This step must be completed by an employee of the company applying and they must be the Application Owner.

Select the checkbox to confirm the declaration.

Click NEXT.

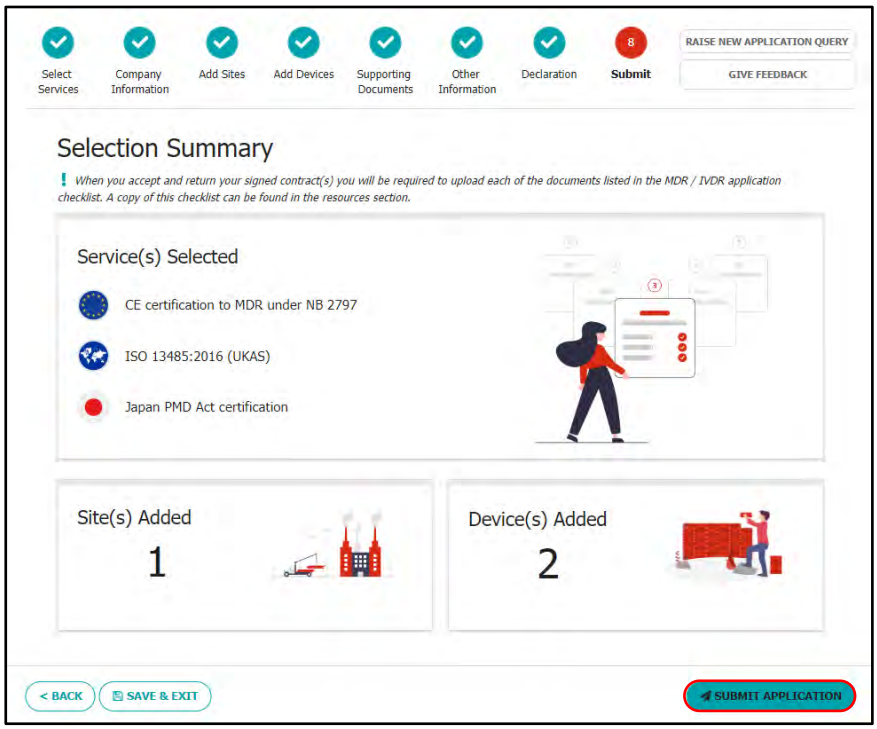


Step 8 → Viewing the application summary and submitting

The Submit section of the application allows you to view a summary of the application, including the service(s) selected and the number of sites and devices added to the application.

If you wish to make any amendments to the application, you must return to earlier stages of the application by clicking BACK. You cannot make changes from this summary screen.

Similarly to the Declaration section, only the Application Owner can submit the application.

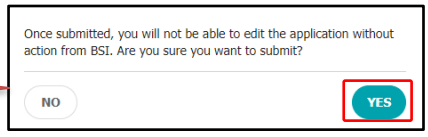


You can click BACK to return to any previous section of the application if any sections require additional checks or to give Application Editors access to the application again after it has been submitted to the Application Owner.

Once your application has been checked, click SUBMIT APPLICATION.

A final confirmation of your submission displays.

Click YES.



You are returned to the Homepage of the portal and your application's status now displays Application Submitted confirming that the application is being sent to BSI for review.