

Providing Additional Application Information



Providing Additional Application Information Overview

If there are any outstanding questions or missing information in your application, it will be returned to you with comments requesting updates to the application. Once updated, the application can be resubmitted.

Step 1 → Accessing your Application

From the homepage of the portal, select your application that has the status: **Additional Application Information Requested**.



<p>Application Details</p> <p>BSI 0001017570 - read only view</p> <p>Application Submission Date</p> <ul style="list-style-type: none"> 09 Jun 2022 <p>Services Requested - Application Type</p> <ul style="list-style-type: none"> MDR (EU) - Initial Application ISO 13485 (UKAS) - Initial Application Japan PMD Act 	<p>Status & Section(s) Completed</p> <p>Status</p> <ul style="list-style-type: none"> Additional Application Information Requested <p>Sections Completed</p> <ul style="list-style-type: none"> Select Services Company Information Add Sites Add Devices Supporting Documents Other Information Declaration Submit 	<p>Next Step by BSI & Your Next Action</p> <p>Next Step by BSI</p> <p>-</p> <p>Your Next Action</p> <p>PROVIDE ADDITIONAL INFORMATION</p>
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Click **PROVIDE ADDITIONAL INFORMATION**.

Your application will display with each section featuring an **!** symbol next to any sections with comments from BSI requesting additional information.



You must navigate through every section of the application using **BACK** and **NEXT** to view all of your application and any feedback.

All sections feature an **Application Review History** section where comments from you or BSI display. Comments display in order of the time and date of creation.

You can record comments in response to BSI comments and edit needed information in the application then click **NEXT** to view each section.

Date Added	Comments added by	Information Requested
10 Jun 2022 - 11:07	Client	Please provide an additional, up to date certificate.

Client Comment

Updated certificate uploaded.

29/5000

! If you have included any other changes as part of this revision please include the details in the comments.

< BACK SAVE & EXIT SAVE NEXT >

You can also make updates to your application if any details have changed since the initial draft. **Any changes or additions to your application must be made directly and not provided in the form of a comment.**

Note: if a change to the site or device data is needed, and you have used the Excel template to upload details or multiple sites or multiple devices, you will need to upload new Excel templates to replace the existing data.

Step 3 → Declaring and resubmitting your application

When any updates have been completed, the Application Owner must repeat the steps of declaring your Application is true and correct and then submitting the application.

Once confirmed, the Application's status updates to Application Submitted and is sent to BSI to review.

The Application Owner will be notified via email if the Application requires additional updates or if a draft contract has been created and uploaded to be reviewed.

Declaration

Name of Applicant: Simon Leslie

Date: 10 Jun 2022

The applicant herewith confirms that the information provided in this application is true and correct.

SAVE NEXT >

Selection Summary

! After you accept and return your signed contract(s) you will be required to upload each of the documents listed in the MDR / ODS application checklist. A copy of this checklist can be found in the resources section.

Service(s) Selected

- CE certification to MDR under NB 2797
- ISO 13485:2015 (UKAS)
- Japan PMD Act certification

Site(s) Added: 1

Device(s) Added: 2

Once submitted, you will not be able to edit the application without action from BSI. Are you sure you want to submit?

NO YES

Once submitted, you will not be able to edit the application without action from BSI. Are you sure you want to submit?

NO YES