

Dealing with a draft contract overview

When a draft contract has been created and uploaded to the portal, you are informed via email that the draft contract is ready to review. You can view the draft contract and either request changes, accept or reject it.

Access	ing	the	draft	contract
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You will be informed via email that the draft contract is available for review with a link to the portal provided. The Application will have the Status of Draft Contract Issued .	Dear Simon Thank you for the opportunity to demonstrate how BSI can help you contract. If you feel that anything needs adjusting or doesn't reflect are happy to proceed, please download the draft contract, sign the The draft contract is available in the client portal: Contract Number(s): Q123456 <u>https://bsisure2test.appiancloud.com/suite?signin=native</u> Kind Regards, BSI Regulatory Services (Medical Devices)	ir organization, and we're delighted to provide you with a draft your precise requirements, please immediately let us know. If you declaration page and submit any additional documents.
Application Details	Status & Section(s) Completed	Nove Stop by PCT 9. Very Nove Artis
		Next Step by BSI & Your Next Action
BSI 0001017570 - read only view	Status	Next Step by BSI & YOUF NEXT ACLION
BSI 0001017570 - read only view Application Submission Date	Status • Draft Contract issued	Next Step by BSI
BSI 0001017570 - read only view Application Submission Date 10 Jun 2022	Status • Draft Contract Issued Sections Completed Ø All Sections Completed	Next Step by BSI - Your Next Action

Click **REVIEW DRAFT CONTRACT**.

The **Review Draft Contract** page displays the Draft Contract and the Audit Duration Calculation Record (if applicable) to download and review. Any supplementary information recorded also displays.

If either documents are in PDF format, they can be previewed on the right-hand side of the page.

Once you have reviewed the draft contract, you have the following options:

Review Draft (Contract				RAISE NEW APPLICATION QUERY
					GIVE HEDBACK
Please review the draft contra Note - draft contract is valid for If you would like to accept it. On the next screen you will You will also be required to up A copy of this checklist can be	ct for your application: or 60 days only. download the contract docum asked to upload your signed load each of the documents li found in the resources sectio	ent, sign it, and click on contract(s). sted in the MDR/IVDR i n. Draft documents will	the "Accept Contra pplication checklis be acceptable at ti	act" button. t. tis stage.	There is no document preview
File Name	Contract Number	t Uploaded By	Date Uploaded		
🗋 Draft Contract v1 🛆	Q123456	Simon Leslie Commercial	10 Jun 2022 - 12:04	VIEW PDF	
Audit Duration Calculation Record	-	Simon Leslie Commercial	10 Jun 2022 - 12:04	8	
upplementary Information					
SAVE & EXIT			ACCEPT CO	INTRACT REQUI	EST CHANGES REJECT CONTRACT

- ACCEPT CONTRACT: the contract is accepted and the signed contract and any supporting documentation will be uploaded.
- REQUEST CHANGES: a request is made for changes to the contract, which will result in either the contract being modified and resent to you for review or you may need to change and resubmit your application following which a new contract will be issued.
- REJECT CONTRACT: the contract is rejected outright. If this is selected BSI will contact you via telephone
 call to confirm and discuss any potential changes that could resolve the issue(s).

Rejecting the contract

Click **REJECT CONTRACT**.

The Reason for rejection page displays.

Select the reason for the rejection of the contract from the drop-down list of options.

If you select Other an additional text box displays to enter additional detail.

Click SUBMIT.

The status of the application displays **Contract Decision: Rejected**. BSI will contact you via telephone call to confirm and discuss any potential changes that could resolve the issue(s).

Project cancelled	
SAVE & EXIT < BACK	SUB

bsi.

Requesting changes to the contract

Click **REQUEST CHANGES**.

The Review Draft Contract page displays.

You must specify the changes you wish to make.

Click **SUBMIT**.

Once the request has been submitted, BSI will contact you regarding the nature of the changes. The application can then return to the draft contract stage, or, if broader changes are required, back to the draft application stage.

Accepting the contract

Click ACCEPT CONTRACT.

A prompt displays, checking you have downloaded the draft contract and any supporting documents.

Click YES.

The **Upload Signed Contract** page displays.

Upload a scanned, complete and signed copy of the contract to the **Upload Signed Contract** section of the listed contract.

Note: The signature for a signed contract must be by an appropriate person or level and BSI will check that.

If any additional supporting documents are required, click **Add Additional Document** and upload the additional document. You can repeat this step for each document.

Additional specific supporting document (such as a Quality Policy must be uploaded for some services (such as an MDR CE Application). An example of some of these documents is shown here.

Review Draft Contract	RAISE NEW	×
	GIVE FEEDBACK	
Please specify the changes you want to request *		
we require an amenoment to page 5 of the orart contract.		
56/1000		
BSI will contact you to discuss these changes		
SAVE & EXIT < BACK	SUBMIT	

Have you downloaded the draft contract document(s)?	
NO	YES

Upload Signed Contract				
Please upload the following documentation: Signed copy of the contract(s) - must contain all pages of the contract				
Contract Number	File	File Name		
Q154236	PAP01 Signed Contract PDF - 76.24 KB	Signed Contract v1		
Once the documents have been s	ubmitted we will review their contents and	we will contact you with our response.		
Additional Supporting	Documentation			
Other Documents				
Please upload any other documents to	support your application:			
Document Type		File		
No items available				
Add Additional Document				
SAVE & EXIT < BACK				

dditional Supporting Docum	nentation	
IDR CE Application Checklist		
nstructions for Manufacturers: Please upload th	e documents listed below to support your application:	
Document Type	Document Type Information	File
Sample Declaration of Conformity	Sample draft Declaration of Conformity (as per Annex IV of MDR) for the highest classification device included in the application	UPLOAD Drop file here
Quality Policy		UPLOAD C Drop file here
Quality Objectives		UPLOAD Drop file here

When all the required documents are uploaded, click **SUBMIT**. The status of the application updates to **Signed Contract Sent** and BSI are sent the signed contract and supporting documents to review.

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Application Details	Status & Section(s) Completed	Next Step by BSI & Your Next Action
BSI 0001017570 - read-only view Application Submission Date • 10 Jun 2022 Services Requested - Application Type • MDR (EU) - Initial Application • ISD 13485 (UKG) - Initial Application • Japan PMD Act	Status • Signed Contract Sent Sections Completed • All Sections Completed	Next Step by BSI Signed Contract Received Pending Review Your Next Action .