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MDG4103

Revision 2 (June 2025)

BSI Electronic Client Portal – User Guide

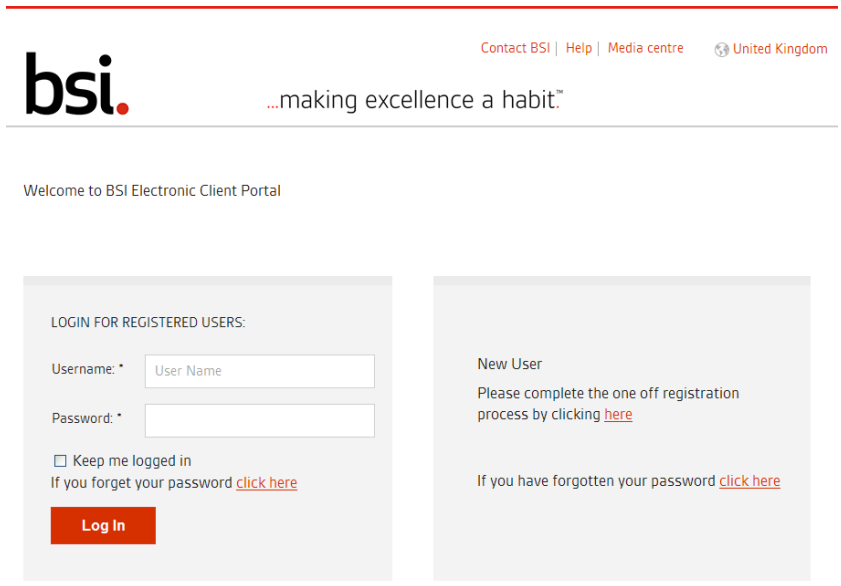
Contents

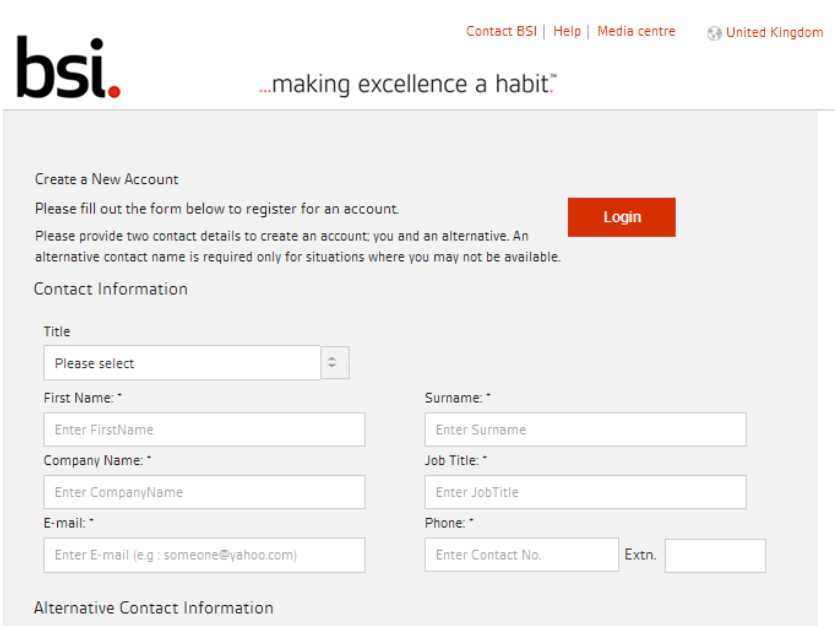
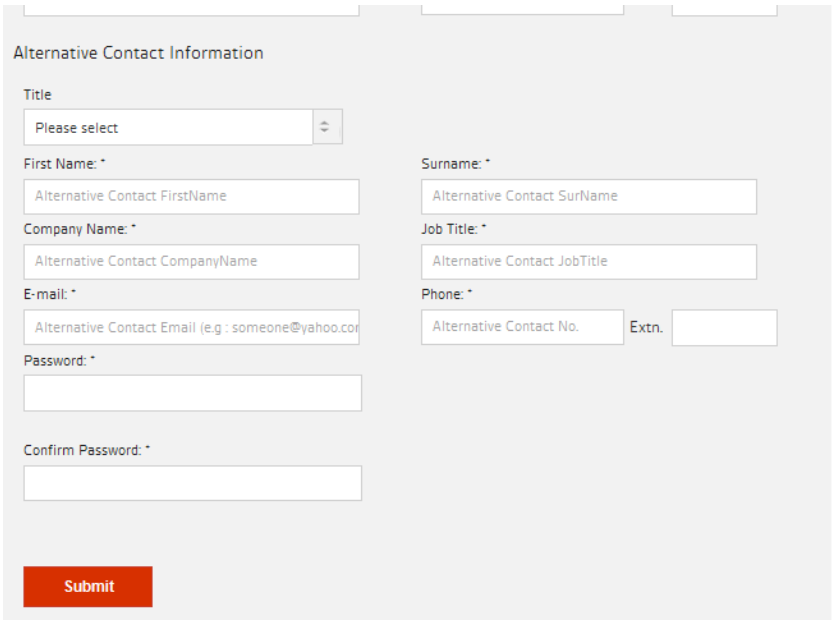
1 Scope

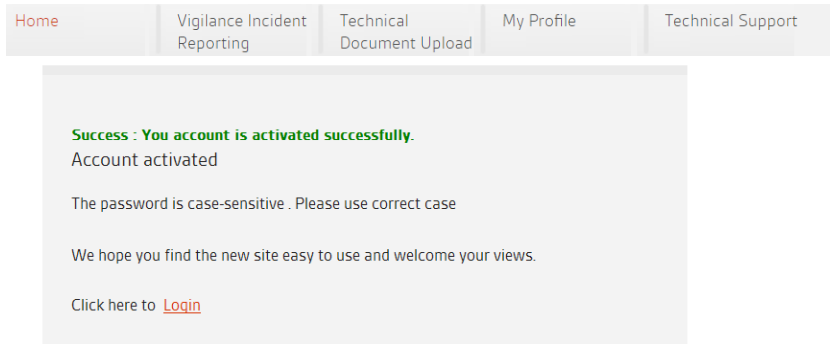
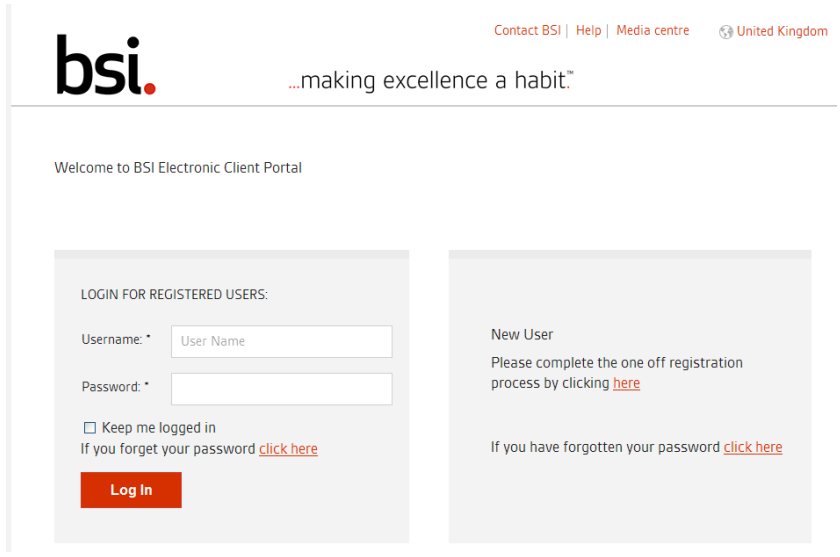
This document is aimed to be a guidance for manufacturers when uploading documents to the BSI Electronic Client Portal (https://medtech.bsigroup.com), such as:

- Technical Documentation, including SS(C)P *(Summary of safety and clinical performance for MDR – SSCP - and Summary of safety and performance for IVDR - SSP)* and PSUR
- Incident (MIR) reports and FSCA reports

Section A. Registration on BSI Electronic Vigilance Database

STEP		
1		**BSI Electronic Client Portal** The BSI Electronic Client Portal database can be accessed via the following link: https://medtech.bsigroup.com Enter your username and password to access the site, then go to Section B of this guide. If you do not already have a username and a password, register for a new account (continue to step 2 below).

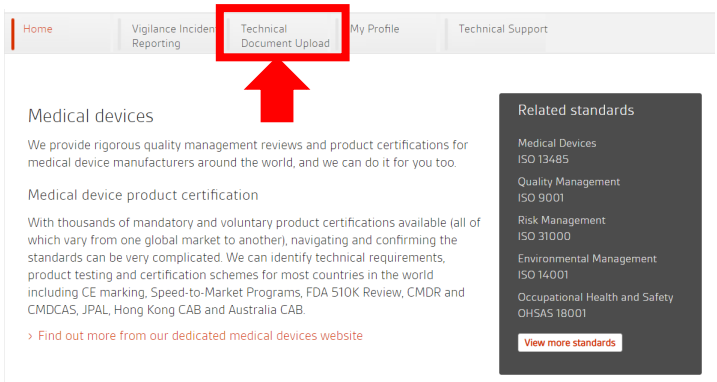
2		**Register a New Account** Enter your name and contact details. You will also be required to provide details for an alternative contact. If part of large organisation where multiple users will be required to upload documents, it may be advisable to create one generic/common account for your staff to access. Alternatively, a request can be made to the Technical Support Team to create a group account for multiple users from the same organisation. Please note that each User must create an account first. Refer to Section D on how to contact the Technical Support Team.
3		An alternative name and contact are required. This is to ensure that BSI can always contact someone if the main account holder is unavailable. In the case where a generic account is created, the alternative contact will need to be a named individual. Choose password. Click “Submit”.

4		A verification email will be sent your email account. Click on link in the email to activate account. Follow link to log in. You will be re-directed to the login page.
5		Enter username and password and click on 'Log in' to access the database.

Section B. Uploading documents

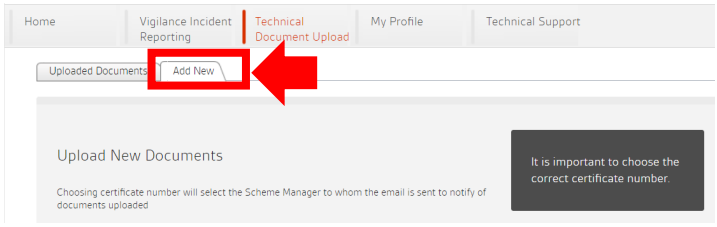
Section B.1 Uploading Technical Documentation

B.1.1 Home page and Technical Document Upload dashboard



Home page

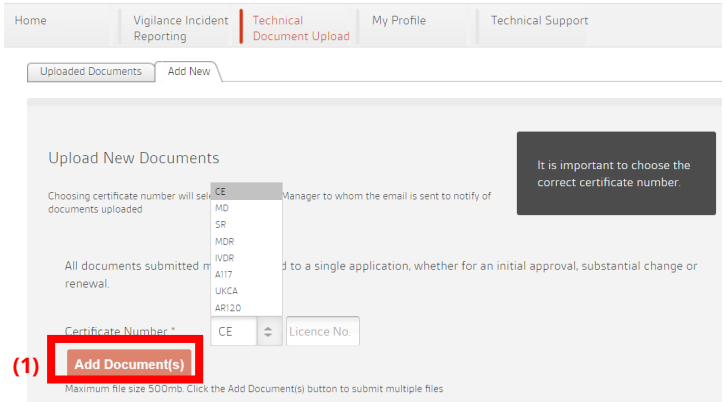
To view all successfully uploaded documents or to upload new technical documents, select "Technical Document Upload" tab.



Technical Document Upload dashboard

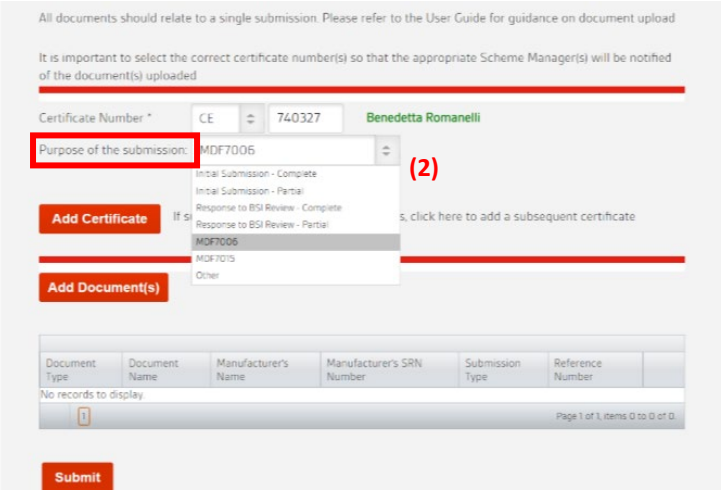
To upload new technical documents, click on the "Add New" tab.

B.1.2 Upload of technical documents



Documents Upload

(1) Enter your certificate number, selecting the correct prefix ('CE' 'MD' 'MDR' or 'IVDR' or A117 or 'AR120' or 'UKCA').



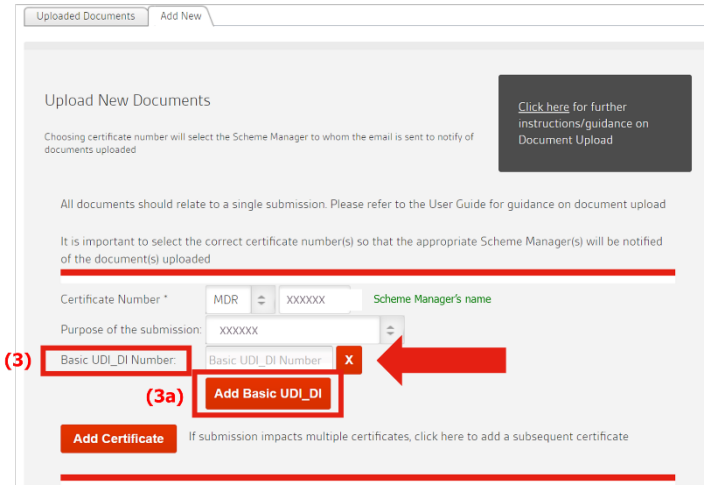
(2) From the dropdown list, select the purpose of the submission:

- Initial submission – Complete
- Initial submission – Partial
- Response to BSI reviewer – Complete
- Response to BSI reviewer – Partial
- PSUR, SSCP, SSP Documentation
- MDF7006 (medical devices), MDF7015 (IVDs)
- Other

When to use the different "Purpose of Submission" variants:

Type of Submission	When to Use	Examples
Initial Submission- Complete *Note: BSI will start its review process only after receiving a complete submission.*	Full Submissions for new reviews that have not yet started. *Note: Where partial submissions have been made previously, this option should be selected when uploading the outstanding documents to complete the submission*	• New applications • Surveillance • Extensions to Scopes • Change reviews
Initial Submission- Partial	Partial Submissions for new reviews that have not yet started where additional documents will be uploaded at a later time. *Note: Where partial submissions have been made previously, select 'Initial Submission- Complete' when uploading the outstanding documents for the review*	• New applications • Surveillance • Extensions to Scopes • Change reviews
Response to BSI Review- Complete *Note: BSI will start its review process only after receiving a complete submission.*	Use when sending complete responses to BSI reviews that are in progress. *Note: Where partial submissions have been made previously, this option should be selected when uploading the outstanding documents to complete the submission.*	• Responses to Rounds of Questions • Requests for additional documents
Response to BSI Review- Partial	Use when sending partial responses to BSI reviews that are in progress where additional documents will be loaded at a later time.	• Responses to Rounds of Questions • Requests for additional documents

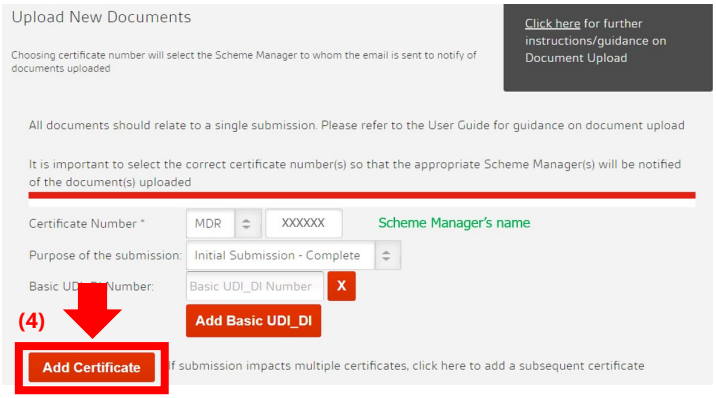
	Note: Where partial submissions have been made previously, select 'Response to BSI Review- Complete' when uploading the outstanding documents for the review	
PSUR, SSCP, SSP Documentation	Use when sending SS(C)P *(Summary of safety and clinical performance for MDR – SSCP - and Summary of safety and performance for IVDR – SSP)* and/or PSUR documents. Refer to section B.1.3 for details.	• Periodic Safety Update Report for high risk devices under EU/UK Legislations • Unvalidated SS(C)P Note: please upload only SS(C)P requiring validation from the NB.
MDF7006	Use when making requests to BSI relating to (EU) 2023/607 for medical devices *Note: When uploading a document, a dialogue box will ask you to select whether you are uploading the MDF7006 or a MDF7006 Supporting Document. Select the one which applies to the document being uploaded.*	• Requesting an MDR Article 120 Notified Body confirmation letter • Requesting to restart or continue appropriate surveillance
MDF7015	Use when making requests to BSI relating to (EU) 2024/1860 for IVDs *Note: When uploading a document, a dialogue box will ask you to select whether you are uploading the MDF7015 or a MDF7015 Supporting Document. Select the one which applies to the document being uploaded.*	• Requesting an IVDR Article 110 Notified Body confirmation letter • Requesting to restart or continue appropriate surveillance
Other	Documentation not covered by other categories.	Change notifications (MDF4900)



(3) Enter the Basic UDI-DI.

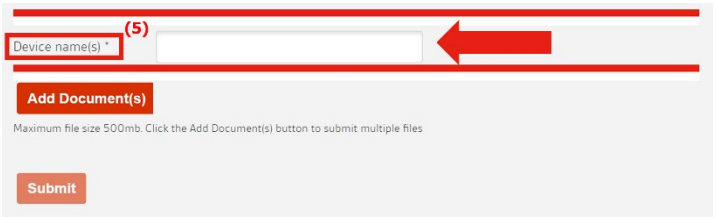
In case more than one Basic UDI-DI apply, click on "Add Basic UDI_DI" **(3a)**.

If you wish to remove a Basic UDI-DI, click on the X button.



(4) If the submission impacts multiple certificates, click the "Add certificate" option and input the additional certificate numbers (maximum 15 certificates can be added).

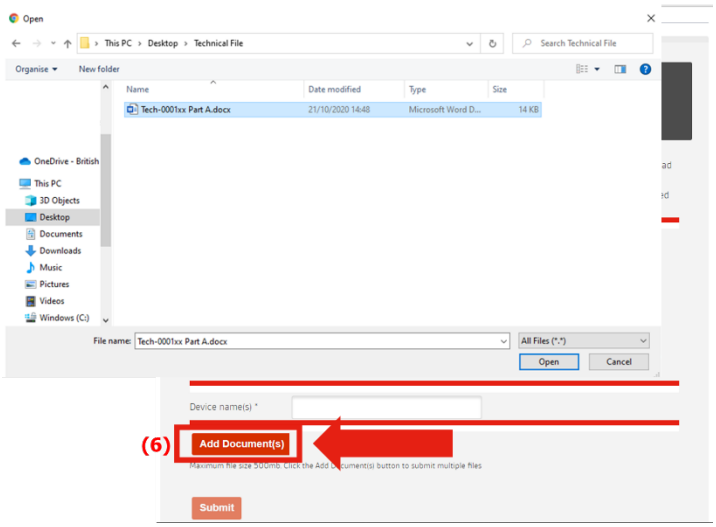
Note: the certificate number is needed to identify and notify your Scheme Manager.
Note: when adding multiple certificates, the document uploaded should be common to all the certificates and Basic UDI-DIs entered.



(5) Input the Device name(s) as per your submission (note this does not appear in case you selected "PSUR, SSCP, SSP Documentation" document type - Refer to section B.1.3 for details on uploading of SS(C)P and/or PSUR documents).

Note: A new submission should be made for each device being submitted to BSI for review, specifying the device name in the 'Device Name(s)' field, i.e., if 3 different technical documentation reviews are scheduled, these should be uploaded as three different submissions stating the relevant device name clearly with each submission. If the submission impacts multiple certificates and the technical documentation is common and only the device name is different, all device names should be detailed in the 'Device Name(s)' field.

When submitting documentation in support of a substantial change and one submission is being made which impacts multiple devices, this can be uploaded under one submission detailing all device names in the 'Device Name(s)' field.

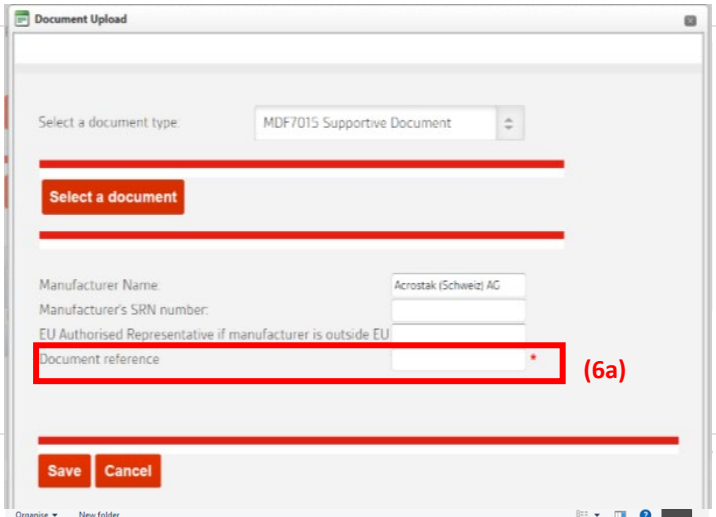


(6) You can now upload documents - click "Add Document(s)" to browse the files you wish to upload.

Note: The maximum individual file upload size is 500mb.

Click the Add Document(s) button to submit multiple files. Multi-select for documents is available from within the pop up "Browse Window" dialogue box. You can use Ctrl+Select or Shift+Arrow or Ctrl+A windows functionality to select multiple documents to be uploaded.

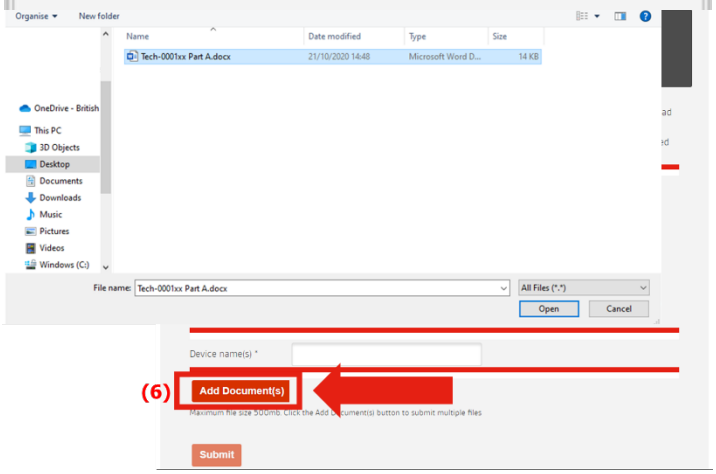
(6a) When uploading a MDF7006 or MDF7015 Supporting Document it is necessary to fill in the document reference field as well



(7) Once the documents have been selected, the browse window will close, and you will be able to see a list of the documents which are being uploaded in the main screen.

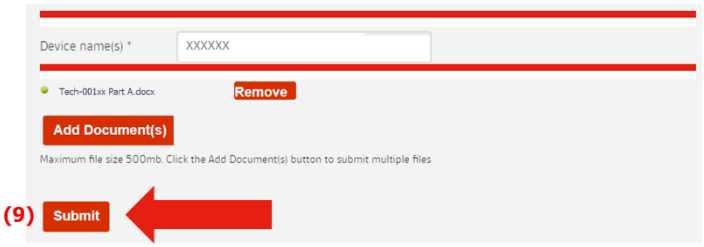
Note: You can remove documents one-by-one if needed from this main screen (after the pop-up window is closed), by clicking the "Remove" button **(7a)**.

Invalid file types are identified via a red dot next to the file name and the error message "Invalid file type" **(7a)**.

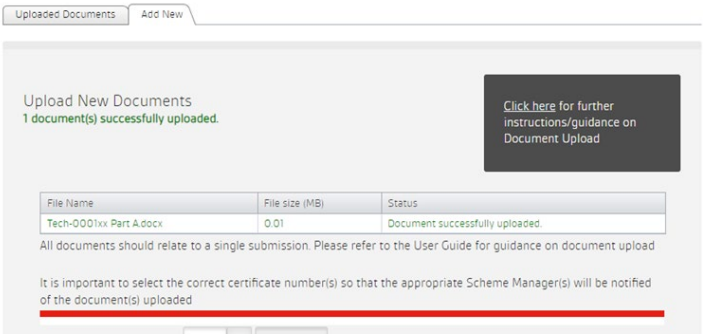


(8) If you wish to add more documents, you can do this by following point 6 again.

Note: To add another document to the already-selected list, you will need to select the full set (including previously selected documents) prior to completing the upload steps.



(9) Click "Submit'.



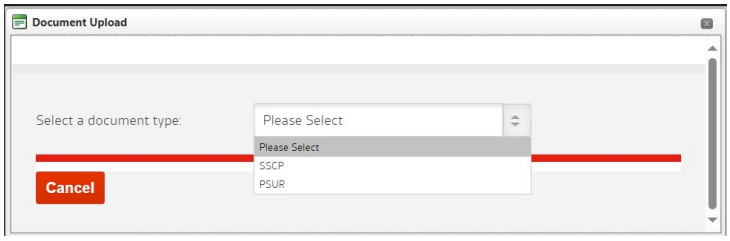
(10) Document Upload- Confirmation: this screen shows a notification that the document has been uploaded successfully.

An e-mail is sent automatically to your BSI Scheme Manager that you have uploaded a document.

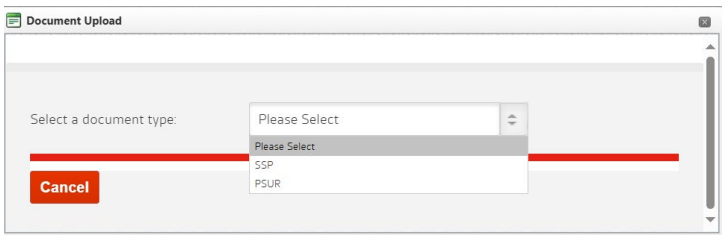
Click "Back" to upload additional documents (follow steps 1-9 above).

B.1.3 Upload of SS(C)P and/or PSUR documents

MDR & UKCA:



IVDR & UKCA:



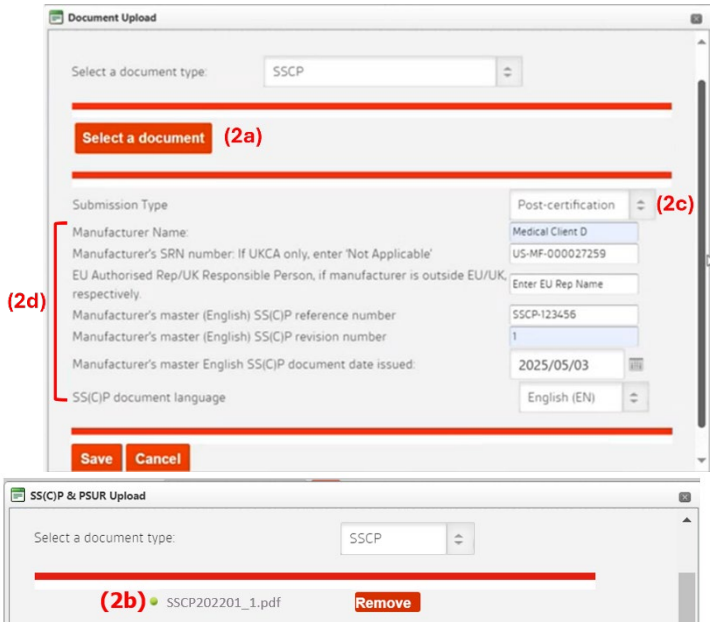
UKCA only:

(1) When selecting "PSUR, SSCP, SSP Documentation" as "Purpose of Submission" from the dropdown list and clicking on "Add document", a pop-up window opens.

From the dropdown list, select the document type:

- SSCP
- SSP
- PSUR

The list will reflect the options available depending on the certificates entered.



(2) When picking "**SSCP**" or "**SSP**" as document type, you are prompt to upload documents - click "Select a document" **(2a)** to browse the file you wish to upload.

(2b) Once the document has been selected, the browse window will close, and you will be able to see the document which is going to be uploaded in the main screen.

Note: You can remove the document if needed from this main screen (after the pop-up window is closed), by clicking the "Remove" button. Invalid file types are identified via a red dot next to the file name.

Select the "Submission Type" from the dropdown list **(2c)**.

Select "Pre-Certification" if you wish to submit English language SS(C)P before the certificate is issued.

Select "Post Certification" if you wish to submit English language SS(C)P after the certificate is issued.

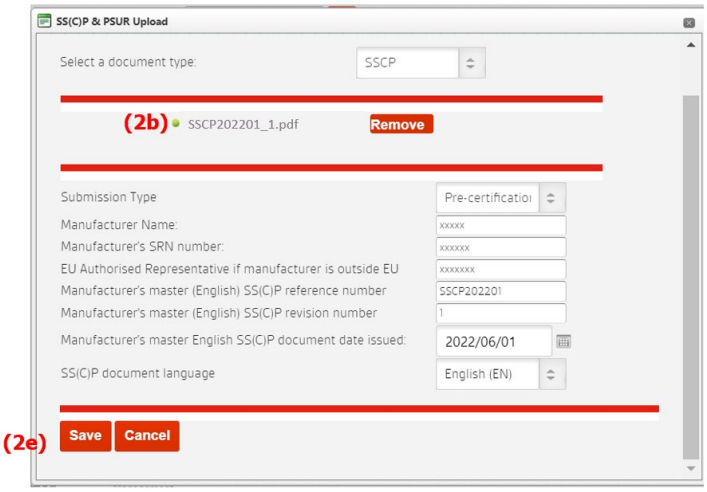
You are then required to provide details about **(2d)**:

- Manufacturer Name
- Manufacturer's SRN number
- EU Authorised Representative/UK responsible Person, if manufacturer is outside EU/UK respectively (state "N.A." if not applicable)
- Manufacturer's master (English) SS(C)P reference number
- Manufacturer's master (English) SS(C)P revision number
- Manufacturer's master English SS(C)P document date issued

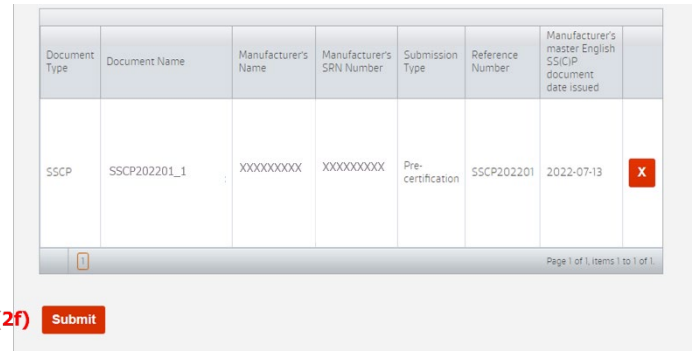
  Note: provide the date when the English version of the SS(C)P (the master version) has been issued.

- SS(C)P document language

  Note: select the SS(C)P document language from the dropdown list. SS(C)P documents should be provided in English.

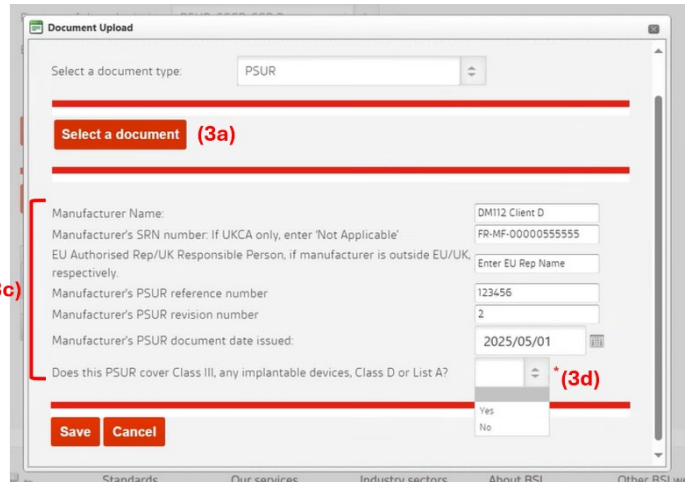


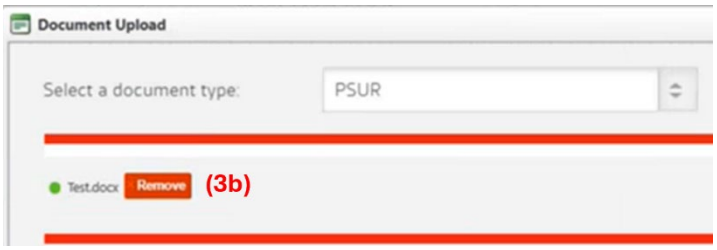
(2e) Click "Save'.



(2f) Click "Submit" to submit the document.

Note: If you wish to remove the document before submitting it, click on the X button.





(3) When picking "**PSUR**" as document type, you are prompted to upload documents - click "Select a document" **(3a)** to browse the file you wish to upload.

(3b) Once the document has been selected, the browse window will close, and you will be able to see the document which is going to be uploaded in the main screen.

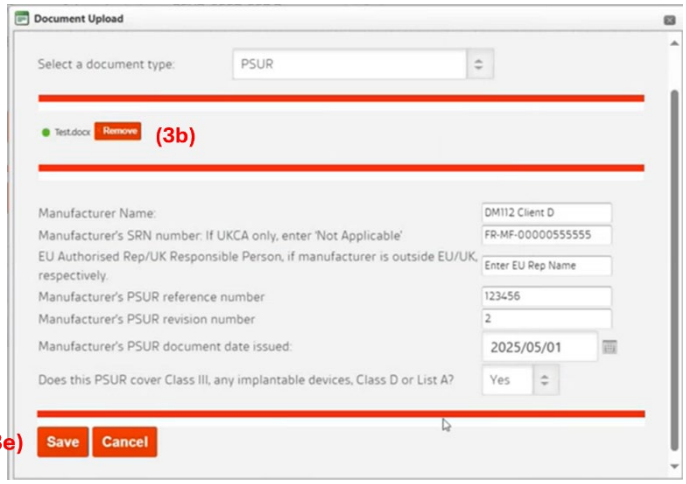
Note: You can remove the document if needed from this main screen (after the pop-up window is closed), by clicking the "Remove" button. Invalid file types are identified via a red dot next to the file name.

Provide details about **(3c)**:

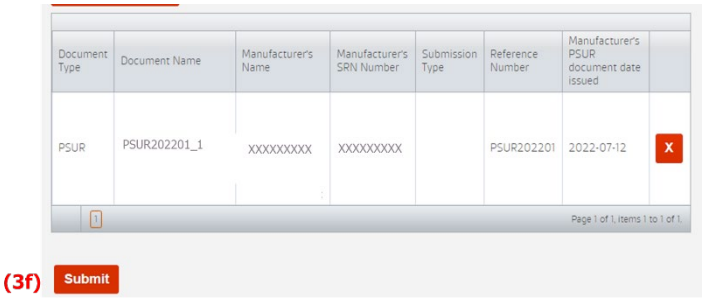
- Manufacturer Name
- Manufacturer's SRN number. If UKCA only, enter 'Not Applicable'

- EU Authorised Representative/UK Responsible Person, if manufacturer is outside EU/UK, respectively
- Manufacturer's PSUR reference number
- Manufacturer's PSUR revision number
- Manufacturer's PSUR document date issued
- Does this PSUR cover, Class III, Implantable, Class D or List A devices?

  *Note: select Yes or No from the dropdown list **(3d)**.*

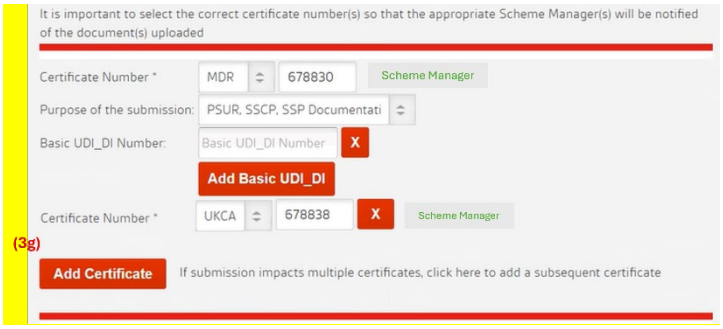


(3e) Click "Save'.

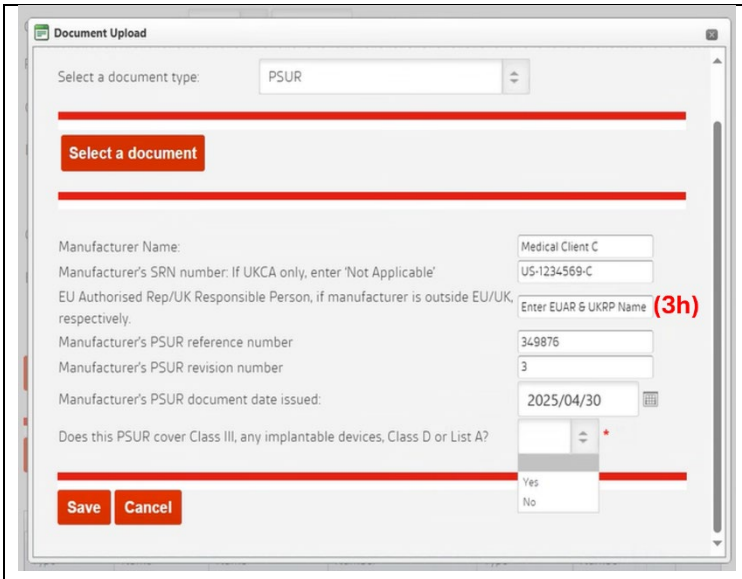


(3f) Click "Submit" to submit the document.

Note: If you wish to remove the document before submitting it, click on the X button. A pop-up box asks you to confirm the document should be deleted.

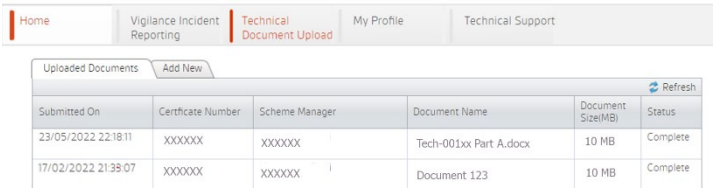


If the PSUR is applicable to more than one certificate i.e. it covers devices on an MDR or IVDR certificate and a UKCA certificate, you can select multiple certificates to apply to the same PSUR submission **(3g)**.



When uploading your PSUR document against a MDR (or IVDR) and UKCA certificate, and where applicable, you must enter both the EU Authorised Rep name and UKRP name in document upload screen **(3h)**

B.1.4 "Uploaded documents" dashboard

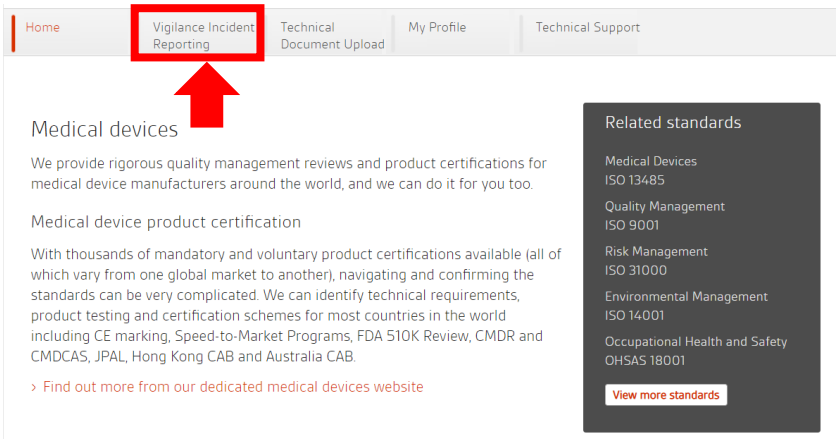


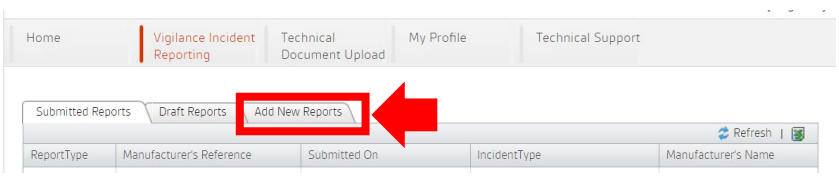
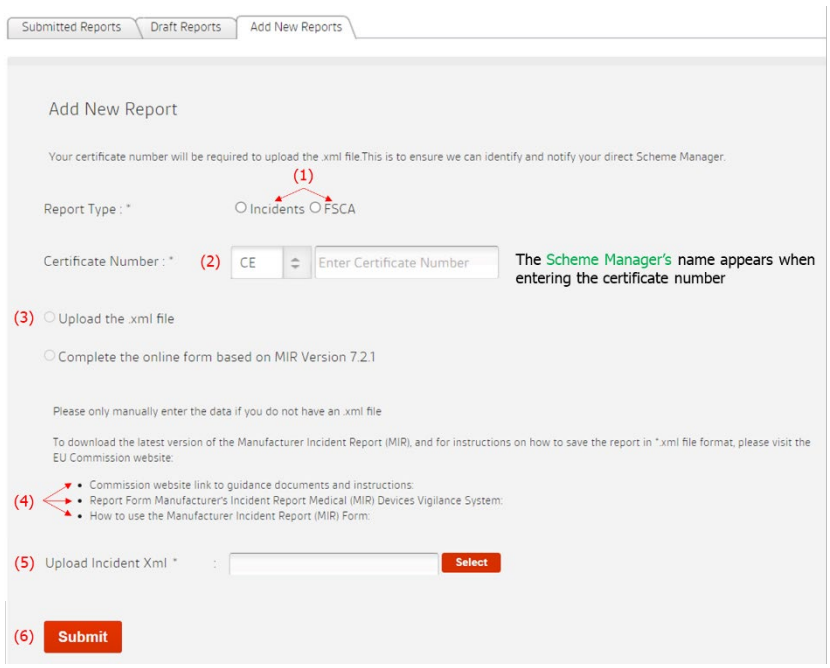
(1) After upload, you will be able to view only those documents uploaded from your account.

By clicking on the headers, you will be able to sort your submissions by date, certificate number, document name, size etc. The status header confirms successful upload.

Note: This is a record of your uploaded documents

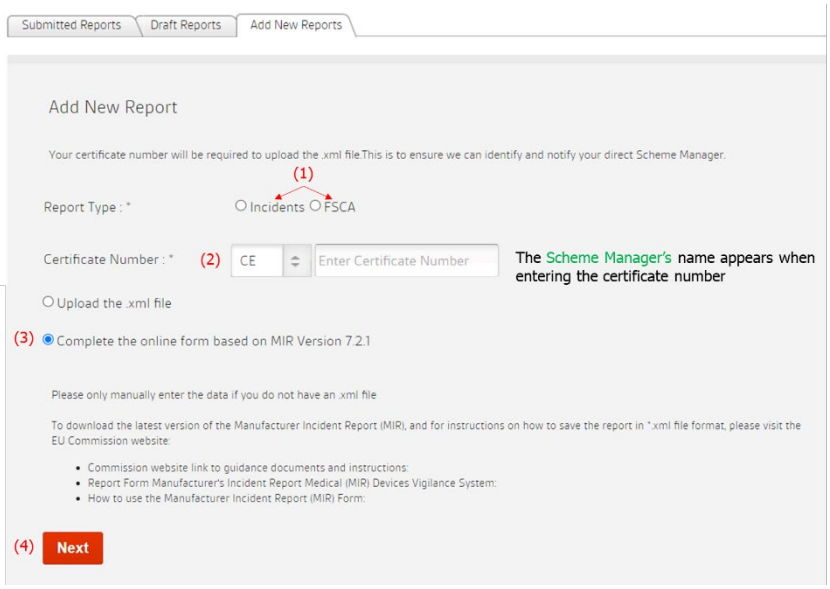
Section B.2 Uploading Vigilance Reports

STEP		
1		**Home page** To view all successfully uploaded incident reports or upload vigilance reports, select "Vigilance Incident Reporting" tab.

2		**Vigilance report dashboard** To upload vigilance reports, click on the "Add New Reports" tab.
Upload of vigilance Incident reports or FSCA reports		
3		(1) Select "Report Type". This can be vigilance Incident reports or Field Safety Corrective Action (FSCA) reports (2) For all submissions, your certificate number is required. This helps identify and notify your Scheme Manager that an incident report/FSCA has been uploaded. Note: The certificate number is usually a 5- or 6-digit number (e.g., CE 00000, MDR 00000, IVDR 00000, UKCA 00000) and it can be your quality certificate number or product certificate number. (3) Select "Upload the .xml file". If no .xml file is available for upload, then go to Step 4 to manually enter the information or, alternatively, refer to Step 9 for instructions on how to create .xml files. (4) If required, these are links to the Commission website with resources for the .xml template and guidance documents. (5) Click "Select" button to browse for file to be uploaded. (6) Click "Submit". Skip to Step 7.

Manual entry of a vigilance incident report or of a FSCA

4



(1) Select "Report Type". This can be vigilance Incident reports or Field Safety Corrective Action (FSCA) reports.

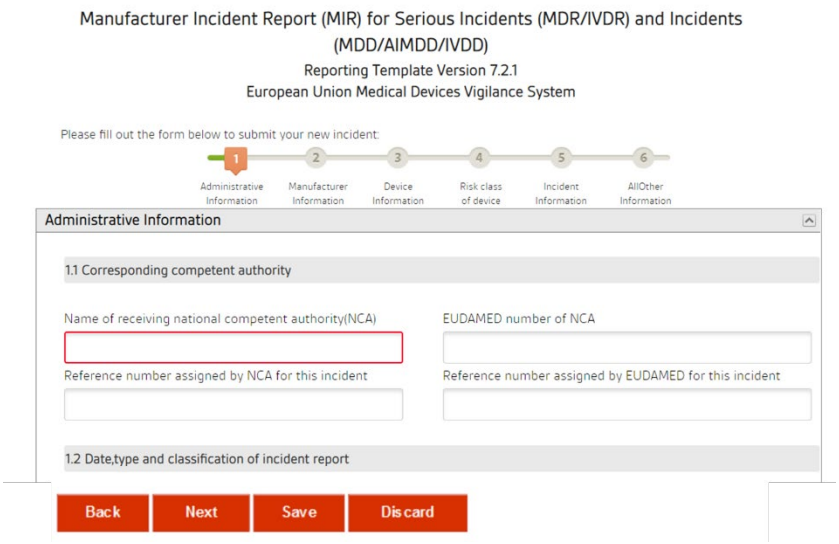
(2) For all submissions, your certificate number is required. This helps identify and notify your Scheme Manager that an incident report/FSCA has been uploaded.

Note: The certificate number is usually a 5- or 6-digit number (e.g., CE 00000, MDR 00000, IVDR 00000, UKCA 00000) and it can be your quality certificate number or product certificate number.

(3) Select "Complete the online form based on MIR Version 7.2.1".

(4) Click "Next".

5



Online form for vigilance incident reports

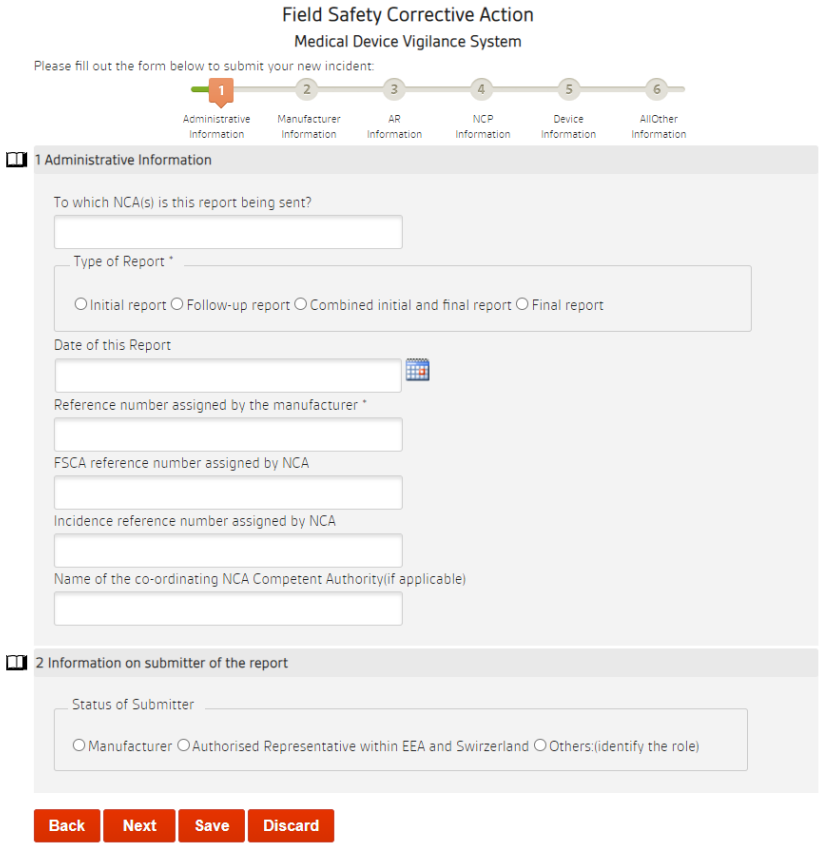
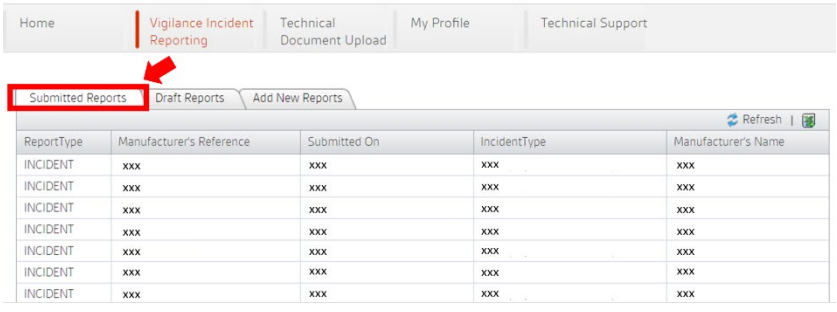
Enter the information required – the online form is a replica of the incident reporting template MIR 7.2.1.

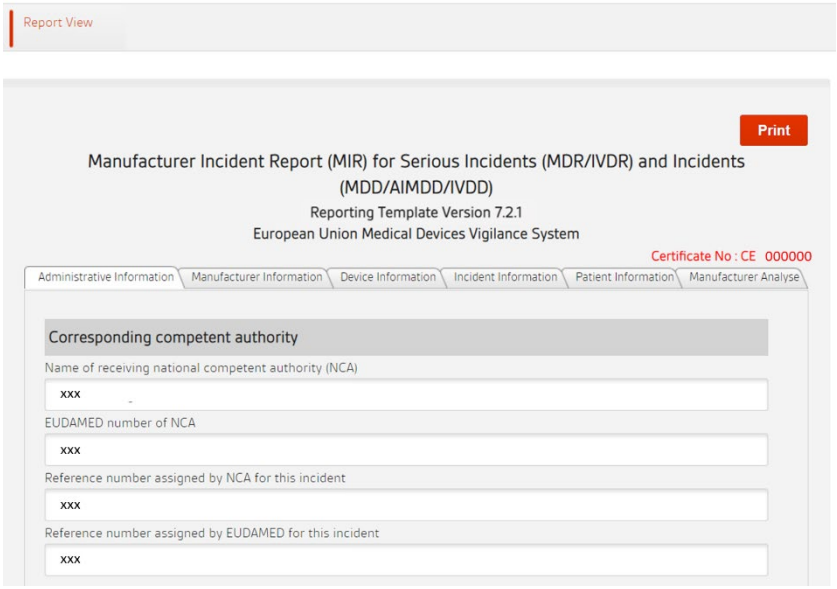
Click "Next" to proceed and continue to enter data.

Click "Save" to save data – you can always return and complete the form.

Click "Discard" to delete the form.

Click "Back" to go back one page of the form.

		Click "Submit" to submit the report.
6		**Online Form for FSCA Reports** Enter the information required – the online form is a replica of the FSCA reporting template in MEDDEV 2.12/1. Click "Next" to proceed and continue to enter data. Click "Save" to save data – you can always return and complete the form. Click "Discard" to delete the form. Click "Back" to go back one page of the form. Click "Submit" to submit the report.
Incident report dashboard		
7		After .xml file has been uploaded, or the information entered using the online form, you will be able to view the incident reports uploaded from your account. Click on the report to open it in a new window.

8		The vigilance incident or FSCA reports cannot be edited after they have been uploaded. Click on the tabs to navigate through the different sections of the report.

Creating .xml files

9

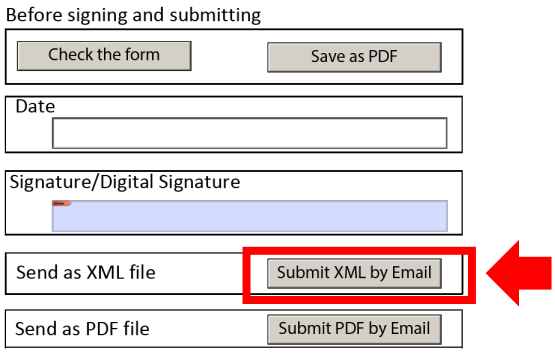
(1) Download the latest Manufacturer's Incident Report form or the FSCA form in PDF format from the EU Commission website.

Incident Report form: https://ec.europa.eu/docsroom/documents/41681

FSCA form: The most recent revision of the forms referred to in MEDDEV 2.12-1 rev. 8 are available on the Commission website, see https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en

(2) Fill the forms as required.

(3) After completing the form, hitting the button "Submit XML by Email" (as per the screenshot below) automatically opens your e-mail provider with the .xml file attached to the email.

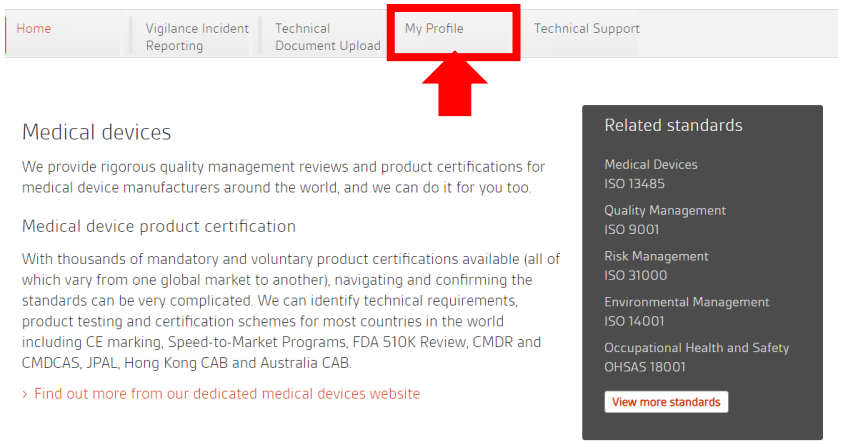


(4) Save the attached .xml file to your local system.

PLEASE DO NOT CHANGE THE ATTACHED .XML FILE.

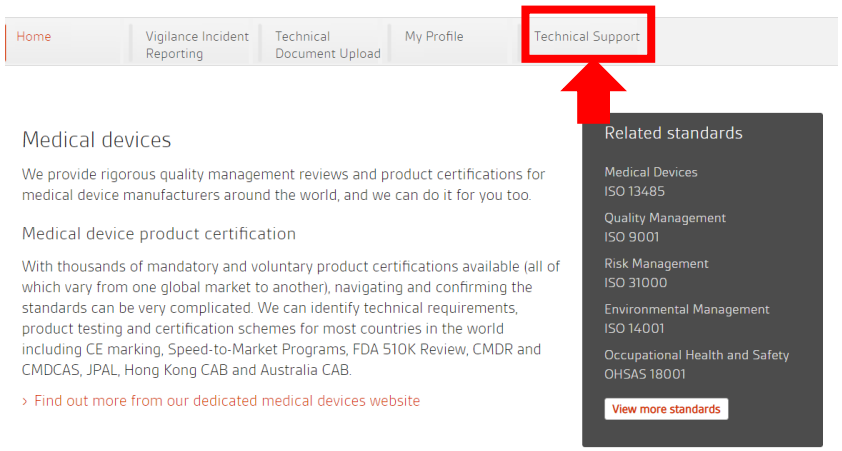
(5) The saved .xml file can then be uploaded to the BSI Electronic Client Portal.

Section C. Changing Password to the BSI electronic vigilance database



Go to the "My Profile" tab to change your password or edit your contact information.

Section D. Contact Technical Support



For any technical difficulty, including errors received when uploading documents, use this tab to report your issues.

Revision History

Rev no	Revision Date Mmm yyyy	Author	Approver	Sec. No	Brief description of change
0	September 2022	Maddalena Pinsi	Medical Devices Document Control	All	First issue
1	March 2024	Maddalena Pinsi	Medical Devices Document Control	A.2, A.5	Updated wording to cover both incident reports and Technical Documentation.
				A.4	Updated screenshot to reflect current portal tabs.
				B.1.2	Added AR120 certificate ID. Removal of the option to upload translated SS(C)Ps as per the draft MDCG 2019-9 rev.2. Added a note to clarify the request to upload only SS(C)P requiring validation from the NB.
				B.1.3	Removed the option to upload non-English language SS(C)P and clarified that SS(C)P documents should be provided in English. Corrected upload type to read as "Pre-certification".
2	Jun 2025	Jenifer Hannon	Medical Devices Document Control	B.1.2	Screen shot (2) of "upload documentation" updated and corresponding instructions to align MDF7006 and MDF7015 added to table. New screen shot (6a) added regarding supporting documentation upload
				B.1.3	Section 1 screen shot replaced with 3 version which are dependent upon certificate entered. SSCP section screen shot for points 2a, 2c and 2d is updated. Instructions related to 2d is updated to align with the new screenshot PSUR section screen shots for points 3a, 3b, 3c 3d and 3e are

					updated to reflect changes due to PSUR requirements for UKCA certified devices Instructions related to 3d are updated to align with the new screenshot New screenshots and instructions added for points 3g and 3h, which relate to submission of PSUR against an MDR or IVDR and UKCA certificate.