Periodic Safety Update Report (PSUR)

March 2023

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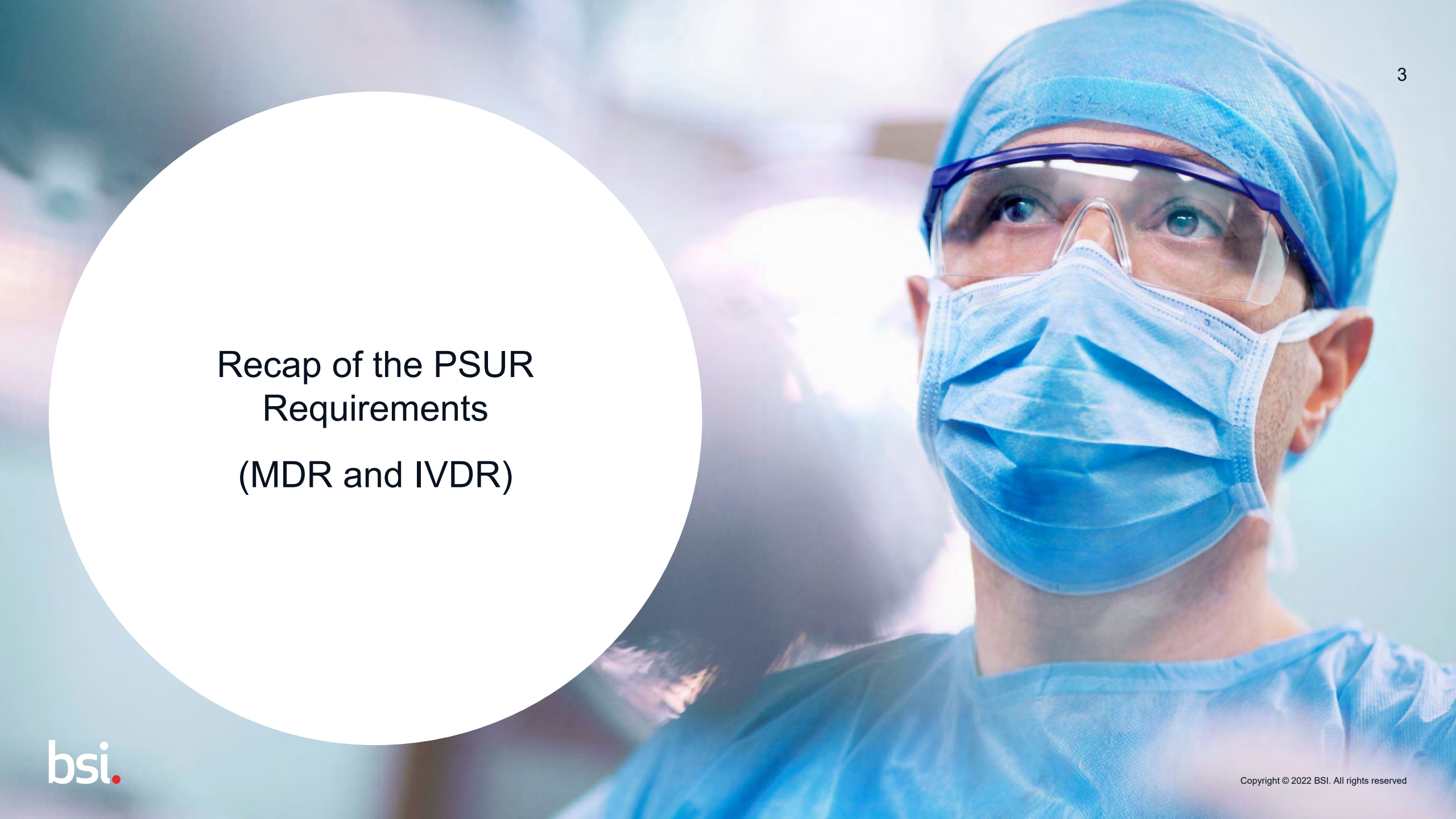
Contents of Webinar

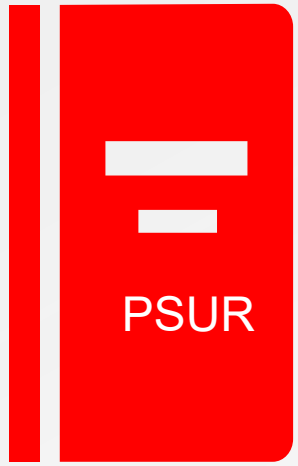
- Recap of the PSUR MDR/IVDR Requirements
- Expected Contents of the PSUR (MDCG 2022-21)
- The notified body process of evaluating the PSUR
- The PSUR and updating the SSCP
- Uploading your PSUR and SSCP to BSI

Recap of the PSUR Requirements

(MDR and IVDR)



What is the Periodic Safety Update Report (PSUR)?



- Article 86 of the MDR requires manufacturers of **Class IIa, IIb, III** devices to prepare a PSUR
- Article 81 of the IVDR requires manufacturers of **Class C & D** devices to prepare a PSUR
- The PSUR is a summary of data coming from the **post market surveillance plan activities** for a given time period.
- The PSUR is a **point in time** of the device(s) current safety and performance.
- This exercise allows the manufacturer to pull together all the outputs of the PMS activities and ensure the **benefit/risk is still favourable** to the device(s) under evaluation.
- The PSUR is an **interim activity** during and after CE certification.
- **Class I devices** are required to prepare **a PMS report** per article 85. The classification under the MDR and not classification under the MDD is the deciding factor whether a PSUR is required.
- **Legacy devices** that are placed on the market under MDD/AIMDD after the date of application (26th May 2021) during the transitional period are required to produce a PSUR based upon the timelines of its classification under MDD/AIMDD.

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	Class IIa	Class IIb	Class III
Frequency of PSUR? (MDR/MDD/AIMDD)	Must be produced at a minimum once every 2 years for **all Class IIa devices.**	Must be produced at a minimum once a year for **all Class IIb devices**.	Must be produced at a minimum once a year for **all Class III devices**.
Upload to EUDAMED*? (MDR) *In the absence of EUDAMED the PSUR must be sent directly to the notified body. (MDCG 2021-1)	**Only Class IIa Implantable** devices will have PSUR uploaded to EUDAMED. PSUR not publicly visible in EUDAMED	**Only Class IIb Implantable** devices will have PSUR uploaded to EUDAMED PSUR not publicly visible in EUDAMED.	**All Class III** will have PSUR Uploaded to Eudamed. PSUR not publicly visible in EUDAMED.
Notified Body PSUR Evaluation?	**Class IIa non-implantable** completed as part of TF surveillance activities. PSUR Evaluation will be reported in Clinical Evaluation Assessment Report (CEAR). **Class IIa implantable** devices have PSUR evaluation report completed every 2 years and uploaded to EUDAMED. PSUR evaluation report is not publicly visible in EUDAMED.	**Class IIb non-implantable** completed as part of TF surveillance activities. PSUR Evaluation will be reported in Clinical Evaluation Assessment Report (CEAR). **Class IIb implantable** devices have PSUR evaluation report completed every year and uploaded to EUDAMED. This includes Well Established technologies (WET) per Article 54 PSUR evaluation report is not publicly visible in EUDAMED.	**All Class III** completed annually and PSUR evaluation uploaded to EUDAMED. PSUR evaluation report is not publicly visible in EUDAMED.

Article 86 (MDR)/Article 81 IVDR

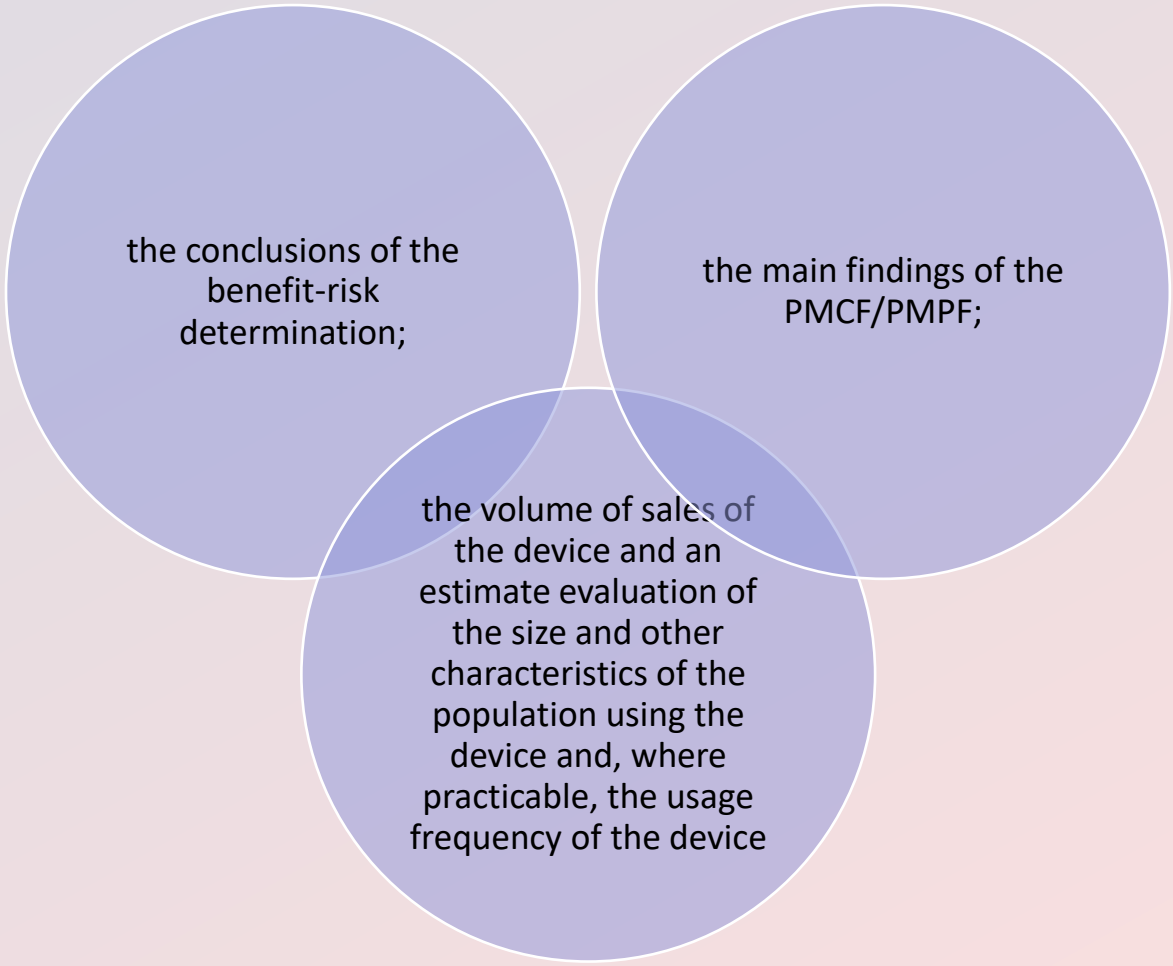
Article 86(MDR) Article 81 (IVDR):

Throughout the lifetime of the device concerned, that PSUR shall set out:

(a) the conclusions of the benefit-risk determination;

(b) the main findings of the PMCF/PMPF; and

(c) the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.



PSUR is the output of the PMS Plan

Article 86 - Class III, IIb, IIa (MDR):

Article 81 - Class C&D (IVDR):

Manufacturers of class IIa, class IIb and class III devices/Class C & D shall prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84(MDR) Article 79(IVDR) together with a rationale and description of any preventive and corrective actions taken.

Article 84 (MDR)– PMS Plan:

Article 79 (IVDR)– PMS Plan:

*The post-market surveillance system referred to in Article 83 (MDR) /Article 78 (IVDR) shall be based on a post-market surveillance plan, **the requirements for which are set out in Section 1.1(MDR)/1 (IVDR) of Annex III.***

For devices other than custom-made devices, the post- market surveillance plan shall be part of the technical documentation specified in Annex II.

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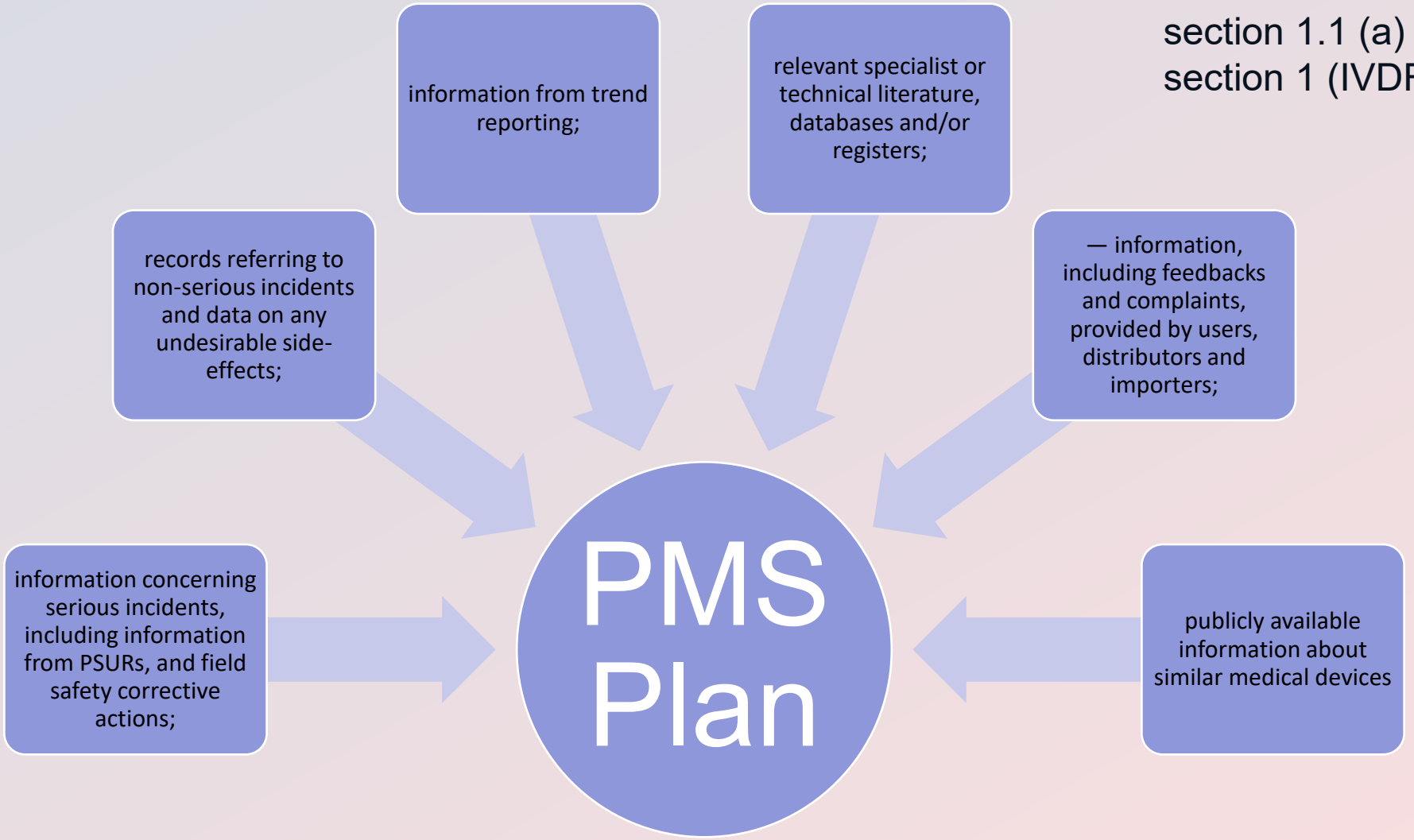
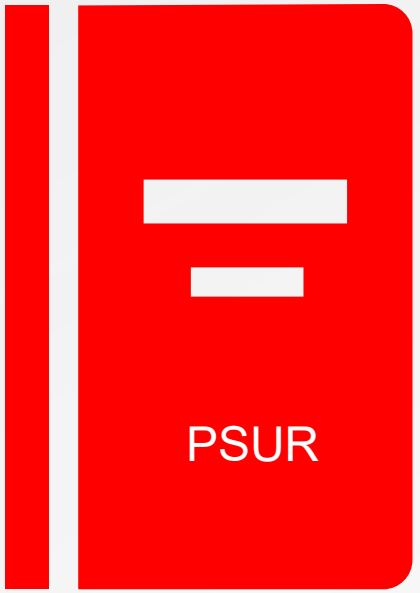
What activities should be included in a PMS Plan? Annex III 1.1 (MDR) / Annex III 1. (IVDR)

These are activities listed in section 1.1 (a) (MDR) and section 1 (IVDR)



Annex III & Article 83 (2) MDR / Article 78 (2) IVDR

*The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 83 to 86 (MDR)/*Articles 78 to 81 (IVDR) *shall be presented in a **clear, organised, readily searchable and unambiguous manner** and shall include in particular the elements described in this Annex.*
(Annex III)



The post-market surveillance system shall be suited to actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.

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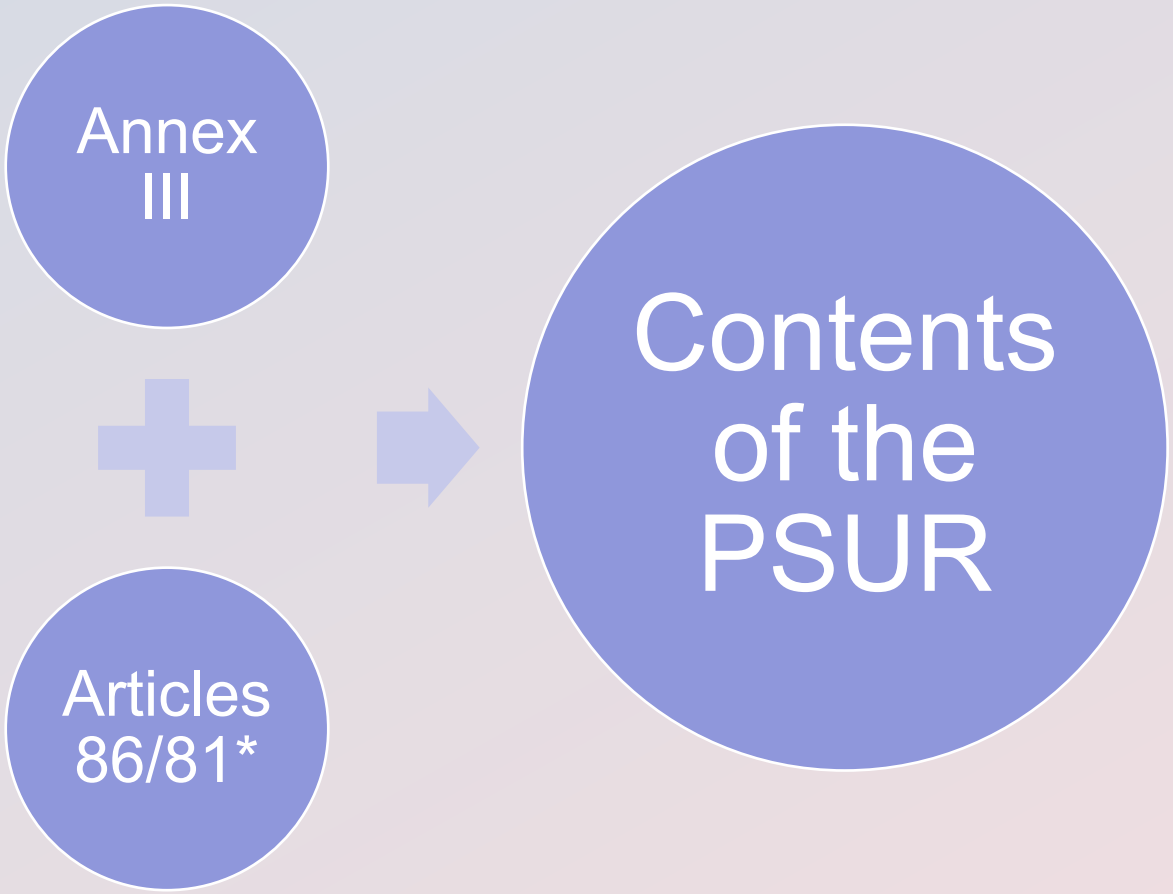
Contents of the PSUR (MDR/IVDR*)



- **Volume of Sales by region over time**
- **Estimated size of the patient population using the device over time.**
- **Characteristics of the population using the device over time**
- **Post-Market Surveillance : Vigilance and CAPA information**
- **Post-Market Surveillance: information including general/specific Post-Market Clinical/Performance Follow-up (PMCF/PMPF) information**

**It is expected that the IVDR guidance will follow the same requirements of MDCG 2022-21*

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MDD/AIMDD/IVD Device PSUR Vs MDR/IVDR Device PSUR

DO **NOT** SUBMIT THE PSUR FOR MDD/AIMDD/IVDD DEVICES TO THE NOTIFED BODY UNLESS SPECIFICALLY REQUESTED.

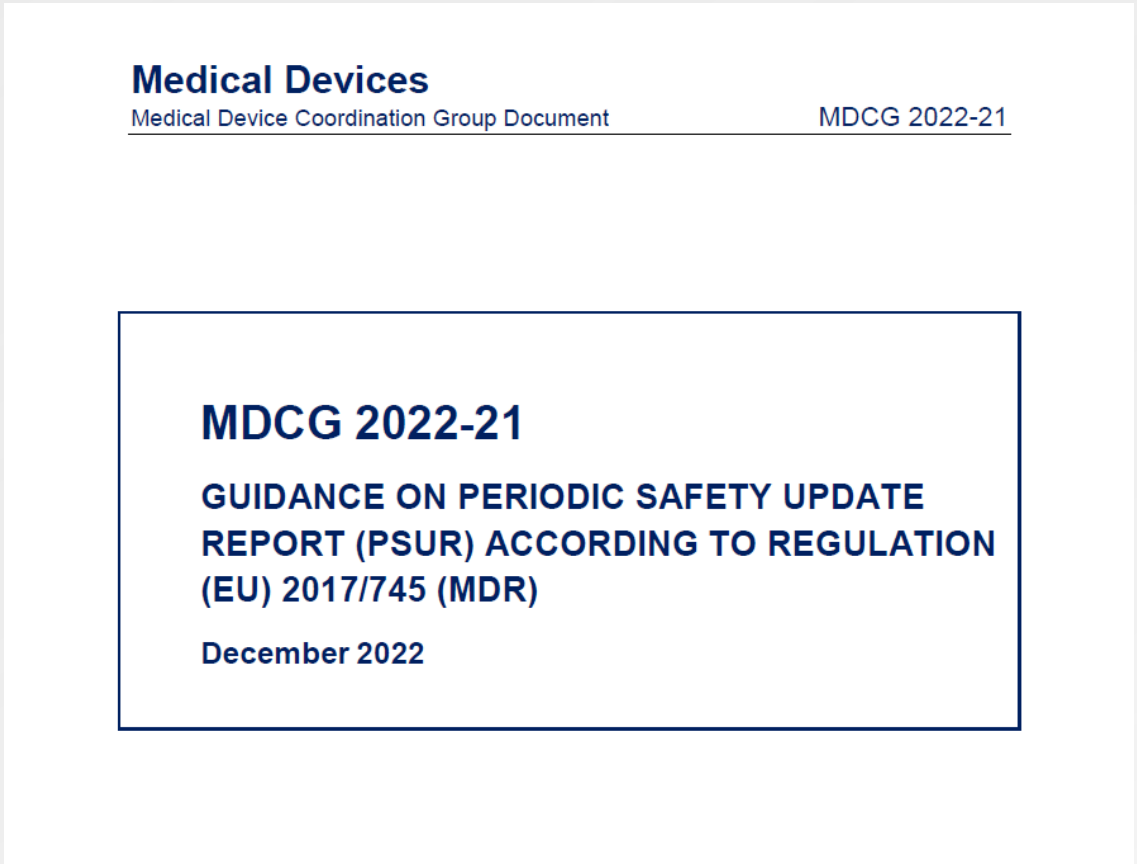
Article 86/81 of the MDR/IVDR requires the manufacturer to generate a PSUR for all class IIa, IIb, III/Class C&D devices.

The notified body will evaluate these PSURs but the process will be based on classification.

Expected Contents of the PSUR

(MDCG 2022-21)

MDCG 2022-21



- Released December 2022.
- Guidance is intended specially for manufacturers
- No notified body guidance.
- Provides information on
  - PSUR Content
  - Scope and Duration of PSUR
  - Grouping of Devices
  - PSUR preparation and issuance
  - Templates
- Specific IVDR PSUR guidance to follow. Task force to be set up in 2023.

Poll Question.

Does a manufacturer have to follow the PSUR template provided in MDCG 2022-21?

- Yes
- No
- It Depends

Poll Question.

Does a manufacturer have to follow the PSUR template provided in MDCG 2022-21?

- Yes (Please!)
- No
- It Depends

Lets remember the wording in Annex III…

*The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 83 to 86 (MDR)/*Articles 78 to 81 (IVDR) *shall be presented in a* ***clear, organised, readily searchable and unambiguous manner*** *and shall include in particular the elements described in this Annex. (Annex III)*

- It is essential manufacturers follow the template/format developed in MDCG 2022-21.
- Ensure that all section titles are presented in the PSUR, and when these sections are not applicable please provide a justification.

- Failure to follow the template and provide the information requested in the PSUR will result in the PSUR being rejected for evaluation and your certificate may be at risk.

- It is critical that you adequately explain in detail within the PSUR any anomalies along with any actions you may be taking to address these concerns.

It is essential that both notified bodies and manufacturers ensure that the PSUR is an efficient process that allows resource to be used for MDR applications .

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This is the minimum expected contents of a PSUR based on MDCG 2022-21

- Grouping Rationale
- Volume of Sales by region over time
- Estimated size of the patient population using the device over time.
- Characteristics of the population using the device over time
- Post-Market Surveillance : Vigilance and CAPA information
- Post-Market Surveillance: information including general Post-Market Clinical/Performance Follow-up (PMCF) information
- Summary of Findings and conclusions
- Actions taken by the manufacturer (If any -this may include updates to SSCP/SSP)

MDCG 2022-21 suggests for any absence of this information a justification should be provided.

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Grouping of Devices

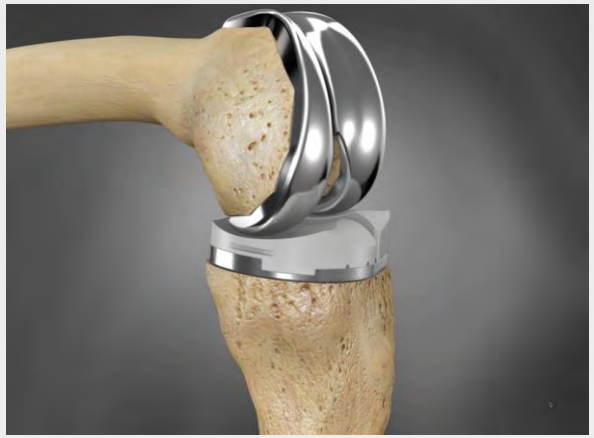
Considerations for Grouping of Devices in PSUR

Grouping of Devices – 1 Basic UDI

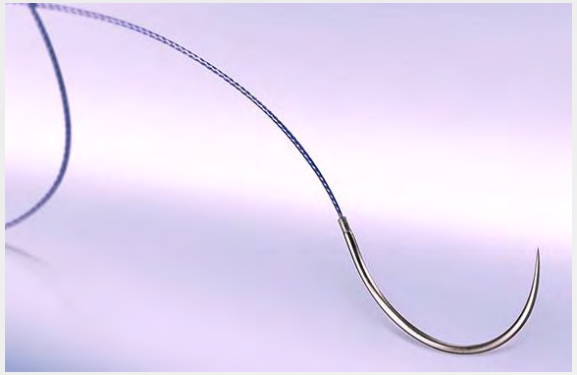
One Basic-UDI → 1 Basic UDI = Common Intended Purpose covering all sizes and variants

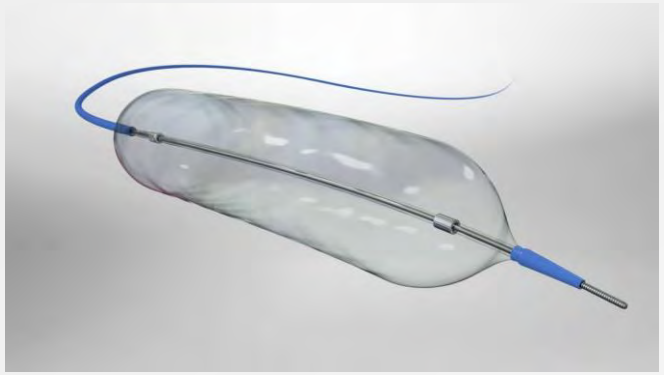
Multiple Basic-UDI → The devices should be linked by a Common Intended Purpose or commonality in design. This should be justified within the PSUR for grouping.

What is not considered appropriate grouping?



Higher risk devices that do not offer a common intended purpose





Devices with different technology design or completely unrelated

The notified body is always required to demonstrate appropriate technical and clinical expertise are applied to the device under evaluation. Therefore from a practical perspective it is not feasible to include devices in a PSUR that have an unrelated common intended purpose or are a different design technology as this will require multiple reviewers to evaluate a single PSUR which will not allow us to meet the required timelines.

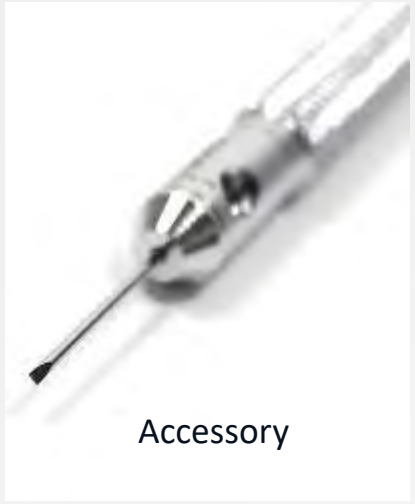
Grouping Devices – Leading Device

- When multiple Basic –UDI are incorporated into the PSUR a leading device needs to be chosen to drive the timepoints for producing the PSUR.
- The *Leading Device* should be the highest risk Classification or the 'main therapeutic/diagnostic device'.
- For variants of the same classification in this example the first timepoint of the device placed on the certificate should be the leading device to ensure that the PSUR reporting time periods are met.

Grouping Devices – Leading Device

- When multiple Basic –UDI are incorporated into the PSUR a Leading Device needs to be chosen
- The *Leading Device* Should Be The Highest Risk Classification **<u>or the 'main device'</u>**
- In this example the pacemaker is the leading device and the accessories although Class III are not the 'main device'

Accessory



Accessory

Accessory

Grouping accessories with the main device in the PSUR is an appropriate method to reflect the safety and performance of the overall system.

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Sales/Usage Information

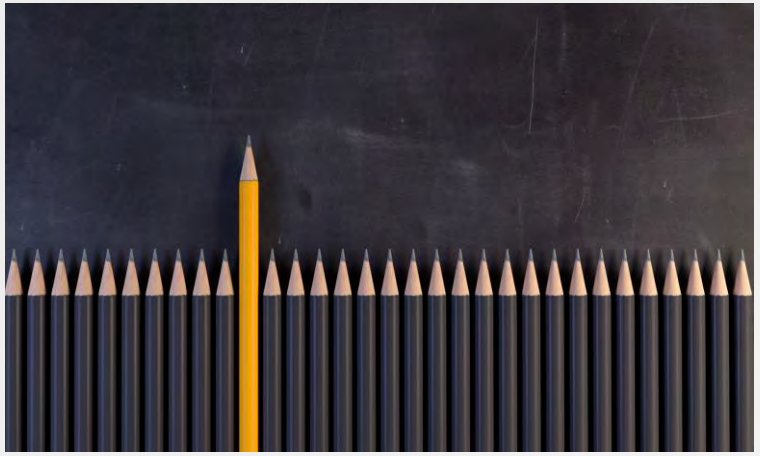
Considerations for Sales/Usage Information

Sales/Usage Information

Volume of sales could be:

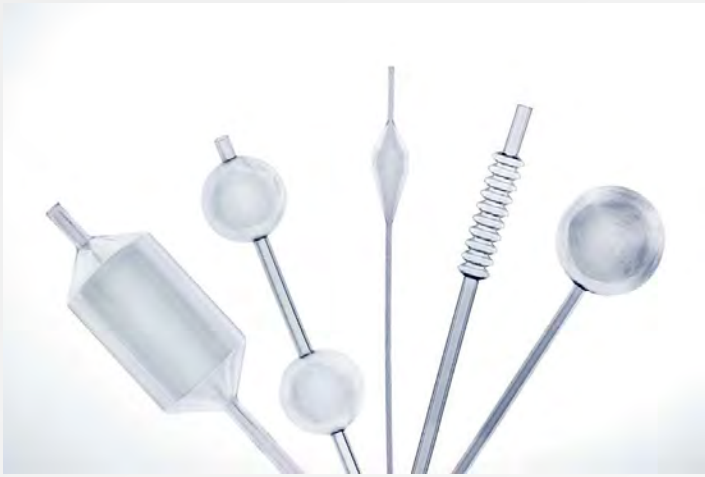
- Actual Sales
- Units Shipped
- Units Implanted
- Or another *Suitable Method*

- *Approximate numbers is not appropriate*



- The method used should be consistent throughout the PSUR when evaluating PMS data.

- Data should be presented on a year-by-year comparison irrespective of classification. This allows for a comparative assessment to be made.



- Volume of Sales should distinguish between:

- Model numbers (UDI)
- Sizes
- Variants

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Usage Information

- Method of use should be justified and be acceptable.

Reusable Devices may choose to report against the number of uses based on a justified calculation

Larger Lower Volume devices may choose to justify against usage and active installed base

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Geographical regions

Volume of Sales – Expectation that EU Data is presented separately to Worldwide Data.

EU Sales Data – Should include EEA + TR + XI

EEA	European Economic Area
TR	Turkey
XI	Northern Ireland

Worldwide data also includes sales of EU.

Example Table within Guidance MDCG 2022-21

Basic UDI-DI/ Legacy device name or model					
	Total Number of devices	Reporting Day+ preceding 12 months (N)	N – 12 months (N2)	N2-12 months (N3)	N3-12 [illegible] (N4)
EEA+TR + XI					
Worldwide					

Number of Total Devices ever sold.

Data Split.
Worldwide data should also include EU Data.

4 Year Data Presented Split ‘Year by Year’.
There is no legal requirement to include data before 26th May 2021 but reference to previous historical data can support the evaluation.

Characteristics of the Population Using the Device

Considerations for Characteristics of the population using the device.

Discussion Points from Working Group…

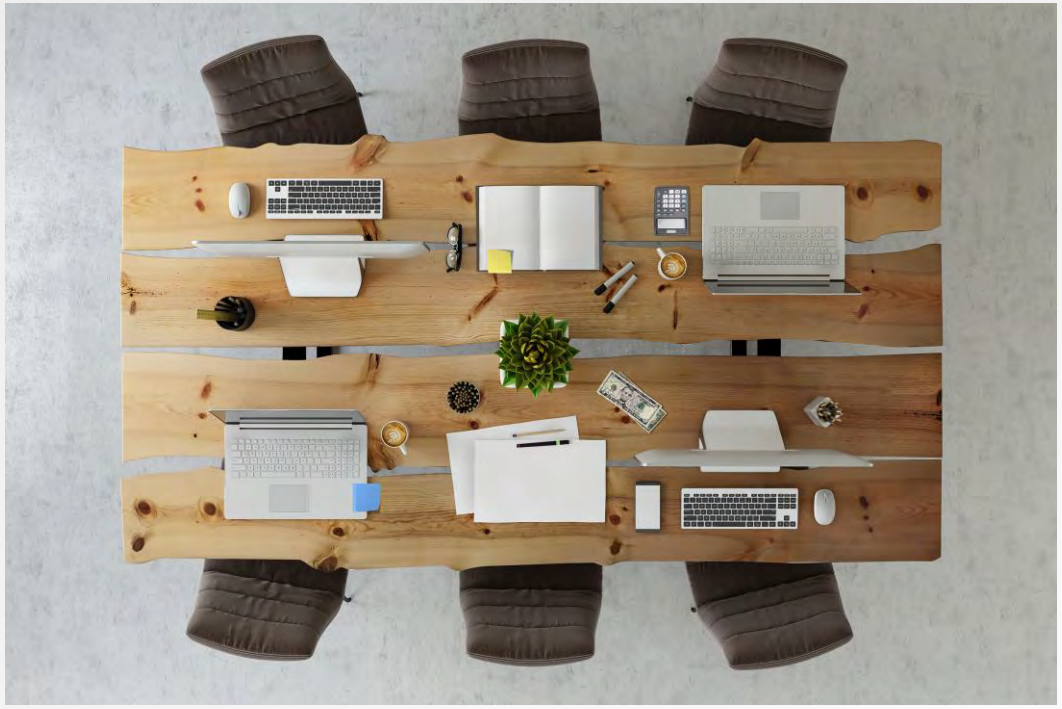
‘Is the device being used as intended purpose?’

‘Is there any off-label use of the device?’

‘What are the sexes, ages, ethnic profiles of the individuals mainly using the device?’

‘This information could help a manufacturer to determine that their intended purpose or indication needs further consideration’

‘Population could be users not necessarily patients’



Collection of population data…

Certain devices may lend themselves to being able to collect patient population data from registries such as implantable devices or devices undergoing specific PMCF activities.

Other devices not be for a specific population and may not hold such detailed information about the use of the device. It is accepted in these circumstances that a justification may be acceptable.

Considerations for Characteristics of population using the device

- Manufacturer may identify
  - The % or number of cases where the device has been used ‘on-label’
  - The profile of patients or users exposed to the device
  - Most used patient group e.g. *95% use in over 65 females*
  - Least common patient groups e.g. 3% of paediatric populations
  - Detailed information may be tabulated based on gender, age and indication

- **Note: This is a specific MDR requirement so a justification should always be provided if no data is presented.**

Vigilance Data

Considerations for Vigilance Data

PSUR & Vigilance

Expectation:

- Individual detailed vigilance reports are not to be provided within the PSUR although absolute reporting rates should be reported against EU & Worldwide Sales.
- Summary of reported vigilance should be provided indicating
  - Most reported vigilance episodes
  - Justification of levels of reported vigilance
  - Commonly frequent occurring Medical Device Problem (Annex A IMDRF)
  - Common Investigation Findings (Annex C IMDRF)
  - Health Impacts (Annex F IMDRF)
  - Investigation Conclusion (Annex D IMDRF)

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What should I be making clear in the PSUR in relation to Vigilance?

New Identified Risks

New risk identified that is not listed within the technical documentation of the device.

Trending or Emerging Risks

A significant trend of a specific serious event over time

What actions are you taking to address the vigilance issues?

Preventive & Corrective Actions

Considerations for Preventive and Corrective Actions

Article 83 (4) Article 78 (4) & CAPAs

When in the course of the post-market surveillance, a need for Corrective Actions or Preventive Actions (CAPAs) as defined in Article 83(4) first sentence is identified, the manufacturer should implement the appropriate measures and inform the Competent Authorities concerned and, when applicable, the Notified Body.

MDCG 2022-21

Article 83 (4)(MDR) Article 78 (4) (IVDR):

*If, in the **course of the post-market surveillance**, a **need for preventive or corrective action or both is identified**, the manufacturer shall implement the appropriate measures and **inform the competent authorities concerned and, where applicable, the notified body**. Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported in accordance with Article 87/Article 82.*

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Reporting of CAPAs in the PSUR

CAPAs under Article 83(4) are not limited to safety issues however it does not cover quality management system related CAPA's unless these could have a direct impact on product safety, performance or quality.

- Devices already placed on the EU market.
- Issues that might have a direct impact on product and that might impact product safety, performance or quality and,
- Evaluation of benefits and risks identified through post-market activities as described in Annex III, point 1.1 (a) of MDR.

A summary of all the above Article 83(4) CAPAs can be made available on request to the Competent Authorities either through the PSUR or through a specific report. However, all safety related CAPAs should be part of the PSUR (see section 2.2). (MDCG 2022-21)

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PMCF (Specific & General)

Considerations for PMCF (Specific & General)

Main Findings of PMCF/PMPF – Article 86(MDR) /81 (IVDR)

Throughout the lifetime of the device concerned, that PSUR shall set out:

(a) the conclusions of the benefit-risk determination;

(b) the **main findings** of the **PMCF/PMPF**; and

(a) the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

The PSUR is a 'standalone report'

It is expected the main conclusions of the PMCF are presented within the PSUR

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General Vs Specific PMCF/PMPF Activities.

General PMCF/PMPF

- ✓ Clinical Experience Gained
- ✓ Feedback from Users
- ✓ Screening of Literature
- ✓ Screening of ‘other sources’

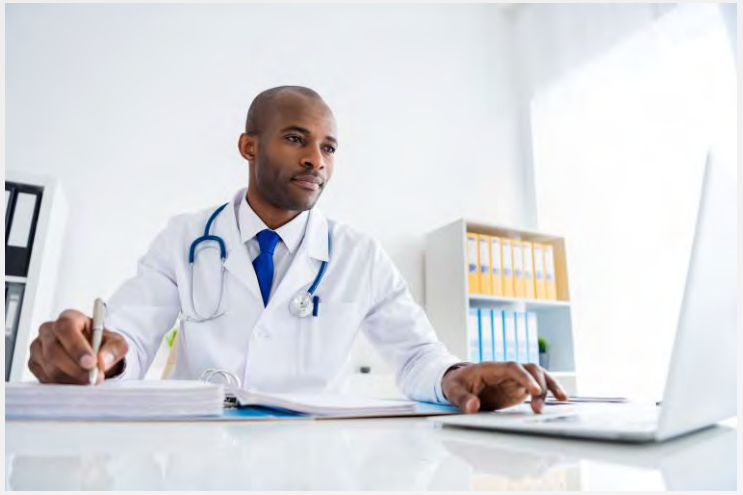
Annex XIV Part B (6.2 (a)) (MDR)
Annex XIII Part B (5.2 (a))(IVDR)

Specific PMCF/PMPF

- ✓ Evaluation of Suitable Registers
- ✓ PMCF/PMPF Studies

Annex XIV Part B (6.2 (a)) (MDR)
Annex XIII Part B (5.2 (b))(IVDR)

What is considered a ‘main finding’ ? (Not Exhaustive)



- ❑ Conclusions of a completed Specific PMCF/PMPF Activity
- ❑ Identification of new risk from General/Specific PMCF/PMPF Activities
- ❑ Identification of usability concerns from PMCF /PMPF Activities
- ❑ Identification of under performance from PMCF /PMPF Activities
- ❑ PMCF/PMPF Enrolment Concerns
- ❑ Identification of Systematic Mis-use or Off-Label Use.
- ❑ Deviation of PMCF /PMPF Protocol

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Purpose/Aim of PMCF

The PMCF/PMPF plan shall specify the methods and procedures for proactively collecting and evaluating clinical data with the aim of:

(a) confirming the safety and performance of the device throughout its expected lifetime,

(b) identifying previously unknown side-effects and monitoring the identified side-effects and contraindications,

(c) identifying and analysing emergent risks on the basis of factual evidence,

(d) ensuring the continued acceptability of the benefit-risk ratio referred to in Sections 1 and 9 of Annex I, and (e)(MDR) /Sections 1 and 8 of Chapter I of Annex I,(IVDR)

(e) identifying possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct.

Annex XIV Part B 6.1 (MDR)
Annex XIII Part B 5.2 (IVDR)

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Updates on PMCF Activity

- The PSUR serves as an opportunity to ensure manufacturers are committing to their PMCF obligations

- There should be some information on the progress of the PMCF Activity mentioned within the PSUR

    - Subject Enrolment
    - Site Enrolment
    - Timepoints of Data Collection
    - Adherence to PMCF Protocol

Overall Conclusions

Considerations for Overall Conclusions

Overall conclusions from the analysis of the collected data

The manufacturer should outline any new or emerging risks identified or when common occurrences of poor performance or claimed benefits have not been achieved within the current reporting period. When there are new or emerging risks that have been identified, the manufacturer should consider any specific patient groups, device models, accessories used, geographical regions impacted, duration of risk etc. Specific information should be provided on the seriousness and the full potential clinical impact of these risks.

- **The manufacturer may also describe any new benefits that have been identified from the reporting period.**
- **The manufacturer should formulate evidence-based conclusions to determine whether the benefit-risk profile of the device has changed.**
- **Finally, within the conclusion, the manufacturer should declare whether there has been an adverse impact on the benefit-risk profile of the device.**

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Actions taken by the manufacturer

- ***The manufacturer should describe any specific actions that have been taken to address any newly identified or emerging risks and occurrences of poor performance.***
- ***The manufacturer should identify all actions initiated during the data collection period as described in Article 83 (3) (MDR)/ Article 78 (3) (IVDR) .***

Please ensure you describe **fully** any actions you are taking in relation to any concerns identified within your PSUR.

Failure to adequately describe the actions being taken may result in a technical documentation assessment to review the safety and performance of the device under evaluation.

PSUR and updating the SSCP

Poll Question.

Can I submit SSCP changes with my PSUR that are outside of the contents of the PSUR?

- Yes
- No
- It Depends!

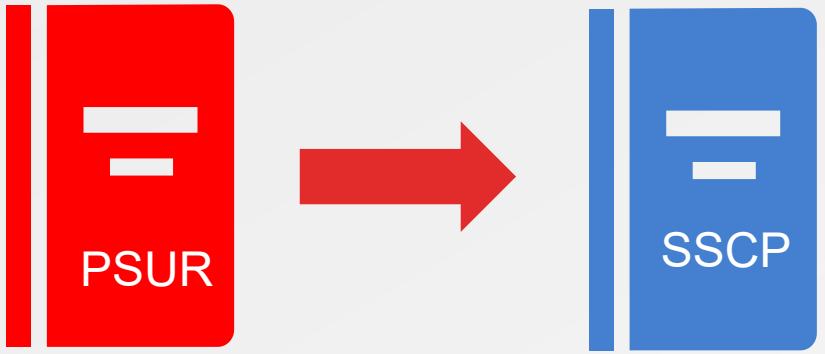
Poll Question.

Can I submit SSCP changes with my PSUR that are outside of the contents of the PSUR?

- Yes
- **No**
- It Depends!

PSUR Evaluation and Updating the SSCP

SSCP updates at time of PSUR evaluation must be limited to the content of the PSUR.



SSCP updates that go beyond the content of the PSUR will require other technical documentation to be submitted (e.g. CER) and this then is **not** a PSUR evaluation but rather a technical documentation assessment.

This will require a change notification request for the validation of these SSCPs to be conducted outside of the PSUR evaluation or when possible they may be completed at another conformity assessment timepoint e.g. Renewal.

Administrative updates to the SSCP may be submitted at time of PSUR evaluation.

Please think carefully before updating your SSCP!

Article 61 (11)

*For class III devices and implantable devices, the PMCF evaluation report and, **if indicated**, the summary of safety and clinical performance referred to in Article 32 shall be updated at least annually with such data.*

- **Remember the purpose of the SSCP – To inform the Health Care Professional (and Patient) of the safety and clinical performance data held on the device.**
- **If new data suggests there is no change to the safety profile of the device or there is no impact to the performance of the device, then an update may not necessarily be required as the information within the SSCP still remains valid.**

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Updating the SSCP

Not every update to an SSCP is required to be validated. You can still perform non-significant updates to the SSCP and wait until the next timepoint such as a renewal of your certificate to validate these updates.

e.g. additional clinical data that does not offer any new insights to safety or performance

Ensure your SOP is clear on what is a significant and non-significant update.

The SOP should be clear when significant updates are required to be sent to the notified body.

When should the SSCP be updated and validated outside of a design change or renewal?

Examples of significant updates that should be validated as part of PSUR evaluation.	Examples of non-significant updates that could be deferred to next conformity assessment for validation – e.g. Renewal, Design Change.
1. New Risk Identified.	1. New Clinical Data that does not impact the safety or performance of the device e.g. Outputs of literature data that does not impact the safety or performance of the device
2. Negative Change in Performance	2. Update and clarification on the text
3. Emerging Trends/Increase in Risk.	3. Changes in risk that are lower than those reported in the validated SSCP

If the benefit/risk profile of the device remains unchanged then what advantage is validating the SSCP at the PSUR evaluation timepoint?

Remember the purpose of the SSCP – To inform the Health Care Professional (and Patient) of the safety and clinical performance data held on the device.

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The notified body process of evaluating the PSUR

Will I receive a copy of the PSUR evaluation report?

Class III, Implantable and Class D

As these devices require a specific PSUR evaluation report to be uploaded into EUDAMED and the notified body are required to evaluate every PSUR at the appropriate frequency.

The notified body is required to provide a copy of the PSUR evaluation report to the manufacturer. In the absence of EUDAMED this will be sent at the end of the evaluation.

Class IIa/IIb Non-Implantable and Class C

For these devices PSURs will be evaluated as part of technical file sampling plans. As these PSUR evaluations do not need to be uploaded into Eudamed a separate evaluation report is **not** required.

The manufacturer will receive the CEAR/PEAR - This will contain the information on the PSUR.

Right First Time. – Class III and Implantable Devices

90 Days*

Failure to submit a PSUR within 90 days **or** a PSUR that provides insufficient information not aligned to MDCG 2022-21 will result in a reminder request being sent by the notified body and a further 30 days to submit the PSUR. Failure to comply with result in the certificate being suspended and eventually cancelled.

PSUR is generated after required timepoint of data collection

*These are timelines identified within the EUDAMED Playground

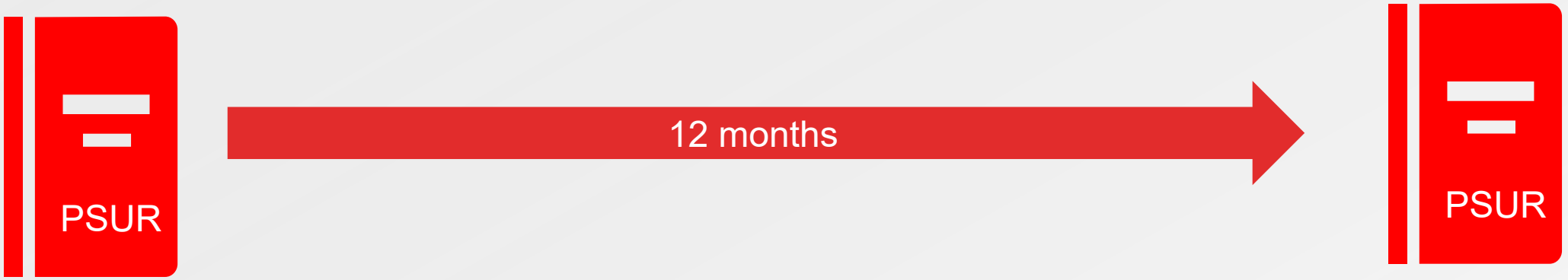
bsi.

What happens if there are issues with my PSUR? (Class III and Implantable)

If the notified body can agree through the contents of the PSUR that the benefit/risk is not adversely impacted however, improvements could be made then the notified body will provide general feedback in the PSUR Evaluation that must be considered as part of your next PSUR Submission.

If the notified body does not agree through the contents of the PSUR that the benefit/risk is not adversely impacted then the PSUR evaluation concludes and a technical documentation assessment shall begin to specifically additional documentation and evaluate more widely the benefit/risk assessment.

Next Steps

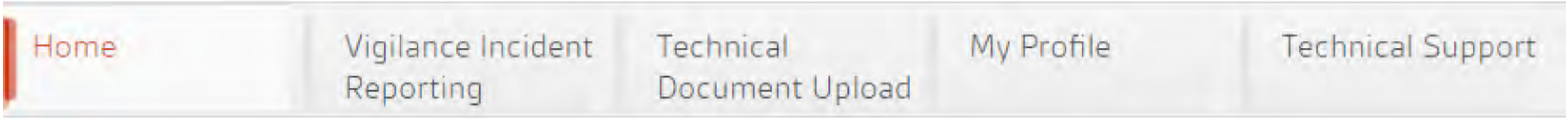


To ensure efficiency in the PSUR evaluation process, and to ensure BSI can focus on MDR application work, BSI is unlikely to allow rounds of questions during the PSUR Evaluation so it is critical that you ensure that your PSUR is compliant to the template provided in MDCG 2022-21 and contains adequate explanations for the data within the PSUR to avoid unnecessary technical documentation assessments.

A client communication will follow in the coming weeks to confirm the evaluation process.

BSI Electronic Client Portal and PSUR/SS(C)P

Portal tabs



Vigilance Incident Reporting

- MIR
- FSCA

Technical Document Upload

- Initial submission
- Response to BSI reviewer
- SS(C)P & PSUR Document
- Other

Technical Support

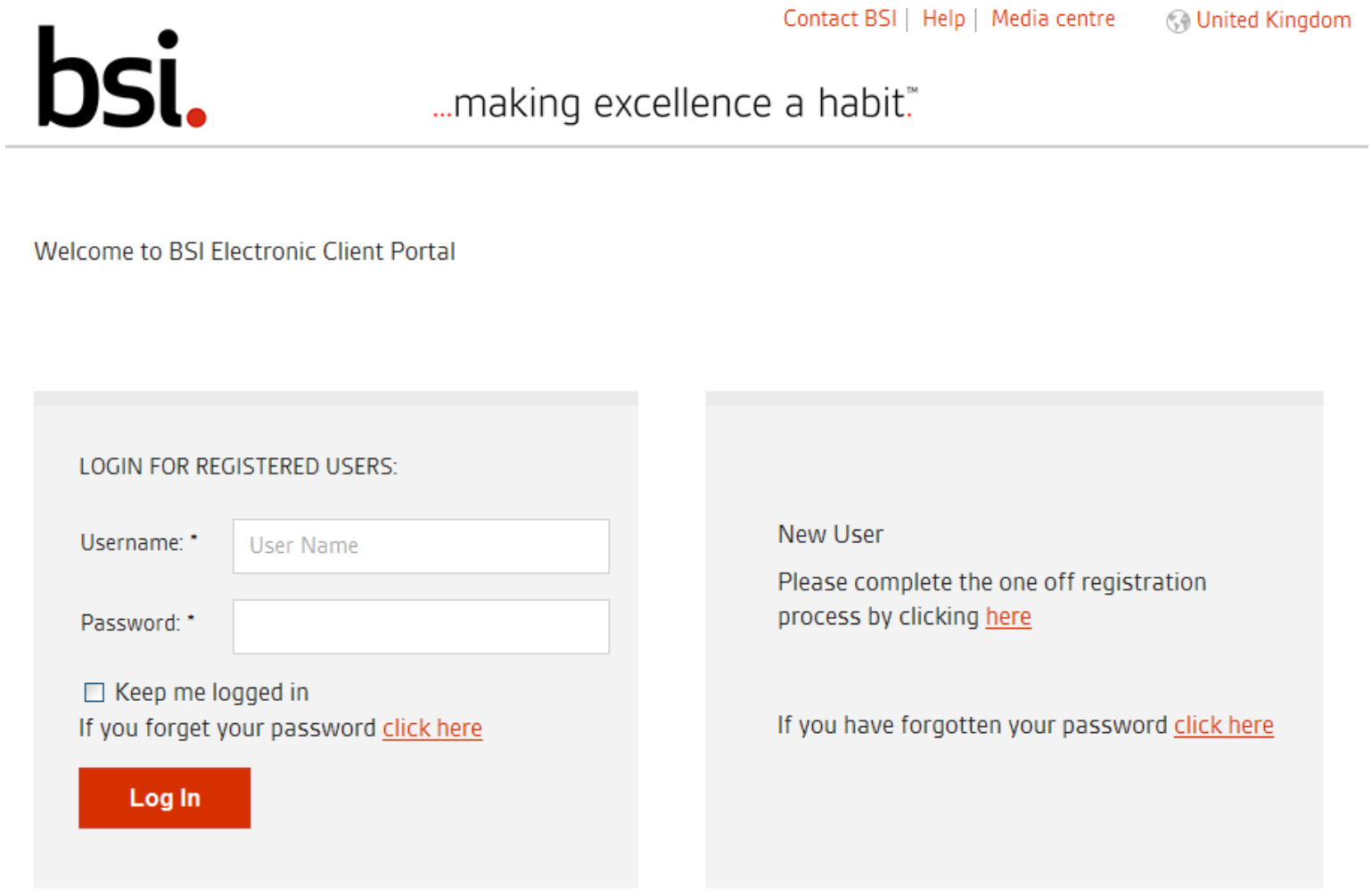
To report your issues or any technical difficulty

Accessing the 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.

If you do not already have a username and a password, register for a new account.



Setting up your account

Large organisation with multiple users

- Create one generic/ common account for your staff to access
- Request our Technical Support Team to create a group account

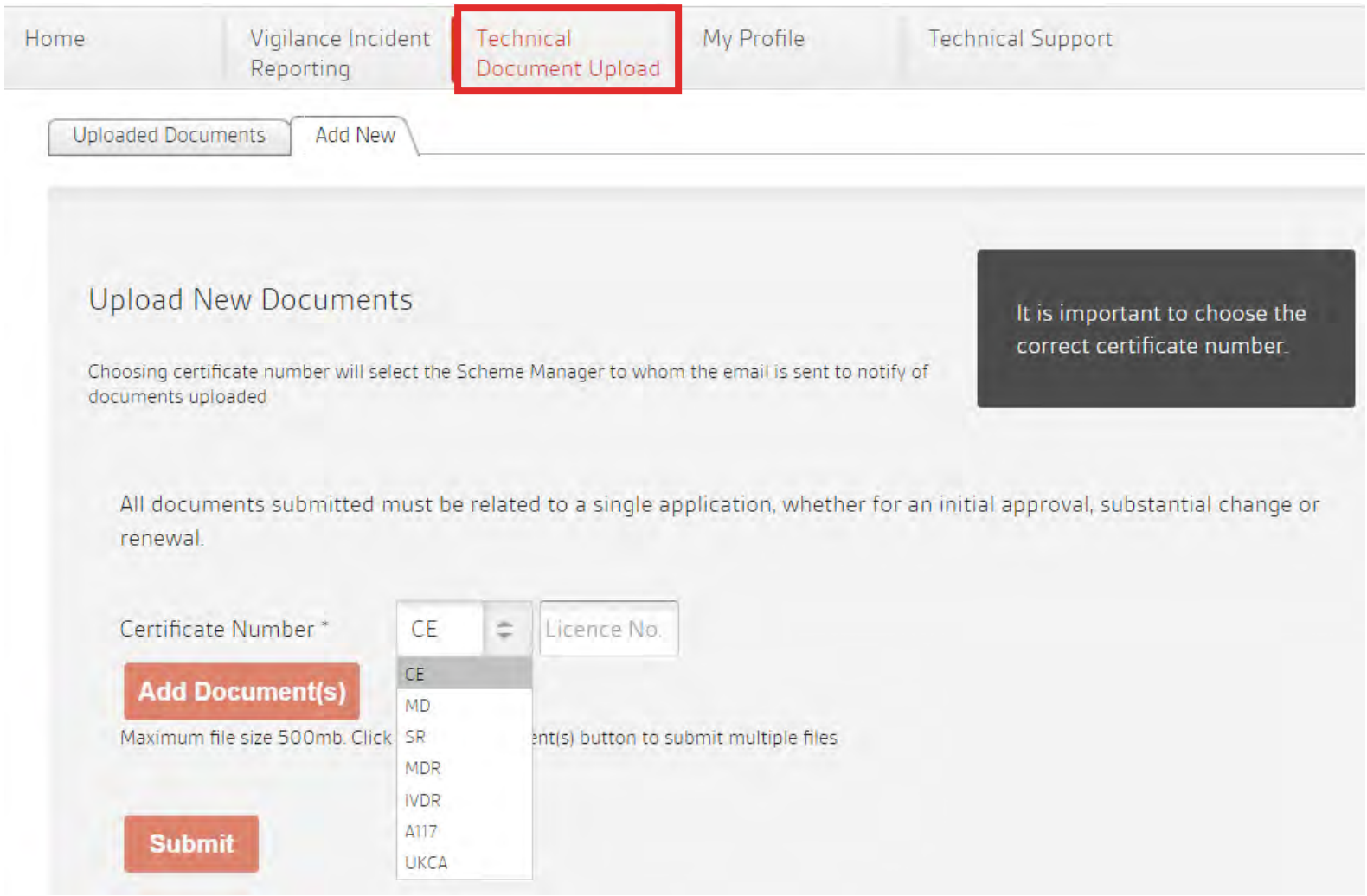
Alternative name and contact

Required to ensures that BSI can always contact someone if the main account holder is unavailable

NOTE

Access is provided to the whole portal (i.e., both Vigilance Incident Reporting and Technical Document Upload), not to a specific area

Uploading SS(C)P/PSUR



Uploading SS(C)P/PSUR

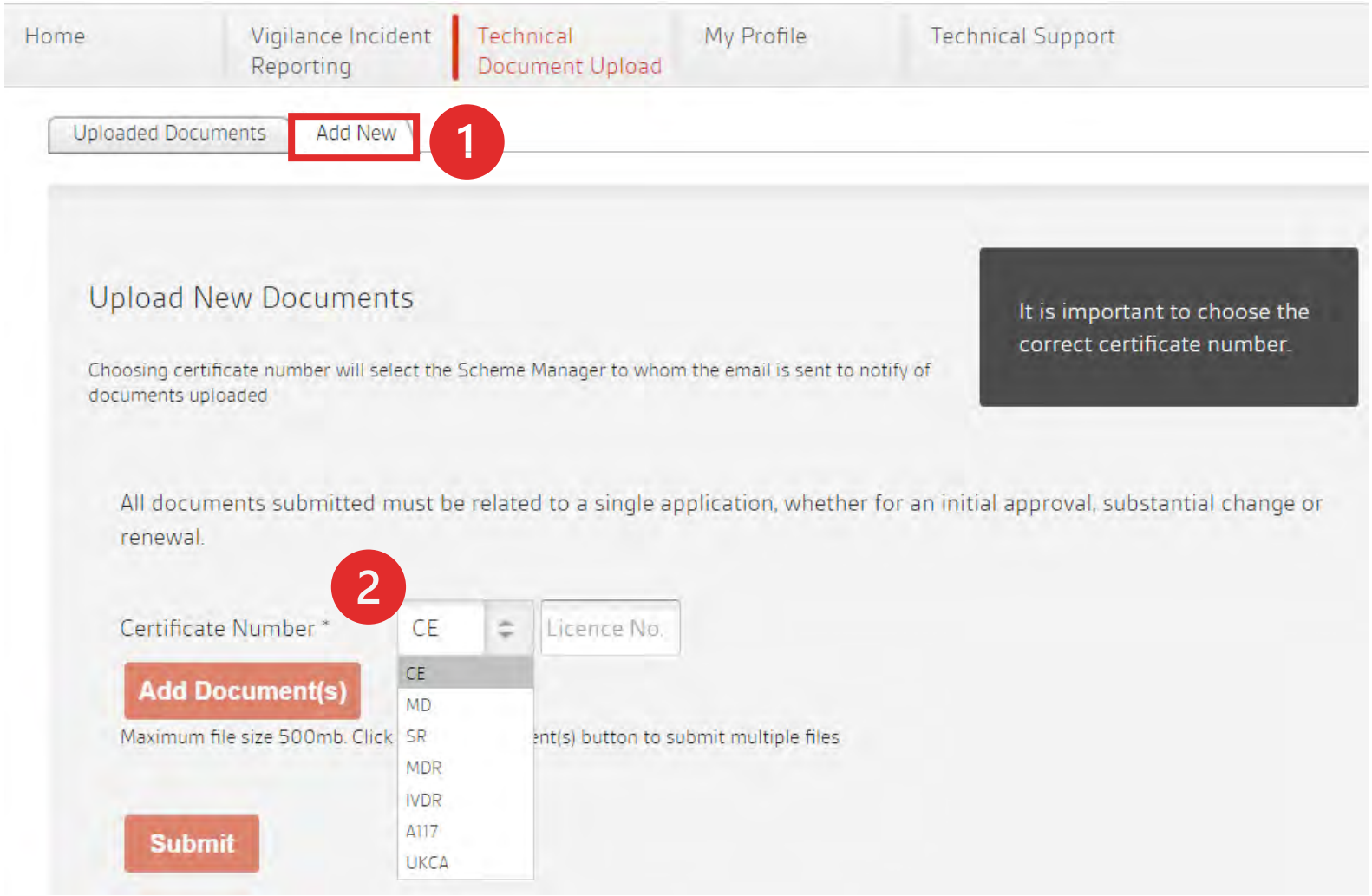
1. Add new
2. Enter your certificate number, selecting the correct prefix

Certificate prefix

- MDR/IVDR for Regulations

What certificate to enter

Devices covered by a product certificate and a quality based one: enter the Product Certificate only

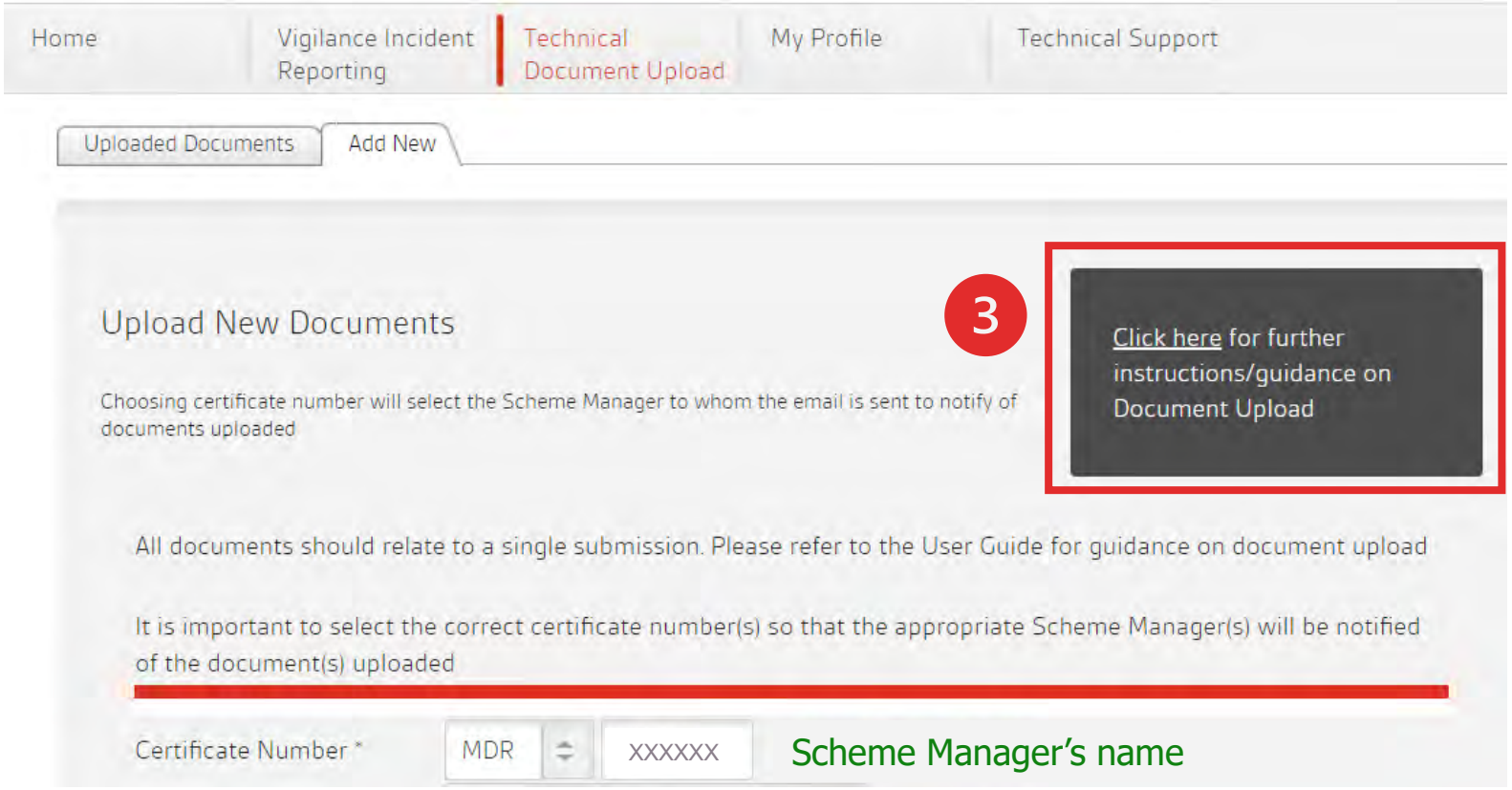


Uploading SS(C)P/PSUR

3 Download guidance on document upload, if needed

Important!

Enter the correct certificate number, since the portal will send an automatic notification to the Scheme Manager once you have uploaded your documents



Uploading SS(C)P/PSUR

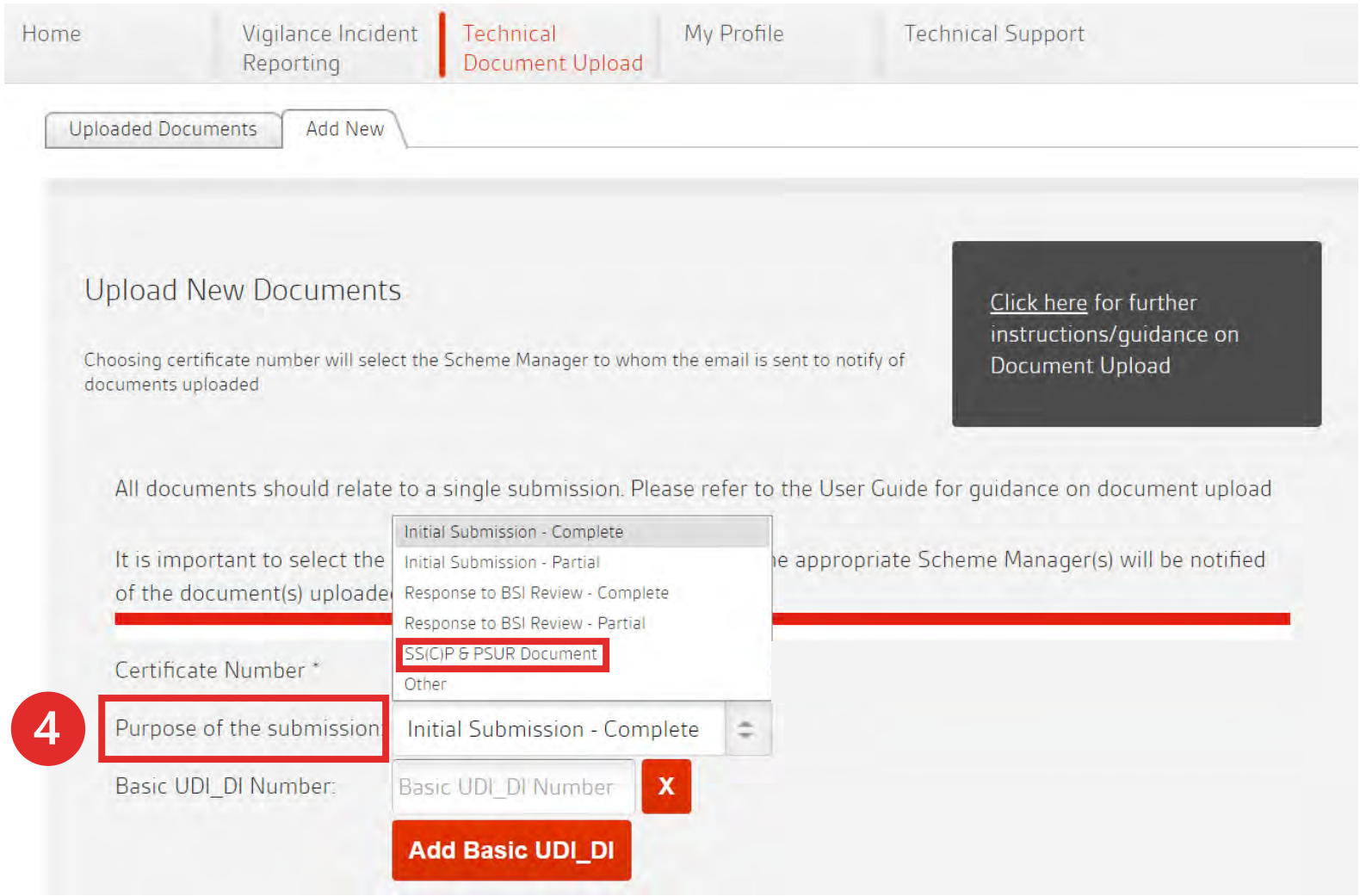
4 Purpose of submission

SS(C)P & PSUR Document

Use when sending SS(C)P and/or PSUR documents.

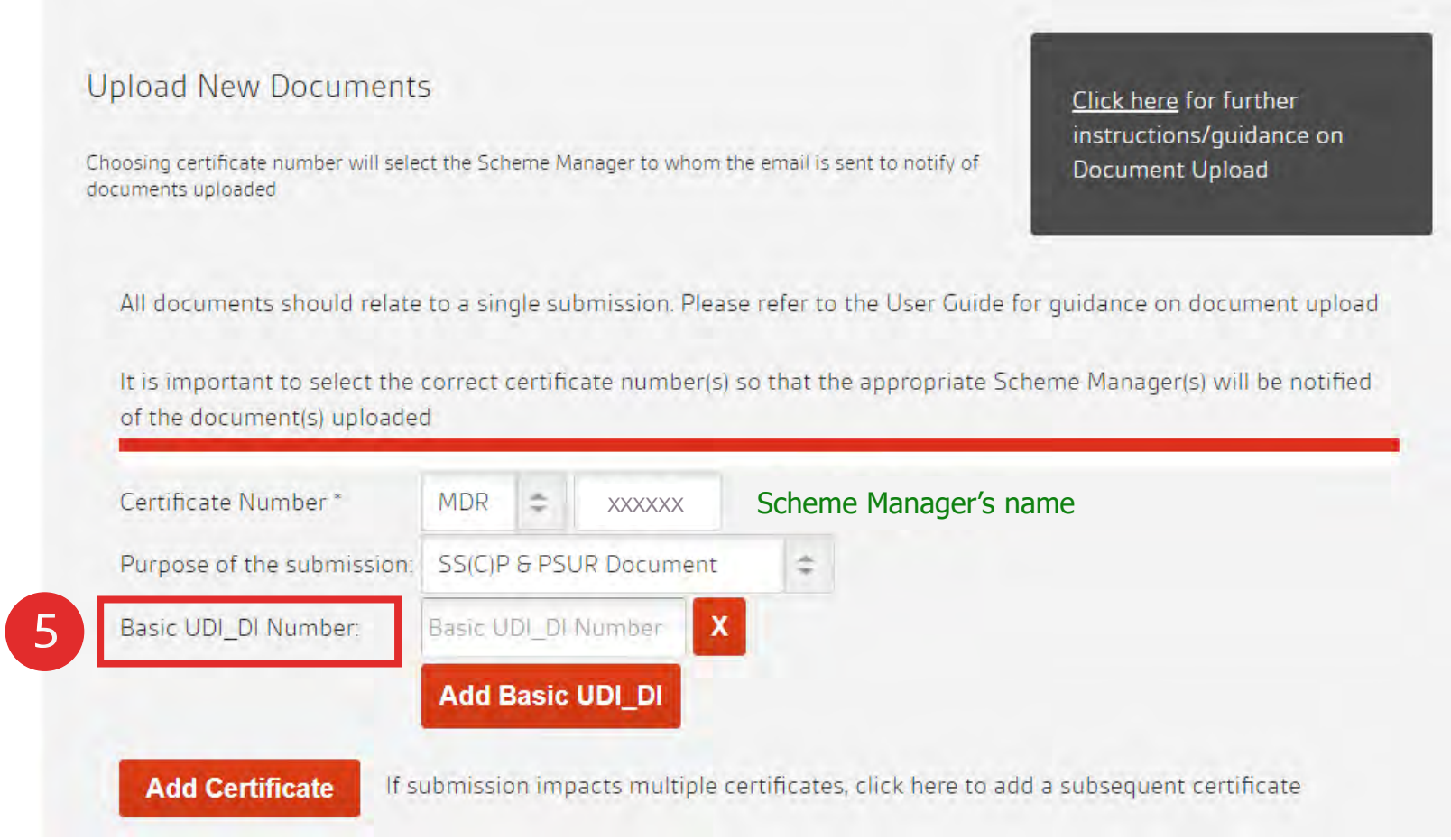
- PSUR
- Unvalidated SS(C)P
- Translated SS(C)P

DO NOT submit translations of SS(C)P documents until BSI sends notification that uploads are starting to EUDAMED



Uploading SS(C)P/PSUR

5 Enter the Basic UDI-DI

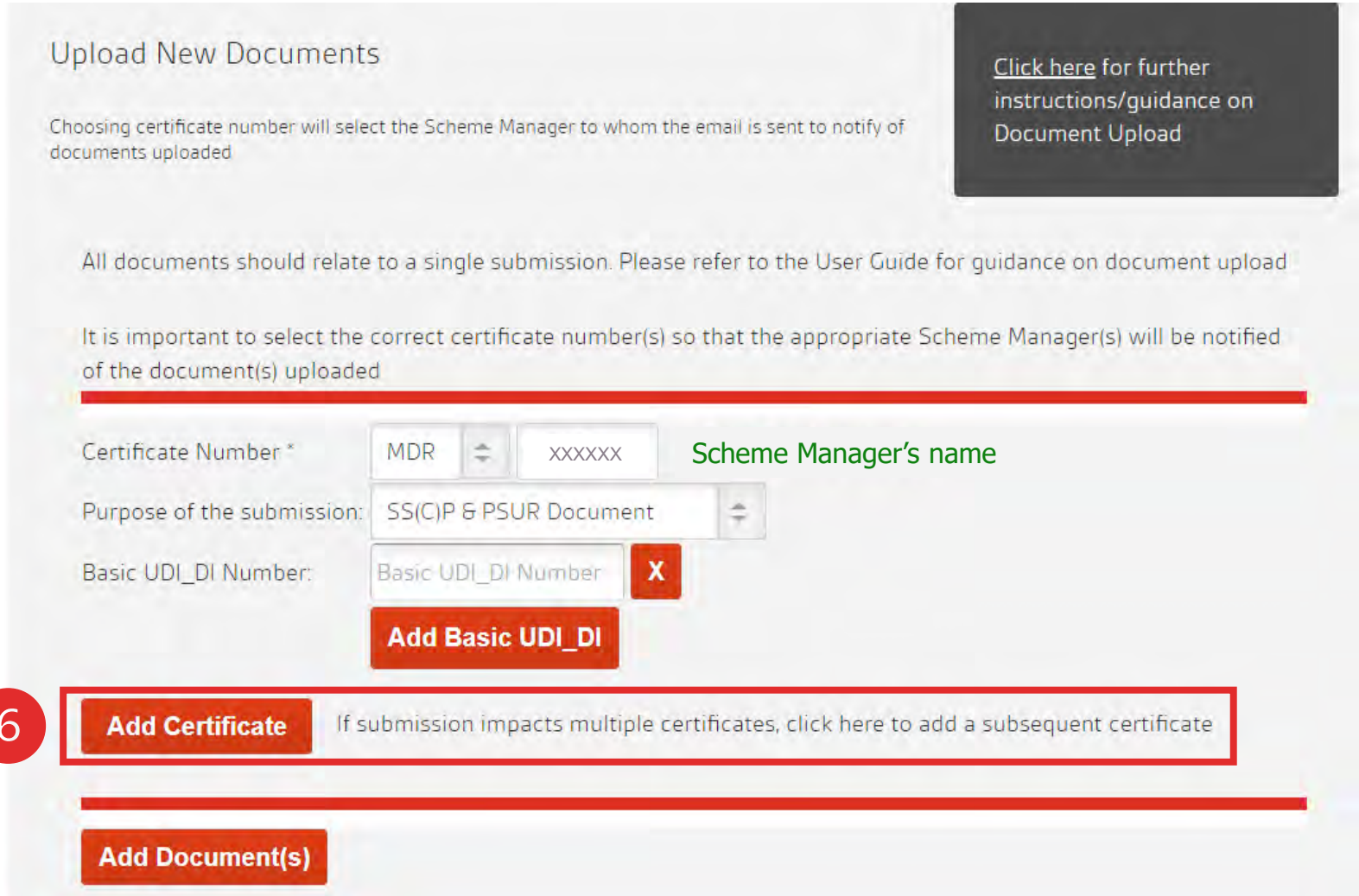


Uploading SS(C)P/PSUR

6 Add multiple certificates, if applicable (max 15)

Multiple certificates

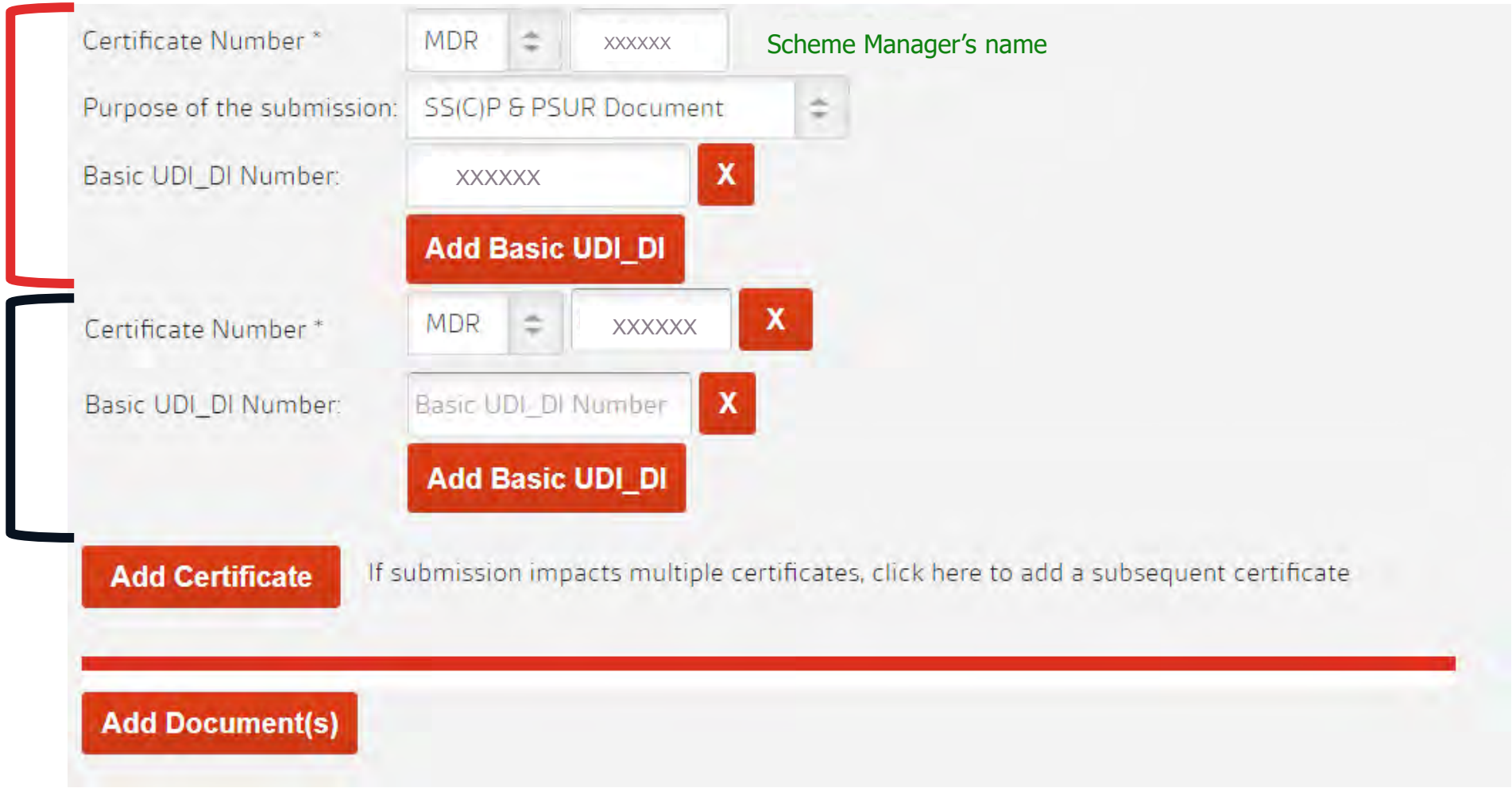
Only if the document uploaded is common to all the certificates and Basic UDI-DIs entered



Uploading SS(C)P/PSUR

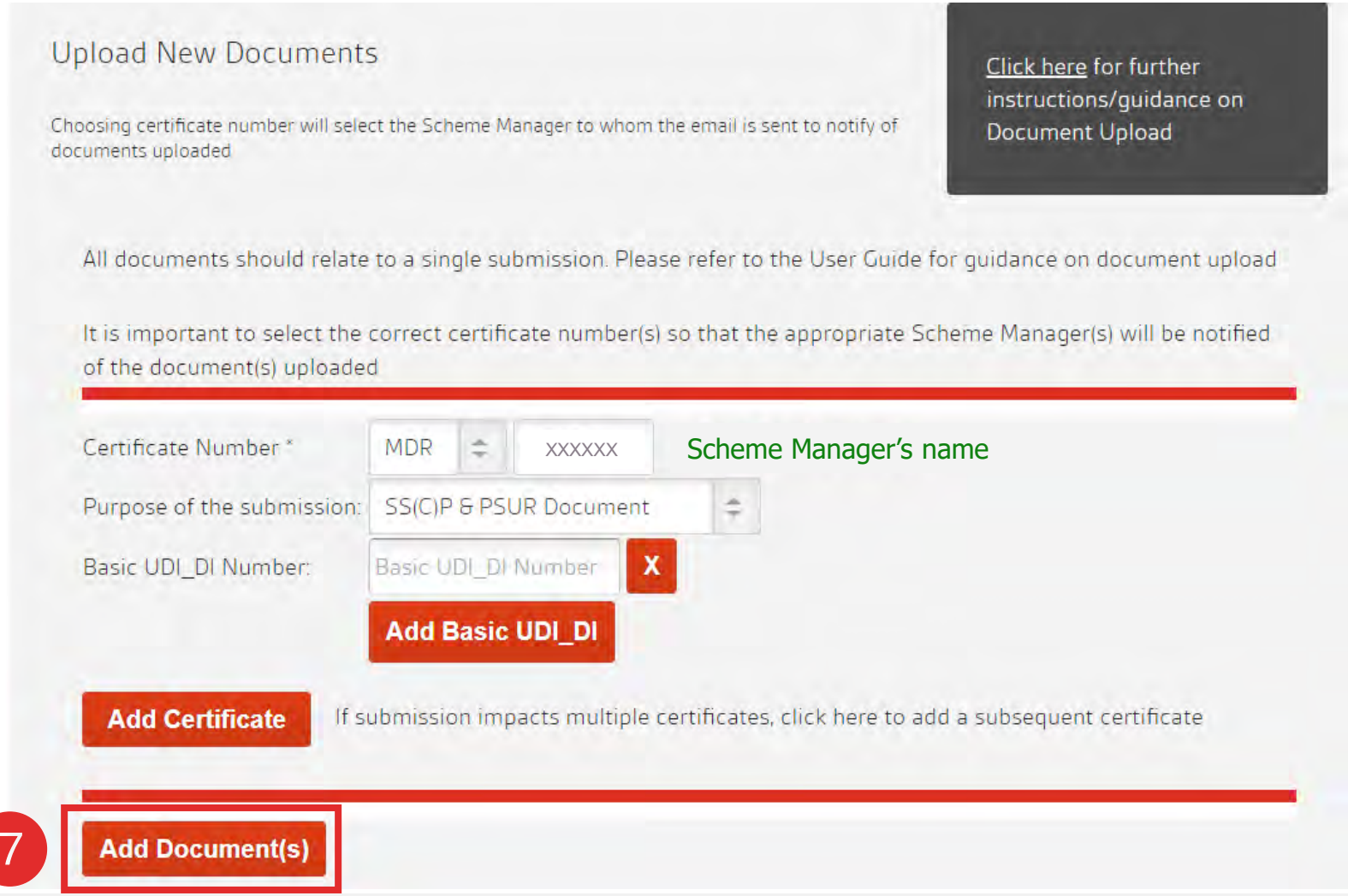
Certificate n.1

Certificate n.2



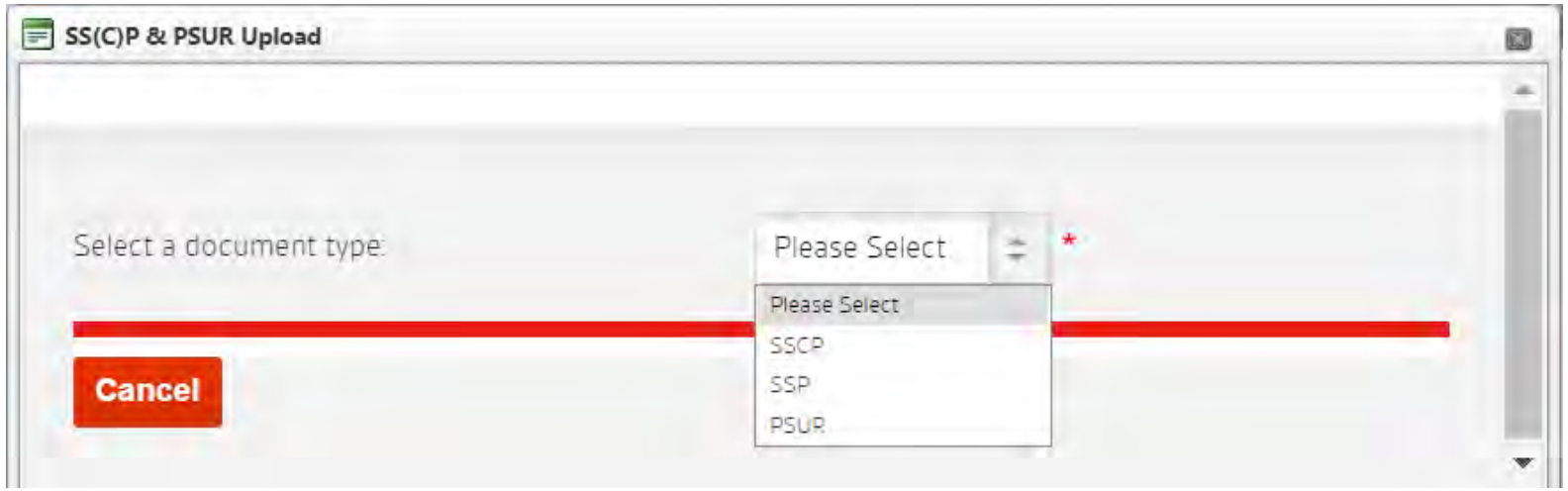
Uploading SS(C)P/PSUR

7 Add document(s)



Uploading SS(C)P/PSUR

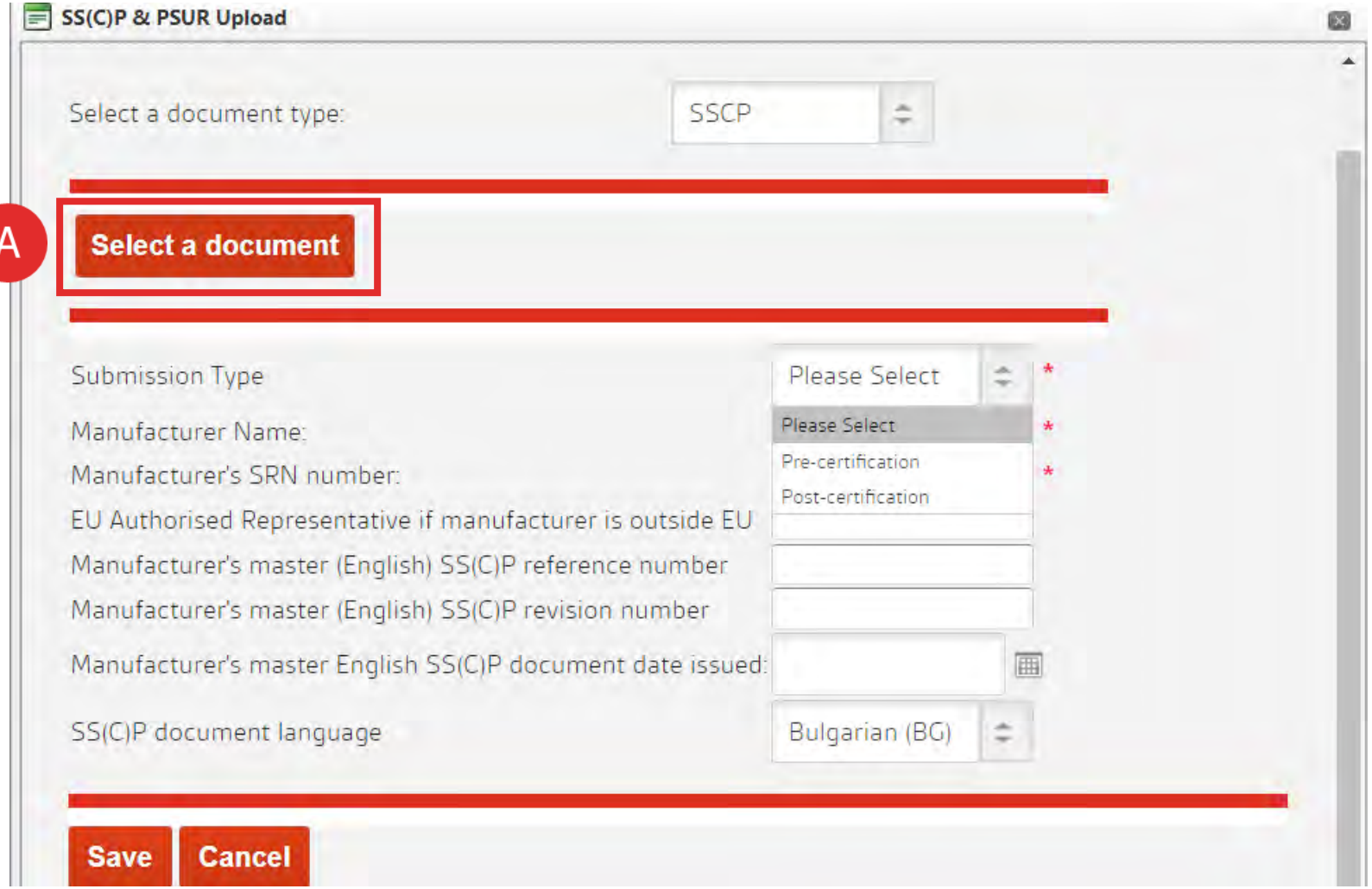
8 Select document type



Uploading SS(C)P

Uploading SS(C)P

A Upload document



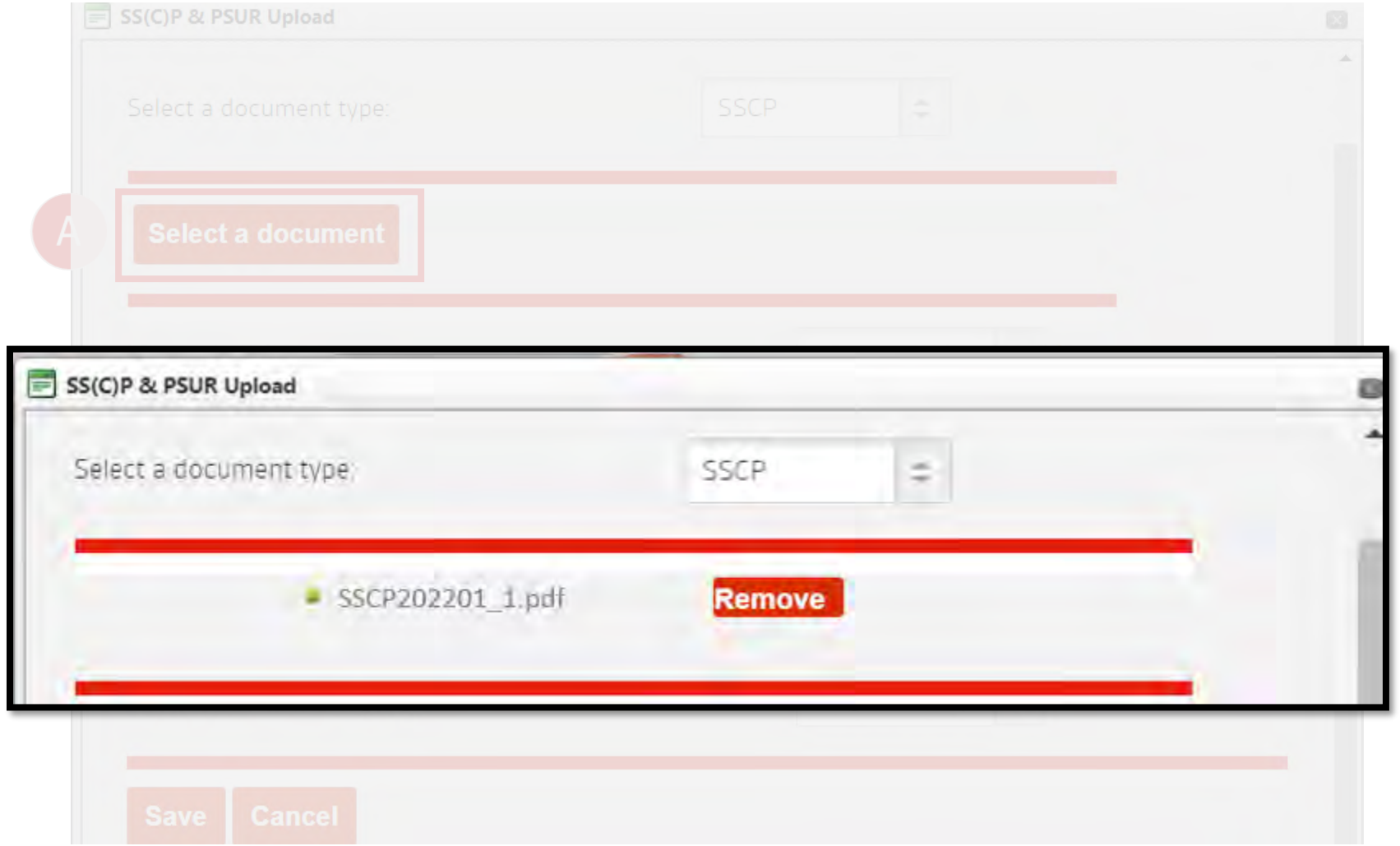
Uploading SS(C)P

A Upload document

- Invalid file type
- Valid file type

Max upload size

The maximum individual file upload size is 500mb



Uploading SS(C)P

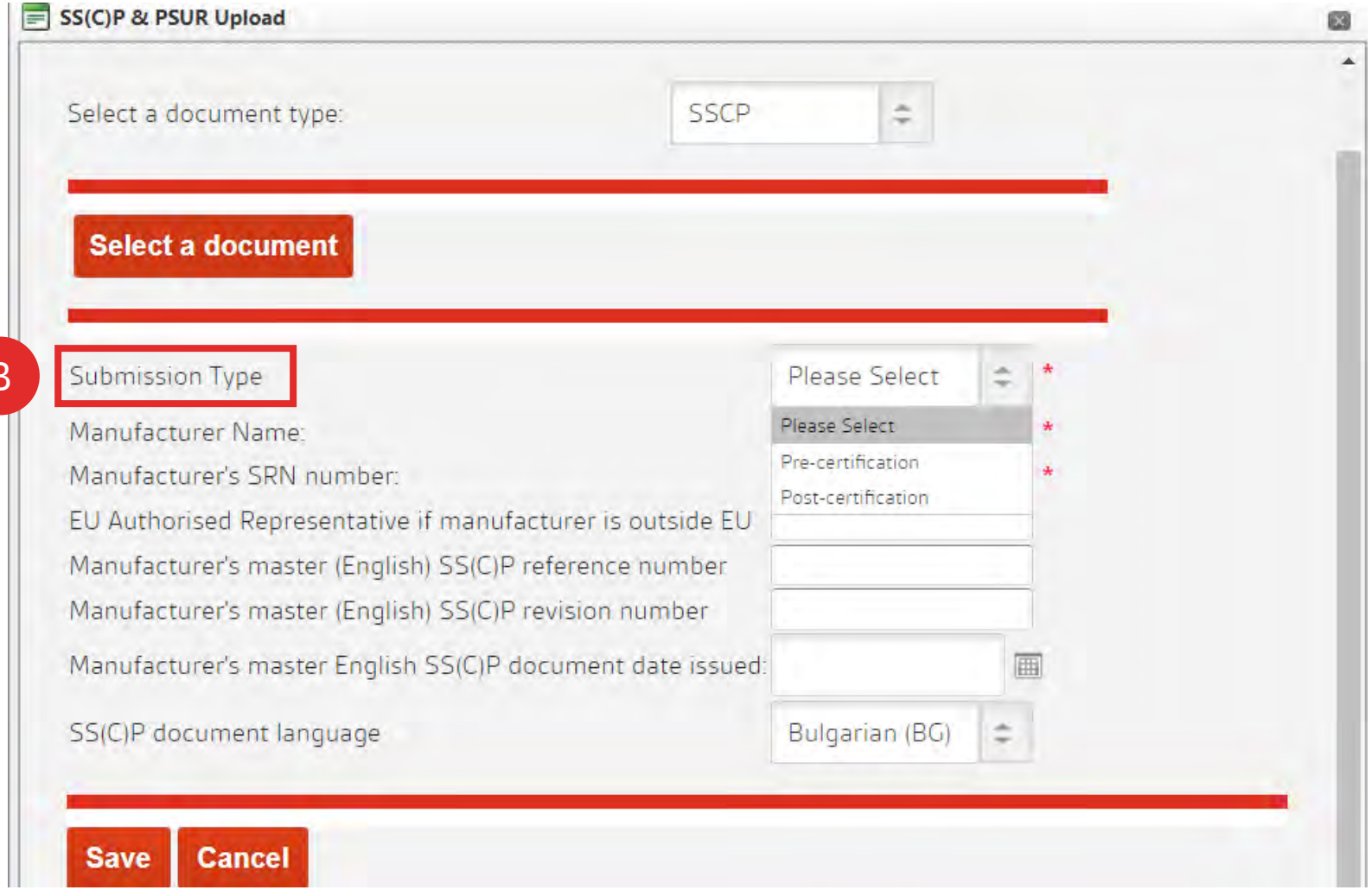
B Select the "Submission Type"

Pre-certification

English language or non-English language SS(C)P **before** the certificate is issued

Post-certification

English language or non-English language SS(C)P **after** the certificate is issued

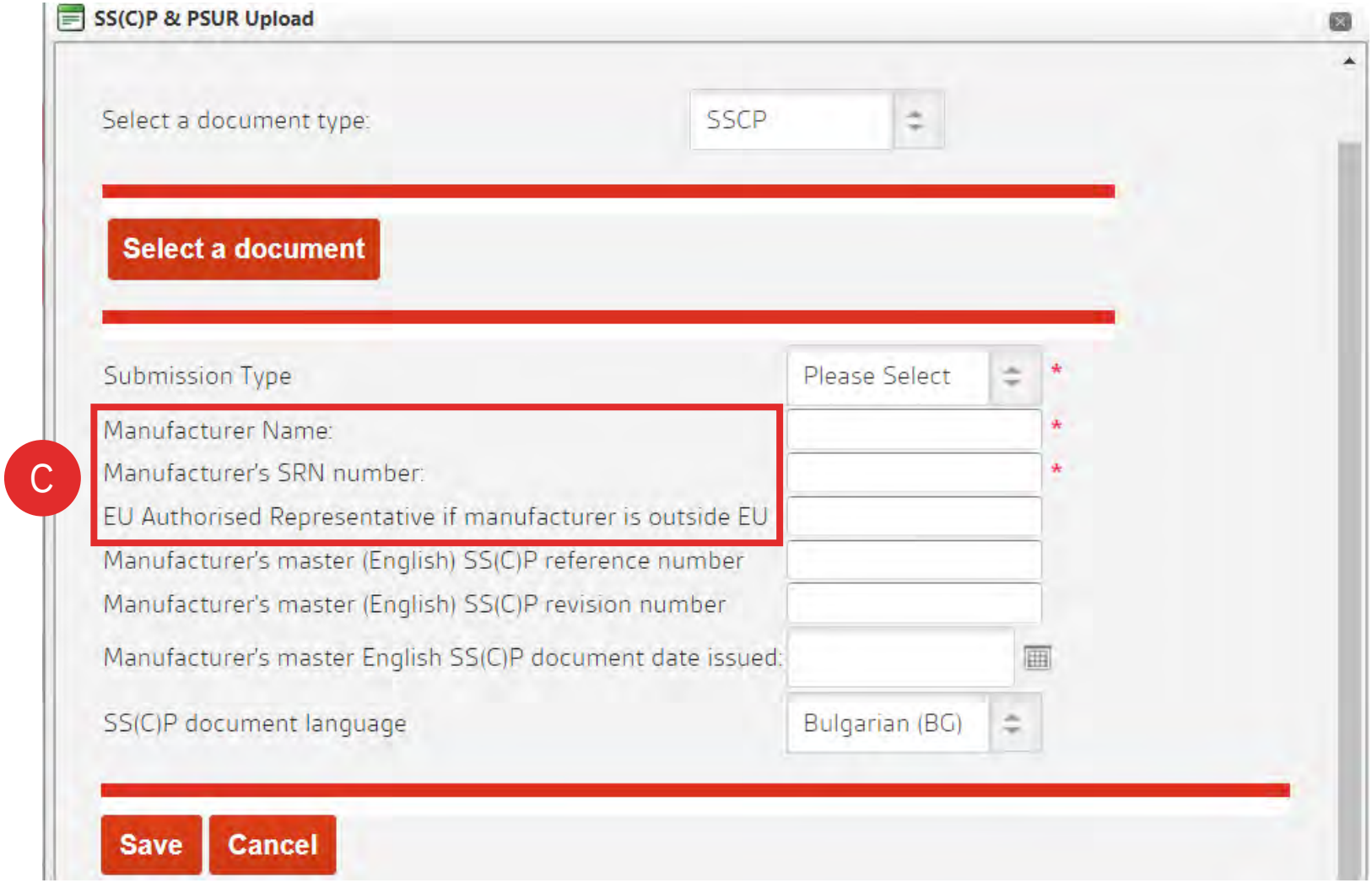


Uploading SS(C)P

C

Provide information:

- Manufacturer Name
- Manufacturer's SRN number
- EU Representative, if applicable



C

Uploading SS(C)P

D Provide information on Master (English) SS(C)P:

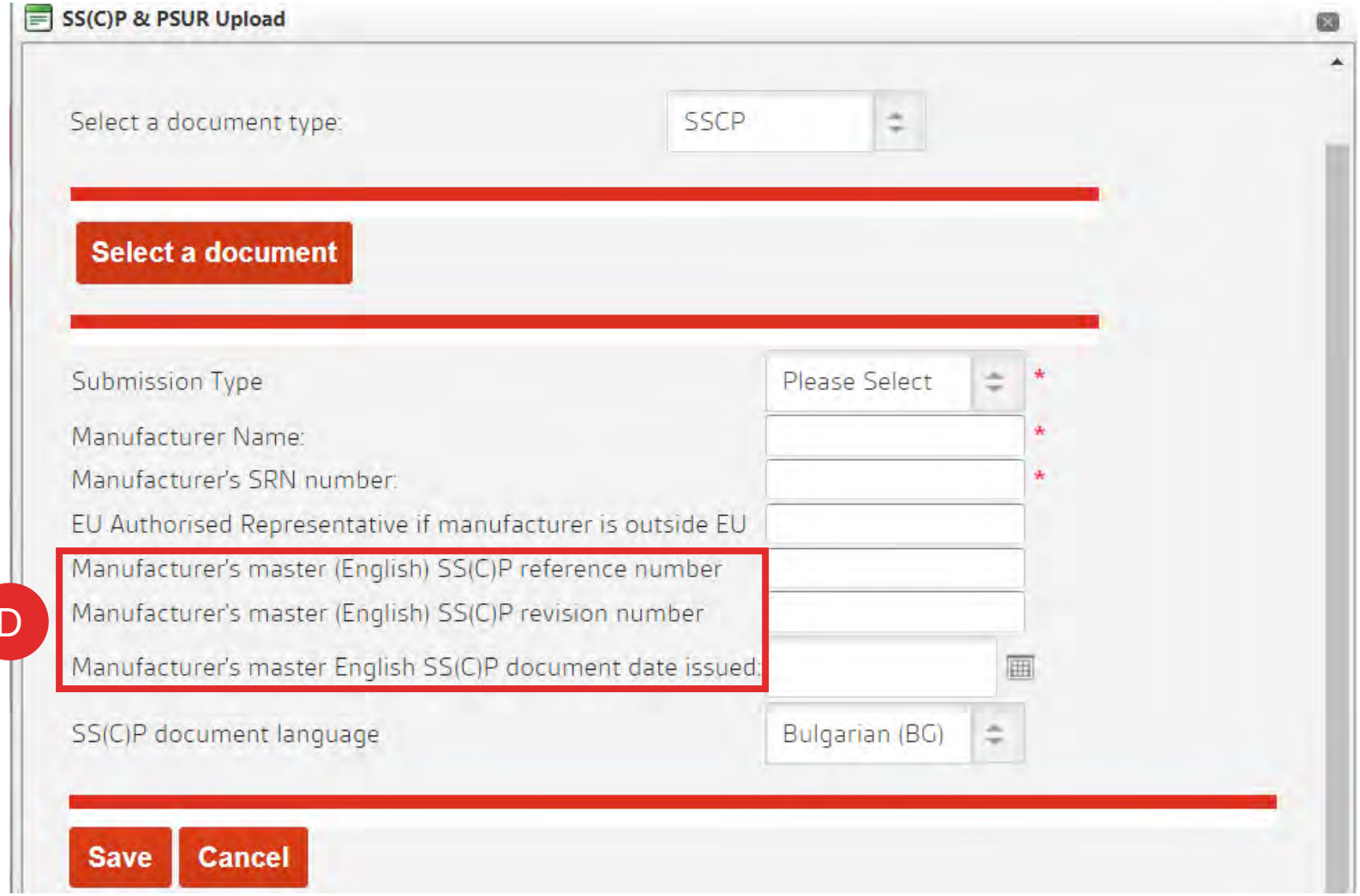
- Reference number
- Revision number
- Document date issued

Reference number

Same reference for the English version (the master version) and other language translations

Example

3 SS(C)P documents (1 in English version, 1 in Italian and 1 in Spanish): all 3 documents will have the same reference number



Uploading SS(C)P

D Provide information on Master (English) SS(C)P:

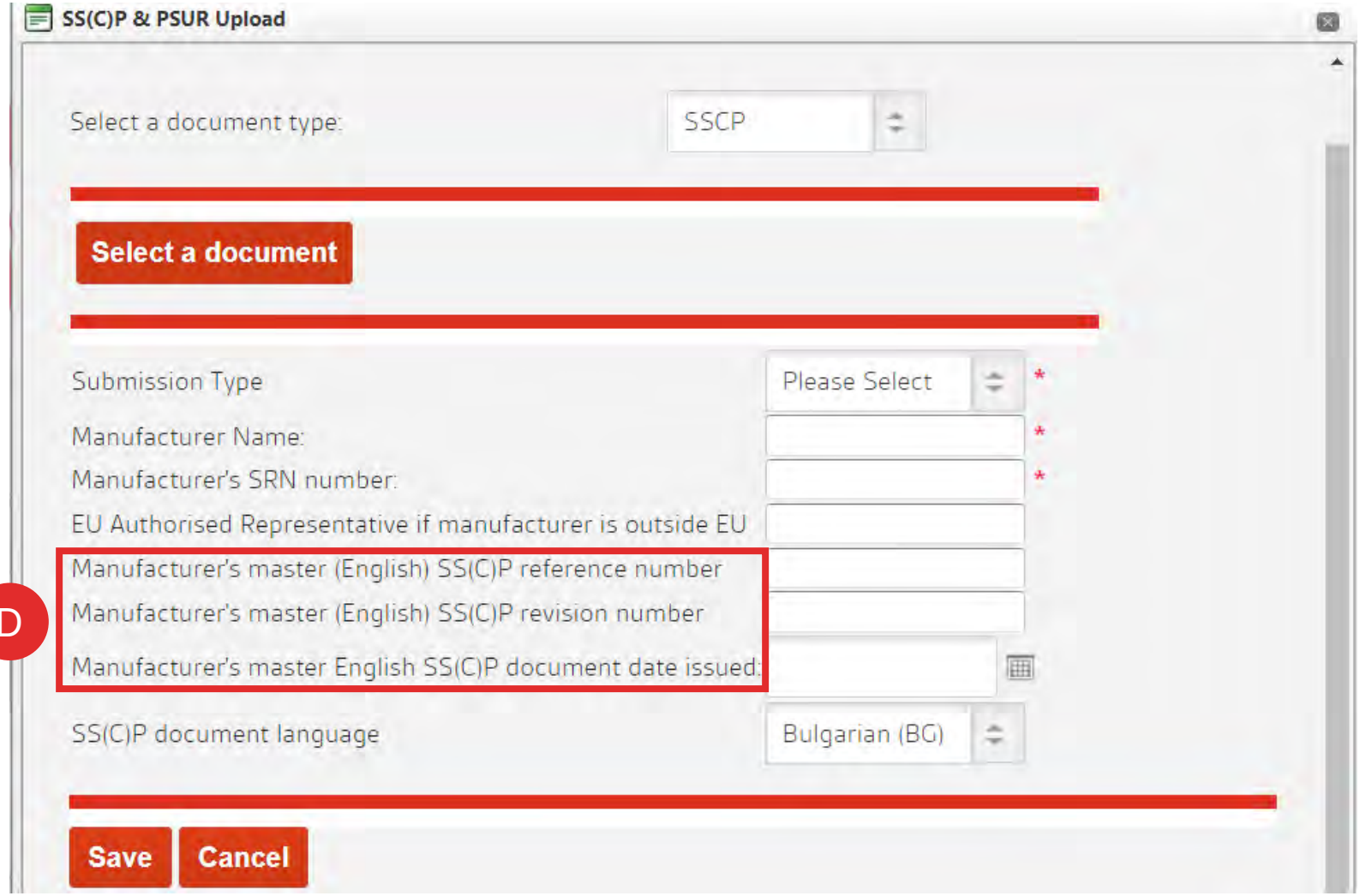
- Reference number
- Revision number
- Document date issued

Revision number

Same revision number for the English version (the master version) and other language translations

Example

3 SS(C)P documents (1 in English version, 1 in Italian and 1 in Spanish): all 3 documents will have the same revision number



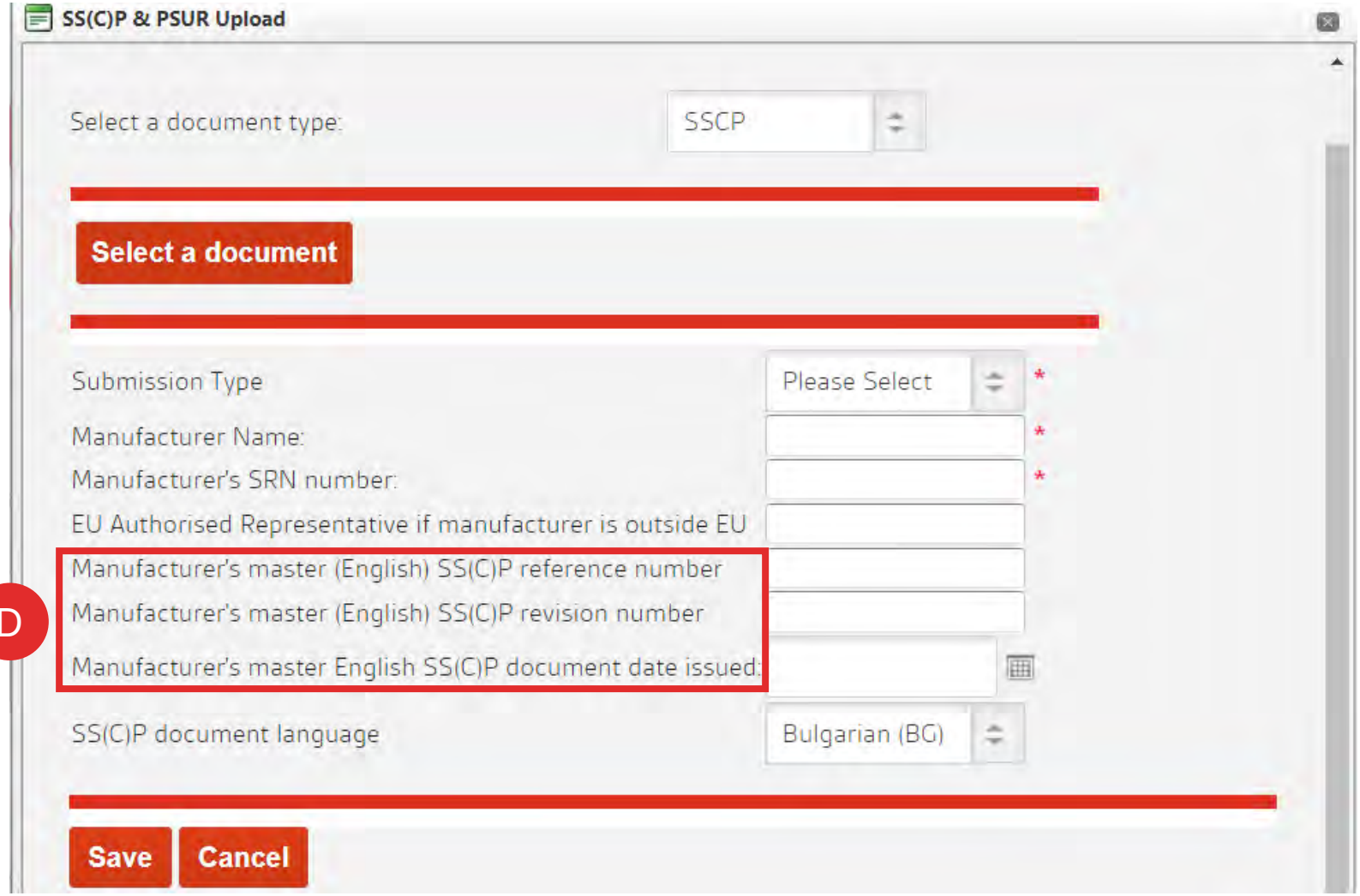
Uploading SS(C)P

D Provide information on Master (English) SS(C)P:

- Reference number
- Revision number
- Document date issued

Document date issued

Date when the English version of the SS(C)P (the master version) has been issued



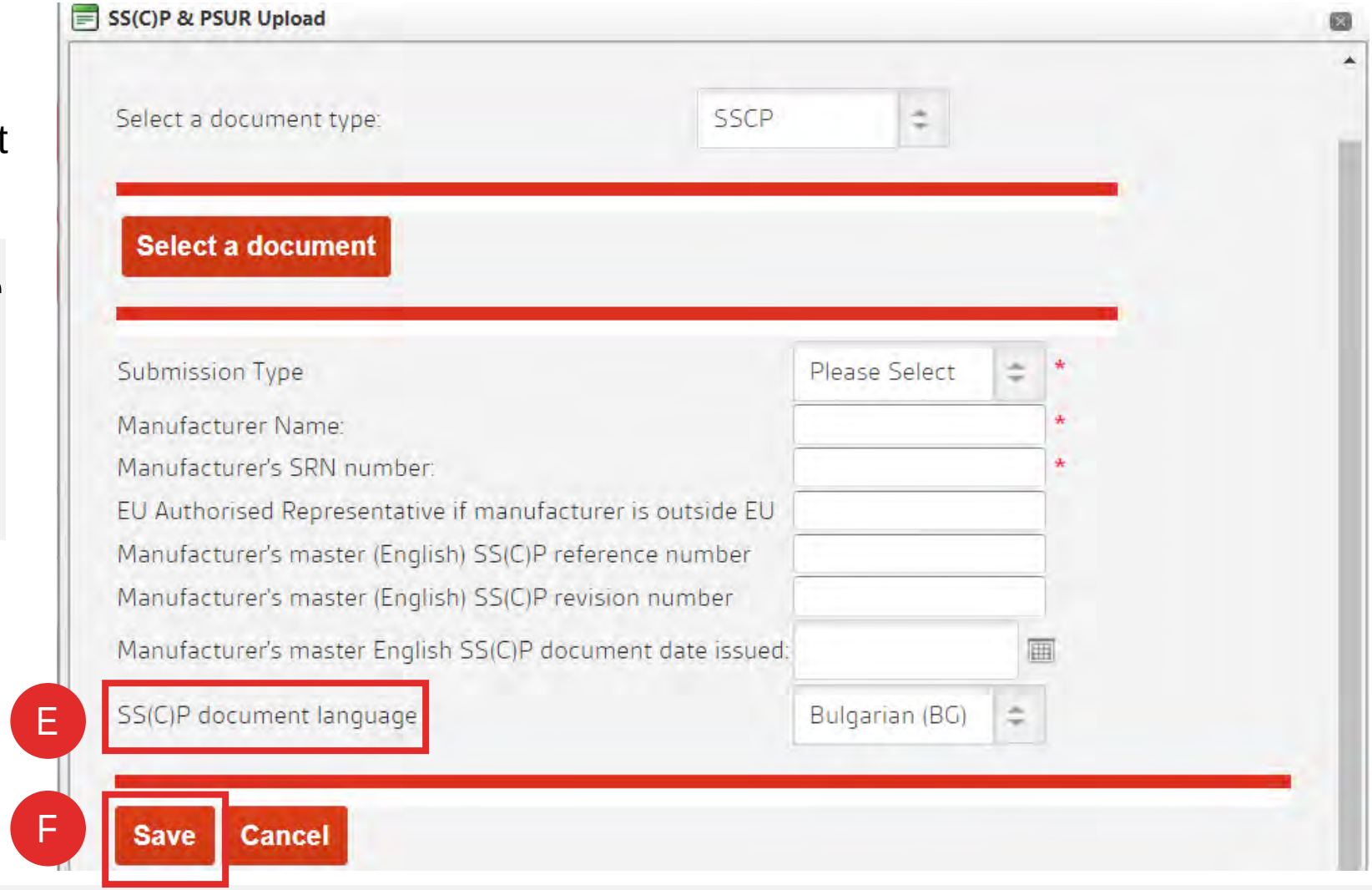
Uploading SS(C)P

E Select the SS(C)P document language

SS(C)P document language

DO NOT submit translations of SS(C)P documents until BSI sends notification that uploads are starting to EUDAMED

F Save

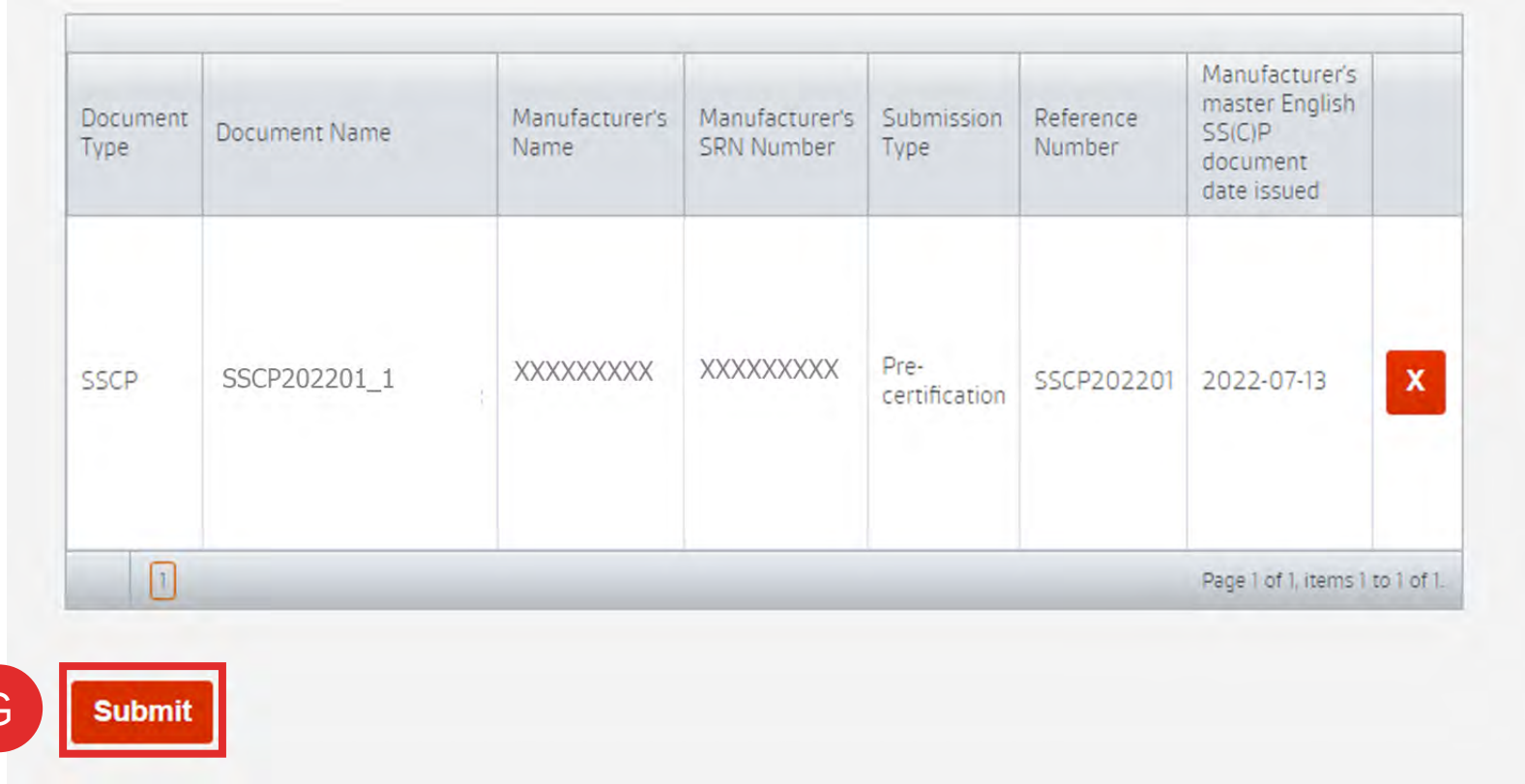


Uploading SS(C)P

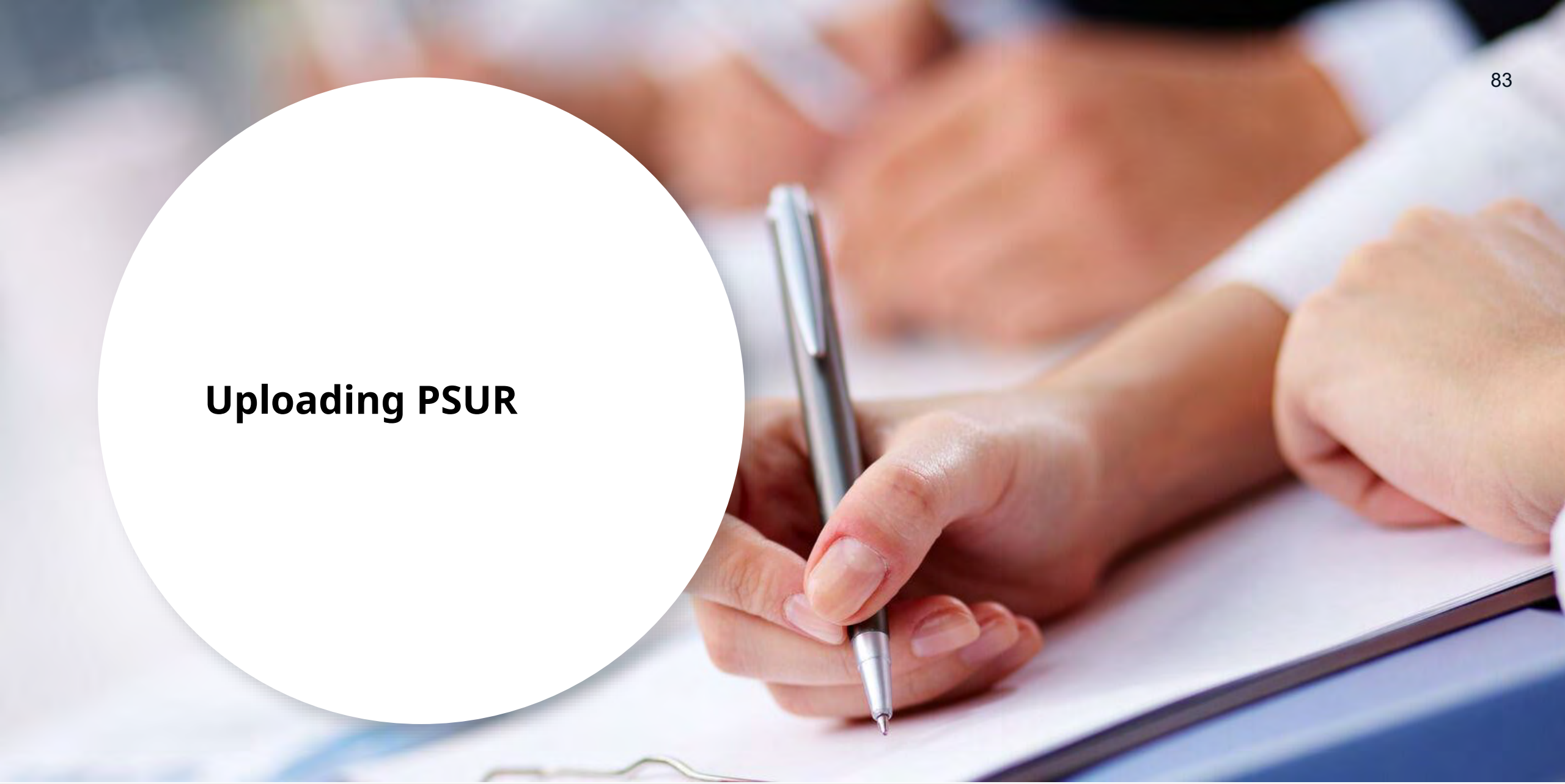
G Submit

Scheme Manager notified

Automatic notification to your Scheme Manager

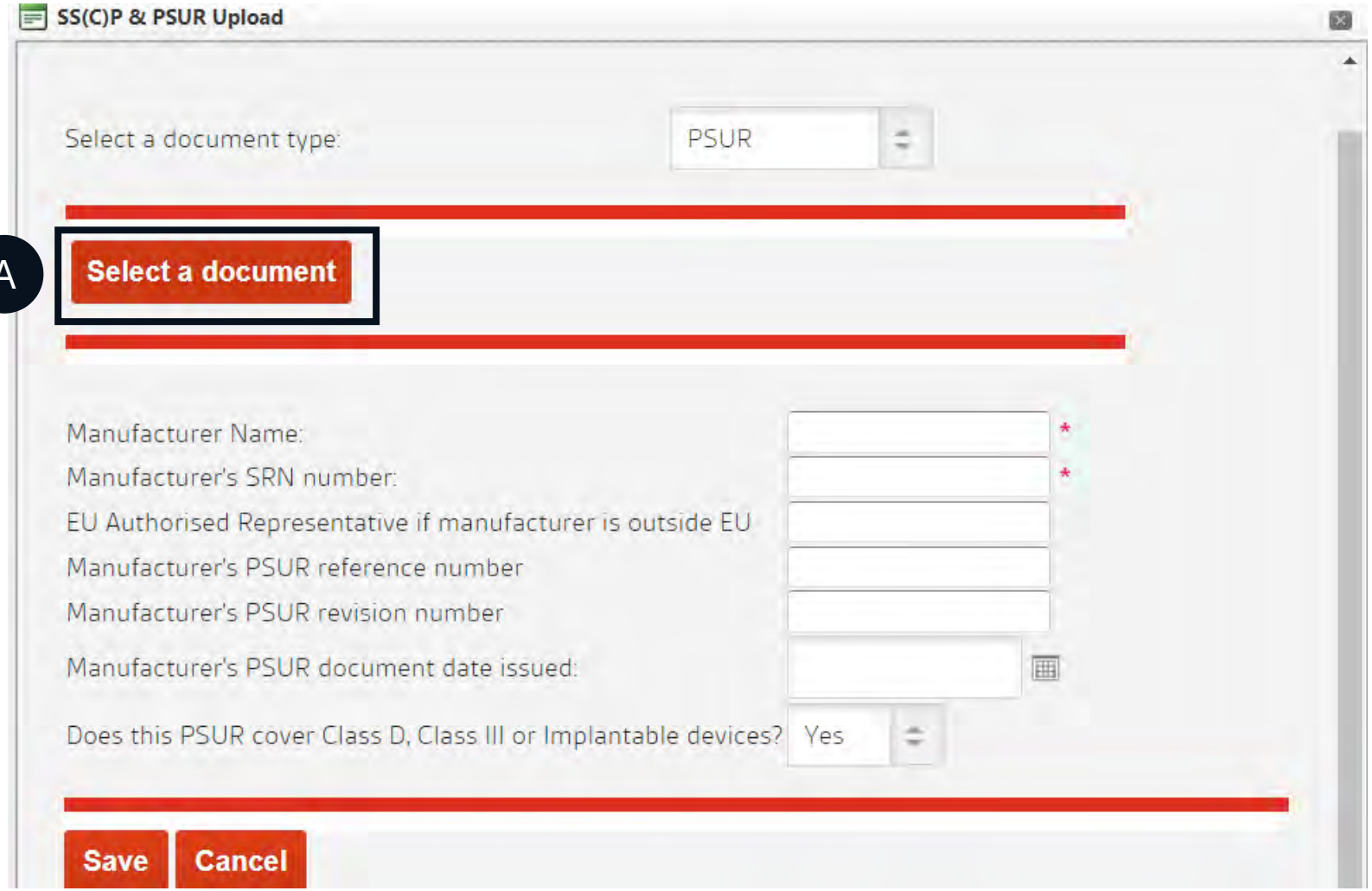


Uploading PSUR



Uploading PSUR

A Upload document

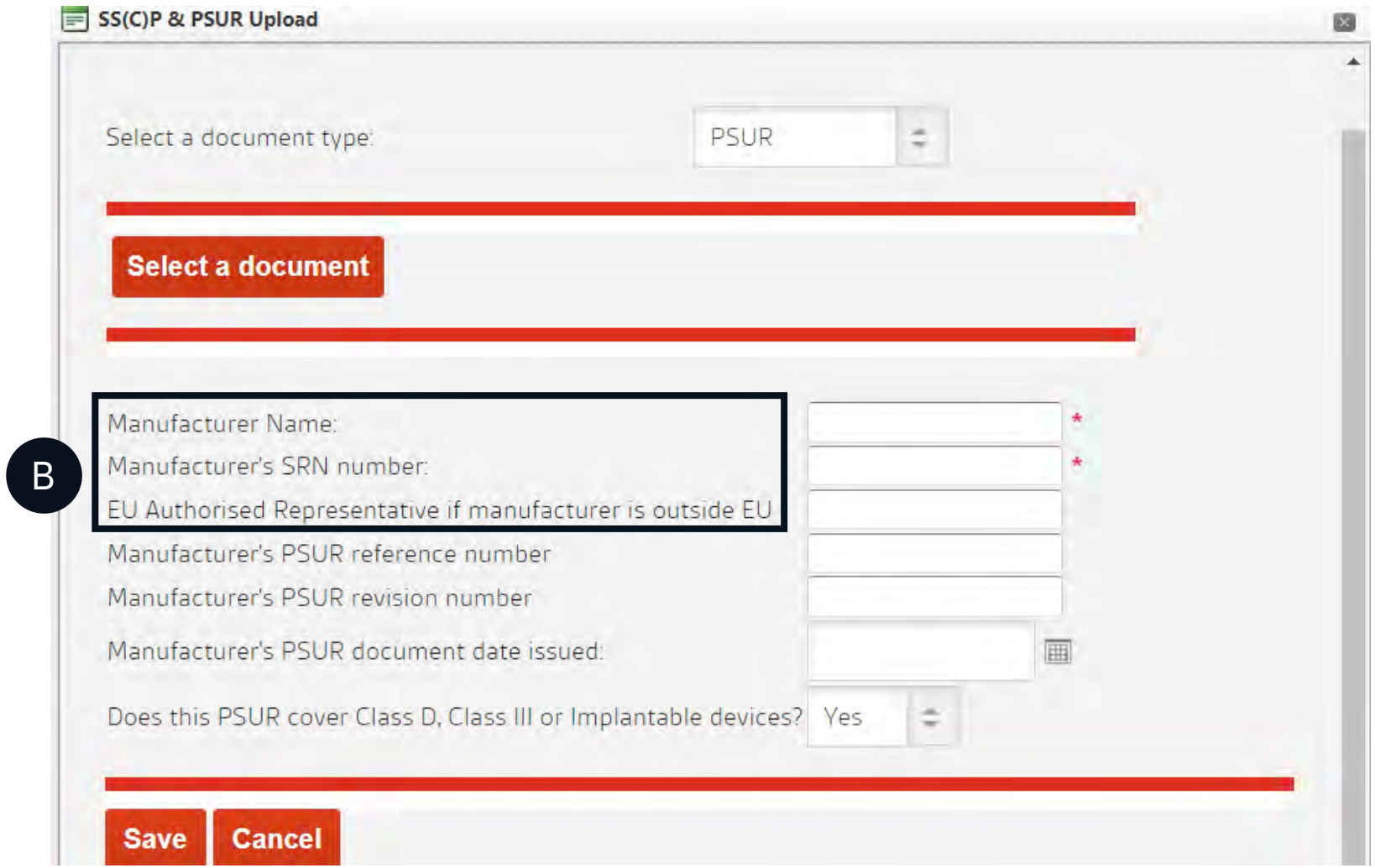


Uploading PSUR

B

Provide information:

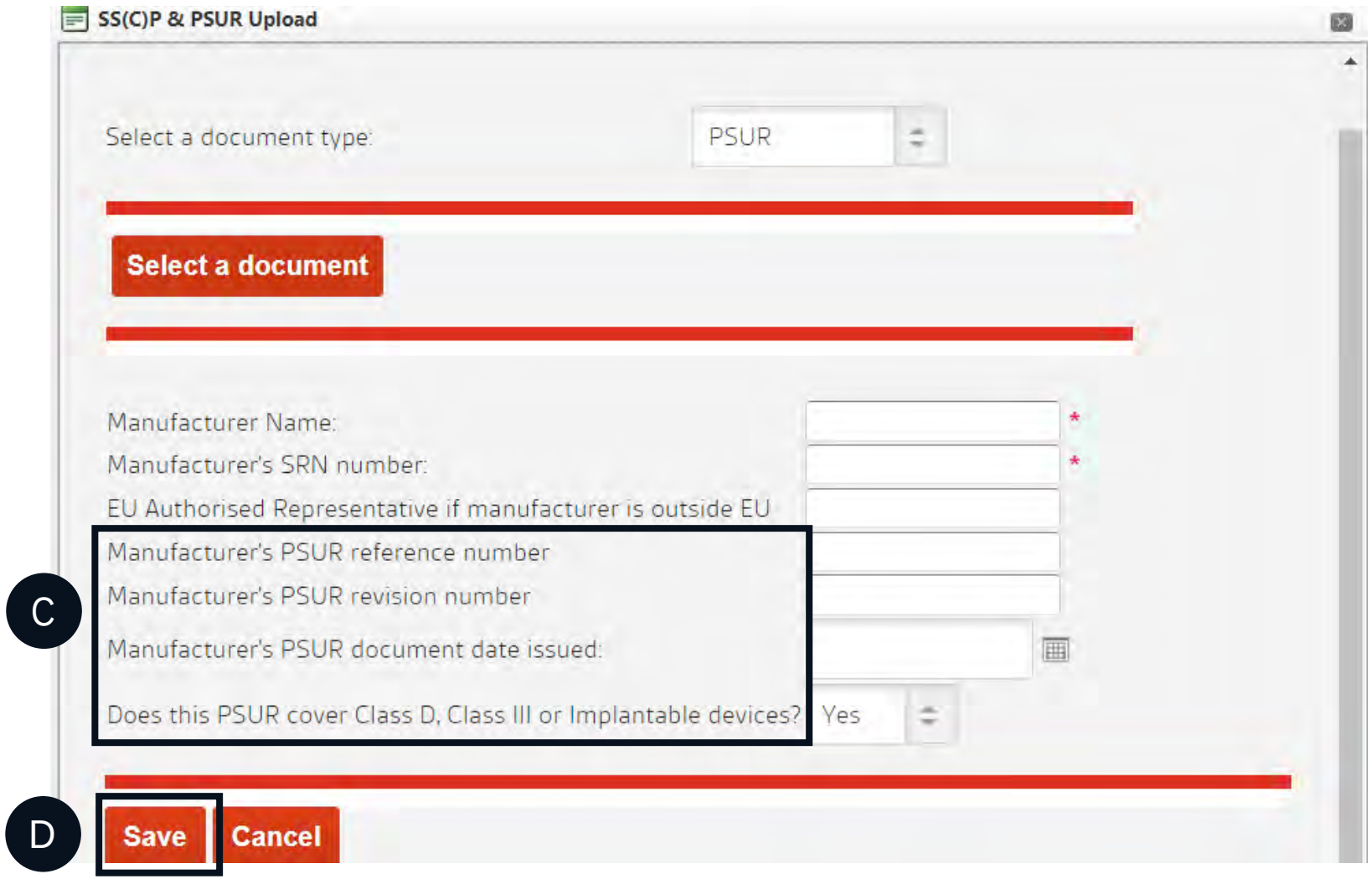
- Manufacturer Name
- Manufacturer's SRN number
- EU Representative, if applicable



Uploading PSUR

C Provide information on **Manufacturer's PSUR**:
- Reference number
- Revision number
- Document date issued
- If it covers class D/III or implantable devices

D Save

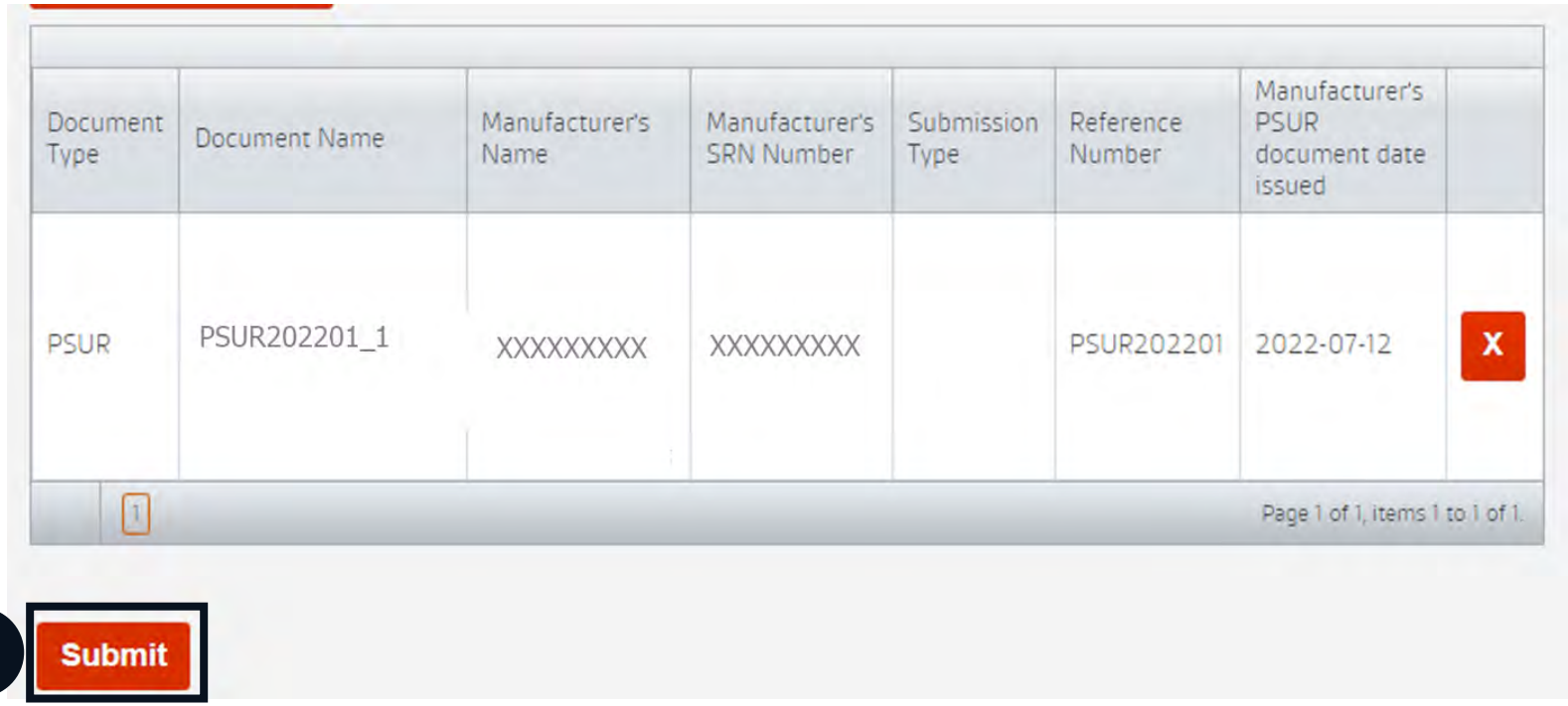


Uploading PSUR

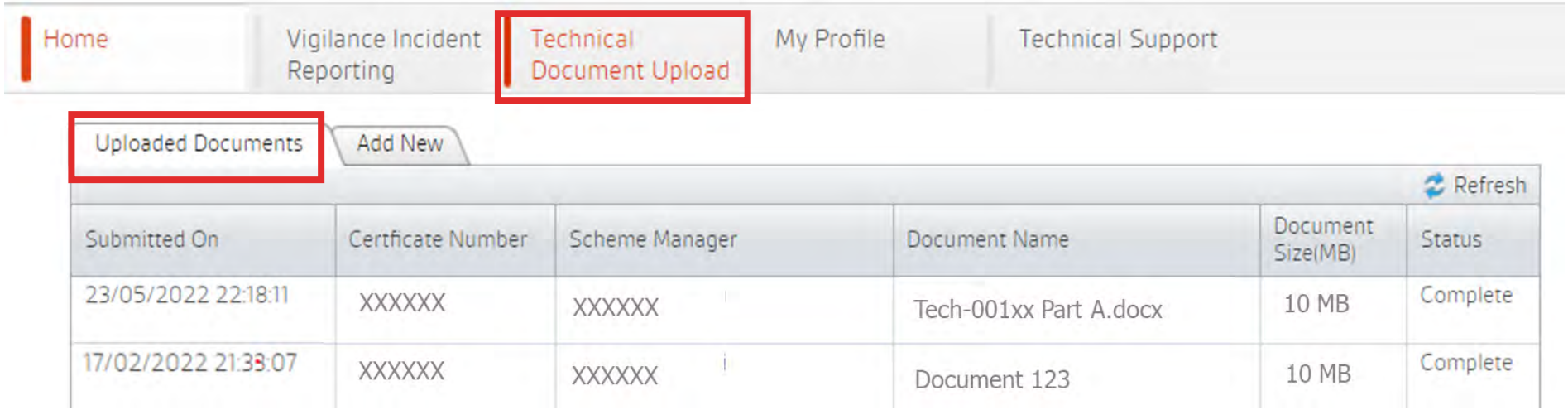
E Submit

Scheme Manager notified

Automatic notification to your Scheme Manager



“Uploaded documents” dashboard



“Uploaded documents” tab

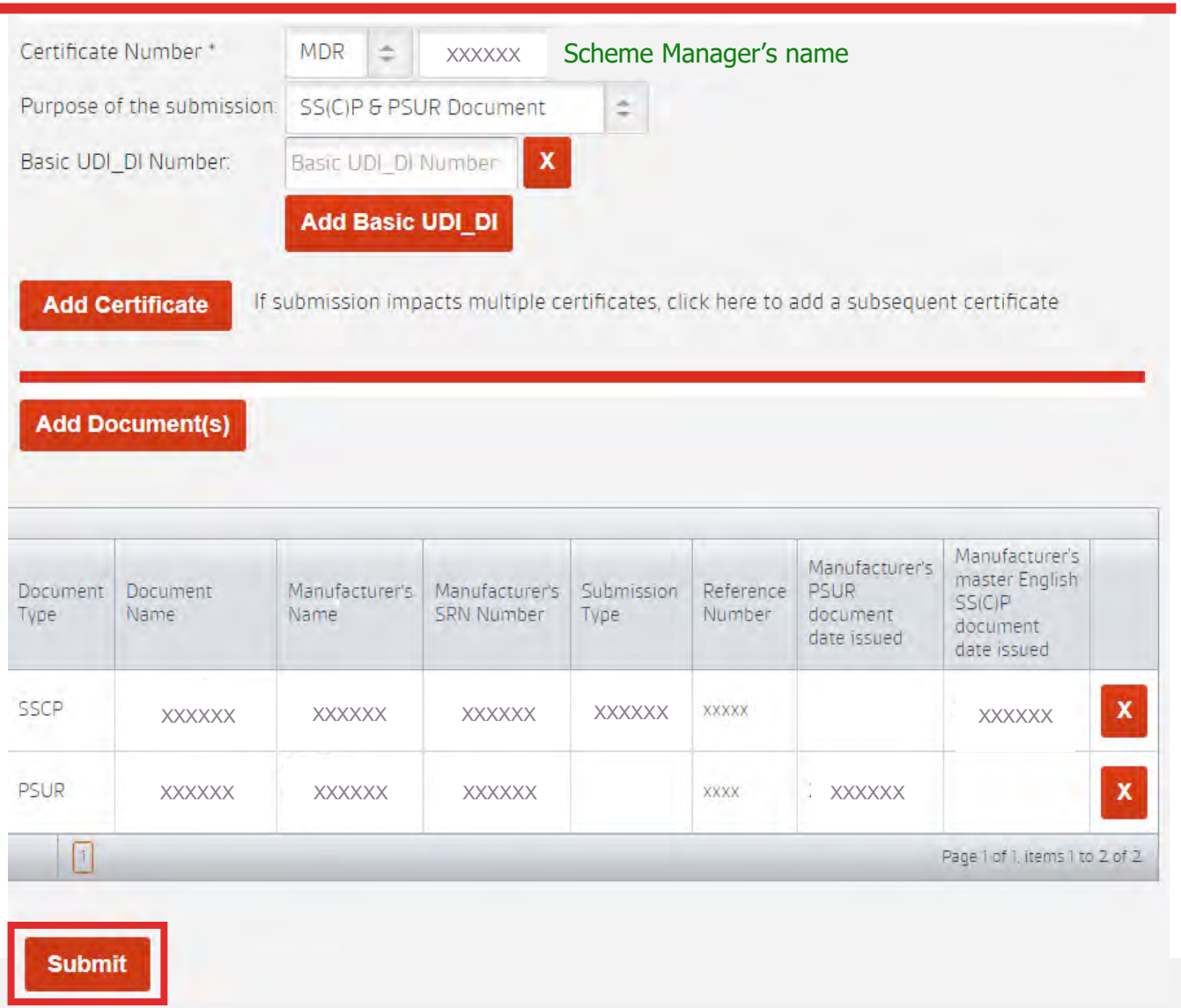
Record of documents uploaded from your account

Uploading SS(C)P and PSUR at the same time

One submission

You can submit PSUR and SS(C)P documents at the same time, **against the same Certificate(s) and Basic UDI-DI(s)**

Single submission can include both PSUR and SS(C)P, selecting both the documents via “Add Documents”



Revised PSUR and/or SS(C)P

If, during our evaluation process of your PSUR and/or SSCP, you wish to submit any updated revisions, please DO NOT submit through the portal.

Contact your Scheme Manager as we will need to confirm if the review has commenced and whether it is still possible to submit any updates at the point of the assessment.

One Slide Reminder

- Do **NOT** send MDD/AIMDD/IVDD PSURs for to BSI unless specifically requested.
- Please follow the template/minimum content provided in MDCG 2022-21 when producing your PSUR.
- Ensure you adequately explain all actions taken to address any anomalies within the PSUR.
- Only submit an SSCP for validation with your PSUR if the contents of the SSCP need updating based on the data from the PSUR.
- **If you wish to resubmit an SSCP/PSUR during an evaluation please speak with your scheme manager first before submitting as we will need to check the stage of the review.**

Questions…

End slide