EUDAMED user guide

Notified Bodies & Certificates

Production v 2.11
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1 Introduction

The purpose of this user guide is to help you navigate through the Notified Bodies and Certificates process of registering certificates module in into EUDAMED.[1]

In order to successfully register a certificate in EUDAMED, this guide illustrates two scenarios including additional pre-requisite steps when registering a certificate issued for a high-risk class device.

This guide assumes the reader is acquainted with the Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices, hence no rules or any other guidance will be provided in relation to certain registration steps.

WARNING
EUDAMED does not contain all constraints defined in the MDR/IVDR, guidance and good practices, and therefore, it is not because something is possible in EUDAMED that it is necessarily allowed.

[1]For a wider understanding on how to use the platform, visit the EUDAMED Information Centre.

2 Basic Concepts – types and classes of certificates

In EUDAMED and in line with the Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices, certificates are classified into two main classes: **Product** class and **Quality** class, with each class having its own types of certificates.

Certificate types of Product class:

- EU Type Examination certificate (Annex X);
- EU Technical Documentation certificate (Annex IX Chapter II);
- EU Product Verification certificate (Annex XI Part B).

Certificate types of Quality class:

- EU Quality Management System certificate (Annex IX chapter I);
- EU Quality Assurance certificate (Annex XI part A);
- EU Production Quality Assurance certificate (Annex XI).

3 Getting started

Prerequisites to access EUDAMED: EU Login (ECAS) account

For information on how to gain access to EUDAMED, please consult the Notified Bodies Access user guide in the User guides section.

Once the first *Local Actor Administrator (LAA)* is approved by your Designating Authority, subsequent user access or profile change requests for the Notified Body will be approved by this user (not the Designating Authority). This responsibility can then be delegated to other *LAA/LUAs* in the Notified Body. It is good practice for each actor to have **at least two LAAs**.

Every user in EUDAMED is granted the profile *Viewer*. They can search and view registered certificates. In order to register a certificate in EUDAMED, you must request access to the Notified Bodies & Certificates module as:

- **Proposer**: this profile may create and delete draft records in the Certificates module
- **Confirmer**: this profile may also submit and discard records in the Certificates module

IMPORTANT
As a *LAA/LUA* user cannot approve their own profile change requests, these requests must be approved by a **different** user with *LAA/LUA* profile.

4 Registering an issued certificate

Click on the following link to arrive to EUDAMED Playground page:

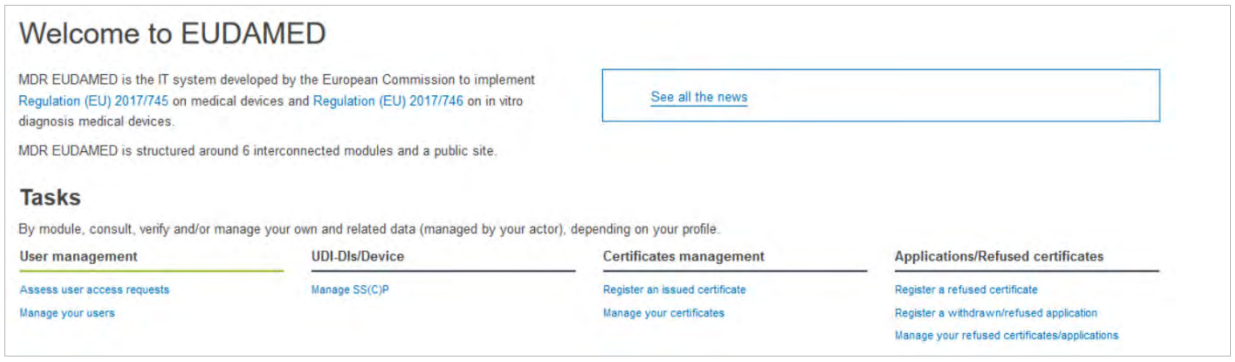
https://webgate.training.ec.europa.eu/eudamed-play

You will be prompted to enter EUDAMED via your EU Login account.

The EUDAMED homepage opens on your personal dashboard.

4.1 Register an issued certificate: Quality class

Click **Register an issued certificate** on the *Certificates management* section:



4.1.1 Provision of core data

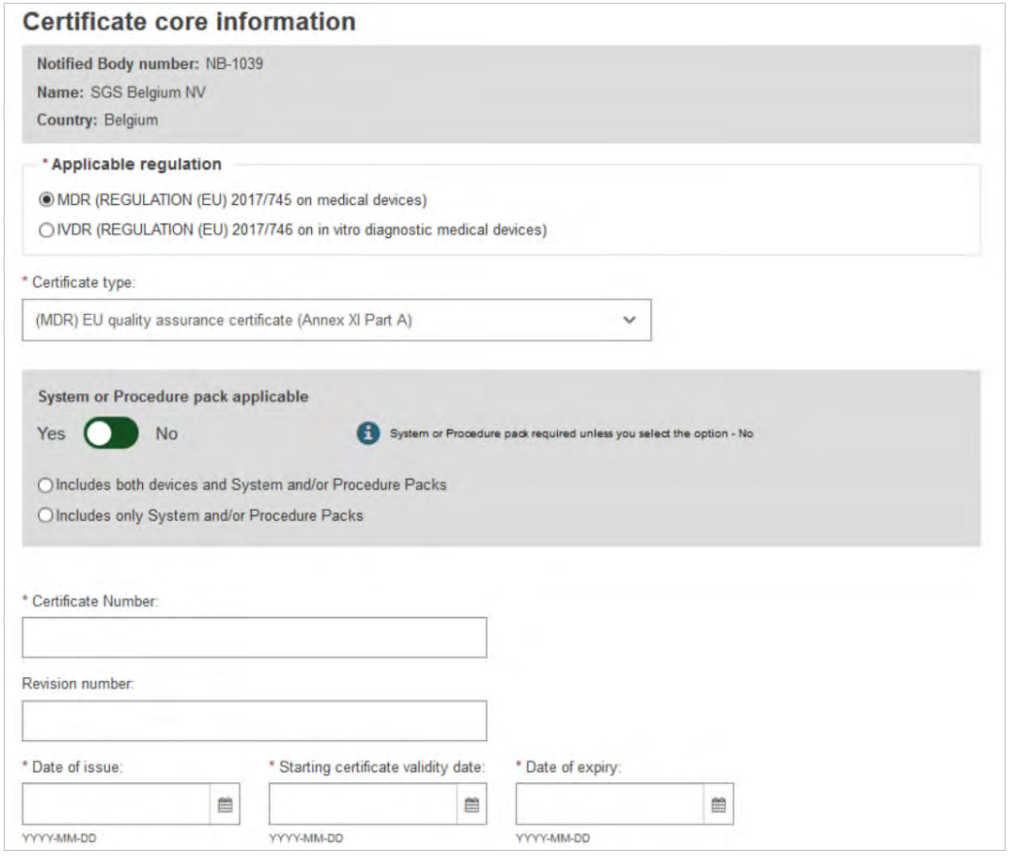
1. Select the applicable regulation, and the certificate type. The type of the certificate will change depending on the regulation, MDR or IVDR.

> **NOTE**
> In this scenario we will choose a Quality certificate type.

2. Select **Yes** or **No** whether the certificate is for a system or procedure pack.

3. Enter the certificate number and a revision number if applicable.

4. Enter the *Date of issue*, the *Starting certificate validity date* and the *date of expiry*:



NOTE
Manufacturer information

Enter the Actor ID/SRN or name of the manufacturer or the system/procedure pack producer, click **Find** and select from the list displayed.

5. Click **Save & Next**.

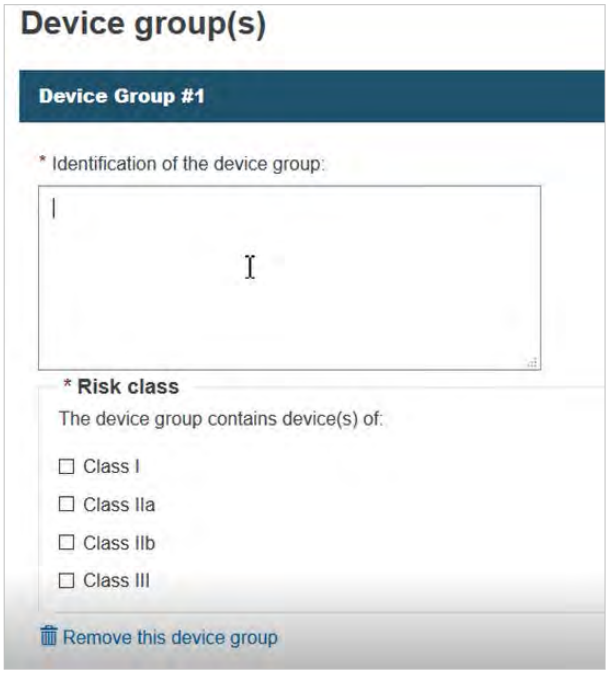
4.1.2 Provision of certificate language

1. Click **Add languages** and select the certificate language(s) from the list of EU languages:

2. Click **Save** to save as a draft or click **Save & Next** to continue to the next step.

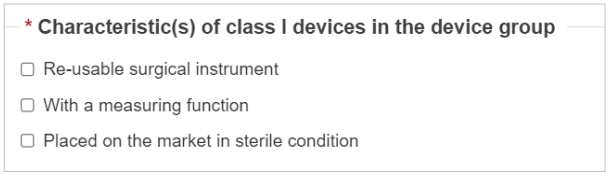
4.1.3 Provision of device group data

1. Click **Add device group** and complete the required information:



   You can select more than one risk class for a device group.

2. If you choose *class I*, provide the characteristics of class I devices in the device group:



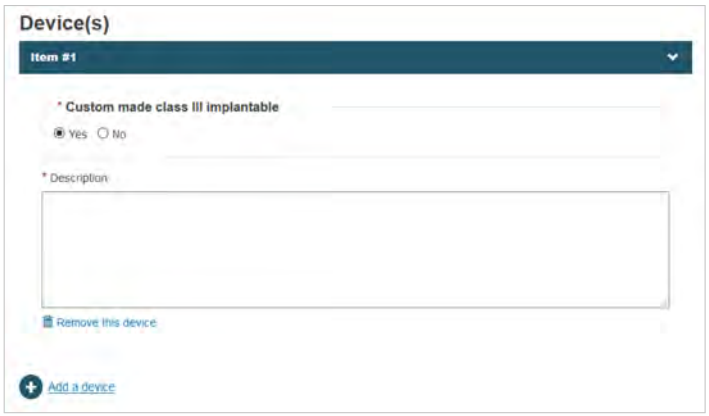
4.1.4 Provision of device data

If the certificate also includes devices, indicate whether the certificate is for a Custom made class III implantable, if yes provide a description, if no provide:

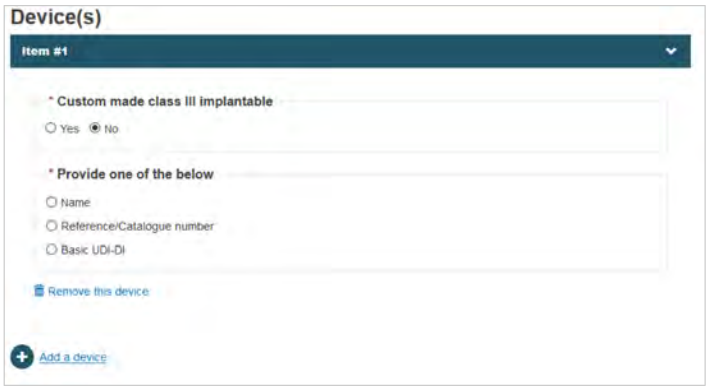
The name and the risk class, the reference/catalogue number and the risk class or the Basic UDI-DI (Basic UDI-DIs must be already submitted by the manufacturer in EUDAMED)

1. In this step you may choose to provide a custom-made device by selecting *Yes* within *Custom made class III implantable* box:

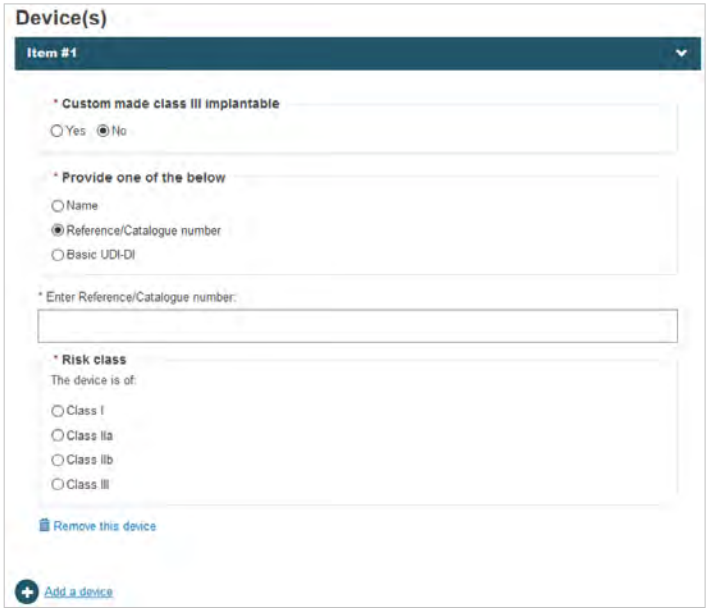
2. By doing so, EUDAMED will allow you to provide a description for the custom-made device:



3. When you select *No*, then the system will provide a dialog to select *Name* or *Reference/Catalogue number* options in order to register a device by its name, its reference/catalogue number or its basic UDI-DI:



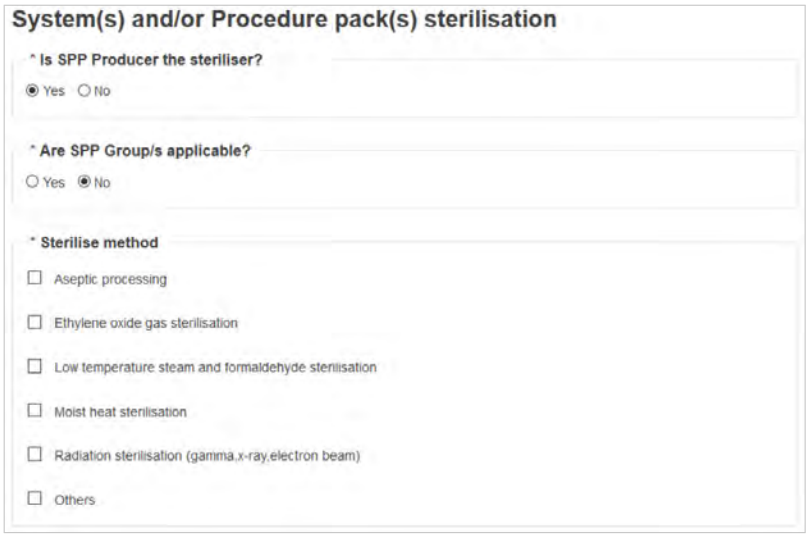
4. When either *Name* or *Reference/catalogue number* is selected, you must provide the risk class of the device:



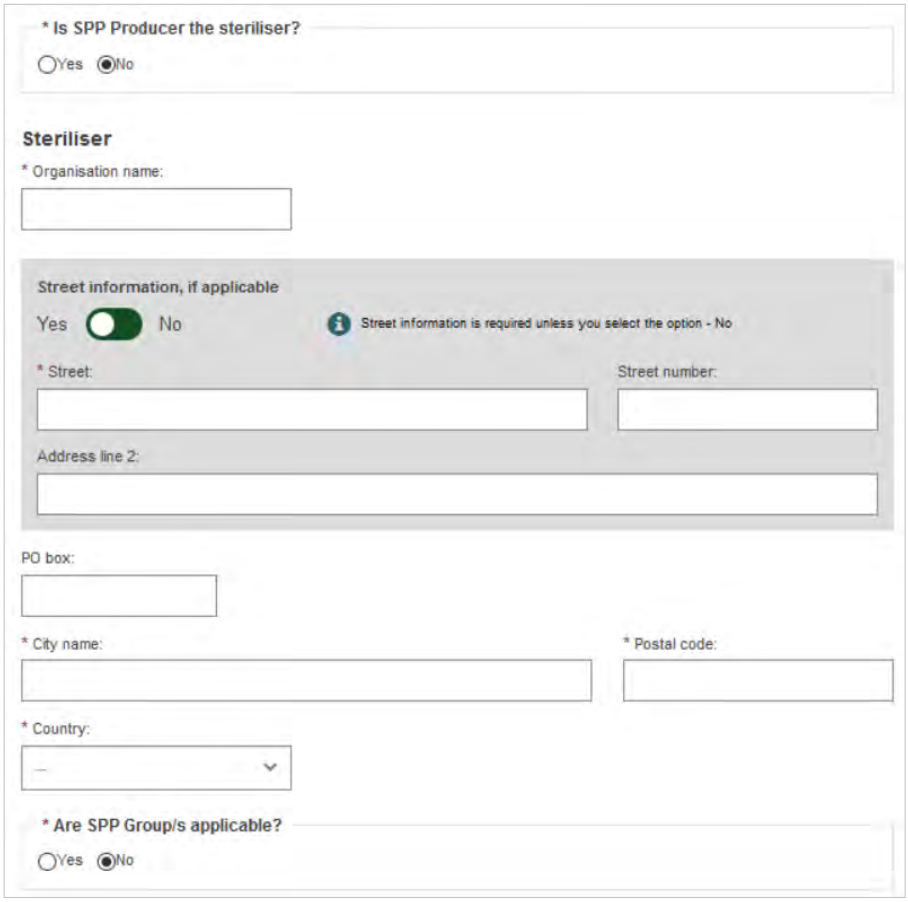
5. Click **Save** to save your draft or **Save & Next** to continue to the next step.

4.1.5 Provision of SPP details

1. If you have chosen a system or procedure pack (SPP), you must answer questions on sterilisation:



2. If the steriliser is not the SPP producer identified in the initial step of the certificate registration, answer *No* to *Is the SPP Producer the steriliser?* and provide the information requested about the sterilising organisation.



NOTE
You may now add sterilisers in addition to the SPP Producer being a steriliser. More than one steriliser can be referenced in System and/or Procedure pack(s) sterilisation step.

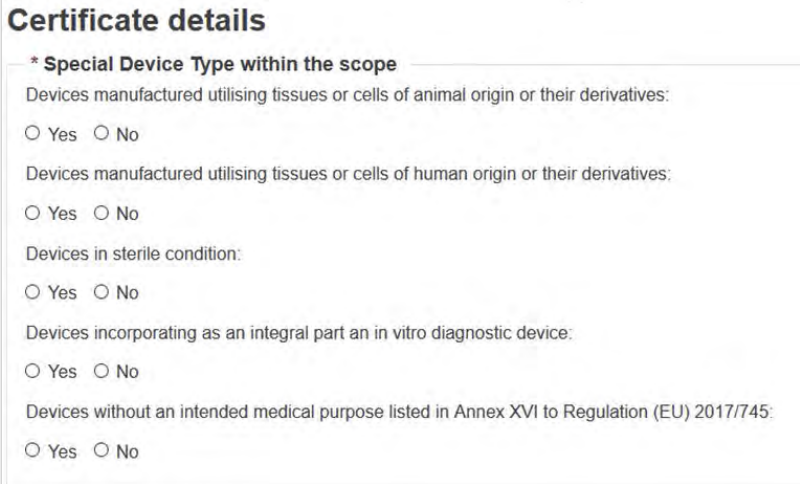
3. By default, the system assumes there are no SPP Group(s) within this sterilised SPP. If you click *Yes* to *Are SPP Group/s applicable?*, you will be asked to enter information about the SPP group:

4. Add at least one SPP group:

5. Once complete, click on **Save** or **Save & Next**.

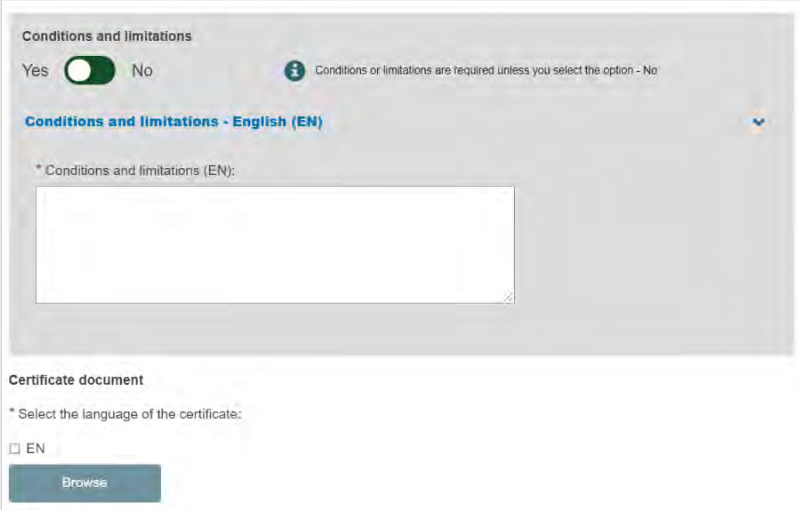
4.1.6 Provision of certificate details

1. Select the correct options:



NOTE
When you have defined the scope of the certificate with a device group and/or device having risk class I that has the property *Placed on the market in sterile condition*, then the system will set *Yes* for the *Devices in sterile condition* question within the *Special Device Type within the scope*.

2. Enter the conditions and limitations if there are any. If none, toggle to **No**:



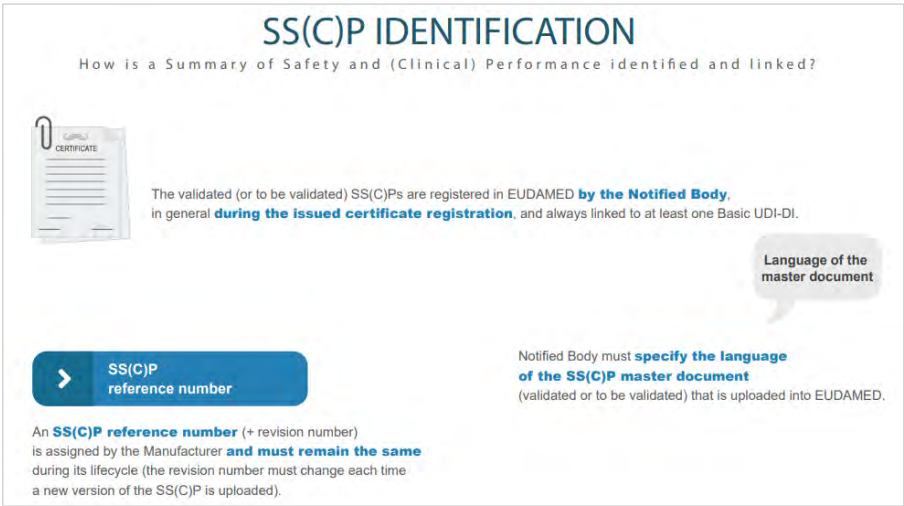
3. Select the languages in which the electronic version of the certificate is issued. You may upload more than one electronic document if it covers different languages, and you may upload several documents at once.

4. Click on either **Save** or **Save & Next**.

4.1.7 Provision of SS(C)P documents

For implantable devices of class IIa, some implantable devices of class IIb, and devices of class C that are not companion diagnostic and not self/near-near-patient testing, the provision of a Summary of Safety and Clinical Performance SS(C)P is required.[2]

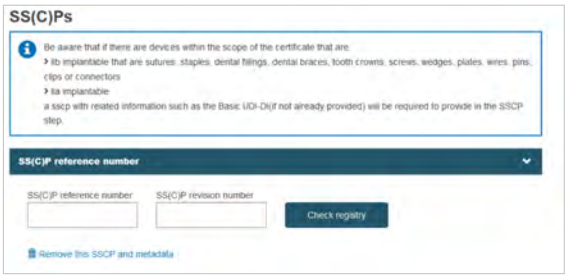
INFOGRAPHIC: SS(C)P steps and principles

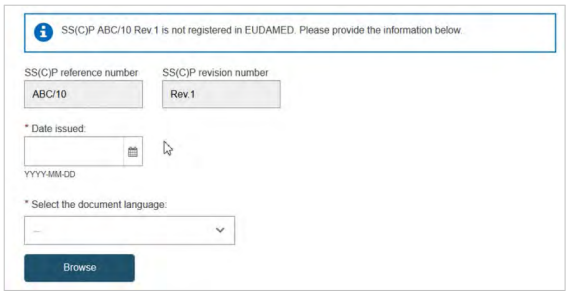


1. An SS(C)P can be attached to certificates, so the initial dialog requires the provision of *SS(C)P reference number* and *SS(C)P revision number*. Once provided, click **Check registry**. If the SS(C)P exists already in EUDAMED it will be selected and

[2]For background information, see the MDCG guidance: "Summary of safety and clinical performance A guide for manufacturers and notified bodies".

displayed. Otherwise, you may enter a new SS(C)P. You may also create a new SS(C)P version of an already registered SS(C)P (see *Create a new SS(C)P version of a registered SS(C)P [13]*).
Enter the issued date and select the language of the document. Click **Browse** to upload the SS(C)P master document:

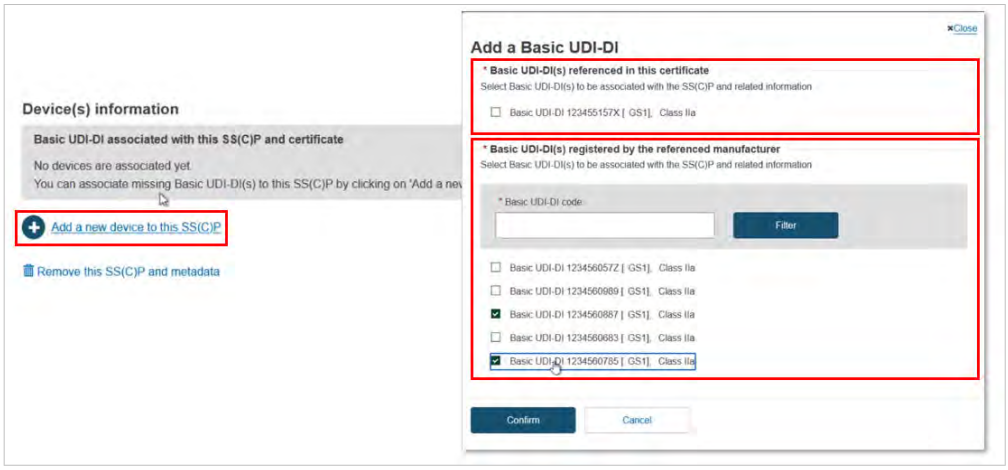




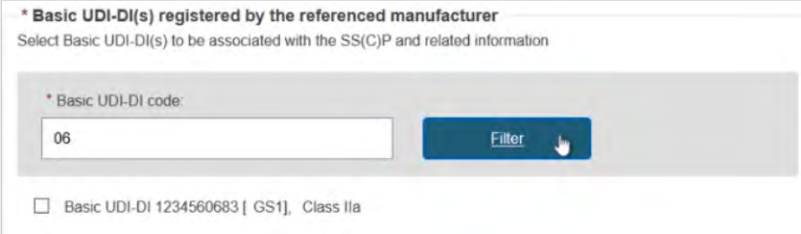
2. Click *Yes* to the question *Is this SS(C)P validated* to indicate that the uploaded master document is validated, otherwise click on *No*:

3. In order to register an SS(C)P, the reference of the related Basic UDI-DI(s) within the scope of the certificate is required. Within the *Device(s) information* box, a respective Basic UDI-DI can be added:

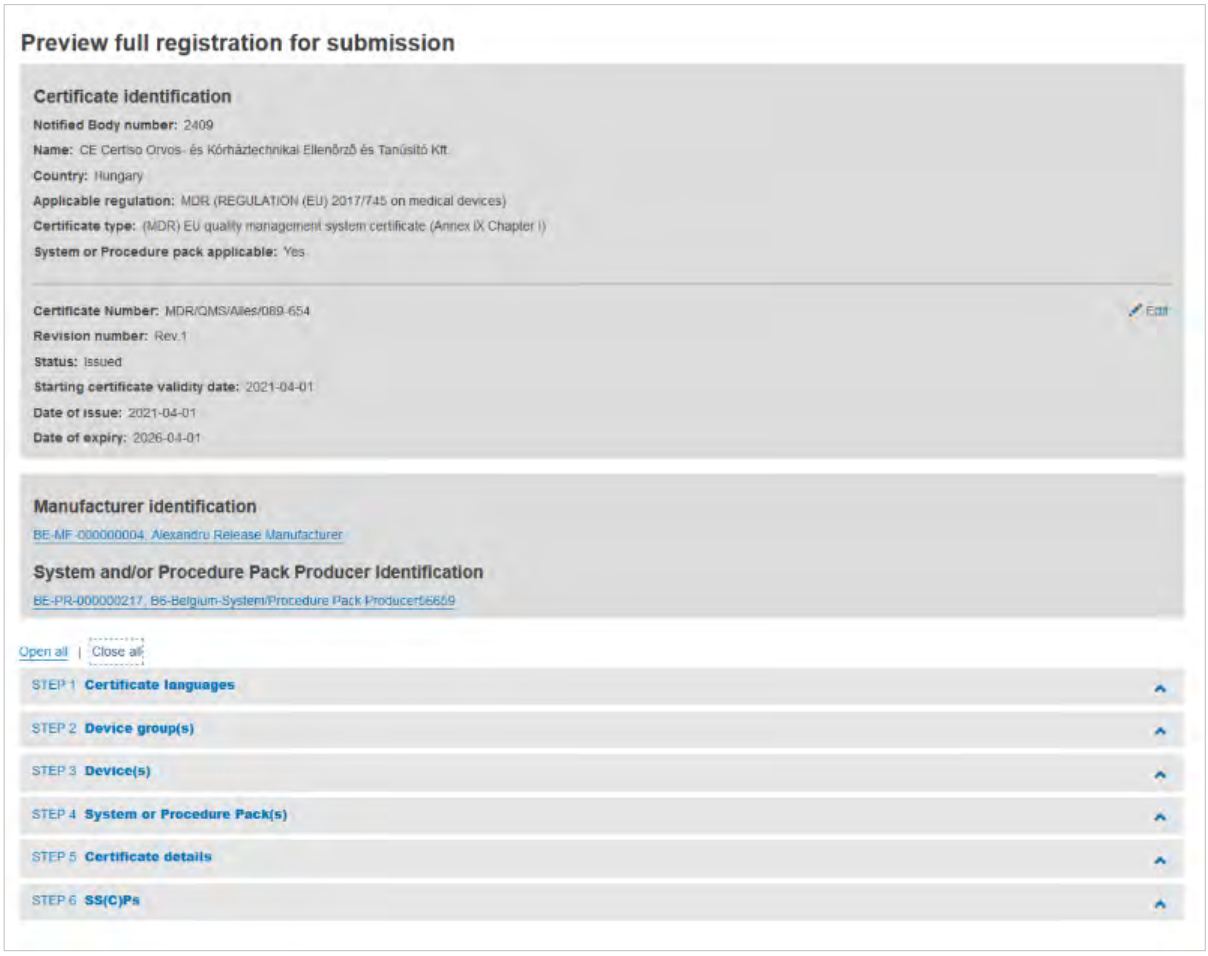
4. The *Device(s) information* box confirms no associated devices. Click **Add a new device to this SC(C)P**. The pop-up shows two sections: the Basic UDI-DI(s) referenced in this certificate of class IIa implantable and relevant class IIb implantable or relevant class C, and (for Quality certificates only) a list of all Basic UDI-DIs of class IIa implantable and relevant class IIb implantable or relevant class C registered by the referenced manufacturer. You can select multiple devices:



5. You can input a partial Basic UDI-DI number and click **Filter** to narrow down the search results:

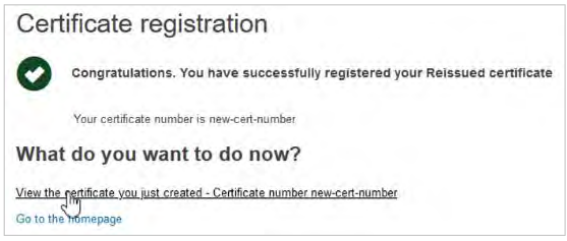


6. Once selected, click **Confirm** to link the devices to this new SC(C)P. Nothing is yet submitted, and you can delete this SS(C)P by clicking **Remove this SS(C)P and metadata** to return to the previous screen.
When finished, click on the **Preview** button to review the provided information:



From this page you can easily access other steps by clicking the respective link:

7. When you click **Submit** and confirm your submission, the certificate will be registered in EUDAMED and you will see a *Confirmation* page:

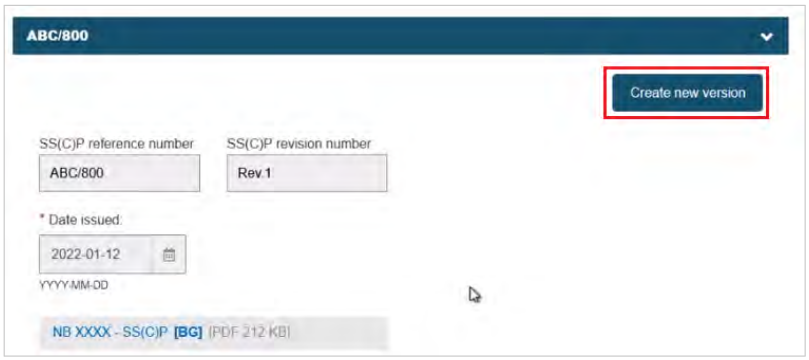


From the confirmation page you can click on **View the certificate you just created** to open the registered certificate view page, or you can click on **Go to homepage** to return to your homepage.

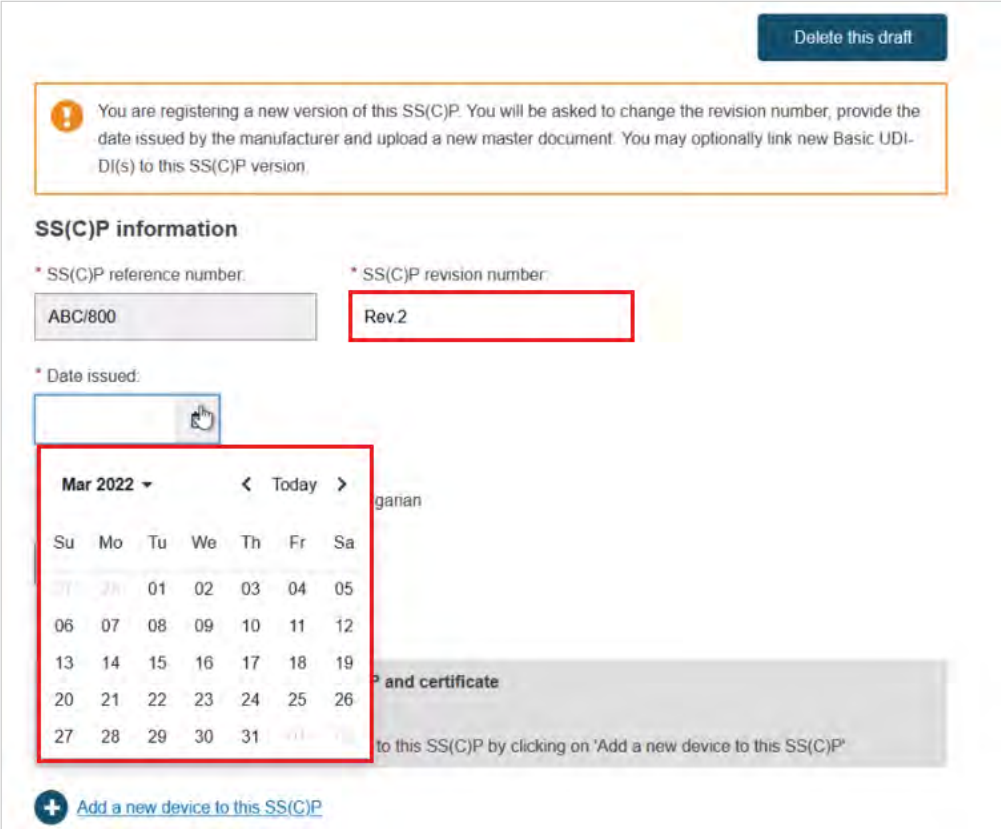
4.1.8 Create new version of a registered SS(C)P

You can reference an existing SS(C)P that is already registered, and link other devices to it. However, you can also create a new SS(C)P version, while referencing an existing SS(C)P.

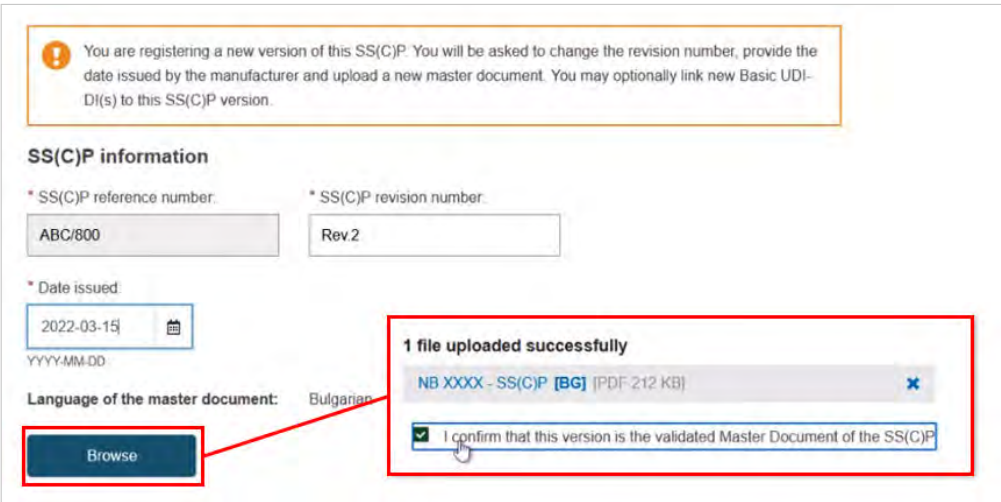
1. Click **Create new version**:



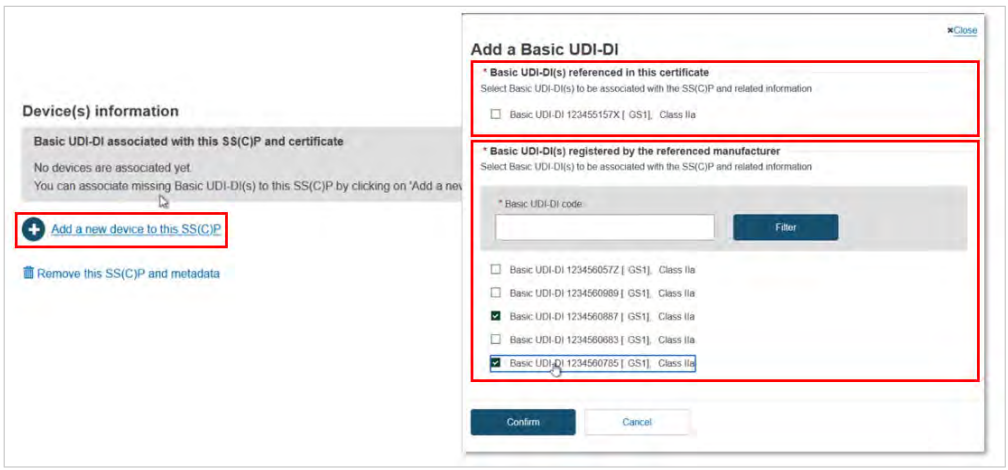
2. The warning message requests a revision number that must be different from the previous version, a manufacturer-provided issue date and a new master document. Click **Date issued** and input the date:



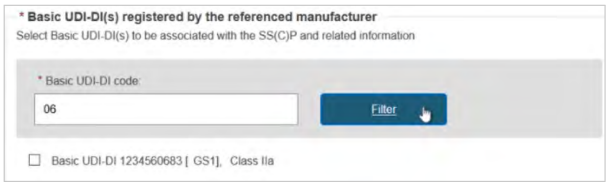
3. Click **Browse** to upload the new master document in the pre-selected language, and confirm that it has been validated where applicable (SS(C)P on devices that only need a quality certificate may not necessarily be validated already):



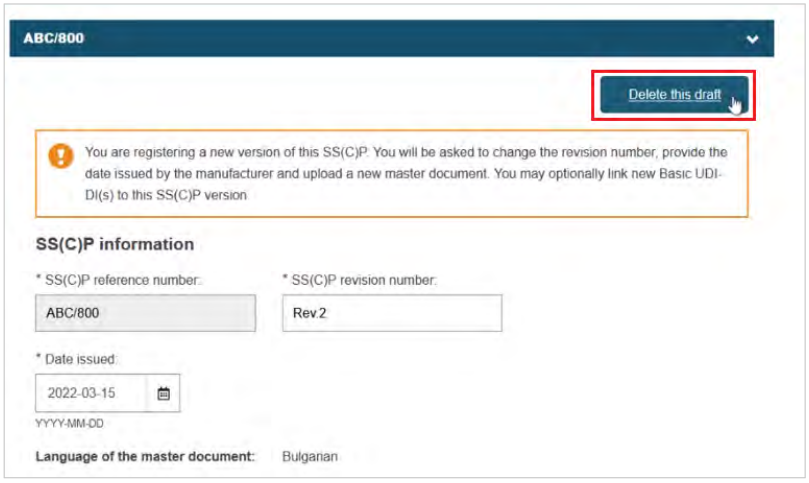
4. The *Device(s) information* box confirms no associated devices. Click **Add a new device to this SC(C)P**. The pop-up shows two sections: the Basic UDI-DI(s) referenced in this certificate of class IIa implantable and relevant class IIb implantable or relevant class C, and (for Quality certificates only) a list of all Basic UDI-DIs of class IIa implantable and relevant class IIb implantable or relevant class C registered by the referenced manufacturer. You can select multiple devices:



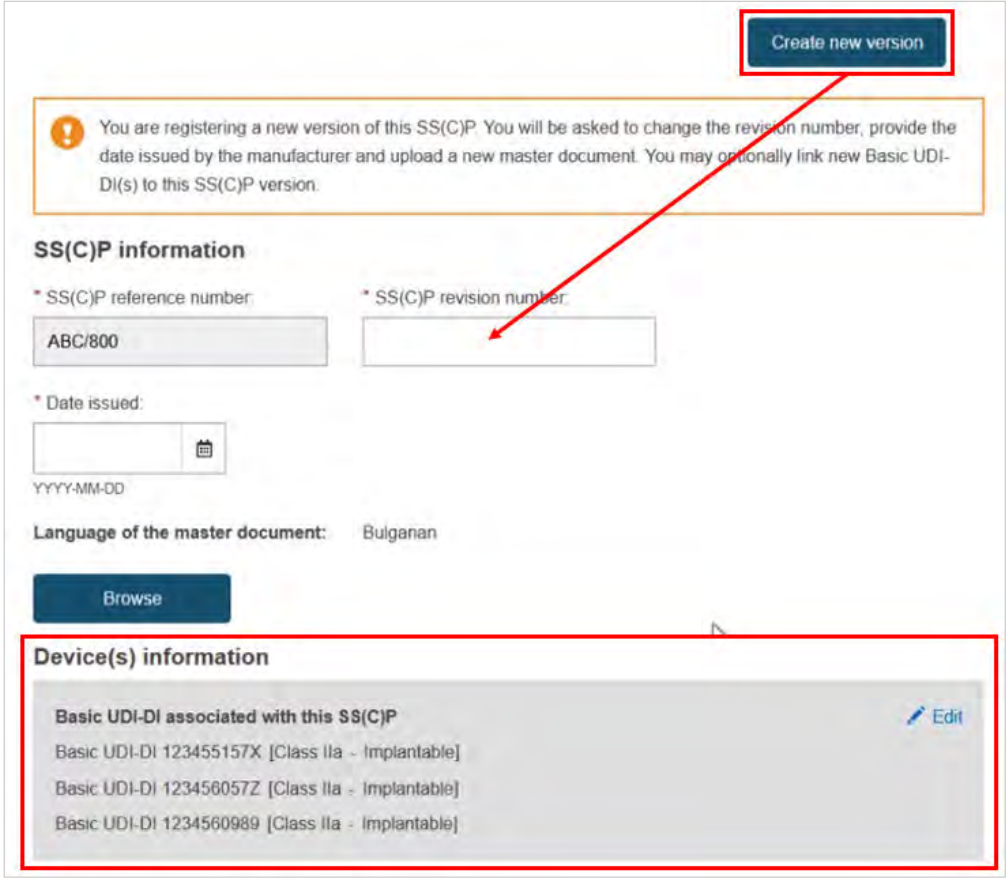
5. You can input a partial Basic UDI-DI number and click **Filter** to narrow down the search results:



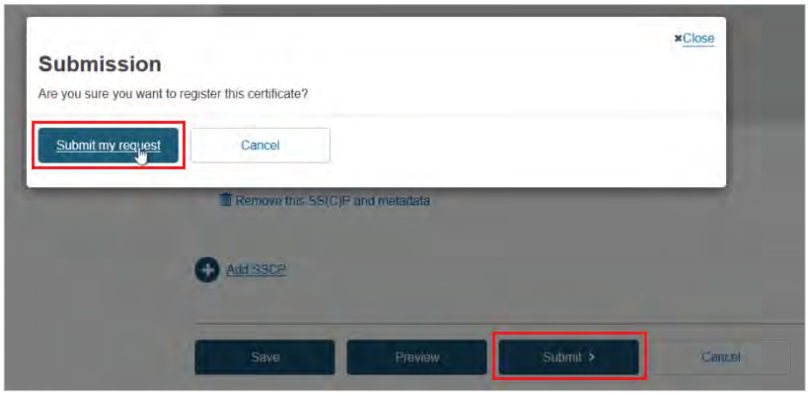
6. Once selected, click **Confirm** to link the devices to the SC(C)P new version. Nothing is yet submitted, and you can delete the inputs/links by clicking **Delete this draft** to return to the previous screen:



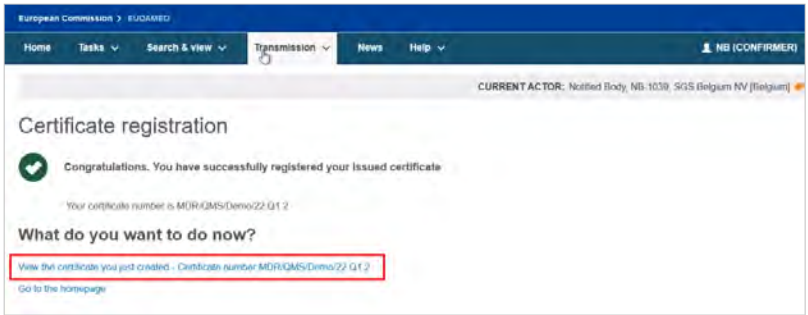
7. You may also perform the tasks in reverse order. First select the Basic UDI-DI(s), then click **Create new version** and input the revision number, date and master document etc.:



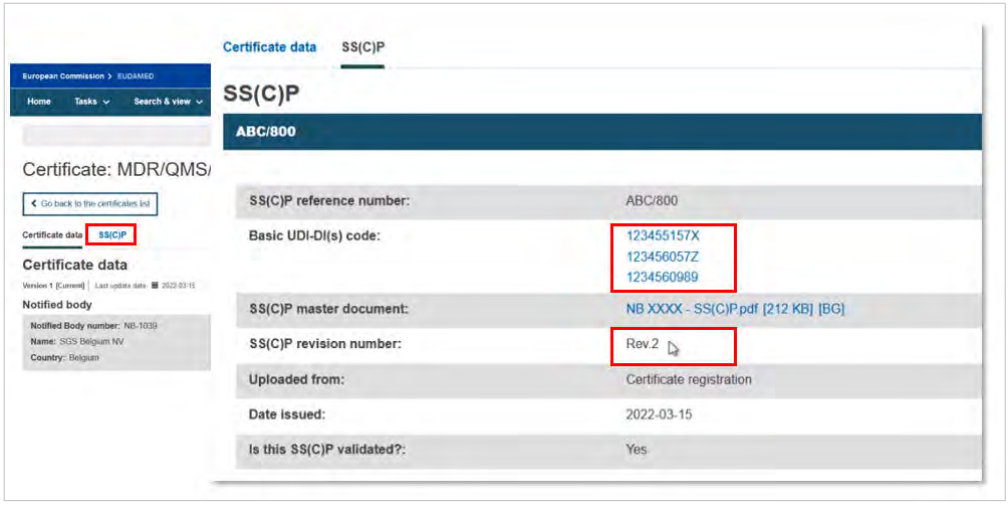
8. Click **Save** to continue, or **Submit**. In the confirmation click **Submit my request**:



9. From the confirmation page, click **View the certificate you just created**:

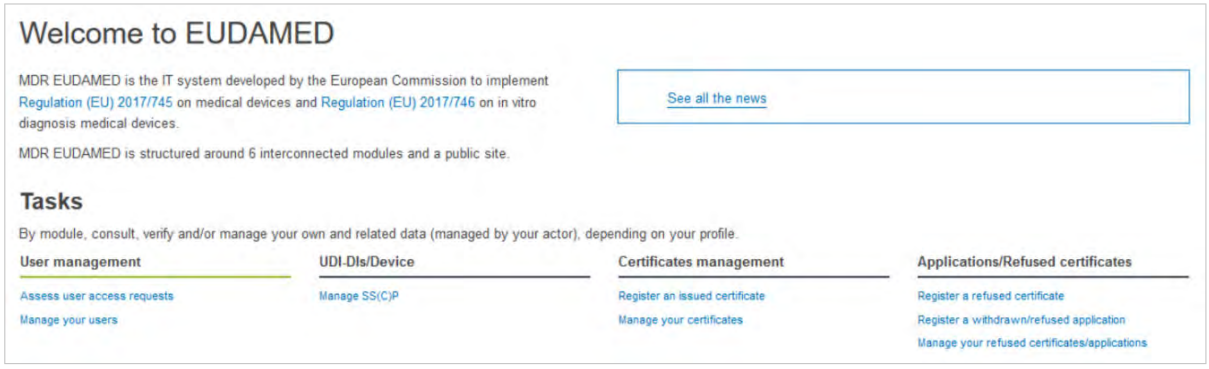


10. You can view the newly created certificate version, and all the devices linked to the new registered SS(C)P version:



4.2 Register an issued certificate: Product class

Click on **Register an issued certificate** on the *Certificates management section*. In this scenario we will choose a product type certificate:

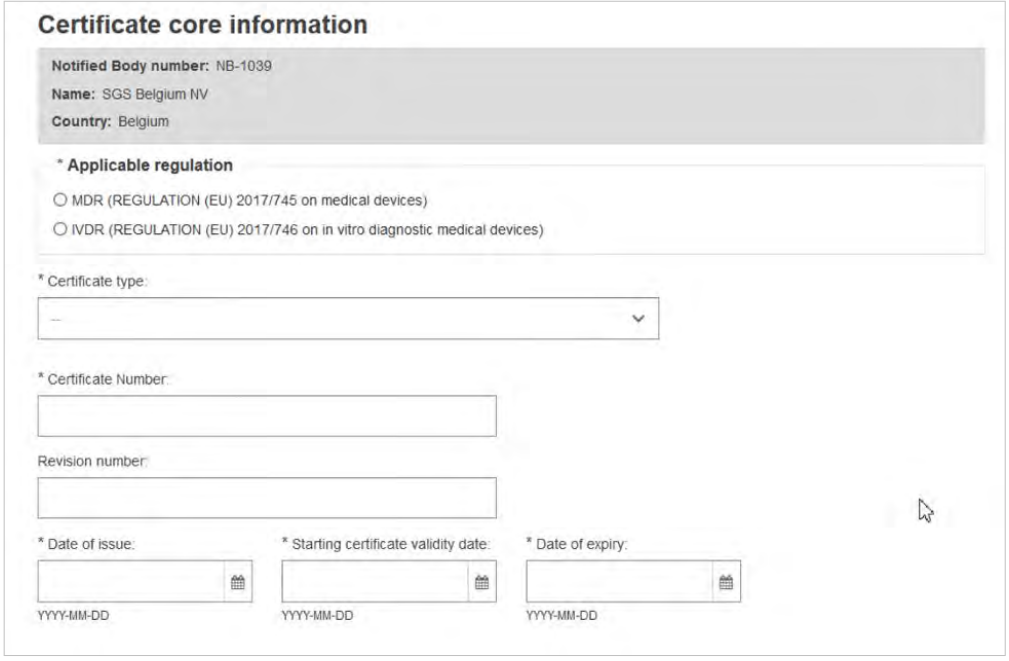


4.2.1 Provision of core data

1. Select the applicable regulation, and the certificate type.

> **NOTE**
> In this scenario we will choose a Product certificate type.

2. Enter the certificate number and a revision number if applicable:



3. Enter the *Date of issue*, the *Starting certificate validity date* and the *Date of expiry*.

4. **Manufacturer identification:**
   Enter the Actor ID/SRN or name of the manufacturer or the system/procedure pack producer. Click **Find** and select from the list displayed.

5. Click **Save & Next**.

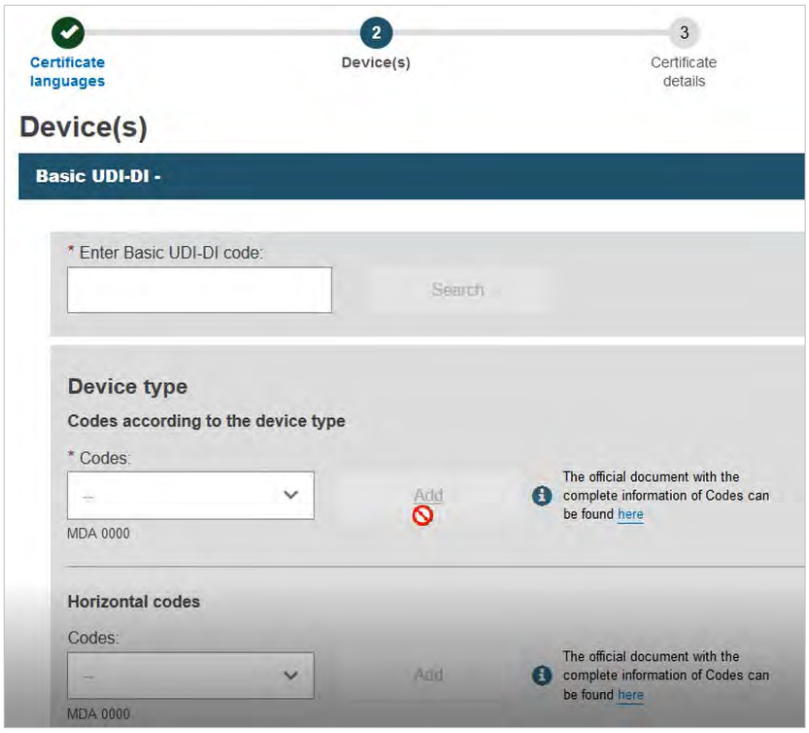
4.2.2 Provision of certificate language

1. Click **Add languages** and select the certificate language(s) from the list of EU languages:

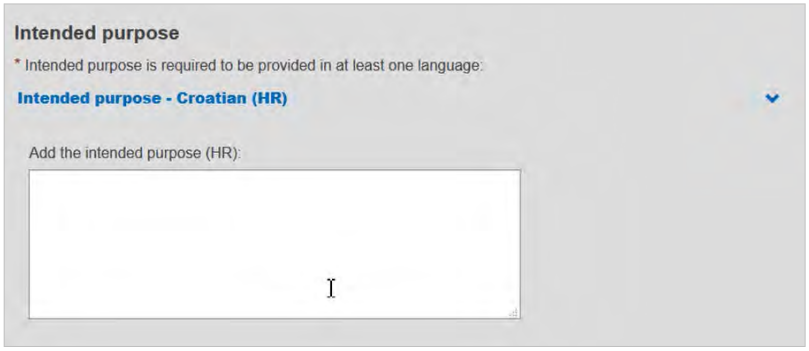
2. **Save** your draft or click **Save & Next** to continue to the next step.

4.2.3 Provision of device data

1. Enter the Basic UDI-DI code and choose the codes for the device type from the drop-down list:



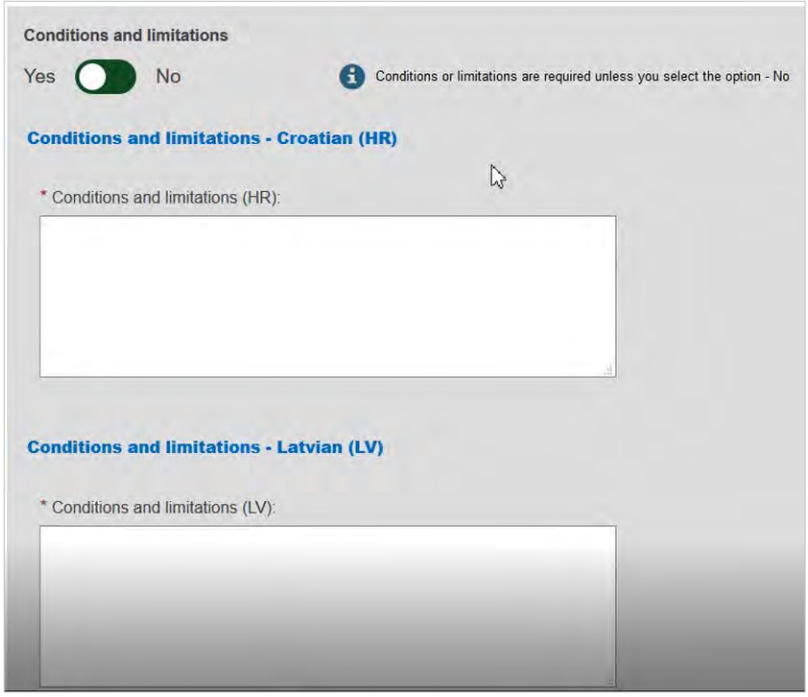
2. Enter the Intended purpose of the device in each language you selected in the prior steps:



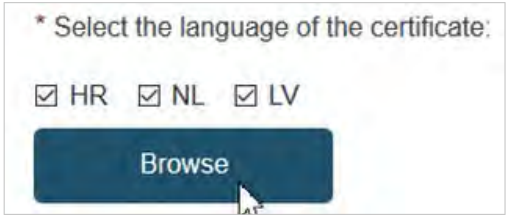
3. Click either **Save** or **Save & Next**.

4.2.4 Provision of certificate details

1. Enter the conditions and limitations, if any, in each language:



2. Select the languages in which the electronic version of the certificate has been issued. Click **Browse** to upload the files. You may upload more than one file if it covers the chosen languages:

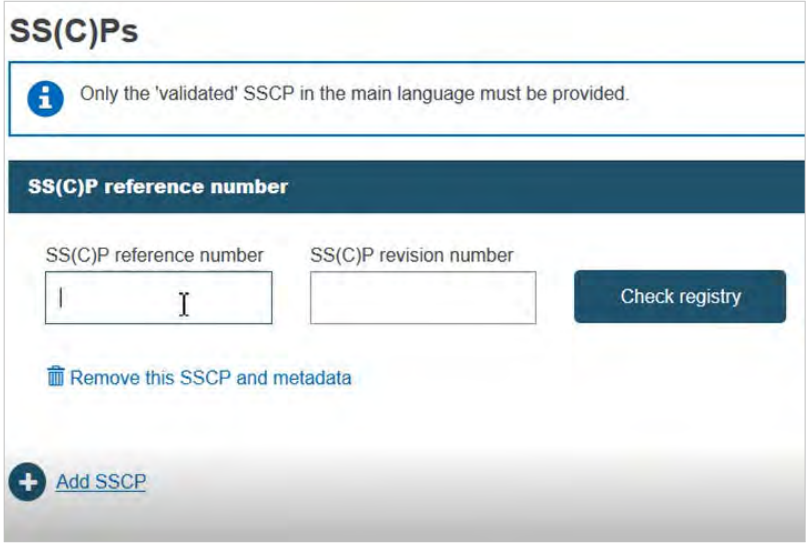


3. Click either **Save** or **Save & Next**.

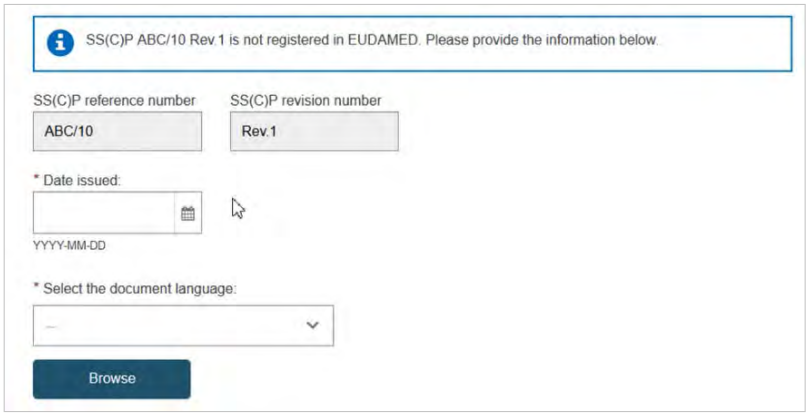
4.2.5 Provision of SS(C)P documents

For certain high-risk devices that are implantable, the provision of an SS(C)P applies.

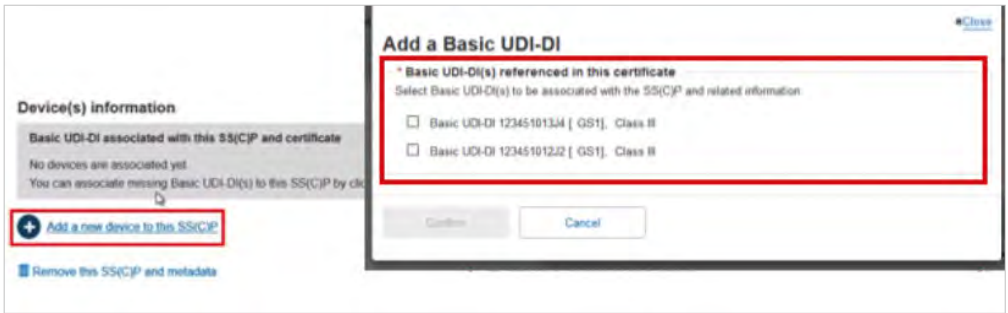
1. An SS(C)P record within EUDAMED can be attached to many certificates. Hence, the initial dialog requires the provision of an *SS(C)P reference number* and *SS(C)P revision number*. Once provided, click **Check registry**:



2. If the record exists in EUDAMED, it will be displayed. Otherwise, you may enter a new SS(C)P registration. Enter the issued date and select the language of the document. Click **Browse** to upload the SS(C)P master document:

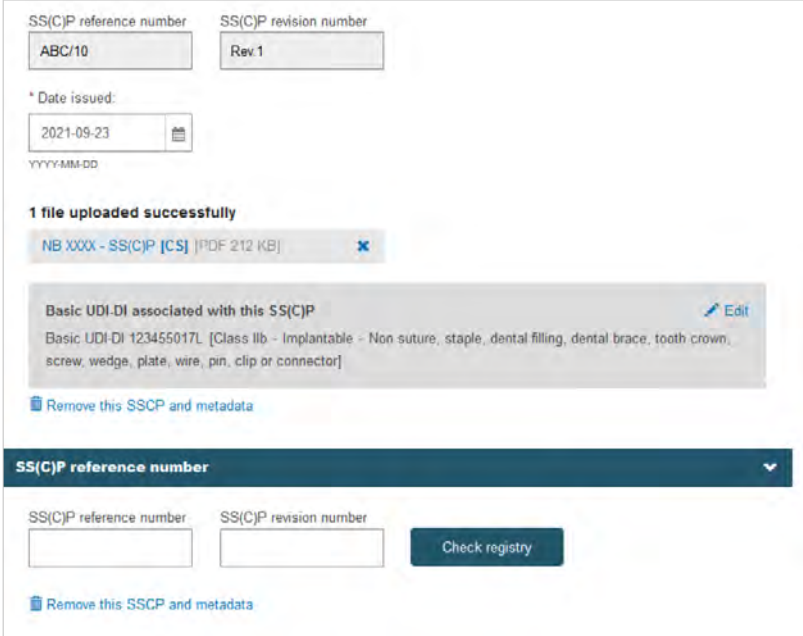


3. The *Device(s) information* box confirms no associated devices. Click **Add a new device to this SC(C)P**. The pop-up shows the Basic UDI-DI(s) referenced in this certificate. You can select multiple devices to associate to this SS(C)P:

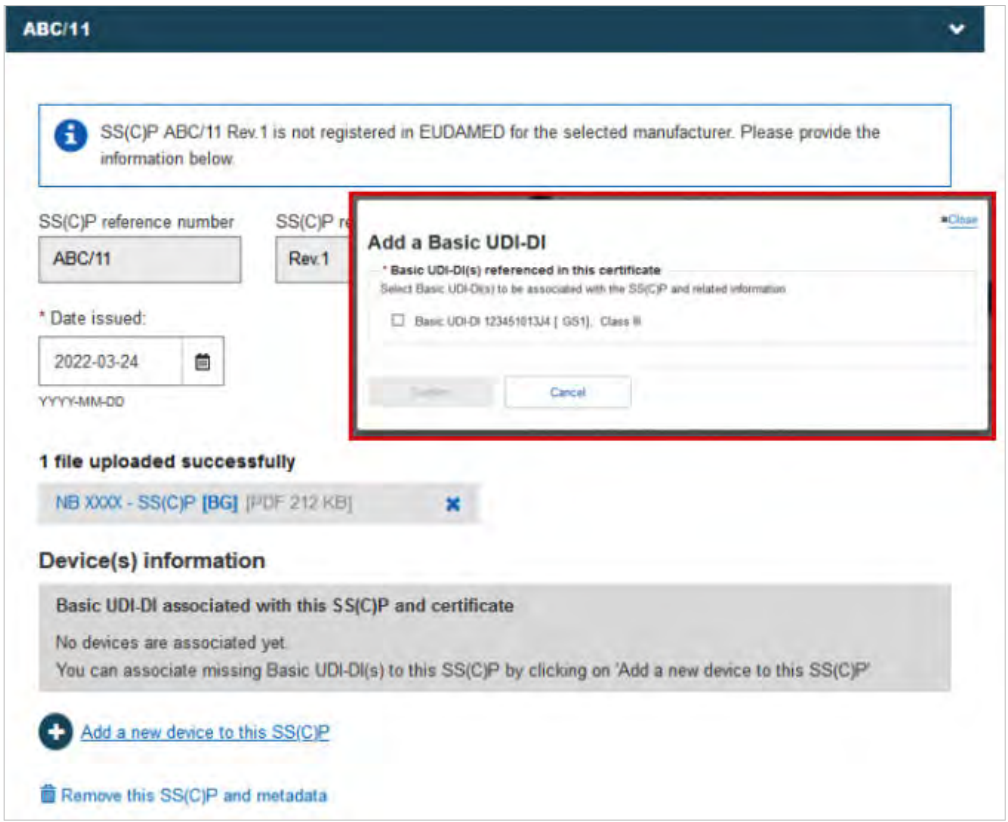


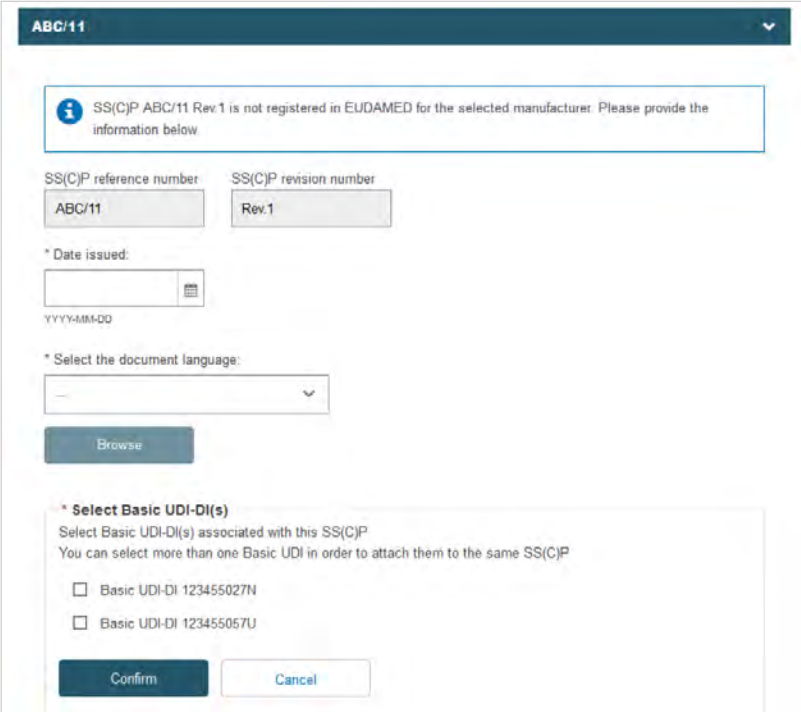
Once selected, click **Confirm** to link the devices to the SC(C)P. Nothing is yet submitted, and you can remove this SS(C)P by clicking on **Remove this SS(C)P and metadata** and return to the previous screen.
You may register more than one SS(C)P. Select the device that is described by the SS(C)P being registered and click **Confirm**:

4. To register additional SS(C)Ps, click on **Add SSCP**. You will be provided with a new SS(C)P search dialog:



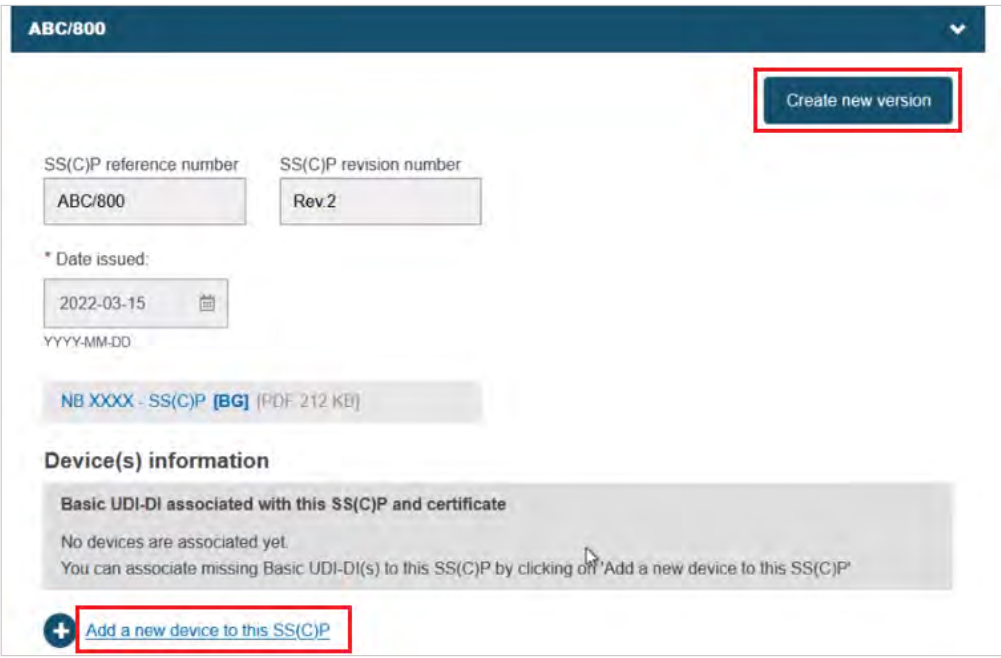
5. When registering additional SS(C)Ps, by clicking on **Add a new device to this SS(C)P** the system will display the remaining devices in the scope of the certificate to be linked to the additional SS(C)P:





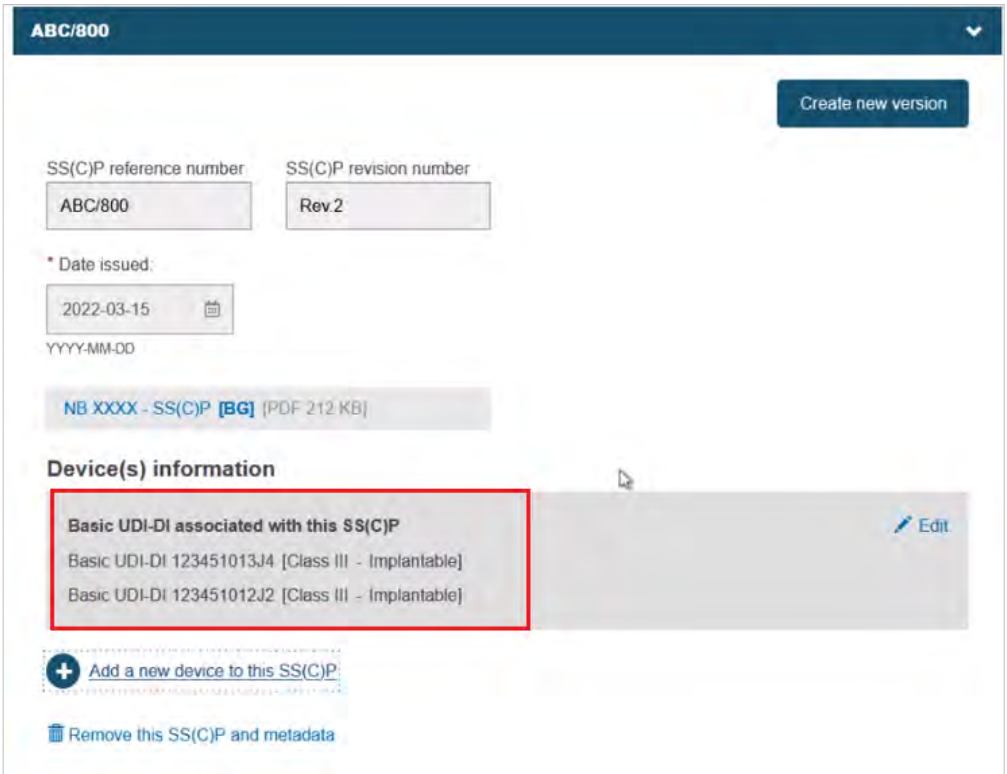
6. When finished, click **Save** or **Save & Next**.

7. Alternatively, you can create a new version of an existing SS(C)P. Click **Create new version** and provide a version number, issue date and master document (see *Provision of SS(C)P documents [10]* for Quality certificates). Click **Add a new device to this SS(C)P** to add new devices to this new SS(C)P version:

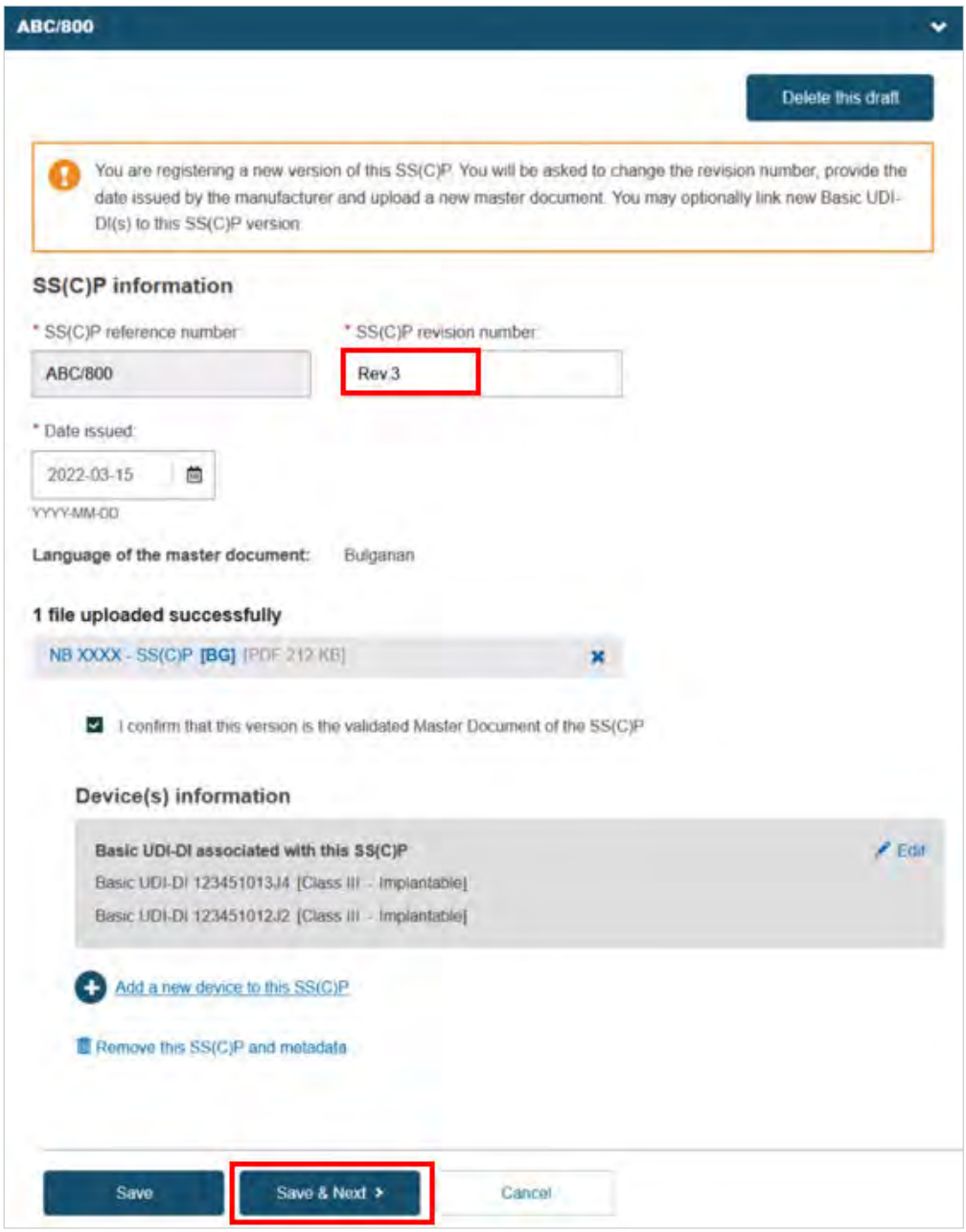


8. The pop-up lists Basic UDI-DI(s) which are referenced in the certificate. No others can be added. Select one or multiple from the display, and click **Confirm**:

The selected devices are listed:



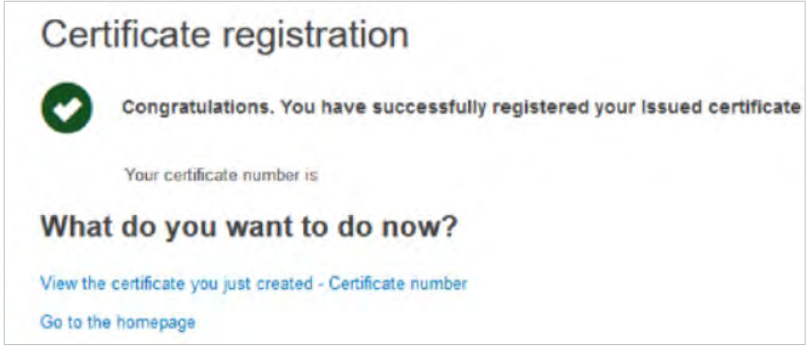
9. You can still create a new version using the **Create new version** button as shown previously, and the selected devices will link to it. Click **Save & Next** to proceed:



10. Click **Save** or **Save & Next**.

11. Confirm your submission by clicking on **Submit my request** in the pop-up window:

You will be shown a page confirming your registration:

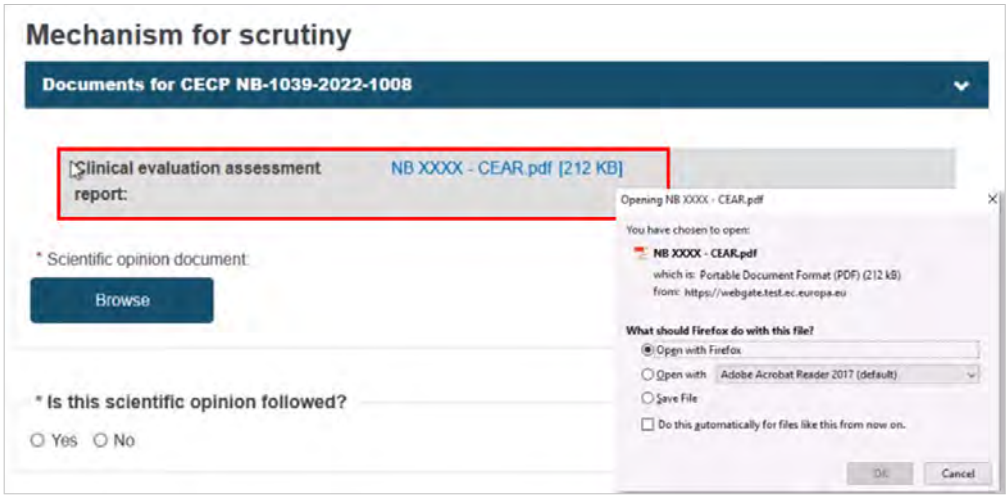


From here you can click **View the certificate you just created** to view the certificate, or you can click the **Go to homepage**.

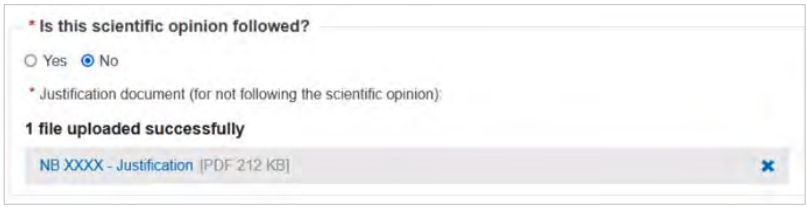
4.2.6 Provision of 'Mechanism for scrutiny'

For the Product certificate type, higher risk devices will require a Mechanism for scrutiny:

1. The system will verify and display all CECP records registered for the Basic UDI-DI(s) in the scope of this certificate. By default, the Clinical Evaluation Assessment Report (CEAR) will display, which is viewable and downloadable. Based on the CECP status, the system will identify if a scientific opinion has to be provided by the NB. In which case, the **Browse** button enables the NB to upload the scientific opinion document:

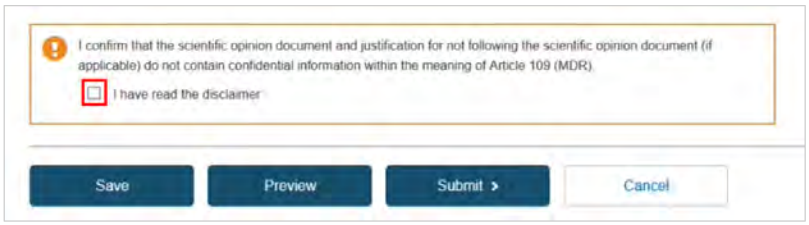


2. Confirm if the scientific opinion is followed. If yes, click *Yes* and no further action is required. If no, click *No* and upload a justification document for this approach:



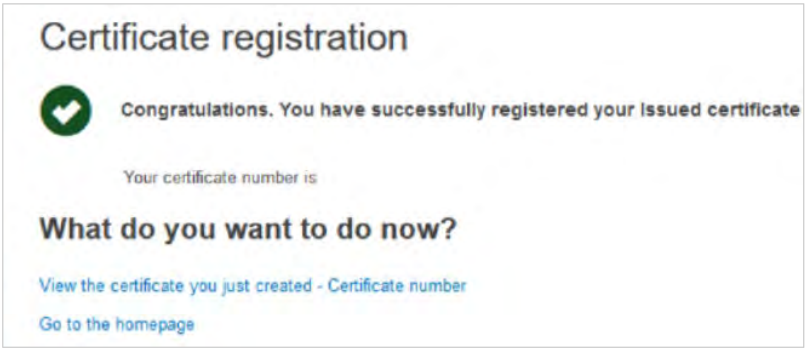
3. For each Basic UDI-DI, select the language(s) for of the *Instructions for use* document(s). Each document may contain multiple languages, which display next to the file once uploaded:

4. Note that the confidentiality disclaimer needs to be confirmed as read in order to continue. Now click **Save** to save as a draft, **Preview** to verify the information provided, or **Submit** to submit your registration.



5. Confirm the accuracy of the device data in the pop-up window:

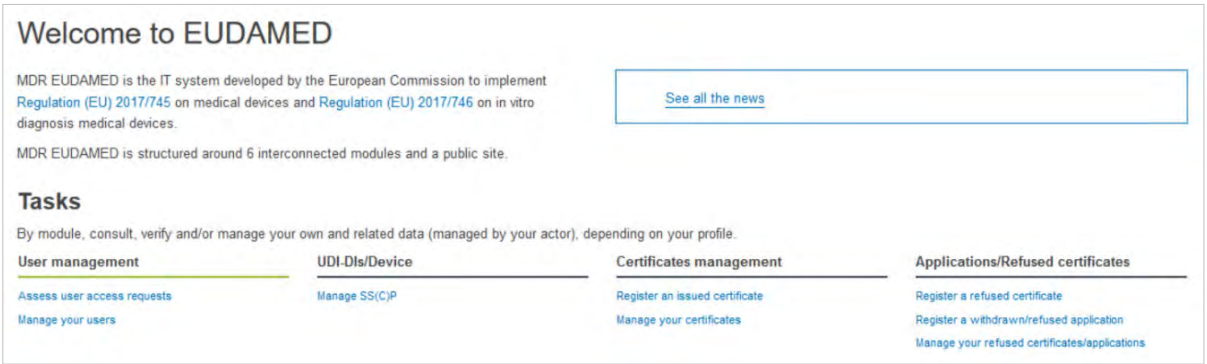
You will be shown a page confirming your registration:



From here you can click **View the certificate you just created** to view the certificate, or you can click the **Go to homepage** link in order to return to your homepage.

5 Register a refused certificate

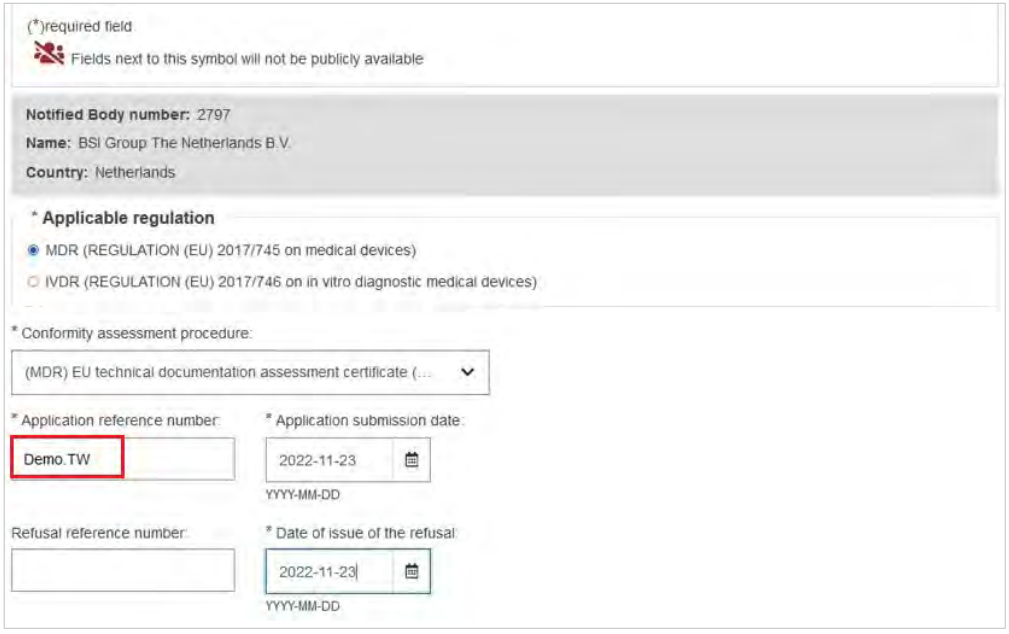
Click **Register a refused certificate** in the *Application/Refused Certificates* section.



5.1 Product-type certificate

5.1.1 Provision of core data

1. Enter the core information for the refused certificate:



2. Select the applicable Regulation and the conformity assessment procedure. Then enter the application reference.

> **NOTE**
> In this scenario we will choose a Product certificate type.

3. Provide the dates for both the application submission and the date of issue of the refusal.

4. **Manufacturer identification**
   Enter the Actor ID/SRN or name of the manufacturer or the system/procedure pack producer, then select the appropriate one from the displayed list:

5. Click **Save & next**.

5.1.2 Decision languages

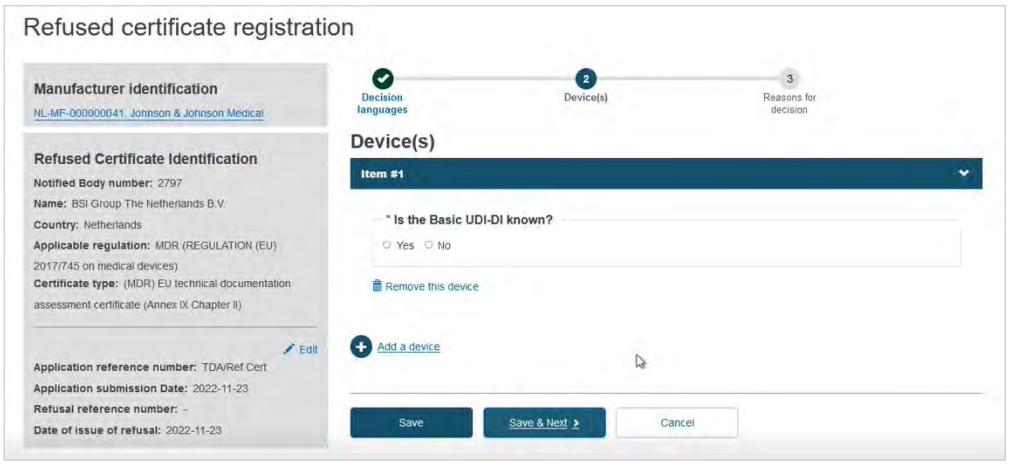
In this step, click **Add language(s)** and select the languages from the pop-up:

You can remove languages using the *x* symbol, or add more if you wish to:

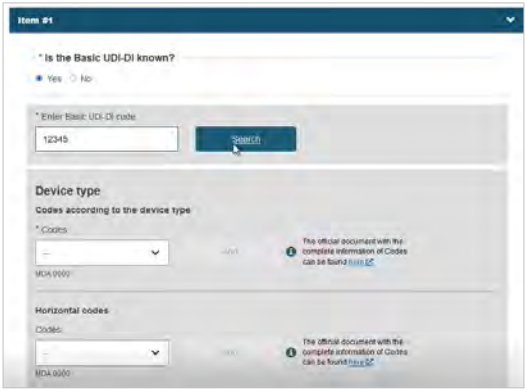
When you are done click **Save & Next**.

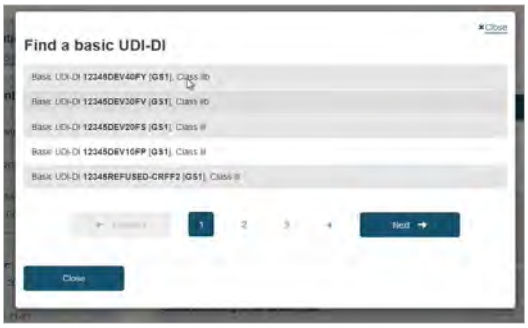
5.1.3 Add a device

1. Is the **Basic UDI-DI** known?:

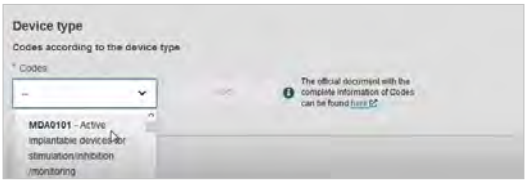


- If *Yes*, enter part/all of the Basic UDI-DI code and select from the list displayed. Now continue the registration:



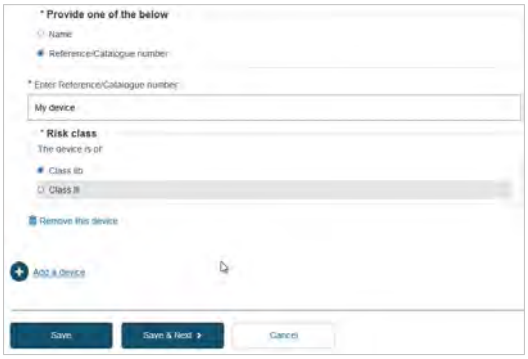


Add some characteristics of the device:

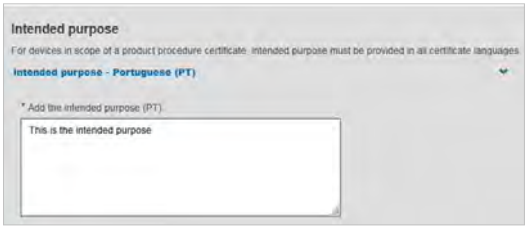


Add a description of the purpose:

- If *No*, identify the device by *Name*.
  Alternatively, provide the *Reference/Catalogue number* in free-text and select the *Risk Class*. Note the *Name* or *Reference/Catalogue number* options also apply when registering Refused/withdrawn applications:



Provide the device type and the intended purpose:



2. Click **Save** or **Save and Next**.

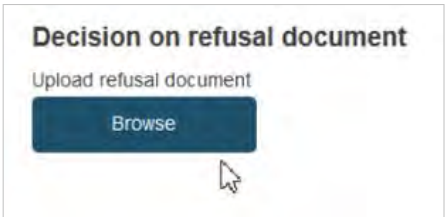
3. For additional devices, click **+ Add a device**:

5.1.4 Reasons for decision

1. Select one or more reasons from the list below, and enter the *Reason for refusal* comment in the languages you chose in the *Decision languages* step:

> **NOTE**
> If you select *Other*, you will have to provide the reason in the languages you chose in the *Decision languages* step.

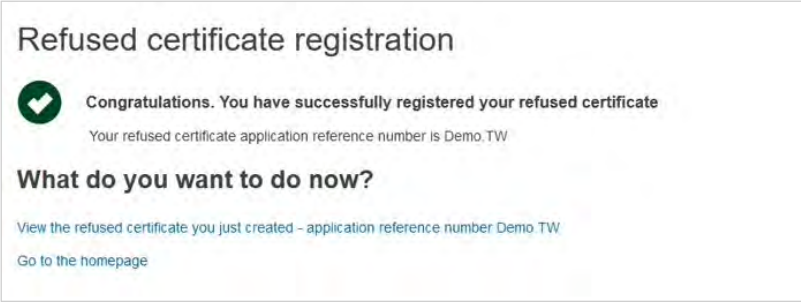
2. The refusal document is optional:



> **IMPORTANT**
> **Decision on refusal document** will be accessible only by Competent Authorities, the European Commission, and the Notified Body that registered it.

3. You can **Preview** your choices, or click **Submit** to complete the registration:

4. A confirmation message displays:



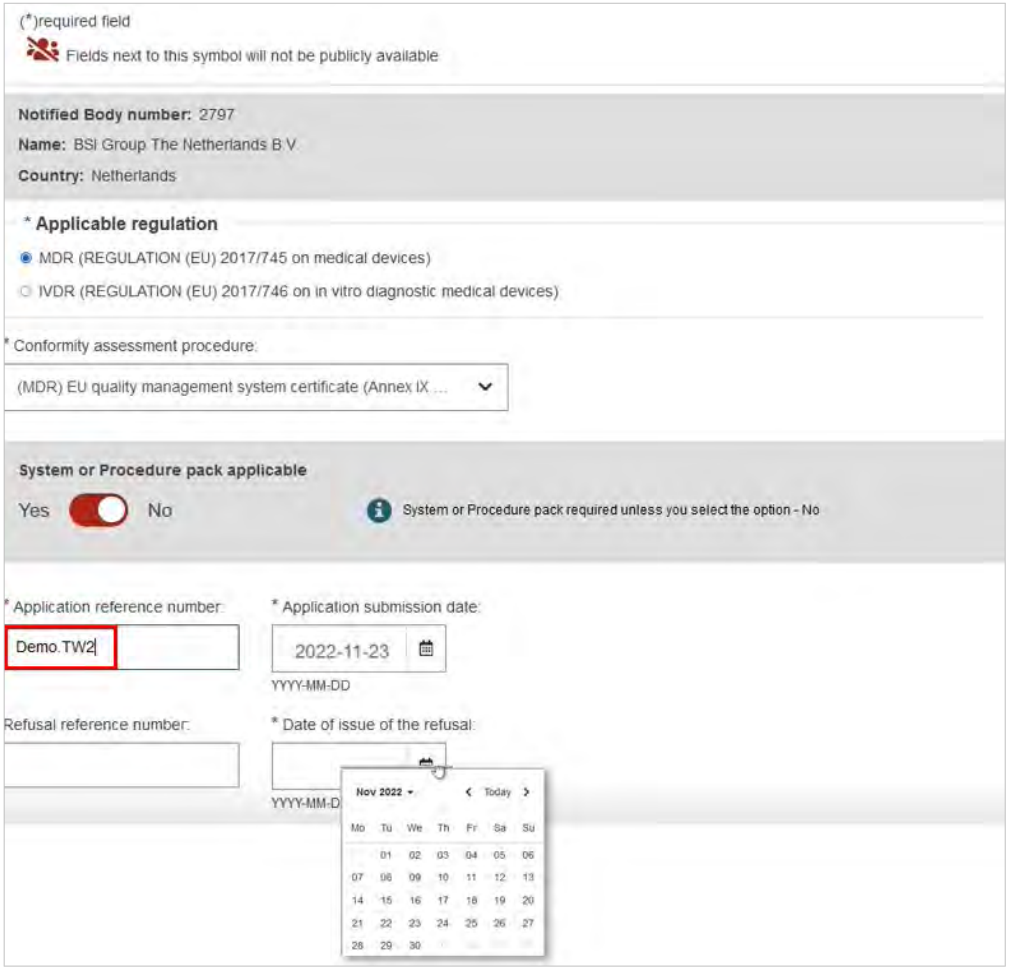
5.2 Quality-type certificate

5.2.1 Provision of core data

1. Enter the core information for the refused certificate.
2. Select the applicable Regulation and the conformity assessment procedure.

> **NOTE**
> In this scenario we will choose a Quality certificate type.

3. Indicated **Yes** or **No** for a System Procedure Pack, then, enter the application reference number.
4. Provide the dates for both the application submission and the date of issue of the refusal:

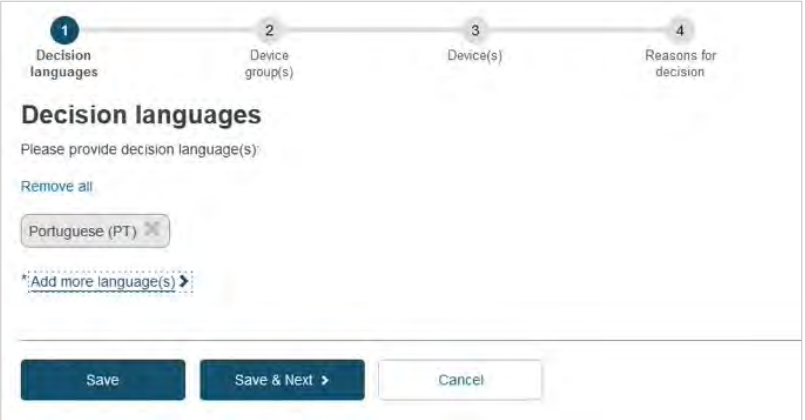


5. **Manufacturer information**
   Enter the Actor ID/SRN or name of the manufacturer or the system/procedure pack producer, then select the appropriate on from the displayed list:

6. Click **Save & next**.

5.2.2 Decision languages

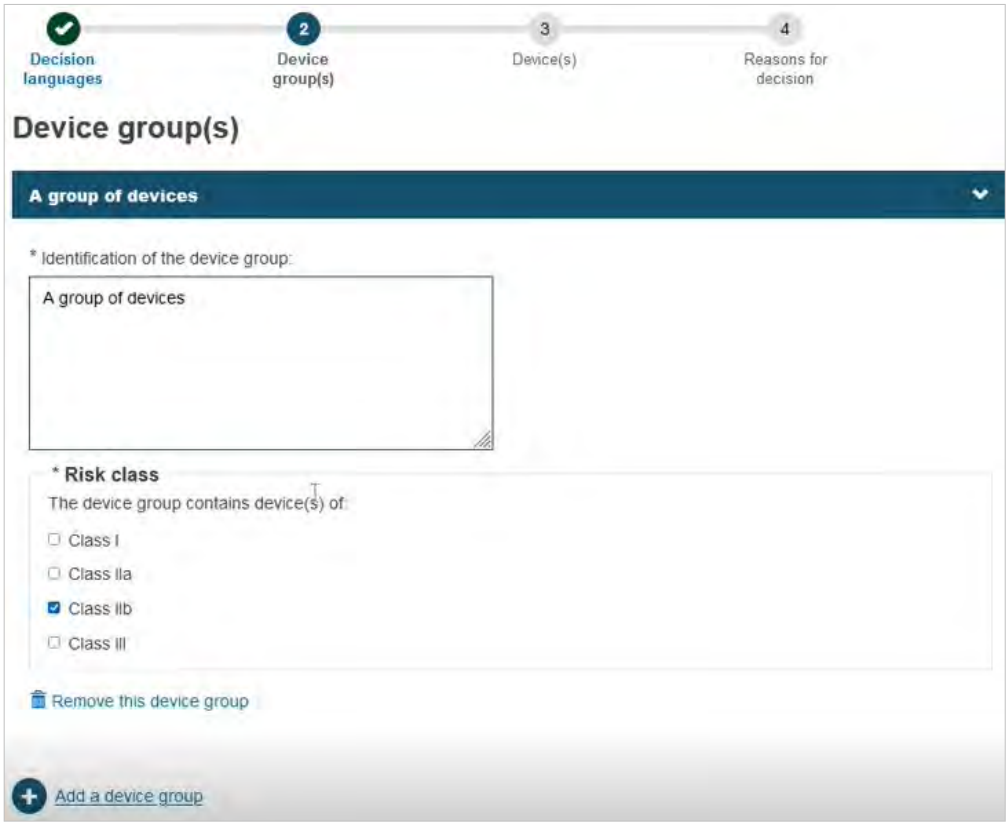
Select one, or multiple, languages in which the certificate was issued:



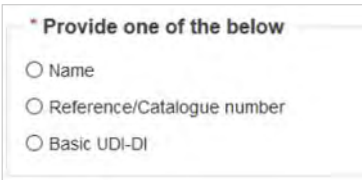
5.2.3 Device group and device

A device groups or a device is mandatory to provide for Quality-type certificates.

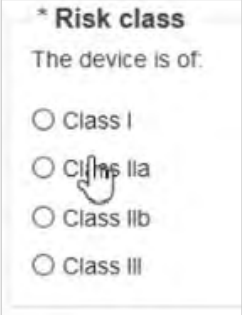
1. Click **+ Add a device**:



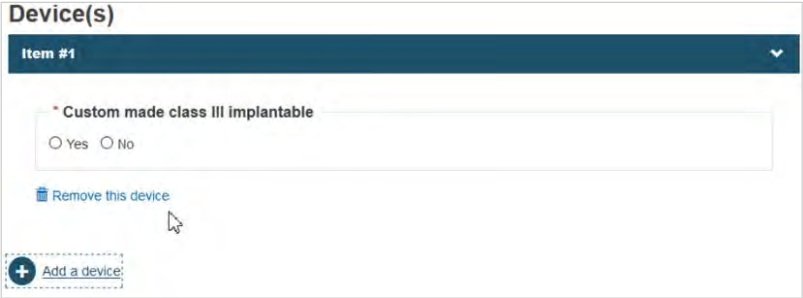
2. Provide either a *Name*, *Reference/Catalogue number* or *Basic UDI-DI*. Note that these options also apply when registering a **Refused/withdrawn application** for a Quality-type certificate:



3. Choose the *Risk class*:



4. Depending on the risk class, choose *Yes* or *No* whether the device is custom-made or not:

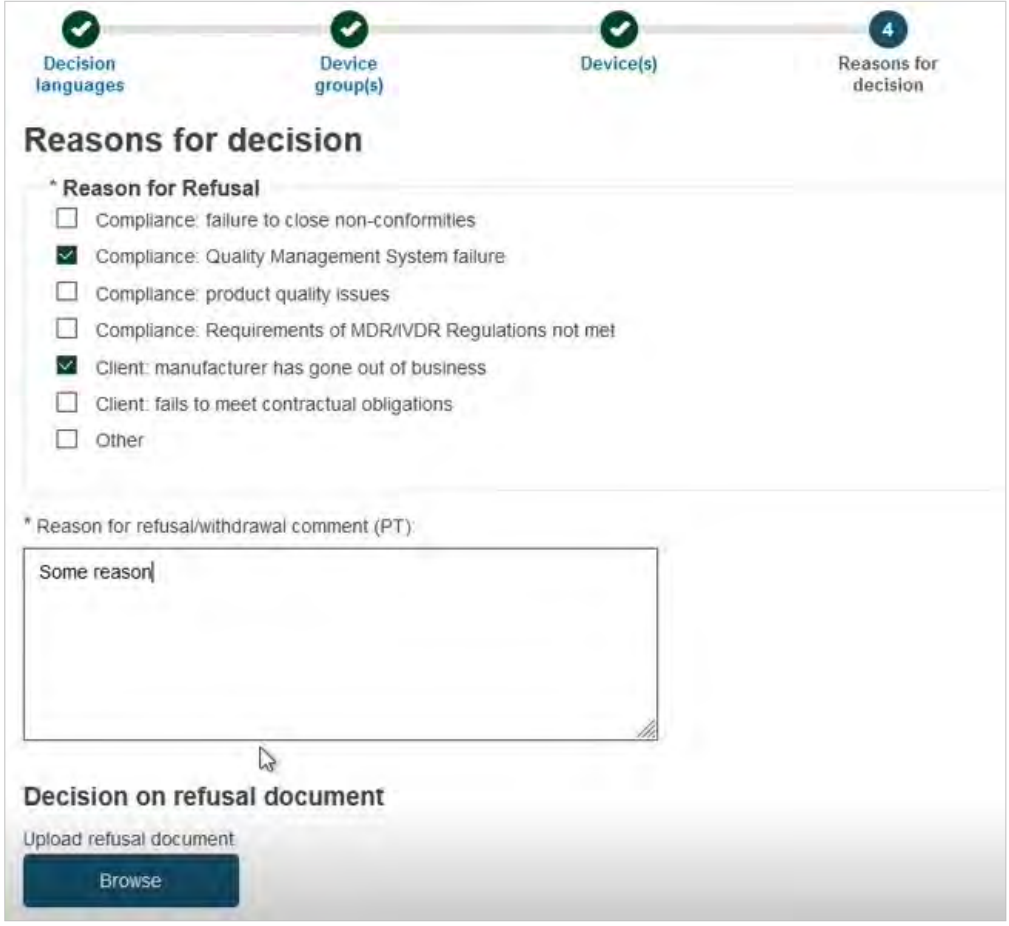


5. Click **Save & Next**.

6. Add a device and its Basic UDI-DI, and click **Save & Next**. This is optional:

5.2.4 Reasons for the decision

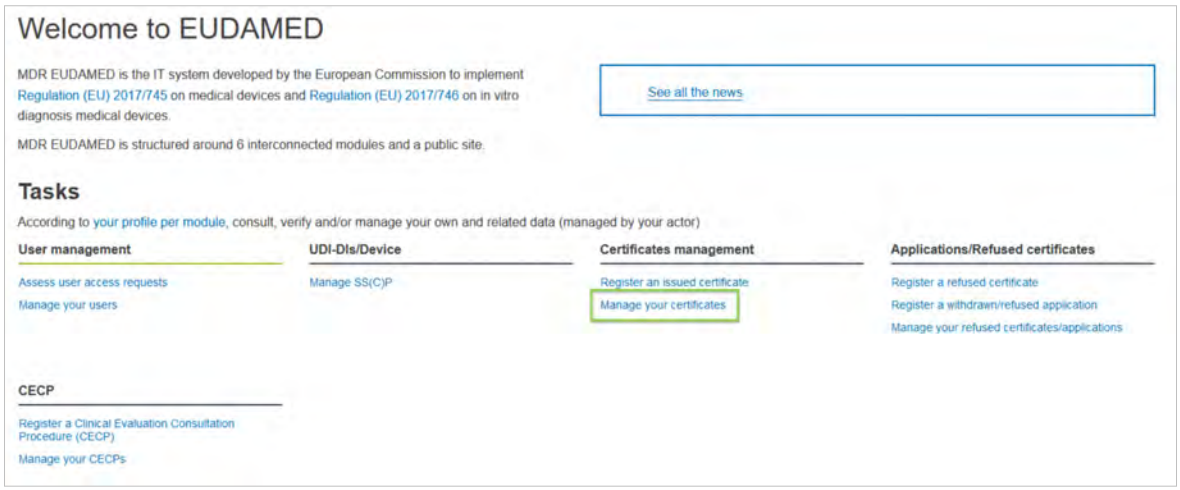
Select one, or multiple, reason(s) for the refusal/withdrawal decision, and provide a comment. The **Decision on refusal document** is optional:



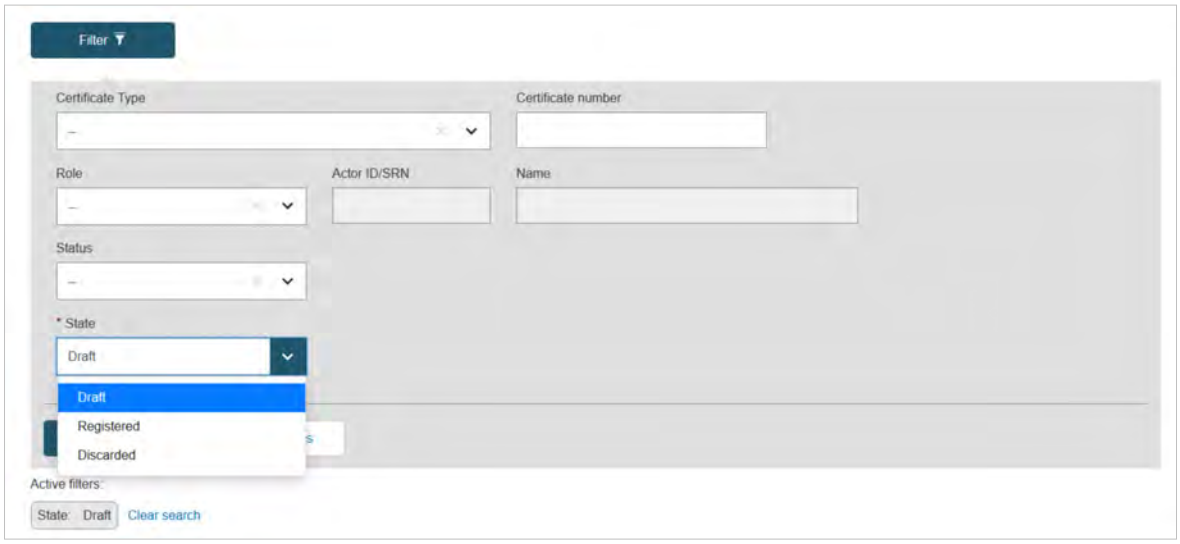
You may preview your choice, or click **Submit**:

6 Update a certificate

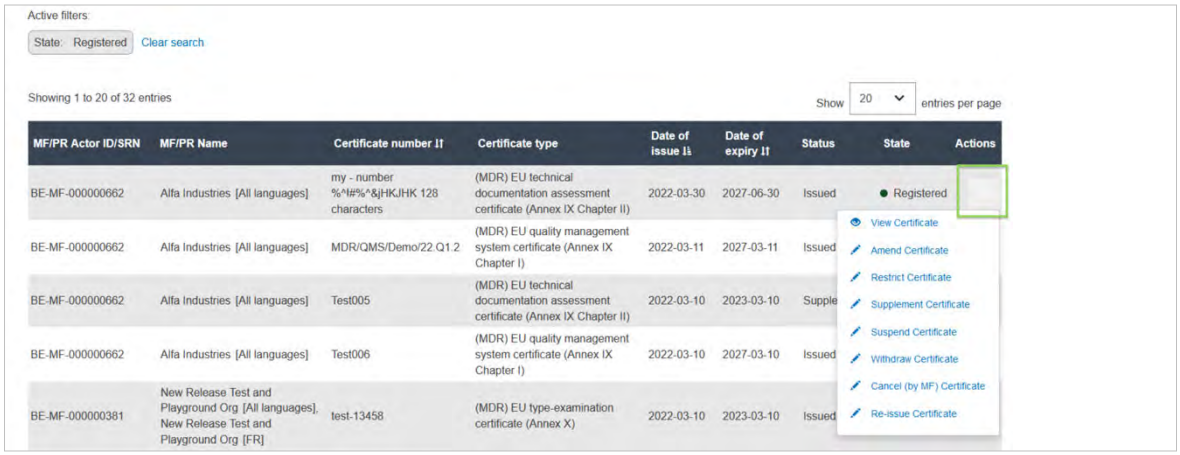
1. On the EUDAMED Dashboard, click on **Manage your certificates**:



2. Filter the certificates to state *Registered*, by default, the state filter is on *draft*:



3. Click on the three dots under *Action* for the certificate you want to upload, a contextual menu will display the possible operations over the selected certificate:



TIP

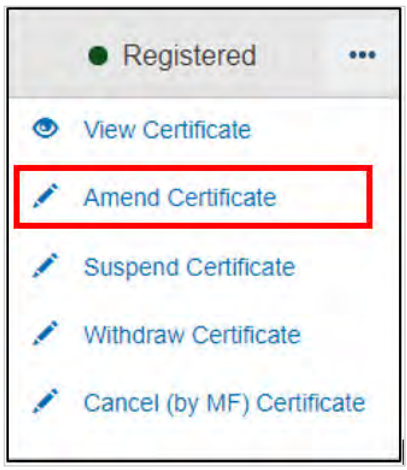
The certificate you want to update is missing?

Verify that your certificate is not in *draft* state within the *certificate management* page.

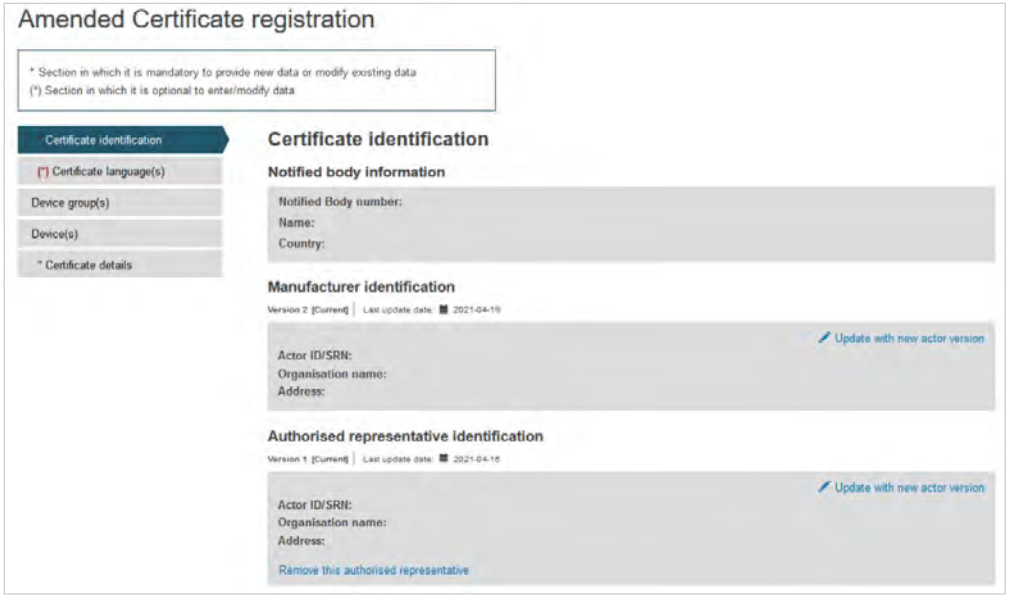
If a draft version exists, it must be registered or deleted; only certificates in *registered* state can be updated.

6.1 Amend

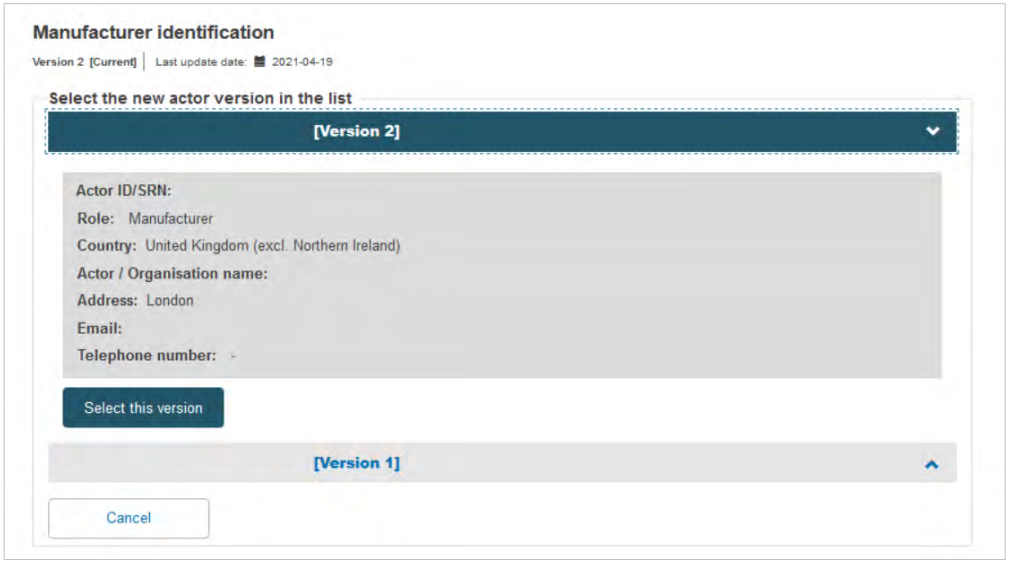
1. To amend a certificate, repeat steps from *Update a certificate*, click the three dots under *Actions* and click **Amend Certificate**:



2. You will arrive to the following page:

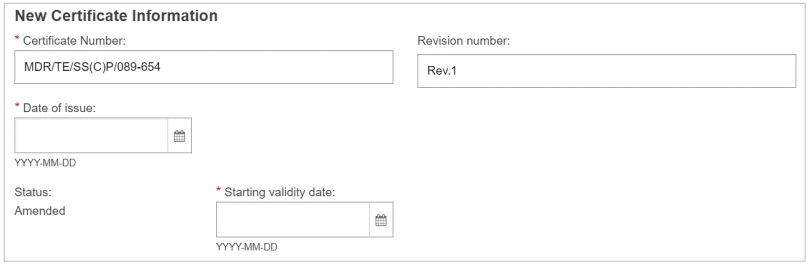


3. To select another version of the Manufacturer, Producer or Authorised representative, click on **Update with new actor version** link.
   You will see a dialog to select another version of this actor (if one exists):

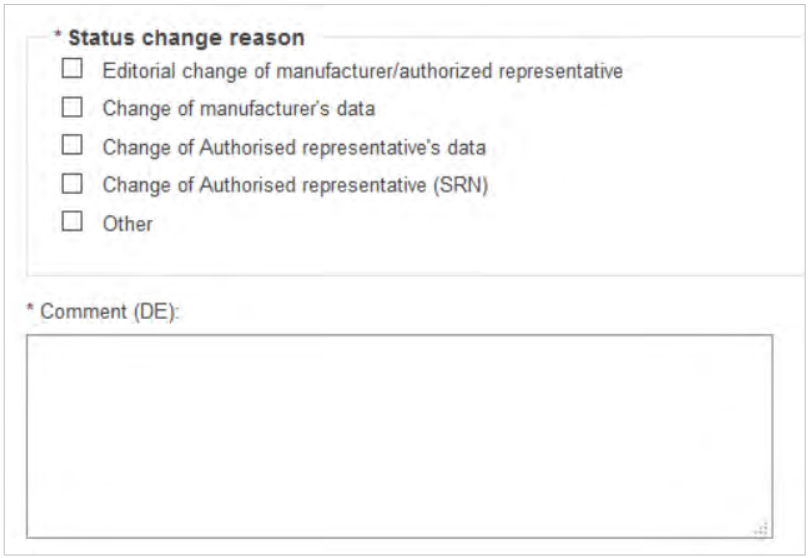


4. Click the **Select this version** button to select the actor version and close this dialog.
   The *Preceding certificate information* box displays core information about the preceding certificate:

5. Below that, you will see the following:

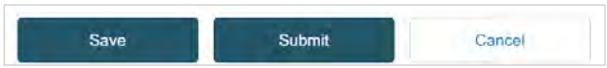


6. The certificate number might change, if it is the case, enter the new *Certificate Number* and add a revision number. Enter the date of issue and the starting validity date.
   Select one of the reasons for the change to the certificate and add a comment in the language in which the certificate was registered:



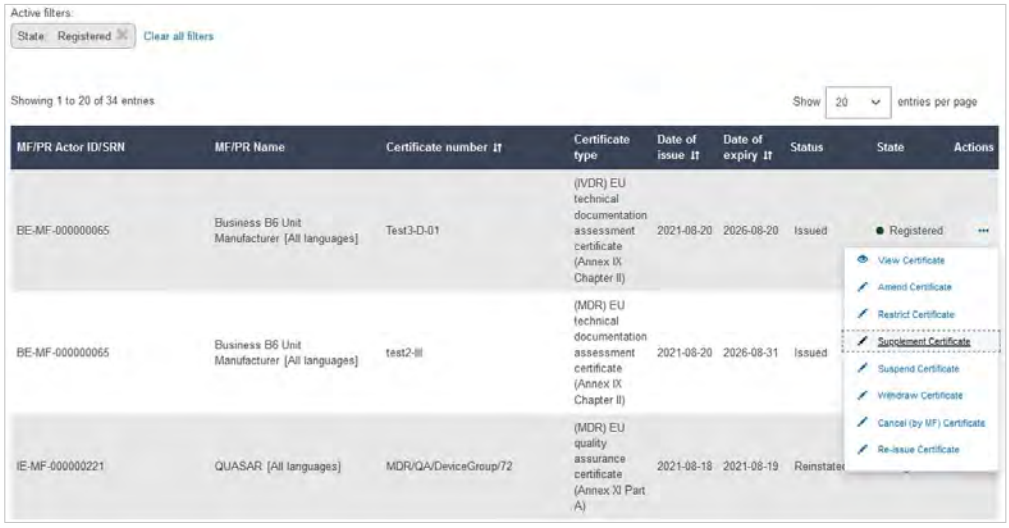
7. In the next steps, you will have to enter the information as if you were creating a new certificate. When you are done, click **Submit**:

8. Once complete, click either **Save** to save your work without submitting, or **Submit** to submit it:



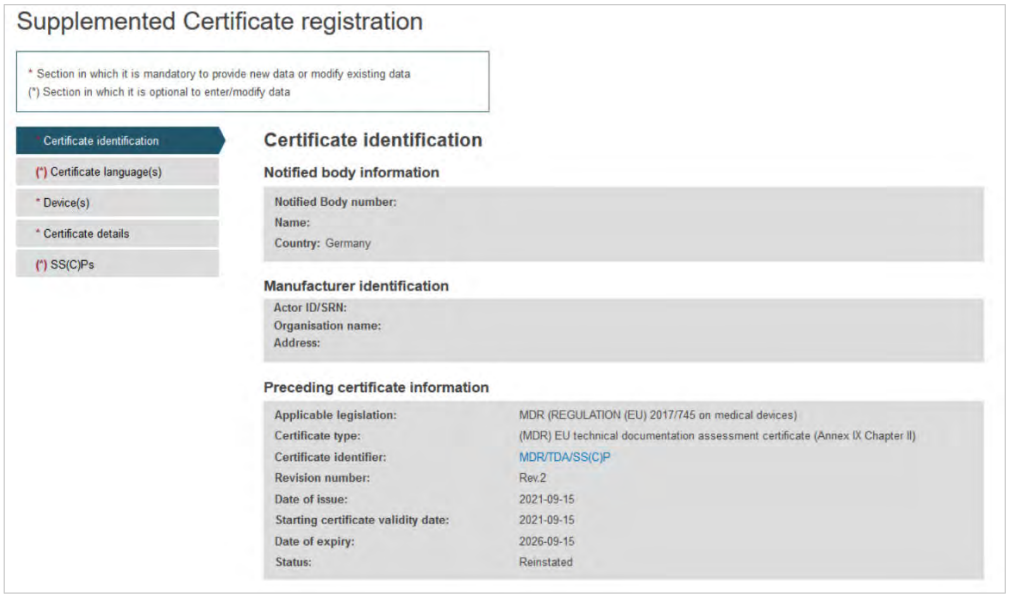
6.2 Supplement

To supplement a certificate, click the three dots next to the desired certificate and then click **Supplement Certificate** from the dropdown menu:

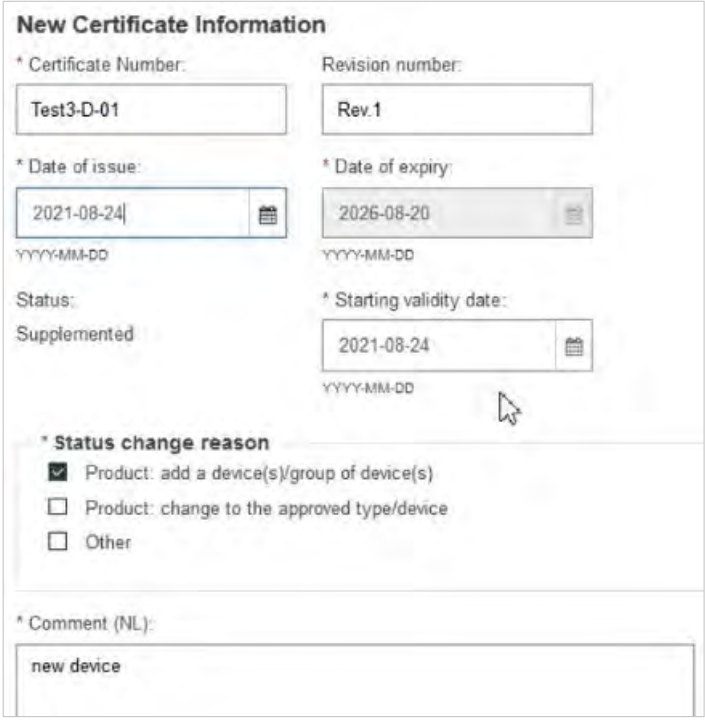


On the next screen, you will find all information relevant to the specific certificate and a menu with different sections on the left.

1. Complete the information in the *Certificate identification* section:

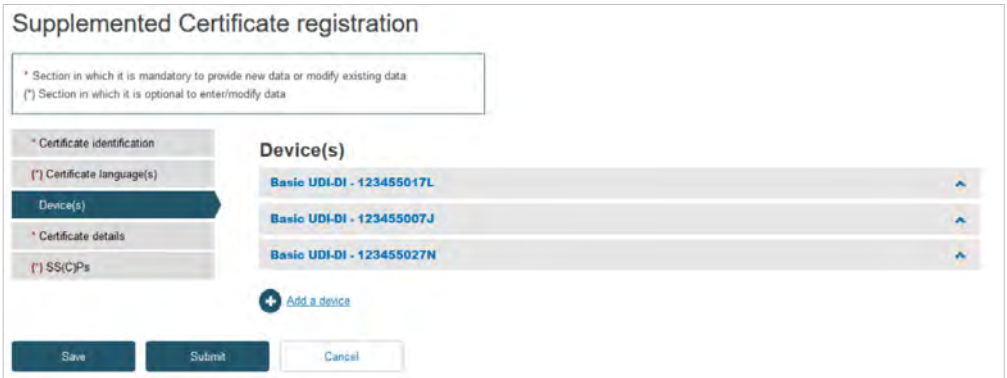


2. Scroll down and fill in the *New Certificate Information*:

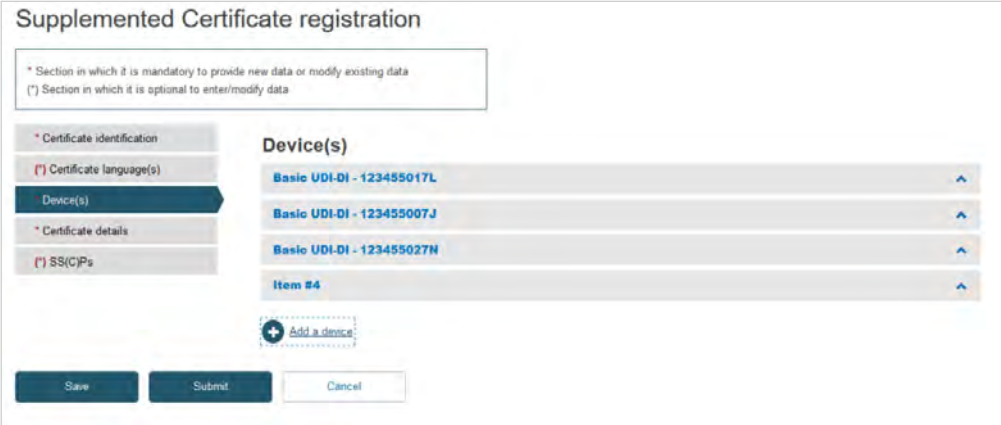


3. Provide comments in each certificate language and click **Save** to proceed:

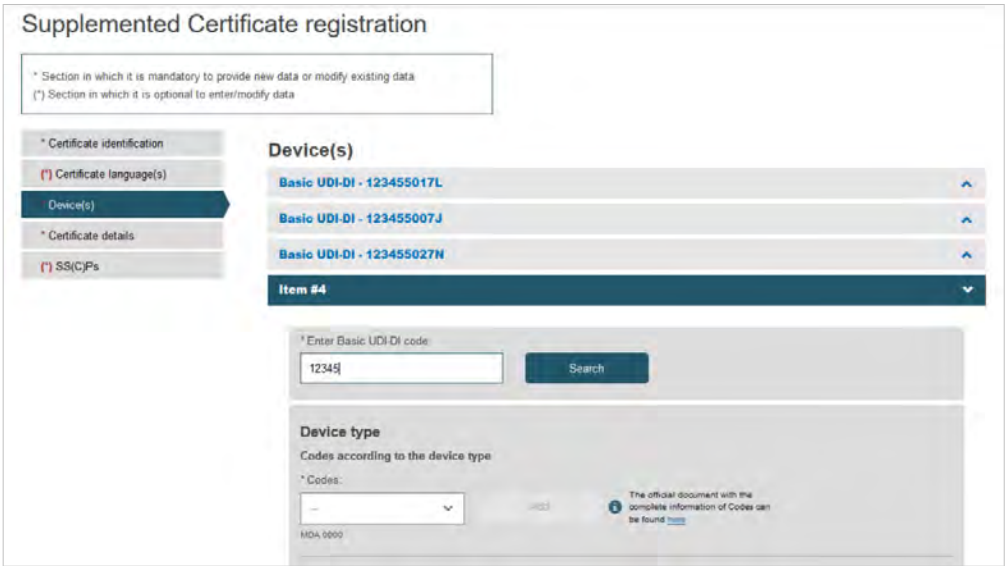
4. Click on the **Devices** tab on the menu on the left, then click **Add a device**:



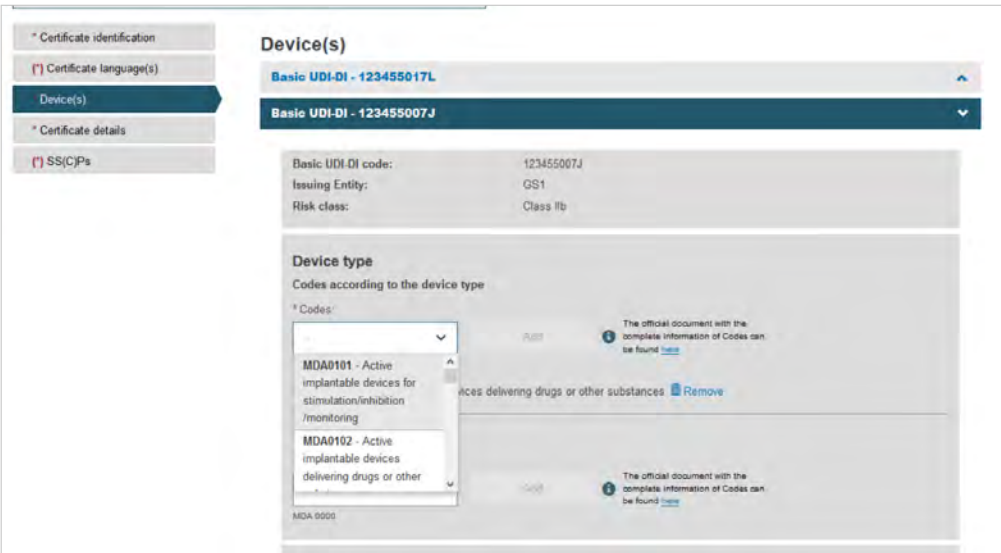
5. Click on the banner marked *Item* to expand the information for this device:



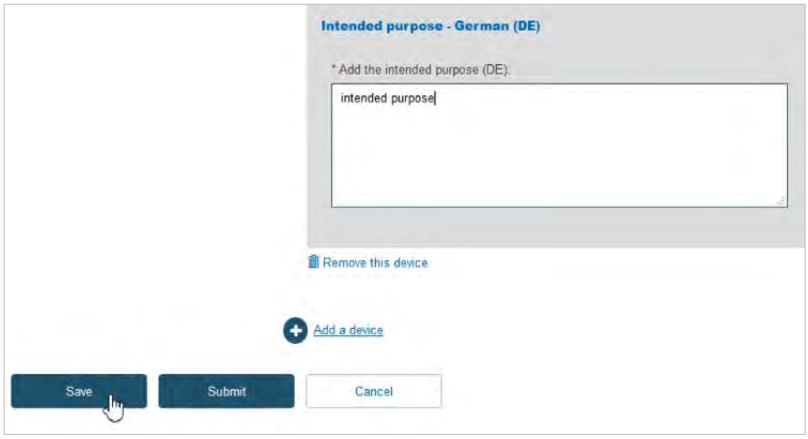
6. Type the desired Basic UDI-DI code and click **Search**:



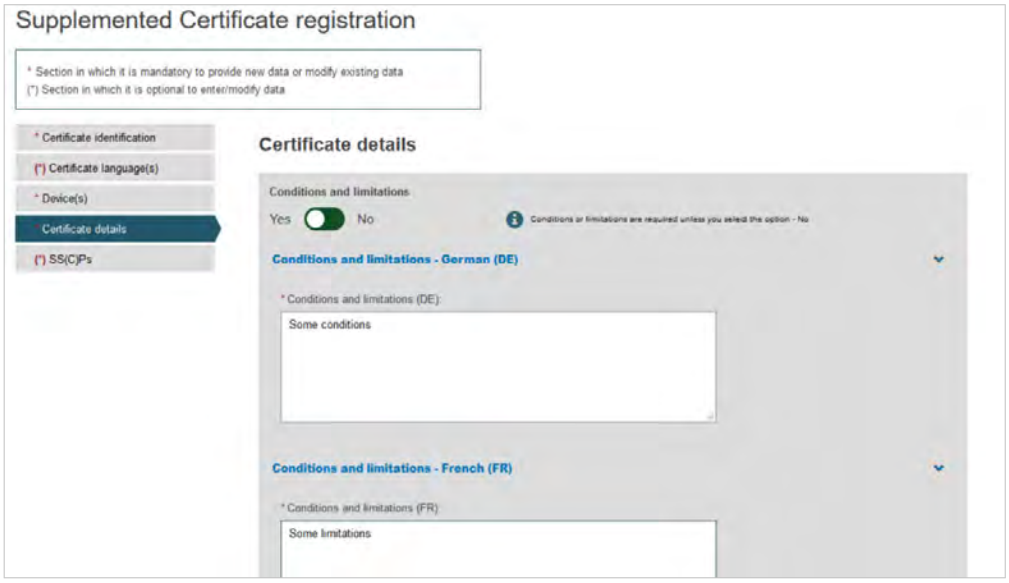
7. Fill in all the new details for the supplement, i.e. choose *Device type* and provide the intended purpose:



8. Once you have provided the necessary information, click **Save**:

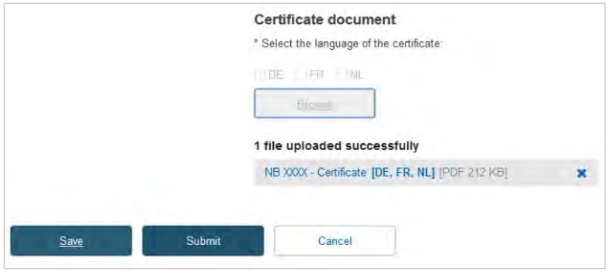


9. Click on the **Certificate details** section from the menu on the left and complete all the steps:

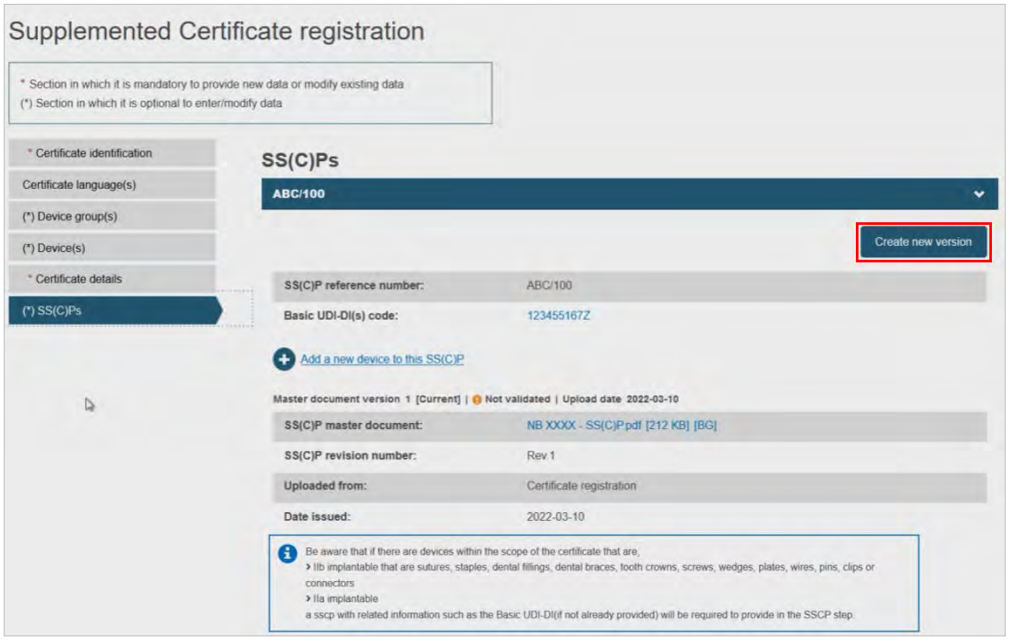


10. To provide the new *Certificate document*, tick the relevant languages and click **Browse** to upload the document(s) from your computer. You can upload either one document containing one/some language(s) or one document covering all languages:

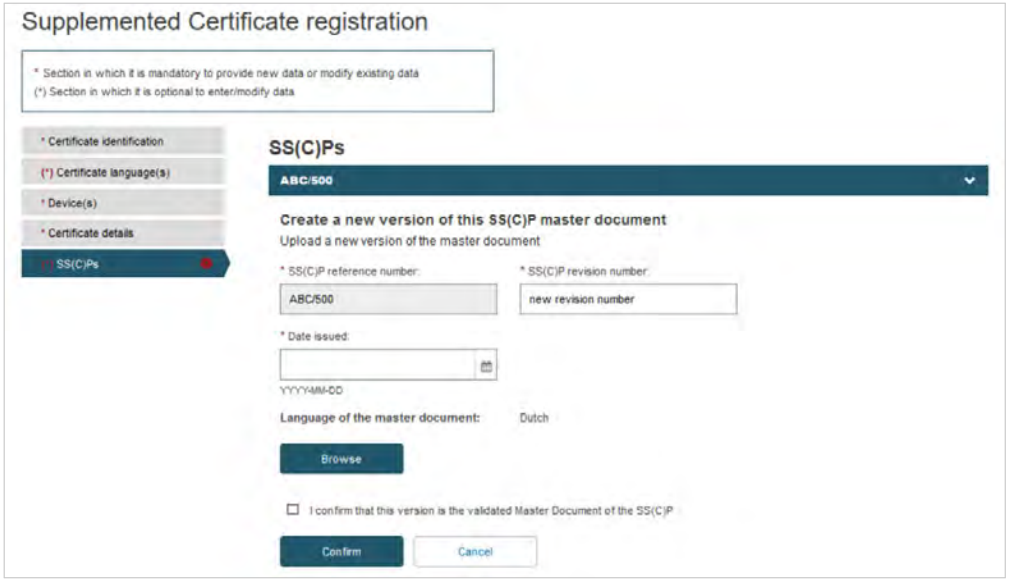
11. Once you have successfully uploaded the new certificate document(s), click **Save**.



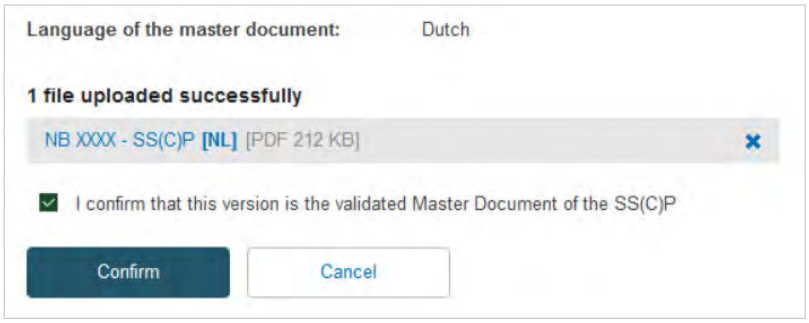
12. Next, decide either to create a new version of the SS(C)Ps, or link new devices to the existing one. Click on the next menu section, i.e. *SS(C)Ps*, then click **Create new version**:



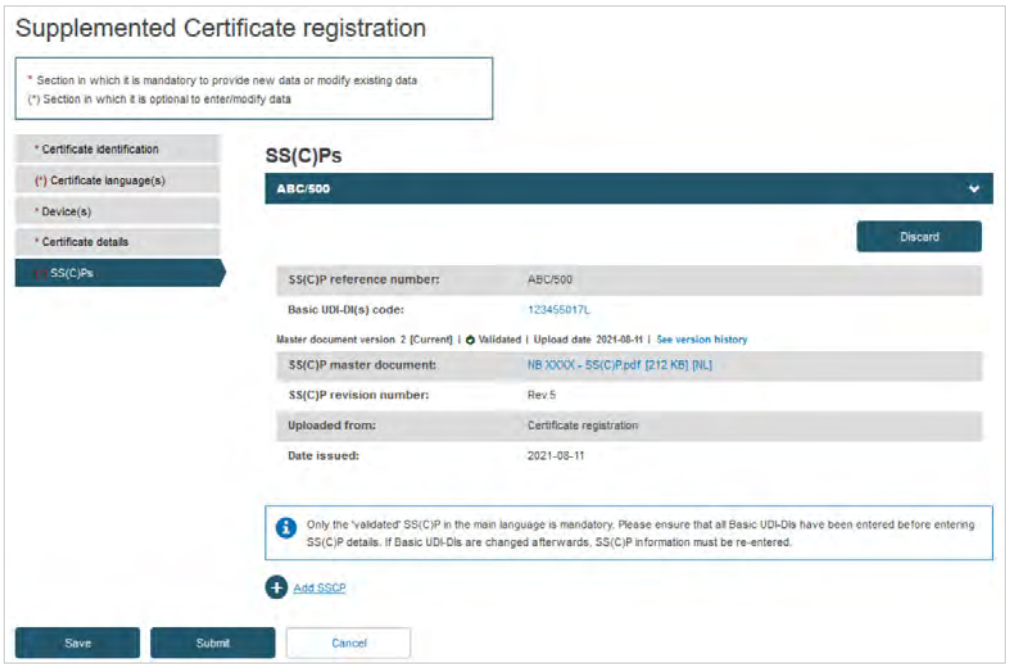
13. Fill in the information for the new SS(C)P document version and upload the new master document in the pre-selected language:



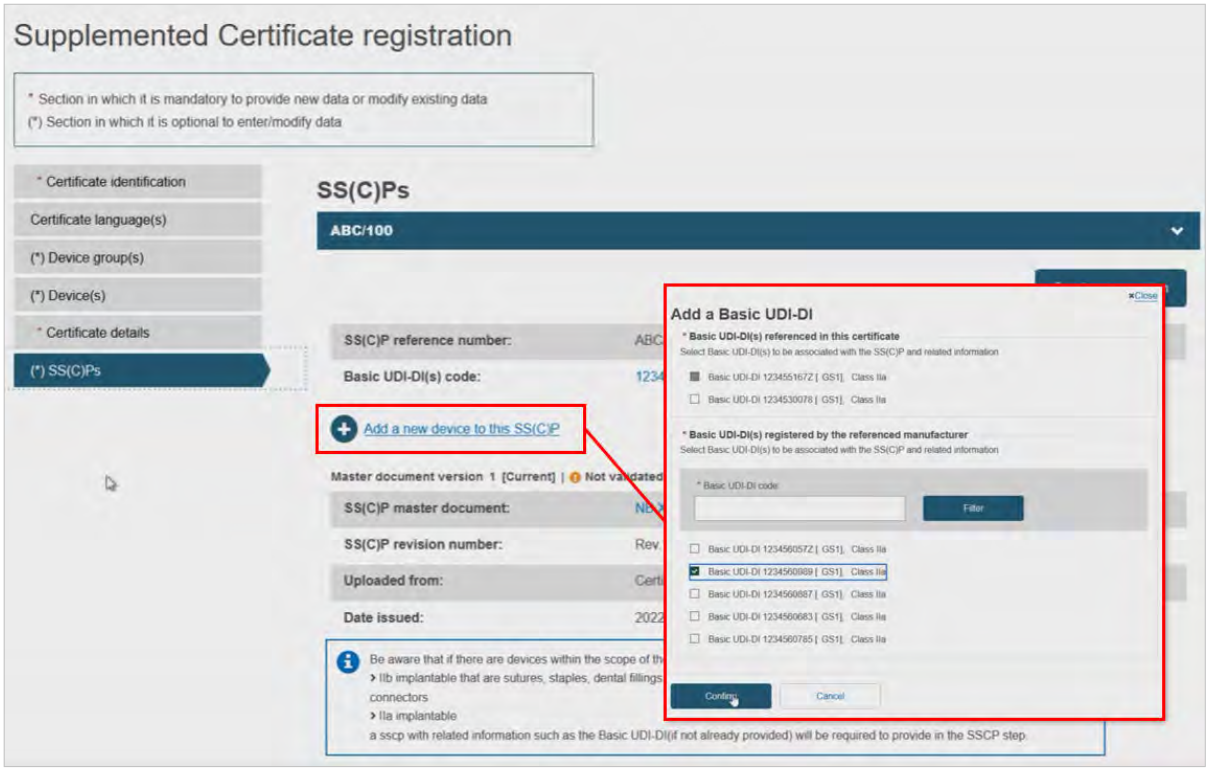
14. Once you have uploaded the new SS(C)P master document, tick the confirmation box and click **Confirm**:



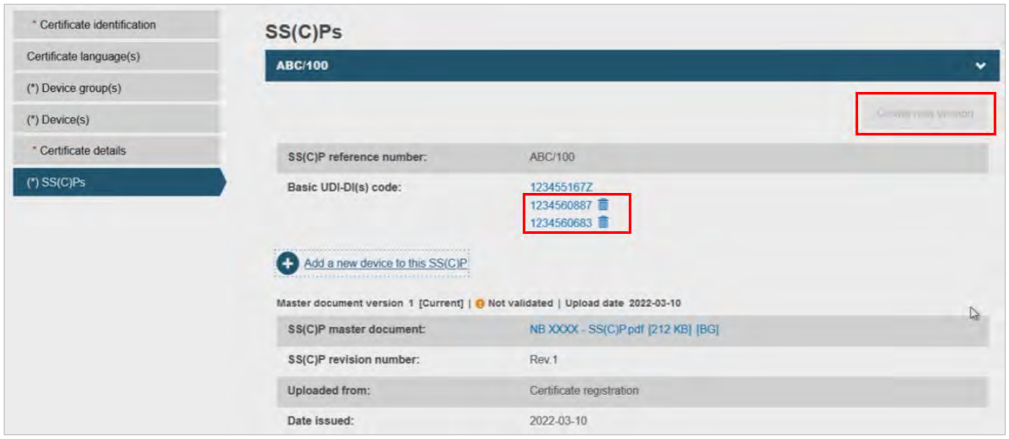
15. The system will display your newly created SS(C)P version for you to review. If you discover a mistake, you can click **Discard** and re-do the process, alternatively click **Save**:



16. Rather than create a new SS(C)P version, the Notified Body may instead link new devices to the original SS(C)P (version) by clicking *Add a new device to this SS(C)P*. Select the device(s) from the pop-up display, then click **Confirm**:

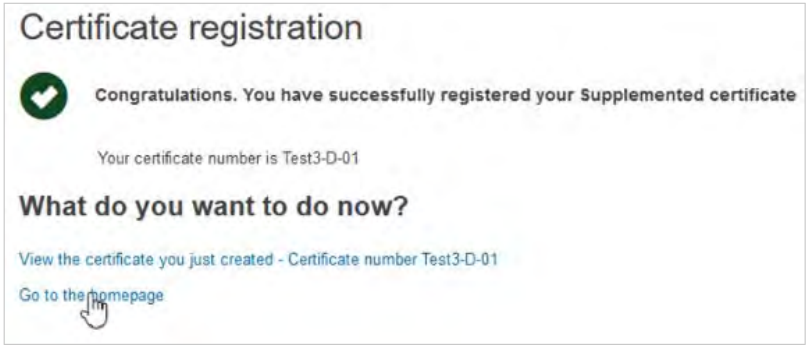


17. The selected device(s) will appear on the SS(C)P window, removable by clicking the dustbin icon. You will notice the **Create new version** button is now inactive, only reactivated if all newly linked devices are removed:



18. When you have fully reviewed all the information provided, click **Submit**:

19. The system will confirm the successful registration of the Supplemented certificate:

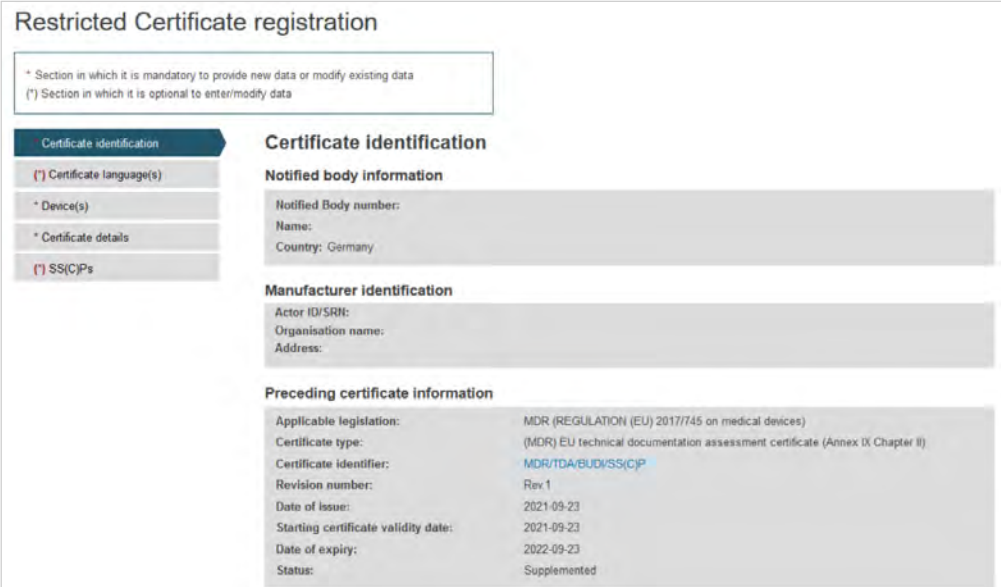


6.3 Restrict

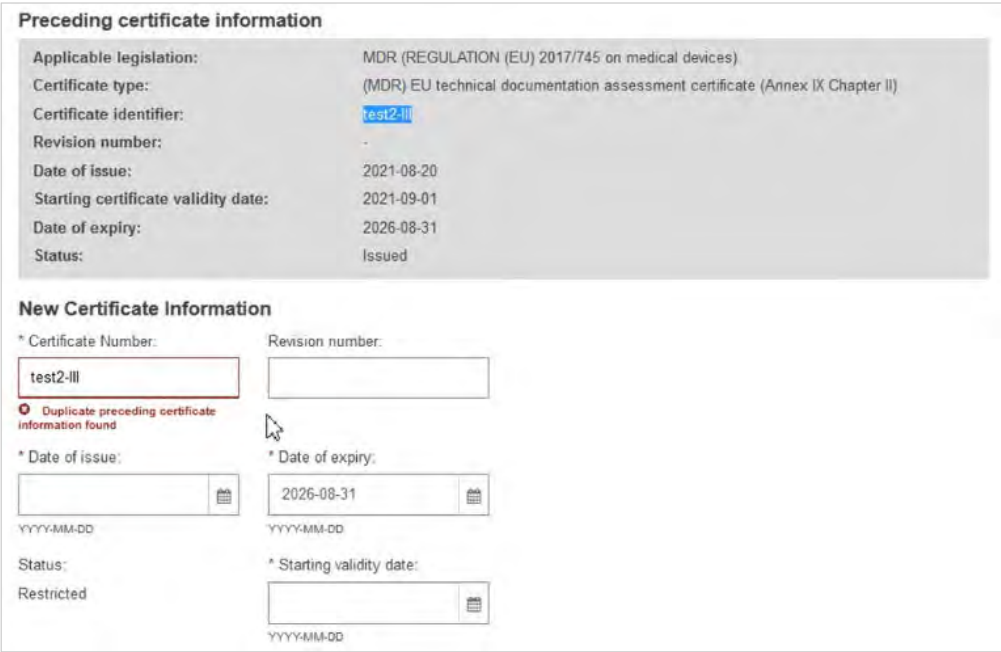
To restrict a certificate, click on the three dots next to the desired certificate and then from the dropdown menu, click **Restrict Certificate**:

On the next screen, you will find all information relevant to the specific certificate and a menu with different sections on the left.

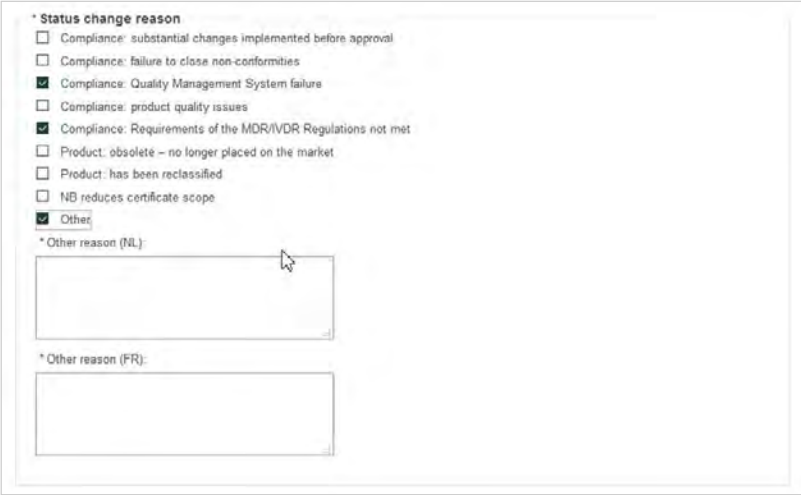
1. Complete the details for the default *Certificate identification* tab:



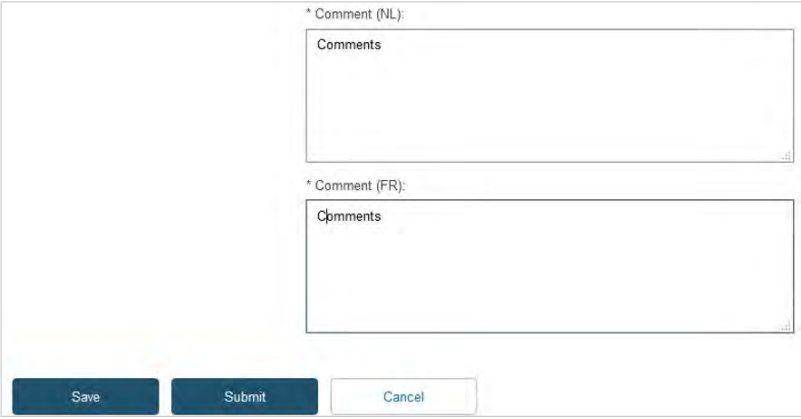
2. Scroll down and fill in the *New Certificate Information*:
   - The certificate number might change, if it is the case, enter the new *Certificate number* and a revision number. Alternatively, provide a Revision Number while keeping the same Certificate Number.
   - Select the date of expiry for this certificate and the starting date of validity of the restriction.



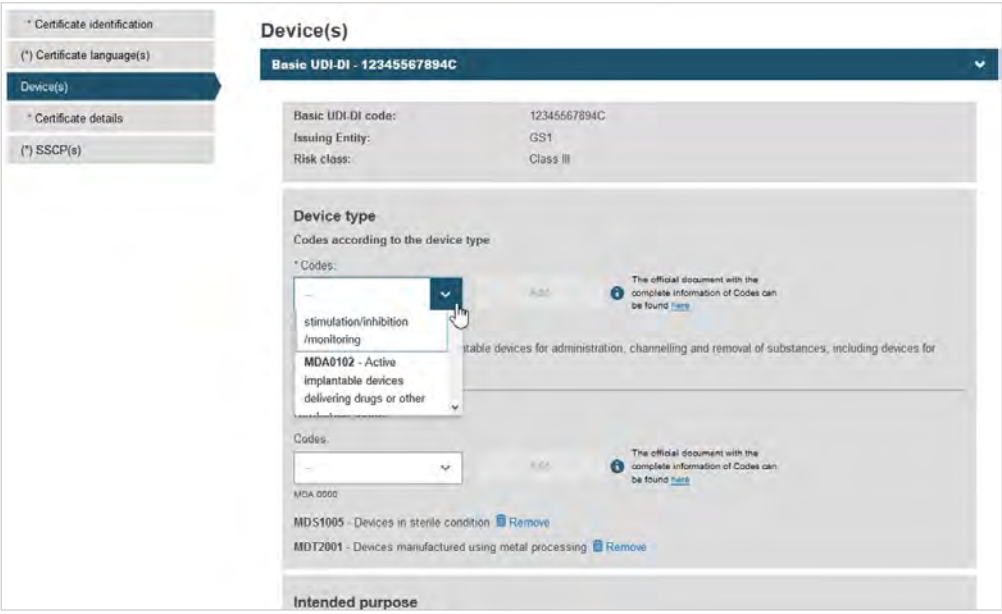
3. Scroll further down to the section *Status change reason* and select the reasons for the certificate's restriction (you can select more than one). In case you select *Other*, you **must** provide comments in all relevant languages of the specific certificate:



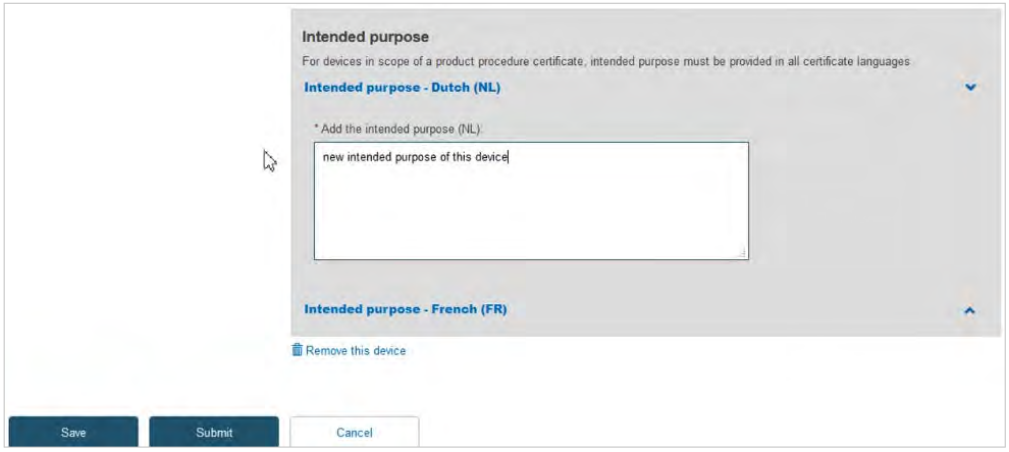
4. Provide comments in all the languages of the certificate and click **Save**:



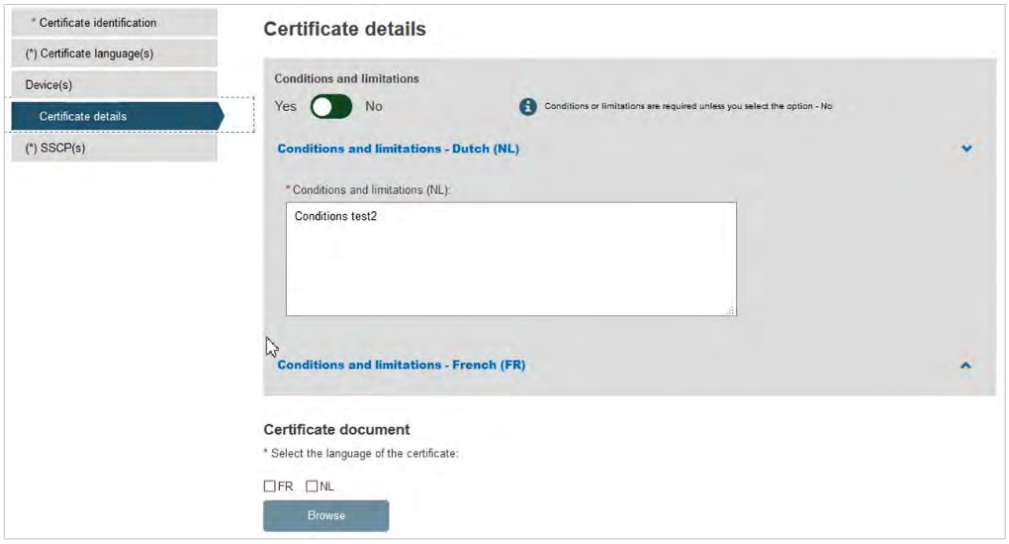
5. Review all information under the *Device(s)* section, e.g. intended purpose, and where needed/possible, update or remove information accordingly:



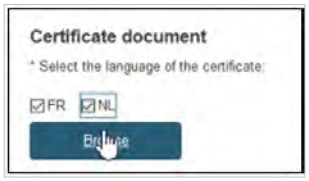
6. Fill in the intended purpose of the device in all the certificate's languages and click **Save**:



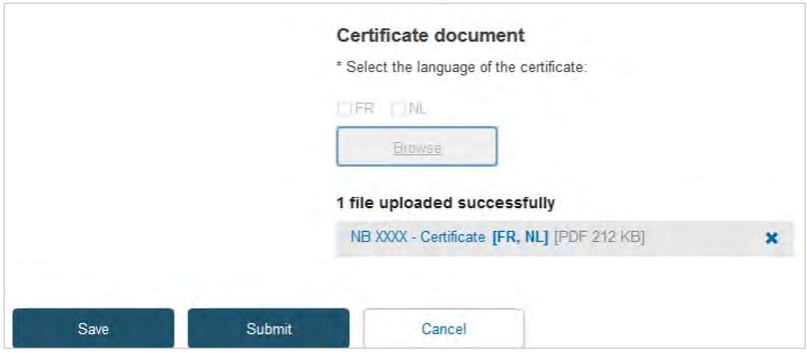
7. Review and update information under the *Certificate details* section in all relevant languages:



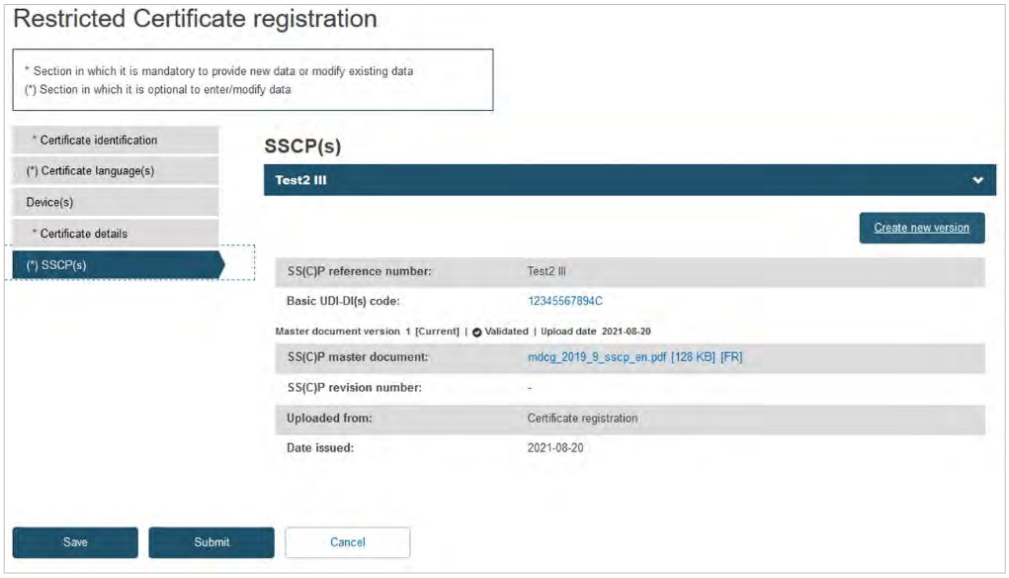
8. To provide the new Certificate document, tick the relevant languages and click **Browse** to upload the document(s) from your computer. You can upload either one document per language or one document covering all languages:



9. Once you have successfully uploaded the new certificate document(s), click **Save**:



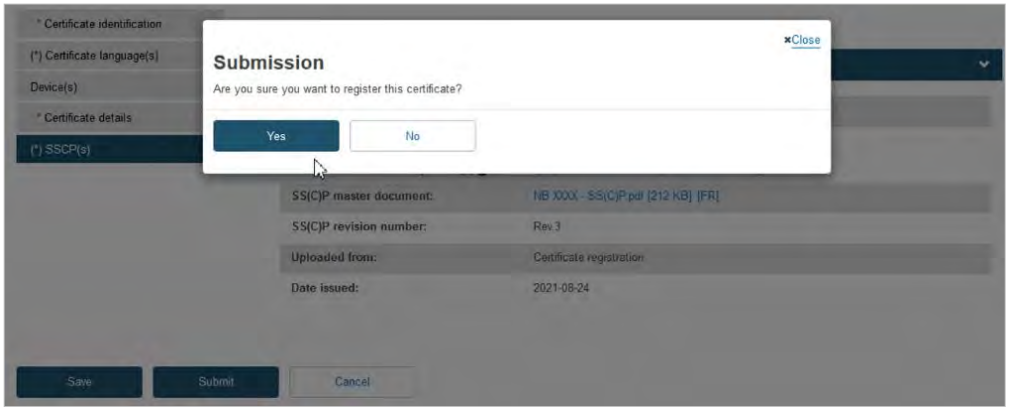
10. Click on the *SS(C)Ps* section from the menu on the left and click **Create new version**:



11. On the next screen, complete all the steps to create a new version, i.e. provide SS(C)P revision number, issue date, upload SS(C)P document and click **Confirm**:

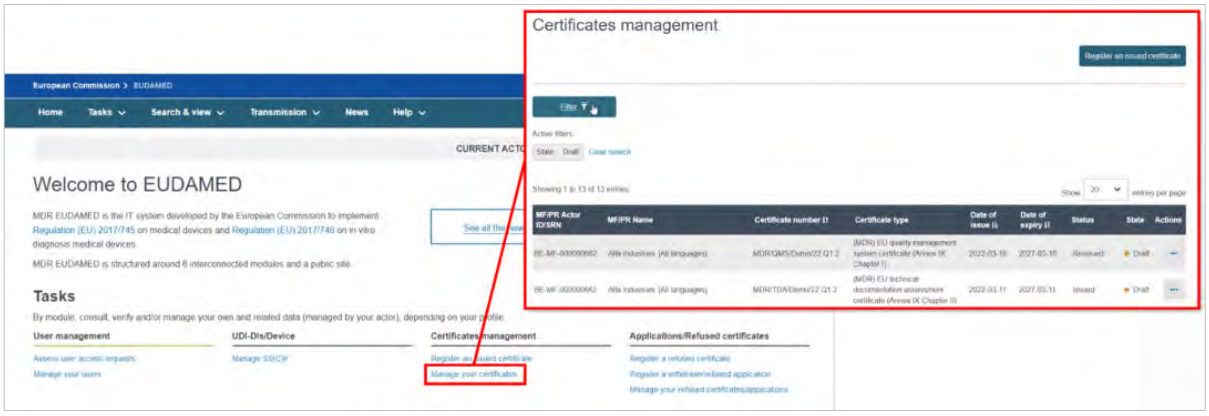
12. Next, the system will display your newly created SS(C)P version for you to review. If you discover a mistake, you can click **Discard** and re-do the process, alternatively click **Save**:

13. When you have fully reviewed all the information provided, click **Submit**. The system will prompt you to confirm your submission. Click **Yes** to complete the process:

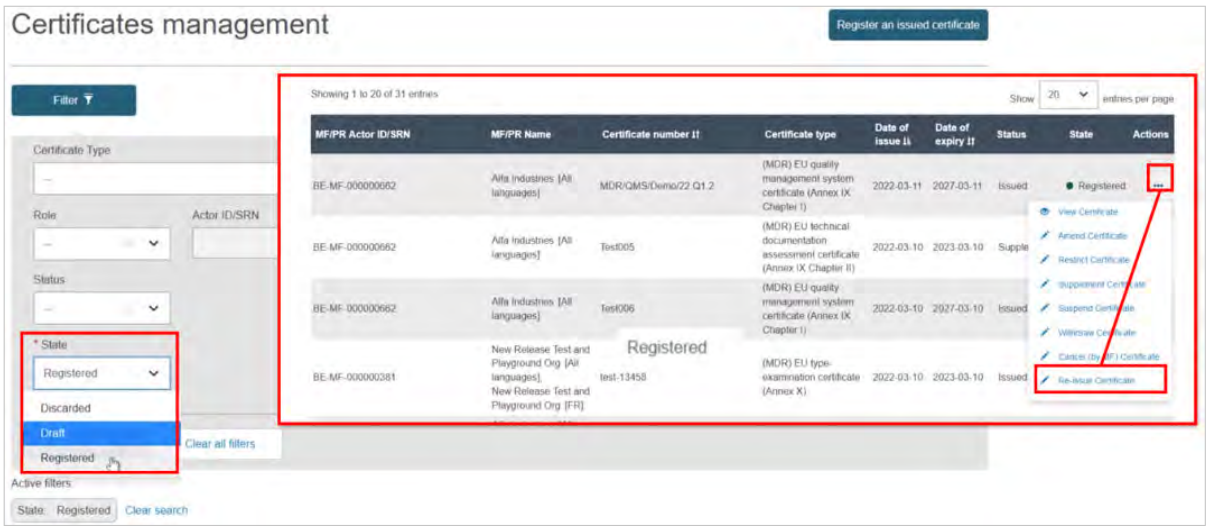


6.4 Re-issuing a Quality/Product certificate

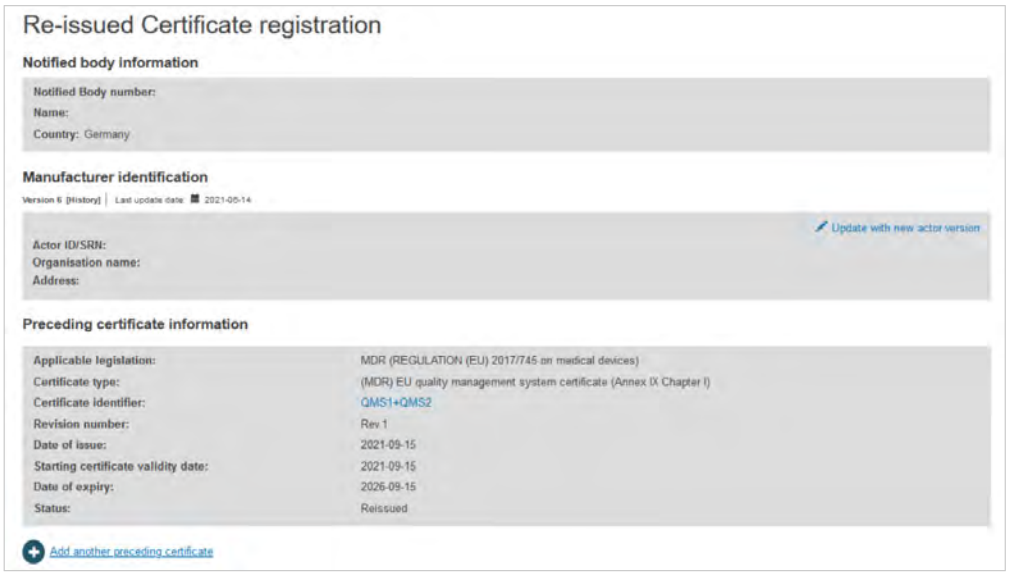
1. To re-issue a certificate, for example due to its imminent expiry, click on the **Certificates management** page then filter to identify the certificate you want to re-issue:



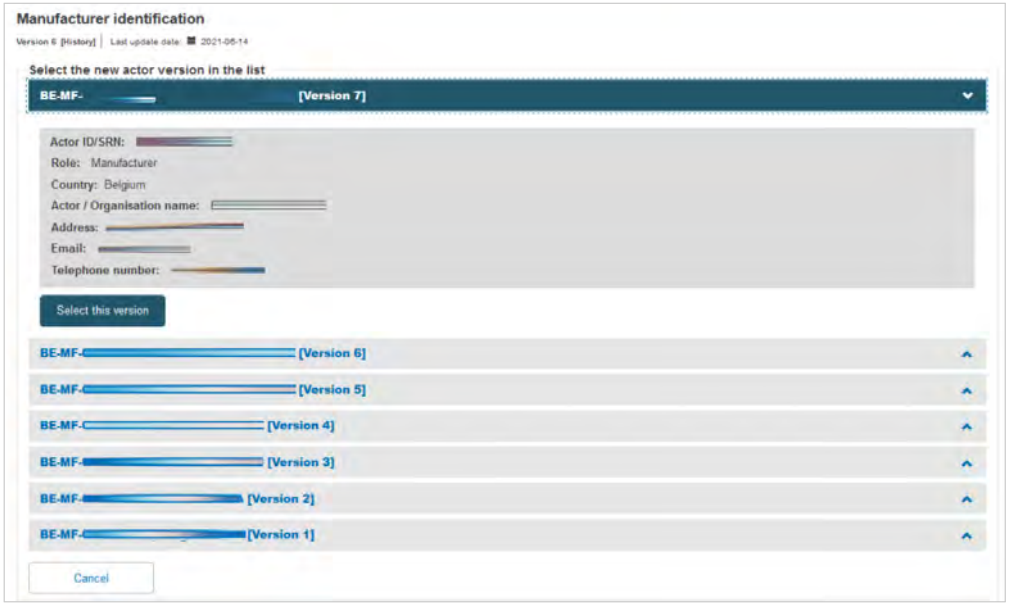
2. Select *Registered* as the state. From the list generated, in the *Actions* menu click the three dots next to the intended issued certificate and select **Re-issue Certificate**:



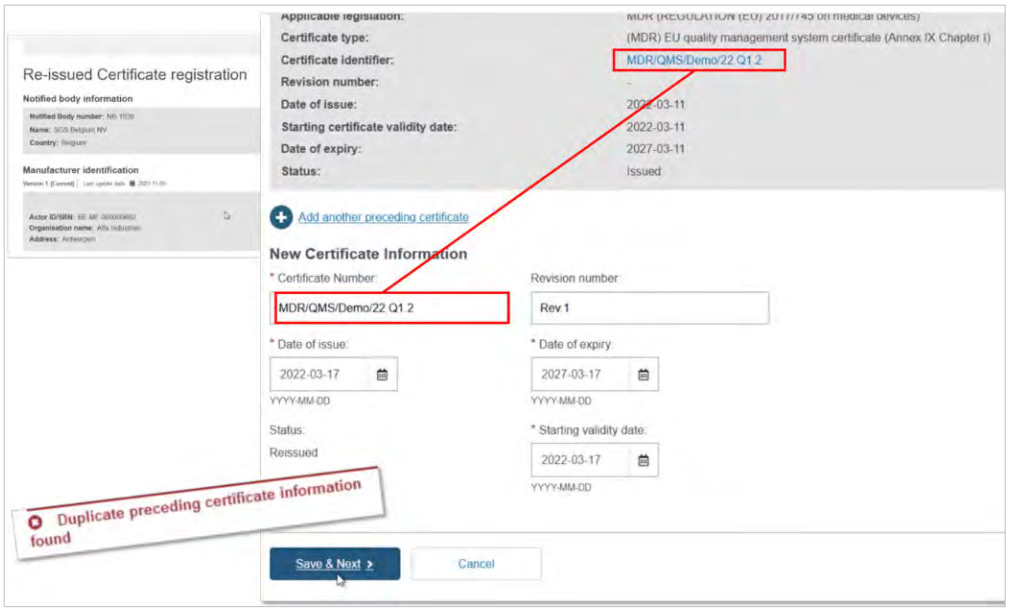
3. The next screen will display all relevant information of the certificate. If necessary, click **Update with new actor version**:



4. Select the right actor version from the list:

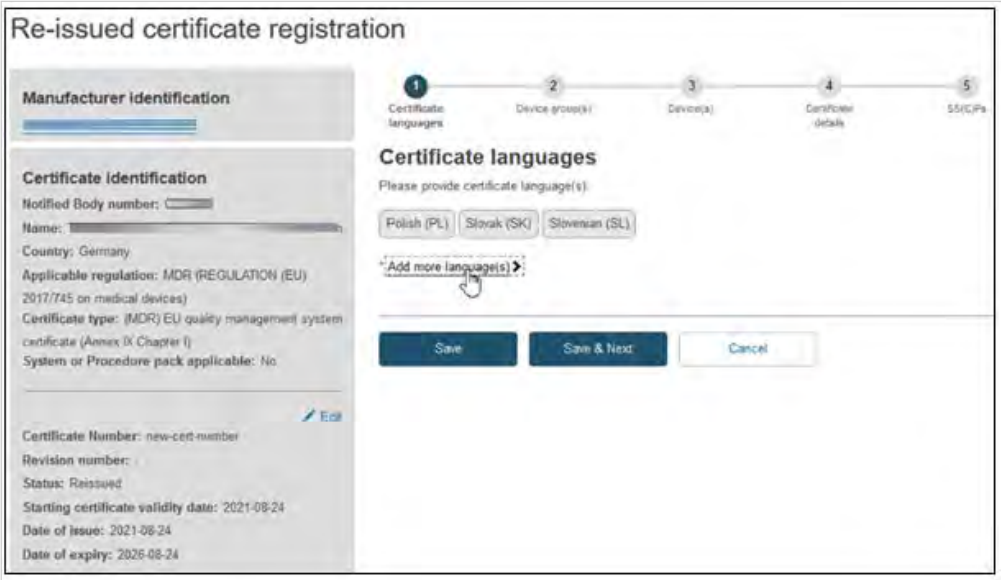


5. Scroll down to the *New Certificate Information* section. Duplicate the certificate identifier, and note the duplication warning message. Add a *Revision number* so it differs from the preceding certificate – the warning disappears. Select the new issue date, validity date and expiry date (noting the maximum period is five years). Now click on **Save & Next** to proceed:

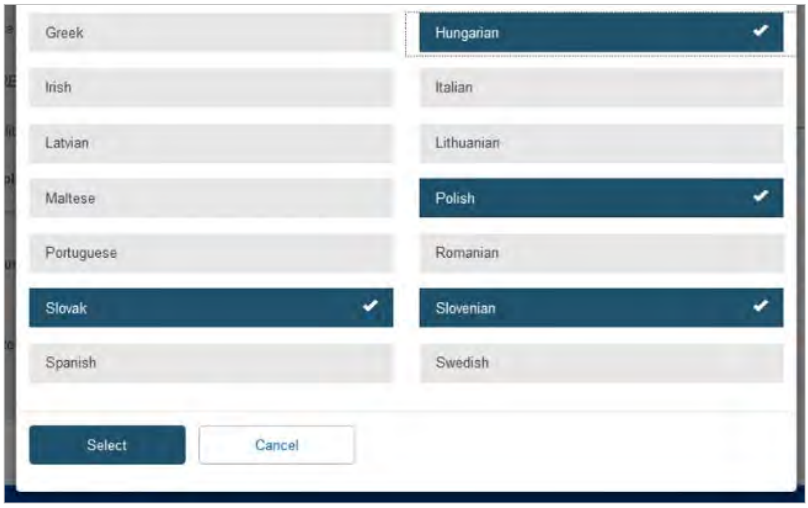


The next screen will display a timeline of steps to follow. Follow the order, starting from the first section *Certificate languages*.

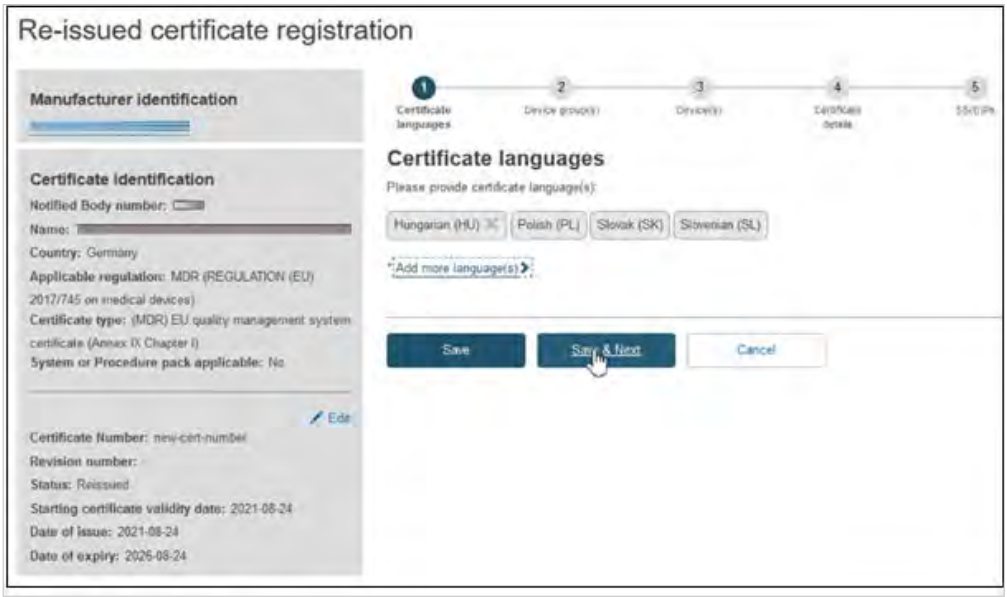
6. Click on **Add more languages** if necessary:



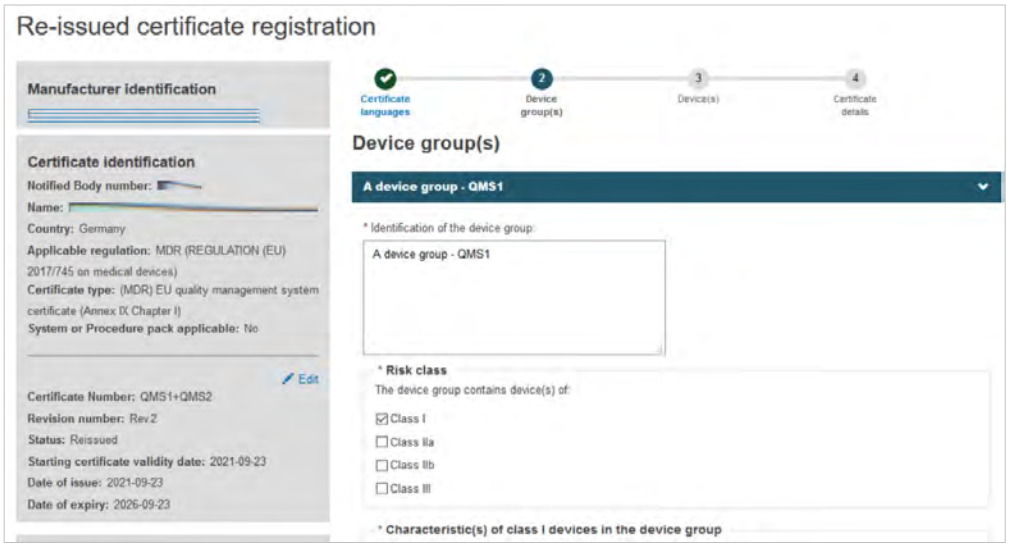
7. On the pop-up window, click on the desired languages and press **Select**:



8. Click **Save & Next** to proceed to the next section:

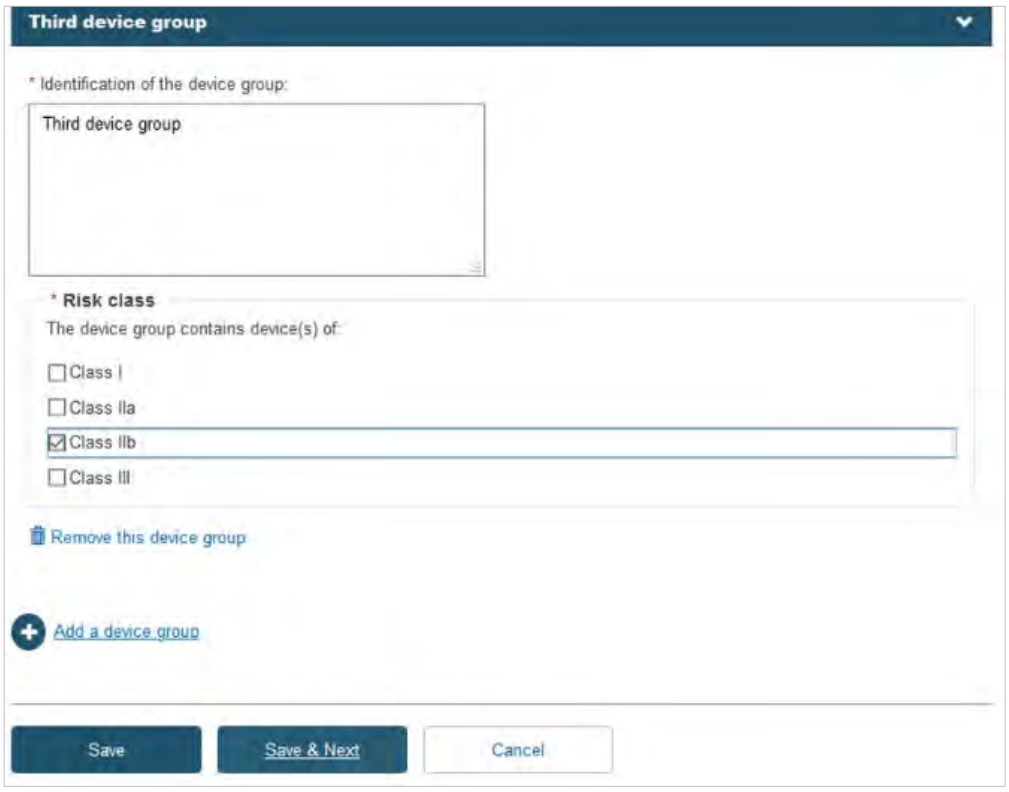


9. Fill in the information required to complete the *Device group(s)* step, when a certificate is re-issued, no change can be made.

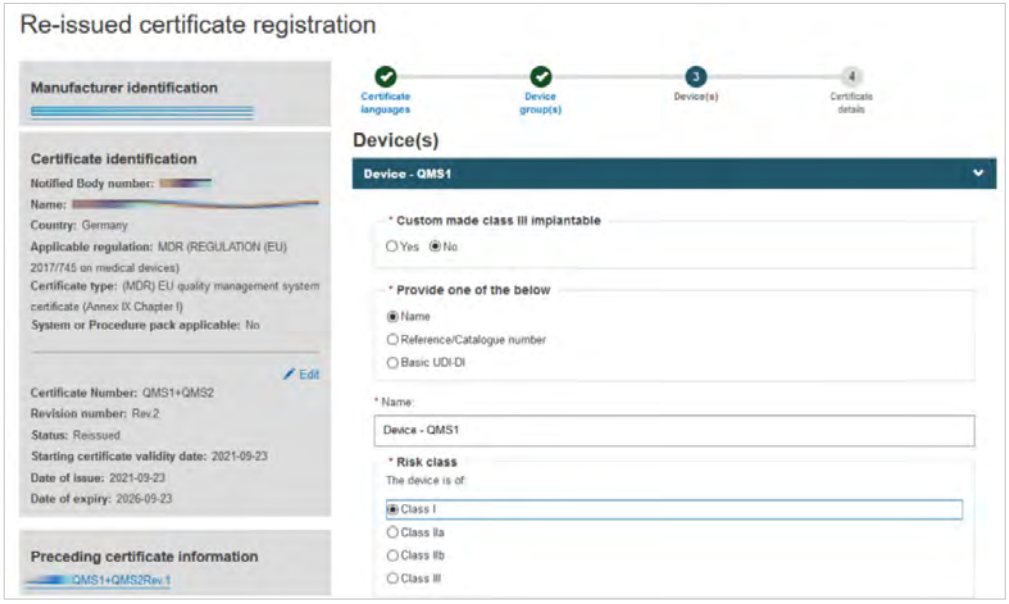


10. Click **+ Add a device group** and then again on the appearing *Device group* item:

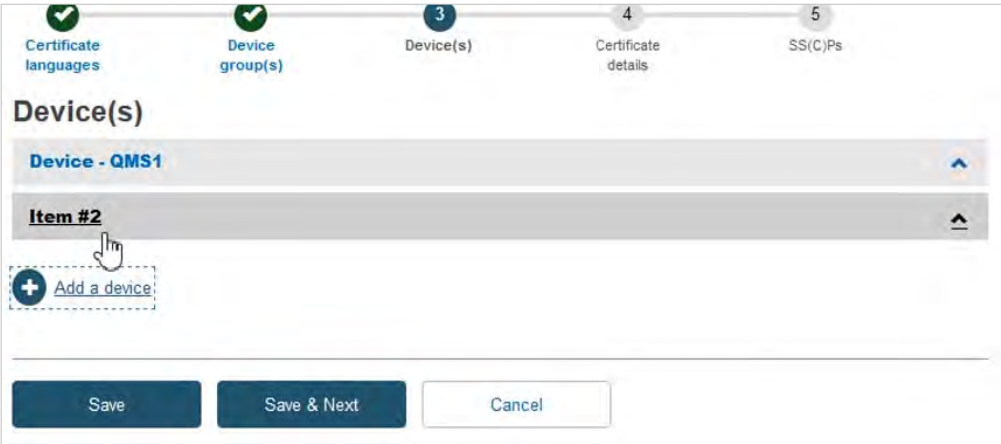
11. Fill in the required information and click **Save & Next**:



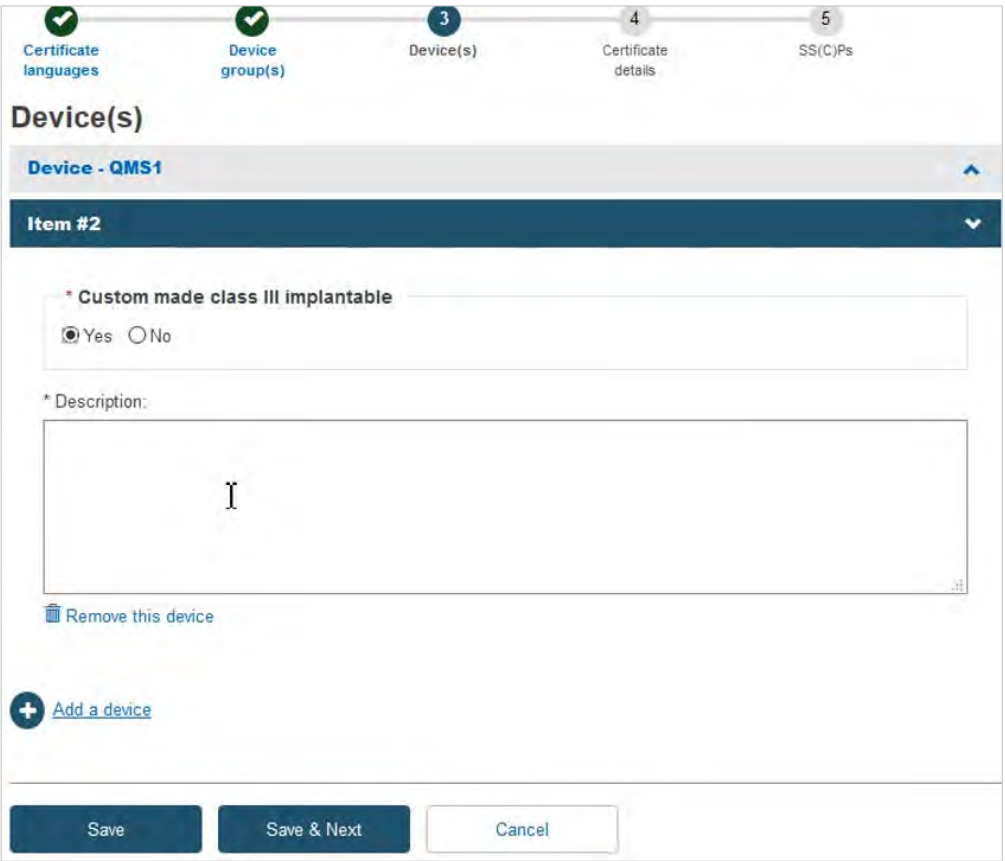
12. Fill in the information for the *Device(s)* step:



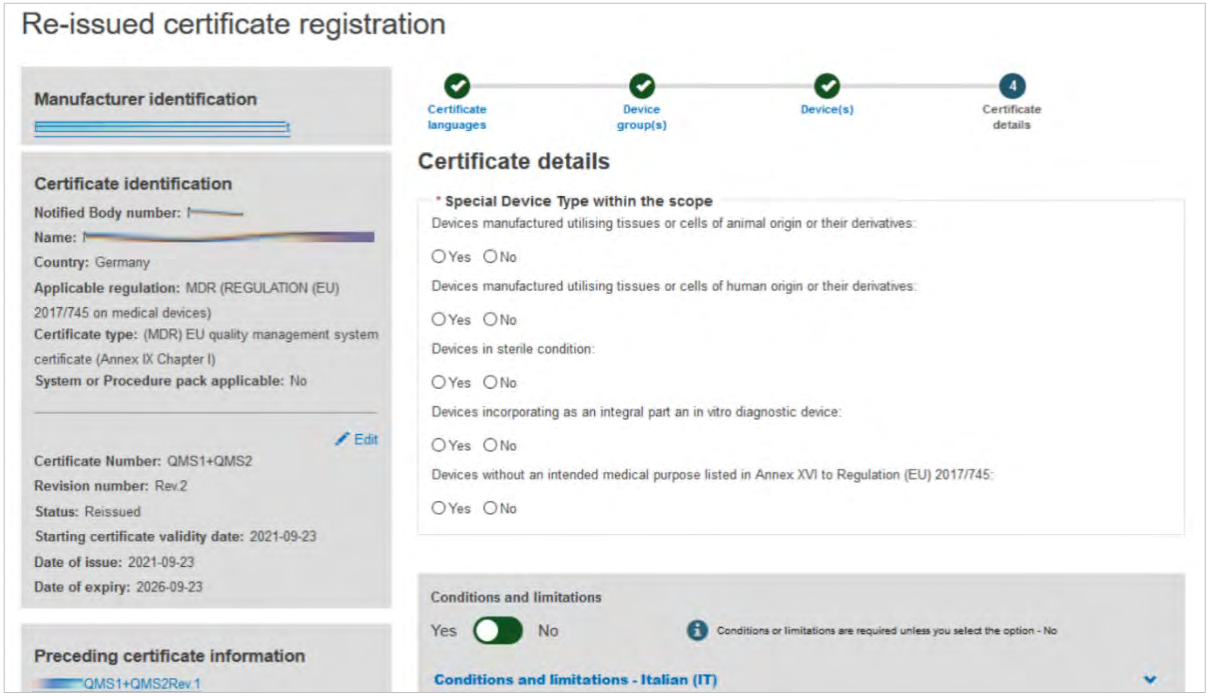
13. Click **+ Add a device group** and then click on the *Item* that displays under *Device(s)*:



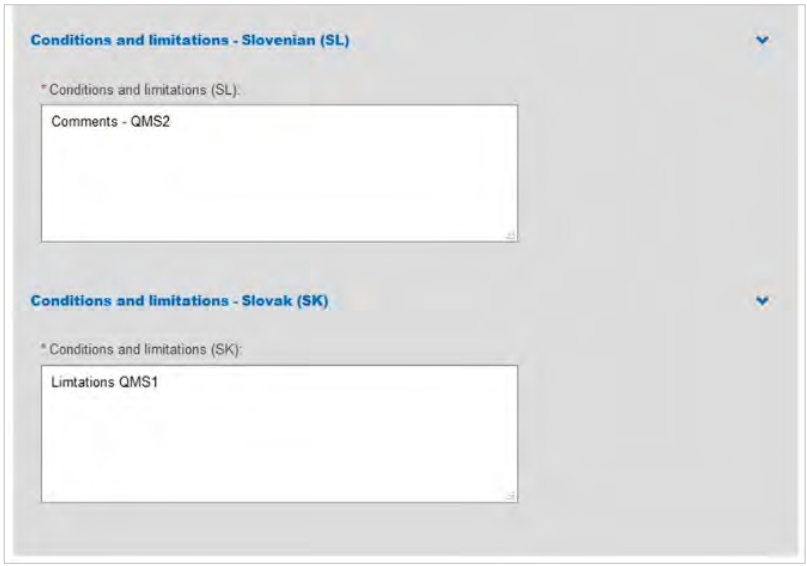
14. Add the required information to complete this step and then click **Save & Next**:



15. Fill in the information required to complete the *Certificate details* step:

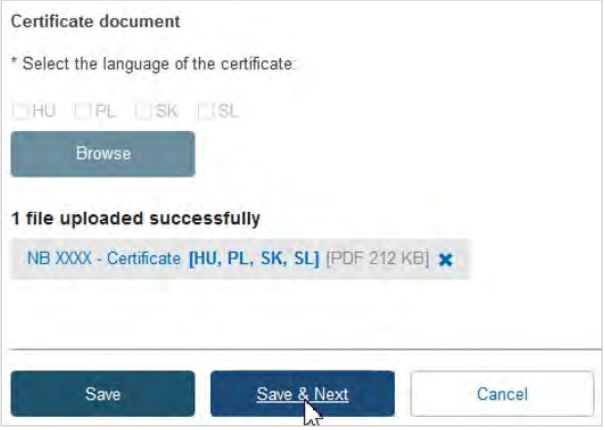


16. Provide comments regarding Conditions and Limitations in each language you selected:



17. To provide the new re-issued certificate document, tick the relevant languages and click **Browse** to upload the document(s) from your computer. You can upload either one document per language or one document covering all languages:

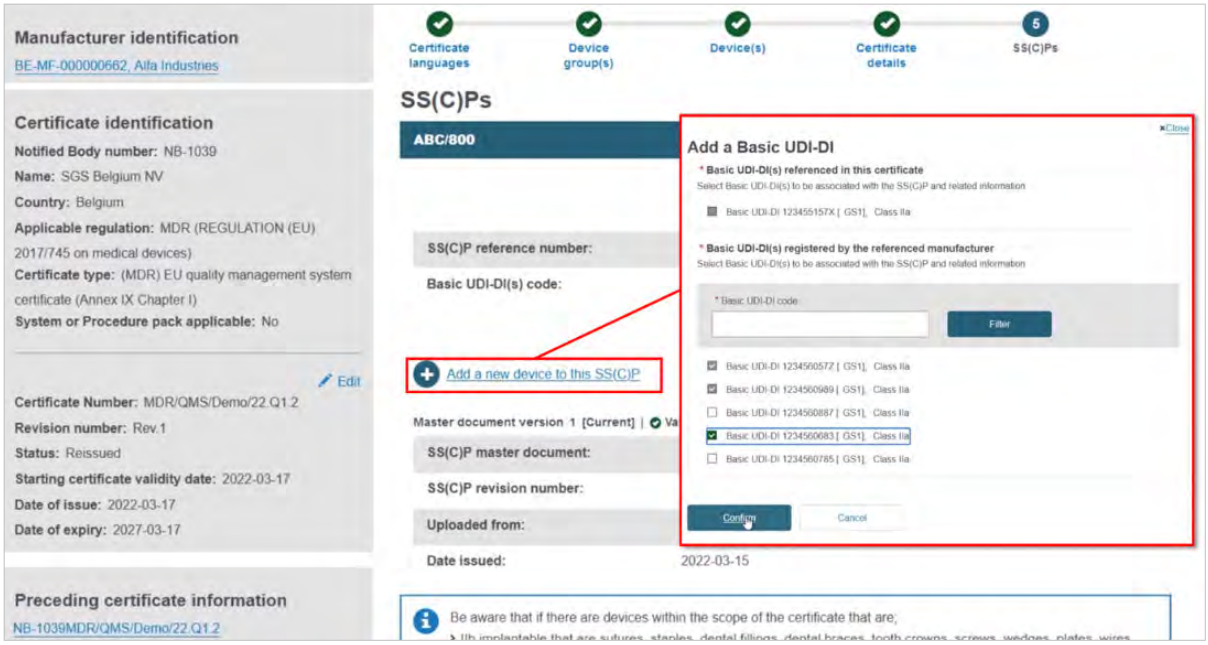
18. Once you have successfully uploaded the new certificate document(s), click **Save & Next**:



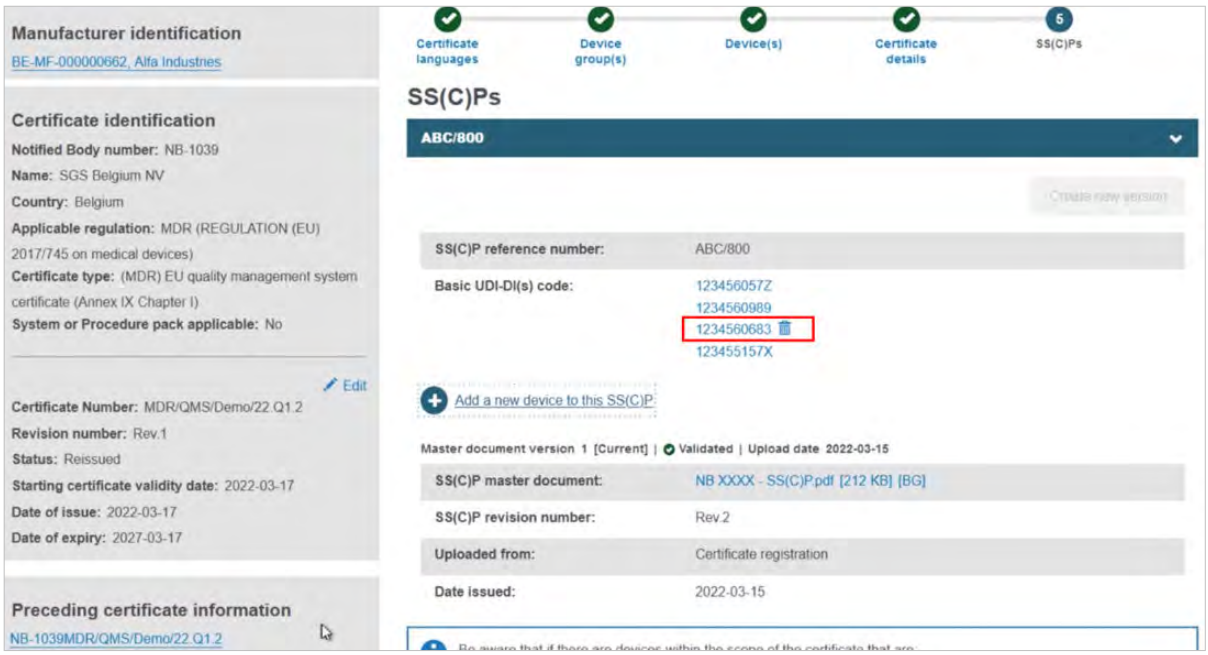
At this point, depending on the specifics of the certificate, the system may take you to the next step called *SS(C)Ps*. If not relevant for the specific certificate, this step will be omitted. You have three possibilities when adding new devices.

- **Add device(s) to an existing SS(C)P from the preceding certificate** (see *Step 19*).
- **Add device(s) to a new version of the SS(C)P from the preceding certificate** (see *Step 20*).
- **Add device(s) to a newly registered SS(C)P** (see *Step 21*).

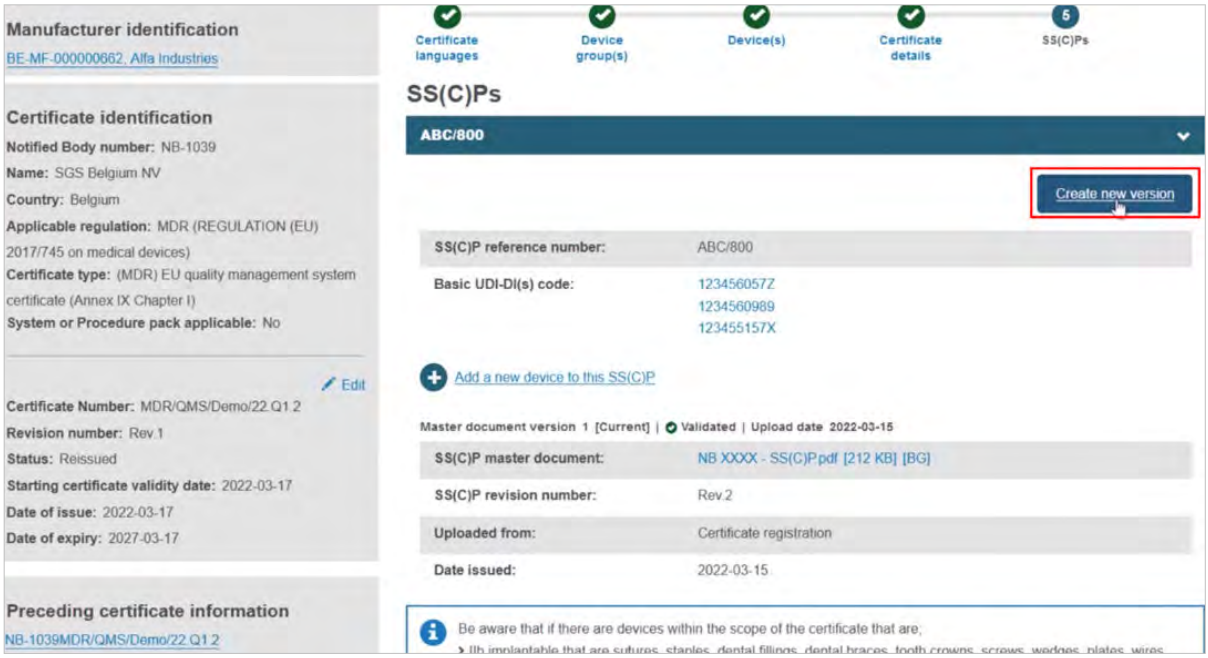
19. Add device(s) to an existing SS(C)P from the preceding certificate.
Click on **Add SS(C)P**. The existing devices show, but are inactive. Select any new device(s) and click **Confirm**:



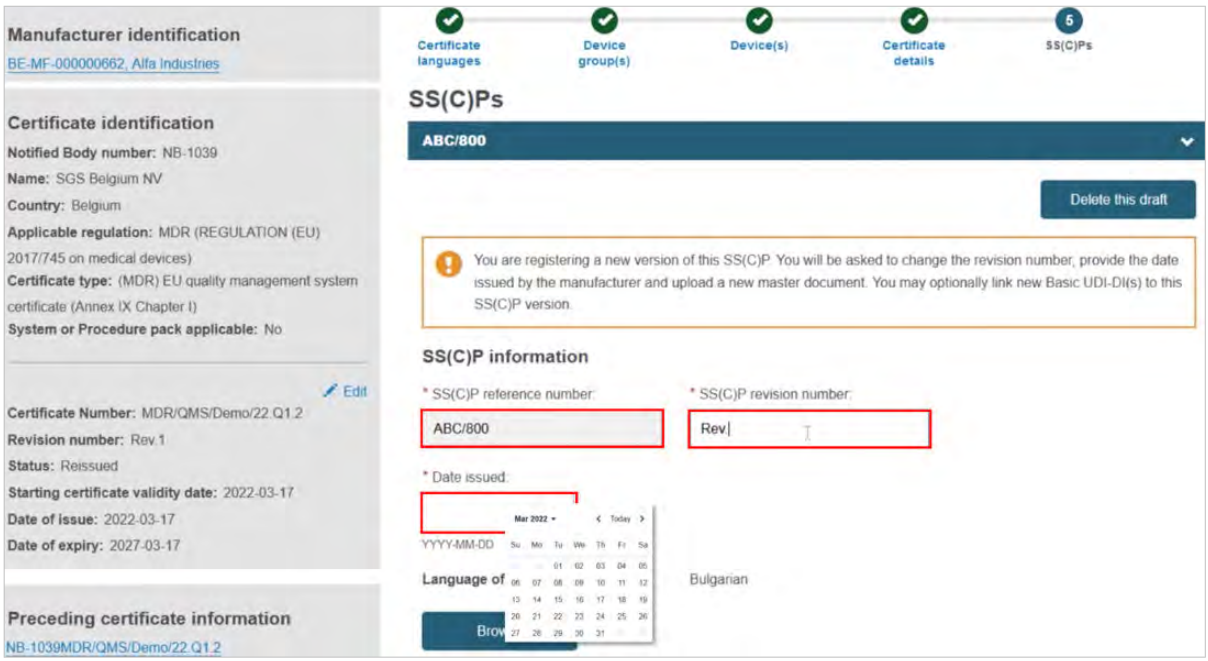
The new device appears next to the dustbin icon. If you save now, the new device will be linked to this version of the SS(C)P:



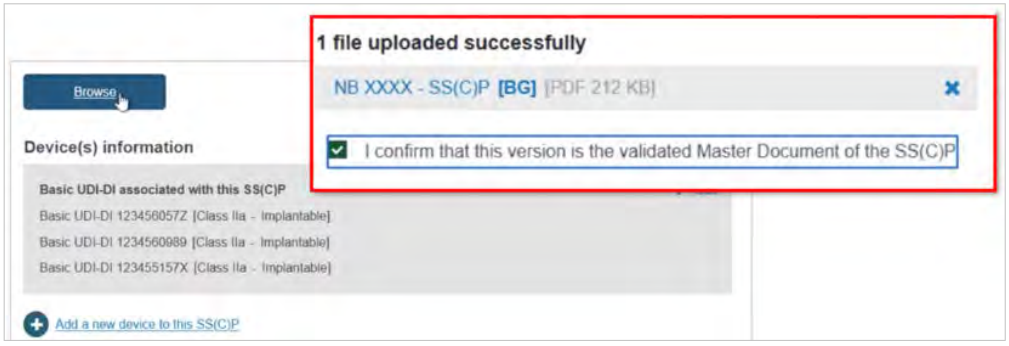
20. Add devices to a new version of the SS(C)P from the preceding certificate. With this approach, click **Create new version**:



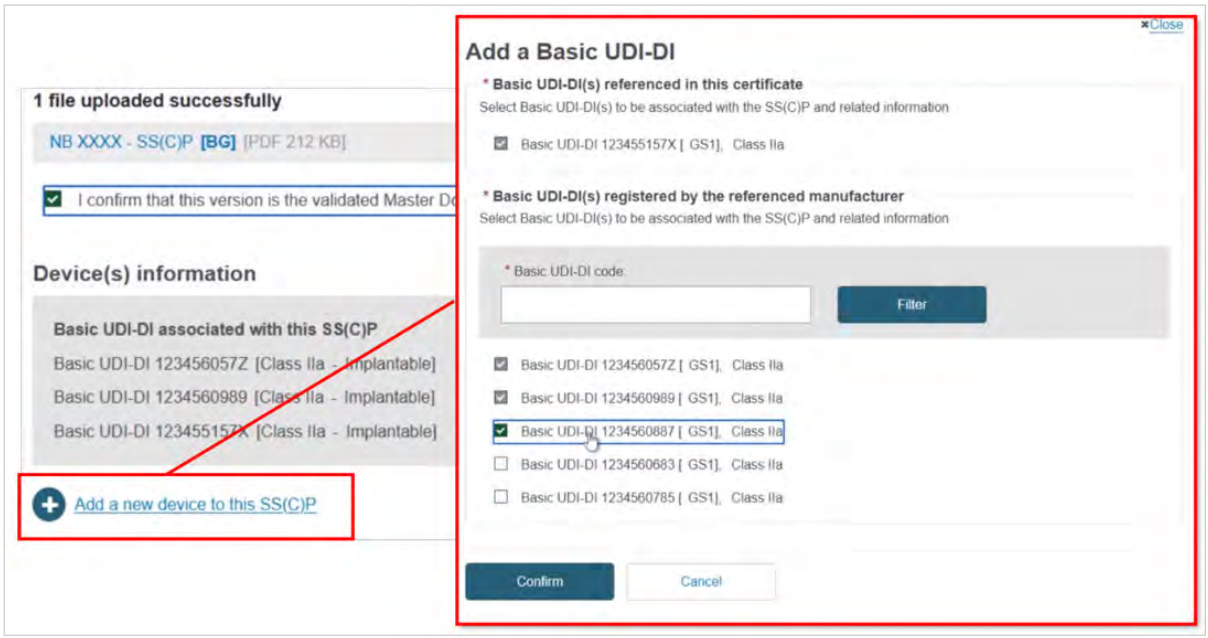
Input the SS(C)P reference number, and create a revision number, then specify the issue date:



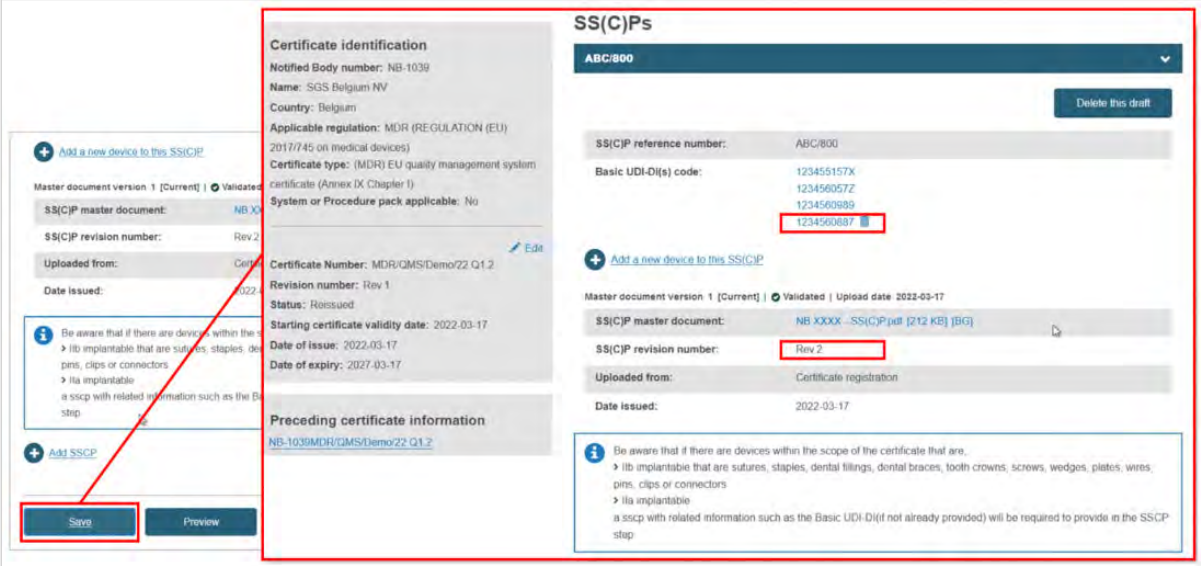
Click **Browse** to locate and upload the master document, and click to confirm it is validated:



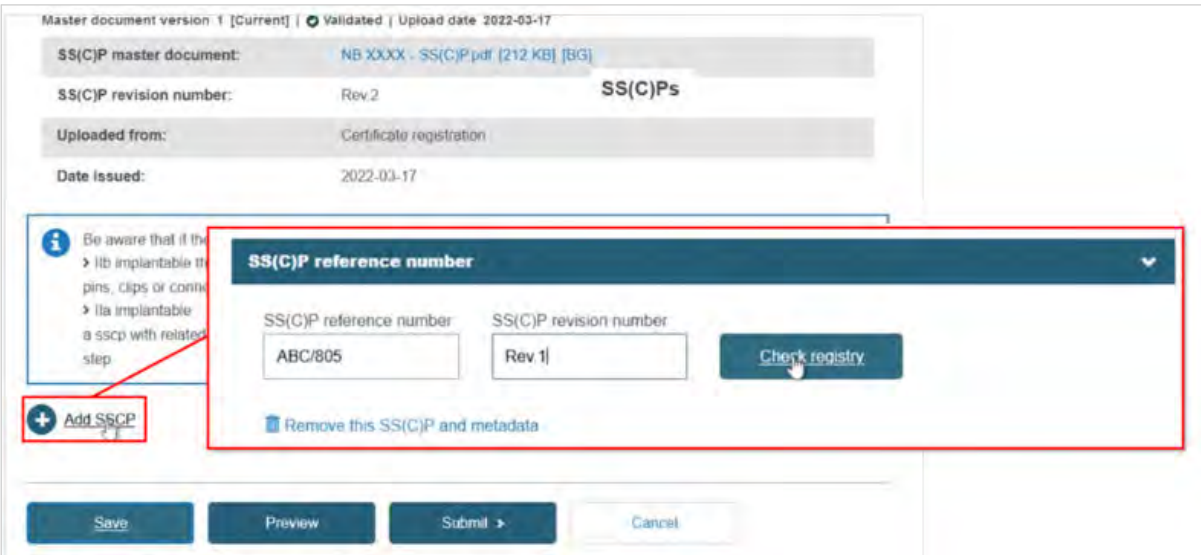
Click **+ Add a new device** to this SS(C)P, locate and select the new device, and click **Confirm** to link it to this new SS(C)P version:



Click **Save**, and when you register the certificate, this SS(C)P will be saved:

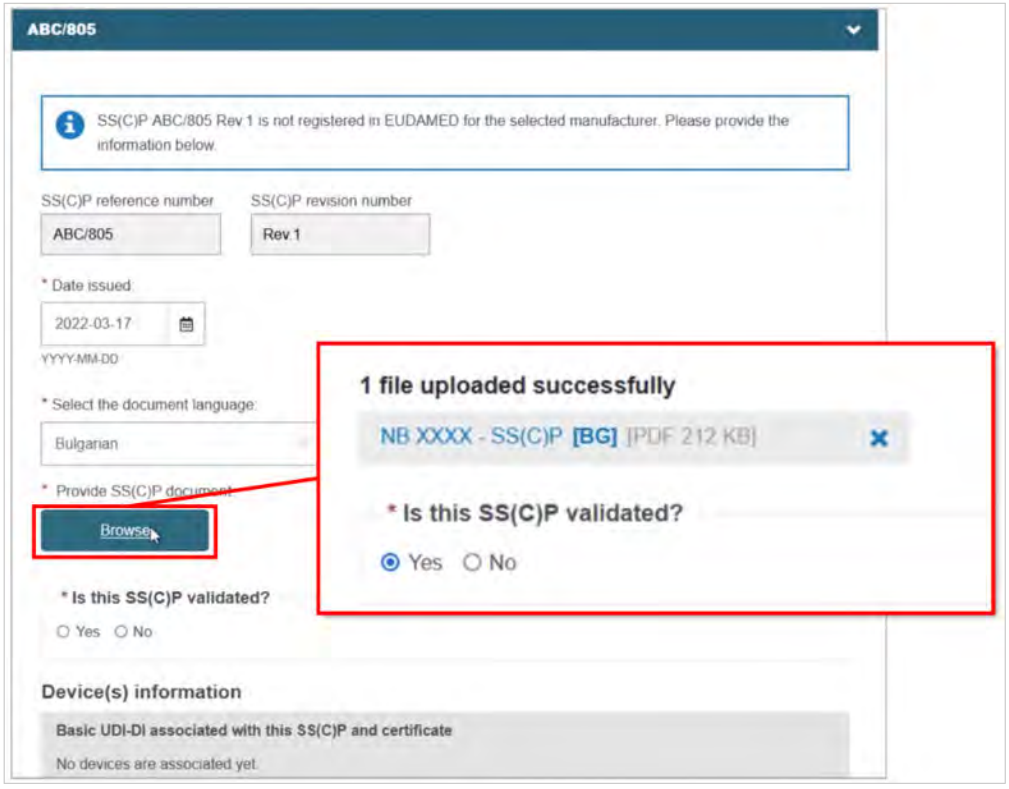


21. Registering a new SS(C)P, then adding device(s) to it. Click **+ Add SSCP**, then provide the reference and revision number:

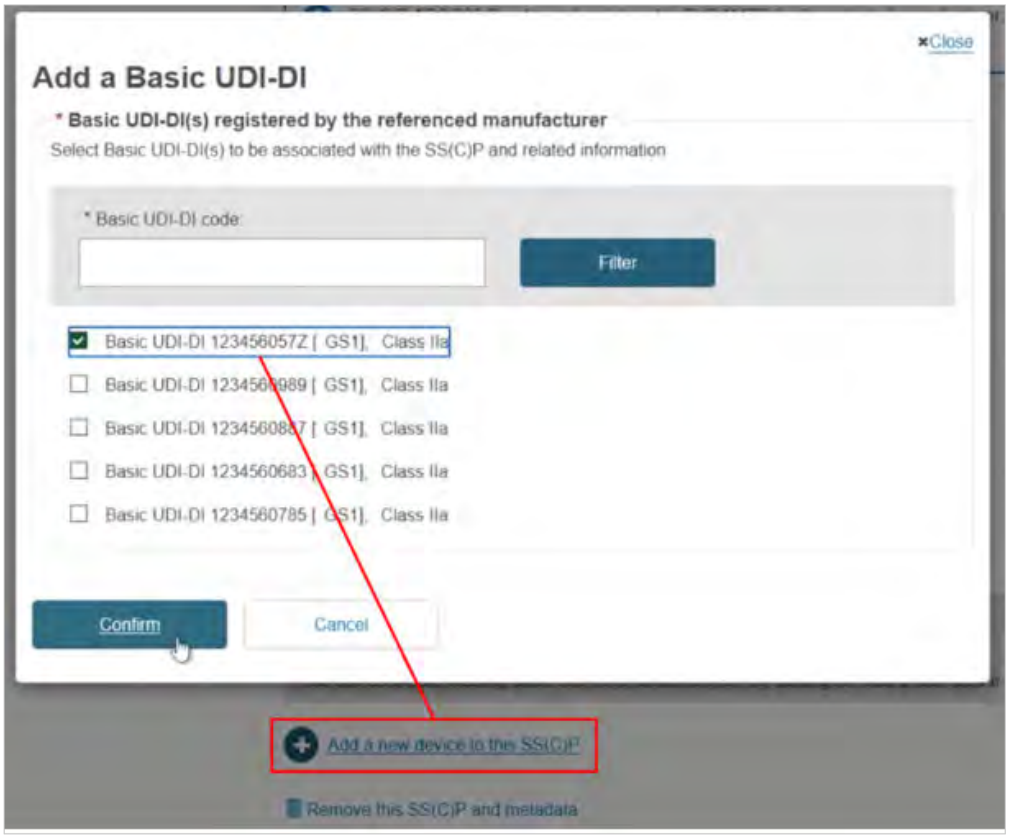


Click **Check registry**. The system will confirm this is a new SS(C)P:

Complete the fields for the new SS(C)P, including the master document language. Click **Browse** to locate and upload the master document, confirming it is validated (for Quality-type certificates):



Scroll to the bottom and click **+ Add a new device to this SS(C)P**, then select the device(s). Click **Confirm** and **Save**:

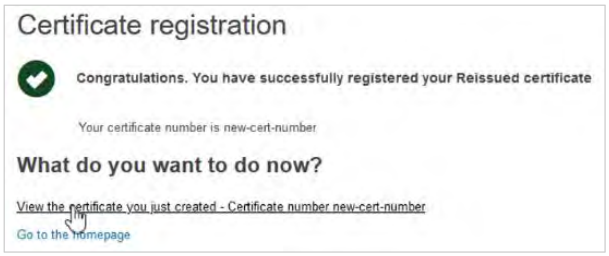


22. After having reviewed all information, click **Submit**:

The system will prompt you to confirm your submission of a re-issued certificate.

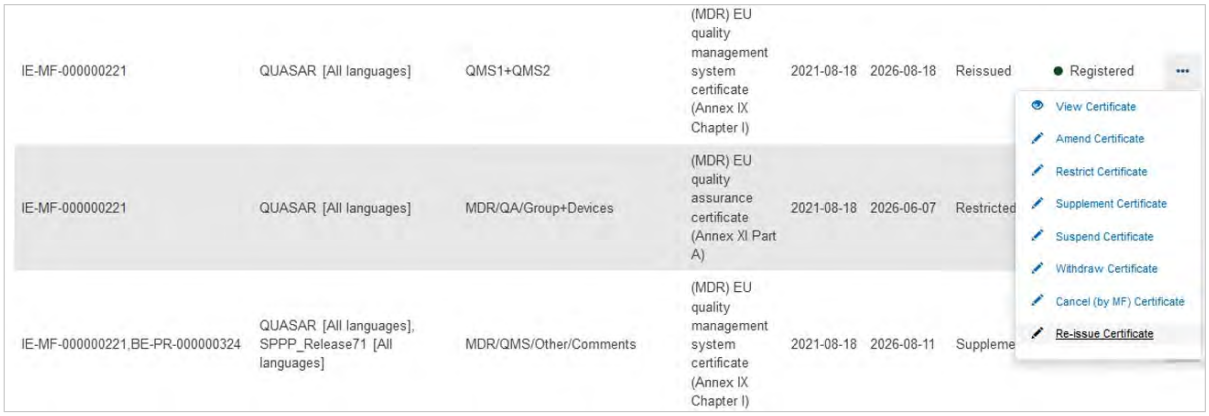
23. Click **Submit my request** to finalise the process:

24. The system will confirm your submission has been successful. You can also view the newly created certificate by clicking on the link provided:

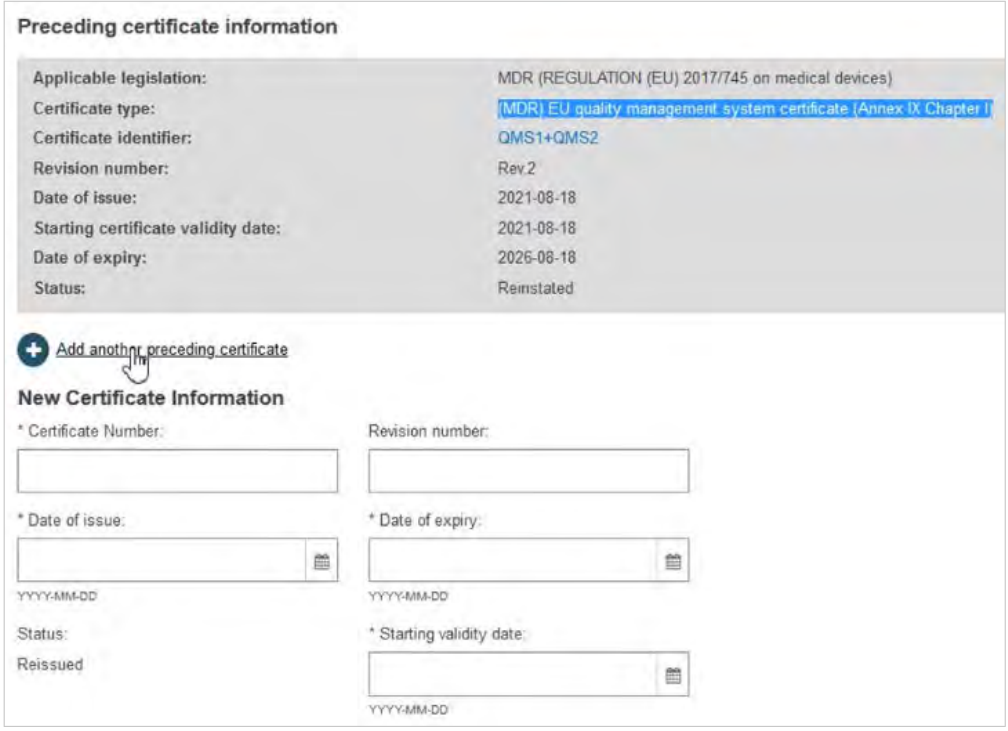


6.4.1 Merge certificates when re-issuing a Quality certificate

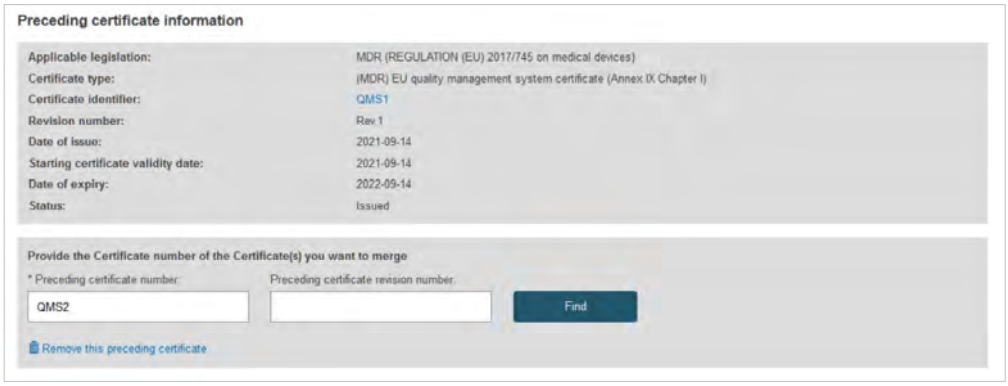
1. Click on the three dots next to the desired certificate, then click **Re-issue Certificate**:



2. On the next screen, click **+ Add another preceding certificate**:

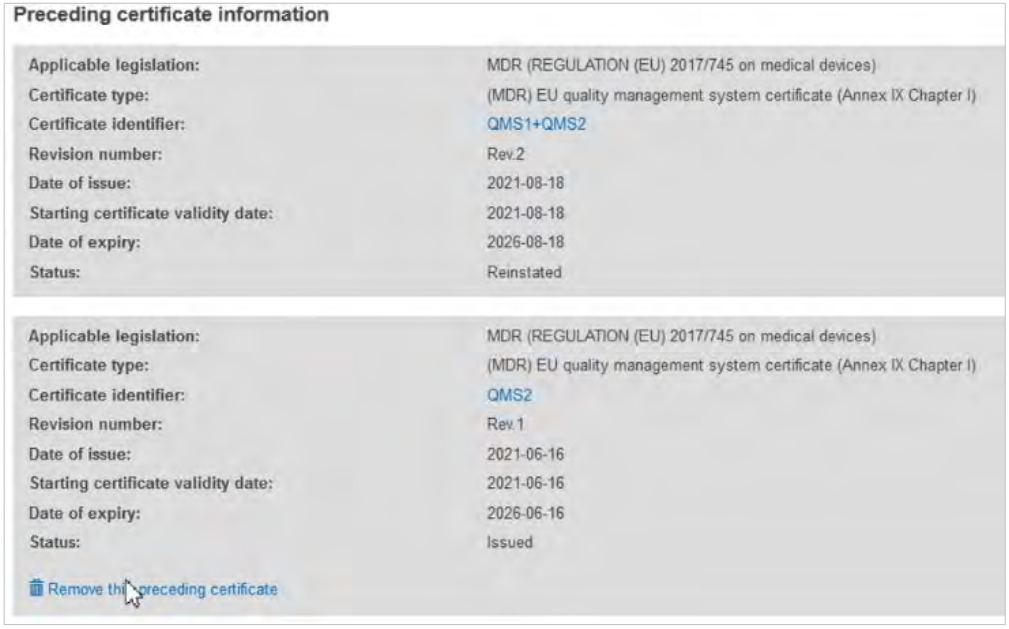


3. Type the new preceding certificate number and optional revision number then click **Find**:

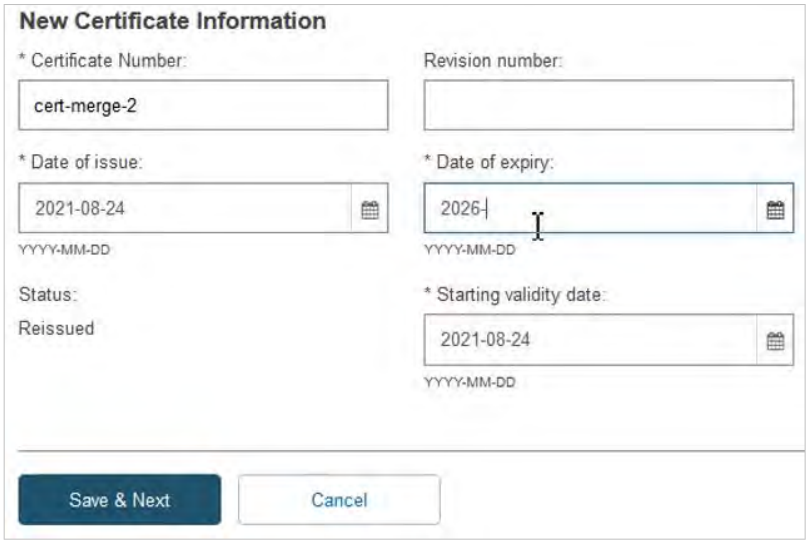


4. When there is more than one certificate with the same reference number and no revision number is provided, the system will display a selection dialog:

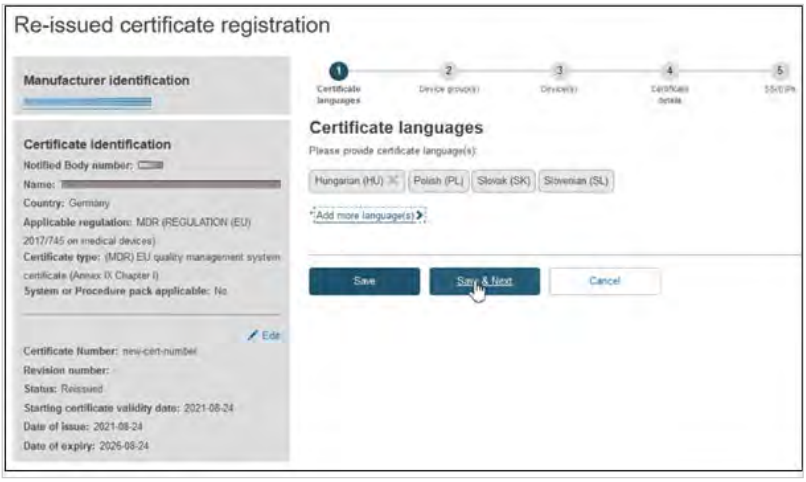
5. The new preceding certificate information will appear on the list. You have the option of removing it:



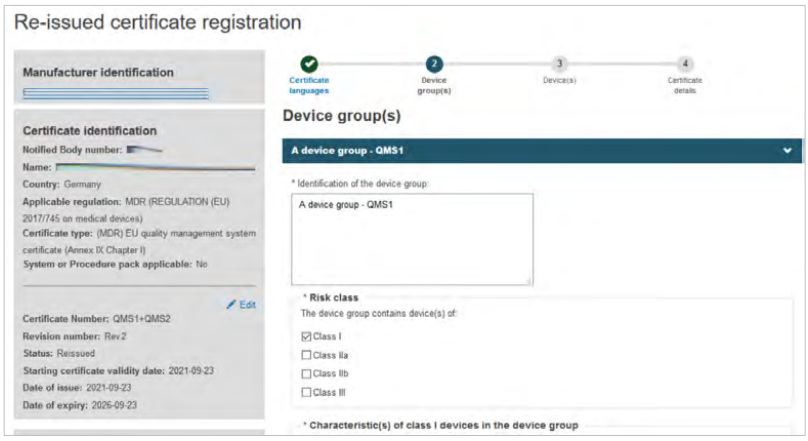
6. Next, fill in the *New Certificate Information* and click **Save & Next**:



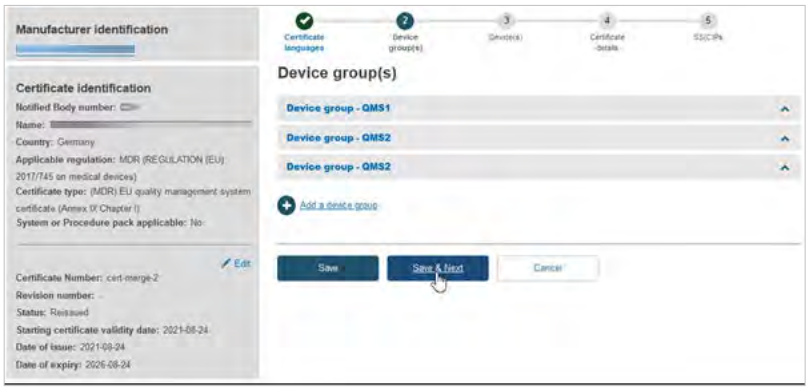
7. The next screen will display a timeline of steps. Follow the order, starting from the first section *Certificate languages*.
   Click **Add more languages** if necessary and click **Save & Next** to complete this step:



8. In the next step – *Device group(s)* – EUDAMED will populate the device groups from the preceding certificate(s), if any. Verify the merged certificate and fill in any required information:



9. To proceed to the next step, click **Save & Next**:



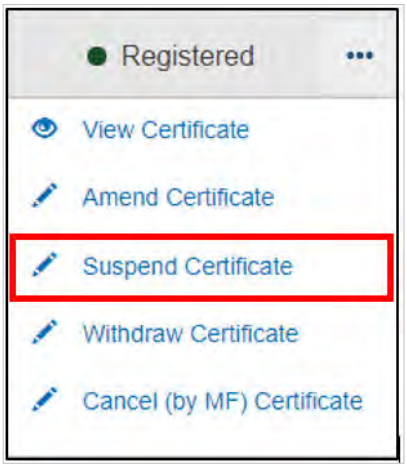
As the remaining actions to complete the process are identical to re-issuing a Quality certificate, please consult steps 11-20 of *Section 6.4* [54].

7 Decisions over a certificate

7.1 Suspend

1. Click on the **Certificates management** page and then filter to identify the certificate you want to suspend.

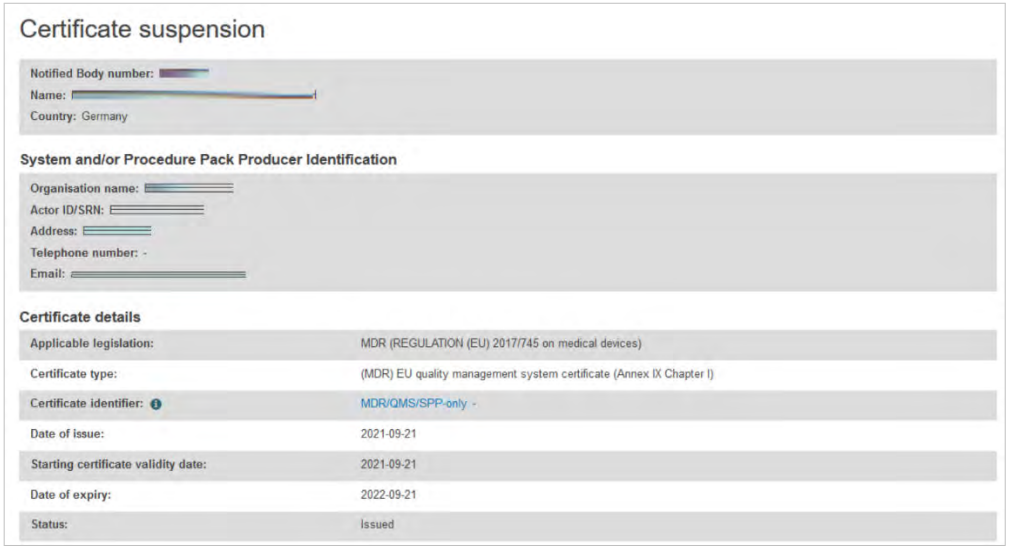
2. Click on the three dots under *Actions* and click **Suspend Certificate**:



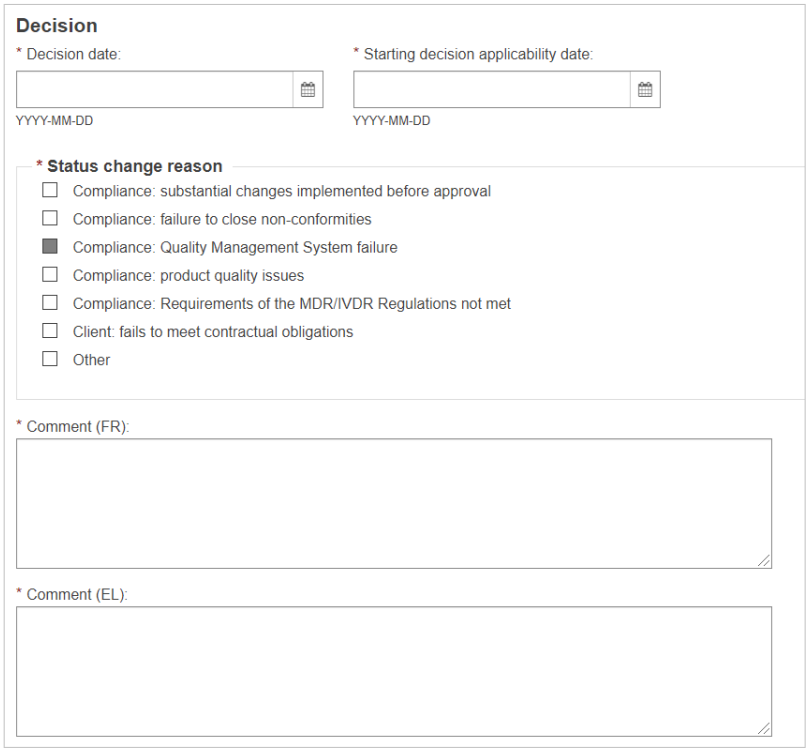
TIP
***Suspend Certificate* is missing?**

- Verify that your certificate is not in *Draft* state within the certificate management page.
- If a draft version exists, it must be registered or deleted. The *Suspend Certificate* operation will now be available.

3. You will arrive to the following page:



4. Below you will find the *Decision* section:



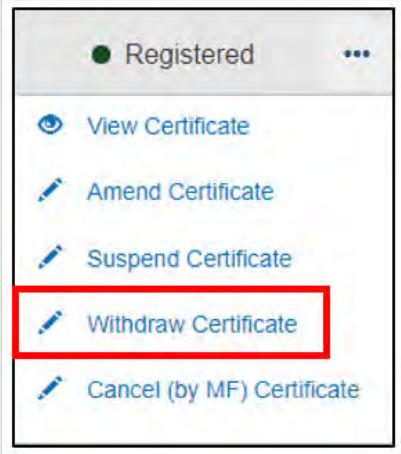
5. Enter the date when the decision to suspend the certificate was taken, the date it will apply from, and the reason for the suspension.

6. Upload the decision document in the correct language. Once you are done, click **Submit**.

7.2 Withdraw

1. Click on the **Certificates management** page then filter to identify the certificate you want to withdraw.

2. Click on the three dots under *Actions* to withdraw and click **Withdraw Certificate**:

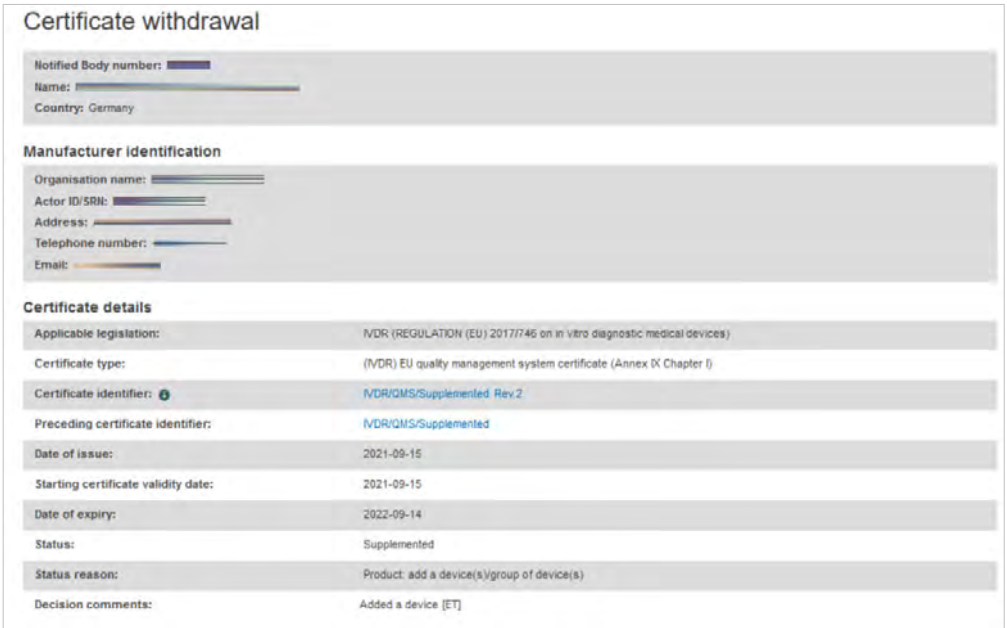


TIP
***Withdraw Certificate* is missing?**

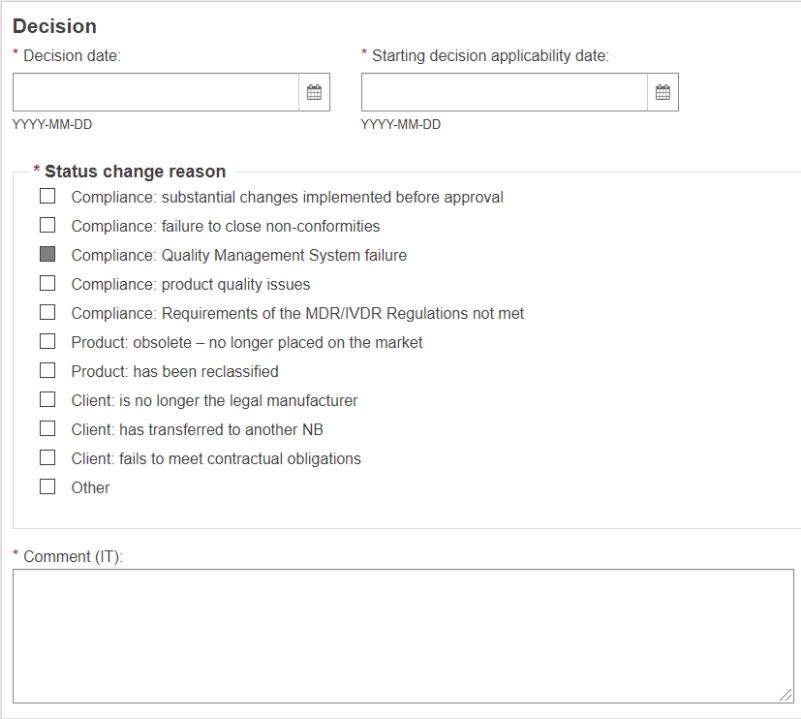
Verify that your certificate is not in Draft state within the certificate management page.

If a draft version exists, it must be registered or deleted. The *Withdraw Certificate* operation will now be available.

3. You will arrive to the following page:



4. Below you will find the *Decision* section:

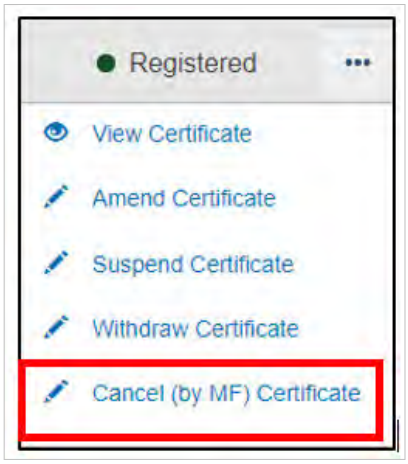


5. Enter the date when the decision to withdraw the certificate was taken, the date it will apply from and the reason it is being withdrawn.

6. Upload the decision document in the correct language. Once you are done, click **Submit**:

7.3 Cancel (by MF) Certificate

1. To cancel a certificate (by the manufacturer), click on the three dots under *Actions* to cancel and then click **Cancel (by MF) Certificate**:

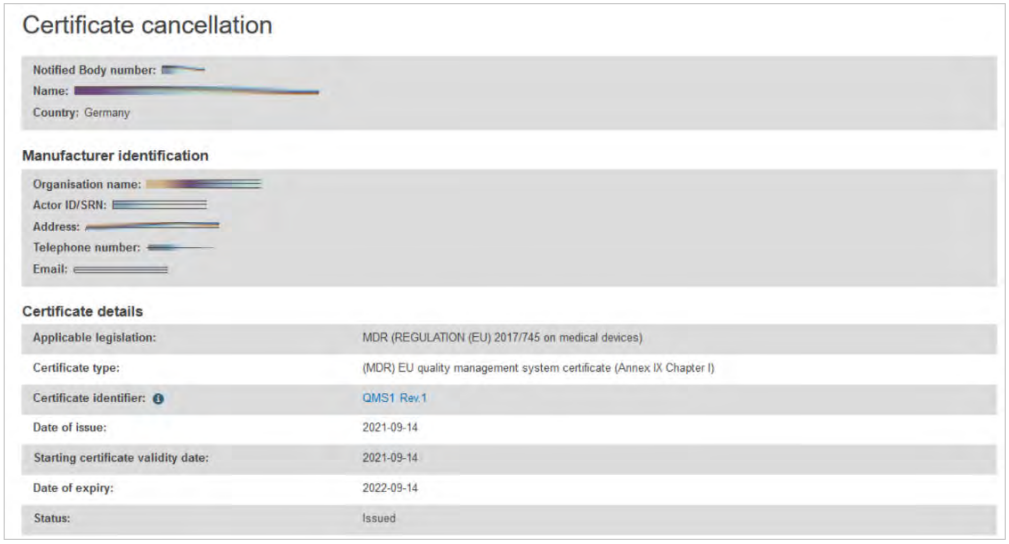


TIP

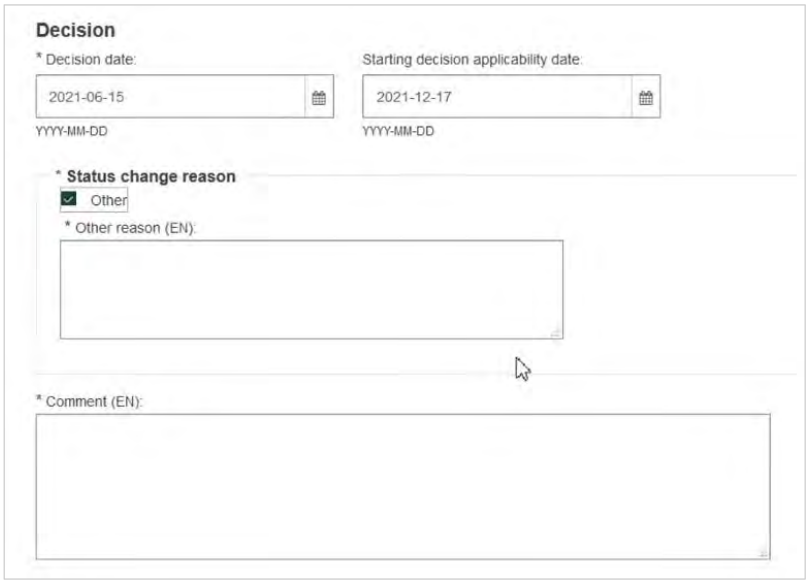
***Cancel (by MF) Certificate* is missing?**

- Verify that your certificate is not in Draft state within the certificate management page.
- If a draft version exists, it must be registered or deleted. The *Cancel (by MF) Certificate* operation will now be available.

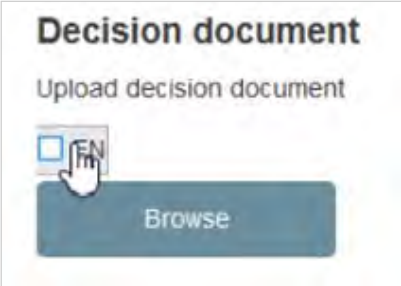
2. You will arrive to the following page:



3. Below you will find the *Decision* section. Enter the date when the decision to cancel the certificate was taken, the date the cancellation applies from, and the reason for the cancellation:



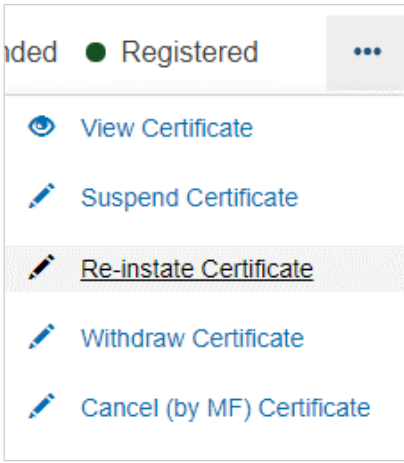
4. Upload the decision document in the correct language:



5. Once you are done, click **Submit**.

7.4 Re-instate

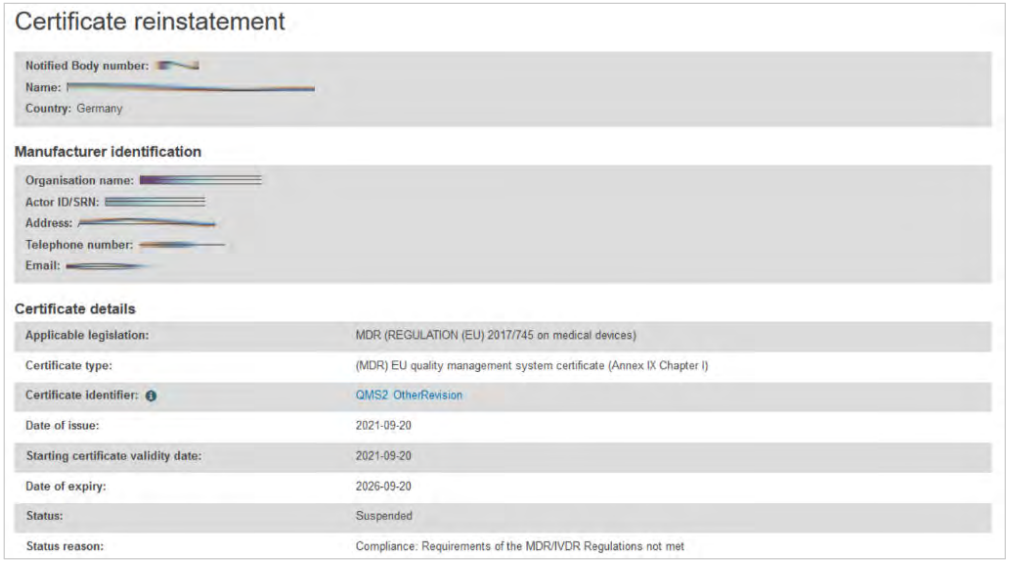
1. To re-instate a certificate, click on the three dots under *Actions* to reinstate and click **Re-instate Certificate**:



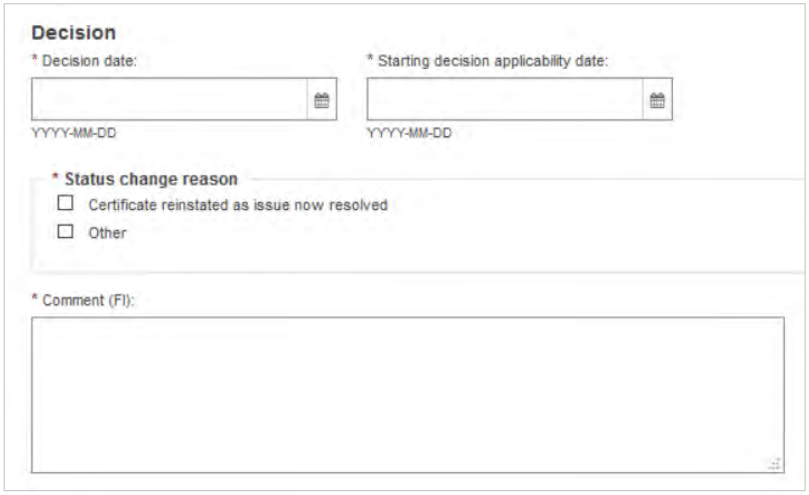
TIP
***Re-instate Certificate* is missing?**

- Verify that the status of the certificate is Suspended'.
- Only suspended certificates can be reinstated.

2. You will arrive to the following page:

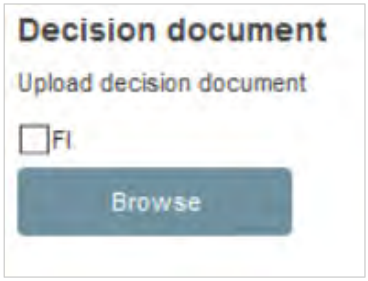


3. Below you will find the *Decision* section:



4. Enter the date when the decision to reinstate the certificate was taken, the date from which the reinstatement applies, and the reason for the reinstatement.

5. Upload the decision document in the correct language:

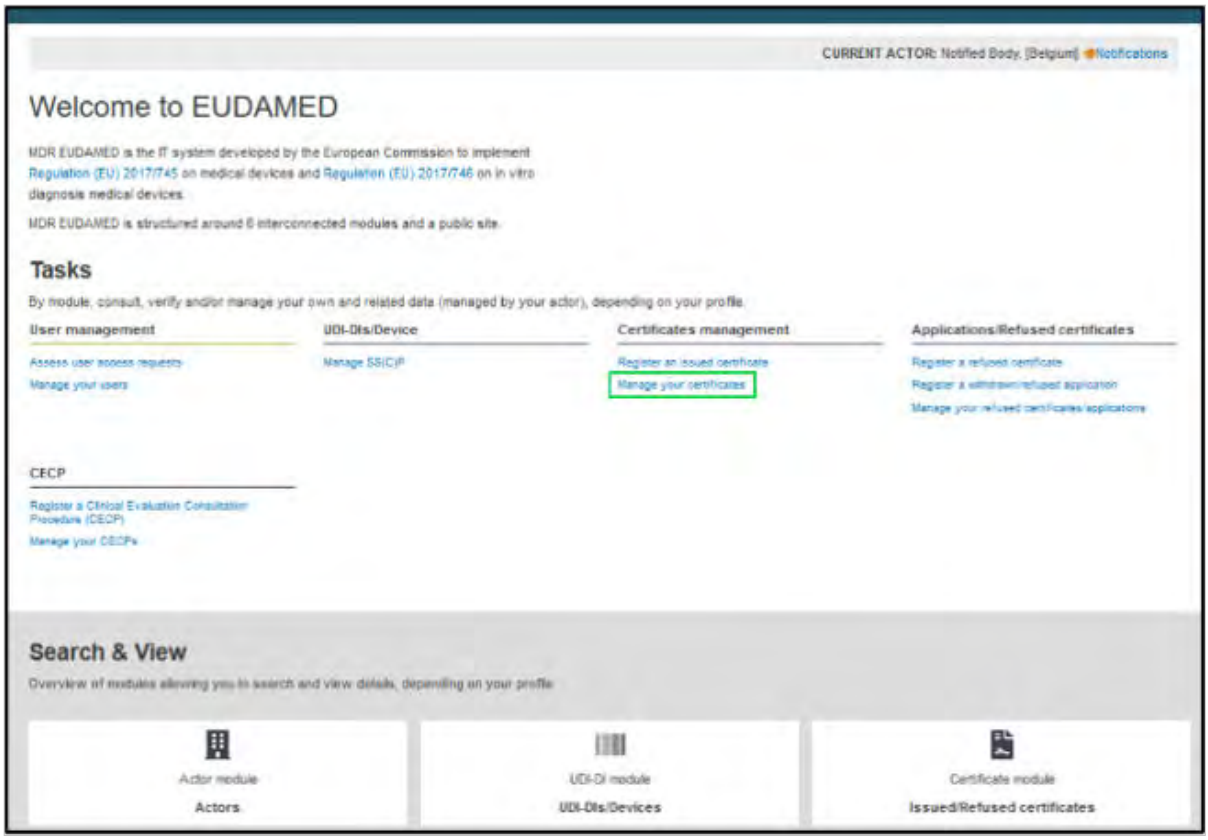


6. Once you are done, click **Submit**.

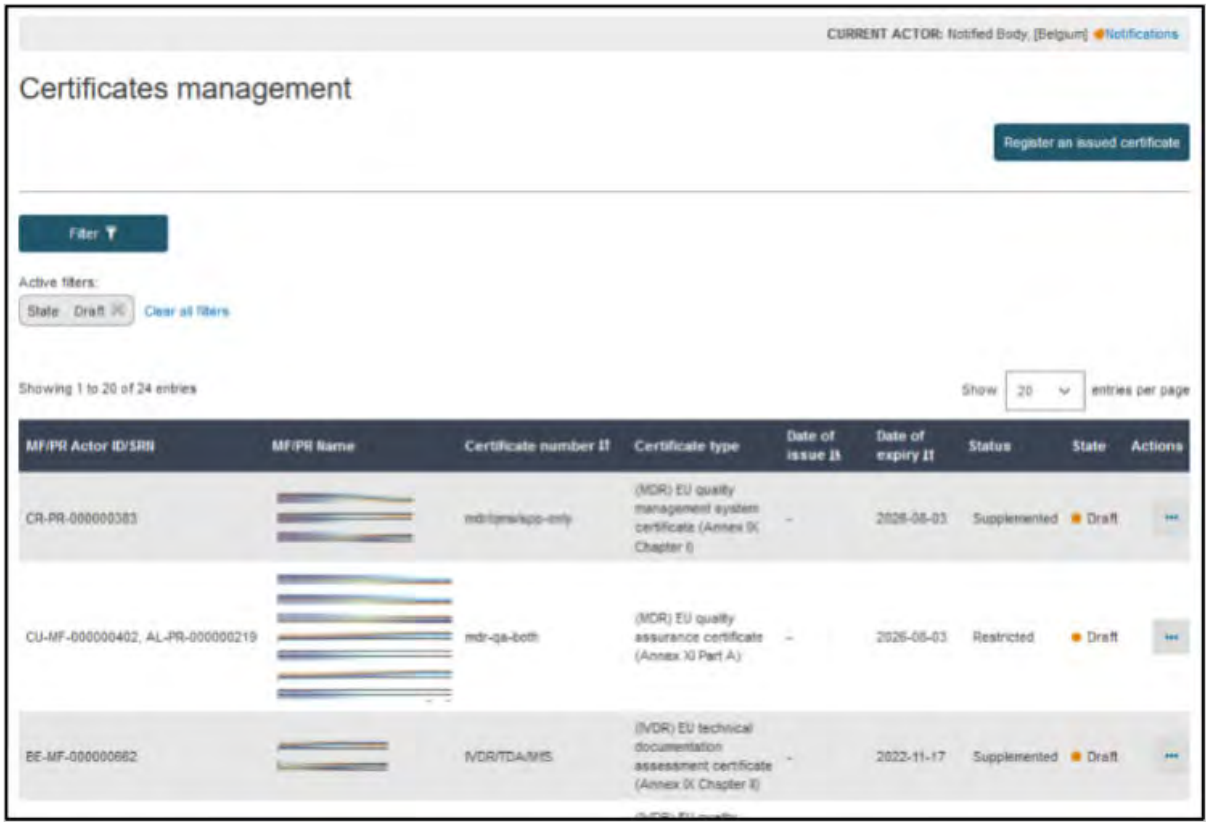
8 Certificate management

8.1 View certificate

1. Click the **Manage your certificates** link within your dashboard:

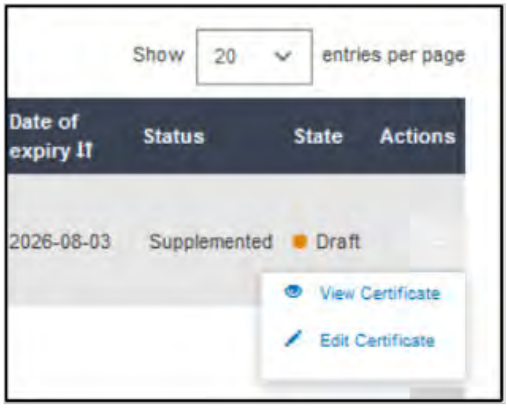


2. By default the system will display your certificates in Draft state. Use the **Filter** button to help find the required certificate, enter you search criteria (at least one). Then click **Apply filters**:

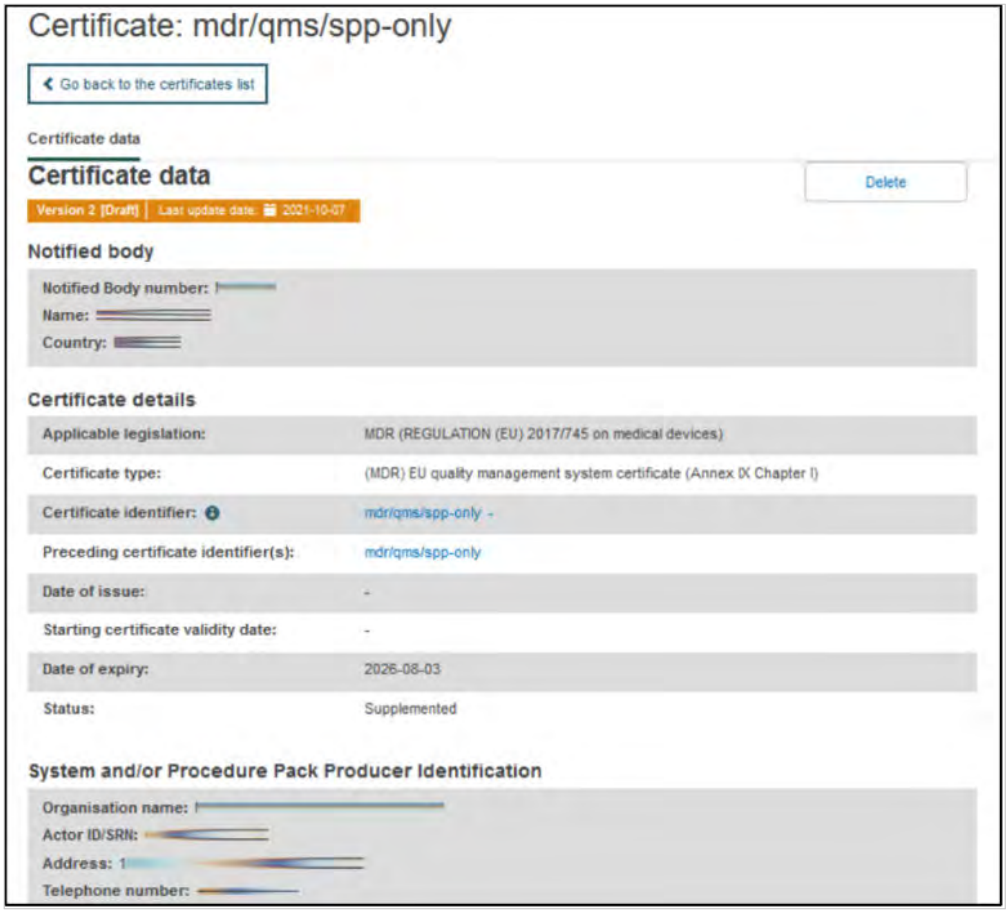


8.2 Delete a draft certificate

1. Within the result list, click on the three dots under the *Actions* column for a specific entry. A drop-down menu displays:



2. Click on **View Certificate** to see its details. Within the view page, click the **Delete** button at the top right:



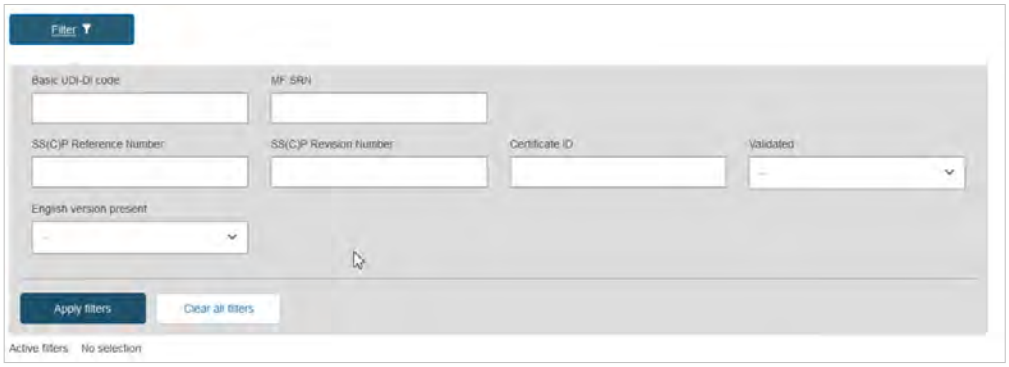
3. A confirmation dialog displays. Click **Confirm**, and the certificate will be deleted:

9 SS(C)P Management

1. Click **Manage SS(C)P** under *UDI-DIs/Device*:

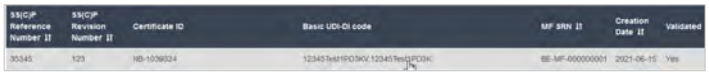
The following page will display:

2. You are presented with a list of all the SS(C)Ps to which you have access. Use the **Filter** button to find the required SS(C)P:

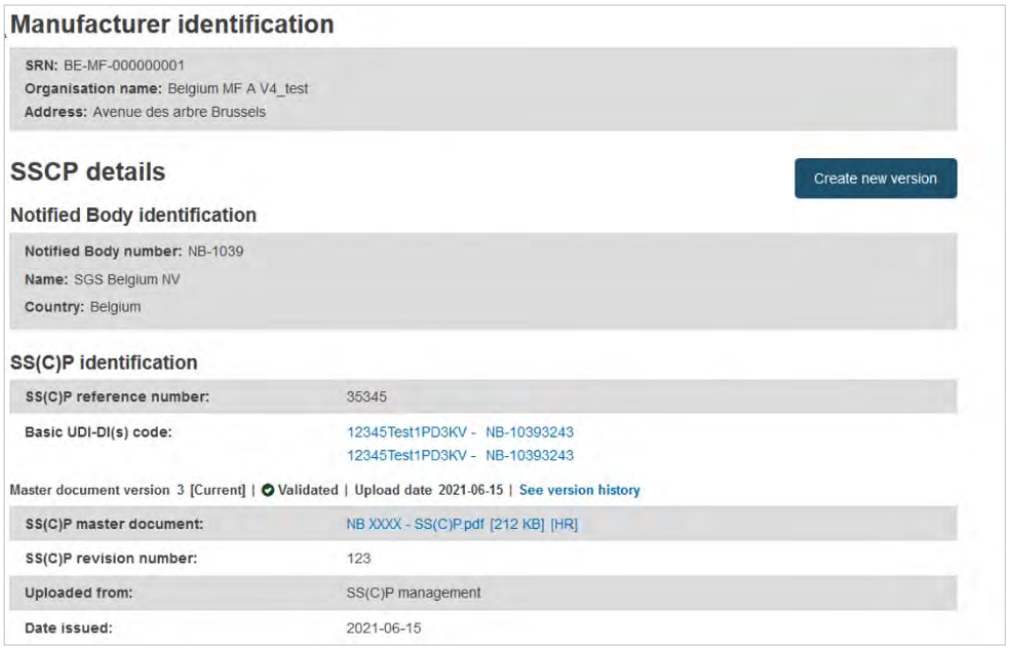


3. You can search by different values.
   You can enter a Basic UDI-DI code, the Manufacturer's Actor ID/SRN, SS(C)P Reference/Revision number, Certificate ID (whether it was validated or not, and whether an English translation version exists or not).
   When you are done, click **Apply filters** to refresh your list.

Click on the SS(C)P in the list you would like to manage:



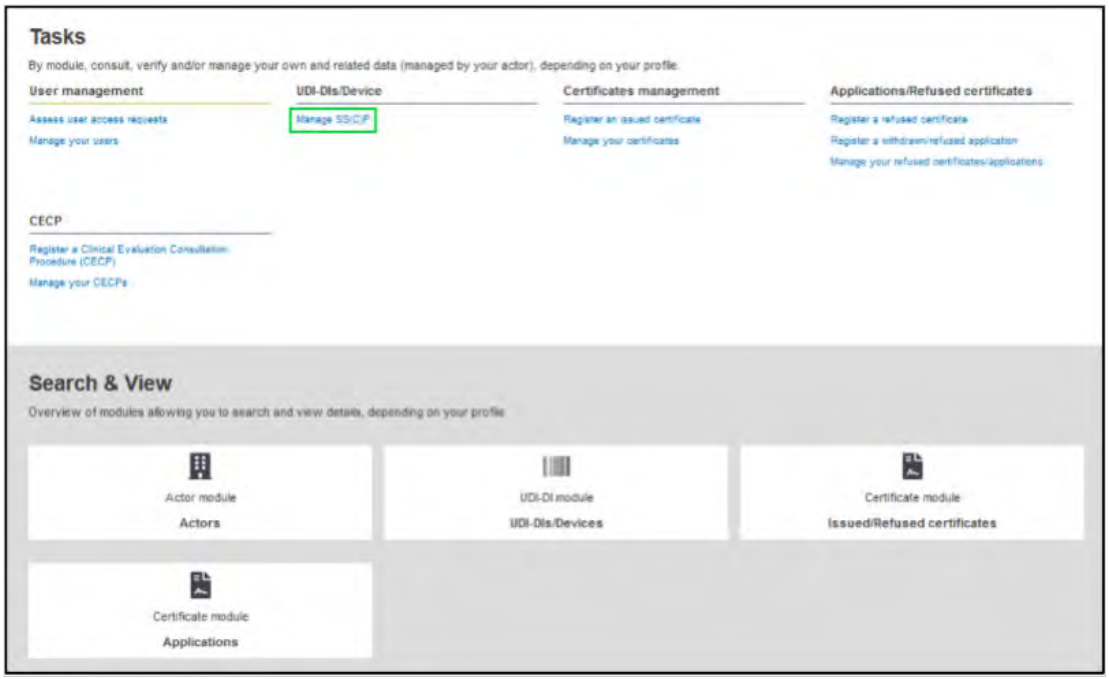
4. A summary of SCCP-related information displays:



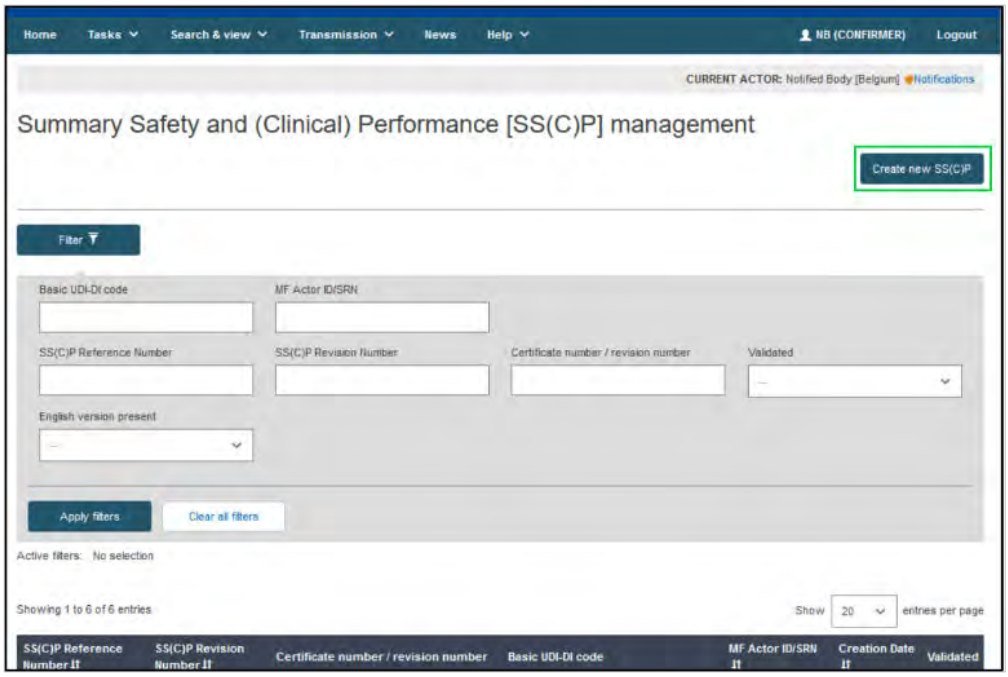
5. Clicking on the Basic UDI-DI codes will open the Basic UDI-DI in a new tab. Next to this code is the certificate data that is linked to the Basic UDI-DI.

9.1 Register new SS(C)P

1. Click on *Manage SS(C)P* to navigate to SS(C)P management page from your dashboard:



2. On the next page, click on **Create new SS(C)P**:



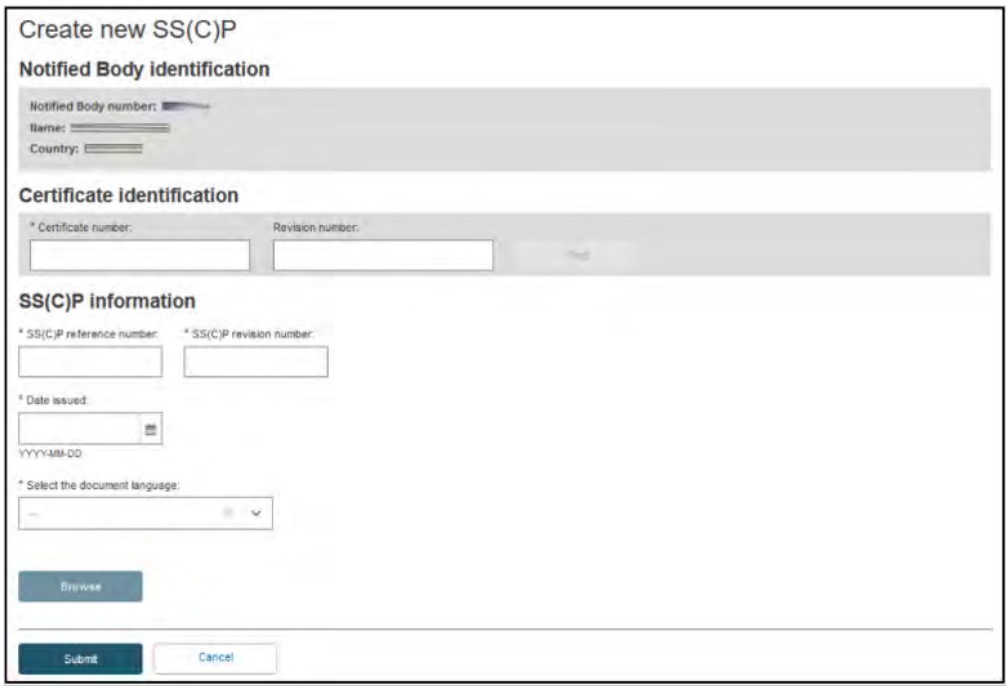
3. Provide the certificate's number, and its revision number if applicable, to identify the certificate registered before. Click **Find**:

NOTE

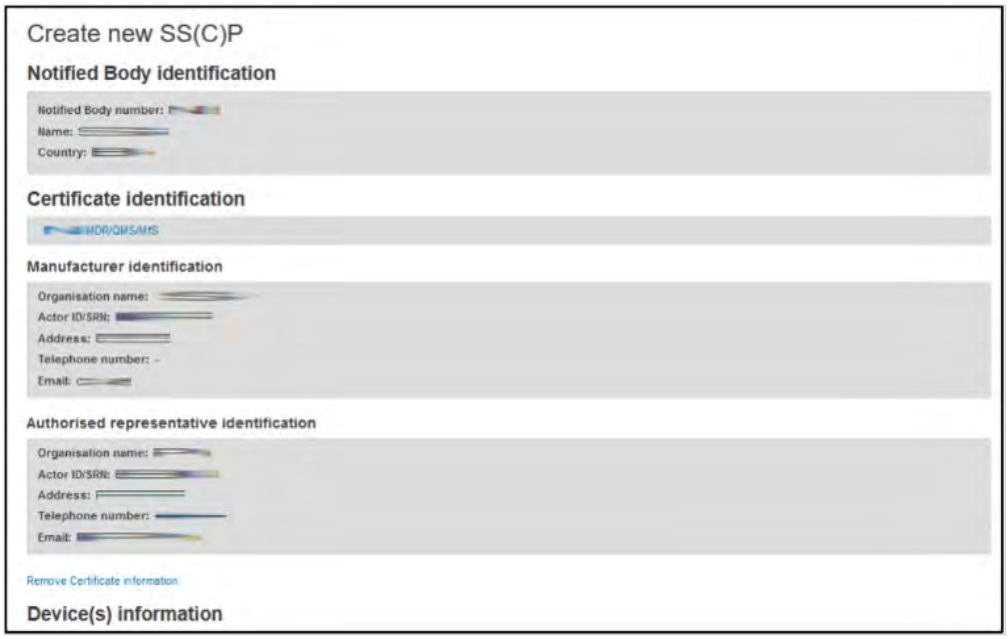
Only the following certificate types can be linked to new SS(C)P created within the *SS(C)P management* page:

– (MDR/IVDR) EU Quality Management System certificate (Annex IX Chapter I)

– (MDR) EU Quality Assurance certificate (Annex XI Part A)

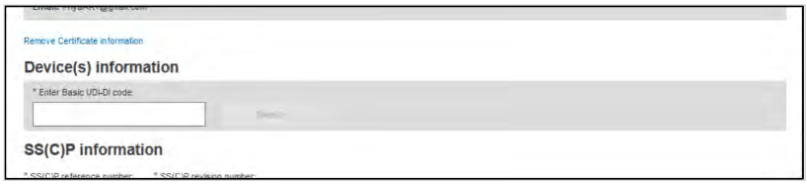


4. Once the certificate has been identified, its link will be populated in the box along with information about the manufacturer, and, if applicable, the authorised representative:



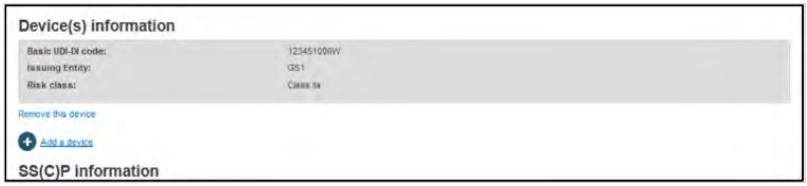
5. Click the **Remove Certificate information** link if the certificate displayed is not the intended one. The process to identify the certificate will restart.

6. Within *Device(s) information*, enter the Basic UDI-DI to be linked to this SS(C)P:



7. You may provide at least the first five characters of a Basic UDI-DI and click **Search**. The system will retrieve Basic UDI-DI(s) according to the Quality certificate types, risk class and their specific characteristics:

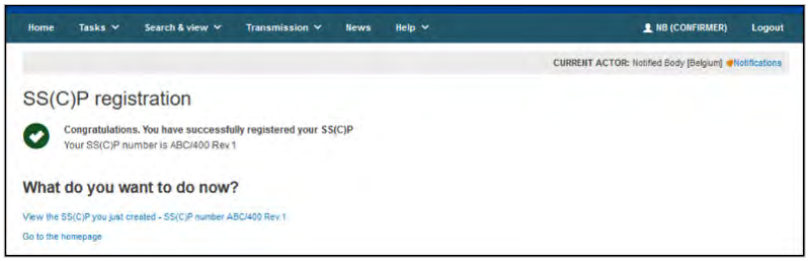
8. Once a Basic UDI-DI is selected, the system will populate its details:



You may add another Basic UDI-DI by clicking on the **Add a device** link, or remove this Basic UDI-DI by clicking on ‘Remove this device’.

9. You need to specify SS(C)P reference and revision numbers, date issued and the language in which the SS(C)P master document is provided. Click **Browse** to upload the SS(C)P master document. Select *Yes* if this SS(C)P master document is validated, otherwise select *No*:

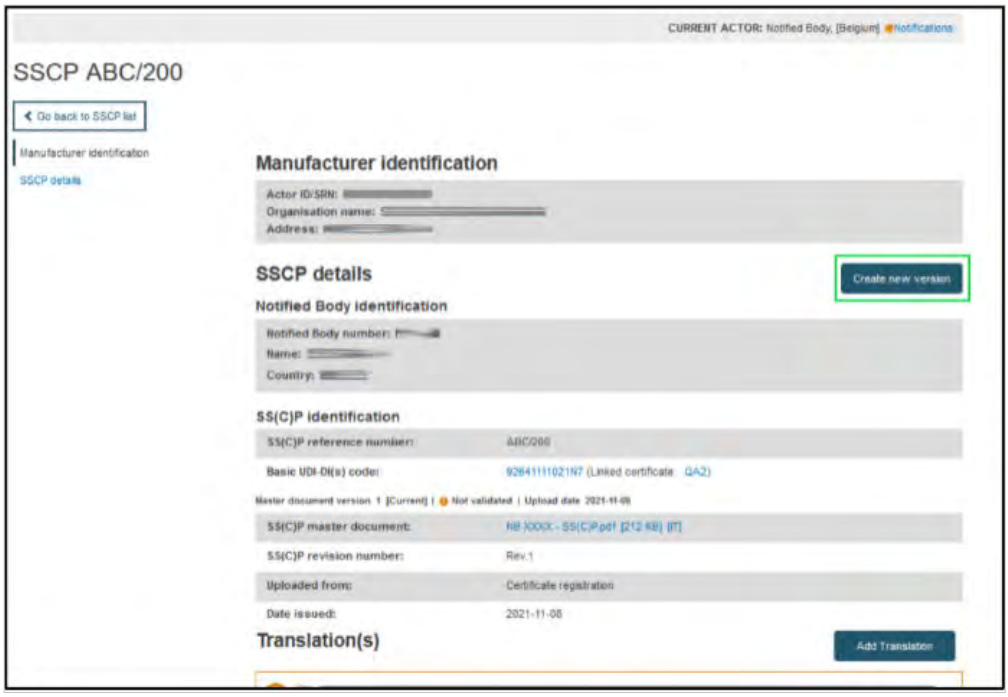
10. Click **Submit** and **Confirm** when asked. A confirmation page will appear:



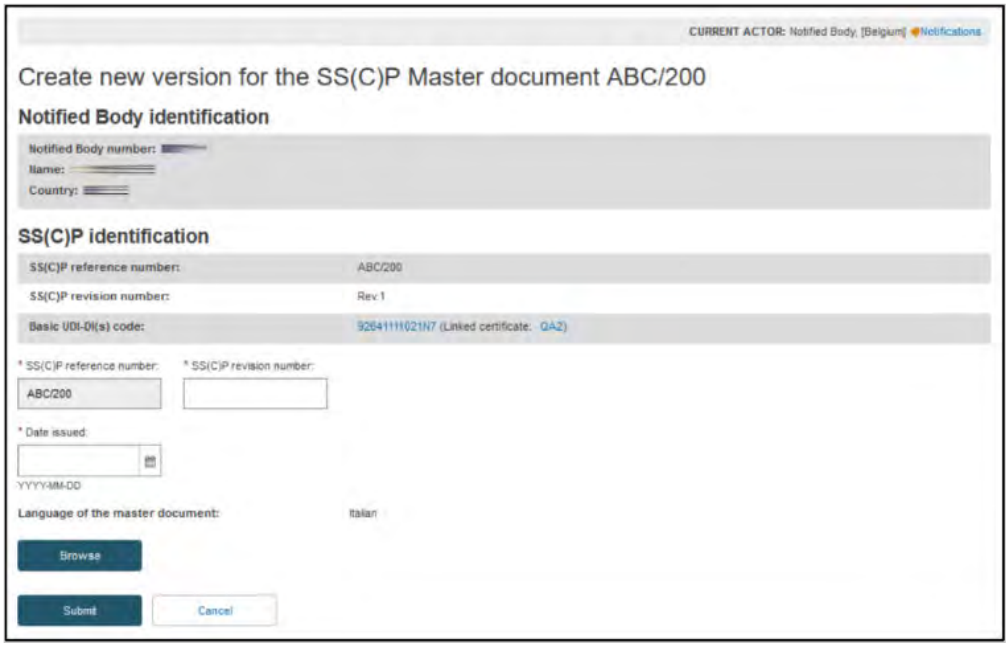
Your new SS(C)P record will appear under the list of SS(C)Ps within the SS(C)P management page.

9.2 Create new SS(C)P version

1. When viewing an SS(C)P record, click on **Create new version**:



2. Provide the *SS(C)P revision number*, *Date issued*, and then upload the SS(C)P master document for the new version:

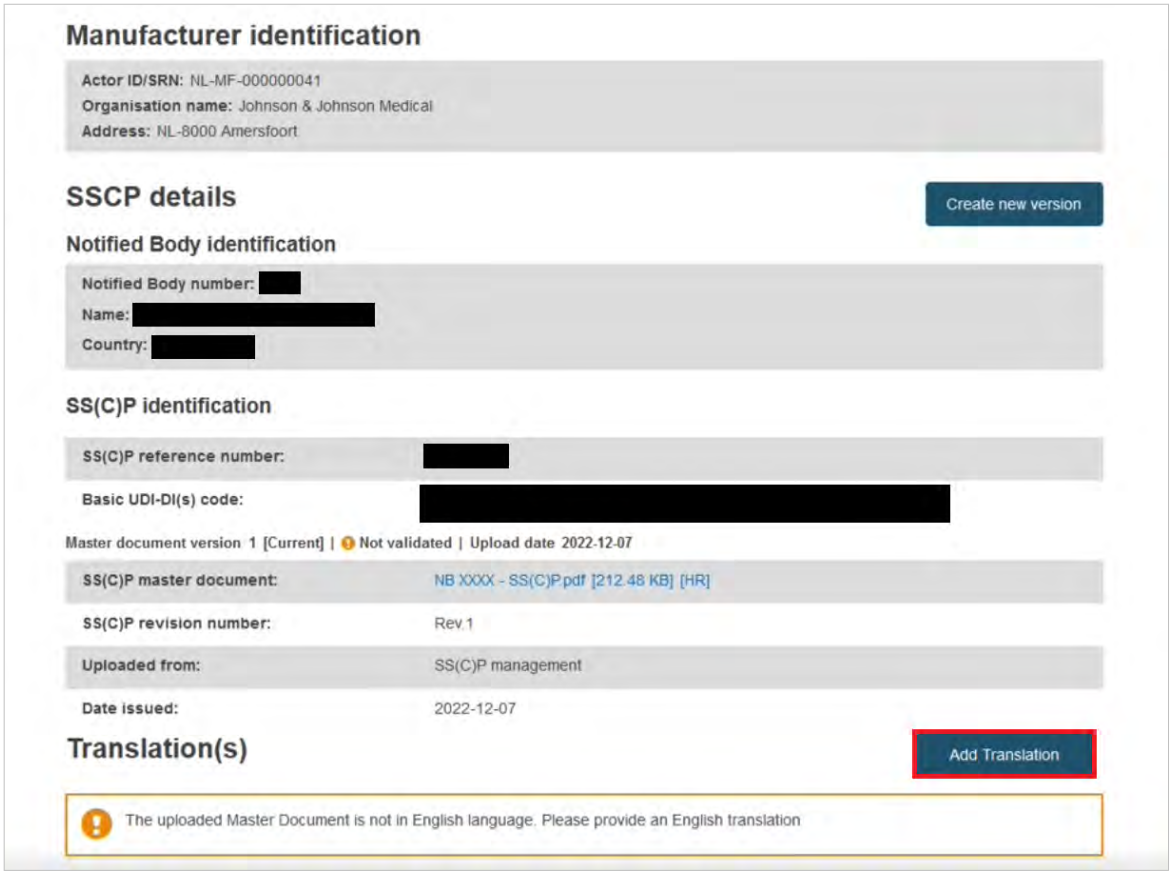


NOTE
The new SS(C)P version will be automatically linked to the last active version of the certificates it is linked to.

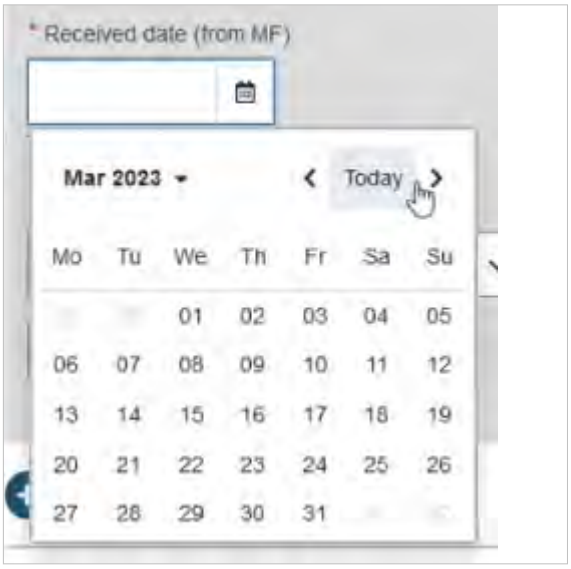
9.3 Adding translations

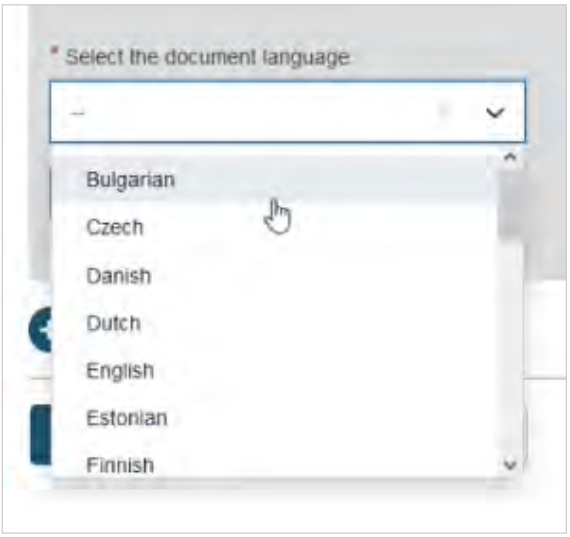
To add a translation to an SS(C)P, please follow the steps in SS(C)P Management [81] (steps 1-3) and then continue with the steps below:

1. Scroll to the bottom of the page and click on **Add Translation**:

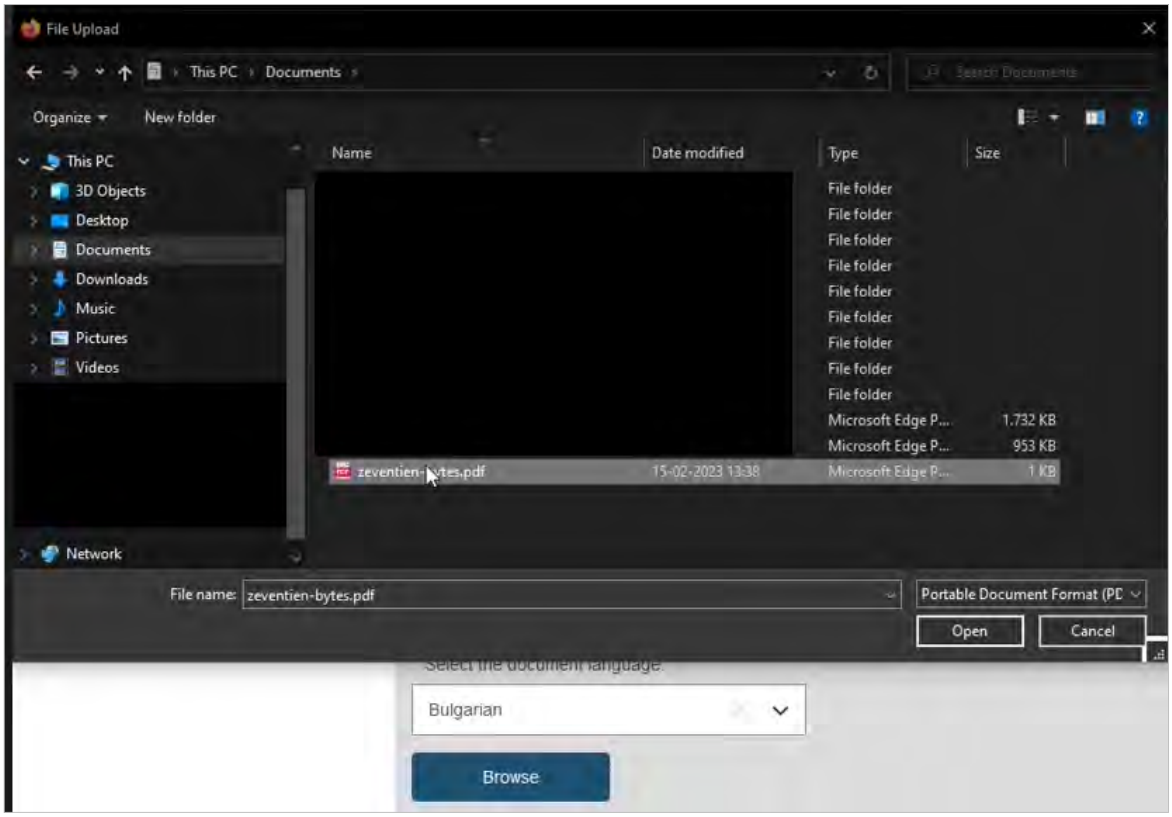


2. In the new window, select the date by clicking on the calendar icon and select the document language from the drop-down list.



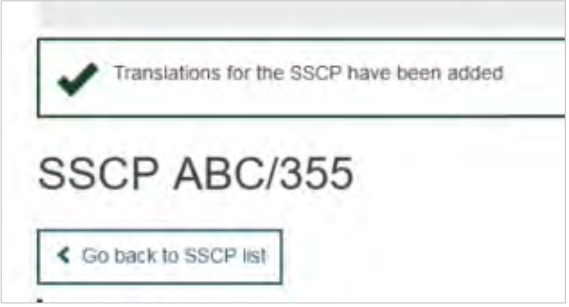


3. Click on **Browse** and select the document from your computer, click on **Open**, you will receive a message the file was successfully uploaded:



NOTE
You can also add multiple translations at once by clicking + *Add translation*.

4. When you are done, click **Submit**, a success message will appear:

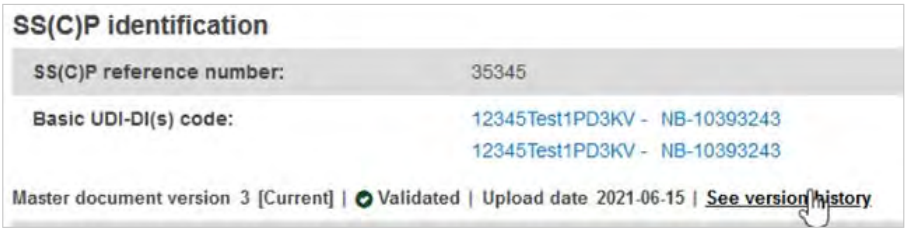


Translation documents are displayed within the *Translation(s)* section.

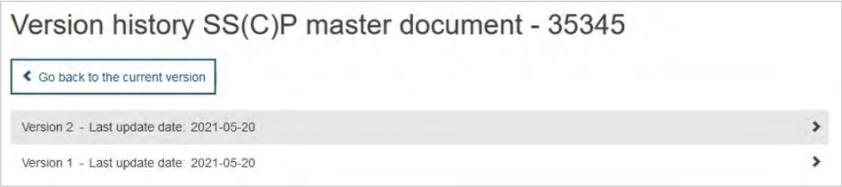
NOTE
If a translation in English is not provided, the system will display a warning message that an English translation is required.

9.4 View SS(C)P version history

If you want to check the SS(C)P version history, click on **See version history** under the Basic UDI-DI codes:



A list with the different versions for the SS(C)P displays:

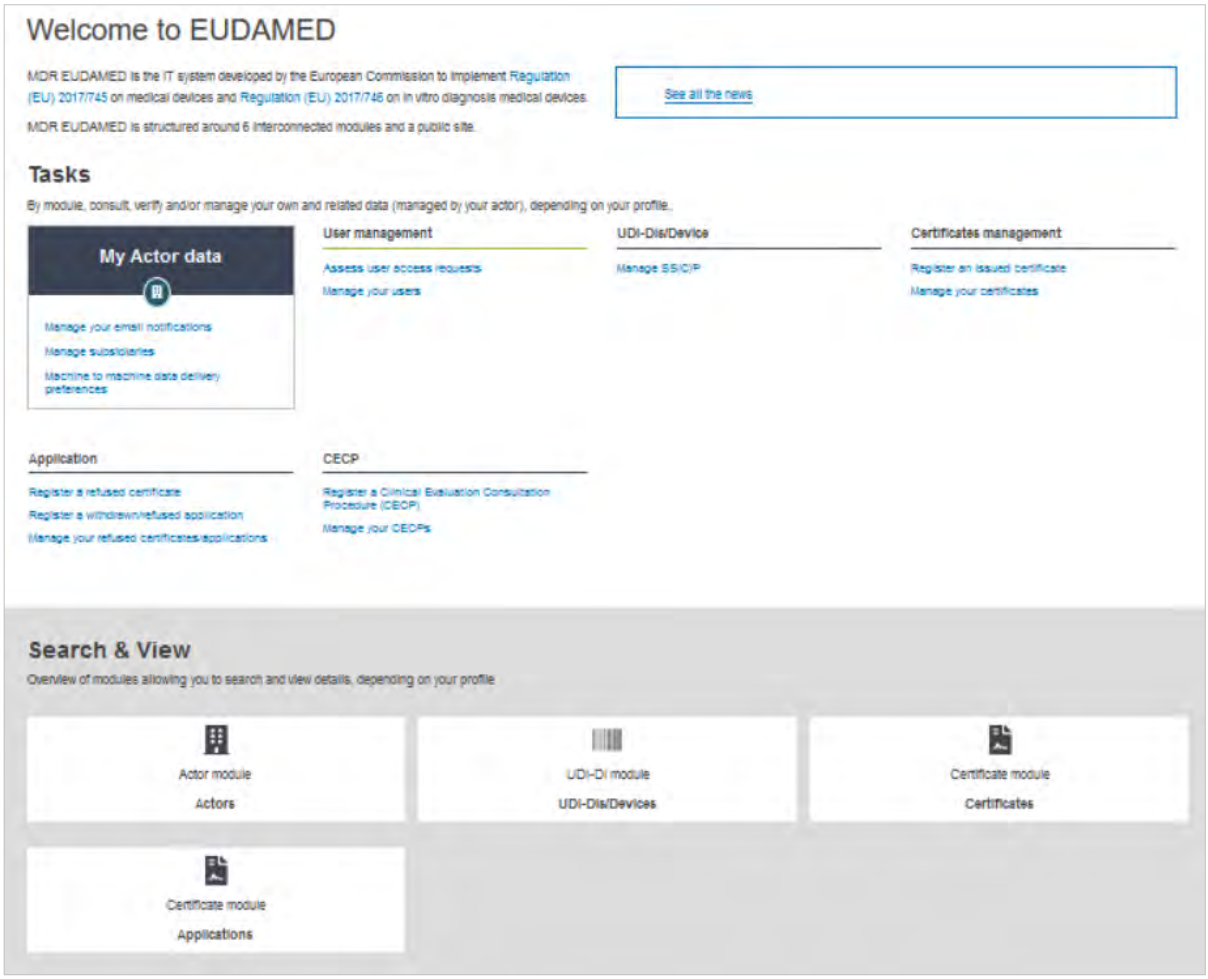


Click on the version you wish to review, opening a summary of it.

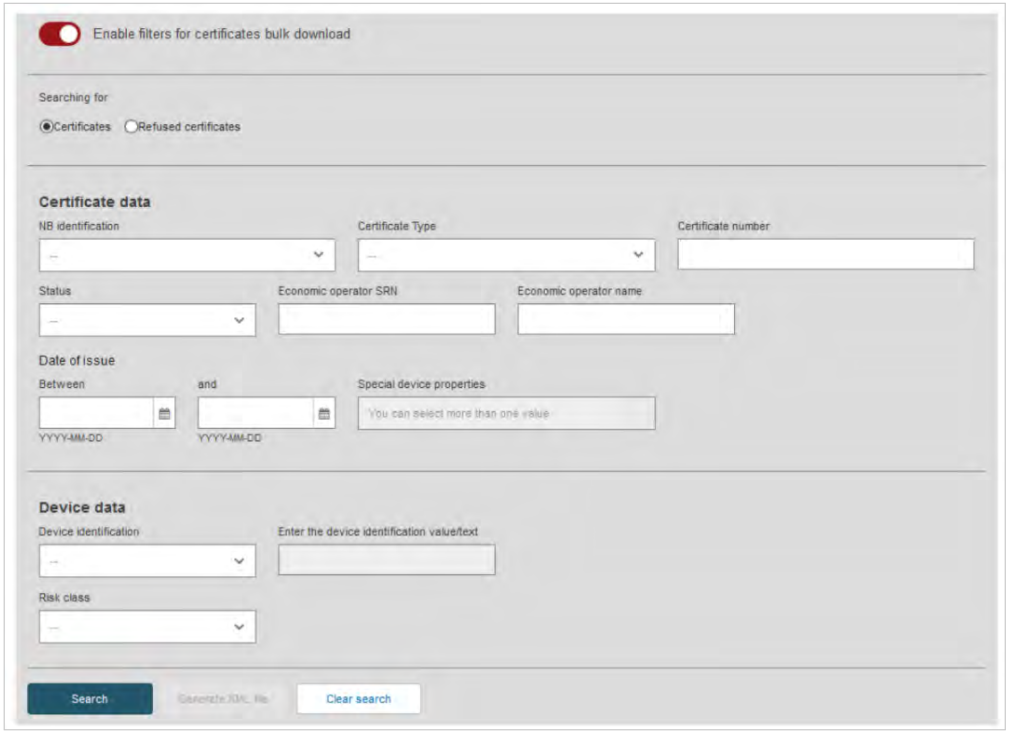
10 Search and view certificates

1. On the header menu, click **Search & View** and then *Certificates*:

2. Alternatively, use the option available in the *Search & View* dashboard:



3. EUDAMED will display the filters available for searching:



4. Click **Search**. A list of matching records will be displayed:

Showing 1 to 6 of 6 entries

Show 20 entries per page

NB number	MF/PR SRN	SRN AR	Certificate number	Certificate type	Date of issue	Date of expiry	Status
NB-1039	BE-MF-000000121		3317_44	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2021-07-22	2021-07-31	Issued
NB-1039	BE-MF-000000001		mdr-tech-doc-B	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2021-07-08	2024-07-29	Issued
NB-1039	BE-MF-000000001		mdr-tech-doc-C	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2021-07-01	2021-07-31	Issued
NB-1039	JP-MF-000000061	BE-AR-000000021	suspended-suspend-product-A	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2021-06-01	2021-10-01	Suspended
NB-1039	JP-MF-000000061	BE-AR-000000021	suspended-suspend-product-B	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2021-06-01	2021-10-01	Suspended
NB-1039	BE-MF-000000001		123	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2021-04-01	2021-04-30	Reinstated

5. Click on the desired result record to see the details of that record:

Version 1 - Date: 2021-07-22

Certificate data

Notified body

Notified Body number: NB-1039
Name: SGS Belgium NV
Country: Belgium

Certificate details

Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Certificate type:	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)
Certificate identifier:	3317_44 -
Date of issue:	2021-07-22
Starting certificate validity date:	2021-07-22
Date of expiry:	2021-07-31
Status:	Issued

Manufacturer identification

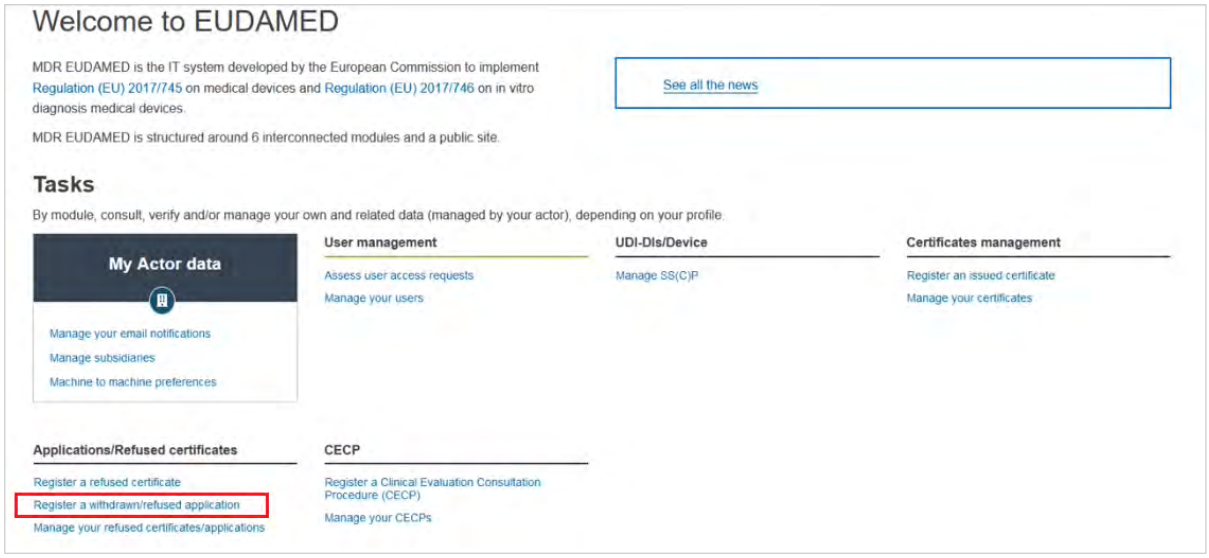
Organisation name: Dev Env - Manufacturer_Shriya
SRN: BE-MF-000000121
Address: 23 Rue willems 9089 Brussels
Telephone number: +32567654545
Email: manu_dev@eudamed.com

Certificate details

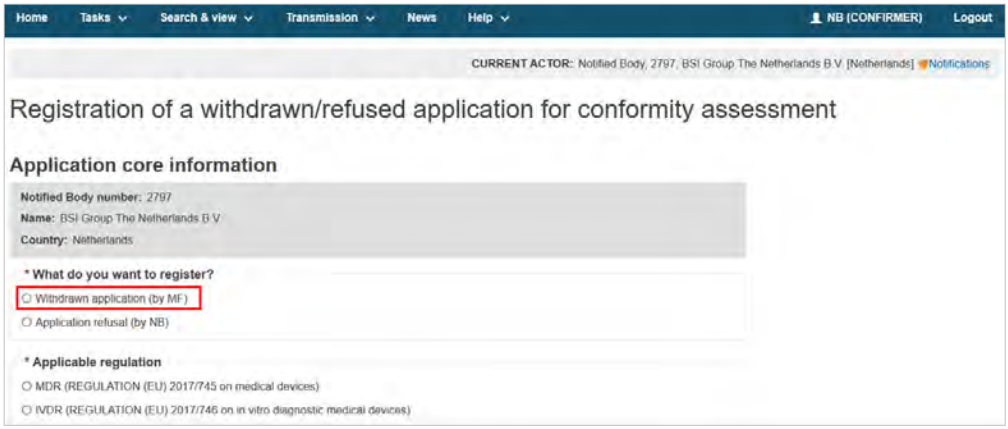
Certificate languages:	Portuguese (PT)
Certificate document:	Lang Certificate.pdf [174 KB] [PT]

11 Register a withdrawn application

Click **Register a Withdrawn/refused application** on the *Applications/refused certificates* section:

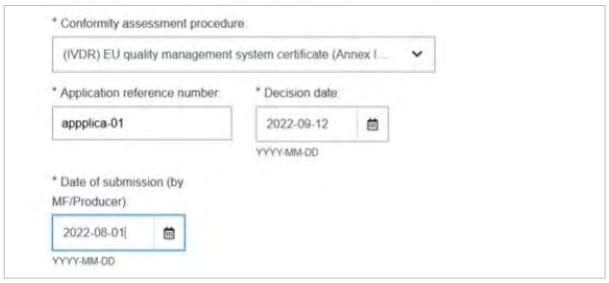


1. Select what you want to register:

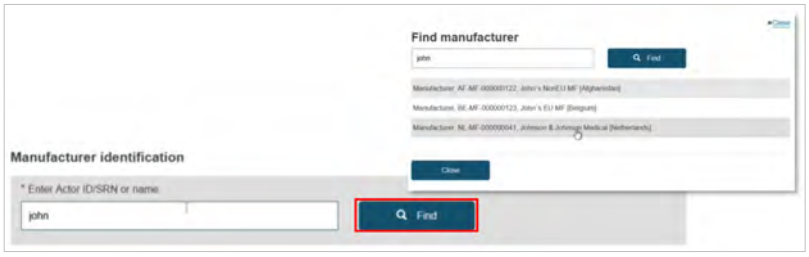


2. Select the applicable regulation, in this case IVDR, and then select the conformity procedure:

3. Provide the *Application reference number*, the *Decision date* and the *Date of submission by*:

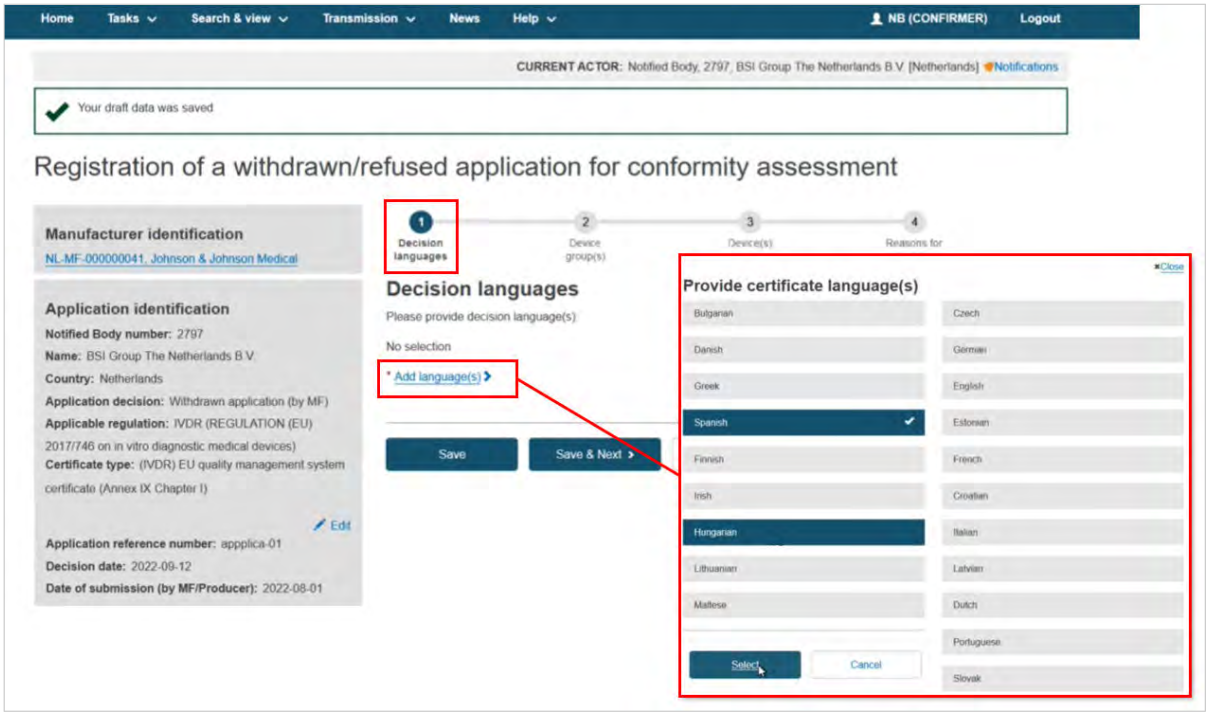


4. Enter the Actor ID/SRN or name of the manufacturer or the system/procedure pack producer, click **Find** and select from the list displayed:

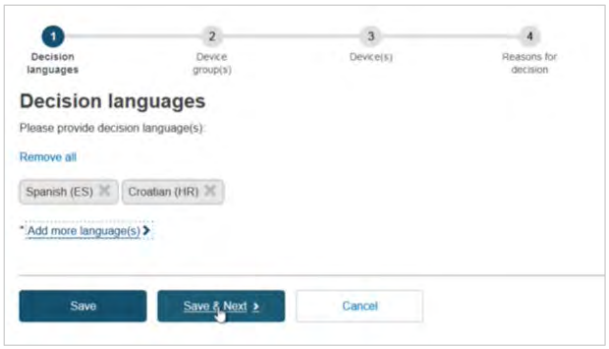


5. Click **Save & Next**:

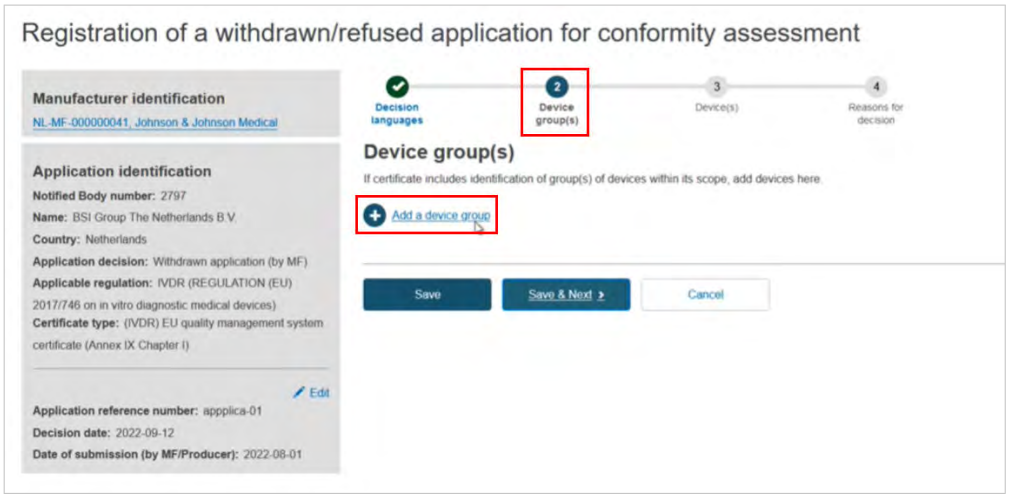
6. The process flow displays. First add the *Decision language(s)*. You can select multiple languages, then click **Select**:



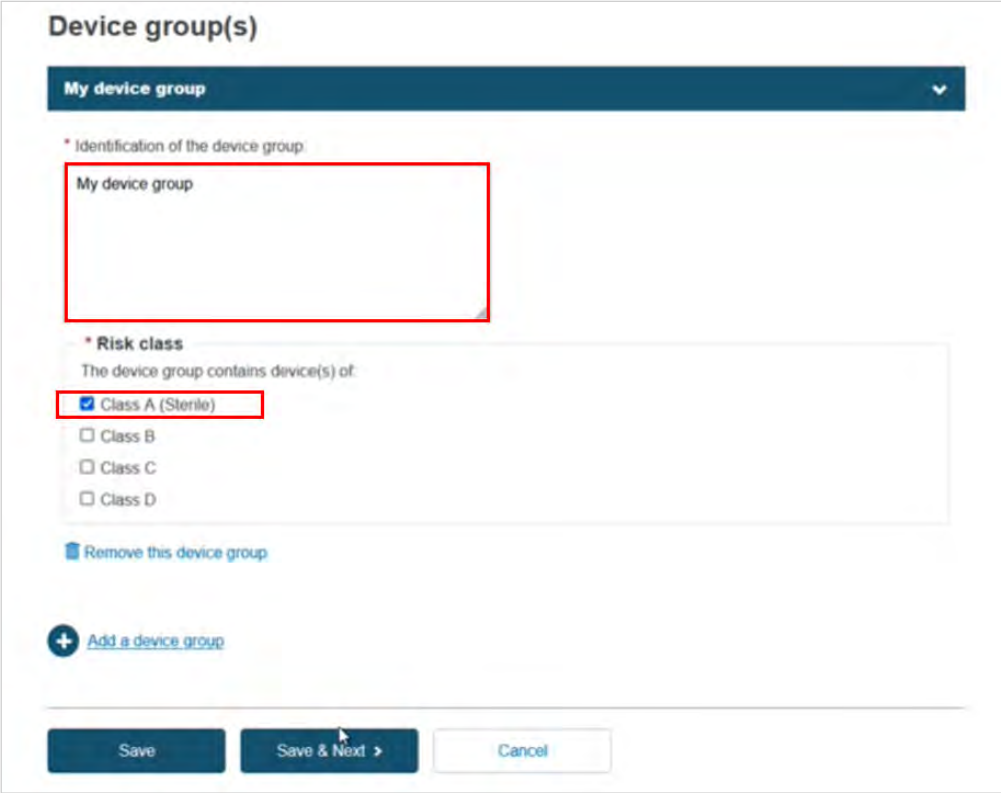
7. The language tabs display, which can be removed using the *x*. Click **Save & Next**:



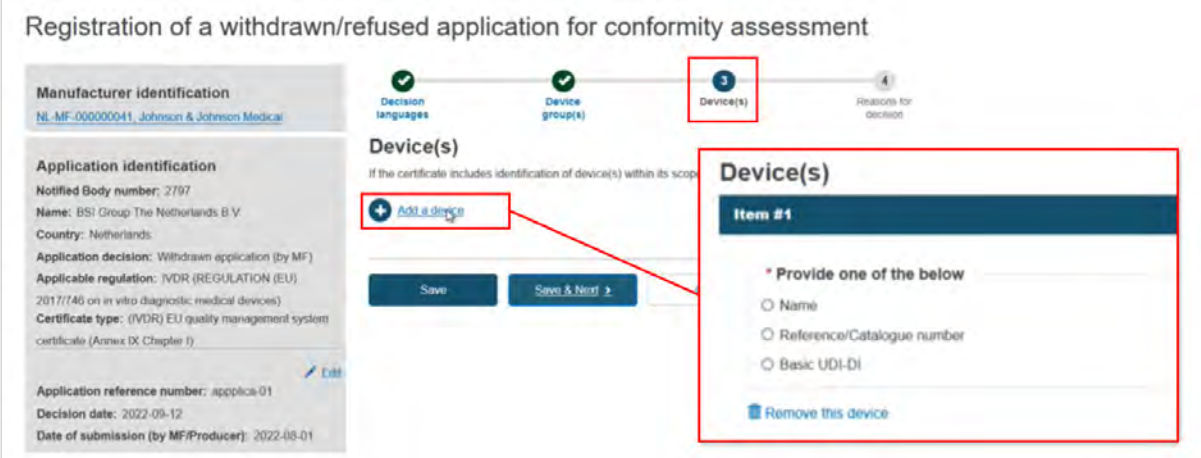
8. The next step in flow is **Add a device group**:



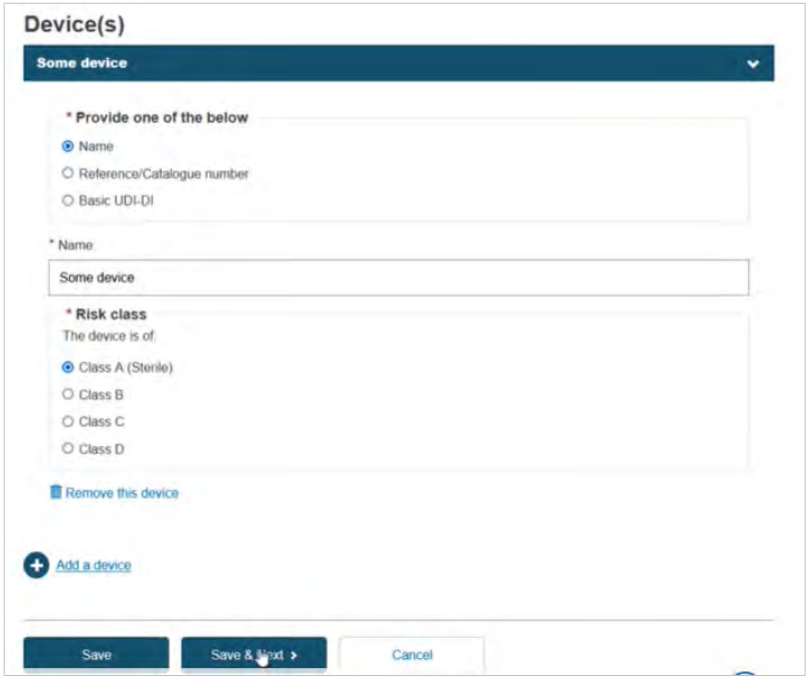
9. Enter the device group identification and select the risk class. Click **Save & Next**:



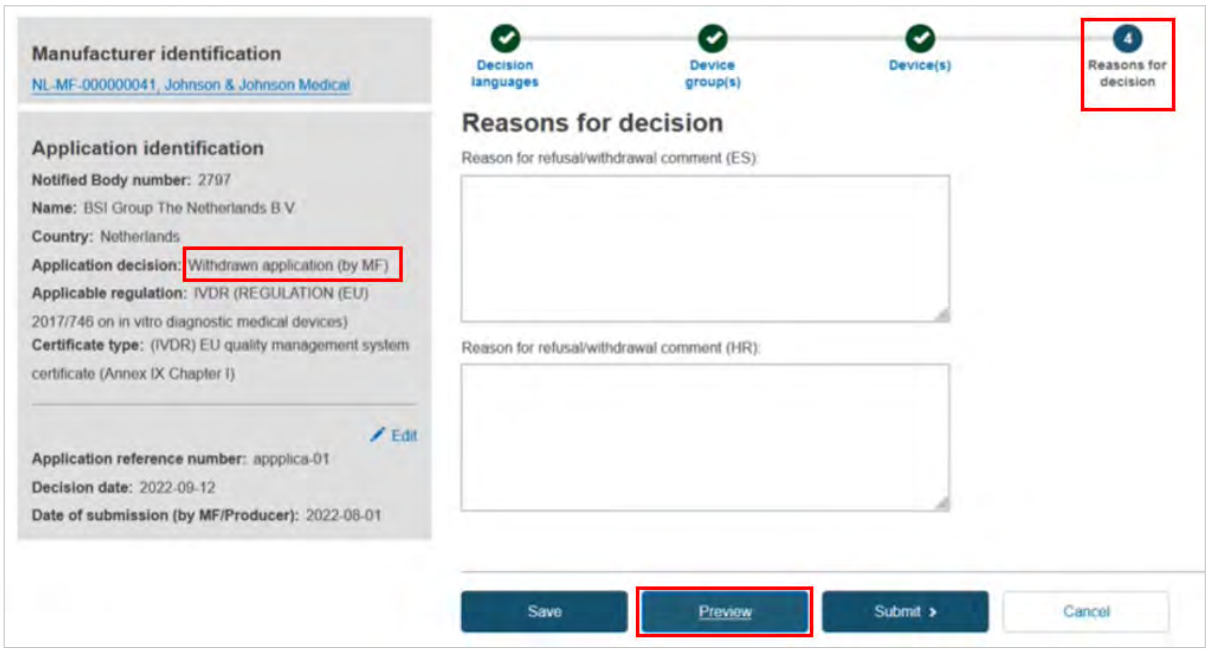
10. Add a device. Click **Add a device**, which can be identified by *Name*, *Reference/ catalogue number* or *Basic UDI-DI*:



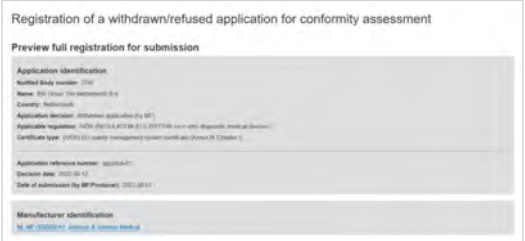
11. In this case we input the name and identify the risk class:



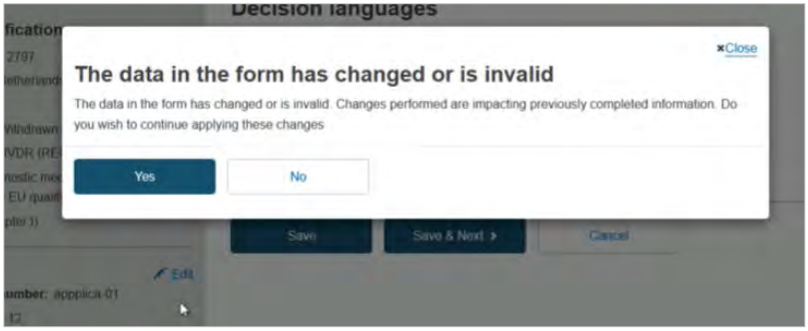
12. The reasons for the withdrawal/refusal in the language indicated above the text box. You can click **Preview** to double-check the content in each step:



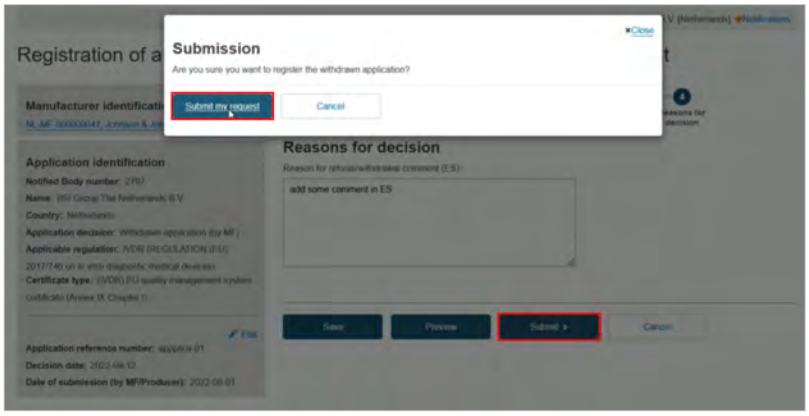
a. Scroll through the preview. You can return to a specific step by clicking **Go back to step x** to make edits:



b. If you make edits, click **Save & Next**, then you will see this confirmation message. Click **Yes**, and proceed out of any further steps until you reach the last one:



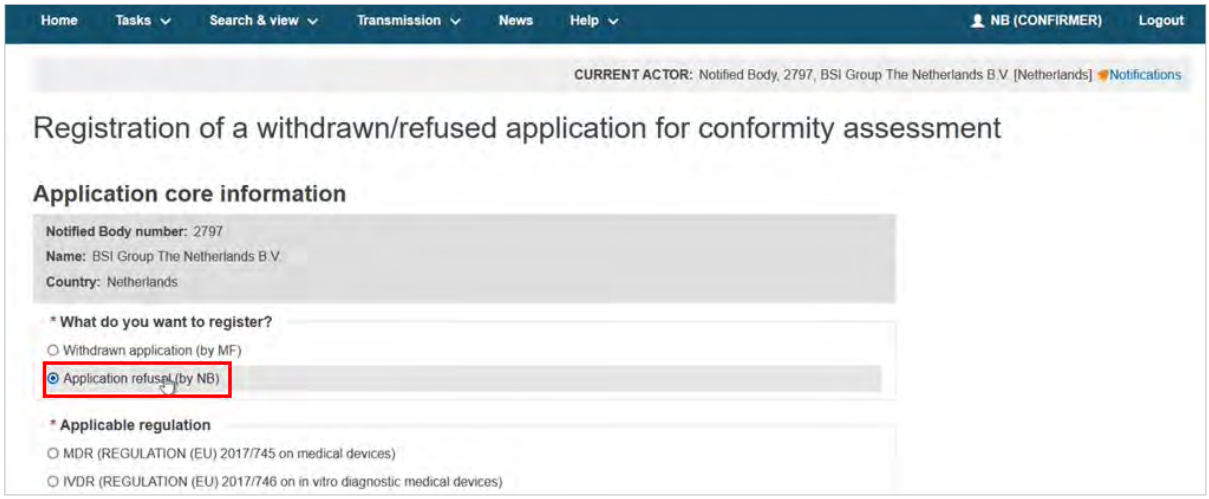
13. Click **Submit my request**:



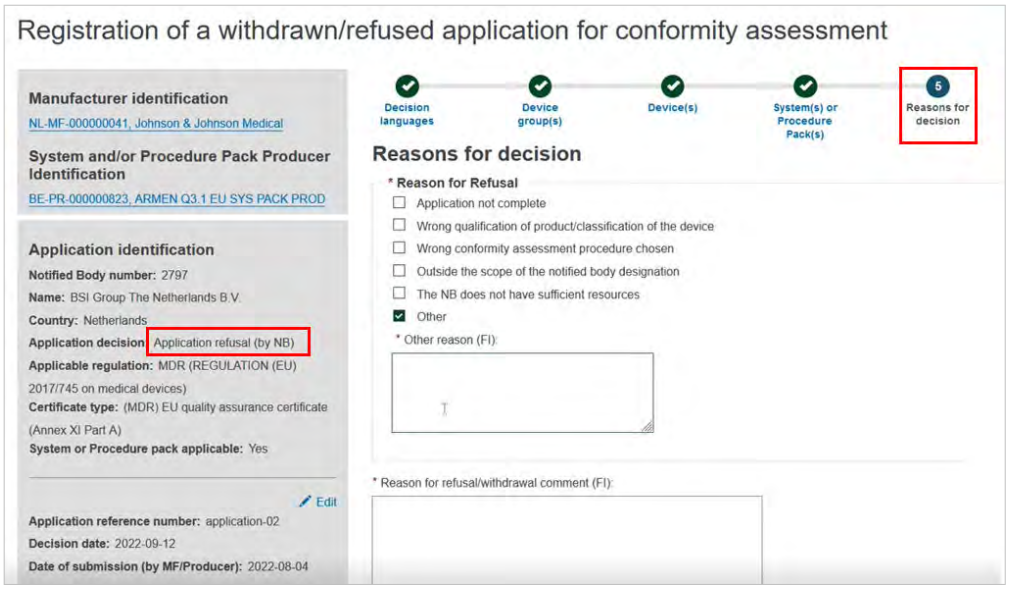
14. The *Confirmation* message displays:

11.1 Register a refused application

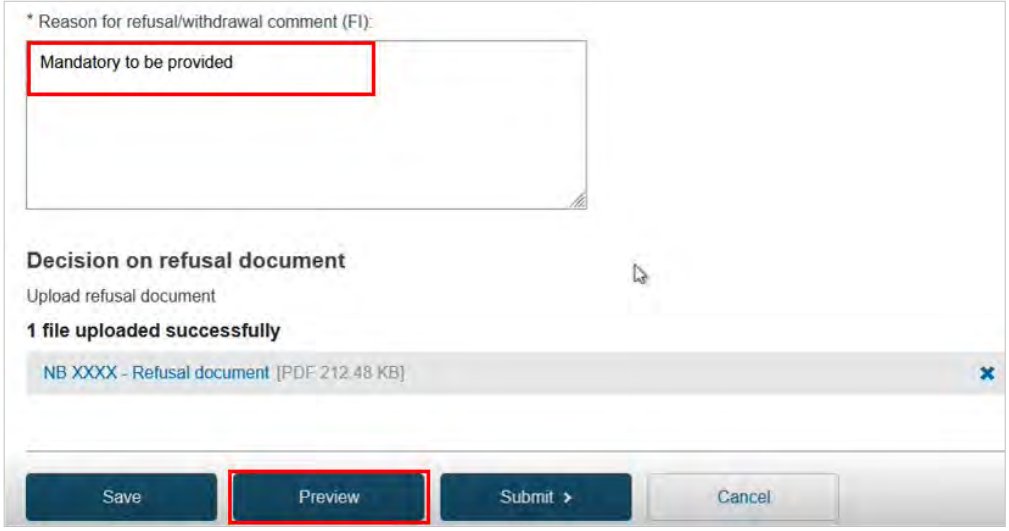
Select **Application refusal (by NB)**, then the steps are the same as when registering an application withdrawal [94], until you are asked to provide the reason:



1. From the list provided, select the reason for refusal. If you choose *Other*, provide the explanation in the *Other reason* text box:

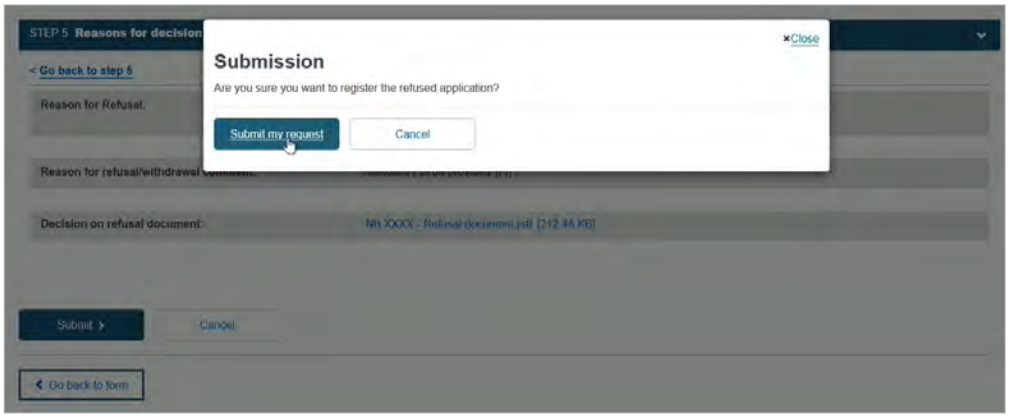


2. Provide the reason for the refusal in the language(s) previously selected and upload the refusal document if applicable.
   Click **Preview** to see and/or edit your entries, or click **Submit**:

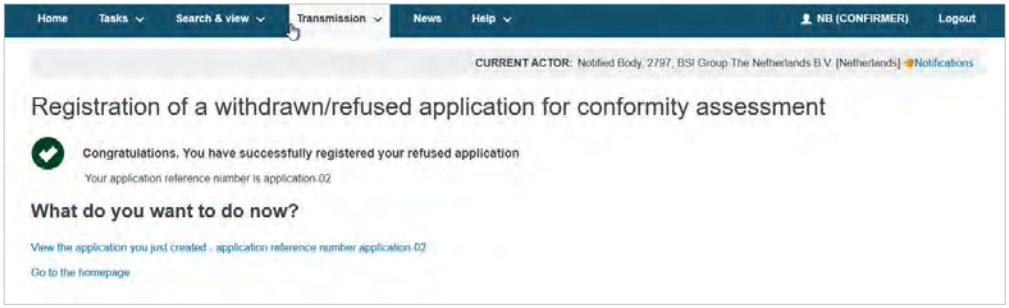


3. Scroll through the preview screen. Click the step 'x' link to return to that section:

4. Click **Submit my request**:

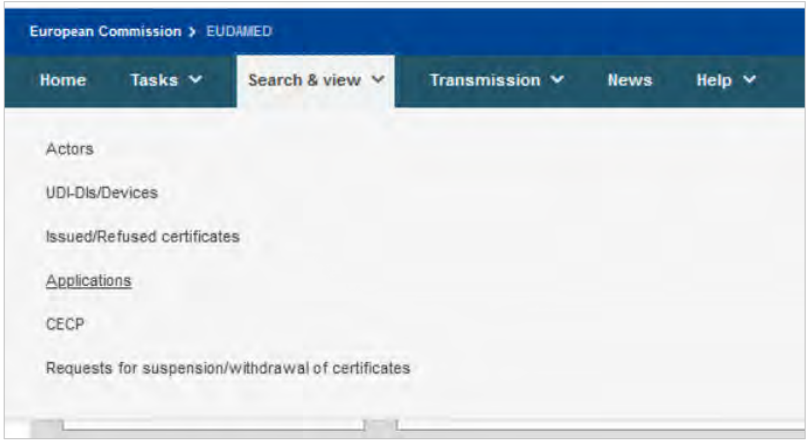


5. The request is submitted, and the *Confirmation* message displays:

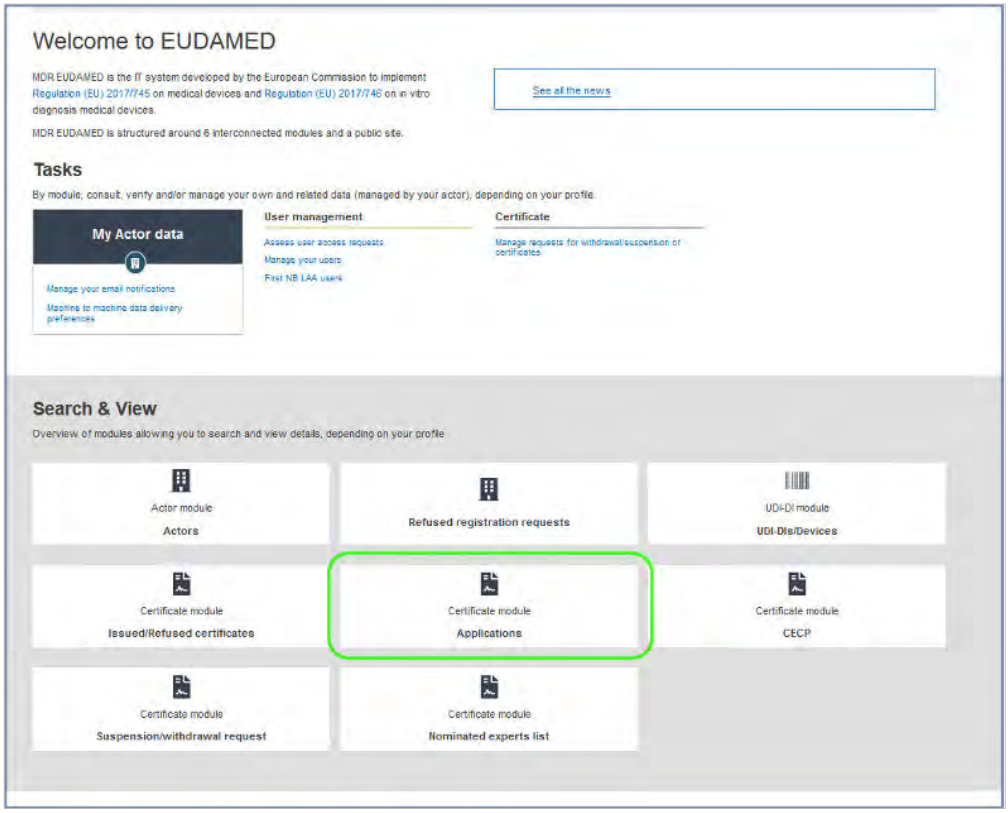


11.2 Search and view refused/withdrawn applications for conformity assessment

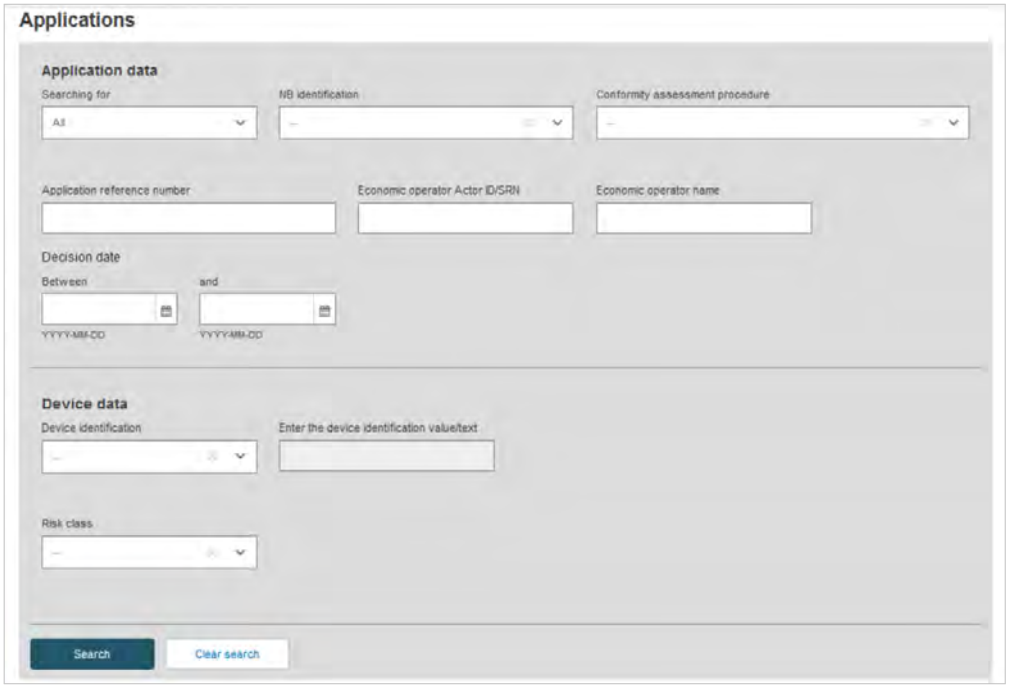
1. On the header menu, click on **Search & View**, then click on **Applications**:



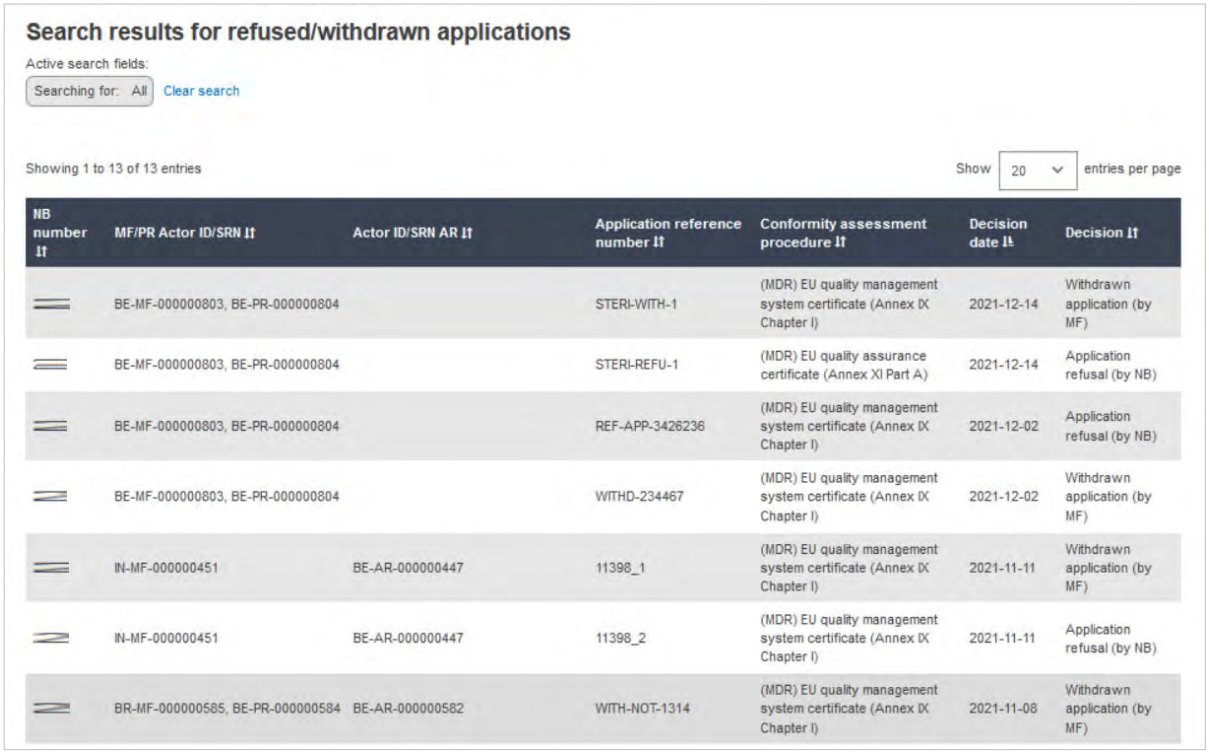
Alternatively, use the *Search & View* section in the dashboard:



2. Next, the refused/withdrawn applications search page will be displayed:

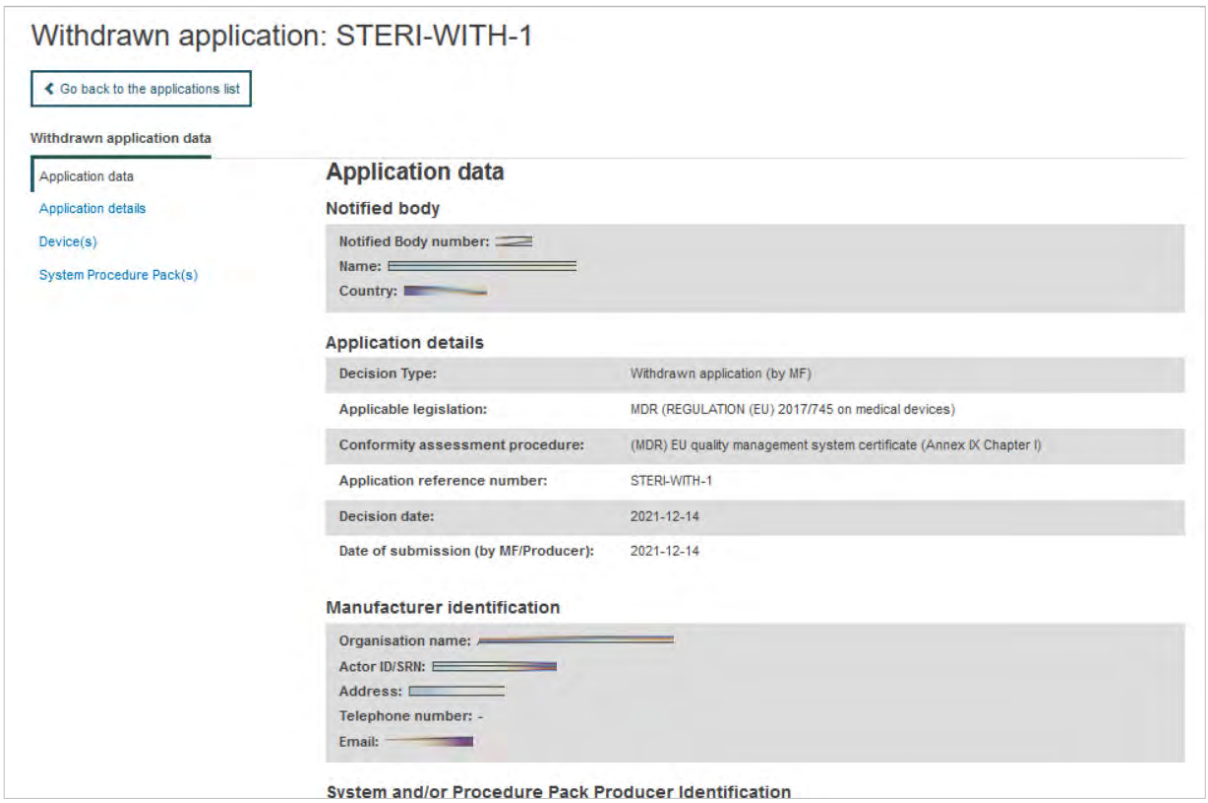


3. Enter the search criteria and click on **Search**. A list of refused/withdrawn applications will be displayed:



NB number	MF/PR Actor ID/SRN	Actor ID/SRN AR	Application reference number	Conformity assessment procedure	Decision date	Decision
	BE-MF-000000803, BE-PR-000000804		STERI-WITH-1	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-14	Withdrawn application (by MF)
	BE-MF-000000803, BE-PR-000000804		STERI-REFU-1	(MDR) EU quality assurance certificate (Annex XI Part A)	2021-12-14	Application refusal (by NB)
	BE-MF-000000803, BE-PR-000000804		REF-APP-3426236	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-02	Application refusal (by NB)
	BE-MF-000000803, BE-PR-000000804		WITHD-234467	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-02	Withdrawn application (by MF)
	IN-MF-000000451	BE-AR-000000447	11398_1	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-11-11	Withdrawn application (by MF)
	IN-MF-000000451	BE-AR-000000447	11398_2	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-11-11	Application refusal (by NB)
	BR-MF-000000585, BE-PR-000000584	BE-AR-000000582	WITH-NOT-1314	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-11-08	Withdrawn application (by MF)

4. Click on the desired result record to see its details:

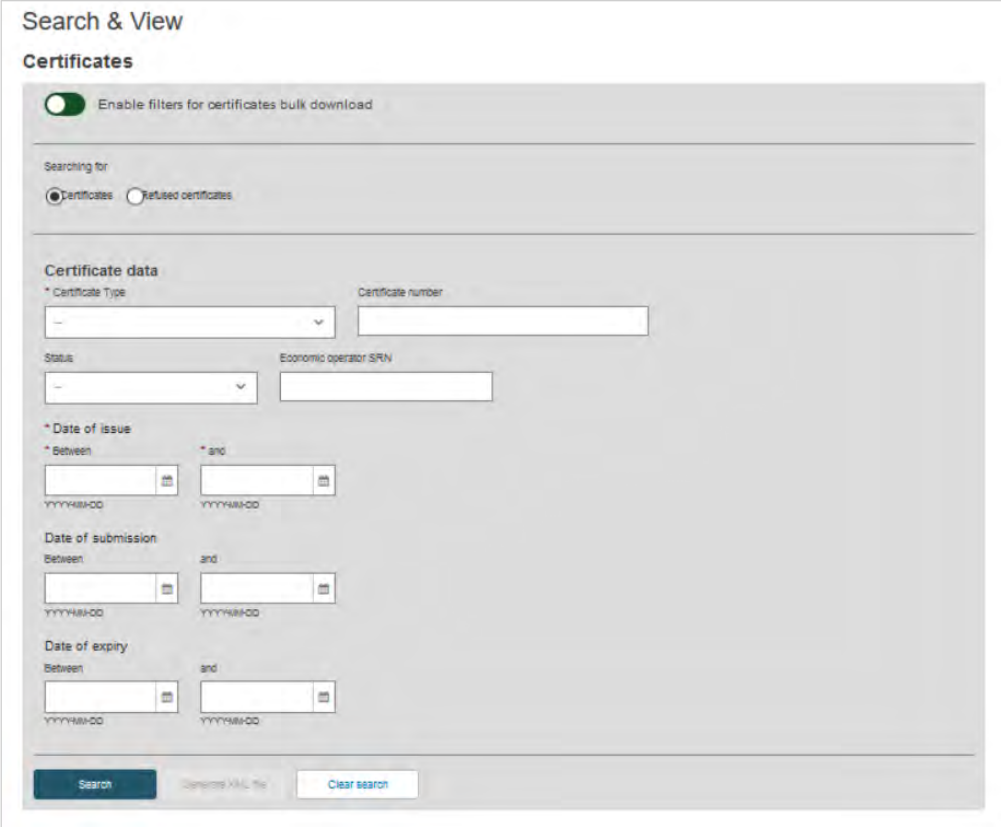

Withdrawn application: STERI-WITH-1
Go back to the applications list
Withdrawn application data
Application data
Application details
Device(s)
System Procedure Pack(s)
Application data
Notified body
Notified Body number:
Name:
Country:
Application details
Decision Type: Withdrawn application (by MF)
Applicable legislation: MDR (REGULATION (EU) 2017/745 on medical devices)
Conformity assessment procedure: (MDR) EU quality management system certificate (Annex IX Chapter I)
Application reference number: STERI-WITH-1
Decision date: 2021-12-14
Date of submission (by MF/Producer): 2021-12-14
Manufacturer identification
Organisation name:
Actor ID/SRN:
Address:
Telephone number: -
Email:
System and/or Procedure Pack Producer Identification

Download certificates and refused certificates in a structured format

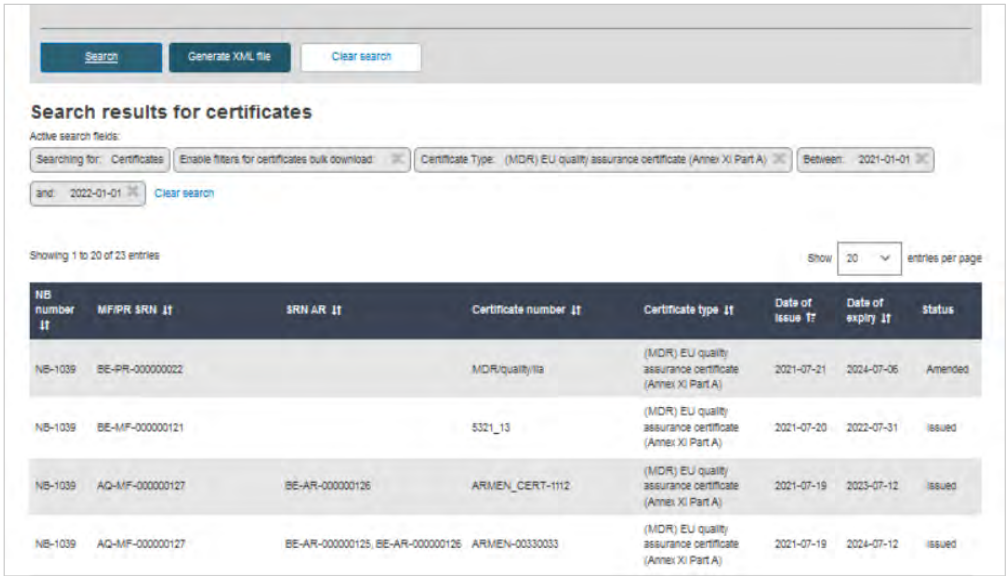
NOTE
Notified Bodies can only download **their own** registered certificates or refused certificates.

Follow the steps in *Search and view certificates [91]* to search and view certificates.

1. On the search parameters screen, slide the toggle to enable only the search criteria that can be downloaded in an XML format, and enter your search criteria:



2. Complete the search criteria, and click **Search** to generate the result:

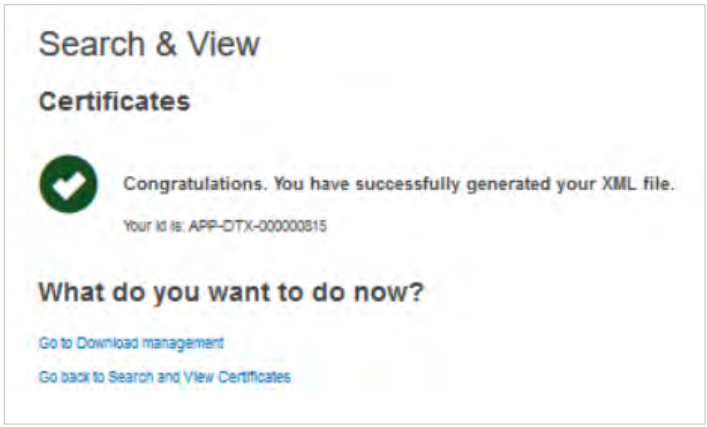


3. Once there is at least one result, click **Generate XML file**:

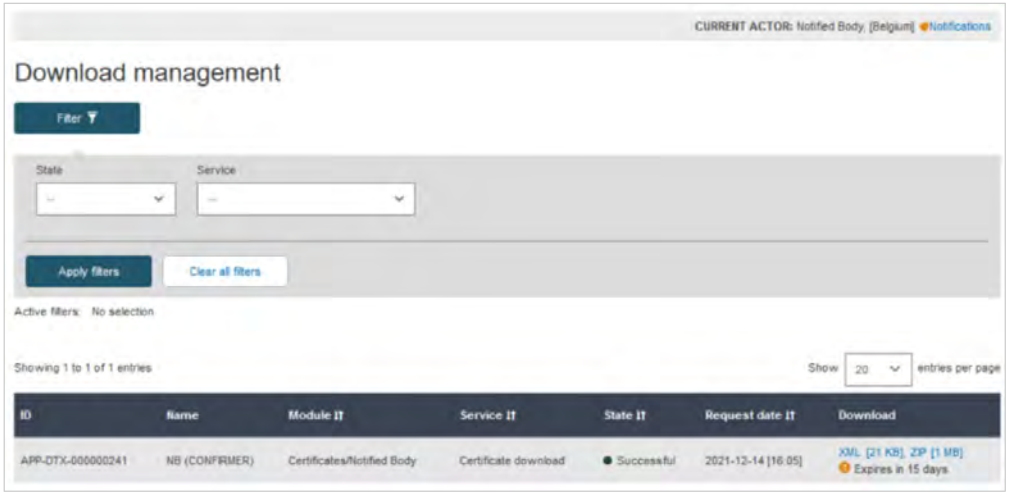
NOTE
Only what is shown in the result list will be included in the generated file, not all the results of your search (in cases where these exceed the default number of results on one page).

4. A pop-up window prompts you to confirm your action:

5. The system informs you that the action has been successful and will prompt you to take further action. Click *Go to Download Management*:



6. The generated XML response file, along with related zipped documents, can be downloaded within the 'Download management' page by clicking on it:


CURRENT ACTOR: Notified Body, [Belgium] Notifications
Download management
Filter
State
Service
Apply filters
Clear all filters
Active filters: No selection
Showing 1 to 1 of 1 entries
Show 20 entries per page
ID
Name
Module
Service
State
Request date
Download
APP-DTX-000000241
NB (CONFIRMER)
Certificates/Notified Body
Certificate download
Successful
2021-12-14 [16:05]
XML [21 KB], ZIP [1 MB]
Expires in 15 days

European Commission