European Commission

Notified Bodies user guide

– for the Production environment

EUDAMED v2.7
April 2022

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1. Introduction

The purpose of this user guide is to help you navigate through the process of registering certificates into EUDAMED.

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.

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

If you do not have an EU account, please follow the instructions for creating an account and requesting access from the competent authority before attempting to use the database.

For information on how to gain access to EUDAMED, please consult the the *User Access Guide for Notified Bodies*.

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 user cannot approve their own profile change requests, these requests must be approved by a **different** LAA/LUA from the Notified Body.

Before you start entering details of a certificate in EUDAMED, please make sure that you have all required information at hand.

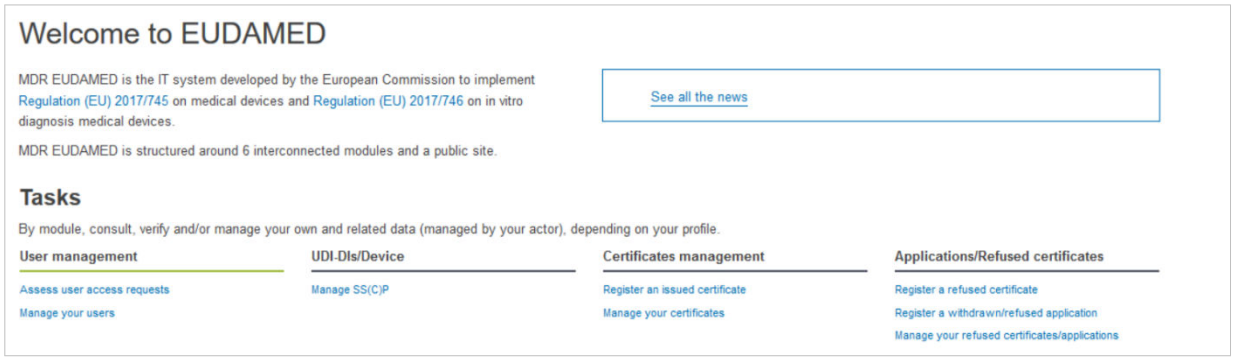
4. Registering an issued certificate

Click on the following link to arrive to EUDAMED Production page: https://webgate.ec.europa.eu/eudamed.

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

4.1. Quality class certificate registration

On the dashboard of EUDAMED, click **Register an issued certificate** on the Notified Bodies homepage:



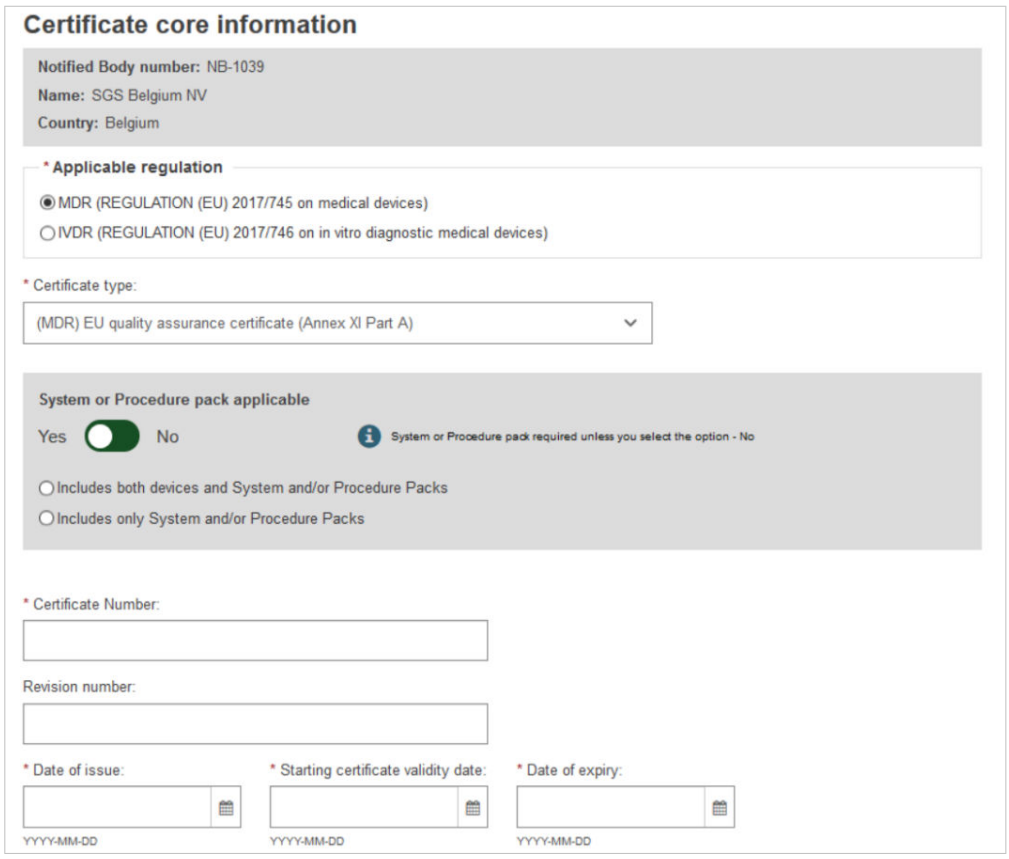
4.1.1. Provision of core data

In the first step, you must choose between one of two applicable regulation types, then a certificate type. The type of the certificate will change depending on which option you choose, MDR or IVDR.

NOTE
In this scenario we will choose a quality class certificate type

You must also enter a certificate number and an optional revision number.

Enter the correct dates concerning the certificate, and enter the Actor ID/SRN or name of the manufacturer or the system or procedure pack producer:

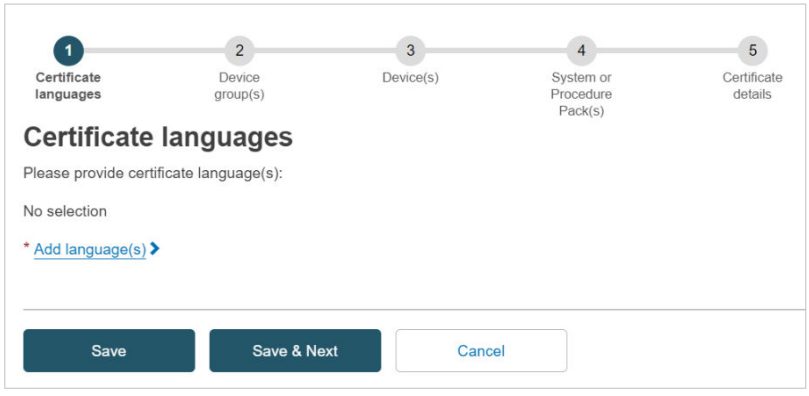


NOTE
You may specify whether your certificate contains System or Procedure Pack(s) sterilisation by choosing MDR (Regulation (EU) 2017/745 and selecting any quality certificate type.

Click **Save & Next**.

4.1.2. Provision of certificate language

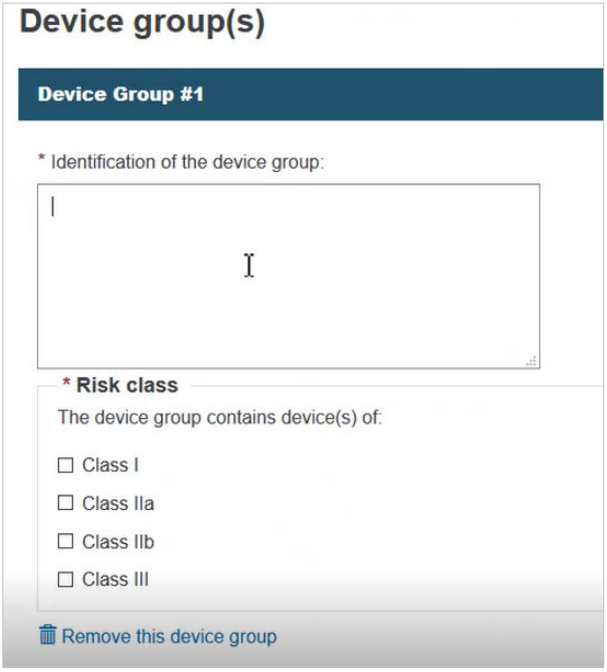
Click 'Add languages' and the system will display a dialog from where you can multi-select from a list of official EU languages:



Once you are done you can **Save** your draft or click **Save & Next** to continue to the next step.

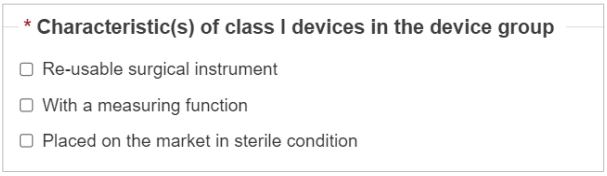
4.1.3. Provision of device group data

Click 'Add device group data' and complete the required information:



You may provide more than one risk class for a device group by selecting the corresponding checkboxes.

If you choose class I, you will have to provide the characteristics of class I devices in the device group:

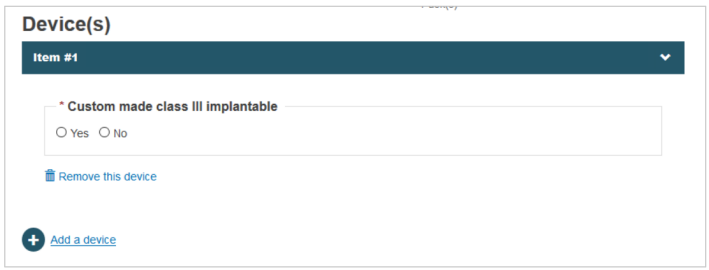


4.1.4. Provision of device data

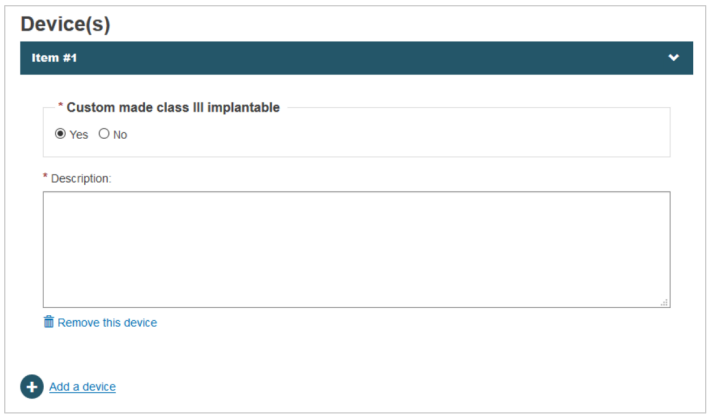
The device registered can be a:

- Custom made device
- Device referenced by name
- Device referenced by a reference/catalogue number
- Basic UDI-DI

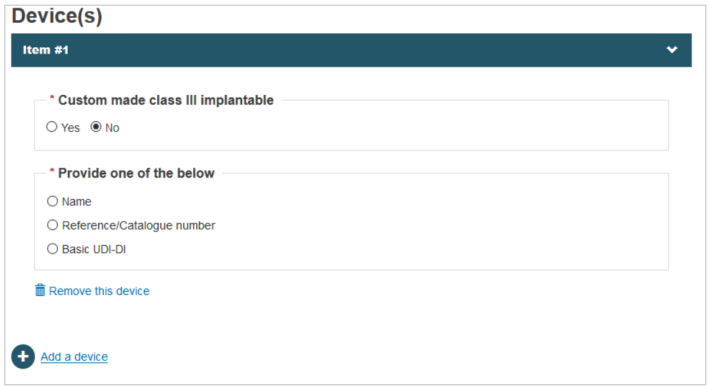
In this step you may choose to provide a custom-made device by selecting 'Yes' within *Custom made class III implantable* box:



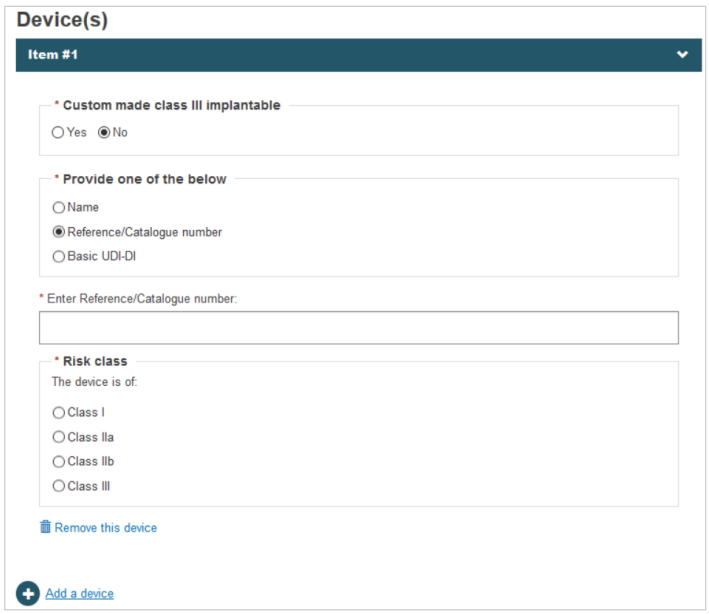
By doing so, EUDAMED will allow you to provide a description for the custom-made device:



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:



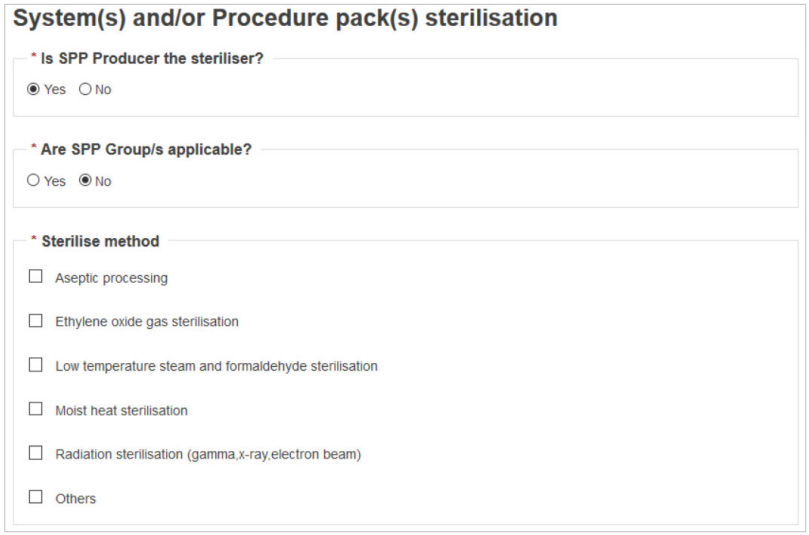
When either 'Name' or 'Reference/catalogue number' is selected, you must provide the risk class of the device.



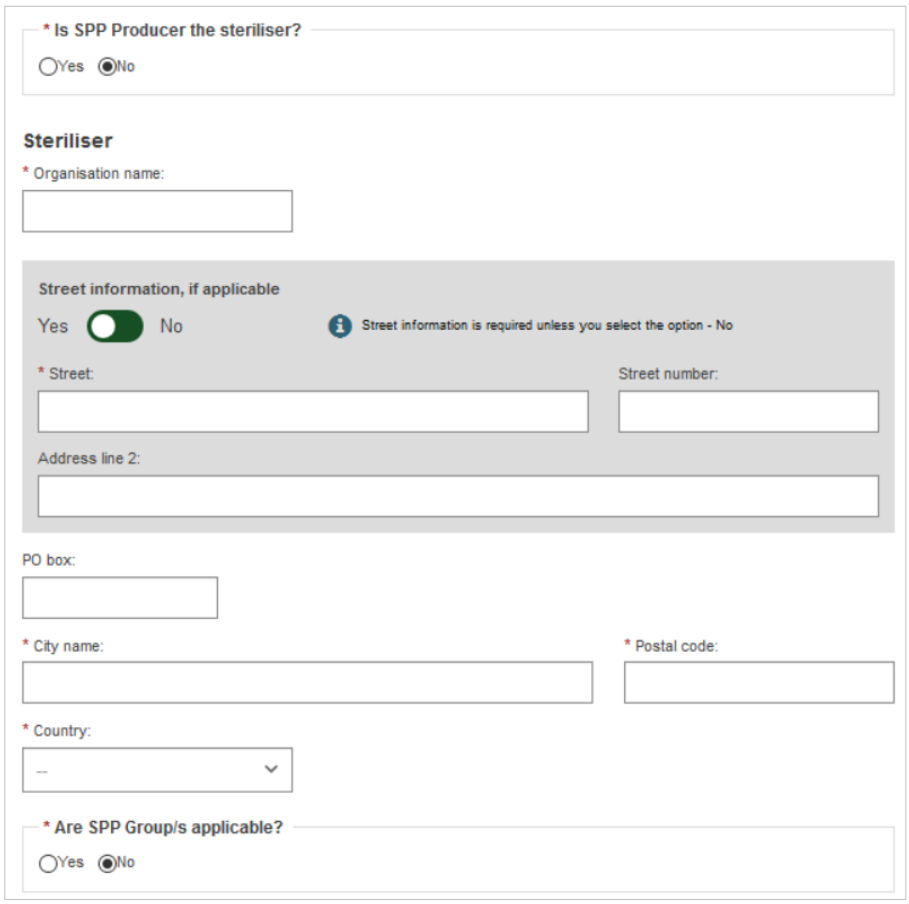
Click **Save** to save your draft or **Save & Next** to continue to the next step.

4.1.5. Provision of SPP details

If you have chosen a system or procedure pack, you must answer questions on sterilisation:

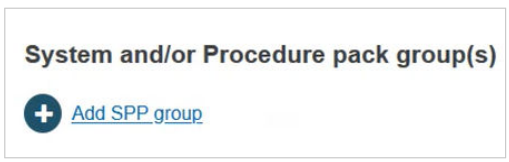


If the steriliser is not the SPP producer identified in the initial step of the registration wizard, answer 'No' to 'Is the SPP Producer the steriliser?' and provide the information requested to identify the sterilising organisation.



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.

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:

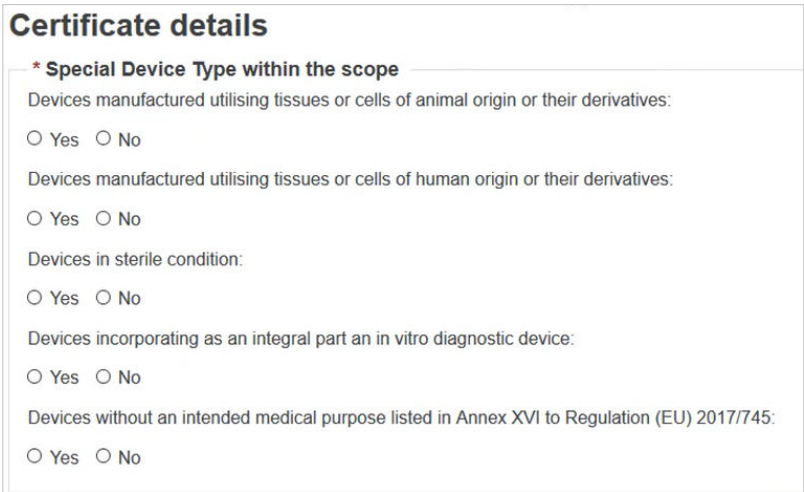


Add at least one SPP group:

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

4.1.6. Provision of certificate details

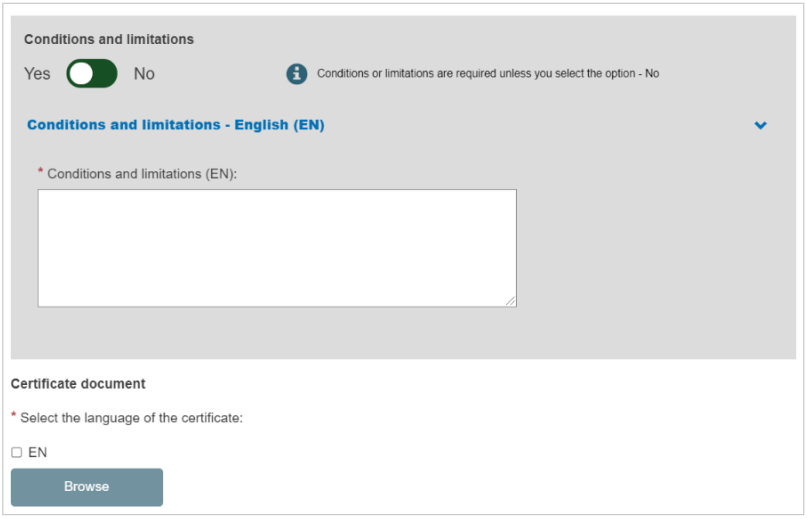
Select the correct options in the following list:



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’.

Enter the conditions and limitations if there are any, if none you can toggle to 'No':



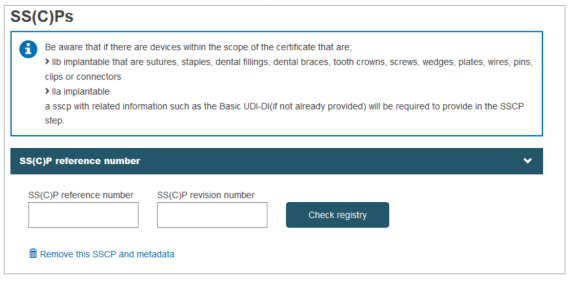
Select the languages in which the electronic version of the certificate is issued. You may upload more than one electronic document if it covers different languages, and you may upload several documents at once.

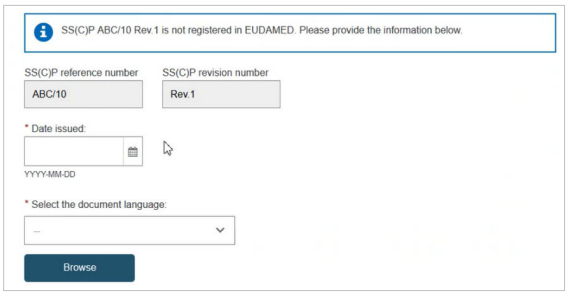
Click on either **Save** or **Save & Next**.

4.1.7. Provision of SS(C)P documents

For certain high-risk devices that are implantable as required by the Regulation, the provision of an SS(C)P is required. An SS(C)P record within EUDAMED can be attached to many certificates. Hence, 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 record exists in EUDAMED that record will be displayed. Otherwise, you may enter a new SS(C)P registration. You may also create a new SS(C)P version of a reused SS(C)P (*see Step* 4.1.8 [14]):



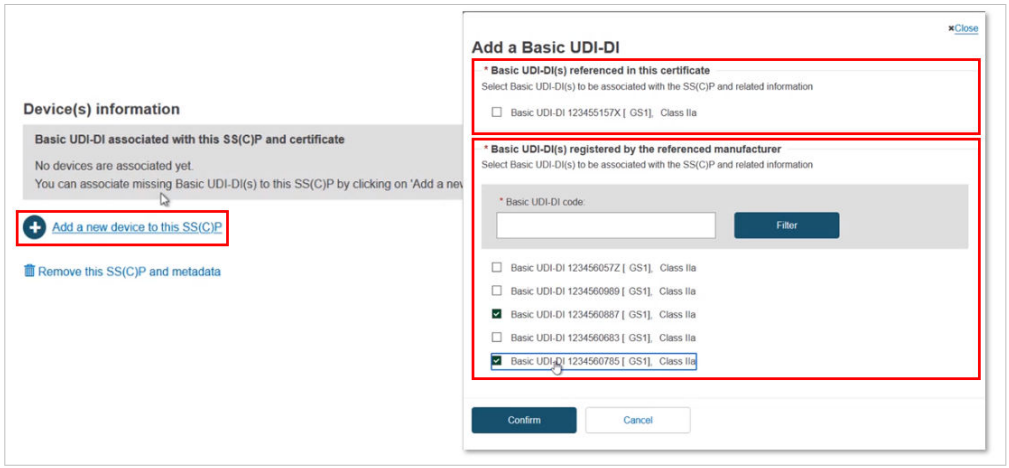


Enter the issued date and select the language of the document. Click **Browse** to upload the SS(C)P master document.

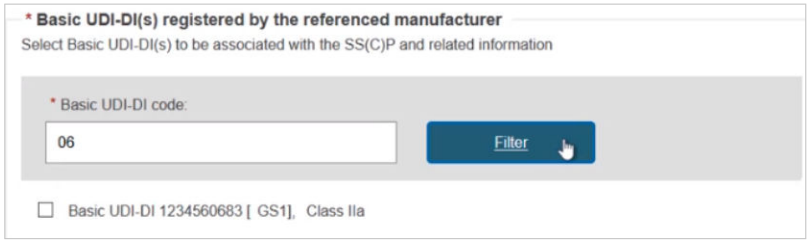
Click 'Yes' to the question 'Is this SS(C)P validated' to indicate that the uploaded master document is validated, otherwise click on 'No':

In order to register an SS(C)P, a Basic UDI-DI is required. Within the ‘Device(s) information’ box a respective Basic UDI-DI can be added.

The *Devices 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, and (for quality certificates only) a list of all devices registered by the referenced manufacturer. You can select multiple devices.:

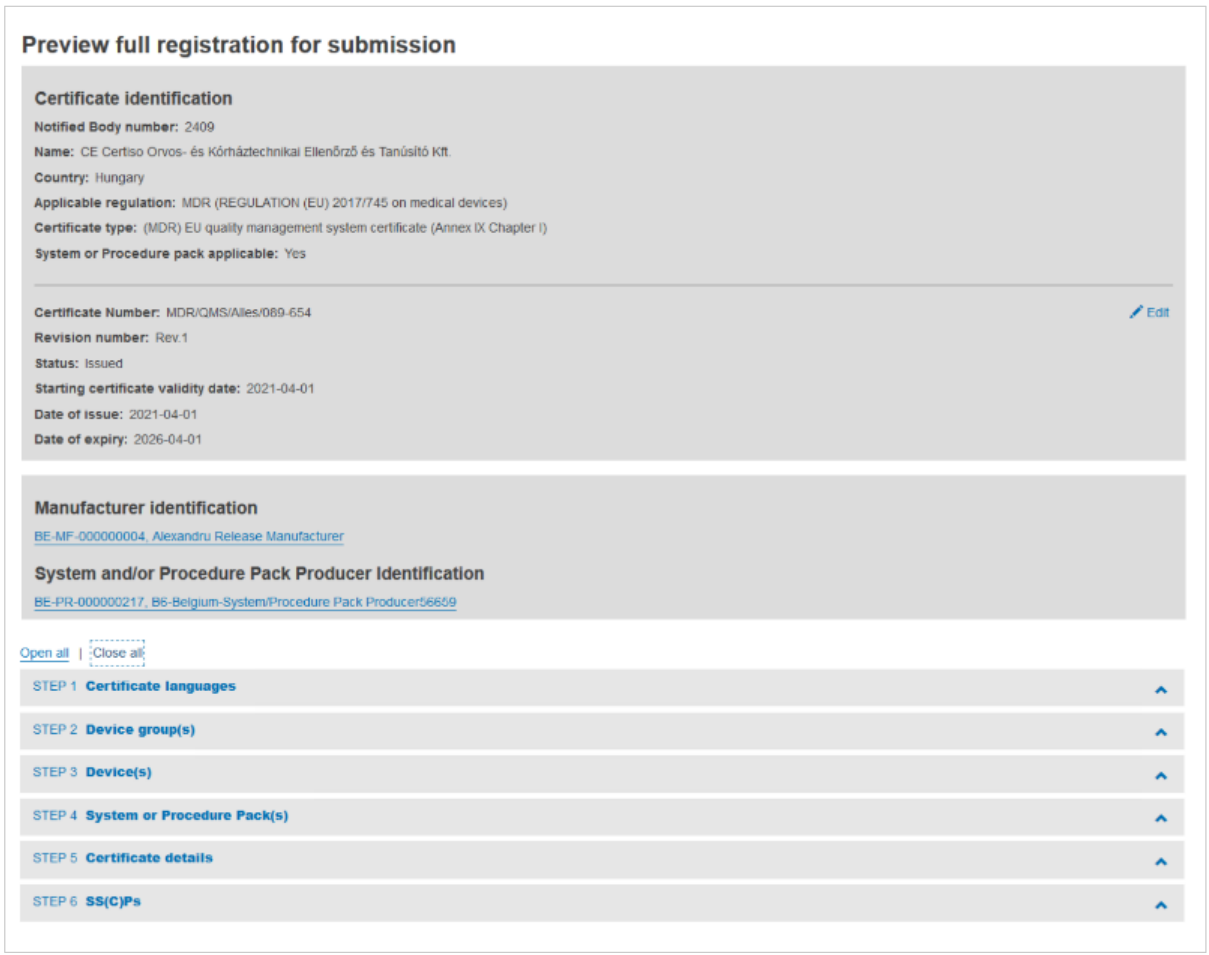


You can input a partial Basic UDI-DI number and click **Filter** to narrow down the search results.

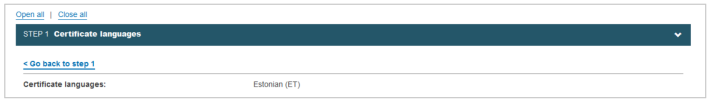


Once selected, click **Confirm** to link the devices to this new SC(C)P. Nothing is yet submitted, and you can delete this SS(C)P by clicking ‘Remove this SS(C)P and metadata’ to return to the previous screen.

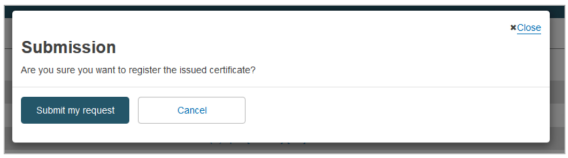
When finished click on the **Preview** button to review the provided information:

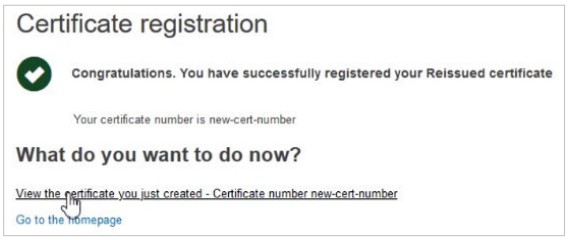


From this page you can easily access desired step of the wizard by clicking the respective link:



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

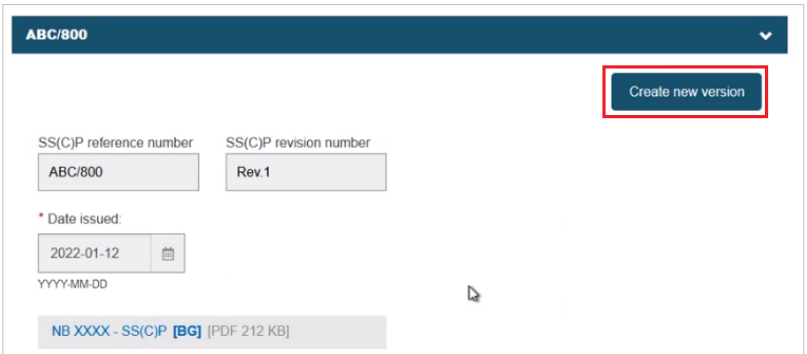




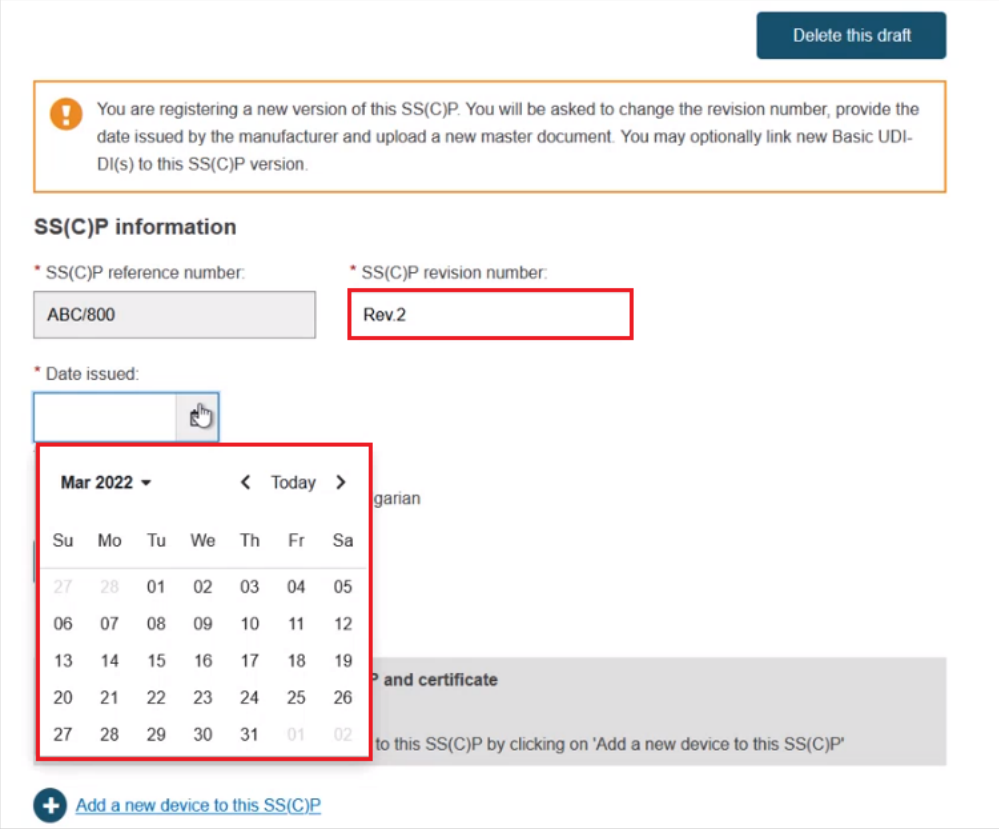
From the congratulation page you can click on *View the certificate you just created* to open the registered certificate view page or you can click on *Go to homepage* to return to your homepage.

4.1.8. Create a new SS(C)P version of a reused SS(C)P

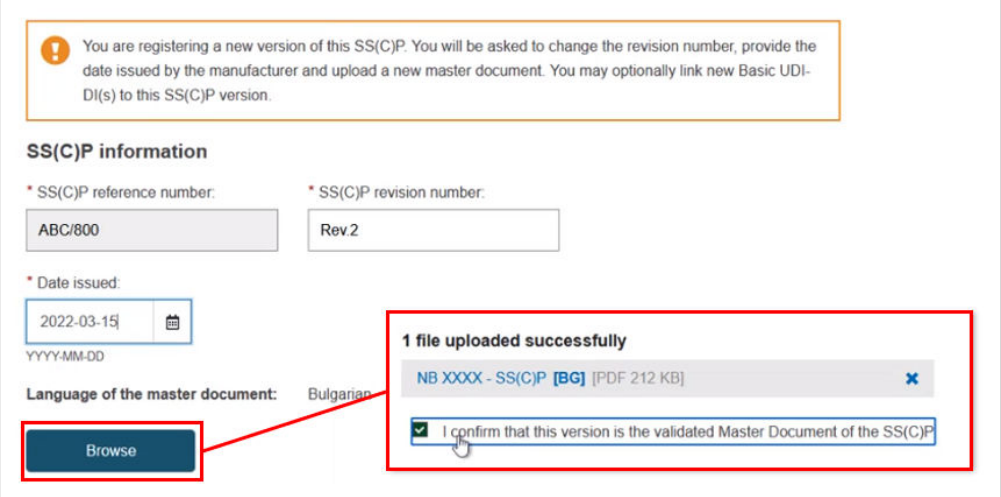
You can reuse and existing SS(C)P if one is already registered, and link your devices to it. However, you can also create a new SS(C)P version, while referencing an existing SS(C)P. Click **Create new version**.



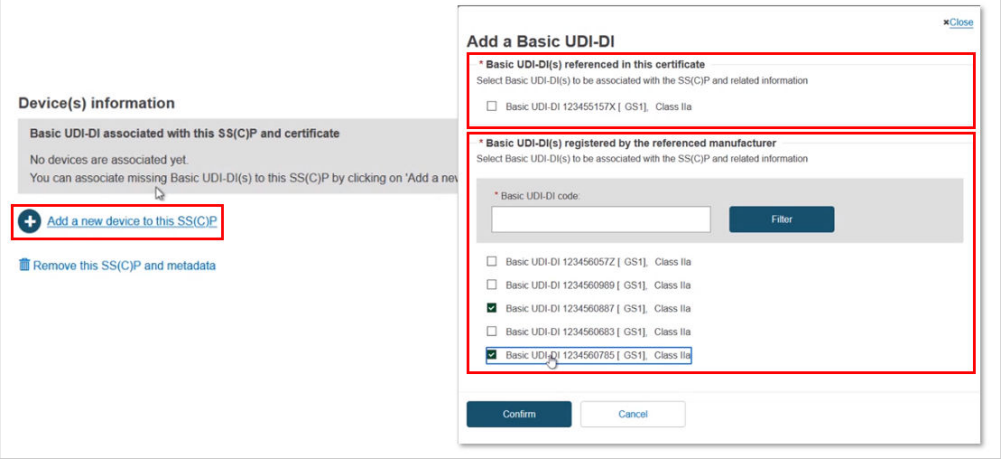
The warning message requests a revision number that must be different from the previous version, a manufacturer-provided issue date and a new master document. Click ‘Date issued’ and input the date.



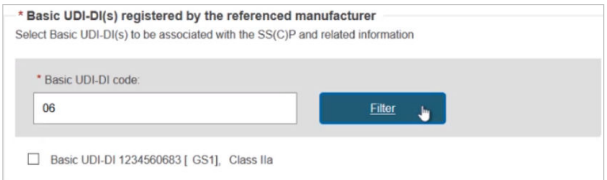
Click **Browse** to upload the new master document in the pre-selected language, and confirm that it has been validated.



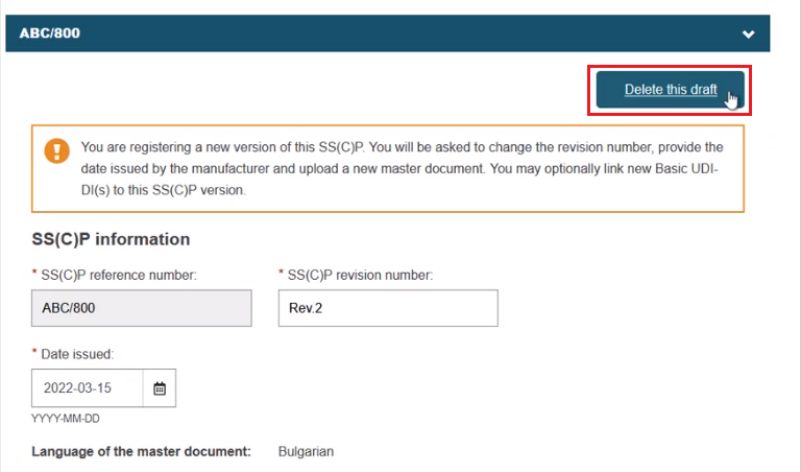
The *Devices information* box confirms no associated devices. Click 'Add a new device to this SC(C)P'. The pop-up shows two sections: the Basic UDI-DI(s) referenced in this certificate, and (for quality certificates only) a list of all devices registered by the referenced manufacturer. You can select multiple devices.



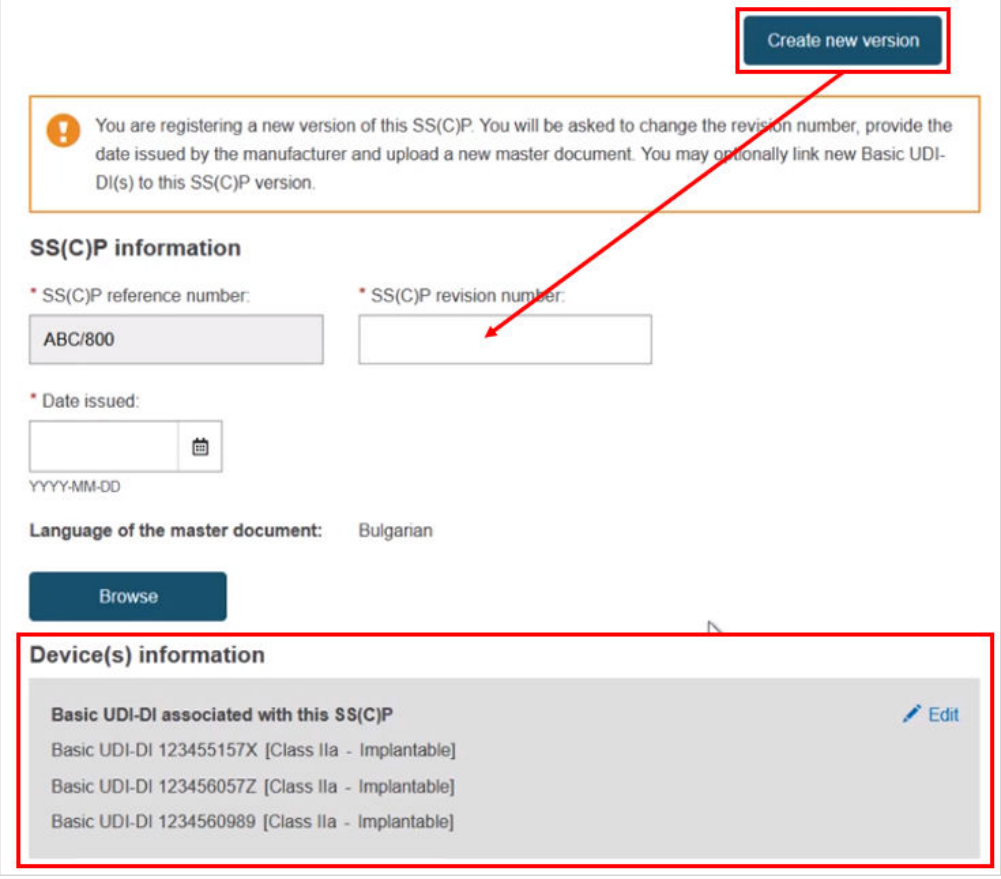
You can input a partial Basic UDI-DI number and click Filter to narrow down the search results.



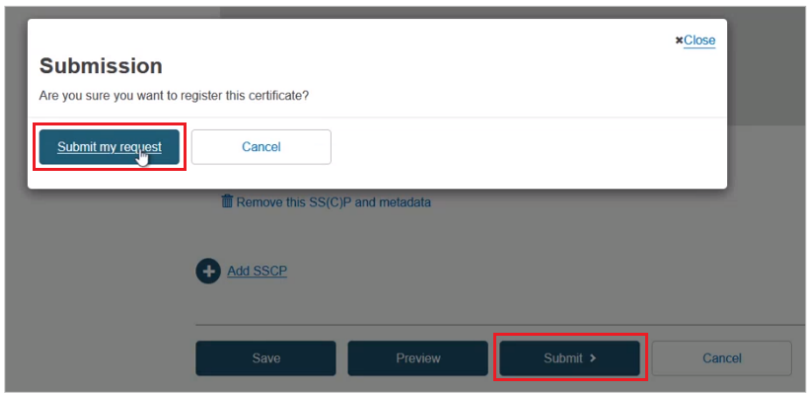
Once selected, click **Confirm** to link the devices to the revised SC(C)P. Nothing is yet submitted, and you can delete the inputs/links by clicking **Delete this draft** to return to the previous screen.



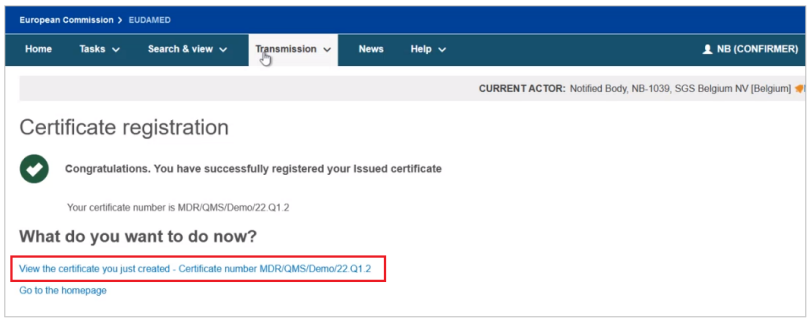
You may also perform the tasks in reverse order. First select the Basic UDI-DI(s) so they display, then click Create new version and input the revision number, date and master document etc.



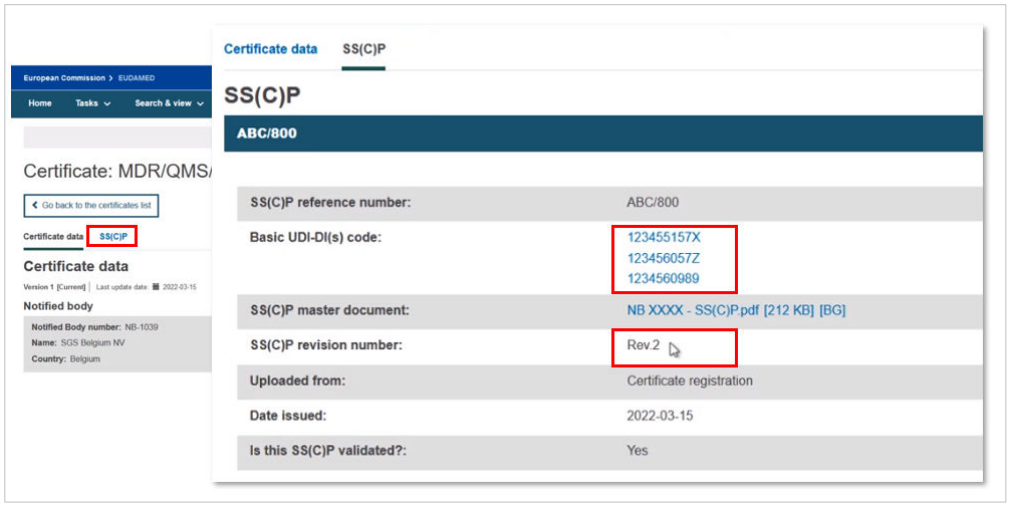
Click **Save** to continue, or **Submit**. In the confirmation click **Submit my request**.



From the congratulation page, click ‘View the certificate you just created’.

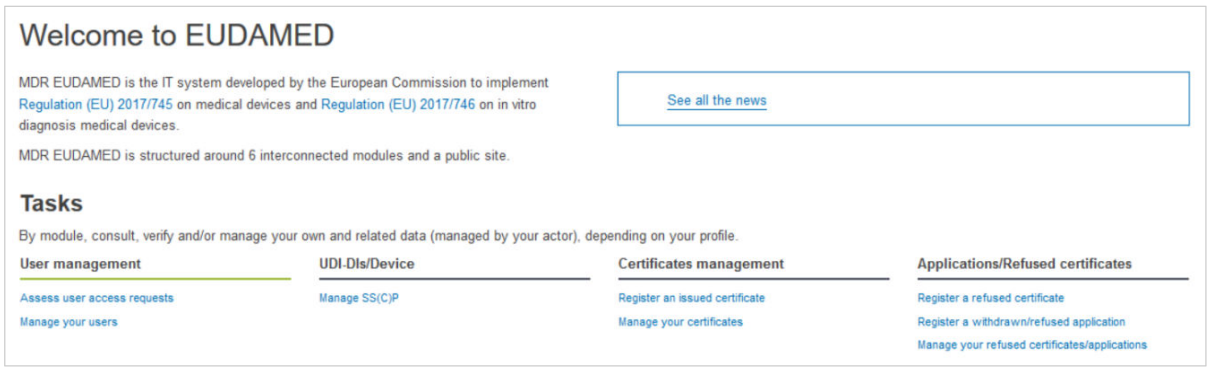


You can view the newly created certificate version, and all the devices linked to the new registered SS(C)P version.



4.2. Product class certificate registration

On the homepage of EUDAMED, click on 'Register an issued certificate'. In this scenario we will choose a product type certificate:

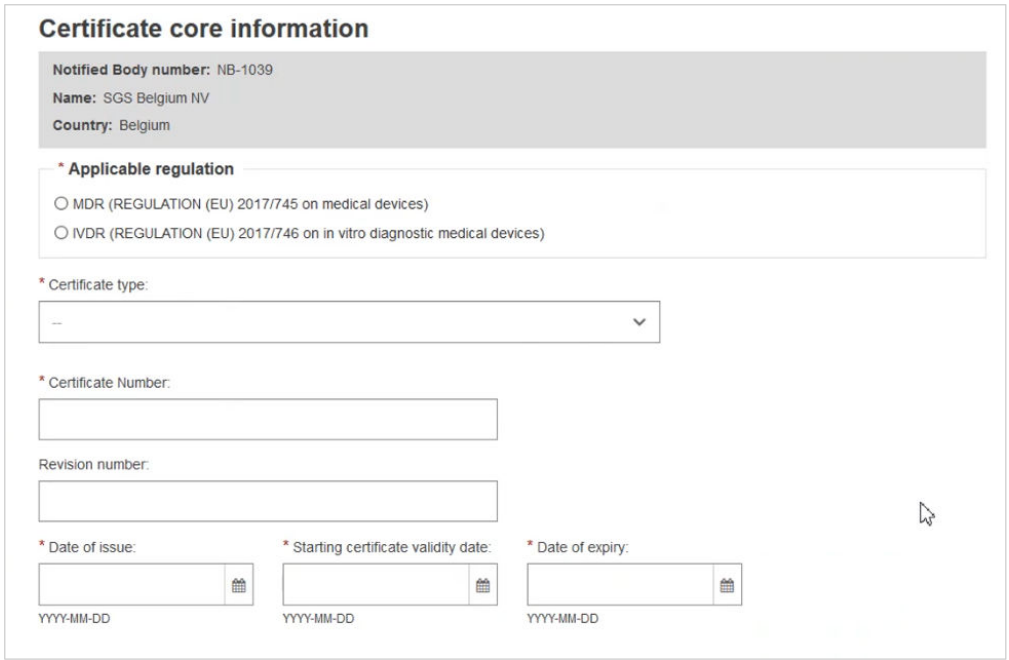


4.2.1. Provision of core certificate data

In the first step you must choose between one of two applicable regulation types, then a certificate type.

You must also enter a certificate number and an optional revision number.

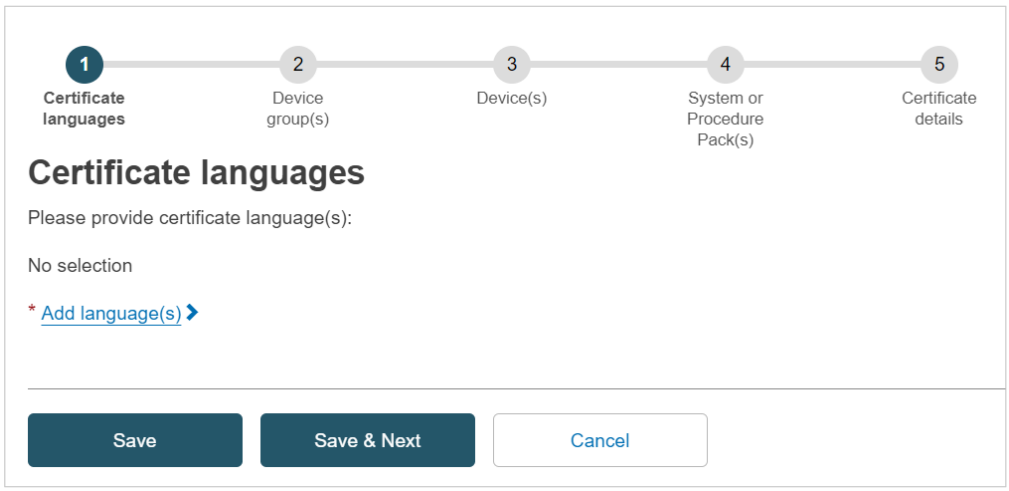
Enter the correct dates concerning the certificate, and enter the Actor ID/SRN or name of the manufacturer:



Click on **Save & Next**.

4.2.2. Provision of certificate language

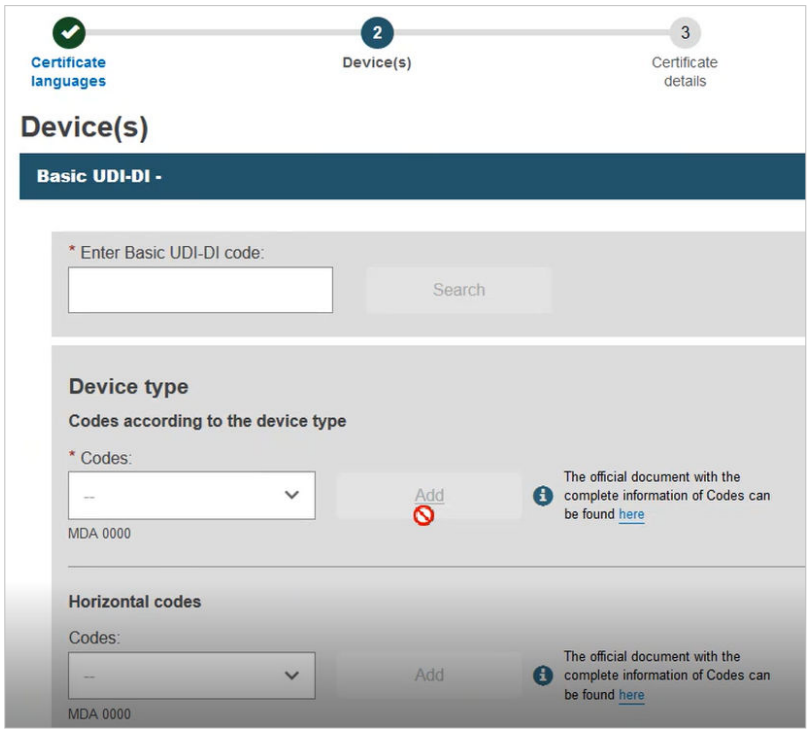
Click 'Add languages' and the system will display a dialog from where you can multi-select from a list of official EU languages:



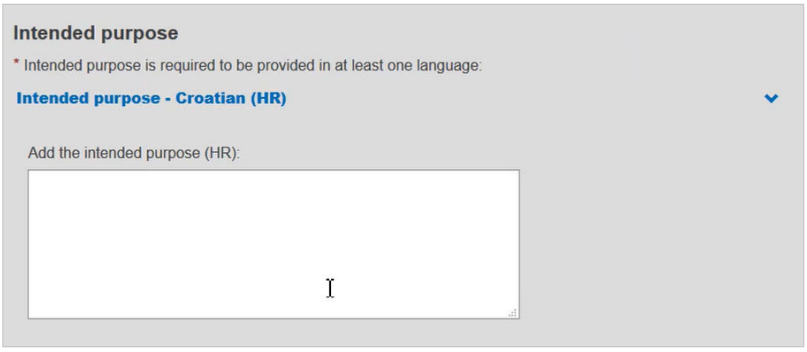
Once you are done you can either **Save** your draft or click **Save & Next** to continue to the next step.

4.2.3. Provision of device data

In this step, you must enter a Basic UDI-DI code and choose the codes for the device type from the dropdown list:



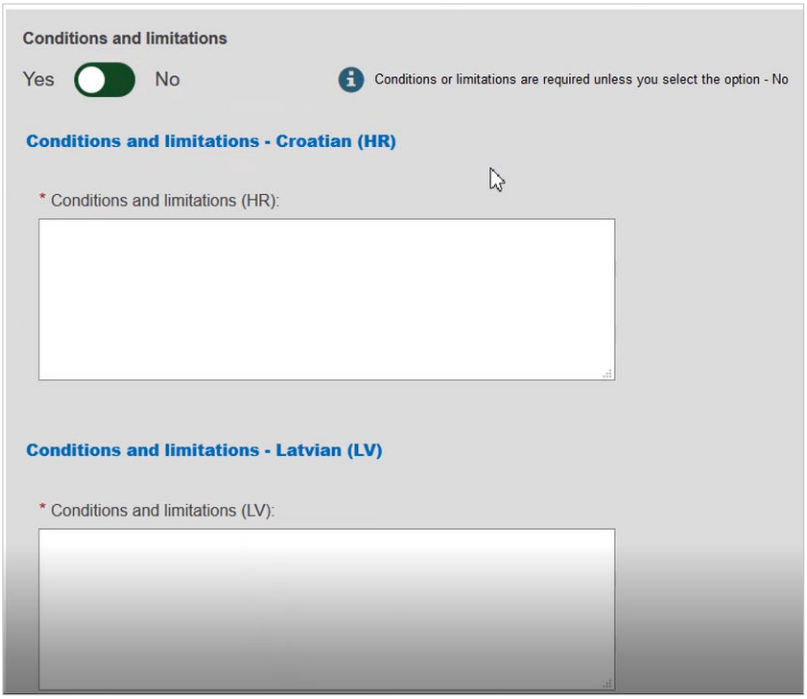
Enter the Intended purpose of the device in each language you have chosen in the prior steps:



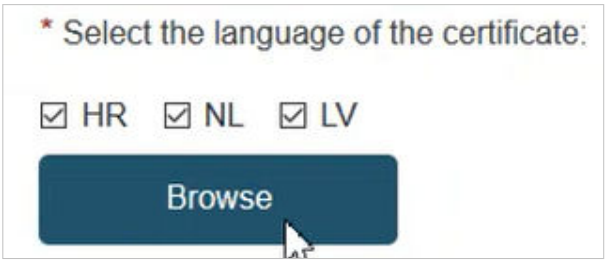
Click either **Save** or **Save & Next**.

4.2.4. Provision of certificate details

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



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:



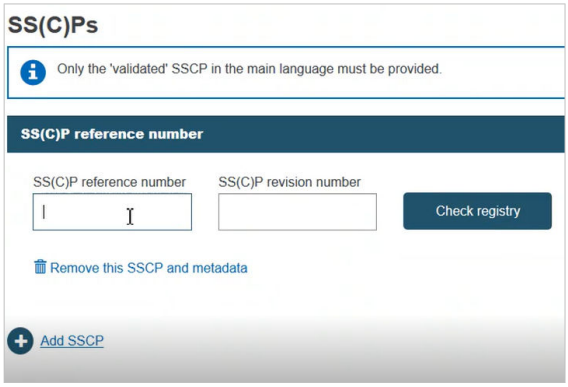
Click either **Save** or **Save & Next**.

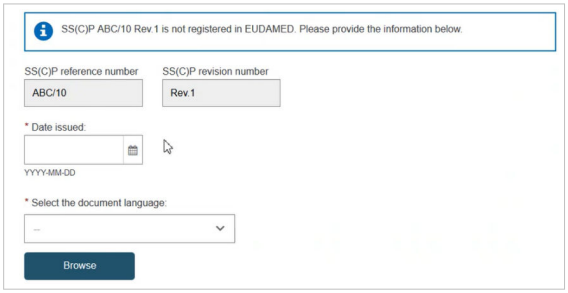
4.2.5. Provision of SS(C)P documents

For certain high risk devices that are implantable as required by the Regulation, the provision of an SS(C)P is required.

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

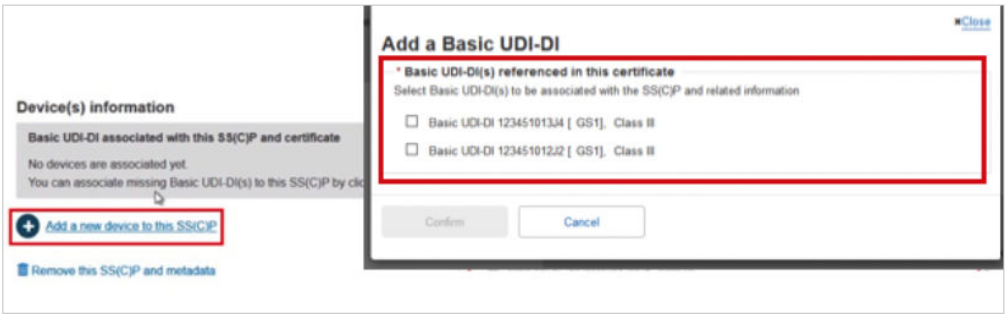
If the record exists in EUDAMED that record will be displayed. Otherwise, you may enter a new SS(C)P registration:





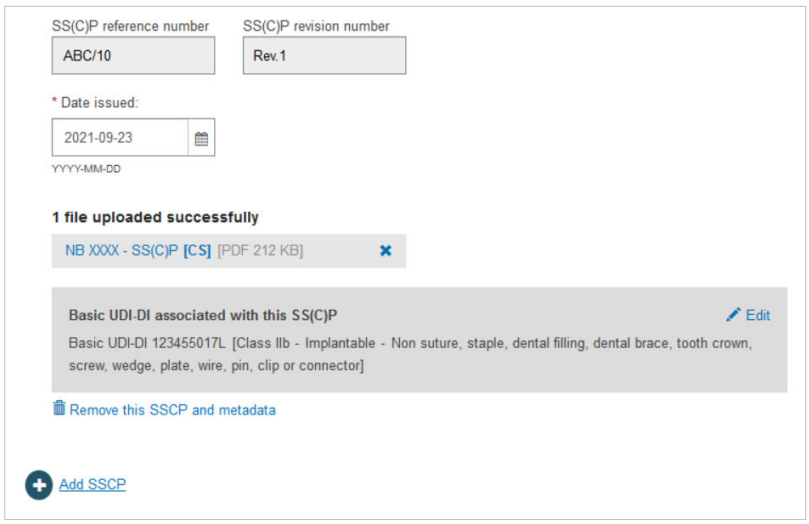
Enter the issued date and select the language of the document. Click **Browse** to upload the SS(C)P master document.

The *Devices 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.

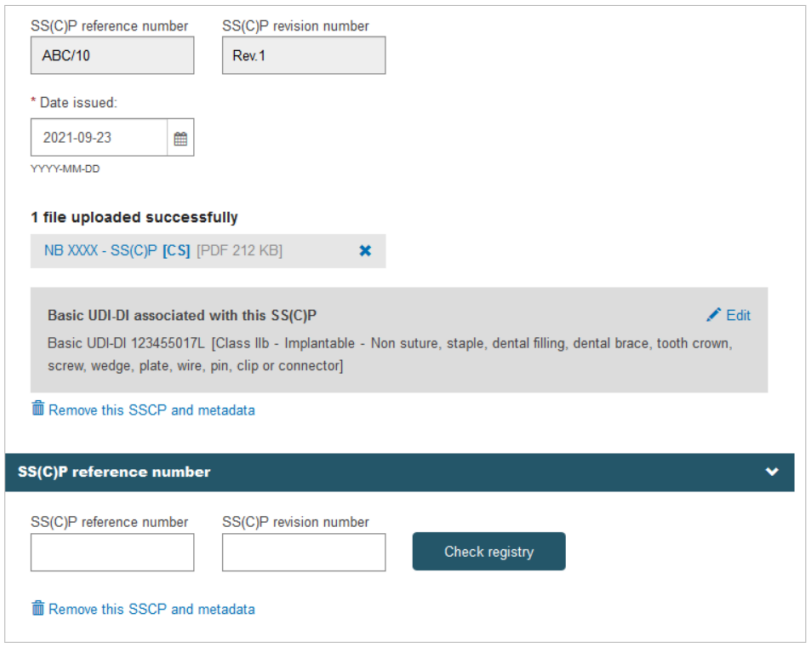


Once selected, click **Confirm** to link the devices to the SC(C)P. Nothing is yet submitted, and you can remove this SS(C)P by clicking on ‘Remove this SS(C)P and metadata’ and return to the previous screen.

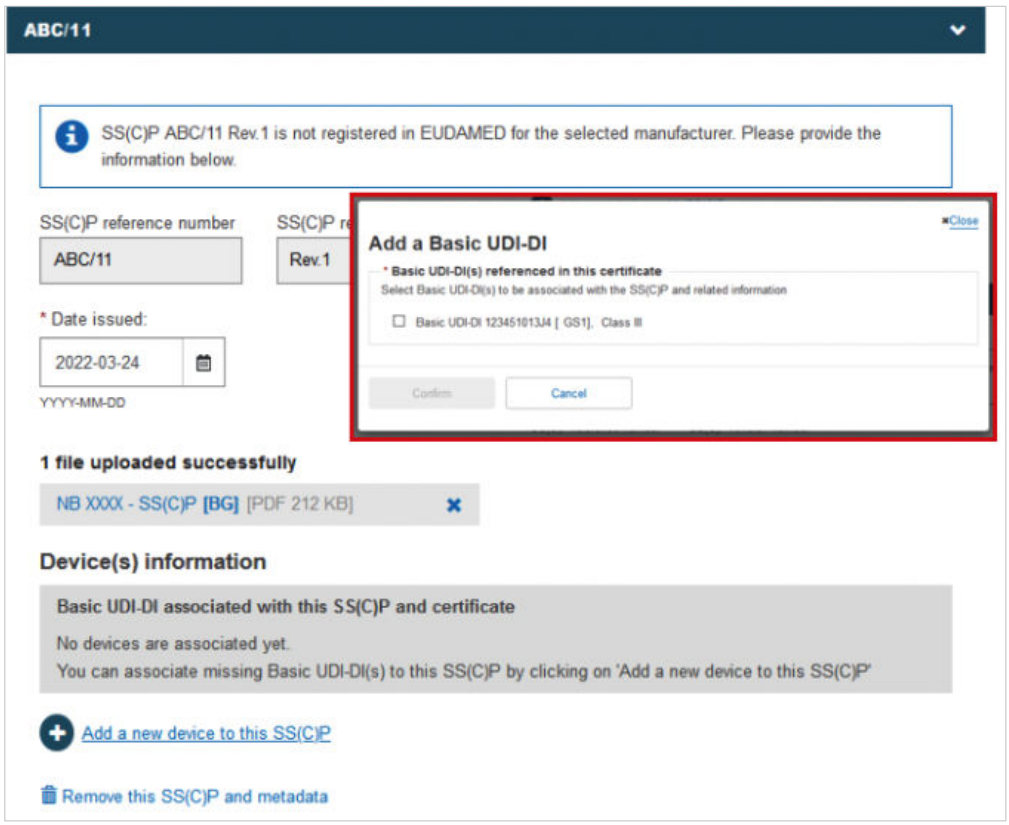
You may register more than one SS(C)P. Select the device that is described by the SS(C)P being registered and click the **Confirm** button.

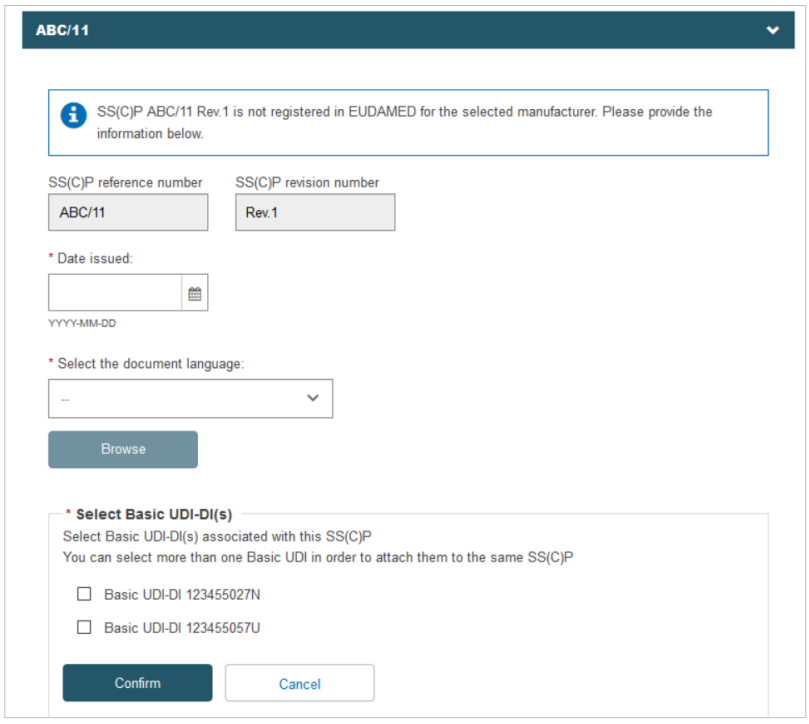


To register additional SS(C)Ps, click on 'Add SSCP'. You will be provided with a new search dialog for an SS(C)P.



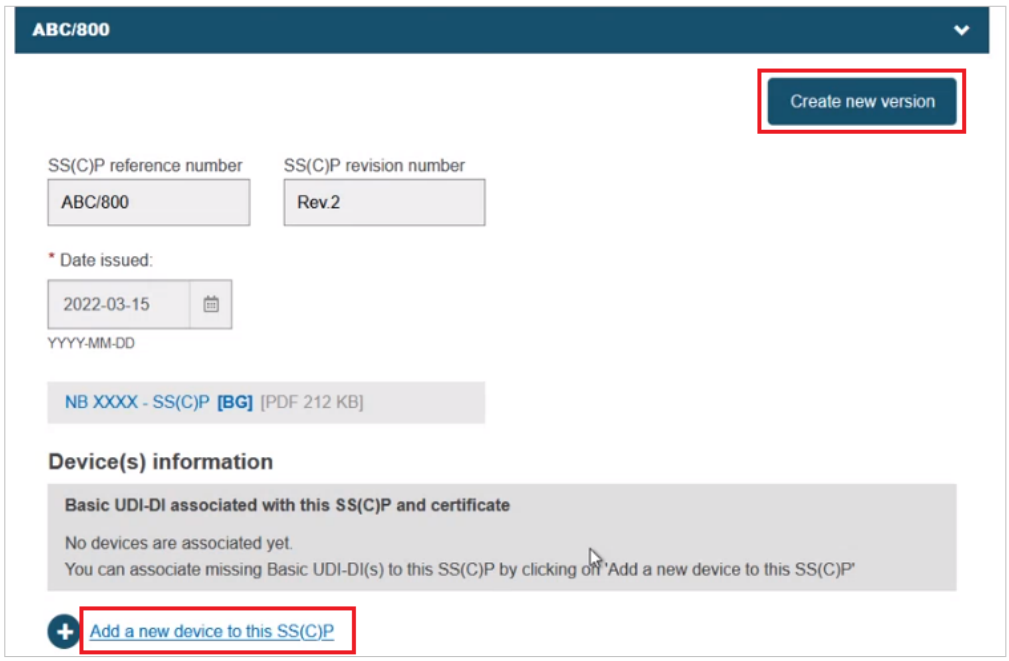
When registering additional SS(C)Ps, by clicking on ‘Add a new device to this SS(C)P’, the system will display the remaining devices in the scope of the certificate to be linked to the additional SS(C)P.



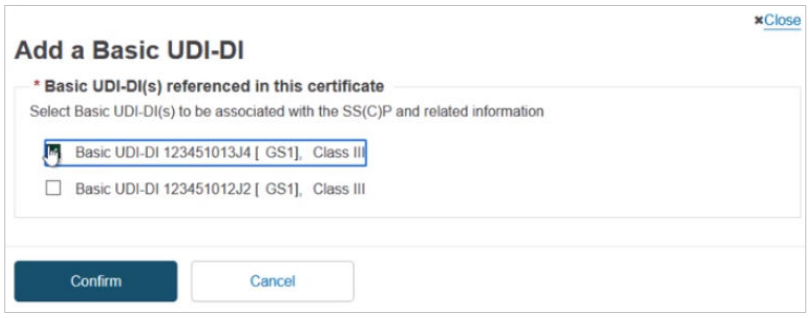


When finished click **Save** or **Save & Next**.

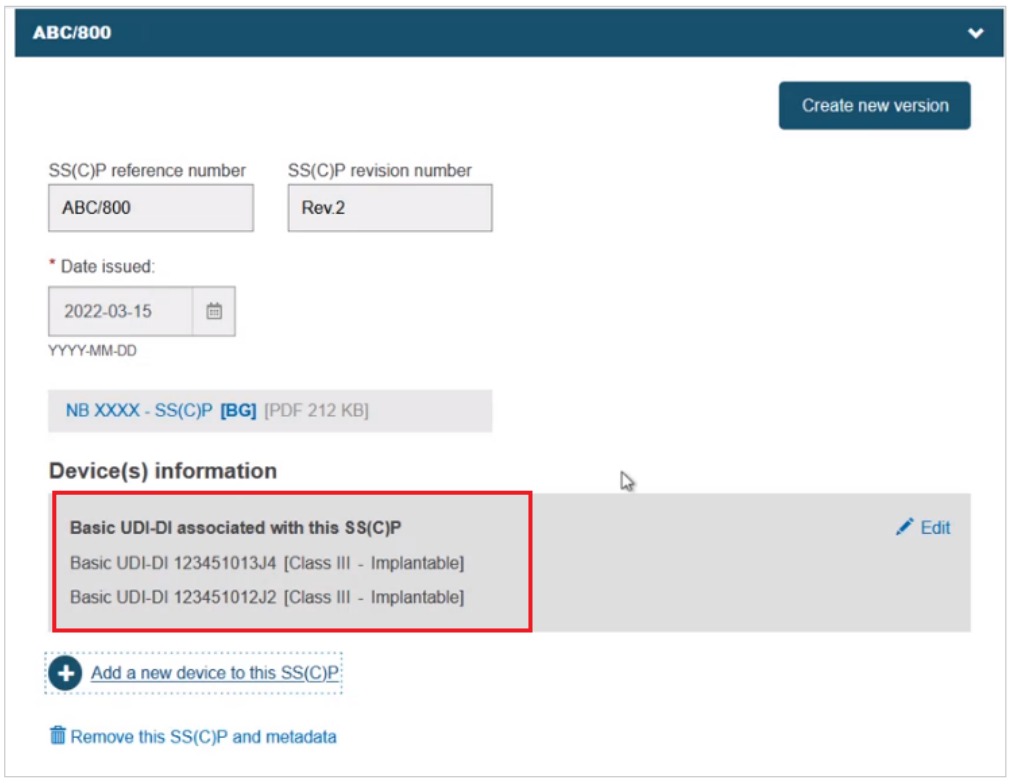
Alternatively, you can create a new version of an existing SS(C)P. Click 'Create new version' and provide a version number, issue date and master document (see *Step 4.1.7 [11]* for Quality certificates). Click 'Add a new device to this SS(C)P' to add new devices to this new SS(C)P version:



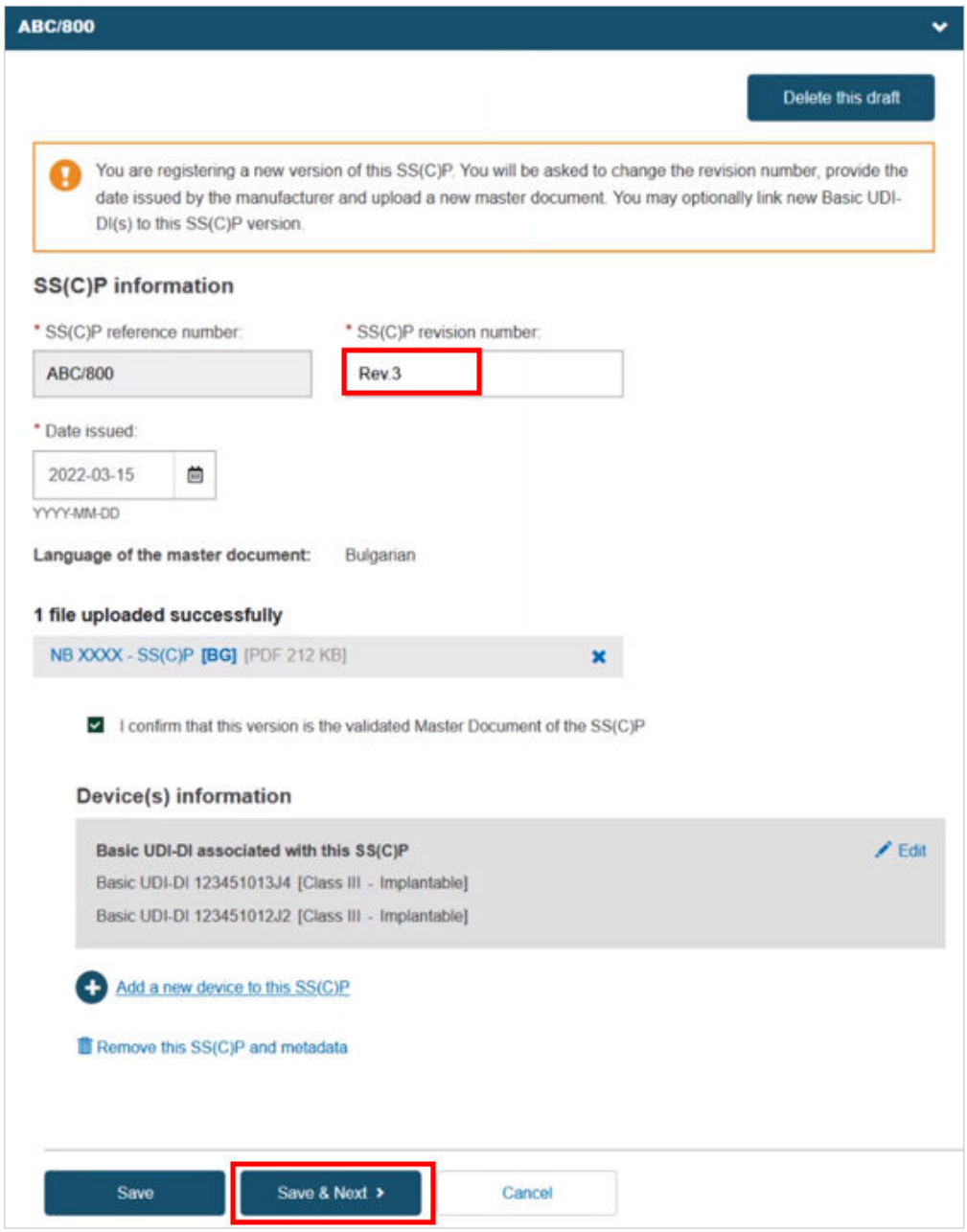
The pop-up lists Basic UDI-DI(s) which are referenced in the certificate. No others can be added. Select one or multiple from the display, and click Confirm:



The selected devices are listed:

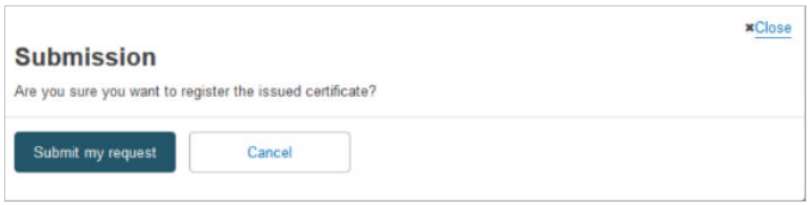


You can still create a new version using the Create new version button as shown previously, and the selected devices will link to it. Click **Save & Next** to proceed:

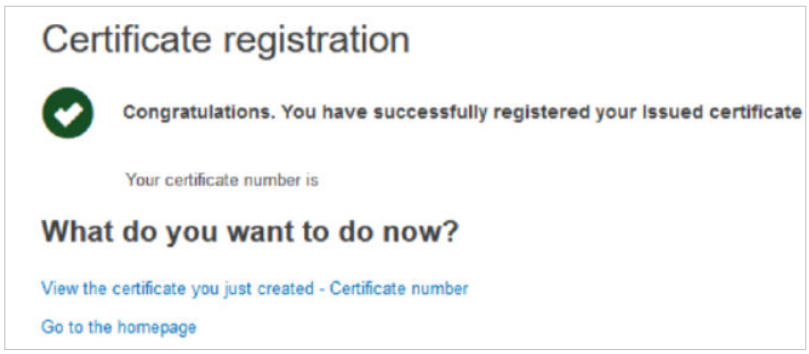


Click **Save** to save as a draft, **Preview** to verify the information provided, or **Submit** to submit your registration.

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



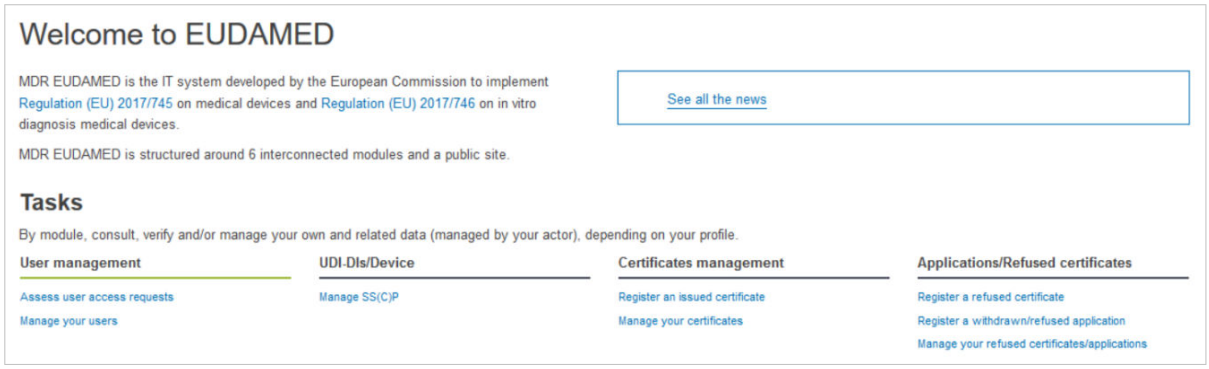
You will be shown a page confirming your registration.

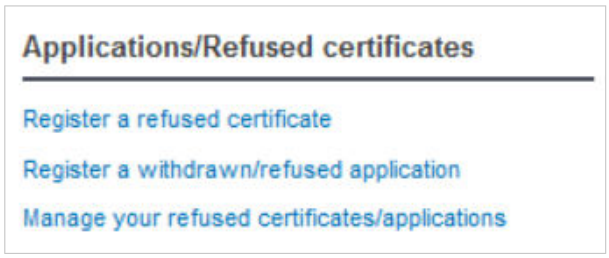


From here you can click 'View the certificate you just created'' to view the certificate, or you can click the 'Go to homepage' link in order to return to your homepage.

5. Register a refused certificate

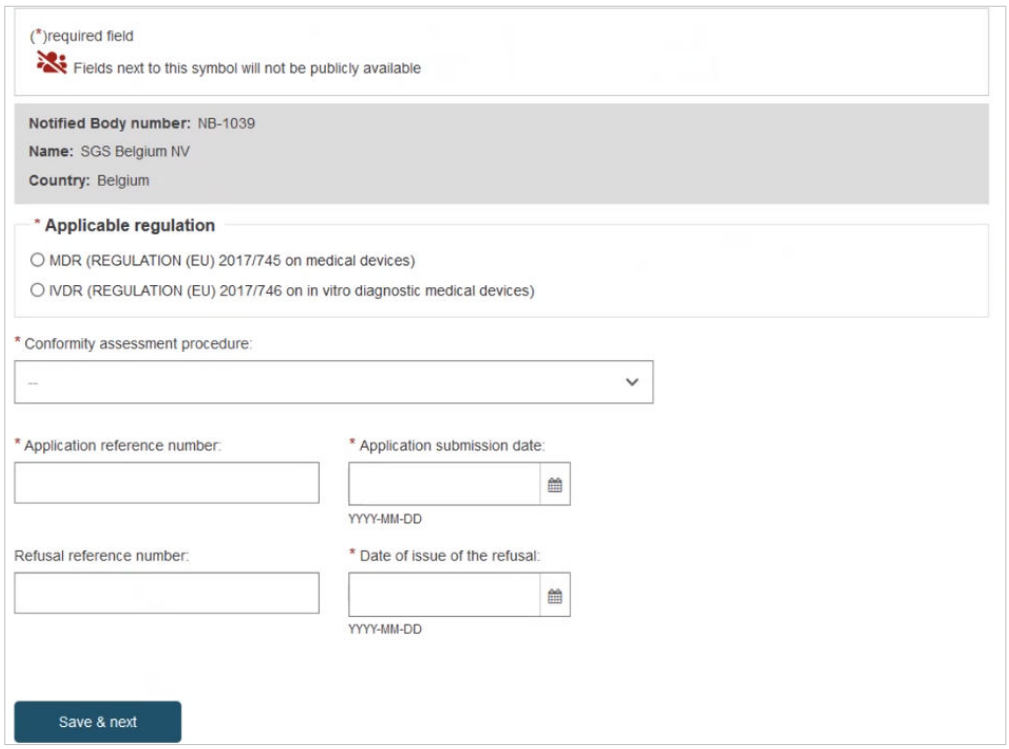
To register a refused certificate, go to the homepage of EUDAMED as a Notified Body, look for the *Application/Refused* section and there click 'Register a refused certificate'.





5.1. Provision of core data

You are now brought to the core information page for the refused certificate, this step resembles the process for registering a normal certificate.



Select the applicable Regulation and the conformity assessment procedure from the list. Then, enter the application reference number.

NOTE
The system will warn you when the application reference number is not unique.

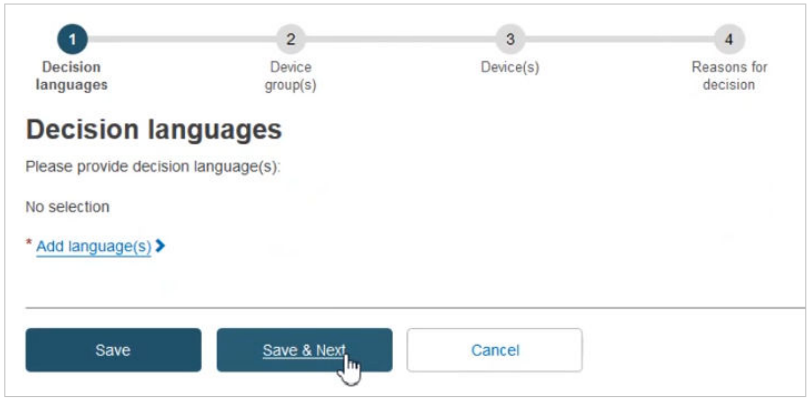
Provide the correct dates for both the application submission and the date of issue of the refusal.

Enter the Manufacturer information (after entering the Actor ID/SRN or Name).

Click **Save & next**.

5.2. Decision languages

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



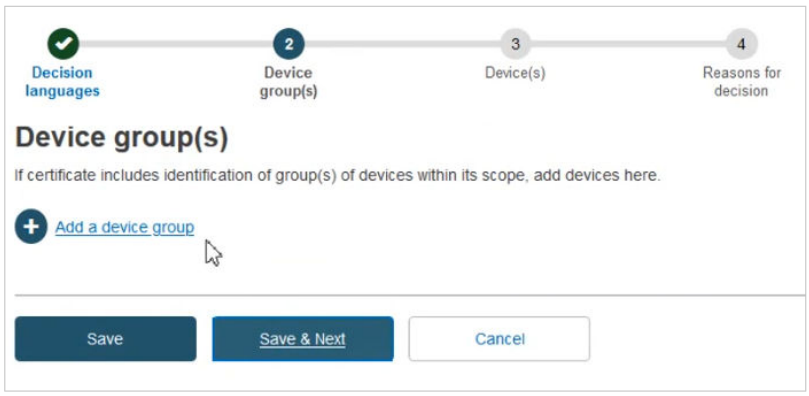
You can remove all the languages or add more if you wish to.

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

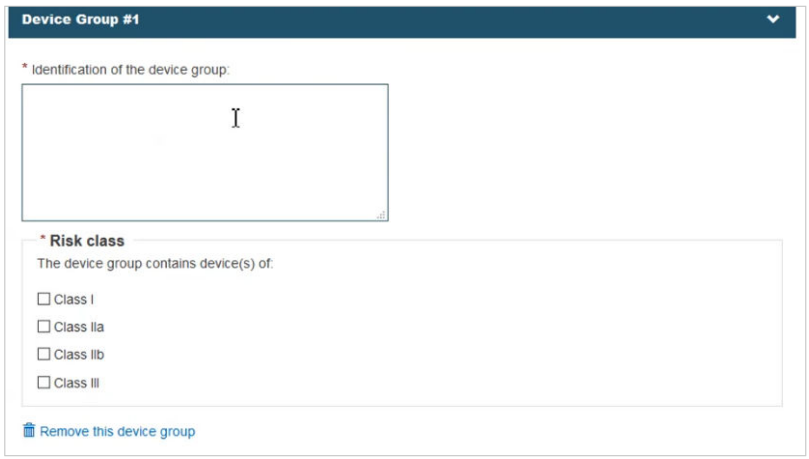
5.3. Device group(s)

Next, you will need to add a device group.

Click **+ Add a device group**.



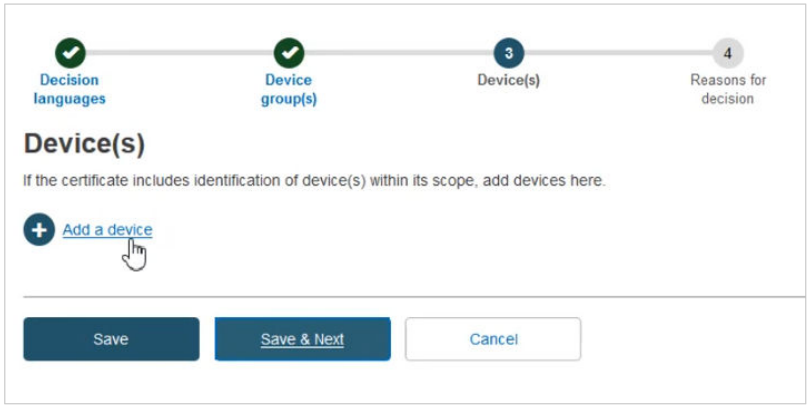
Enter the identification of the device group and the risk class.



Click **Save & Next**.

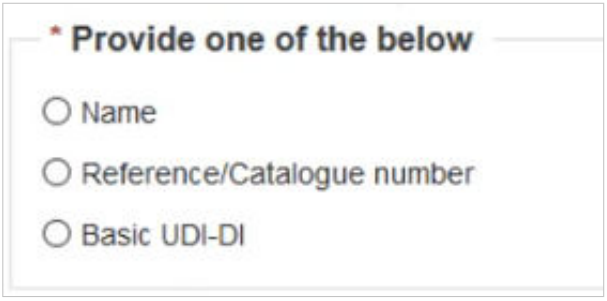
5.4. Devices

Click **+ Add a device**.

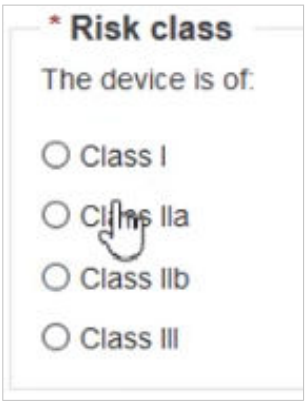


Choose 'Yes' or 'No' whether the device is custom made or not.

Provide either a Name/Reference/Basic UDI-DI.



Choose the 'Risk class'.



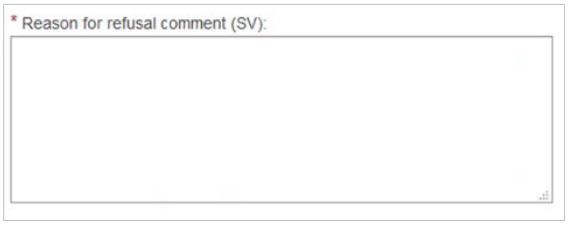
Click **Save & Next**.

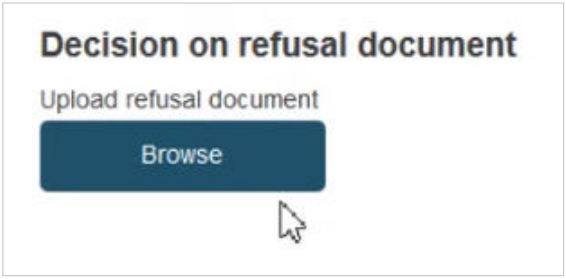
5.5. Reasons for decision

In this step you need to provide the information to why you have refused this certificate.

Select one or more reasons from the list below, and enter the reason for the refusal comment in the languages you have chosen in the *Decision languages* step (in this case, Spanish and Slovak).

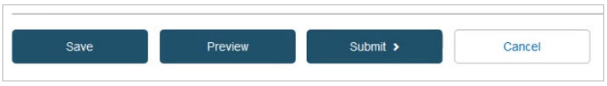
NOTE
If you select 'Other', you will have to provide the reason in the languages you have chosen in the *Decision languages* step.

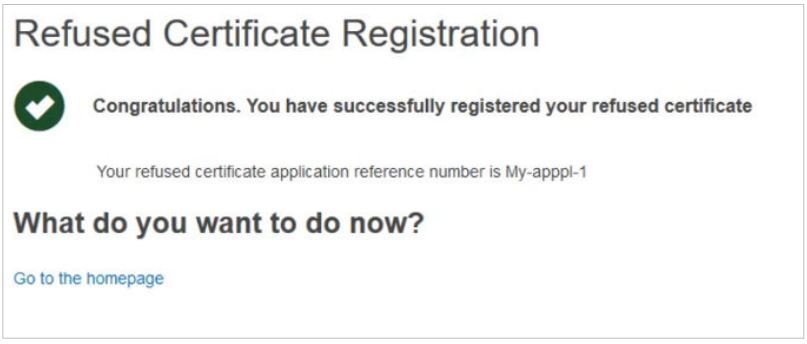




IMPORTANT
Decision on refusal document will be accessible only by competent authorities, the European Commission, and the Notified Body that registered it.

Click **Submit** to finish the registration:



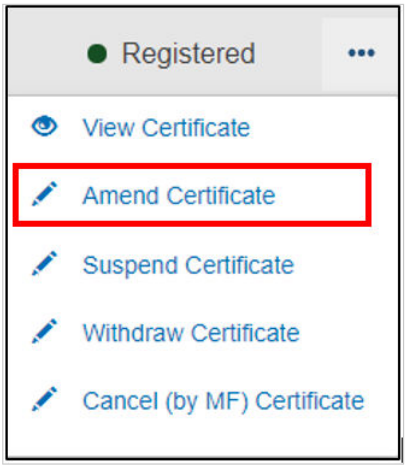


6. Update a certificate

NOTE
In order to update a certificate, be sure to change the status in the search filters on the *Manage your certificates* page to 'Registered'.

6.1. Amend

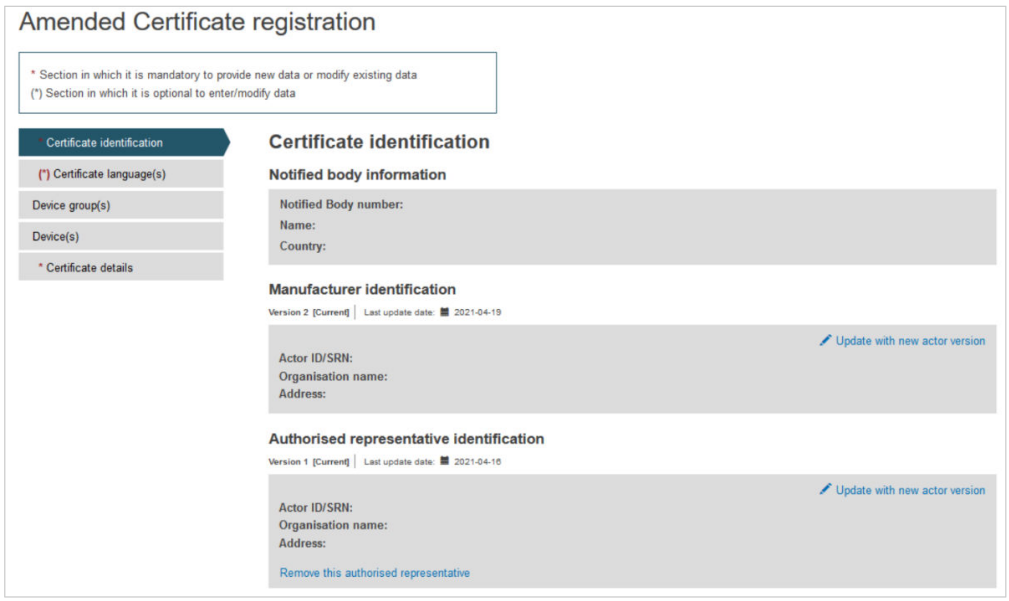
To amend a certificate, you will have to click the three dots next to the certificate you wish to amend and click 'Amend Certificate'.



TIP
'Amend Certificate' is missing?

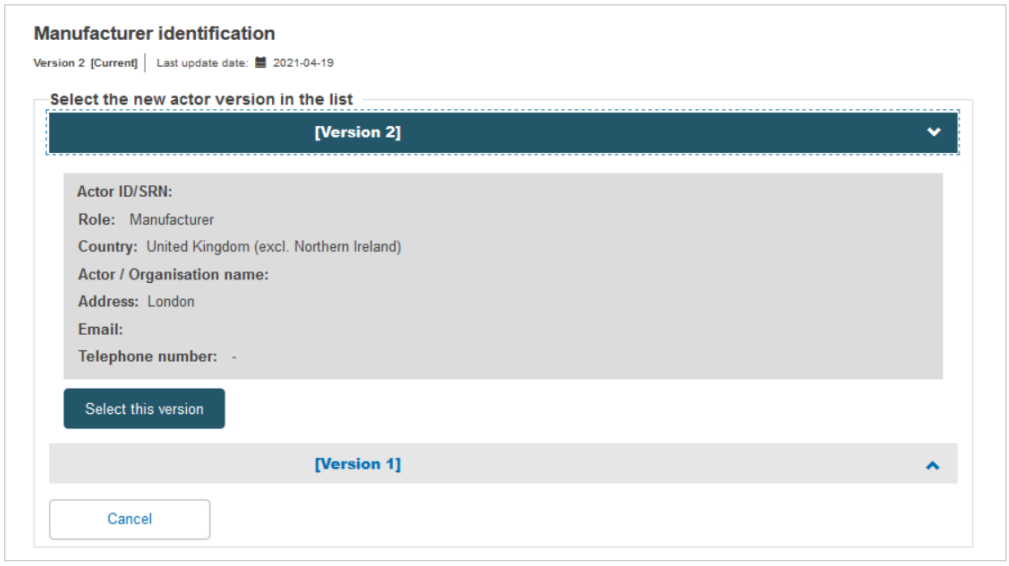
- Verify that your certificate is not in draft state within the certificate management page.
- If a draft version exists, it must be finalised or deleted. The 'Amend Certificate' operation will now be available.

You will arrive to the following page.



To select another version of the Manufacturer, Producer or Authorised representative, click on 'Update with new actor version' link.

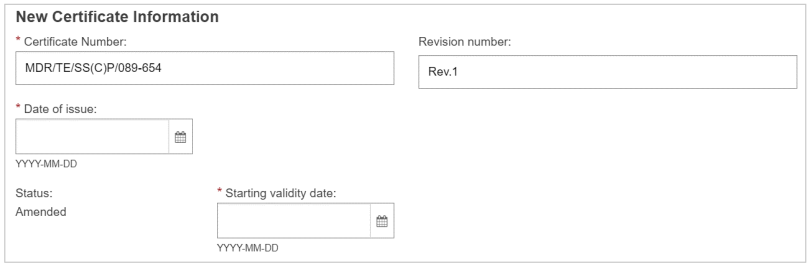
You will see a dialog to select another version of this actor (if it exists):



Click the **Select this version** button to select actor version and close this dialog.

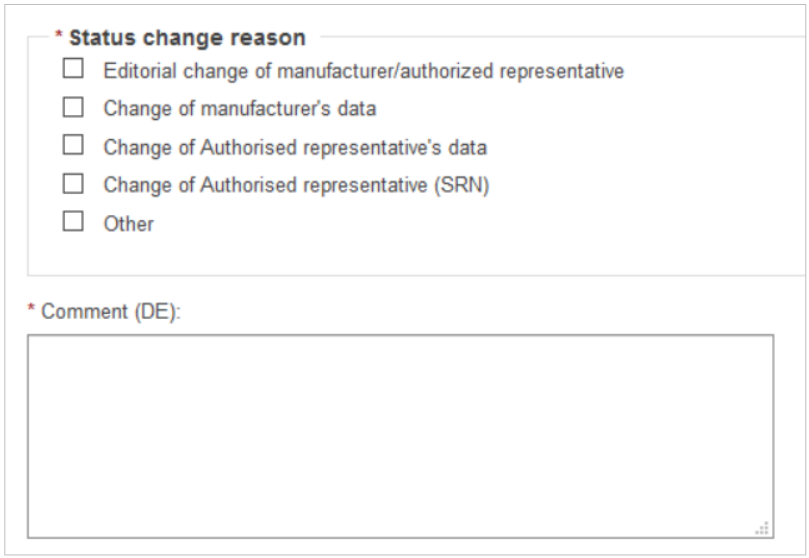
The preceding certificate information box displays core information about the preceding certificate.

Below that, you will see the following.

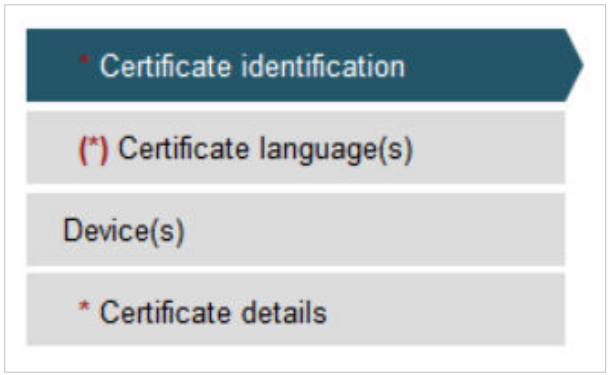


Enter the new 'Certificate Number' and add a revision number if you want to. Enter the date of issue and the starting validity date.

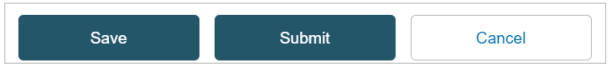
Select one of the reasons for the change to the certificate and add a comment in the comment box in the language the certificate was registered.



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

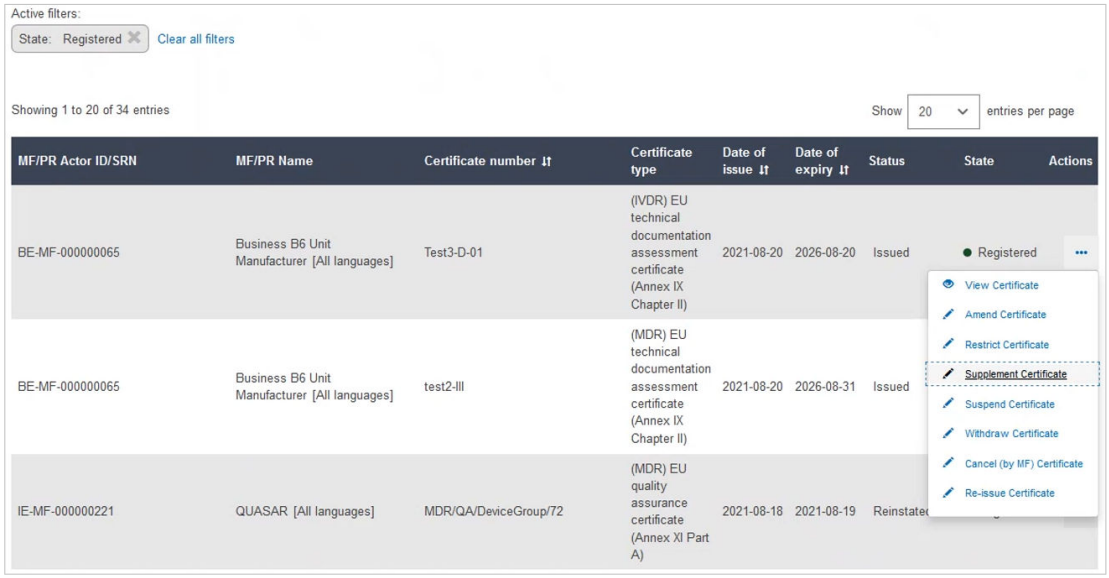


Once you are done, click either **Save** to save your work without submitting or **Submit** to submit it straight away.



6.2. Supplement

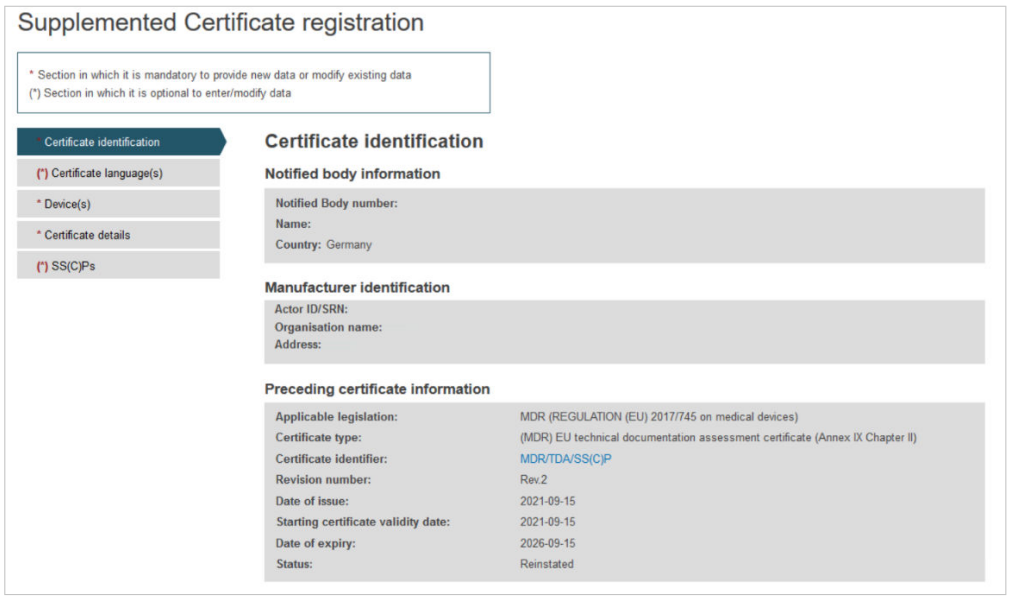
To supplement a certificate, click the three dots next to the desired certificate and then click 'Supplement Certificate' from the dropdown menu:



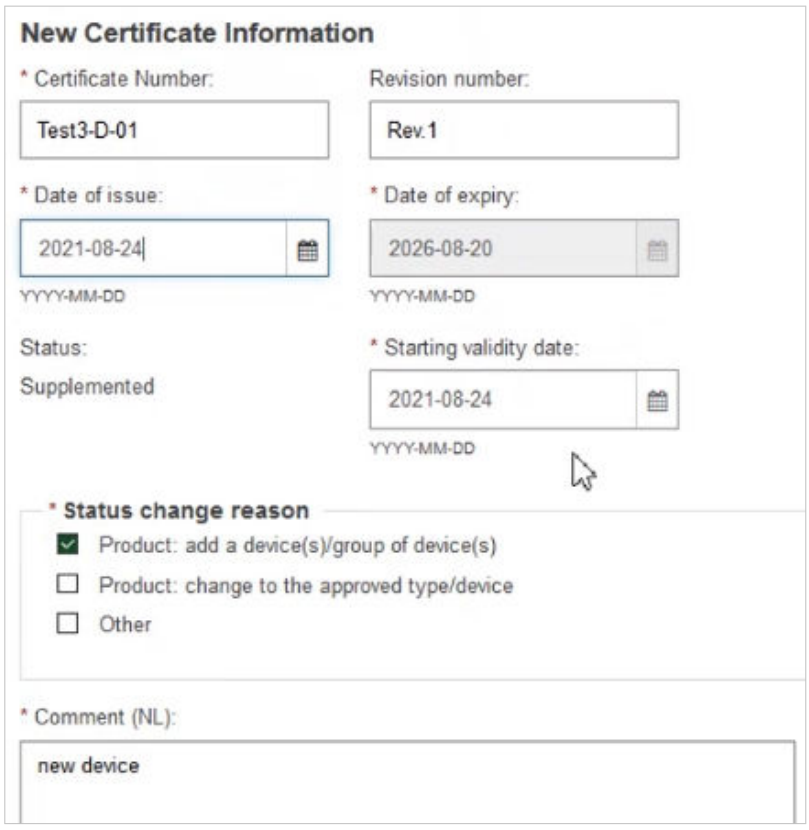
TIP
'Supplement Certificate' is missing?

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

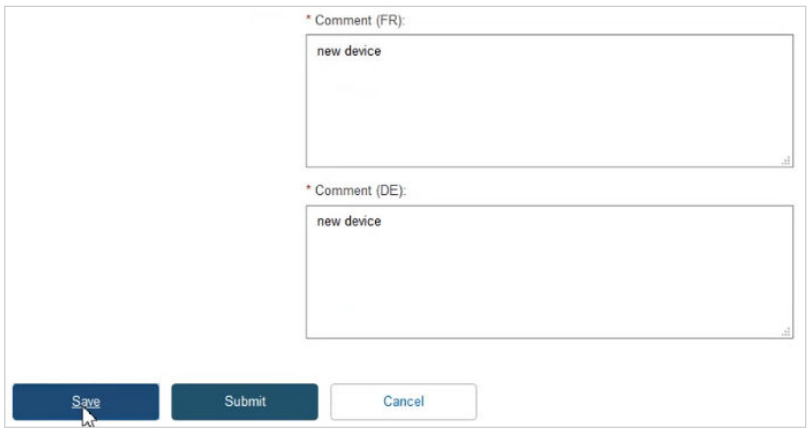
On the next screen, you will find all information relevant to the specific certificate and a menu with different sections on the left. Complete the information on the *Certificate identification* tab:



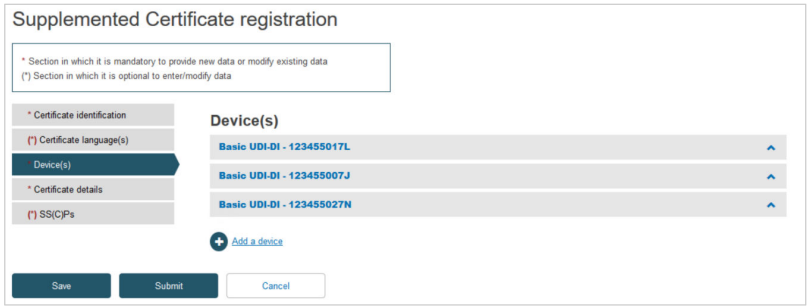
Scroll down and fill in the 'New Certificate Information':



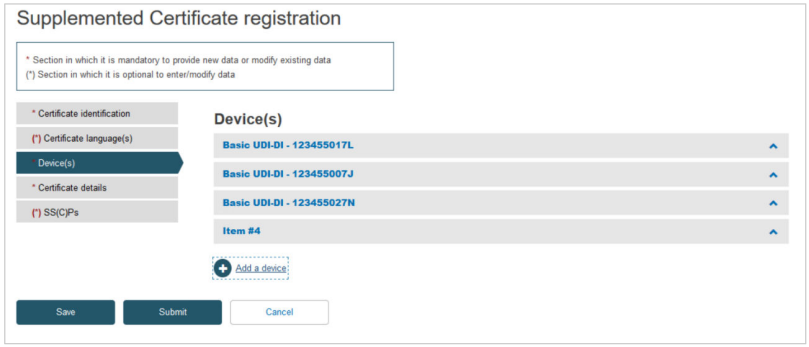
Provide comments in each certificate language and click **Save** to proceed:



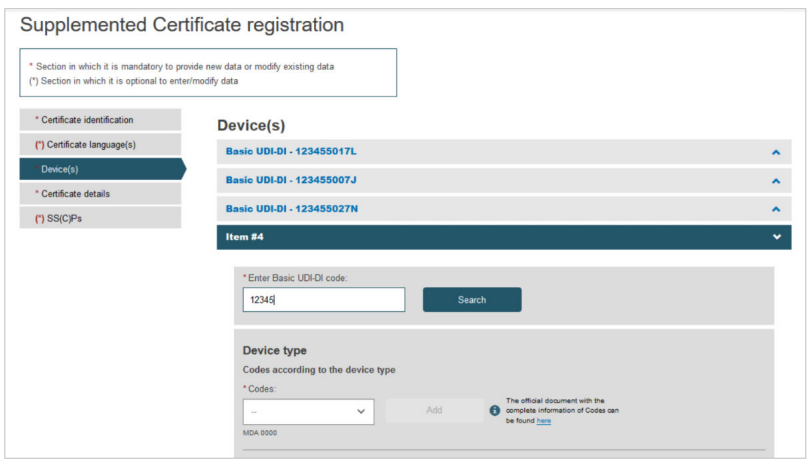
Click on the section *Devices* from the menu on the left and click 'Add a device':



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



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



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

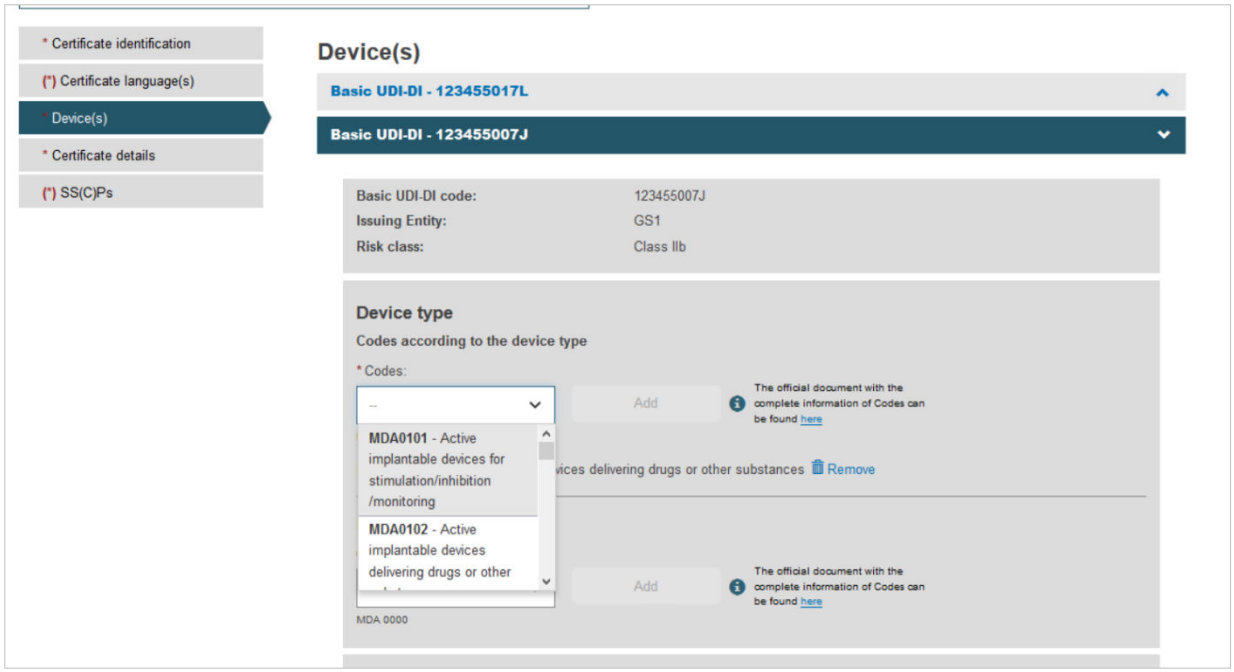


Figure 97: Provision of details to a Basic UDI-DI

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

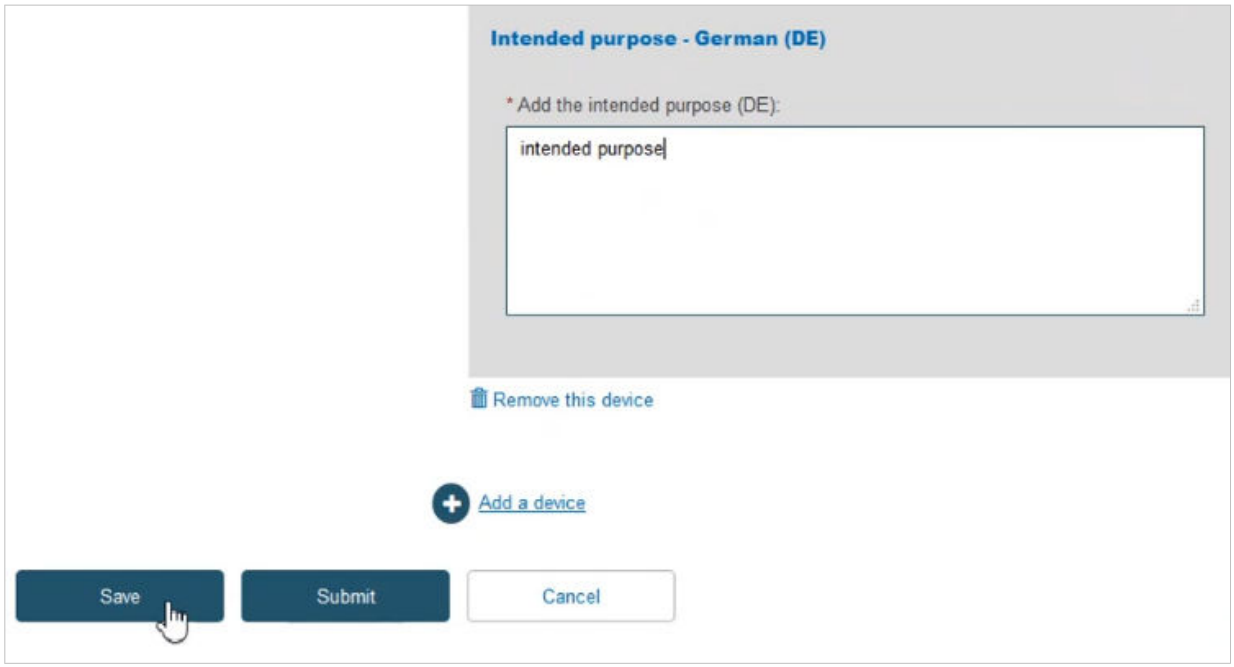
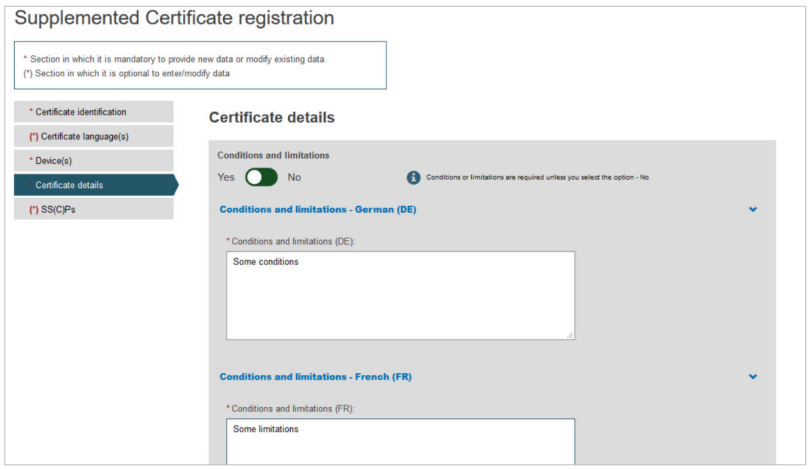
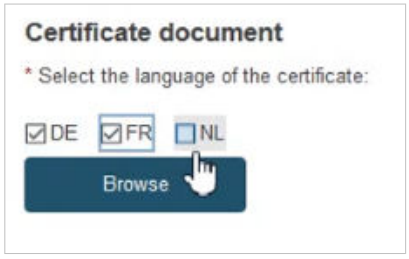


Figure 98: Intended purpose of a Basic UDI-DI

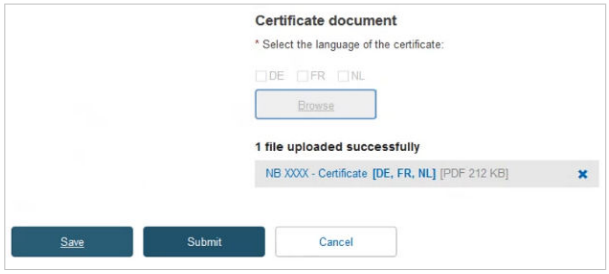
Click on the *Certificate details* section from the menu on the left and complete all the steps:



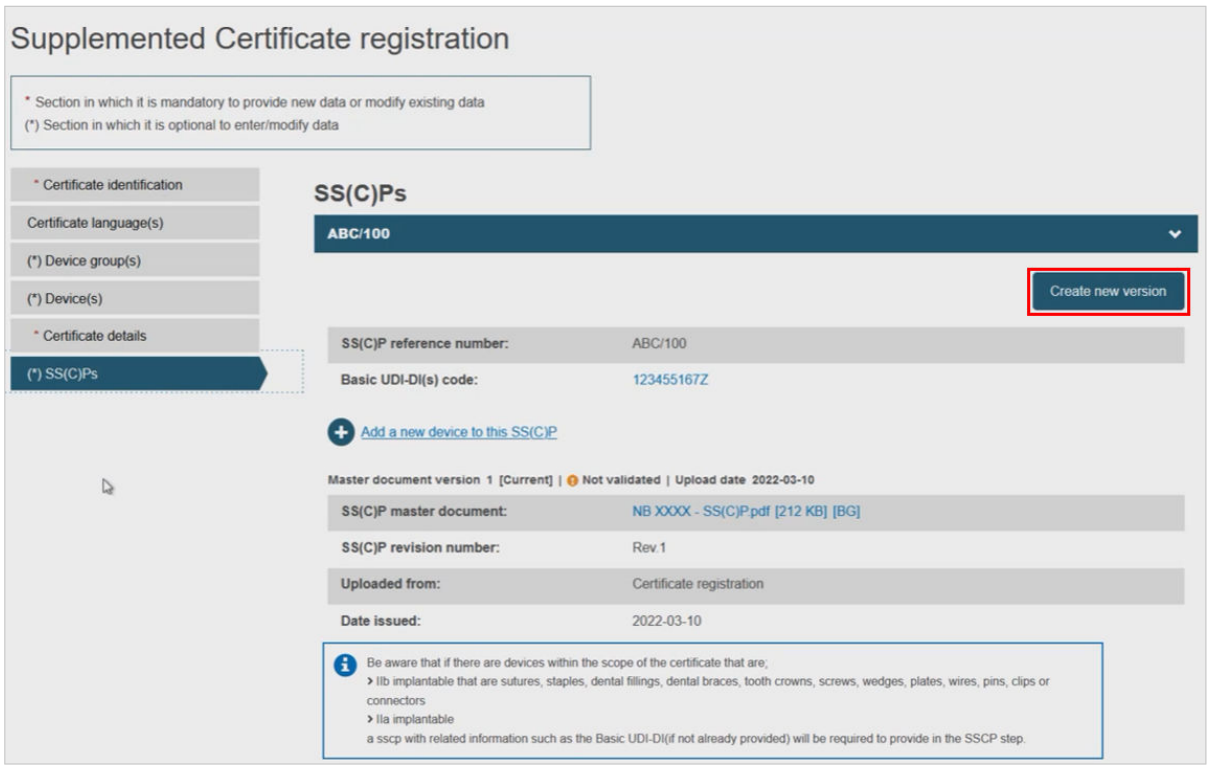
To provide the new 'Certificate document', tick the relevant languages and click **Browse** to upload the document(s) from your computer. You can upload either one document containing one/some language(s) or one document covering all languages:



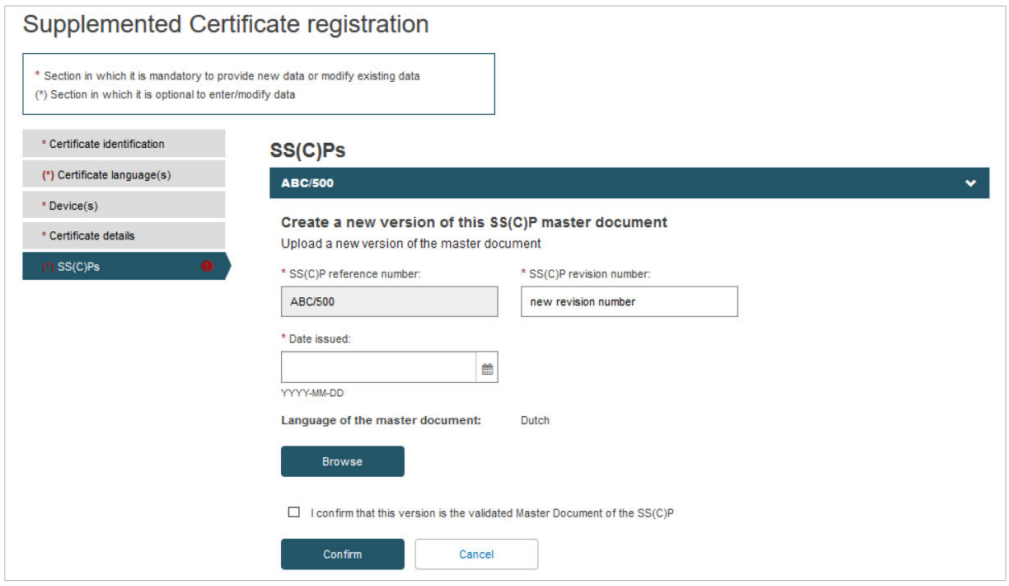
Once you have successfully uploaded the new certificate document(s), click on **Save**.



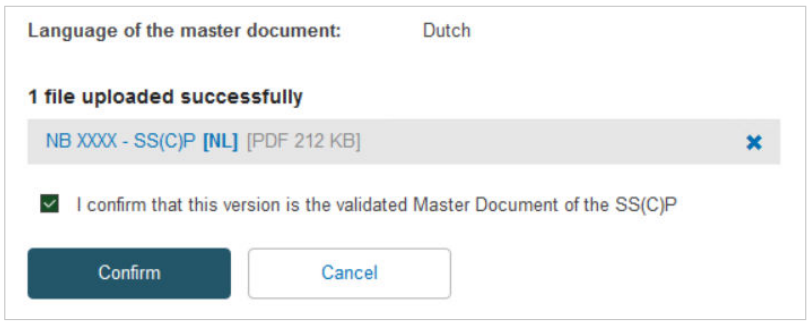
Next, decide either to create a new version of the SS(C)Ps, or link new devices to the existing one. Click on the next menu section, i.e. *SS(C)Ps*, then click 'Create new version':



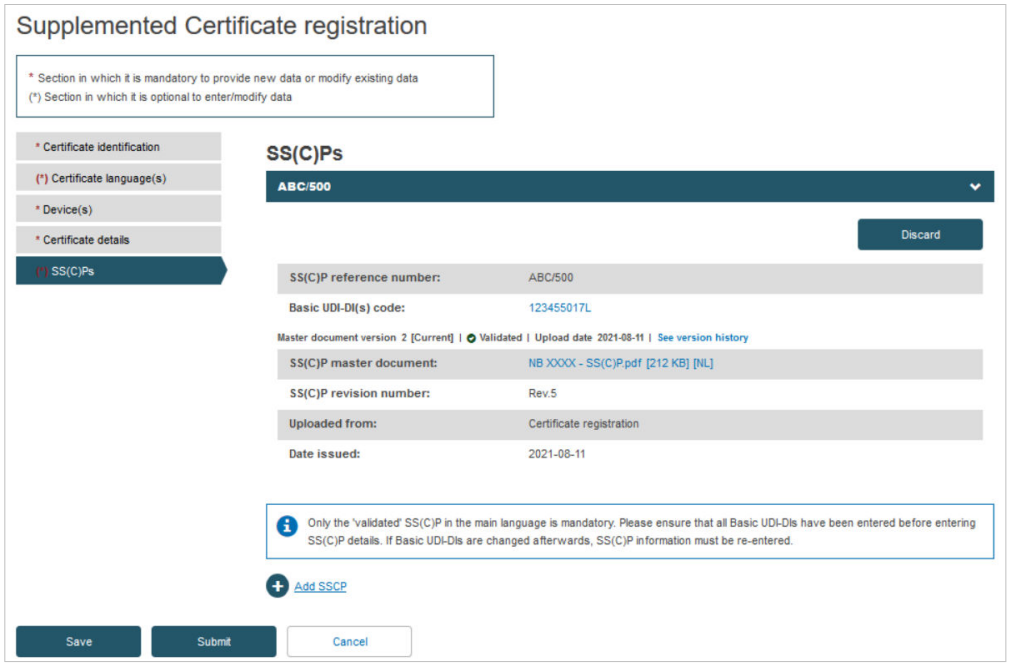
Fill in the information for the new SS(C)P document version and upload the new master document in the pre-selected language.



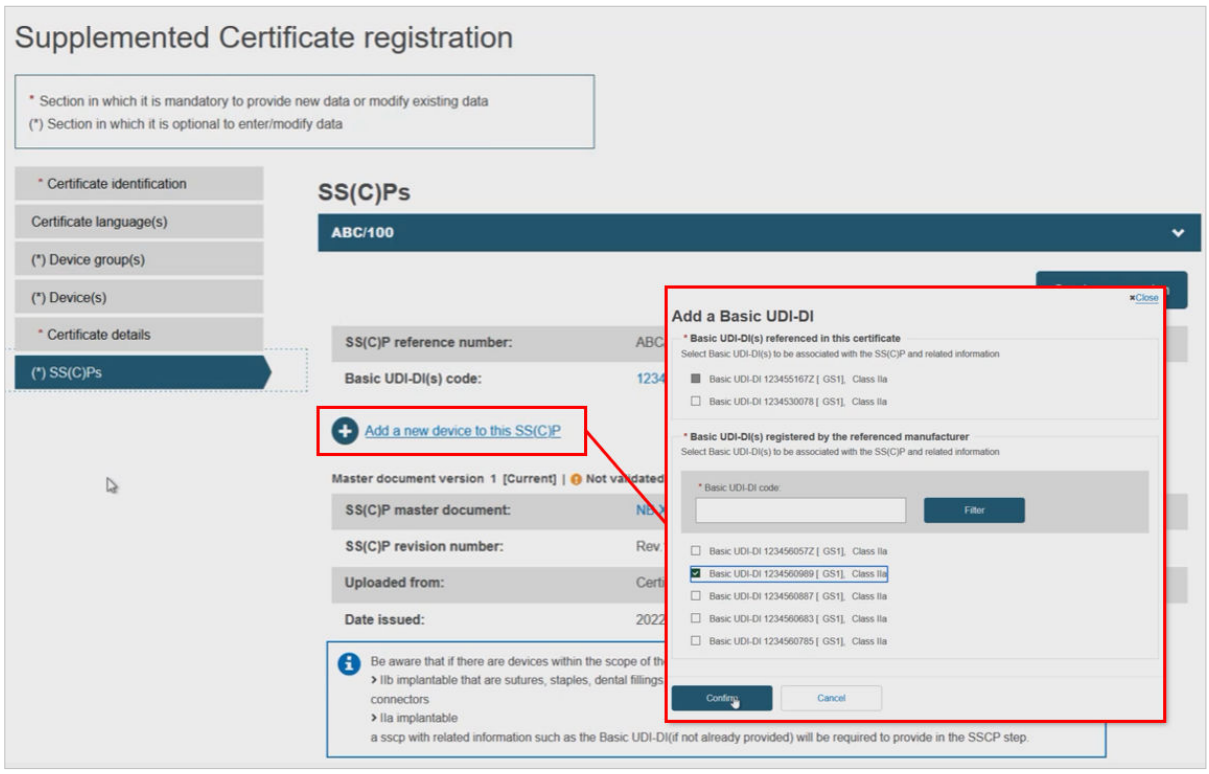
Once you have uploaded the new SS(C)P master document, tick the confirmation box and click **Confirm**.



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**:

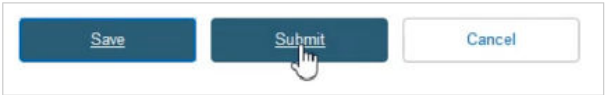


Rather than create a new SS(C)P version, the Notified Body may instead link new devices to the original SS(C)P (version) by clicking ‘Add a new device to this SS(C)P’. Select the device(s) from the pop-up display, then click **Confirm**:

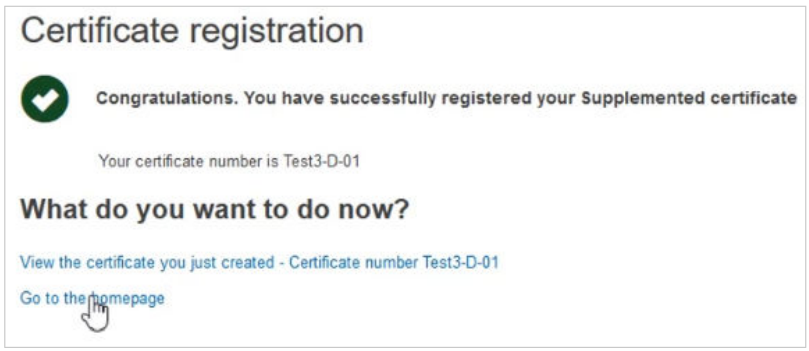


The selected device(s) will appear on the SS(C)P window, removable by clicking the dustbin icon. You will notice the 'Create new version' button is now inactive, only reactivated if all newly linked devices are removed:

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

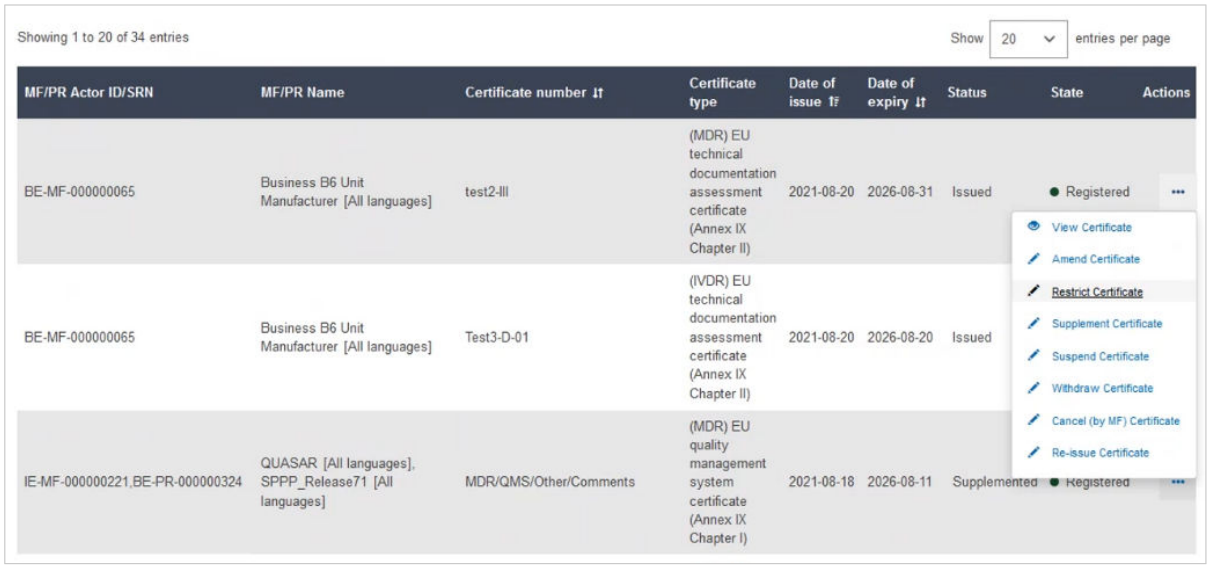


The system will confirm the successful registration of the Supplemented certificate.



6.3. Restrict

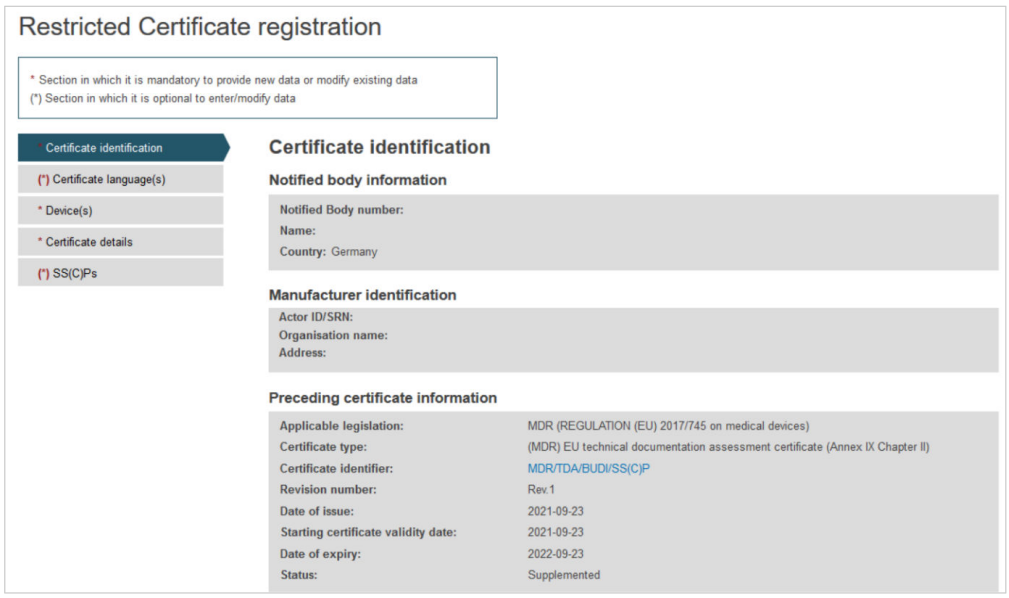
To restrict a certificate, click on the three dots next to the desired certificate and then from the dropdown menu, click 'Restrict Certificate':



TIP
'Restrict Certificate' is missing?

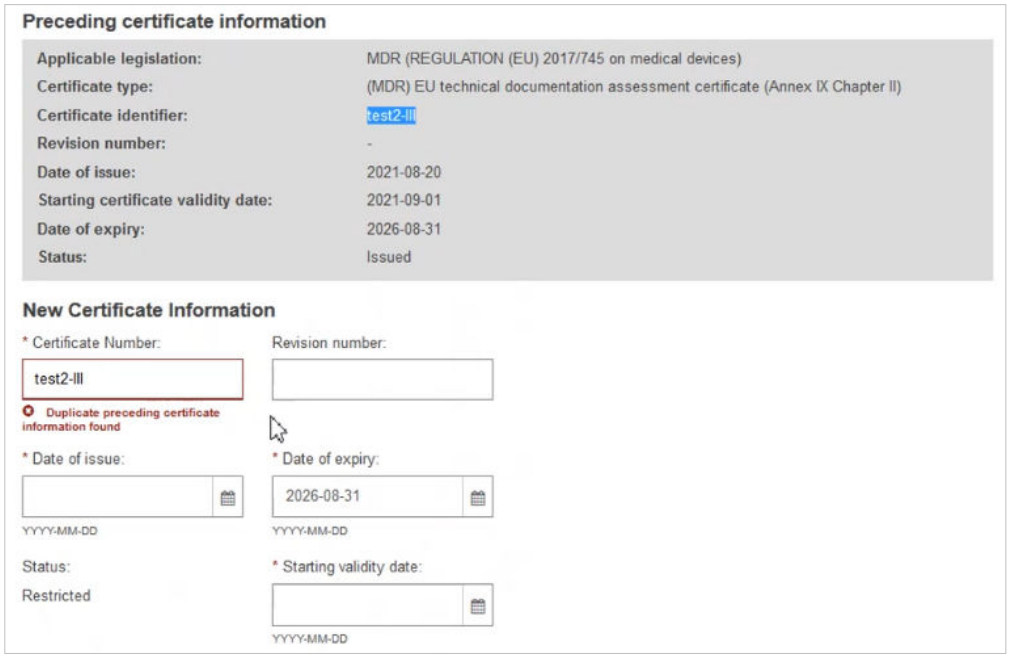
- Verify that your certificate is not in draft state within the certificate management page.
- If a draft version exists, it must be finalised or deleted. The 'Restrict Certificate' operation will now be available.

On the next screen, you will find all information relevant to the specific certificate and a menu with different sections on the left. Complete the details for the default *Certificate identification* tab:

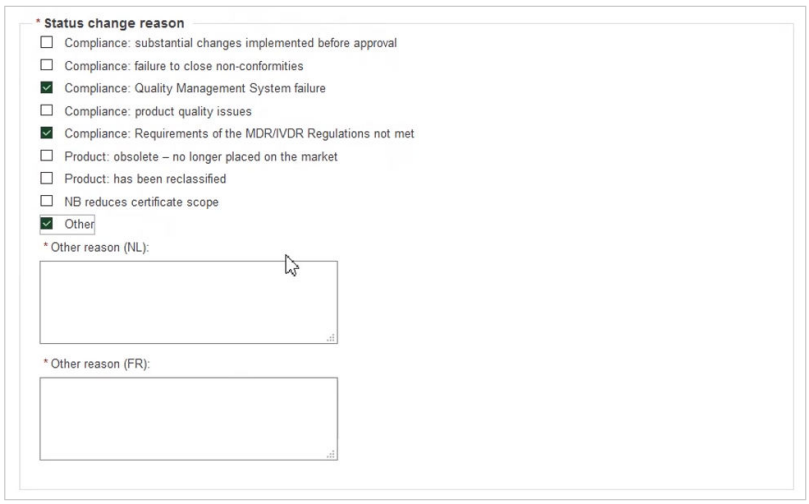


Scroll down and fill in the 'New Certificate Information':

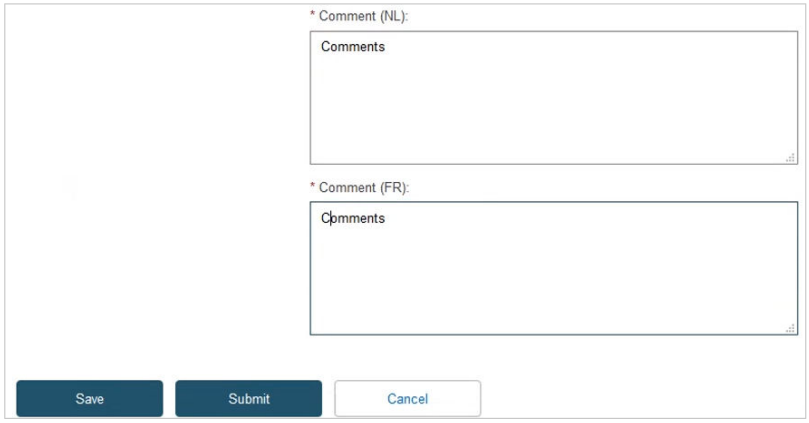
- Make sure to change the Certificate Number, otherwise the system will recognise the restricted certificate as a duplicate of the registered certificate (see below). Alternatively, provide a Revision Number while keeping the same Certificate Number.
- Select the date of expiry for this certificate and the starting date of validity of the restriction.



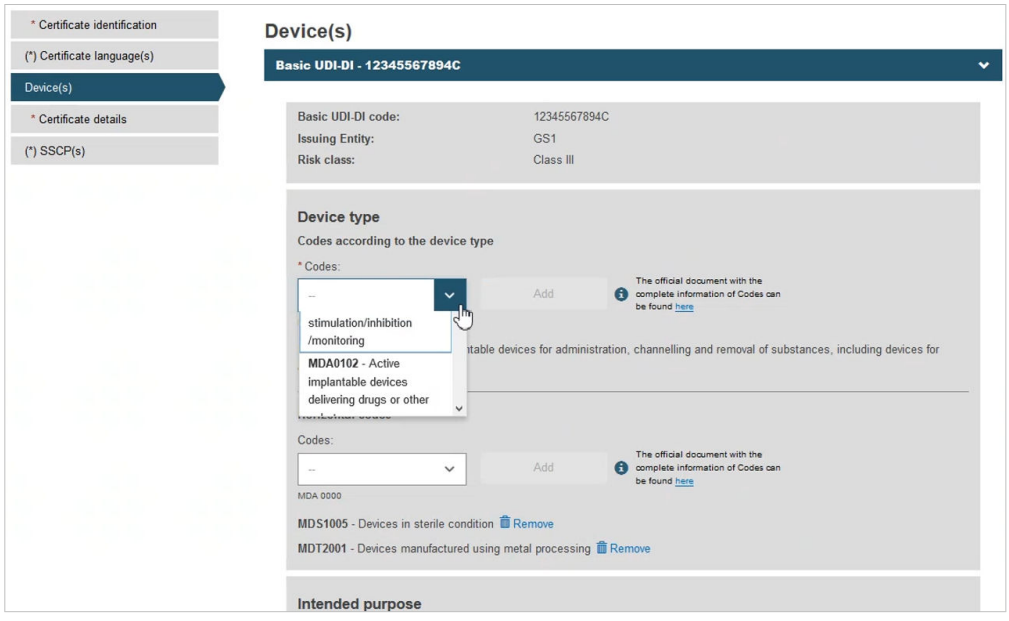
Scroll further down to the section *Status change reason* and select the reasons for the certificate's restriction (you can select more than one). In case you select *Other*, you **must** provide comments in all relevant languages of the specific certificate.



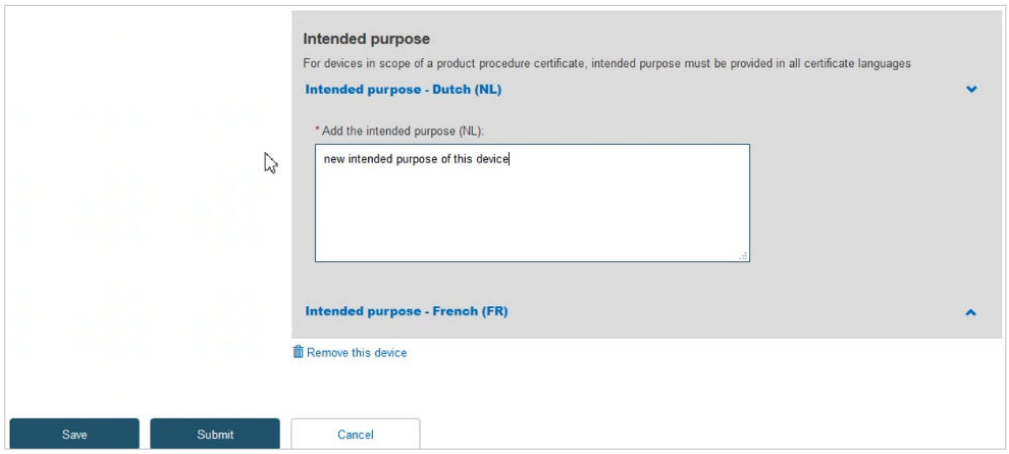
Provide comments in the Comment box in all the languages of the certificate and click **Save**.



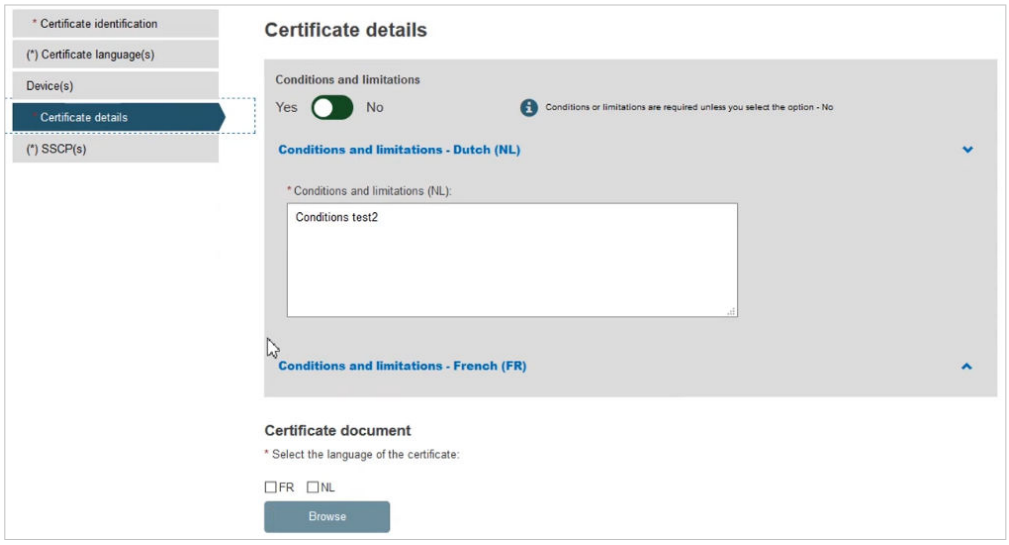
Review all information under the *Device(s)* section, e.g. intended purpose, and where needed/possible, update or remove information accordingly.



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

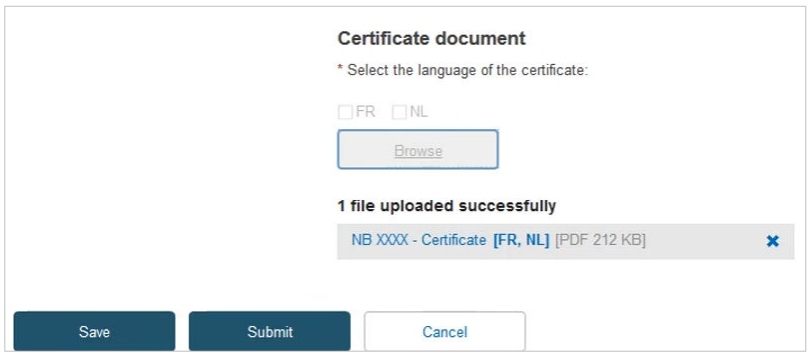


Review and update information under the *Certificate details* section in all relevant languages:

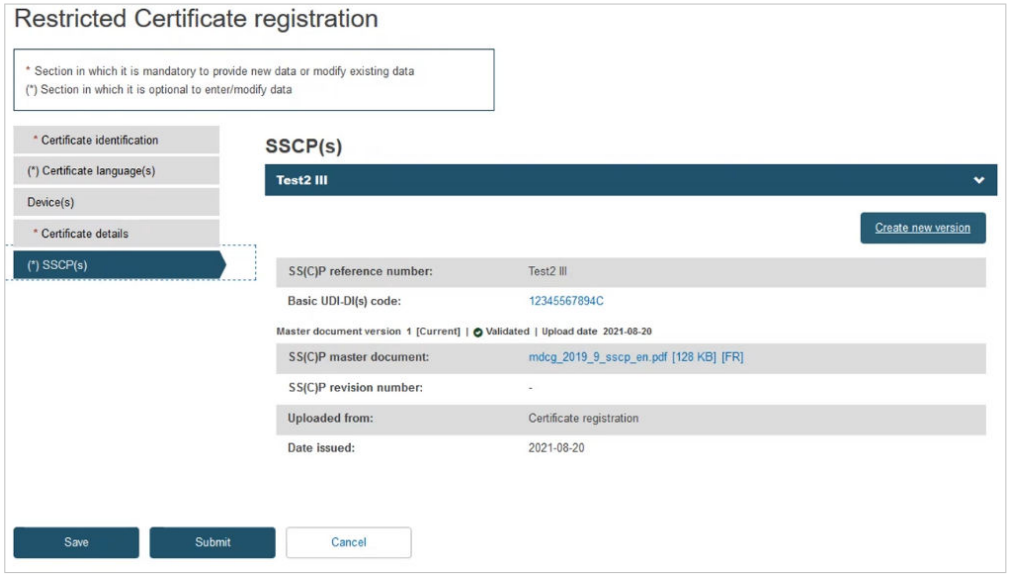


To provide the new Certificate document, tick the relevant languages and click **Browse** to upload the document(s) from your computer. You can upload either one document per language or one document covering all languages:

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

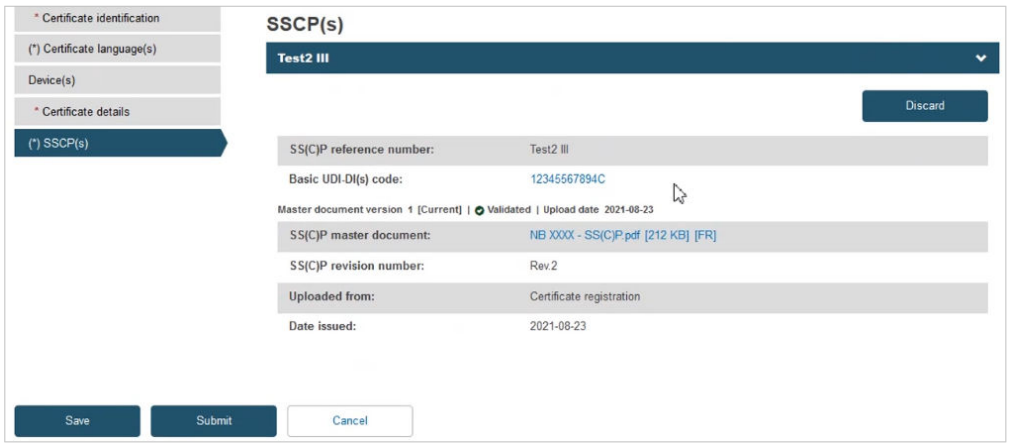


Click on the *SS(C)Ps* section from the menu on the left and click **Create new version**:

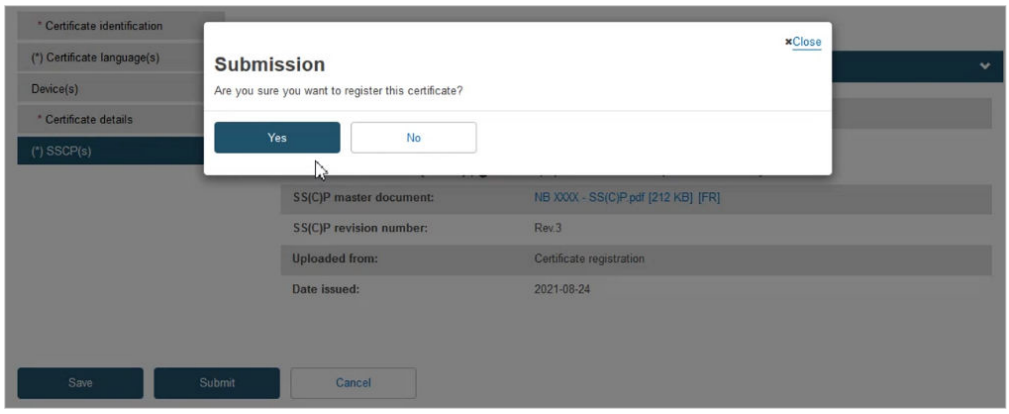


On the next screen, complete all the steps to create a new version, i.e. provide SS(C)P revision number, issue date, upload SS(C)P document and click *Confirm*:

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**:

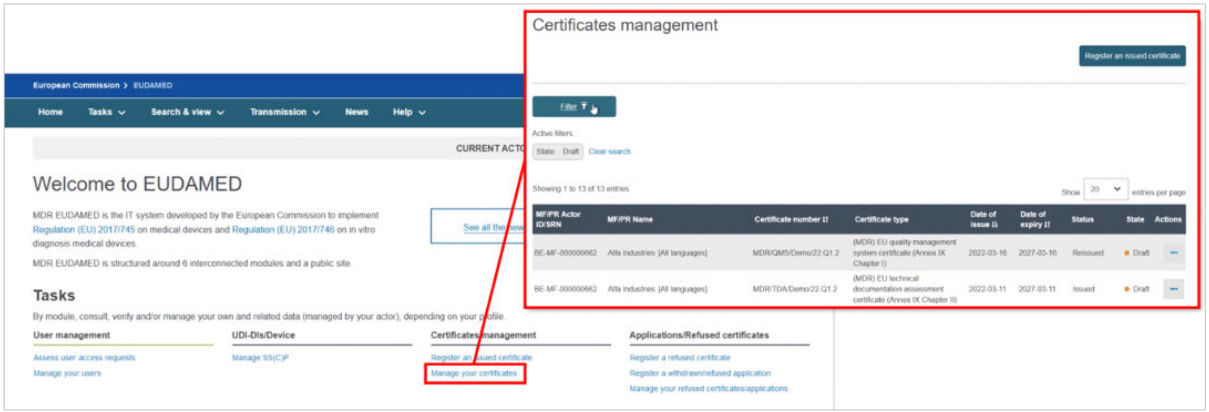


When you have fully reviewed all the information provided, click **Submit**. The system will prompt you to confirm your submission. Click **Yes** to complete the process.



6.4. Re-issuing a quality/product certificate

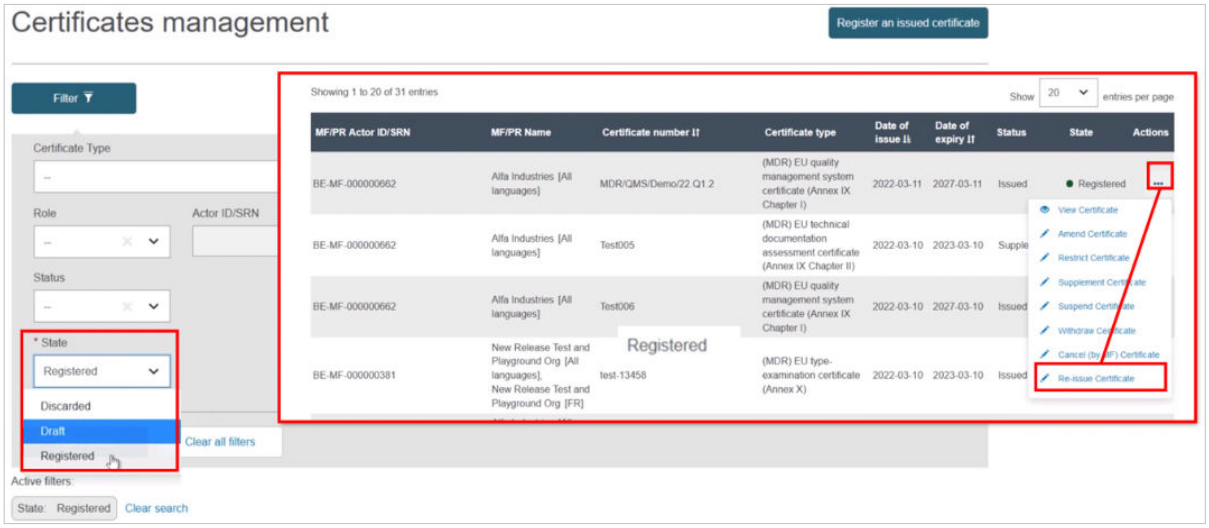
1. To re-issue a certificate, for example due to its imminent expiry, click to the *Certificates management* page then filter to identify the certificate you want to re-issue:



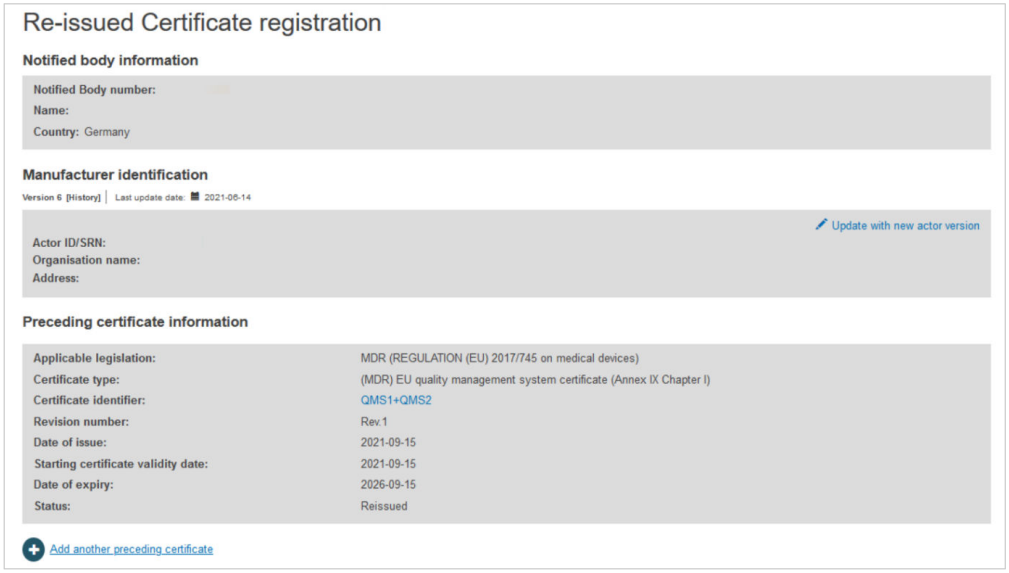
TIP
'Re-issue Certificate' is missing?

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

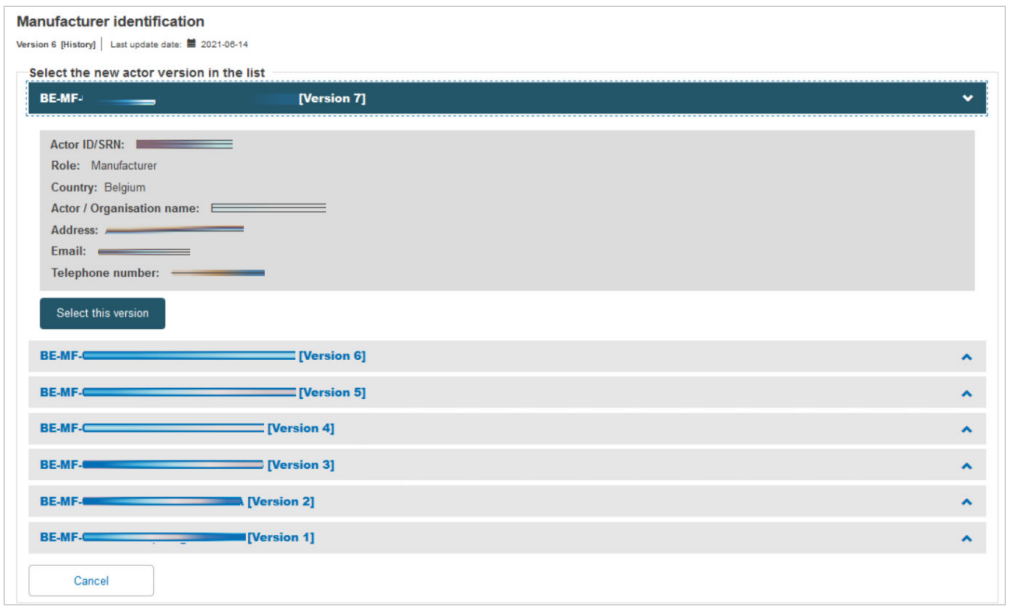
2. Select *Registered* as the state. From the list generated, in the ‘Actions’ menu click the three dots next to the intended issued certificate and select ‘Re-issue Certificate’:



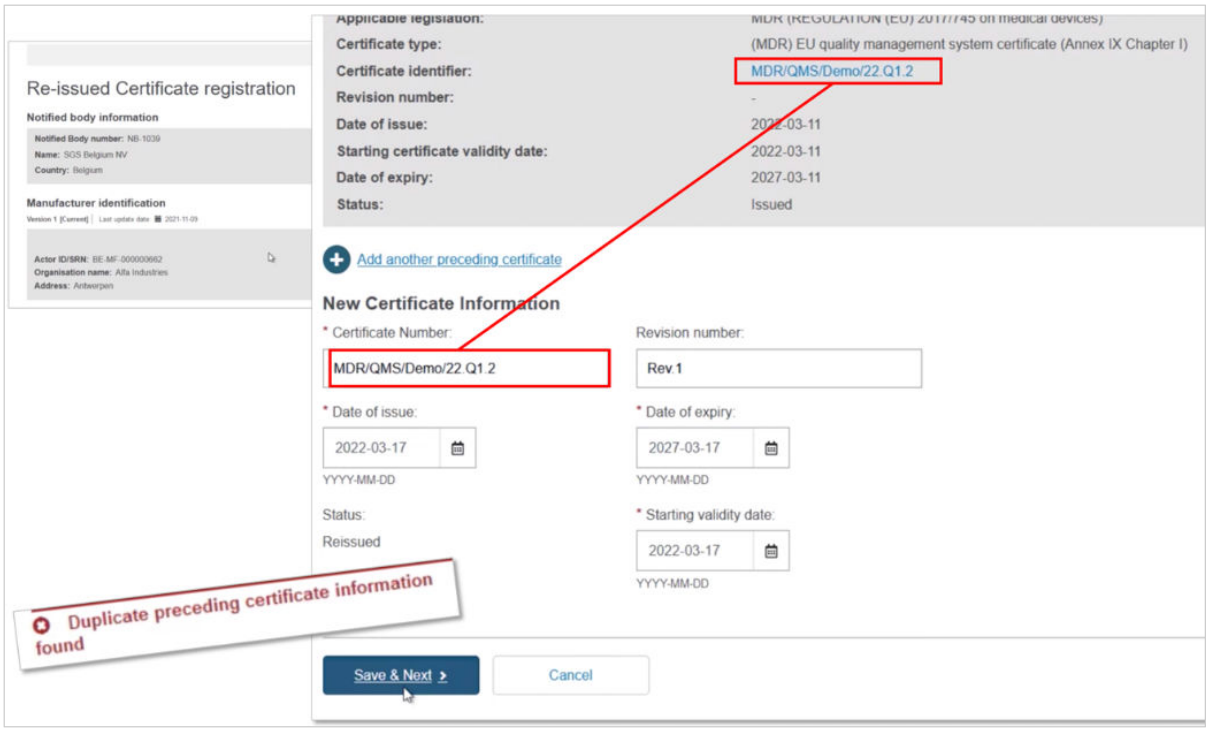
3. The next screen will display all relevant information of the certificate. If necessary, click 'Update with new actor version'.



4. Select the right actor version from the list:

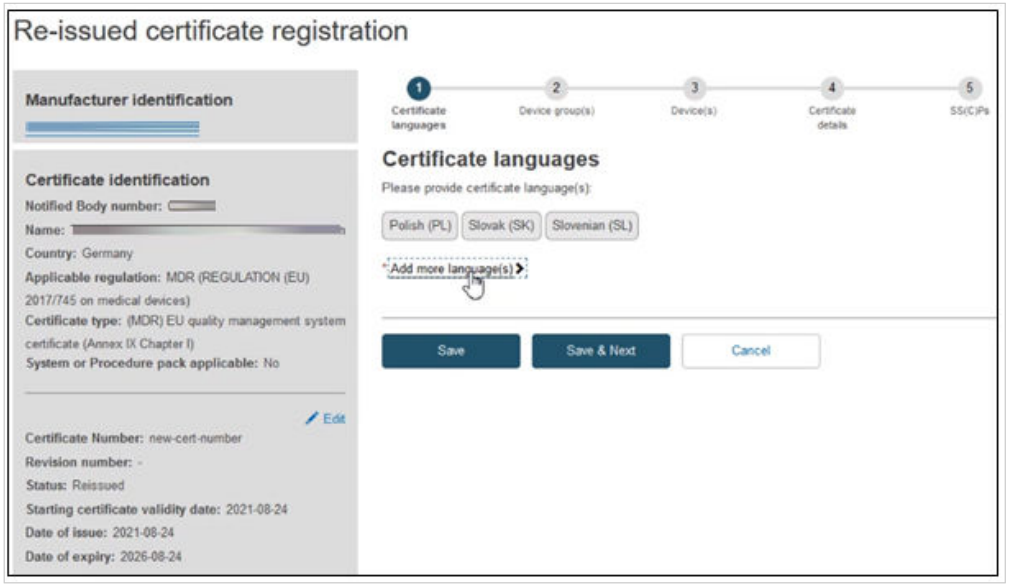


5. Scroll down to the *New Certificate Information* section. Duplicate the certificate identifier, and note the duplication warning message. Add a ‘Revision number’ so it differs from the preceding certificate – the warning disappears. Select the new issue date, validity date and expiry date (noting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

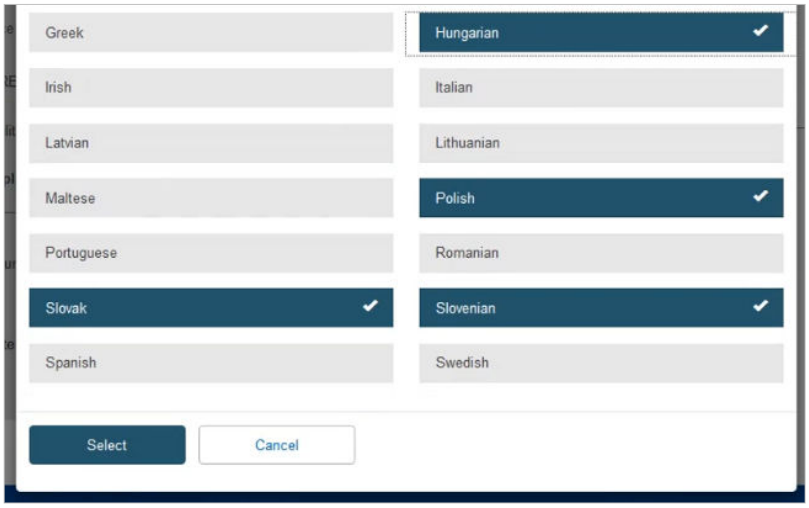


The next screen will display a timeline of steps to follow. Follow the order starting from the first section 'Certificate languages'.

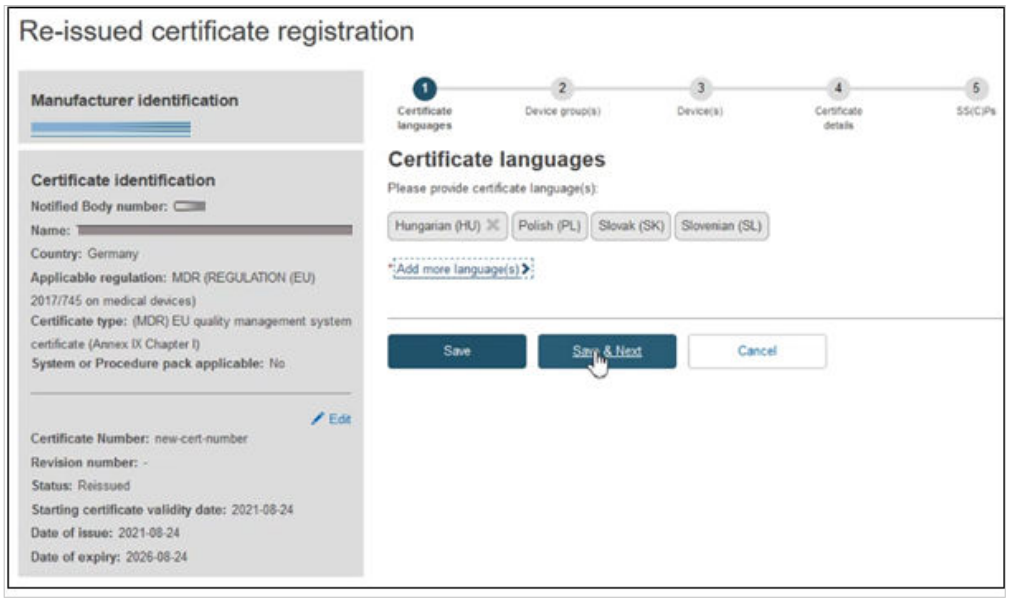
6. Click on ‘Add more languages’ if necessary: Click 'Add more languages' if necessary:



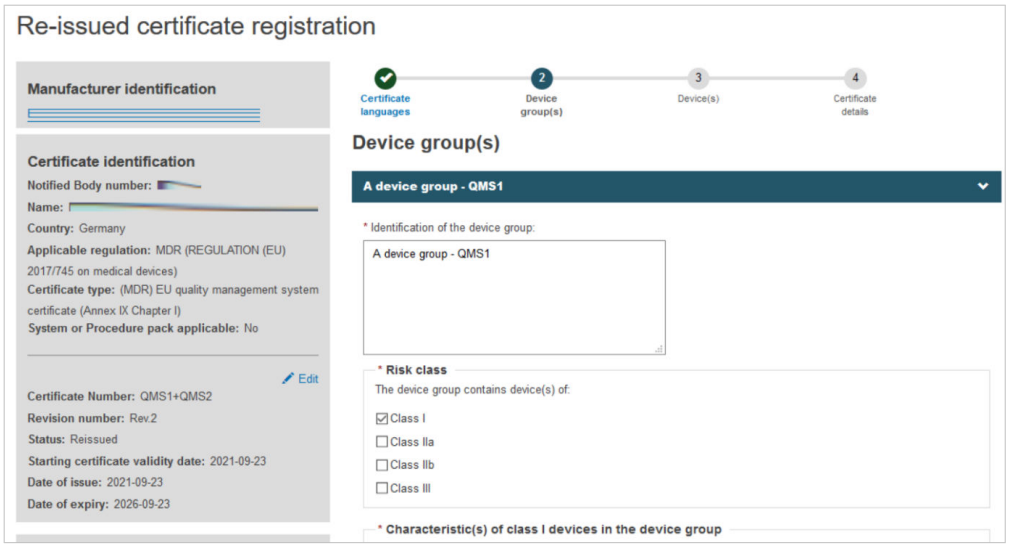
7. On the pop-up window, click on the desired languages and press **Select**:



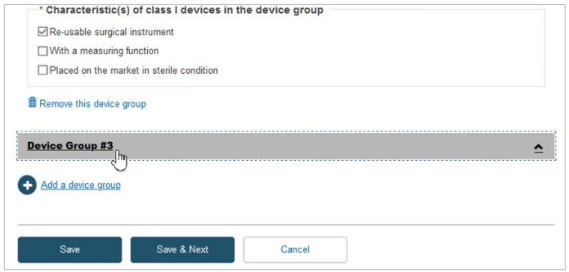
8. Click **Save & Next** to proceed to the next section:



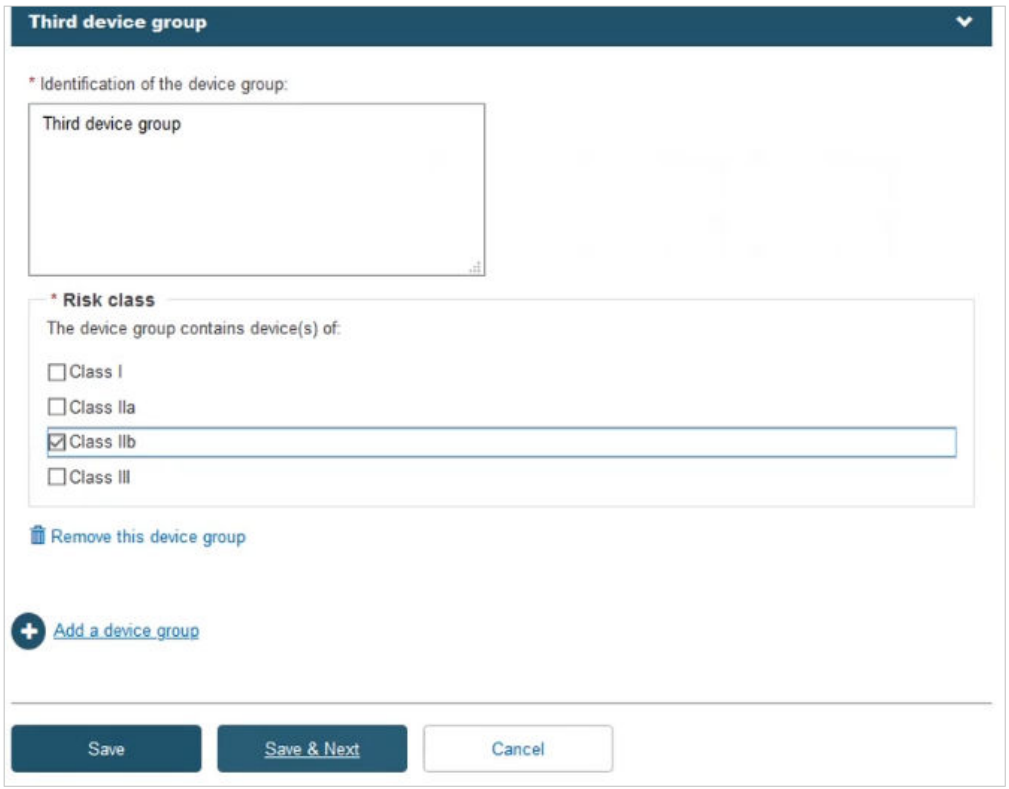
9. Fill in the information required to complete the *Device group(s)* step:



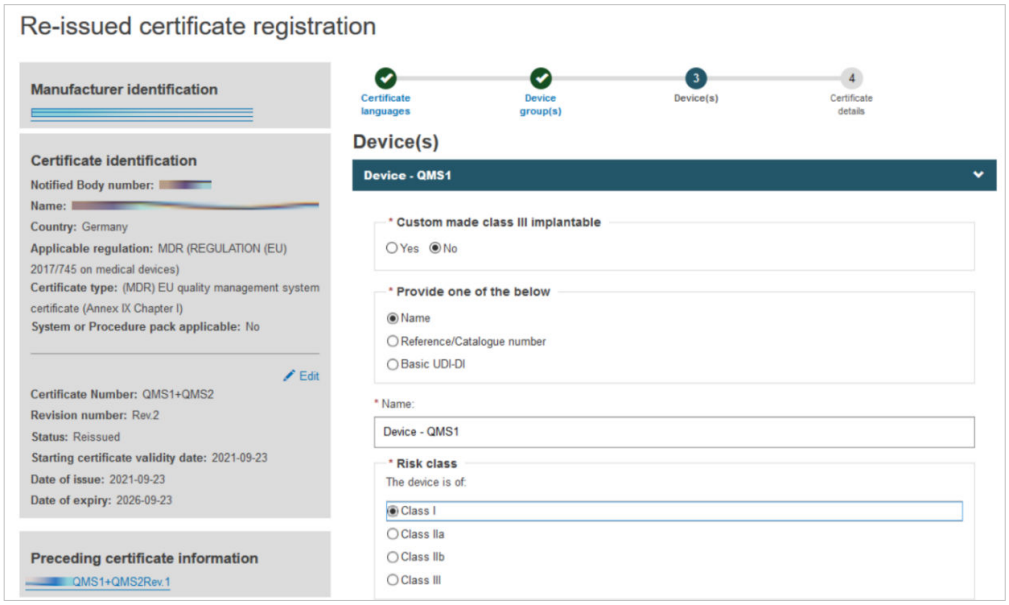
10. Click **+ Add a device group** and then again on the appearing 'Device group' item:



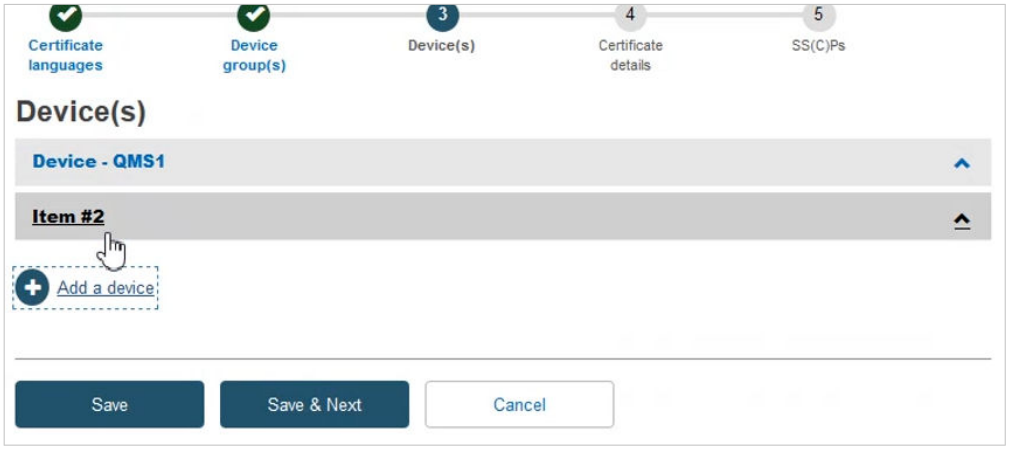
11. Fill in the required information and click **Save & Next**:



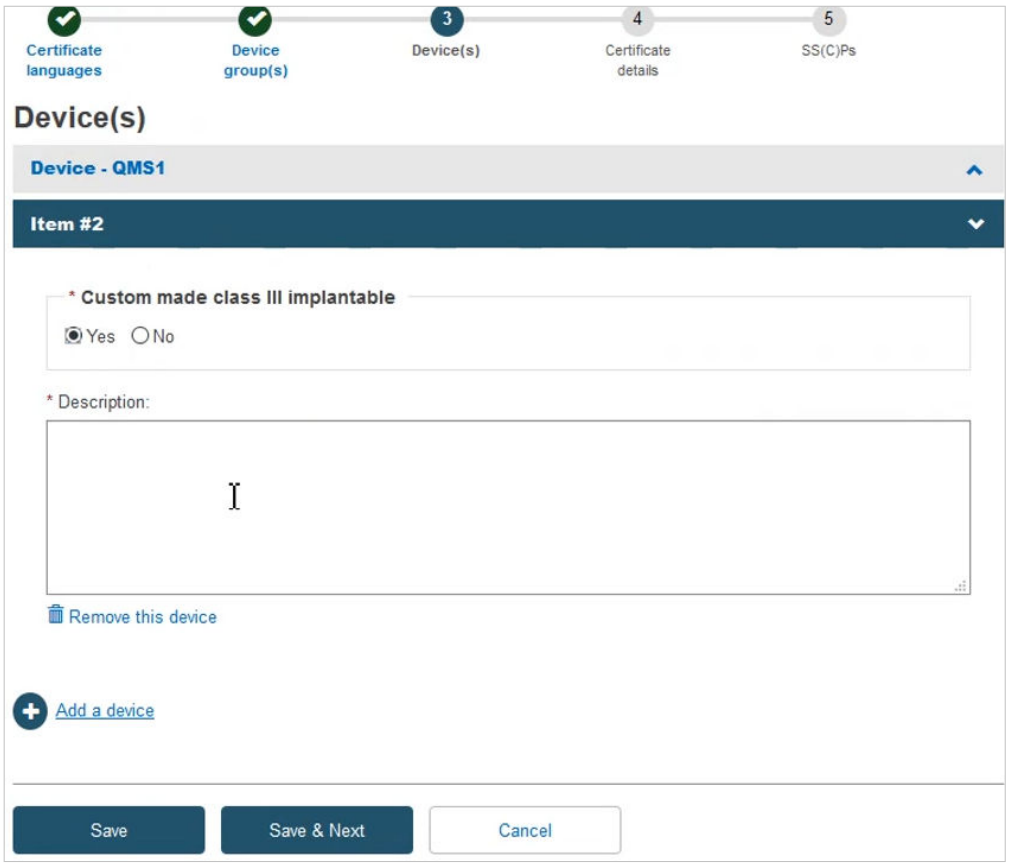
12. Fill in the information for the *Devices*: step:



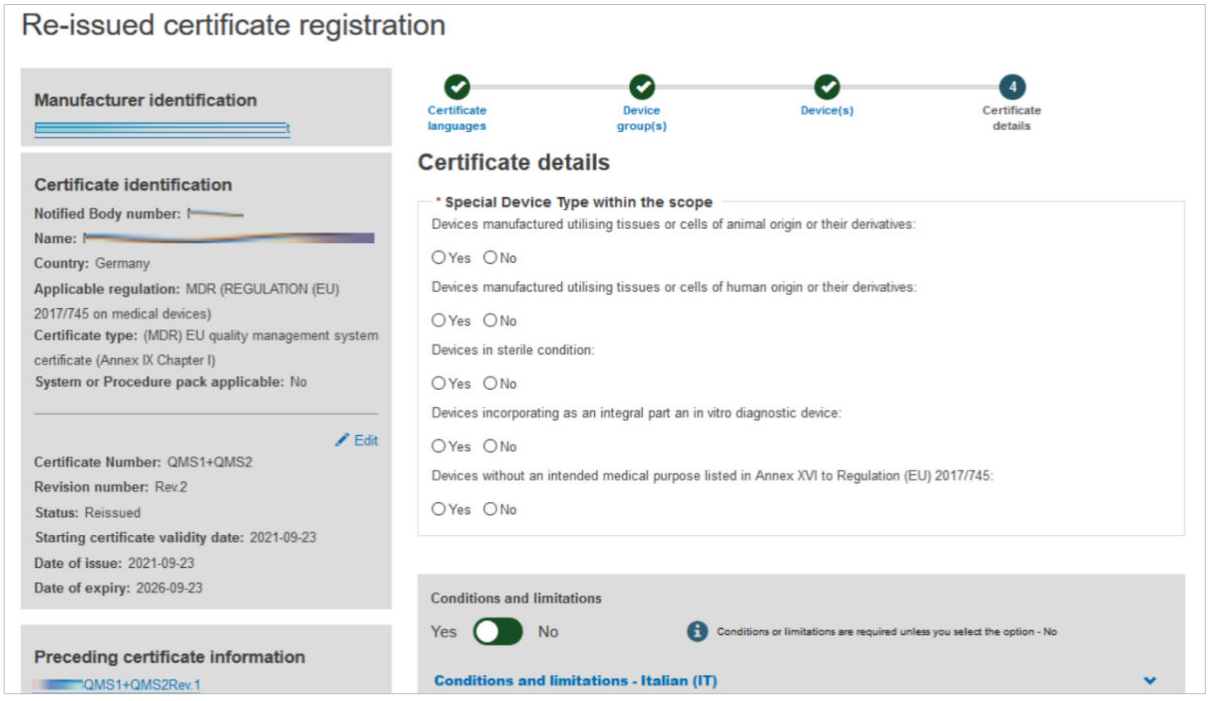
13. Click **+ Add a device group** and then click on the appearing 'Item' under 'Devices':



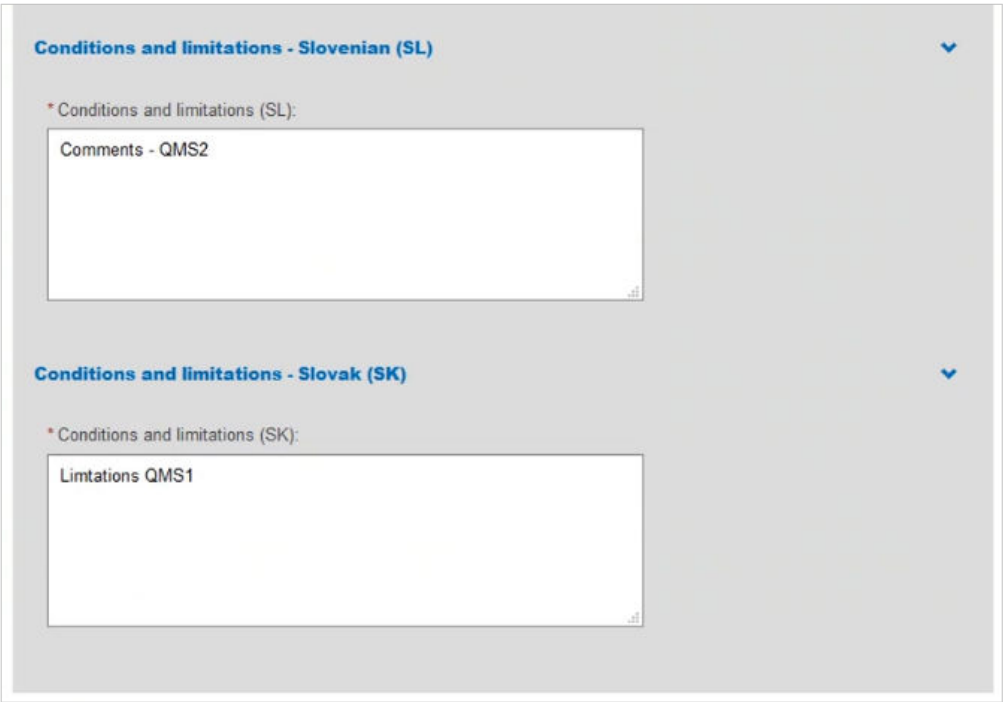
14. Add the required information to complete this step and then click **Save & Next**:



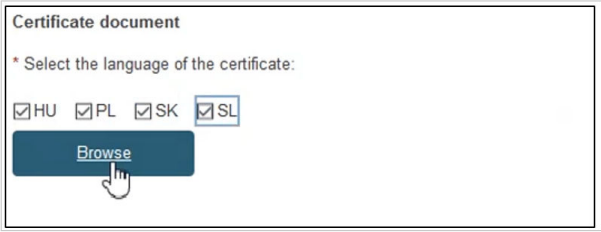
15. Fill in the information required to complete the *Certificate details* step:



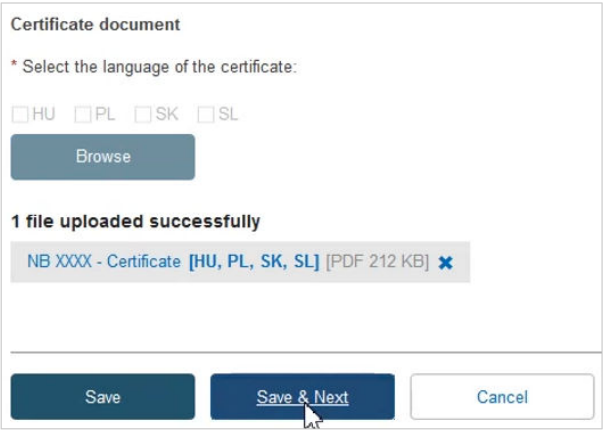
16. Provide comments regarding Conditions and Limitations in each language you selected:



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**:

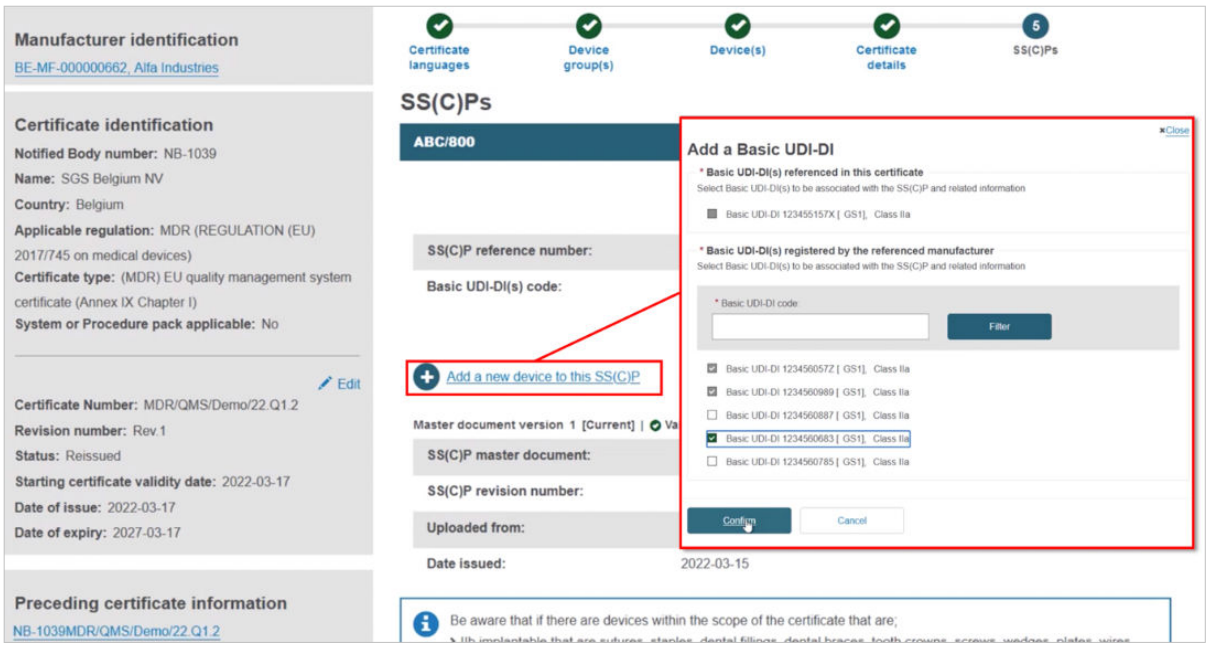


At this point, depending on the specifics of the certificate, the system may take you to the next step called *SS(C)Ps* step; if not relevant for the specific certificate, this step will be omitted. You have three possibilities when adding new devices:

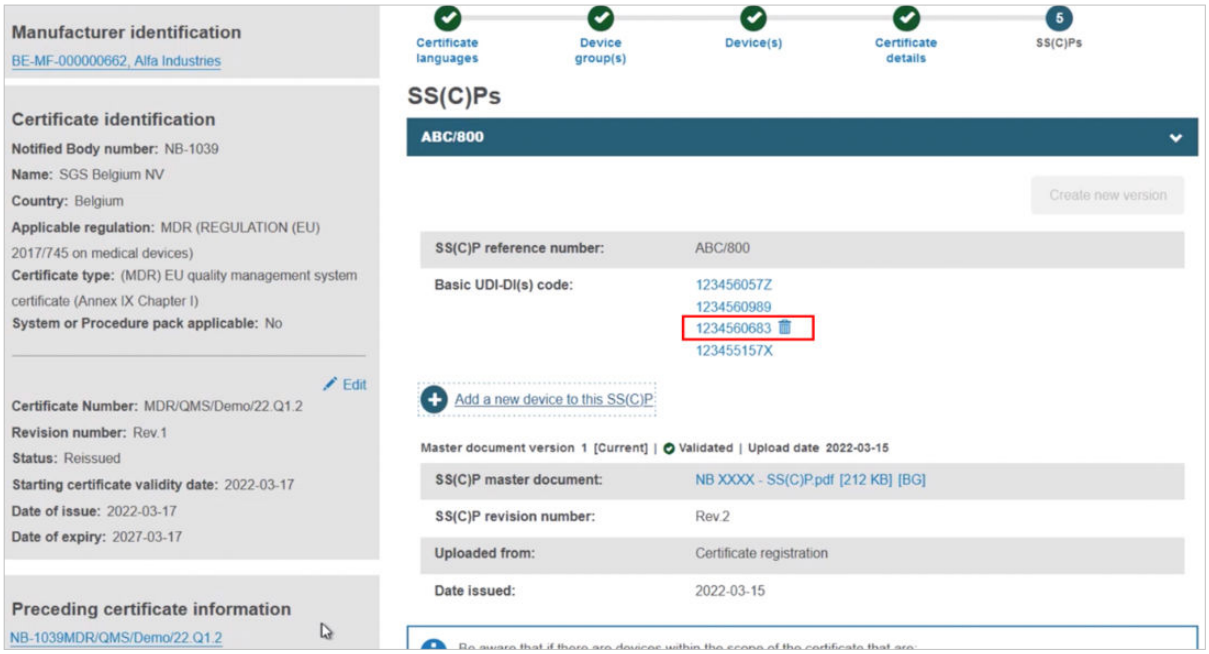
- **Add device(s) to an existing SS(C)P from the preceding certificate** (see *Step 19*).

- **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*).

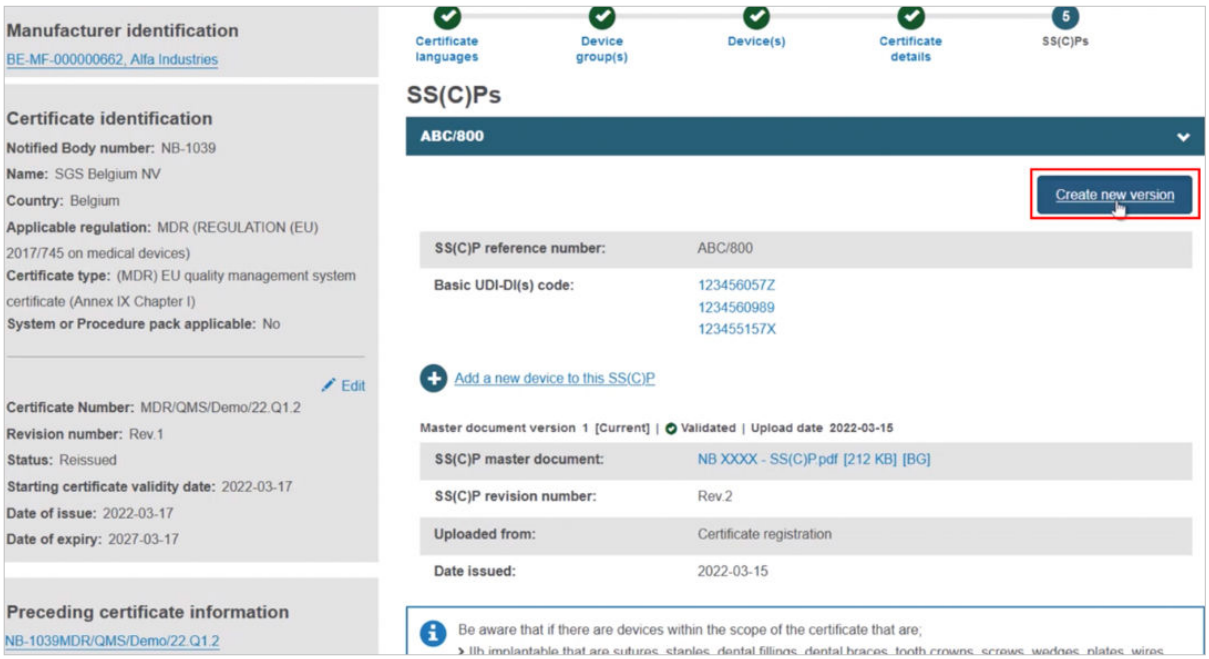
19. Add device(s) to an existing SS(C)P from the preceding certificate
Click on 'Add SS(C)P' . The existing devices show, but are inactive. Select any new device(s) and click **Confirm**.



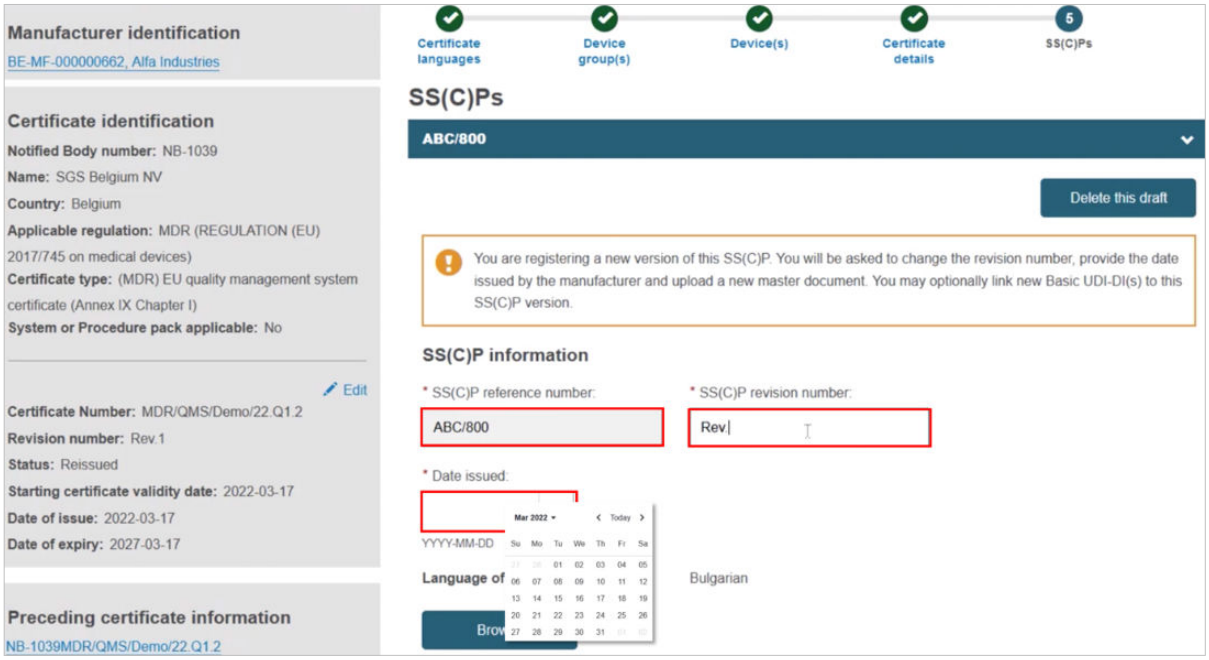
The new device appears next to the dustbin icon. If you save now, the new device will be linked to this version of the SS(C)P:



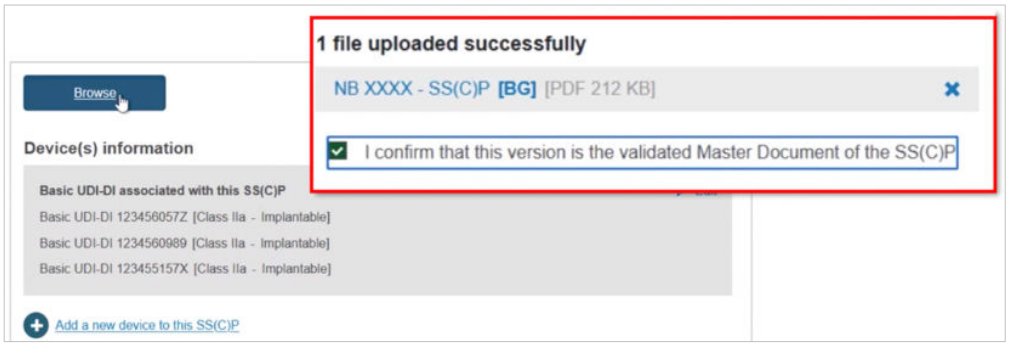
20. Add devices to a new version of the SS(C)P from the preceding certificate. With this approach, click **Create new version**:



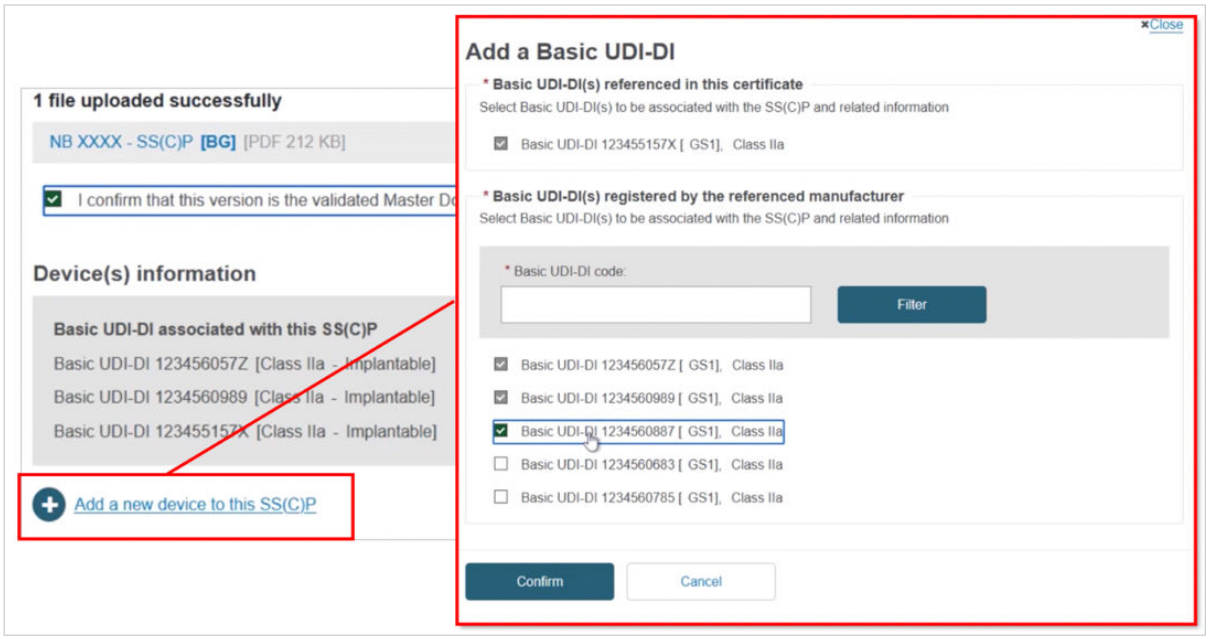
Input the SS(C)P reference number, and create a revision number, then specify the issue date:



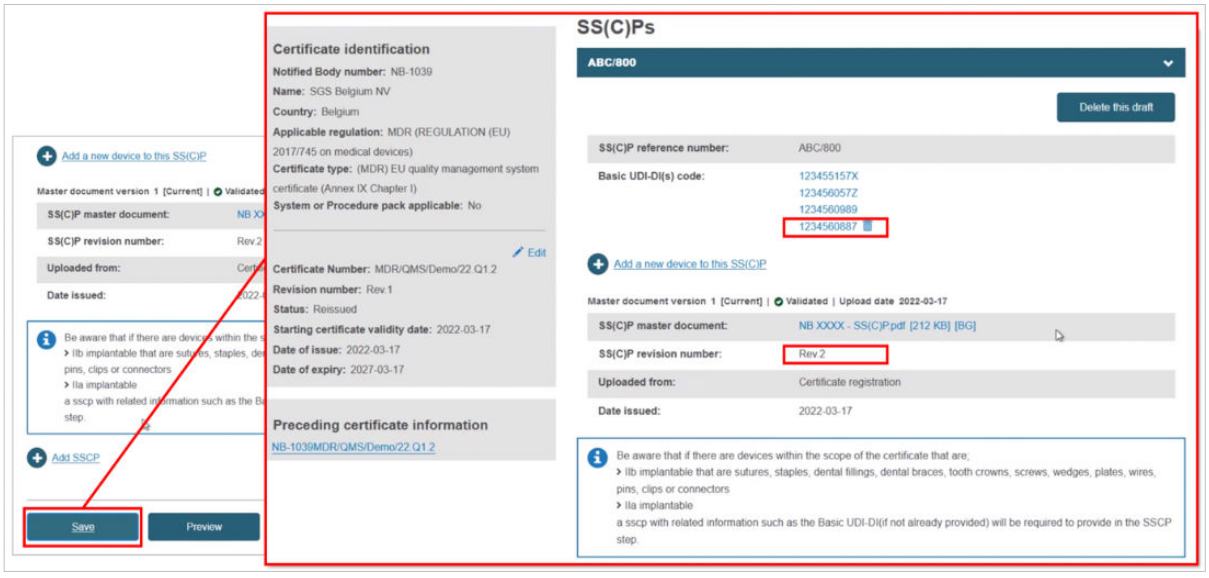
Click Browse to locate and upload the master document, and click to confirm it is validated:



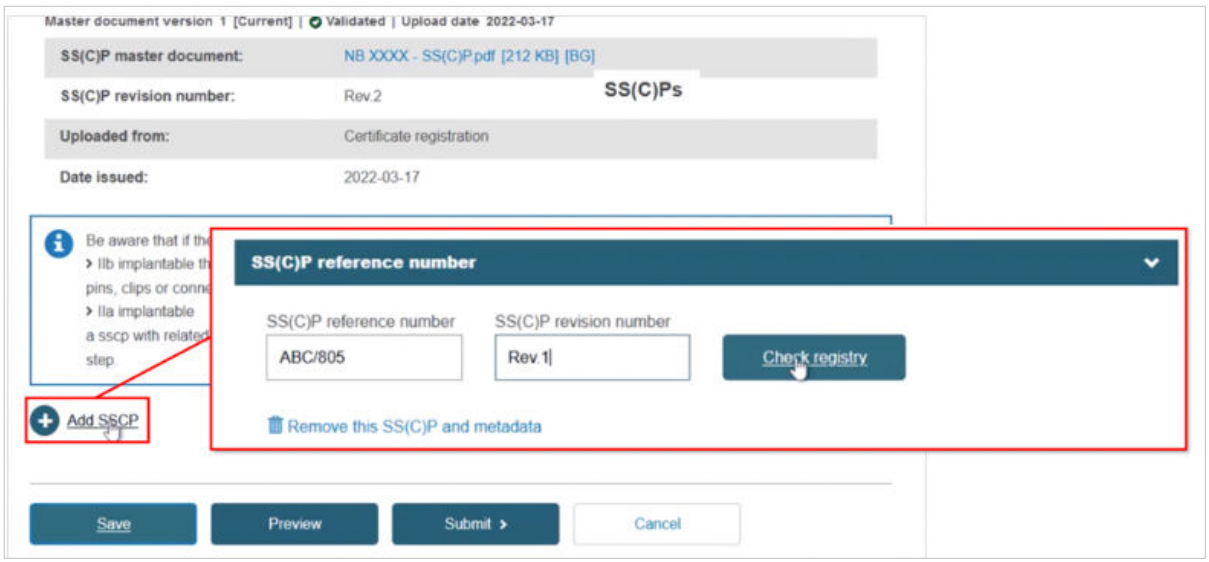
Click **+ Add a new device** to this SS(C)P, locate and select the new device, and click **Confirm** to link it to this new SS(C)P version:



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

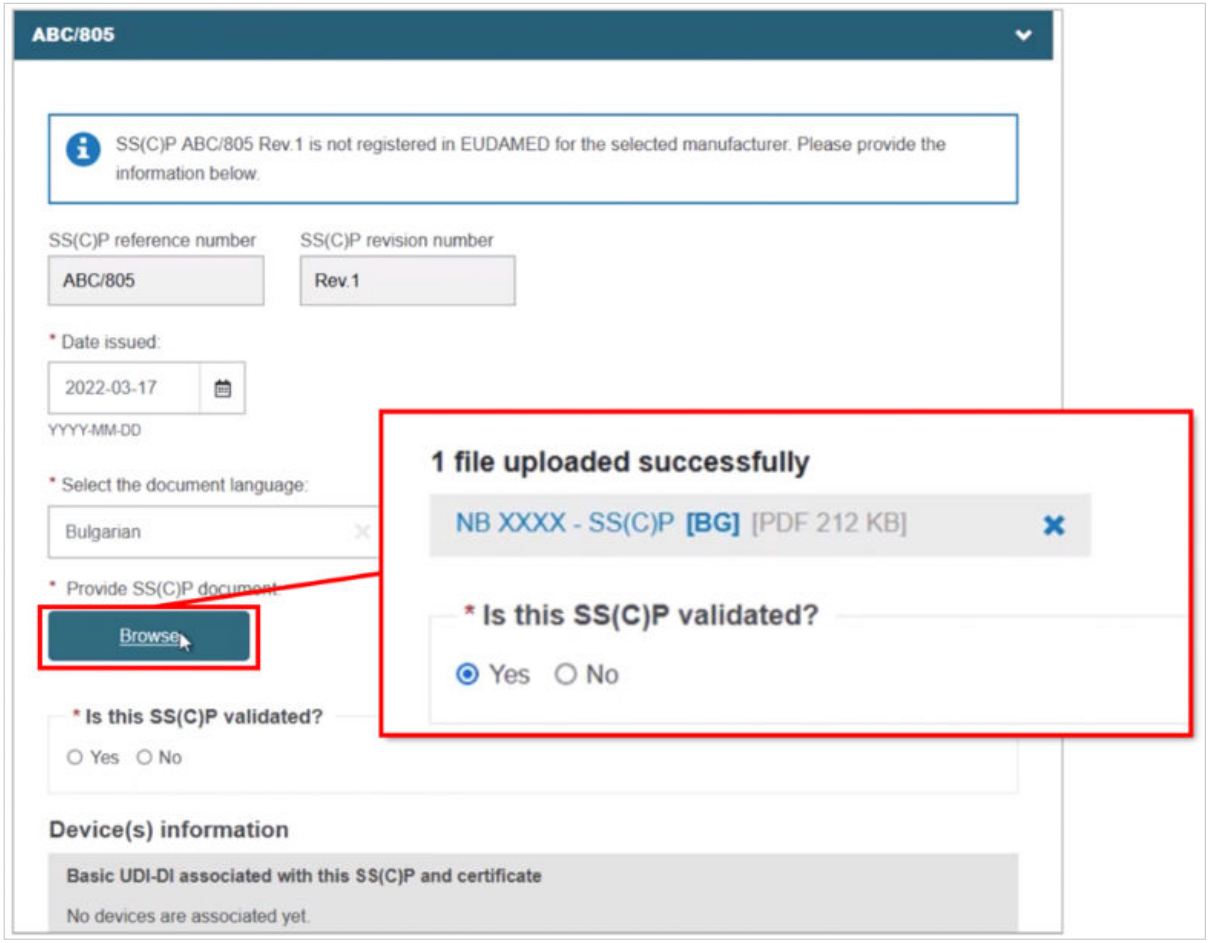


21. Registering a new SS(C)P, then adding device(s) to it. Click **+ Add SSCP**, then provide the reference and revision number:

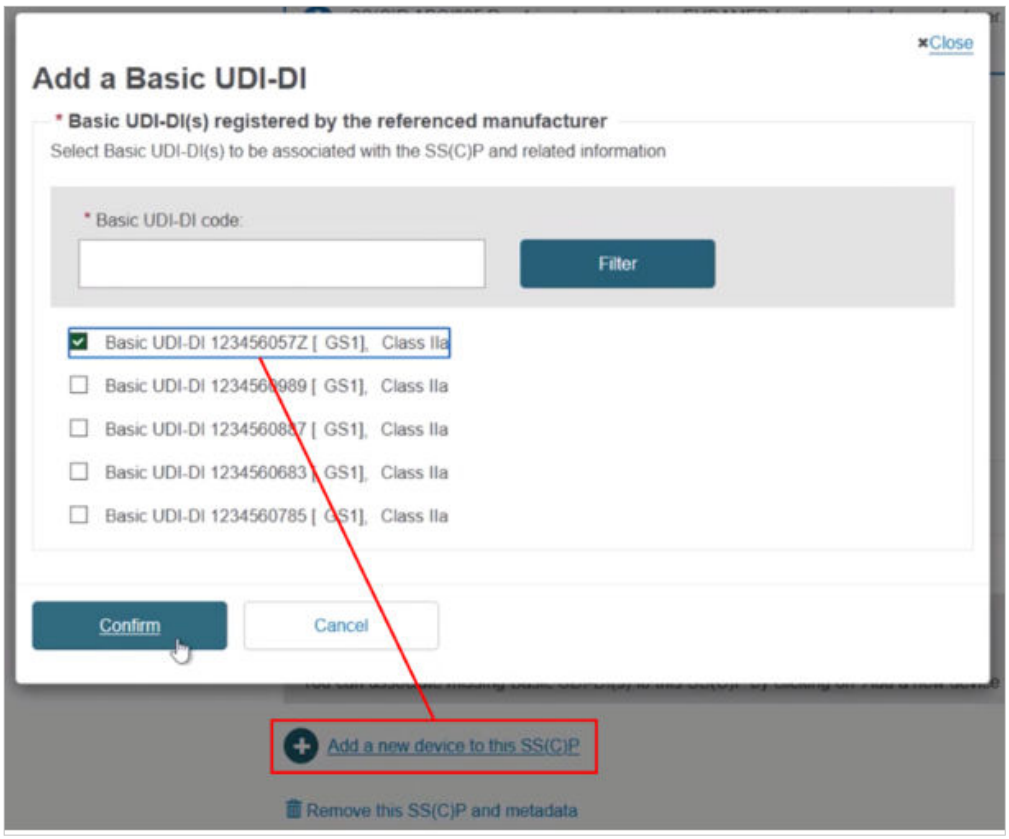


Click **Check registry**. The system will confirm this is a new SS(C)P:

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):



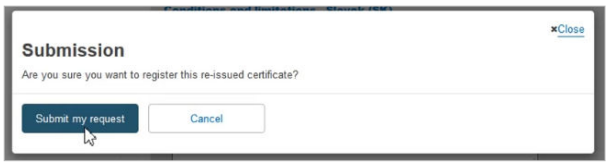
Scroll to the bottom, and click **+ Add a new device to this SS(C)P**, and select the device(s). Click **Confirm**, then **Save**:



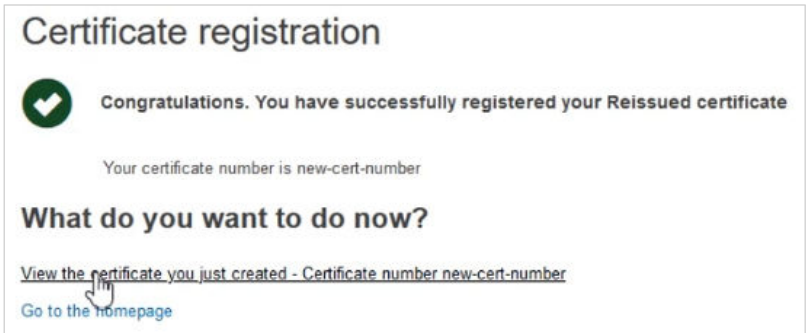
22. After having reviewed all information, click **Submit**:

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

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

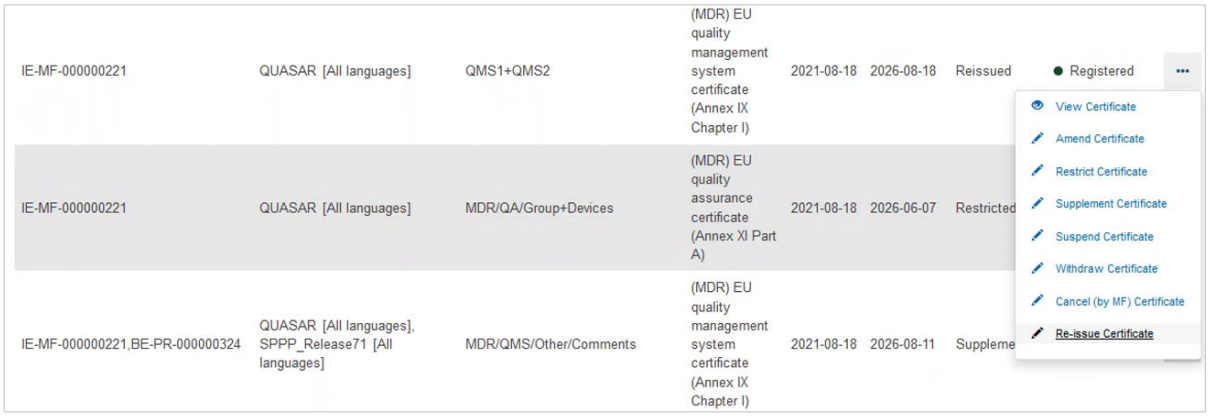


24. The system will confirm your submission has been successful. You can also view the newly created certificate by clicking on the link provided:



6.4.1. Merging two or more certificates when re-issuing a quality certificate

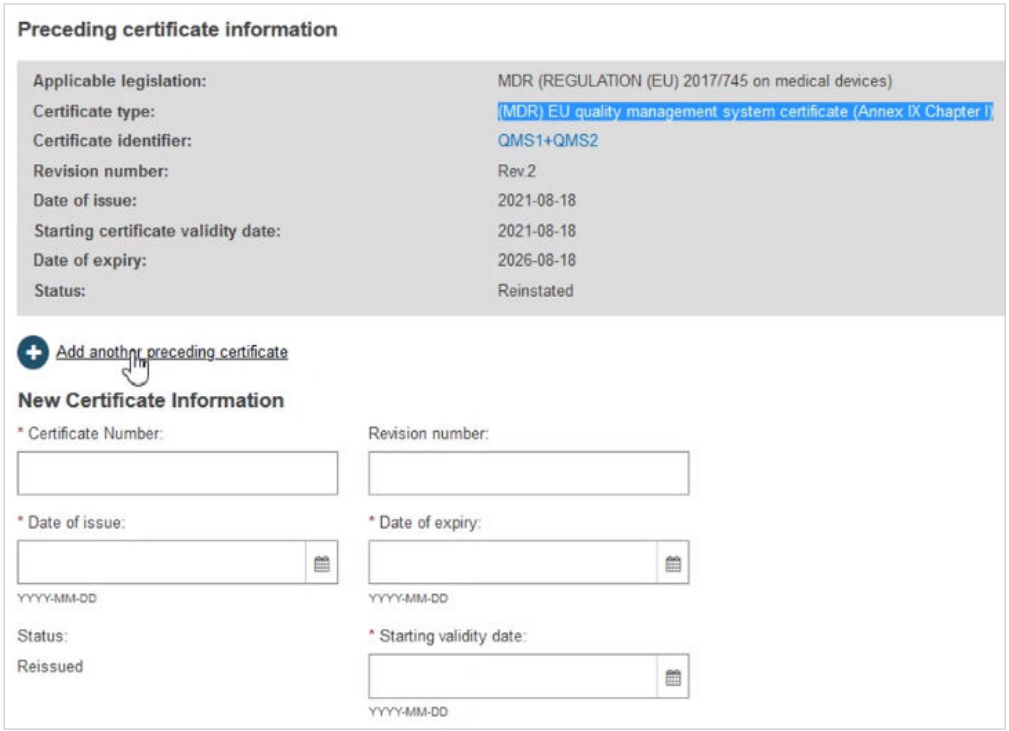
1. Click on the three dots next to the desired certificate, then click 'Re-issue Certificate':



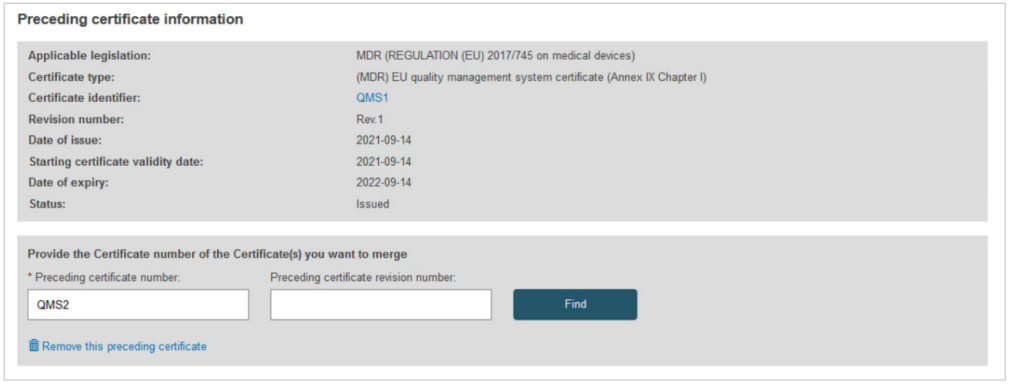
TIP
'Re-issue Certificate' is missing?

- Verify that your certificate is not in draft state within the certificate management page.
- If a draft version exists, it must be finalised or deleted. The 'Re-issue Certificate' operation will now be available.

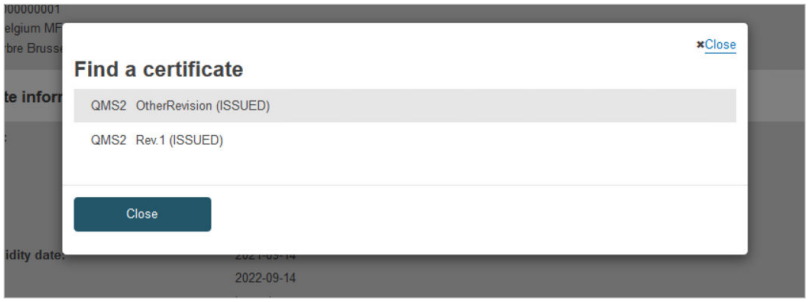
2. On the next screen, click **+ Add another preceding certificate**:



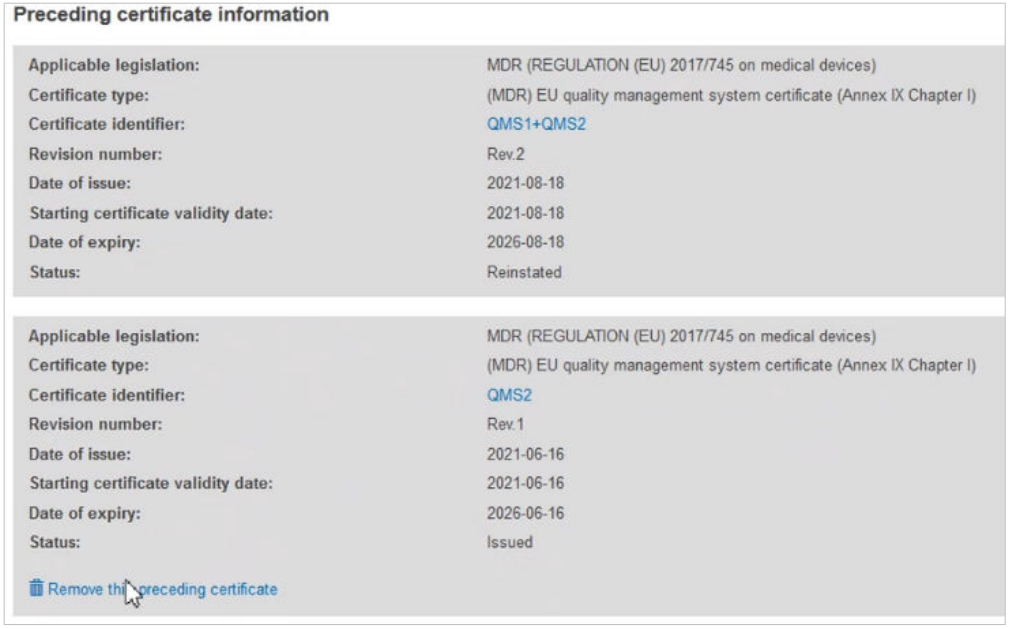
3. Type the new preceding certificate number and optional revision number and click **Find**:



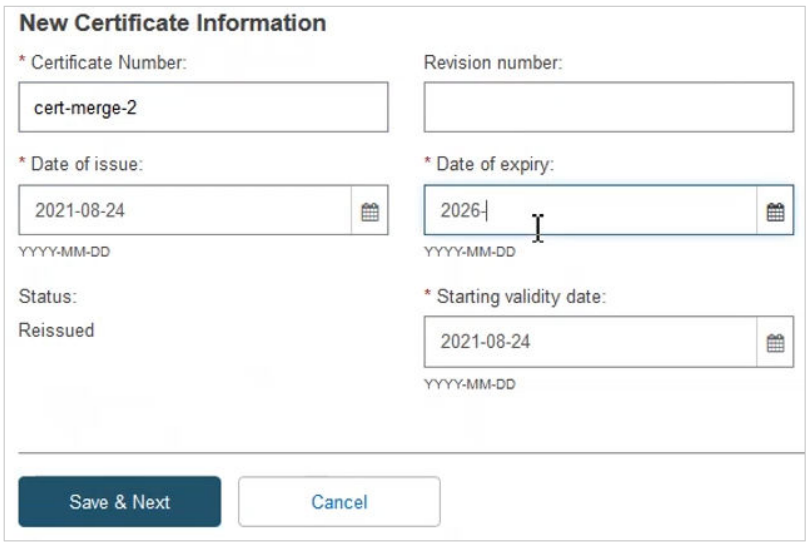
4. When there is more than one certificate with the same reference number and no revision number is provided, the system will display a selection dialog:



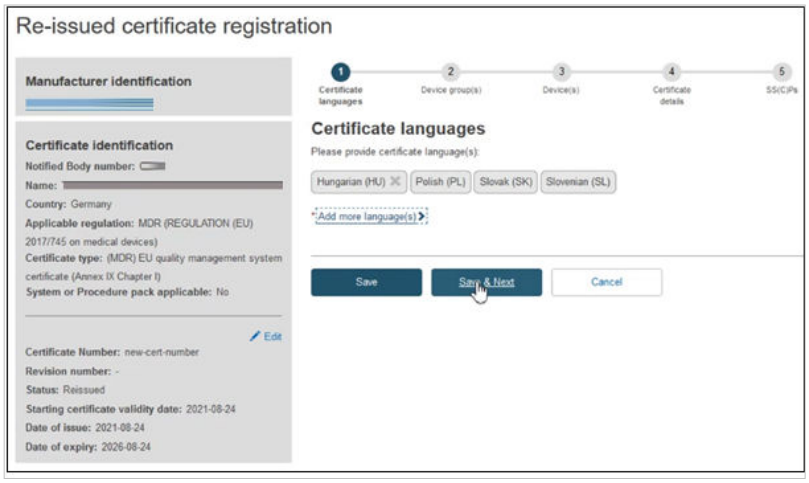
5. The new preceding certificate information will appear on the list. You have the option of removing it:



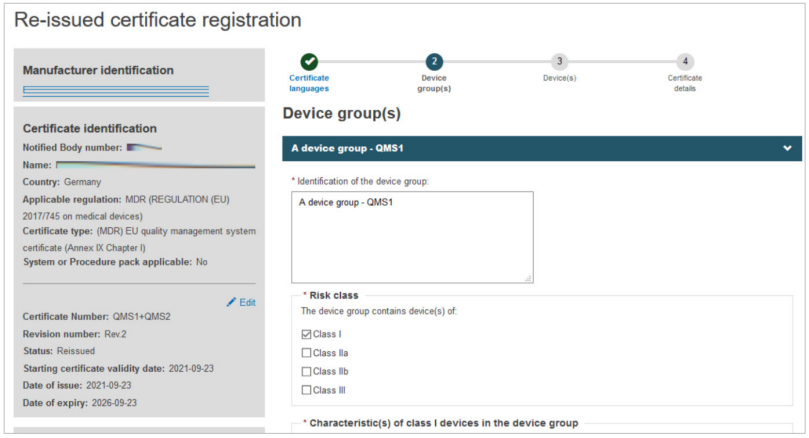
6. Next, fill in the 'New Certificate Information' and click **Save & Next**:



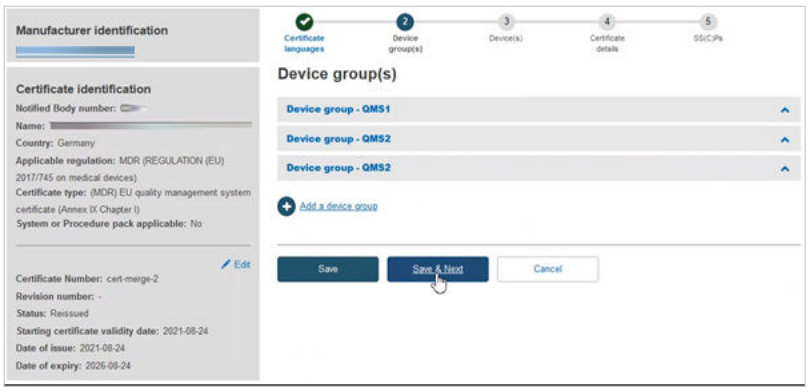
7. The next screen will display a timeline of steps to follow. Follow the order starting from the first section *Certificate languages*.
   Click Add more languages if necessary and click **Save & Next** to complete this step:



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**:

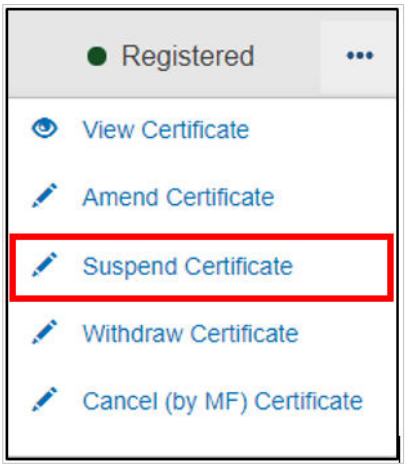


As the remaining actions to complete the process are identical to re-issuing a quality certificate, please consult steps 11-20 of section 6.4 [50].

7. Decisions over a certificate

7.1. Suspend

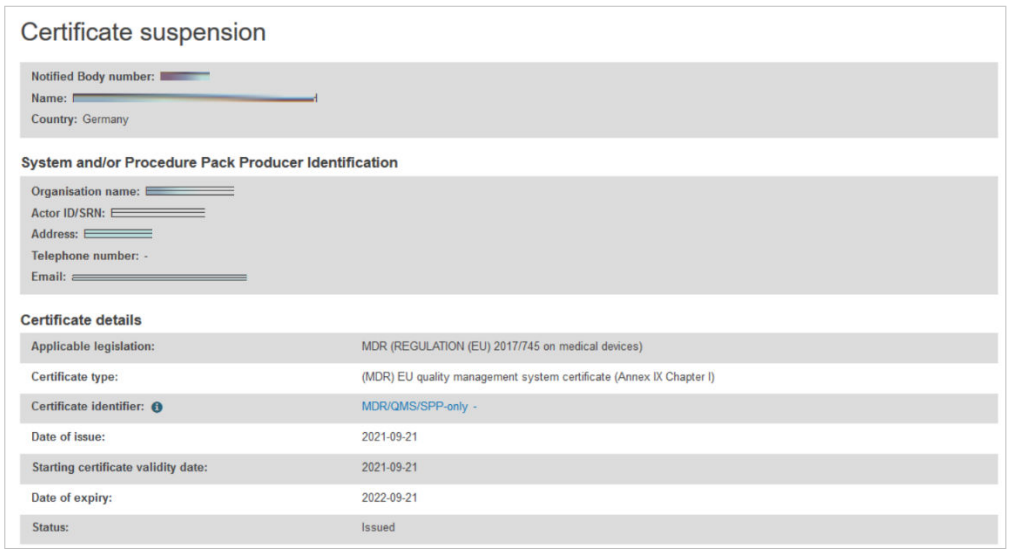
To suspend a certificate, click on the three dots next to the certificate you wish to suspend and click 'Suspend Certificate':



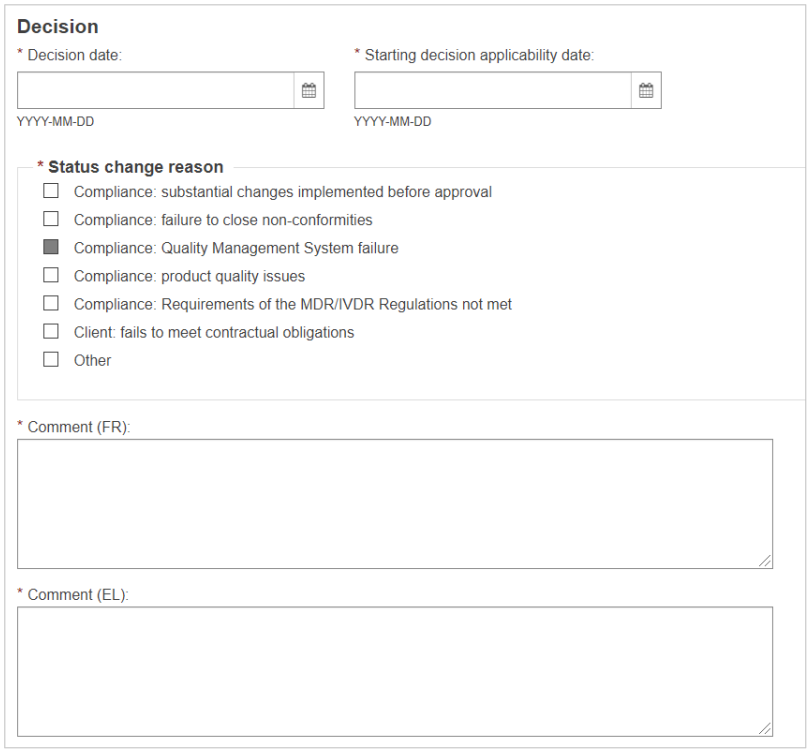
TIP
'Suspend Certificate' is missing?

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

You will arrive to the following page:



Below you will find the *Decision* section:



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

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

7.2. Withdraw

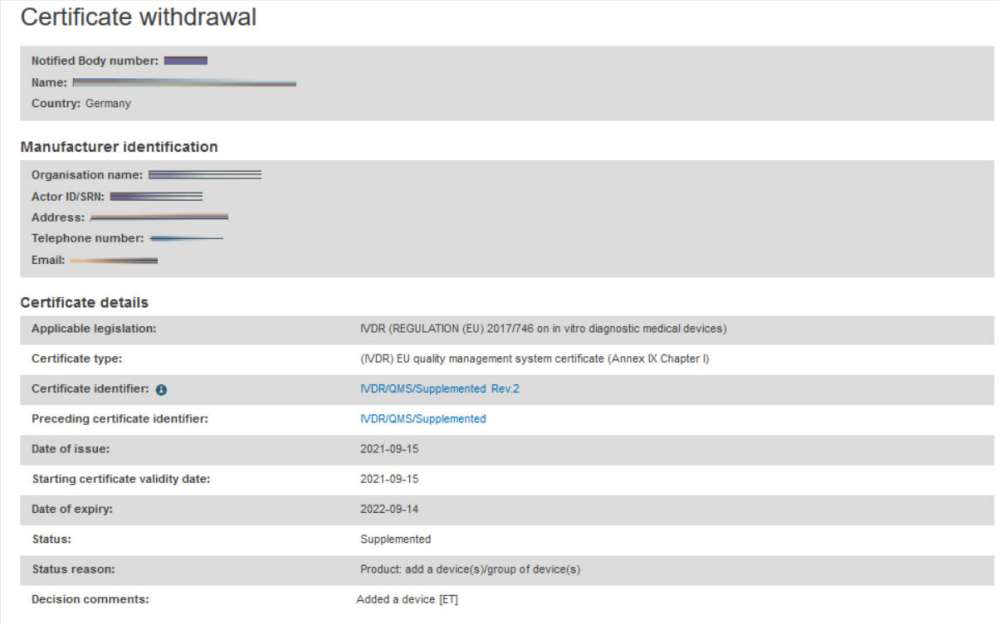
To withdraw a certificate, click on the three dots next to the certificate you wish to withdraw and click 'Withdraw Certificate'.

TIP
'Withdraw Certificate' is missing?

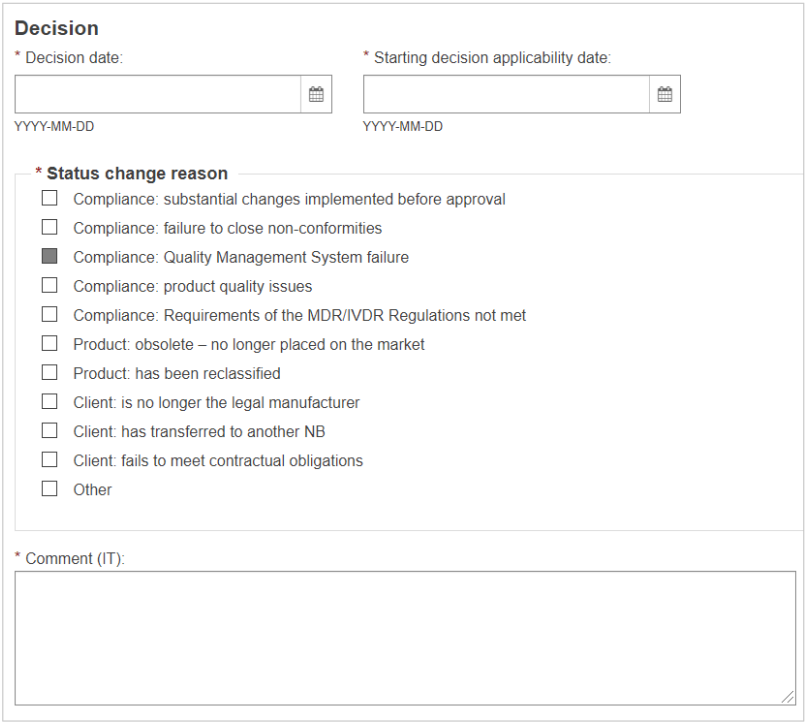
Verify that your certificate is not in draft state within the certificate management page.

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

You will arrive to the following page:



Below you will find the *Decision* section:

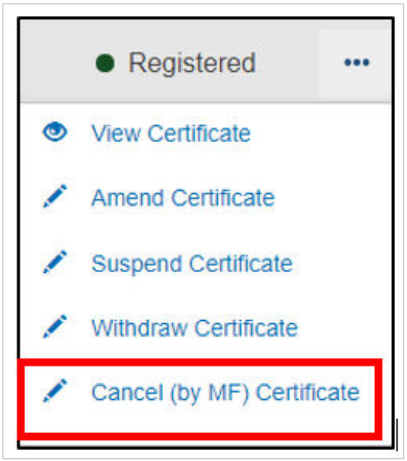


Enter the date when the decision to withdraw the certificate was taken, the date it will apply from, and the reason it is being withdrawn.

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

7.3. Cancel by MF Certificate

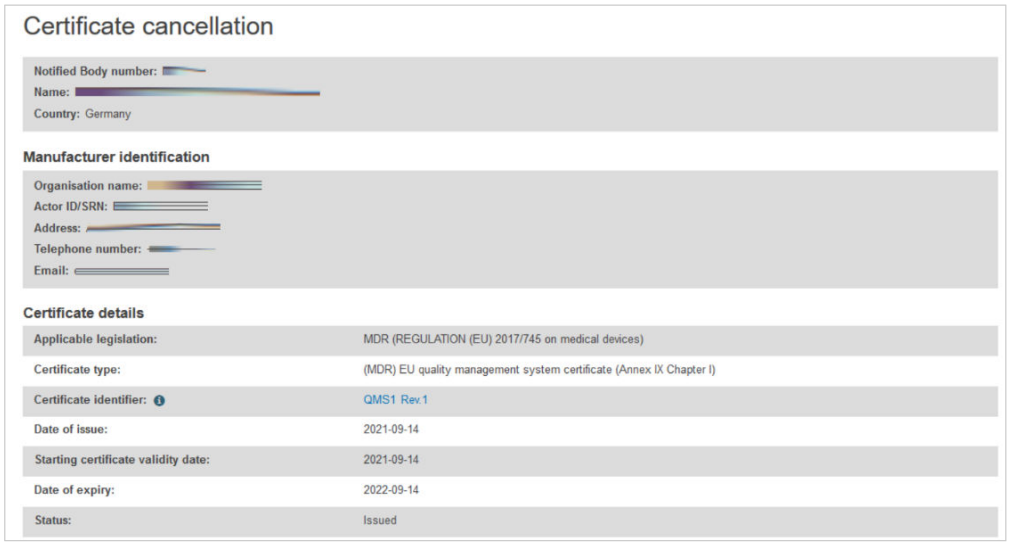
To cancel a certificate (by the manufacturer), click on the three dots next to the certificate you wish to cancel and then click 'Cancel (by MF) Certificate'.



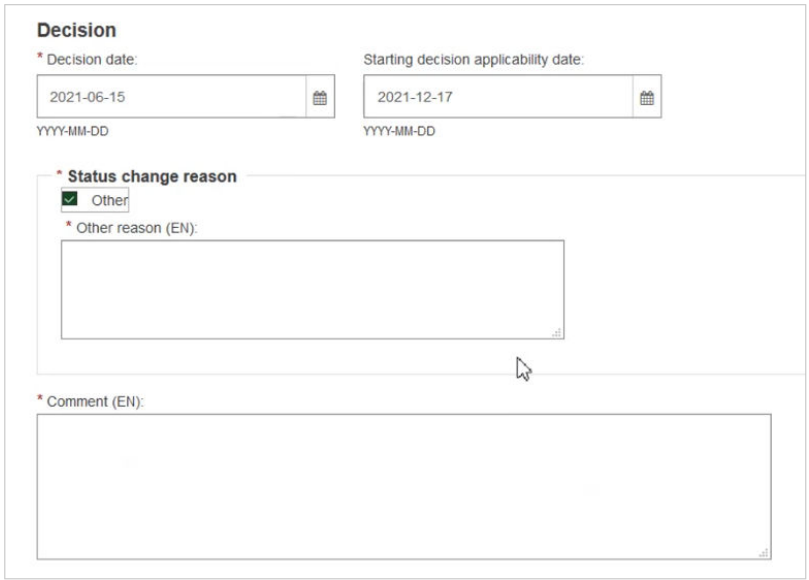
TIP
'Cancel (by MF) Certificate' is missing?

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

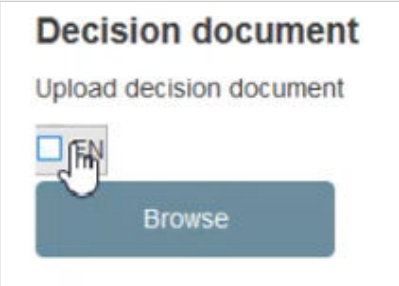
You will arrive to the following page:



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:



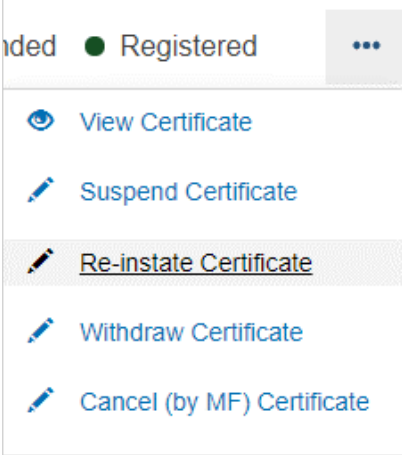
Upload the decision document in the correct language:



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

7.4. Reinstate

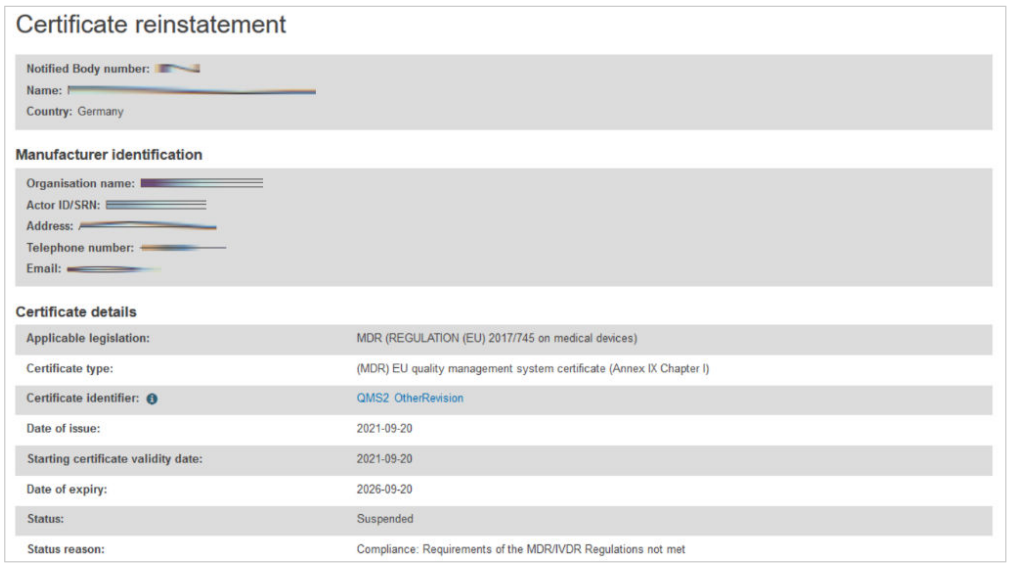
To re-instate a certificate, click on the three dots next to the certificate you wish to reinstate and click 'Reinstate Certificate'.



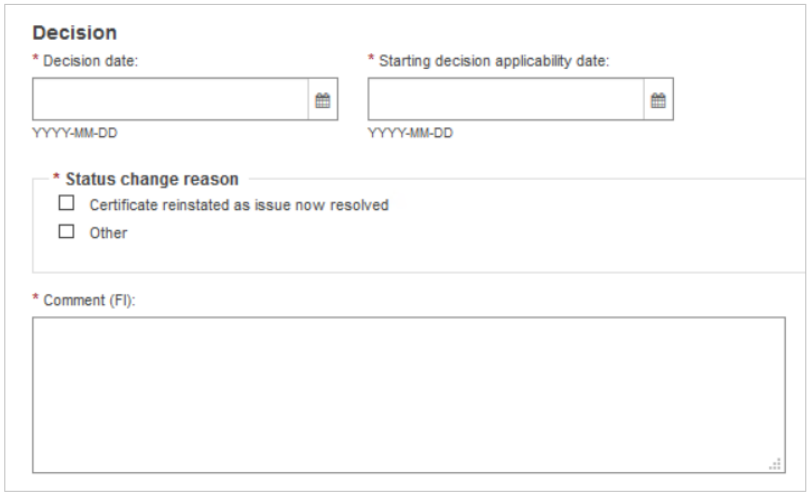
TIP
'Reinstate Certificate' is missing?

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

You will arrive to the following page:

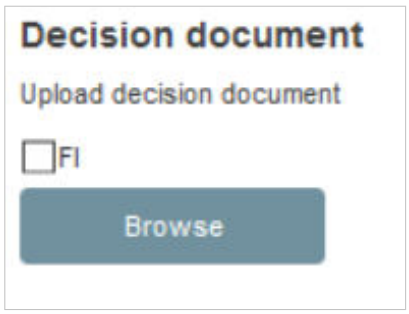


Below you will find the *Decision* section:



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.

Upload the decision document in the correct language.



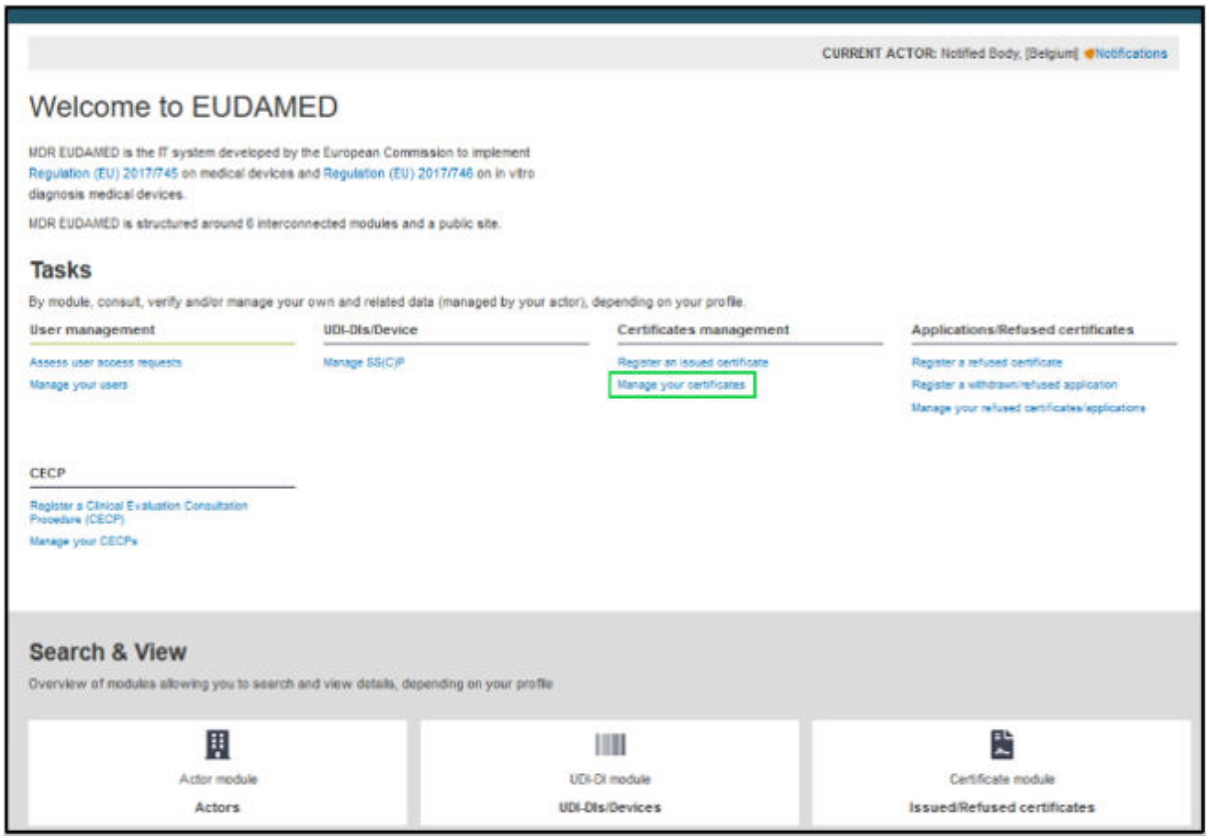
Once you are done, click **Submit**.


Submit
Cancel

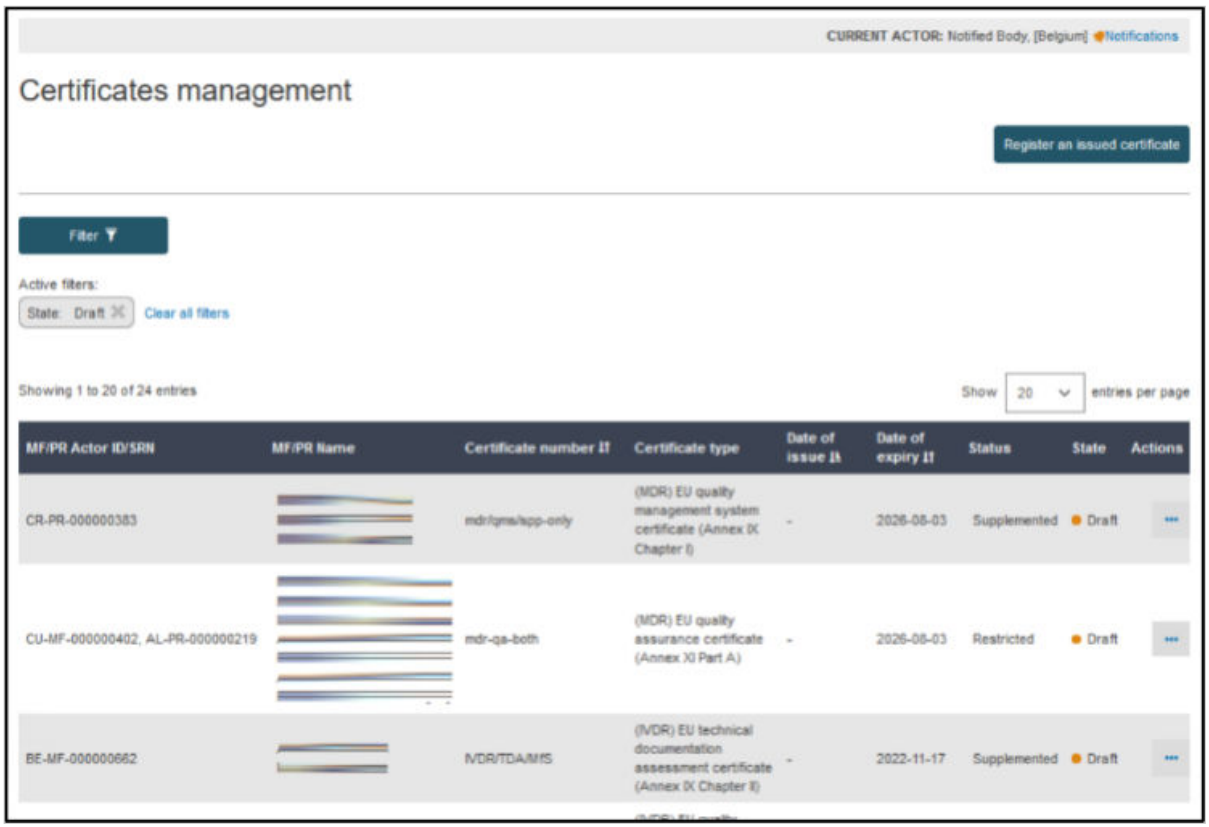
8. Certificate management

8.1. View certificate

1. Click on ‘Manage your certificates’ link within your dashboard

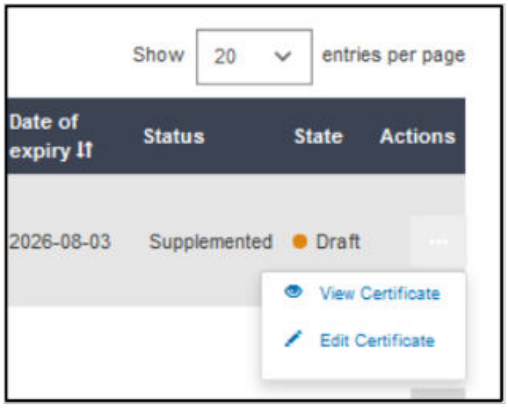


2. On the following certificate management page, by default, the system will display your certificates in draft state. Click the **Filter** button and select a certificate type from the dropdown list, select the role of an economic operator and fill in any other criteria, such as SRN etc. and click on ‘Apply filters’:

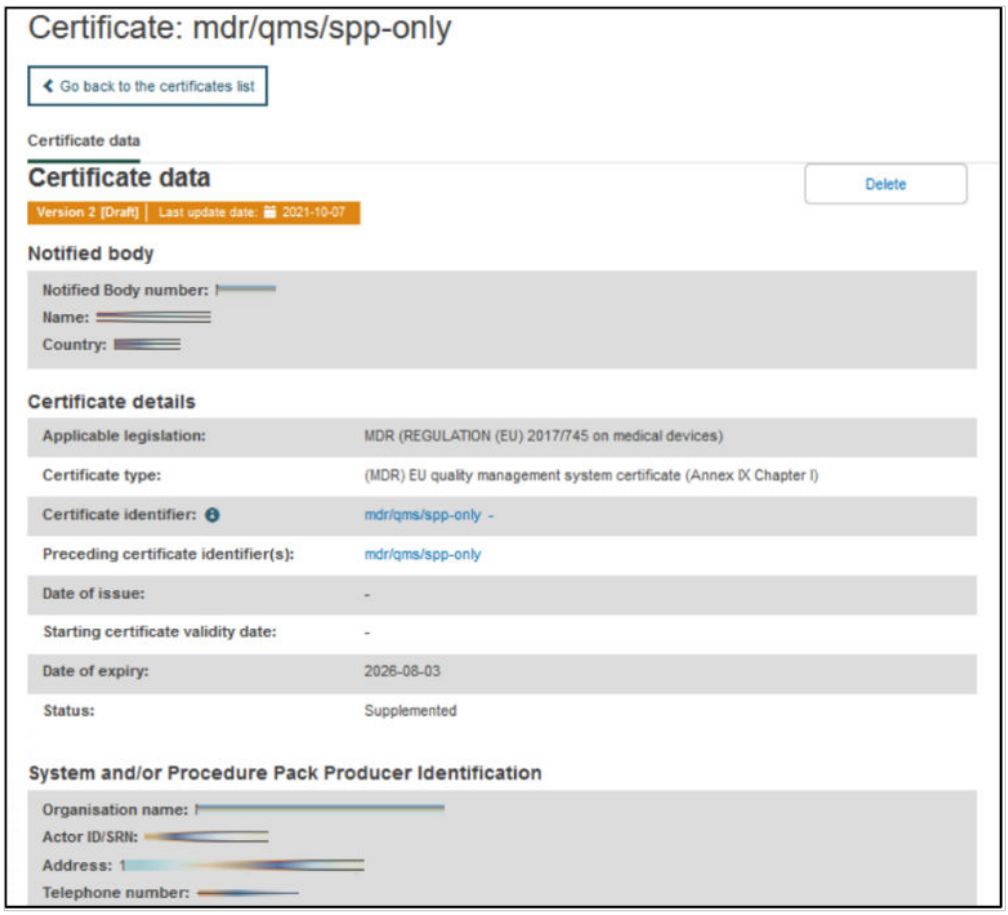


8.2. Delete a draft certificate

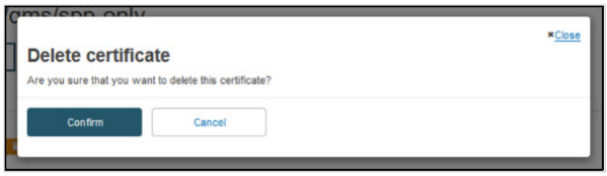
1. Within the result list, click on the three dots under the Actions column for a specific entry. A contextual menu will show:



2. Then click on ‘View Certificate’ to see its details. Within the view page, click the **Delete** button:

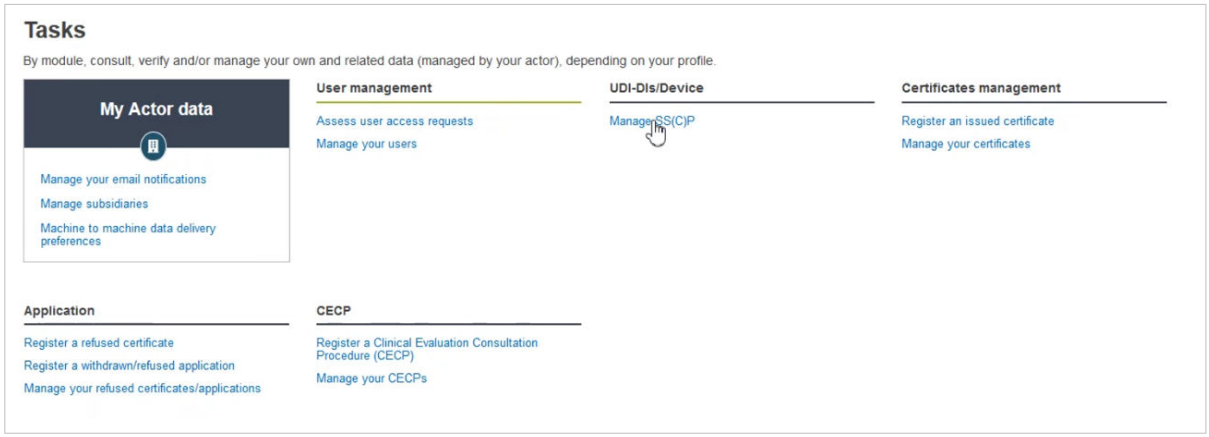


3. A confirmation dialog will display. Click **Confirm**, and the certificate will be purged from EUDAMED:

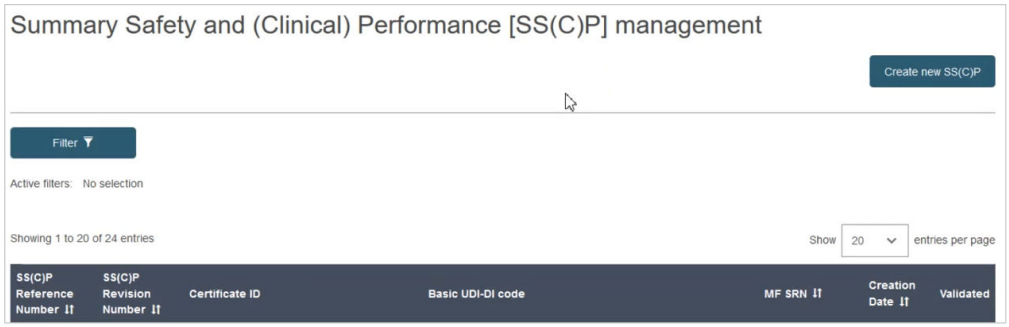


9. SS(C)P management

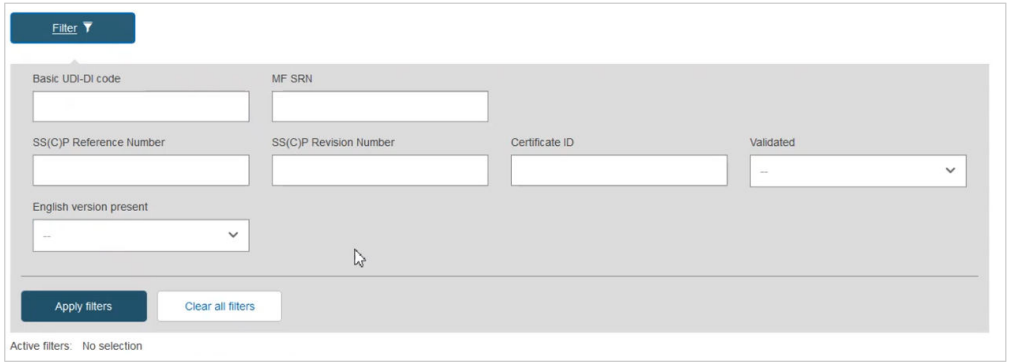
To manage your SS(C)Ps, under 'UDI-Dis/Device' on the Notified Body dashboard click 'Manage SS(C)P':



Once you have clicked 'Manage SS(C)P', you will be brought to the following page:



You will be 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:



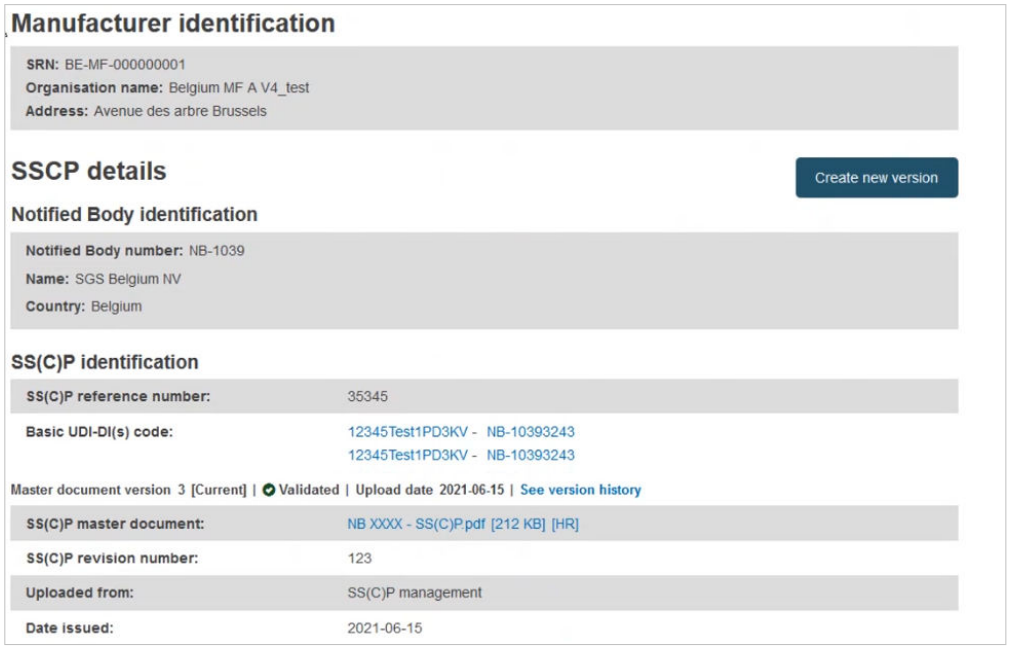
You can search by different values.

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.

When you find the SS(C)P you want to manage in the list, simply click on it:

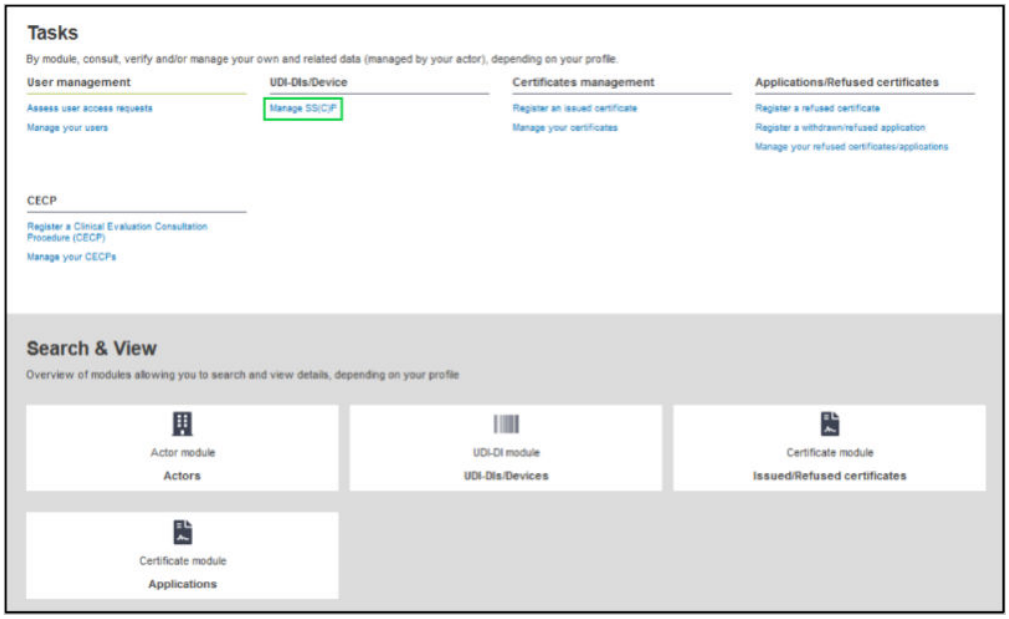
You will see a summary of the information related to the SSCP:



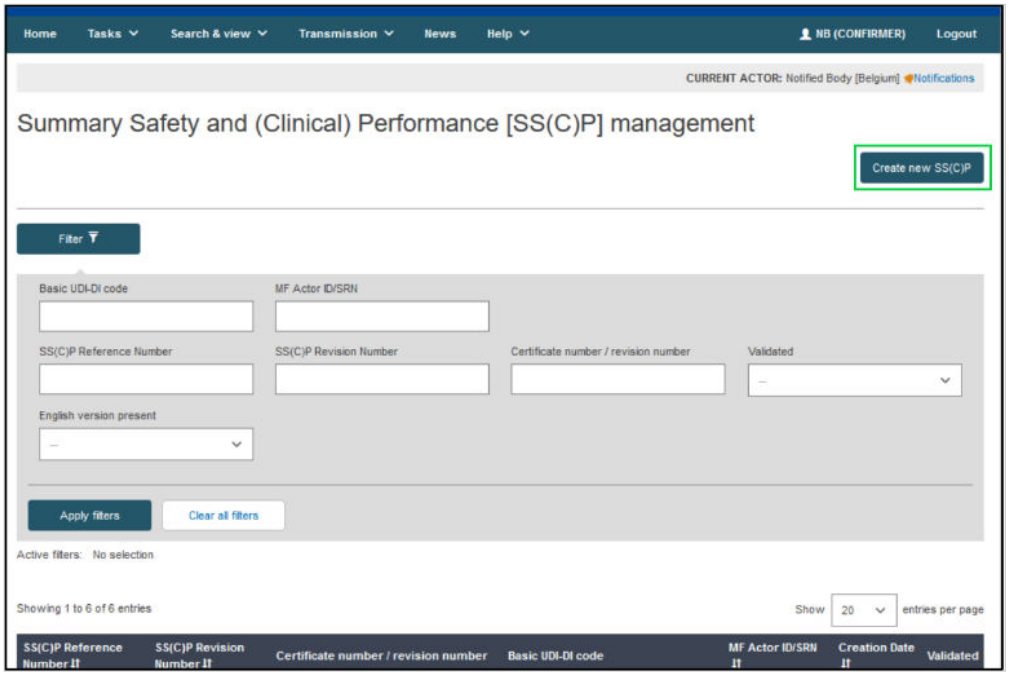
Clicking on the Basic UDI-DI codes will open the Basic UDI-DI in a new tab. Next to this code is the certificate data that is linked to the Basic UDI-DI.

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**:

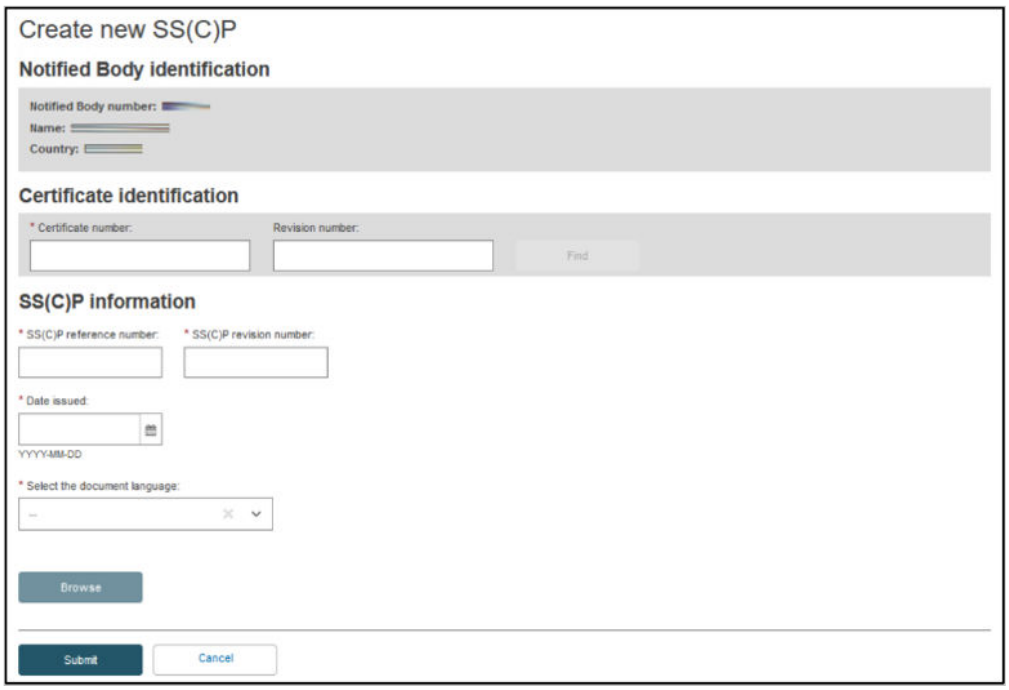


3. Provide certificate's number and optionally revision number to identify the certificate registered before and click **Find**:

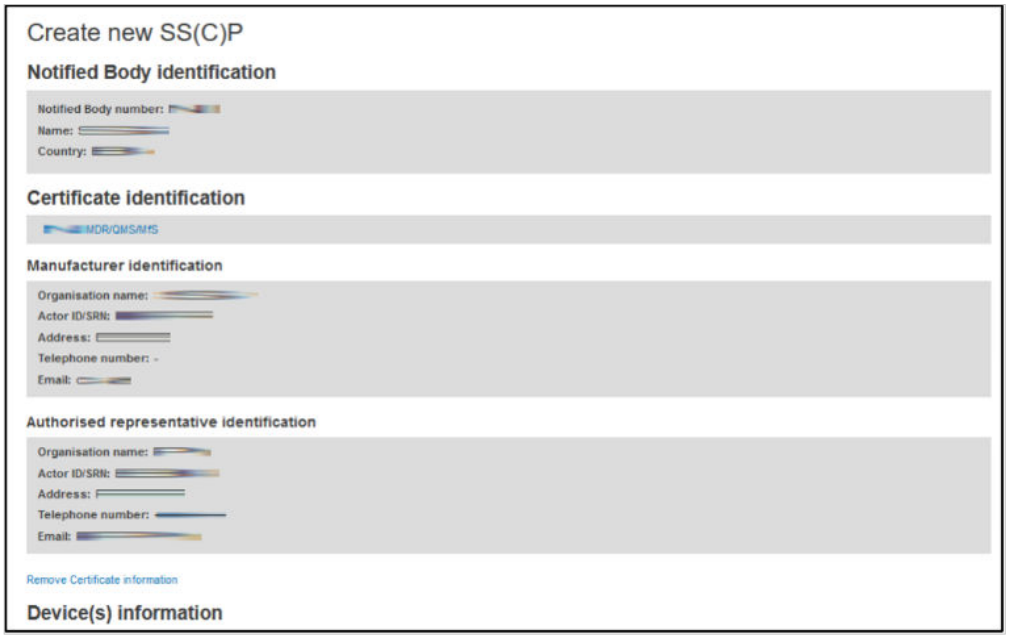
NOTE
Only the following certificate types can be linked to new SS(C)P created within the SS(C)P management page:

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

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

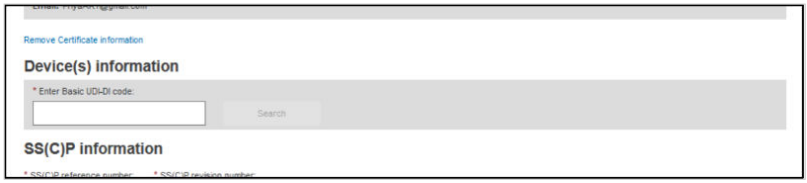


4. Once the certificate has been identified, its link will be populated in the box along with information about the manufacturer, and the applicable authorised representative(s):



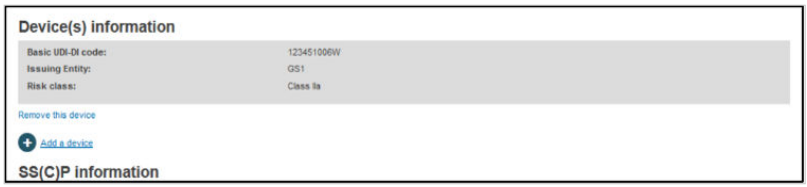
5. Click the ‘Remove Certificate information’ link if the certificate displayed is not the intended one. The process to identify the certificate will restart.

6. Within ‘Device(s) information’ you need to identify the Basic UDI-DI to be linked to this SS(C)P:



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

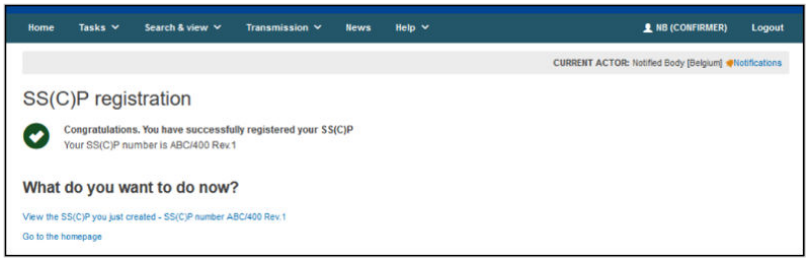
8. Once a Basic UDI-DI is selected, the system will populate its details:



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’ link.

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’:

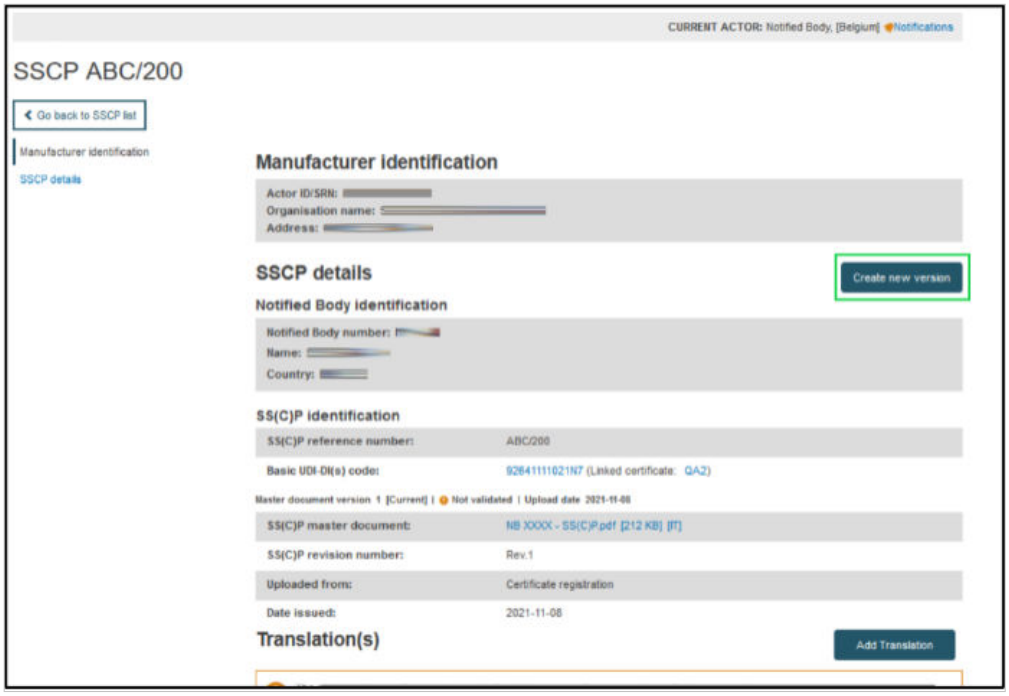
10. Click **Submit** and confirm when asked. A congratulations page will appear:



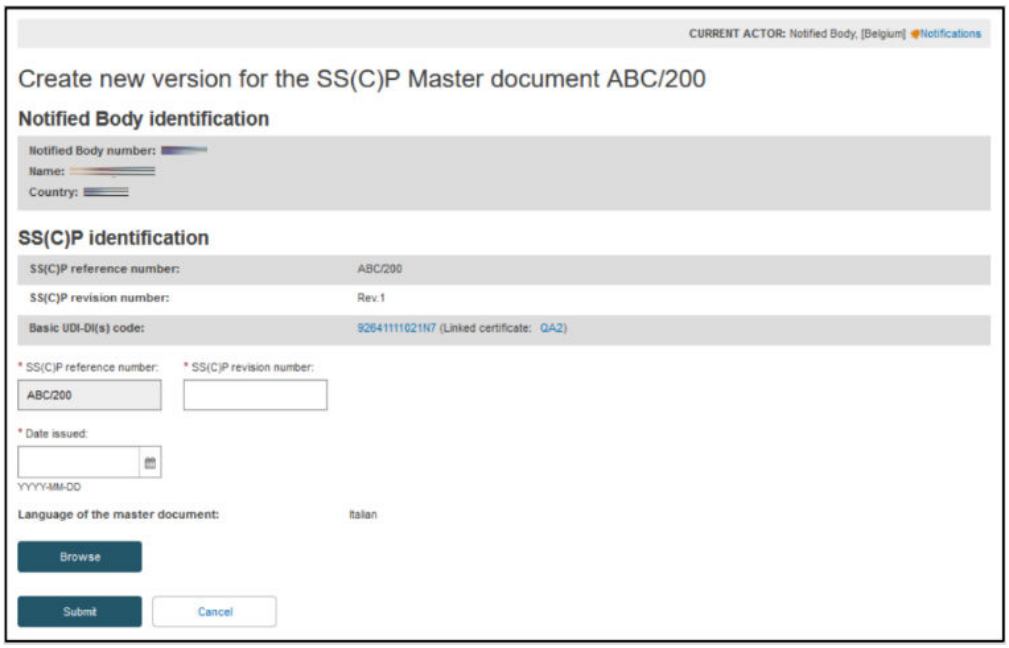
Your new SS(C)P record will appear under the list of SS(C)Ps within the SS(C)P management page.

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:

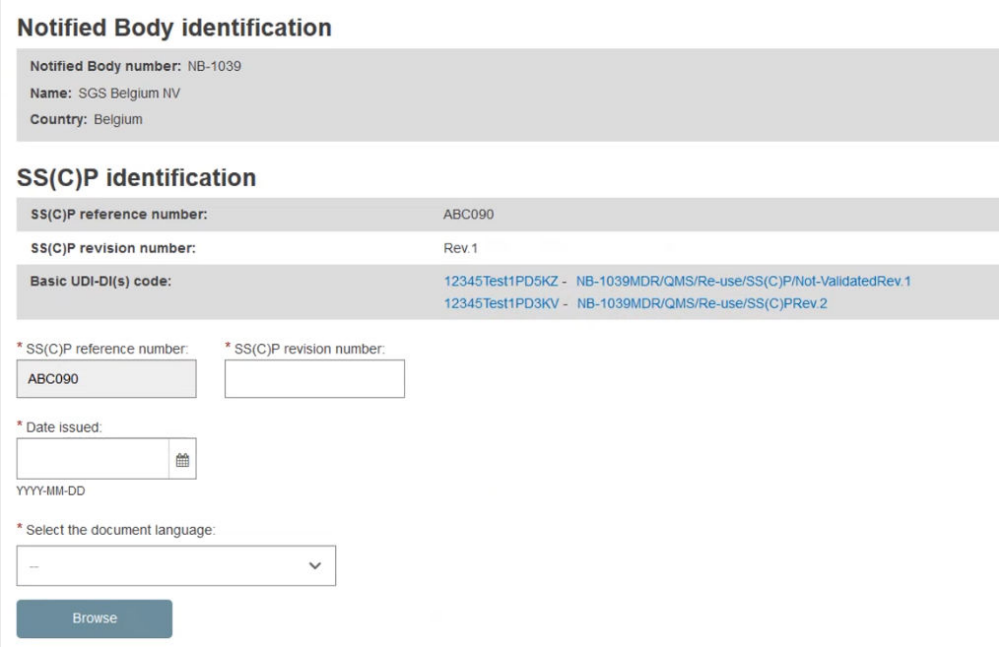


NOTE
The new SS(C)P version will be automatically linked to the last active version of the certificates it is linked to.

9.3. Adding translations

If you want to add a translation to a SS(C)P that is not validated you must create a new version.

When you click on it, a new window will open:

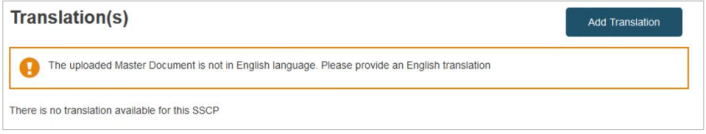


You **must** enter a new SS(C)P revision number.

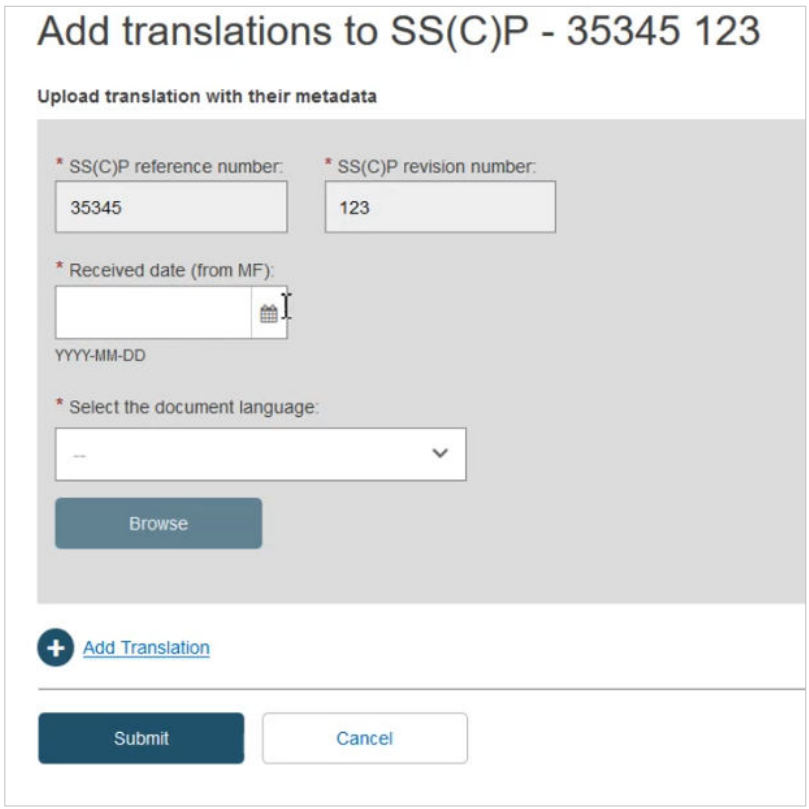
Choose the date and upload the master document.

Check the *I confirm* box and click *Submit*.

To add translations to a SS(C)P, click *Add Translation* on the right side of the screen:

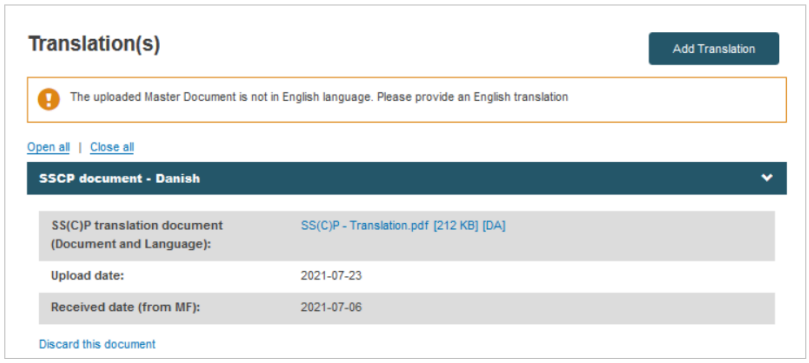


In the new window, select the date by clicking on the calendar icon and select the document language from the dropdown list. You can add multiple translations at once by clicking on + *Add translation*.



Click *Submit*.

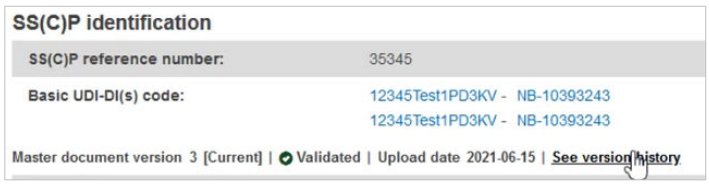
Translation documents are displayed within the Translation(s) section.



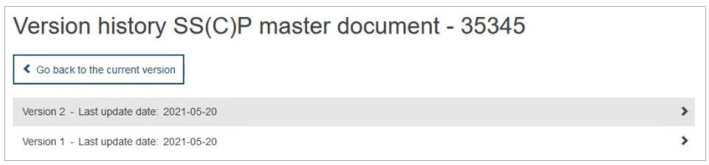
NOTE
If a translation in English is not provided, the system will display a warning message that an English translation must be provided.

9.4. View version history

If you want to check the SS(C)P version history, you can do so by clicking on 'See version history' under the Basic UDI-DI codes.



After clicking on it, you will see a list with the different versions for the SS(C)P:

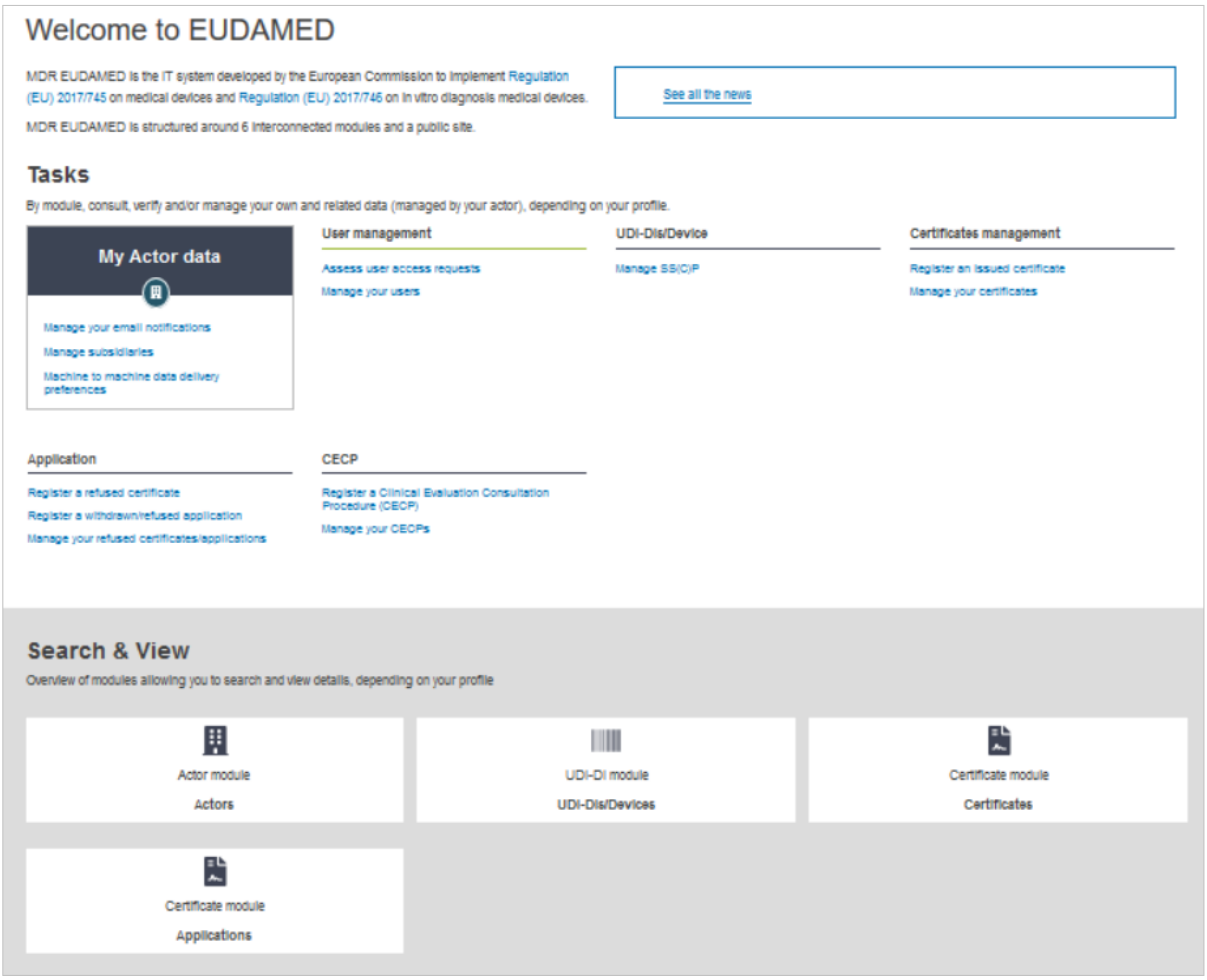


Click on the version you wish to review, opening a summary of it.

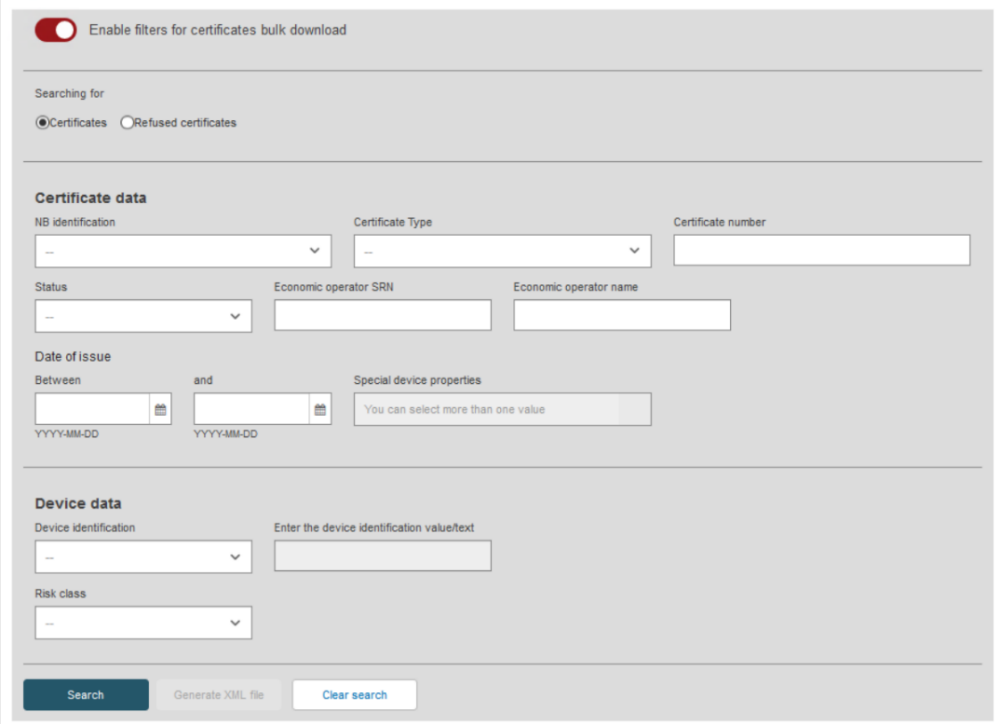
10. Search and view certificates

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

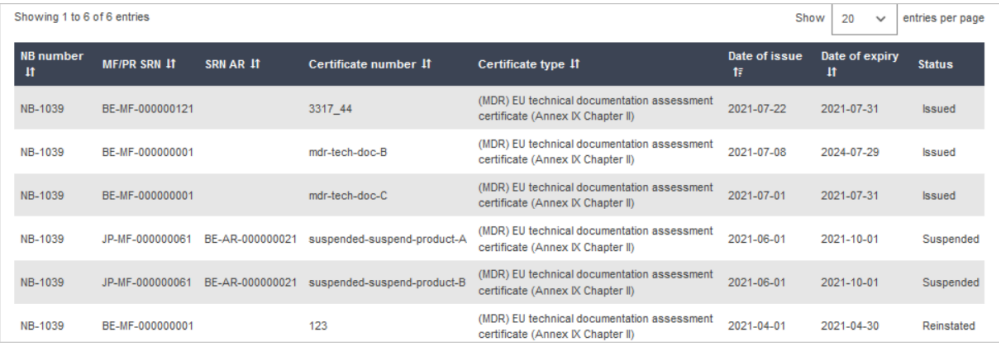
Alternatively, use the option available in the *Search and View* dashboard:



EUDAMED will display the filters available for searching through the list of certificates registered in EUDAMED:

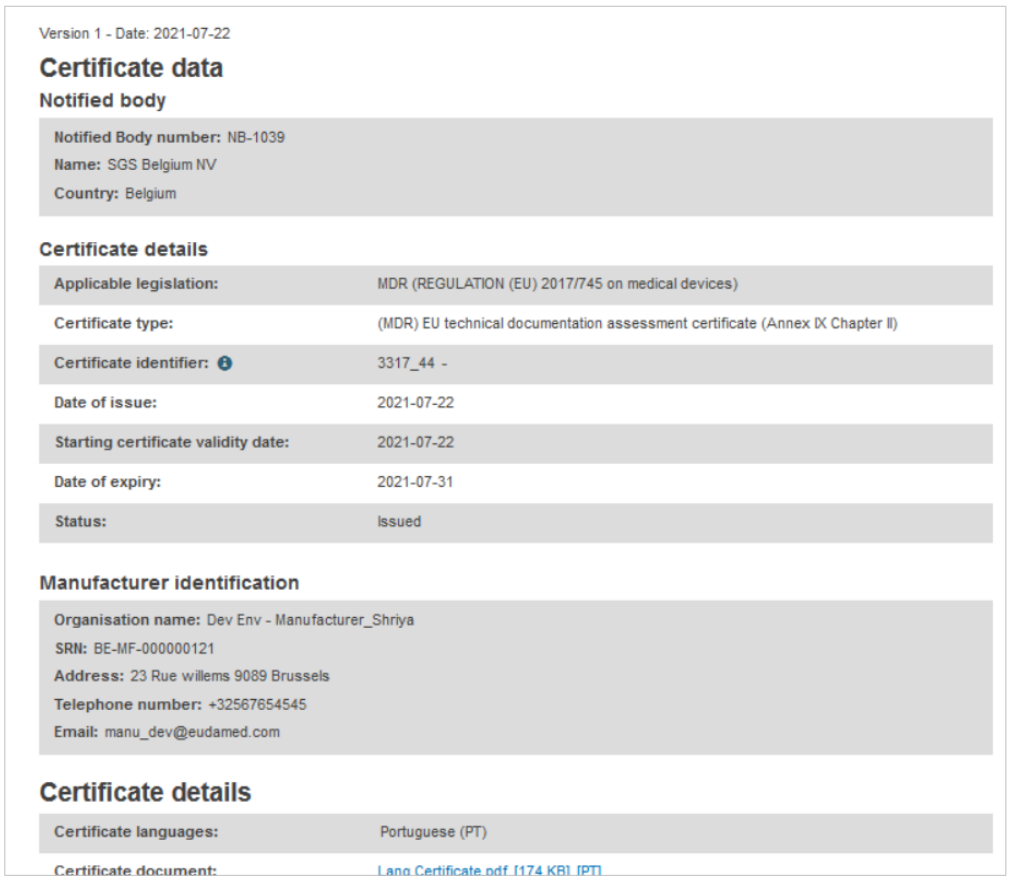


Once you have entered the desired search filters, click **Search**. A list of certificates will be displayed:



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

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

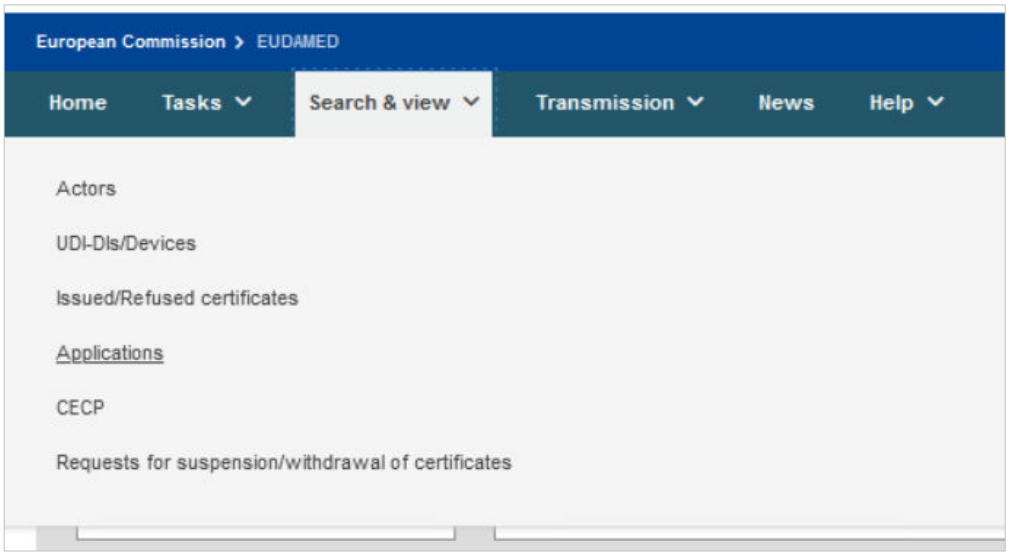
Organisation name: Dev Env - Manufacturer_Shriya
SRN: BE-MF-000000121
Address: 23 Rue willems 9089 Brussels
Telephone number: +32567654545
Email: manu_dev@eudamed.com

Certificate details

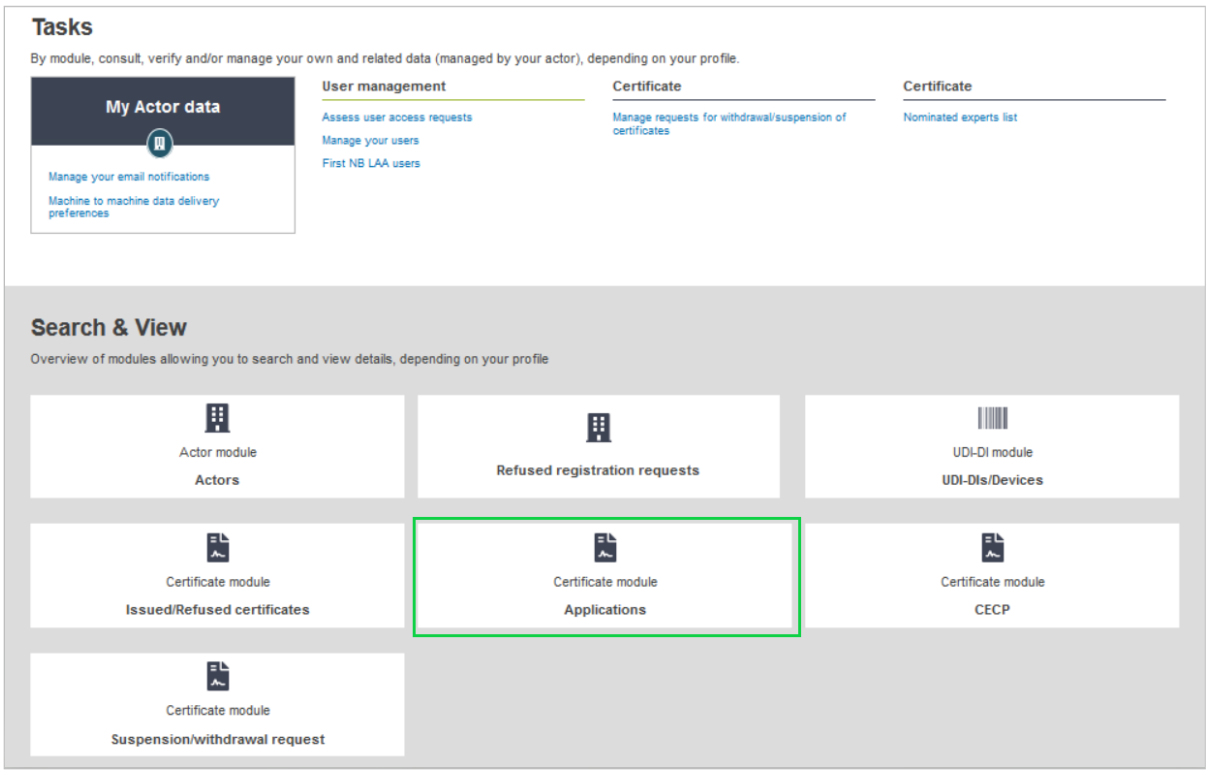
Certificate languages:	Portuguese (PT)
Certificate document:	Lang Certificate.pdf [174 KB] [PT]

11. Search and view refused/withdrawn applications for conformity assessment

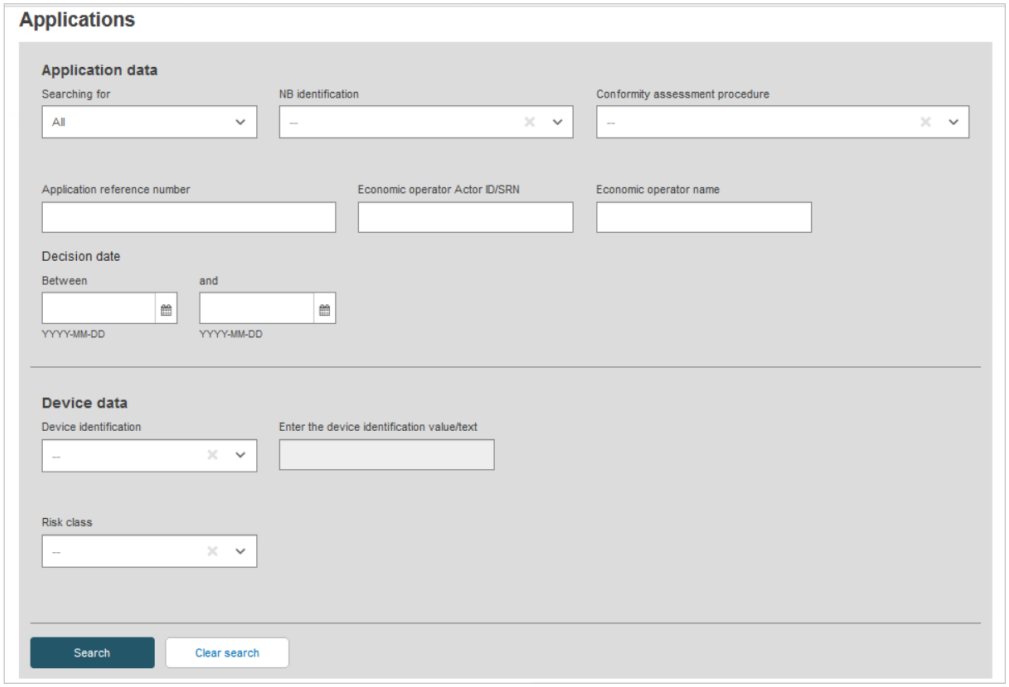
1. On the header menu, click on **Search & View**, then click on *Applications*:



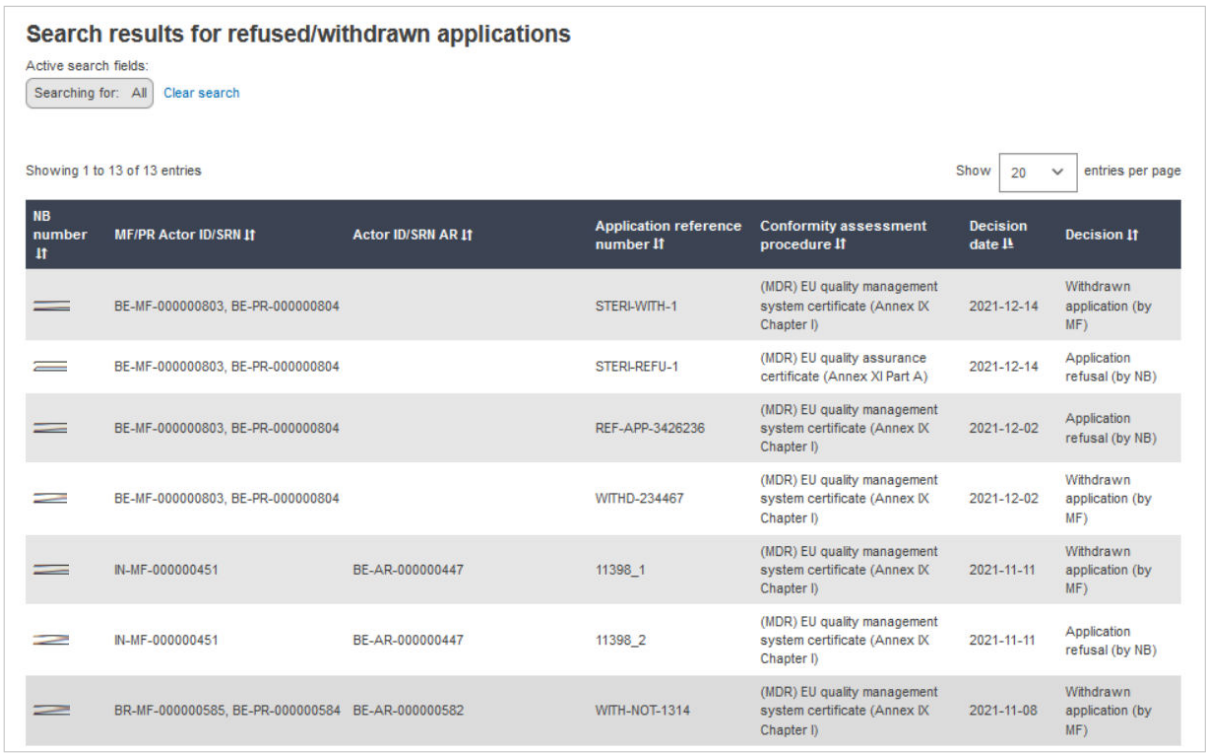
Alternatively, use the option available in the *Search & View* dashboard:



2. When clicked, the search for applications page will be displayed:



3. Once you have entered the desired search filters, click **Search**. A list of applications will be displayed:



Search results for refused/withdrawn applications

Active search fields:

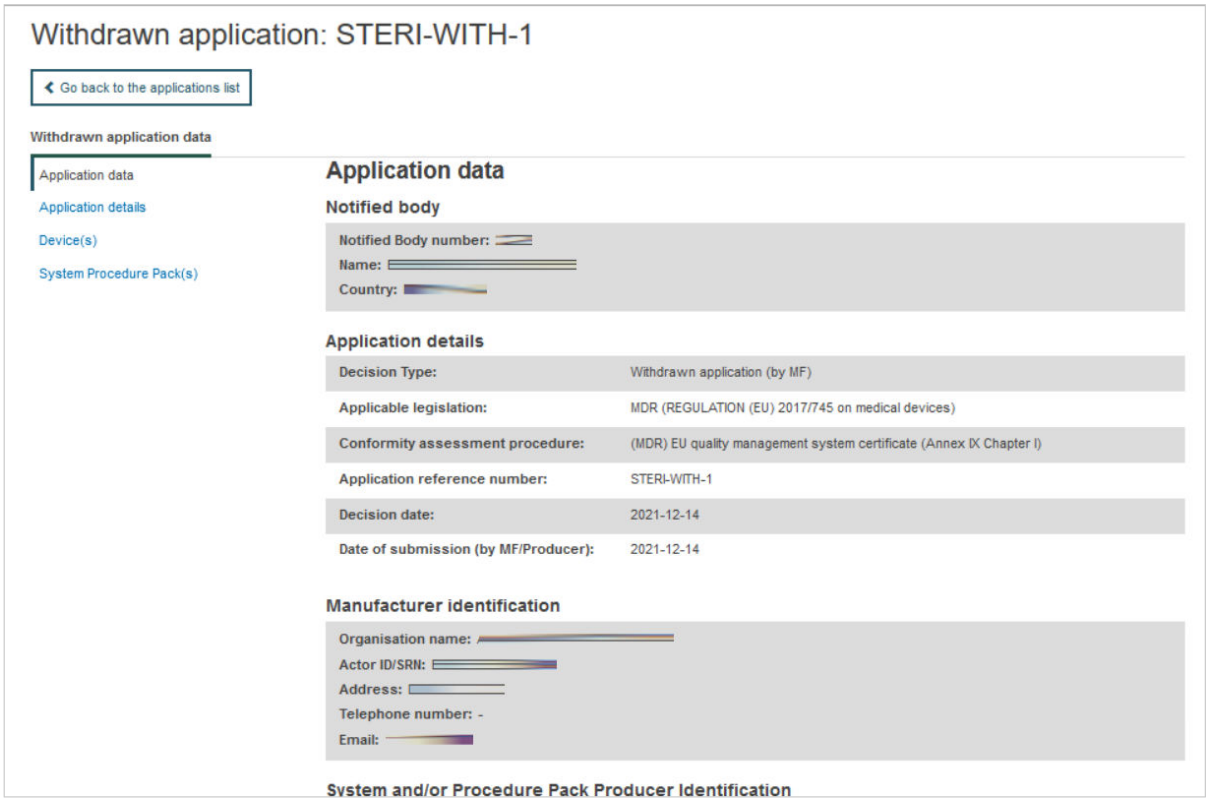
Searching for: All Clear search

Showing 1 to 13 of 13 entries

Show 20 entries per page

NB number	MF/PR Actor ID/SRN	Actor ID/SRN AR	Application reference number	Conformity assessment procedure	Decision date	Decision
[redacted]	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)
[redacted]	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)
[redacted]	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)
[redacted]	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)
[redacted]	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)
[redacted]	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)
[redacted]	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 the details of that record:



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: [redacted]

Name: [redacted]

Country: [redacted]

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: [redacted]

Actor ID/SRN: [redacted]

Address: [redacted]

Telephone number: -

Email: [redacted]

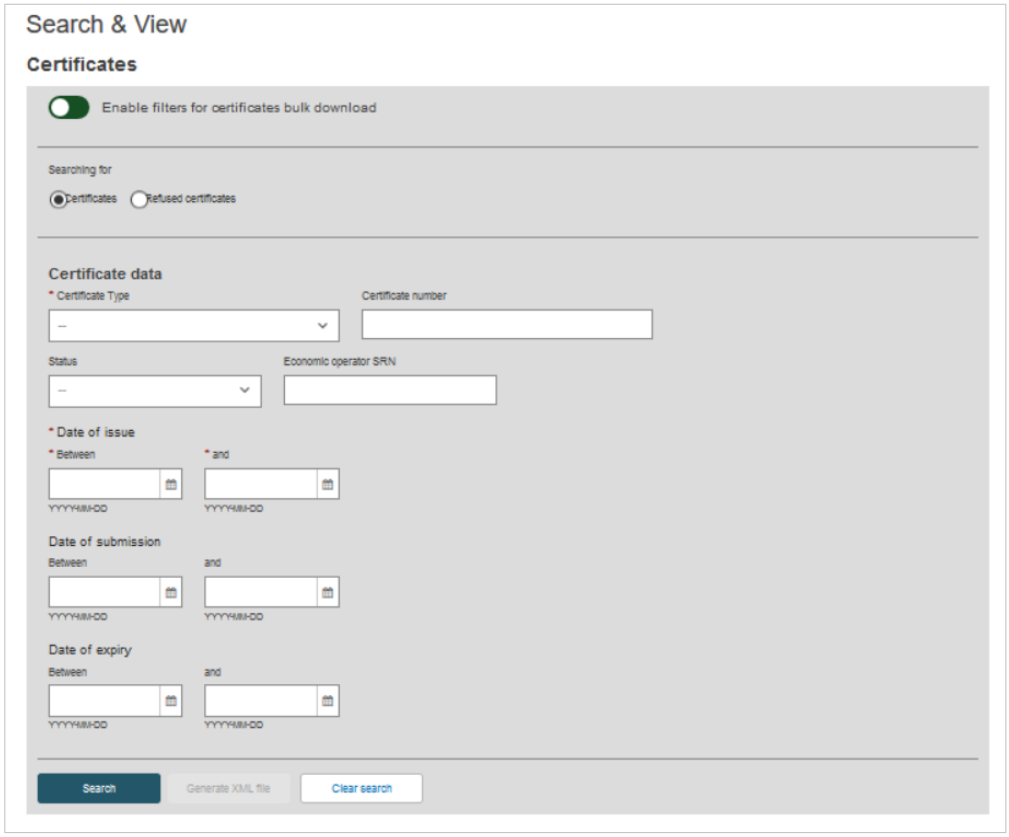
System and/or Procedure Pack Producer Identification

12. Download certificates and refused certificates in a structured format

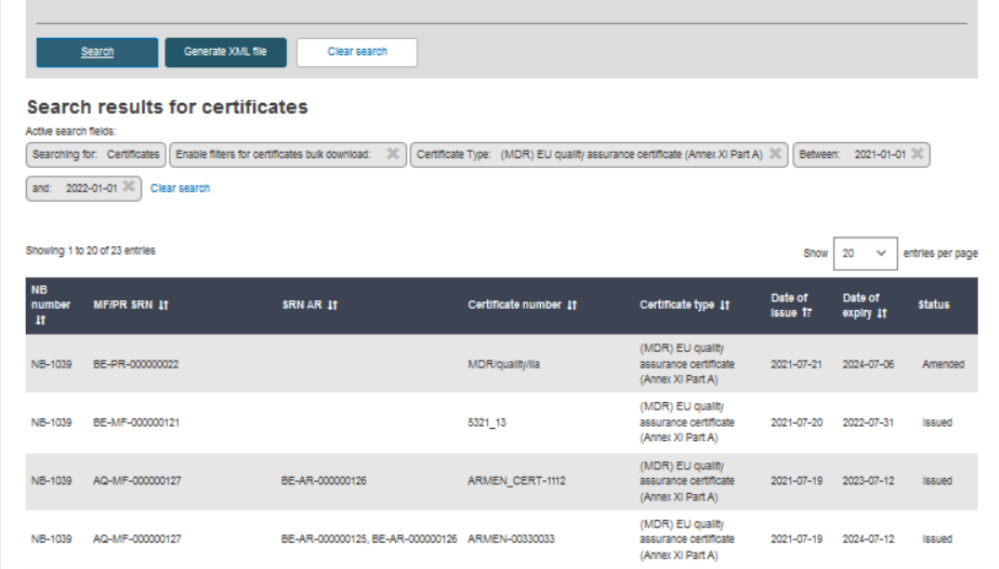
NOTE
Notified Bodies can only download **their own** registered certificates or refused certificates.

Follow the steps in chapter 11 [87] to search and view certificates.

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:



Complete the search criteria you wish to enter, and click **Search**, to generate the result:

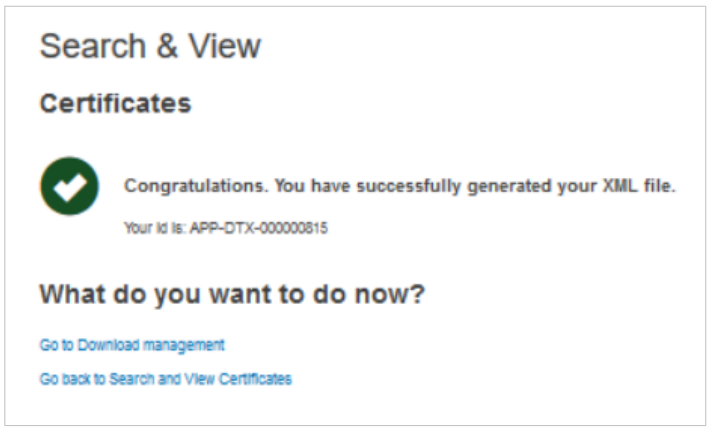


Once there is at least one result click **Generate XML file**:

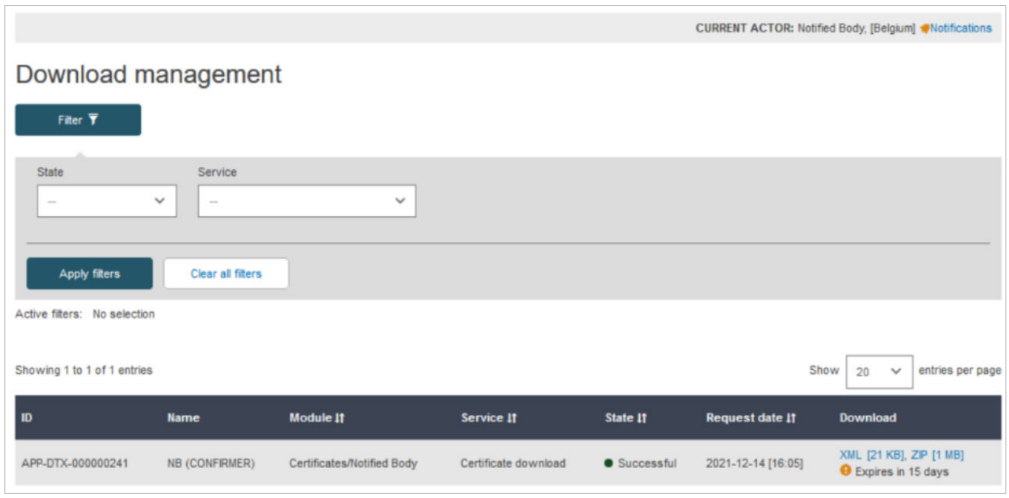
NOTE
Only what is shown in the result list will be included in the generated file and not all the results of your search (in cases where these exceed the default number of results on one page).

A pop-up window will prompt you to confirm your action:

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



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

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