EUDAMED user guide

Vigilance for EOs

Playground v 3.11.0
2025

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1 Basic Concepts – types of Vigilance & Post-Market Surveillance reports

For the current EUDAMED Playground release, the following types of reports can be managed:

- **MIR (Manufacturer Serious Incident Report)**
- **FSCA (Field Safety Corrective Action)**
- **PSUR (Periodic Safety Update Report)**
- **NCAR (National Competent Authority Report)**
- **MTR (Manufacturer's Trend Report)**
- **FSN (Field Safety Notice)**
- **PSR (Periodic Summary Report)**
- **PSRP (PSR Periodic Analysis Update)**

2 Getting started – access the Vigilance & Post-Market Surveillance module

Prerequisite to access EUDAMED:

EU Login (ECAS) account

If you do not have an EU Login account, please follow the instructions for creating an account before using the EUDAMED database.

Access the EUDAMED Playground environment.

You will be prompted to enter EUDAMED via your EU Login account.[1]

User profiles in the Vigilance module:

Profiles in Vigilance applicable for all Actor types:

Profile	Create new Vigilance report/Edit Drafts/ Delete Drafts	Search and Preview Vigilance reports (including own Draft)	Search and Preview Vigilance reports (Drafts are not seen)
Confirmer	✓ (can register and submit reports)	✓	✓
Proposer	✓ (cannot submit the new report or the changes created to an existing one)	✓	✓
Fat Viewer		✓	✓
Slim Viewer			✓

Useful EUDAMED symbols and their meaning:

- **Red asterisk**: mandatory field, e.g.:

- **Open green padlock**: publicly available information, e.g.:

[1]For a broader understanding of how to use the platform (in the Playground environment), visit the EUDAMED Information Centre.

NOTE
The system saves the data you enter automatically; there is no **Save** button.

INFOGRAPHIC: Vigilance reports description

3 MIR

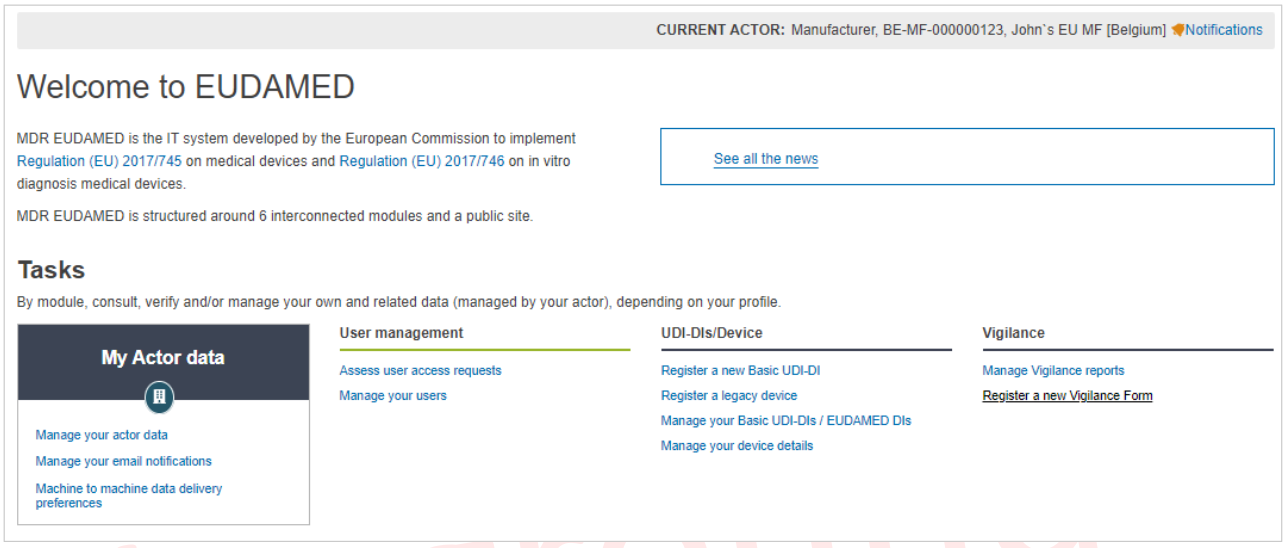
3.1 Register a new MIR

NOTICE
Only Manufacturers and Authorised Representatives with an active mandate and a delegation to register vigilance records can access the menu for registering a new MIR report.

In case of MIR reports managed by Authorised Representatives, when an Authorised Representative's mandate is terminated or expired and/or the delegation for vigilance is removed, the concerned Manufacturer will be able to access and manage the vigilance reports from that point on.

3.1.1 Step 0: Create initial MIR dossier

1. On the EUDAMED dashboard, click on *Register a new Vigilance Form* under the *Vigilance* section:



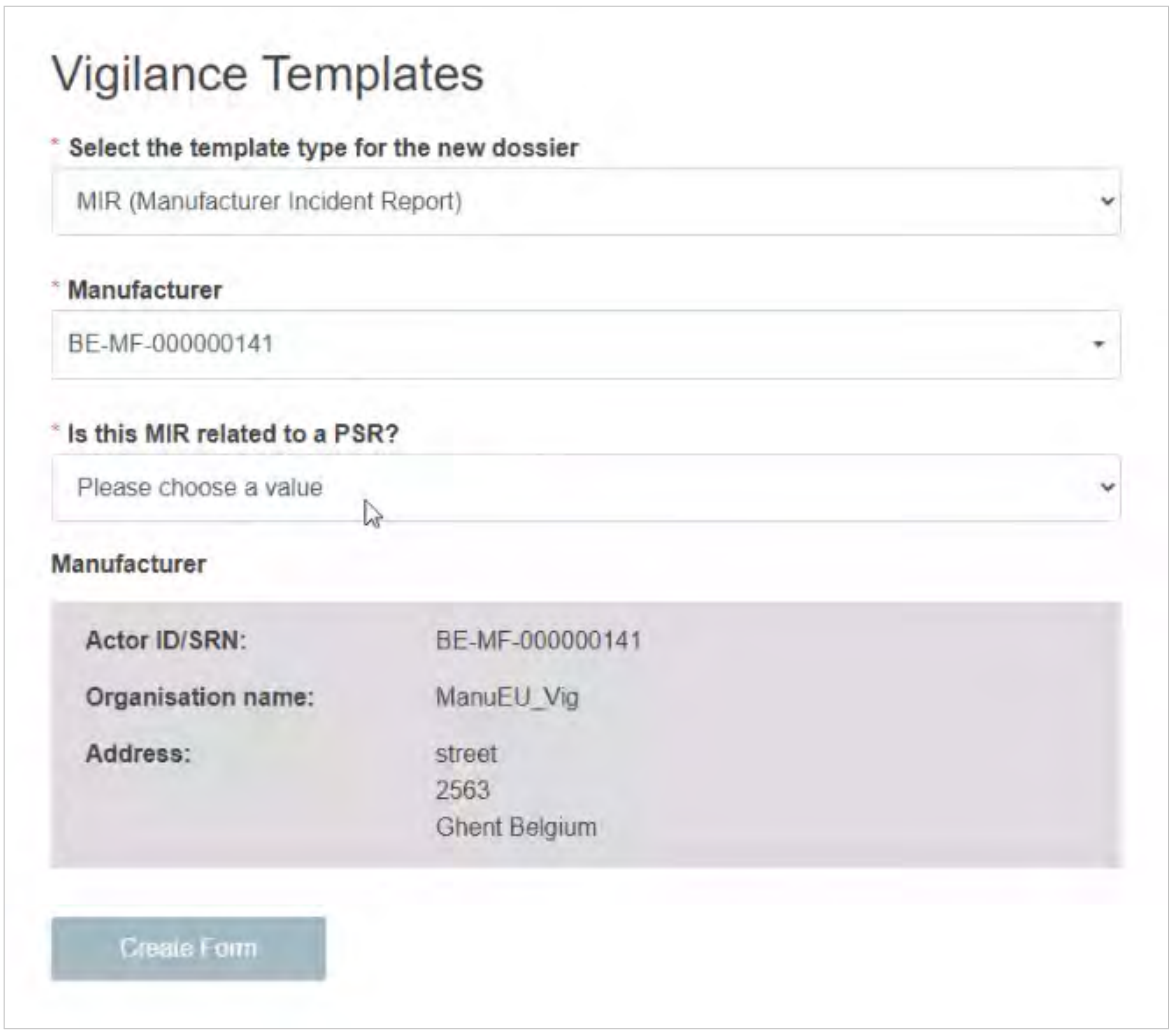
2. Select *MIR* from the drop-down list:

3. Insert the unique manufacturer Actor ID/ SRN in the *Manufacturer* field appearing below:

The system will automatically retrieve your Actor ID/ SRN.

TIP
If the MIR is registered by the Authorised Representative, the user selects the Manufacturer the AR has an active mandate for.

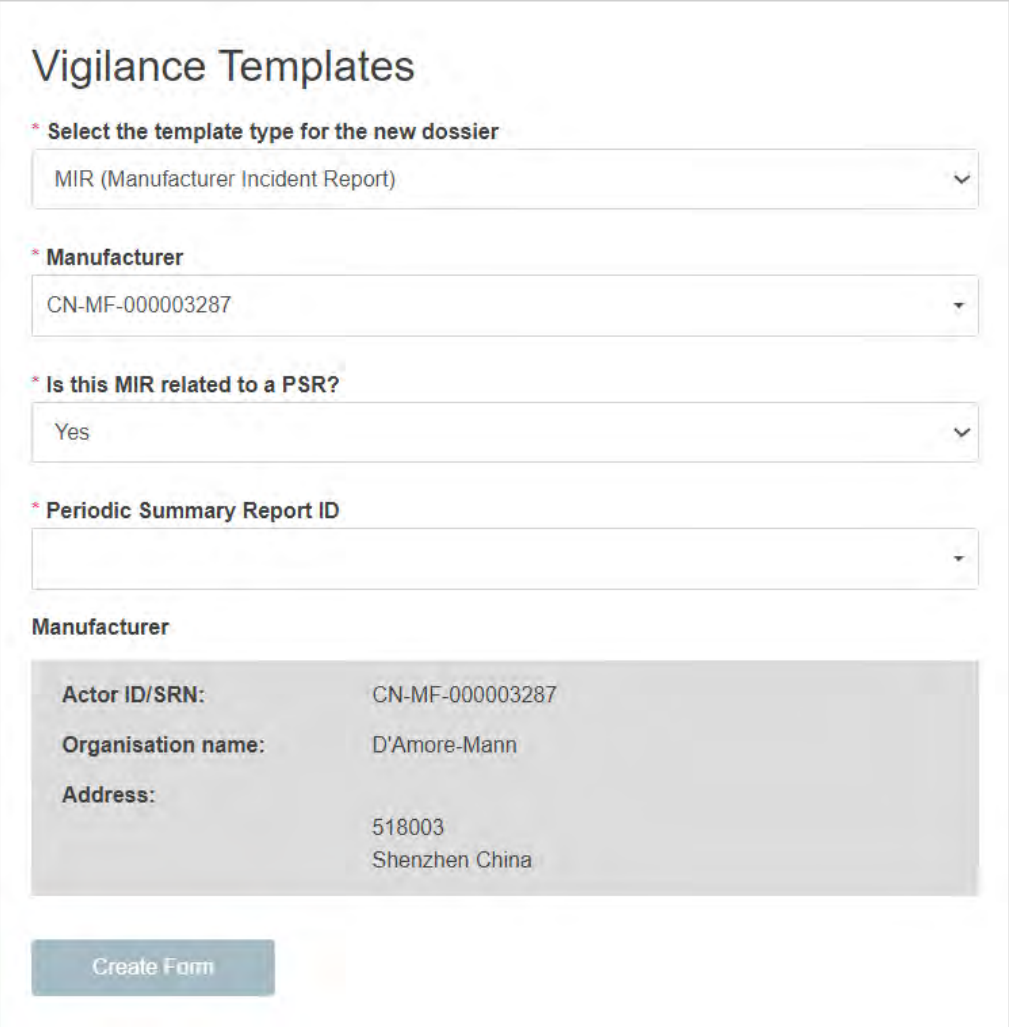
4. Answer the question *Is this MIR related to a PSR?*:


Vigilance Templates
* Select the template type for the new dossier
MIR (Manufacturer Incident Report)
* Manufacturer
BE-MF-000000141
* Is this MIR related to a PSR?
Please choose a value
Manufacturer
Actor ID/SRN:
BE-MF-000000141
Organisation name:
ManuEU_Vig
Address:
street
2563
Ghent Belgium
Create Form

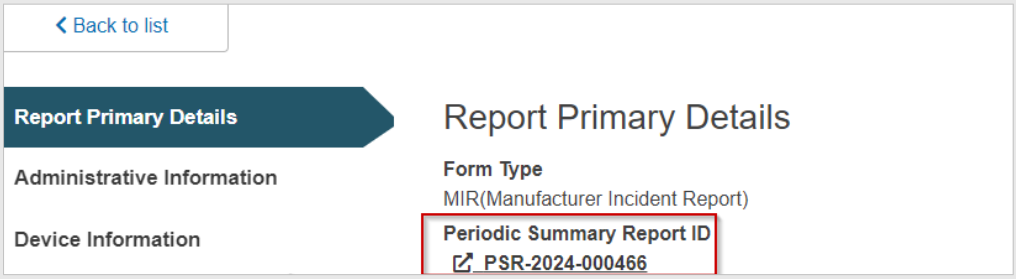
TIP
PSR MIR

If the MIR is linked to a PSR (*PSR MIR*) the submission process will vary slightly.

In case of a PSR MIR, you must select the appropriate *PSR ID* from the list appearing in the field *Periodic Summary report ID* (the list comprises all PSRs previously created for the Manufacturer):



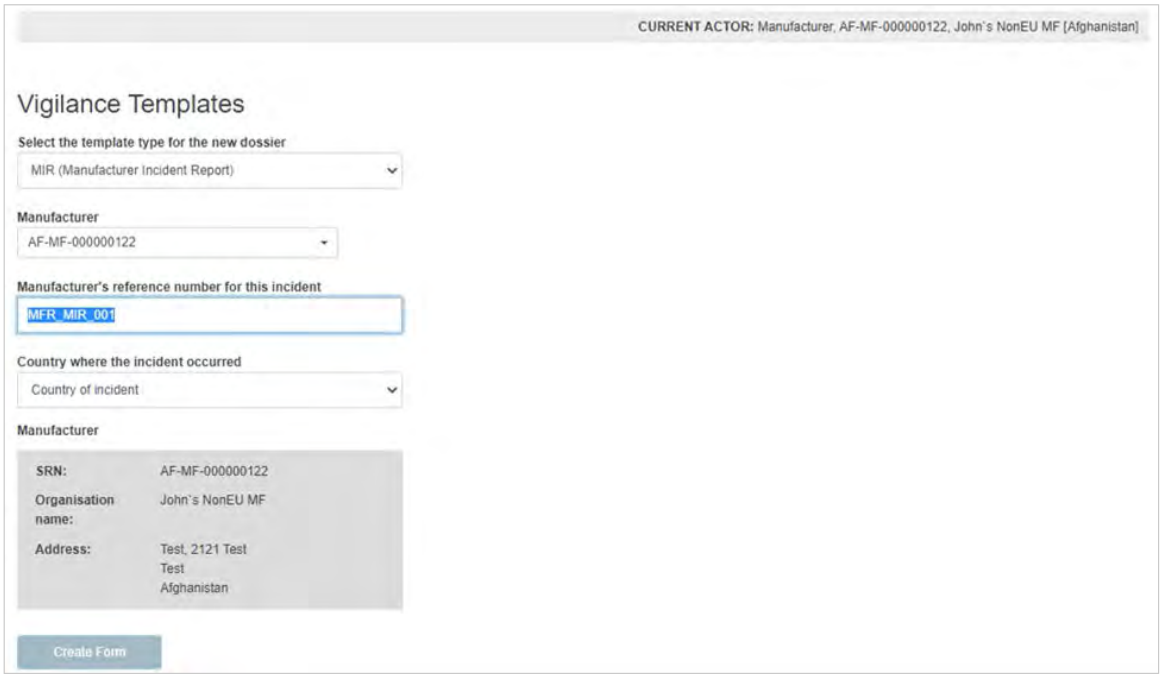
The referenced PSR will be accessible (read-only) inside the *Report Primary Details* section of the PSR MIR:



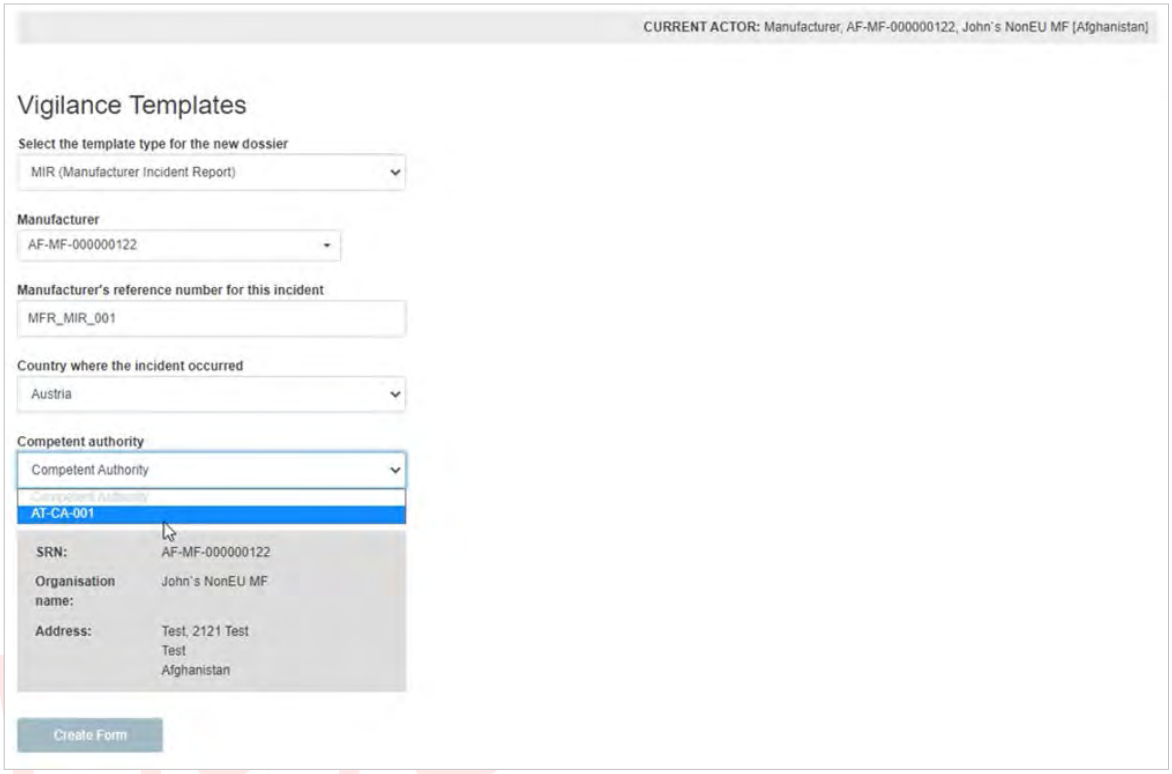
The PSR MIR will automatically be linked to the PSRP (Periodic Analysis Update of the PSR) of the concerned PSR, depending on when the PSR MIR is

registered. PSR MIRs must be registered **before the end of the period covered by the PSRP**.

5. Provide the *Manufacturer's reference number for this incident* and select the country in which the incident took place from the *Country* drop-down list:

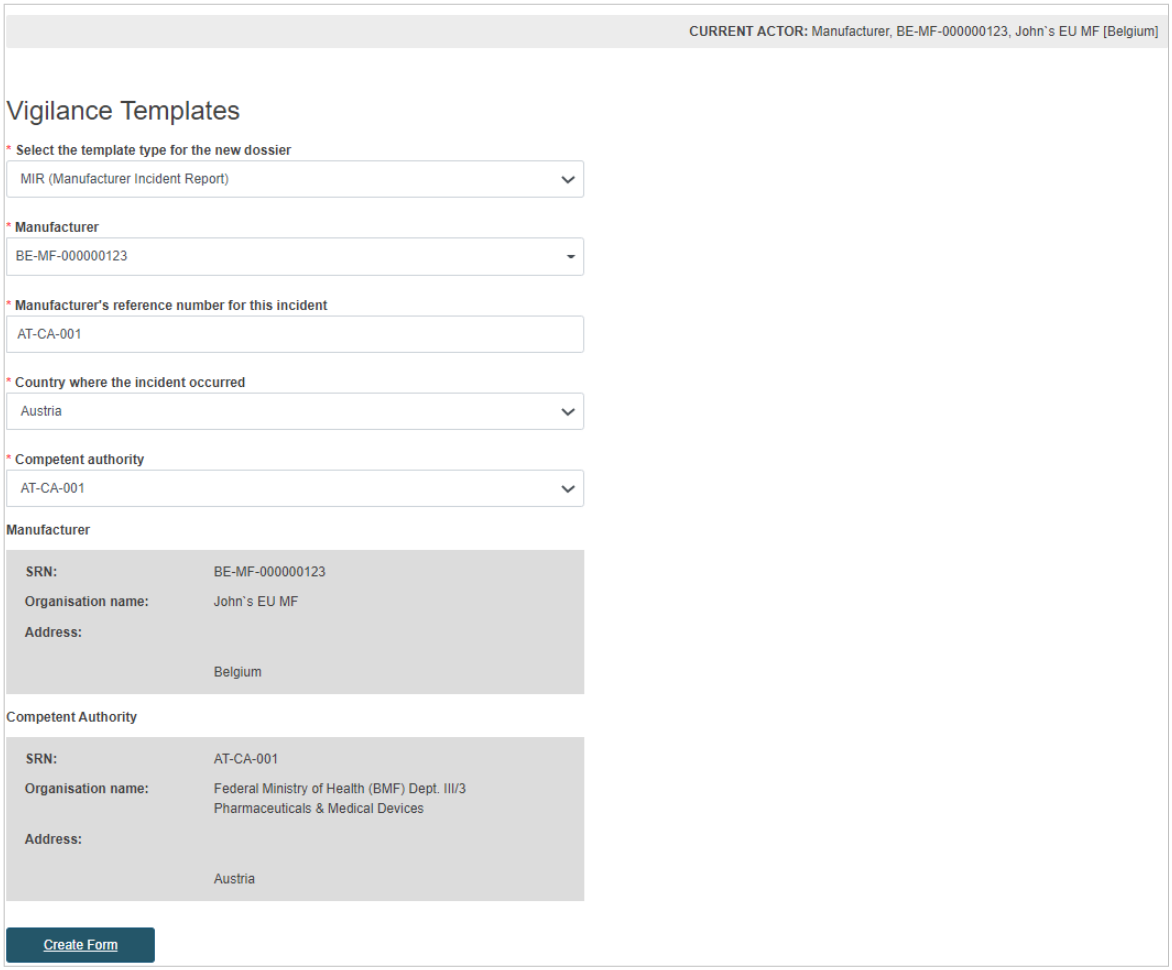


6. Select the correct *Competent Authority* from the drop-down list:



The system will automatically retrieve the CAs responsible for Vigilance.

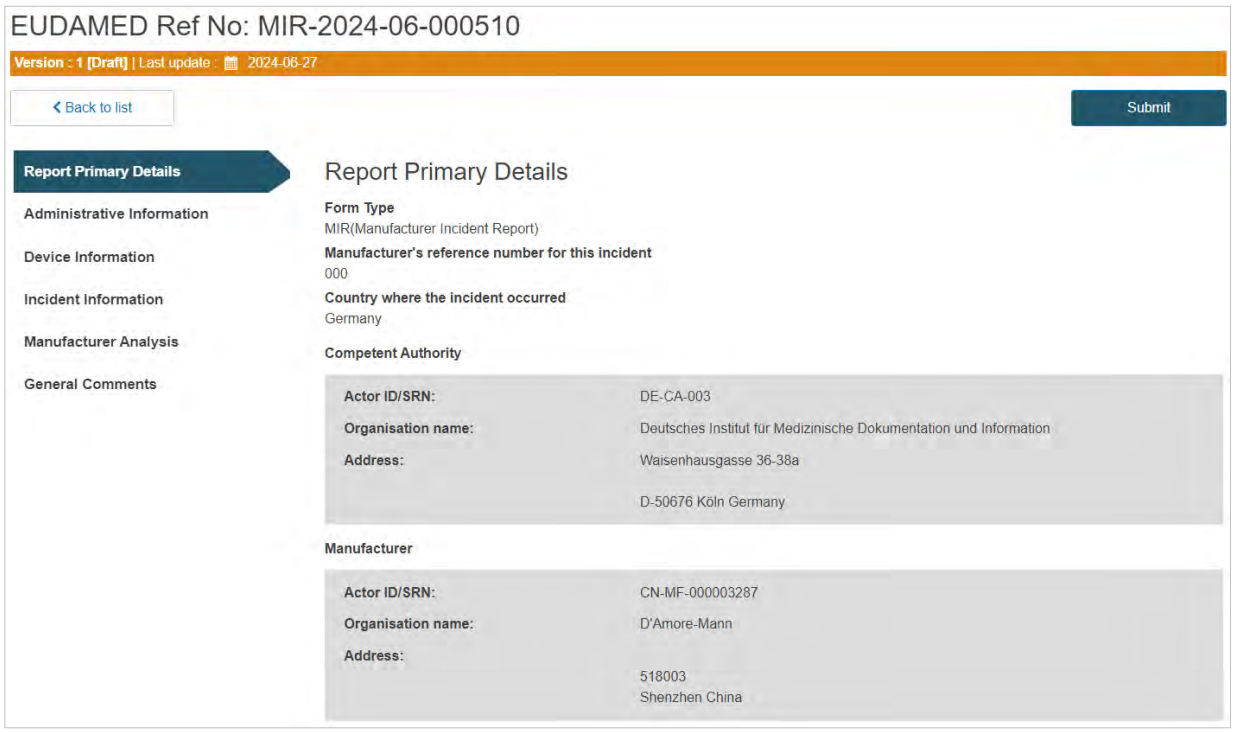
7. Click on **Create Form** at the bottom of the screen:



IMPORTANT
Please remember that the information that you provide in this step cannot be modified after you click **Create form**.

3.1.2 Step 1: Report primary details

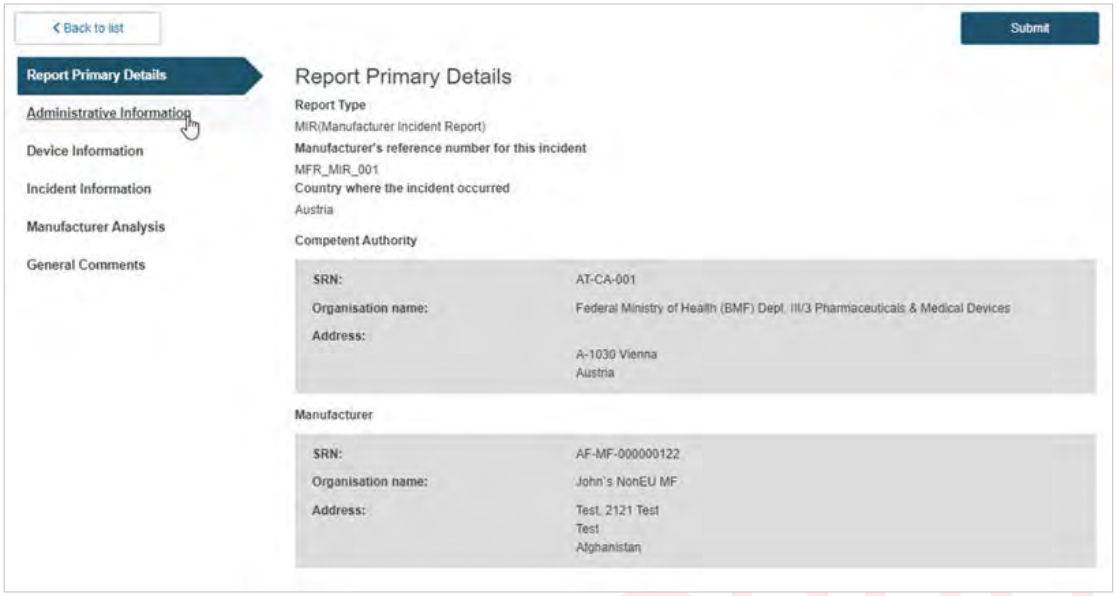
The *Report Primary Details* section provides an overview of the initial dossier created:



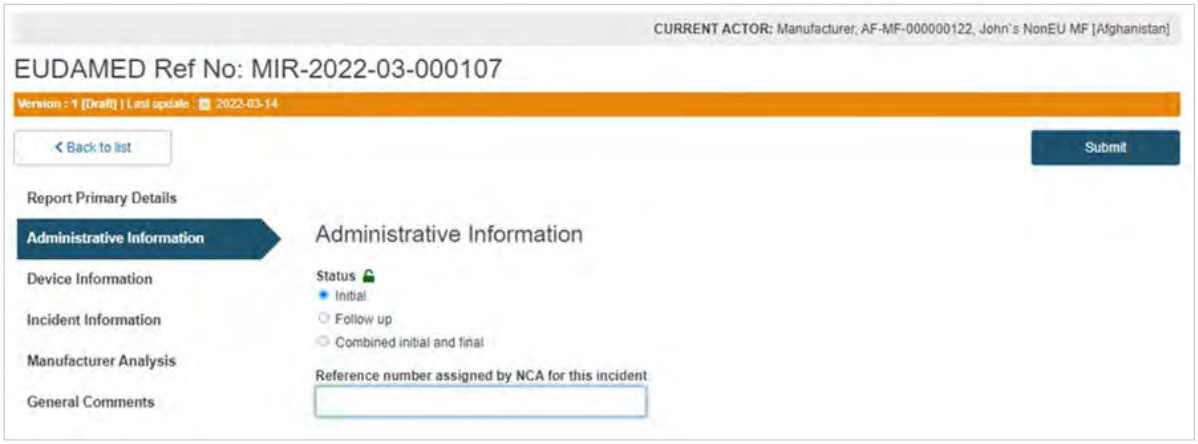
Please ensure the information provided is correct.

3.1.3 Step 2: Administrative information

1. Click on the *Administrative Information* section from the menu on the left:



2. Choose the status of the MIR and, if known, provide the reference number assigned by the National Competent Authority in the field below:

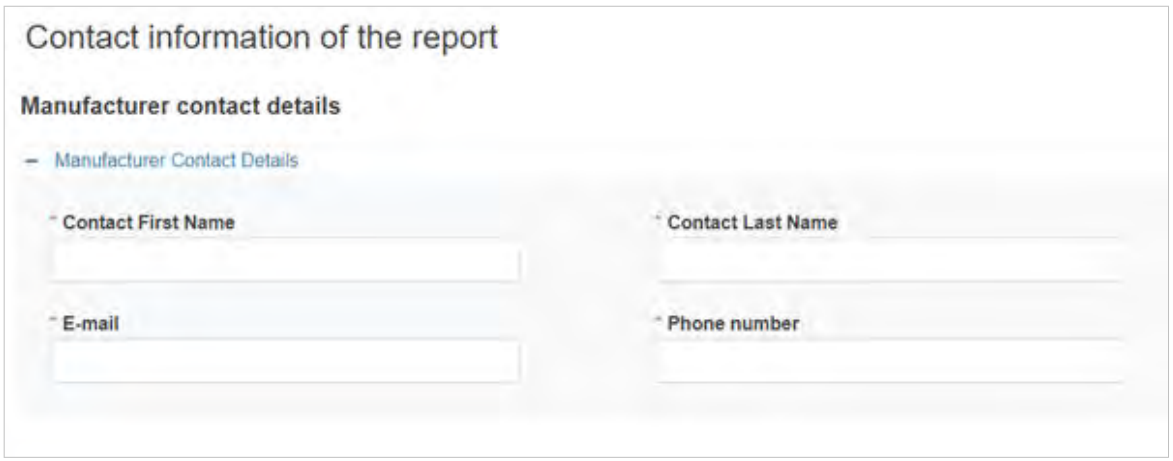


3. Provide all the relevant dates:

NOTE
The *Expected date of the next report* is mandatory only for a MIR in *Initial* or *Follow-up* status.

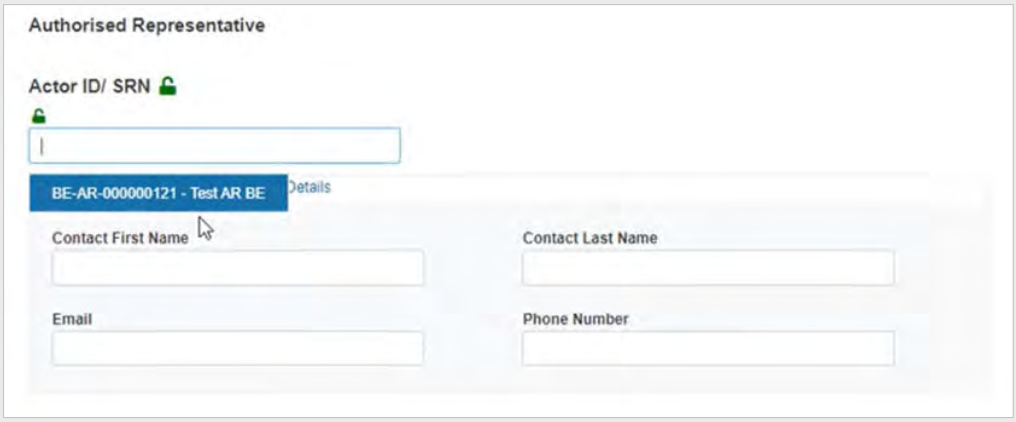
4. Select the classification of the incident:

5. Provide the contact details of the report in the corresponding sections:

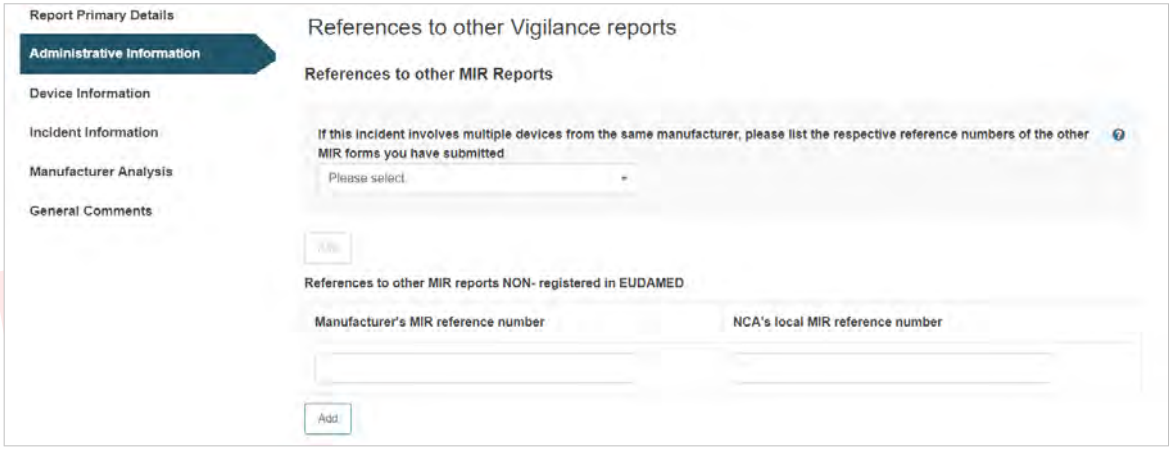


TIP
In case of a PSR MIR, the *Contact information of the report* section will state that the MF and its details are the same as the ones in the linked PSR.

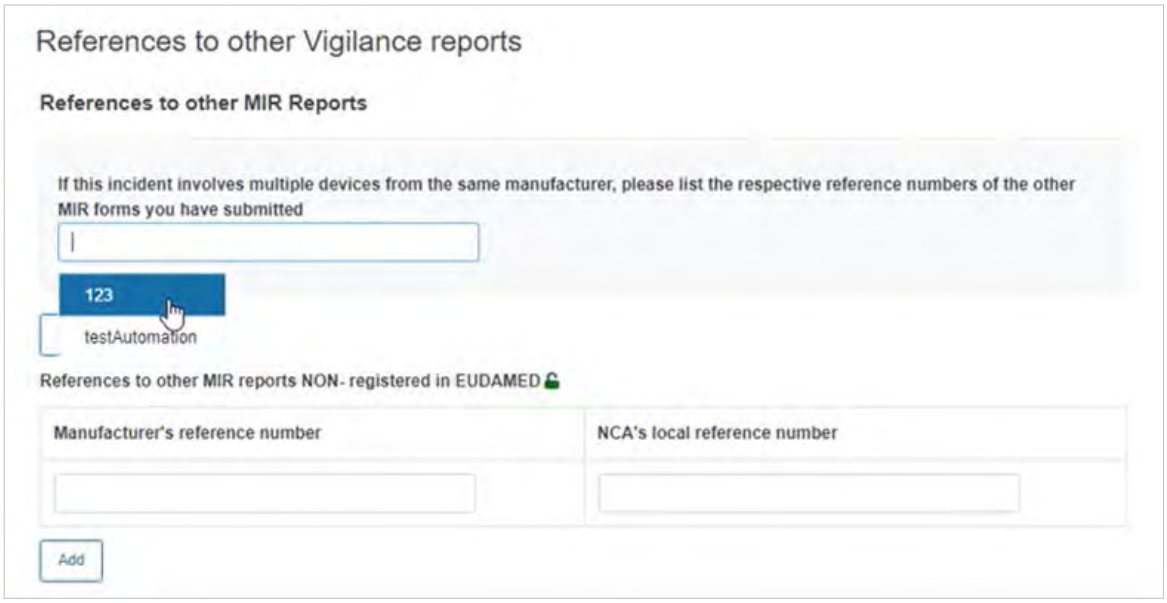
NOTE
Non-EU manufacturers must provide the Actor ID / SRN of the concerned Authorised Representative (regardless of the AR's mandate status):



6. If you wish to link this MIR to other MIRs, please provide the relevant references:

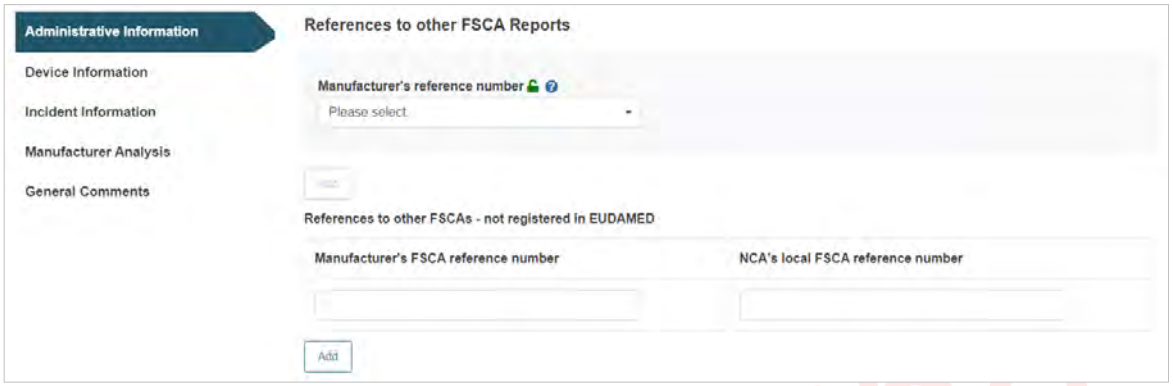


Insert the Manufacturer's reference number of the relevant report and select it from the list:

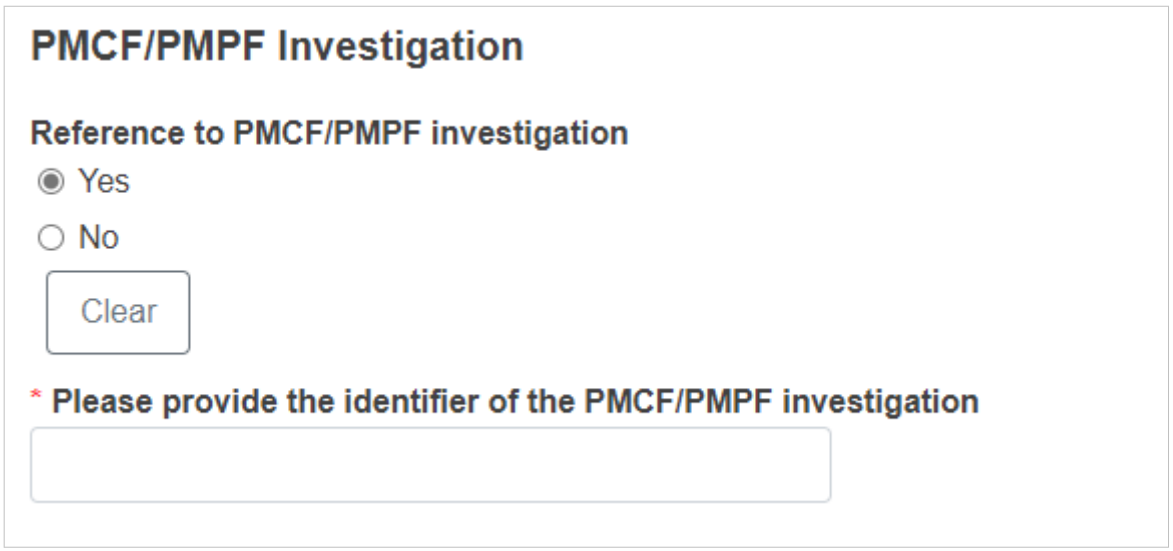


In case the report is **not** yet registered in EUDAMED, use the field for **non-registered reports** to type the manufacturer reference of the relevant report:

7. Similarly, you can provide references to FSCA reports, either registered or non-registered in EUDAMED:



8. If the incident occurred within a PMCF/PMPF investigation, provide the EUDAMED ID of the relevant investigation:



TIP
The PMCF/PMPF reference section is not applicable in case of a PSR MIR (MIR referencing a PSR ID) and will not be visible.

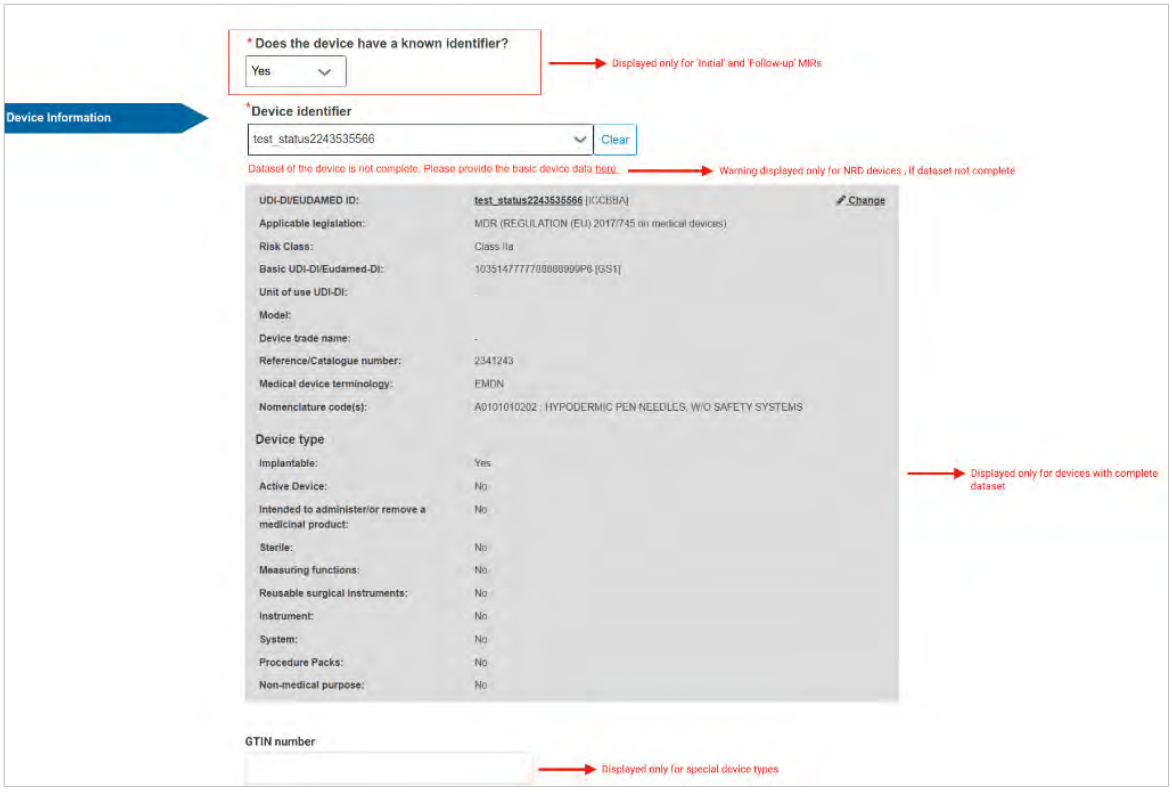
3.1.4 Step 3: Device information

Click on **Device information** from the menu on the left.

Complete the *Device information* step considering whether the device involved has a known identifier or not.

Case A: Device with identifier registered in EUDAMED

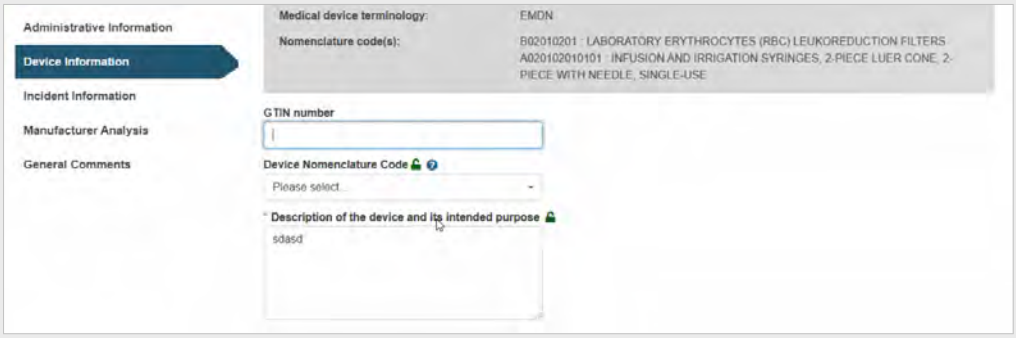
1. If the device identifier is known, answer *Yes* to the question *Does the device have a known identifier?* and type the device identifier in the *Device Identifier* field below:



The system will retrieve the device's details.

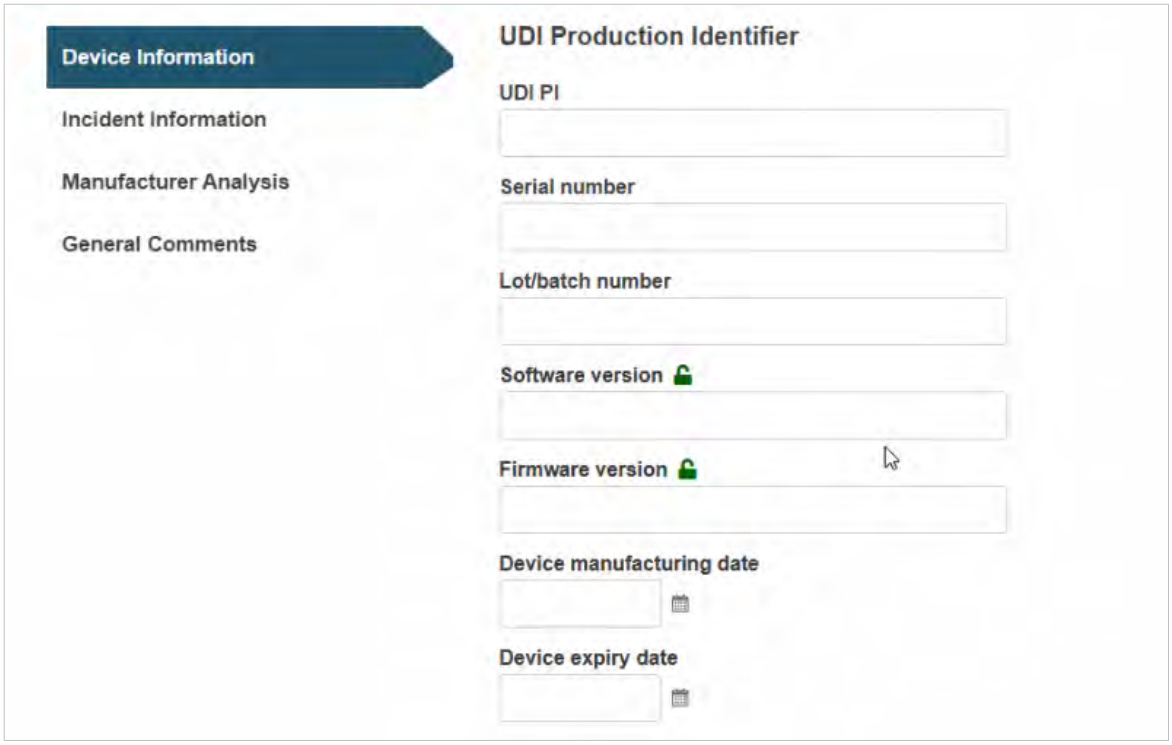
NOTE

In case of a special device (requiring a Master UDI-DI), an additional GTIN field will appear in the *Device information* section for you to fill in:

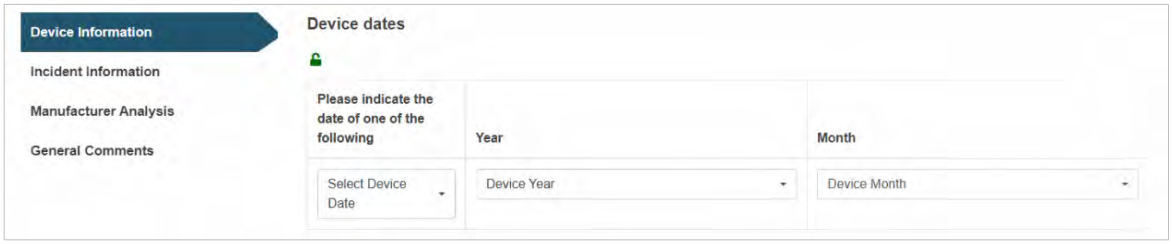


2. Describe the device and its intended purpose:

3. Fill in the *UDI Production Identifier* section:

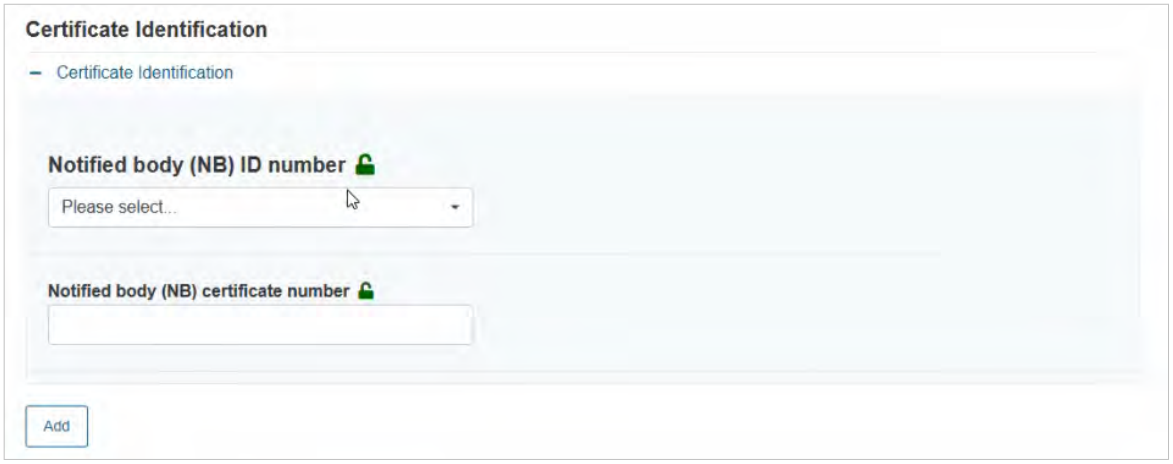


4. Fill in the *Device dates* section:



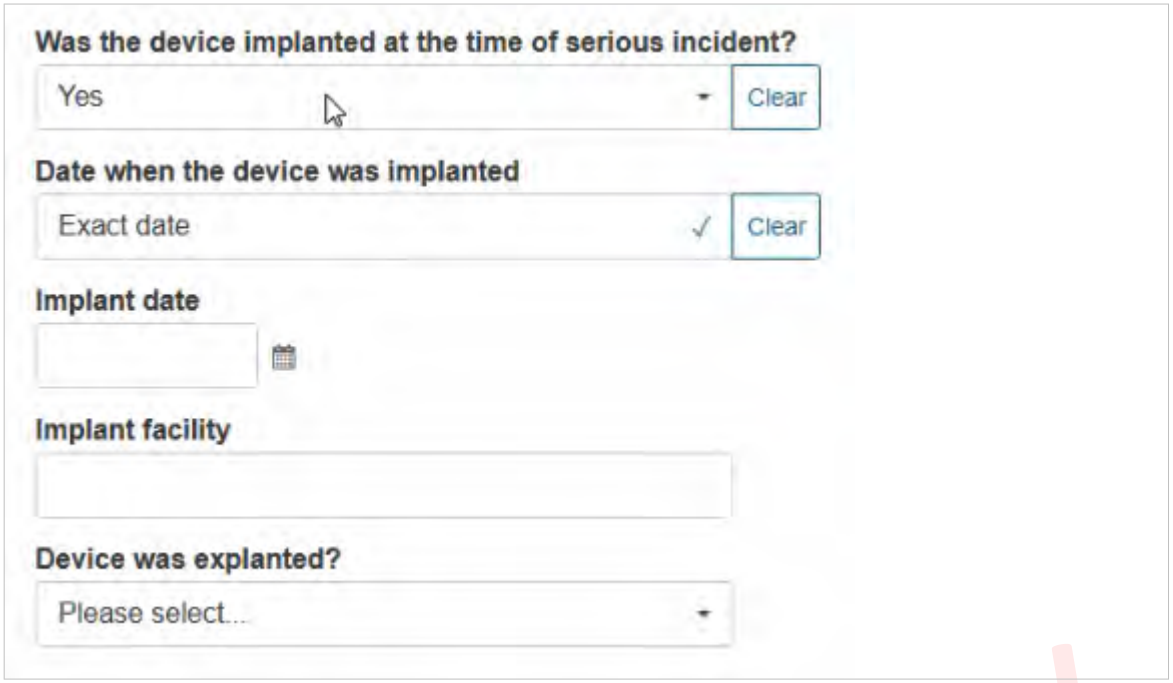
5. In the *Certificate Identification* section, click on the *plus* sign to add the *Notified Body (NB) details* and the *NB certificate number*:

6. Select the *NB ID number* from the drop-down list and type the certificate number (click on **Add** for more than one certificates):

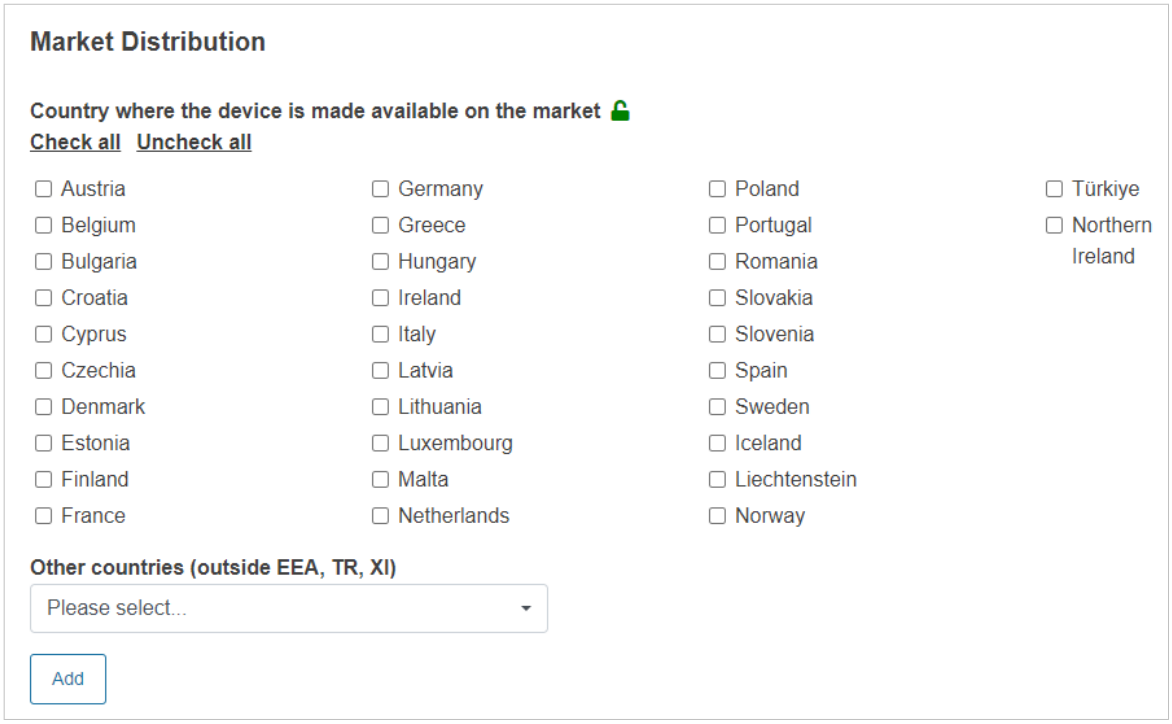


NOTE
The *Certificate Identification* fields will vary slightly depending on the type of device selected; in some cases the user will enter data manually and in others the system will auto-fill the data.

7. In case of an *implantable device* the system will prompt you to fill in the relevant section:



8. Under *Market Distribution*, select the country(-ies), in which the device is made available:

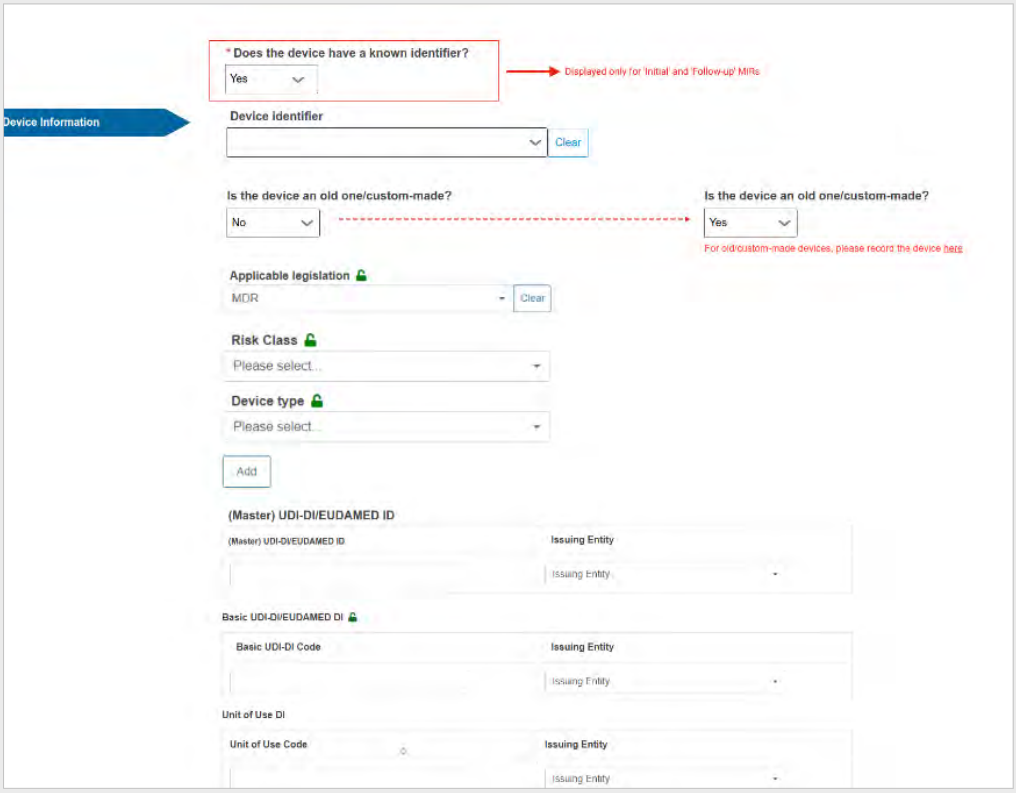


Case B: Device without known identifier or with identifier not registered in EUDAMED

1. If the device identifier is not known, answer *No* to the question *Does the device have a known identifier?*:

NOTE

Variation for device with known identifier not registered in EUDAMED, with *initial* or *follow-up* MIR:

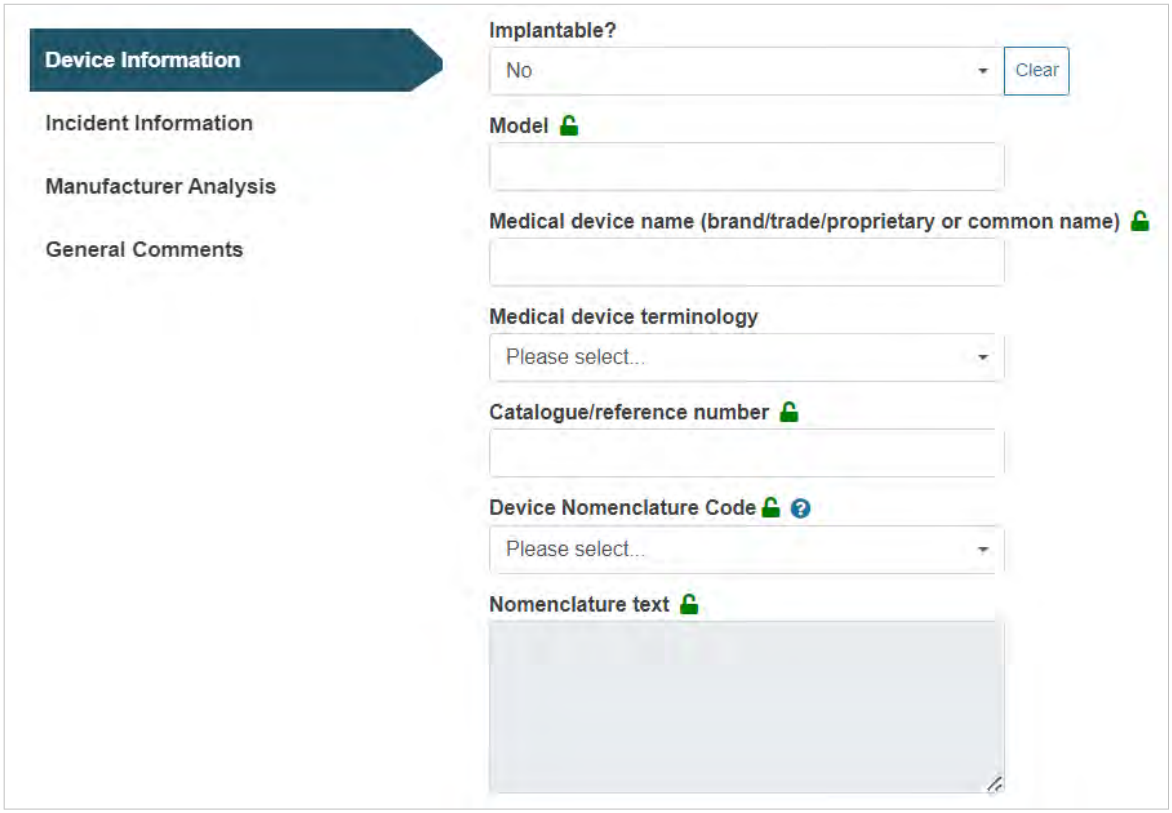


2. Provide the applicable *legislation*, *Risk class* and *device type*:

NOTE

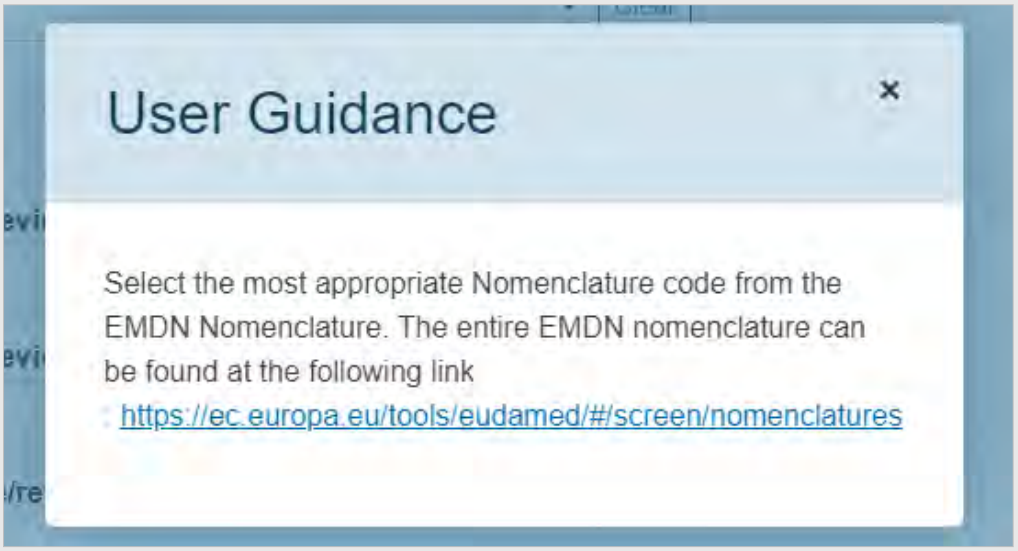
There will be slight variations in the fields appearing next, depending on the legislation chosen.

3. Specify if the device is *implantable* or not:



4. Enter the *Model* and *Medical device name (brand/trade/proprietary or common name),* select the appropriate *Medical device terminology*, *Catalogue/reference number* and *Device Nomenclature Code*.

TIP
Click on the blue question mark for a link to the entire EMDN nomenclature via the pop-up window:



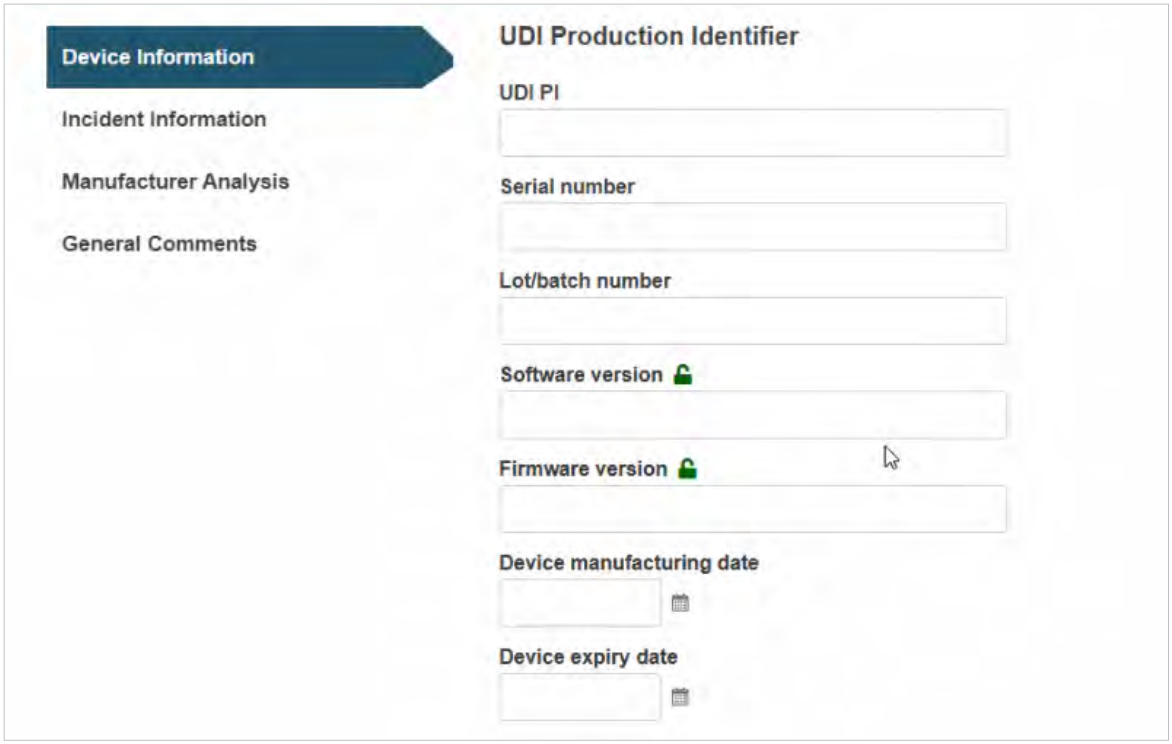
When you click on the code, the nomenclature description box is auto-filled with the selected code description:

5. Describe the device and its intended purpose:

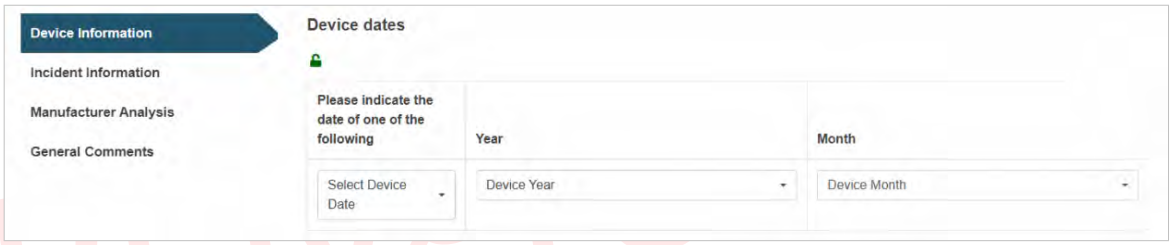
6. Select *Yes* or *No* regarding a scientific opinion or CA consultation regarding a companion diagnostic. If *Yes*, the system will prompt you to provide additional data:

TIP
The scientific opinion fields above apply only for MDR/IVDR regulations.

7. Fill in the *UDI Production Identifier* section:

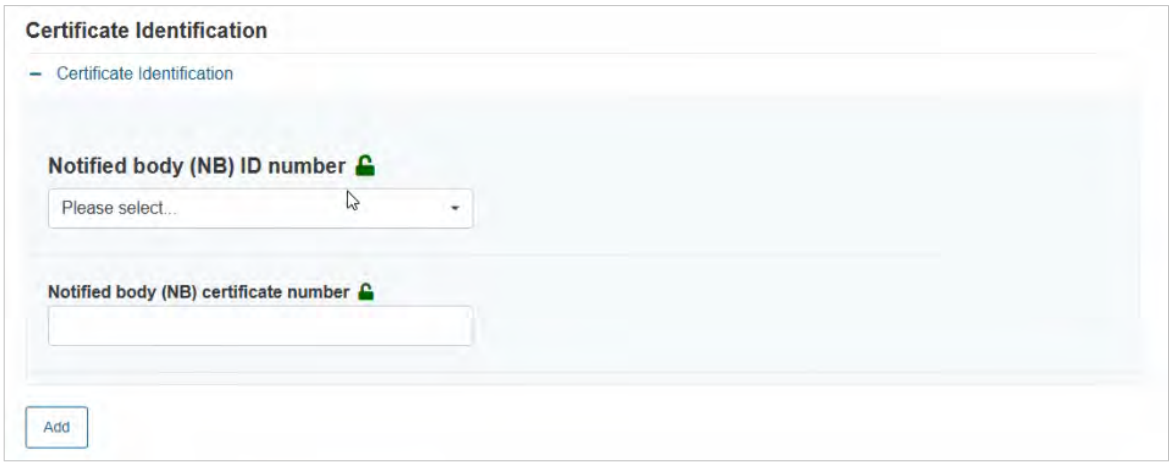


8. Fill in the *Device dates* section:

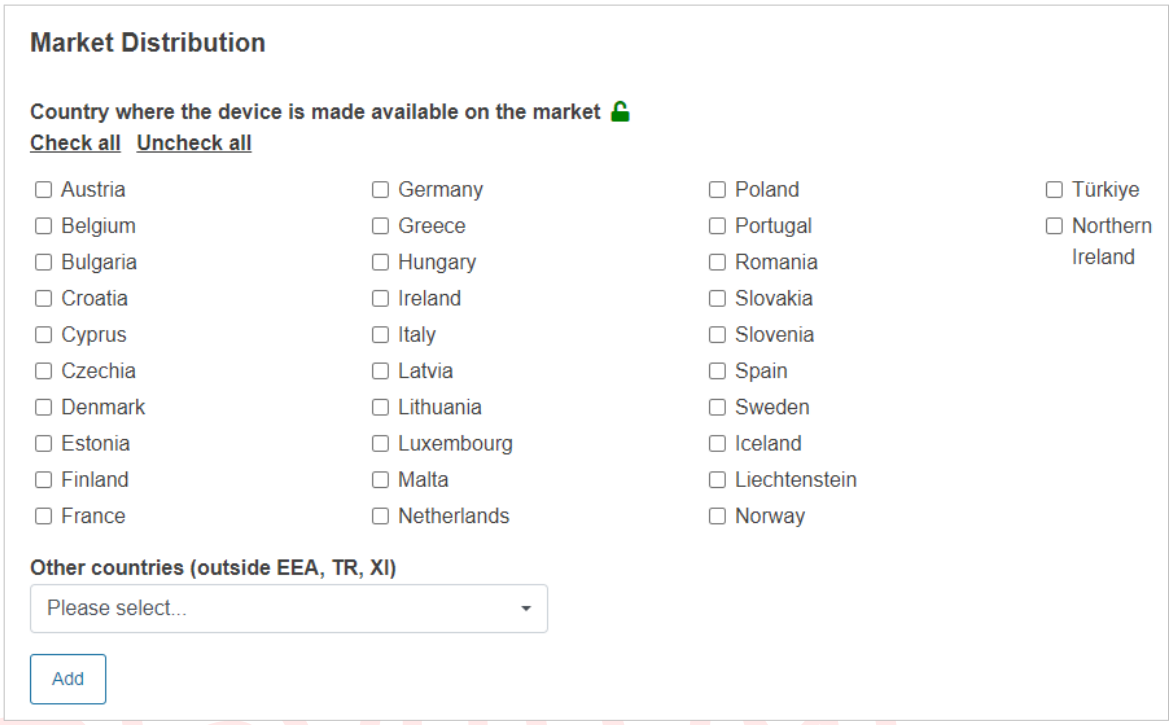


9. In the *Certificate Identification* section, click on the *plus* sign to add the *Notified Body (NB) details* and the *NB certificate number*:

10. Select the *NB ID number* from the drop-down list and type the certificate number (click on **Add** for more than one certificates):

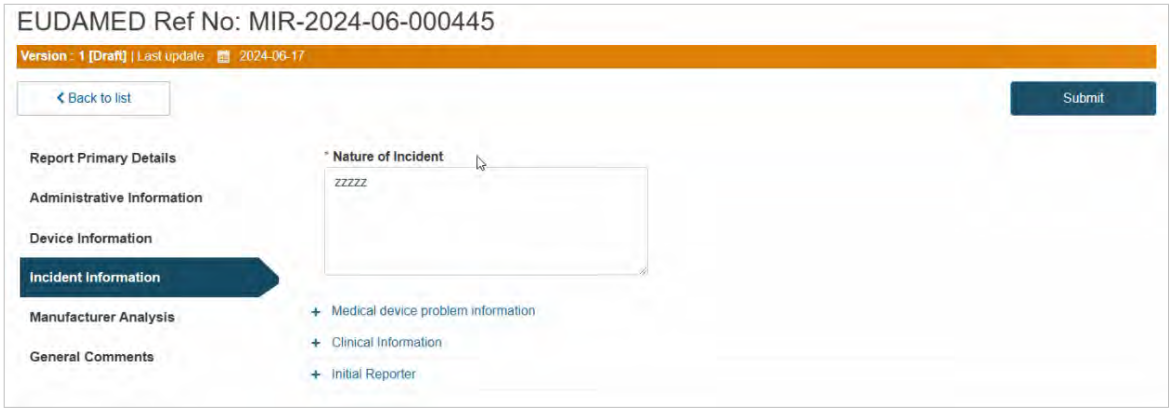


11. Under *Market Distribution*, select the country(-ies), in which the device is made available:

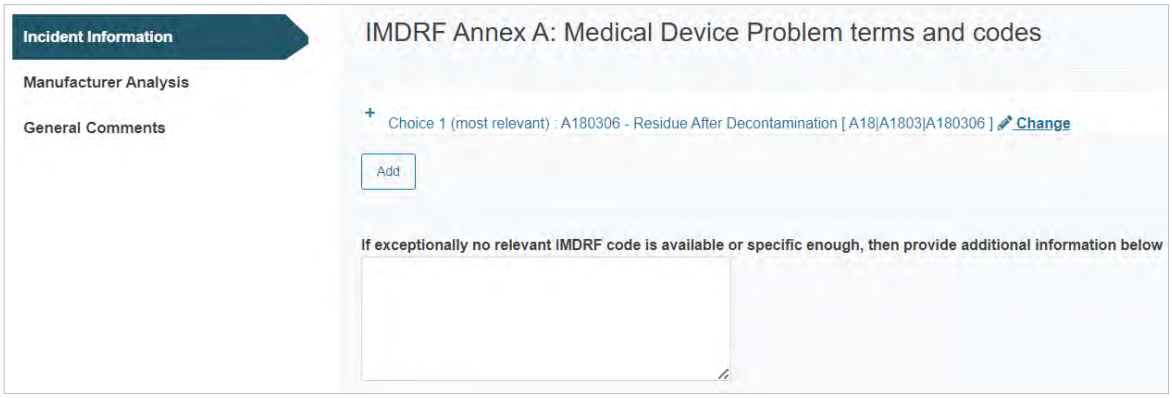


3.1.5 Step 4: Incident information

1. Under the *Incident information* section, fill in the field *Nature of incident*:

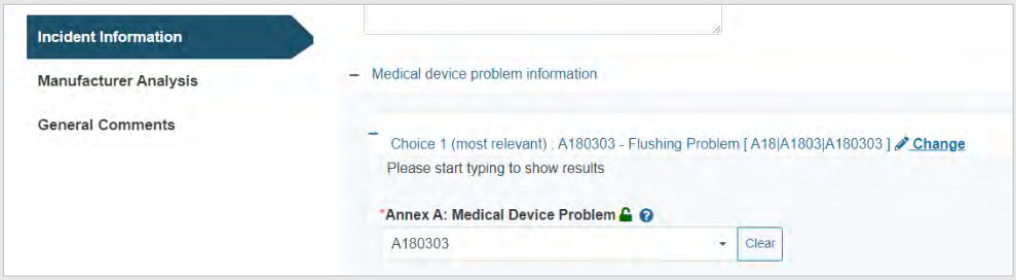


2. Click on the plus sign next to *Medical device problem information* and complete *IMDRF Annex A* using the drop-down:



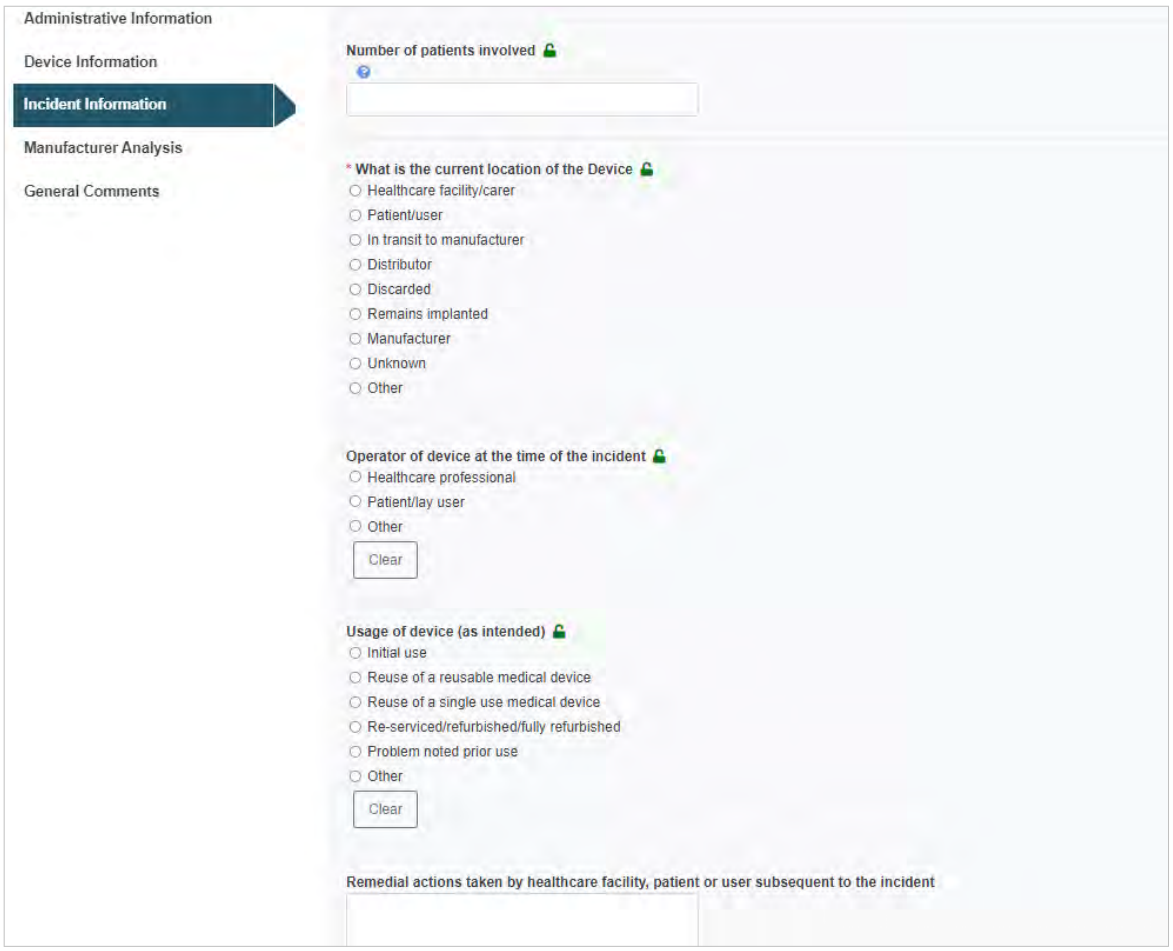
TIP
Find the correct IMDRF codes

Click on the blue question mark for a link to the entire list of IMDRF codes via a pop-up window:

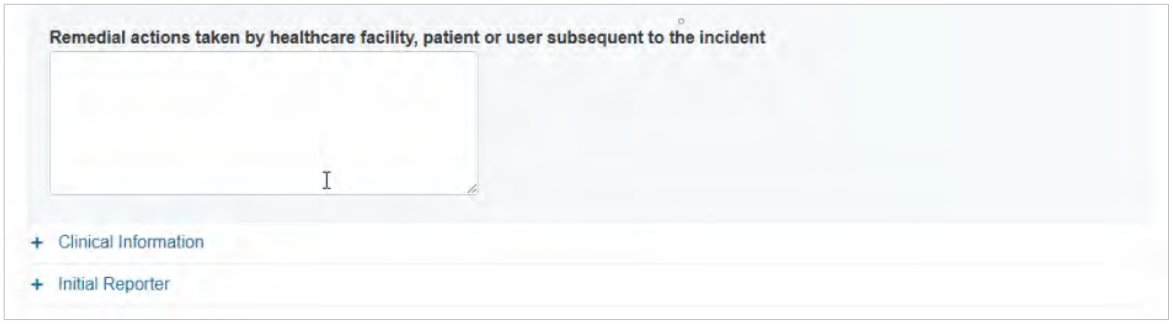


The link will redirect you to the IMDRF Codes list for the specific Annex.

3. Type the number of patients involved and select the current location of the device, the operator at the time of the incident, the usage of the device:

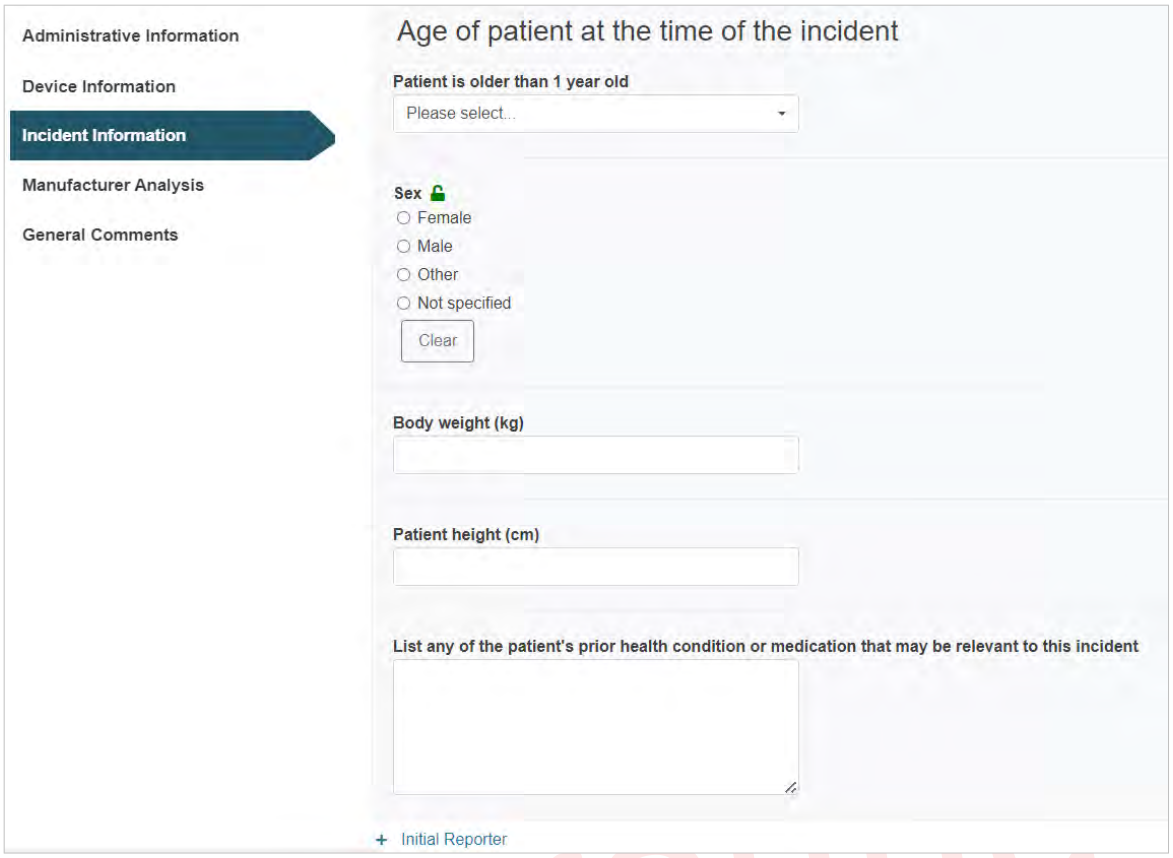


4. Enter the remedial actions:

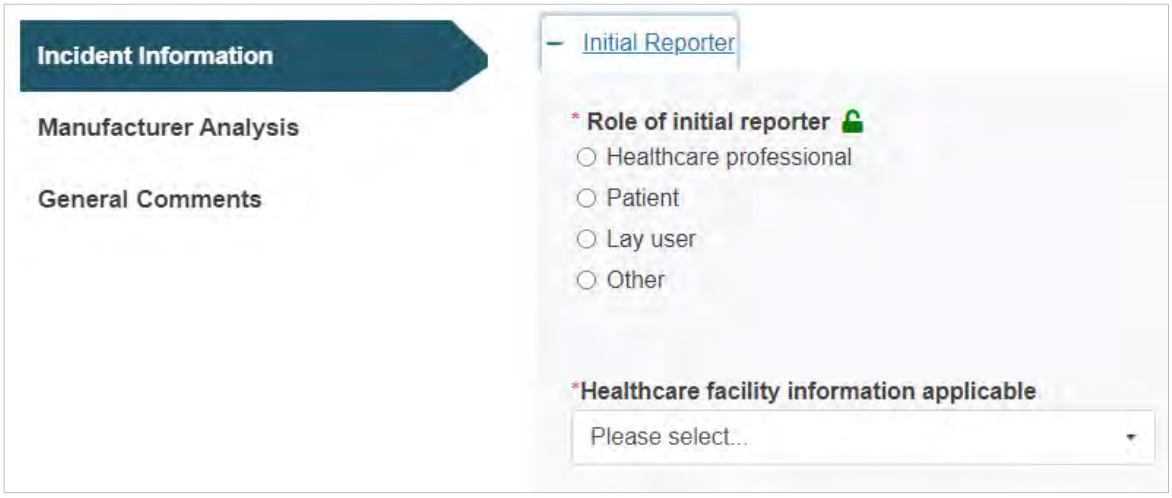


5. Click on the *plus* sign next to *Clinical information* and complete *IMDRF Annex E, F* using the dropdowns:

6. Provide the patient's age and other details:



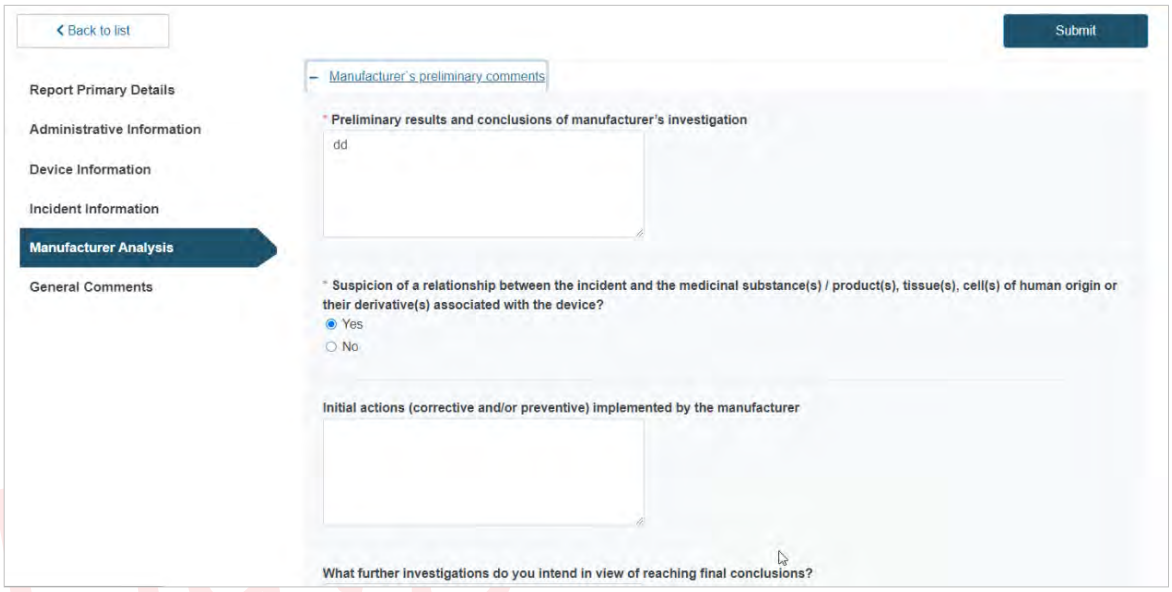
7. Click on the *plus* sign next to *Initial Reporter* and fill in the fields:



3.1.6 Step 5: Manufacturer analysis

1. Click on the plus sign next to *Manufacturer's preliminary comments*:

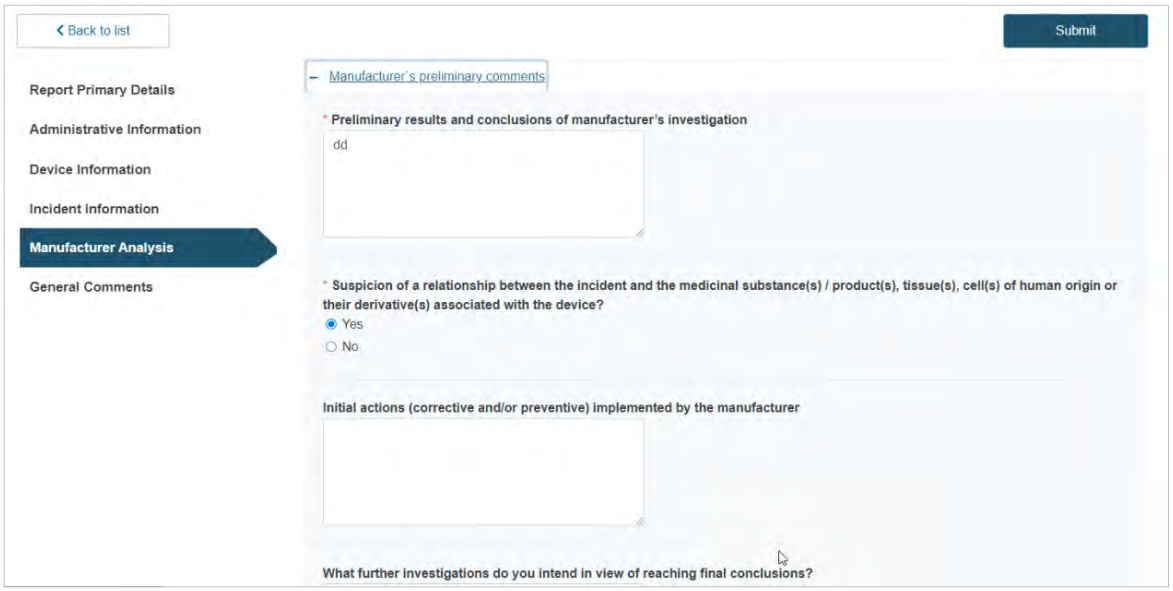
2. Fill in all fields as required:



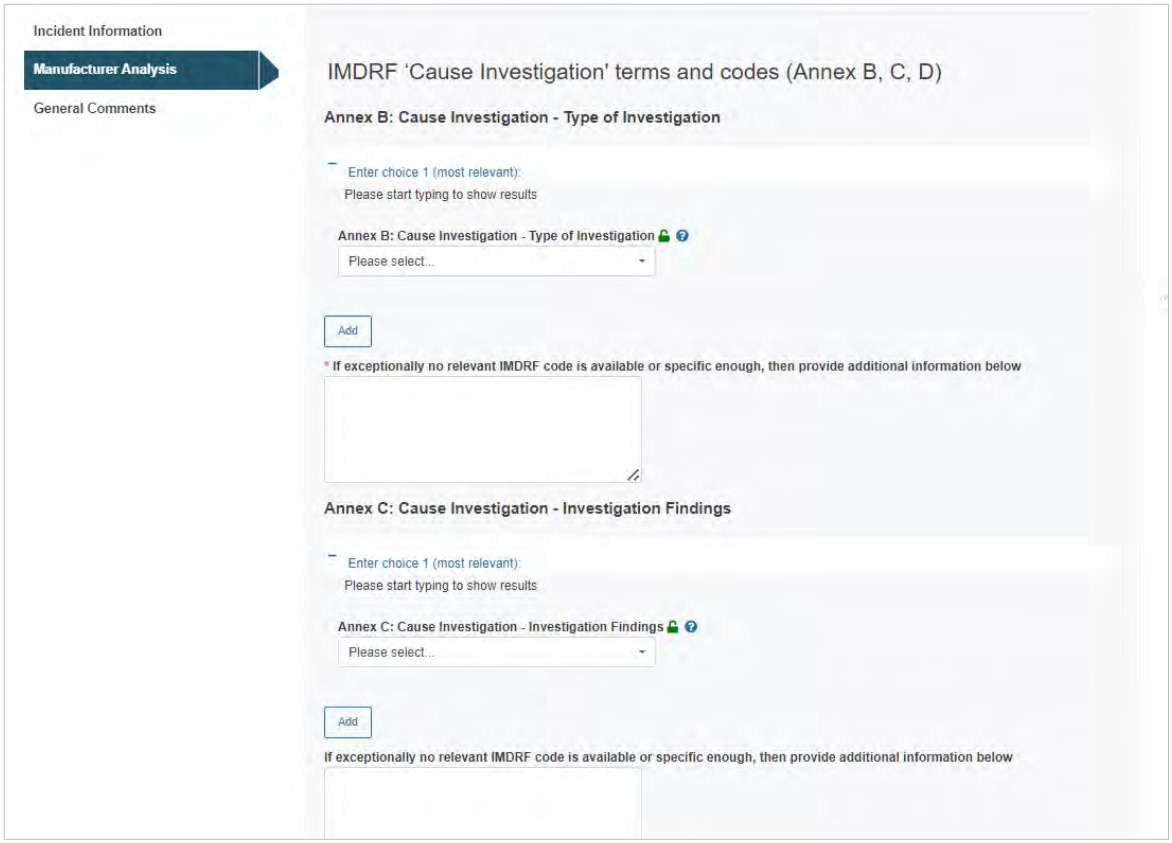
TIP
The *Manufacturer Analysis* fields may vary slightly depending on the device type.

3. Click on the plus sign next to *Cause investigation and conclusion*:

4. Fill in all fields as required:



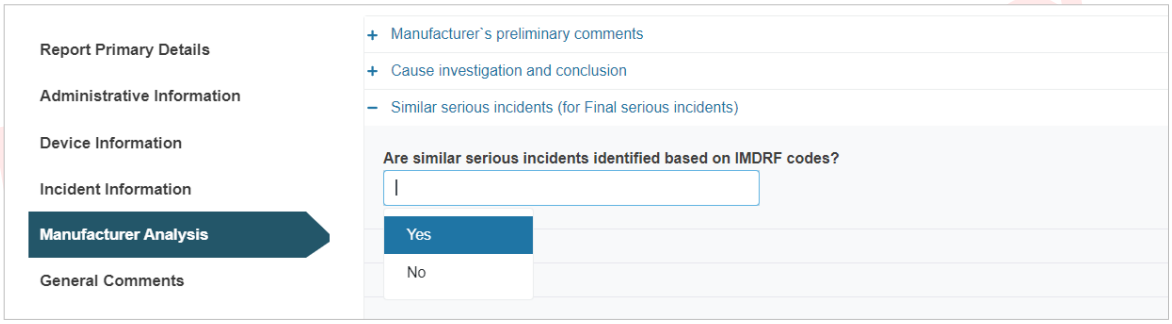
5. Fill in the *IMDRF terms and codes* Annex section:



TIP
If needed, press **Add** to add more codes per Annex.

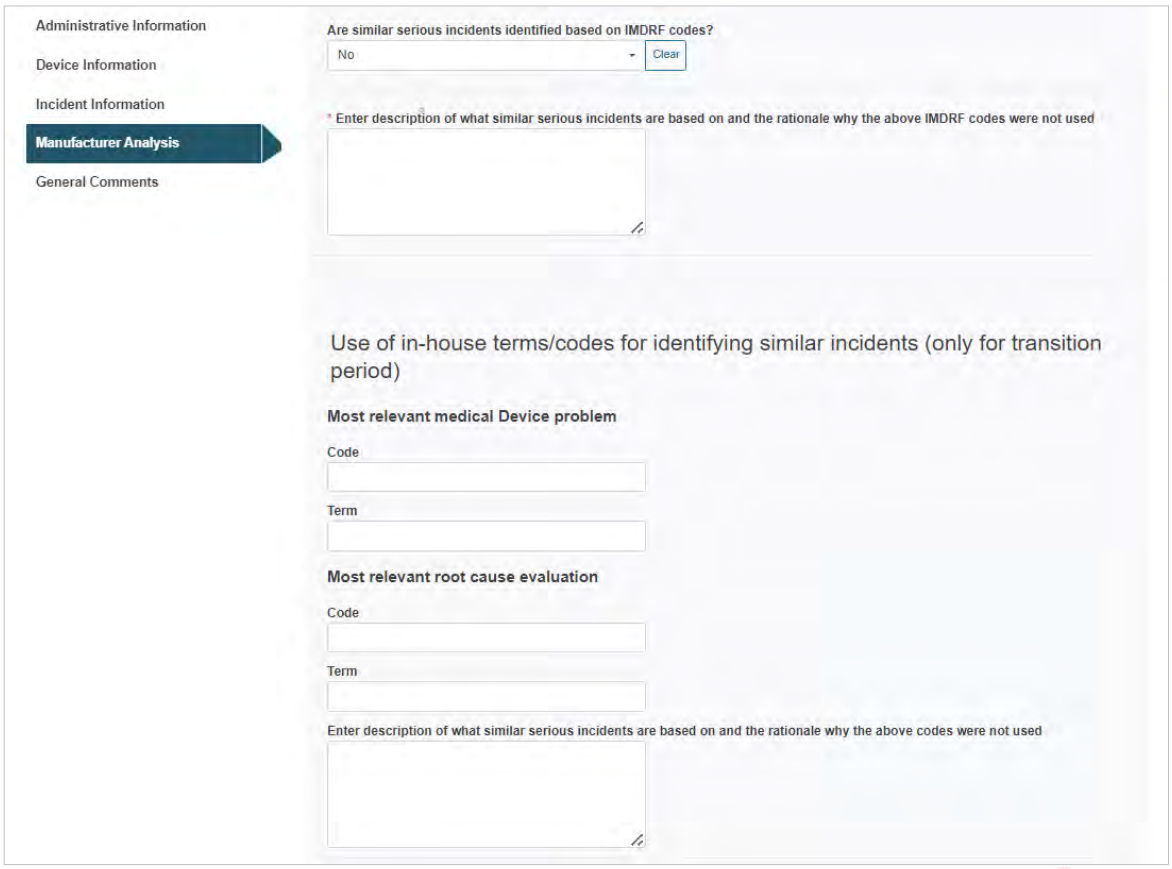
6. Click on the plus sign next to the last segment, i.e. *Similar serious incidents*:

7. Answer the first question on IMDRF code identification with *Yes* or *No*:

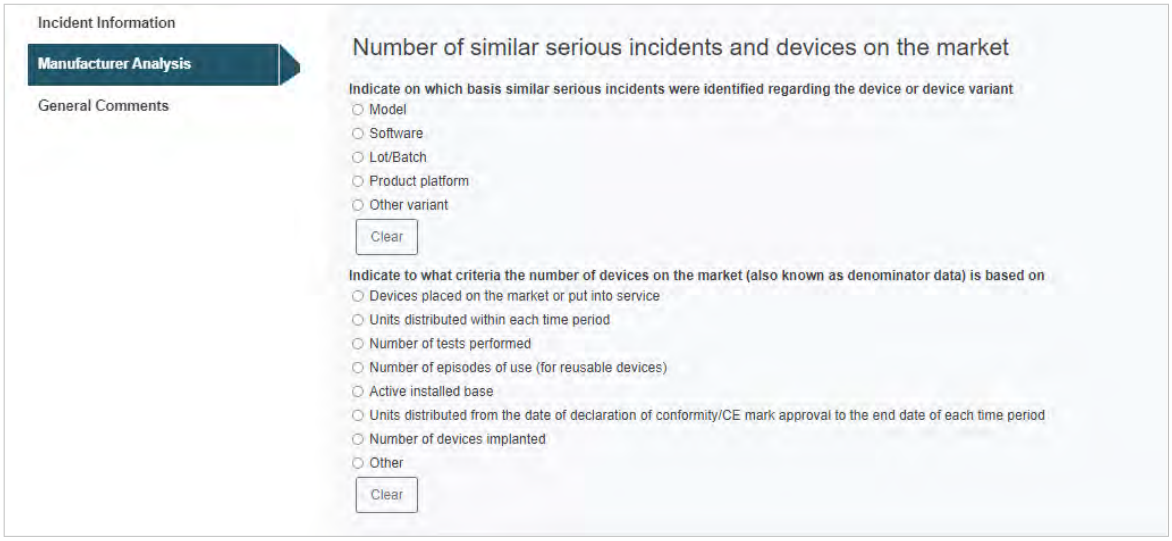


If you answered *Yes*, specify the *Identification of similar incidents using IMDRF Adverse Event Reporting terms and codes*:

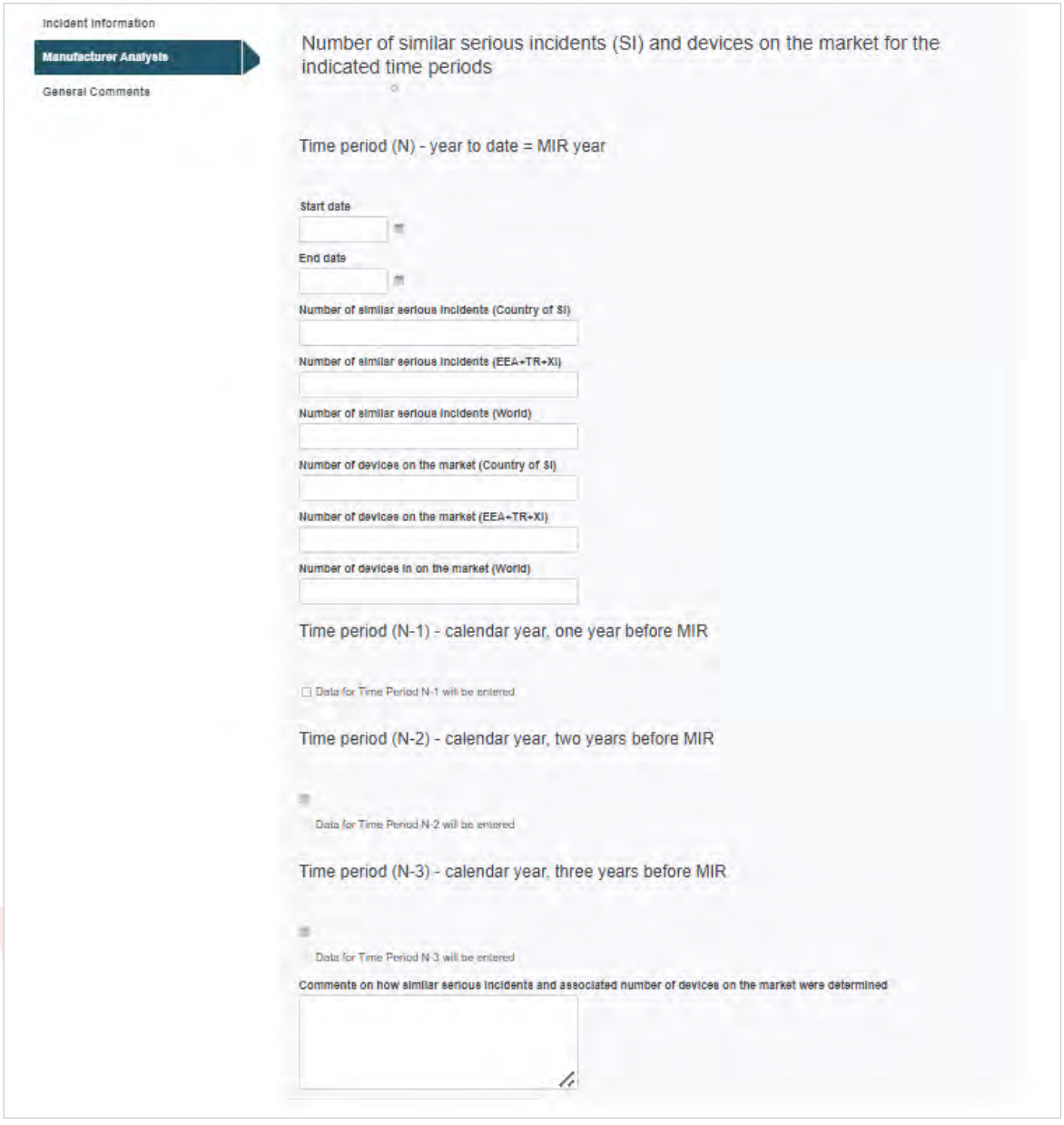
If you answered *No*, type a description in the text box and provide in-house codes and terms to identify similar incidents in the corresponding fields:



8. Provide information about the number of similar incidents and devices on the market:



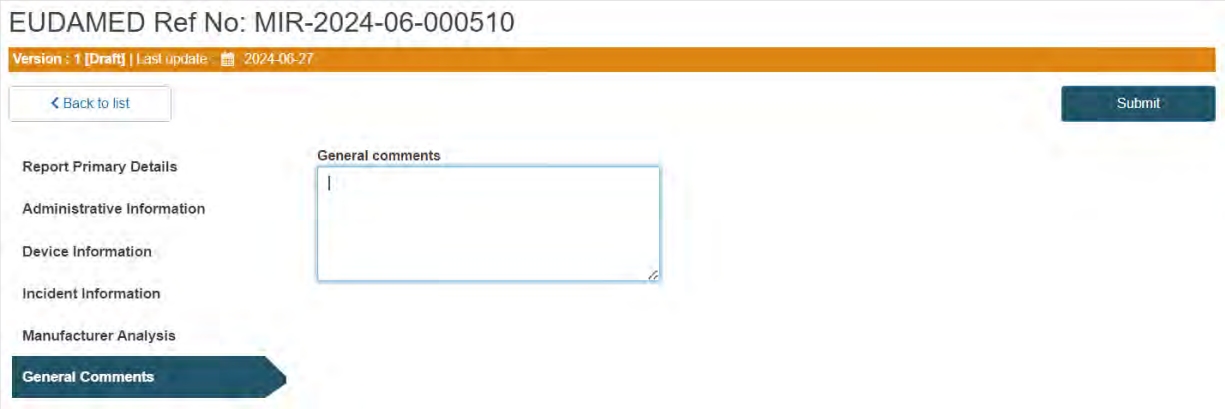
9. Fill in the *Number of incidents* section with the appropriate time periods:



3.1.7 Step 6: General comments / Submission

Comments

Type in the general comments:



Submission

1. Click on the **Submit** button on the top right corner:

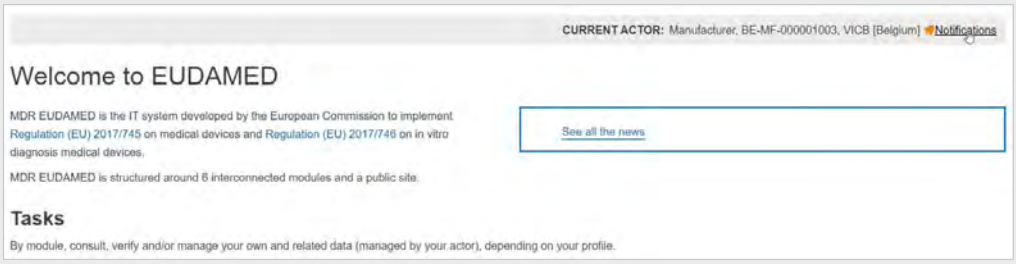
2. Attach a PDF document if necessary and click on **Complete action** in the pop-up window to finalise the submission:

After submission, the system redirects you to the *Report Primary Details* section for this MIR in *view-only* mode.

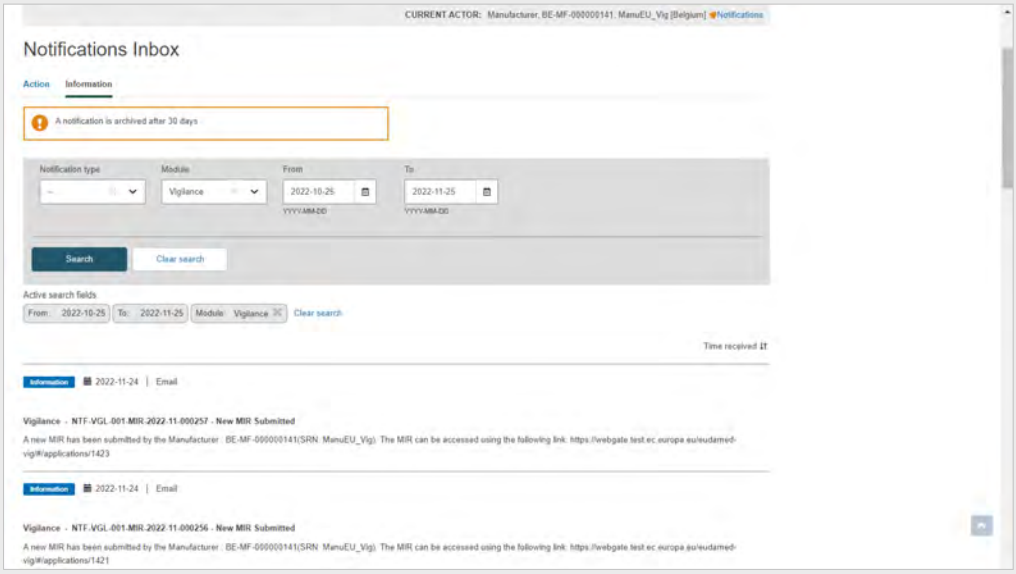
Notice that once the MIR has been submitted, it displays its version under the reference number, e.g. *Version: 1* and its last update:

You have now completed the MIR registration process.

NOTE
After submitting a MIR, users with *LAA* profile (MF, AR, CA and NB) and users who have subscribed to receive Vigilance notifications will receive a notification in their *Notifications inbox*, located at the top right corner of the dashboard, next to the user profile:



Inside the *Notifications Inbox*, under the *Information* tab you can preview all major updates requiring your attention, e.g.:



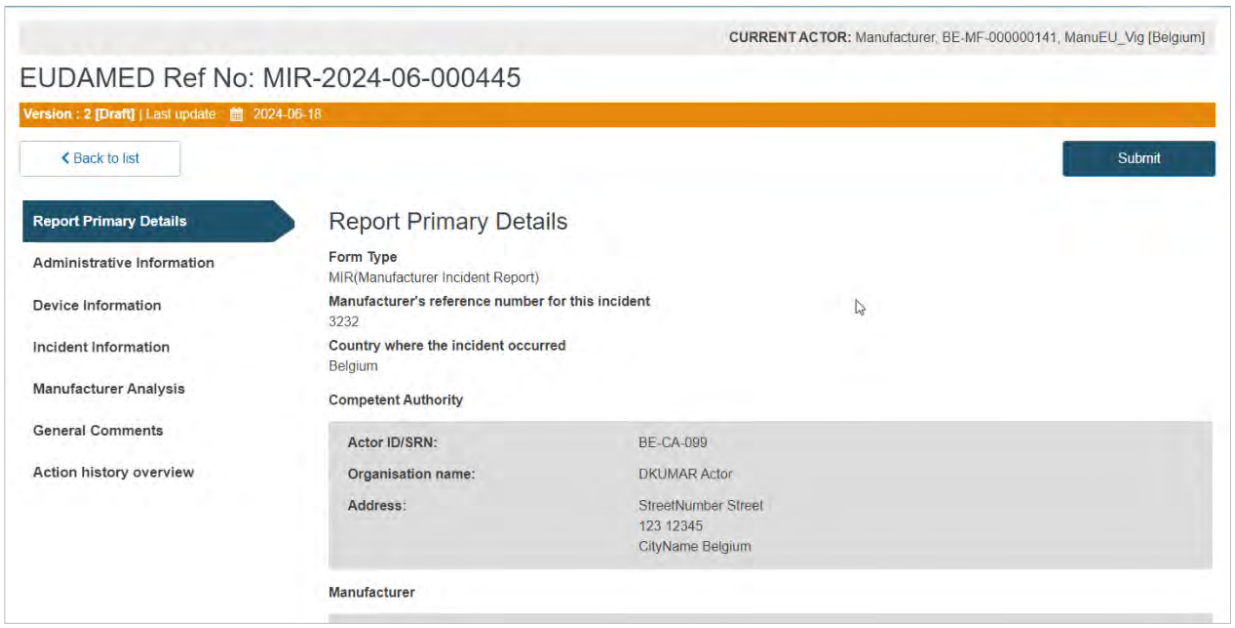
Notifications are also sent by email.

3.2 Manage MIR

3.2.1 Action history overview

Once a MIR has been submitted, it contains an *Action history review* in which you can see its different historical versions.

This chapter assumes the user has already selected the appropriate MIR report and can preview the default *Report Primary Details* screen, as shown below:



TIP
Looking for a report?

Consult chapters *Manage Vigilance reports* and *Search & View Vigilance items*.

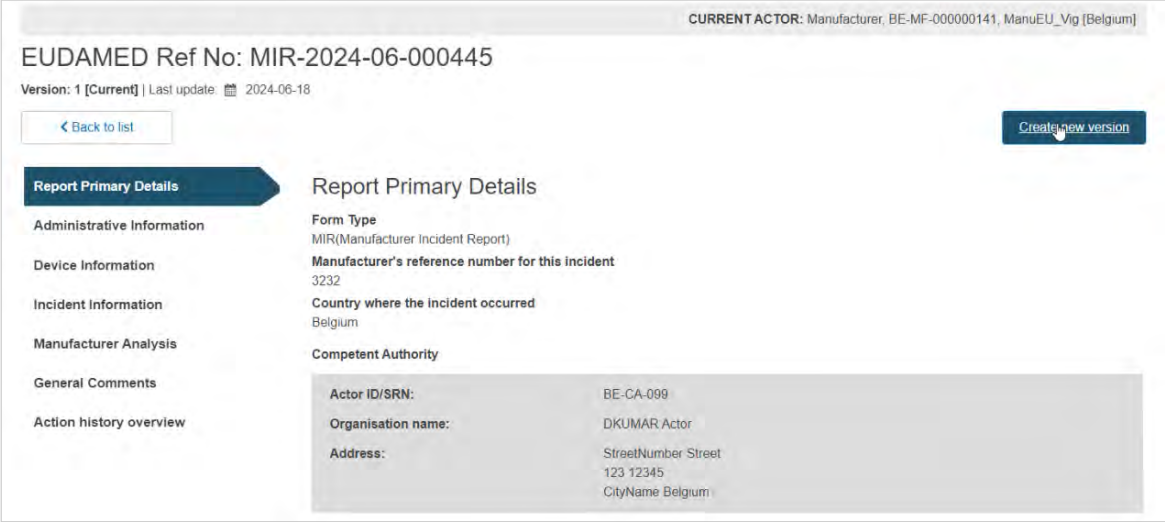
1. Click on the *Action history overview* tab from the list on the left:

2. Inside this section, you can see all previous versions for this report, their date of creation and the report *status* and *state* (in the case of MIR):

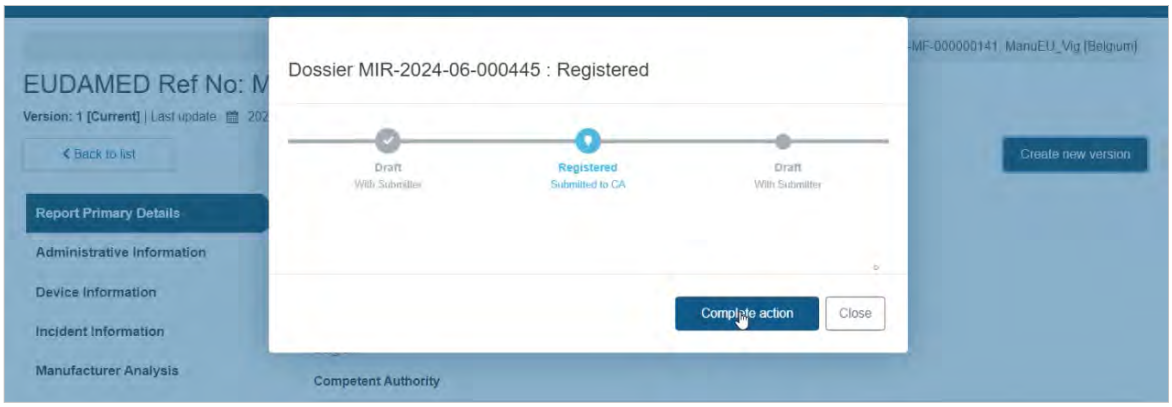
TIP
Click on the link of a previous version to see its contents.

3.2.2 Update MIR (create new version)

1. From the default *Report Primary Details* screen, click on **Create new version** at the top right corner:



2. Click on **Complete action** in the pop-up window, to confirm the initiation of a new version:

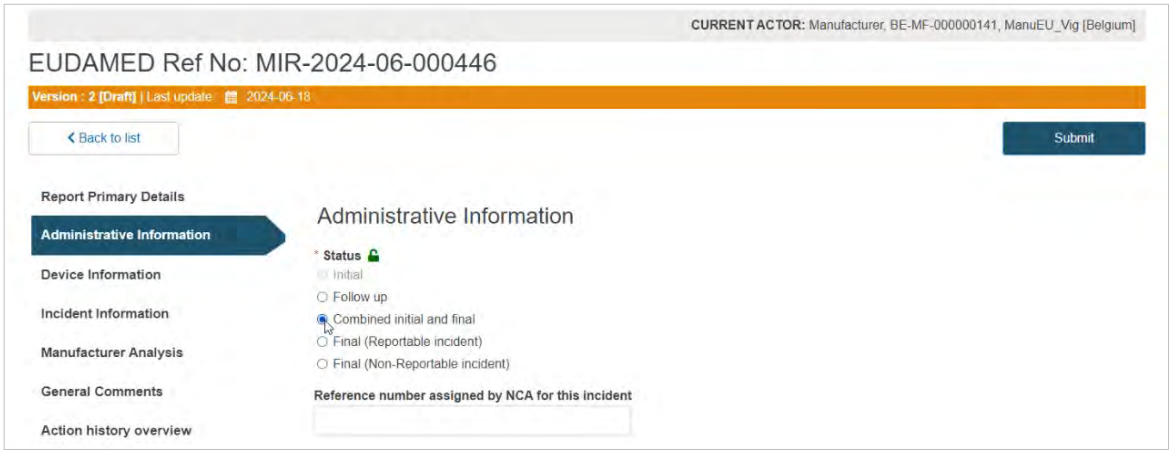


The MIR sections will become editable.

3. Modify the appropriate fields inside the relevant sections as necessary (most fields can be updated except for the device identifier in case it has been already provided).

TIP
When creating a new version of a report, some fields vary depending on the status of the report (*initial* or *follow-up, final reportable* or *final non-reportable incident)*.

4. When you have made all the necessary updates, click on **Submit** at the top right corner:

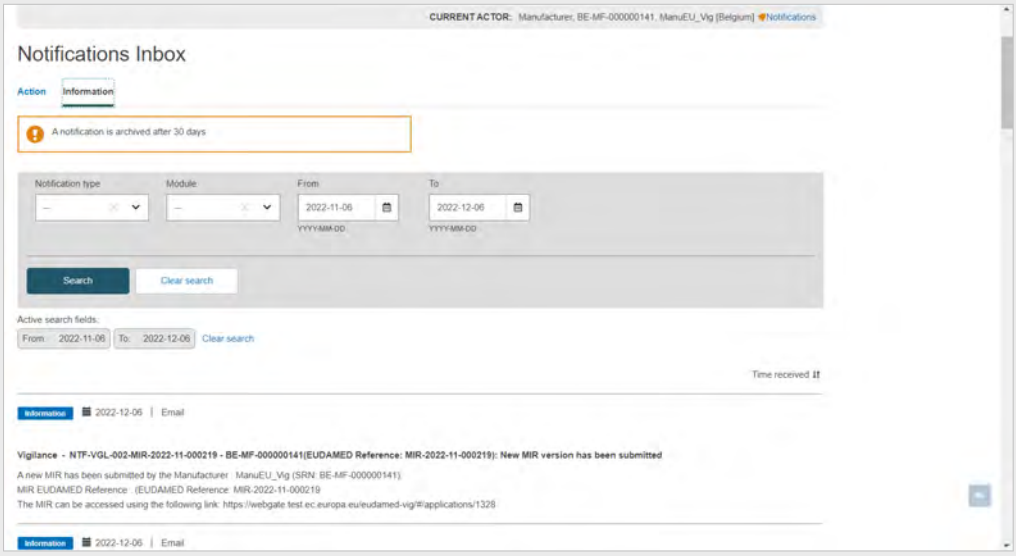


5. Click on **Complete action** in the pop-up window to finalise the action:

The newly created version is now in state *registered* and is shown in the *Action history overview* section.

NOTE

When creating a new MIR version, users with *LAA* profile (MFs, ARs, CAs, NBs) and users who have subscribed to receive Vigilance notifications will receive a notification in their Notifications inbox (*Information* tab), located at the top right corner of the dashboard, next to the user profile:



Notifications are also sent by email.

4 FSCA

4.1 Register a new FSCA

NOTE
Only Manufacturers and Authorised Representatives can access the menu for registering a new FSCA report.

4.1.1 Step 0: Create initial FSCA dossier

1. On the EUDAMED dashboard, click on *Register a new Vigilance Form* under the *Vigilance* section:

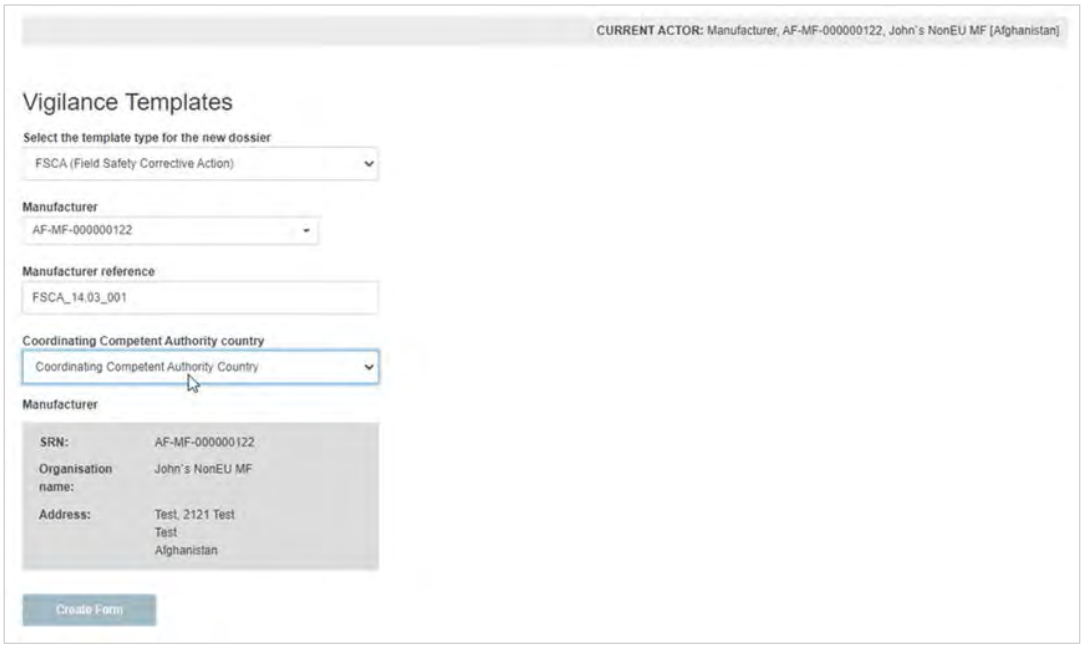
The system will redirect you to the *Vigilance Templates* screen.

2. Select the *FSCA report template* from the drop-down list:

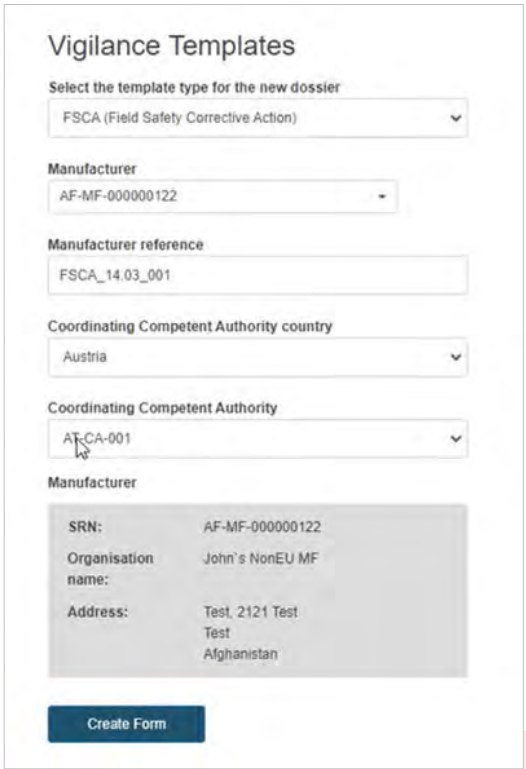
3. Select the manufacturer from the *Manufacturer* field:

The system will automatically retrieve your Actor ID/SRN.

4. Provide the unique FSCA *Manufacturer reference* in the next field as well as the country of the coordinating Competent Authority:



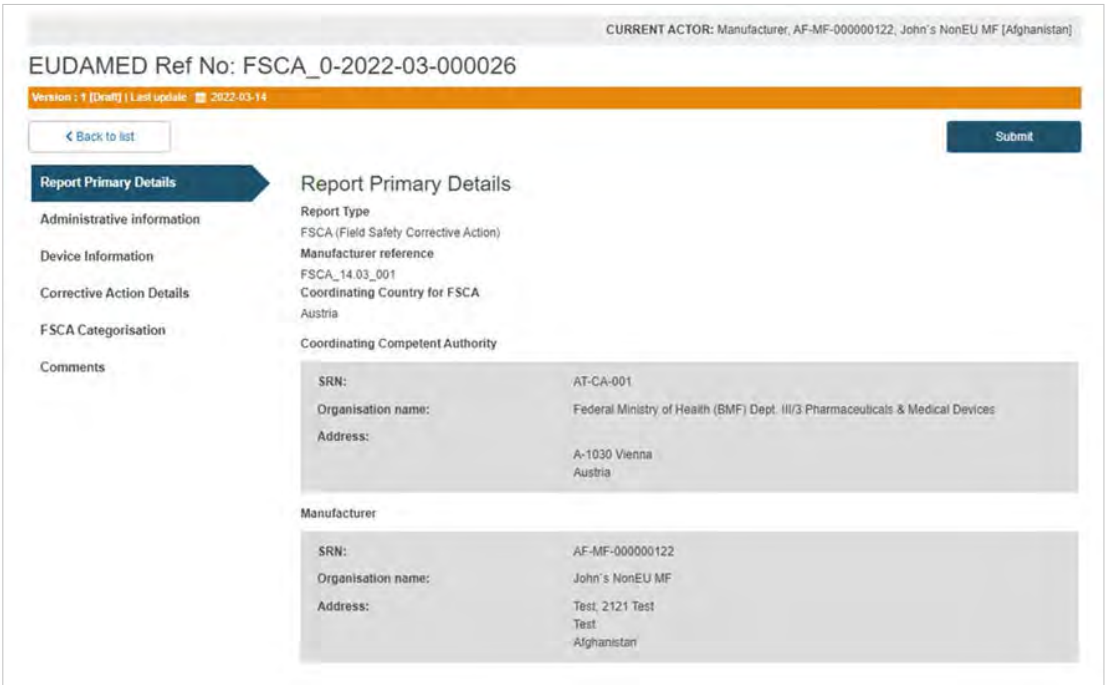
5. Depending on the country selected, you might have to choose a specific Competent Authority among several:



6. Click on **Create Form** to complete the creation of the FSCA:

4.1.2 Step 1: Report primary details

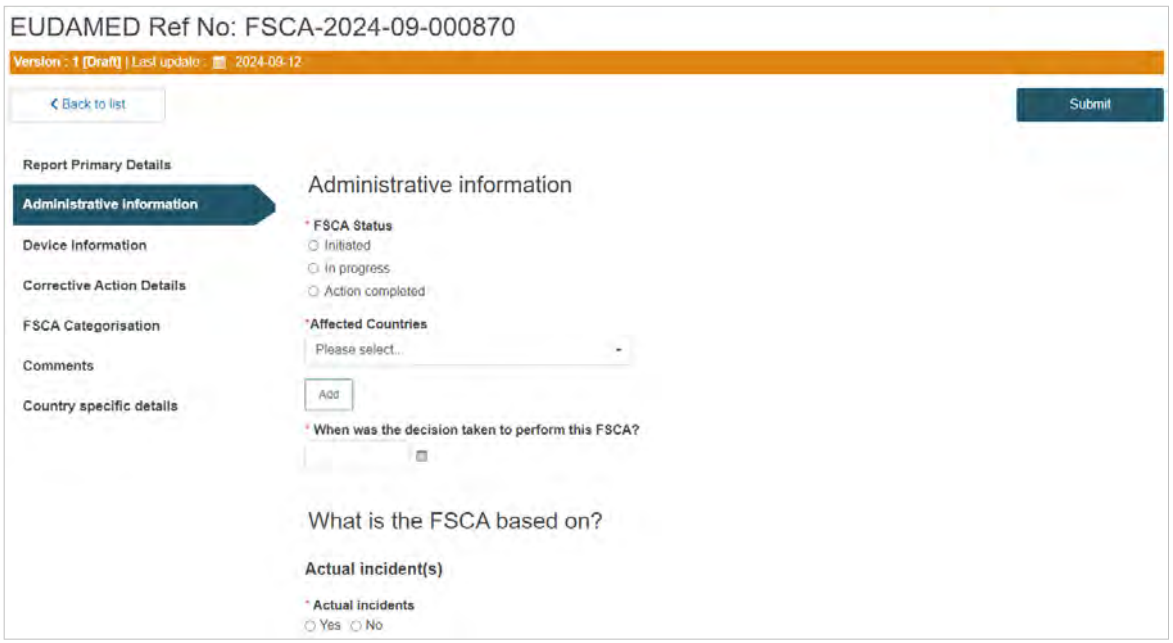
The next screen provides an overview of the data entered under the section *Report Primary Details*:



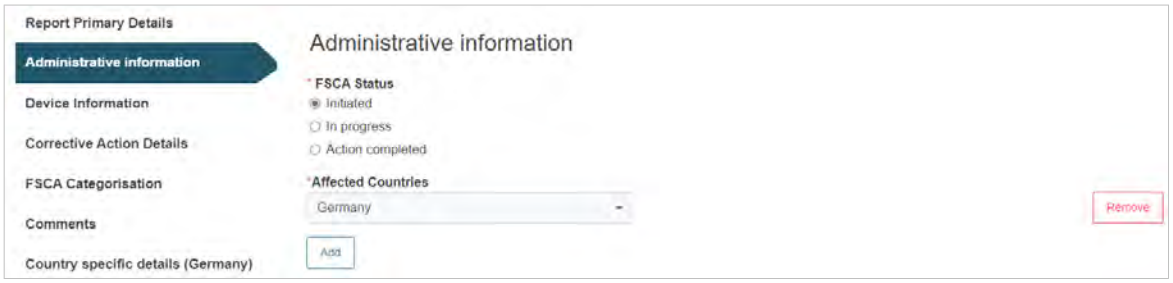
Please ensure the information provided is correct.

4.1.3 Step 2: Administrative information

1. Click on the *Administrative information* section from the menu on the left:

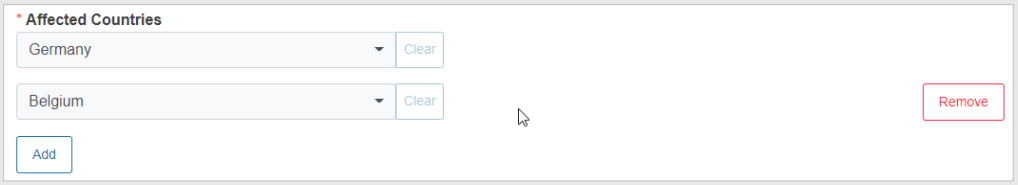


2. Select the FSCA status and choose the countries affected from the drop-down list:



TIP

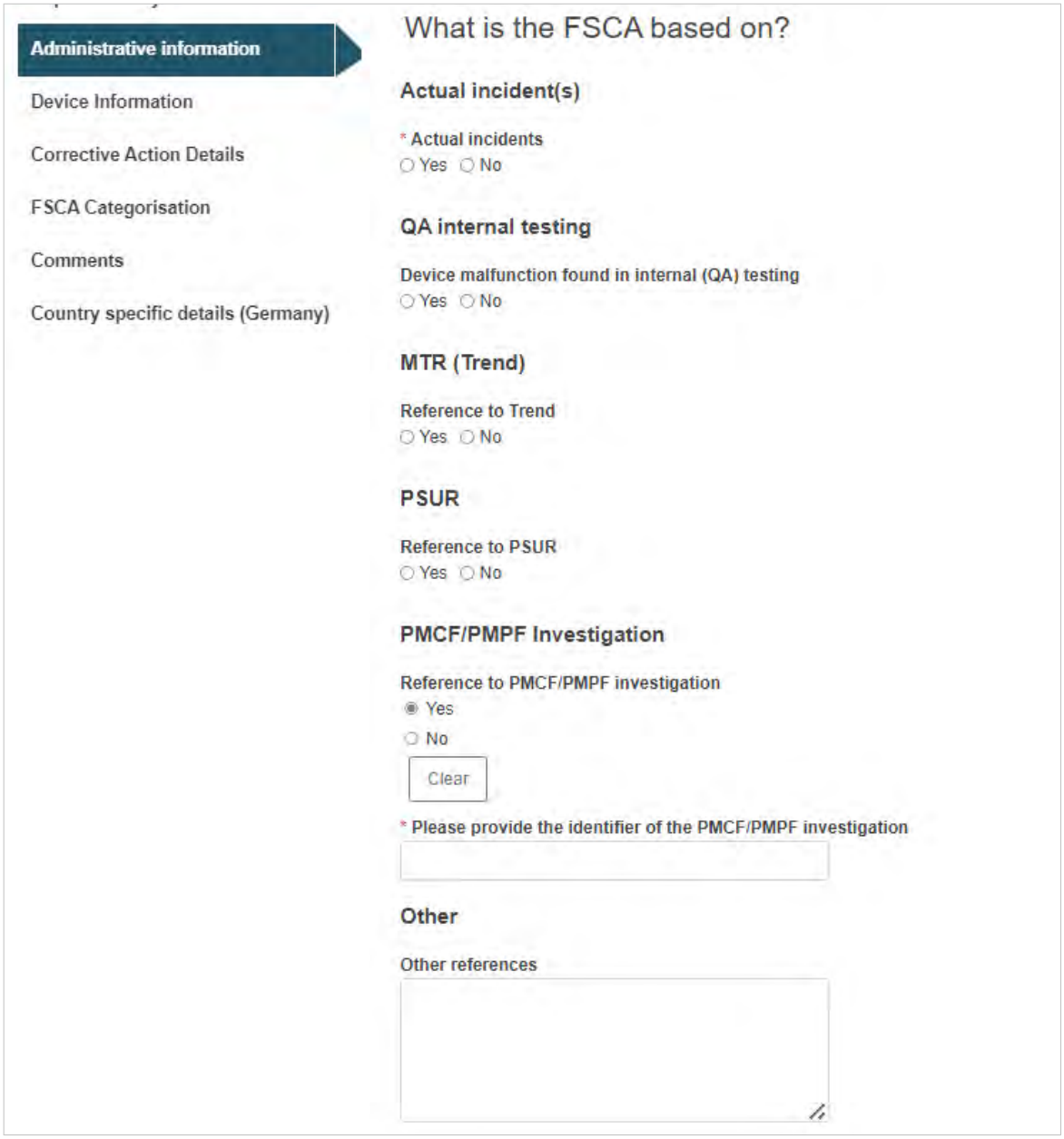
Add more affected countries by clicking the **Add** button under the countries field:



Remember that for a **new FSCA version** you can add more affected countries but you cannot delete existing countries.

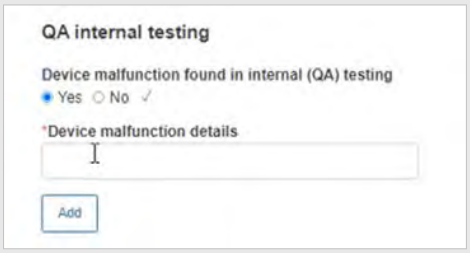
3. Insert the date on which the decision was taken to perform this FSCA:

4. Fill in the fields under *What is the FSCA based on?* and type any other references in the text box provided:

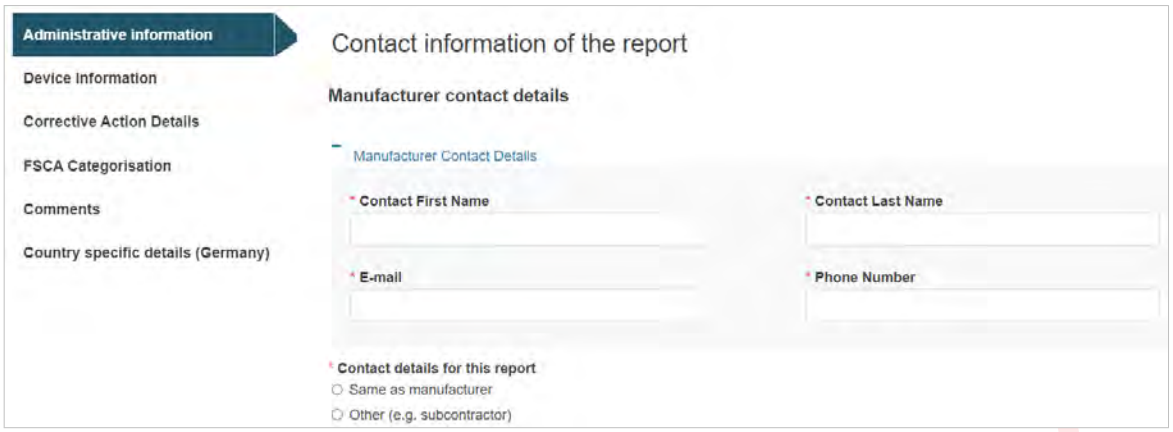

Administrative information
Device Information
Corrective Action Details
FSCA Categorisation
Comments
Country specific details (Germany)
What is the FSCA based on?
Actual incident(s)
* Actual incidents
Yes No
QA internal testing
Device malfunction found in internal (QA) testing
Yes No
MTR (Trend)
Reference to Trend
Yes No
PSUR
Reference to PSUR
Yes No
PMCF/PMPF Investigation
Reference to PMCF/PMPF investigation
Yes
No
Clear
* Please provide the identifier of the PMCF/PMPF investigation
Other
Other references

TIP
If the FSCA is based on actual incidents, please provide the MIR reference to the actual incident:

Similarly, if the FSCA is based on *QA internal testing*, provide the malfunction details of the device:



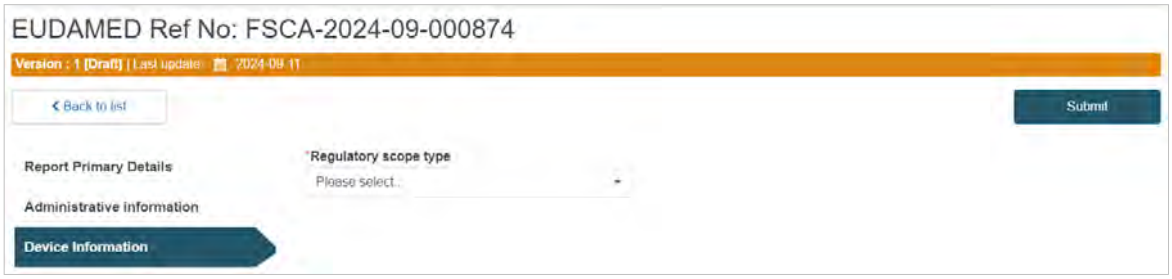
5. Provide the contact details of the report in the corresponding sections:



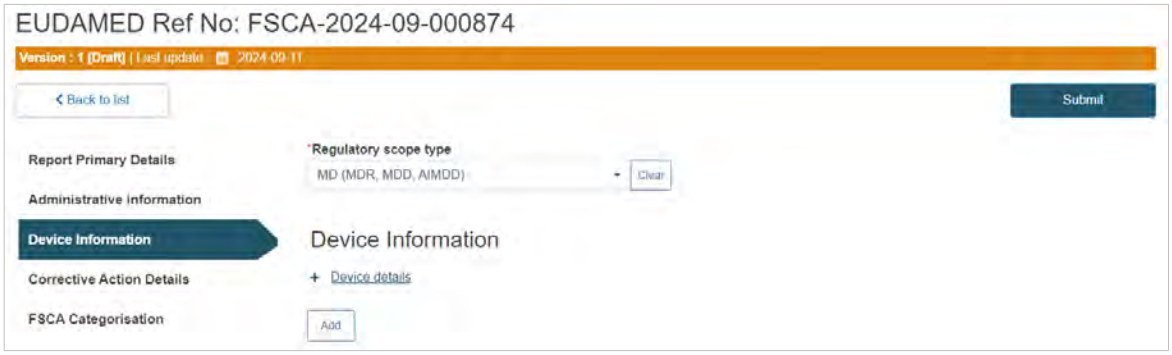
4.1.4 Step 3: Device information

1. Click on the *Device Information* tab from the menu on the left:

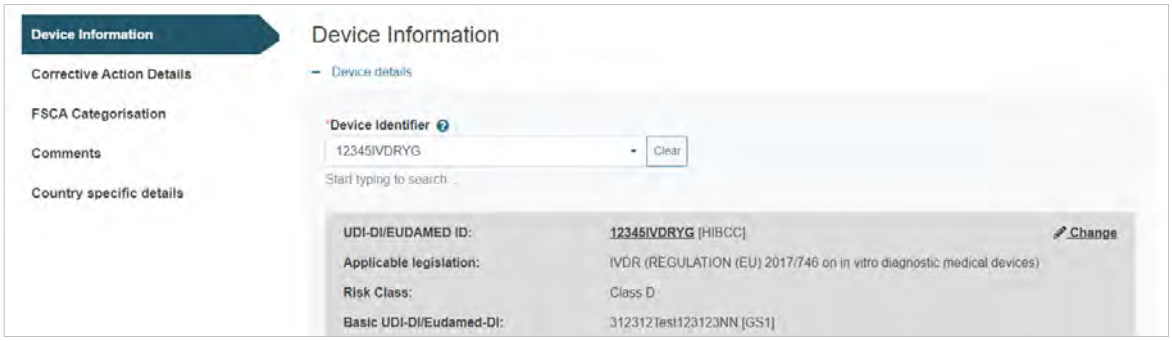
2. Select the regulatory scope:



3. Click on the *plus* sign next to *Device details*:

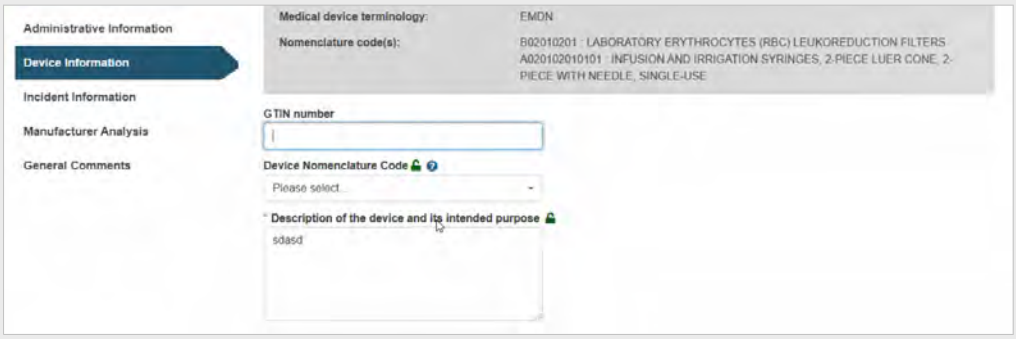


4. Provide the *Device Identifier*:

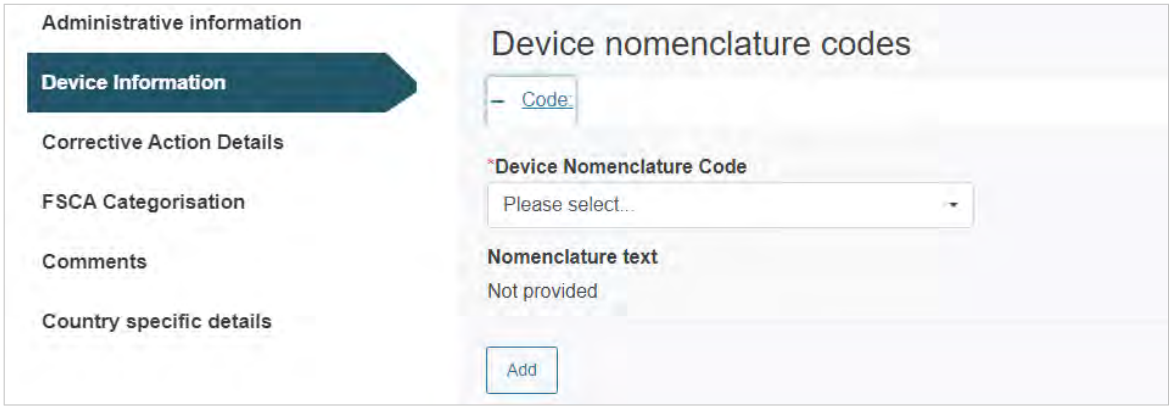


NOTE

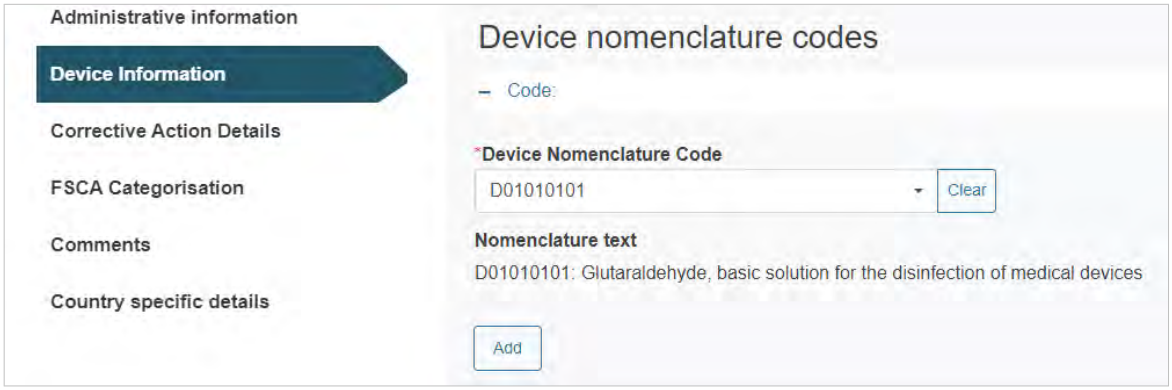
In case of a special device (requiring a Master UDI-DI), an additional *GTIN* field will appear in the *Device information* section for you to fill in:



5. Click on **Code** to select the nomenclature code:

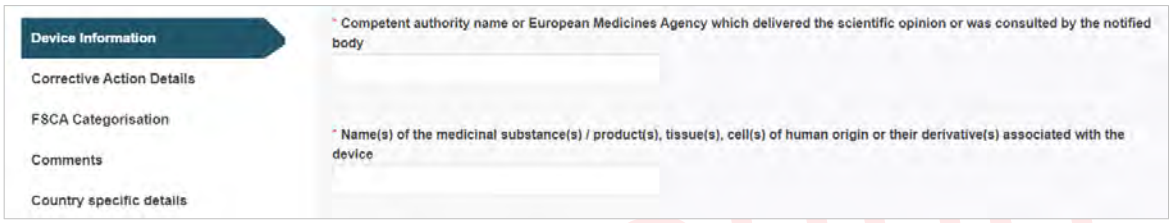


The system will auto-fill the *Nomenclature text* field:



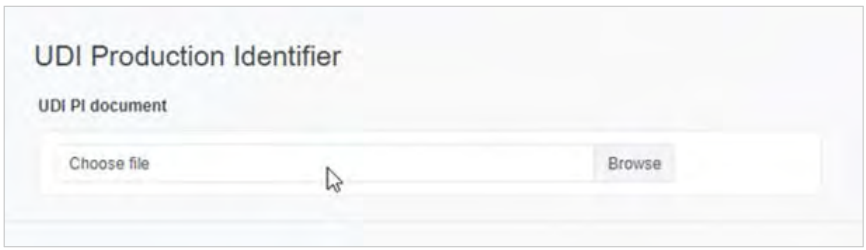
6. Describe the device and its intended purpose:

7. Fill in the next two fields regarding the scientific opinion CA and medicinal substance:

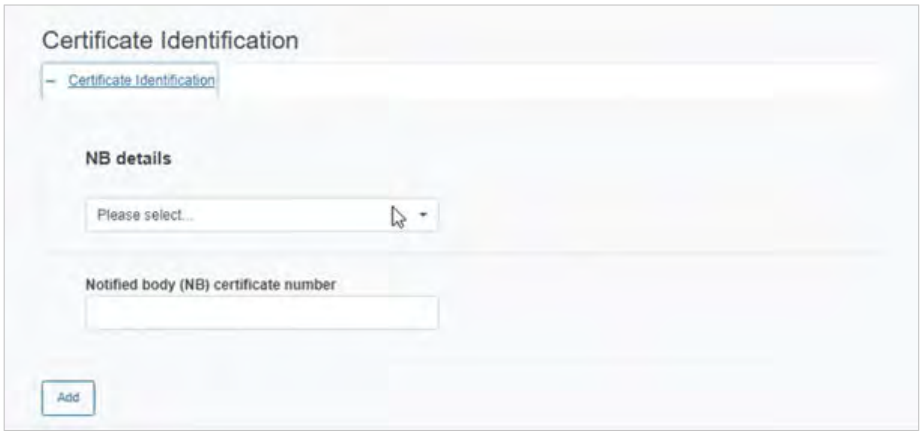


IMPORTANT
The mandatory field regarding a scientific opinion above will only appear for MDR and IVDR legislations.

8. Click on **Browse** to upload a UDI-PI document in PDF format:

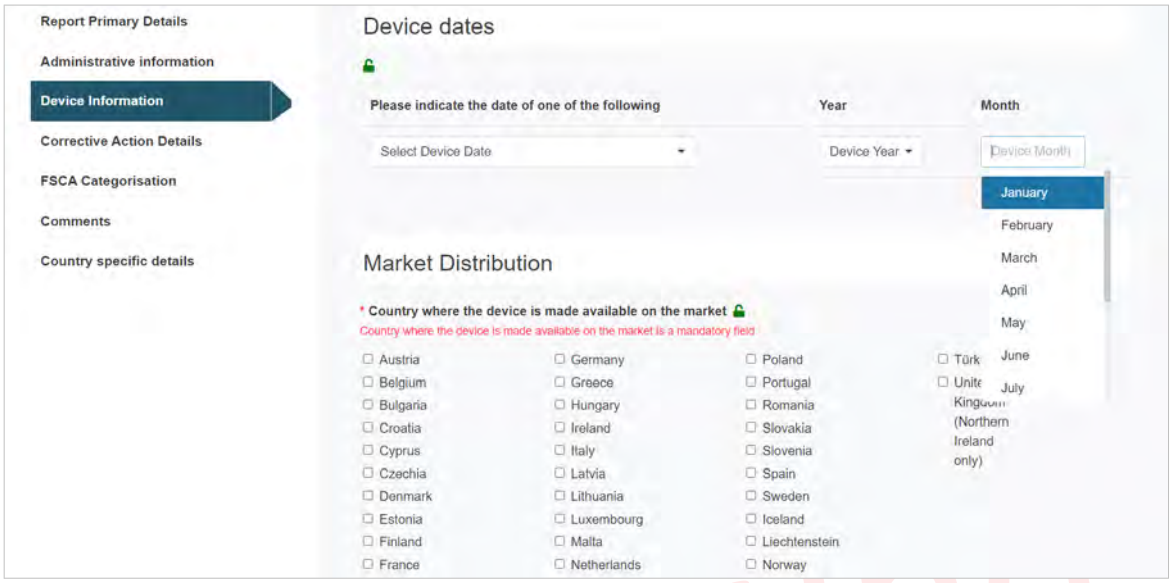


9. Click on the plus sign next to *Certificate Identification* and complete the appearing fields:

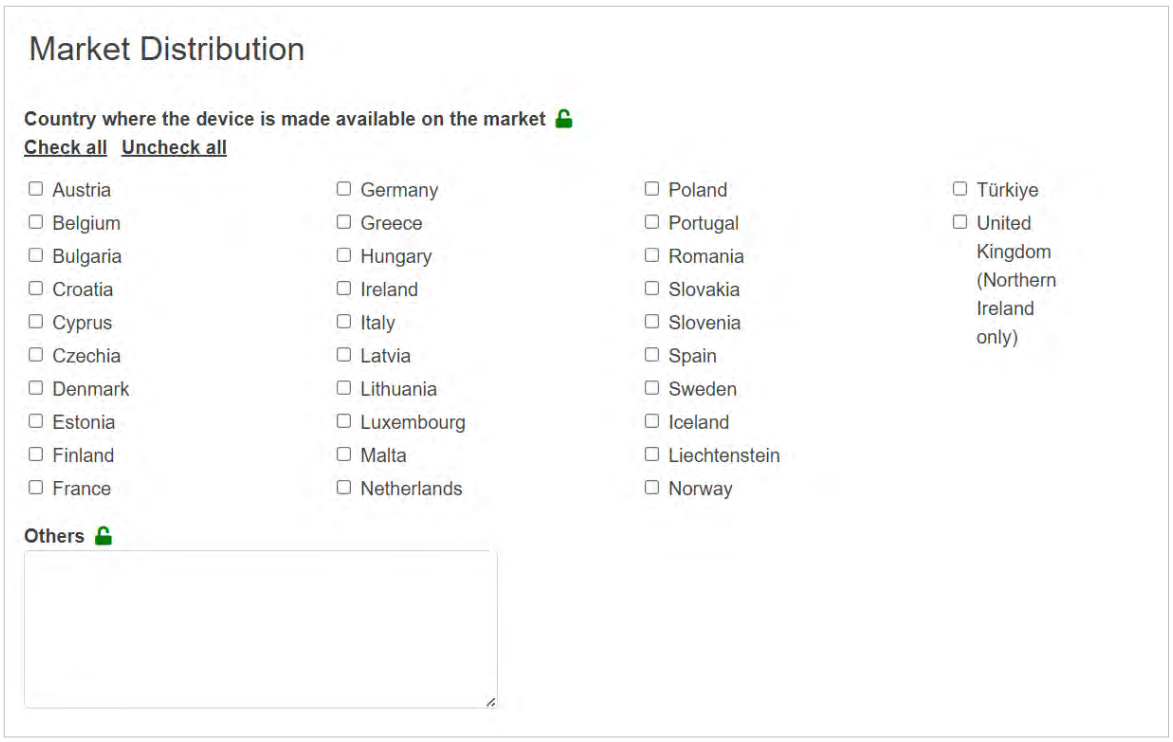


Select the *Notified Body details* from the drop-down list and insert the *NB certificate number* for the device.

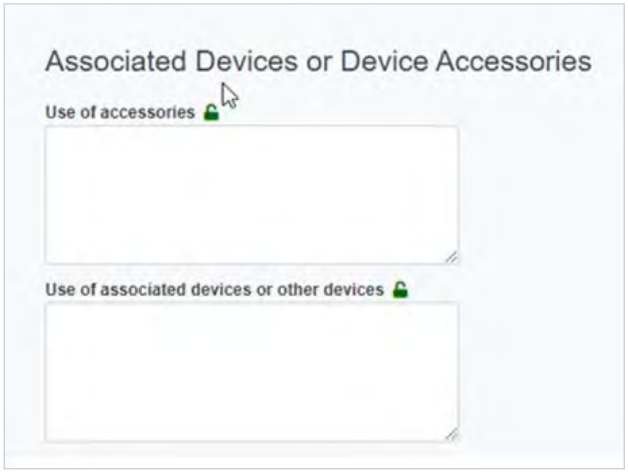
10. Select the appropriate *Device date* and fill in the year and month:



11. Tick the countries where the device is made available on the market:

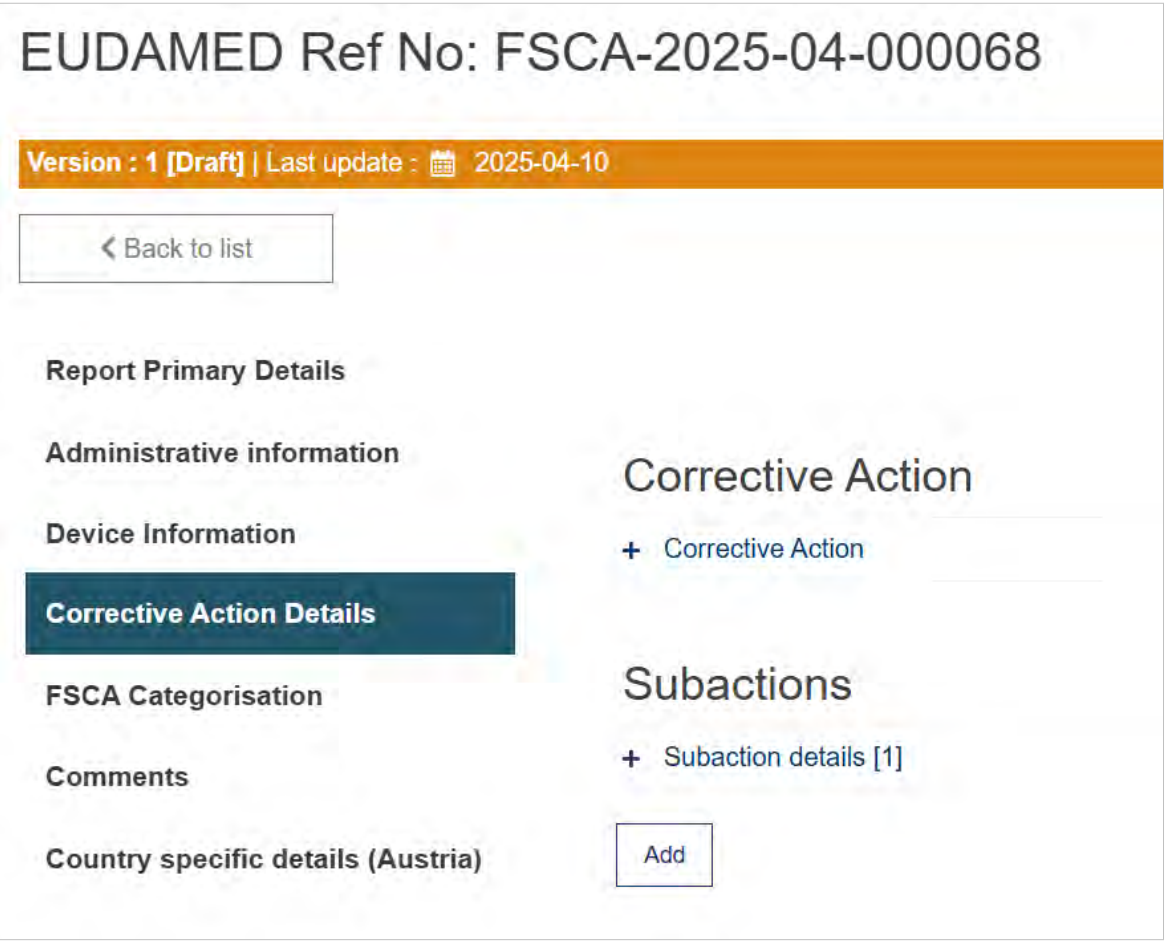


12. Provide information for the *Associated Devices and Device Accessories* section:



4.1.5 Step 4: Corrective action details

1. Click on the *Corrective Action Details* section from the menu on the left:



NOTE
Corrective action* vs *Sub-action details

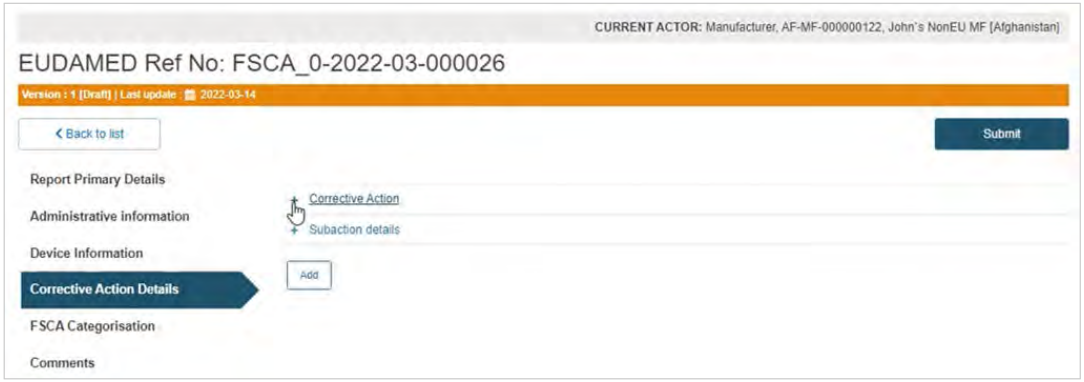
The *Corrective action details* section includes the information on the corrective action itself and the related sub-action(s) at global level.

Moreover, you have sub-action(s) details at country level.

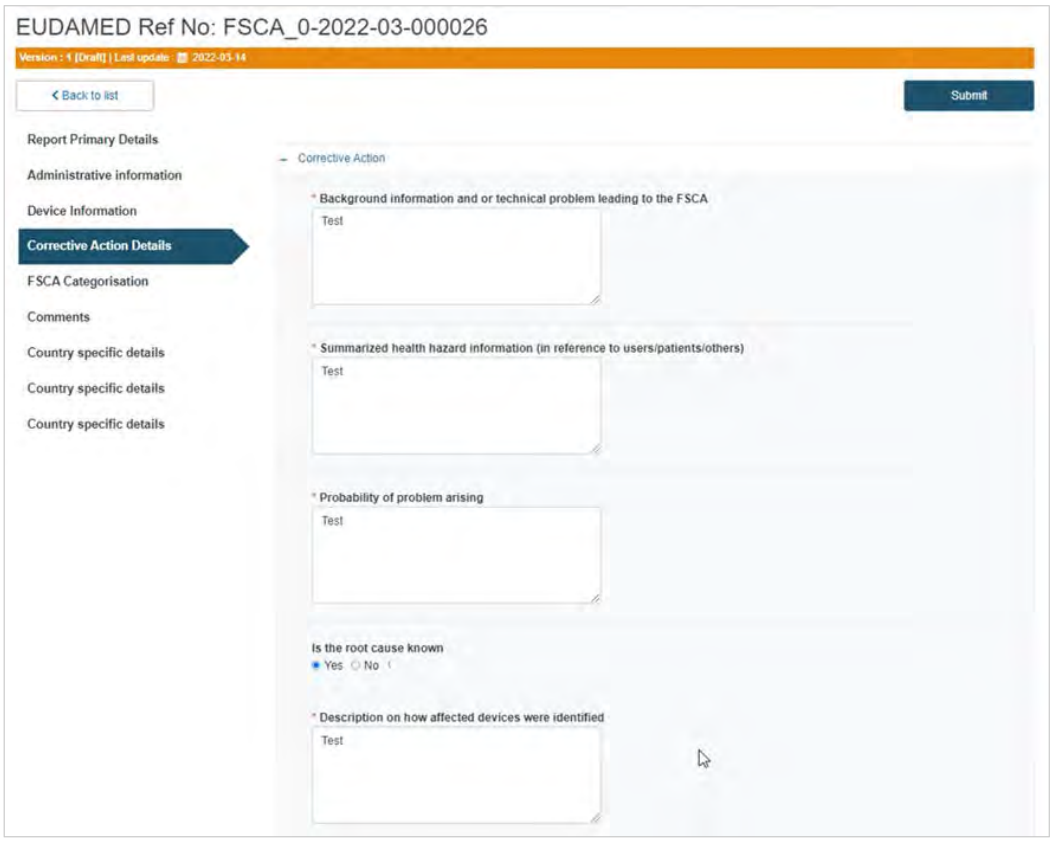
The *Sub-action details* sections identify more specific details with additional information on their schedule and progress at global and country-specific levels.

It is only when all sub-actions are at 100% progress and finalised that the corrective action can be considered as completed.

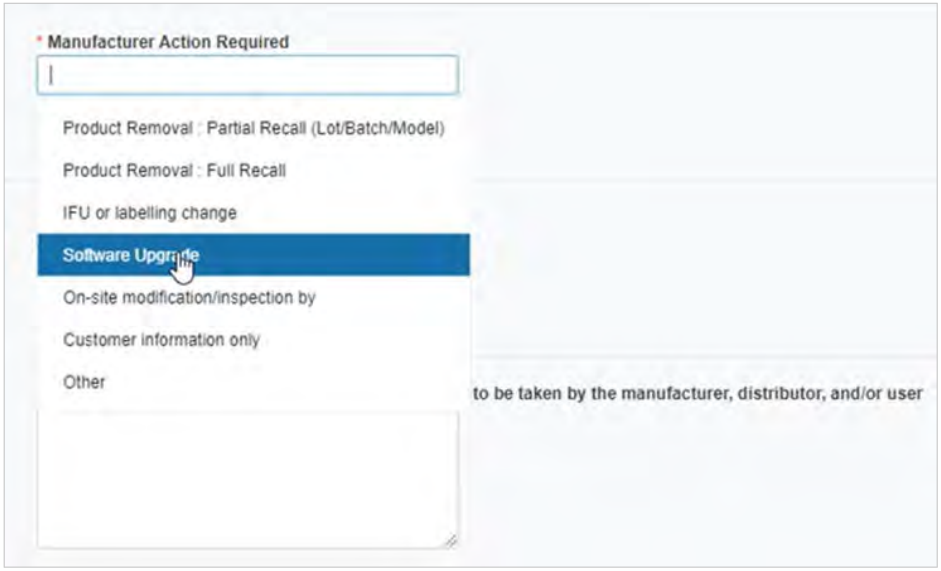
2. Click on the plus sign next to the *Corrective Action* segment to access the fields to be completed:



3. Provide information in each of the fields inside the *Corrective Action* segment:

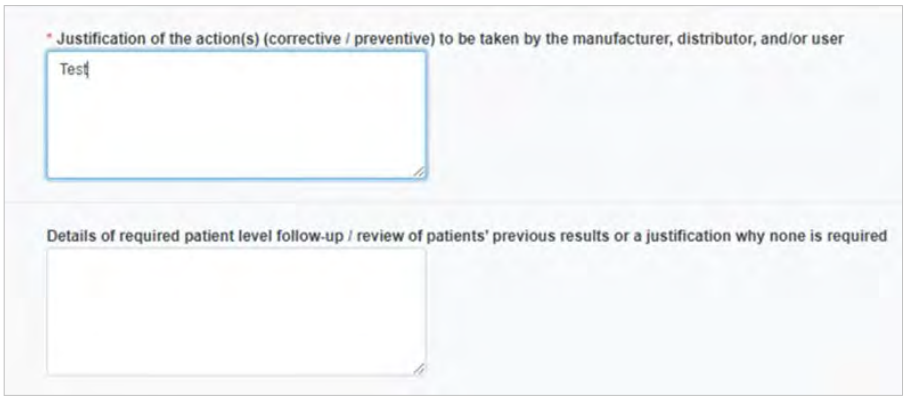


4. Specify the manufacturer action required from the drop-down list:

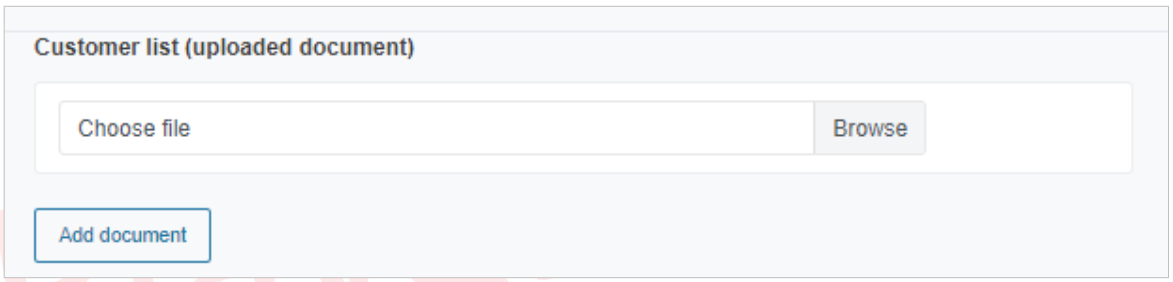


5. Similarly, select *User action(s) required* from the drop-down list:

6. Insert a justification of the actions and the details in the two fields below:



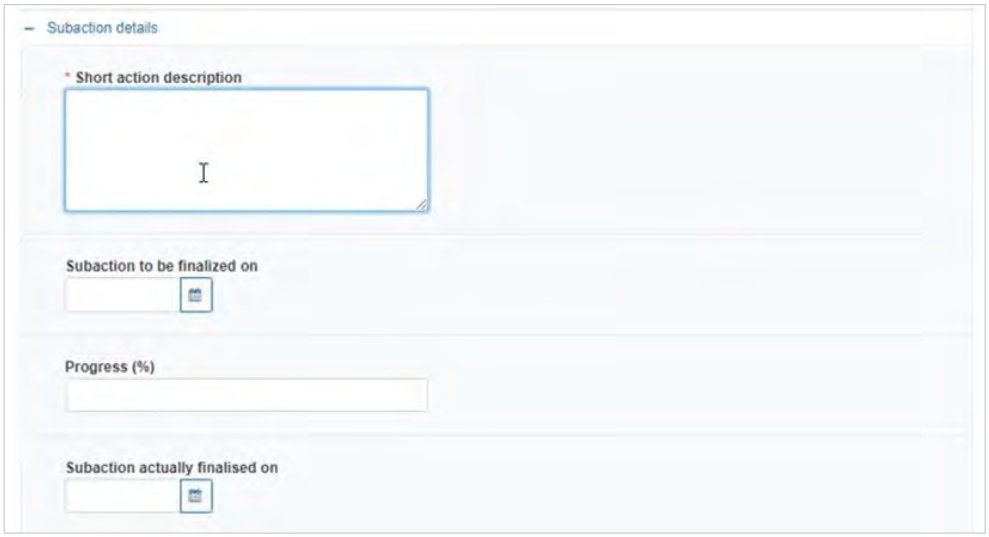
7. Click **Browse** to upload a document under *Customer list*:



8. Click **Browse** to upload other important documents relevant to this FSCA:

9. Click on the plus sign next to the *Sub-action details* section to view its fields for completion:

10. Fill in the *Sub-action details* fields:

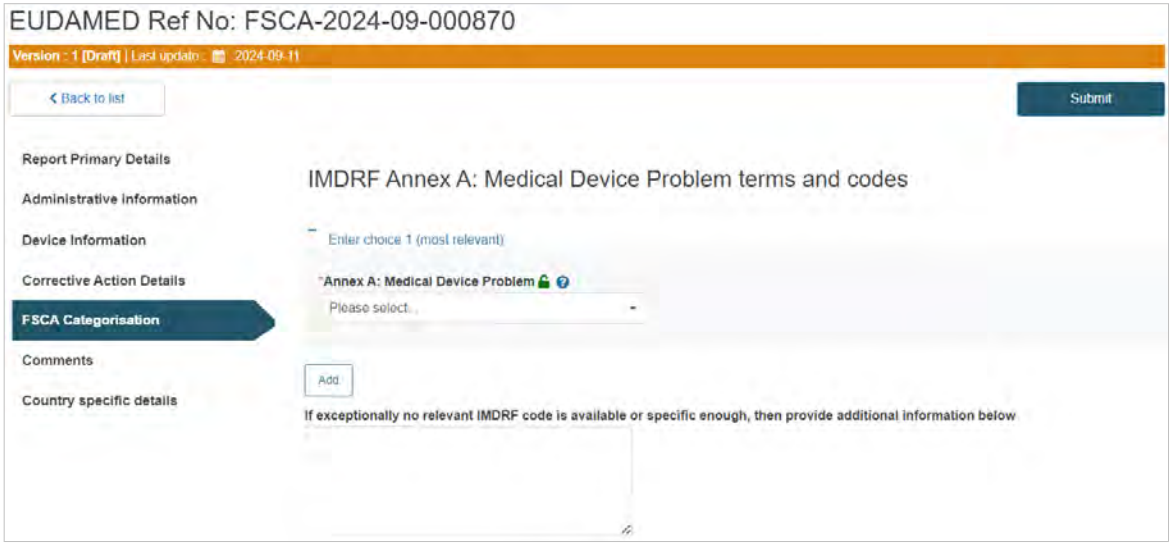


IMPORTANT
In the field *Sub-action actually finalised on* only dates in the past can be entered.

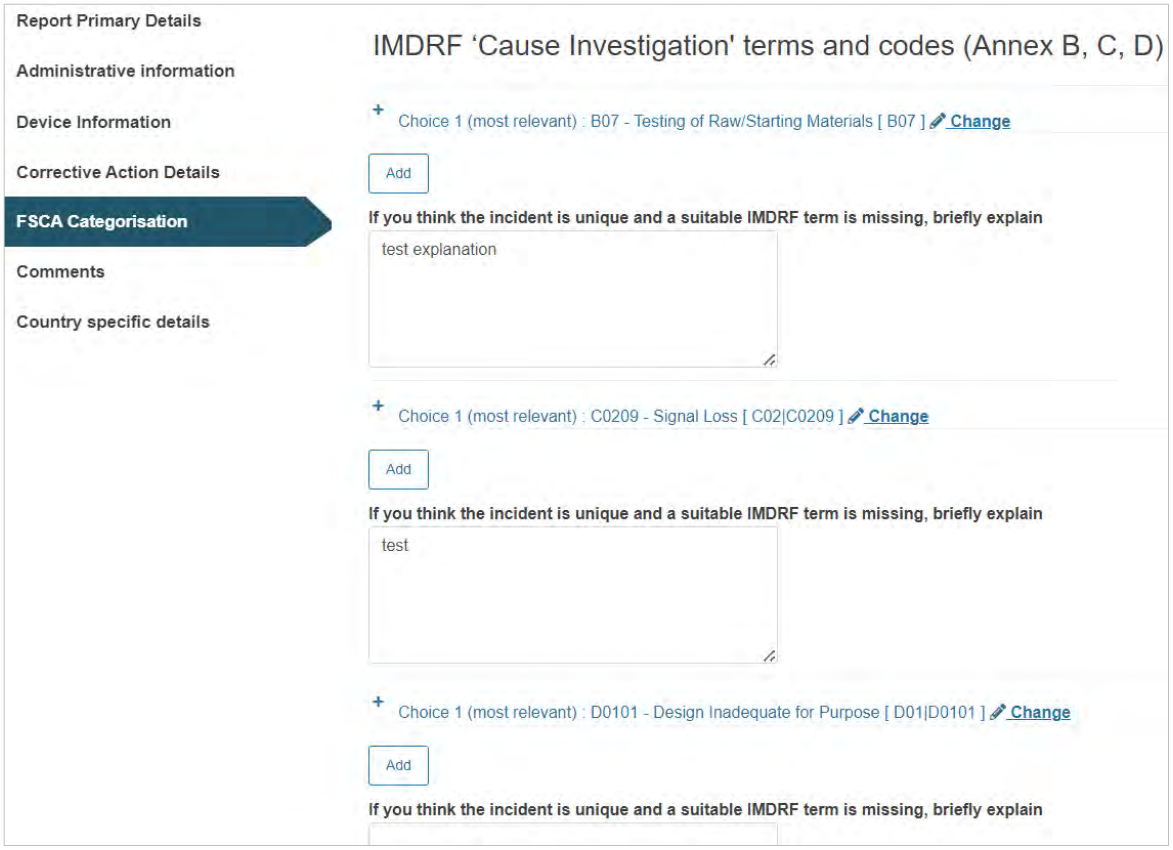
11. Click **Browse** to upload any relevant important documents (only PDF):

4.1.6 Step 5: FSCA categorisation

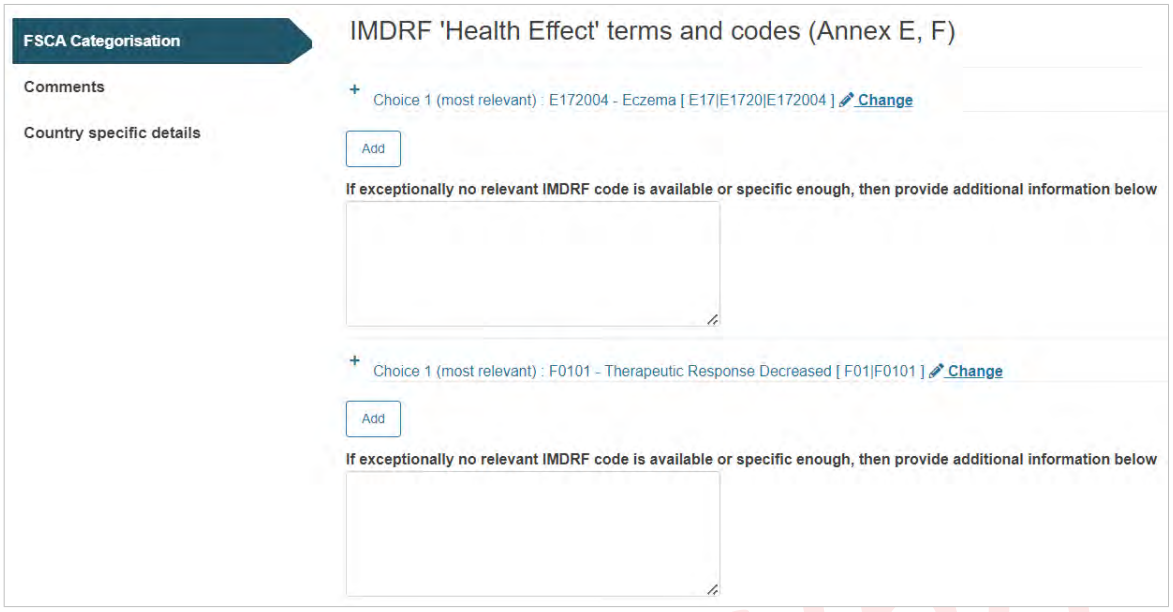
1. Under *FSCA categorisation*, fill in the fields under *IMDRF Medical Device problem terms and codes (Annex A)*:



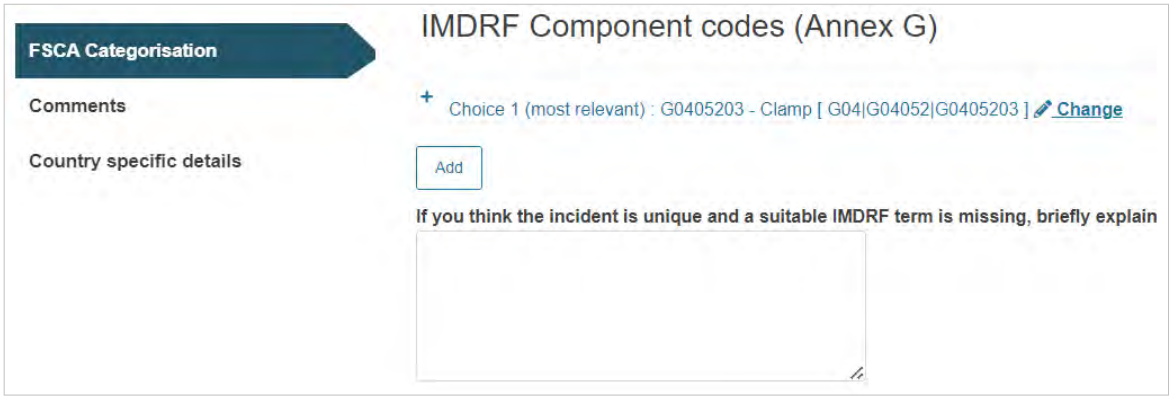
2. Fill in the *IMDRF 'Cause Investigation' terms and codes (Annex B, C, D)* section using the drop-down lists:



3. Similarly, fill in the *IMDRF 'Health Effect' terms and codes (Annex E, F)* section:



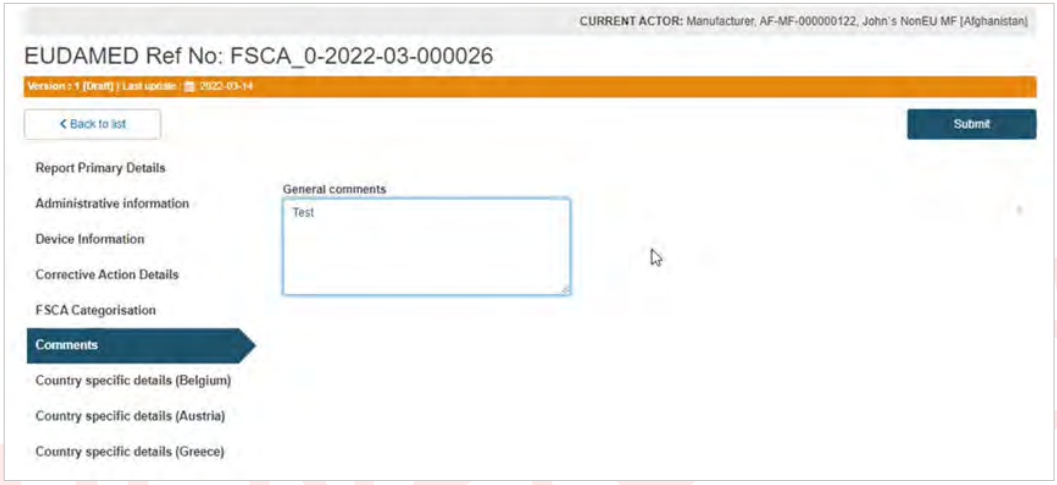
4. Complete the section by filling in the *IMDRF Component codes* section using the drop-down list:



4.1.7 Step 6: Comments

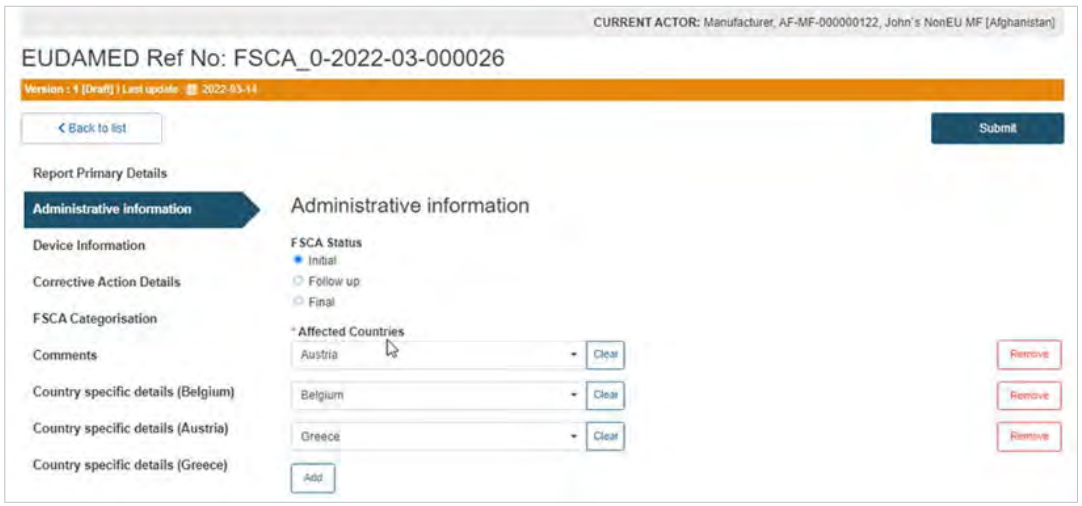
1. Click on the *Comments* section from the menu on the left:

2. Type any general comments relevant to this FSCA:

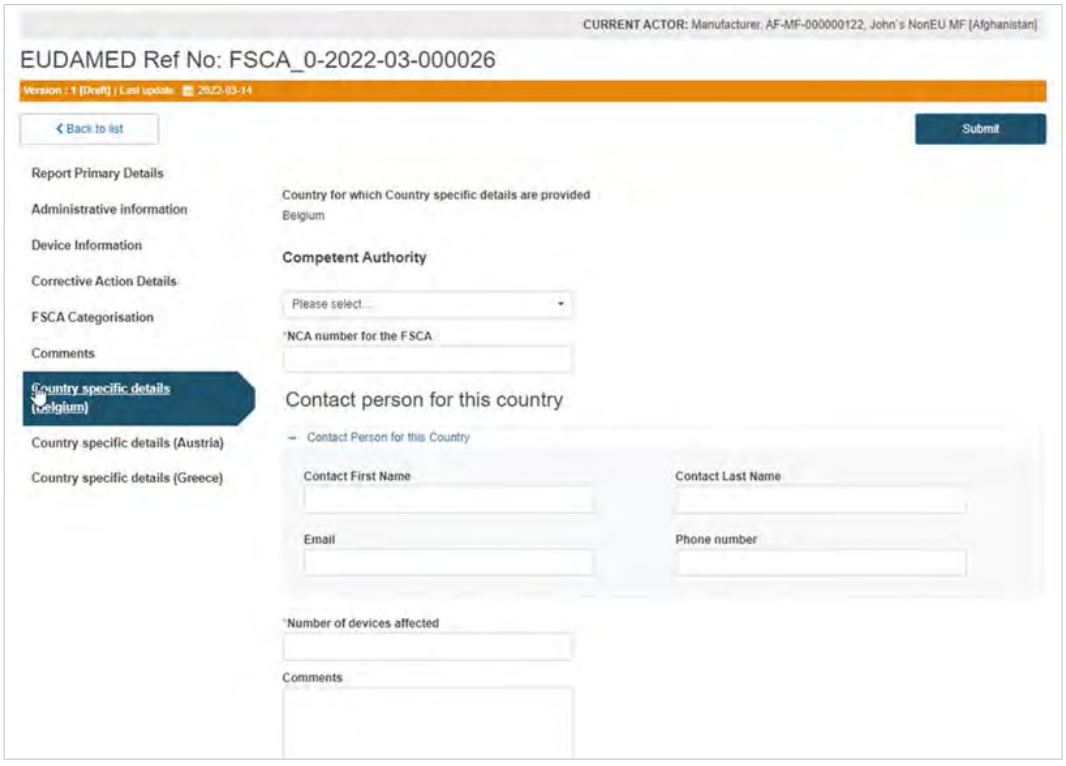


4.1.8 Step 7: Country-specific details / Submission

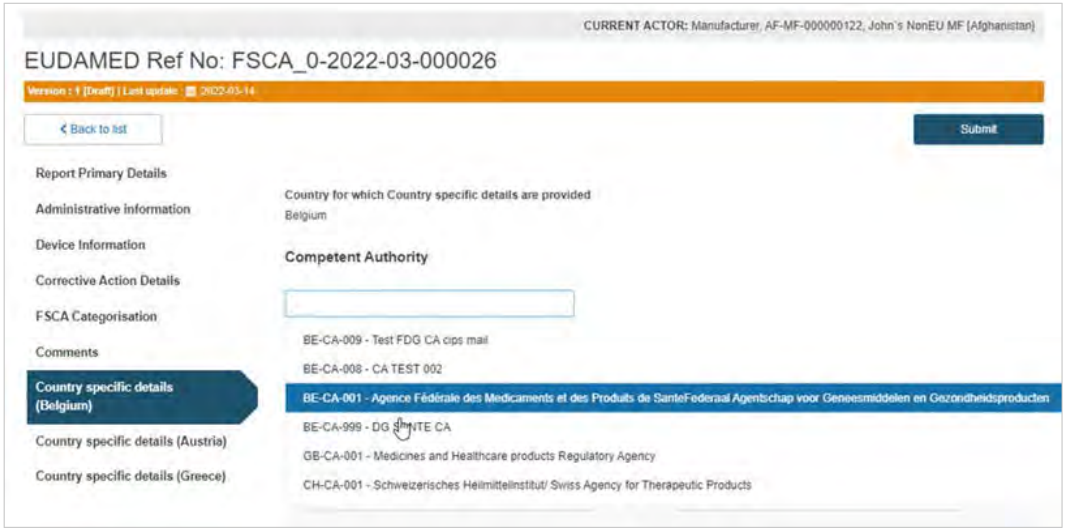
This example assumes that in the *Administrative information* section several countries have been added as shown below (the process is the same but simpler for one country):



1. Click on the country-specific details of one of the countries added from the menu on the left:

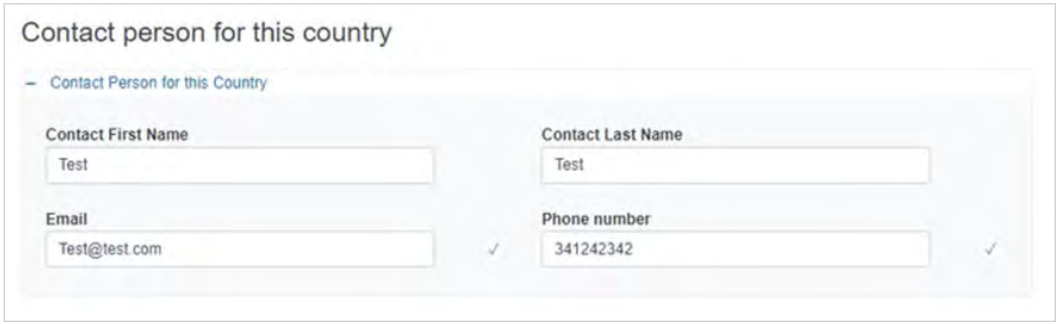


2. Select the appropriate Competent Authority for this country:

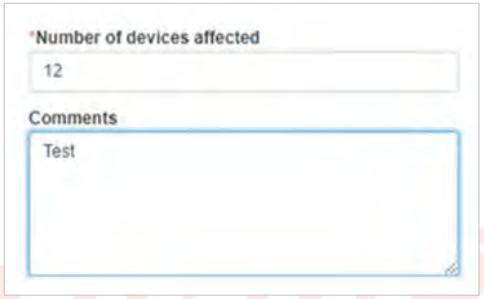


3. Type the National Competent Authority (NCA) number allocated to this specific FSCA:

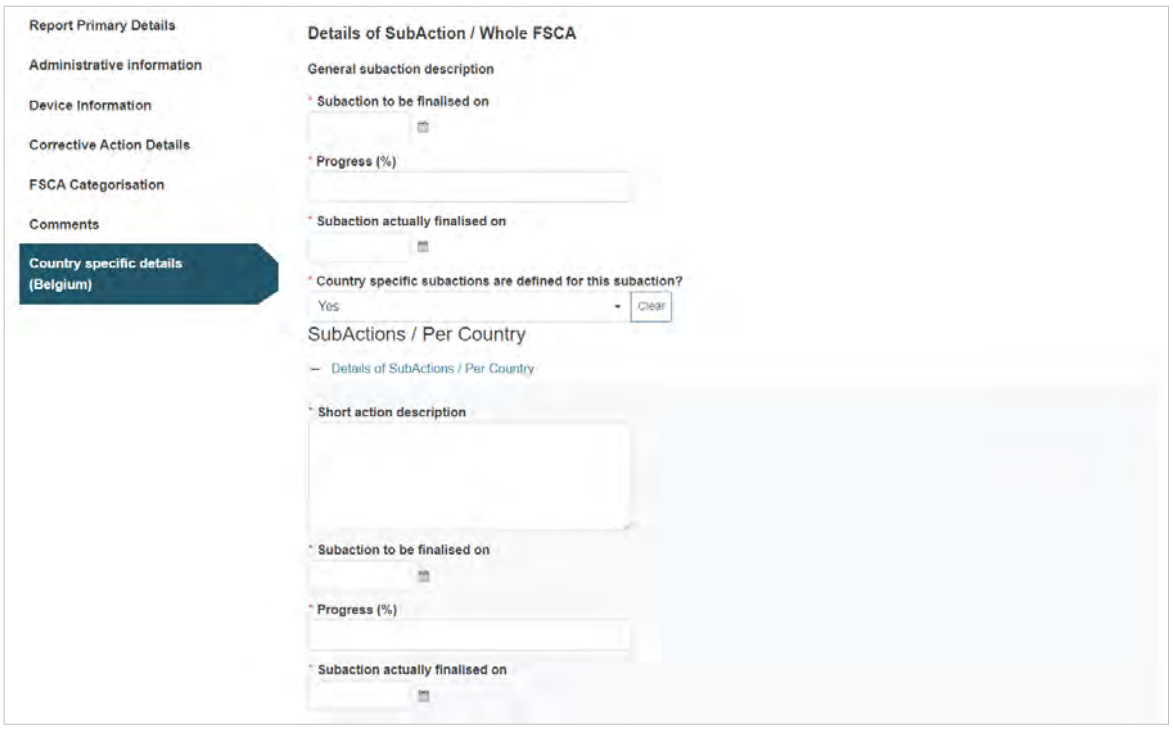
4. Provide the contact person's details for the specified country:



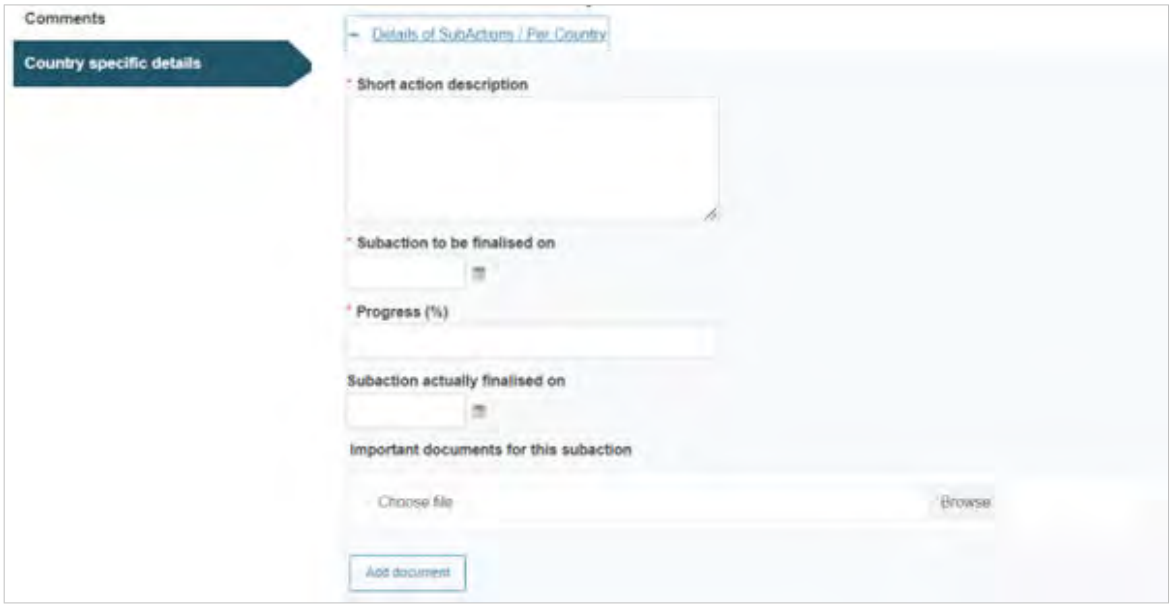
5. Provide the number of affected devices and any related comments below:



6. As sub-actions need to be further specified for each country selected, fill in the information in the mandatory fields:

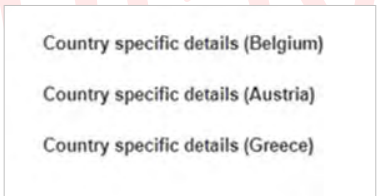


7. Click on the plus sign next to *Details of sub-actions per country* and provide details:

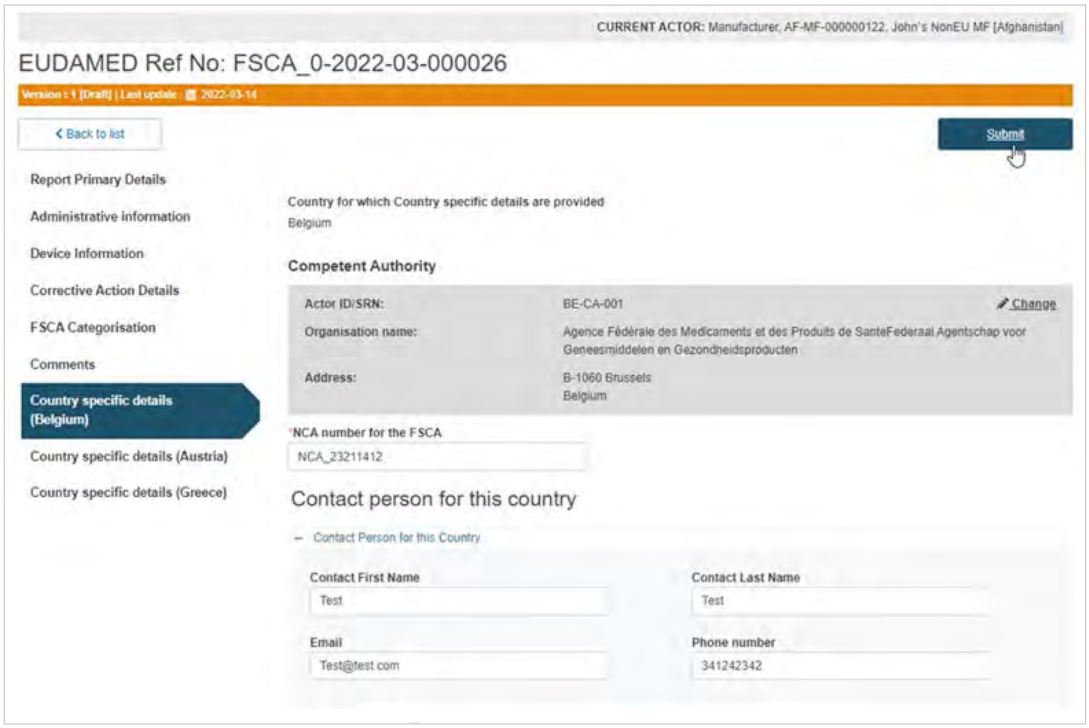


8. Follow the same process for all sub-actions listed inside this country's *Country-specific details* section.

9. Click on each *Country-specific details* section and repeat the process for each country added:

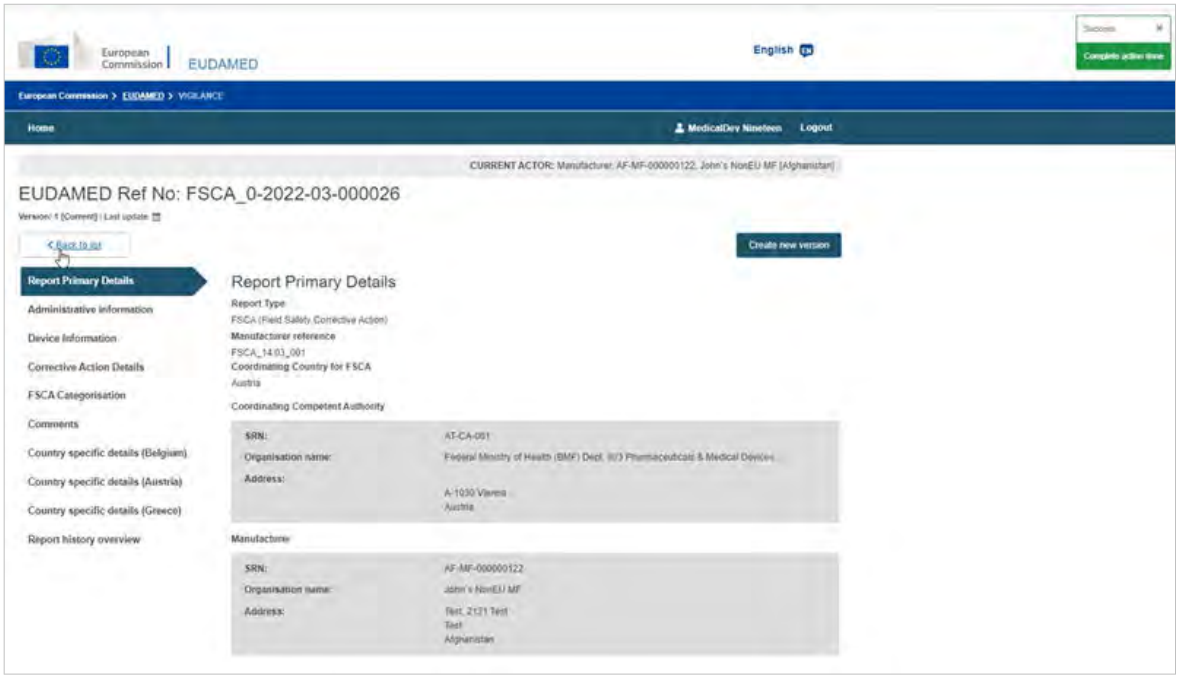


10. **Submission**: When all country-specific detail sections have been completed, click on the **Submit** button at the top right corner:



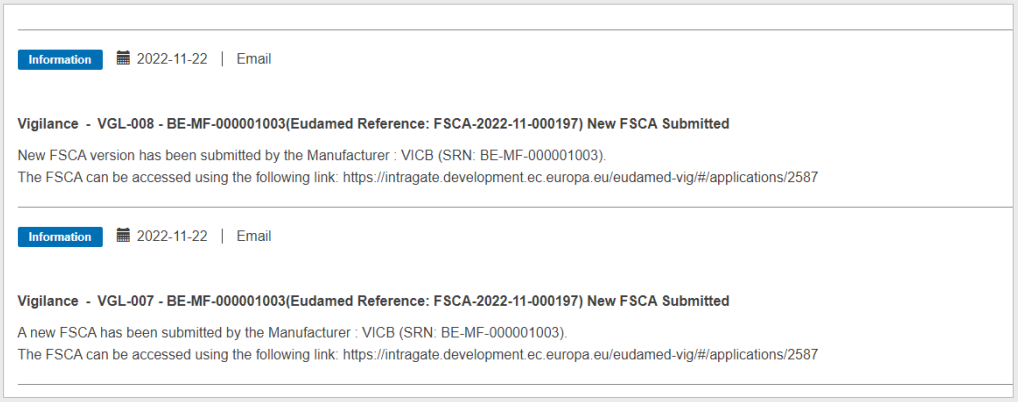
11. In the pop-up window click **Complete action** to finalise the process:

The system will redirect you to the *Report Primary Details* screen of the submitted FSCA report in preview mode with a green *Success* message at the top right corner confirming your action:



NOTE

After submitting an FSCA or creating a new version, for users with LAA profile only, the CAs of the countries referenced in the report and NBs will receive a notification in their *Notifications inbox* (*Information* tab):



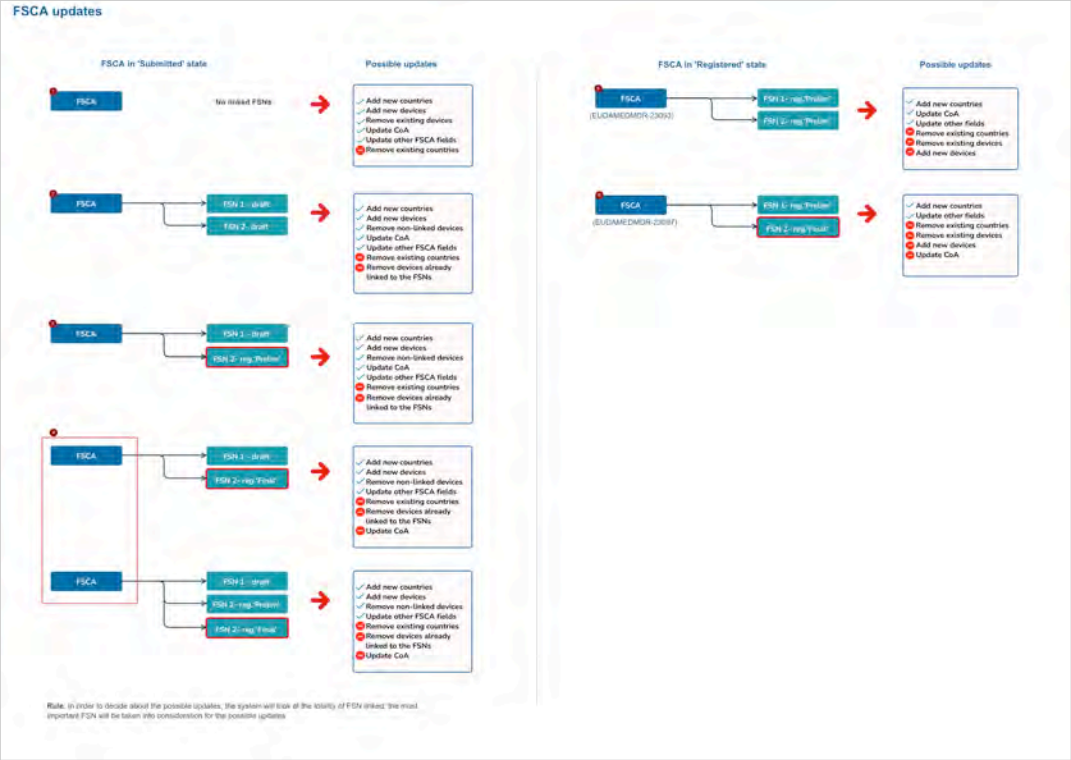
4.2 Update FSCA (create new version)

Once an FSCA is submitted, it can be updated through the creation of a new version.

NOTE

Due to the inter-dependence between FSCA and FSN reports, the available options when updating an FSCA can vary.

Here is a cheat sheet of all possible updates depending on the FSCA's state and FSN variations:



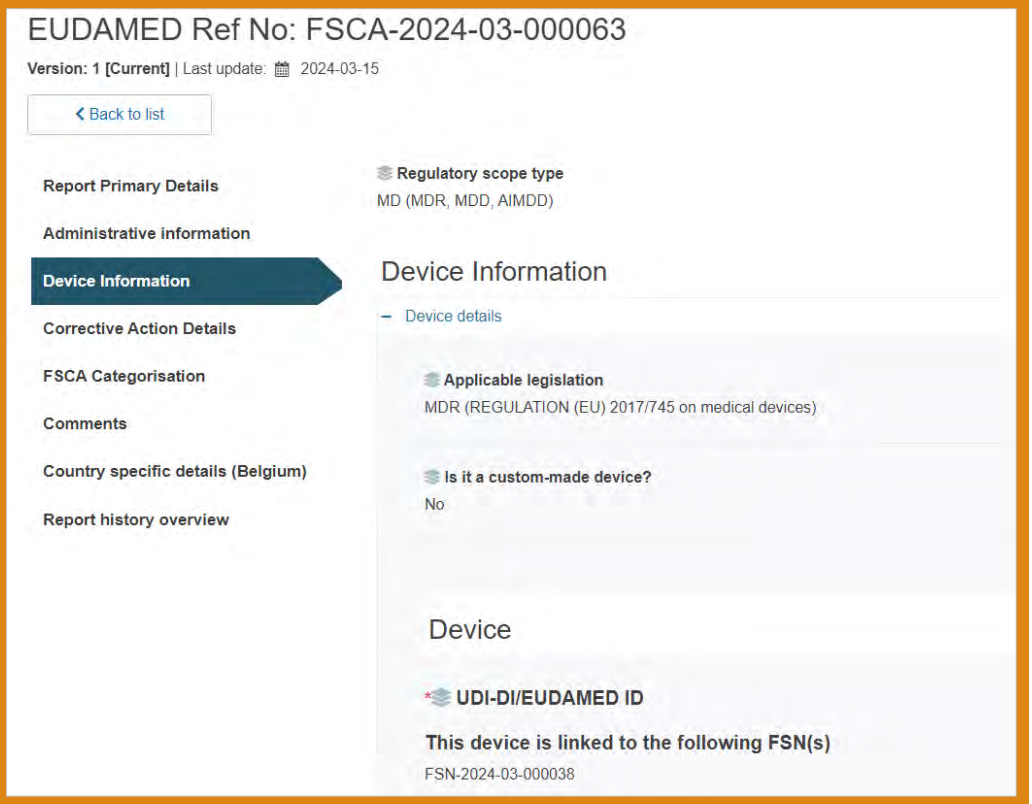
1. Having accessed the relevant FSCA on the default *Report Primary Details* screen via Search & view Vigilance items [149], click on **Create new version** at the top right corner:

2. Click on **Complete action** in the pop-up window, to confirm the initiation of a new FSCA version:

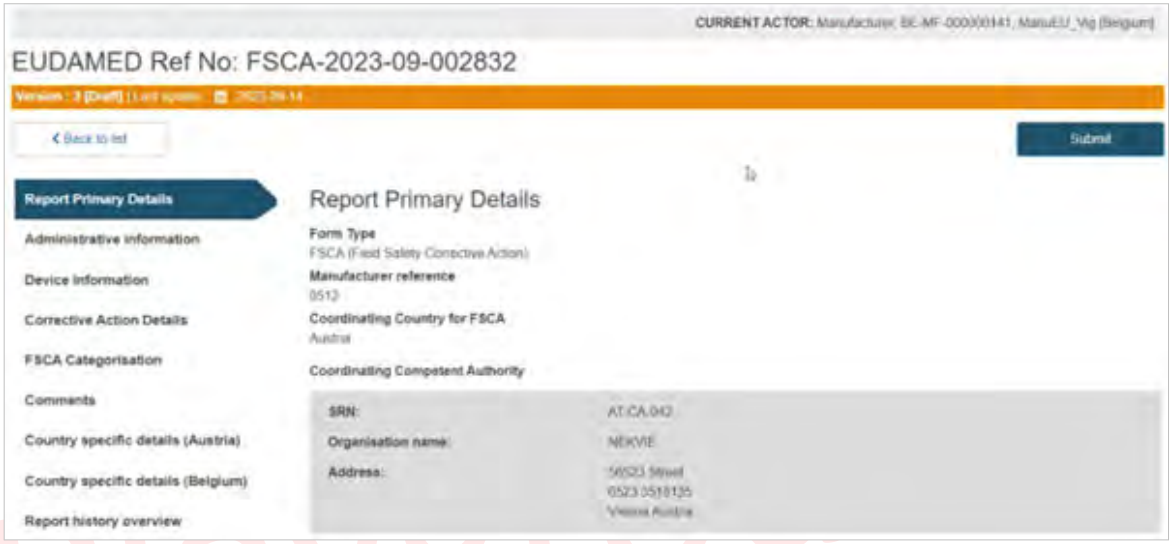
The applicable FSCA sections will become accessible for updates.

3. Modify the relevant fields selecting the appropriate sections from the list on the left, for example:

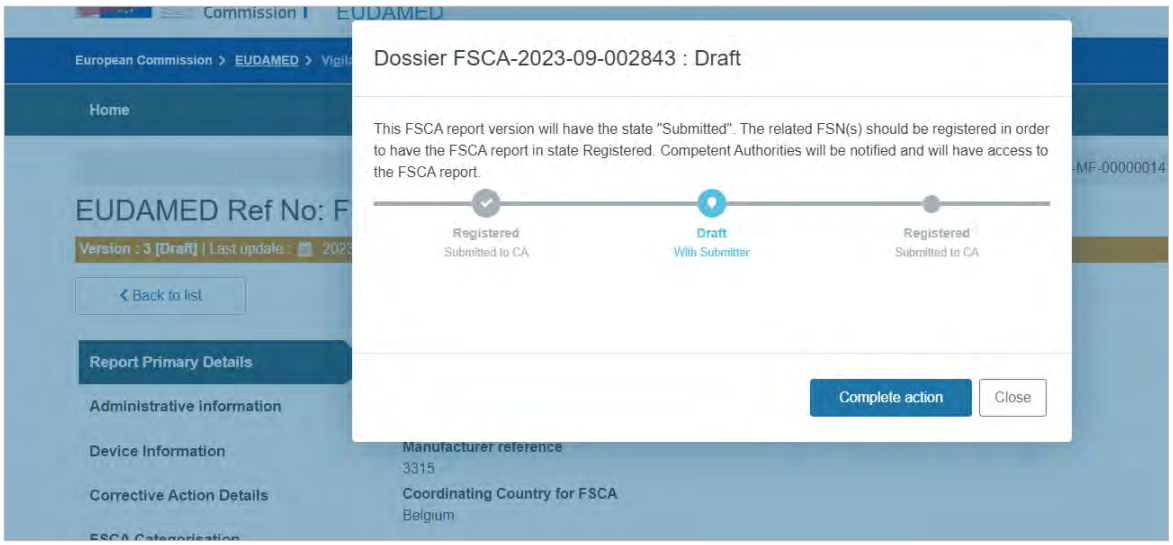
IMPORTANT
Under the *Device information* section you can see any FSNs linked to the current FSCA:



4. When you have made all necessary updates, click on the **Submit** button at the top right corner:

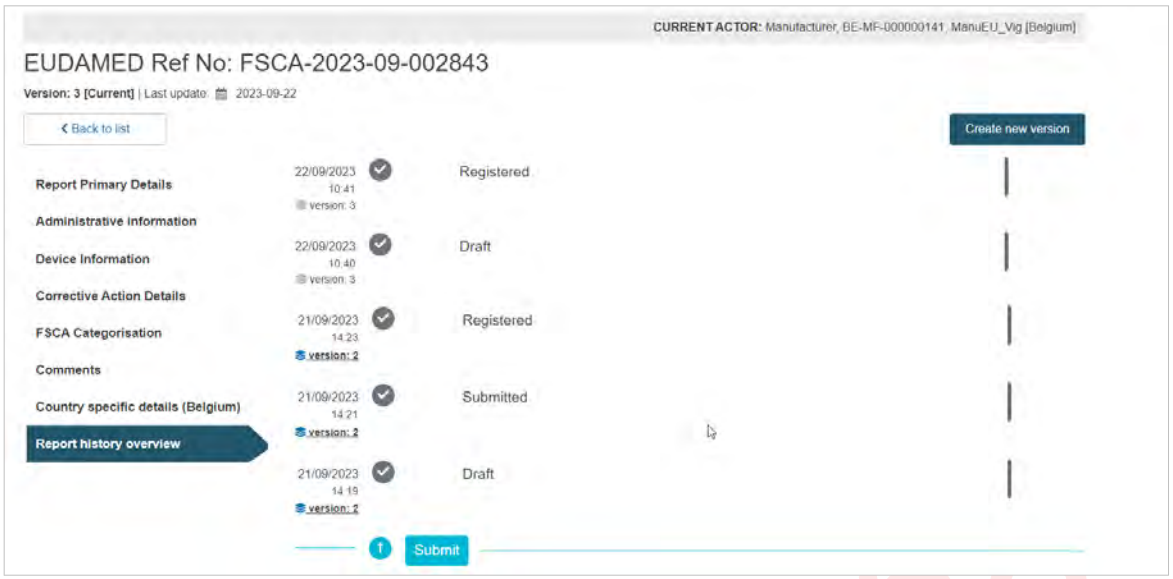


5. Click on **Complete action** in the pop-up window to finalise the action:



The system will save the new version, and the current version number will also be visible under the report's reference number:

The newly created version is shown in the *Action history overview* section:



NOTE

When creating a new FSCA version, CAs and NBs will receive a notification:

5 FSN

5.1 Register a new FSN

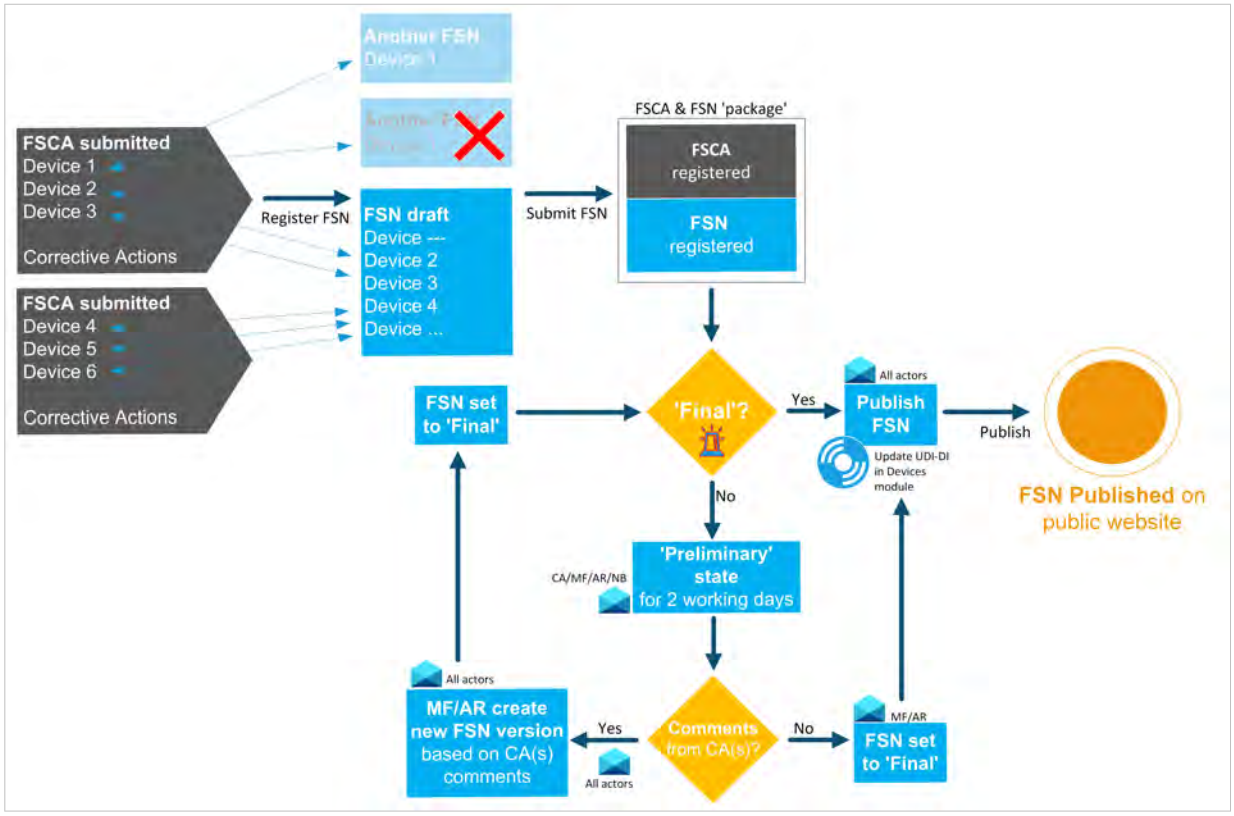
NOTE
Only Manufacturers and Authorised Representatives can access the menu for registering a new FSN report.

VIDEO: Register a new FSN

NOTICE
The following items are automatically retrieved from the FSCA and included in the FSN: *devices*, *affected countries* and their *CAs*, *corrective actions* to be performed.

Good to know: An FSCA with multiple devices can be linked to more than one FSNs, and an FSN can be linked to multiple FSCAs.

General process flow for an FSN



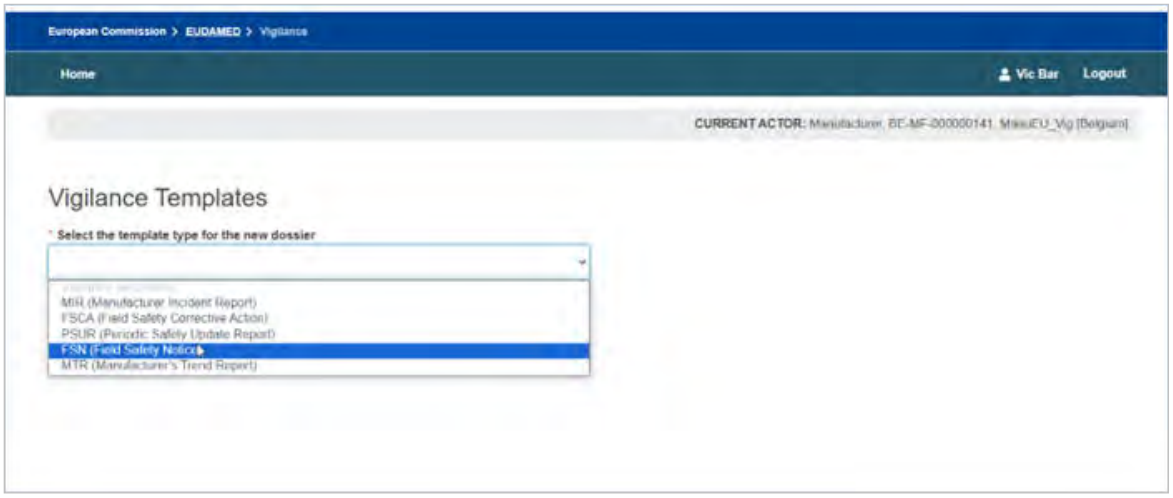
5.1.1 Step 0: Create initial FSN dossier

IMPORTANT
An FSN is always linked to at least one FSCA and can be created **only if** at least one of the FSCAs to be linked is in *submitted* state.

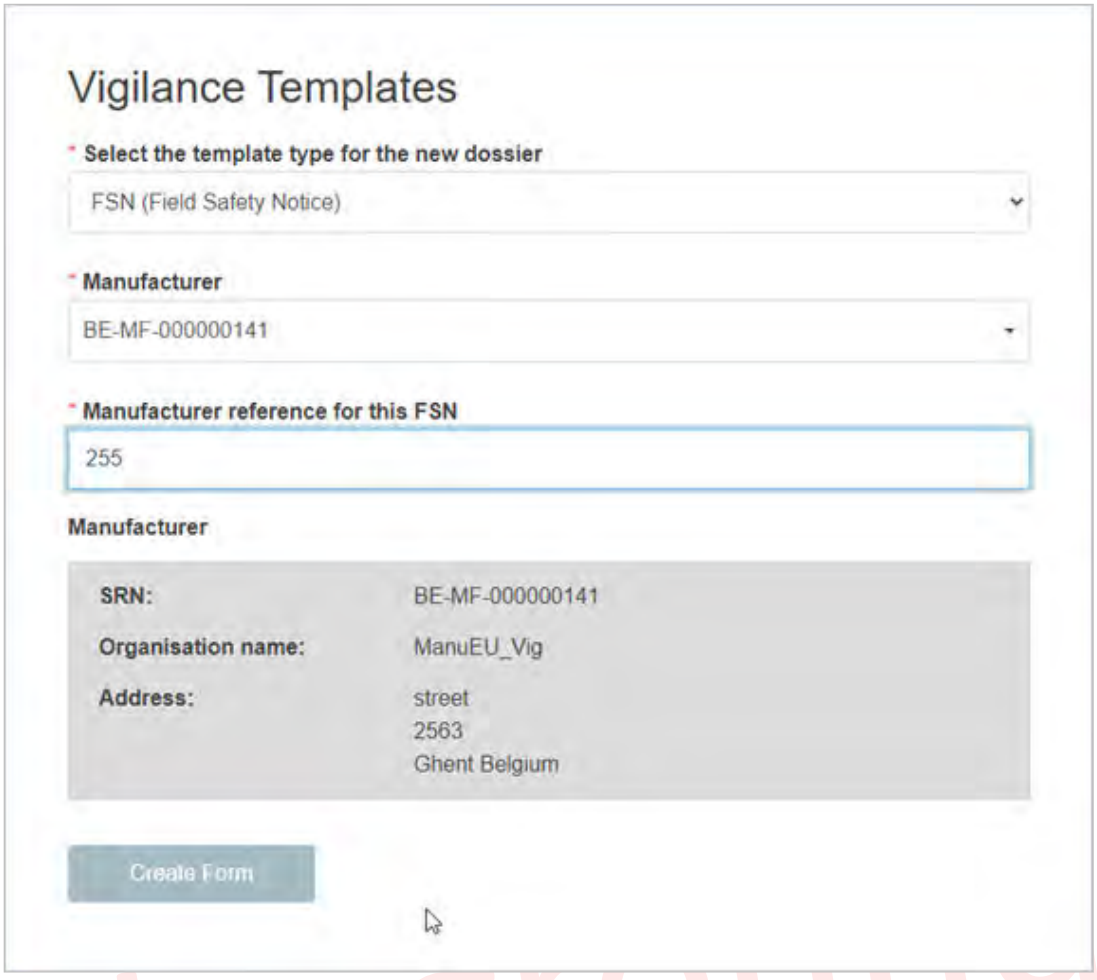
1. From the EUDAMED dashboard, click on *Register a new Vigilance Form* under the *Vigilance* section:

IMPORTANT
The information that you provide in step 0 **cannot be modified** after you click **Create form**.

2. Select *FSN* from the drop-down list of report templates:



3. Select the manufacturer Actor ID/ SRN in the *Manufacturer* field. The system will automatically retrieve the correct details:

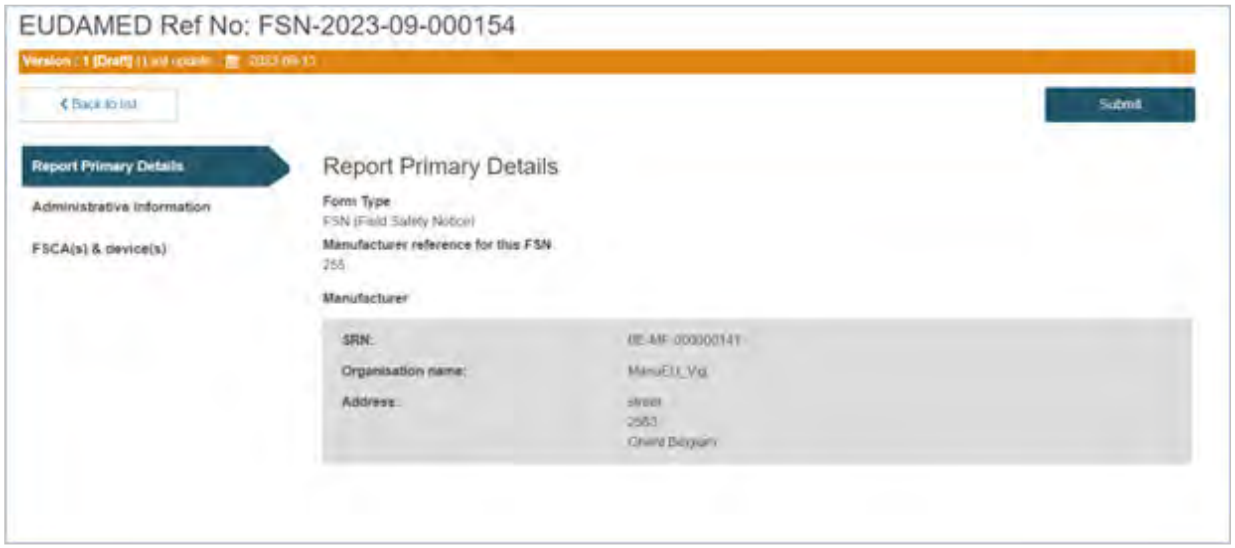


4. Provide the *Manufacturer's reference for this FSN* (uniquely used for this specific FSN).

5. Click on **Create Form**.

5.1.2 Step 1: Report primary details

The *Report primary details* screen provides an overview of the data entered in *Step 0* under the section *Report Primary Details*:



5.1.3 Step 2: Administrative information

1. On the *Administrative information* tab, select whether the FSN is *urgent* or *not urgent*:

IMPORTANT

To the question *Urgent FSN*, the MF/AR must select *Yes* or *No*.

- If *No*, you can only select FSN type *Preliminary*. For the next two days the FSN type cannot be modified into *Final*.
- If *Yes*, you can only select the FSN type *Final*.
- Attention: A *Final* FSN once submitted is directly publicly available.

Member States can provide comments to both FSN types without timeline constraints, but comments for a Preliminary FSN should be provided within two days.

2. The FSN date is mandatory only for *Final* FSN:

TIP
FSN date

- In case of a **new FSN registration**, FSN date is the date of submission of the newly registered FSN.
- In case of a **pre-existing FSN**(already registered), FSN date is the date of the latest saved FSN version.

5.1.4 Step 3: FSCAs and devices

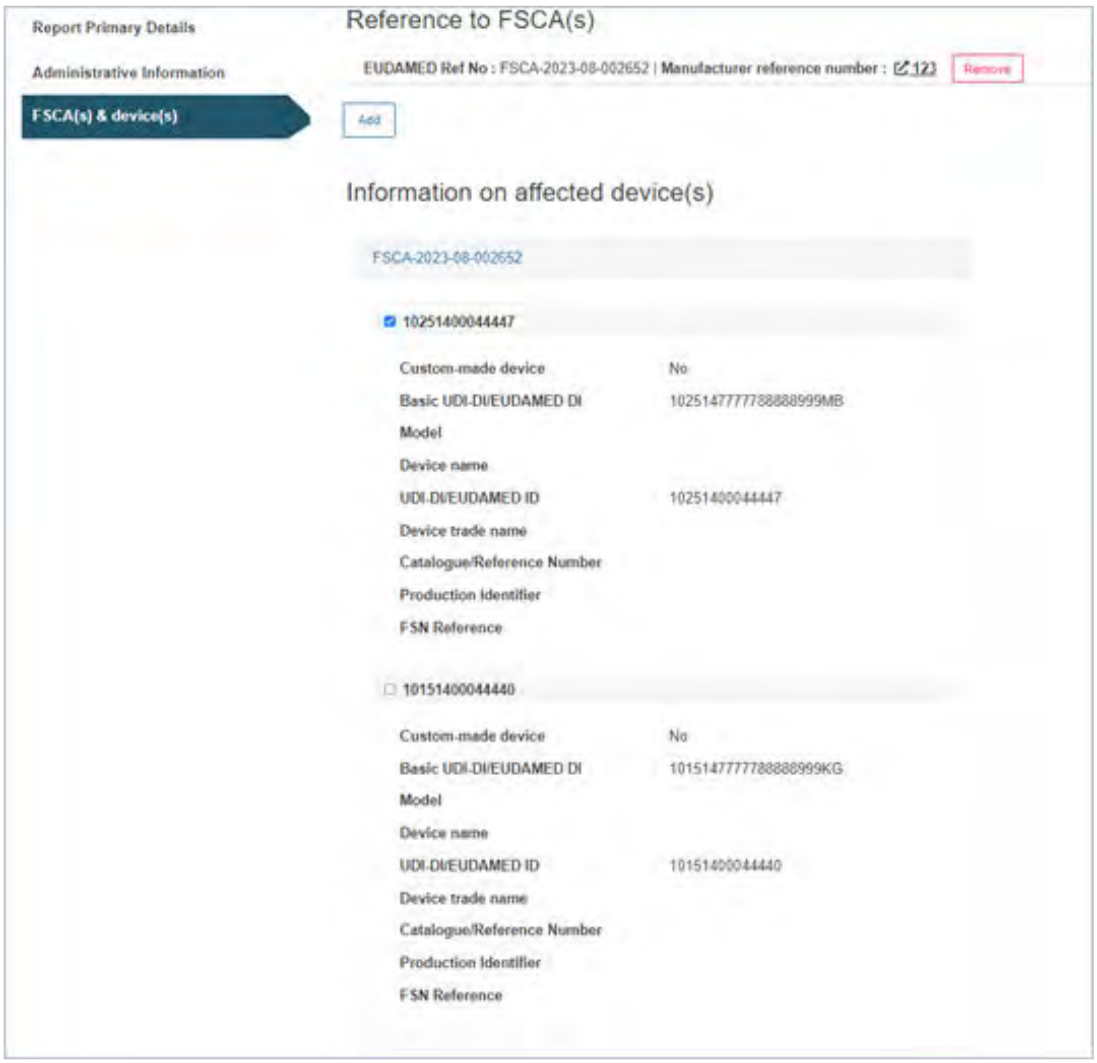
1. Provide any pertinent information relating to the current FSN inside *Further advice*:

2. Choose the FSCA(s) to be linked to the current FSN from the *Select the relevant Manufacturer reference* drop-down list.

TIP
The FSCA(s) to be selected from the drop-down must:

- be in *submitted* state (with no *draft* versions pending).
- contain **at least one device** not yet linked to another FSN (in *draft* or *registered* state).

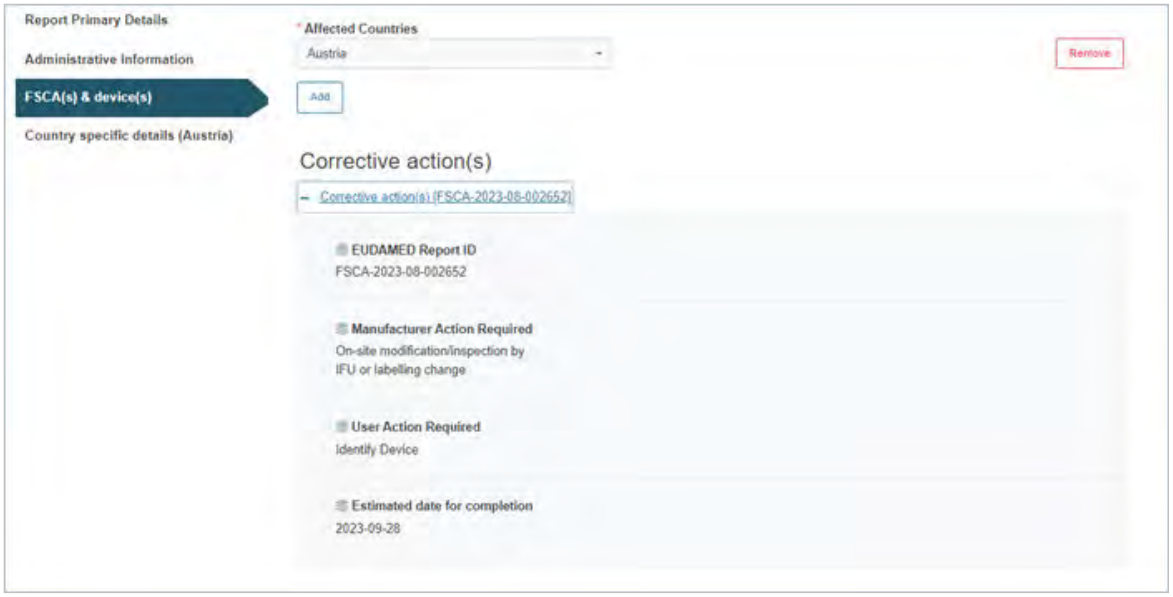
Once selected, the system will display the FSCA as a link and all the devices inside it:



3. Using the checkbox, select the affected devices.

> **TIP**
> Despite all devices inside the FSCA being visible, **the user can only select devices which are not already linked to other FSNs**. The devices already linked to other FSN(s) will be *greyed out*.

4. Select one or more affected countries using the **Add** button:

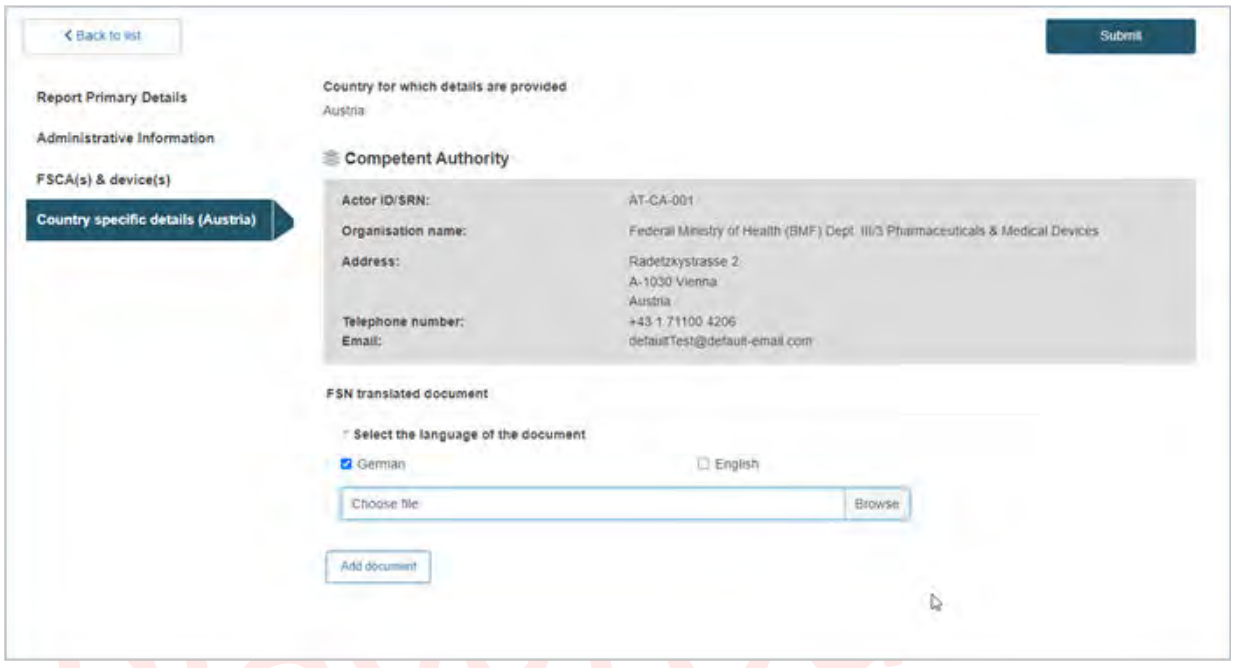


The system will retrieve the corrective actions.

NOTE
For each selected affected country, the system will create a separate *Country-specific details* tab.

5.1.5 Step 4: Country-specific details

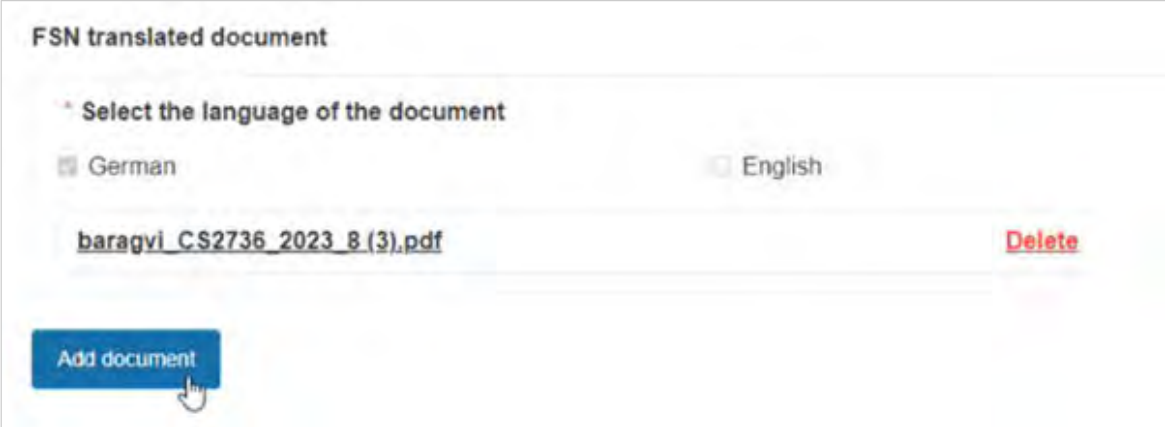
The system retrieves the Competent Authority details for each affected country:



1. In order to upload an *FSN translated document*, first select the document's language.

TIP
English is a default language option for all countries, in addition to other possible languages.

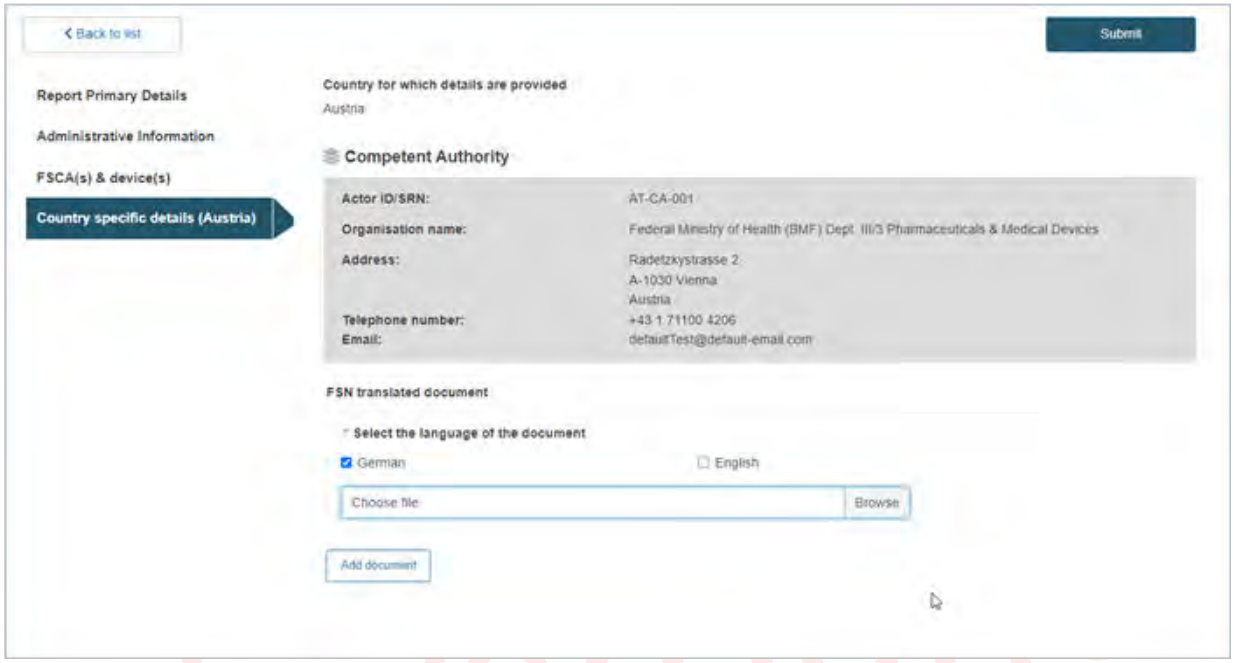
2. Click on **Browse** to upload the document:



3. Click **Add document** to provide more translations and repeat the process.

5.1.6 Step 5: FSN submission

After having completed all previous steps, click on **Submit** at the top right corner of the screen to submit the FSN:

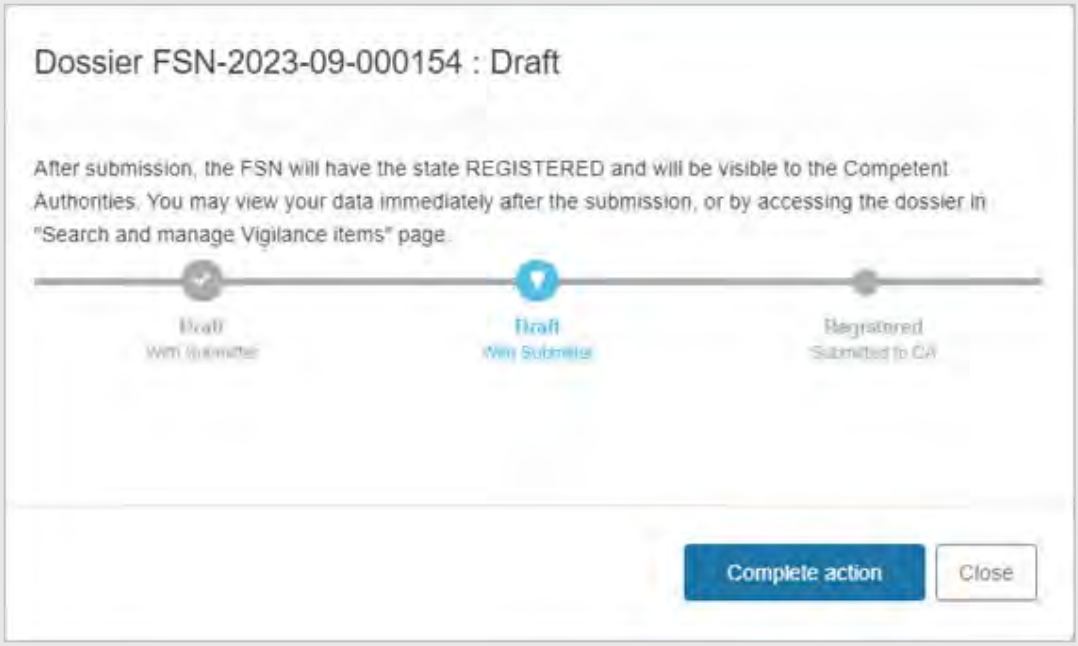


TIP
The system will confirm the submission via a pop-up dialogue box as follows:

1. **Preliminary FSN**: After submission, the *preliminary* FSN will be in *registered* state and visible to the Competent Authorities. CAs will be notified and will have **two days** to provide comments.

2. **Final FSN**: After submission, the *final* FSN will be in *registered* state and will also be publicly available on the public EUDAMED website. A sub-status for the referenced device(s) will be triggered (visible) in the EUDAMED Devices module.

IMPORTANT
You may either proceed with the submission (**Complete action** button) or cancel the submission (**Close**).



Notification after submission

After submission, notifications will be issued as follows:

1. **Preliminary FSN**: *action notification* to the referenced CAs and *information notification* to all EOs/NBs.

2. **Final FSN**: *information notification* to the referenced CAs and to all EOs/NBs.

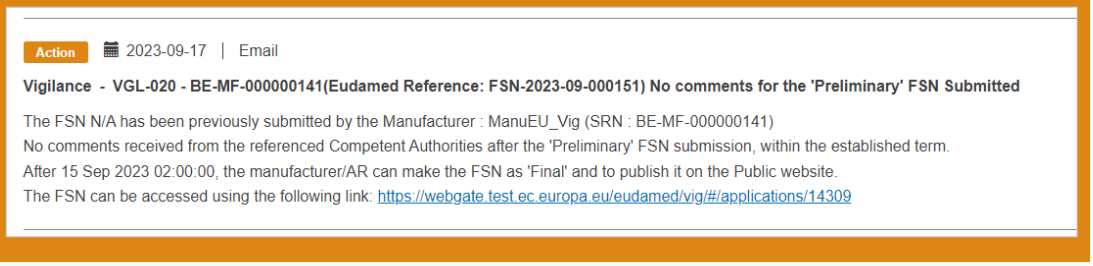
5.2 Manage FSN

5.2.1 Step 6: View & follow-up CA Comments

If the CAs provide comments to the Preliminary FSN, the FSN record will contain a new *Competent Authority comments* tab where the comments are visible.

IMPORTANT

If the CA(s) do not provide comments **within two working days** after the Preliminary FSN submission, the MF/AR will receive an action notification to change the FSN type from *preliminary* to *final*:



Having accessed the relevant FSN via *Search & View Vigilance items*, click on the *CA comments* tab on the left:

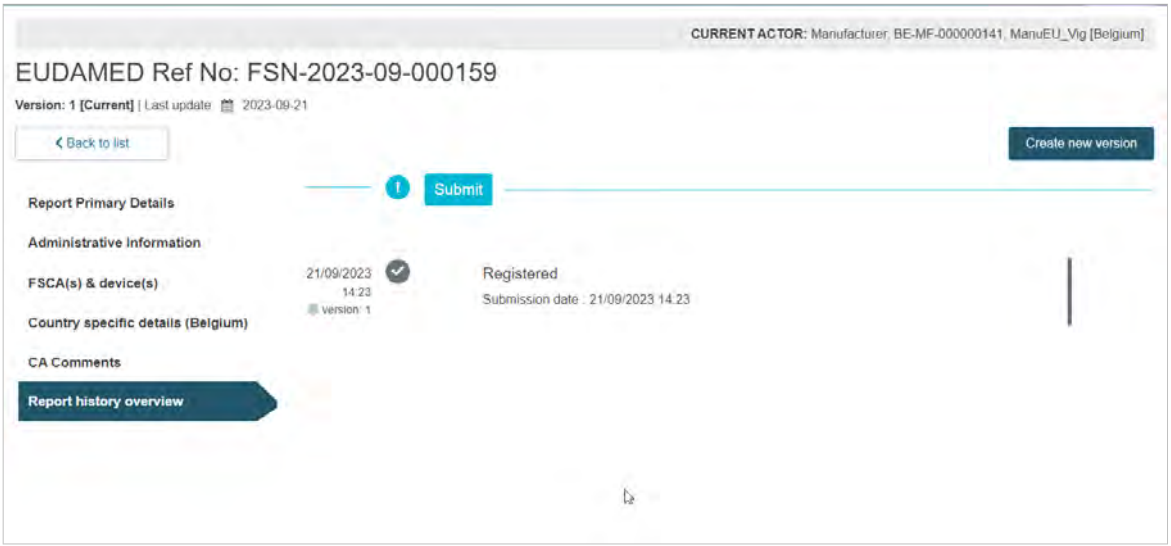
TIP

CA comment entries can also be viewed under the *Action history overview* tab, inside the relevant historical version.

5.2.2 Action history overview

Once an FSN has been submitted, you can view its historical versions under the *Action history overview* tab.

1. Access the relevant FSN from *Search & View Vigilance items*.
2. Click on the *Action history overview* tab on the left:



3. Inside this section, you can see all previous versions of this FSN, their date of creation and the report status and state.

5.2.3 Update FSN (create new version)

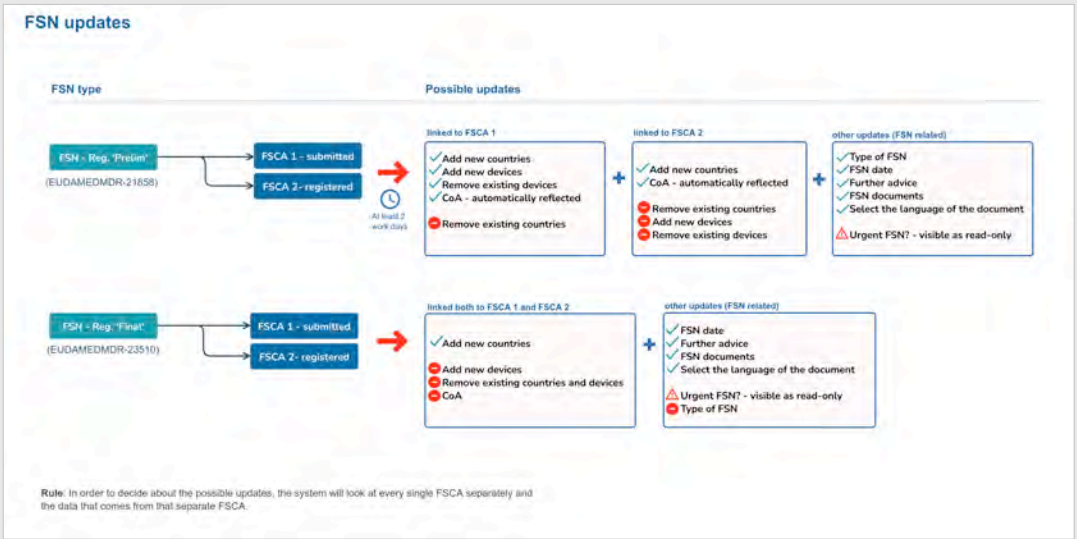
IMPORTANT
A new FSN version can only be created if:

1. there are no *draft* FSCAs linked to this FSN, **and**
2. **either** the FSN is *Final* and *registered*,
   or the FSN is *Preliminary* but **two working days** have elapsed since the Preliminary FSN submission.

TIP

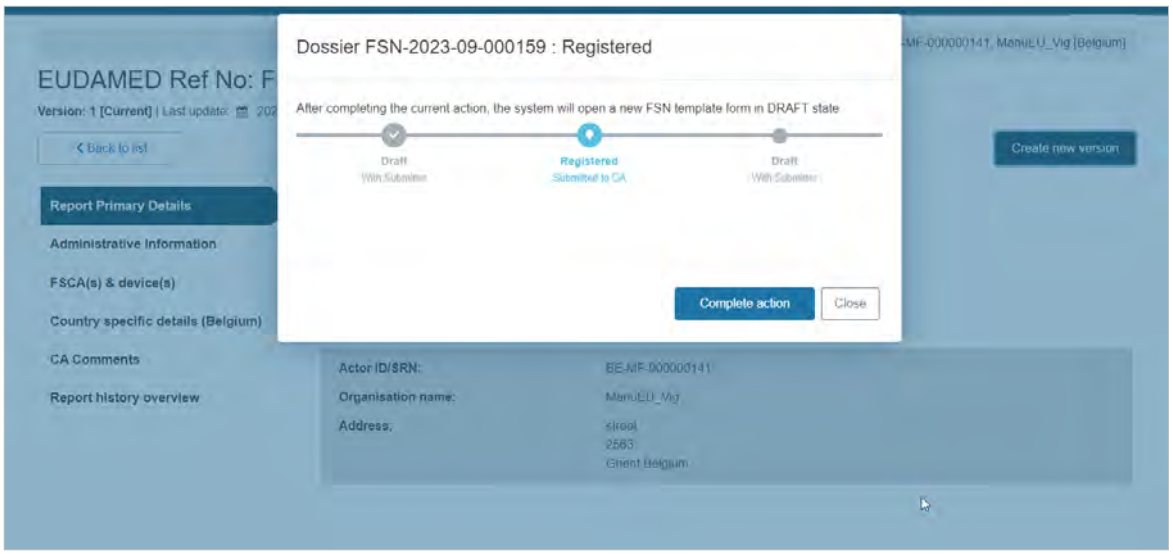
Due to the inter-dependence between FSCA and FSN, the available options when updating an FSN can vary.

Here is a cheat sheet of all possible updates depending on the FSN's type and linked FSCA variations:



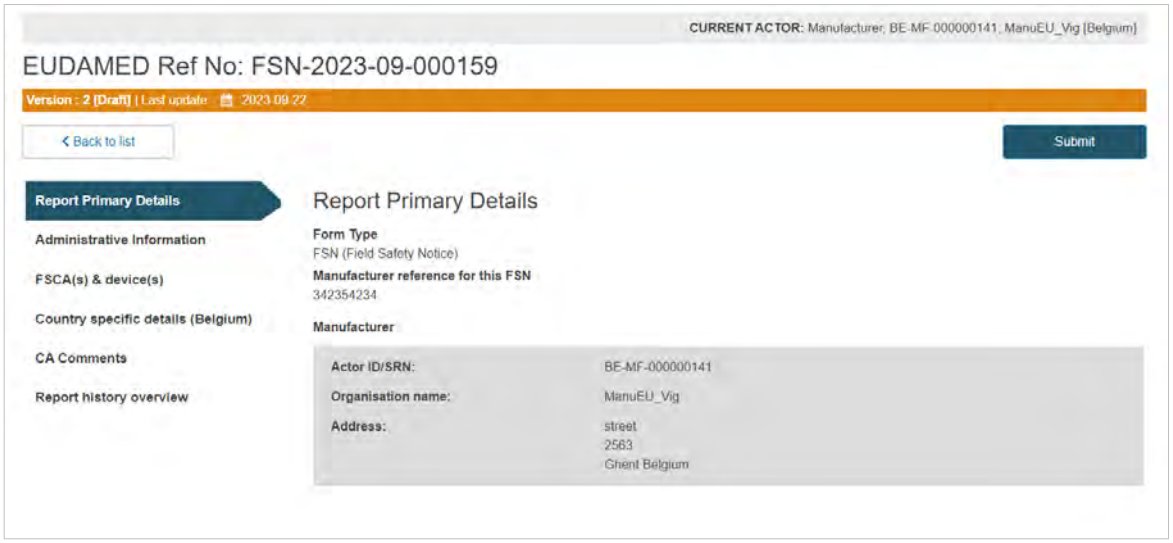
1. Having accessed the relevant FSN via Search & view Vigilance items [149], on the default *Report Primary Details* screen, click on **Create new version** on the top right corner:

2. Click on **Complete action** in the pop-up window, to confirm the initiation of a new FSN version:

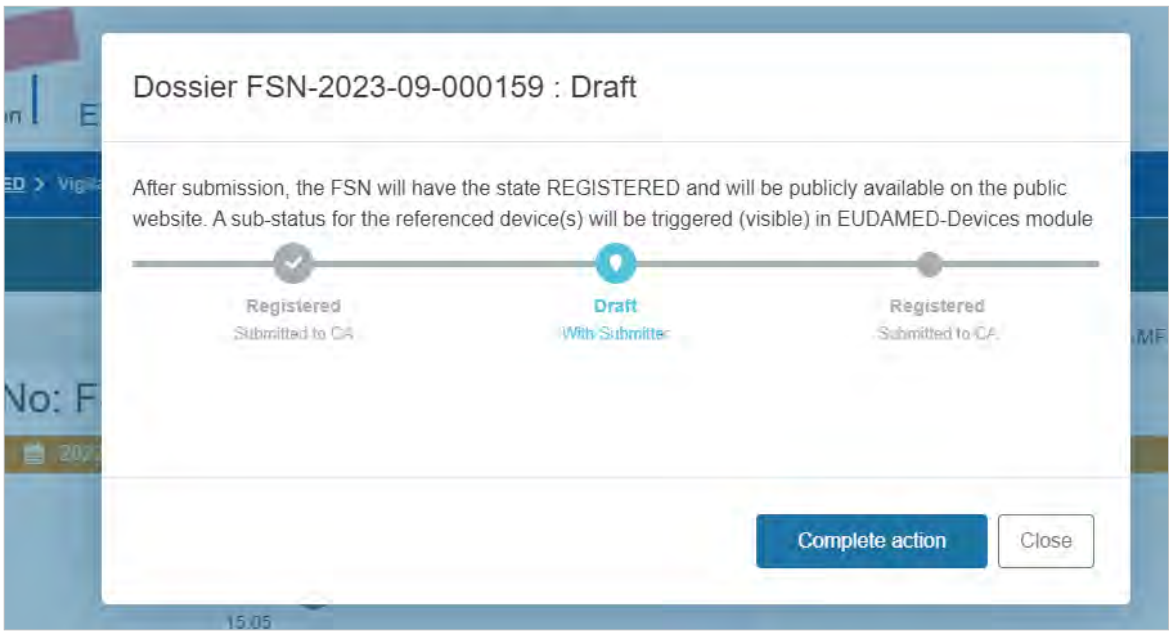


The applicable FSN sections will become editable.

3. After you have modified the appropriate sections, click on the **Submit** button at the top right corner:



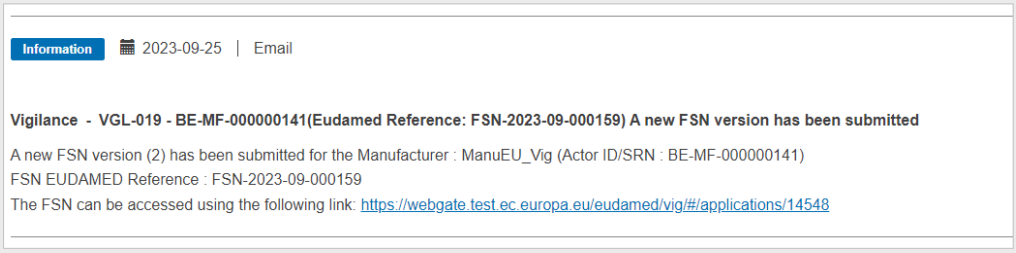
4. Click on **Complete action** in the pop-up window to finalise the action:



The newly created version is also shown in the *Action history overview* section.

NOTE

Following the creation of a new FSN version, CAs and NBs will receive a notification:



6 PSUR

6.1 Register a new PSUR

NOTE
Only Manufacturers and Authorised Representatives can access the menu for registering a new PSUR report.

6.1.1 Step 0: Create initial PSUR dossier

1. From the EUDAMED dashboard, click on *Register a new Vigilance Form* under the *Vigilance* section:

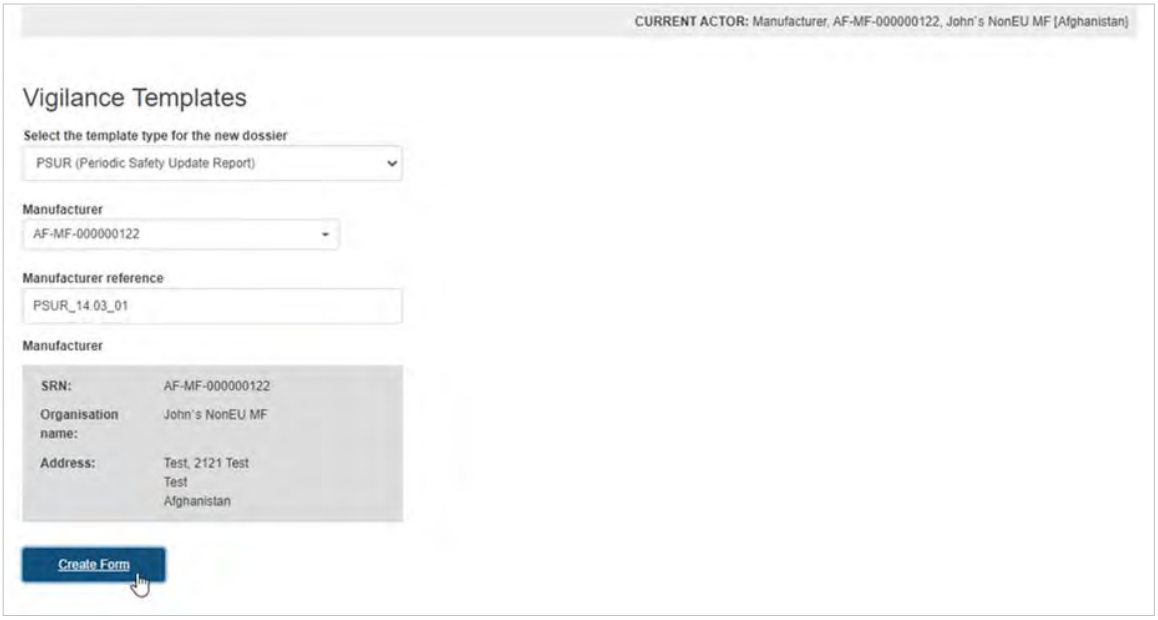
The system will redirect you to the *Vigilance Templates* screen.

2. Select the PSUR template from the dropdown list:

3. Select the manufacturer from the appearing *Manufacturer* field:

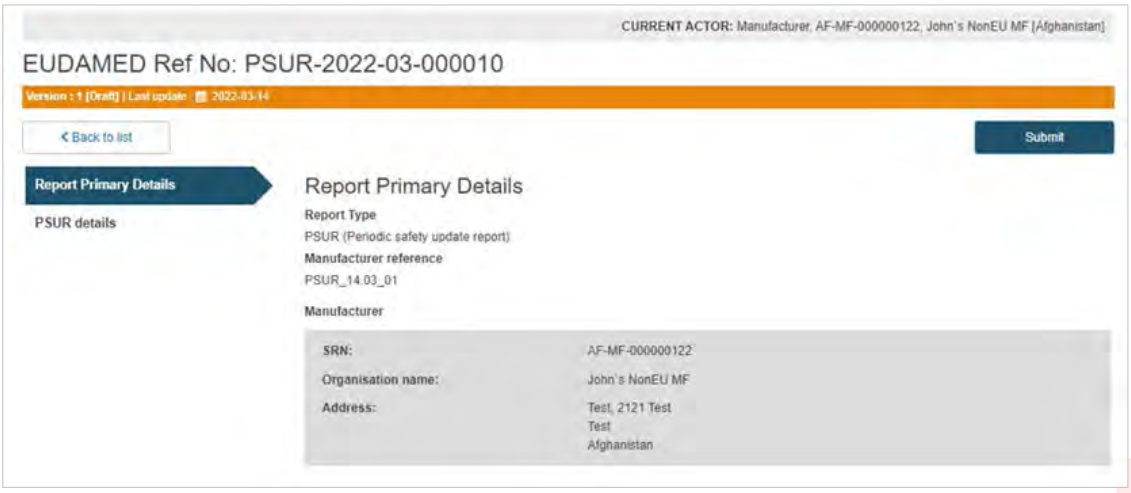
The system will automatically retrieve your Actor ID/SRN.

4. Provide the unique Manufacturer reference in the next field and click on **Create Form**, to complete this initial step:



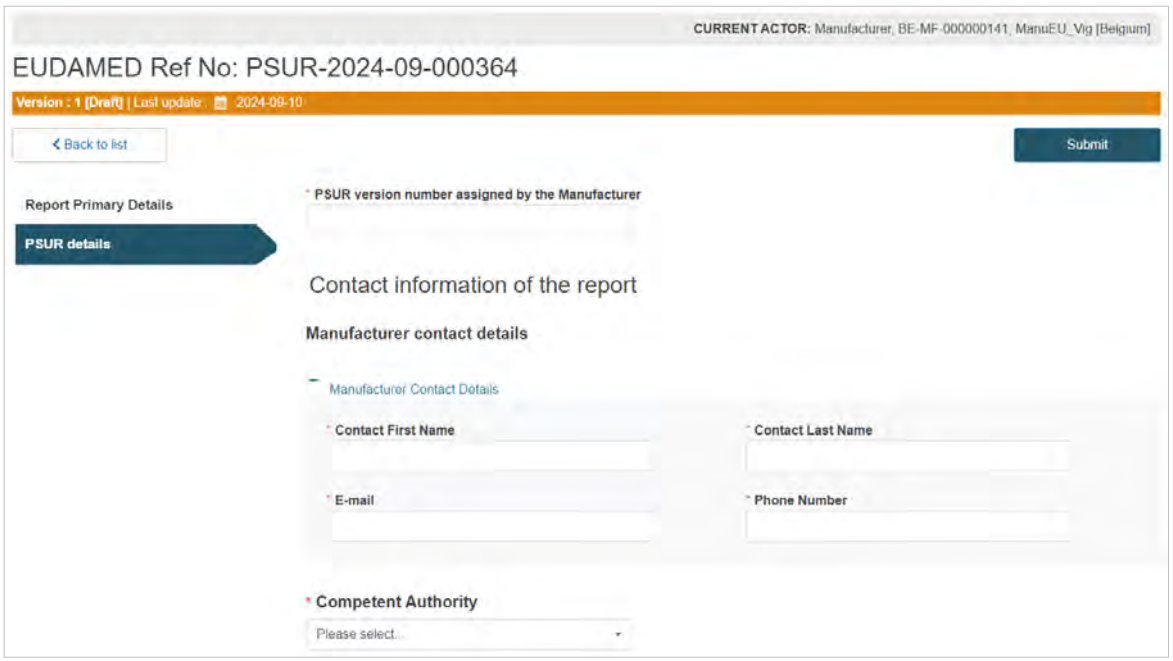
6.1.2 Step 1: Report primary details

The next screen provides an overview of the data entered under the section *Report Primary Details*:

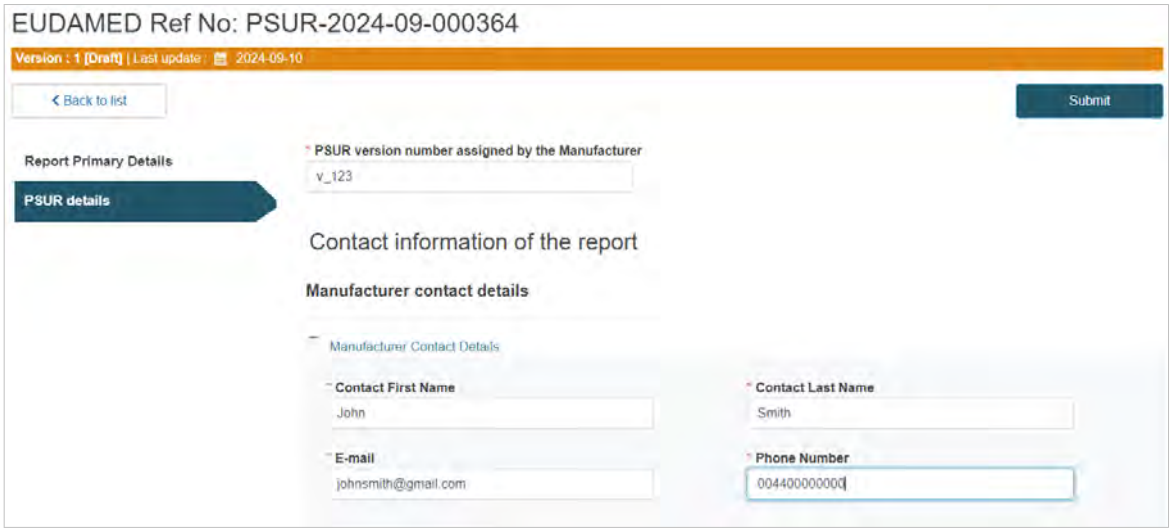


6.1.3 Step 2: PSUR details / Submission

1. Click on the *PSUR details* tab from the menu on the left:

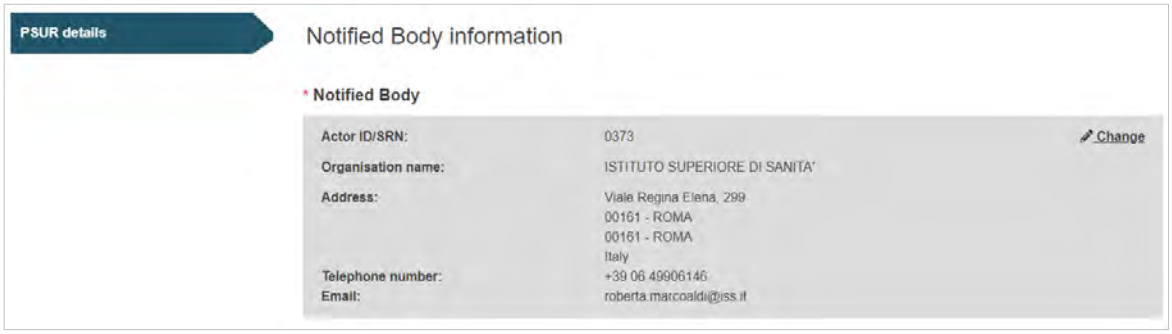


2. Enter the *PSUR version number assigned by the Manufacturer* and fill in the *Manufacturer contact details*:

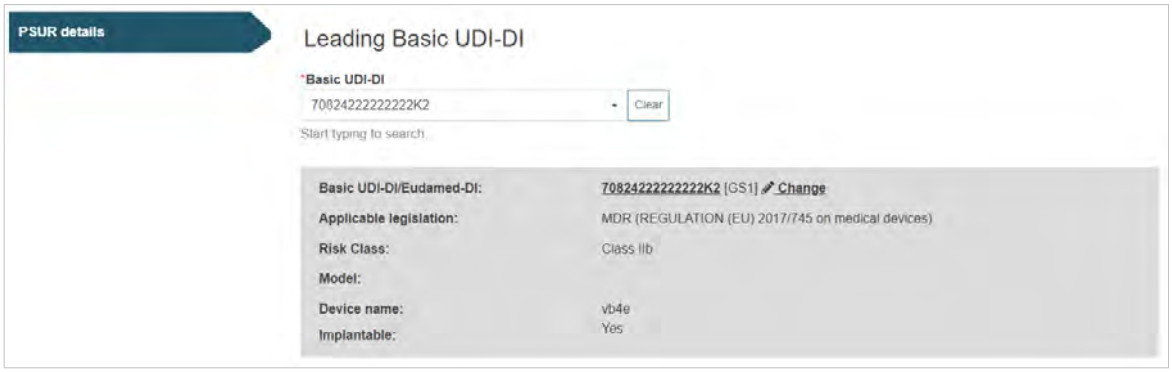


3. Select the Competent Authority in the manufacturer's place of business from the dropdown (this CA will receive notifications regarding this PSUR):

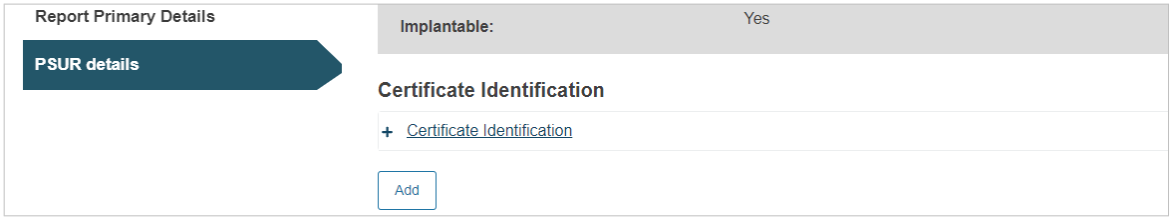
4. Select the Notified Body which will provide an evaluation for this report from the dropdown:



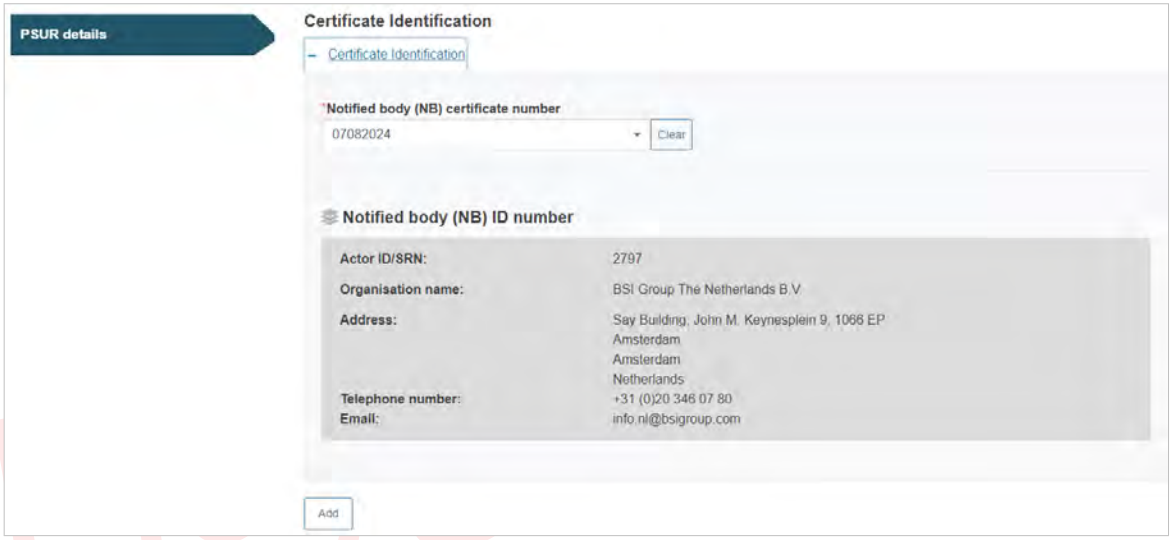
5. Select the *Basic UDI-DI* for the *Leading Basic UDI-DI* for the current PSUR:



6. Click on the *plus* sign next to *Certificate Identification* to access the fields for completion:

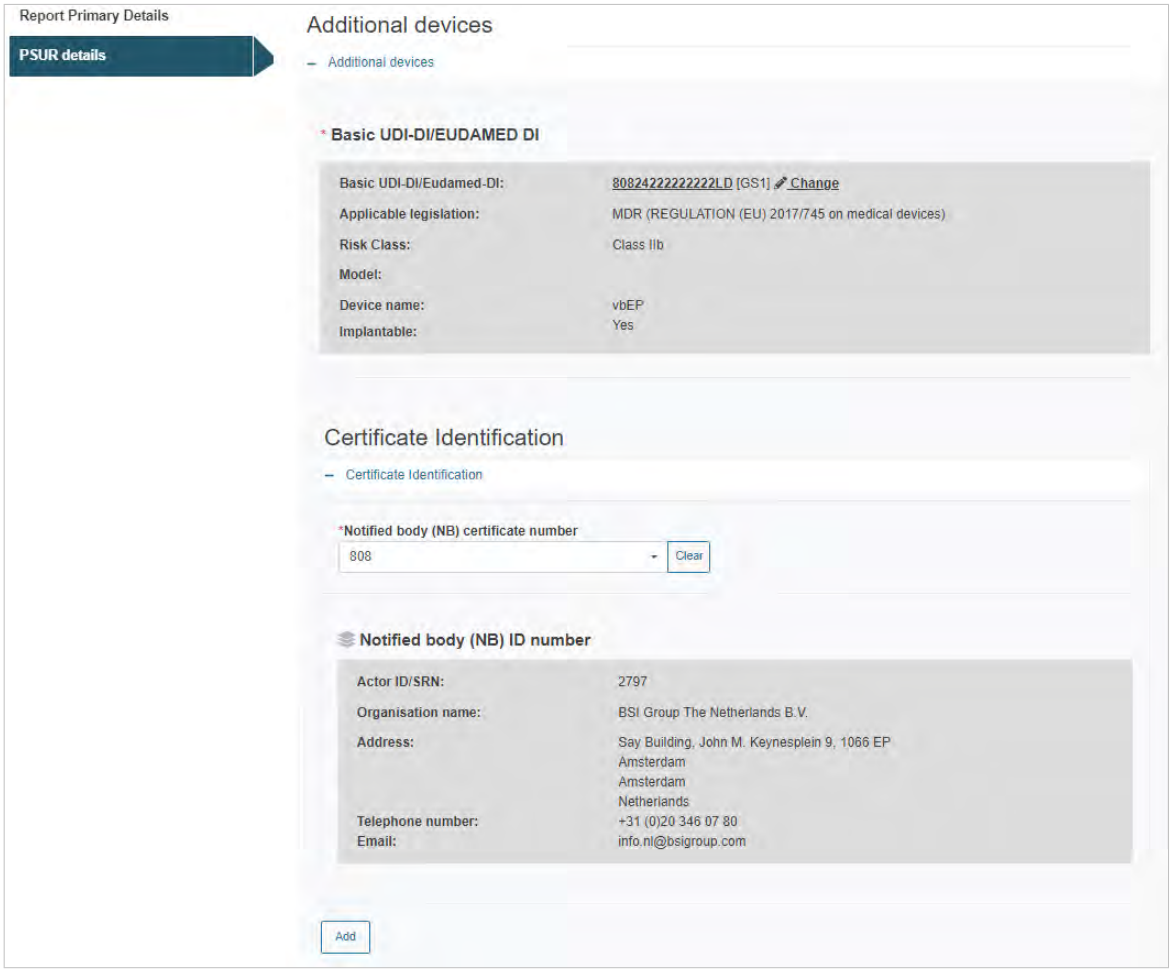


7. Fill in the *Notified Body details* and the NB certificate number in the text box below:

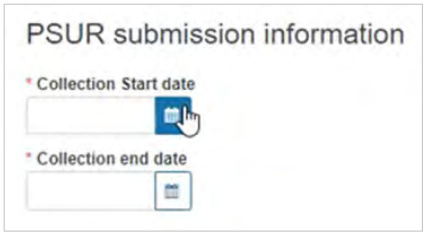


TIP
If the device has a certificate linked to it, the user will be able to select the certificate number from the drop-down and the system will auto-display the NB ID number. Otherwise the user may fill in the info manually.

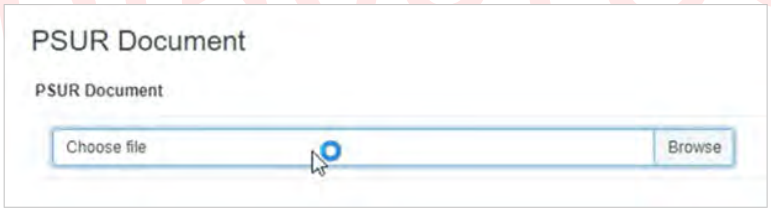
8. If other devices apply to the current PSUR, fill in the *Additional Devices* section:



9. Fill in the PSUR collection dates:



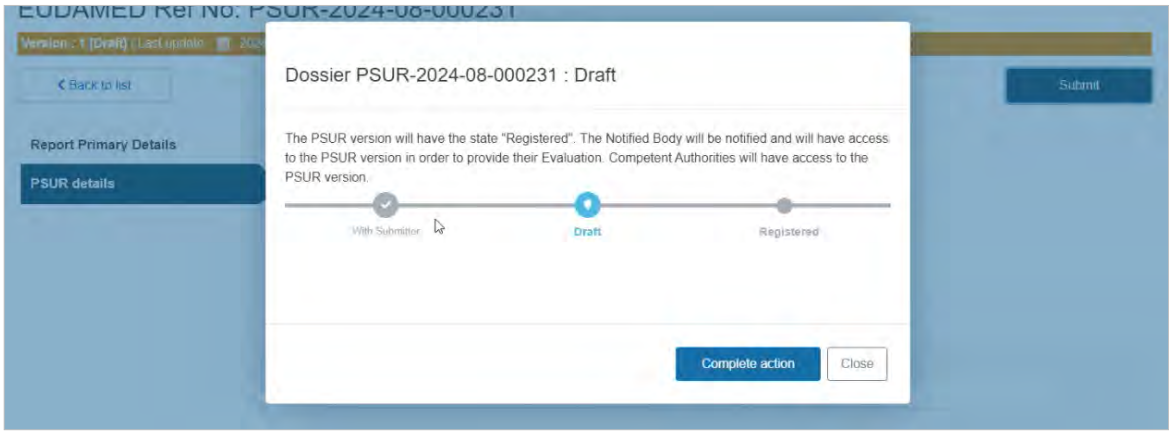
10. Click on **Browse** to upload the PSUR document in PDF format:



11. **Submission**

Click the **Submit** button on the top right corner, to submit the PSUR:

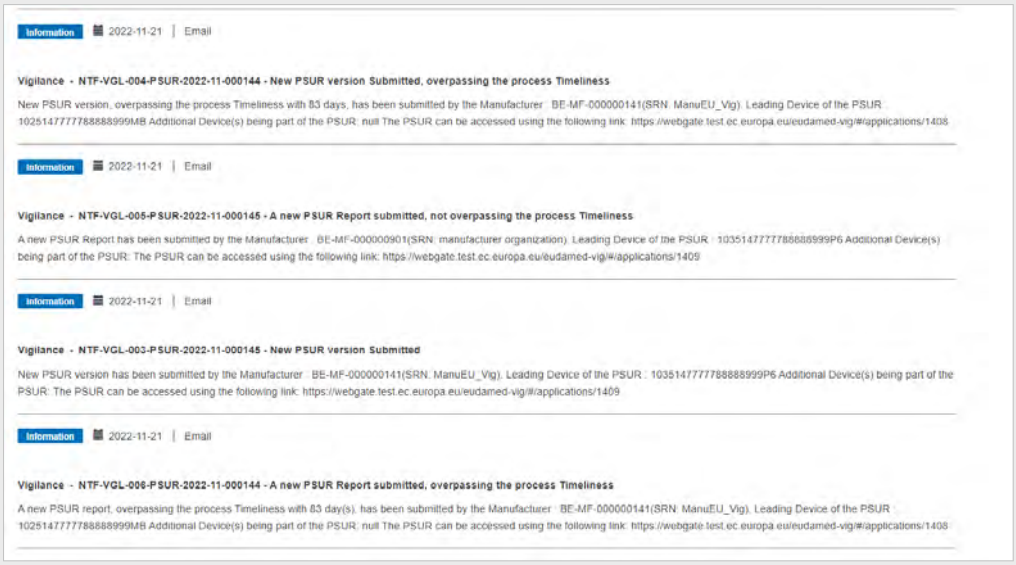
12. Click **Complete action** in the pop-up window to finish the process:



The system will redirect you to the *Report Primary Details* screen of the submitted PSUR in preview mode.

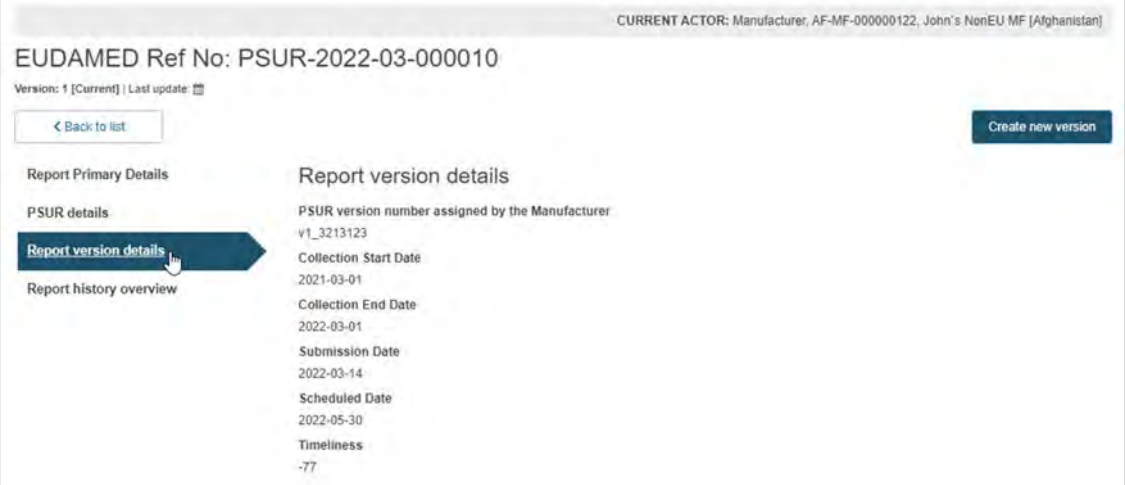
NOTE

After submitting a PSUR or creating a new version, for users with LAA profile only, CAs and NBs referenced in the report will receive a notification in their *Notifications inbox* (*Information* tab):



6.1.4 Report version details

After a PSUR has been registered, a new section called *Report version details* appears in the menu on the left:



IMPORTANT
The PSUR needs to be submitted 90 days after the Collection end date.

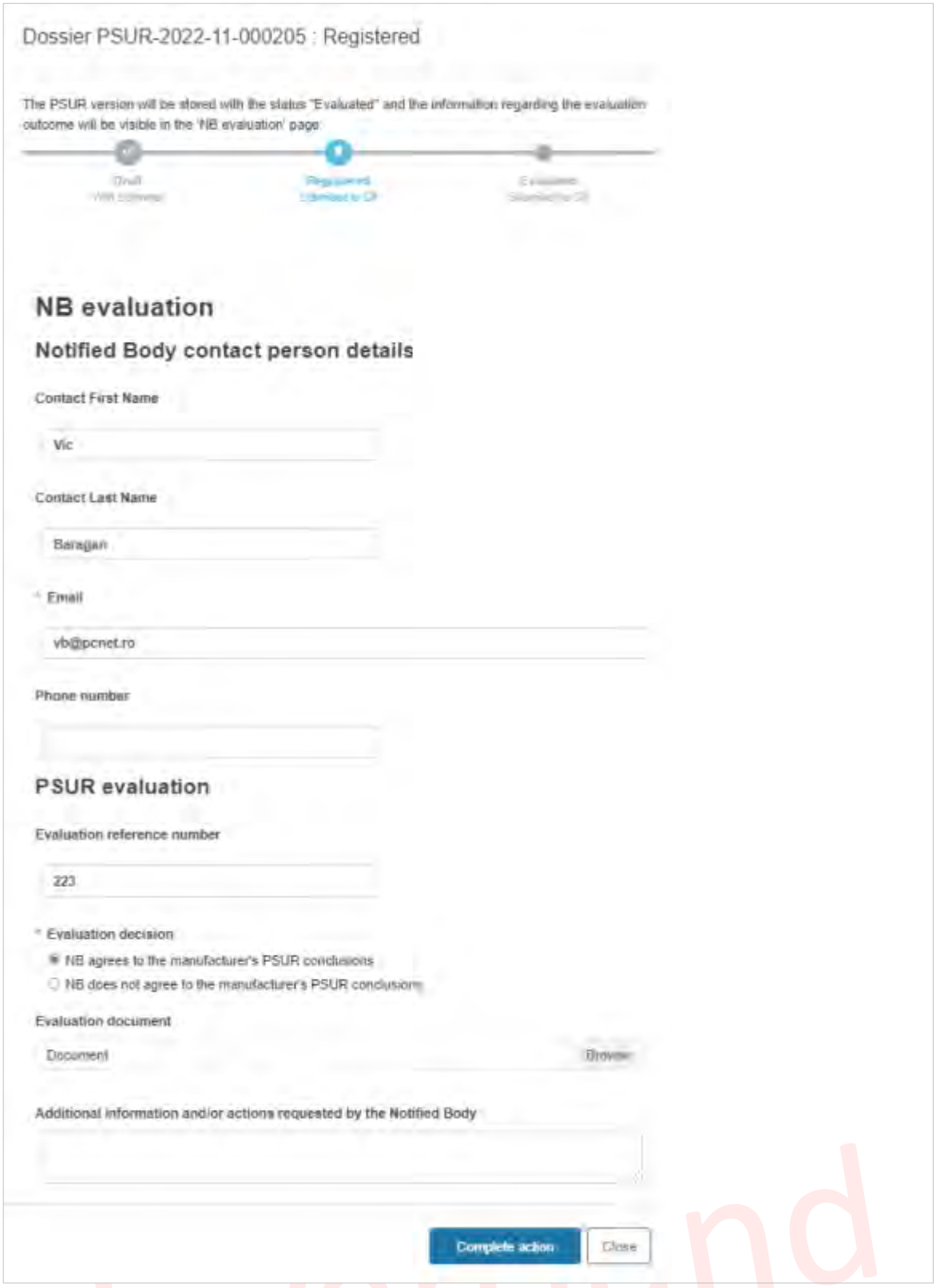
NOTE
Timeliness concept: Depending on how this timeline is followed, the timeliness score will also be affected accordingly (e.g. -77 days indicates a submission 77 before the *Collection end date* and within the deadline, whereas +5 days indicates an overdue submission 5 days after the *Collection end date*).

6.2 NB evaluation

After a PSUR has been registered following the previous steps, the NB referenced in the PSUR report can start the evaluation process.

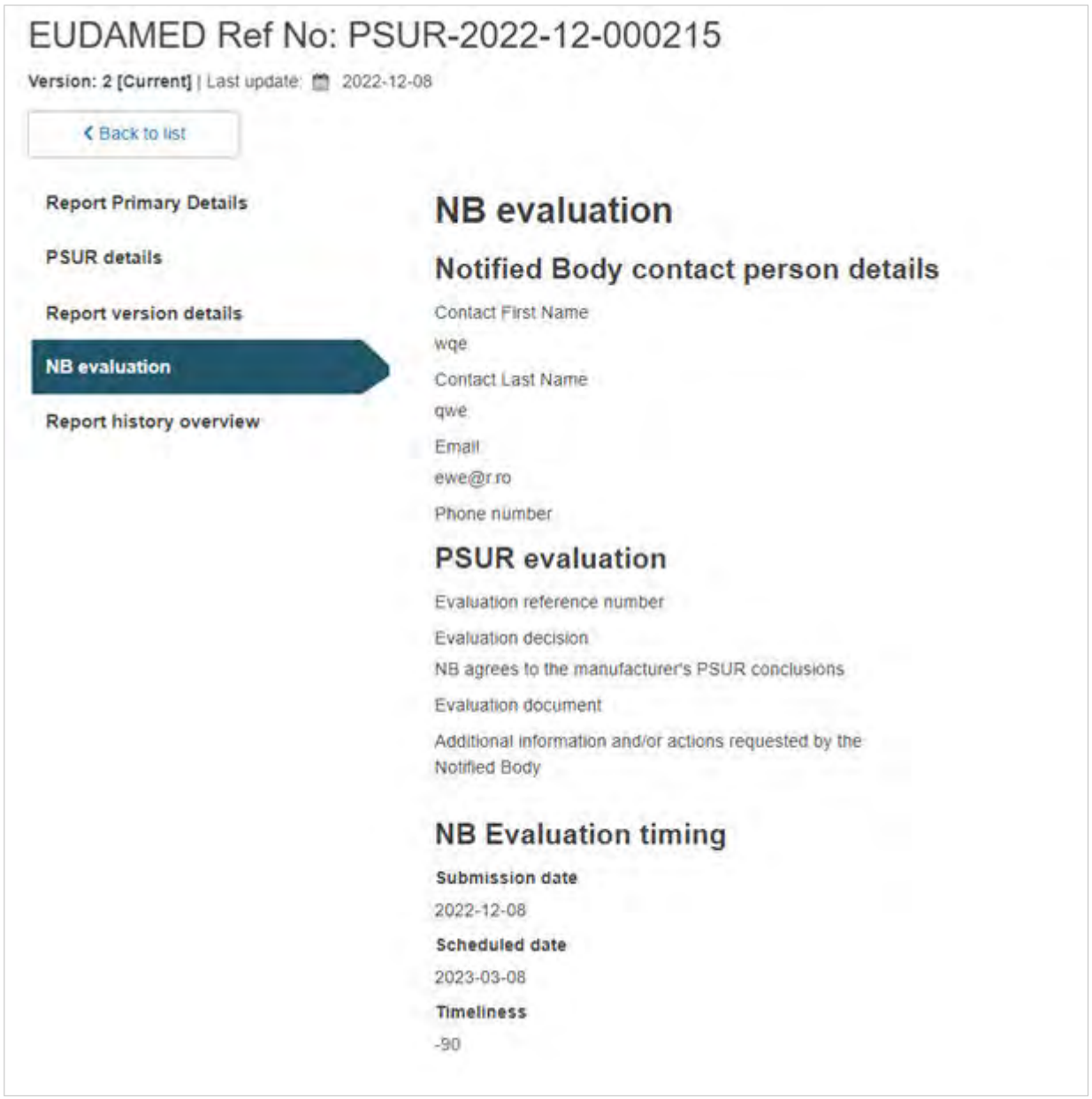
1. Click on **Provide Evaluation**:

2. In the pop-up window fill in the required fields and press **Complete action** to finish the process:



NOTE
Regarding the *Evaluation decision* field, if you select *NB does not agree to manufacturer's PSUR conclusions*, the uploading of a document in the *Evaluation document* field is **mandatory**.

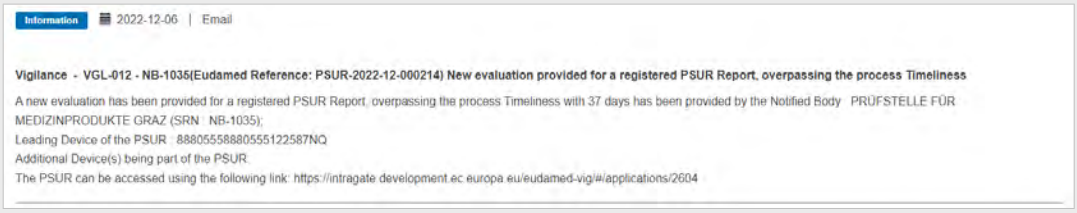
The PSUR report will be stored with a status *evaluated*. In the next screen you can see the outcome of the evaluation as well as some useful information regarding the NB evaluation timeliness of this report:



NOTE

After providing an NB evaluation within the deadline, for users with LAA profile only, the NB referenced in the PSUR report, and the MF assigned to the PSUR report will receive a notification in their *Notifications* inbox (*Information* tab):

After providing an overdue NB evaluation, for users with LAA profile only, the NB referenced in the PSUR report, the MF assigned to the PSUR report as well as the CA selected in the PSUR report will receive a notification in their *Notifications* inbox (*Information* tab):



7 MTR

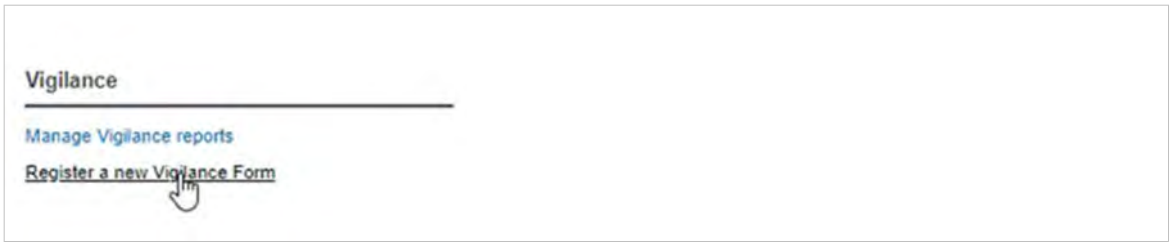
7.1 Register a new MTR

NOTE
Only Manufacturers and Authorised Representatives can access the menu for registering a new MTR report.

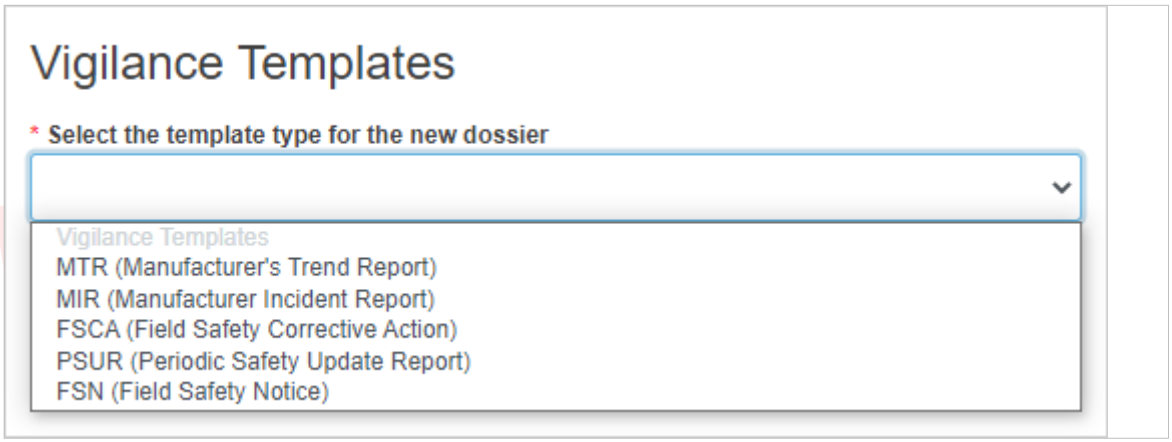
VIDEO: Create Manufacturer Trend Report

7.1.1 Step 0: Create initial MTR dossier

1. On the EUDAMED dashboard, click on *Register a new Vigilance Form* under the *Vigilance* section:

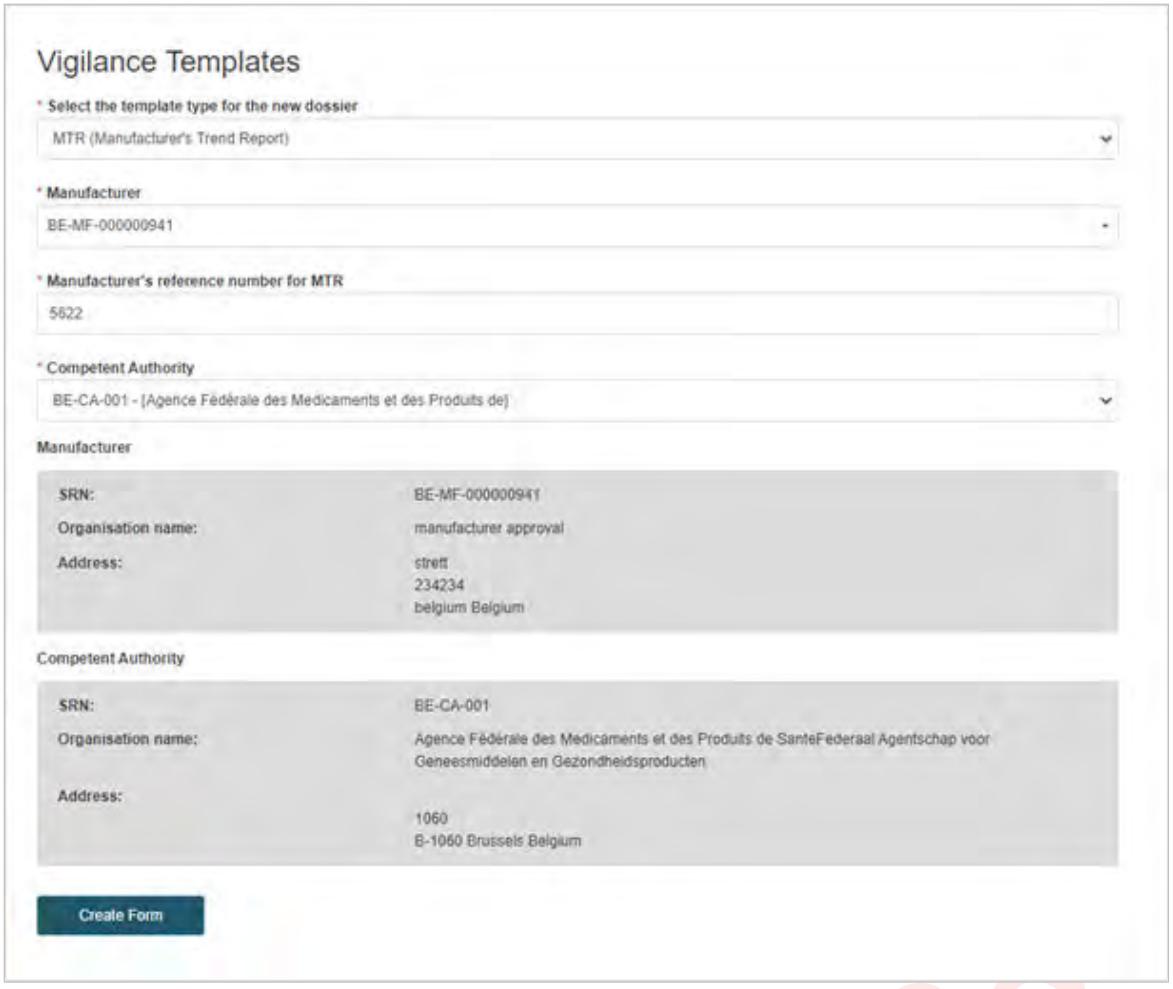


2. Select the MTR template from the dropdown list:



3. Select the manufacturer from the *Manufacturer* field. The system will automatically retrieve your Actor ID/SRN:

4. Enter the unique *Manufacturer reference* and select the *Competent Authority* from the drop-down list:

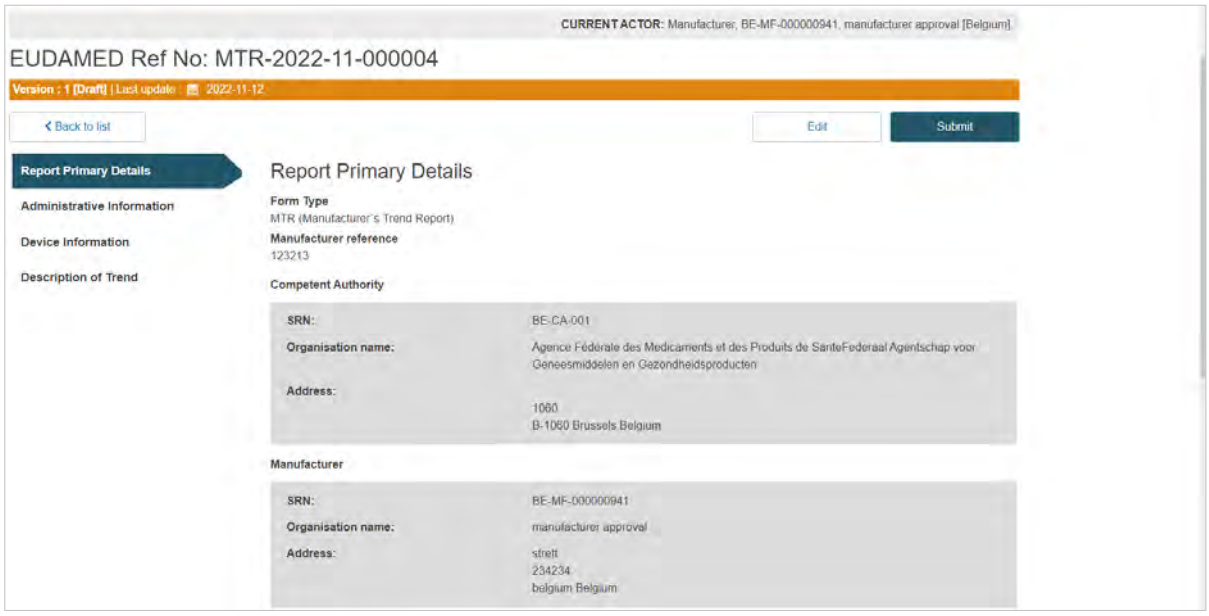


5. Click on **Create Form** to complete this initial step.

IMPORTANT
The information provided in this step cannot be modified after you click **Create form**.

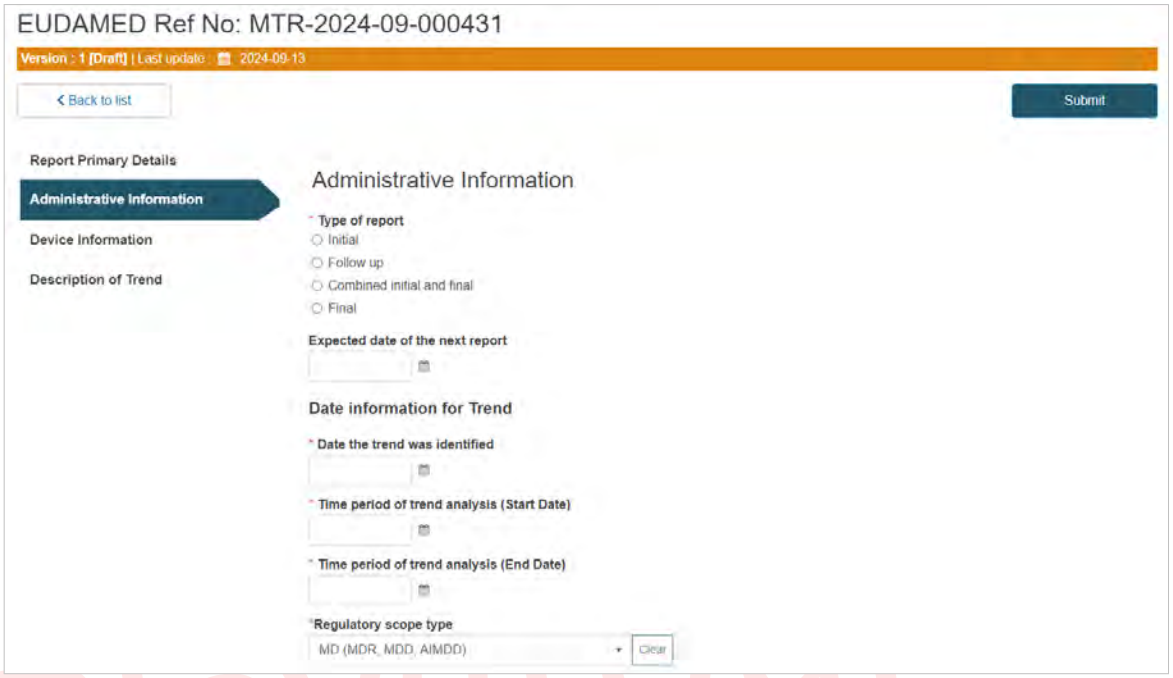
7.1.2 Step 1: Report primary details

The next screen provides an overview of the data entered under the section *Report Primary Details*:

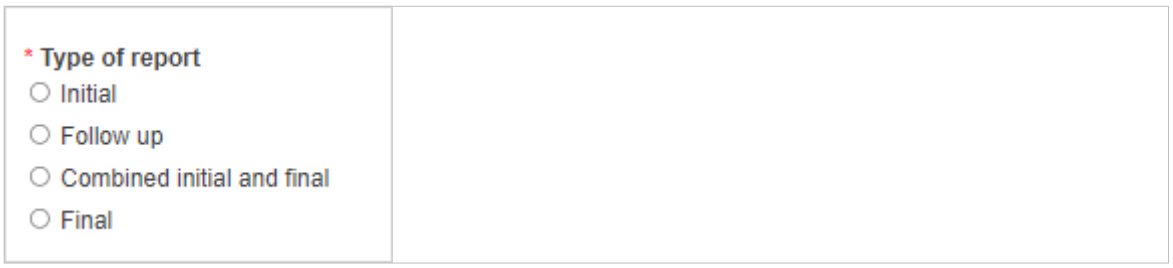


7.1.3 Step 2: Administrative information

1. Click on *Administrative Information* from the menu on the left to access the section:

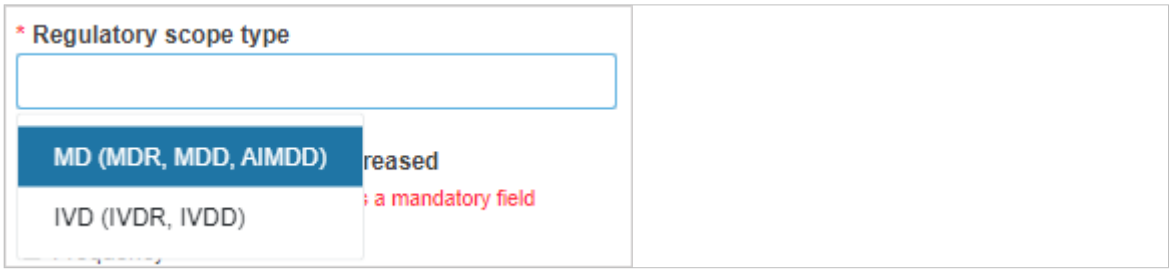


2. Choose the type of the report:

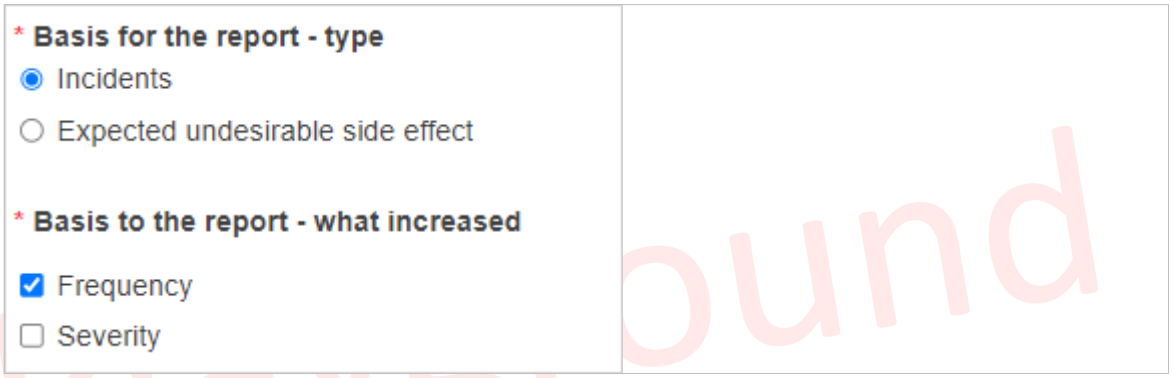


3. Fill in the expected date of the next report and all the relevant dates:

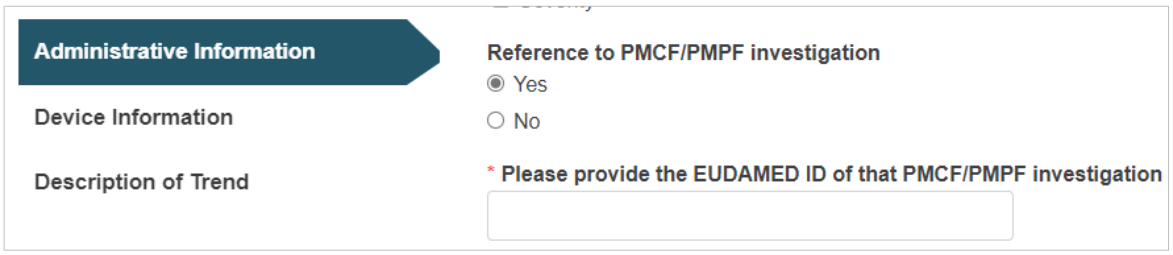
4. Select the applicable legislation:



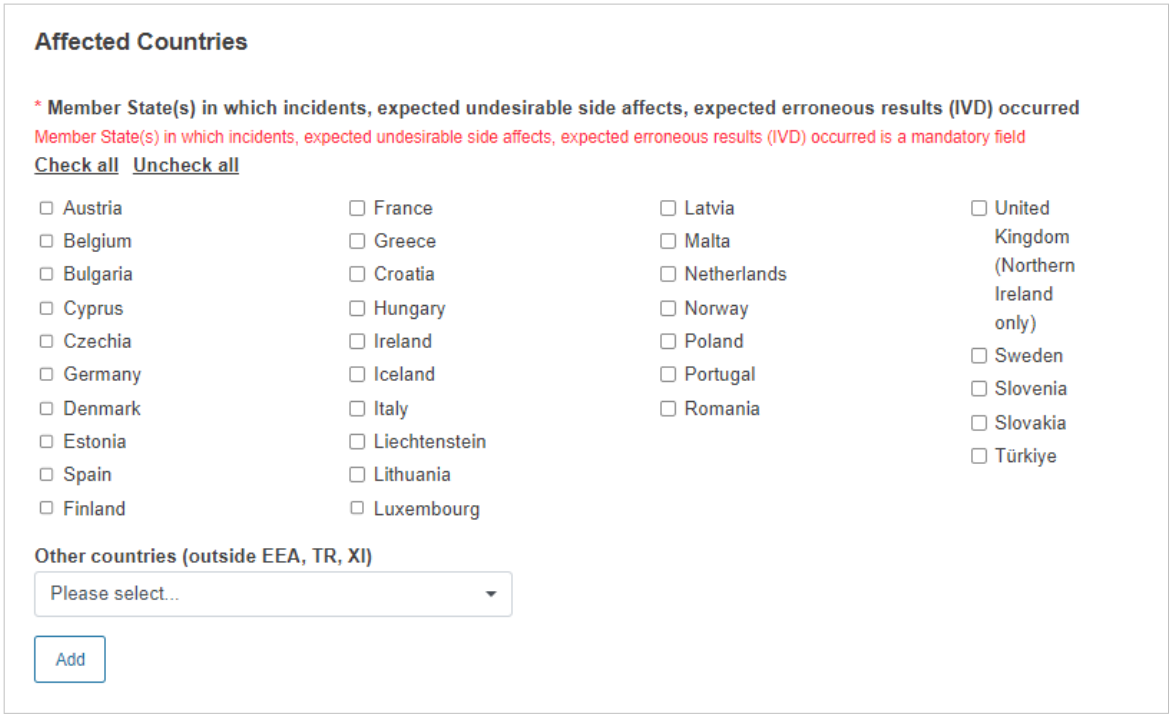
5. Choose the criteria forming the basis of the report:



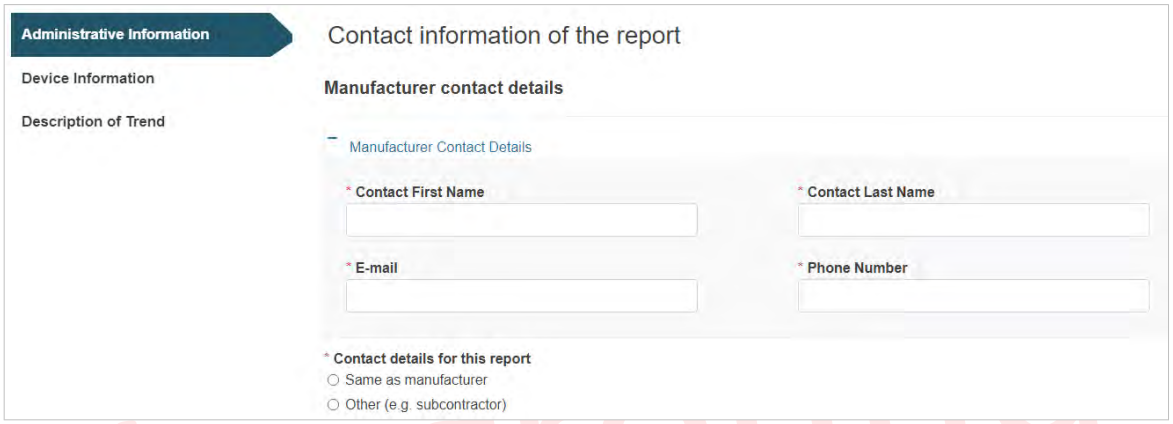
6. If applicable, provide the PMCF/PMPF EUDAMED ID reference to a PMCF/PMPF investigation:



7. Select the affected country(-ies):

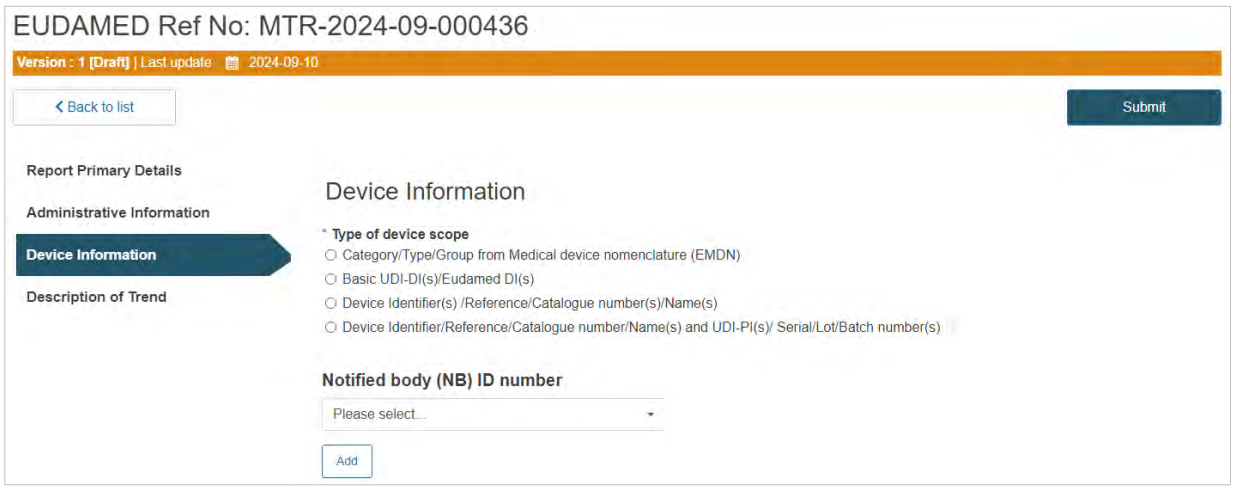


8. Provide the contact details of the Manufacturer (or Authorised Representative) and the Submitter for this report:



7.1.4 Step 3: Device information

Click on **Device information** from the menu on the left:

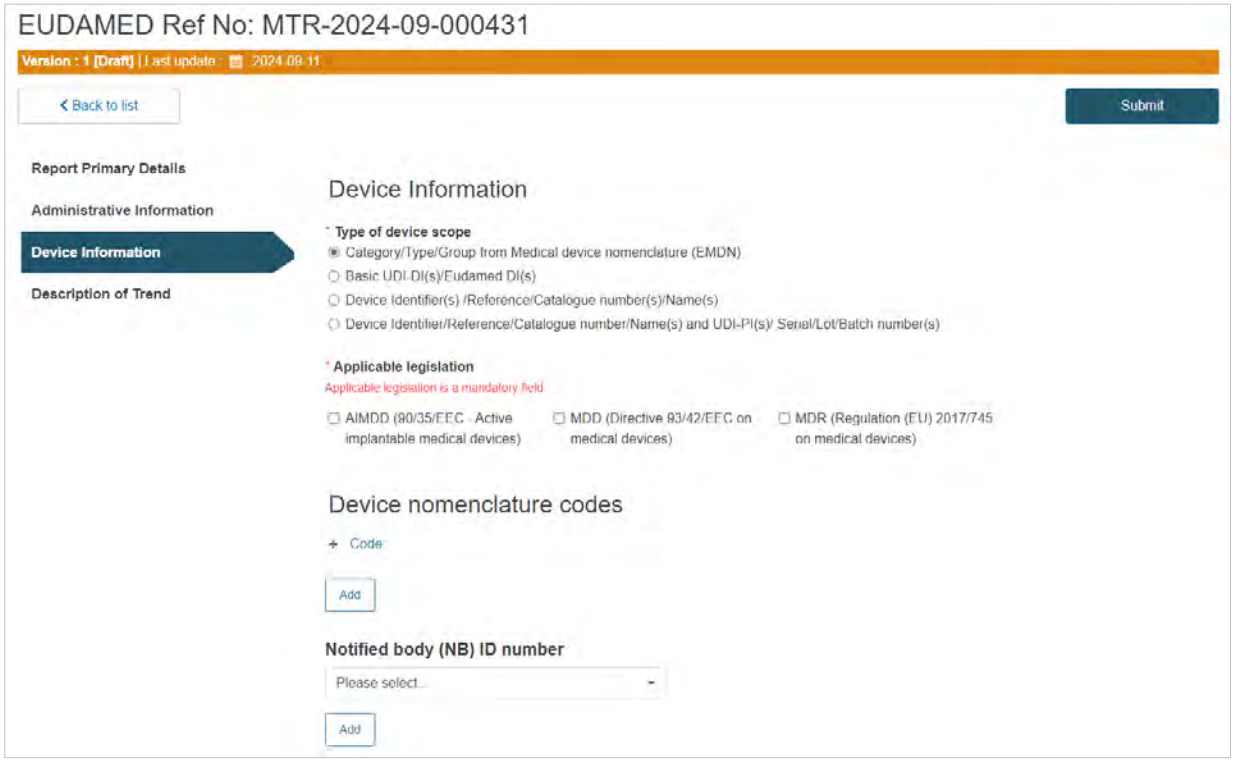


Select the type of the device scope.

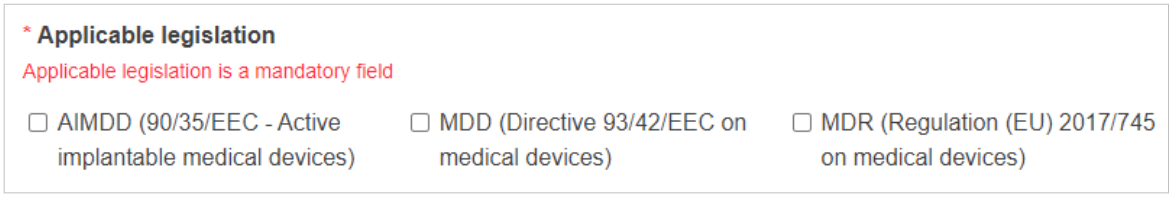
TIP
Depending on the device scope type selected, the process will slightly vary, as demonstrated in each of the four options below.

Follow **Option A, B, C or D**:

A. Steps for Category/Type/Group from Medical device nomenclature (EMDN):



1. Select the applicable legislation:

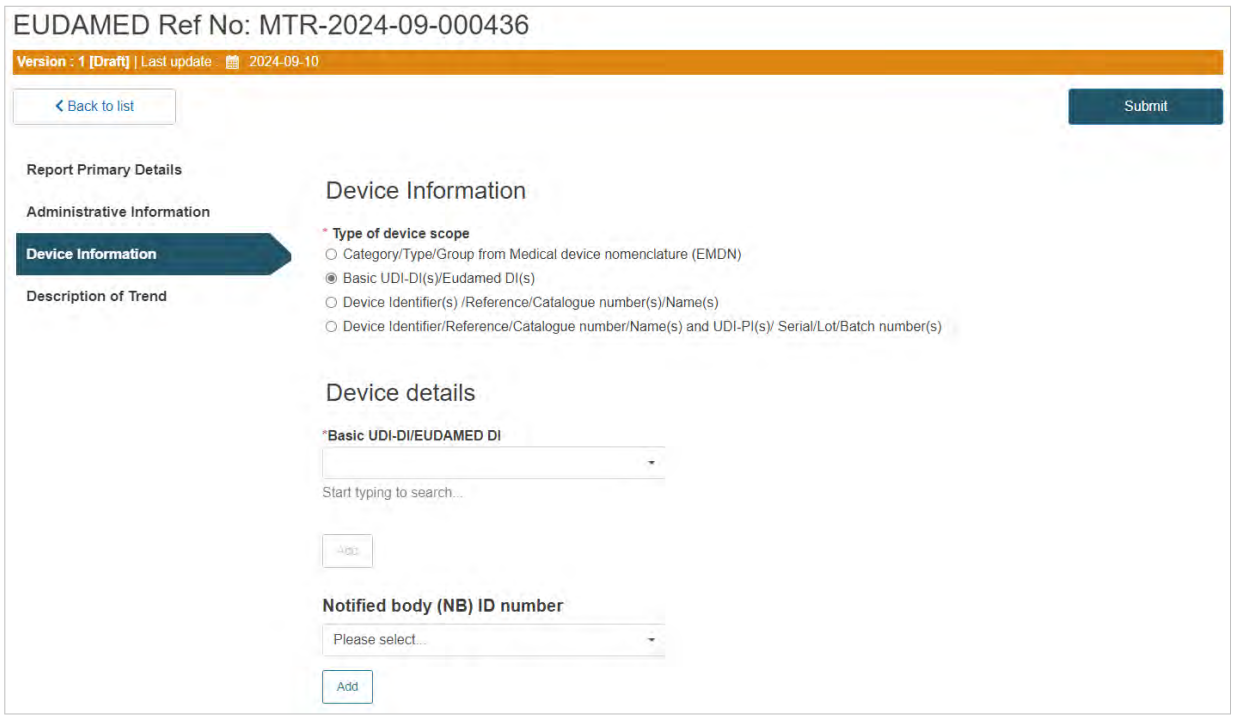


2. Click on the *plus* sign next to **Code** to enter the device nomenclature code:

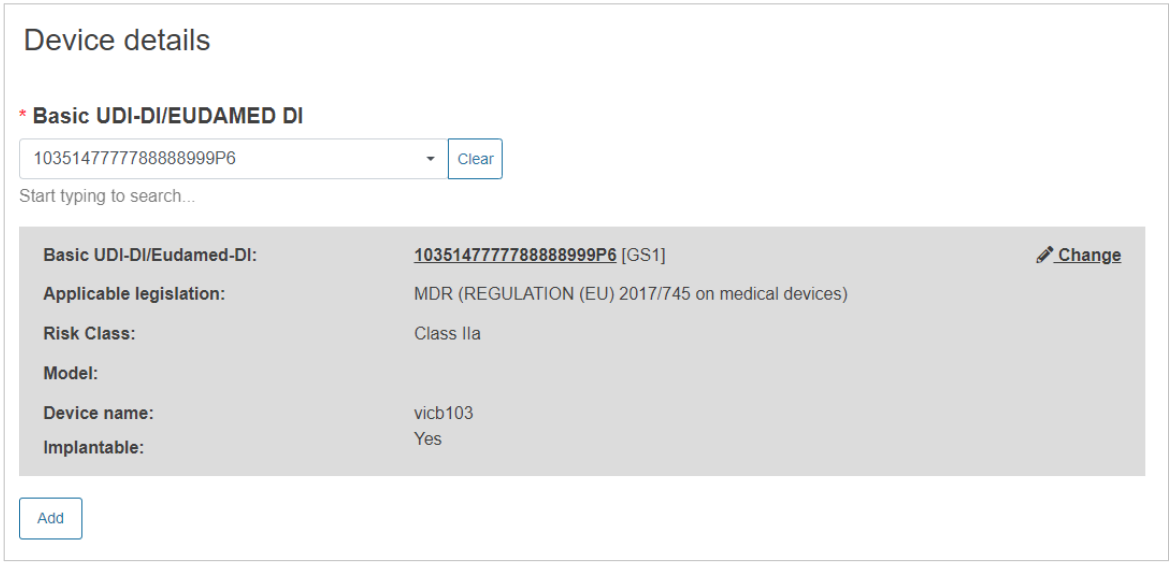
To add more nomenclature codes, click on **Add**.

3. Select the Notified Body ID number:

B. Steps for Basic UDI-DI(s)/EUDAMED DI(s):

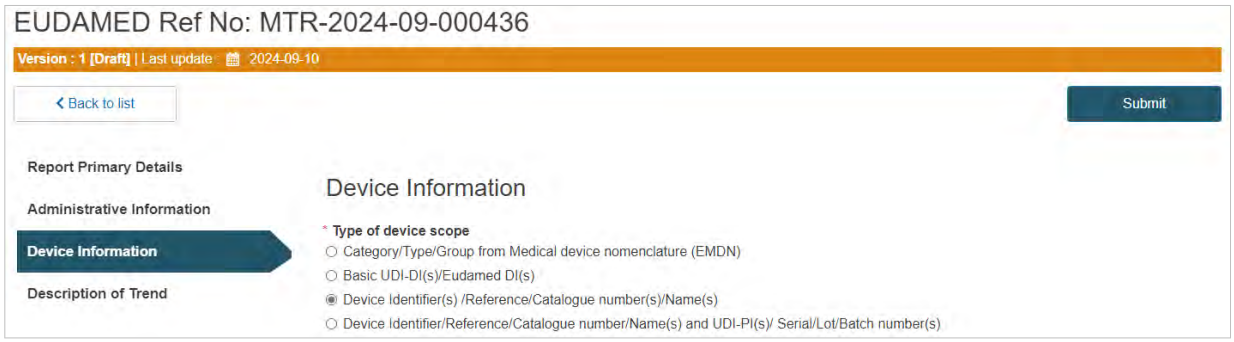


1. Enter the Basic UDI-DI/EUDAMED DI:

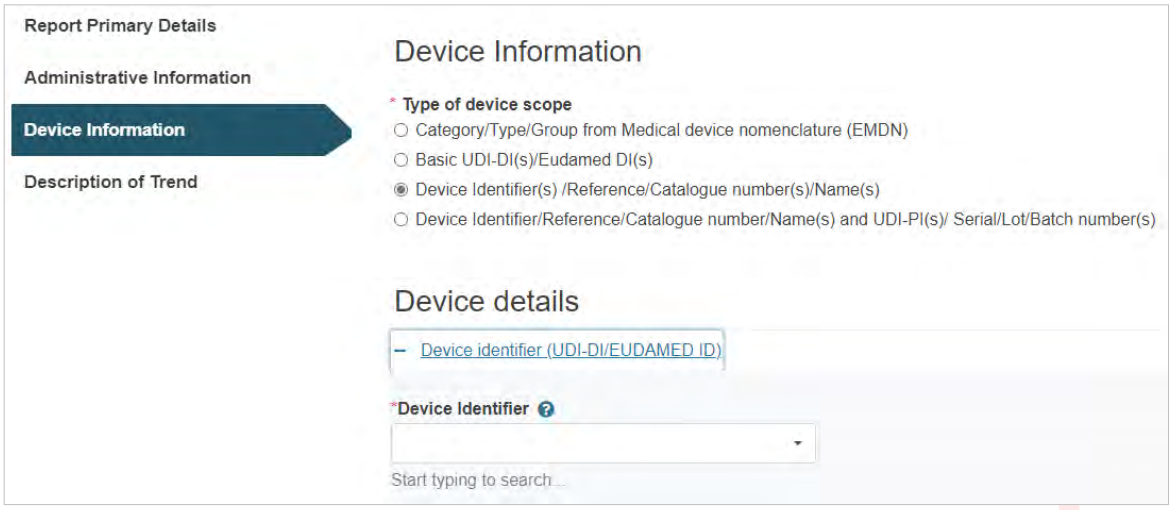


2. Select the Notified Body ID number:

C. Steps for Device Identifier(s) /Reference/Catalogue number(s)/Name(s):



1. Click on the plus sign next to *Device identifier* and type it in:

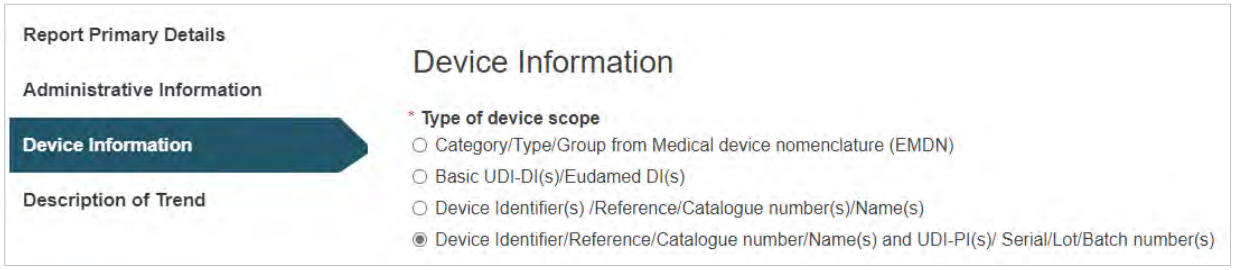


NOTE

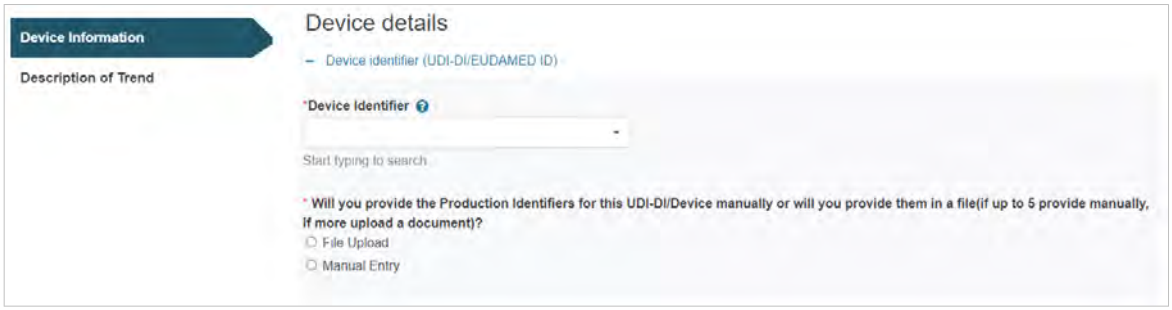
In case of a special device type (requiring a Master UDI-DI), the GTIN field will appear for you to fill in:

2. Select the Notified Body ID number:

D. Device Identifier/Reference/Catalogue number/Name(s) and UDI-PI(s)/ Serial/Lot/ Batch number(s):

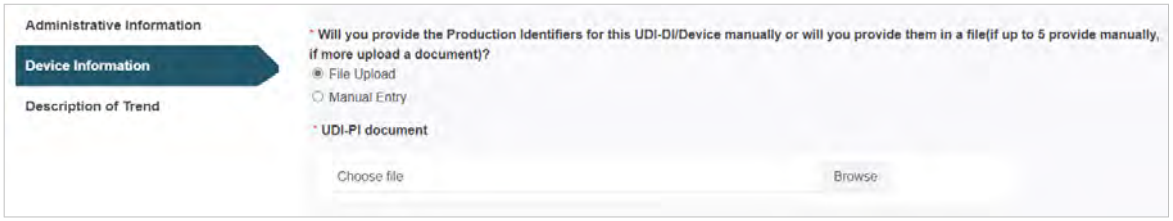


1. Click on the plus sign next to *Device identifier* to select it:



NOTE
In case of a special device type (requiring a Master UDI-DI), the GTIN field will appear for you to fill in:

2. Click **Browse** to upload a UDI-PI file:

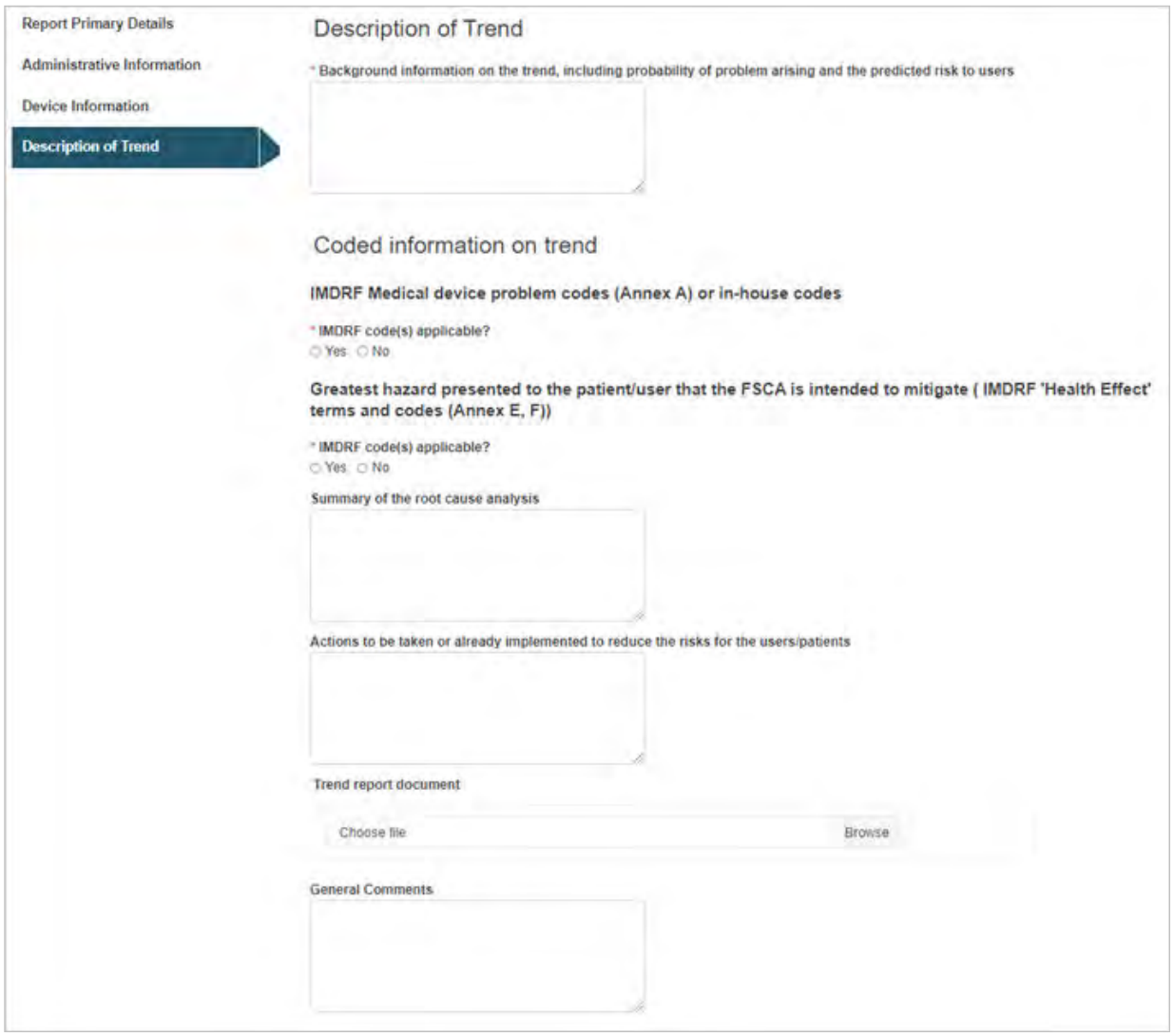


Alternatively, enter the UDI-PI manually:

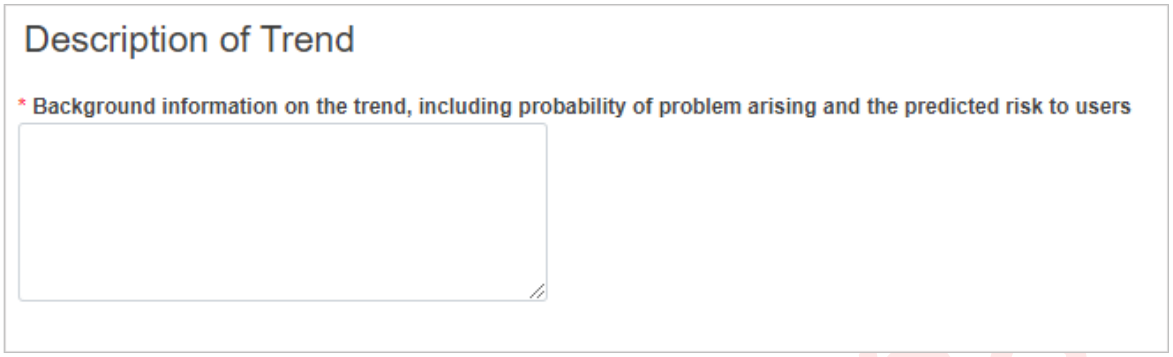
3. Select the Notified Body ID number:

7.1.5 Step 4: Description of Trend

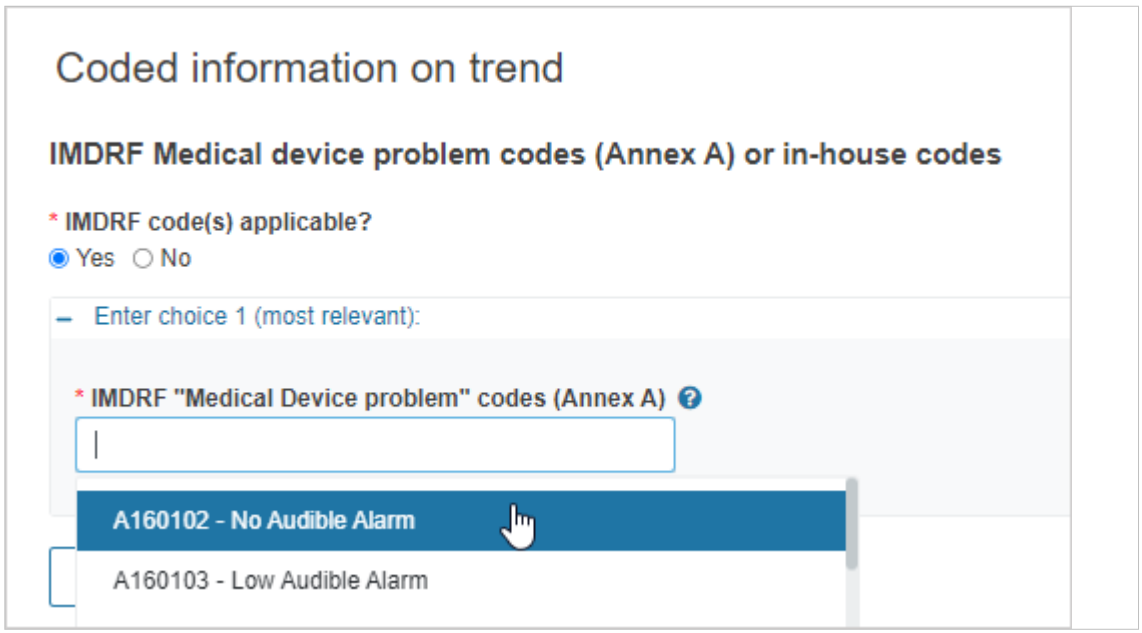
Click on *Description of Trend* from the menu on the left:



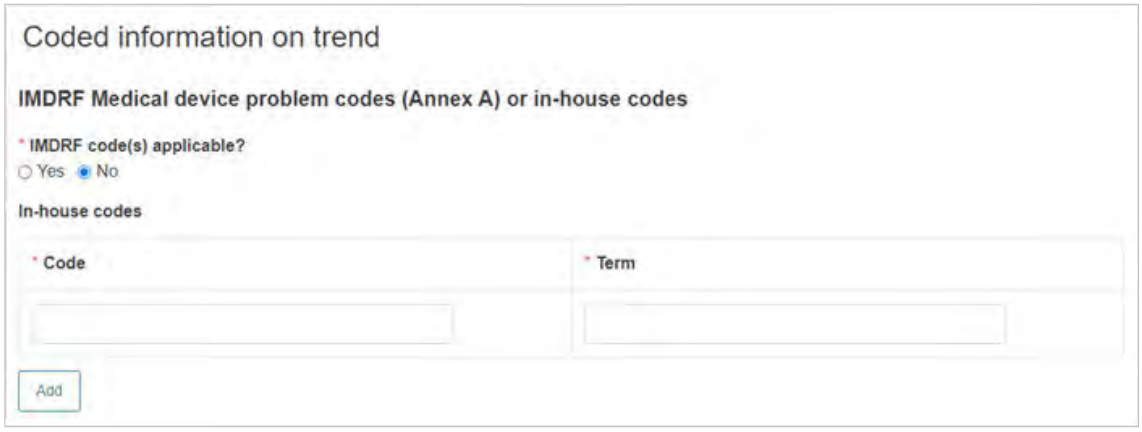
1. Enter the background information:



2. Specify if there are IMDRF codes (Annex A) or in-house codes:
   - Answer *Yes* if there are IMDRF codes applicable and enter the code(s):

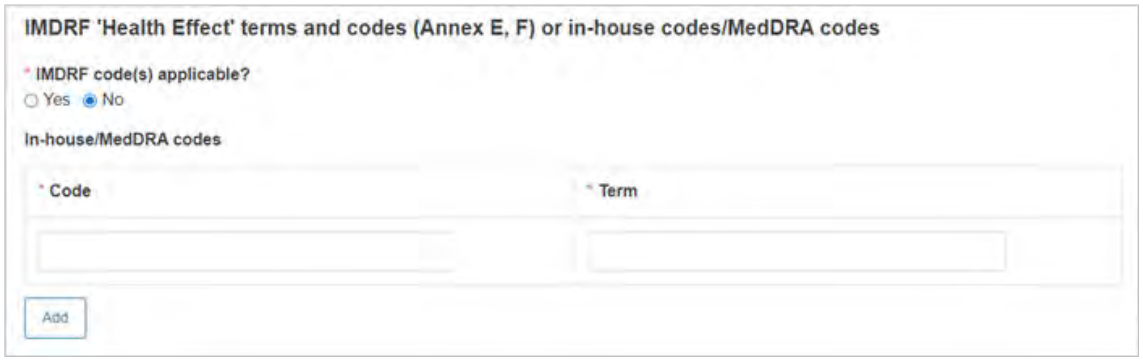


- If you answer *No*, enter the *Code* and the *Term* of the in-house/MedDRA codes:

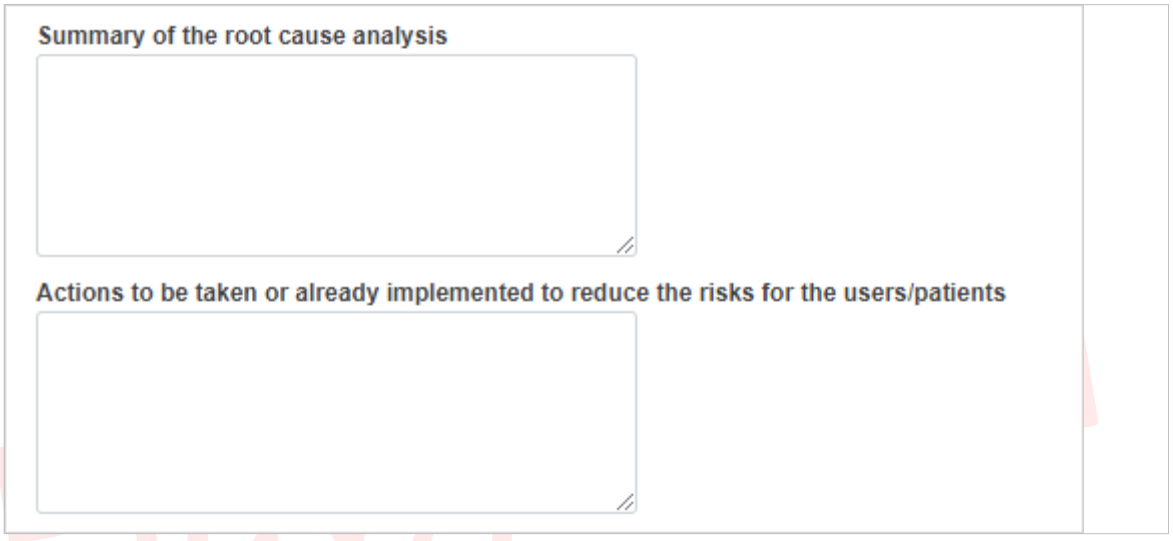


3. Specify if there are IMDRF codes applicable (Annexes E and F) or in-house codes:
   - Answer *Yes* if there are IMDRF codes applicable and enter the code(s):

- If you answer *No*, enter the *Code* and the *Term* of the in-house/MedDRA codes:



4. Enter the summary of the root cause analysis and the actions to be taken or already implemented to reduce the risks for the users/patients:

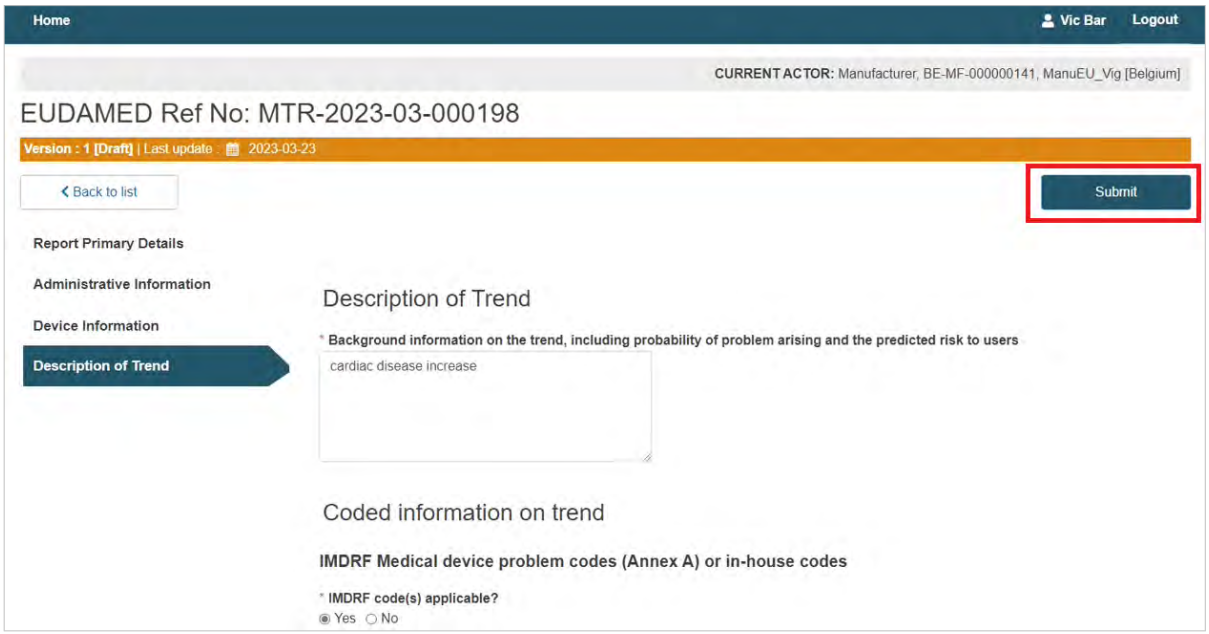


5. Upload a Trend report document (PDF file only):

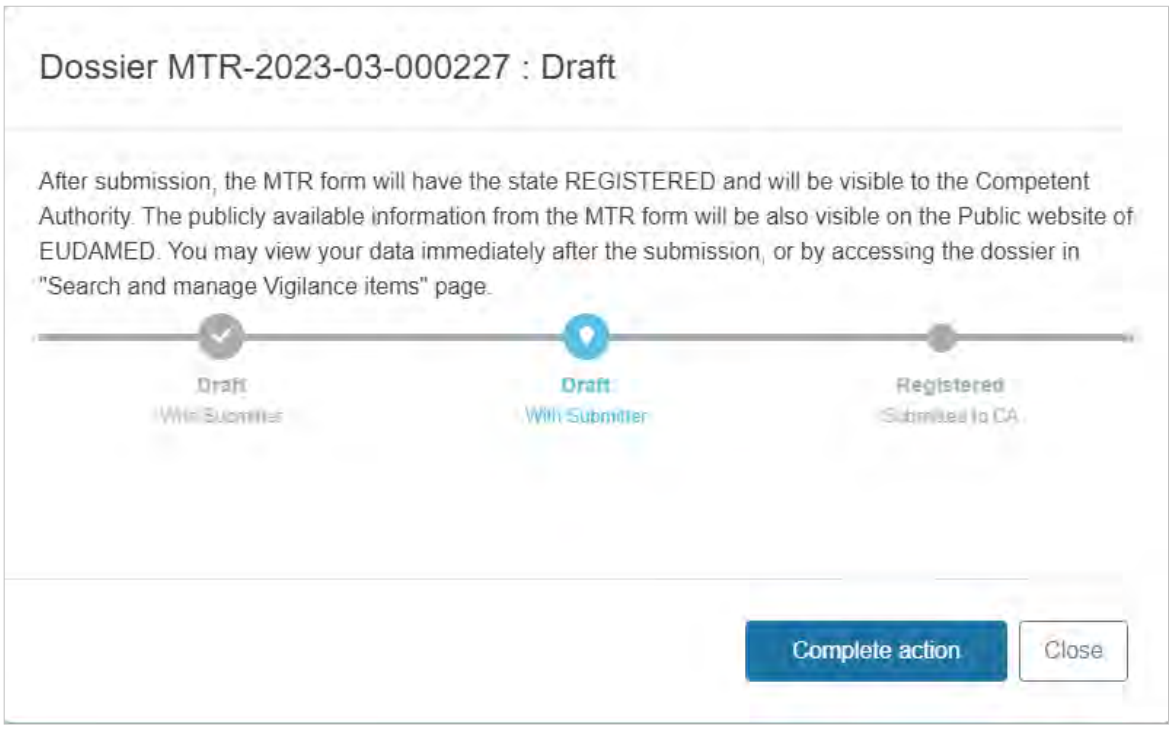
6. Enter any general comments:

7.1.6 Step 5: MTR submission

1. Click on **Submit** on the top right corner:

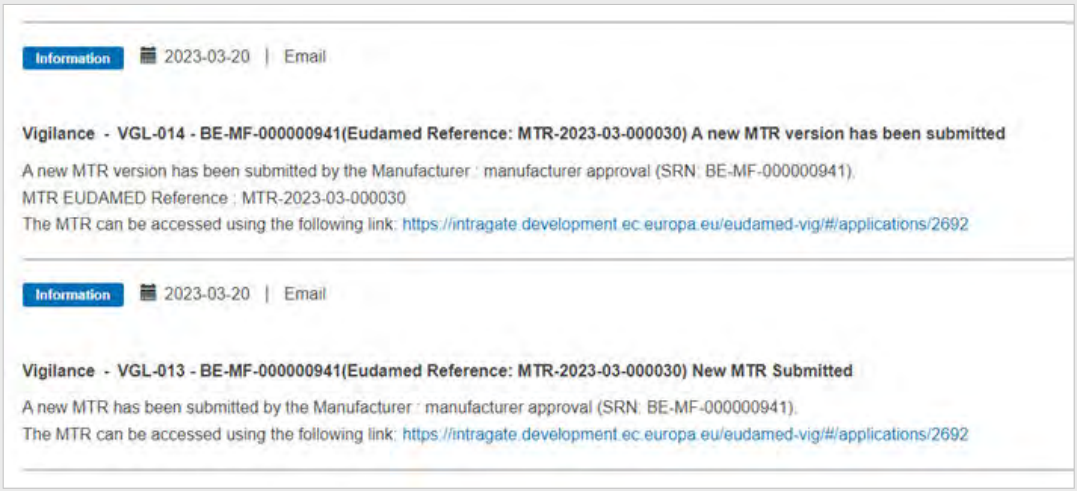


2. Click on **Complete action** in the pop-up window to finalise the submission:



You have now completed the MTR registration process.

NOTE
After submitting an MTR, CAs, ARs, MFs and NBs referenced in the report will receive a notification:



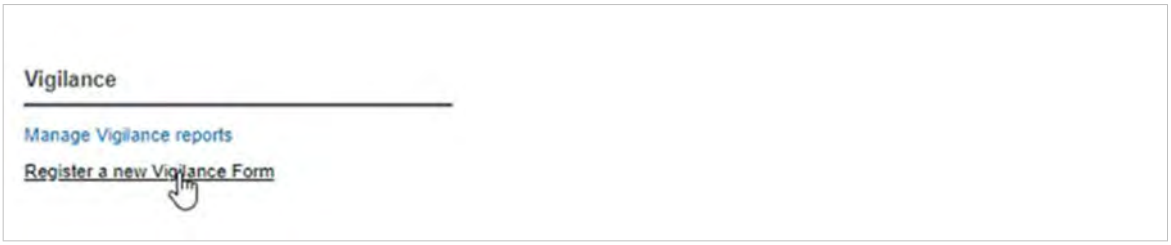
8 PSR

8.1 Register a new PSR

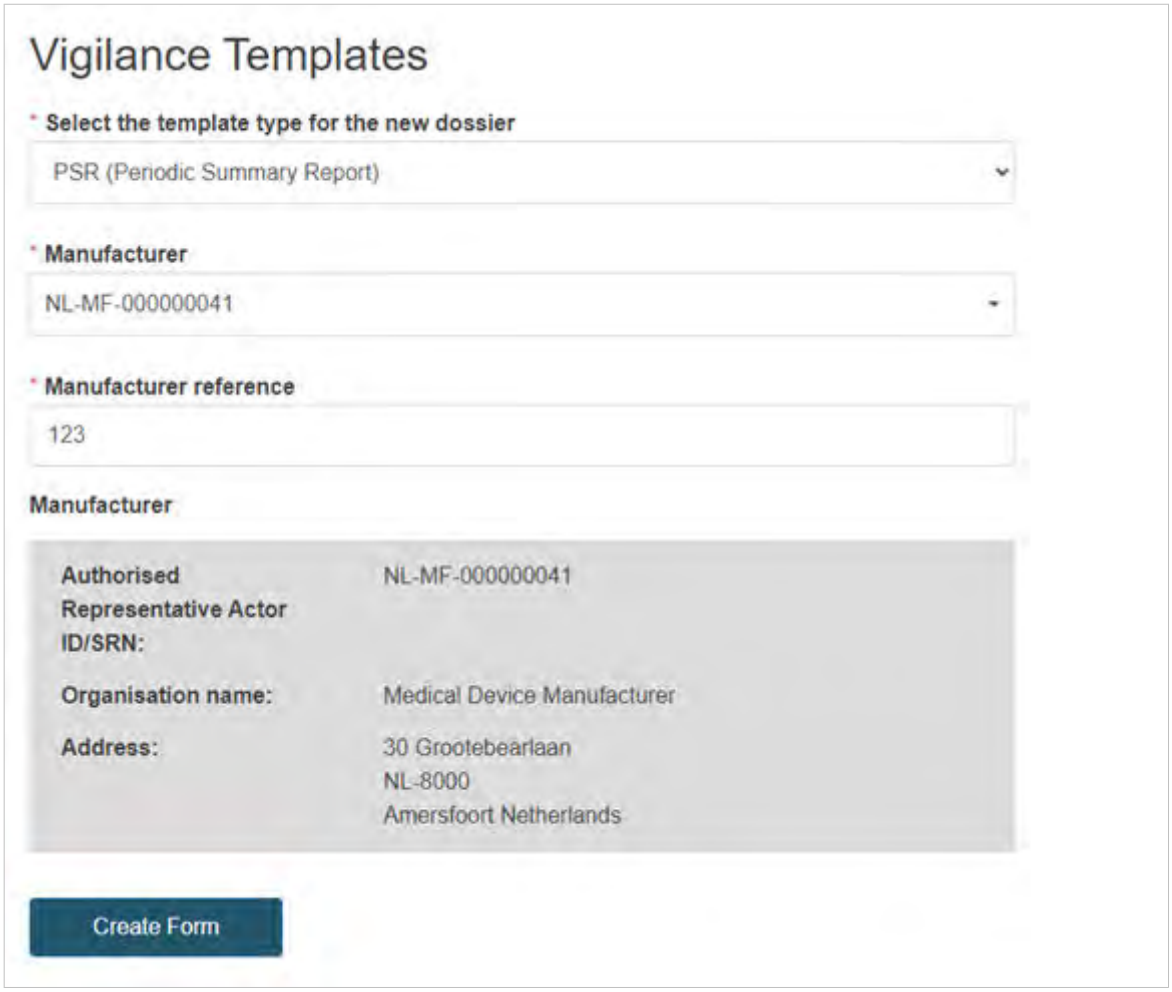
NOTE
Only Manufacturers and Authorised Representatives can access the menu for registering a new PSR report.

8.1.1 Step 0: Create initial PSR dossier

1. On the EUDAMED dashboard, click on *Register a new Vigilance Form* under the *Vigilance* section:



2. Select the PSR template from the dropdown list:



3. Select the manufacturer from the *Manufacturer* field.
   The system will automatically display your Actor information.

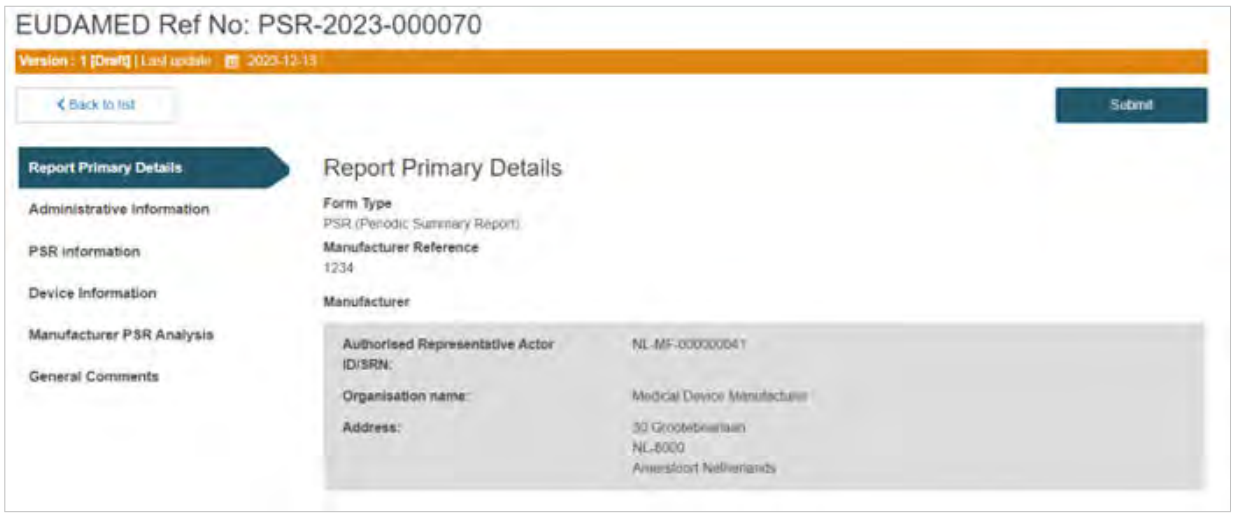
4. Enter the unique *Manufacturer reference*.

5. Click on **Create Form** to complete this initial step.

IMPORTANT
The information provided in this step cannot be modified after you click **Create form**.

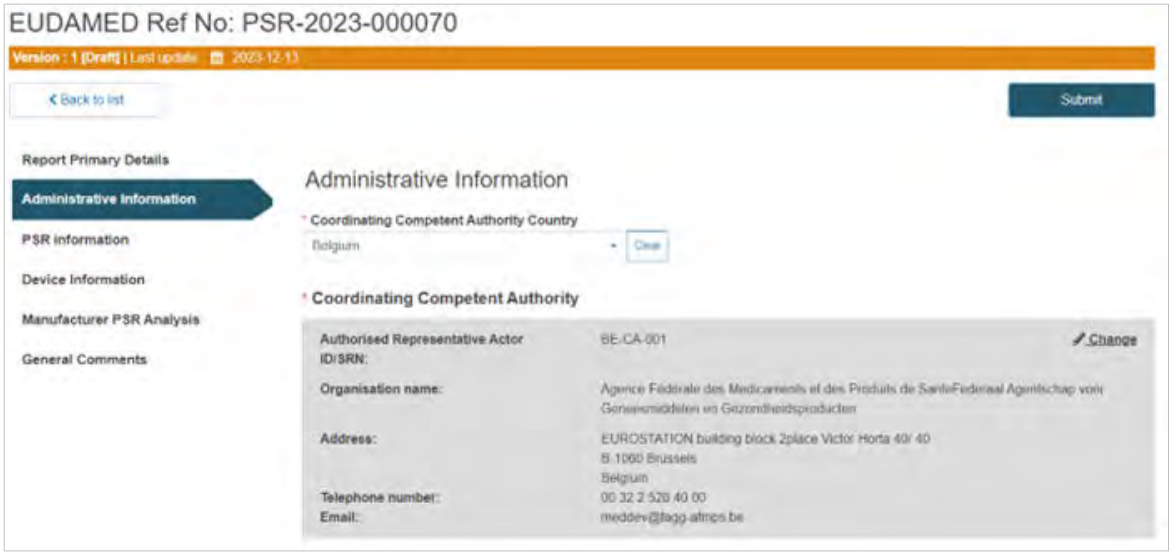
8.1.2 Step 1: Report primary details

The *Report primary details* section provides an overview of the data entered in the initial creation of the dossier:



8.1.3 Step 2: Administrative information

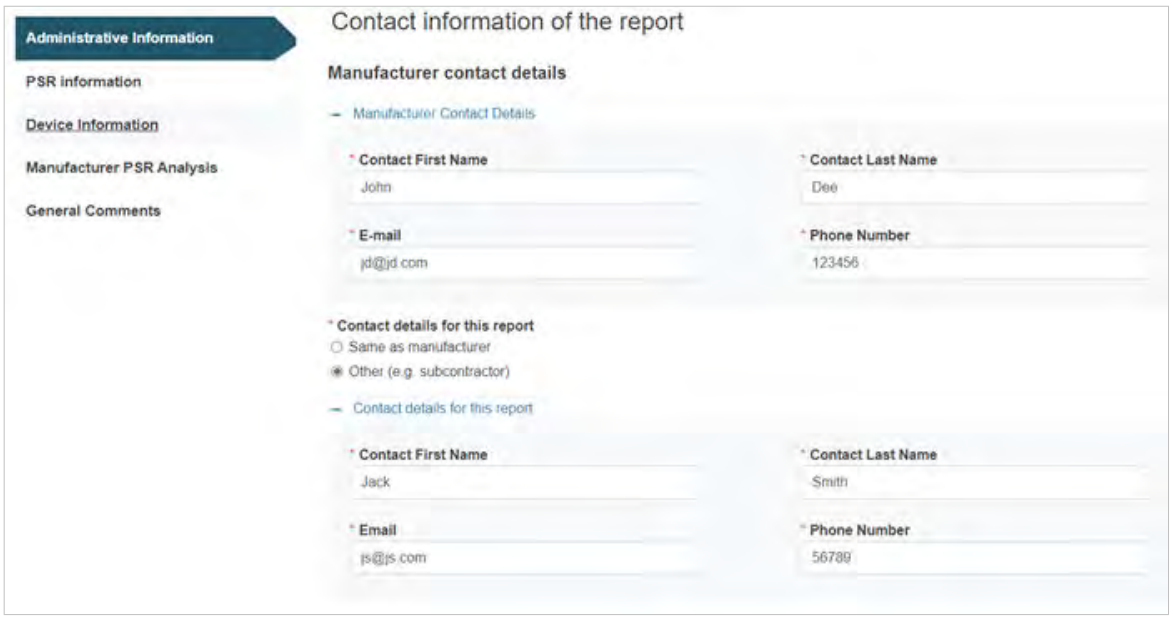
1. Under the *Administrative information* tab, select the country of the CCA (Coordinating Competent Authority), as well as the CCA itself from the dropdown list:



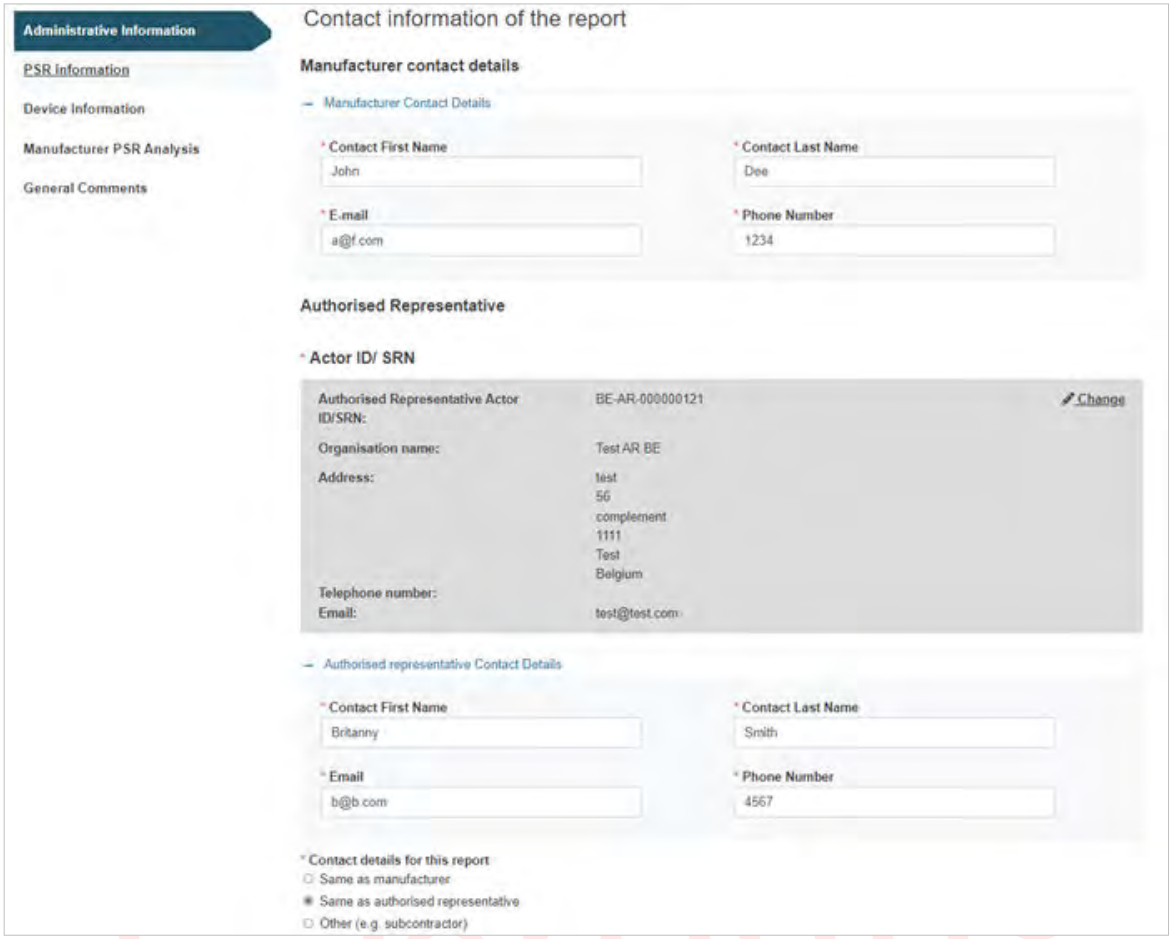
NOTE
Coordinating Competent Authority must be either:

- a CA from the country of the Manufacturer/ Authorised Representative, or
- a CA from one of the participating countries selected in the PSR.

2. Fill in the Manufacturer contact details in the next section:



If the actor is an Authorised Representative, insert the Actor ID/SRN:

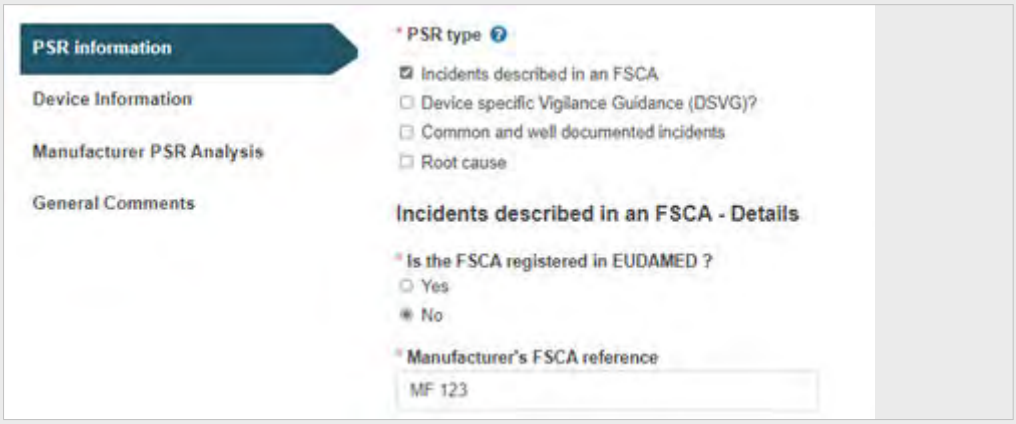


3. Specify if the report's contact details are the same as the Manufacturer's or Authorised Representative's or select *Other* if neither is applicable.

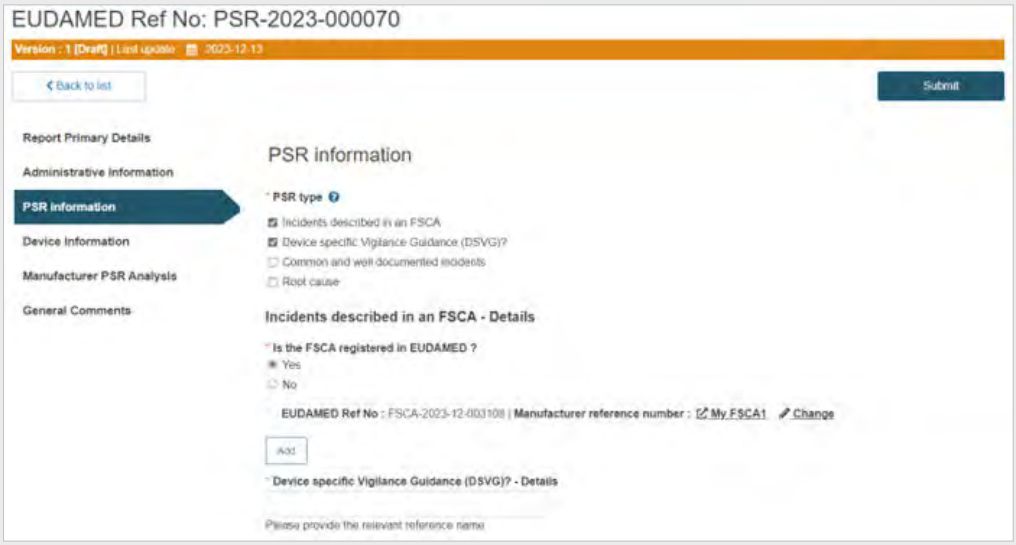
8.1.4 Step 3: PSR information

1. Under the *PSR information* tab, select one or more PSR types:

NOTE
If the PSR type is related to incidents described in an FSCA, you have to additionally specify if the FSCA is registered in EUDAMED:



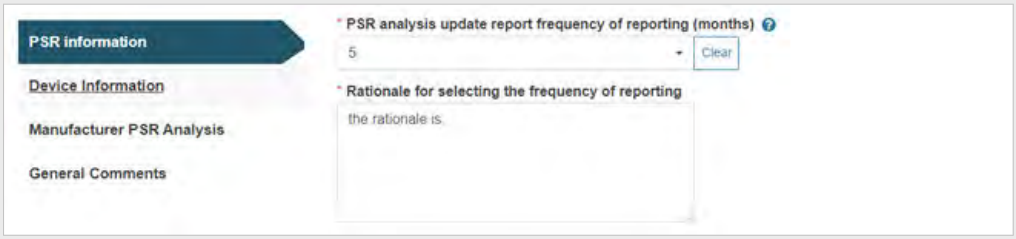
Similarly, if the PSR type is *Device-specific Vigilance Guidance*, you must insert the relevant reference name in the mandatory field *Device specific Vigilance Guidance (DSVG)? - Details*:



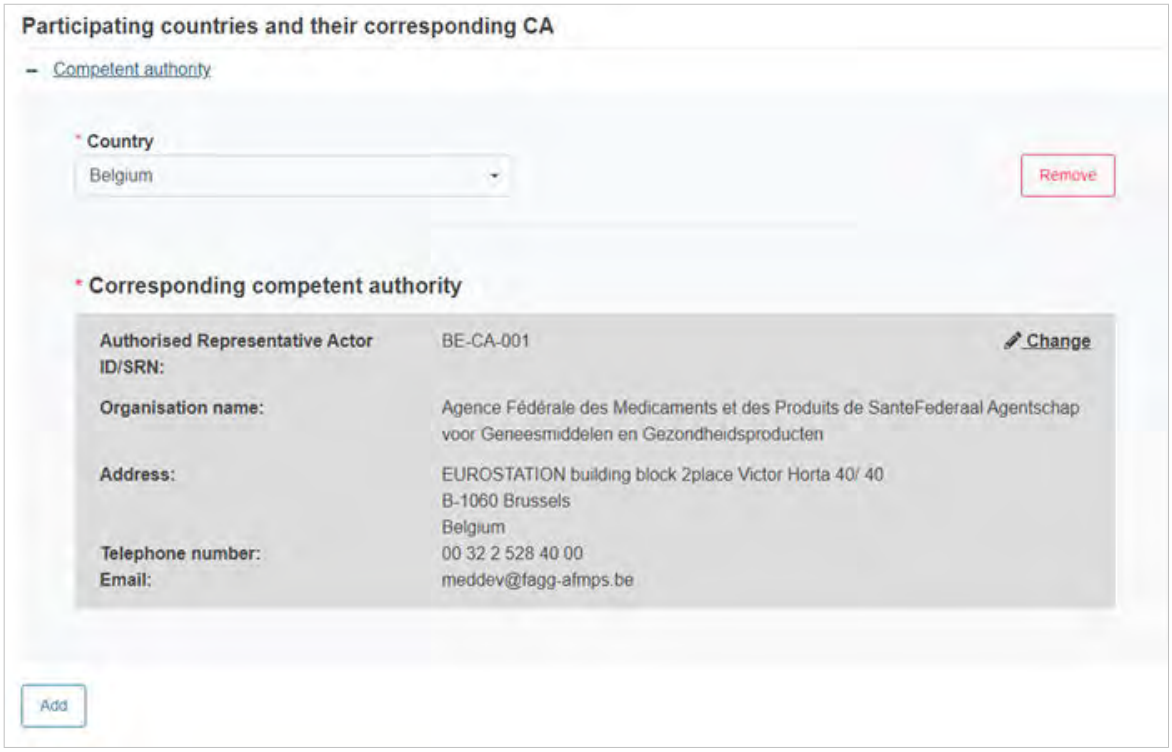
2. Provide at least one IMDRF code relating to the PSR in each of the three Annexes provided:

3. Next, provide the frequency of reporting for the PSR analysis update (the default value is **three months**):

NOTE
If the value selected is other than the default three months, a rationale must be provided:



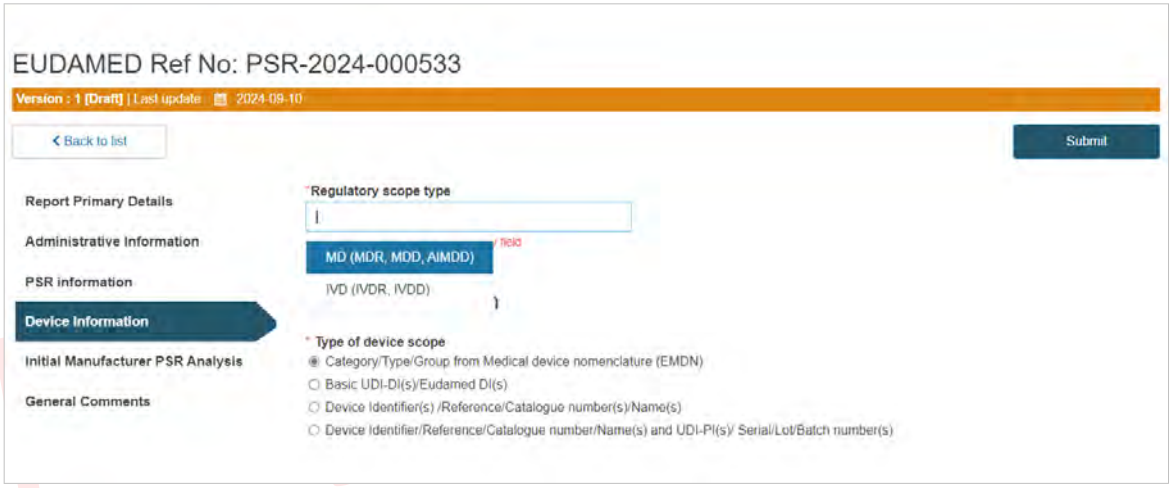
4. Finally, add other participating countries and their CAs:



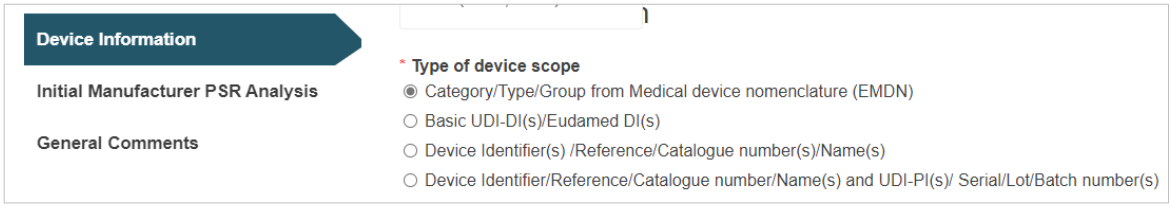
Click **Add** to add more countries and their CAs, if needed:

8.1.5 Step 4: Device information

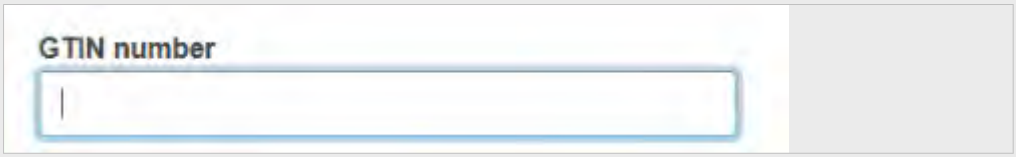
1. Under the *Device information* section, start by selecting the regulatory scope type:



2. Select the type of device scope:



NOTE
Please note that in case of a special device type (requiring a Master UDI-DI), the GTIN field will appear for you to fill in:



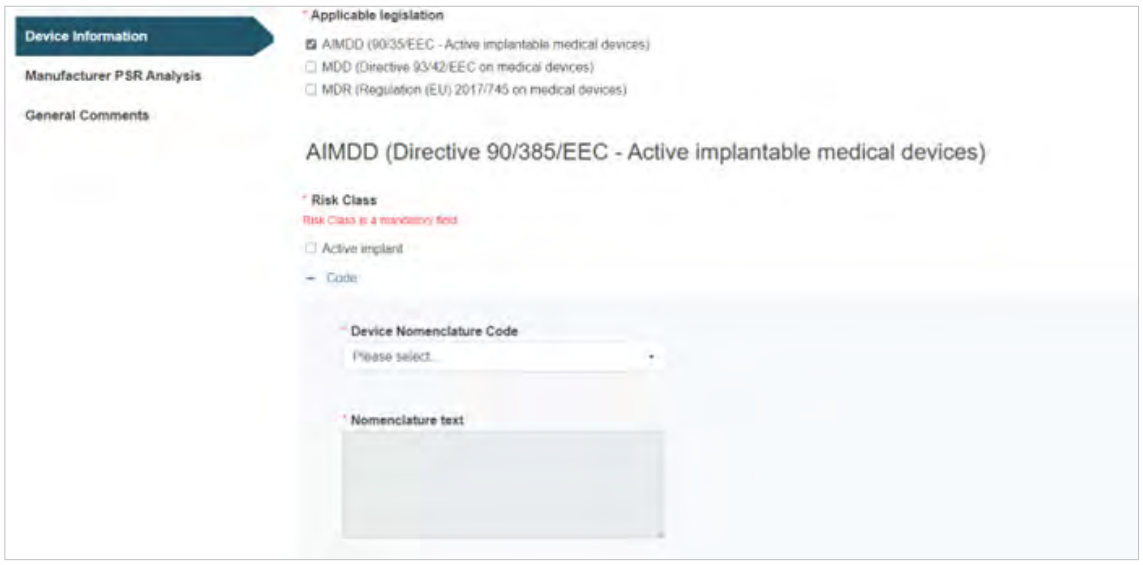
3. Follow **Option A, B, C or D**

A. Category/Type/Group from Medical device nomenclature (EMDN):

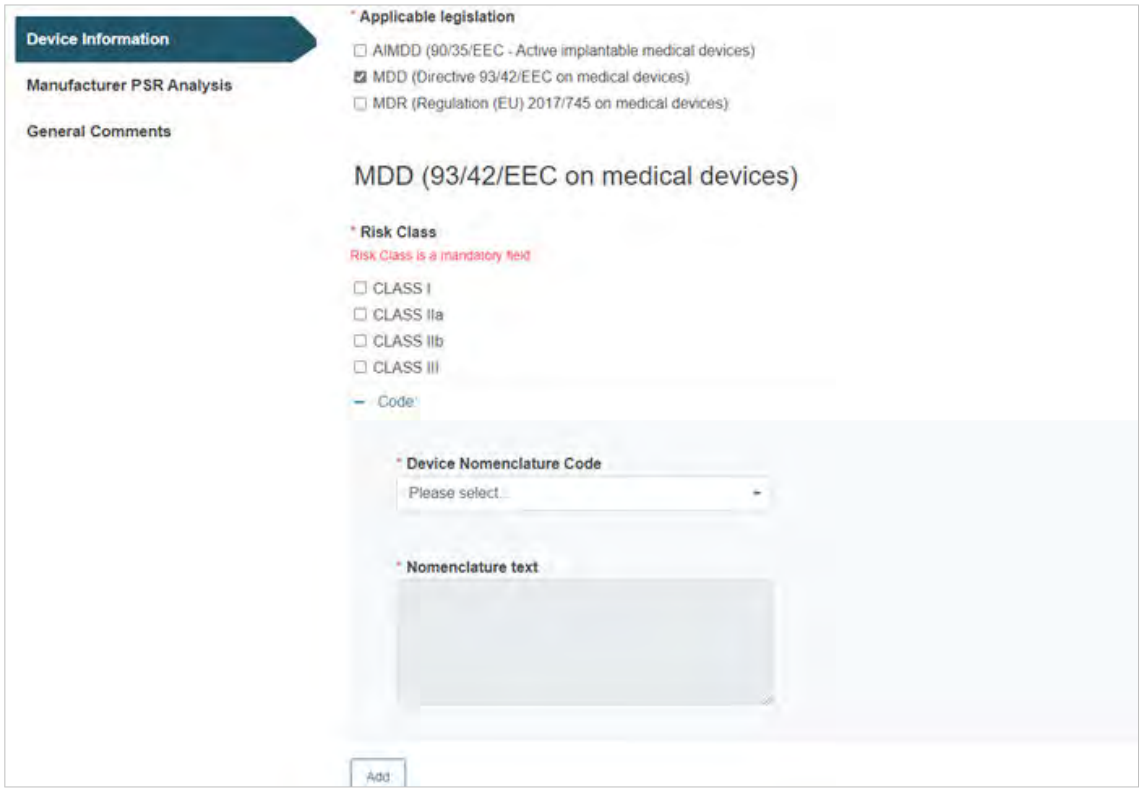
- For the *Category/Type/Group from Medical device nomenclature (EMDN)* option, you **must** select the applicable legislation(s):

Depending on the applicable legislation(-s) selected, different *Risk Class* and *Device type* values will be displayed.

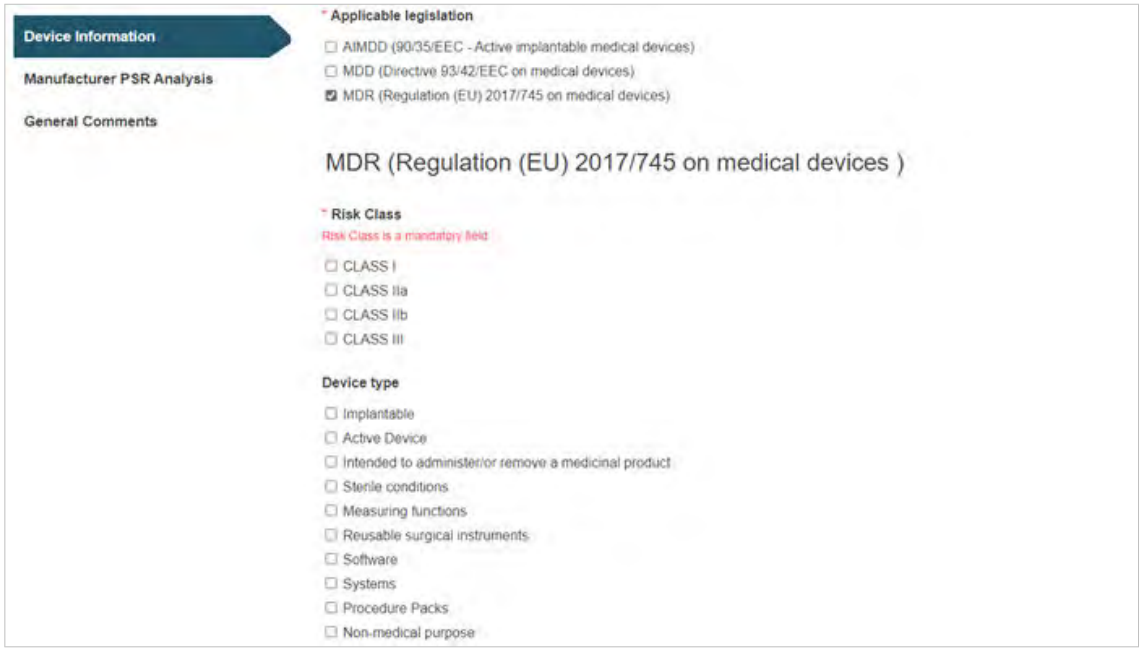
- Fill in the fields *Device Nomenclature Code* and *Nomenclature text* accordingly: *Example with AIMDD as applicable legislation*:

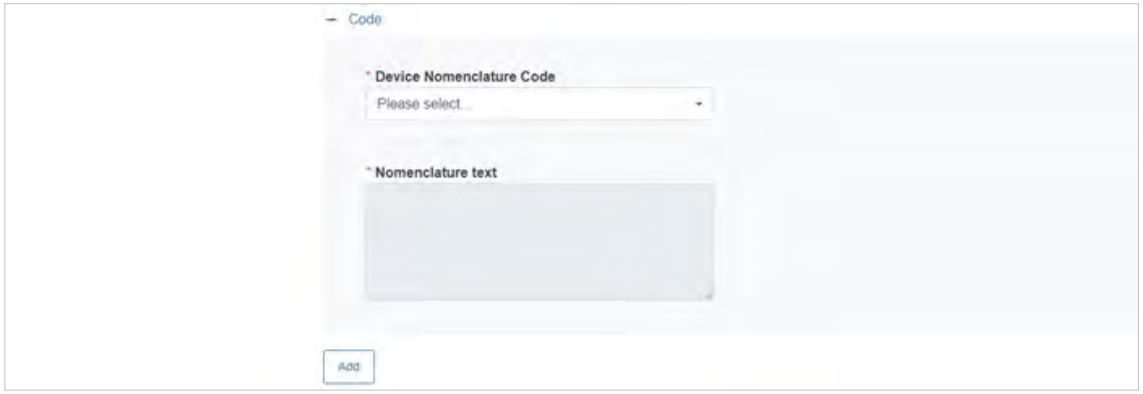


Example with MDD as applicable legislation:



Example with MDR as applicable legislation:





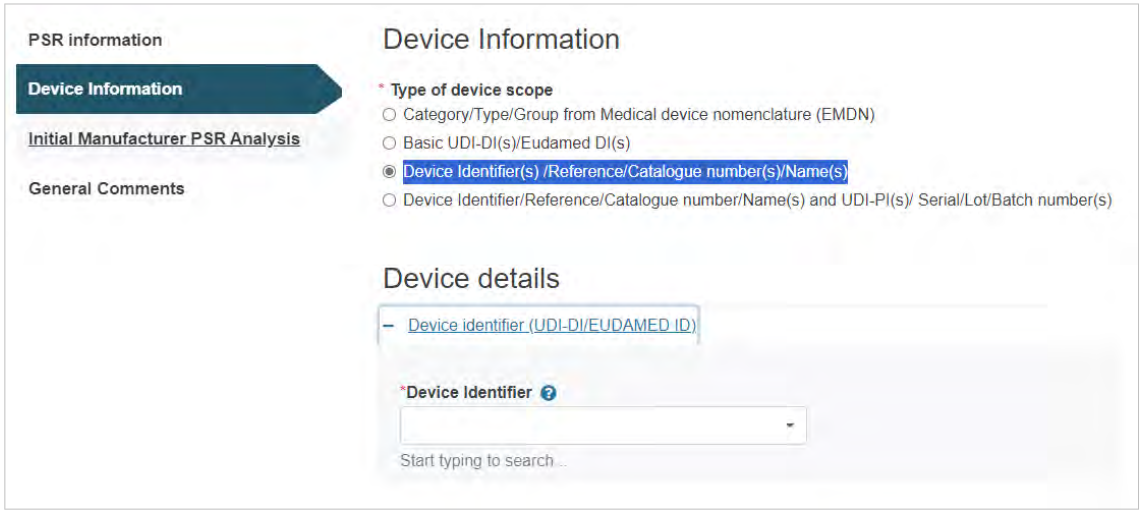
To add more nomenclature codes, click **Add**.

B. Basic UDI-DI(s)/EUDAMED DI(s):
Enter the Basic UDI-DI/EUDAMED DI:

Click on **Add** to add more Basic UDI-DI(s)/EUDAMED DI(s).

C. Device Identifier(s) /Reference/Catalogue number(s)/Name(s):

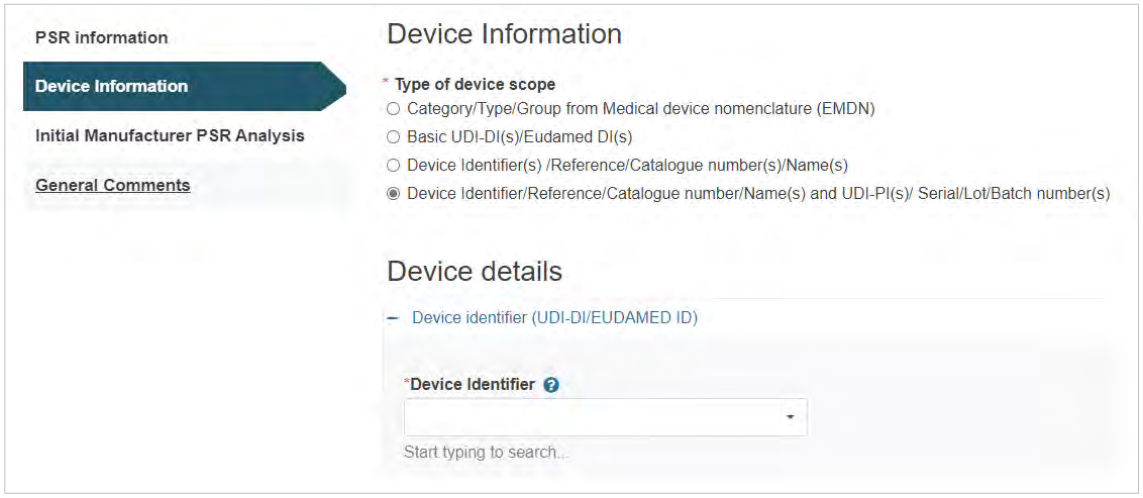
- Under *Device details*, click on the plus sign next to *Device identifier* to select it:



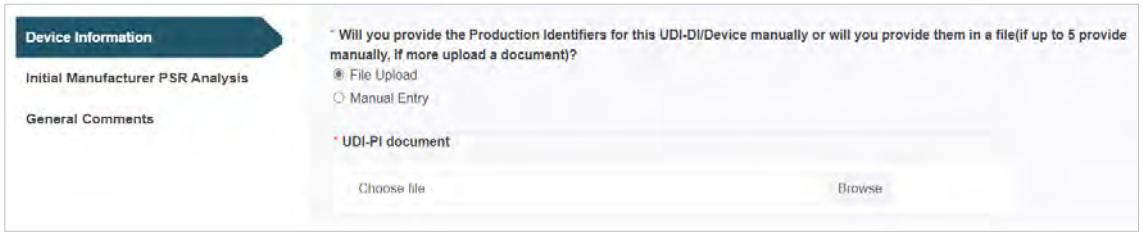
Click **Add** to add more devices if necessary.

D. Device Identifier/Reference/Catalogue number/Name(s) and UDI-PI(s)/ Serial/Lot/Batch number(s):

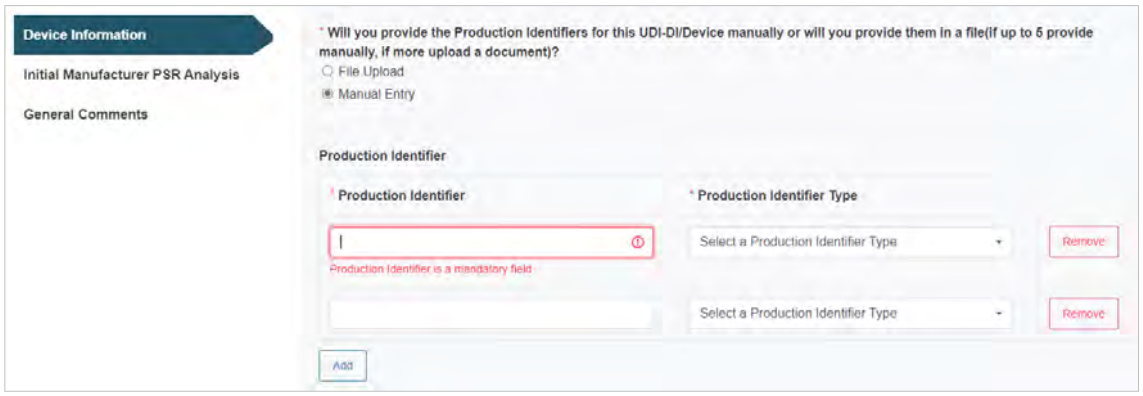
- Click on the plus sign next to *Device identifier* to select it:



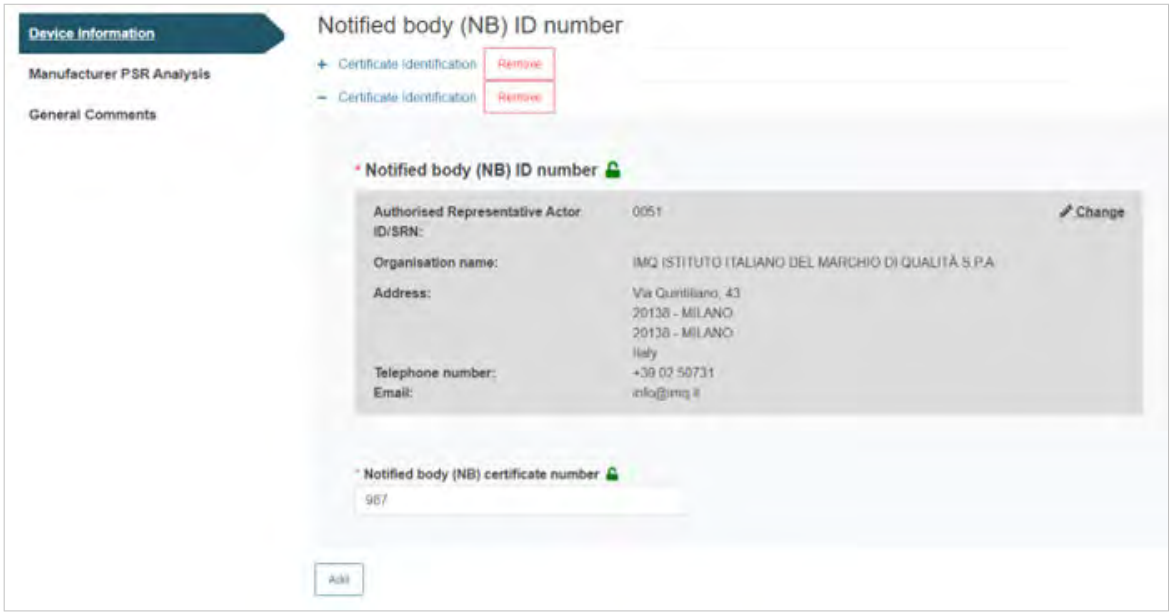
- Next, upload the UDI-PI:



Alternatively, enter the *Production Identifier* information manually:



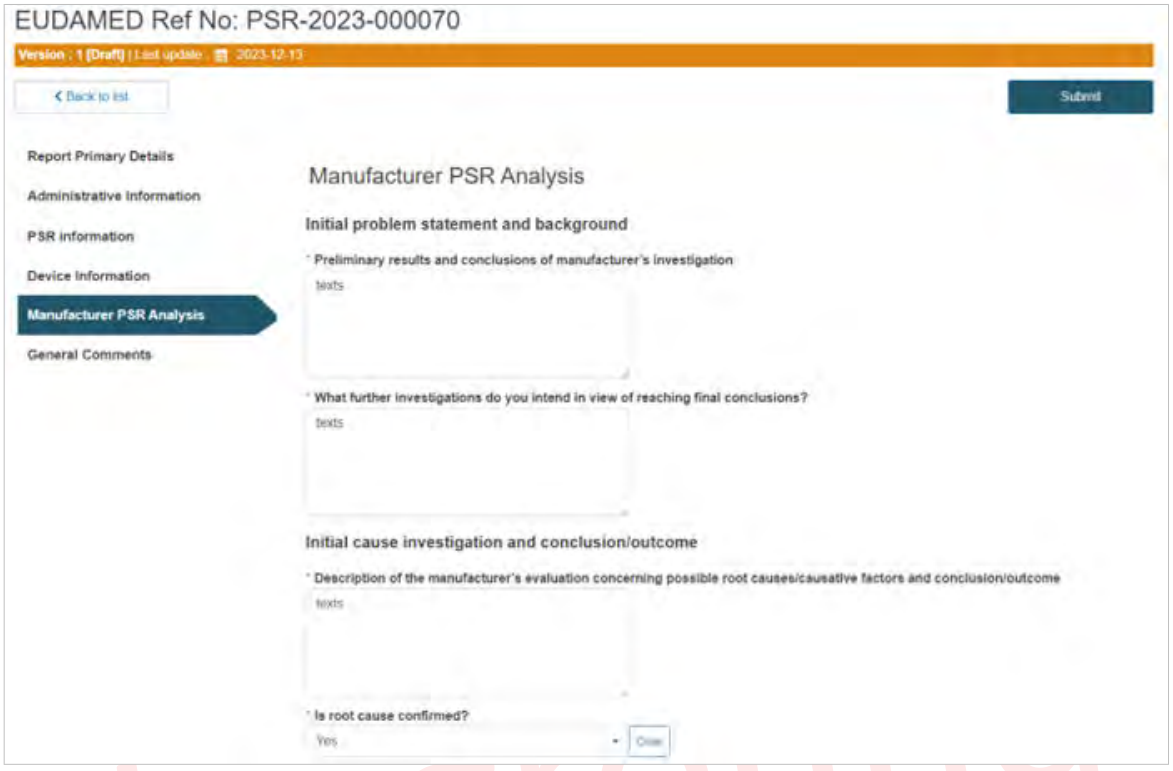
4. Select the Notified Body ID number and enter the Notified Body certificate number manually:



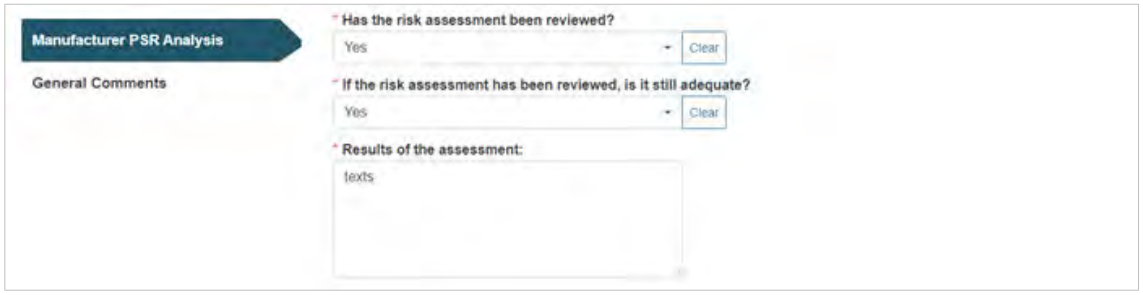
Click **Add** for multiple entries.

8.1.6 Step 5: Initial Manufacturer PSR analysis

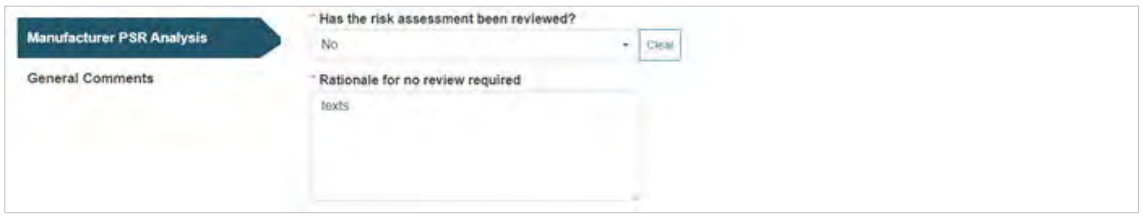
1. Under the *Initial Manufacturer PSR analysis* tab, fill in the mandatory fields:



2. Answer the question *Has the risk assessment been reviewed?*
   - If **Yes**, specify if the risk assessment is still adequate and its results:



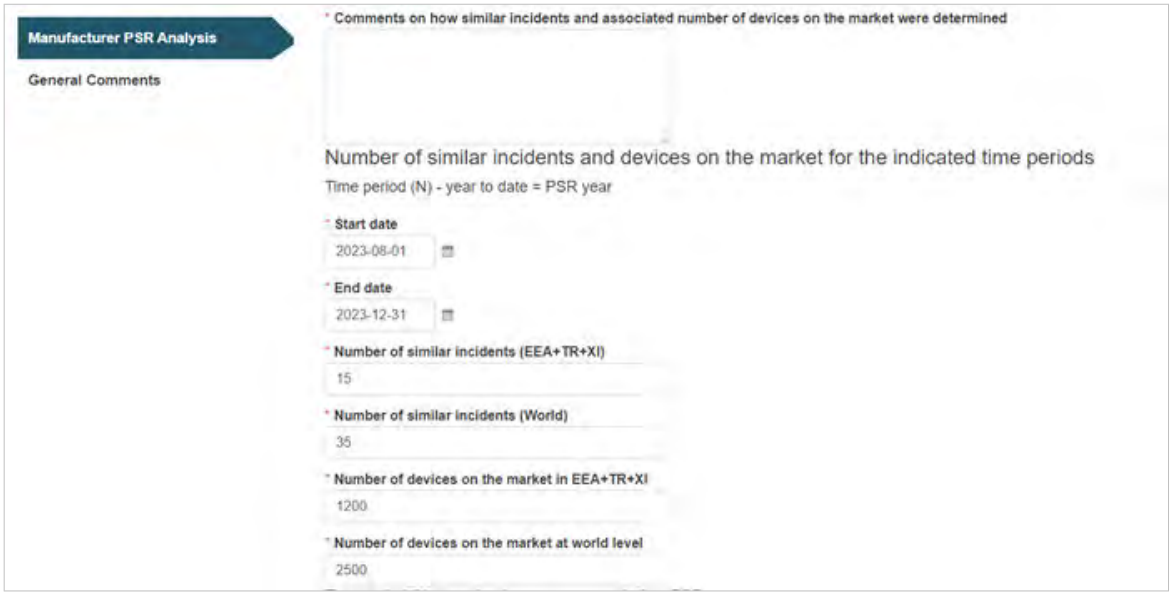
- If **No**, explain the rationale for no review:



3. Fill in the fields in the *Similar incidents* section:

- Choose minimum **one IMDRF code** option.
- Choose the **identification basis variant** of similar incidents.
- Choose the **criteria of the number of devices** on the market.
- Provide **comments** on how similar incidents and associated number of devices were determined.

4. Provide the number of similar incidents and devices on the market for the **indicated time periods in the past**:

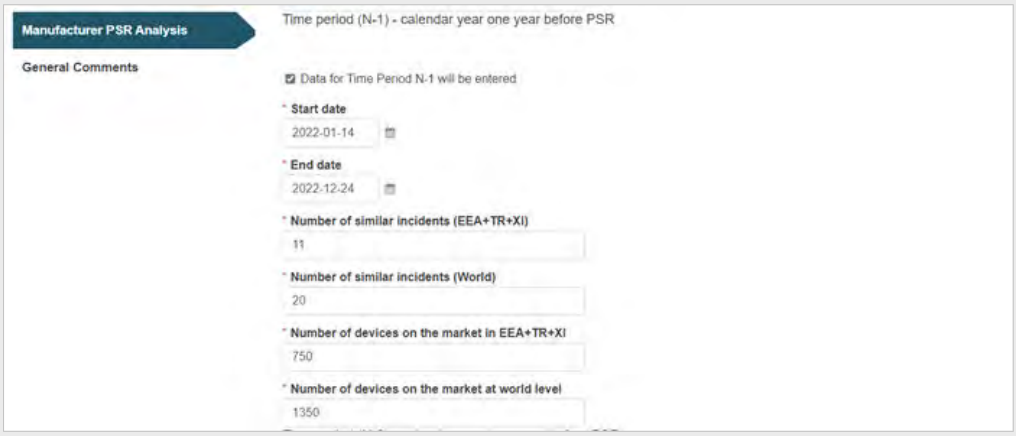


NOTE

Time period (N) stands for the **current calendar year** (the year in which the PSR is being submitted) and is a mandatory field.

If you need to enter data for **years preceding Time period N**, you have the option of selecting the corresponding N-(x) period and follow the same process:

*Example of data entered for **time period N-1** (one calendar year prior to the present PSR):*

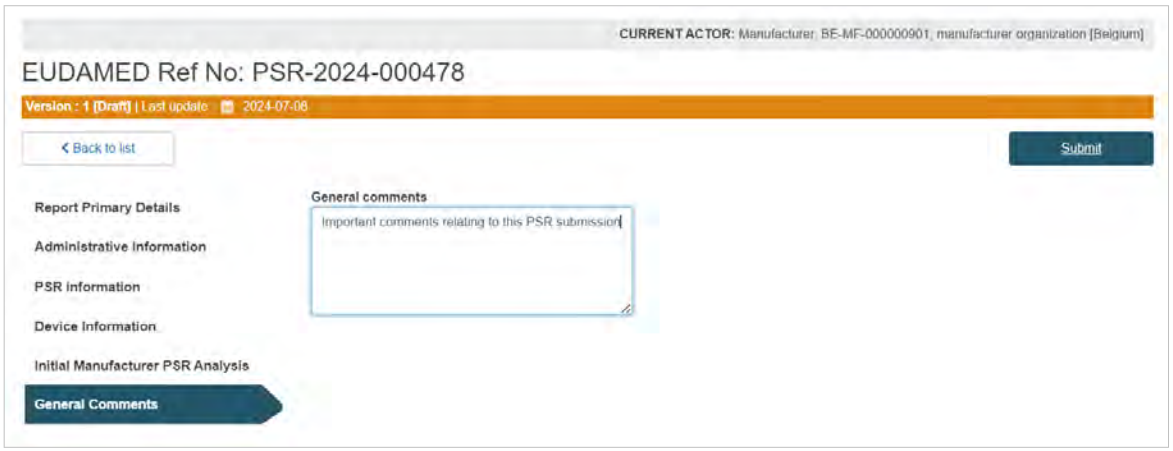


8.1.7 Step 6: General comments

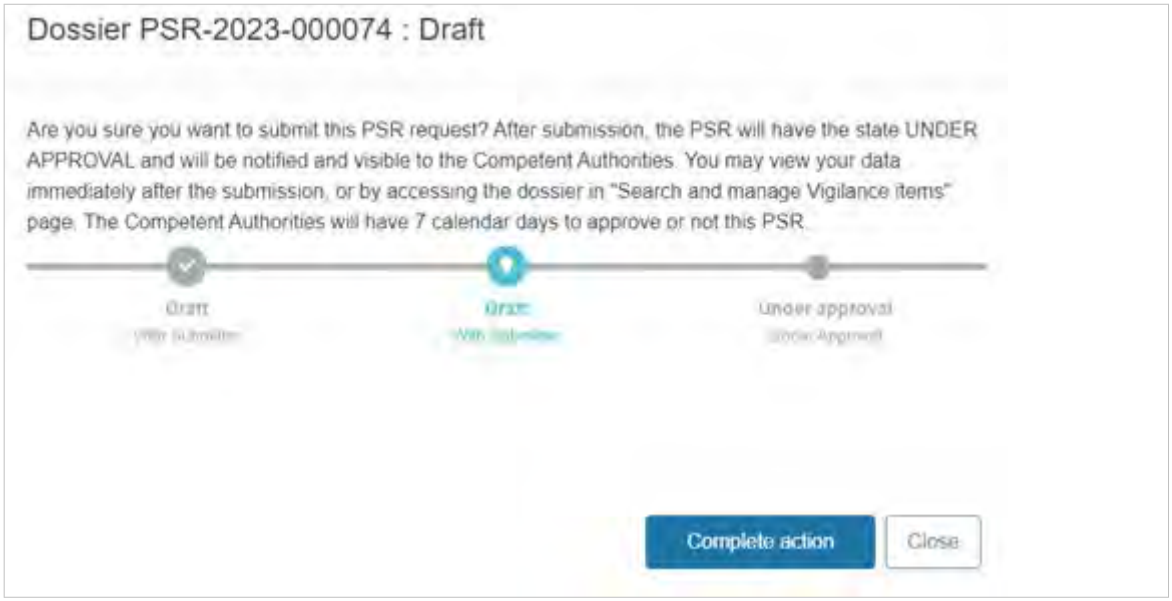
In the *General comments* section, type any comments that are relevant to the submission of the present PSR:

8.1.8 Step 7: PSR Submission

1. After you have completed all previous necessary steps, click on **Submit** at the top right corner to register your PSR:



2. Click on **Complete action** in the pop-up window to finalise the registration or **Close** to go back:

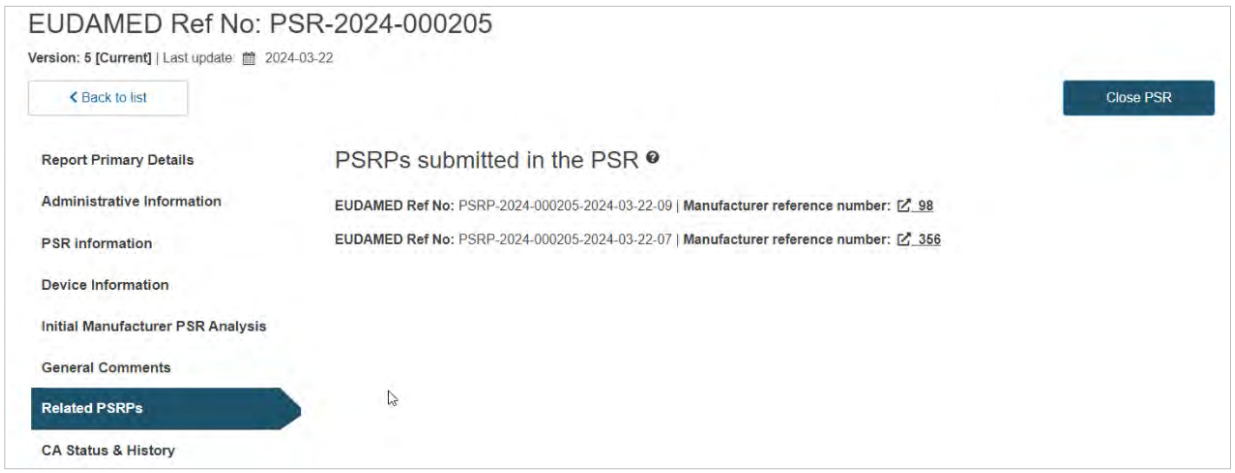


NOTE
After submission of a PSR, the Coordinating CA, participating CAs, ARs and/or MFs (depending on the actor submitting) and NBs referenced in the report will receive a notification. The PSR will have the default status *Under approval* pending CCA/CA approval:

8.2 Manage PSR

8.2.1 Related PSRPs

The *Related PSRPs* tab in the PSR serves to preview any linked PSRPs. By default this section is empty but is automatically updated as soon as any linked PSRPs are registered:

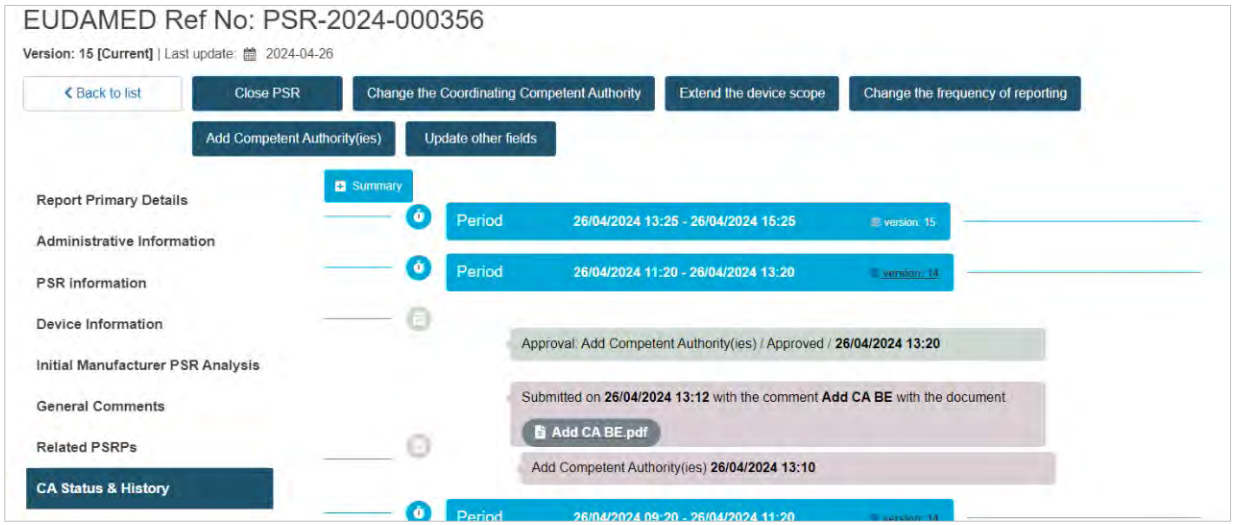


TIP
Each linked PSRP can be accessed via the hyperlink provided.

8.2.2 CA Status & History

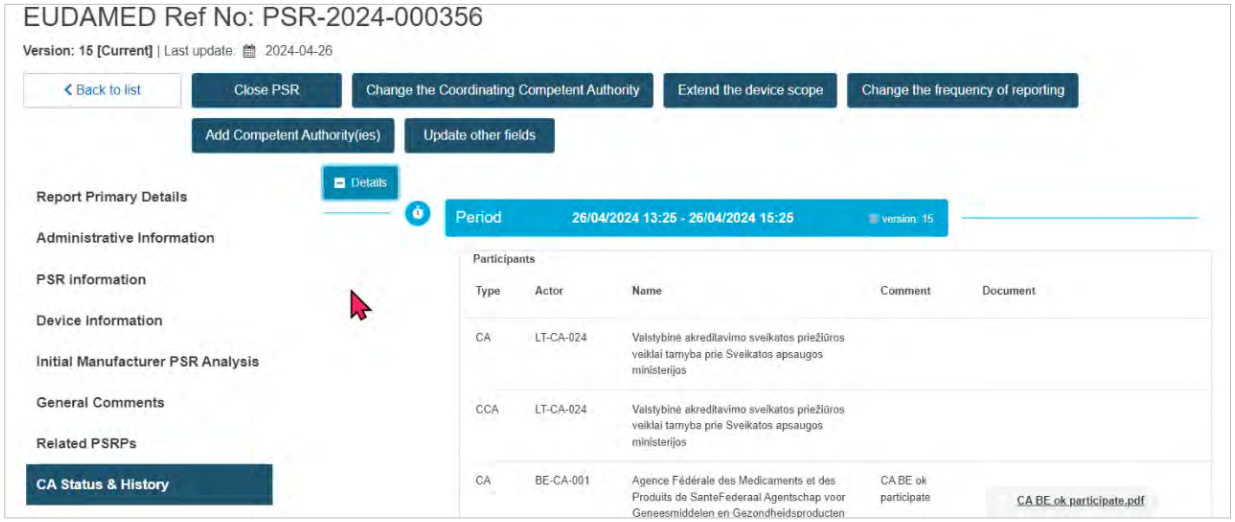
NOTE
The *CA Status & History* section contains all activity relevant to the specific PSR (e.g. CCA/CA approval or refusal, important attachments, PSRP participation and CA opt-out etc.).

After initial submission of a PSR by an MF/AR, the *CA Status & History* section becomes visible inside the PSR dossier:



By default, the section displays activity grouped by periods in a *summary mode*.

Click on **+Summary** at the top of the section to view the data in *detail mode*:



8.2.3 PSR Approval or Refusal – first version

NOTE

When a first version of a PSR has been submitted, the Coordinating Competent Authority (CCA) and the participating Competent Authorities have **seven calendar days** to either **approve** or **refuse** the PSR.

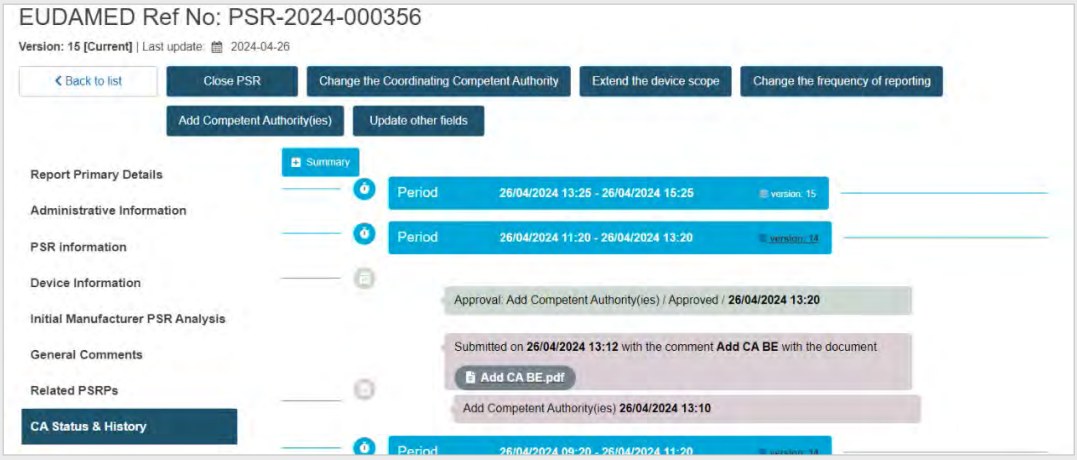
- If the CCA does not perform any action within the 7-day deadline, the PSR is considered refused.
- If a CA does not perform any action within the 7-day deadline, the PSR is considered refused by this CA, which means that this CA **will not be participating** in the PSR.

NOTE
Approved status

The PSR's status will switch from *Under approval* to *Approved* and will be set to *Active* on the first day of the next month only when the CCA approves it.

Ultimately, the CCA's decision overrules that of the CA, i.e. the participating CA's approval alone is not enough for the PSR to be approved. If the CCA refuses the PSR, the PSR is refused regardless of any approval by a participating CA.

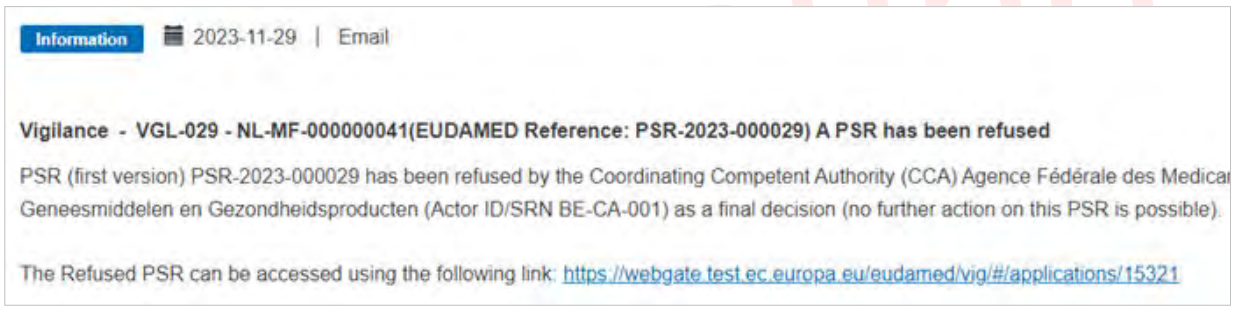
Once a PSR is submitted, you can view the approval status of the PSR under section *CA Status & History*:



Upon approval or refusal of the PSR by the CCA and the participating CAs, the MF and if applicable the AR, as well as any referenced NBs will receive information notifications:

Notification example: PSR approval by the CCA:

Notification example: PSR refusal by the CCA or deadline lapsed:

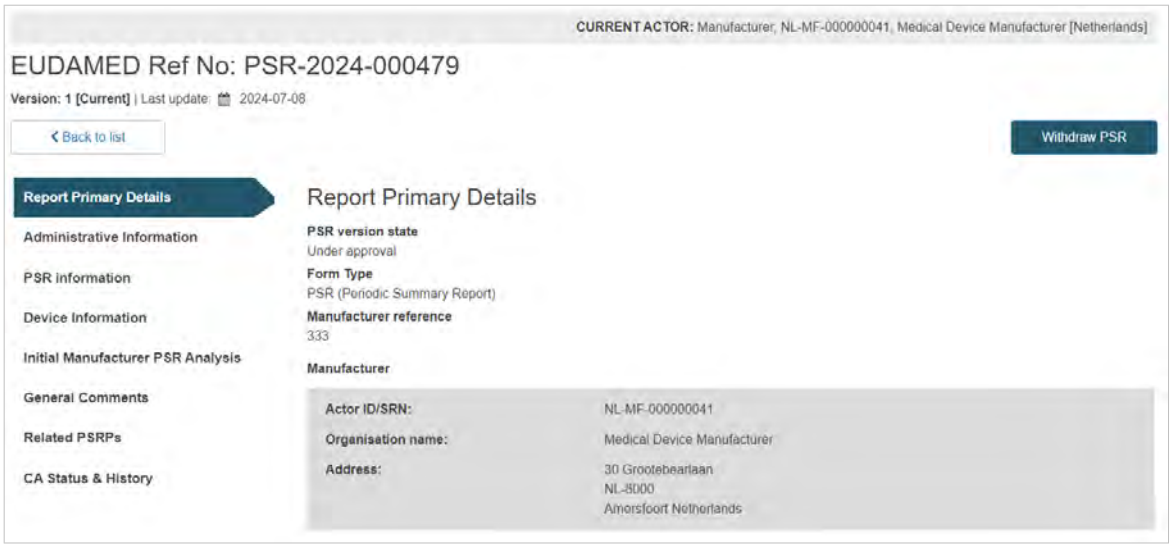


8.2.4 PSR Withdrawal – first version

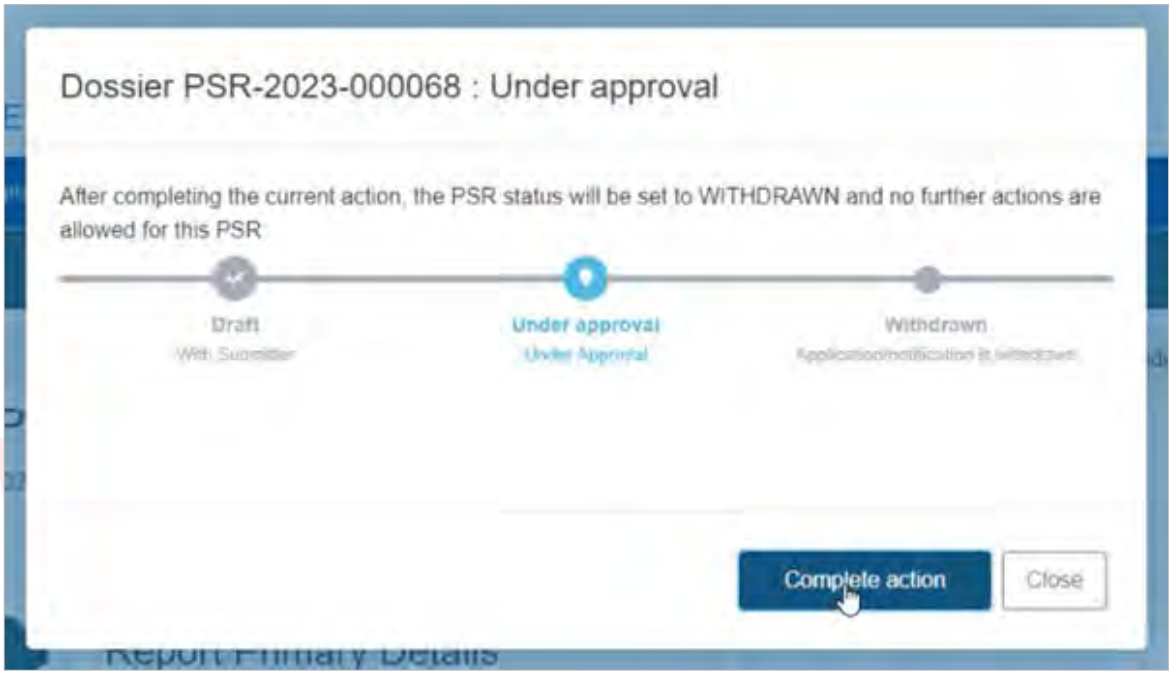
NOTE
After initial submission of a PSR and **provided that the CCA has not made an approval or refusal decision yet** (i.e. PSR status is *Under approval*), the MF or the AR can withdraw the submitted PSR.

1. Access the relevant PSR via the *Search and Manage Vigilance items* page.

2. Inside the PSR main page, click on **Withdraw** at the top right corner:

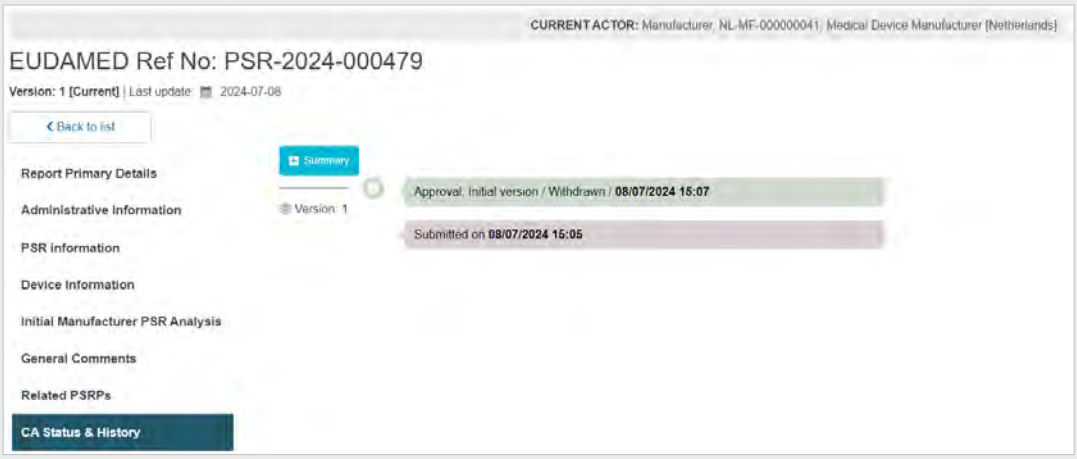


3. Click on **Complete action** in the pop-up window to finalise the withdrawal:



Upon withdrawal, the CCA, participating CAs, referenced NBs, MF and if applicable AR will receive a notification of the PSR withdrawal.

NOTE
Once a PSR is withdrawn, you can also see the action logged under *CA Status & History*:



8.2.5 Update PSR (create new version)

NOTE
Once a PSR is submitted, the MF/AR can update it and the update will be saved as a new version, pending CCA/CA approval (*Under approval* state).

Important:

In the **1st PSR period**, the update can be done as soon as the PSR is in status *Active*.

In the **subsequent periods**, a PSR update can only be done after the PSRP assessment for the period has been completed.

Once a PSR is submitted, it can be updated and the update will be saved as a new version.

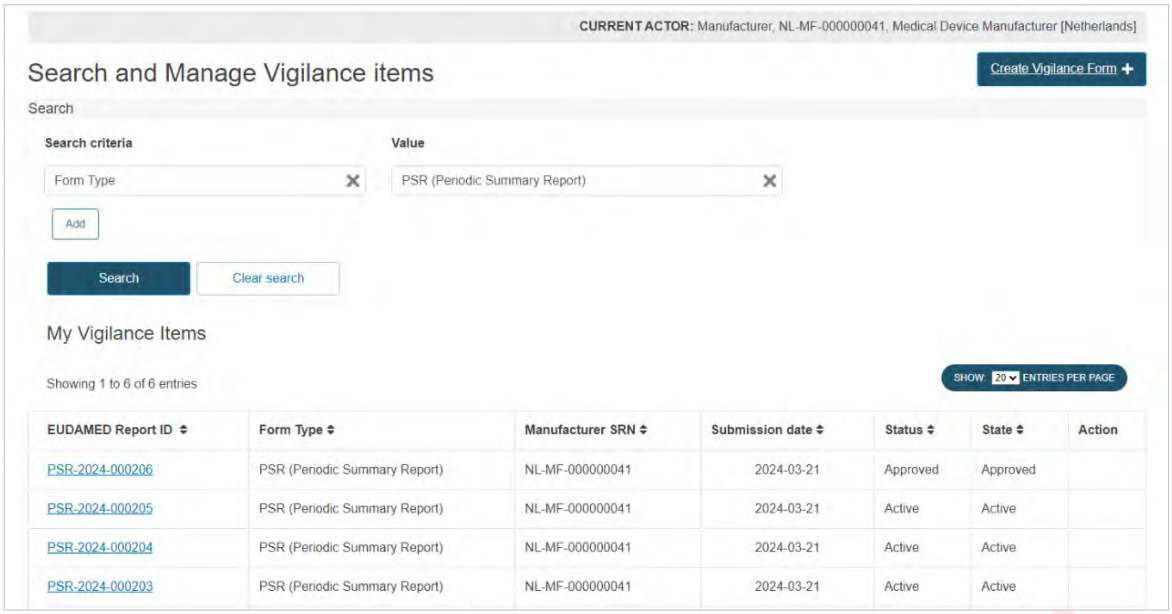
NOTE
There are five possible types of updates in a PSR:

1. **Change the Coordinating Competent Authority:** put another CA in charge of coordinating this specific PSR **(CA approval required)**
2. **Add Competent Authority(-ies):** add other participating CA(s) to this specific PSR **(CA approval required)**
3. **Extend the device scope:** add more devices **(CA approval required)**
4. **Change the frequency of reporting: (CCA approval required)**
5. **Update other fields:** all other possible updates **(no approval required)**

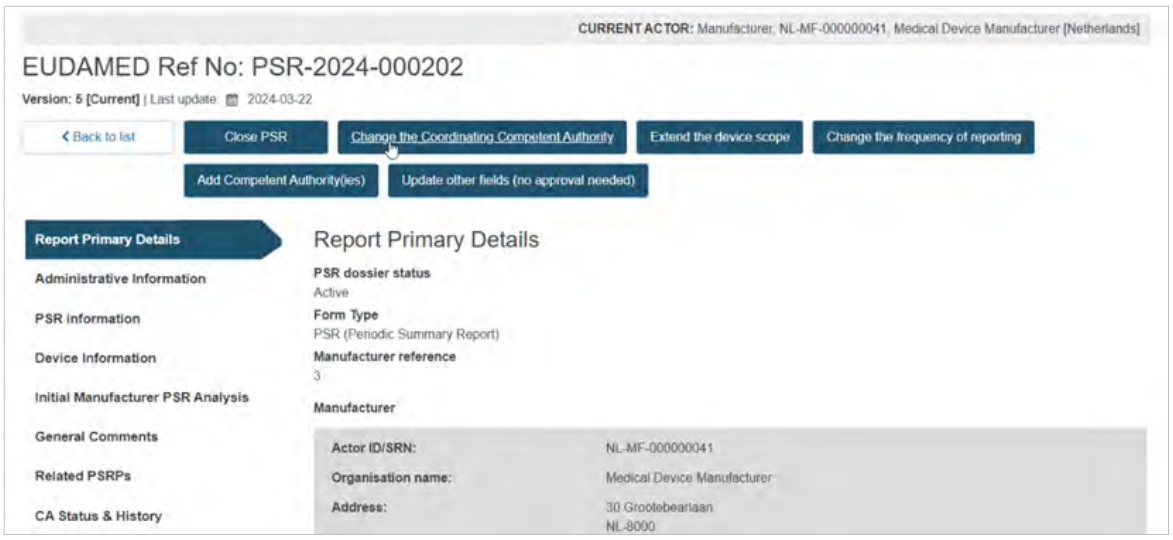
Only **one** of these update types can be performed at a time.

Depending on the update selected, **only the relevant sections will become accessible** for updating. All other sections remain **locked**, therefore please pay attention to the update button clicked, as each workflow varies.

1. Access the PSR you wish to update via the *Search & Manage Vigilance items* page:



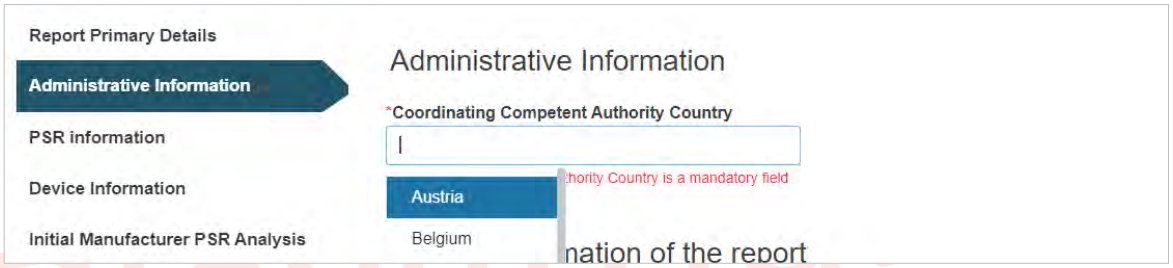
2. Inside the PSR, click on one of the five update options at the top:



In the present example the CCA is updated.

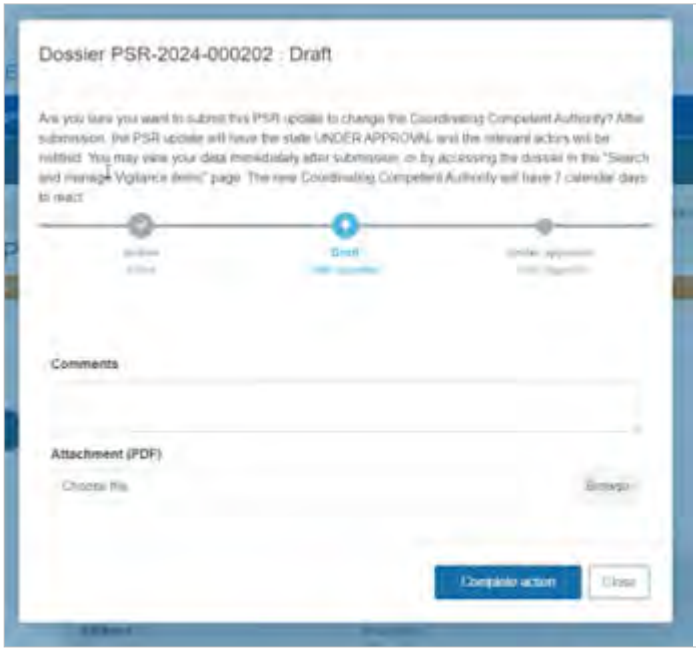
3. Click on **Complete action** in the pop-up window, to confirm the initiation of a new PSR version:

4. Navigate to the editable section(s) and update the relevant fields, e.g.:



5. Click on **Submit** at the top right of the screen:

6. Click on **Complete action** in the pop-up window, to submit the new PSR version:



The newly created version is logged under *CA Status & History*.

NOTE
Following the submission of the update, action or information notifications will be sent to involved actors. E.g. in the case of a CCA update, the newly selected CCA will receive a notification to approve or reject the update within **seven calendar days**.

8.2.6 Approval or Refusal of PSR update

NOTE
Once a PSR is updated, the new version is saved in state *Under approval* and needs to be approved (or refused) by either a) the CCA or b) the CCA and participating CA(s) within **seven calendar days**.

All following updates require approval:

1. Change the Coordinating Competent Authority *(approval by the new CCA)*
2. Add Competent Authority(-ies) *(approval by the added CAs)*
3. Extend the device scope *(approval by the CCA and all CAs)*
4. Change the frequency of reporting *(approval by the CCA)*

TIP
Approved state of PSR following an update

The PSR's state will switch from *Under approval* to *Approved* and will be set to *Active* on the first day of the next period only when it is approved.

Upon approval or refusal of the updated PSR by the CCA and if applicable, the participating CAs, the MF and/or AR, as well as referenced NBs will receive information notifications.

8.2.7 Participating CA opt-out of PSR

NOTE
Participating CAs may choose to participate or stop participating in a PSR; this is an action that becomes effective either:

- **from the beginning of the current period** - if the decision was confirmed in a linked PSRP, or
- **from the start of the next period** - if the decision was confirmed in the PSR itself.

All Actors involved in a PSR will be notified.

8.2.8 Close PSR

NOTE
The Manufacturer or Authorised Representative may decide to close the PSR at any given moment.

1. Navigate to the relevant PSR via the *Search and Manage Vigilance items* page.
2. Inside the PSR, click on **Close PSR** at the top of the screen:

3. Click on **Complete action** in the pop-up window:

TIP

The status of the PSR will be set to *Pending closure* (which will also be reflected in the *CA Status & History* section).

After the end of the last PSR period, the system will automatically set the PSR version to *Closed*:

- When the PSRP of the last PSR period is submitted, **or**
- At the end of the period when no PSRP is submitted.

Following closure, all involved Actors will receive information notifications.

9 PSRP

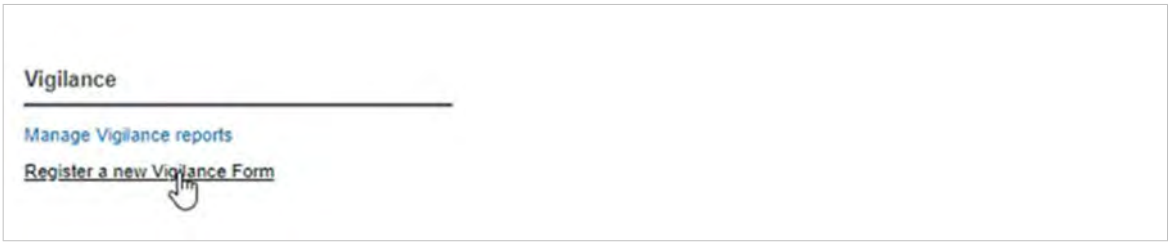
9.1 Register a new PSRP

9.1.1 Step 0: Create initial PSRP dossier

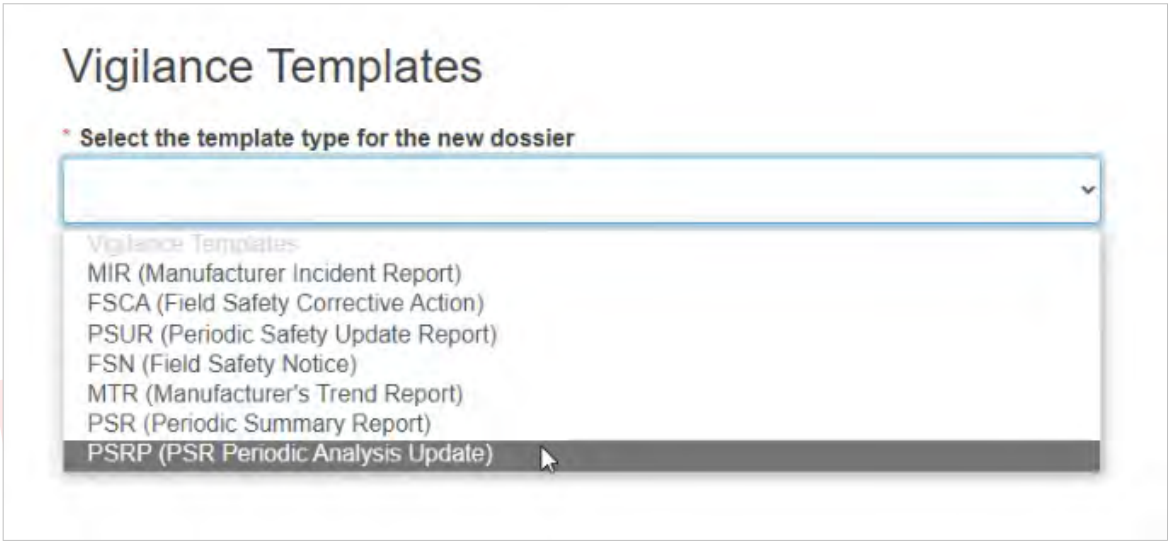
NOTE
A **PSRP (PSR Periodic Analysis Update)** must be linked to an *active* PSR and serves as a tool for periodic reporting updates after the PSR period has elapsed.

Keep in mind that if a PSRP has already been created for a specific PSR period, it is not possible to create another PSRP for the same period. The PSRP can however be updated (new version).

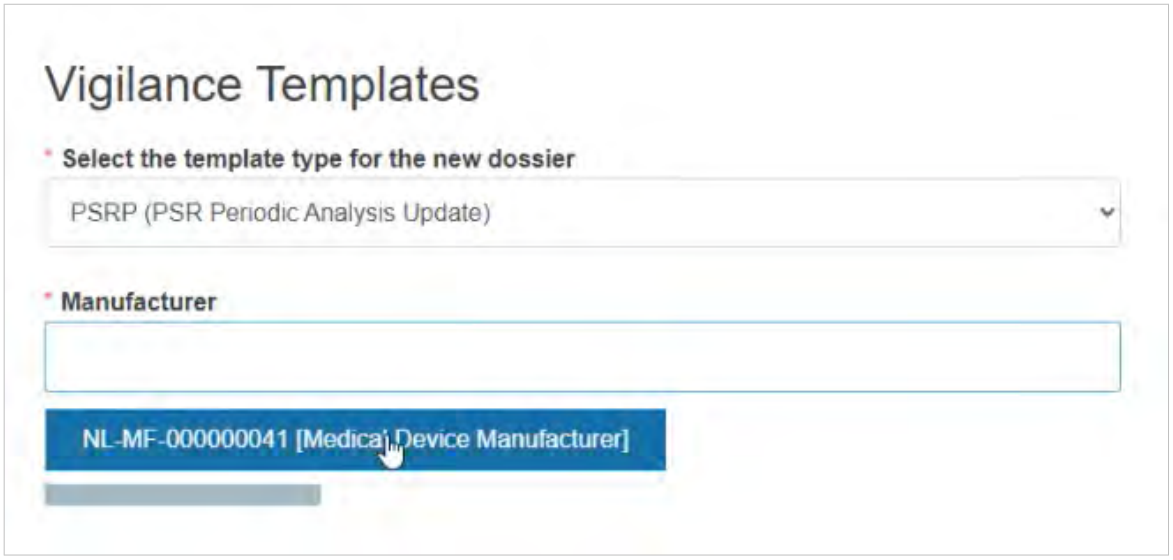
1. On the EUDAMED dashboard, click on *Register a new Vigilance Form* under the *Vigilance* section:



2. Select the PSRP template from the dropdown list:



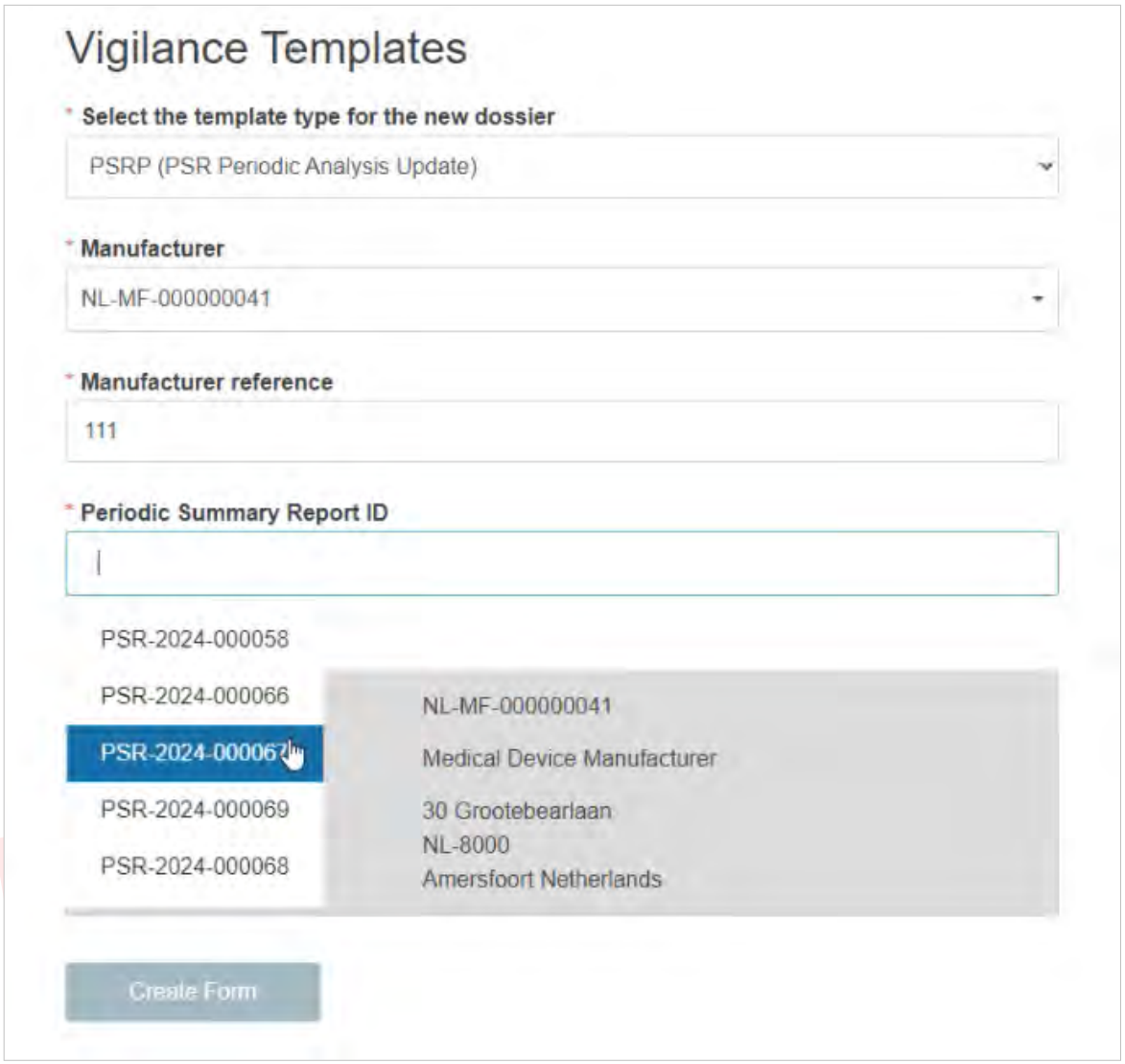
3. Select the manufacturer from the *Manufacturer* field:



The system will automatically retrieve your Actor information.

4. Enter the unique *Manufacturer reference*.

5. Select the PSR ID you wish to link the PSRP to:



TIP
The system will only display PSRs for which a new PSRP can be created.

6. Click on **Create Form** to complete this initial step.

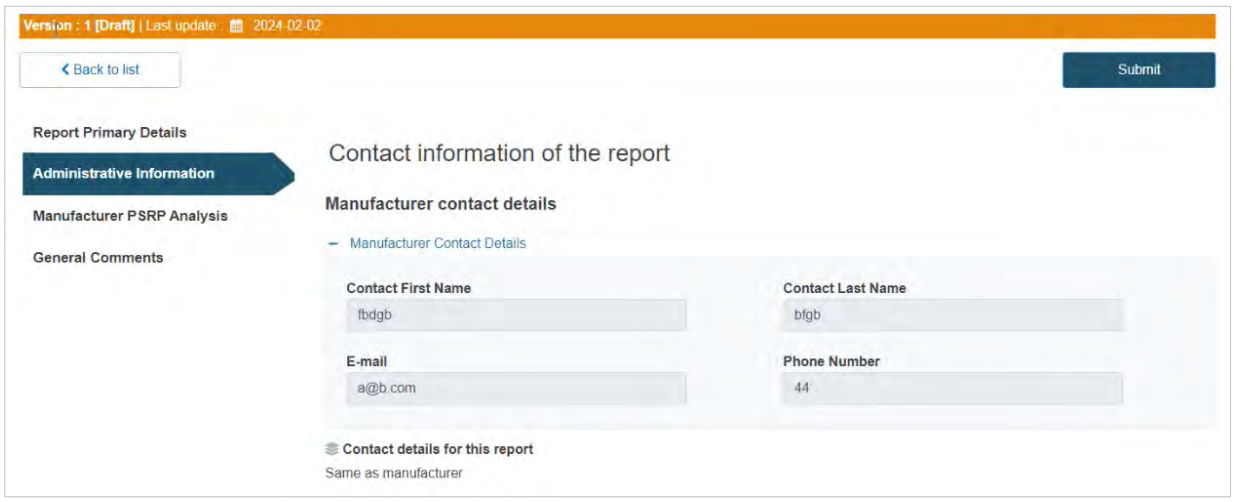
IMPORTANT
The information provided in this step cannot be modified after you click **Create form**.

9.1.2 Step 1: Report primary details

The *Report primary details* section provides an overview of the data entered in the initial creation of the dossier:

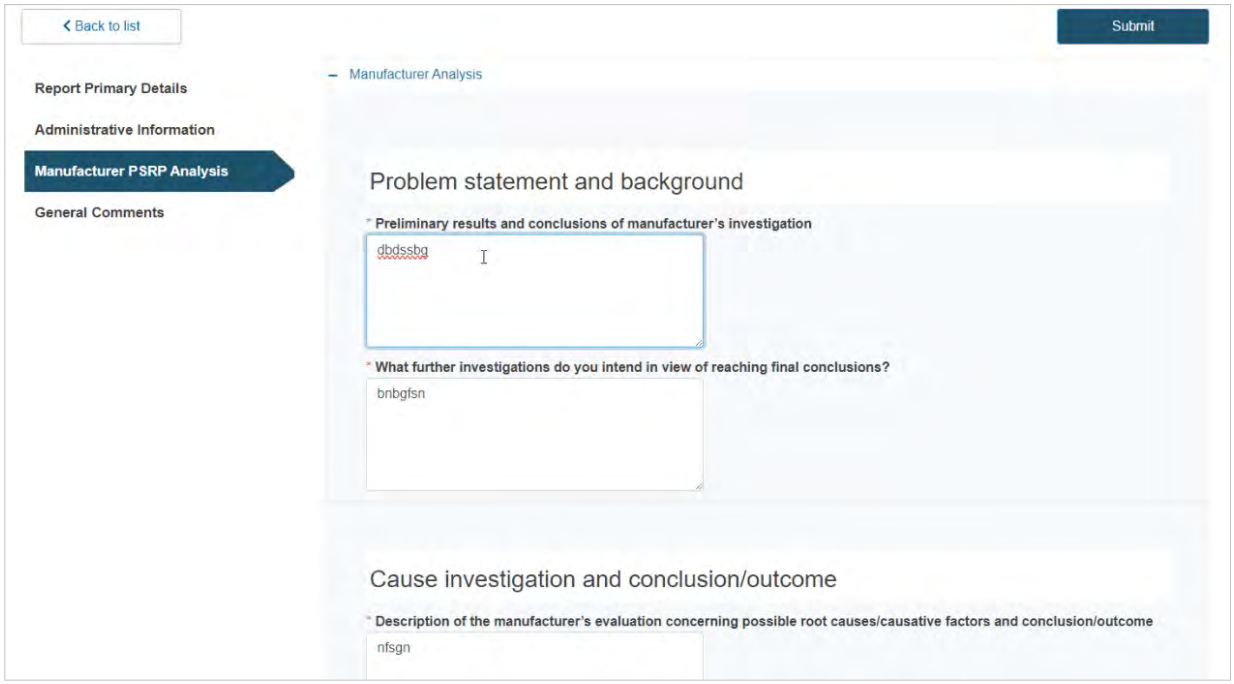
9.1.3 Step 2: Administrative information

The PSRP *Administrative information* section contains the pre-filled contact details for this report, same as the contact details entered in the linked PSR.



9.1.4 Step 3: Manufacturer PSRP analysis

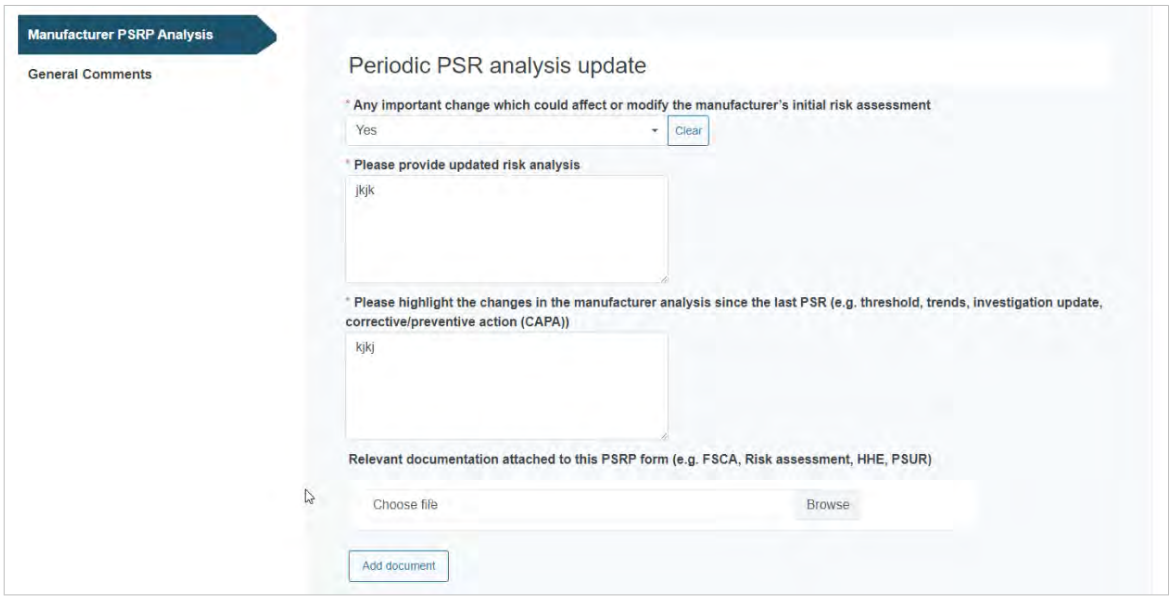
This section contains information about the problem statement, the cause investigation and conclusions as well as similar incidents. By default, most fields are pre-filled with information from the linked PSR but you can add or modify the data accordingly.



1. Verify that the information entered is applicable or adjust accordingly in the following sections:
   - *Problem statement and background*
   - *Cause investigation and conclusion/outcome*
   - *Similar incidents*

TIP
If necessary, consult the user guide's Initial Manufacturer PSR analysis [121] section.

2. Fill in the *Periodic PSR Analysis Update* section:



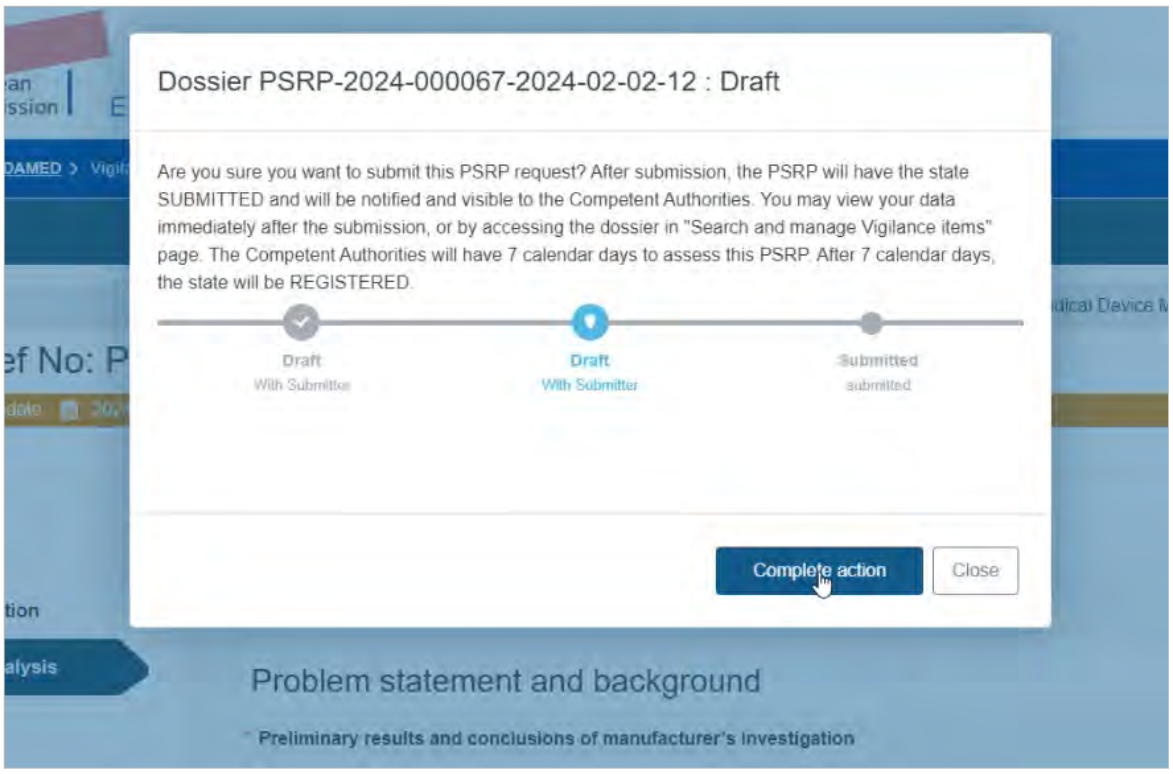
3. Fill in the *Comments* field:

9.1.5 Step 4: General comments / Submission

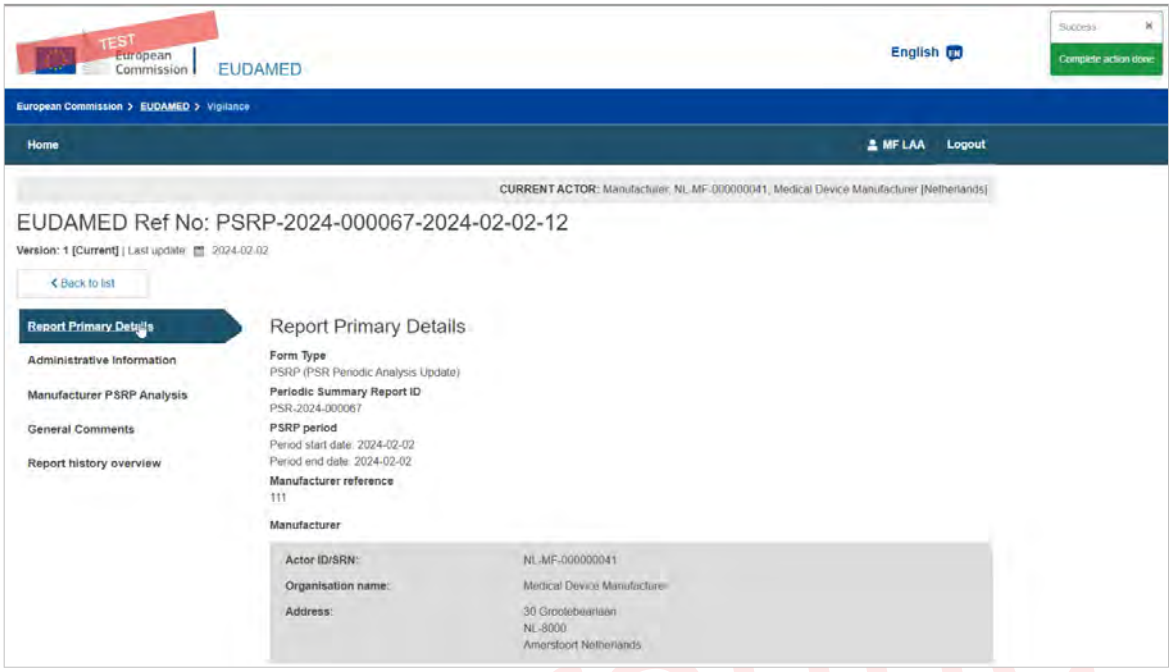
1. Fill in the *General Comments* field with any other pertinent information:

2. After having verified that all information included in all previous steps is correct, click on **Submit**.

3. Click on **Complete action** in the pop-up window to finalise the submission or **Close** to go back:



The system will redirect you to the *Report Primary Details* screen of the submitted PSRP in preview mode with a green *Success* message at the top right corner confirming your action:



9.2 Manage PSRP

9.2.1 Related incidents submitted (under development)

The *Related incidents submitted* section contains the linked incidents (MIRs) (if any) which were submitted during the PSRP period.

If needed, click on the hyperlink next to each one of the MIRs in order to preview them.

9.2.2 PSRP first version assessment by participating CA (opt-in/opt-out)

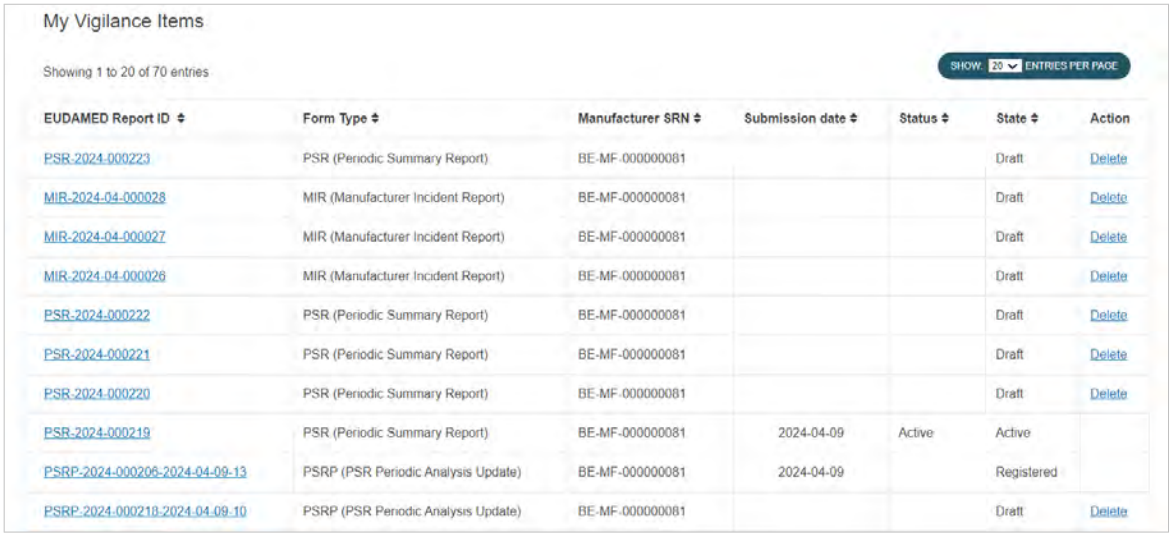
NOTE
Following the submission of a new PSRP (first version), participating CAs receive a notification to assess it within seven calendar days:

- If the participating CA **stops participating** in the PSR, they will be considered not participating from the beginning of the current period.
- If the participating CA performs **no action**, the CA continues to participate in the PSR.
  The PSRP changes to status *Registered* after seven calendar days from submission.

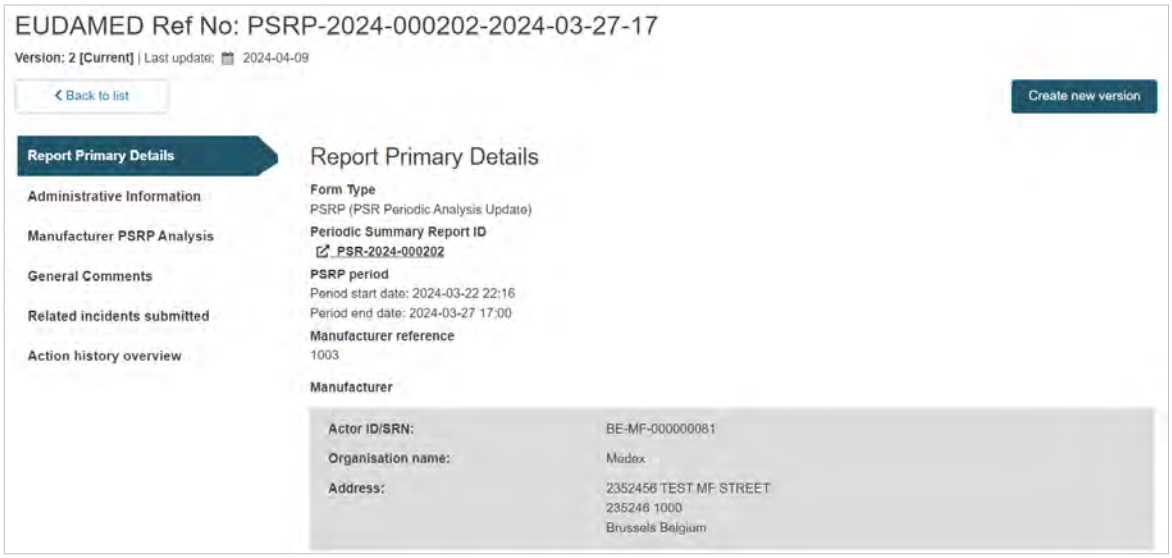
9.2.3 Update PSRP (create new version)

NOTE
Once a PSRP is submitted, it can be updated and the update is saved as a new version.

1. Access the PSRP you wish to update via *Search & Manage Vigilance items* page:



2. On the *Report Primary Details* page, click on **Create new version** at the top:

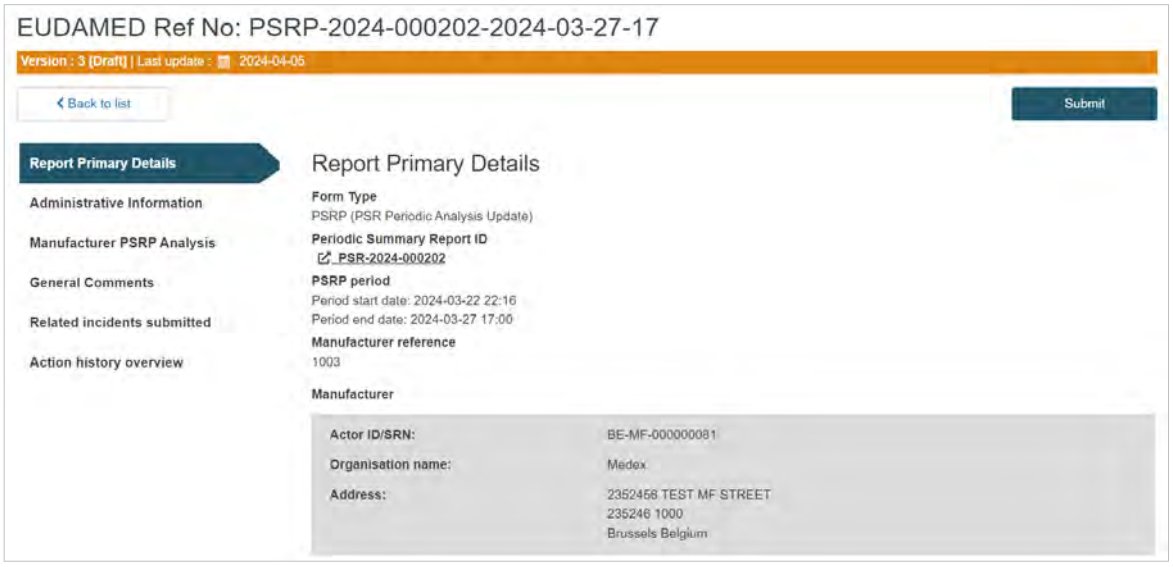


3. Click on **Complete action** in the pop-up window, to confirm the initiation of a new PSRP version:

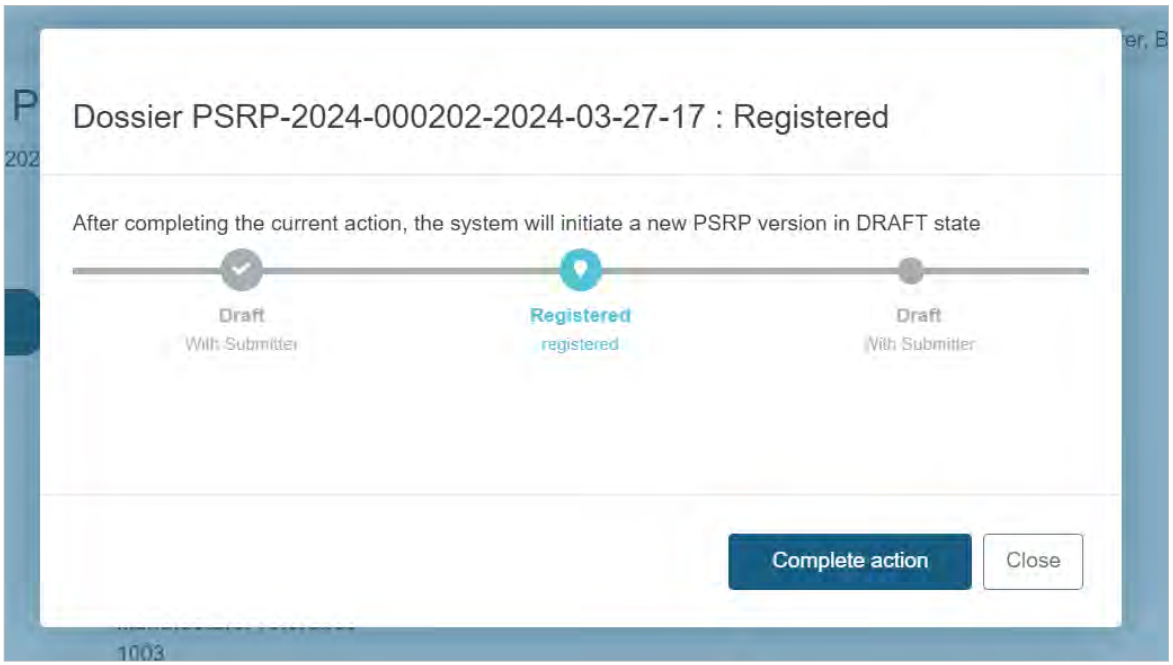
The applicable sections will become accessible for updates.

4. Navigate to the editable section(s) and update the relevant fields as necessary.

5. Click on **Submit** at the top right of the screen to submit the new version:

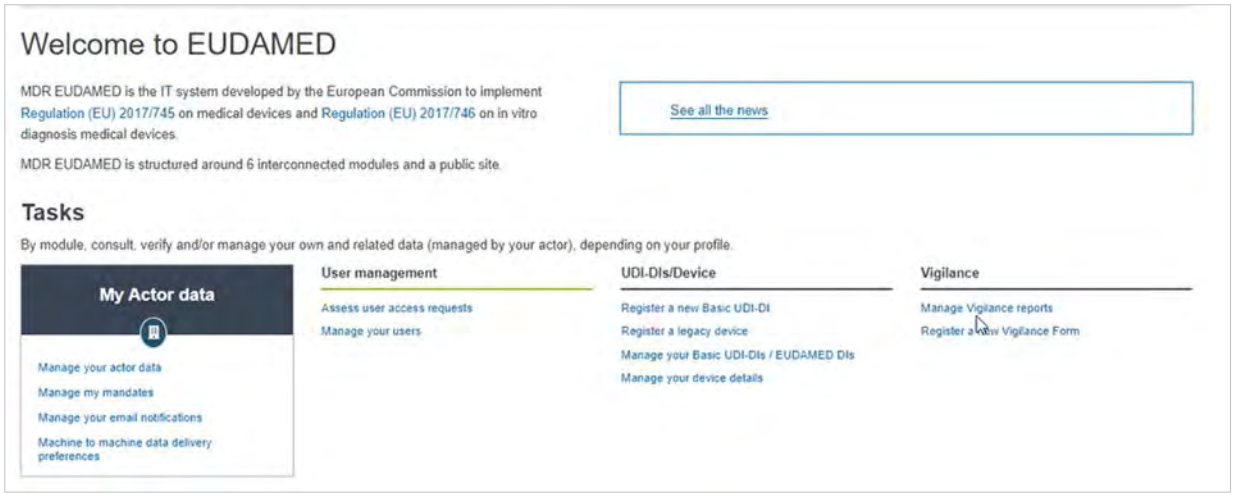


6. Click on **Complete action** in the pop-up window, to confirm the submission of the new PSRP version:

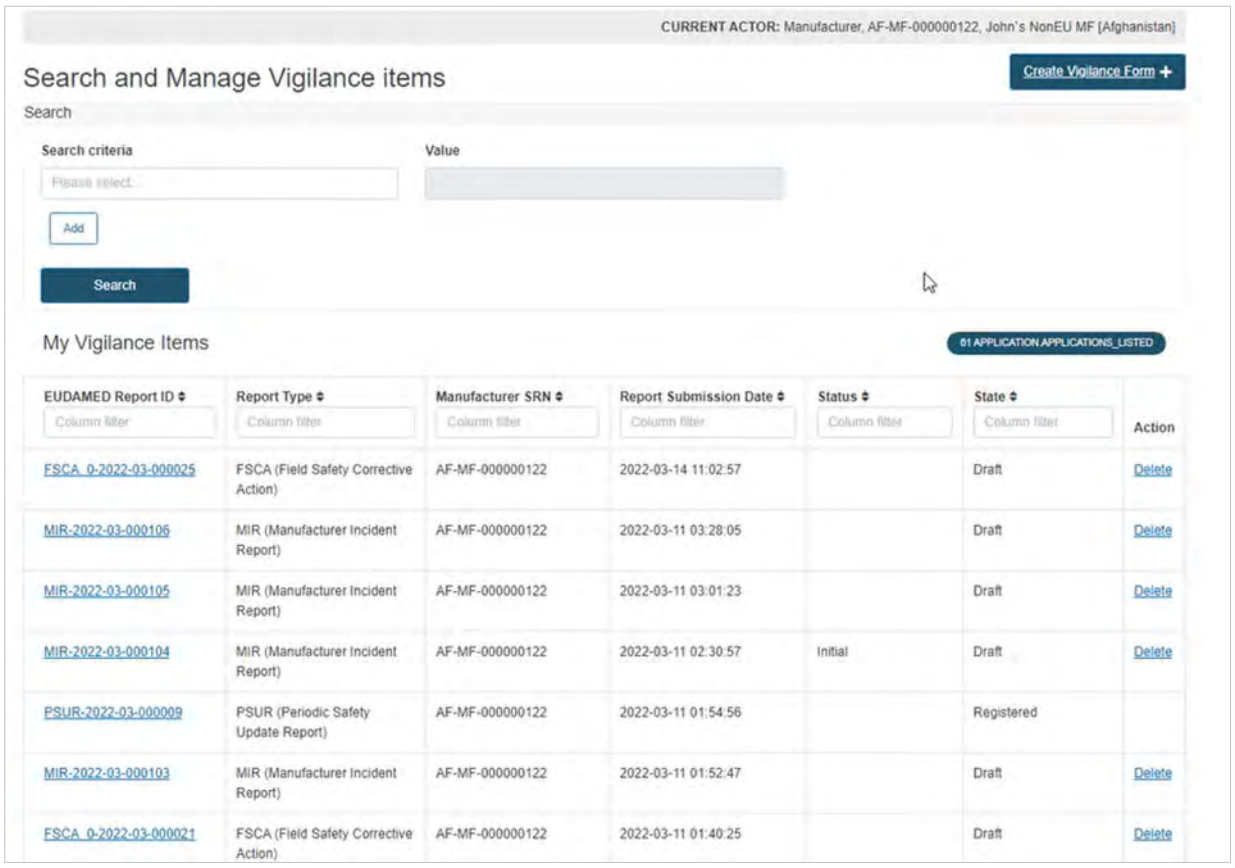


10 Manage Vigilance & Post-Market Surveillance reports

From the EUDAMED dashboard, click on *Manage Vigilance reports* under the Vigilance section:

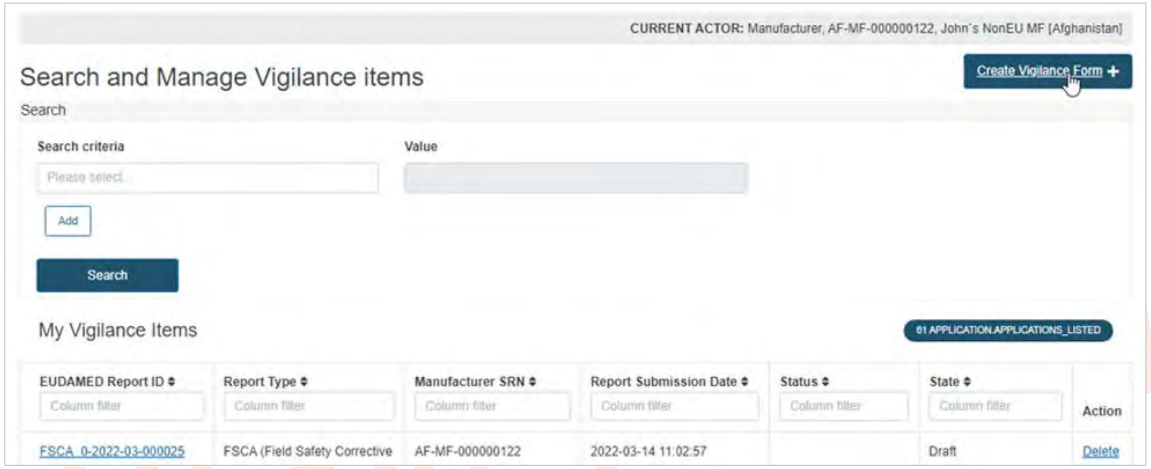


The system will redirect you to the page *Search and Manage Vigilance items*:



10.1 Create Vigilance & Post-Market Surveillance form

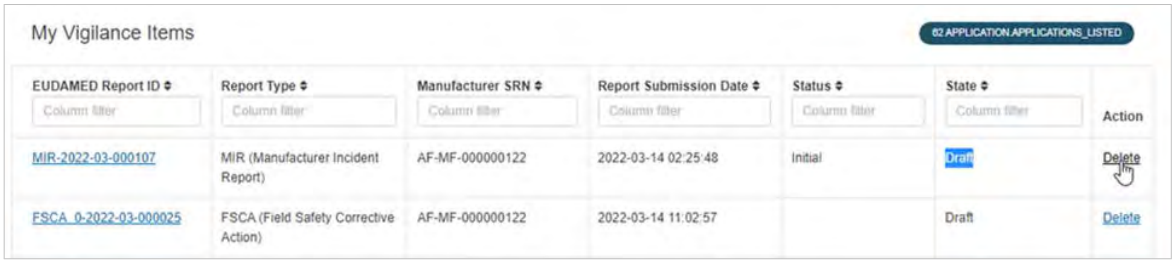
This is an alternative path to the command *Register a new Vigilance Form* that can be found on the EUDAMED dashboard under the *Vigilance* tab (both lead to the same *Step 0* for the initiation of a Vigilance dossier).



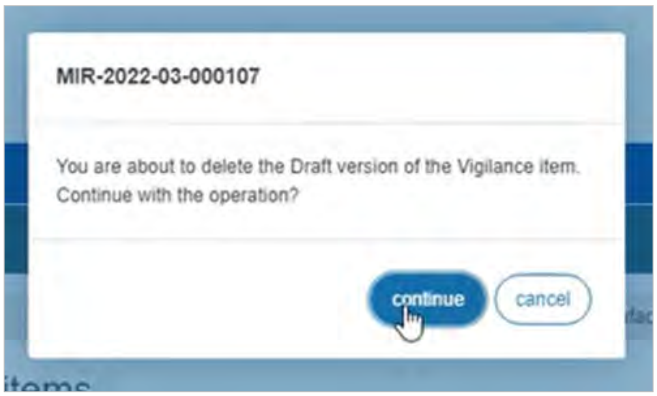
10.2 Delete Vigilance & Post-Market Surveillance draft report

Newly created versions in state *draft* (not yet submitted) can be deleted from *My Vigilance items*.

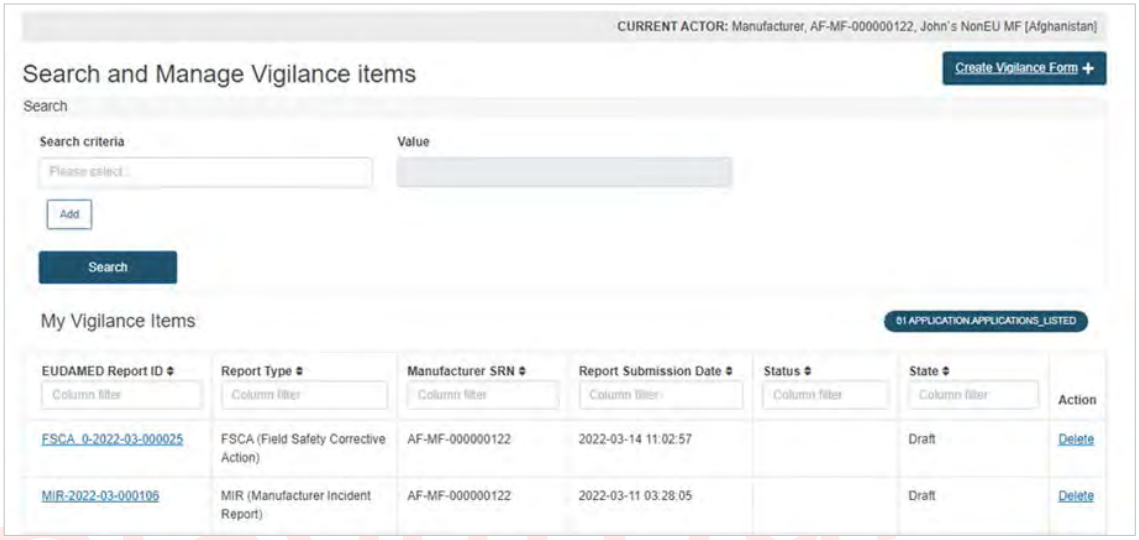
1. Click on **Delete** next to the relevant report under *Action*:



2. Click on **Continue** in the pop-up window to finalise the action:



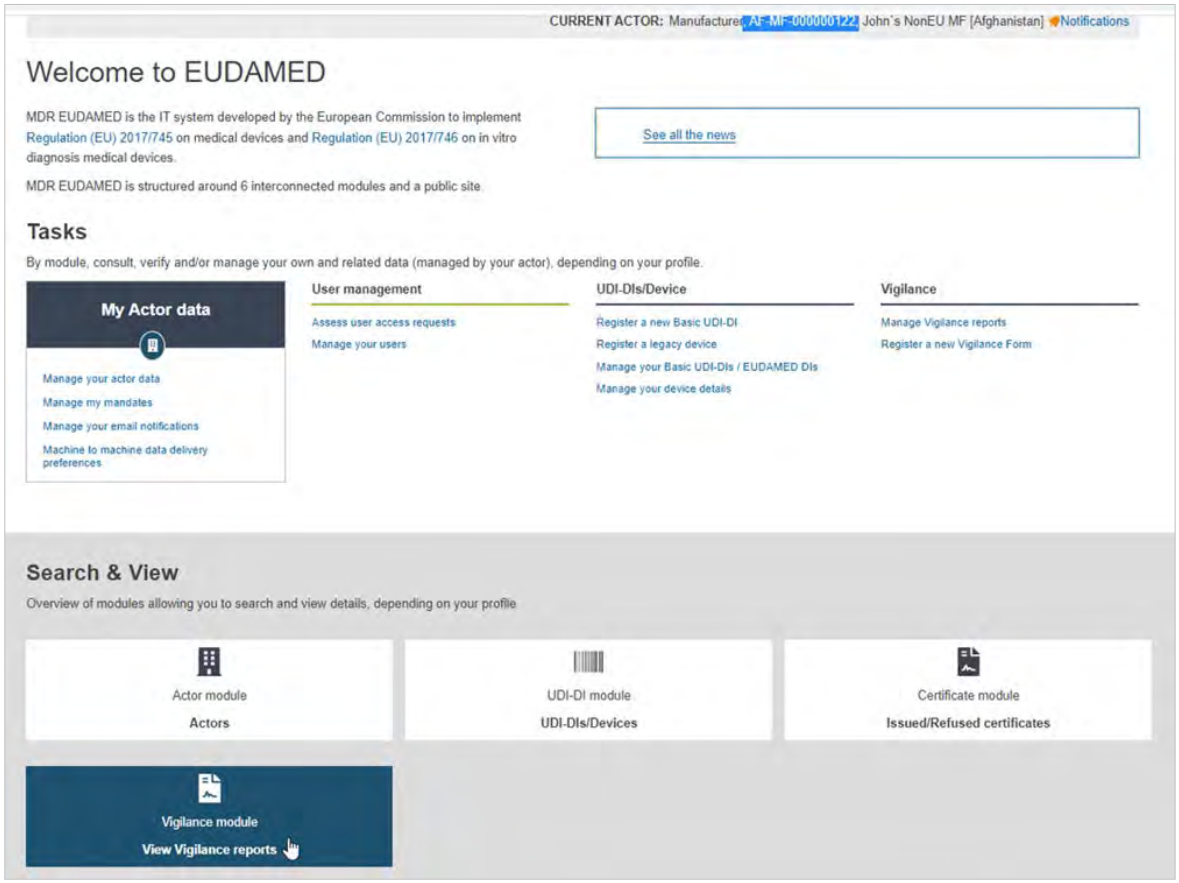
The system will redirect you to the *Search and Manage Vigilance items* page:



10.3 Search & View Vigilance & Post-Market Surveillance reports

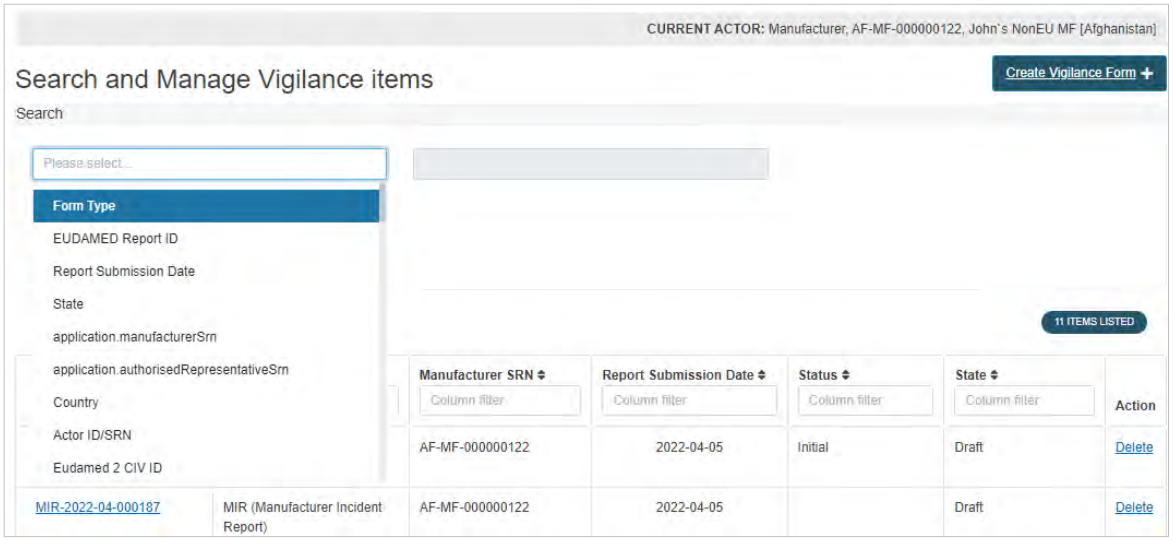
All users having access to the Vigilance module can use the *Search & View* functionality for Vigilance reports.

To do so, from the EUDAMED dashboard click on *View Vigilance reports* under the *Search & View* section:



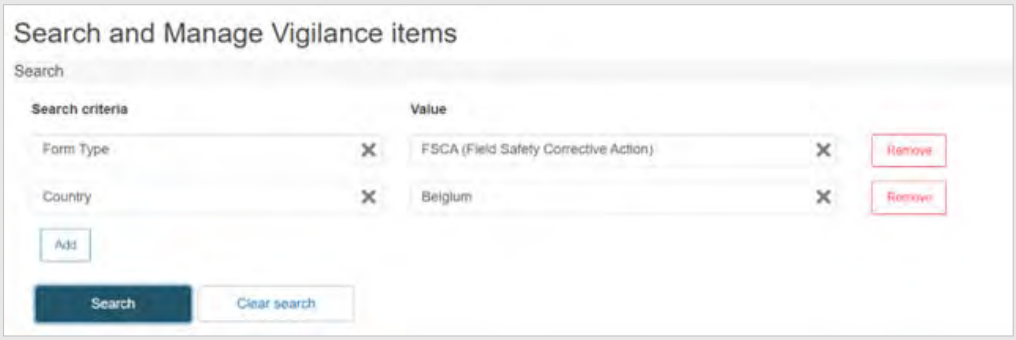
The system will redirect you to the *Search and Manage Vigilance items* page:

1. Select the *Search criteria* (or filter) that you wish to apply and provide the chosen value:



TIP

Click **Add** to apply several search criteria:



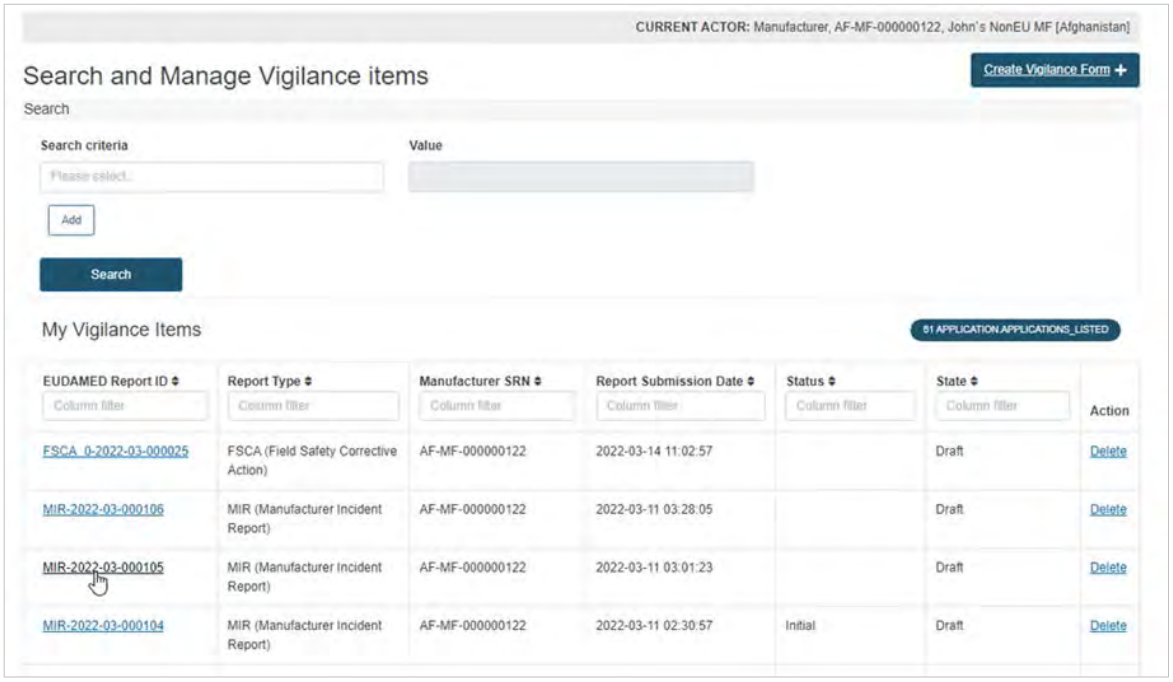
2. Click on the **Search** button.

View Vigilance & Post-Market Surveillance report

NOTE

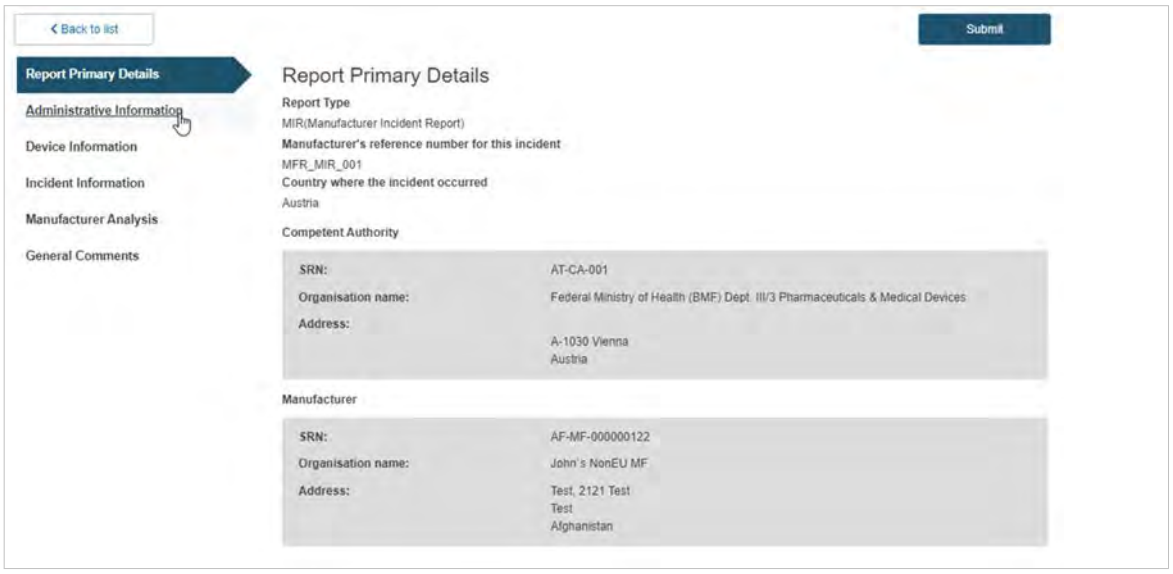
All users with *Viewer* profile or higher can click on a report from the list and preview its contents:

1. Click on the chosen Vigilance item under the *EUDAMED Report ID* column:



The system will redirect you to the *Report Primary Details* screen of the chosen Vigilance item in preview mode.

2. Click on the section of your choice to preview its information:

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