EUDAMED user guide

Market Surveillance

Playground v 3.11.0
2025

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1 Data structure

Access EUDAMED Market Surveillance (Playground).

1.1 Procedure characteristics

Unacceptable Risk (UNR) must include at least one corrective action at submission, linked to one or more Economic Operator(s) (EO) and one or multiple devices.

Measures from the initiating CA should only be registered in EUDAMED after the period has passed for the EO to take adequate corrective actions, when EO did not comply with the requirements.

Other CAs may also add measures and additional information, but they can only object to the initiating CA's measure(s),

Other Non-Compliance (ONC) does not require corrective action(s) and must link to one or multiple EOs and one or multiple devices.

There must be at least one measure linked to the procedure before it can be submitted.

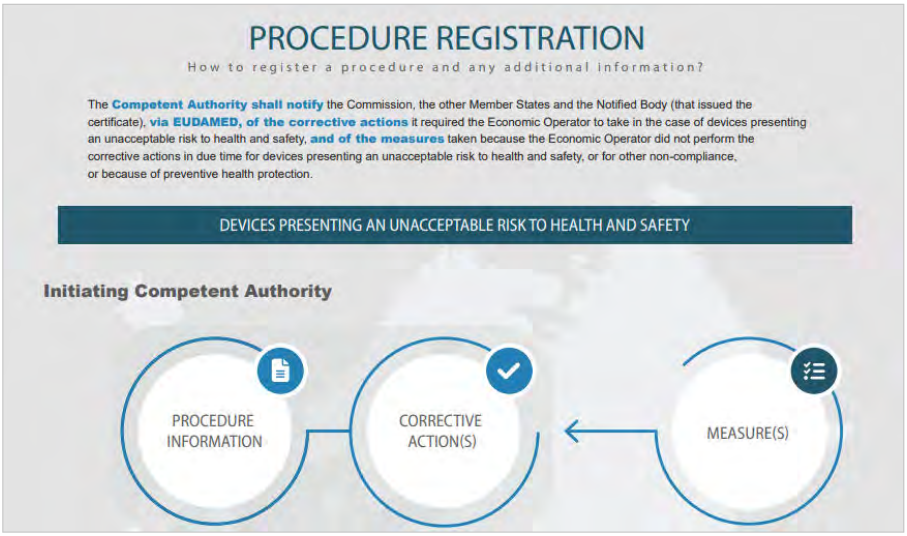
There is no possibility to register objections on measures for ONC.

Preventive Health Protection (PHP) follows the same rules as ONC. The only difference for the device scope type is that the category can be used for preventive health protective measures while for ONC and PHP it is not an option.

Procedure and linked items

Procedure type	Linked Corrective action(s) – by initiating CA?	Linked Measure(s) – by initiating CA?	Other CA can add Measure?	Other CA can add Additional information?	If linked measure: other CA can object?	EO	Device
UNR	At least 1 at submission – cannot be added afterwards	Only when Procedure = Open (i.e. can only be added after submission)	Yes	Yes	Yes, but only within two months of first submission of measure by initiating CA (cannot object to measure by other CA)	=/>1	=/>1
ONC	No	At least one at submission; cannot be added afterwards	No	No	No	=/>1	=/>1
PHP	No	At least one at submission; cannot be added afterwards	No	No	No	=/>1	=/>1

INFOGRAPHIC: MSU procedure processes



Who has access

The main actor in the Market Surveillance (MSU) module is the Competent Authority. CA users must request access to the CA to which they belong.

A *slim viewer* profile is assigned by default to the MSU users for Vigilance and CI/PS.

A Notified Body (NB) referenced in a procedure is notified once the procedure is submitted, and will have read-only access to the record via the *Search & View [71]* page.

Economic Operators and Sponsors have no access to the MSU module.

The icon indicates the fields the NB will not view:

1.2 User profiles

Any user who wishes to have access to the MSU module in Playground will have to submit a user access request in EUDAMED Playground.

To request a change/upgrade of your profile, click on your name in the top right of the screen to reach the *My Account* page. Click on the link next to your profiles called **Request for change**. Follow the steps to select the profiles for the module you need. Your Actor LAA/LUA will approve the request. Please keep in mind that an LAA cannot approve their own requests. Therefore, a second user with an LUA or LAA profile will be needed to approve any profile upgrade request submitted by the first LAA.

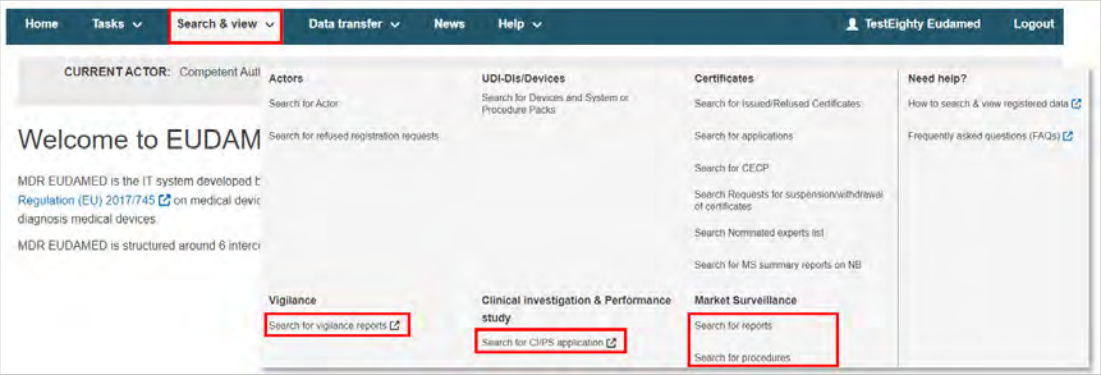
2 Getting started

Prerequisites to access EUDAMED

EU Login Account: If you do not have an **EU Login account**, please follow the instructions for creating an account before attempting to use the EUDAMED database.

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

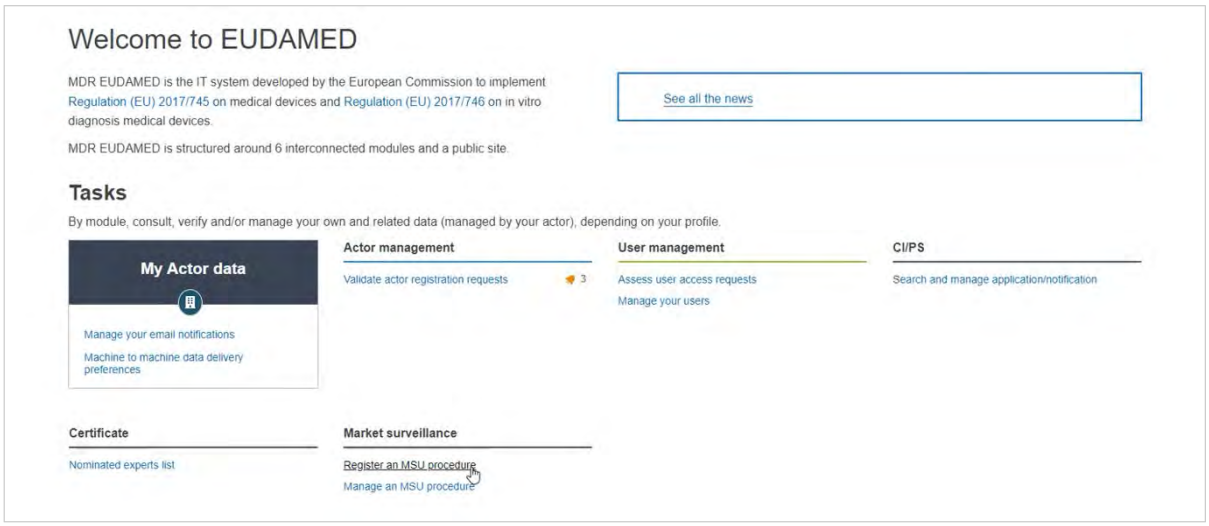
You will be prompted to enter EUDAMED via your EU Login account. Once you are logged in,[1] your dashboard will show links to the **Market Surveillance module**.



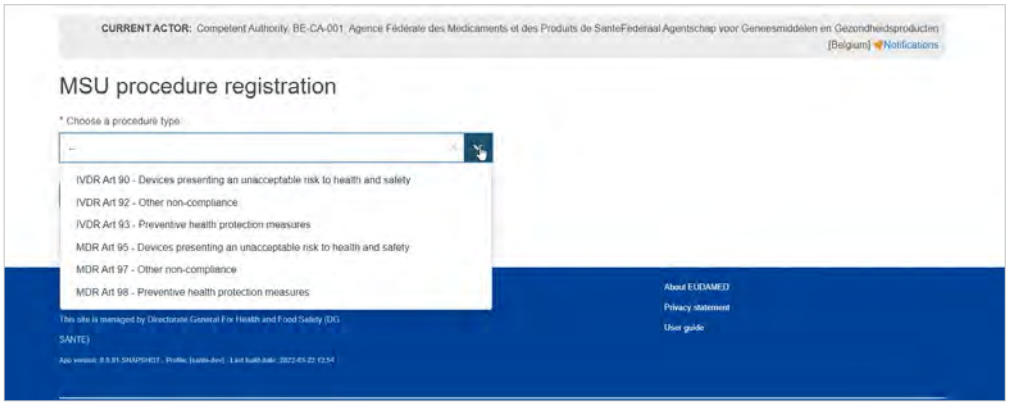
[1]For a wider understanding of how to use the platform (in the Playground environment), visit the EUDAMED Information Centre.

3 Registration of procedure

1. From the dashboard, select *Register an MSU procedure*:



2. The pull-down lists the three types of procedure (UNR, ONC and PHP):



NOTE

Before the new procedure has been submitted, it is listed in the dashboard as a *1st Draft*. A procedure listed as *draft* is a new version of the submitted procedure.

PHP-BE-2022-0105	MDR Art 98 - Preventive health protection measures	BE-CA-001	Open	-	2022-11-23	Draft
UNR-BE-2022-0286	MDR Art 95 - Devices presenting an unacceptable risk to health and safety	BE-CA-001	Open	-	2022-11-23	1st Draft

3.1 Device-applicable legislation values

Procedure types

Procedure type description	Procedure type
MDR Art 95 – Devices presenting an unacceptable risk to health and safety	MDR UNR
MDR Art 97 – Other non-compliance	MDR ONC
MDR Art 98 – Preventive health protection measures	MDR PHP
IVDR Art 90 – Devices presenting an unacceptable risk to health and safety	IVDR UNR
IVDR Art 92 – Other non-compliance	IVDR ONC
IVDR Art 93 – Preventive health protection measures	IVDR PHP

Applicable legislation

Label	Abbreviation
Regulation (EU) 2017/745 on medical devices	MDR
Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices	IVDR
Council Directive 93/42/EEC on Medical devices	MDD
Council Directive 90/385/EEC – Approximation of the laws of the Member States relating to active implantable medical devices	AIMDD
Directive 98/79/EC on *in vitro* diagnostic medical devices	IVDD

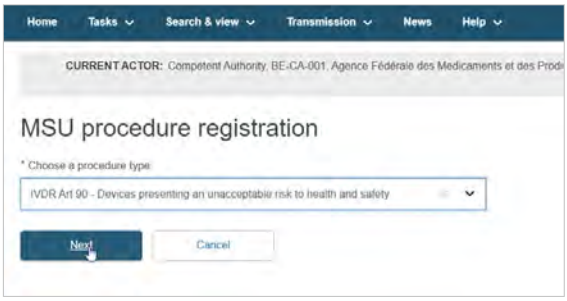
The system will limit available applicable legislation values for non-registered devices based on procedure type. Only combinations marked **Y** presented in the Procedure type/ Applicable legislation table will be available for the user.

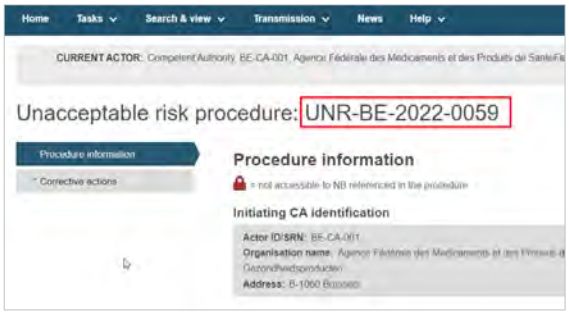
Procedure type / applicable legislation

Procedure type	MDR	IVDR	MDD	AIMDD	IVDD
MDR UNR	Y	N	Y	Y	N
MDR ONC	Y	N	Y	Y	N
MDR PHP	Y	N	Y	Y	N
IVDR UNR	N	Y	N	N	Y
IVDR ONC	N	Y	N	N	Y
IVDR PHP	N	Y	N	N	Y

3.2 Unacceptable risk procedure

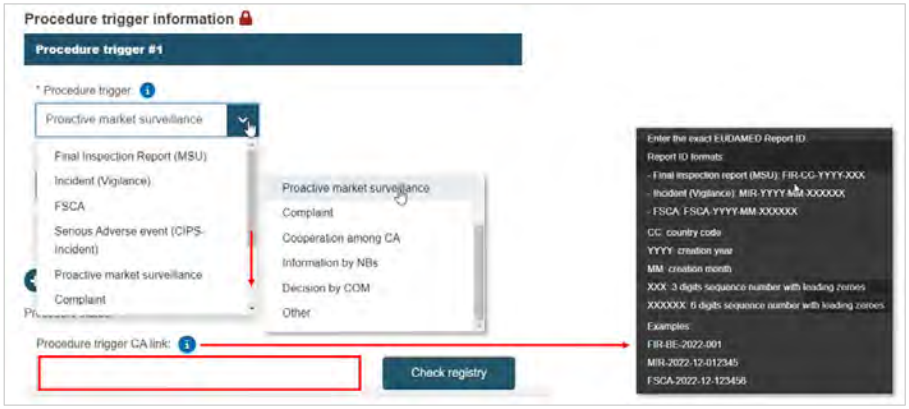
1. Select *Unacceptable risk procedure* from the dashboard, click **Next**, and EUDAMED generates a procedure identifier with the abbreviation 'UNR', the country, year and reference. Note the **Corrective action** button already appears, because it is a mandatory requirement of this procedure type and cannot be added after submission:





2. Enter the *Local CA procedure reference*.

3. Select at least one *Procedure trigger* and provide the *Procedure trigger CA link* (see the tooltip for details):

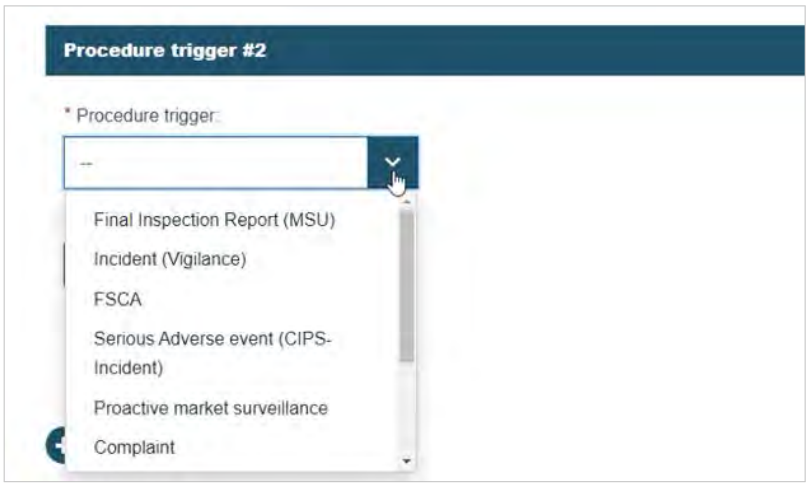


For other trigger types, except for 'Other', the user may provide a Procedure trigger CA reference not mentioned in the text:

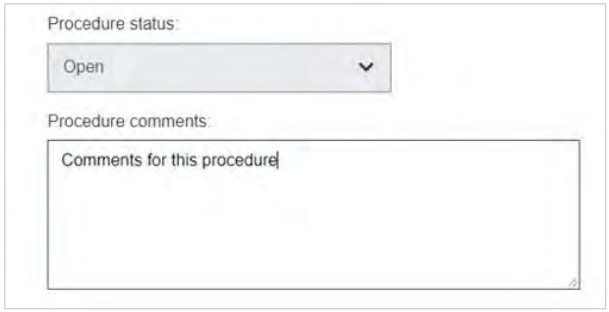
4. If you select *Other*, provide the description:

You may upload several *Procedure trigger files* (PDF format, max 10MB each):

5. You can register multiple triggers in the same way via the **Add procedure trigger** button:

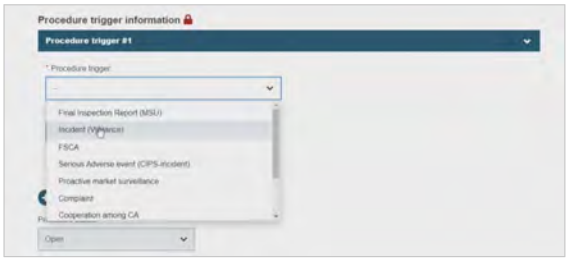


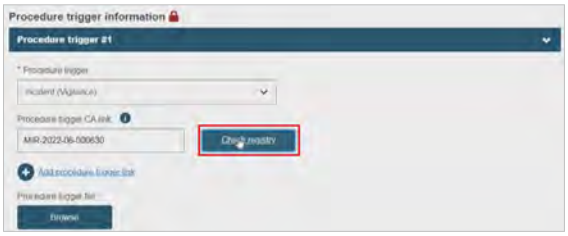
The *Procedure status* is set to *Open* in the initial version of the procedure. The field becomes editable only in a new version:



3.2.1 Trigger: Incident (Vigilance)

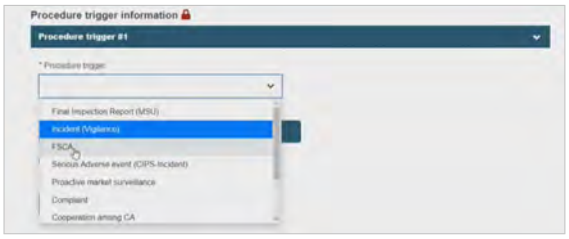
Select *Incident (Vigilance)*. If the Manufacturer Incident Report (MIR) is registered in EUDAMED, provide the full EUDAMED reference and click **Check registry**:

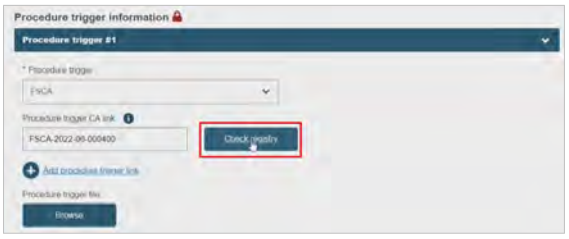




3.2.2 Trigger: FSCA

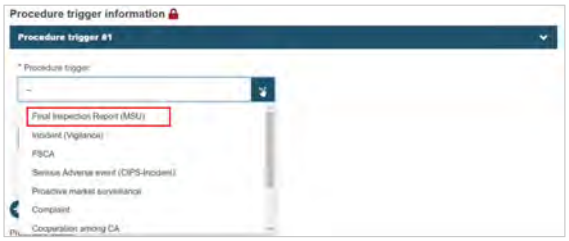
Select *Field Safety Corrective Action (FSCA)*, then provide the FSCA reference if registered in EUDAMED. Click **Check registry**:

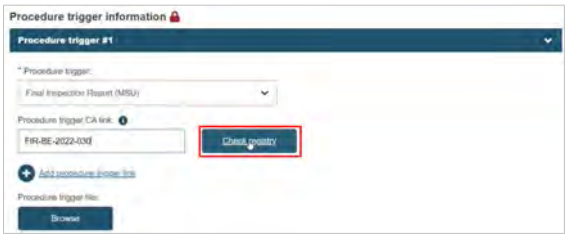




3.2.3 Trigger: FIR

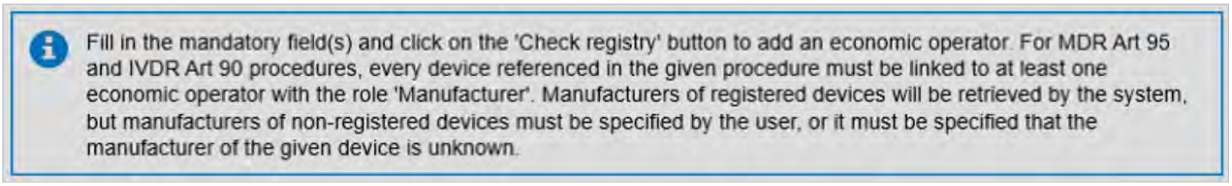
Select *Final Inspection Report (MSU)*. If registered in EUDAMED, provide the CA link, which is the ID of the inspection report, and click **Check registry**:



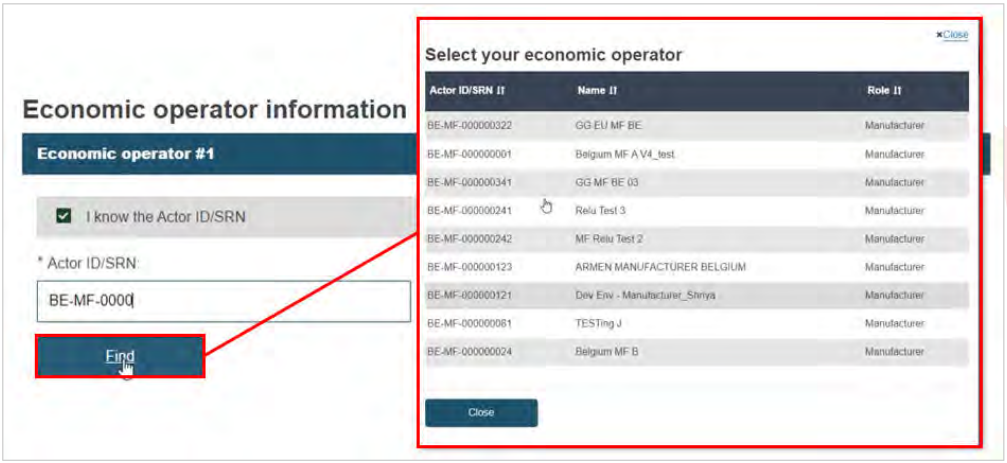


3.2.4 Economic operator information

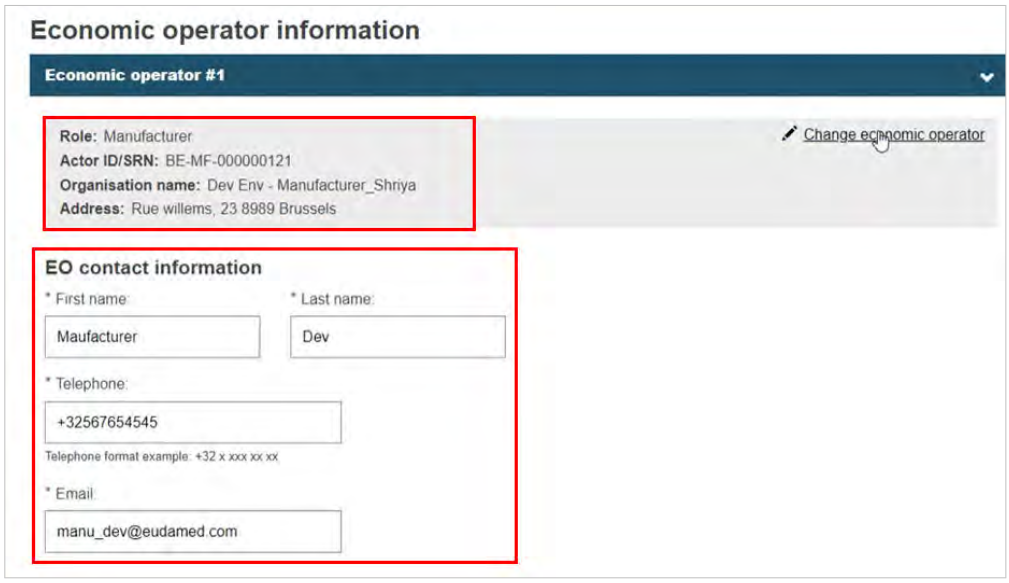
At least one EO must be identified. Note the system message before proceeding:



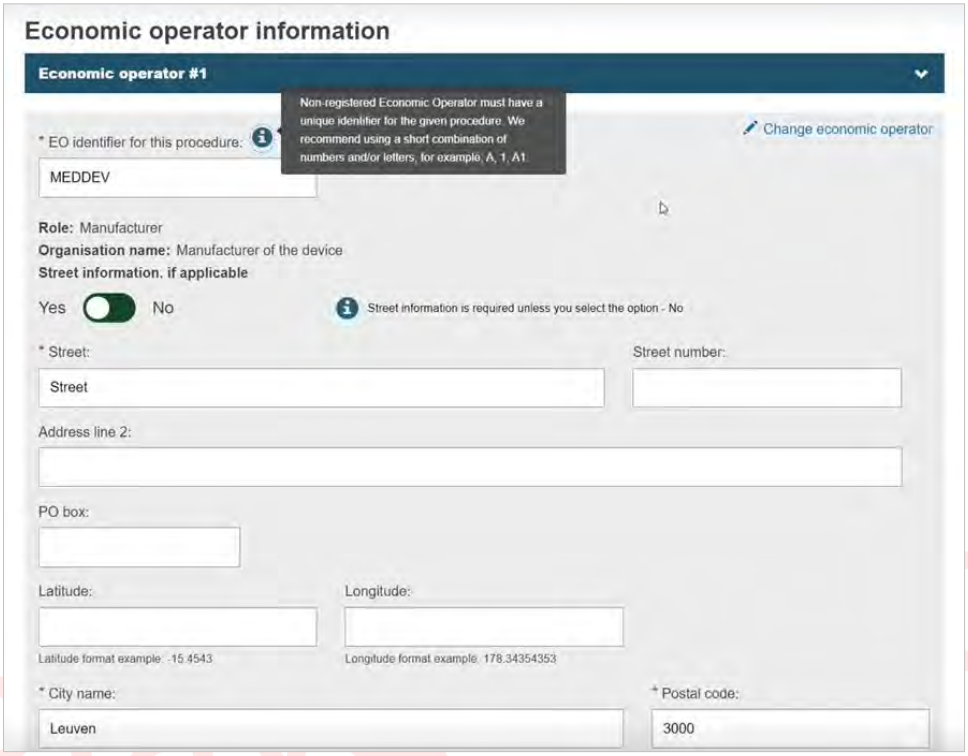
If you know the *Actor ID/SRN*, click the box and enter at least five characters. Click **Find** and select the intended EO:



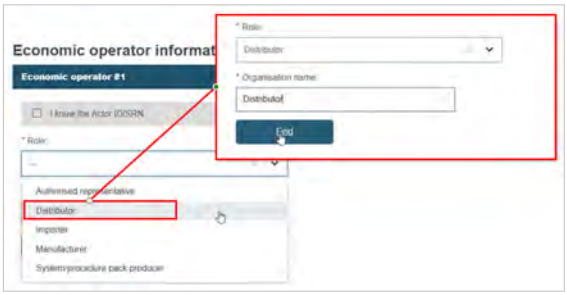
The system pre-populates the EO information fields, and the EO contact information can be edited. If you register new contact information, it only relates to this Market Surveillance procedure. You can change your choice of EO by clicking **Change economic operator** and follow the same steps:

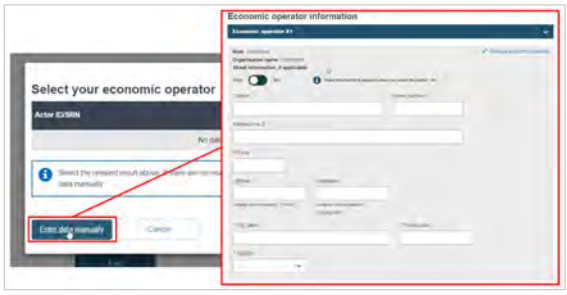


1. If the EO is not registered, enter the data manually.
   a. Provide a unique EO identifier (up to 20 characters), which is used when linking a device to it.

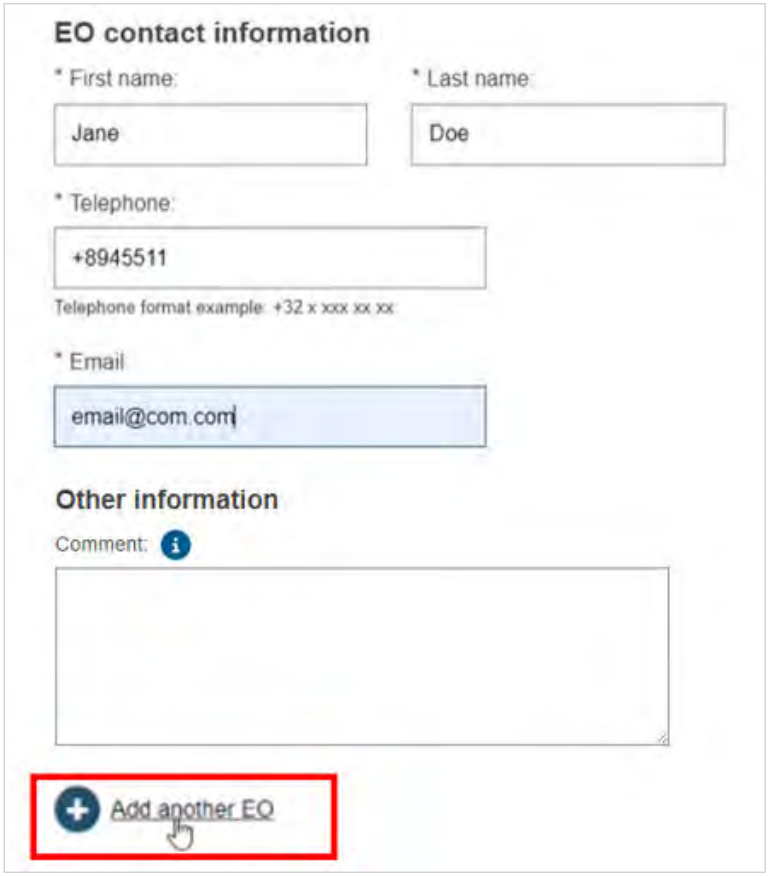


2. While a *Distributor* is not an actor in EUDAMED, it can be linked to a procedure. Select *Distributor*, type in the Distributor name and click **Find**. As no result will be shown, click **Enter data manually** and complete the distributor information:





3. To add additional EOs, click **Add another EO**:

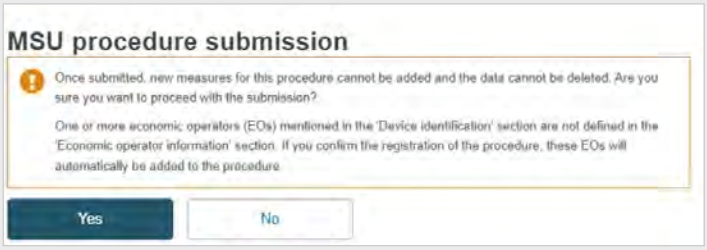


4. Every EO must be linked to at least one device (see Device information [11]). This could be ensured by linking EO(s) to the device in the device section. Manufacturers and Authorised Representatives of the registered device are linked automatically.

NOTE

On submission, if a Manufacturer or Authorised Representative referred to in the procedure Device is not linked to the Procedure, the confirmation warning displays.

EO contact information fields are automatically populated when submitted a procedure or the new version of the procedure:



3.2.5 Device information

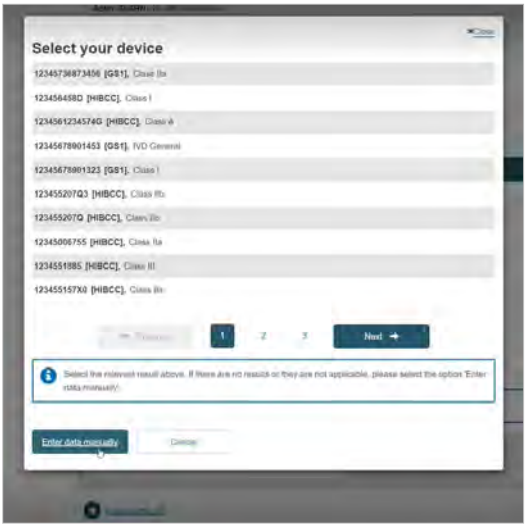
Click **Device scope type** and select the *Device scope type* from the pulldown.

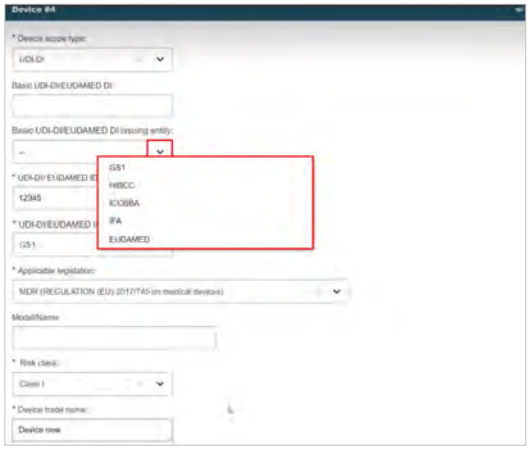
1. **UDI-DI**

a. Select *UDI-DI/EUDAMED DI* in *Device identification*. Enter the value and click **Check registry**. No manual entry is possible if the search returns only one record and there is an exact match for the device identifier (UDI-DI in this case). Click on the device:

The system retrieves the Manufacturer information, and you can also link other EOs:

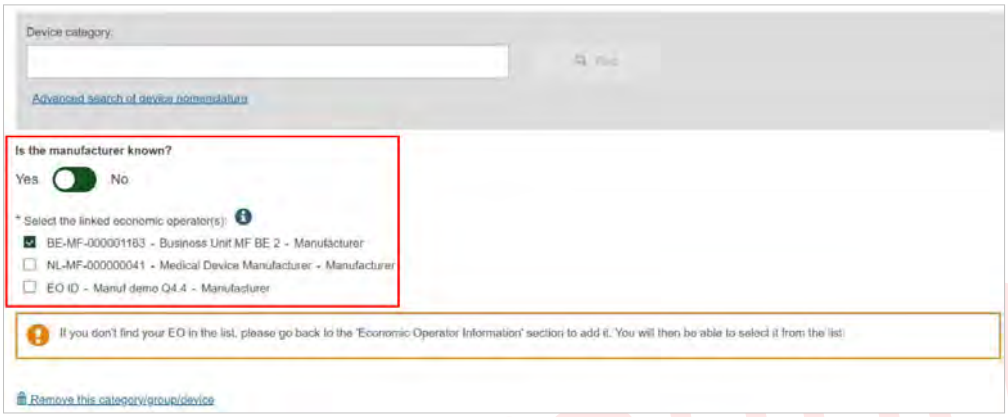
b. If the device is **not listed** because it is not registered in EUDAMED, click **Enter data manually** and complete the fields:



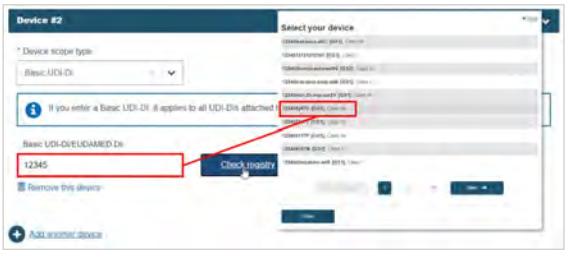


The **Is the manufacturer known** toggle allows you to proceed without a known manufacturer:

If one/several manufacturers are known, toggle to **Yes** and you now **must** link the device to at least one manufacturer. The possible EOs are displayed. See the EO information [8] Chapter):



2. **Basic UDI-DI**
Select *Basic UDI-DI*. Select a device from the displayed list:

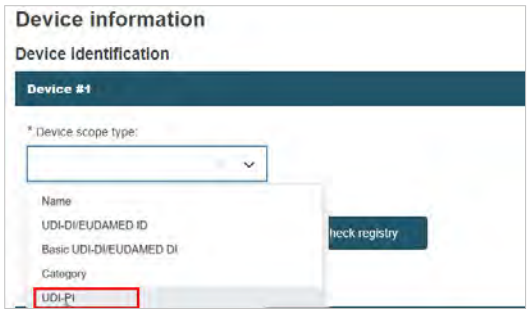


As in *Step 1a*, if the device is **not registered**, enter the data manually and link to at least one EO, or confirm that the EO is unknown.

3. UDI-PI

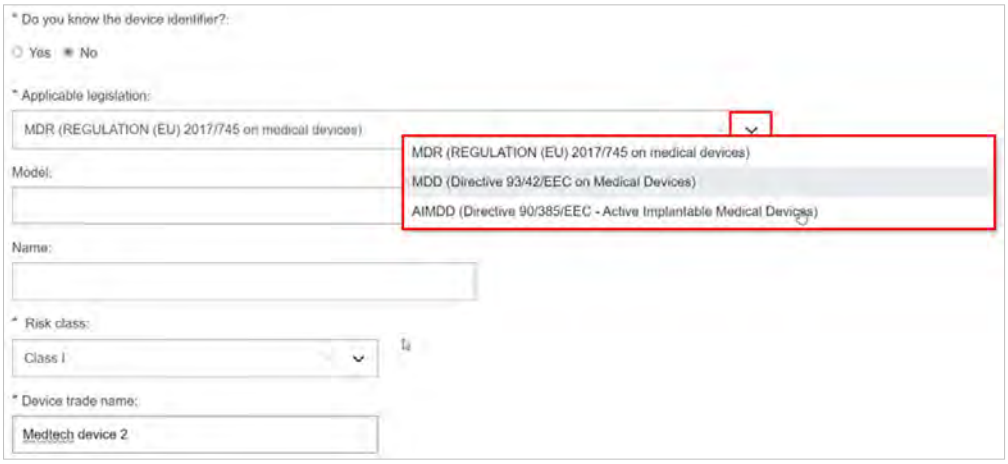
   Select *UDI-PI* device scope type.

   a. Select the **Device scope type** as 'UDI-PI', select one *Production identifier* (PI) type and provide the *Production identifier value* for that type:

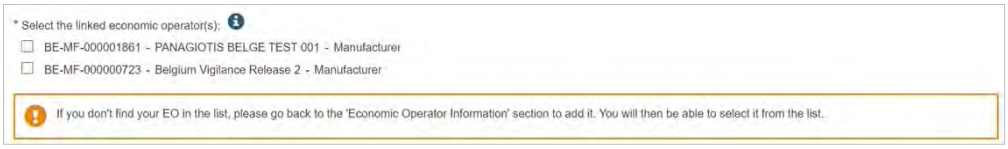


The *Production identifier* information must be linked to a device.

b. Indicate whether you know the device identifier. If you do not, click **No** and provide the data.
The legislation dropdown is filtered for the procedure type (i.e. here are the MDR-related options):

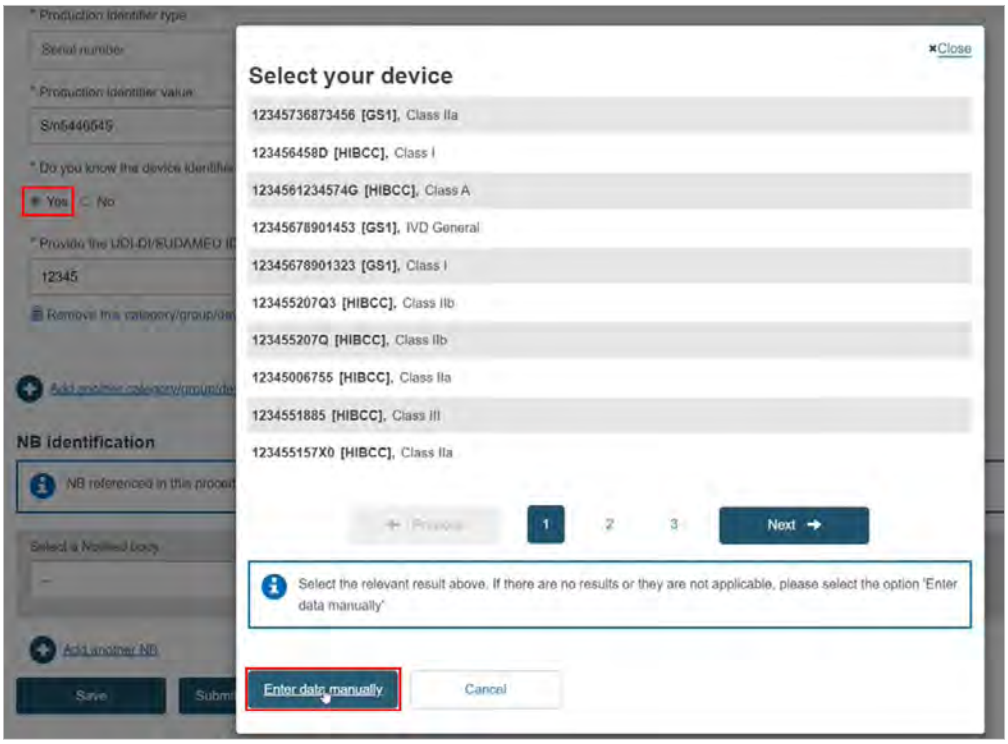


Select the appropriate linked EO(s) from the display list:



c. If the UDI-DI/EUDAMED DI is known, click **Yes** and enter it. Click **Check registry**:

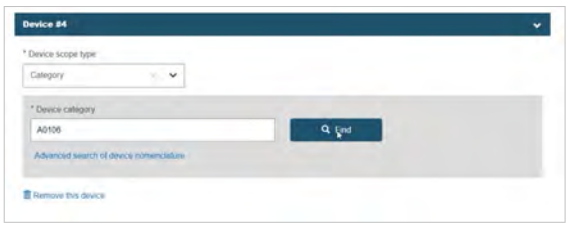
d. If the exact UDI-DI/EUDAMED DI is **not listed** (i.e. the device is not registered), click **Enter data manually**. If there is a match (i.e. the device is registered), the manual entry option is disabled:



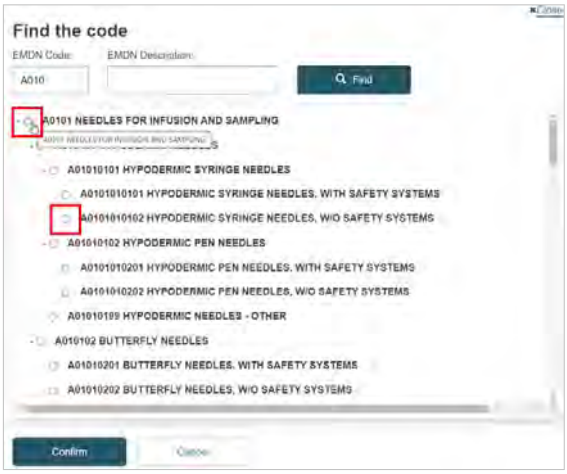
Link the device to at least one EO, as per *Step 1b*.

4. **Category**

Select *Category*, enter the EMDN code (several codes can be entered) and click **Find**:



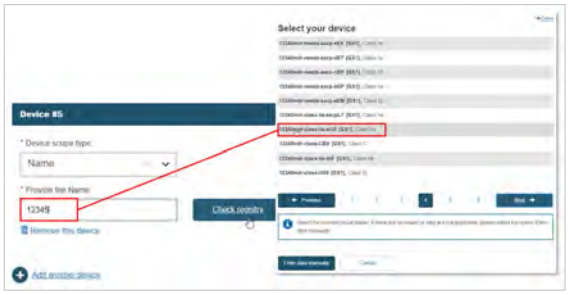
Select any single item – at any level (the branch is not selected). Click **Confirm**. To make additional selections, return to the list and repeat:



Link to at least one EO, as per *Step 1b*.

5. **Name**

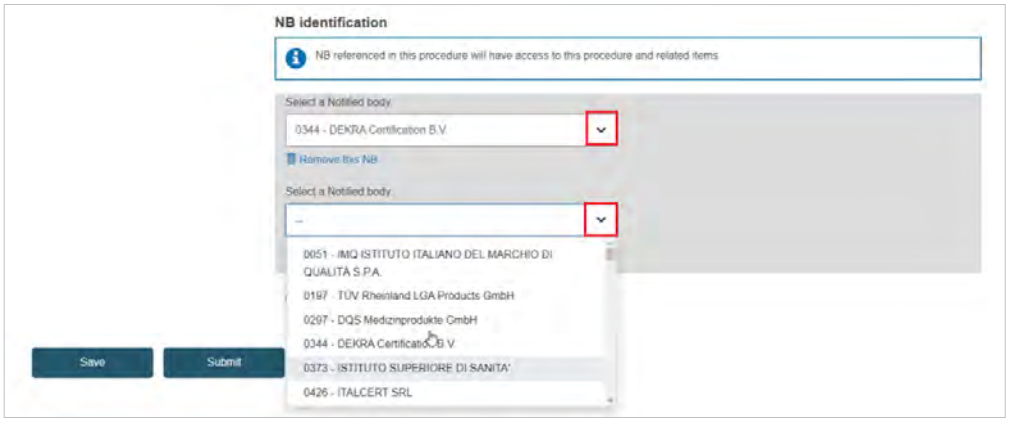
Select *Name*. Enter the name, or part of it, and click **Check registry**. Select the intended device:



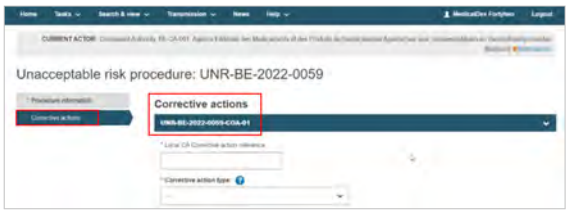
Click **Yes** to link to additional EOs, or opt not to with **No**:

If the name is not registered, enter the data manually (see *Step 1b*), and link to at least one EO.

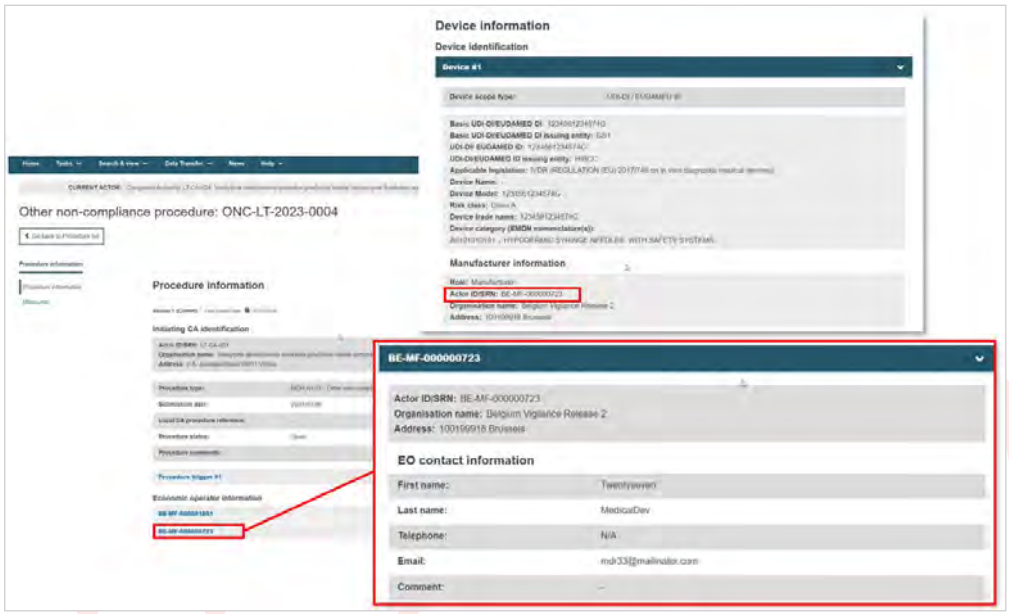
6. **Notified Body identification**
   Click **Select a Notified Body**:



7. Click **Save**.
   The *Corrective actions* tab already shows an initiated *Corrective actions* identifier:

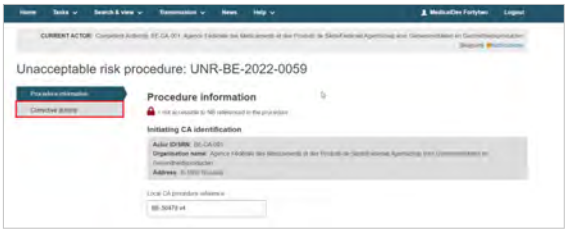


Once submitted, the EO details of a registered device are populated in the procedure **EO contact information** section:



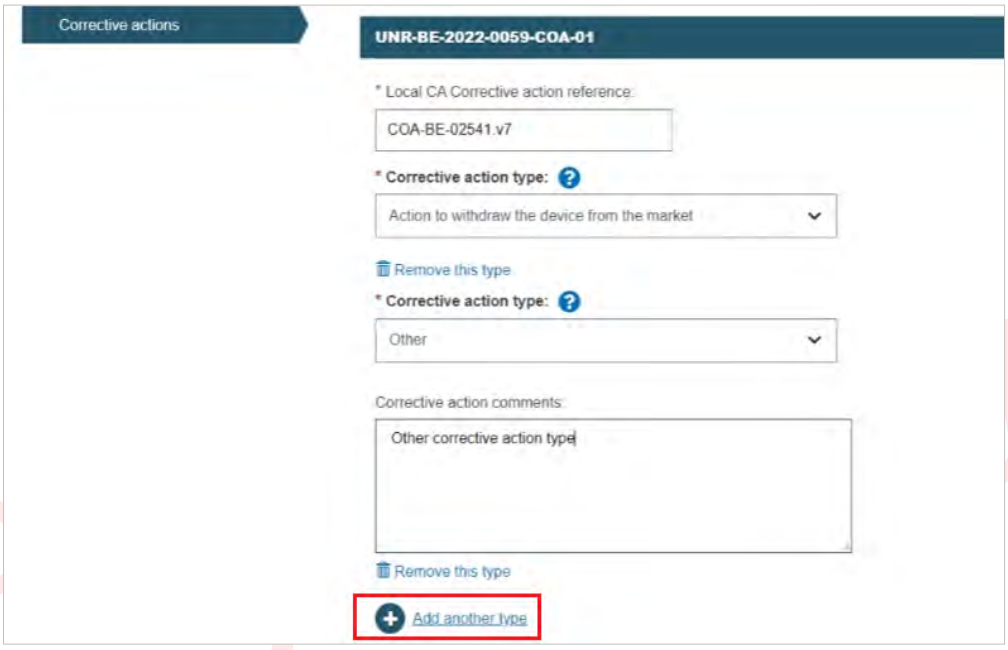
3.2.6 Corrective actions

1. The *Unacceptable risk procedure data reference* displays. A corrective action is mandatory to be able to submit the procedure. Click the **Corrective actions** tab. The corrective actions identifier displays, containing the procedure reference, and the abbreviation 'COA' followed by a reference number:

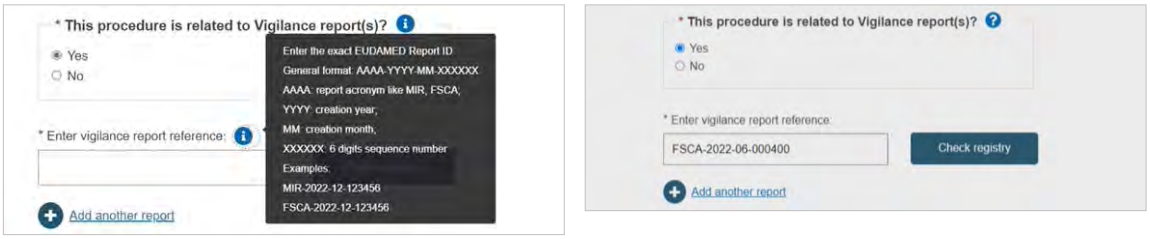


2. Provide a corrective action reference number, and define the corrective action type:

   a. You can specify multiple types. If you select *Other*, enter an explanation:

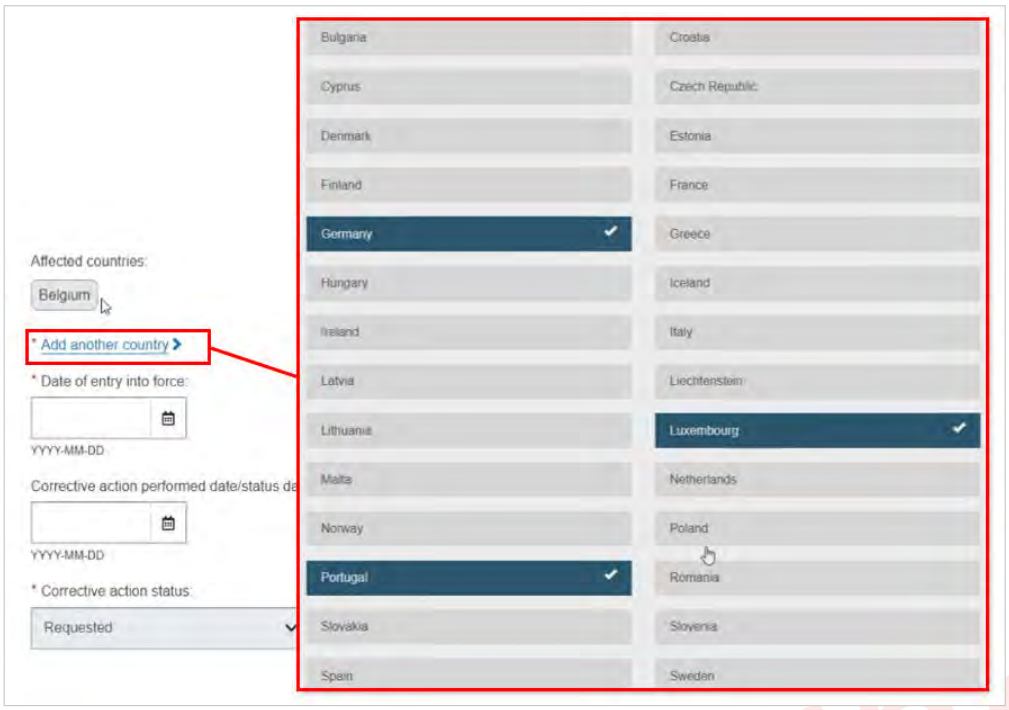


3. Indicate if the procedure is related to *Vigilance* report(s) and enter the reference(s):

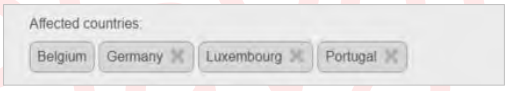


4. Provide a justification for the corrective action, and clicking **Browse** you can upload one or multiple supporting files:

5. The affected country is already set, i.e. the country of the initiating CA. You can select other affected countries:



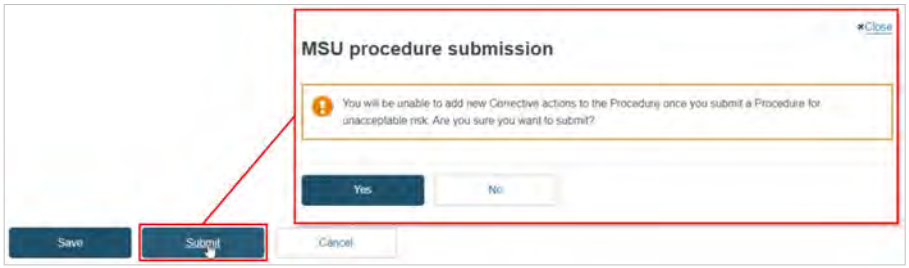
a. The countries can be removed, however the initial actor country cannot, i.e. the Belgian CA:



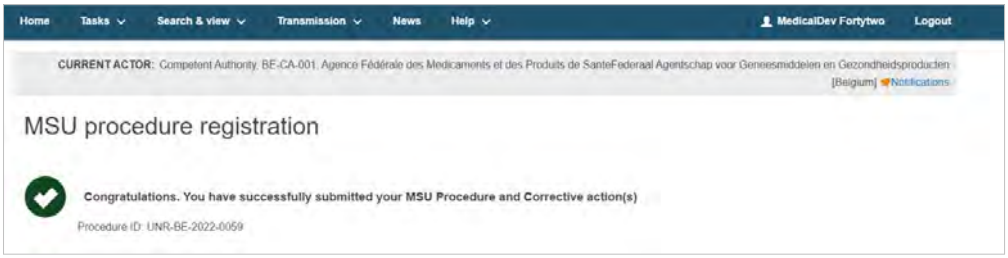
6. Provide the date of the entry into force of the corrective action – this may be in the past, present or future, i.e. in the case that the action has already been carried out. The *Corrective action performed data/status date* is not mandatory:

7. Click **Add corrective action** to add additional corrective actions in the same way. A sequential identifier will be generated:

8. Submit the procedure with the corrective action(s). Click **Yes** that you understand the disclaimer:



   a. The Commission, all CAs with market surveillance responsibility, and any NBs referenced in the procedure are notified:

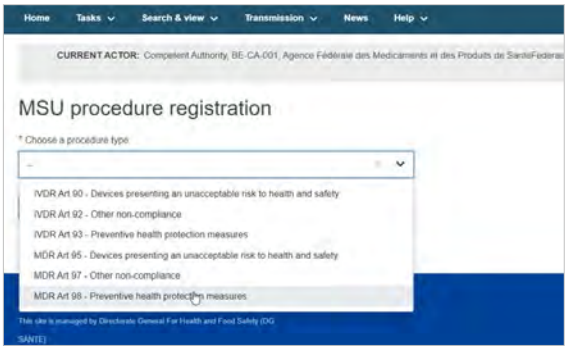


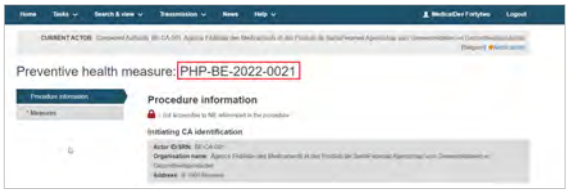
Once the unacceptable risk procedure has been submitted, the initiating CA can add measures to the procedure. Moreover, other CAs can submit an objection to the measure(s) submitted by the initiating CA, and they can also register their own measures. For these items, new versions can be created and submitted.

IMPORTANT
Remember to click **Save** during the completion of each step. There is **no autosave** function, and unsaved inputs will be lost if you log out or otherwise lose connection to EUDAMED.

3.3 Preventive Health Protection (PHP) and Other Non-Compliance (ONC) procedures

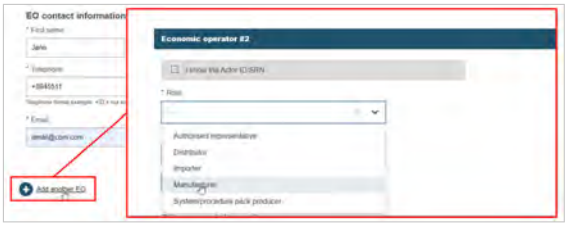
1. From the dashboard, select the Preventative Health Protection (PHP) measure and click **Next**. The landing page opens showing the actor (CA) information. EUDAMED generates an identifier containing the abbreviation 'PHP', the country, year and reference:

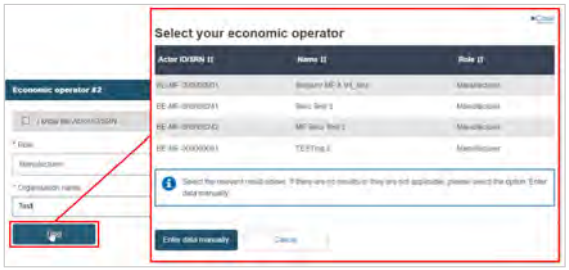




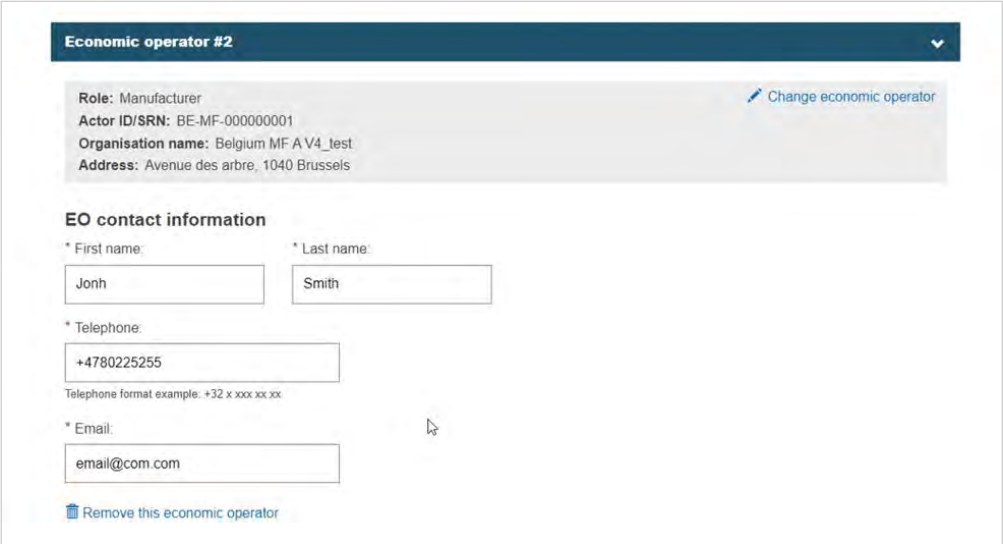
2. Establishing the trigger for the procedure and defining the EO(s) is done the same way as for the Unacceptable risk procedure [5].

3. You can add more EOs. Click *Add another EO* and select the actor type from the dropdown. Type in the EO name and select it from the list. If it does not appear, click **Enter data manually**:

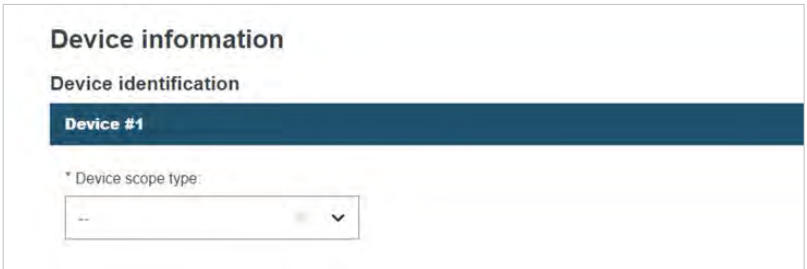




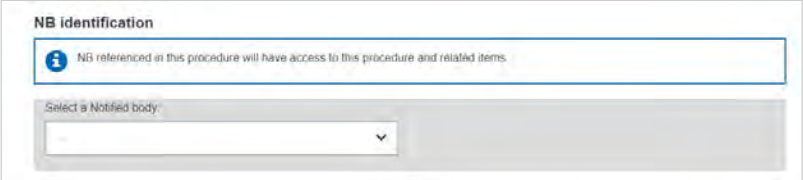
4. When the EO is registered, the system retrieves the EO contact information. Enter a contact for this particular procedure:



5. Identify the device. These steps are the same as for the UNR procedure (see Device information [11]):

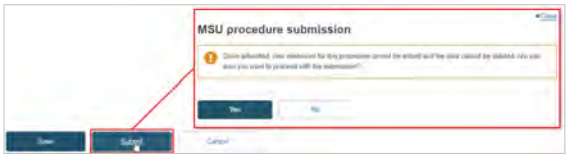


6. You can identify several Notified Bodies (NB) (see UNR, Device information [11], *Step 6*). Now create the measure(s) associated to the procedure:



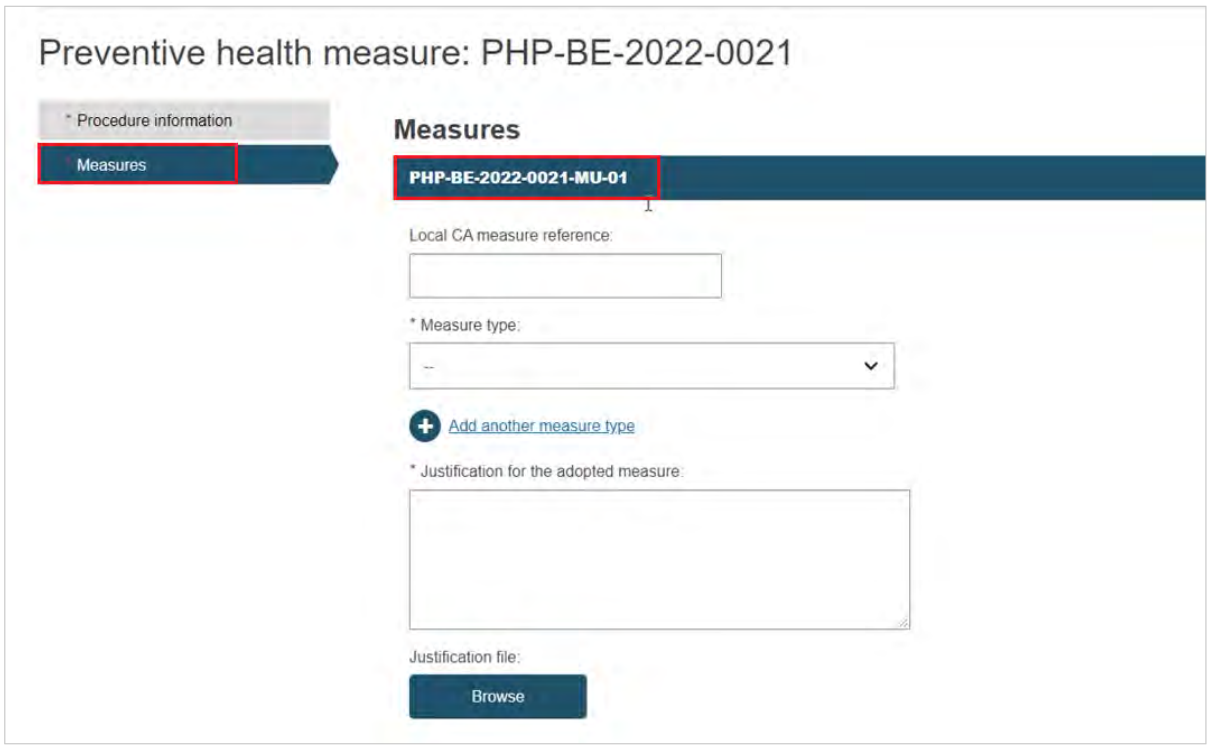
The procedure can only be submitted when the *Measures* section has been completed.

If a Manufacturer or Authorised representative referred to in the procedure device is not linked to the Procedure, the following confirmation warning displays:

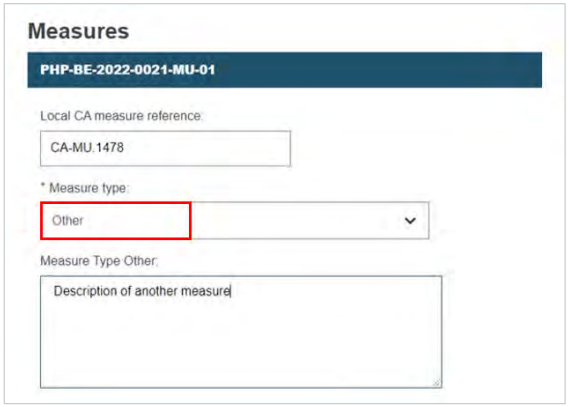


3.3.1 Measures

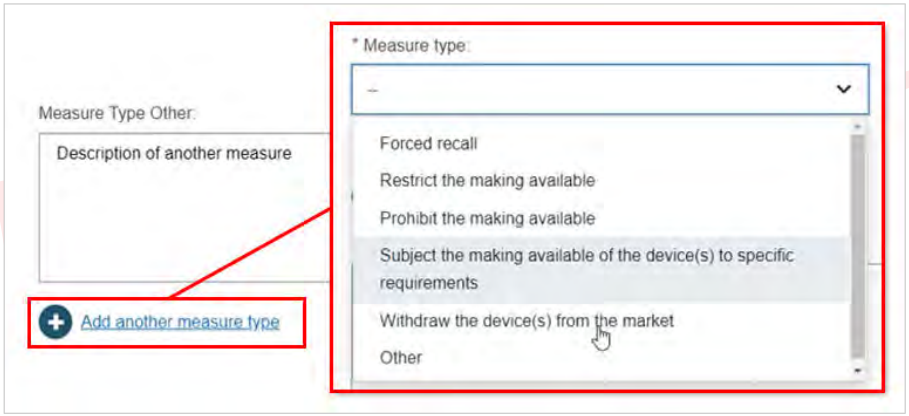
Click on the *Measures* tab. The system creates the first measure identifier within the procedure, made up of the procedure type abbreviation (in this case *PHP*), the country, year, reference and measure (MU) number:



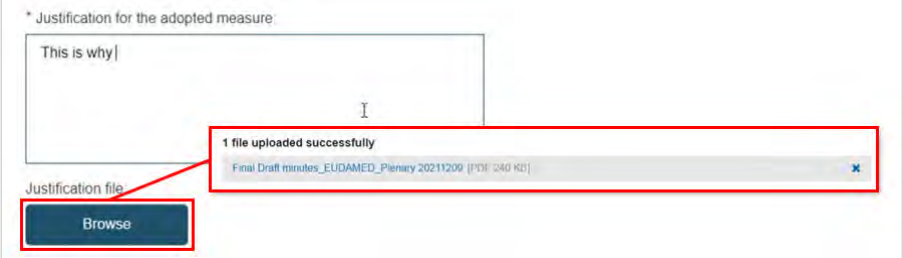
1. Provide the CA's measure reference number and select the measure type. If you select *Other*, enter an explanation:



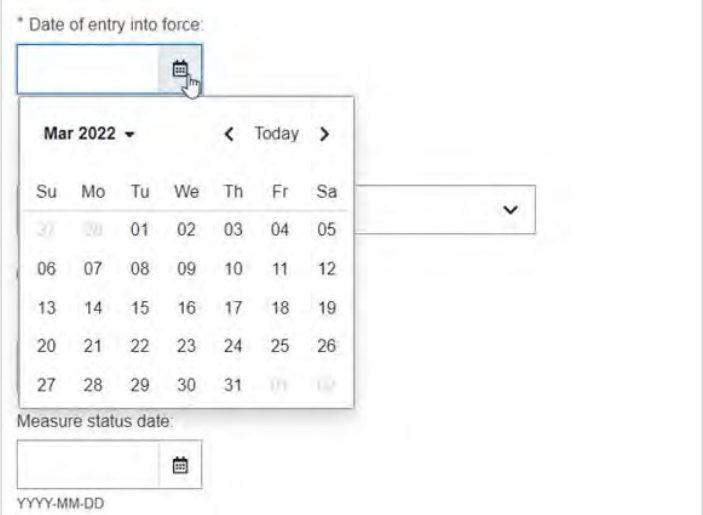
2. To add other measures, click **Add another measure type**, and select the measure type:



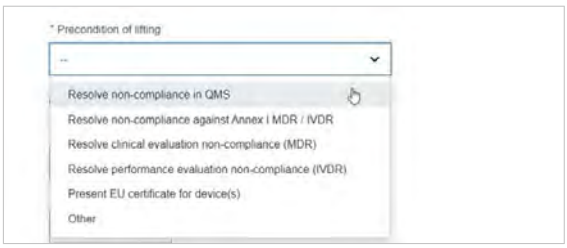
3. Provide a justification, and upload a justification file if necessary:

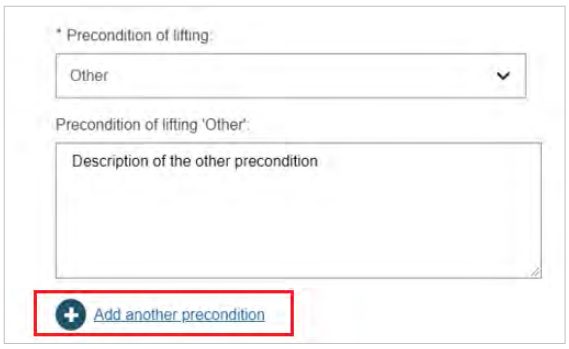


4. Enter the date that the measure comes/came/will come into force:

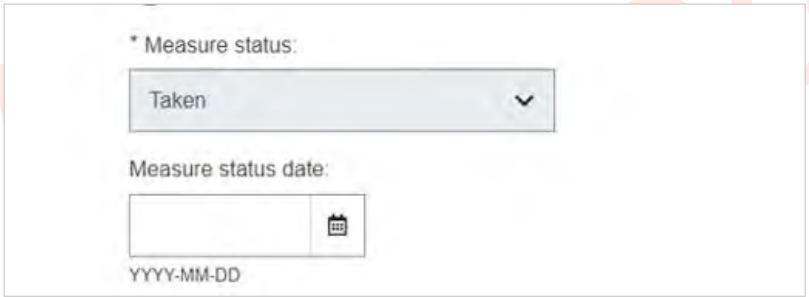


5. Select a *Preconditions for lifting* the measure. If you select *Other*, provide an explanation. You can select additional preconditions by clicking **Add another precondition**:

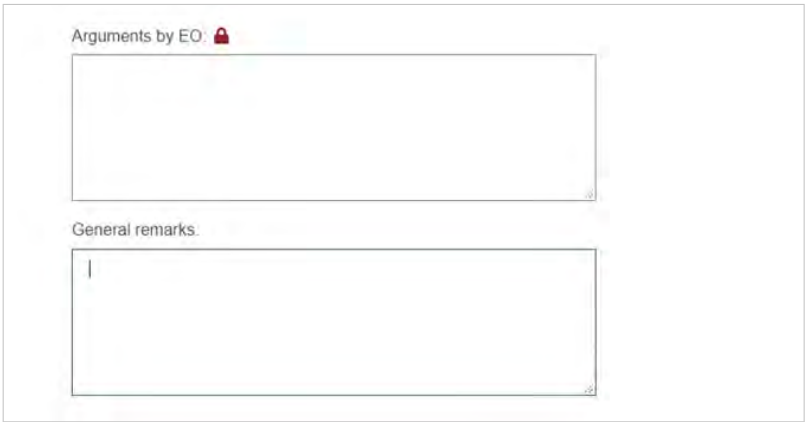




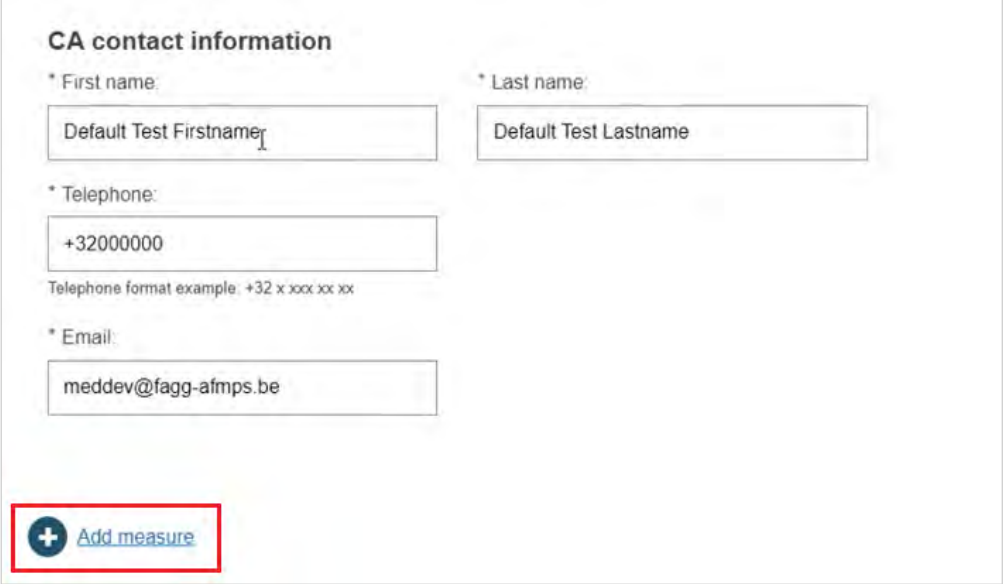
6. The *Measure status* is set to *Taken* by default. This cannot be changed. The *Measure status date* in this case can be filled in if relevant:



7. You can enter arguments provided by the EO in the *Arguments by EO* and *General remarks* fields:



8. Provide a CA contact specific to this measure. The default contact information shown is editable. You can add another measure to the procedure by clicking **Add measure**:

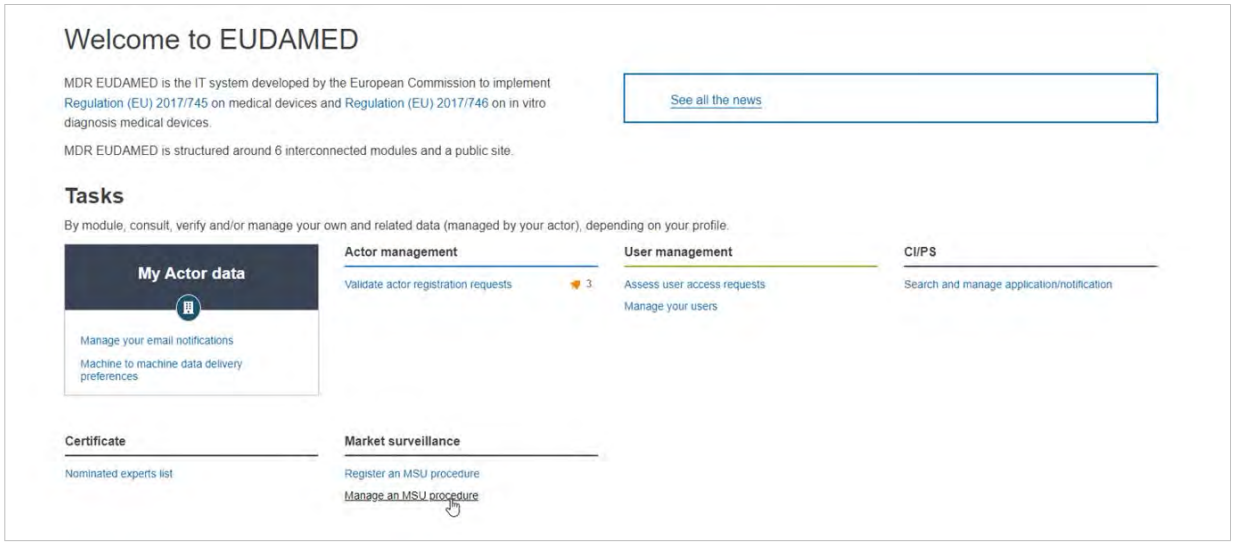


9. Click **Submit** for the procedure to be registered once your measure(s) is in place, either from here or from the *Procedure* section. A confirmation message appears:

IMPORTANT
Remember to click **Save** during the completion of each step. There is **no autosave** function, and unsaved inputs will be lost if you log out or otherwise lose connection to EUDAMED.

4 Manage a procedure

From the dashboard, select *Manage an MSU procedure*:

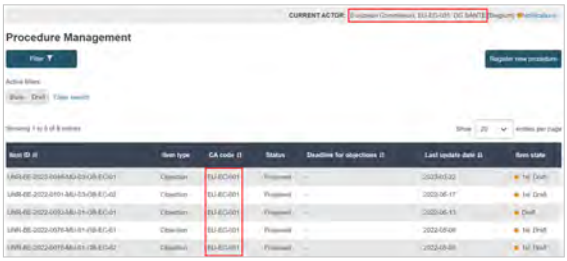


The dashboard lists all procedures, measures and corrective actions:

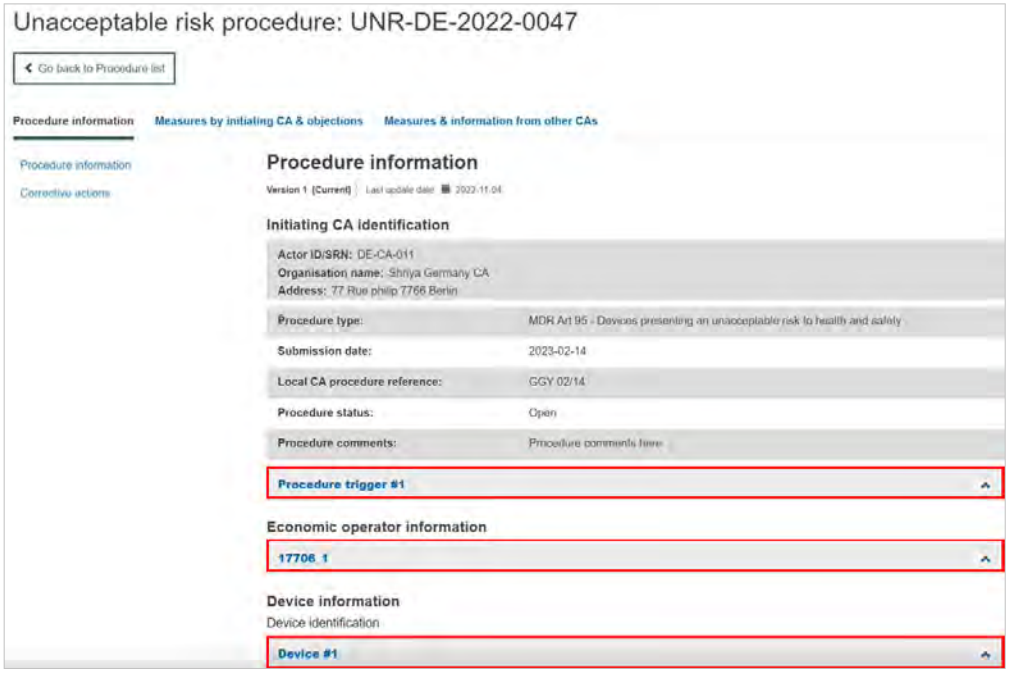
- They display by default in *draft* status, and only the user CA drafts are displayed.
- They are grouped by procedure reference with their items (i.e. corrective actions, measures and/or objections).
- The deadline for objection value appears only for UNR procedures and for measures linked to this procedure as soon as the measure is submitted.

1. Click the **Filter** button to arrive at the detailed filter screen:

If a Procedure item was initiated by the Commission, its Actor code is displayed in the results and within the record:



2. Select the intended record. Section information is contained within each accordion. Click ^ to open:



NOTE
A procedure is discarded automatically once the last corrective action or measure is discarded, i.e. there are no open items connected to the procedure.

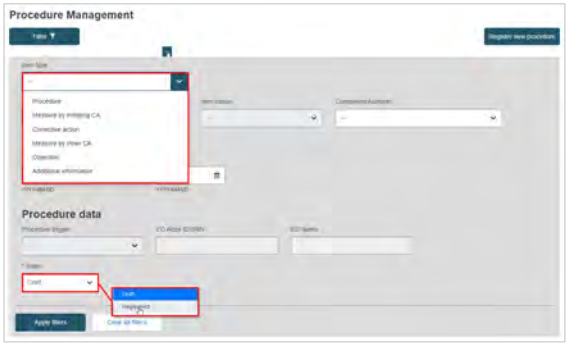
4.1 Using the filter

The filter tool enables you to narrow your search based on the *Item type*. If known, input part of the *Item ID* specific to that *Item type*, and the filter will display records containing that text.

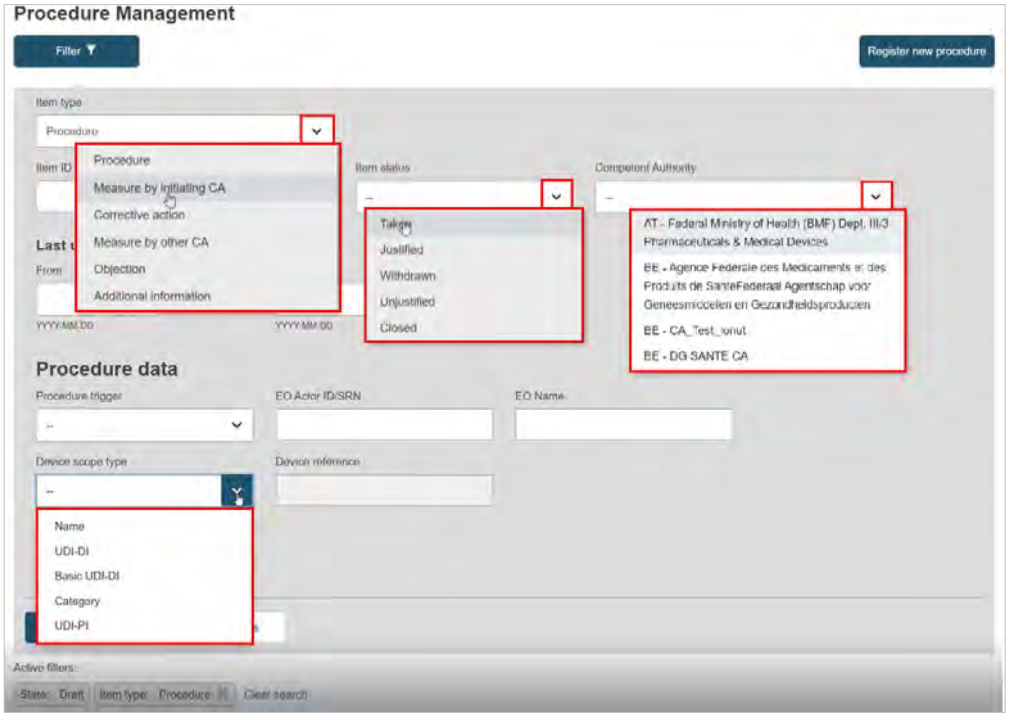
Filter structure

Item type	Example Item ID	Notes
Procedure	UNR-BE-2023-1584	Procedure ID, containing the year of submission.
Measure by initiating CA	ONC-BE-2023-0907-**MU**-01	'MU-01' indicates that this the first measure of that Belgian CA
Corrective action	UNR-BE-2023-1572-**COA**-01	'COA-01' refers to the first corrective action

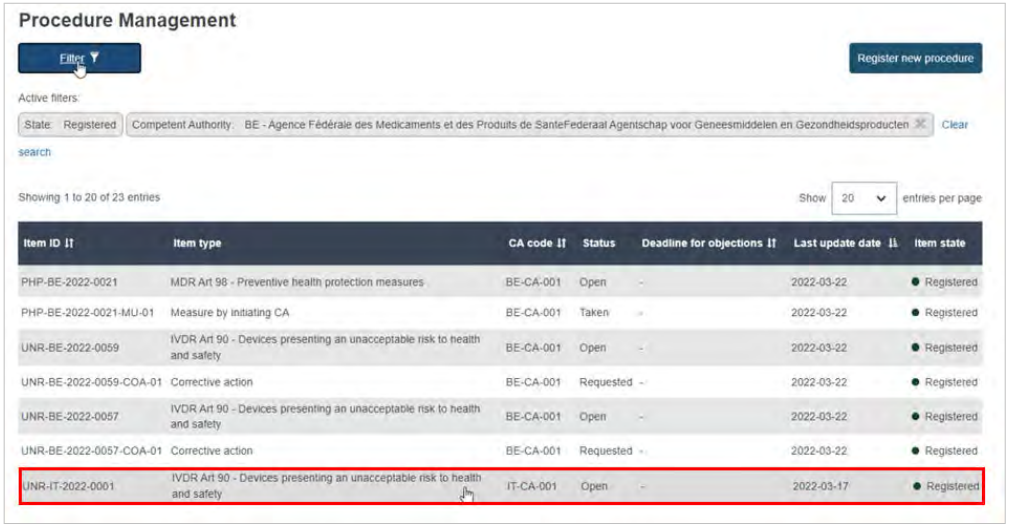
Item type	Example Item ID	Notes
Measure by other CA	UNR-BE-2023-0448-**MU**-DE-01	"DE-01 The German CA submitted a measure for the Belgian CA's procedure
Objection	UNR-DE-2023-0030-MU-01-**OB**-BE-01	'OB-BE-01' indicates a Belgian objection to the German CA's first measure
Additional information	UNR-LT-2023-0002-**AD**-BE-01	'AD-BE-01' relates to additional information provided by the Belgian CA



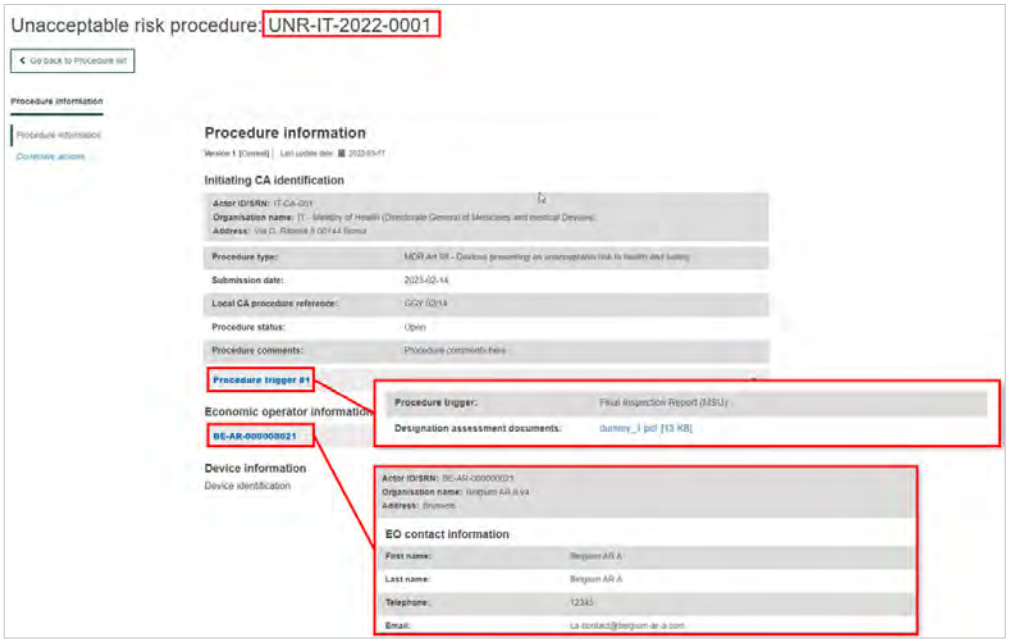
1. Note that the European Commission is not listed as a CA. Instead input 'EC' in the *Item ID* so all records containing *EC* in the *Item ID* will display.
   Once you have selected your search filters, click **Apply filters**:



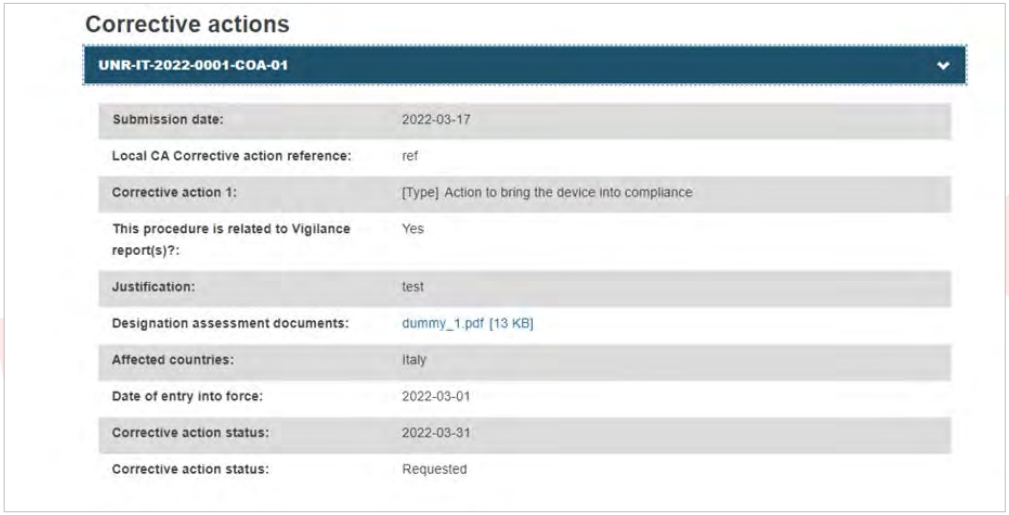
   The dashboard displays search results, with the applicable filters listed above:



2. Click on a Procedure reference to see the procedure record:

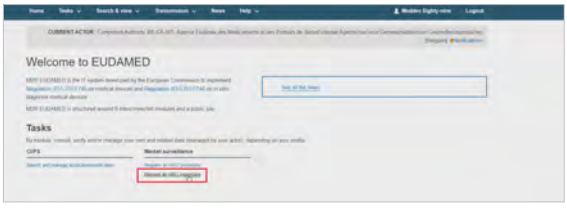


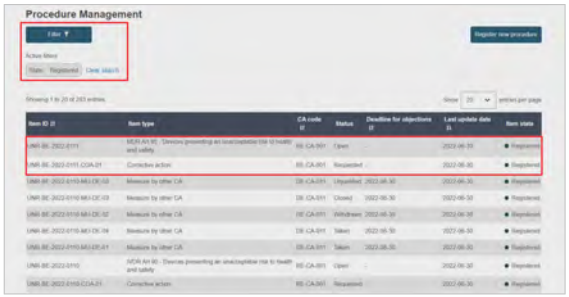
Corrective action information is also viewable:



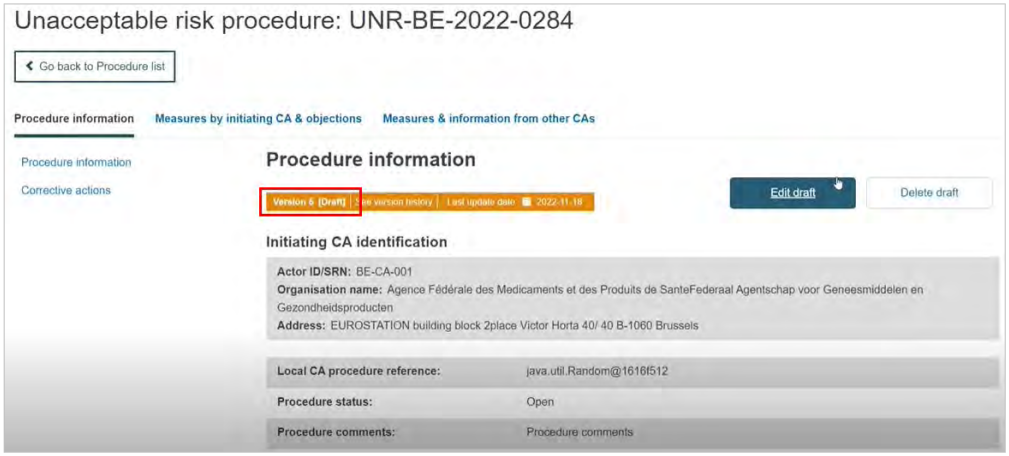
4.2 Create new version of procedure

1. From the management screen, filter for *Registered* or *Draft* procedures, and select the one intended for update:

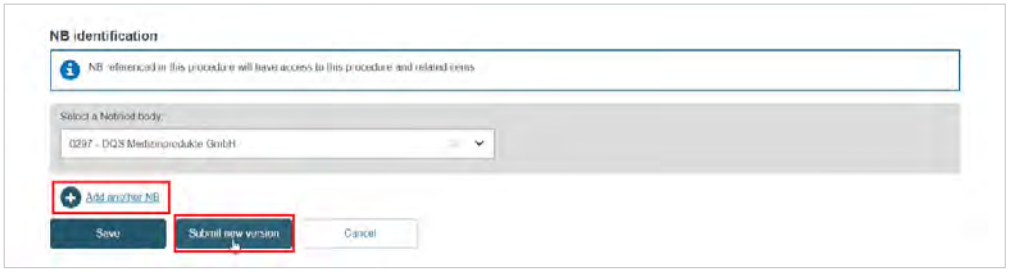




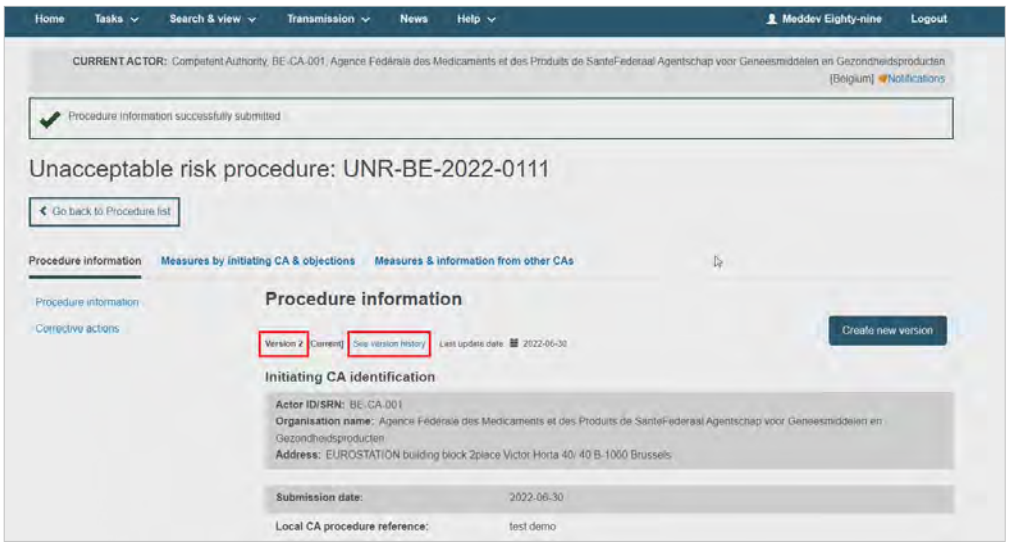
2. Click **Edit draft**. You can only update the editable fields, the greyed out parts cannot be changed:



3. Click **Submit new version:**

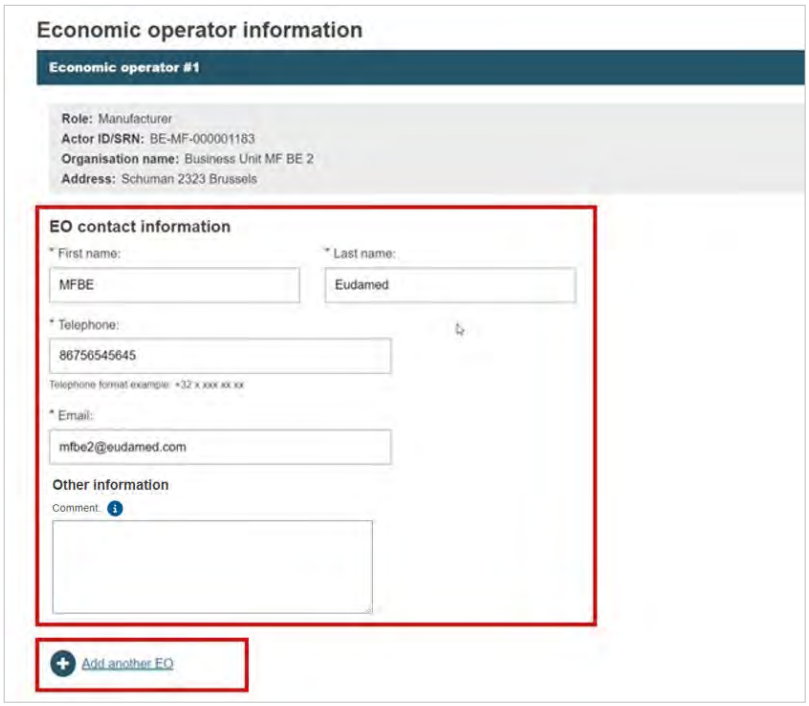


4. The new version is created, with the version number displayed. Registered EOs cannot be changed, unregistered EOs may still be changed or removed.
Click **See version history** to display previous versions of the procedure:

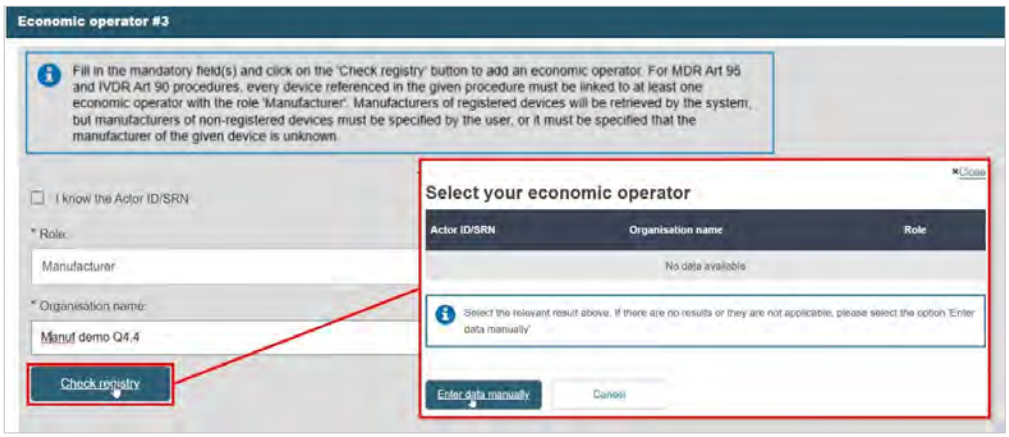


4.2.1 New version and EOs

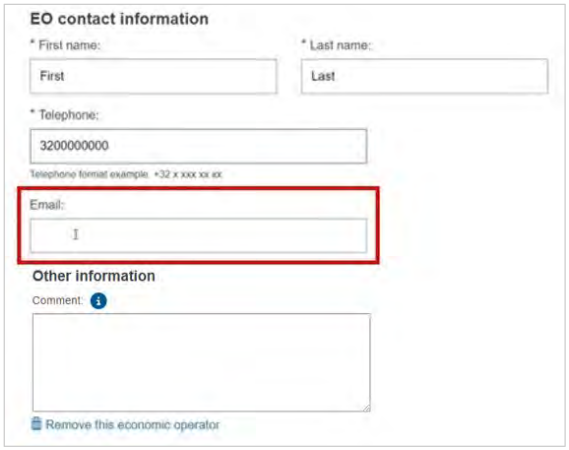
1. The registered Economic Operator is greyed out, not editable and cannot be removed. However, you can edit the contact information.
   Click **Add another EO**, to link additional EOs to the procedure:



2. Complete the mandatory fields, then click **Check registry**. In this case, click **Enter data manually**, since the results are not in the system:



3. Provide the *EO identifier for this procedure* and complete the mandatory fields. Because this is a new **unregistered** EO for this new version, it can be changed and the contact email is not mandatory:



4. However, if the EO was not registered during the initial submission, but has been subsequently, you will be able to select/alter its details. The contact information can be changed, as can the NB, and multiple NBs added.

4.2.2 New version and devices

Each device scope type allows different levels of edit or update. These are shown in the tables below, and they apply to **all procedure types**:

Possible device scope type actions

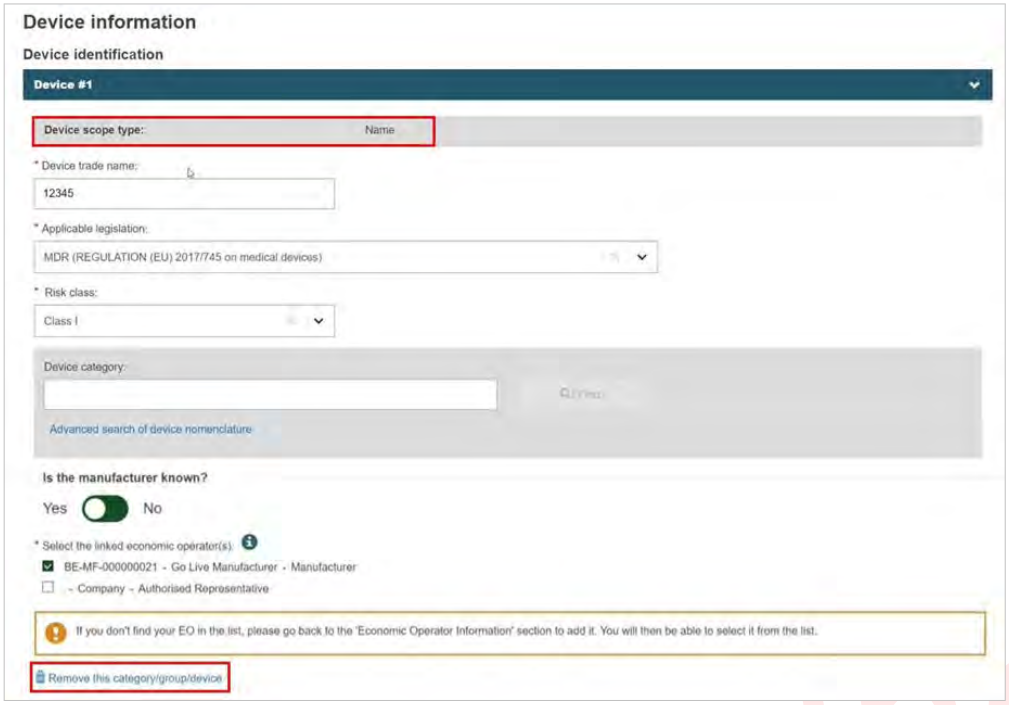
Device scope type description	Registered / Non-registered	Device may be changed	Device may be removed	Device information may be edited
Name (No UDI / EUDAMED DI)	Non-registered	No	Yes	yes
UDI-DI / EUDAMED ID	Registered	No	No	No
	Non-registered	No	Yes	Yes
Basic UDI / EUDAMED DI	Registered	No	No	No
	Non-registered	No	Yes	Yes
Category		No	Yes	Yes (EMDNs may be added or removed)
Production identifier (UDI-PI)	Production identifier data	No	No	Yes

Possible actions for a device linked to Production identifier data

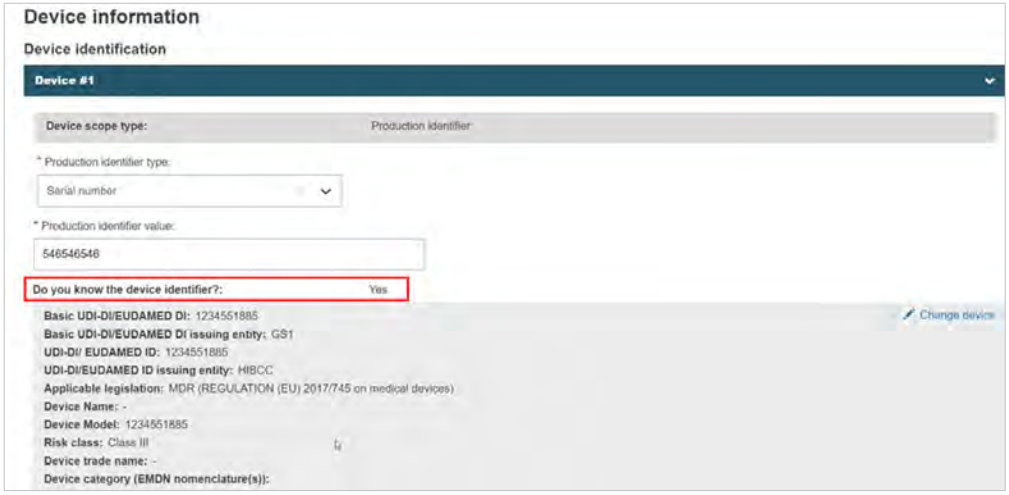
Registered / Non-registered	Linked to PI Device may be changed	Linked to PI Device may be removed	Linked to PI Device information may be edited
Registered UDI-DI / EUDAMED ID	No	No	No
Non-registered and device identifier is not available (not known)	No	No	Yes
Non-registered and device identifier is available (known)	Yes (using 'Check registry' functionality)	No	Yes

Example scenarios:

1. The *Device scope type* **is always greyed out**, not editable and cannot be removed. In this case we use the minimal *Name* identifier that can only link to non-registered devices, for which the fields can be edited and EO(s) must be identified if known.
   If however, information for the *UDI-DI/EUDAMED DI* or other device scope types become known and you wish to link the device to the procedure using these instead, click **Remove category/link/device** and add a new device based on the new information (see Section Device information [11]).
   For a registered device, *Remove category/link/device* (and the toggle) function would not appear:

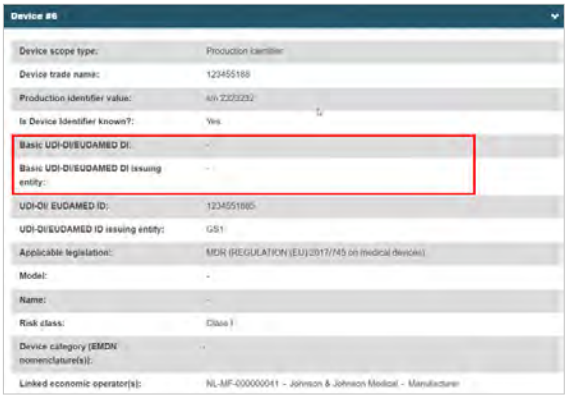


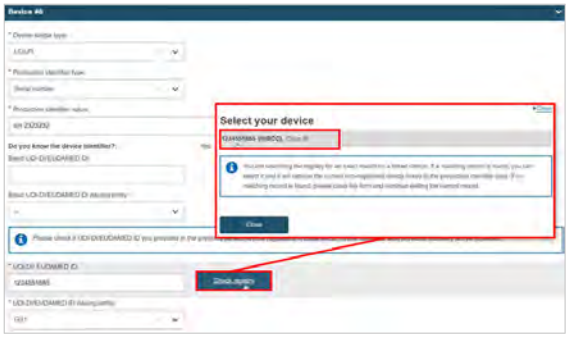
2. Here the device is registered to the procedure with a UDI-PI, so it cannot be removed. The *Device scope type* is fixed, but the PI type and values are editable. The *UDI applicable* option cannot be changed to *No*:



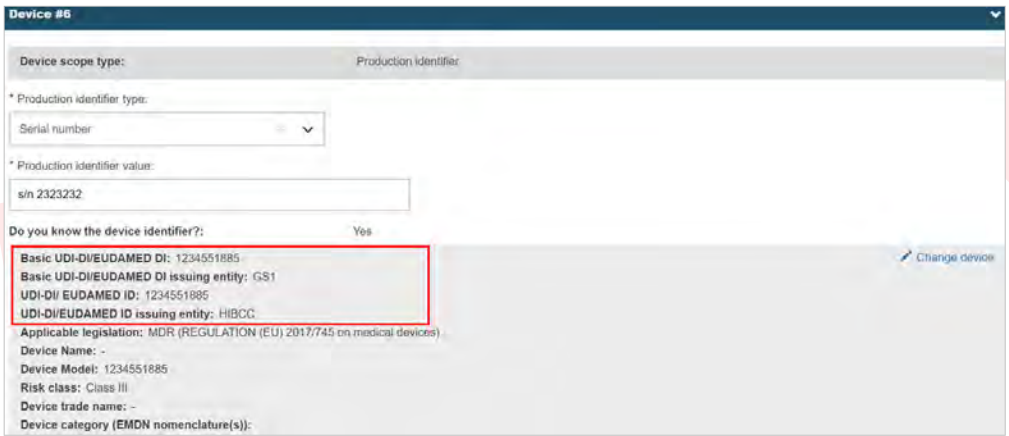
3. However, a non-registered device linked to the procedure with a UDI-PI device scope type can be removed, and the *Do you know the device identifier?* question would allow a *No* to *Yes* change.

4. **If, in the meanwhile, the device has been registered in EUDAMED**, you can link to this registered device instead. Here we see data provided through the device identifier only, so create a **new procedure version** to allow this to be updated. Provide the UDI-DI/EUDAMED ID and click **Check registry**. If system finds the exact match, you can select the device:



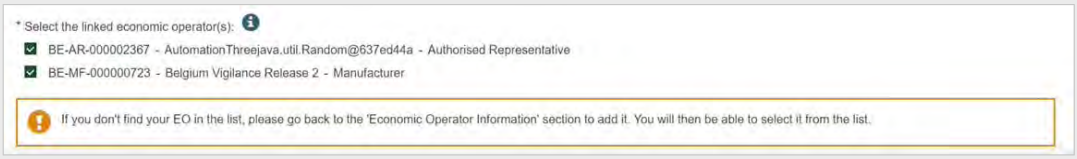


The system replaces the non-registered device with the registered device and retrieves the data:



Click **Submit new version**. The registered device is linked to the procedure. If the device is not found, the user can close search result pop-up window and continue editing the procedure.

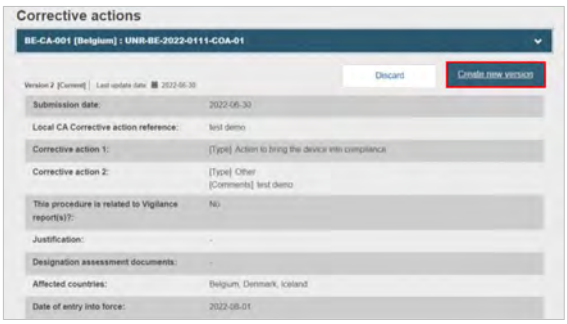
NOTE
In the new version, when replacing a non-registered device with a registered one for the Production Identifier scope type, the linked EO(s) remain linked. The user can now update the EO link(s) if necessary.

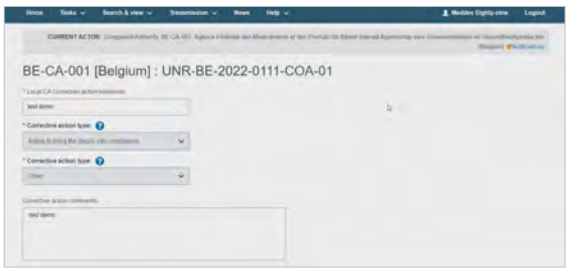


4.3 Create a new version of a corrective action

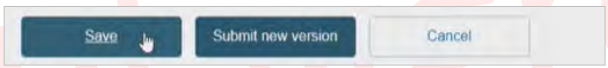
Open the procedure from the *Reports Management* page. It is possible to search for a specific corrective action by its EUDAMED ID and open the procedure that contains the specified corrective action. Expand the accordion header of the corrective action to see its details.

1. Click the **Create new version** button (note that the *Corrective action type* cannot be changed):





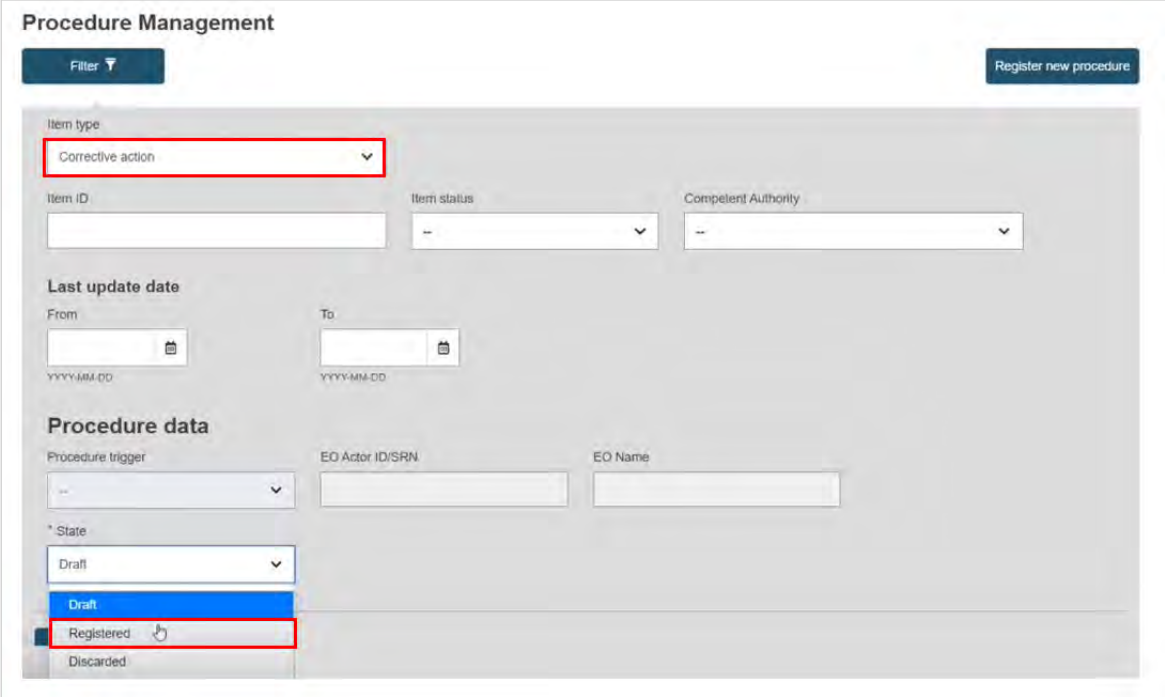
2. Update the editable fields and submit the new version. You can also **Save** and return later, or **Cancel** to remove the update without deleting the new version:



4.4 Discard a corrective action

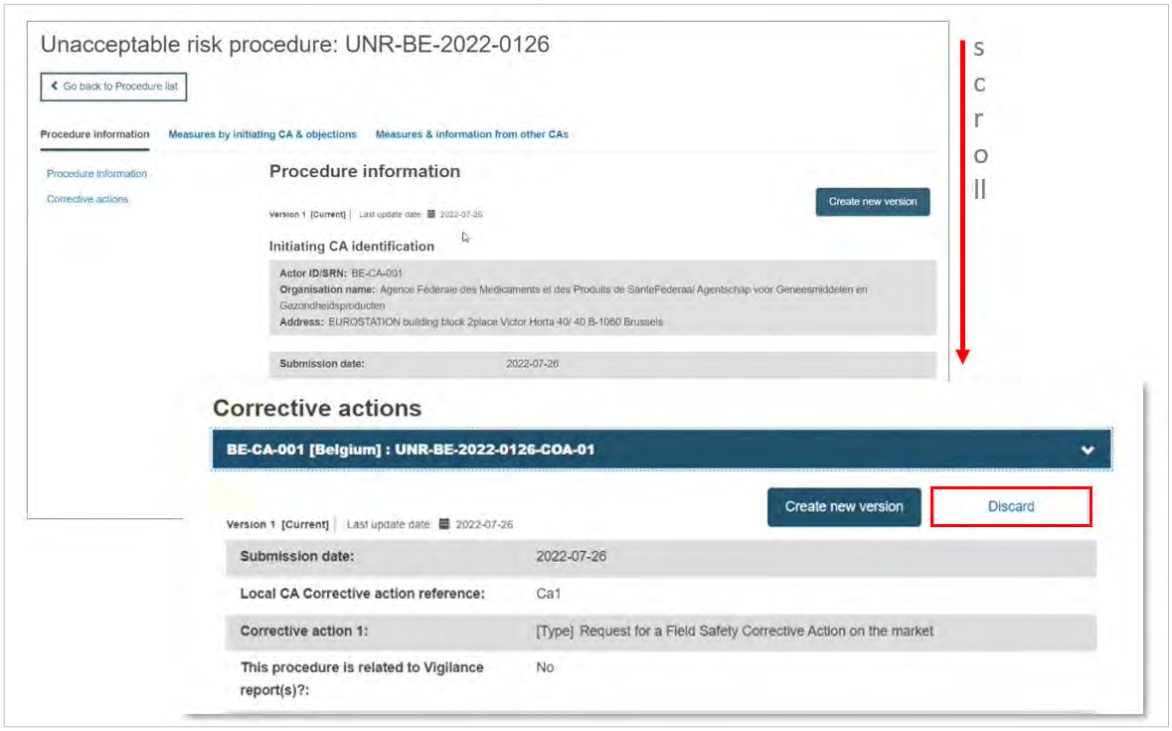
Identify the corrective action you intend to discard using the *Procedure Management* page filter.

1. Select *Corrective Action* as the item types and *Registered* as the state. Click **Apply filters**:



2. Select the record you want to discard:

3. The procedure is displayed. Scroll down to the *Corrective Action* section, select the target record, click **Discard**:



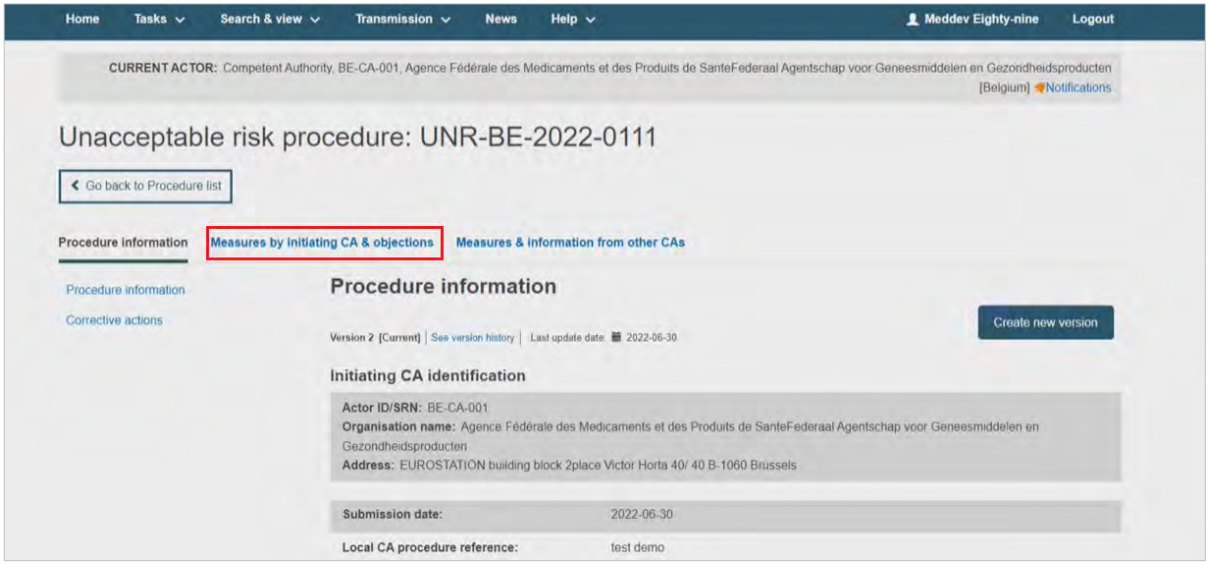
4. The confirmation message displays. Click **Discard** to confirm the action:

CAs, EC and NBs (if referred to in the procedure) are notified of discarded corrective actions. The record will be viewable in the *Search & View* page.

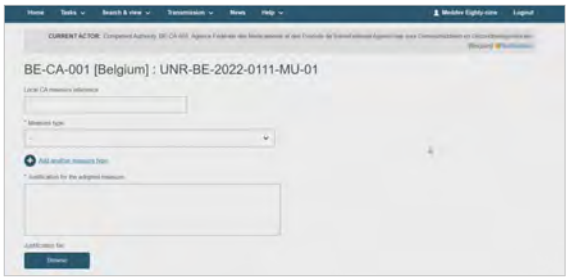
5 Measure(s) linked to UNR procedures

After first submission of the unacceptable risk procedure, the initiating CA can add one or several measures. This is only possible when the corrective action(s) has not been implemented by the EO within the specified time-period, and the procedure is therefore still 'open'. Measures cannot be added to a *closed* procedure.

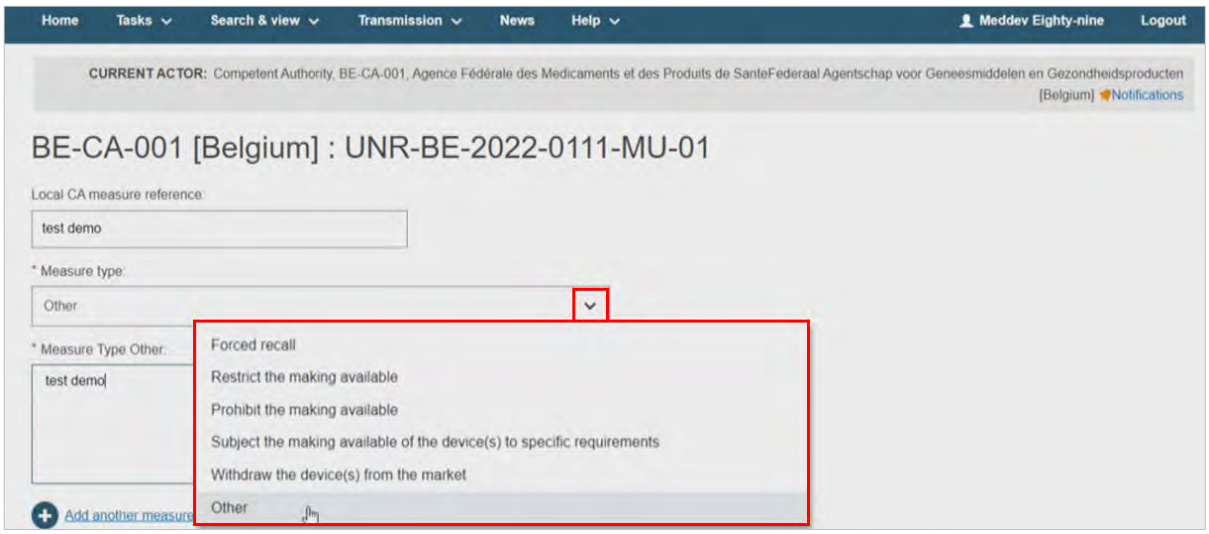
1. Click **Measures by initiating CA & objections**:



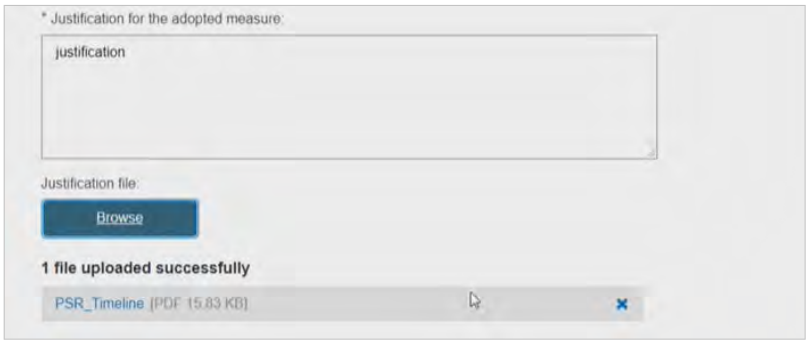
2. A list of possible measures will appear. Select from this or click **Add new measure**. The input screen is the same for measures for all three procedure types:



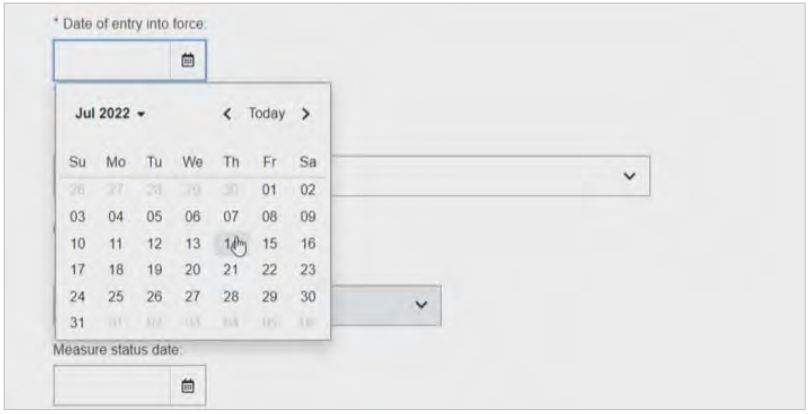
3. Enter the *Local CA measure reference*. Select the *Measure type*. The *Other* option requires more information:



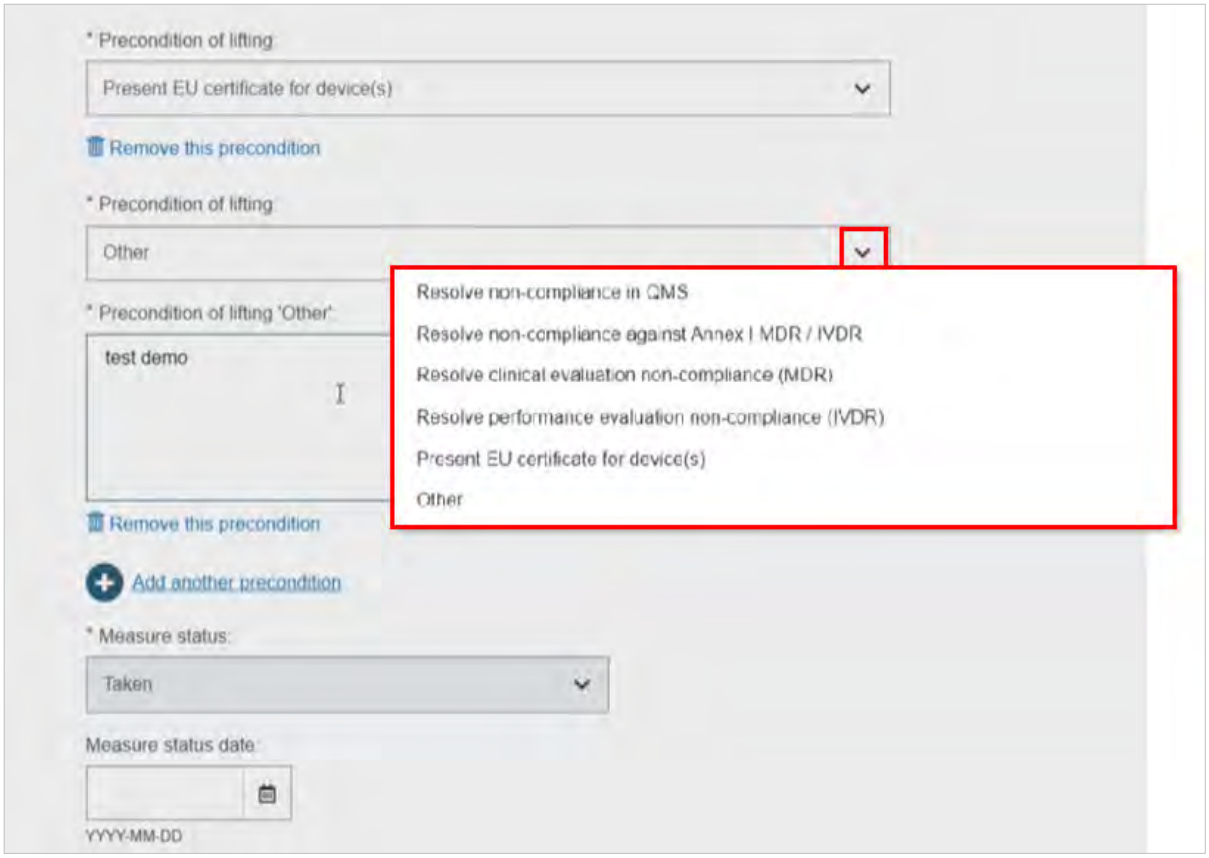
4. Provide a justification and upload one or multiple supporting files:



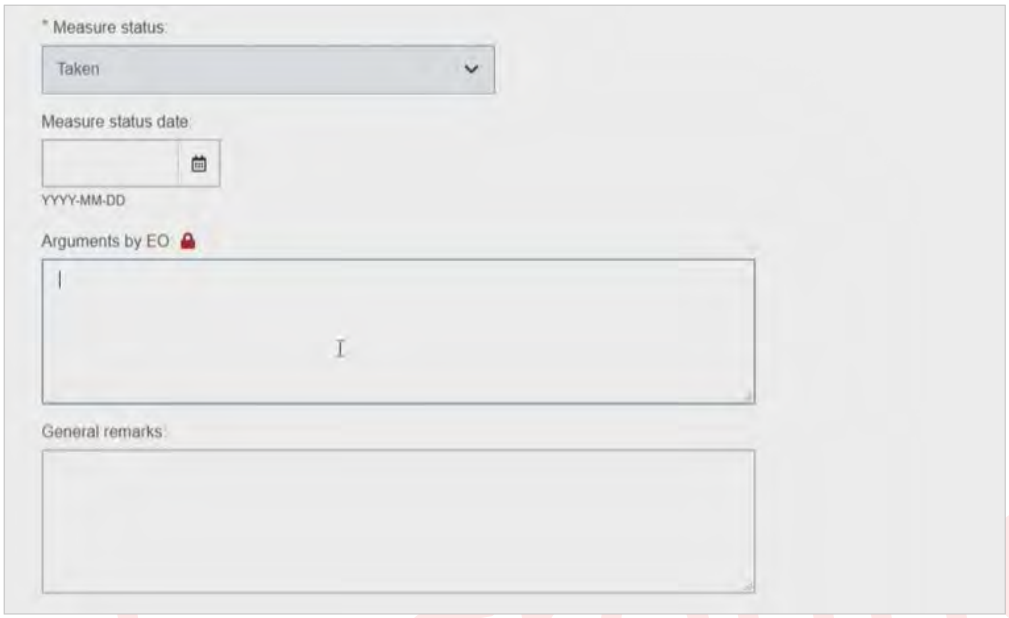
5. Provide the *Date of entry into force* for the measure:



6. Select the *Precondition of lifting* the measure. The drop-down list is the same for all procedure measures, and the option *Other* requires more information. Click **Add another precondition** to add more:

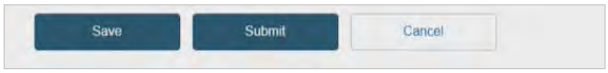


7. The *Measure status* cannot be changed. Provide the *Measure status date*, the *Arguments by EO* and any *General remarks*:

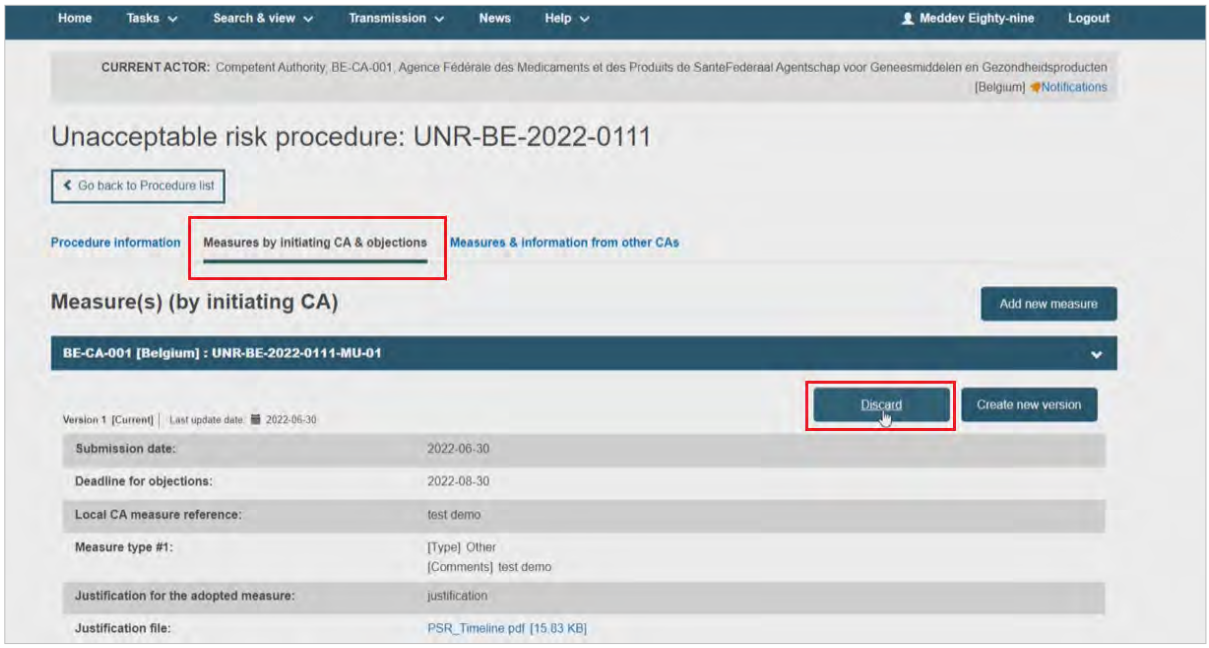


8. Enter the CA contact information:

9. Click **Save** and return later, or **Submit**. Click **Cancel** to remove all the modification on the page, without deleting the new measure:



The measure is now viewable in the *Measures by initiating CA & objections* section:



There is a **Discard [46]** possibility, which removes the measure and all its versions from the procedure (State = Discard). However, the discarded measure information is still viewable in the management screen.

You can enter additional measures by clicking **Add new measure**.

5.1 Create a new measure

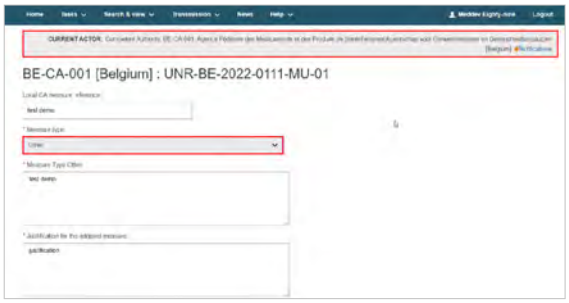
Follow the steps to create a new measure [23] outlined for a PHP procedure.

5.2 Create new version of a measure

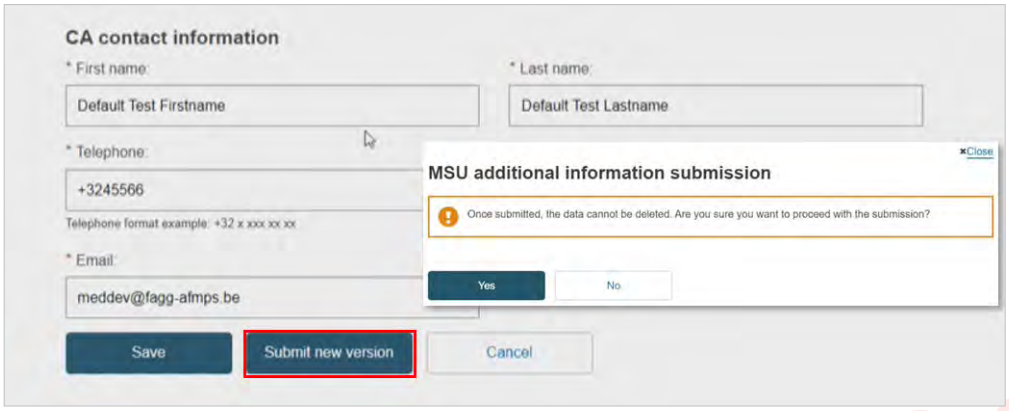
IMPORTANT
When the initiating CA creates a new version of its UNR measure, the two-month response window for objections **does not change**. While the *Measure type* is not editable, the *Justification* field for *Other* is editable.

Open the procedure from the Reports Management page. It is possible to search for a specific measure by its EUDAMED ID and open the procedure that contains the specified measure. Expand the accordion header of the measure to see its details.

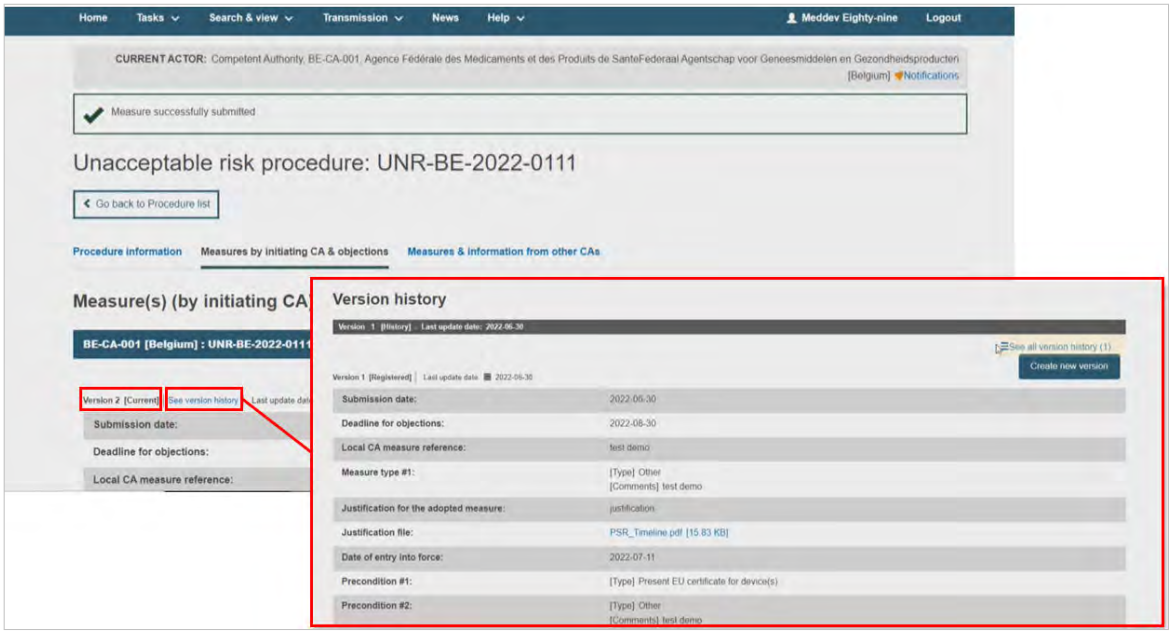
1. Click on **Create new version** and update the required editable fields. The *Measure type* cannot be changed:



2. The contact details are editable for this record and will not alter the original archived actor details. Click **Submit**, **Save** to return later, or **Cancel**:



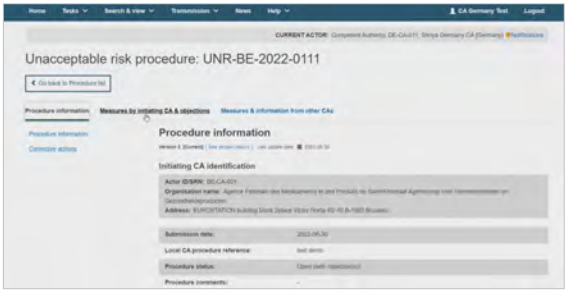
3. The new version of the measure is submitted, showing the *Version number* and *Version history*. The historical content appears in read-only format. *See all version history* recovers all versions of this measure:



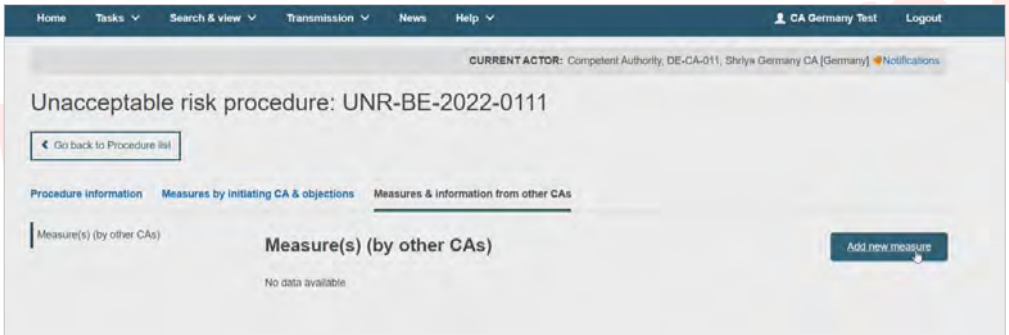
5.3 Register a measure (and new version) for another CA's procedure

Any CA user with a *Confirmer* profile for Market Surveillance can register a measure to another CA's unacceptable risk procedure, so long as it is not *closed*. Unlike an initiating CA's unacceptable risk procedure's measure, **objections cannot be raised** against these measures. The measure's submission will trigger notifications to EC, all other CAs, and the NB(s) referenced in the procedure.

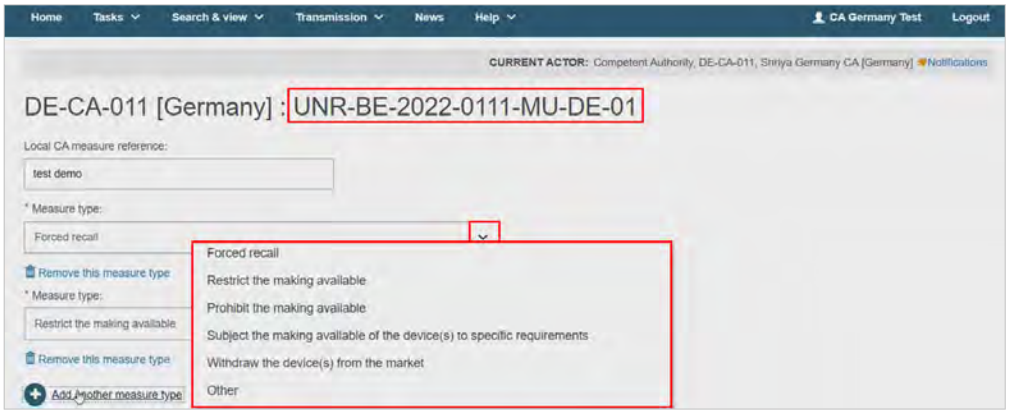
1. Here the German CA is logged into a Belgian CA's procedure. Click **Measures by initiating CA & objections** to see a break-down of the procedure:



2. Click **Measure & information from other CAs**, then click **Add new measure**:

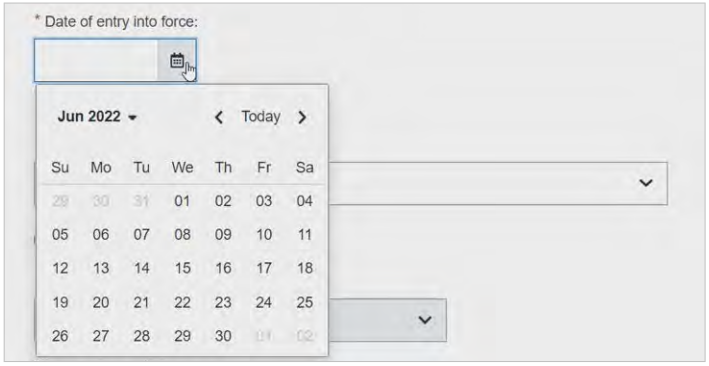


3. The input page shows the assigned identifier. Input the optional *Local CA measure reference* and select the *Measure type*. There can be multiple – click **Add another measure type**, and delete using the icon:



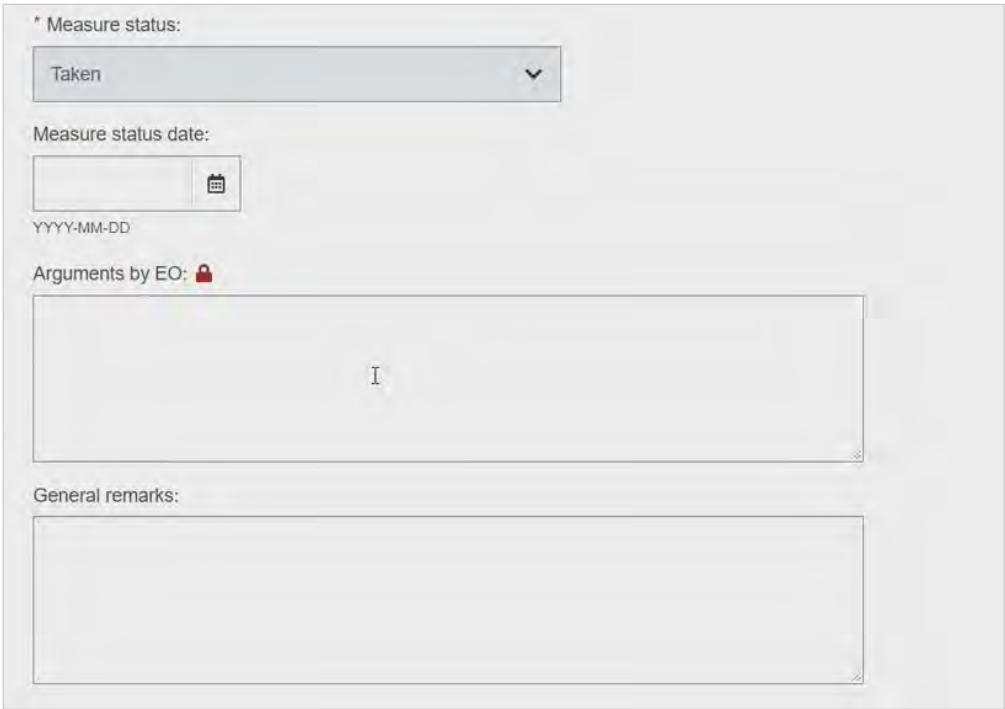
4. Provide a justification and upload one or multiple supporting files.

5. Provide the *Date of entry into force*:



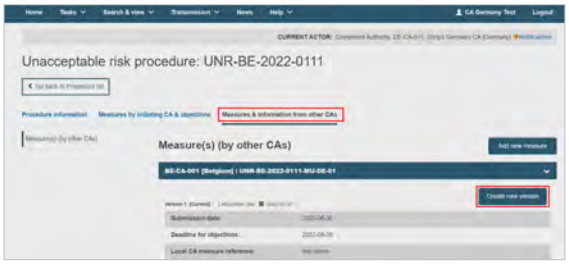
6. Select the *Precondition of lifting*. The values are the same as displayed for the initiating CA:

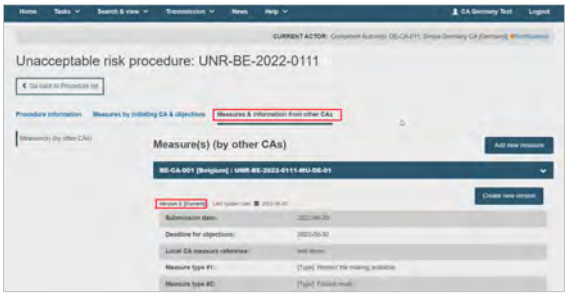
7. The *Measure status* cannot be changed. Enter the relevant information in the editable fields and **Submit** (or **Save** or **Cancel**):



8. The submission of the measure will trigger notifications to the Commission and all other CAs, also to the NB(s) referenced in the procedure. It appears in the *Measures & information from other CAs* tab.

You can create a new version of the measure by clicking **Create new version** and follow the steps of the Section Create new version of a measure [43]. Note that the version number is displayed:

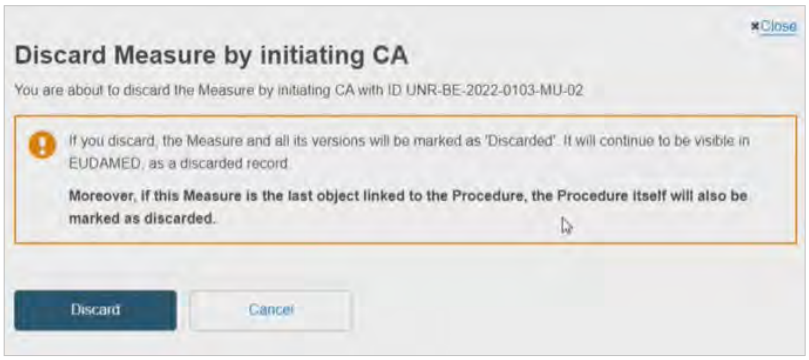




5.4 Discard a measure

1. Within the *Measures by initiating CA & objections* section of the procedure, open the record and click **Discard**:

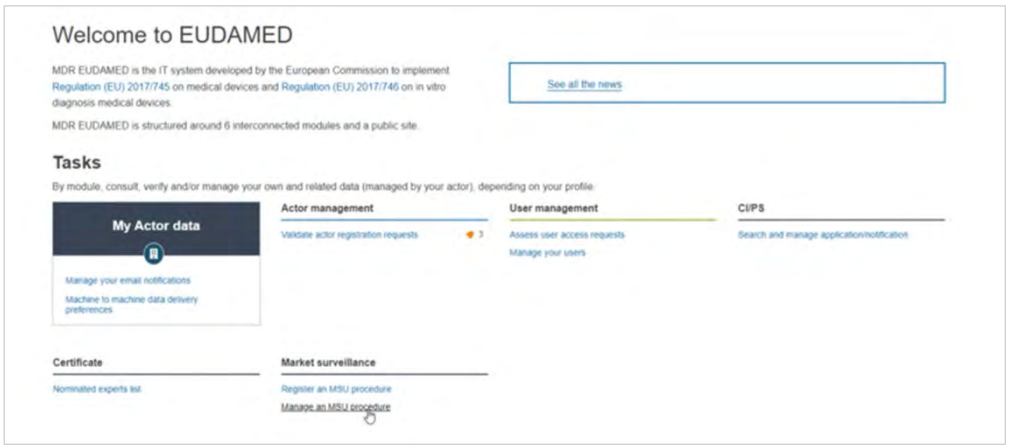
2. A confirmation message displays. Click **Discard** again. The measure and all its versions will be discarded. The record(s) will remain in the *Search & View* page and in the *Procedure Management* page which shows your own actions. The measure will no longer be visible in the procedure:



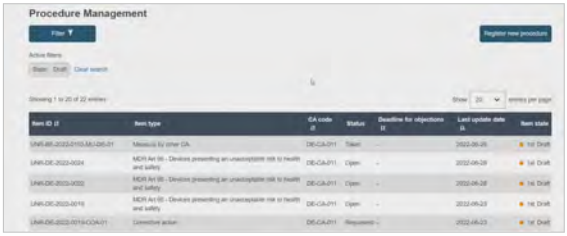
NOTE
If the measure is the last item linked to the procedure, the procedure itself will also be discarded.

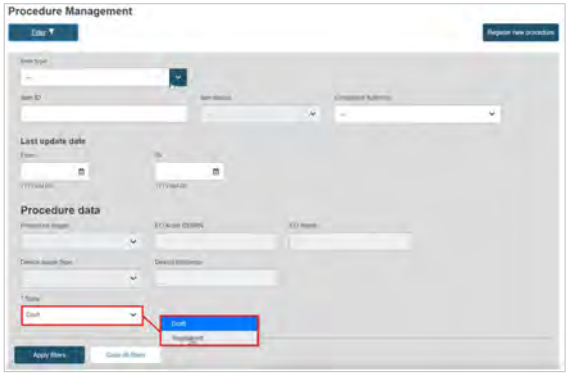
6 Raising objections

1. Click on **Manage an MSU procedure**:

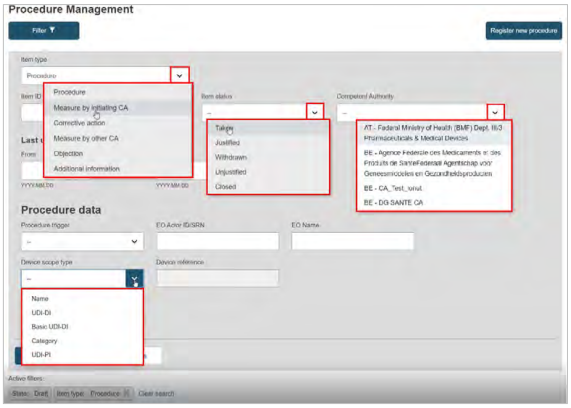


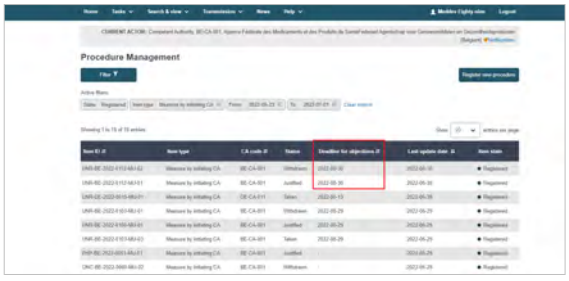
2. You can only raise objections on submitted measures by another CA, so use the **Filter** button and select *State Registered*. Click **Apply filters**:



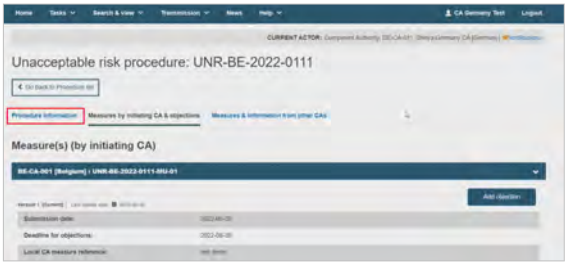


3. Alternatively, filter by *Item type* and select *Measure by initiating CA*, which is in *Taken* status; and/or select from the CA list, which only shows those able to initiate measures or procedures. Click **Apply filters**. The resulting list displays the objection deadline. Click on the measure from the list provided:

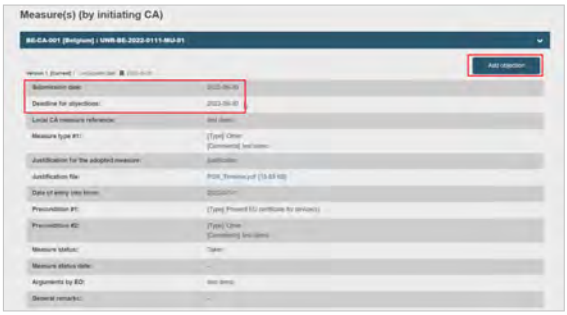


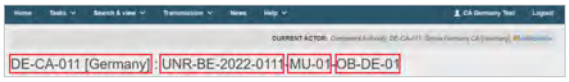


4. You arrive directly on the *Measures by initiating CA & objections* section for the procedure. For information on the procedure itself, click **Procedure information**, where you can access the full data, including versions, trigger, device identifiers, and any corrective actions:

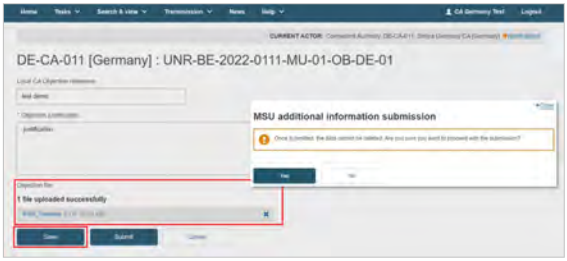


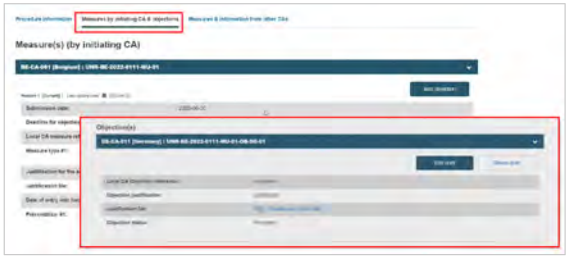
5. Click the **Add objection** button, noting the two-month action window. After this period, objections are not possible, and the button will not appear. An action identifier is assigned, preceded by the Actor ID of the logged-in CA, the procedure reference, the measure reference against which you are raising an objection, and the objection identifier:



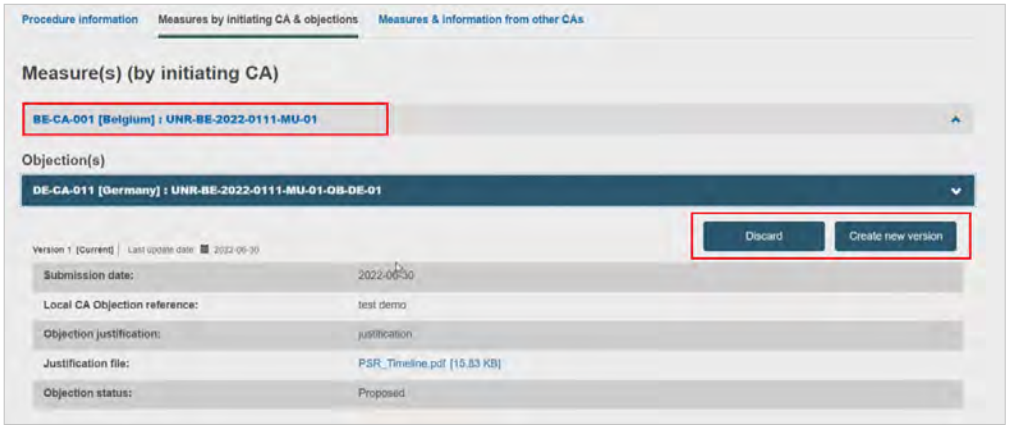


6. Provide a *Local CA Objection* reference and the objection justification. You may upload **one** supporting file. Click **Save** to create a draft, or **Submit** and acknowledge the confirmation message:

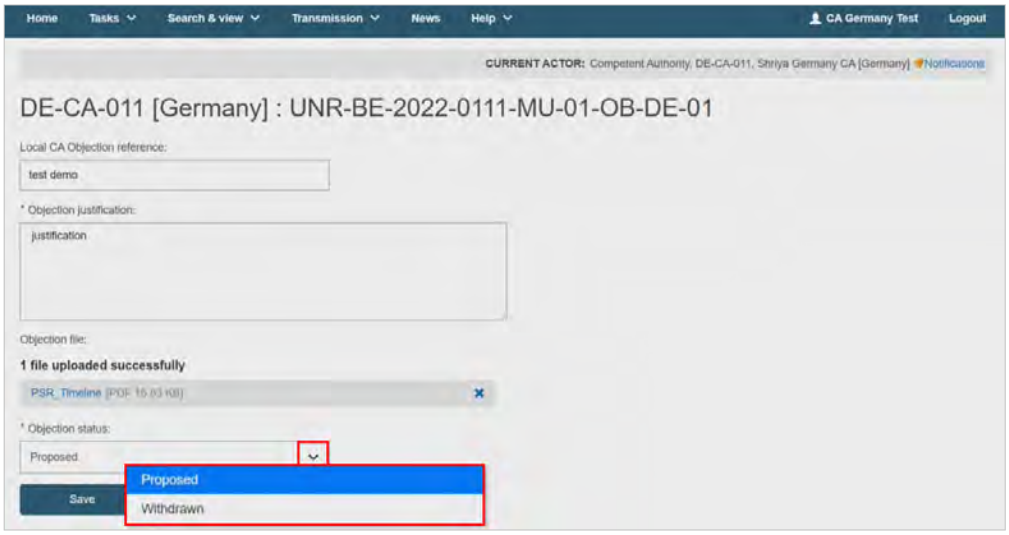




7. To create a new version of an objection, open the procedure from the *Reports Management* page. It is possible to search for a specific objection by its EUDAMED ID and open the procedure that contains the specified objection. Expand the accordion header of the objection to see its details.
   Click **Create new version**:

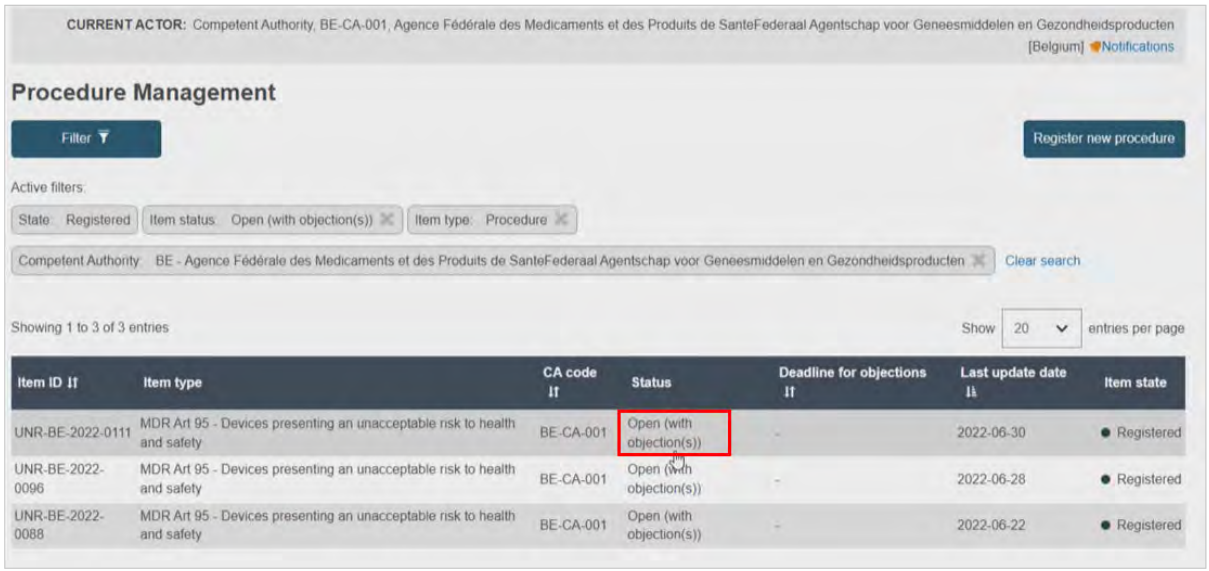


8. Update the required editable fields and click **Save**:

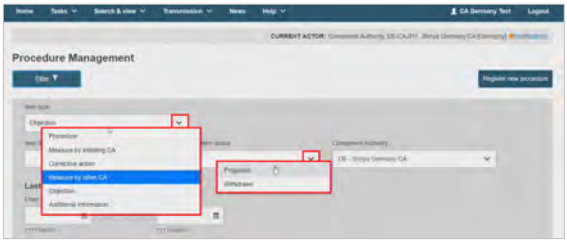


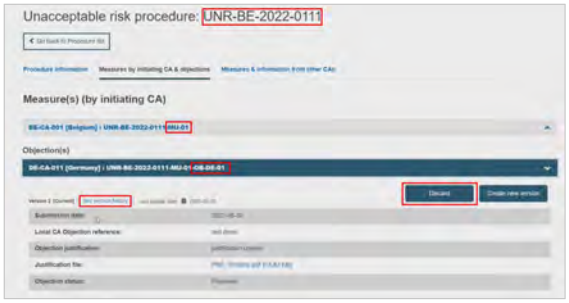
6.1 Discard an objection

In the *Procedure Management* page, as the initiating CA, you will see the procedure status as *Open with objection(s)*. You cannot discard another CA's objection(s):



1. Open the record to discard and click **Discard**. Note that you can see the version history, as show in *Step 3*, Create new version of a measure [43]:





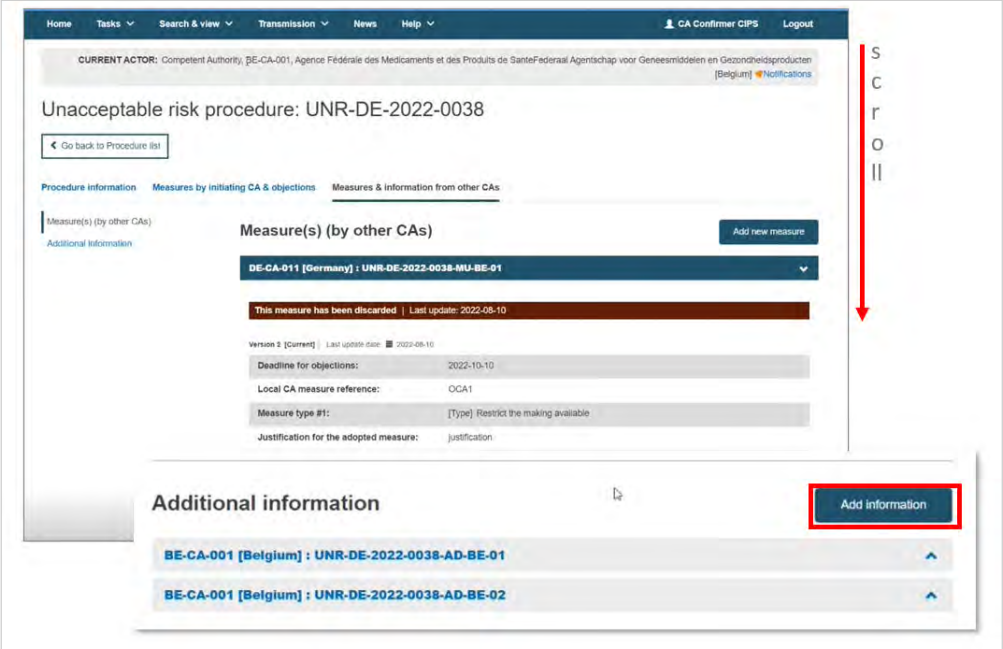
2. A confirmation message displays. Click **Discard** again to complete the action:

3. The process is complete, but the record can still be found in the *Procedure Management* page. Here we can see the impact on the procedure status. When logged in as the initiating CA again, the procedure status is *Open (with measure(s))*. The CA objection has been removed:

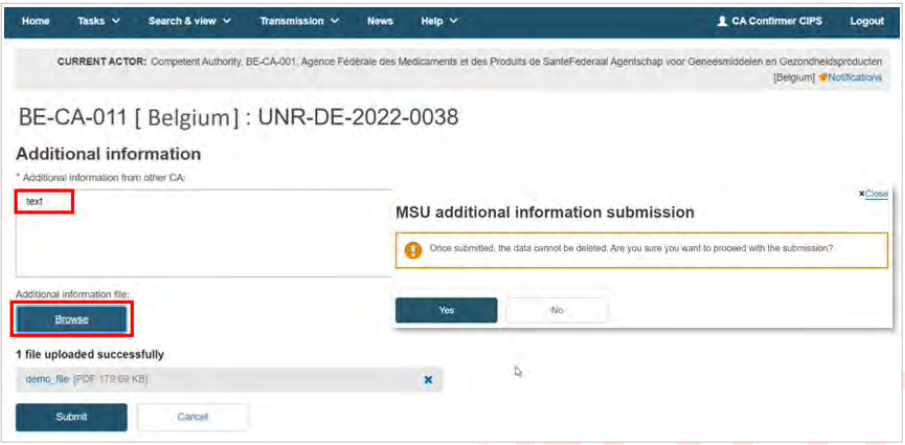
7 Additional information

A CA can only add additional information to another CA's UNR procedures.

1. Scroll to the bottom of the procedure screen and click **Add information**:



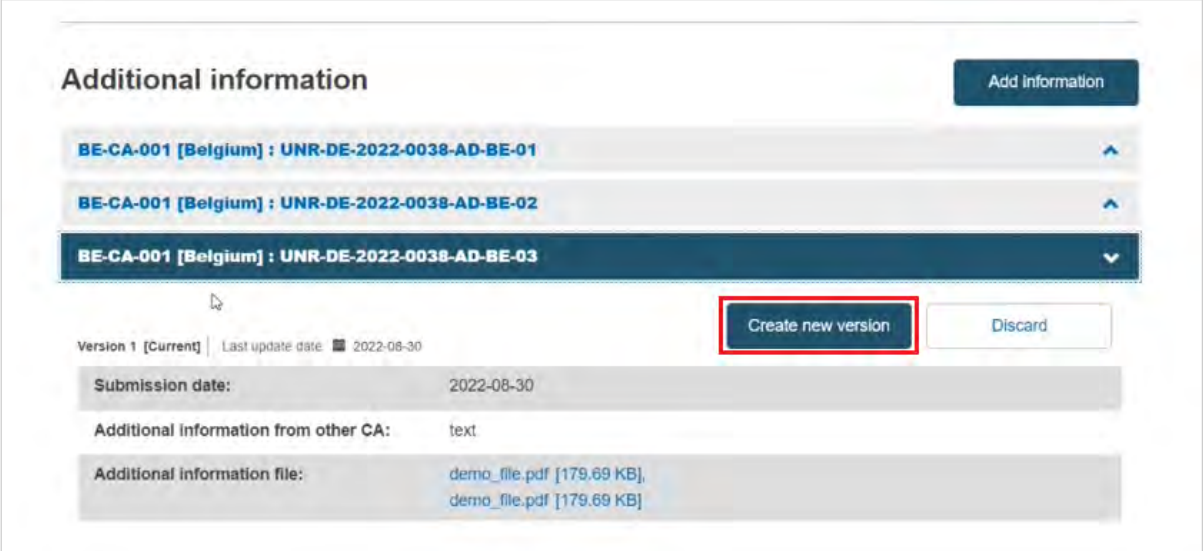
2. Enter the additional information and click **Browse** to upload one or multiple file(s). Click **Submit** to register the additional information, or **Cancel** to delete entirely (there is no **Save draft** option). Acknowledge the confirmation message:



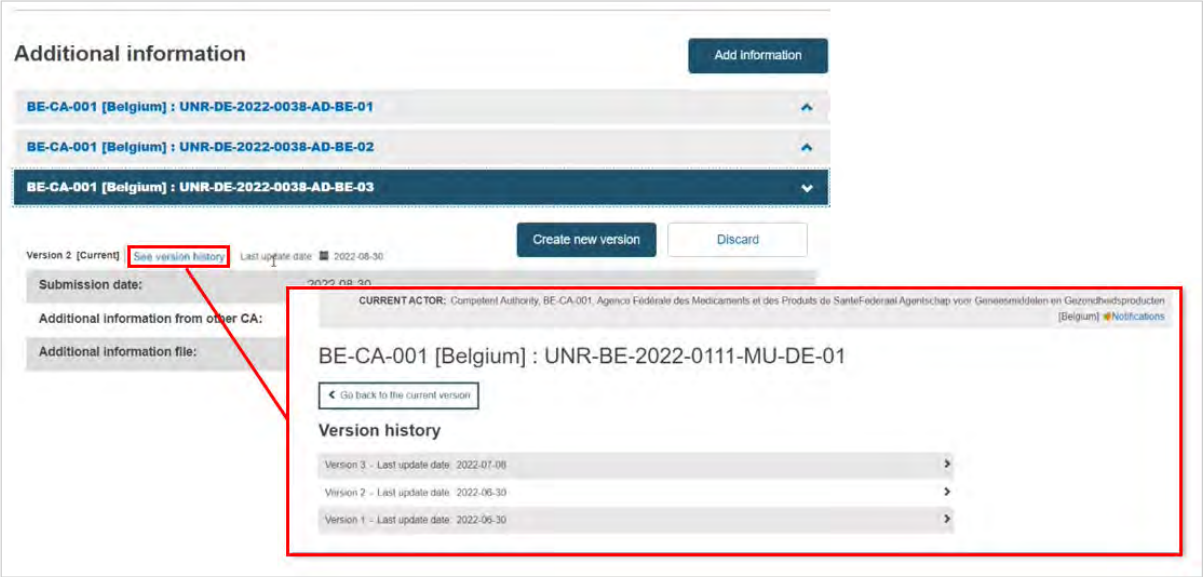
3. The additional information appears in the procedure screen:

7.1 Create a new version of additional information

1. Click **Create new version** and follow the steps as previously:

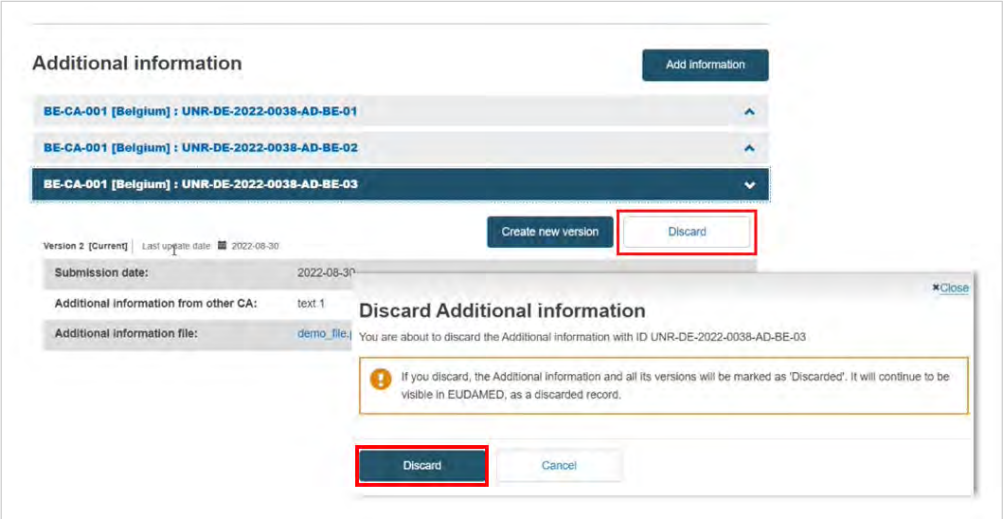


2. The new version appears. Click **See version history** to access earlier records:

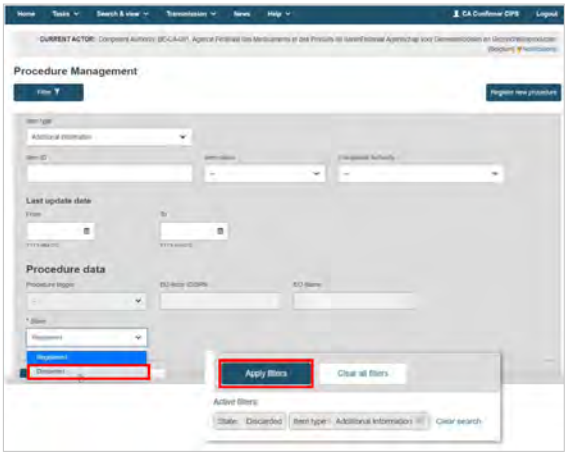


7.2 Discard additional information

1. Click **Discard** to remove the additional information. A confirmation message displays. Click **Discard** again, to complete the action:

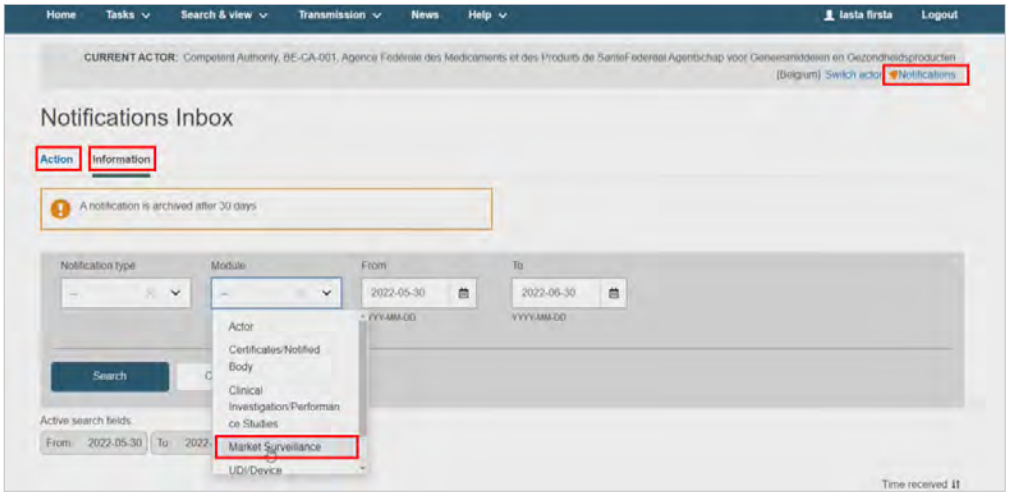


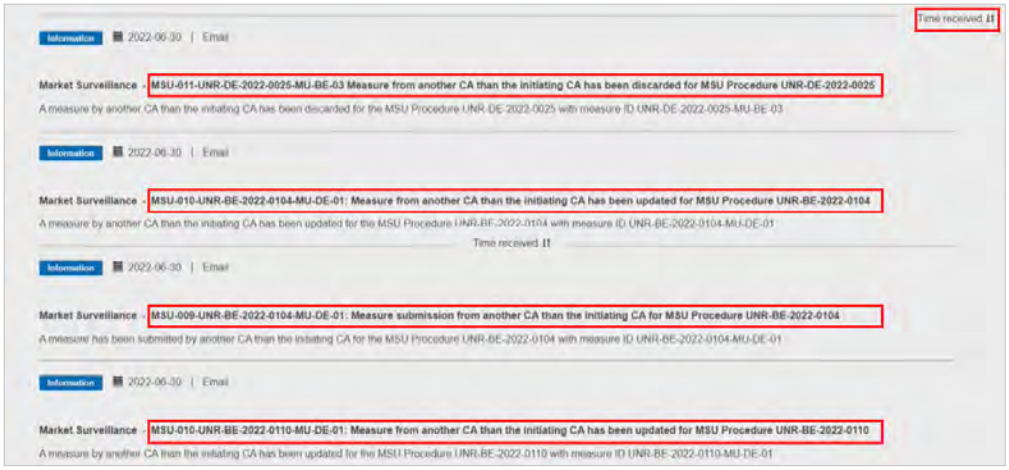
2. On the *Procedure Management* page, you can search for discarded records. Change the search item status to *Discarded*, and click **Apply Filters**:



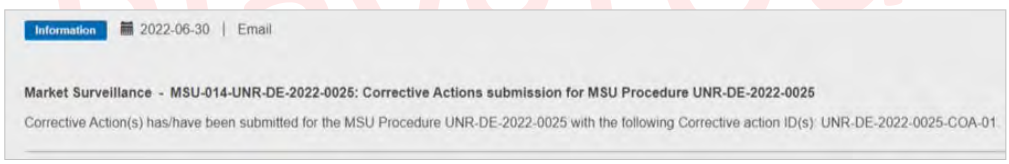
8 Notifications

1. Each submission of a record **generates** an email notification which is sent to the Commission, all other CAs, and the NBs referred to in a procedure (if any). EOs are never notified.
   The notifications are also available in EUDAMED itself. Click the notifications icon Notifications. The *Notifications Inbox* shows two sections: *Actions* and *Information* with the most recent notifications. The *Search* criteria allow a filter by *Notification type*, *Module* and *dates*. Click **Search**:

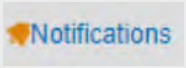




Once a UNR procedure is submitted, the notification states that it is a *Corrective actions submission*, since the procedure type requires correction action(s) at the point of submission:



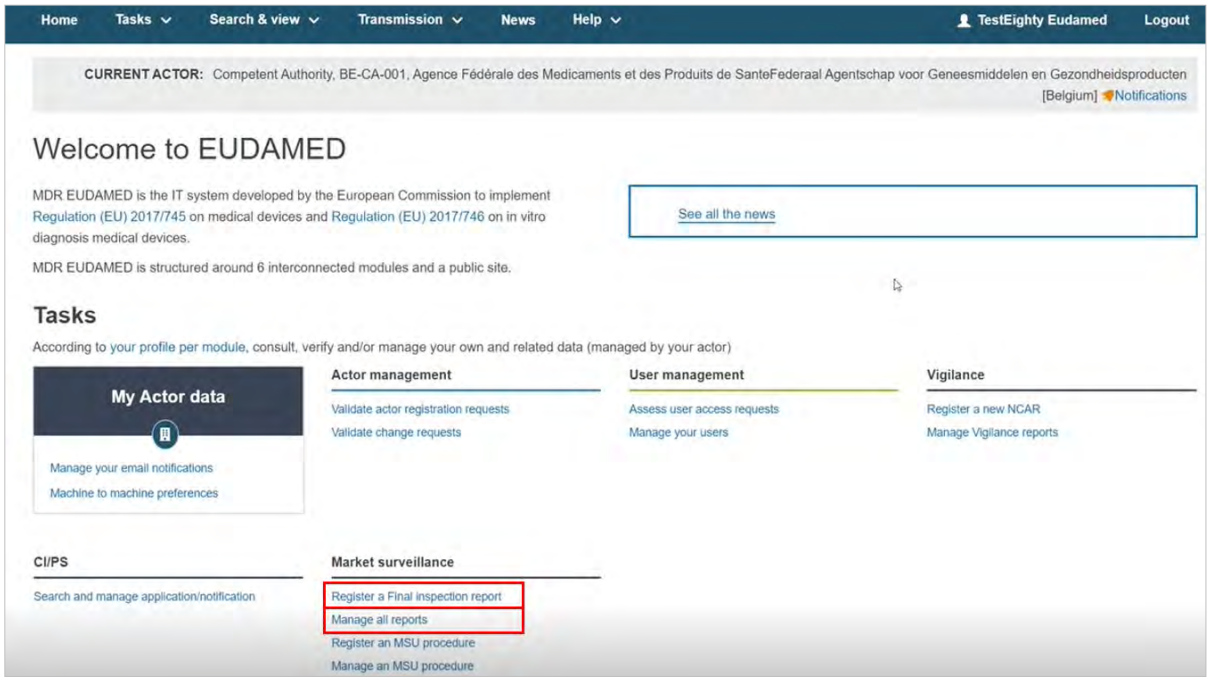
NOTE
Notification emails will only be sent when EUDAMED is fully functional. The notifications in Playground are only available via the notifications icon at the top right.



9 MSU reports

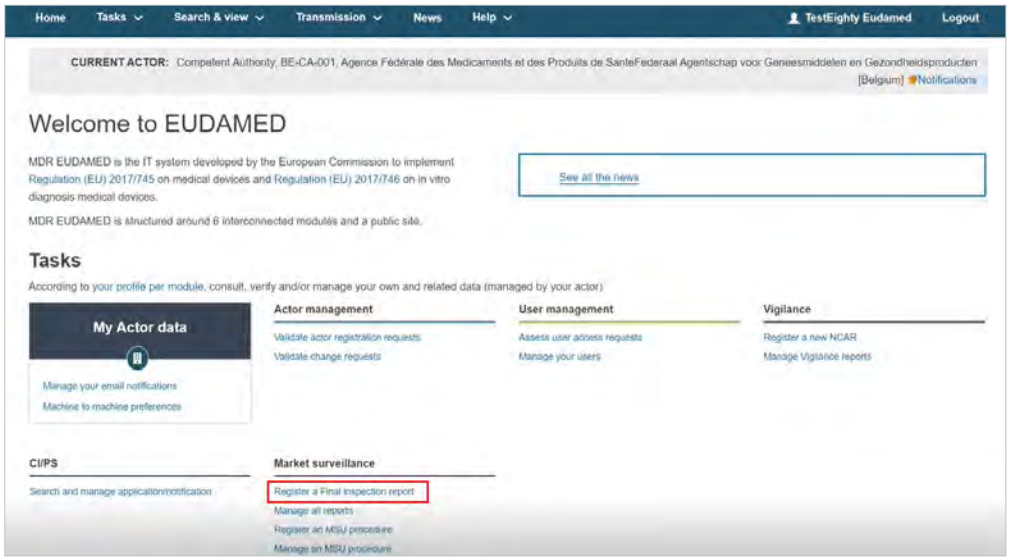
There are three reports in the MSU module, of which only the FIR can be registered from the dashboard *Register a Final inspection report* link. All reports can be registered using the *Manage all reports* link.

- **Annual Summary of Results Report**
- **4 Years MS Review Report**
- **Final inspection report** (FIR)

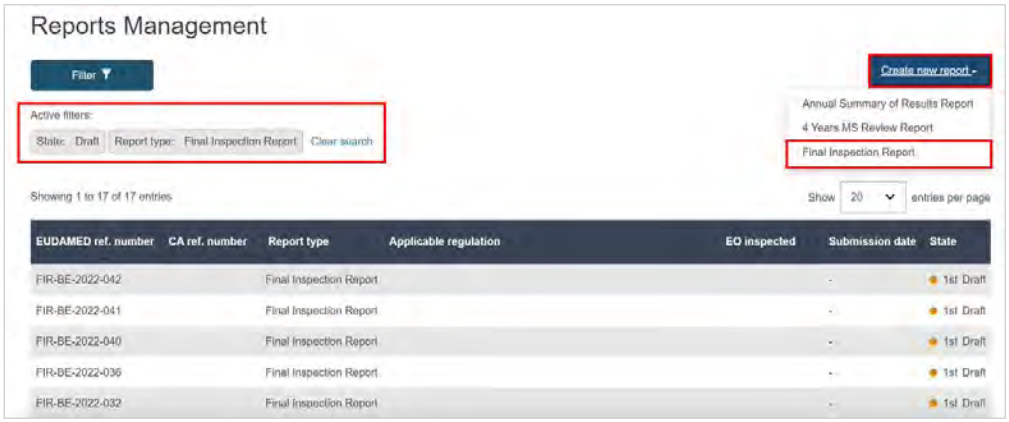


9.1 Register your reports

9.1.1 Final Inspection Report

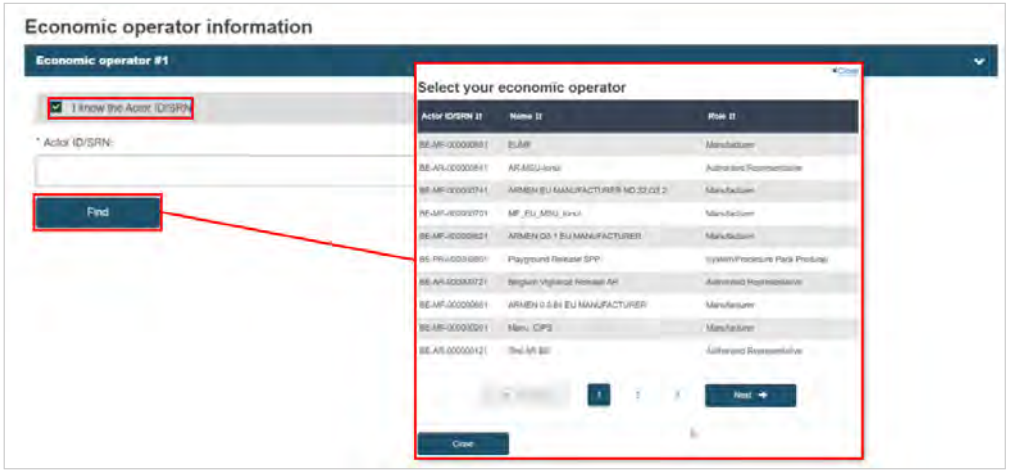


1. Click **Create new report** and select the Final Inspection Report (FIR).

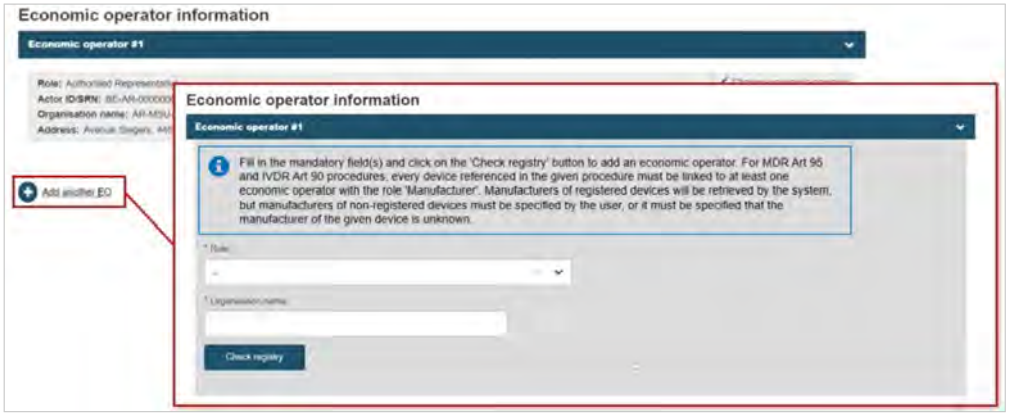


2. Enter the CA reference number and select the applicable regulation(s):

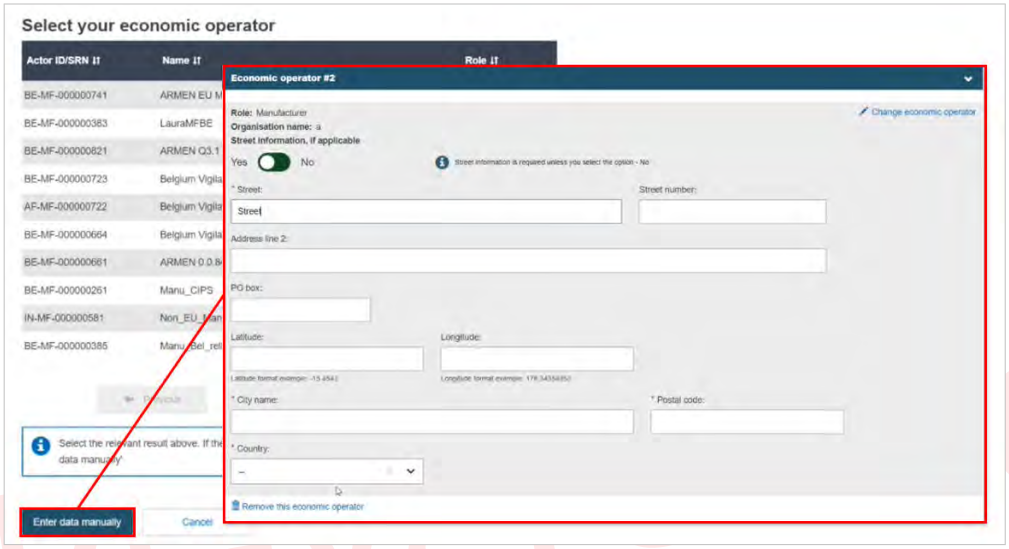
3. Identify the Economic Operator(s) inspected. Click *I know the Actor ID/SRN* to input the data or partial data, then click **Find** to select the EO:



4. You may select multiple EOs. Click **Add another EO**. You can also search by *Role* or *Organisation name*, then click **Check registry**:

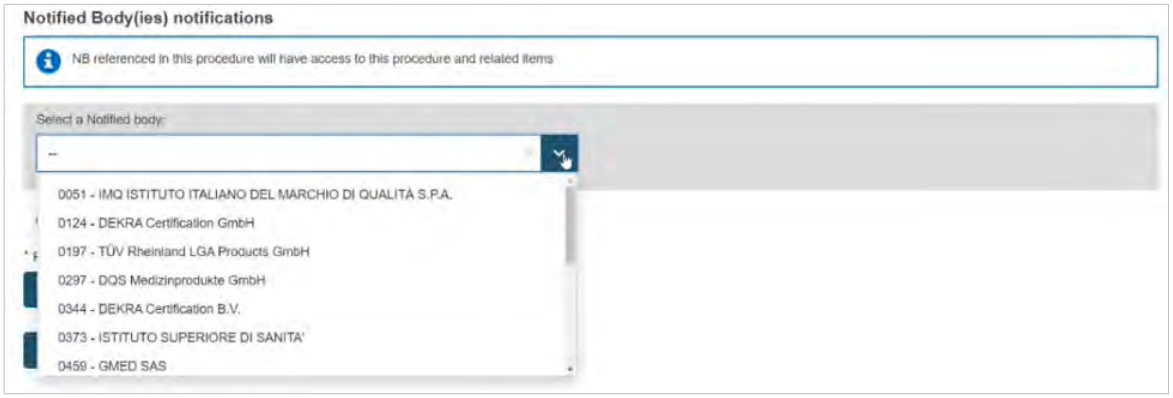


5. If the EO does not appear in the selection results, you can **Enter data manually** (manually entered EO are saved as separate entity with no links to Actors):



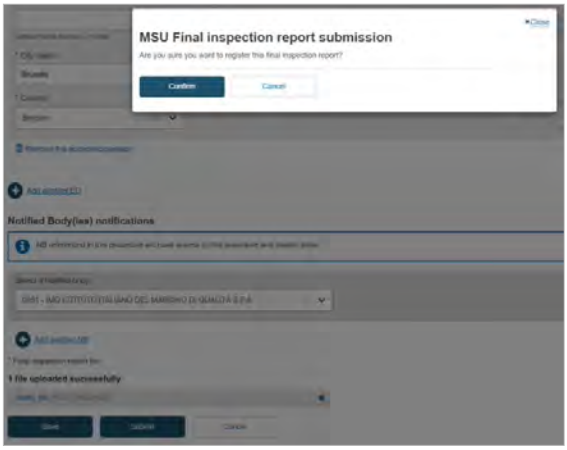
6. Remember to click **Save** at the bottom of the page. A message confirms the data is saved, so you can return to this later:

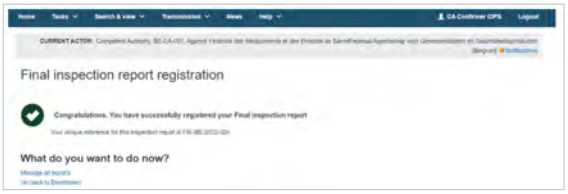
7. You may add one (or multiple) NBs, which will receive a notification of the report. They are now **referenced** in the procedure, and therefore they have access to related procedure items/objects:



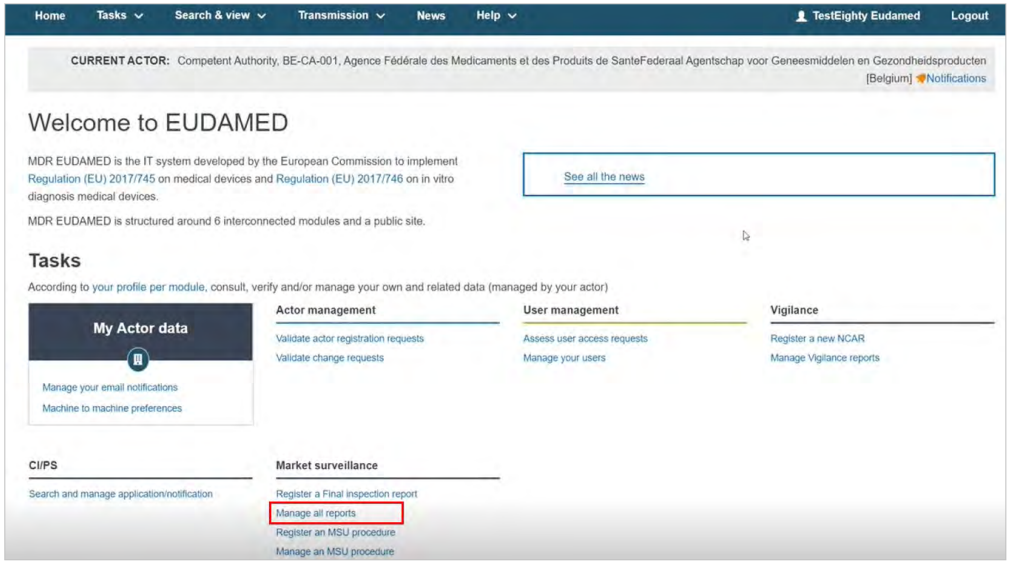
8. Finally, upload **one** PDF-format report. Click **Submit**:

9. **Confirm** that you want to register this FIR report. The confirmation page displays, which links back to the *Dashboard* or the *Manage all reports* page:

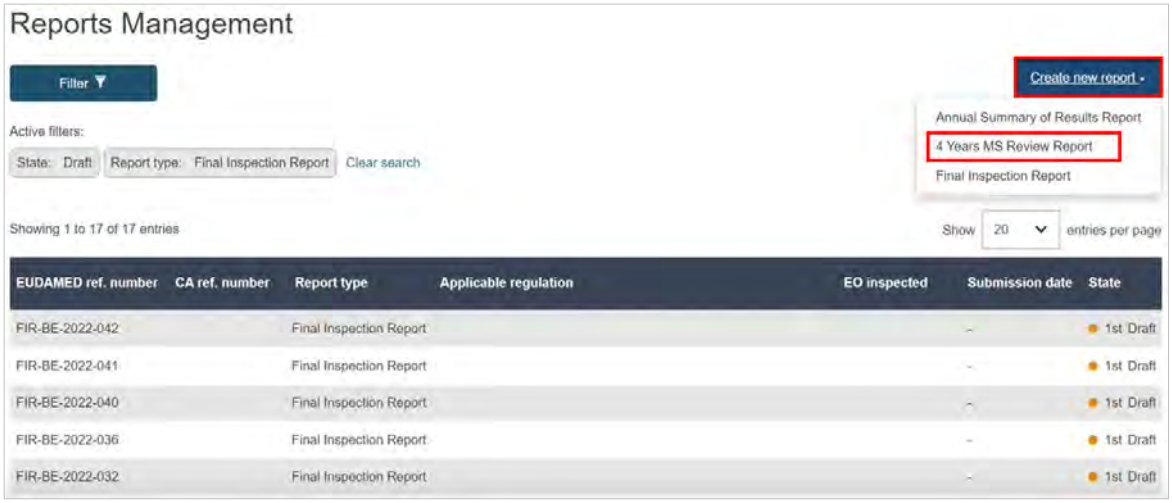




9.1.2 4-Years MS Review Report

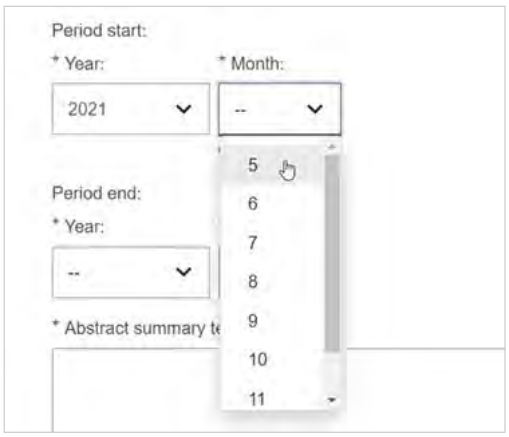


1. Click **Manage all reports**, click **Create new report** and select the *4-Years MS Review Report* option.



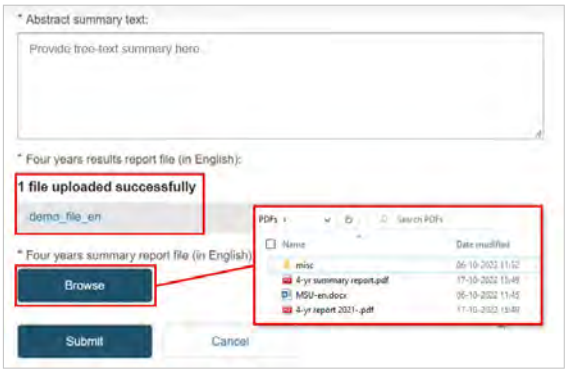
2. Provide a unique local CA reference and select the applicable regulation(s). (If you select both, you should provide a single report covering both):

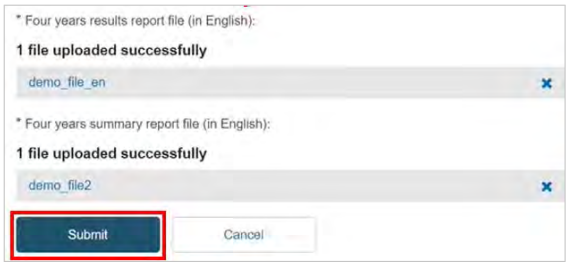
3. Input the review period start date (year and month). The values depend on the application legislation as selected. For example, MDR selected alone would start from May 2021, while IVDR would start from 2022. Both selected would offer the May 2021 start-date possibility.



4. The *Period end* year appears in the report identifier.

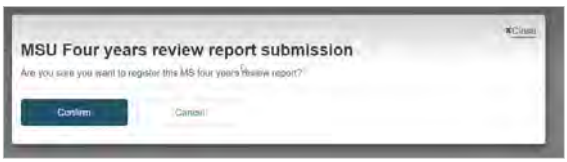
5. Two different files are to be uploaded: **one** *4-Years Results Report* file, and **one** *4-Years Summary Report* file.
Click **Submit**:





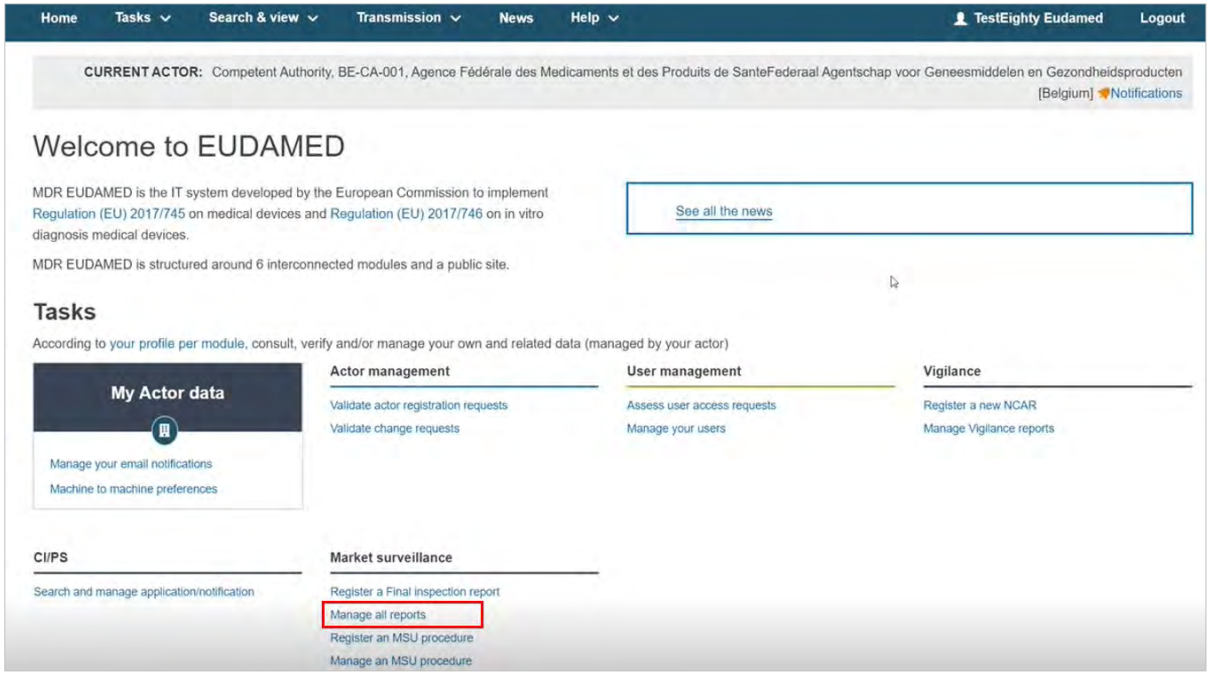
> **NOTE**
> There is no report *draft*. The record will be directly submitted.

6. Click **Confirm**, and the confirmation screen displays the successful registration of the 4-year review (i.e. the results and summary combination):

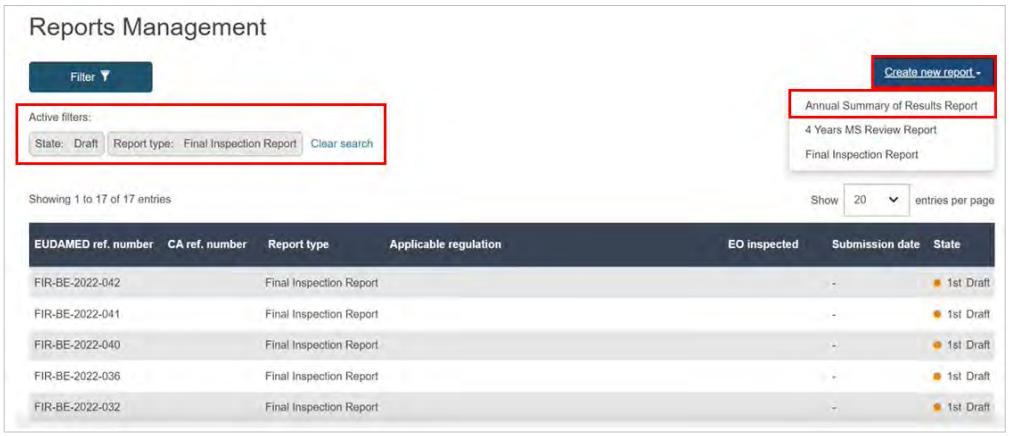


A **notification** is sent to all related users.

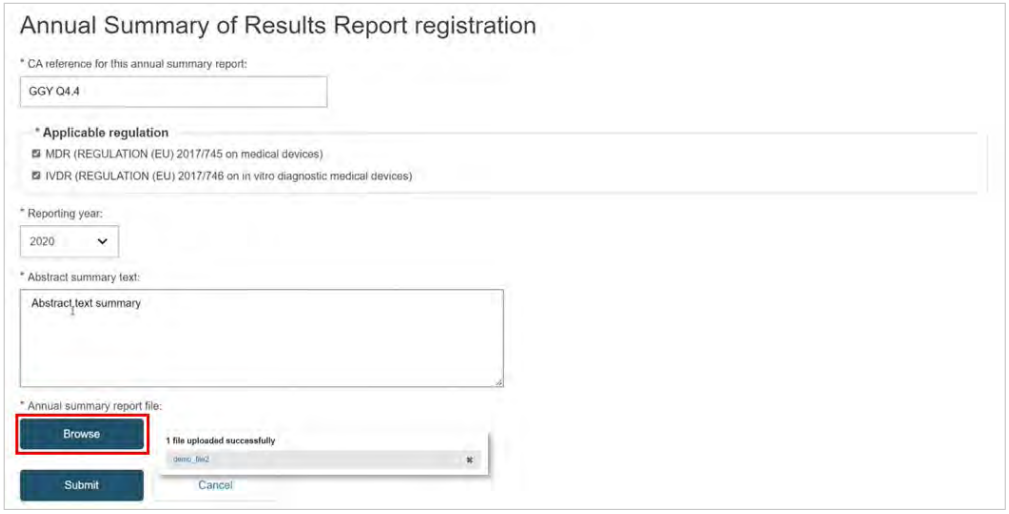
9.1.3 Register Annual Summary of Results report



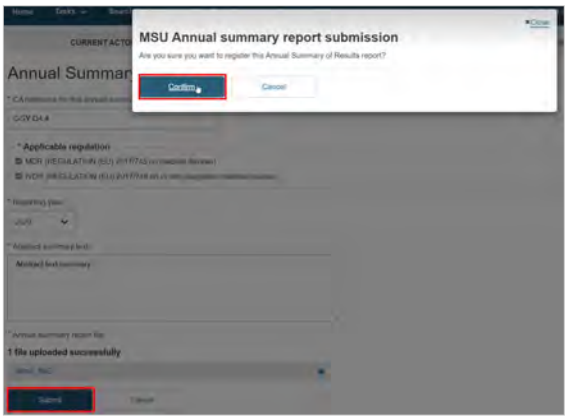
1. Click **Manage all reports**, click **Create New Version** and select the *Annual Summary of Results Report* option. This report type has no *draft* state, and no versions are created:



2. Provide a unique local CA reference and select the applicable regulations(s) (if you select both, you should provide a single report covering both), and provide the data required for all the fields. Note all fields are mandatory.
   Click **Browse** to upload the (one) report file:

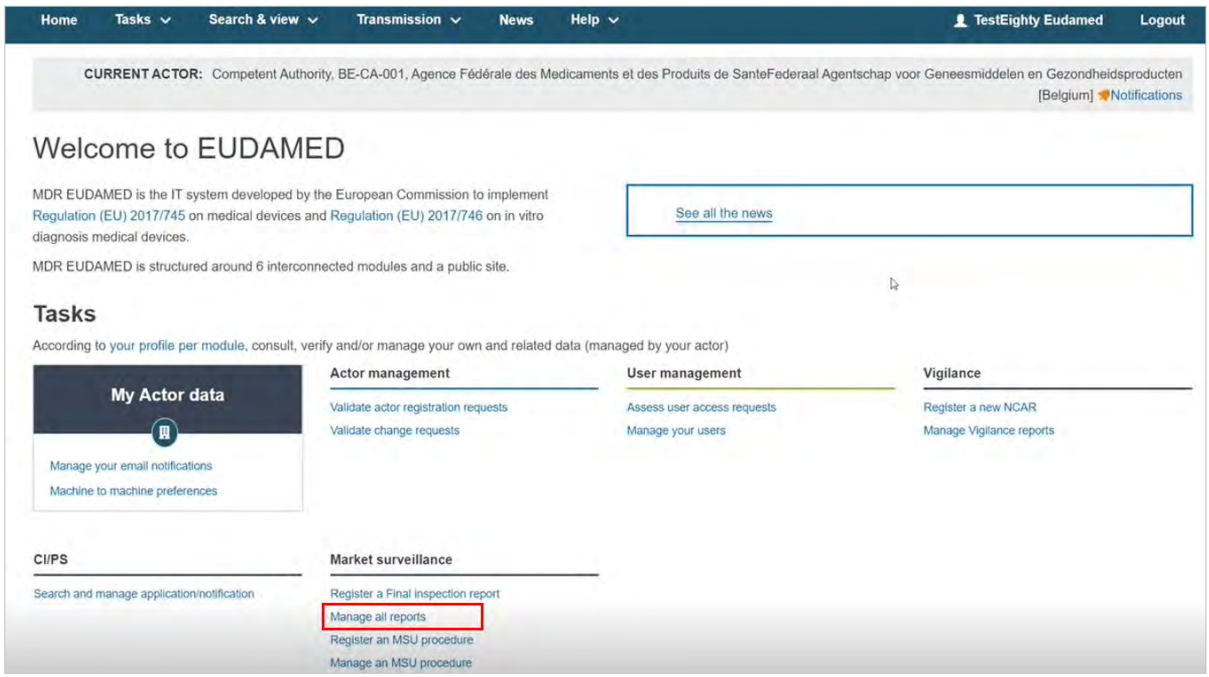


3. Click **Submit** and **Confirm** to register the report. The confirmation message displays, and a notification is sent to all actors concerned:

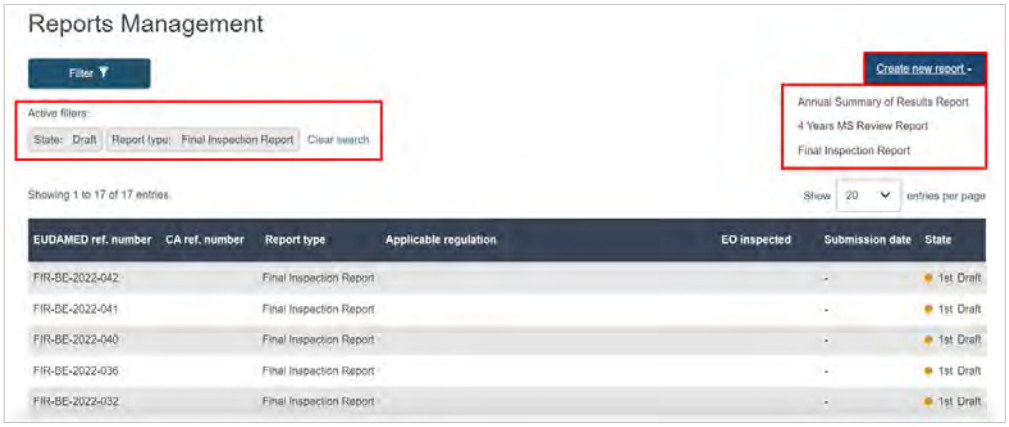


9.2 Manage all reports

Click *Manage all reports* on the dashboard.



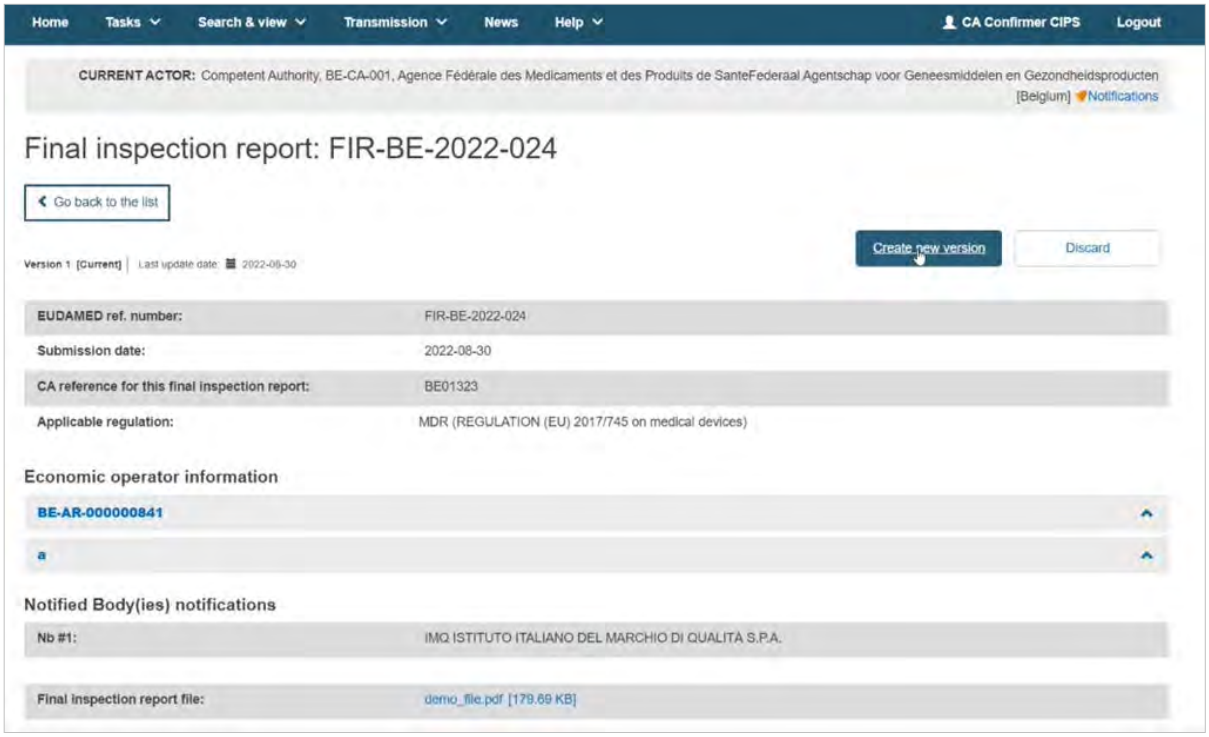
1. By default, the page shows draft records:



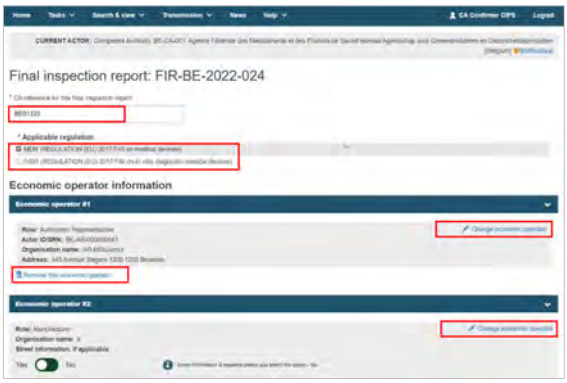
2. Click **Filter** and enter your filter criteria (i.e. change the selection to *Registered*.) Click **Apply filters** and the concerned records display:

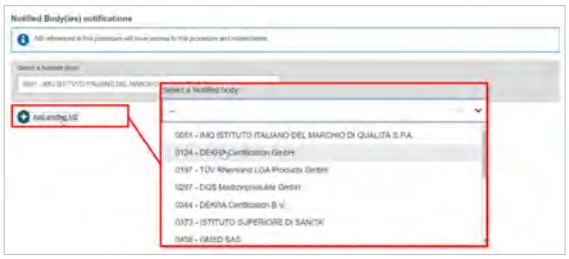
9.3 Create new version of a report

1. Click **Create new version**:



2. A new version is created. All fields are editable:





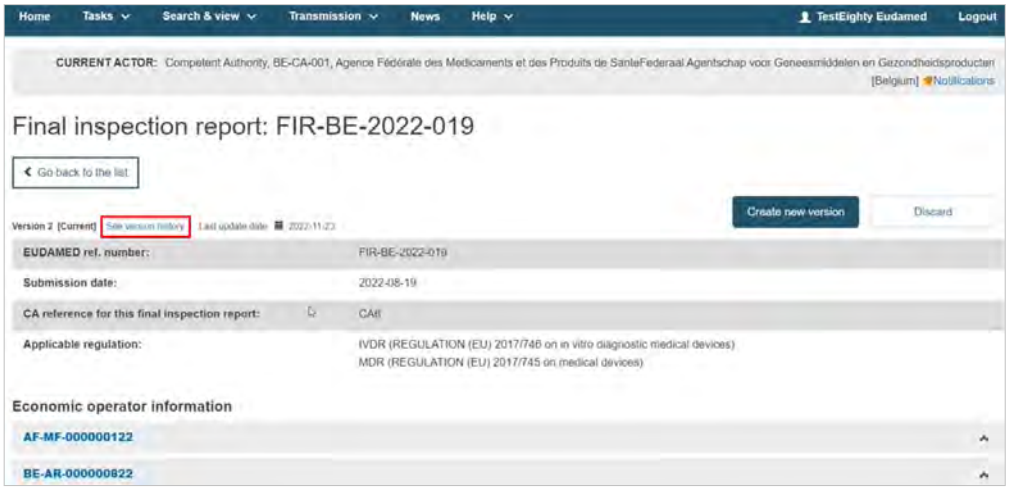
3. You can also change the FIR file itself. Click the **x** to remove the existing file and browse/upload a new PDF file:

4. Click **Submit new version** (**Save** to create a draft version or **Cancel**):

9.3.1 Records version history

When there are multiple versions of a record, you can view earlier versions.

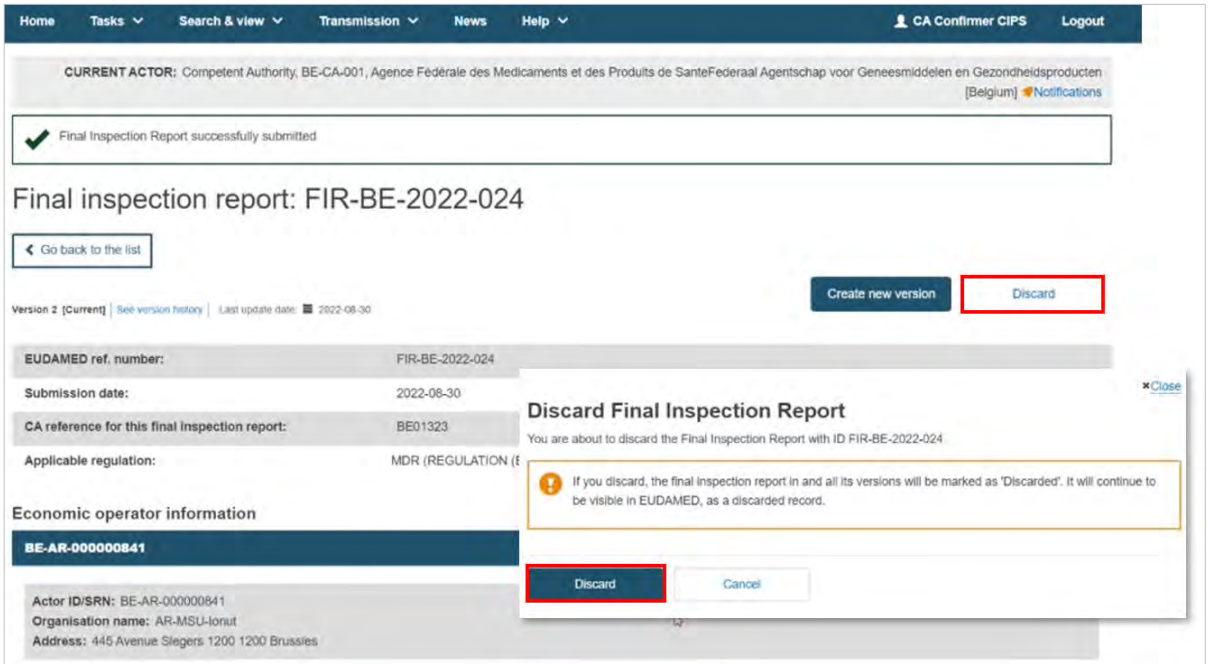
1. Click *See version history*:



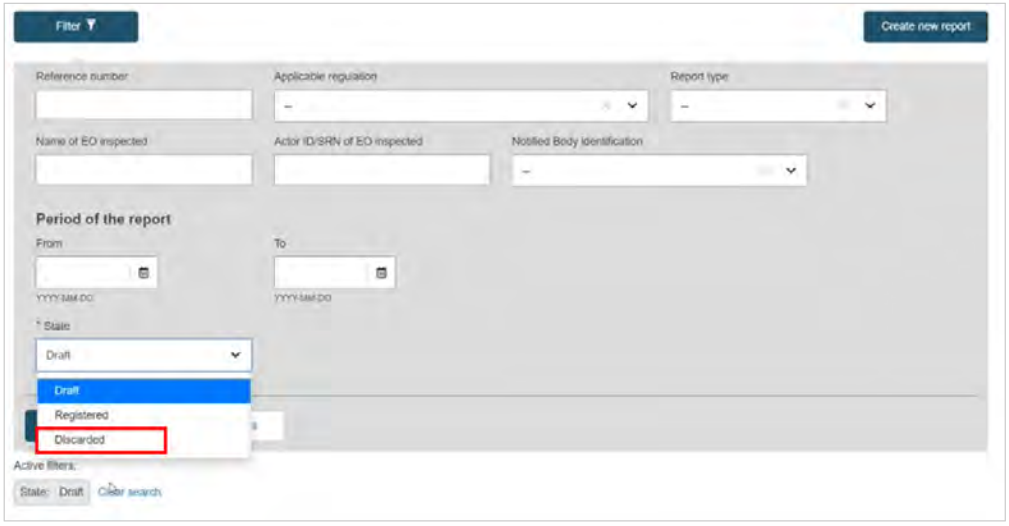
9.4 Discard a report

Locate the report to be discarded using the *Reports Management* functionality and open the selected report. Report details will be displayed, including a **Discard** button. The screenshot shows the report page that opens via *Reports Management*. The same behaviour below applies to all reports.

1. Click **Discard**. The pop-up warning appears, click **Discard** again:



2. You can later search for the record using the *Discarded* filter:

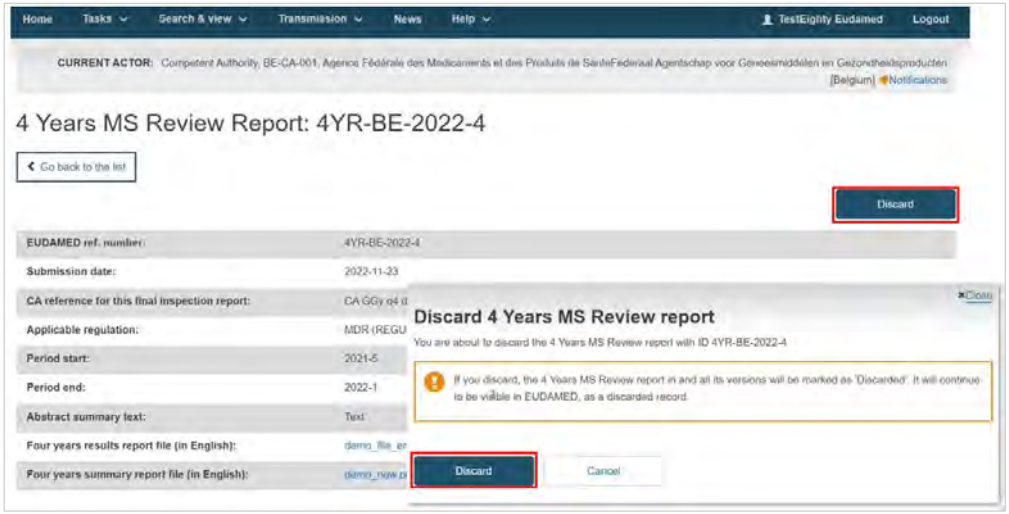


3. The discarded record displays, showing a red *discarded* banner:

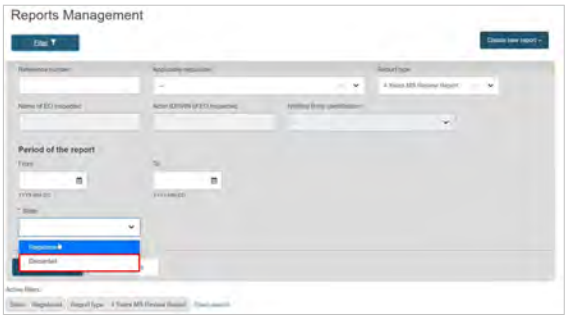
Notifications are sent to all actors concerned, including NBs referenced within the FIR report.

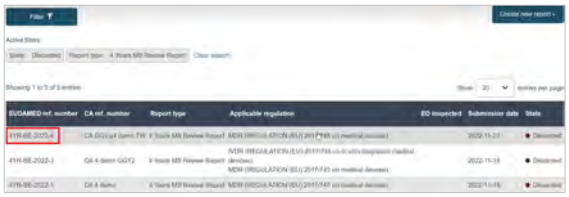
9.4.1 Discard a 4-Years MS Review Report

1. Click **Discard**. The pop-up warning appears, click **Discard** again:



2. You can check by filtering to the state *Discarded*, then select the intended record:

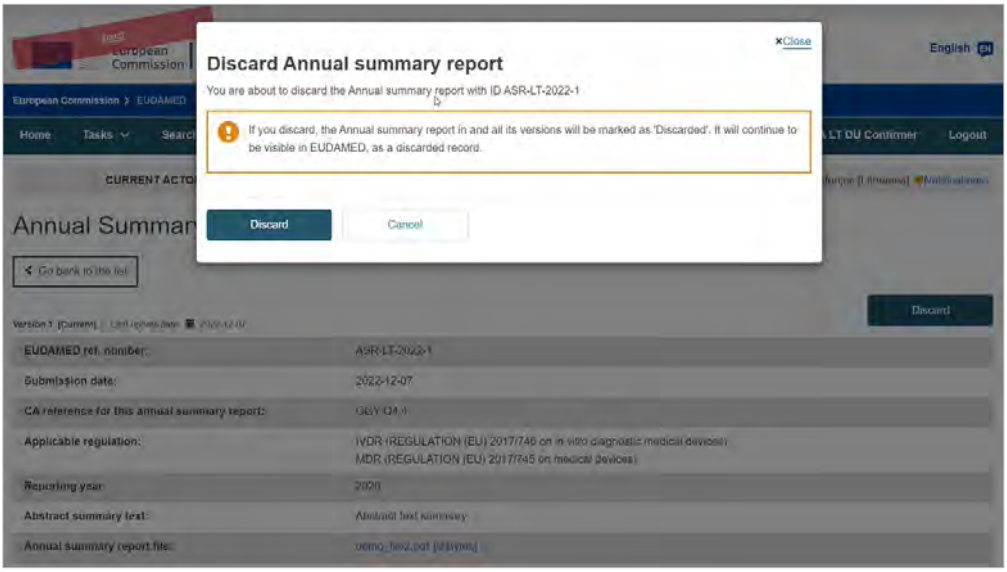




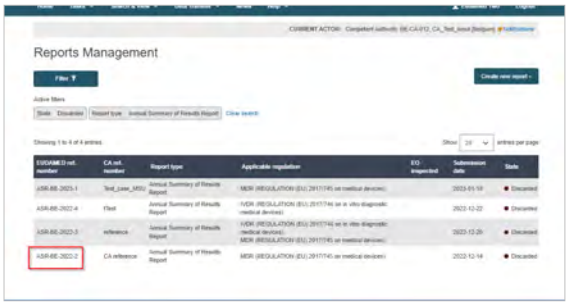
3. The record displays, showing a red *discarded* banner. **Both PDF uploads are discarded with the single record**:

9.4.2 Discard Annual Summary of Results Report

The process and principles are the same for all reports, (see Discard a report [67]):



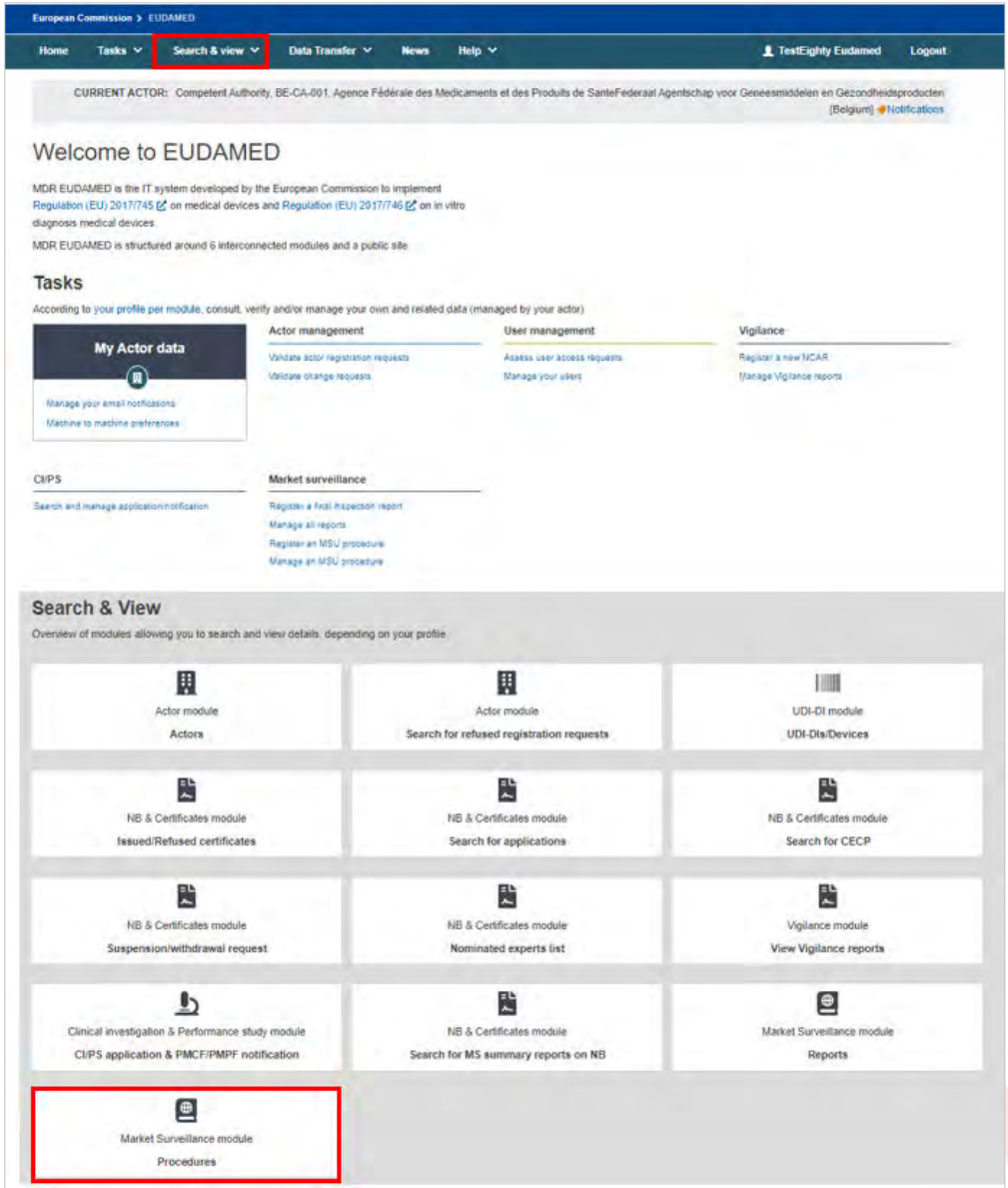
The discarded report displays in Reports Management, and a notification is sent to the actors concerned:



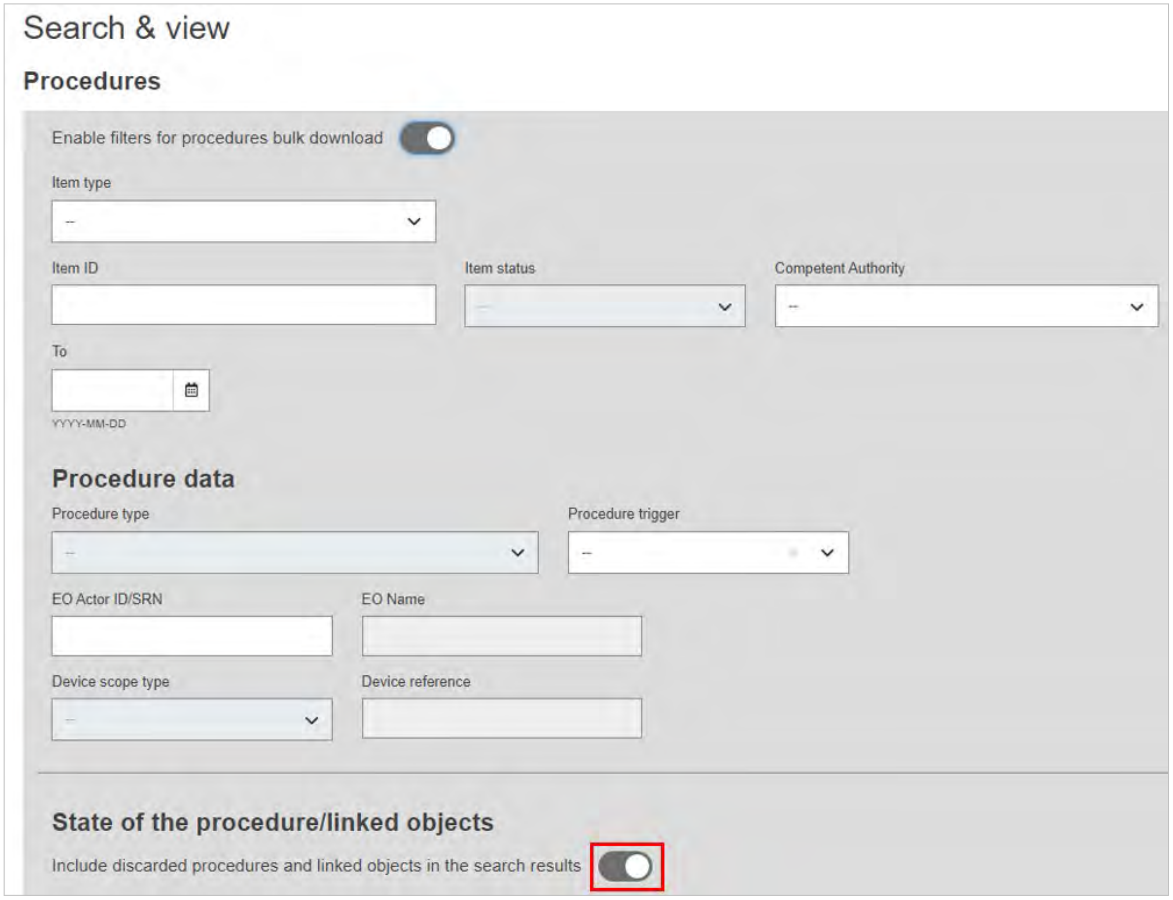
10 Search & View

10.1 Search & View procedures

On the header menu, click on **Search & View**, then under the *Market Surveillance* section click **Search for Procedures**. Alternatively, in the *Search & View* area click the **Market Surveillance module Procedures** tile:

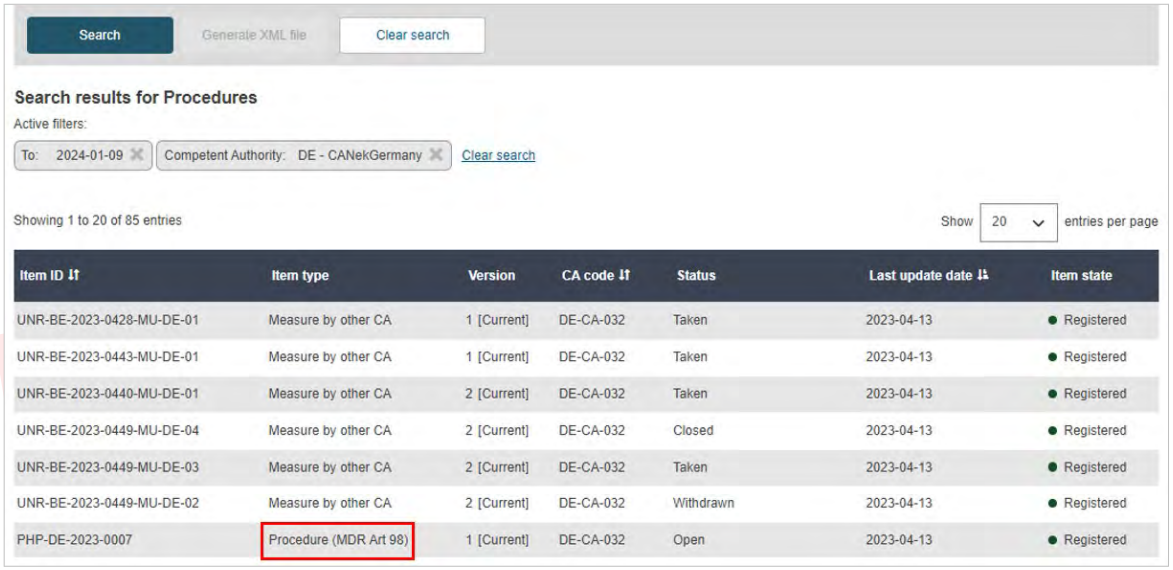


1. By default, the filter is set to pull registered procedures/linked items. Discarded records can be included by sliding the toggle (green = yes, grey = no).
   In Search and view, all discarded objects will be displayed. Filtering by owner CA applies only to Procedure management:



2. The data criteria are the same as described in Using the filter [28]. Click **Search** to proceed, or **Clear search** to re-enter fields.

3. Search results display. The *Item type* column displays a shortened 'Procedure type' description for Procedures, and an 'Item type' description for other item types:



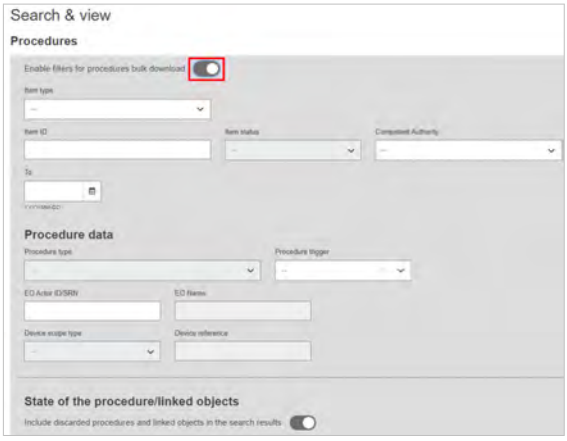
Item ID	Item type	Version	CA code	Status	Last update date	Item state
UNR-BE-2023-0428-MU-DE-01	Measure by other CA	1 [Current]	DE-CA-032	Taken	2023-04-13	Registered
UNR-BE-2023-0443-MU-DE-01	Measure by other CA	1 [Current]	DE-CA-032	Taken	2023-04-13	Registered
UNR-BE-2023-0440-MU-DE-01	Measure by other CA	2 [Current]	DE-CA-032	Taken	2023-04-13	Registered
UNR-BE-2023-0449-MU-DE-04	Measure by other CA	2 [Current]	DE-CA-032	Closed	2023-04-13	Registered
UNR-BE-2023-0449-MU-DE-03	Measure by other CA	2 [Current]	DE-CA-032	Taken	2023-04-13	Registered
UNR-BE-2023-0449-MU-DE-02	Measure by other CA	2 [Current]	DE-CA-032	Withdrawn	2023-04-13	Registered
PHP-DE-2023-0007	Procedure (MDR Art 98)	1 [Current]	DE-CA-032	Open	2023-04-13	Registered

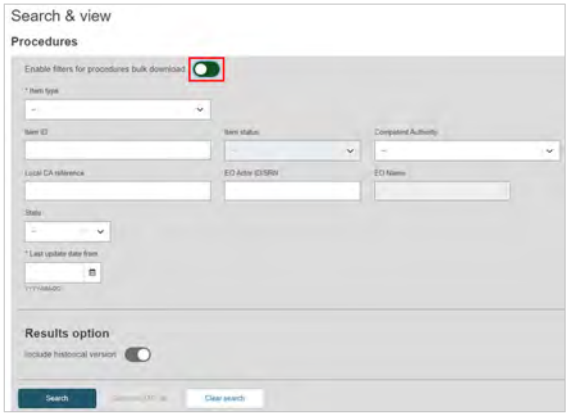
NOTE
The procedure data not available to NBs is:

- Objections
- Additional information
- Procedure trigger information section
- Arguments by EO of the Measure
- Economic operator information: *EO contact information* and *Other information* sections

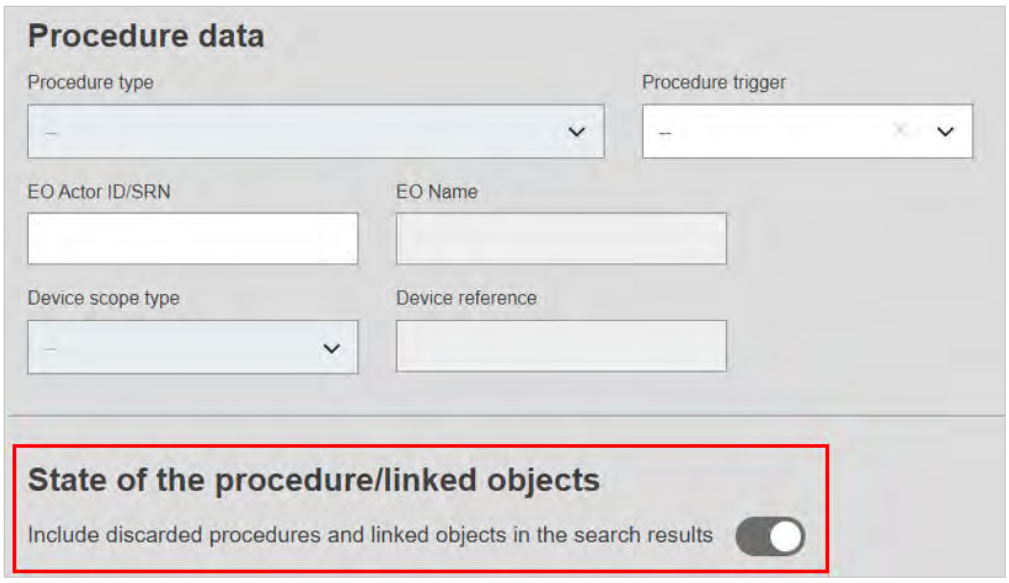
10.2 Bulk download procedures

1. To enable bulk XML download and access the specific filters, slide the toggle (green = yes, grey = no). Note the toggle to include historical versions appears. The *Item type* and *Last update date from* become mandatory fields:

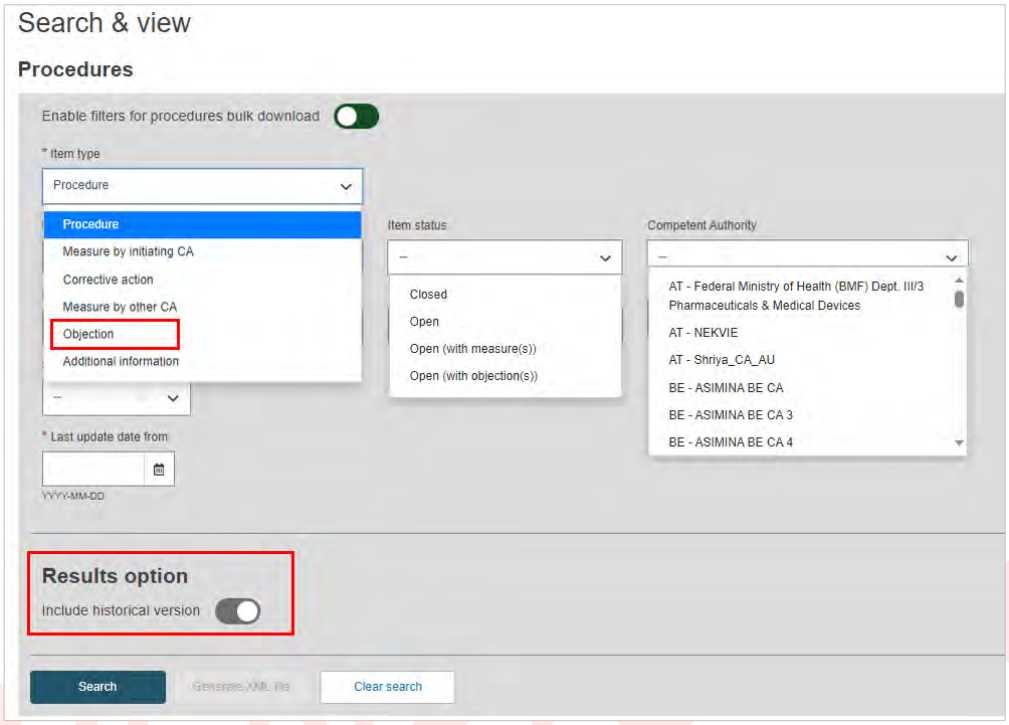




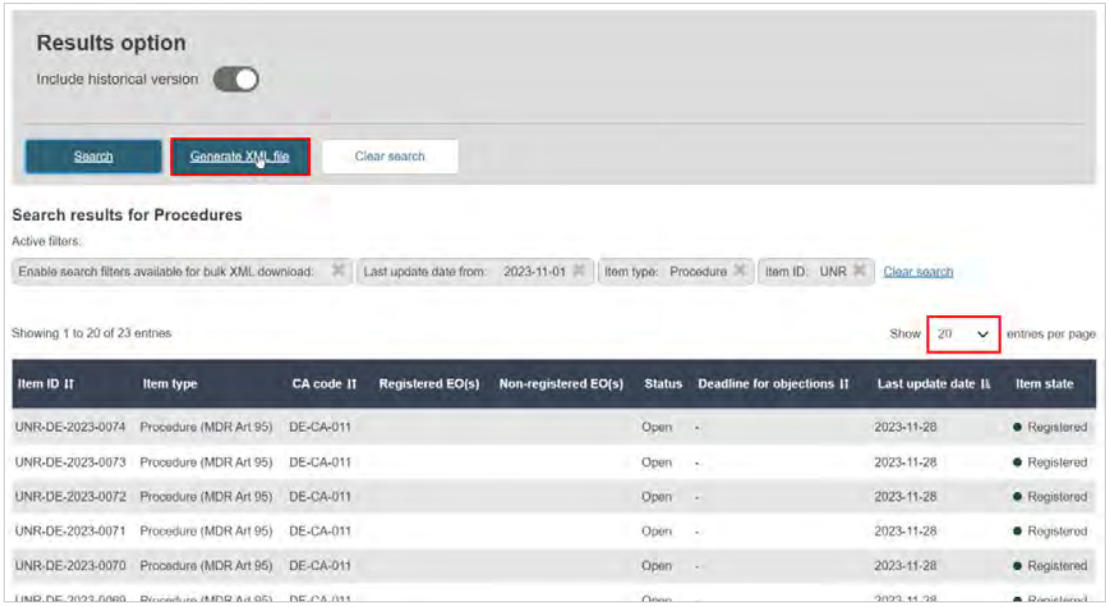
2. By default, the filter is set to pull registered procedures/linked items. Discarded records can be included by sliding the toggle (green = yes, grey = no).
In Search and view, all discarded objects will be displayed.



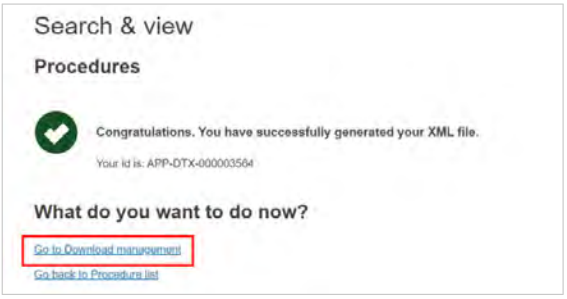
3. The *Item type* criteria are the same as in the *Procedure Management* screen. The *Procedure* results will include children objects in the XML payload, but only Procedures will be displayed on screen. *Objections* and *Additional information* item types will not be displayed for NBs. You can include historical versions in the search by sliding the toggle, or click **Clear Search** to re-enter fields.
During a bulk download, 'historical versions' will return all procedure versions in the system, and historical versions of children objects will be included.
Click **Search**:



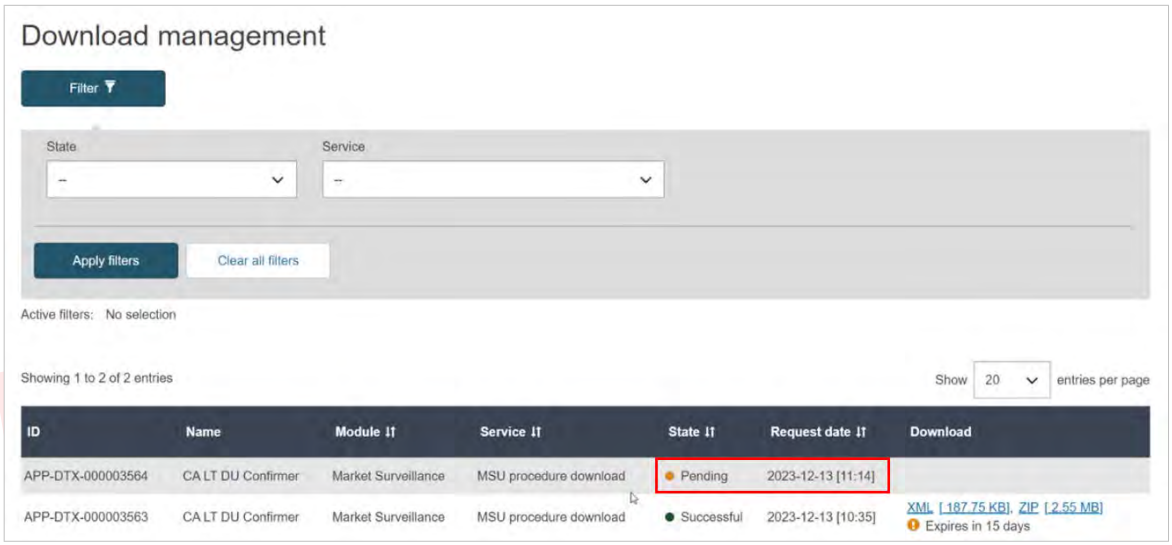
4. By default, up to 20 entries are displayed – this can be increased to maximum 50. Click the now-active **Generate XML file** button:



5. Click **Generate XML file**, and **Confirm** you wish to proceed. The congratulations screen confirms that the bulk download has been initiated. To access the files, go to the *Download management* page via the link, or via the *Data transfer* section from the top menu.



6. File generation may take a few minutes. Meanwhile, a 'Pending' label displays. Refresh the page:



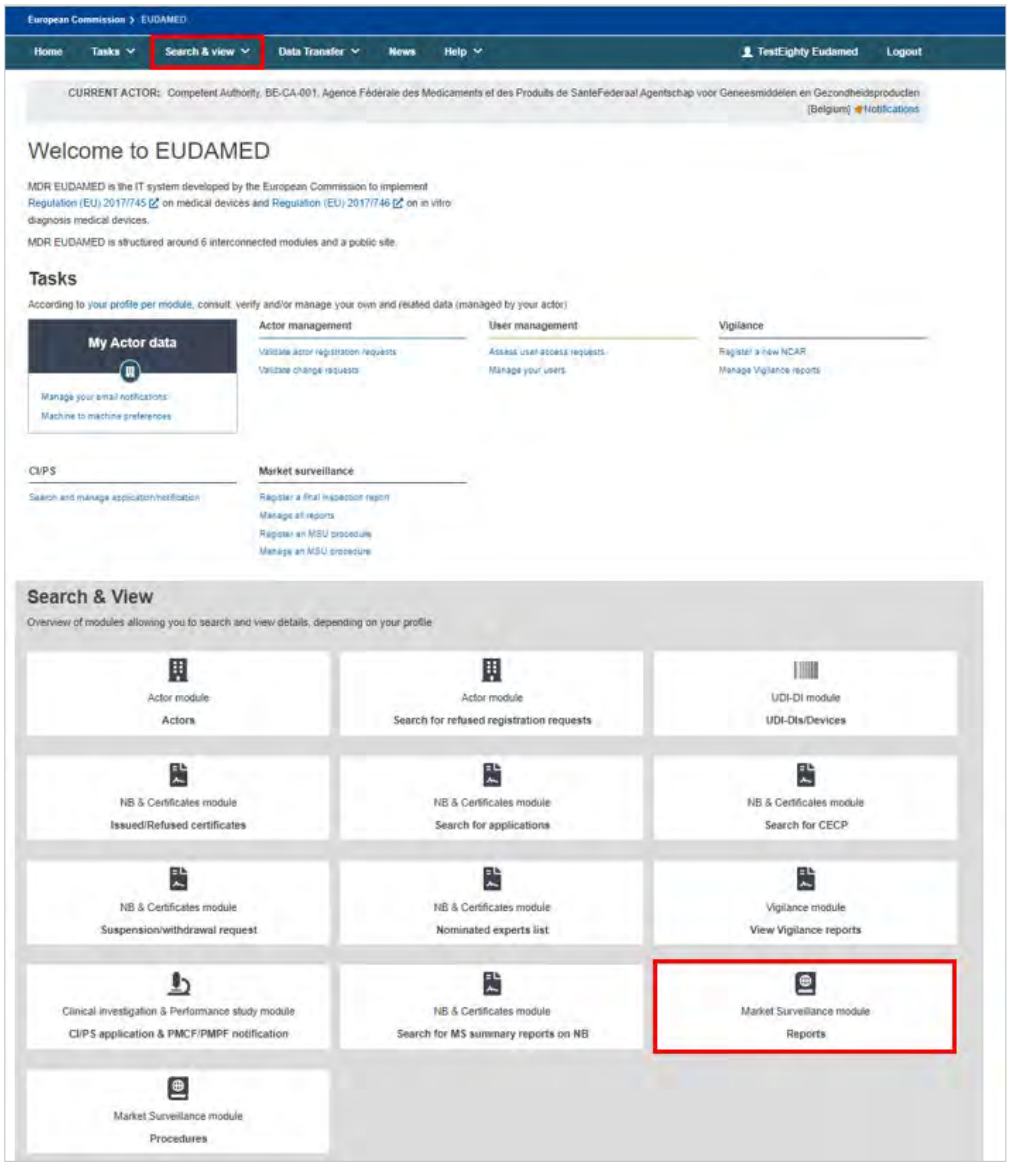
7. The downloadable files appear with an expiry date, after which they are not accessible. The **XML** file contains the data from the displayed records, while the **ZIP** file contains attached documents:

NOTE
The procedure data not available to NBs is:

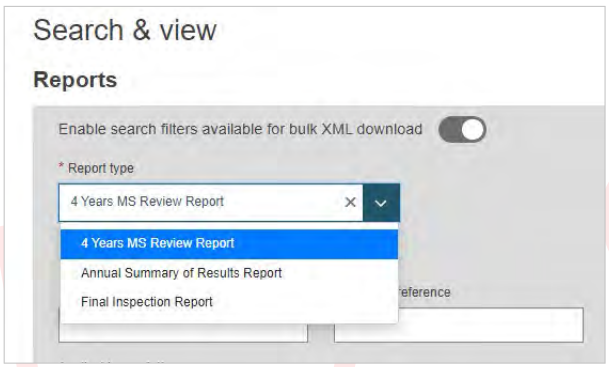
- Objections
- Additional information
- Procedure trigger information section
- Arguments by EO of the Measure
- Economic operator information: *EO contact information* and *Other information* sections

IMPORTANT
For bulk download, if search results span multiple pages, only records of the current page will be included.

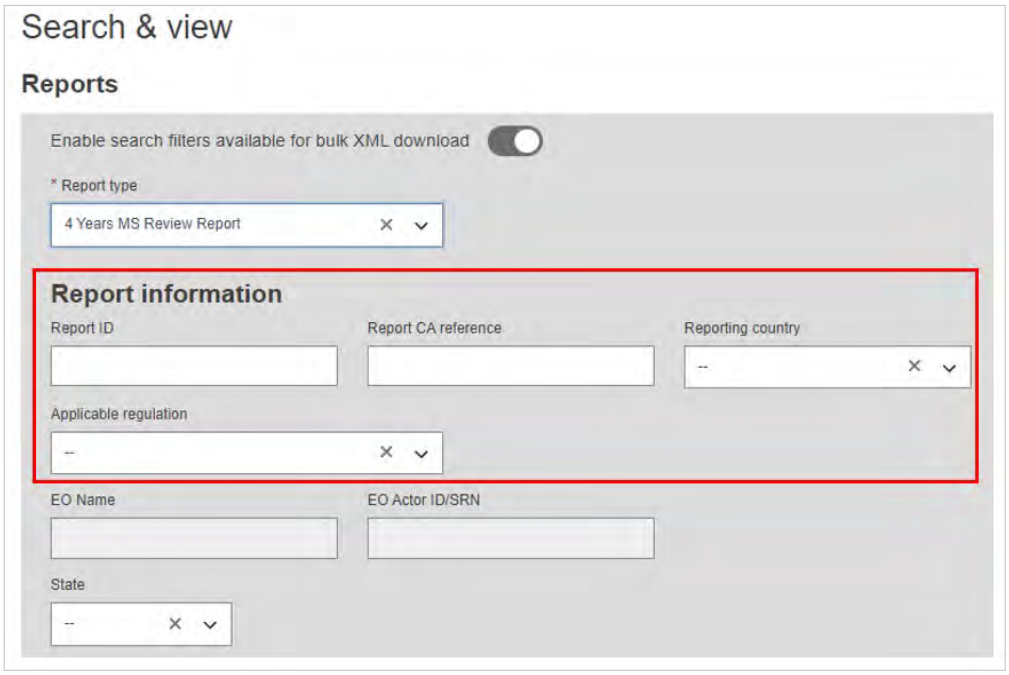
10.3 Search & View reports



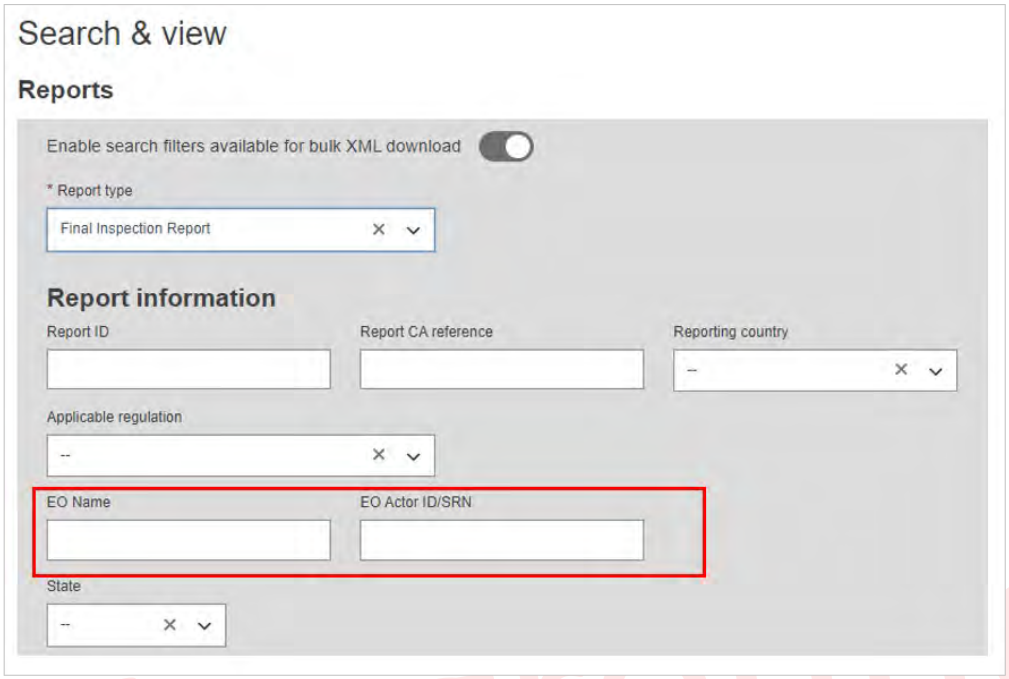
1. For a standard report search, do not enable the bulk download toggle. Select the *Report type*:



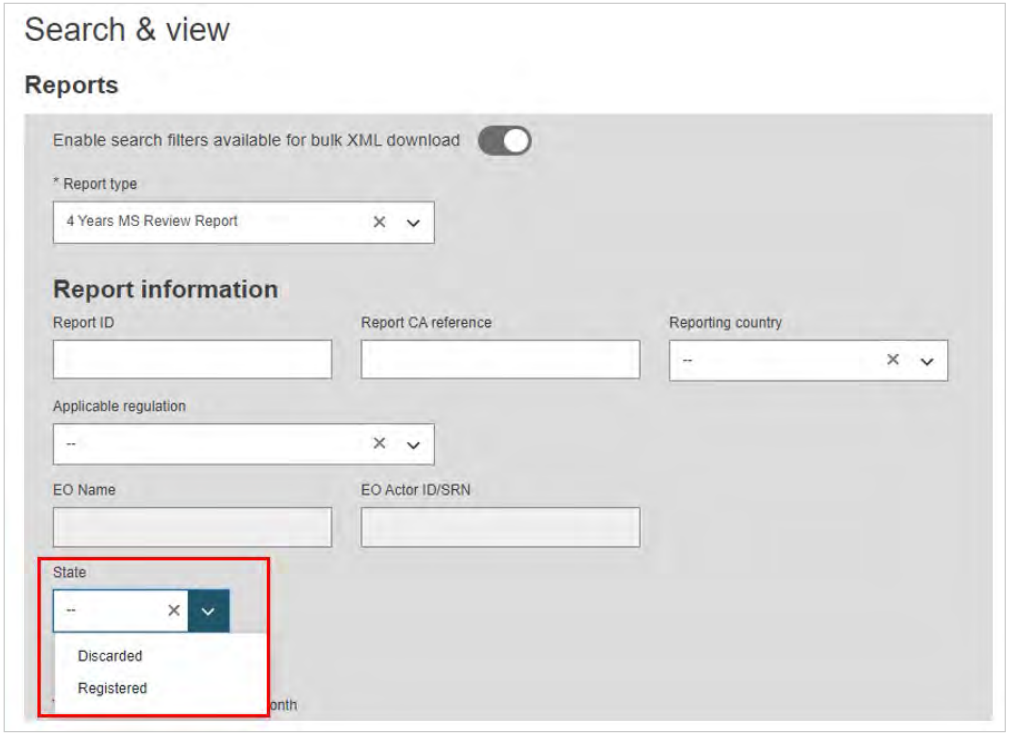
2. Select the *Report ID*, the *Report CA reference*, the *Reporting country* (relates to the Competent Authority, listing EC Member States, 'extended' and 'special' countries) and the *Applicable regulation*:



3. For the *Final Inspection Report* only, the *EO Name* and *EO Actor ID/SRN* fields will be enabled. For all other report types, those fields will be greyed out:

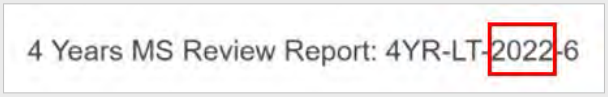


4. Select the state of the report:



5. Provide the *Last update date from* value.

NOTE
For the *4 Years MS Review Report*, both the *Year* and the *Month* fields are enabled. The year of the *Reporting period to* becomes a component in the report ID for this report.

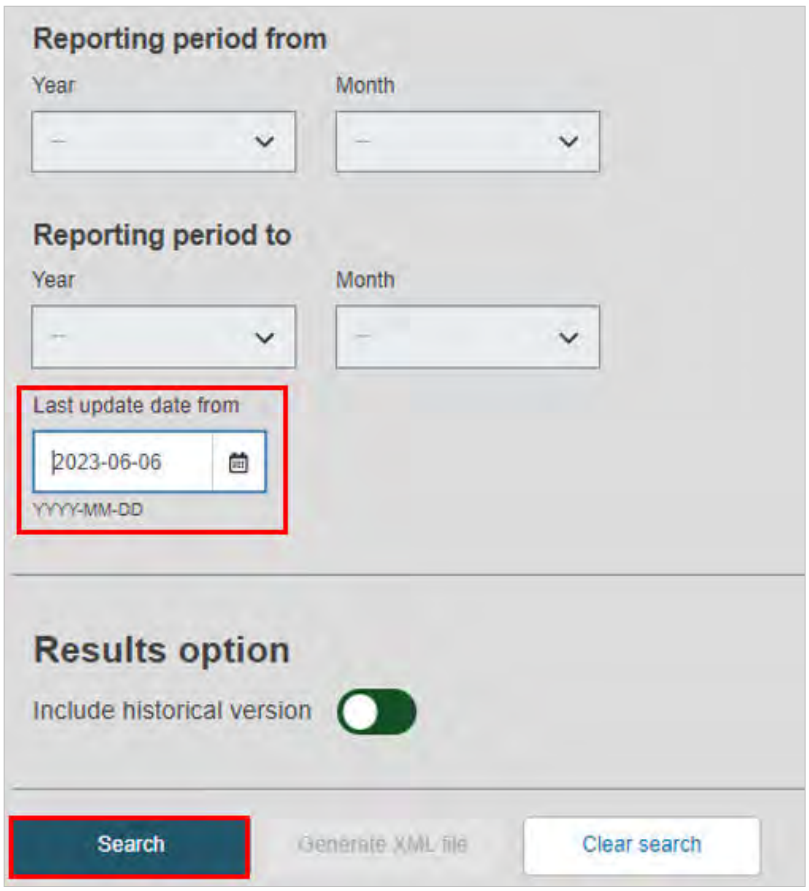


For the *Annual Summary of Results Report*, the *Month* field is greyed out.

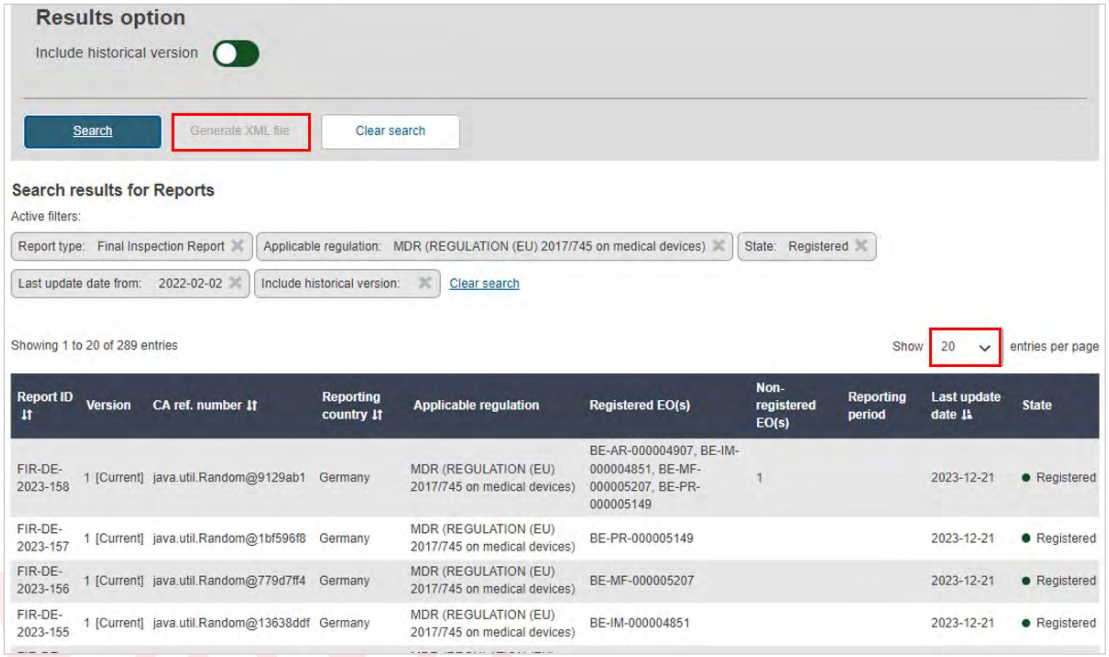
For the *Final Inspection Report*, both the *Year* and the *Month* fields are greyed out.

For the *Final Inspection Report* only, slide the toggle (green = yes, grey = no) to enable the *Include historical version* field. For all other report types, the option does not apply because historical versions do not exist.

Click **Search** to view the results:



6. The table displays the report results based on the criteria you selected. By default, up to 20 entries are displayed – this can be increased to maximum 50.
Note the disabled **Generate XML file** button.

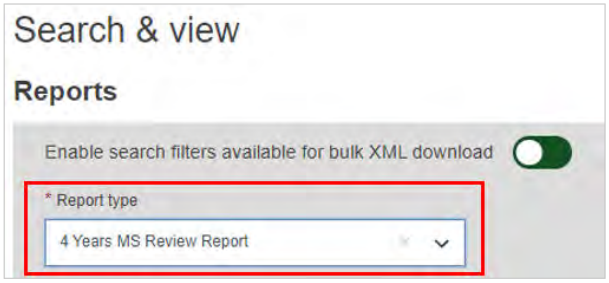


NOTE
All the historical versions of the FIR report after the selected date in the *Last update date from* field will be displayed.

10.4 Bulk download reports

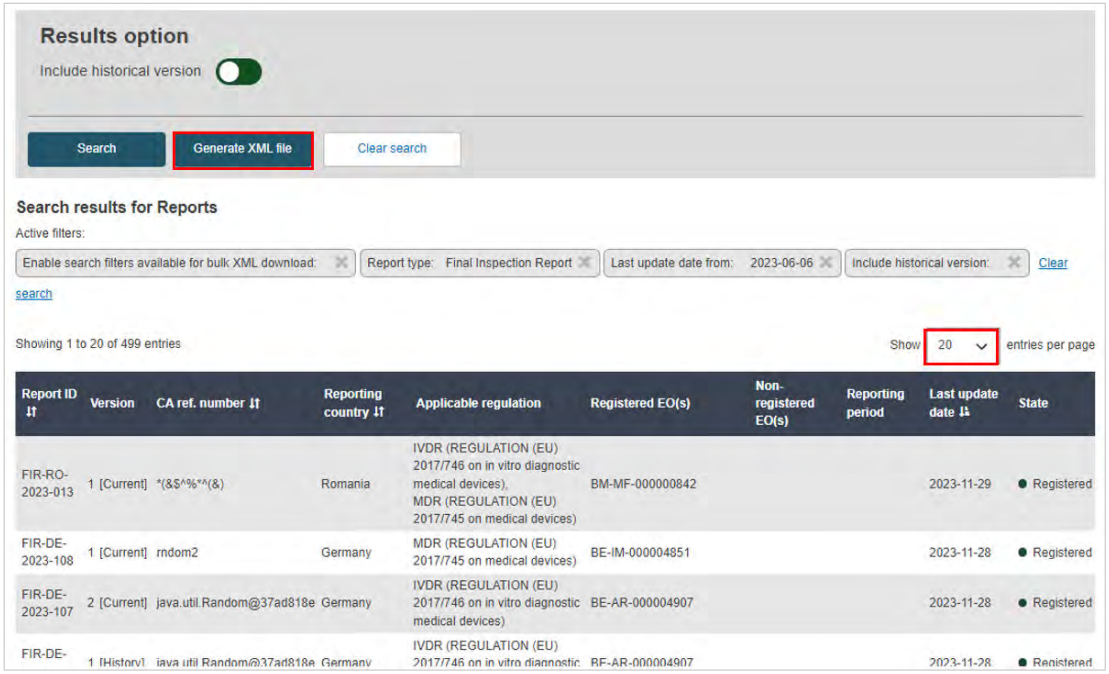
VIDEO: MSU reports bulk download

1. Slide the toggle (green = yes, grey = no) to enable search bulk XML download for reports:
   Select the *Report type*:



2. Complete steps 2-5 from Search & View reports [77], then click **Search**.

3. The table displays the report results based on the criteria you selected. By default, up to 20 entries are displayed – this can be increased to maximum 50.
   Click the now-active **Generate XML file** button, and follow the steps outlined in Bulk download procedures [73] to obtain the XML file:



NOTE

All the historical versions of the FIR report after the selected date in the *Last update date from* field will be displayed.

IMPORTANT

Only what is shown on the current page – as above – will be included in the generated file, and not all the results of your search. If the search yields multiple pages of results, you will need to download an XML file for each page to capture all the data.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