



# **EUDAMED user guide**

## **Market Surveillance**

Playground v 3.11.0  
2025

ground

## Table of Contents

1. Data structure .....	1
1.1. Procedure characteristics .....	1
1.2. User profiles .....	2
2. Getting started .....	3
3. Registration of procedure .....	4
3.1. Device-applicable legislation values .....	5
3.2. Unacceptable risk procedure .....	5
3.2.1. Trigger: Incident (Vigilance) .....	7
3.2.2. Trigger: FSCA .....	8
3.2.3. Trigger: FIR .....	8
3.2.4. Economic operator information .....	8
3.2.5. Device information .....	11
3.2.6. Corrective actions .....	19
3.3. Preventive Health Protection (PHP) and Other Non-Compliance (ONC) procedures .....	22
3.3.1. Measures .....	23
4. Manage a procedure .....	27
4.1. Using the filter .....	28
4.2. Create new version of procedure .....	31
4.2.1. New version and EOs .....	32
4.2.2. New version and devices .....	33
4.3. Create a new version of a corrective action .....	36
4.4. Discard a corrective action .....	36
5. Measure(s) linked to UNR procedures .....	39
5.1. Create a new measure .....	42
5.2. Create new version of a measure .....	43
5.3. Register a measure (and new version) for another CA's procedure .....	44
5.4. Discard a measure .....	46
6. Raising objections .....	48
6.1. Discard an objection .....	50
7. Additional information .....	52
7.1. Create a new version of additional information .....	53

7.2. Discard additional information .....	53
8. Notifications .....	55
9. MSU reports .....	57
9.1. Register your reports .....	58
9.1.1. Final Inspection Report .....	58
9.1.2. 4-Years MS Review Report .....	61
9.1.3. Register Annual Summary of Results report .....	63
9.2. Manage all reports .....	64
9.3. Create new version of a report .....	65
9.3.1. Records version history .....	66
9.4. Discard a report .....	67
9.4.1. Discard a 4-Years MS Review Report .....	68
9.4.2. Discard Annual Summary of Results Report .....	69
10. Search & View .....	71
10.1. Search & View procedures .....	71
10.2. Bulk download procedures .....	73
10.3. Search & View reports .....	77
10.4. Bulk download reports .....	81

Playground

# 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.

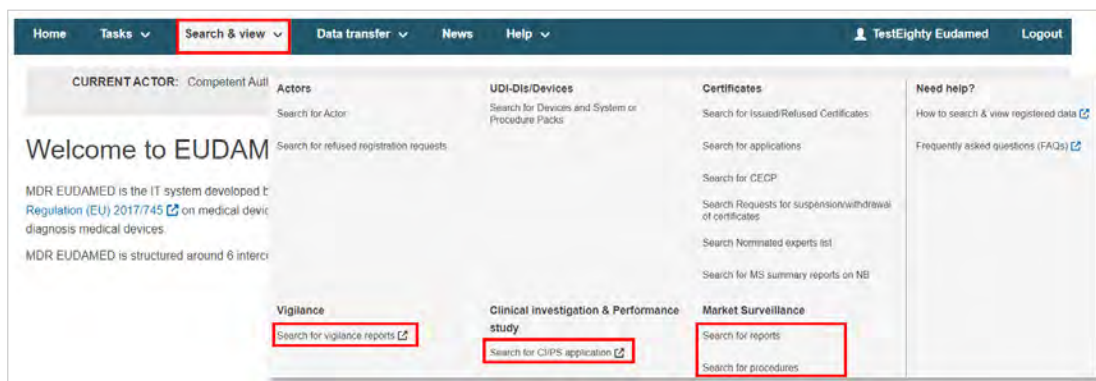
## 2 Getting started

### 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,<sup>1</sup> your dashboard will show links to the **Market Surveillance module**.



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

# 3 Registration of procedure

- From the dashboard, select *Register an MSU procedure*:

Welcome to EUDAMED

MDR EUDAMED is the IT system developed by the European Commission to implement Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices.

MDR EUDAMED is structured around 6 interconnected modules and a public site.

[See all the news](#)

### Tasks

By module, consult, verify and/or manage your own and related data (managed by your actor), depending on your profile.

#### My Actor data

- Manage your email notifications
- Machine to machine data delivery preferences

#### Actor management

- Validate actor registration requests 3

#### User management

- Assess user access requests
- Manage your users

#### CI/PS

- Search and manage application/notification

#### Certificate

- Nominated experts list

#### Market surveillance

- Register an MSU procedure**
- Manage an MSU procedure

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

CURRENT ACTOR: Competent Authority, BE-CA-001, Agence Fédérale des Médicaments et des Produits de Santé/Federale Agentschap voor Geneesmiddelen en Gezondheidsproducten [Belgium] Notifications

### MSU procedure registration

\* Choose a procedure type:

- IVDR Art 90 - Devices presenting an unacceptable risk to health and safety
- IVDR Art 92 - Other non-compliance
- IVDR Art 93 - Preventive health protection measures
- MDR Art 95 - Devices presenting an unacceptable risk to health and safety
- MDR Art 97 - Other non-compliance
- MDR Art 98 - Preventive health protection measures

This site is managed by Directorate General for Health and Food Safety (DG SANTE)

App version: 8.0.0.1 (2022-11-23) | Profile: (sanite.be) | Last built date: 2022-11-23 12:54

About EUDAMED | Privacy statement | User guide



## 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	<span>🟡 Draft</span>
UNR-BE-2022-0286	MDR Art 95 - Devices presenting an unacceptable risk to health and safety	BE-CA-001	Open	-	2022-11-23	<span>🟡 1st Draft</span>

## 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 <i>in vitro</i> 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 <i>in vitro</i> 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):

Procedure trigger file:

[Browse](#)

1 file uploaded successfully

04 Final Summary Assessment [PDF 394 KB]

[Remove this procedure trigger](#)

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

**Procedure trigger #2**

\* Procedure trigger:

Final Inspection Report (MSU)

Incident (Vigilance)

FSCA

Serious Adverse event (CIPS-Incident)

Proactive market surveillance

Complaint

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

Procedure status:

Open

Procedure comments:

Comments for this procedure

### 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**:

Procedure trigger information

Procedure trigger #1

\* Procedure trigger:

Final Inspection Report (MSU)

Incident (Vigilance)

FSCA

Serious Adverse event (CIPS-Incident)

Proactive market surveillance

Complaint

Cooperation among CA

Open

Procedure trigger information

Procedure trigger #1

\* Procedure trigger:

Incident (Vigilance)

Procedure trigger CA ref:

MIR-2023-08-000630

[Check registry](#)

[Add procedure trigger](#)

Previous trigger list

Remove

### 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:

**i** Fill in the mandatory field(s) and click on the 'Check registry' button to add an economic operator. For MDR Art 95 and IVDR Art 90 procedures, every device referenced in the given procedure must be linked to at least one economic operator with the role 'Manufacturer'. Manufacturers of registered devices will be retrieved by the system, but manufacturers of non-registered devices must be specified by the user, or it must be specified that the manufacturer of the given device is unknown.

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

**Select your economic operator**

Actor ID/SRN IT	Name IT	Role IT
BE-MF-000000322	GG-EU MF BE	Manufacturer
BE-MF-000000001	Belgium MF A V4_test	Manufacturer
BE-MF-000000341	GG MF BE 03	Manufacturer
BE-MF-000000241	Relu Test 3	Manufacturer
BE-MF-000000242	MF Relu Test 2	Manufacturer
BE-MF-000000123	ARMEN MANUFACTURER BELGIUM	Manufacturer
BE-MF-000000121	Dev Env - Manufacturer_Shrinya	Manufacturer
BE-MF-000000061	TESTing J	Manufacturer
BE-MF-000000024	Belgium MF B	Manufacturer

Close

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:

**Economic operator information**

**Economic operator #1**

Role: Manufacturer  
 Actor ID/SRN: BE-MF-000000121  
 Organisation name: Dev Env - Manufacturer\_Shiya  
 Address: Rue willems, 23 8989 Brussels

[Change economic operator](#)

**EO contact information**

\* First name: Manufacturer  
 \* Last name: Dev  
 \* Telephone: +32567654545  
 Telephone format example: +32 x xxx xx xx  
 \* Email: manu\_dev@eudamed.com

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.

**Economic operator information**

**Economic operator #1**

Non-registered Economic Operator must have a unique identifier for the given procedure. We recommend using a short combination of numbers and/or letters, for example A, 1 A1.

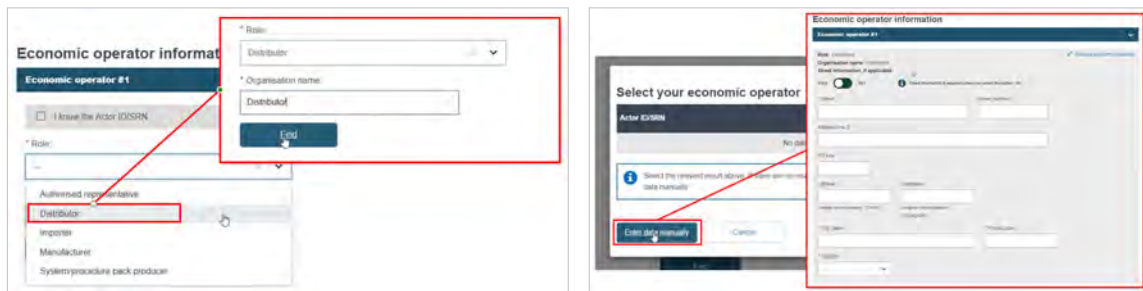
\* EO identifier for this procedure: MEDDEV

[Change economic operator](#)

Role: Manufacturer  
 Organisation name: Manufacturer of the device  
 Street information, if applicable  
 Yes ☒ No ☐ Street information is required unless you select the option - No

\* Street: Street Street number:  
 Address line 2:  
 PO box:  
 Latitude: Longitude:  
 Latitude format example: -15.4543 Longitude format example: 178.34354353  
 \* City name: Leuven \* Postal code: 3000

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**:

**EO contact information**

\* First name:  \* Last name:

\* Telephone:   
Telephone format example: +32 x xxx xx xx

\* Email:

**Other information**

Comment:

**+ Add another EO**

**Economic operator information**

Economic operator #1	▲
Economic operator #2	▲
Economic operator #3	▲

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.



**Manufacturer information**

Role: Manufacturer  
Actor ID/SRN: BE-MF-000000723  
Organisation name: Belgium Vigilance Release 2  
Address: 100199918 Brussels

\* Is this device linked to another economic operator?

☒ Yes ☐ No

**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:

**MSU procedure submission**

Once submitted, new measures for this procedure cannot be added and the data cannot be deleted. Are you sure you want to proceed with the submission?

One or more economic operators (EOs) mentioned in the 'Device identification' section are not defined in the 'Economic operator information' section. If you confirm the registration of the procedure, these EOs will automatically be added to the procedure.

### 3.2.5 Device information

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

1. **UDI-DI**

Playground

Device information

Device identification

Device #1

\* Device scope type:

UDI-DI/UDI-MEI ID

Name

UDI-DI/UDI-MEI ID

Basic UDI-DI/UDI-MEI ID

Category

UDI-PI

Check registry

\* Device scope type:

Basic UDI-DI/UDI-MEI ID

Device information

Device identification

Select your device

Device #1

\* Device scope type:

UDI-DI/UDI-MEI ID

Basic UDI-DI/UDI-MEI ID

NAME

Check registry

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

Device #3

Basic UDI-DI/EUDAMED DI: 1234551885

Basic UDI-DI issuing entity: GS1

UDI-DI/ EUDAMED ID: 1234551885

UDI-DI issuing entity: HiBCC

Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices)

Device Name: 1234551885

Device Model:

Risk class: Class III

Device trade name: -

Device category (EMDN nomenclature(s)):

Change device

Manufacturer information

Role: Manufacturer

Actor ID/SRN: NL-MF-000000041

Organisation name: Johnson & Johnson Medical

Address: NL-8000 Amersfoort

Is this device linked to another economic operator?

☐ Yes
 ☐ No

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

The left screenshot shows the 'Select your device' screen with a list of device categories and a 'Next' button. The right screenshot shows the 'Device #4' form with fields for 'Device name type', 'Basic UDI-DI', 'Basic UDI-DI issuing entity', 'UDI-DI/EUDAMED ID', 'UDI-DI/EUDAMED ID', 'Applicable legislation', 'Model name', 'Risk class', and 'Device trade name'.

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

The screenshot shows the 'Is the manufacturer known?' toggle. The toggle is currently set to 'No'. Below the toggle is a link 'Remove this category/group/device'.

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](#):

The screenshot shows the 'Is the manufacturer known?' toggle with the toggle set to 'Yes'. Below the toggle is a list of linked economic operators (EOs) with checkboxes. A red box highlights the 'Is the manufacturer known?' toggle and the list of EOs. A yellow box highlights a warning message: 'If you don't find your EO in the list, please go back to the 'Economic Operator Information' section to add it. You will then be able to select it from the list!'.

## 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.

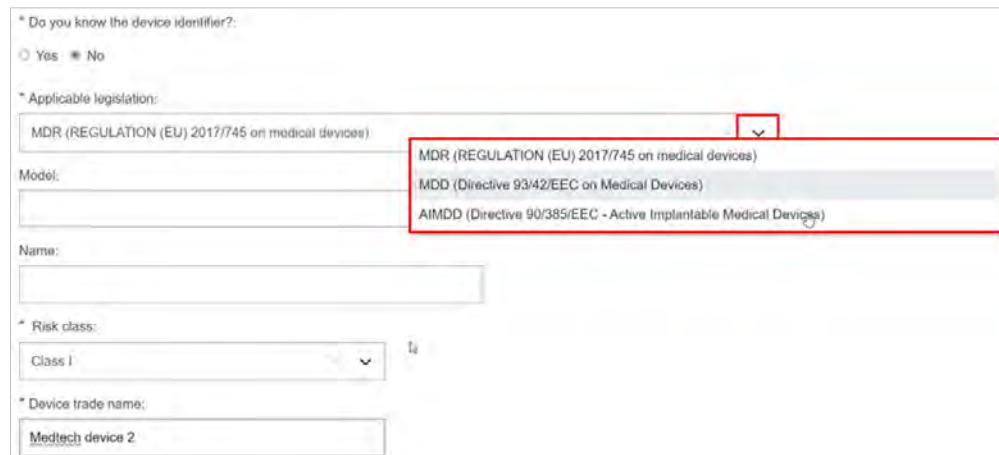
- a. Select the **Device scope type** as 'UDI-PI', select one *Production identifier* (PI) type and provide the *Production identifier* value for that type:

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

Playground

- 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):



\* Do you know the device identifier?:  
☐ Yes ☒ No

\* Applicable legislation:  
 MDR (REGULATION (EU) 2017/745 on medical devices)  
 MDD (Directive 93/42/EEC on Medical Devices)  
 AIMDD (Directive 90/385/EEC - Active Implantable Medical Devices)

Model:

Name:

\* Risk class:  
 Class I

\* Device trade name:  
 Medtech device 2

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



\* Select the linked economic operator(s):  
☐ BE-MF-000001861 - PANAGIOTIS BELGE TEST 001 - Manufacturer  
☐ BE-MF-000000723 - Belgium Vigilance Release 2 - Manufacturer

If you don't find your EO in the list, please go back to the 'Economic Operator Information' section to add it. You will then be able to select it from the list.

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



\* Do you know the device identifier?:  
☒ Yes ☐ No

\* Provide the UDI-DI/EUDAMED ID:

Check registry

[Remove this category/group/device](#)

- 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:

The left screenshot shows the 'Find the code' search results for 'A010'. The search results are listed under 'A0101 NEEDLES FOR INFUSION AND SAMPLING'. The selected item is 'A010110101 HYPODERMIC SYRINGE NEEDLES, WITH SAFETY SYSTEMS'. The right screenshot shows the 'Device #1' details page. The 'Device scope type' is 'A010110101 HYPODERMIC SYRINGE NEEDLES, WITH SAFETY SYSTEMS'. The 'Device category' is 'A010110101 HYPODERMIC SYRINGE NEEDLES, WITH SAFETY SYSTEMS'. The 'Device name' is 'A010110101 HYPODERMIC SYRINGE NEEDLES, WITH SAFETY SYSTEMS'. The 'Device model' is 'A010110101 HYPODERMIC SYRINGE NEEDLES, WITH SAFETY SYSTEMS'. The 'Device risk class' is 'A010110101 HYPODERMIC SYRINGE NEEDLES, WITH SAFETY SYSTEMS'.

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:

The left screenshot shows the 'Device information' page. The 'Device scope type' is 'Name'. The 'Device name' is '12345'. The 'Device model' is '12345'. The 'Device risk class' is '12345'. The right screenshot shows the 'Select your device' page. The 'Device scope type' is 'Name'. The 'Device name' is '12345'. The 'Device model' is '12345'. The 'Device risk class' is '12345'.

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

The screenshot shows the 'Device identification' page for 'Device #1'. The 'Basic UDI-DI/EUDAMED DI' is '12345678912022022195'. The 'Basic UDI-DI issuing entity' is 'GS1'. The 'Applicable regulation' is 'MDR (REGULATION (EU) 2017/745 on medical devices)'. The 'Device Name' is 'Model: 12345678912022022195'. The 'Risk class' is 'Class I'. The 'Manufacturer information' section shows 'Role: Manufacturer', 'Actor ID/SRN: BE-MF-000000723', 'Organisation name: Belgium Vigilance Release 2', and 'Address: 100199918 Brussels'. The question 'Is this device linked to another economic operator?' has 'Yes' selected.

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):



\* This procedure is related to Vigilance report(s)?

☒ Yes  
☐ No

\* Enter vigilance report reference:

Enter the exact EUDAMED Report ID  
General format: AAAA-YYYY-MM-XXXXXX  
AAAA: report acronym like MIR, FSCA,  
YYYY: creation year,  
MM: creation month,  
XXXXXX: 6 digits sequence number  
Examples:  
MIR-2022-12-123456  
FSCA-2022-12-123456

FSCA-2022-06-000400

Check registry

+ Add another report

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

Justification:

Justification for the COA

Justification file:

Browse

1 file uploaded successfully

eudamed-overview [PDF: 1 MB]

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

Affected countries:

Belgium

\* Add another country >

\* Date of entry into force:

YYYY-MM-DD

Corrective action performed date/status date:

YYYY-MM-DD

\* Corrective action status:

Requested

Bulgaria	Croatia
Cyprus	Czech Republic
Denmark	Estonia
Finland	France
Germany	Greece
Hungary	Iceland
Ireland	Italy
Latvia	Liechtenstein
Lithuania	Luxembourg
Malta	Netherlands
Norway	Poland
Portugal	Romania
Slovakia	Slovenia
Spain	Sweden

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

Affected countries:

Belgium Germany Luxembourg Portugal

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:

\* Date of entry into force:  
   
 YYYY-MM-DD

Corrective action performed date/status Date:  
   
 YYYY-MM-DD

\* Corrective action status:

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

**UNR-BE-2022-0059-COA-02**

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

**MSU procedure submission**

You will be unable to add new Corrective actions to the Procedure once you submit a Procedure for unacceptable risk. Are you sure you want to submit?

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

Home Tasks Search & view Transmission News Help Logout

CURRENT ACTOR: Competent Authority: BE-CA-001, Agence Fédérale des Médicaments et des Produits de Santé/Federale Agentschap voor Geneesmiddelen en Gezondheidsproducten (Belgium)

**MSU procedure registration**

Congratulations. You have successfully submitted your MSU Procedure and Corrective action(s)  
 Procedure ID: UNR-BE-2022-0059

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.



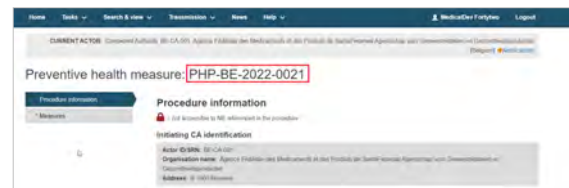
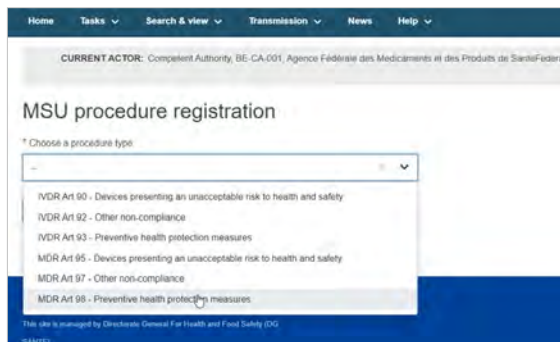
### IMPORTANT

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.

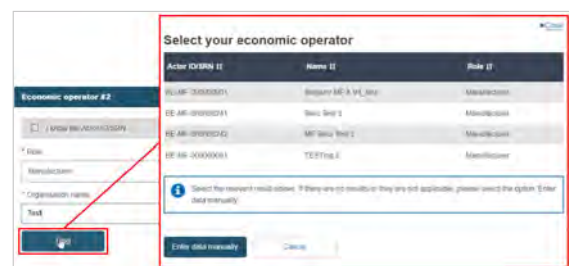
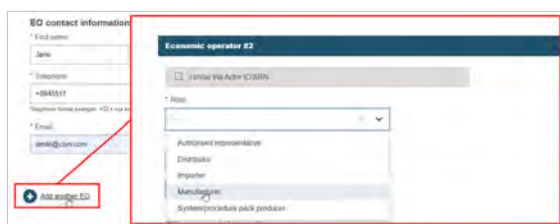


## 3.3 Preventive Health Protection (PHP) and Other Non-Compliance (ONC) procedures

- 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:



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



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

**Economic operator #2**

Role: Manufacturer  
 Actor ID/SRN: BE-MF-000000001  
 Organisation name: Belgium MF A V4\_test  
 Address: Avenue des arbre, 1040 Brussels

[Change economic operator](#)

**EO contact information**

\* First name: Jonh  
 \* Last name: Smith  
 \* Telephone: +4780225255  
 Telephone format example: +32 x xxx xx xx  
 \* Email: email@com.com

[Remove this economic operator](#)

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

**Device information**

**Device identification**

**Device #1**

\* Device scope type: [dropdown]

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

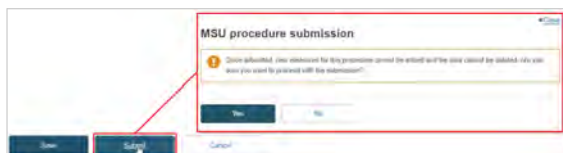
**NB identification**

NB referenced in this procedure will have access to this procedure and related items.

Select a Notified body: [dropdown]

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:

Preventive health measure: PHP-BE-2022-0021

\* Procedure information

Measures

**PHP-BE-2022-0021-MU-01**

Local CA measure reference:

Measure type:

+ Add another measure type

\* Justification for the adopted measure:

Justification file:

Browse

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

Preventive health measure: PHP-BE-2022-0021

\* Procedure information

Measures

**PHP-BE-2022-0021-MU-01**

Local CA measure reference:

CA-MU 1478

\* Measure type:

Other

Measure Type Other:

Description of another measure

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

Measure Type Other:

Description of another measure

+ Add another measure type

\* Measure type:

Forced recall

Restrict the making available

Prohibit the making available

Subject the making available of the device(s) to specific requirements

Withdraw the device(s) from the market

Other

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

\* Justification for the adopted measure:

This is why |

Justification file:

Browse

1 file uploaded successfully  
Final Draft minutes\_EUDAMED\_Plenary 20211209 [PDF 340 KB]

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

\* Date of entry into force:

Mar 2022 < Today >

Su	Mo	Tu	We	Th	Fr	Sa
27	28	01	02	03	04	05
06	07	08	09	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

Measure status date:

YYYY-MM-DD

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**:

\* Precondition of lifting:

- Resolve non-compliance in QMS
- Resolve non-compliance against Annex I MDR / IVDR
- Resolve clinical evaluation non-compliance (MDR)
- Resolve performance evaluation non-compliance (IVDR)
- Present EU certificate for device(s)
- Other

\* Precondition of lifting:

Other

Precondition of lifting 'Other':

Description of the other precondition

+ 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:

\* Measure status:

Taken

Measure status date:

YYYY-MM-DD

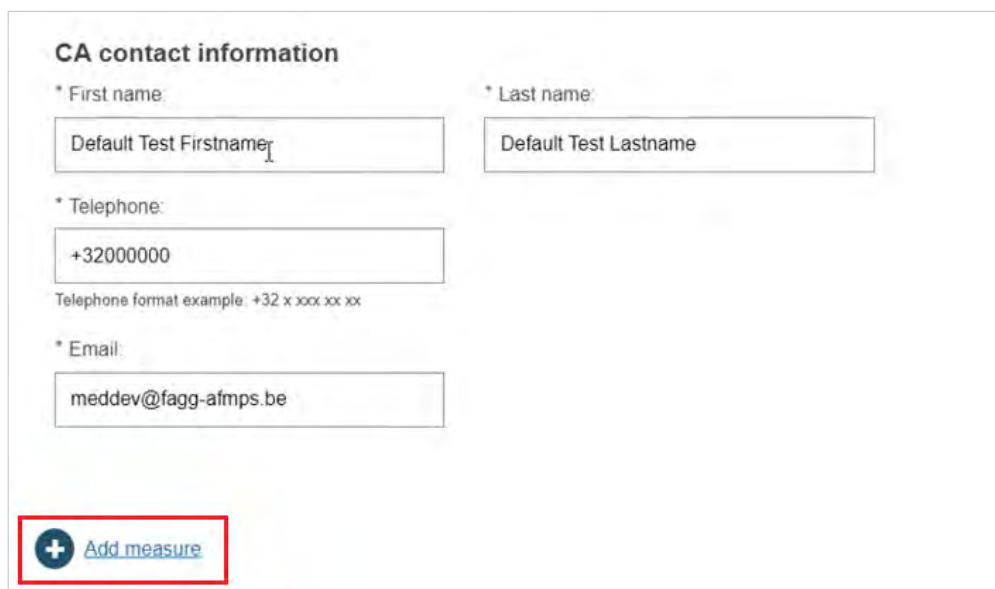
7. You can enter arguments provided by the EO in the *Arguments by EO* and *General remarks* fields:



Arguments by EO: 

General remarks:

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**:



**CA contact information**


\* First name:

\* Last name:

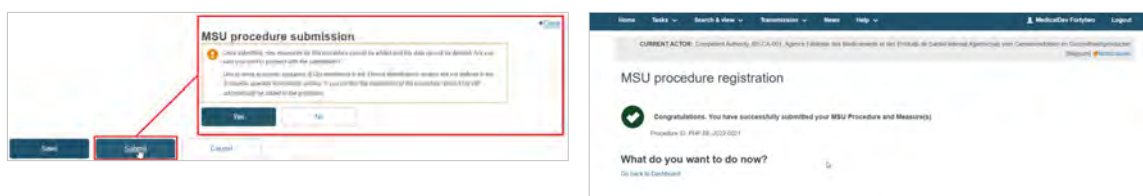
\* Telephone:

Telephone format example: +32 x xxx xxx xx

\* Email:

 **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:




**MSU procedure submission**

1. After submitting, the measure(s) to this procedure cannot be edited and this data cannot be deleted. It is only visible in your profile and the procedure(s).

2. Please make sure the measure(s) is/are relevant to the procedure(s) to which you are submitting them. If not, the procedure(s) will be rejected by the system.

3. If you are submitting multiple measures to this procedure, please use the 'Add measure' button to add more measures.

**MSU procedure registration**

 Congratulations. You have successfully submitted your MSU Procedure and Measure(s).

Procedure ID: PMP-2023-001

What do you want to do now?

[Go back to Dashboard](#)



### 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*:

Welcome to EUDAMED

MDR EUDAMED is the IT system developed by the European Commission to implement Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices.

MDR EUDAMED is structured around 6 interconnected modules and a public site.

[See all the news](#)

### Tasks

By module, consult, verify and/or manage your own and related data (managed by your actor), depending on your profile.

#### My Actor data

Manage your email notifications  
Machine to machine data delivery preferences

#### Actor management

Validate actor registration requests 3

#### User management

Assess user access requests  
Manage your users

#### CI/PS

Search and manage application/notification

#### Certificate

Nominated experts list

#### Market surveillance

Register an MSU procedure  
**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:

CURRENT ACTOR: Competent Authority: BE-CA-001, Agence Fédérale des Médicaments et des Produits de Santé/Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten [Belgium] Notifications

### Procedure Management

Filter ▼ Register new procedure

Active filters: State: Draft Clear search

Showing 1 to 15 of 15 entries Show 20 entries per page

Item ID II	Item type	CA code II	Status	Deadline for objections II	Last update date II	Item state
UNR-BE-2022-0057	IVDR Art 90 - Devices presenting an unacceptable risk to health and safety	BE-CA-001	Open	-	2022-03-22	Draft
UNR-BE-2022-0058	MDR Art 95 - Devices presenting an unacceptable risk to health and safety	BE-CA-001	Open	-	2022-03-22	1st Draft
UNR-BE-2022-0059-COA-01	Corrective action	BE-CA-001	Requested	-	2022-03-22	1st Draft
UNR-BE-2022-0059-COA-02	Corrective action	BE-CA-001	Requested	-	2022-03-22	1st Draft
UNR-BE-2022-0060	IVDR Art 90 - Devices presenting an unacceptable risk to health and safety	BE-CA-001	Open	-	2022-03-18	Draft

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



CURRENT ACTION: Unacceptable risk procedure: UNR-DE-2022-0047 Register new procedure

Procedure Information

Measure(s) by initiating CA & objections

Measure(s) information from other CAs

Procedure Management

Filter

Active filters

None

Clear

Clear search

Showing 1 to 8 of 8 entries

Show 20

entries per page

Item ID	Item type	CA role ID	Status	Deadline for objections	Last update date	Item state
UNR-DE-2022-0047-01-01-01	Objection	EU-EC-011	Proposed	---	2023-02-14	No [x]
UNR-DE-2022-0047-01-01-02	Objection	EU-EC-011	Proposed	---	2023-02-14	No [x]
UNR-DE-2022-0047-01-01-03	Objection	EU-EC-011	Proposed	---	2023-02-14	No [x]
UNR-DE-2022-0047-01-01-04	Objection	EU-EC-011	Proposed	---	2023-02-14	No [x]
UNR-DE-2022-0047-01-01-05	Objection	EU-EC-011	Proposed	---	2023-02-14	No [x]
UNR-DE-2022-0047-01-01-06	Objection	EU-EC-011	Proposed	---	2023-02-14	No [x]
UNR-DE-2022-0047-01-01-07	Objection	EU-EC-011	Proposed	---	2023-02-14	No [x]
UNR-DE-2022-0047-01-01-08	Objection	EU-EC-011	Proposed	---	2023-02-14	No [x]

Measure(s) (by initiating CA)

BE-CA-001 (Belgium) : UNR-DE-2022-0046-MU-01

Objection(s) on measure: UNR-DE-2022-0046-MU-01

IT-CA-001 (Italy) : UNR-DE-2022-0046-MU-01-01-01


BE-CA-001 (Belgium) : UNR-DE-2022-0046-MU-02

BE-CA-001 (Belgium) : UNR-DE-2022-0046-MU-02

BE-CA-001 (Belgium) : UNR-DE-2022-0046-MU-03

Objection(s) on measure: UNR-DE-2022-0046-MU-03

EU-EC-001 (Belgium) : UNR-DE-2022-0046-MU-03-01-01

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

Unacceptable risk procedure: UNR-DE-2022-0047

[Go back to Procedure list](#)

Procedure information | Measures by initiating CA & objections | Measures & information from other CAs

Procedure information

Version 1 [Current] | Last update date: 2023-11-04

Initiating CA Identification

Actor ID/SRN: DE-CA-011  
 Organisation name: Shitya Germany CA  
 Address: 77 Rue philip 7766 Berlin

Procedure type: MDR Art 95 - Devices presenting an unacceptable risk to health and safety

Submission date: 2023-02-14

Local CA procedure reference: GGY 02/14

Procedure status: Open

Procedure comments: Procedure comments here

Procedure trigger #1

Economic operator information

17706\_1

Device information

Device identification

Device #1



#### 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

- 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:



**Procedure Management**

Filter  Register new procedure

Active filters: State: Registered Competent Authority: BE - Agence Fédérale des Médicaments et des Produits de Santé/Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten Clear

Showing 1 to 20 of 23 entries Show 20 entries per page

Item ID IT	Item type	CA code IT	Status	Deadline for objections IT	Last update date IT	Item state
PHP-BE-2022-0021	MDR Art 98 - Preventive health protection measures	BE-CA-001	Open	-	2022-03-22	Registered
PHP-BE-2022-0021-MU-01	Measure by initiating CA	BE-CA-001	Taken	-	2022-03-22	Registered
UNR-BE-2022-0059	IVDR Art 90 - Devices presenting an unacceptable risk to health and safety	BE-CA-001	Open	-	2022-03-22	Registered
UNR-BE-2022-0059-COA-01	Corrective action	BE-CA-001	Requested	-	2022-03-22	Registered
UNR-BE-2022-0057	IVDR Art 90 - Devices presenting an unacceptable risk to health and safety	BE-CA-001	Open	-	2022-03-22	Registered
UNR-BE-2022-0057-COA-01	Corrective action	BE-CA-001	Requested	-	2022-03-22	Registered
UNR-IT-2022-0001	IVDR Art 90 - Devices presenting an unacceptable risk to health and safety	IT-CA-001	Open	-	2022-03-17	Registered

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

Unacceptable risk procedure: **UNR-IT-2022-0001**

[Go back to Procedure list](#)

**Procedure information**

Version 1 [Download] | Last update date: 2022-03-17

**Initiating CA identification**

Actor ID/URN: IT-CA-001  
 Organisation name: IT - Ministry of Health (Directorate General of Medicines and Medical Devices)  
 Address: Via D. Rubeis 8 00144 Roma

Procedure type: MDR Art 98 - Devices presenting an unacceptable risk to health and safety  
 Submission date: 2022-02-14  
 Local CA procedure reference: G2Y G2Y13  
 Procedure status: Open  
 Procedure comments: Procedure comments here

**Procedure trigger #1**

Economic operator information  
**BE-AR-000000021**

Procedure trigger: Final Request Report (RSU)  
 Designation assessment documents: dummy\_1.pdf [13 KB]

**Device information**

Device identification

Actor ID/URN: BE-AR-000000021  
 Organisation name: Belgium AR A  
 Address: Brussels

**EO contact information**

First name: Belgium AR A  
 Last name: Belgium AR A  
 Telephone: +32345  
 Email: CA-contact@belgium-ar.a.com

Corrective action information is also viewable:

**Corrective actions**

**UNR-IT-2022-0001-COA-01**

Submission date: 2022-03-17

Local CA Corrective action reference: ref

Corrective action 1: [Type] Action to bring the device into compliance

This procedure is related to Vigilance report(s)? Yes

Justification: test

Designation assessment documents: dummy\_1.pdf [13 KB]

Affected countries: Italy

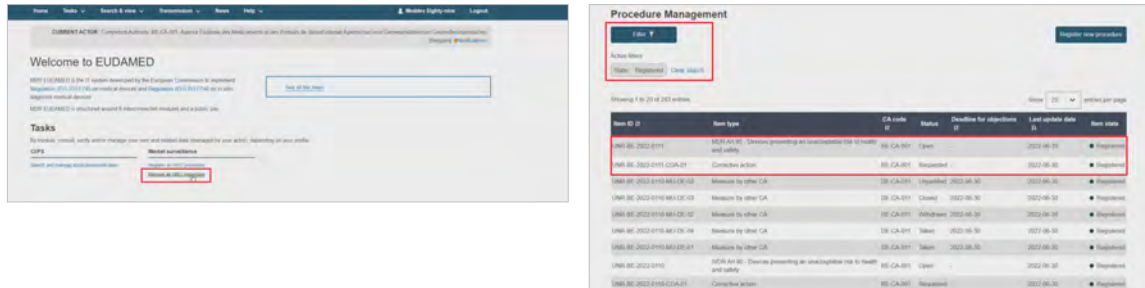
Date of entry into force: 2022-03-01

Corrective action status: 2022-03-31

Corrective action status: Requested

## 4.2 Create new version of procedure

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



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

Unacceptable risk procedure: UNR-BE-2022-0284

[Go back to Procedure list](#)

Procedure information | Measures by initiating CA & objections | Measures & information from other CAs

Procedure information

Corrective actions

**Version 6 (Draft)** | [on version history](#) | Last update date: 2022-11-18

[Edit draft](#) | [Delete draft](#)

**Procedure information**

Initiating CA identification

Actor ID/ISRN: BE-CA-001  
 Organisation name: Agence Fédérale des Médicaments et des Produits de Santé/Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten  
 Address: EUROSTATION building block 2/place Victor Horta 40/40 B-1060 Brussels

Local CA procedure reference: java.util.Random@1616512

Procedure status: Open

Procedure comments: Procedure comments

- Click **Submit new version**:

**NB identification**

[NB referenced in this procedure will have access to this procedure and related items](#)

Select a Notified body:

0297 - DQS Medizinprodukte GmbH

[Add another NB](#)

[Save](#) | [Submit new version](#) | [Cancel](#)

- 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:

Home Tasks Search & view Transmission News Help Meddev Eighty-nine Logout

CURRENT ACTOR: Competent Authority: BE-CA-001, Agence Fédérale des Médicaments et des Produits de Santé-Fédéral Agentschap voor Geneesmiddelen en Gezondheidsproducten (Belgium) Notifications

✓ Procedure information successfully submitted

Unacceptable risk procedure: UNR-BE-2022-0111

Go back to Procedure list

Procedure information Measures by initiating CA & objections Measures & information from other CAs

Procedure information

Version 2 Current See version history Last update date: 2022-06-30 Create new version

Initiating CA identification

Actor ID/SRN: BE-CA-001  
 Organisation name: Agence Fédérale des Médicaments et des Produits de Santé-Fédéral Agentschap voor Geneesmiddelen en Gezondheidsproducten  
 Address: EUROSTATION building block 2 place Victor Horta 40/ 40 B-1060 Brussels

Submission date: 2022-06-30

Local CA procedure reference: test demo

## 4.2.1 New version and EOs

- 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:

Economic operator information

Economic operator #1

Role: Manufacturer  
 Actor ID/SRN: BE-MF-000001183  
 Organisation name: Business Unit MF BE 2  
 Address: Schuman 2323 Brussels

EO contact information

\* First name: MFBE \* Last name: Eudamed

\* Telephone: 86756545645  
 Telephone format example: +32 x xxx xx xx

\* Email: mfbe2@eudamed.com

Other information

Comment:

+ Add another EO

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

**Economic operator #3**

Fill in the mandatory field(s) and click on the "Check registry" button to add an economic operator. For MDR Art 95 and IVDR Art 90 procedures, every device referenced in the given procedure must be linked to at least one economic operator with the role 'Manufacturer'. Manufacturers of registered devices will be retrieved by the system, but manufacturers of non-registered devices must be specified by the user, or it must be specified that the manufacturer of the given device is unknown.

☐ I know the Actor ID/SRN

\* Role:  
Manufacturer

\* Organisation name:  
Manuf demo Q4.4

**Check registry**

**Select your economic operator**

Actor ID/SRN	Organisation name	Role
No data available		

Select the relevant result above. If there are no results or they are not applicable, please select the option 'Enter data manually'

**Enter data manually** **Cancel**

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:

**Economic operator #3**

\* EO identifier for this procedure

EO ID: [Field]

Role: Manufacturer

Organisation name: Manuf demo Q4.4

Yes ☐ No ☒

Latitude: [Field] Longitude: [Field]

City: [Field] Country: [Field]

**EO contact information**

\* First name: [Field] \* Last name: [Field]

\* Telephone: 3200000000

Telephone format example: +32 x xxx xx xx

**Email:** [Field]

**Other information**

Comment: [Field]

**Remove this economic operator**

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*:



**Device information**

**Device identification**

**Device #1**

Device scope type: Production identifier

\* Production identifier type: Serial number

\* Production identifier value: 546546546

Do you know the device identifier?: Yes

Basic UDI-DI/EUDAMED DI: 1234551885  
 Basic UDI-DI/EUDAMED DI issuing entity: GS1  
 UDI-DI/EUDAMED ID: 1234551885  
 UDI-DI/EUDAMED ID issuing entity: HIBCC  
 Applicable legislation: MDR (REGULATION (EU) 2017/745 on medical devices)  
 Device Name: -  
 Device Model: 1234551885  
 Risk class: Class III  
 Device trade name: -  
 Device category (EMDN nomenclature(s)):

[Change device](#)

- 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.
- 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:

**Device #6**

Device scope type: Production identifier

Device trade name: 123455188

Production identifier value: s/n 2323232

Is Device Identifier known?: Yes

Basic UDI-DI/EUDAMED DI: -

Basic UDI-DI/EUDAMED DI issuing entity: -

UDI-DI/EUDAMED ID: 1234551885

UDI-DI/EUDAMED ID issuing entity: GS1

Applicable legislation: MDR (REGULATION (EU) 2017/745 on medical devices)

Model: -

Name: -

Risk class: Class III

Device category (EMDN nomenclature(s)):

Linked economic operator(s): NL-MF-000000041 - Johnson & Johnson Medical - Manufacturer

**Device #6**

Device scope type: UDI-PI

\* Production identifier type: Serial number

\* Production identifier value: s/n 2323232

Do you know the device identifier?: Yes

Basic UDI-DI/EUDAMED DI: -

Basic UDI-DI/EUDAMED DI issuing entity: -

UDI-DI/EUDAMED ID: 1234551885

UDI-DI/EUDAMED ID issuing entity: GS1

**Select your device**

1234551885 (GS1, Class III)

System matching is ongoing for all new records in the system. If a matching record is found, please report it and select the correct (registered) device from the previous window. If no matching record is found, please click the 'Add new device' button.

[Close](#)

Please check if UDI-DI/EUDAMED ID you provided in the previous window is correct.

UDI-DI/EUDAMED ID: 1234551885

UDI-DI/EUDAMED ID issuing entity: GS1

[Check registry](#)

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

**Device #6**

Device scope type: Production identifier

\* Production identifier type: Serial number

\* Production identifier value: s/n 2323232

Do you know the device identifier?: Yes

Basic UDI-DI/EUDAMED DI: 1234551885  
 Basic UDI-DI/EUDAMED DI issuing entity: GS1  
 UDI-DI/EUDAMED ID: 1234551885  
 UDI-DI/EUDAMED ID issuing entity: HIBCC  
 Applicable legislation: MDR (REGULATION (EU) 2017/745 on medical devices)  
 Device Name: -  
 Device Model: 1234551885  
 Risk class: Class III  
 Device trade name: -  
 Device category (EMDN nomenclature(s)):

[Change device](#)

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.

\* Select the linked economic operator(s):

- ☒ BE-AR-000002367 - AutomationThreejava.util.Random@637ed44a - Authorised Representative
- ☒ BE-MF-000000723 - Belgium Vigilance Release 2 - Manufacturer

If you don't find your EO in the list, please go back to the 'Economic Operator Information' section to add it. You will then be able to select it from the list.

## 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.

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

Corrective actions

BE-CA-001 [Belgium] : UNR-BE-2022-0111-COA-01

Version 2 [Current] | Last update date: 2022-06-30

Submission date: 2022-06-30

Local CA corrective action reference: test demo

Corrective action 1: [Type] Action to bring the device into compliance

Corrective action 2: [Type] Other [Comments] test demo

This procedure is related to Vigilance report(s): No

Justification: -

Designation assessment documents: -

Affected countries: Belgium, Denmark, Iceland

Date of entry into force: 2022-08-01

Buttons: Discard, **Create new version**

CURRENT ACTION: Corrective Action, BE-CA-001, Agency Release and Release of the Product for Clinical Investigation and Commercialisation of the Product for Clinical Investigation

BE-CA-001 [Belgium] : UNR-BE-2022-0111-COA-01

\* Local CA corrective action reference: test demo

\* Corrective action type: [Type] Action to bring the device into compliance

\* Corrective action type: [Type] Other [Comments] test demo

Corrective action comments: test demo

Buttons: Discard, **Create new version**

- 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:

Buttons: Save, **Submit new version**, Cancel

## 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**:

**Procedure Management**

Filter ▼

Register new procedure

Item type  
Corrective action ▼

Item ID  
Item status  
Competent Authority

Last update date  
From  
To

Procedure data  
Procedure trigger  
EO Actor ID/SRN  
EO Name

\* State  
Draft  
Registered  
Discarded

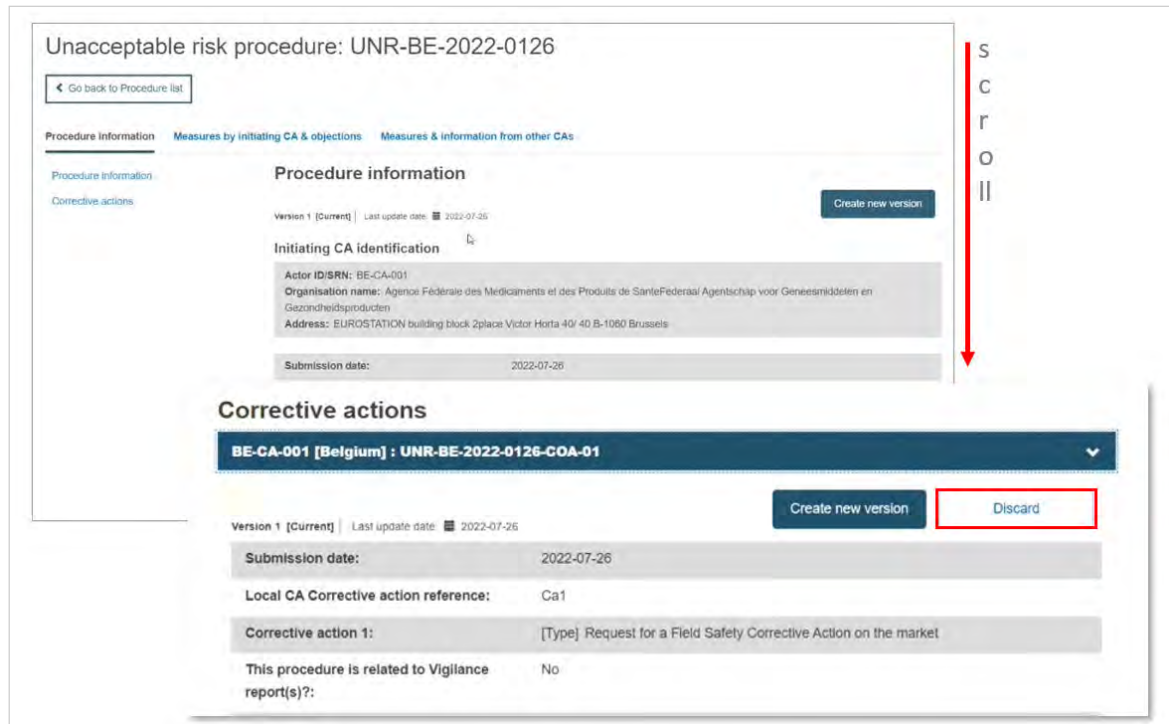
2. Select the record you want to discard:

UNR-BE-2022-0116-COA-01	Corrective action	BE-CA-012	Requested	-	2022-07-27	● Registered
UNR-BE-2022-0094-COA-01	Corrective action	BE-CA-012	Requested	-	2022-07-27	● Registered
UNR-BE-2022-0126-COA-01	Corrective action	BE-CA-001	Requested	-	2022-07-26	● Registered
UNR-DE-2022-0033-COA-01	Corrective action	DE-CA-011	Performed	-	2022-07-26	● Registered
UNR-BE-2022-0056-COA-01	Corrective action	BE-CA-001	Not performed in due time	-	2022-07-25	● Registered
UNR-BE-2022-0121-COA-01	Corrective action	BE-CA-001	Performed	-	2022-07-22	● Registered

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

Playground





Unacceptable risk procedure: UNR-BE-2022-0126

[Go back to Procedure list](#)

Procedure information | Measures by initiating CA & objections | Measures & information from other CAs

Procedure information

Version 1 [Current] | Last update date: 2022-07-26

Create new version

Initiating CA identification

Actor ID/IRN: BE-CA-001  
 Organisation name: Agence Fédérale des Médicaments et des Produits de Santé/Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten  
 Address: EUROSTATION building block 2 place Victor Horta 40/40 B-1060 Brussels  
 Submission date: 2022-07-26

Corrective actions

BE-CA-001 [Belgium] : UNR-BE-2022-0126-COA-01

Version 1 [Current] | Last update date: 2022-07-26

Create new version

Discard

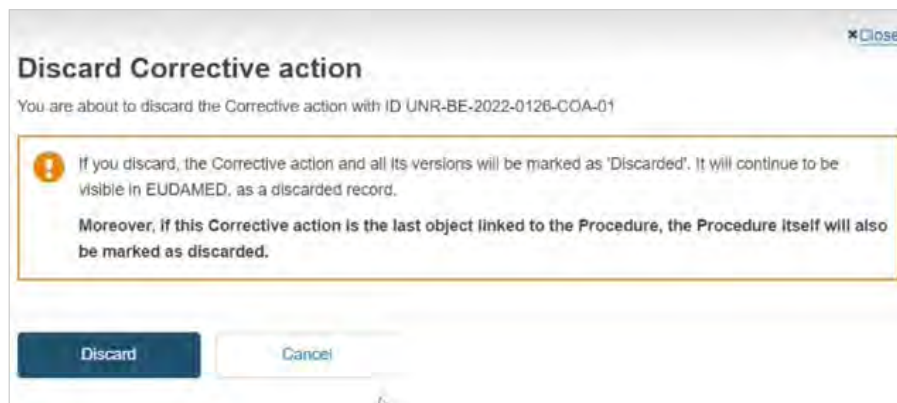
Submission date: 2022-07-26

Local CA Corrective action reference: Ca1

Corrective action 1: [Type] Request for a Field Safety Corrective Action on the market

This procedure is related to Vigilance report(s)?: No

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



Discard Corrective action

You are about to discard the Corrective action with ID UNR-BE-2022-0126-COA-01

If you discard, the Corrective action and all its versions will be marked as 'Discarded'. It will continue to be visible in EUDAMED, as a discarded record.

Moreover, if this Corrective action is the last object linked to the Procedure, the Procedure itself will also be marked as discarded.

Discard

Cancel

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**:

The screenshot shows the EUDAMED interface for an unacceptable risk procedure (UNR-BE-2022-0111). The 'Measures by initiating CA & objections' tab is selected and highlighted with a red box. The interface displays the following information:

- Procedure information:** Version 2 [Current], Last update date: 2022-06-30. A 'Create new version' button is available.
- Initiating CA identification:**
  - Actor ID/SRN: BE-CA-001
  - Organisation name: Agence Fédérale des Médicaments et des Produits de Santé/Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten
  - Address: EUROSTATION building block 2 place Victor Horta 40/ 40 B-1060 Brussels
- Submission date:** 2022-06-30
- Local CA procedure reference:** test demo

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:

The two screenshots show the 'Add new measure' screen in the EUDAMED interface. The left screenshot shows the 'Measures by initiating CA' tab, and the right screenshot shows the 'Add new measure' form. The form includes the following fields:

- Local CA measure reference:** BE-CA-001 [Belgium] : UNR-BE-2022-0111-MU-01
- Measure type:** A dropdown menu with 'Add new measure' selected.
- Justification for the adopted measure:** A text area for providing details.
- Confirmation for:** A button to confirm the measure.

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

Home Tasks Search & view Transmission News Help

Meddev Eighty-nine Logout

CURRENT ACTOR: Competent Authority, BE-CA-001, Agence Fédérale des Médicaments et des Produits de Santé/Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten [Belgium] Notifications

BE-CA-001 [Belgium] : UNR-BE-2022-0111-MU-01

Local CA measure reference:  
test demo

\* Measure type:  
Other

\* Measure Type Other:  
test demo

Forced recall  
Restrict the making available  
Prohibit the making available  
Subject the making available of the device(s) to specific requirements  
Withdraw the device(s) from the market  
Other

+ Add another measure

- Provide a justification and upload one or multiple supporting files:

\* Justification for the adopted measure:  
justification

Justification file:  
Browse

1 file uploaded successfully  
PSR\_Timeline [PDF 15.83 KB]

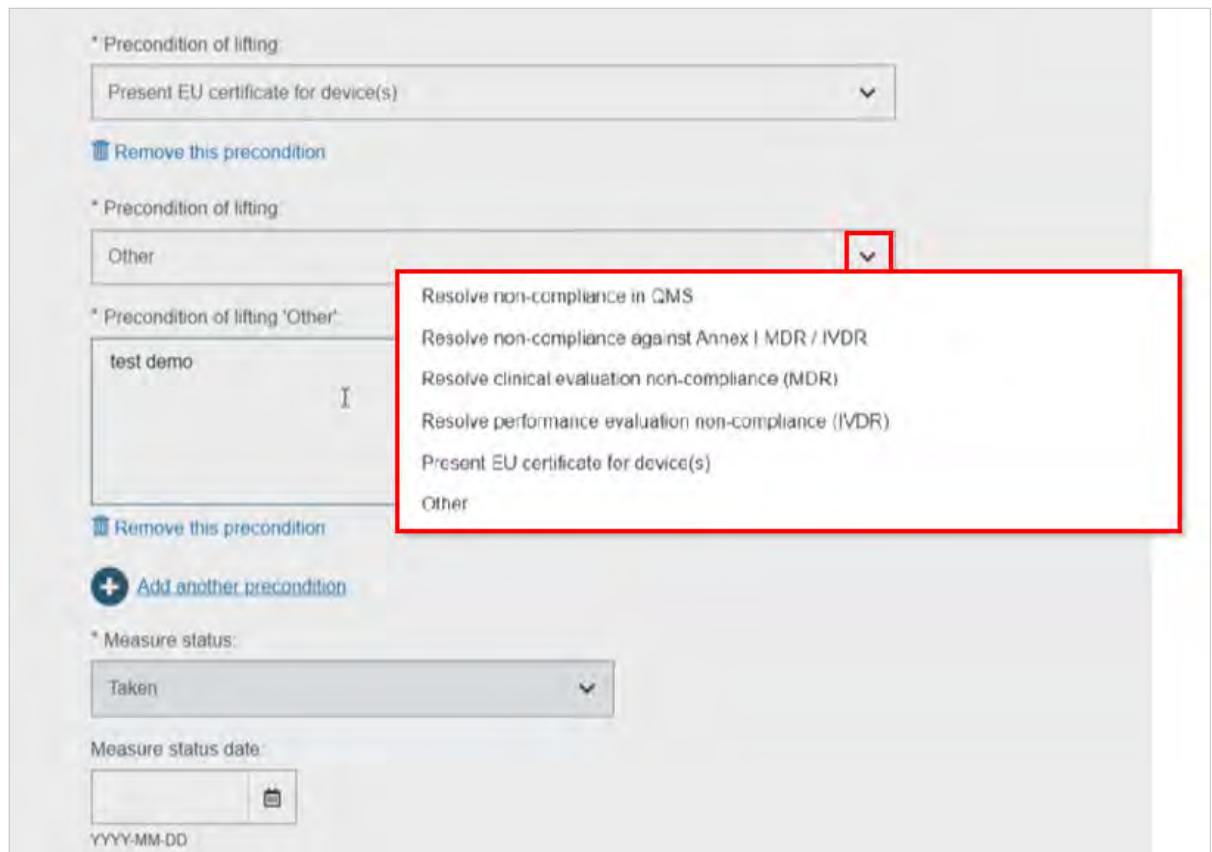
- Provide the *Date of entry into force* for the measure:

\* Date of entry into force:  
Jul 2022 Today

Su	Mo	Tu	We	Th	Fr	Sa
26	27	28	29	30	01	02
03	04	05	06	07	08	09
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31	01	02	03	04	05	06

Measure status date:

- 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:



\* Precondition of lifting:

Present EU certificate for device(s)

Remove this precondition

\* Precondition of lifting:

Other

\* Precondition of lifting 'Other':

test demo

Remove this precondition

+ Add another precondition

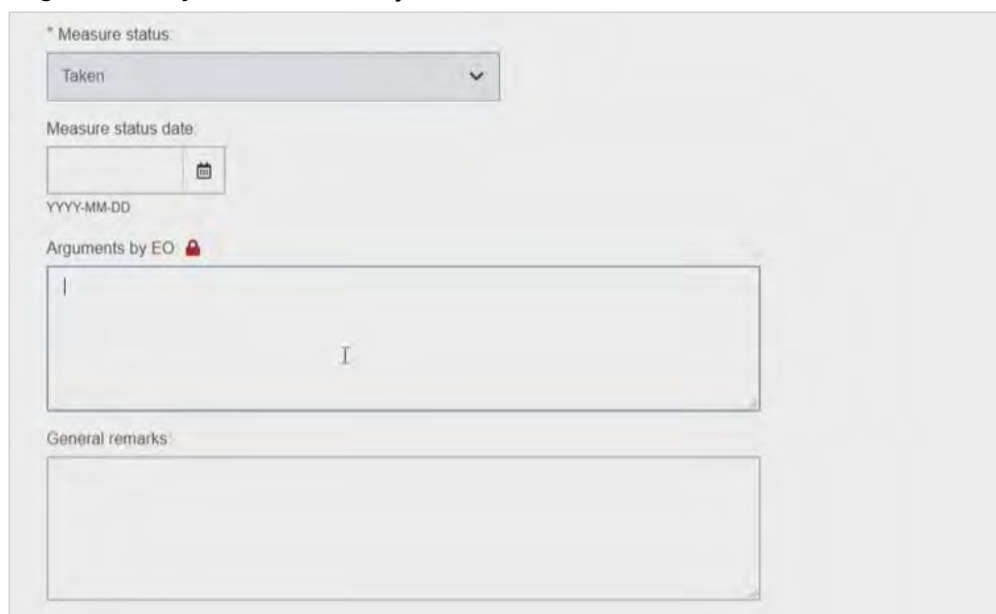
\* Measure status:

Taken

Measure status date:

YYYY-MM-DD

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



\* Measure status:

Taken

Measure status date:

YYYY-MM-DD

Arguments by EO

General remarks:

8. Enter the CA contact information:



**CA contact information**

\* First name:

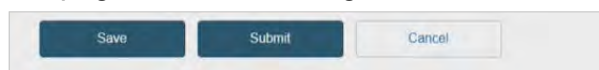
\* Last name:

\* Telephone:

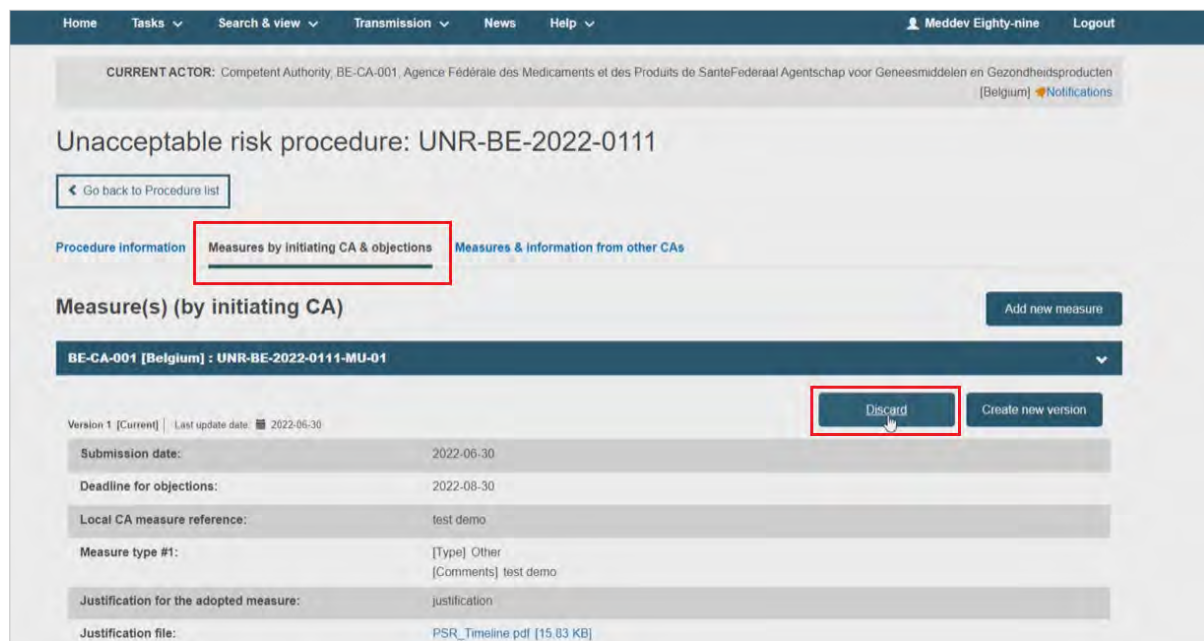
Telephone format example: +32 x xxx xx xx

\* Email:

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:



Home Tasks Search & view Transmission News Help Meddev Eighty-nine Logout

CURRENT ACTOR: Competent Authority, BE-CA-001, Agence Fédérale des Médicaments et des Produits de Santé/Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten [Belgium] Notifications

Unacceptable risk procedure: UNR-BE-2022-0111

[Go back to Procedure list](#)

Procedure information **Measures by initiating CA & objections** Measures & information from other CAs

Measure(s) (by initiating CA)

BE-CA-001 [Belgium] : UNR-BE-2022-0111-MU-01

Version 1 [Current] | Last update date: 2022-06-30

Submission date:	2022-06-30
Deadline for objections:	2022-08-30
Local CA measure reference:	test demo
Measure type #1:	[Type] Other [Comments] test demo
Justification for the adopted measure:	justification
Justification file:	PSR_Timeline.pdf [15.03 KB]

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:



Home Tasks Search & view Transmission News Help Meddev Eighty-nine Logout

CURRENT ACTOR: Competent Authority, BE-CA-001, Agence Fédérale des Médicaments et des Produits de Santé/Federal Agentschap voor Geneesmiddelen en Gezondheidsproducten [Belgium] Notifications

Measure successfully submitted

Unacceptable risk procedure: UNR-BE-2022-0111

Go back to Procedure list

Procedure information Measures by initiating CA & objections Measures & information from other CAs

Measure(s) (by initiating CA)

BE-CA-001 [Belgium] : UNR-BE-2022-0111

Version 2 [Current] See version history Last update date: 2022-06-30

Submission date: 2022-06-30

Deadline for objections: 2022-08-30

Local CA measure reference: test demo

Measure type #1: [Type] Other [Comments] test demo

Justification for the adopted measure: justification

Justification file: PSR\_Timeline.pdf [15.83 KB]

Date of entry into force: 2022-07-11

Precondition #1: [Type] Present EU certificate for device(s)

Precondition #2: [Type] Other [Comments] test demo

## 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.

- 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:

Home Tasks Search & view Transmission News Help CA Germany Test Logout

CURRENT ACTOR: Competent Authority, DE-CA-011, Shryta Germany CA [Germany] Notifications

Unacceptable risk procedure: UNR-BE-2022-0111

Go back to Procedure list

Procedure information Measures by initiating CA & objections Measures & information from other CAs

Procedure information

Version 1 [Current] See version history Last update date: 2022-06-30

Initiating CA Identification

Actor (IDNR): BE-CA-001

Organisation name: Agence Fédérale des Médicaments et des Produits de Santé/Federal Agentschap voor Geneesmiddelen en Gezondheidsproducten

Address: EUROTOPIA Building, Stock Street, Victor Hugo 42-43 & 44-45 Brussels

Submission date: 2022-06-30

Local CA procedure reference: test demo

Procedure status: Open (with objection)

Procedure comments:

Measures by initiating CA & objections

Measure(s) (by initiating CA)

BE-CA-001 [Belgium] : UNR-BE-2022-0111-001-01

Objections(s)

DE-CA-011 [Germany] : UNR-BE-2022-0111-001-01-001-01

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

Home Tasks Search & view Transmission News Help CA Germany Test Logout

CURRENT ACTOR: Competent Authority, DE-CA-011, Shryta Germany CA [Germany] Notifications

Unacceptable risk procedure: UNR-BE-2022-0111

Go back to Procedure list


Procedure information Measures by initiating CA & objections Measures & information from other CAs

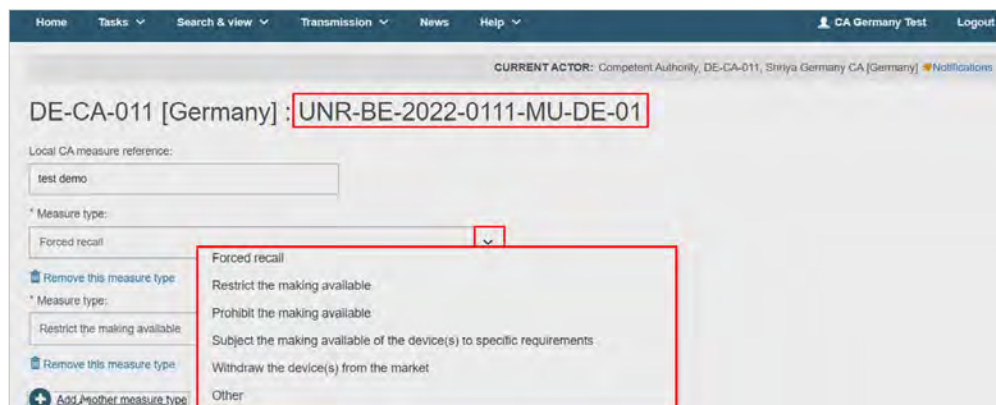
Measure(s) (by other CAs)

Measure(s) (by other CAs)

No data available

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:



Home Tasks Search & view Transmission News Help CA Germany Test Logout

CURRENT ACTOR: Competent Authority, DE-CA-011, Shriya Germany CA [Germany] Notifications

DE-CA-011 [Germany] : UNR-BE-2022-0111-MU-DE-01

Local CA measure reference:  
test demo

\* Measure type:  
Forced recall

Remove this measure type

\* Measure type:  
Restrict the making available

Remove this measure type

Add another measure type

Forced recall

Restrict the making available

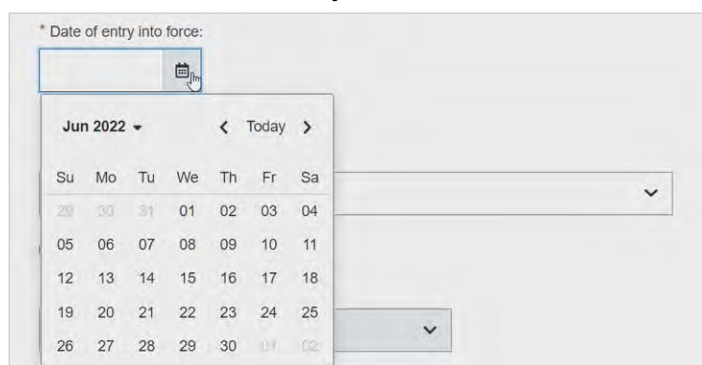
Prohibit the making available

Subject the making available of the device(s) to specific requirements

Withdraw the device(s) from the market

Other

4. Provide a justification and upload one or multiple supporting files.
5. Provide the *Date of entry into force*:

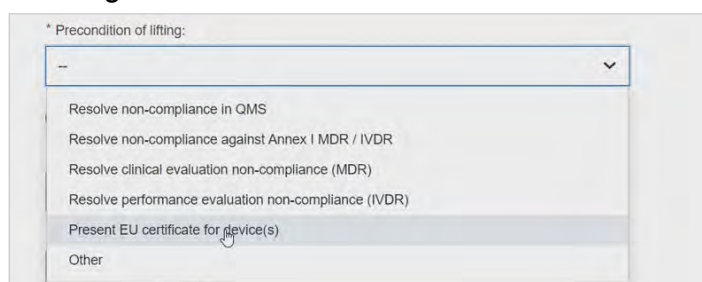


\* Date of entry into force:

Jun 2022

Su	Mo	Tu	We	Th	Fr	Sa
28	29	30	01	02	03	04
05	06	07	08	09	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	01	02

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



\* Precondition of lifting:

Resolve non-compliance in QMS

Resolve non-compliance against Annex I MDR / IVDR

Resolve clinical evaluation non-compliance (MDR)

Resolve performance evaluation non-compliance (IVDR)

Present EU certificate for device(s)

Other

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

\* Measure status:

Taken

Measure status date:

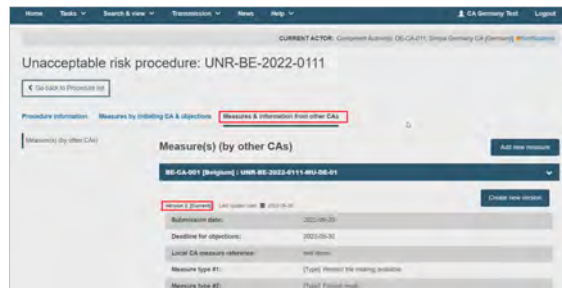
YYYY-MM-DD

Arguments by EO:

General remarks:

- 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

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

Unacceptable risk procedure: UNR-BE-2022-0103

[Go back to Procedure list](#)

Procedure Information | Measures by initiating CA & objections | Measures & information from other CAs

Measure(s) (by initiating CA) Add new measure

BE-CA-001 [Belgium] : UNR-BE-2022-0103-MU-02

Version 1 [Current] | Last update date: 2022-06-29


Discard Create new version

Submission date:	2022-06-29
Deadline for objections:	2022-08-29
Local CA measure reference:	CA2
Measure type #1:	[Type] Forced recall
Measure type #2:	[Type] Subject the making available of the device(s) to specific requirements

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:

**Discard Measure by initiating CA** Close

You are about to discard the Measure by initiating CA with ID UNR-BE-2022-0103-MU-02

 If you discard, the Measure and all its versions will be marked as "Discarded". It will continue to be visible in EUDAMED, as a discarded record.

Moreover, if this Measure is the last object linked to the Procedure, the Procedure itself will also be marked as discarded.

Discard Cancel

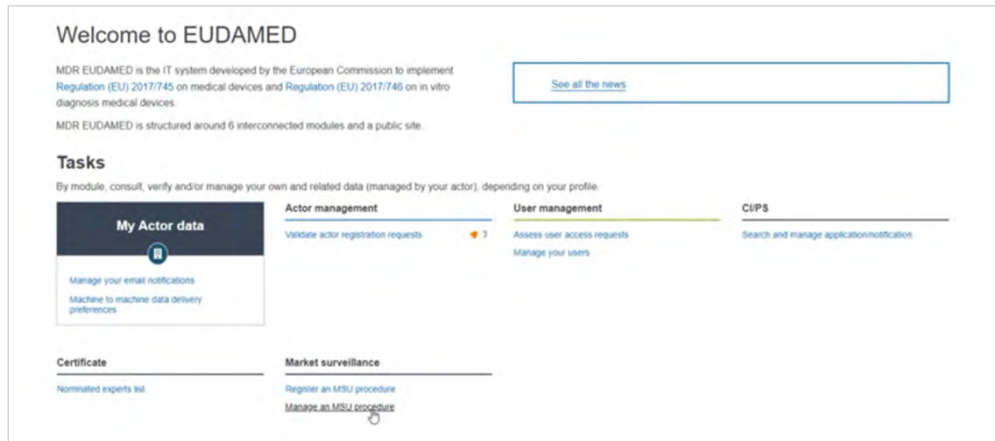
**NOTE**

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

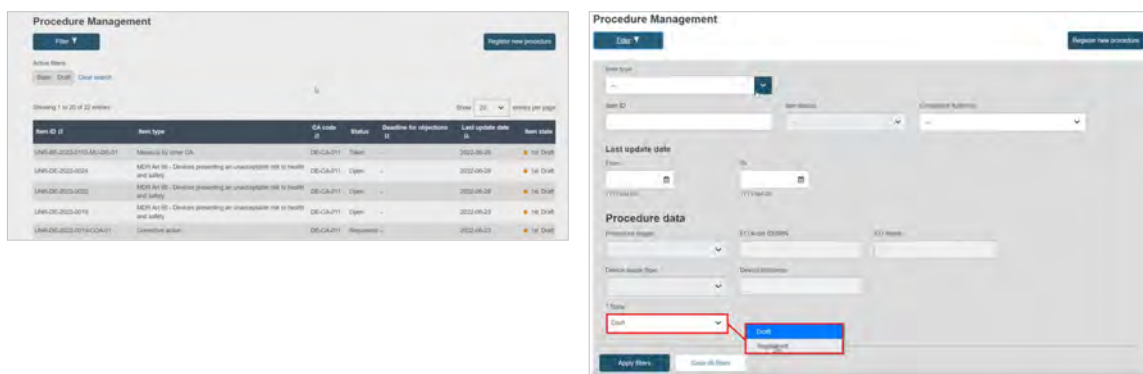
Playground

# 6 Raising objections

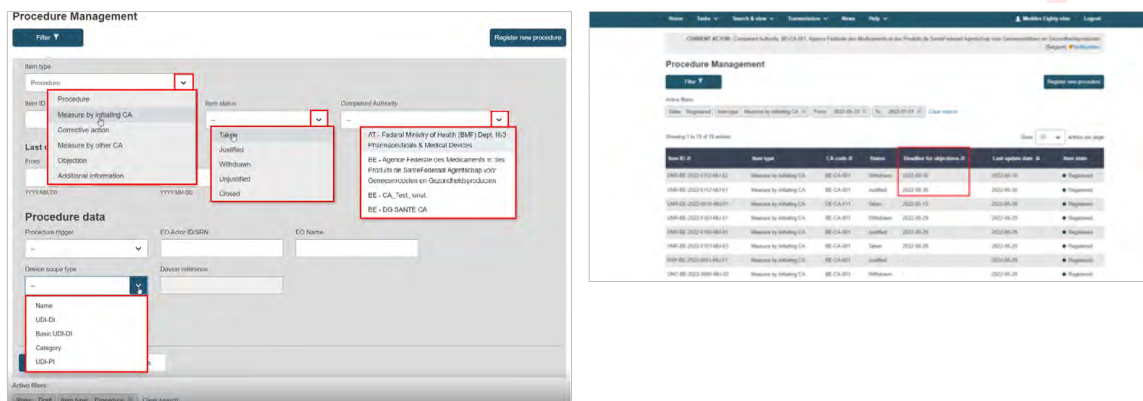
1. Click on **Manage an MSU procedure**:



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

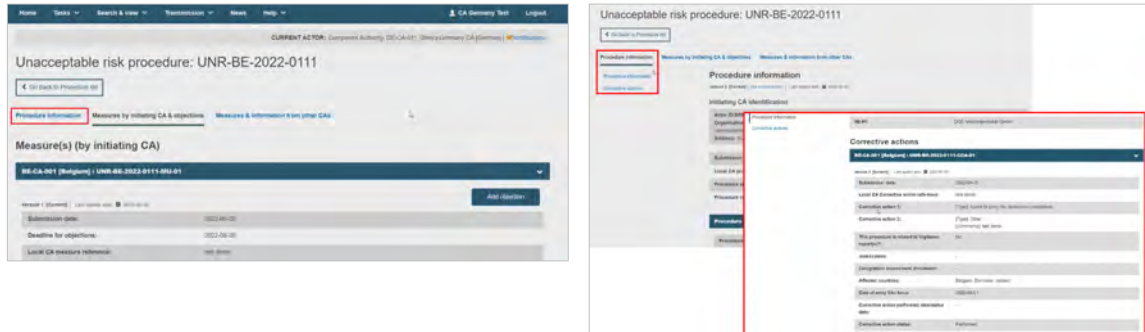


3. Alternatively, filter by *Item type* and select *Measure by initiating CA*, which is in *Taken* status; and/or select from the CA list, which only shows those able to initiate measures or procedures. Click **Apply filters**. The resulting list displays the objection deadline. Click on the measure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

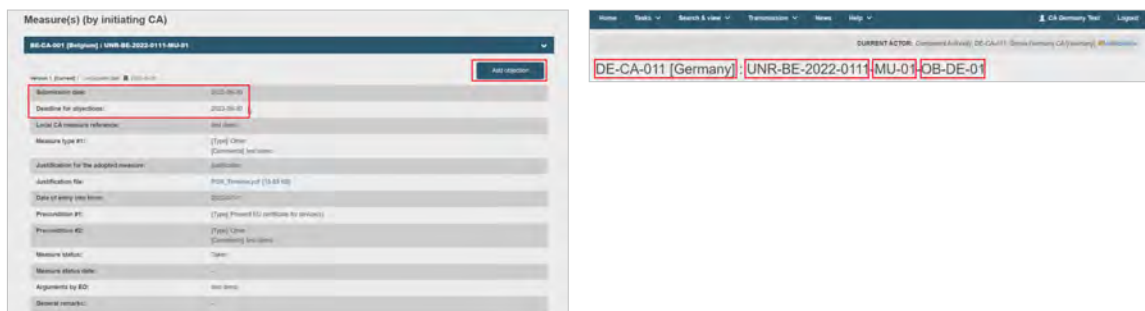




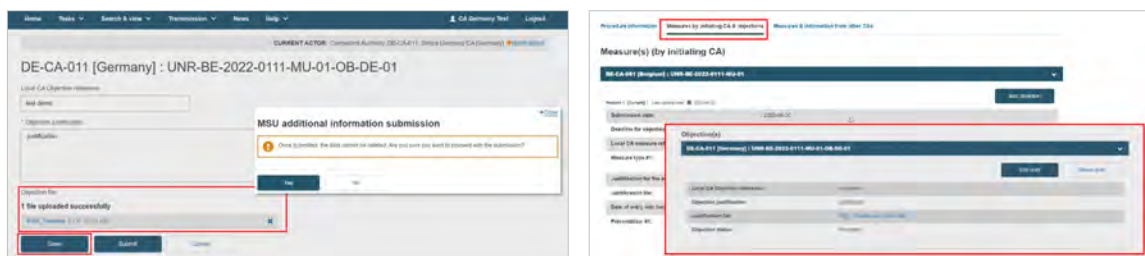
- You arrive directly on the *Measures by initiating CA & objections* section for the procedure. For information on the procedure itself, click **Procedure information**, where you can access the full data, including versions, trigger, device identifiers, and any corrective actions:



- 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:



- 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:



- 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**:



Procedure information Measures by initiating CA & objections Measures & information from other CAs

**Measure(s) (by initiating CA)**

BE-CA-001 [Belgium] : UNR-BE-2022-0111-MU-01

**Objection(s)**

DE-CA-011 [Germany] : UNR-BE-2022-0111-MU-01-OB-DE-01

Version 1 [Current] | Last update date: 2022-06-30

Discard Create new version

Submission date: 2022-06-30

Local CA Objection reference: test demo

Objection justification: justification

Justification file: PSR\_Timeline.pdf [15.83 KB]

Objection status: Proposed

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

Home Tasks Search & view Transmission News Help CA Germany Test Logout

CURRENT ACTOR: Competent Authority DE-CA-011, Striya Germany CA [Germany] Notifications

DE-CA-011 [Germany] : UNR-BE-2022-0111-MU-01-OB-DE-01

Local CA Objection reference: test demo

\* Objection justification: justification

Objection file: 1 file uploaded successfully PSR\_Timeline [PDF: 15.83 KB]

\* Objection status: Proposed

Save Proposed Withdrawn

## 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):

CURRENT ACTOR: Competent Authority, BE-CA-001, Agence Fédérale des Médicaments et des Produits de Santé/Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten [Belgium] Notifications

**Procedure Management**

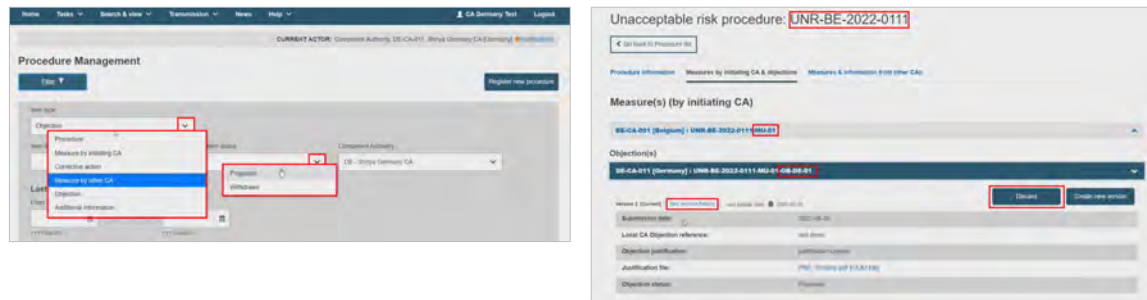
Filter Register new procedure

Active filters: State: Registered Item status: Open (with objection(s)) Item type: Procedure Competent Authority: BE - Agence Fédérale des Médicaments et des Produits de Santé/Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten Clear search

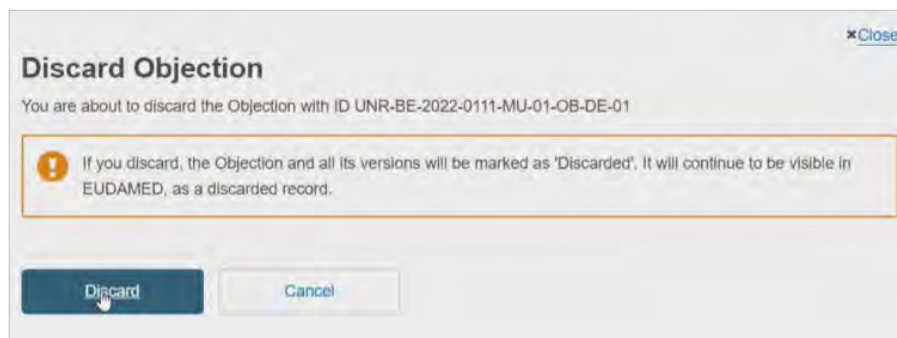
Showing 1 to 3 of 3 entries Show 20 entries per page

Item ID II	Item type	CA code II	Status	Deadline for objections II	Last update date II	Item state
UNR-BE-2022-0111	MDR Art 95 - Devices presenting an unacceptable risk to health and safety	BE-CA-001	Open (with objection(s))	-	2022-06-30	Registered
UNR-BE-2022-0096	MDR Art 95 - Devices presenting an unacceptable risk to health and safety	BE-CA-001	Open (with objection(s))	-	2022-06-28	Registered
UNR-BE-2022-0088	MDR Art 95 - Devices presenting an unacceptable risk to health and safety	BE-CA-001	Open (with objection(s))	-	2022-06-22	Registered

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**:

The screenshot shows the 'Unacceptable risk procedure: UNR-DE-2022-0038' screen. The 'Additional information' section at the bottom is highlighted with a red box, and a red arrow points to the 'Add information' button.

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:

The screenshot shows the 'Additional information' form. The 'text' field is highlighted with a red box, and the 'Browse' button is also highlighted with a red box. A confirmation message 'MSU additional information submission' is displayed.

3. The additional information appears in the procedure screen:

The screenshot shows the 'Additional information' section with three entries: BE-CA-001 [Belgium] : UNR-DE-2022-0038-AD-BE-01, BE-CA-001 [Belgium] : UNR-DE-2022-0038-AD-BE-02, and BE-CA-001 [Belgium] : UNR-DE-2022-0038-AD-BE-03.

## 7.1 Create a new version of additional information

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

The screenshot shows the 'Additional information' form. At the top right is an 'Add information' button. Below it are three rows of information, each with a dropdown arrow on the right. The third row is selected. Below the rows, there is a 'Version 1 [Current]' label and a 'Last update date' of '2022-06-30'. To the right of this is a 'Create new version' button, which is highlighted with a red box, and a 'Discard' button. Below these are three fields: 'Submission date' (2022-08-30), 'Additional information from other CA:' (text), and 'Additional information file:' (two links to 'demo\_file.pdf [179.69 KB]').

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

The screenshot shows the 'Additional information' form after a new version has been created. The 'Version 2 [Current]' label is now visible, and the 'See version history' button is highlighted with a red box. A red arrow points from this button to a 'Version history' section. This section is also highlighted with a red box and contains a 'Go back to the current version' button. The 'Version history' section lists three versions: 'Version 3 - Last update date: 2022-07-06', 'Version 2 - Last update date: 2022-06-30', and 'Version 1 - Last update date: 2022-06-30'. The 'Version 2' entry is the current one. The 'Additional information' section below the version history shows the 'CURRENT ACTOR' and the 'Additional information from other CA:' field.

## 7.2 Discard additional information

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



**Additional information** Add information

BE-CA-001 [Belgium] : UNR-DE-2022-0038-AD-BE-01

BE-CA-001 [Belgium] : UNR-DE-2022-0038-AD-BE-02

BE-CA-001 [Belgium] : UNR-DE-2022-0038-AD-BE-03

Version 2 [Current] | Last update date: 2022-08-30

Create new version Discard

Submission date: 2022-08-30

Additional information from other CA: text 1

Additional information file: demo\_file

**Discard Additional information**

You are about to discard the Additional information with ID UNR-DE-2022-0038-AD-BE-03.

⚠ If you discard, the Additional information and all its versions will be marked as 'Discarded'. It will continue to be visible in EUDAMED, as a discarded record.

Discard Cancel

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

**Procedure Management**

Filter

Item type: Additional information

Item ID: [text input]

Last update date: From [date picker] To [date picker]

Procedure data: Procedure name: [text input] ID: [text input] ID Name: [text input]

Filter: [dropdown menu]

Apply Filters Clear all filters

Active filters: Status: Discarded Item type: Additional information Clear search


Showing 1 of 2 of 2 entries

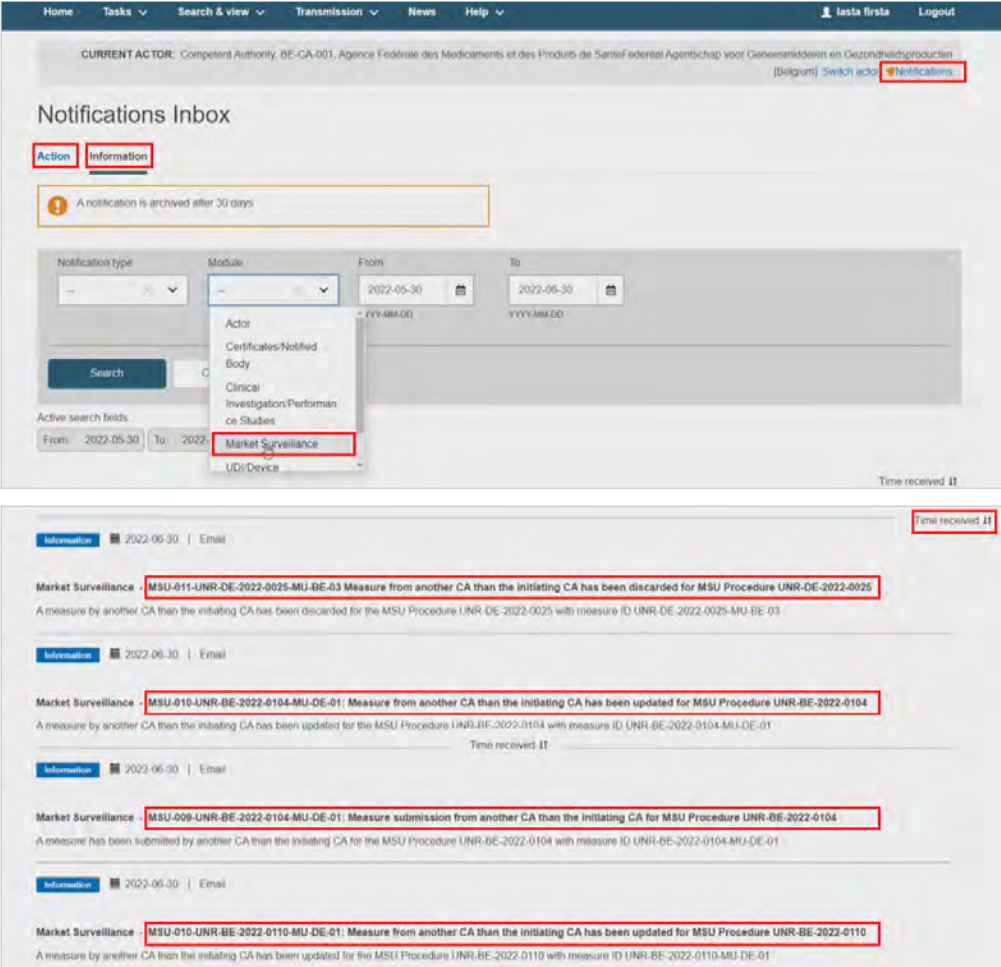
Item ID	Item type	CA code ID	Status	Deadline for objections	Last update date	Item state
UNR-DE-2022-0038-AD-BE-03	Additional information	BE-CA-001	Discarded		2022-08-30	Discarded
UNR-DE-2022-0038-AD-BE-01	Additional information	BE-CA-001	Discarded		2022-08-30	Discarded

Playground

# 8 Notifications

- 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 . 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:

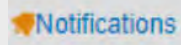






**NOTE**

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.



Playground

## 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)**

The screenshot shows the EUDAMED dashboard interface. At the top, there is a navigation bar with links: Home, Tasks, Search & view, Transmission, News, Help, TestEighty Eudamed, and Logout. Below the navigation bar, a banner displays the 'CURRENT ACTOR' as 'Competent Authority, BE-CA-001, Agence Fédérale des Médicaments et des Produits de Santé' and 'Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten [Belgium]' with a Notifications icon.

The main content area starts with a 'Welcome to EUDAMED' message, followed by a brief description of MDR EUDAMED and a link to 'See all the news'. Below this is a 'Tasks' section with the instruction: 'According to your profile per module, consult, verify and/or manage your own and related data (managed by your actor)'.

The 'Tasks' section is organized into four columns:

- My Actor data**: Manage your email notifications, Machine to machine preferences.
- Actor management**: Validate actor registration requests, Validate change requests.
- User management**: Assess user access requests, Manage your users.
- Vigilance**: Register a new NCAR, Manage Vigilance reports.

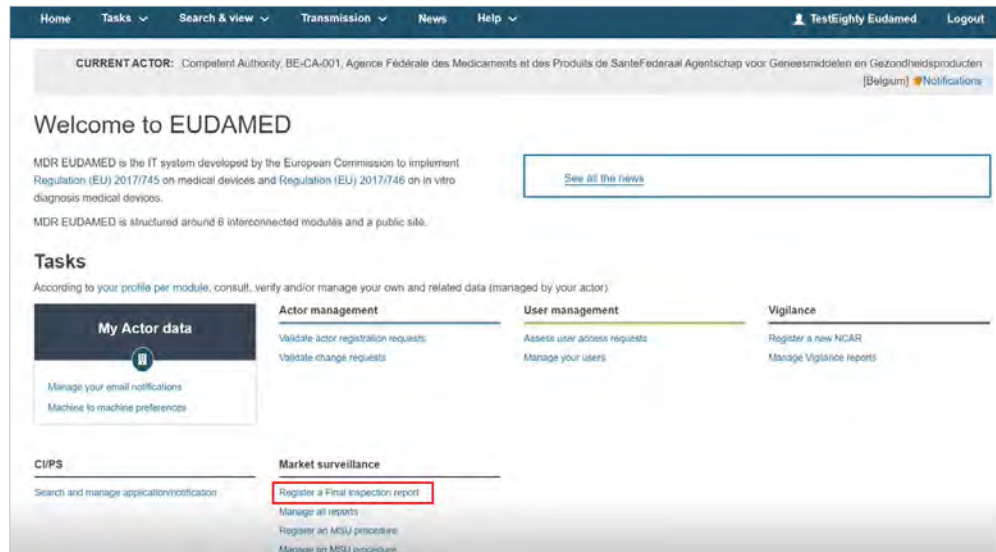
At the bottom, there are two more sections:

- CI/PS**: Search and manage application/notification.
- Market surveillance**: Register a Final inspection report, Manage all reports, Register an MSU procedure, Manage an MSU procedure.

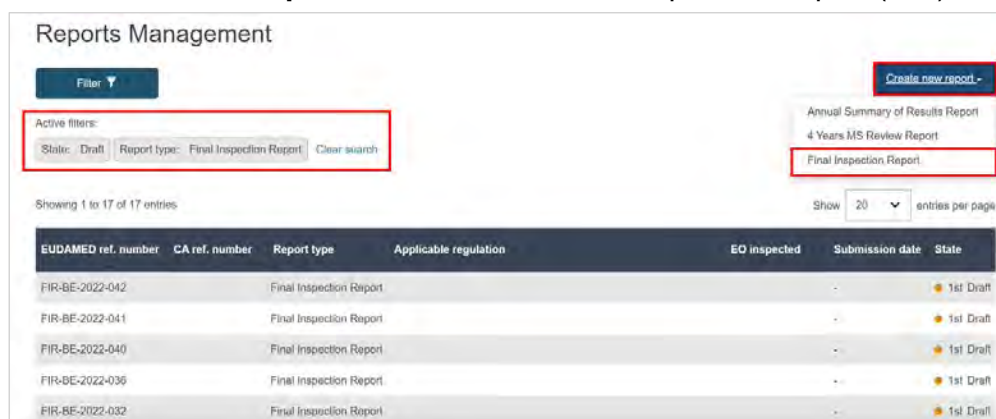
In the 'Market surveillance' section, the links 'Register a Final inspection report' and 'Manage all reports' are highlighted with a red rectangular box.

## 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):

The screenshot shows the 'Final inspection report registration' form. The title is 'Final inspection report registration: FIR-BE-2022-024'. Below the title, there's a field for 'CA reference number for this final inspection report' with the value 'BE01323'. The 'Applicable regulation' section shows two options: 'MDR (REGULATION (EU) 2017/745 on medical devices)' which is selected, and 'IVDR (REGULATION (EU) 2017/746 on in vitro diagnostic medical devices)' which is not selected.

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:

**Economic operator information**

**Economic operator #1**

☒ I know the Actor ID/SRN

\* Actor ID/SRN:

**Find**

**Select your economic operator**

Actor ID/SRN II	Name II	Role II
BE-MF-00000000	EUMR	Manufacturer
BE-AM-00000001	ARMU-Inst	Authorized Representative
BE-MF-00000074	ARMEN EU MANUFACTURER NO.32/02.2	Manufacturer
BE-MF-00000075	MF_EU_MRU_Inst	Manufacturer
BE-MF-00000082	ARMEN Q3.1 EU MANUFACTURER	Manufacturer
BE-MF-00000085	Playground Release SPN	System/Procedure Pack Provider
BE-AM-00000072	Belgium Vigilant Release Api	Authorized Representative
BE-MF-00000081	ARMEN O.S.H EU MANUFACTURER	Manufacturer
BE-MF-00000091	Manu_CIP2	Manufacturer
BE-AM-00000042	Bel_Art_Bi	Authorized Representative

**Next**

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

**Economic operator information**

**Economic operator #1**

**Add another EO**

**Check registry**

Fill in the mandatory field(s) and click on the 'Check registry' button to add an economic operator. For MDR Art 90 and IVDR Art 90 procedures, every device referenced in the given procedure must be linked to at least one economic operator with the role 'Manufacturer'. Manufacturers of registered devices will be retrieved by the system, but manufacturers of non-registered devices must be specified by the user, or it must be specified that the manufacturer of the given device is unknown.

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):

**Select your economic operator**

Actor ID/SRN II	Name II	Role II
BE-MF-000000741	ARMEN EU M	
BE-MF-000000383	LauraMFBE	
BE-MF-000000621	ARMEN Q3.1	
BE-MF-000000723	Belgium Vigil	
AF-MF-000000722	Belgium Vigil	
BE-MF-000000664	Belgium Vigil	
BE-MF-000000661	ARMEN O.D.B	
BE-MF-000000261	Manu_CIP2	
IN-MF-000000581	Non_EU_Ma	
BE-MF-000000385	Manu_Bel_re	

**Enter data manually**

**Manual entry**

**Economic operator #2**

Role: Manufacturer  
Organisation name: a

Street information, if applicable  
Yes ☒ No ☐

Street:  Street number:

Address line 2:

PO box:

Latitude:  Longitude:

City name:  Postal code:

Country:

**Remove this economic operator**

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:

✓ Your draft data was saved.

Save Submit Cancel

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:

Notified Body(ies) notifications

NB referenced in this procedure will have access to this procedure and related items

Select a Notified body:

- 0051 - IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.
- 0124 - DEKRA Certification GmbH
- 0197 - TÜV Rheinland LGA Products GmbH
- 0297 - DQS Medizinprodukte GmbH
- 0344 - DEKRA Certification B.V.
- 0373 - ISTITUTO SUPERIORE DI SANITA'
- 0459 - GMED SAS

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

\* Final inspection report file:

Browse

1 file uploaded successfully

Save Submit Cancel

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:

MSU Final inspection report submission

Are you sure you want to register this final inspection report?

Confirm Cancel

Notified Body(ies) notifications

Select a Notified body:

- 0051 - IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.

1 file uploaded successfully

Save Submit Cancel

Final inspection report registration

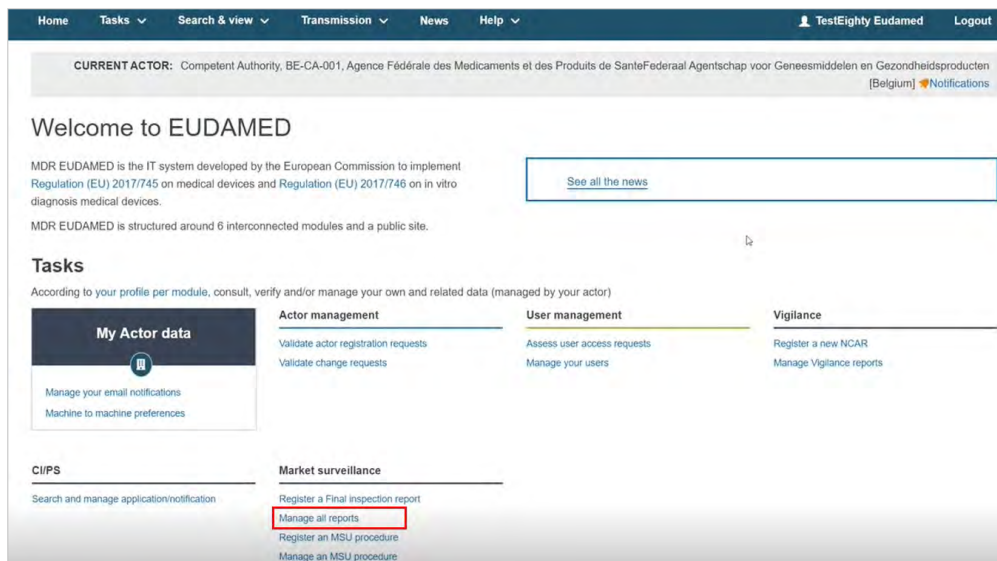
✓ Congratulations, You have successfully registered your Final inspection report

Your unique reference for this inspection report is FIR-2023-001

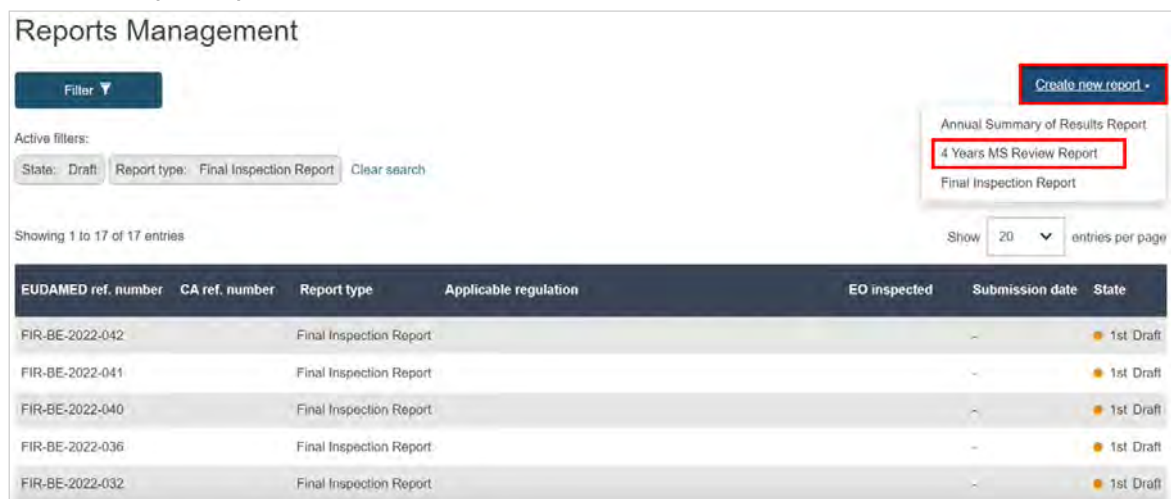
What do you want to do now?

Dashboard Manage all reports

## 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):

The screenshot shows the '4 Years MS Review Report registration' form. It includes a field for 'CA reference for this four years report' with the value 'Qt 4 demo to TW 1'. Below this, there's a section for 'Applicable regulation' with two options: 'MDR (REGULATION (EU) 2017/745 on medical devices)' (selected) and 'IVDR (REGULATION (EU) 2017/746 on in vitro diagnostic medical devices)'.

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.



Period start:

\* Year: 2021

\* Month: --

Period end:

\* Year: --

\* Abstract summary text:

5

6

7

8

9

10

11

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**:

\* Abstract summary text:

Provide free-text summary here.

\* Four years results report file (in English):

1 file uploaded successfully

demo\_file\_en

\* Four years summary report file (in English):

Browse

Submit

Cancel

PDFs

Name	Date modified
misc	06-10-2022 11:52
4-yr summary report.pdf	07-10-2022 13:49
MSU-en.docx	06-10-2022 11:45
4-yr report 2021-.pdf	11-10-2022 13:40

\* Four years results report file (in English):

1 file uploaded successfully

demo\_file\_en

\* Four years summary report file (in English):

1 file uploaded successfully

demo\_file2

Submit

Cancel



#### 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):

MSU Four years review report submission

Are you sure you want to register this MS four years review report?

Confirm

Cancel

4 Years MS Review Report registration

Congratulations, You have successfully registered your MS Four years review report

Your unique reference for Reg four years review report is: 4YR4Q-2022-4

What do you want to do now?

Manage all reports

You have 0 in dashboard

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

## 9.1.3 Register Annual Summary of Results report

The screenshot shows the EUDAMED user interface. At the top, there is a navigation bar with links: Home, Tasks, Search & view, Transmission, News, Help, TestEighty Eudamed, and Logout. Below the navigation bar, the current actor is identified as 'Competent Authority, BE-CA-001, Agence Fédérale des Médicaments et des Produits de Santé/Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten [Belgium]'. A 'Welcome to EUDAMED' message follows, explaining the system's purpose and structure. The 'Tasks' section is divided into several modules: 'My Actor data', 'Actor management', 'User management', 'Vigilance', 'CI/PS', and 'Market surveillance'. The 'Market surveillance' module contains links for 'Register a Final Inspection report', 'Manage all reports' (highlighted with a red box), 'Register an MSU procedure', and 'Manage an MSU procedure'.

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:

The screenshot shows the 'Reports Management' interface. At the top, there is a 'Filter' button. Below it, the 'Active filters' section shows 'State: Draft' and 'Report type: Final Inspection Report'. The 'Create new report' button is highlighted with a red box, and the 'Annual Summary of Results Report' option is selected from the dropdown menu. Below the filters, there is a table with 7 columns: EUDAMED ref. number, CA ref. number, Report type, Applicable regulation, EO inspected, Submission date, and State. The table shows 5 entries, all with 'Final Inspection Report' as the report type and '1st Draft' as the state.

EUDAMED ref. number	CA ref. number	Report type	Applicable regulation	EO inspected	Submission date	State
FIR-BE-2022-042		Final Inspection Report		-		1st Draft
FIR-BE-2022-041		Final Inspection Report		-		1st Draft
FIR-BE-2022-040		Final Inspection Report		-		1st Draft
FIR-BE-2022-036		Final Inspection Report		-		1st Draft
FIR-BE-2022-032		Final Inspection Report		-		1st Draft

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:

**Annual Summary of Results Report registration**

\* CA reference for this annual summary report:

GGY Q4.4

\* Applicable regulation

☒ MDR (REGULATION (EU) 2017/745 on medical devices)

☒ IVDR (REGULATION (EU) 2017/746 on in vitro diagnostic medical devices)

\* Reporting year:

2020

\* Abstract summary text:

Abstract text summary

\* Annual summary report file:

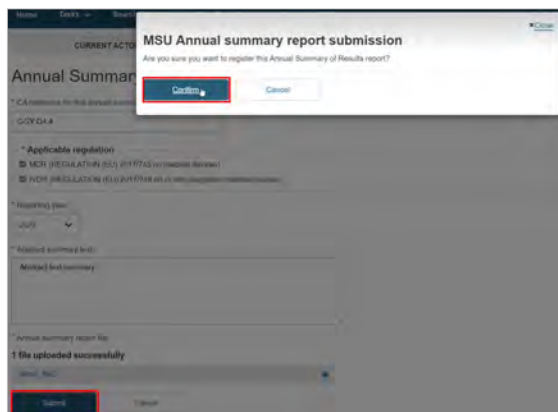
**Browse**

1 file uploaded successfully

Submit

Cancel

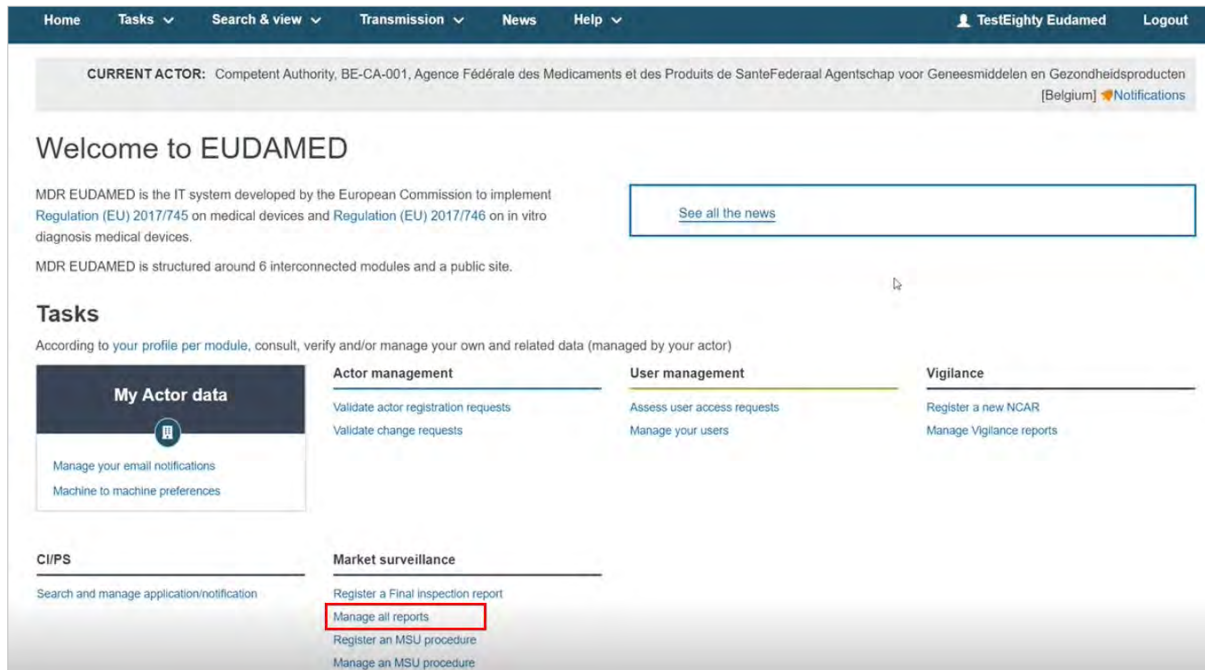
- Click **Submit** and **Confirm** to register the report. The confirmation message displays, and a notification is sent to all actors concerned:



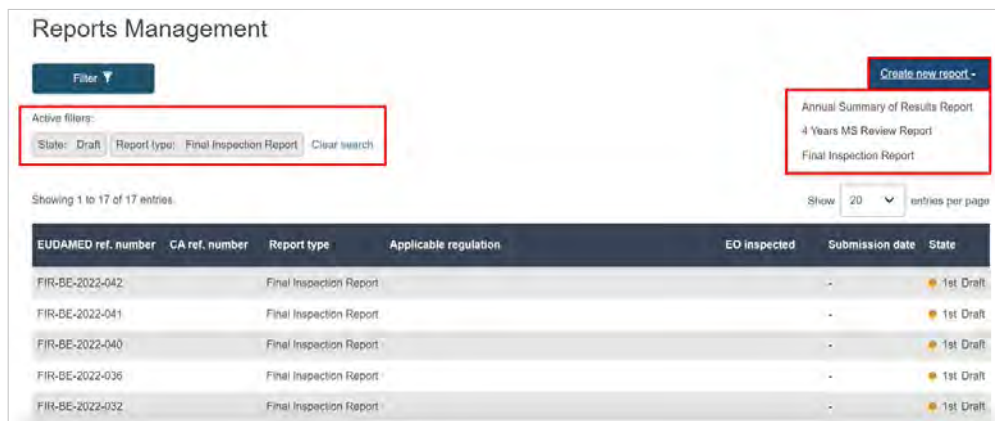
## 9.2 Manage all reports

Click *Manage all reports* on the dashboard.

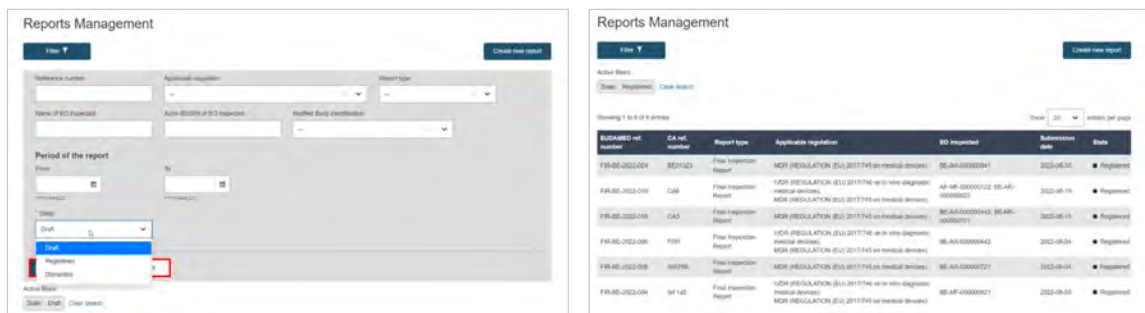
Playground



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*:

Home Tasks Search & view Transmission News Help TestEighty Eudamed Logout

CURRENT ACTOR: Competent Authority, BE-CA-001, Agence Fédérale des Médicaments et des Produits de Santé Fédérale Agentschap voor Geneesmiddelen en Gezondheidsproducten [Belgium] Notifications

### Final inspection report: FIR-BE-2022-019

[Go back to the list](#)

Version 2 [Current] **See version history** Last update date: 2022-11-23 [Create new version](#) [Discard](#)

EUDAMED ref. number:	FIR-BE-2022-019
Submission date:	2022-08-19
CA reference for this final inspection report:	CA#
Applicable regulation:	IVDR (REGULATION (EU) 2017/746 on in vitro diagnostic medical devices) MDR (REGULATION (EU) 2017/745 on medical devices)

Economic operator information

[AF-MF-000000122](#)

[BE-AR-000000822](#)

## 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:

Home Tasks Search & view Transmission News Help CA Confirmer CIPS Logout

CURRENT ACTOR: Competent Authority, BE-CA-001, Agence Fédérale des Médicaments et des Produits de Santé Fédérale Agentschap voor Geneesmiddelen en Gezondheidsproducten [Belgium] Notifications

✓ Final Inspection Report successfully submitted

### Final inspection report: FIR-BE-2022-024

[Go back to the list](#)

Version 2 [Current] [See version history](#) Last update date: 2022-08-30 [Create new version](#) **Discard**

EUDAMED ref. number:	FIR-BE-2022-024
Submission date:	2022-08-30
CA reference for this final inspection report:	BE01323
Applicable regulation:	MDR (REGULATION (EU) 2017/745 on medical devices)

Economic operator information

**BE-AR-000000841**

Actor ID/SRN: BE-AR-000000841  
Organisation name: AR-MSU-Ionut  
Address: 445 Avenue Siegers 1200 1200 Bruxelles

#### Discard Final Inspection Report

You are about to discard the Final Inspection Report with ID FIR-BE-2022-024

⚠ If you discard, the final inspection report in and all its versions will be marked as 'Discarded'. It will continue to be visible in EUDAMED, as a discarded record.

**Discard** [Cancel](#)

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



- The discarded record displays, showing a red *discarded* banner:

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

Information
2023-03-08
Email

Market Surveillance - MSU-004-ASR-LT-2022-1: Annual summary of the results of the CA surveillance activities report has been discarded

An Annual summary of the results of the CA surveillance activities with report ID ASR-LT-2022-1 has been discarded.

The report can be accessed using the following link: <https://webgate.test.ec.europa.eu/eudamed/secure/links/2059be55-d02b-4122-a41e-5b20f44aa45e>.

### 9.4.1 Discard a 4-Years MS Review Report

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

Home Tasks Search & view Transmission News Help Test/Empty Eudamed Logout

CURRENT ACTOR: Competent Authority, BE-CA-001, Agence Fédérale des Médicaments et des Produits de Santé/Federal Agentschap voor Geneesmiddelen en Gezondheidsproducten (Belgium) Notifications

### 4 Years MS Review Report: 4YR-BE-2022-4

Go back to the list

Discard

EUDAMED ref. number: 4YR-BE-2022-4

Submission date: 2022-11-23

CA reference for this final inspection report: CA Ggy q4 0

Applicable regulation: MDR (REGU)

Period start: 2021-5

Period end: 2022-1

Abstract summary text: Text

Four years results report file (in English): demo\_file\_en

Four years summary report file (in English): demo\_new.pdf

Discard 4 Years MS Review report

You are about to discard the 4 Years MS Review report with ID 4YR-BE-2022-4

If you discard, the 4 Years MS Review report is and all its versions will be marked as 'Discarded'. It will continue to be visible in EUDAMED, as a discarded record.

Discard Cancel

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

Reports Management

Filter

Active States: Discarded Report type: 4 Years MS Review Report Clear search

Showing 1 to 3 of 3 entries

EUDAMED ref. number	CA ref. number	Report type	Applicable regulation	MD reported	Submission date	State
4YR-BE-2022-4	CA Ggy q4 demo TW	4 Years MS Review Report	MDR (REGULATION (EU) 2017/745 on medical devices)		2022-11-23	Discarded
4YR-BE-2022-4	CA Ggy q4 demo TW	4 Years MS Review Report	MDR (REGULATION (EU) 2017/745 on medical devices)		2022-11-23	Discarded
4YR-BE-2022-4	CA Ggy q4 demo TW	4 Years MS Review Report	MDR (REGULATION (EU) 2017/745 on medical devices)		2022-11-23	Discarded

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

4 Years MS Review Report: 4YR-BE-2022-4

Go back to the list

This 4 Years MS Review report has been discarded | Last update: 2022-11-23

EUDAMED ref. number: 4YR-BE-2022-4

Submission date: 2022-11-23

CA reference for this final inspection report: CA Ggy q4 demo TW

Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices)

Period start: 2021-5

Period end: 2022-1

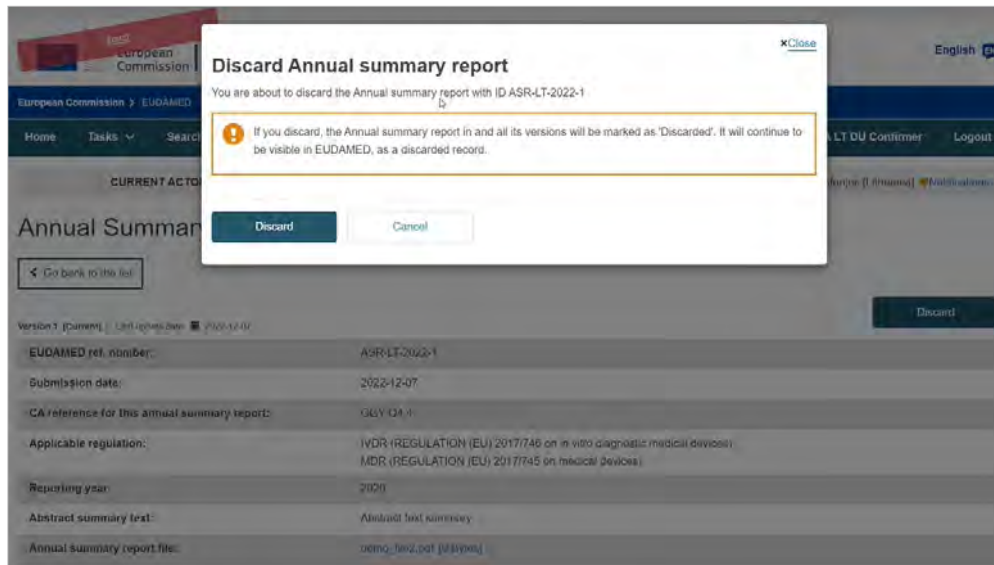
Abstract summary text: Text

Four years results report file (in English): demo\_file\_en.pdf [0 Bytes]

Four years summary report file (in English): demo\_new.pdf [46.11 KB]

## 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:

**Reports Management**

Filter: **Y** [Create new report](#)

Active filters: [Status](#) [Submission](#) [Report type](#) [Annual Summary of Results Report](#) [Clear search](#)

Showing 1 to 4 of 4 entries. 20 entries per page

EUDAMED ref. number	CA ref. number	Report type	Applicable regulation	MDI requested	Submission date	Status
ASR-EE-2022-1	Test_case_MDI	Annual Summary of Results Report	MDR (REGULATION (EU) 2017/745 on medical devices)		2022-01-19	Discarded
ASR-EE-2022-4	Final	Annual Summary of Results Report	IVDR (REGULATION (EU) 2017/746 on in vitro diagnostic medical devices)		2022-12-02	Discarded
ASR-EE-2022-5	reference	Annual Summary of Results Report	IVDR (REGULATION (EU) 2017/746 on in vitro diagnostic medical devices); MDR (REGULATION (EU) 2017/745 on medical devices)		2022-12-26	Discarded
ASR-EE-2022-2	CA reference	Annual Summary of Results Report	MDR (REGULATION (EU) 2017/745 on medical devices)		2022-12-19	Discarded

**Information** 2023-03-08 | Email

**Market Surveillance - MSU-004-ASR-LT-2022-1: Annual summary of the results of the CA surveillance activities report has been discarded**

An Annual summary of the results of the CA surveillance activities with report ID ASR-LT-2022-1 has been discarded. The report can be accessed using the following link: <https://webgate.fest.ec.europa.eu/eudamed/secure/links/2059be55-d026-4122-a41e-5b20844aa45e>.

# 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:

The screenshot displays the EUDAMED user interface. At the top, the navigation bar includes 'Home', 'Tasks', 'Search & view' (highlighted with a red box), 'Data Transfer', 'News', and 'Help'. The user is logged in as 'TestEighty Eudamed'. The main content area shows a 'Welcome to EUDAMED' message and a 'Tasks' section with various modules like 'My Actor data', 'Actor management', 'User management', 'Vigilance', 'CIPS', and 'Market surveillance'. Below this, the 'Search & View' section provides an overview of modules. A grid of tiles is shown, with the 'Market Surveillance module Procedures' tile at the bottom left highlighted by a red box.

Module	Function
Actor module	Actors
Actor module	Search for refused registration requests
UDI-DI module	UDI-DIs/Devices
NB & Certificates module	Issued/Refused certificates
NB & Certificates module	Search for applications
NB & Certificates module	Search for CECF
NB & Certificates module	Suspension/withdrawal request
NB & Certificates module	Nominated experts list
Vigilance module	View Vigilance reports
Clinical investigation & Performance study module	CIPS application & PMCF/PMFP notification
NB & Certificates module	Search for MS summary reports on NB
Market Surveillance module	Reports
Market Surveillance module	Procedures

- 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:

**Search & view**

**Procedures**

Enable filters for procedures bulk download ☒

Item type  
--

Item ID  
--

Item status  
--

Competent Authority  
--

To  
--  
YYYY-MM-DD

**Procedure data**

Procedure type  
--

Procedure trigger  
--

EO Actor ID/SRN  
--

EO Name  
--

Device scope type  
--

Device reference  
--

**State of the procedure/linked objects**

Include discarded procedures and linked objects in the search results ☒

- The data criteria are the same as described in [Using the filter \[28\]](#). Click **Search** to proceed, or **Clear search** to re-enter fields.
- Search results display. The *Item type* column displays a shortened 'Procedure type' description for Procedures, and an 'Item type' description for other item types:

Search results for Procedures

Active filters:  
To: 2024-01-09 ✕ Competent Authority: DE - CANekGermany ✕ [Clear search](#)

Showing 1 to 20 of 85 entries

Show 20 entries per page

Item ID <sup>1</sup>	Item type	Version	CA code <sup>1</sup>	Status	Last update date <sup>1</sup>	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:

The image shows two side-by-side screenshots of the 'Search & view' interface for 'Procedures'. Both screenshots show the 'Enable filters for procedures bulk download' toggle. In the left screenshot, the toggle is grey (disabled). In the right screenshot, the toggle is green (enabled). When enabled, additional search filters appear, including 'Local CA reference', 'EO Actor ID/URN', 'EO Name', 'State', and 'Last update date from'. A 'Results option' section at the bottom includes a toggle for 'Include historical version'.

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.

Playground



**Procedure data**

Procedure type  Procedure trigger

EO Actor ID/SRN  EO Name

Device scope type  Device reference

**State of the procedure/linked objects**

Include discarded procedures and linked objects in the search results ☐

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**:

**Search & view**

**Procedures**

Enable filters for procedures bulk download ☒

\* Item type

Procedure

Measure by initiating CA

Corrective action

Measure by other CA

Objection

Additional information

Item status

Closed

Open

Open (with measure(s))

Open (with objection(s))

Competent Authority

AT - Federal Ministry of Health (BMF) Dept. III/3 Pharmaceuticals & Medical Devices

AT - NEKVIE

AT - Shriya\_CA\_AU

BE - ASIMINA BE CA

BE - ASIMINA BE CA 3

BE - ASIMINA BE CA 4

\* Last update date from

YYYY-MM-DD

**Results option**

Include historical version ☐

Search  Clear 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:

**Results option**  
Include historical version ☐

[Search](#) [Generate XML file](#) [Clear search](#)

**Search results for Procedures**  
Active filters:

Enable search filters available for bulk XML download: ☐ Last update date from: 2023-11-01 ☐ Item type: Procedure ☐ Item ID: UNR ☐ [Clear search](#)

Showing 1 to 20 of 23 entries Show 20 entries per page

Item ID II	Item type	CA code II	Registered EO(s)	Non-registered EO(s)	Status	Deadline for objections II	Last update date II	Item state
UNR-DE-2023-0074	Procedure (MDR Art 95)	DE-CA-011			Open	-	2023-11-28	Registered
UNR-DE-2023-0073	Procedure (MDR Art 95)	DE-CA-011			Open	-	2023-11-28	Registered
UNR-DE-2023-0072	Procedure (MDR Art 95)	DE-CA-011			Open	-	2023-11-28	Registered
UNR-DE-2023-0071	Procedure (MDR Art 95)	DE-CA-011			Open	-	2023-11-28	Registered
UNR-DE-2023-0070	Procedure (MDR Art 95)	DE-CA-011			Open	-	2023-11-28	Registered

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.

**Download**

Are you sure you want to generate XML file?

[Confirm](#) [Cancel](#)

**Search & view**  
**Procedures**

Congratulations. You have successfully generated your XML file.  
Your id is: APP-DTX-000003564

**What do you want to do now?**

[Go to Download management](#)

[Go back to Procedure list](#)

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

**Download management**

[Filter](#)

State:  Service:

[Apply filters](#) [Clear all filters](#)

Active filters: No selection

Showing 1 to 2 of 2 entries Show 20 entries per page

ID	Name	Module II	Service II	State II	Request date II	Download
APP-DTX-000003564	CA LT DU Confirmer	Market Surveillance	MSU procedure download	Pending	2023-12-13 [11:14]	
APP-DTX-000003563	CA LT DU Confirmer	Market Surveillance	MSU procedure download	Successful	2023-12-13 [10:35]	<a href="#">XML [187.75 KB]</a> <a href="#">ZIP [2.55 MB]</a> Expires in 15 days

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:

Request date if	Download
2023-12-13 [11:14]	<a href="#">XML [187.75 KB]</a> ; <a href="#">ZIP [2.55 MB]</a> Expires in 15 days

**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.

Playground

## 10.3 Search & View reports

The screenshot shows the EUDAMED user interface. At the top, there is a navigation bar with 'Home', 'Tasks', 'Search & view', 'Data Transfer', 'News', and 'Help'. The 'Search & view' menu item is highlighted with a red box. Below the navigation bar, the user's current actor information is displayed: 'CURRENT ACTOR: Competent Authority, BE-CA-001, Agence Fédérale des Médicaments et des Produits de Santé Fédérale Agentschap voor Geneesmiddelen en Gezondheidsproducten (Belgium)'. A 'Welcome to EUDAMED' message follows, explaining the system's purpose and structure. The 'Tasks' section lists various actions available to the user, categorized into 'My Actor data', 'Actor management', 'User management', 'Vigilance', 'CLIPS', and 'Market surveillance'. The 'Search & View' section provides an overview of modules for searching and viewing details. A grid of modules is shown, including 'Actor module', 'NB & Certificates module', 'Clinical investigation & Performance study module', and 'Market Surveillance module'. The 'Market Surveillance module Reports' option is highlighted with a red box.

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

The screenshot shows the 'Search & View' Reports section. At the top, there is a toggle switch for 'Enable search filters available for bulk XML download', which is currently turned off. Below the toggle, there is a dropdown menu for 'Report type'. The dropdown menu is open, showing three options: '4 Years MS Review Report', 'Annual Summary of Results Report', and 'Final Inspection Report'. The '4 Years MS Review Report' option is selected and highlighted in blue. There is also a search input field and a 'reference' label.

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*:

Search & view

Reports

Enable search filters available for bulk XML download ☐

\* Report type

4 Years MS Review Report X v

**Report information**

Report ID

Report CA reference

Reporting country -- X v

Applicable regulation -- X v

EO Name

EO Actor ID/SRN

State -- X v

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:

Search & view

Reports

Enable search filters available for bulk XML download ☐

\* Report type

Final Inspection Report X v

**Report information**

Report ID

Report CA reference

Reporting country -- X v

Applicable regulation -- X v

EO Name

EO Actor ID/SRN

State -- X v

4. Select the state of the report:



**Search & view**

**Reports**

Enable search filters available for bulk XML download ☐

\* Report type  
4 Years MS Review Report X v

**Report information**

Report ID

Report CA reference

Reporting country -- X v

Applicable regulation -- X v

EO Name

EO Actor ID/SRN

State  
-- X v  
Discarded  
Registered

Month

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.

4 Years MS Review Report: 4YR-LT-2022-6

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:

Playground

**Reporting period from**

Year  Month

**Reporting period to**

Year  Month

**Last update date from**

YYYY-MM-DD

**Results option**

Include historical version ☒

**Search** **Generate XML file** **Clear search**

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.

**Results option**

Include historical version ☒

**Search** **Generate XML file** **Clear search**

**Search results for Reports**

Active filters:

Report type: Final Inspection Report  Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices)  State: Registered

Last update date from: 2022-02-02  Include historical version:  [Clear search](#)

Showing 1 to 20 of 289 entries

Show  entries per page

Report ID ID	Version	CA ref. number ID	Reporting country ID	Applicable regulation	Registered EO(s)	Non- registered EO(s)	Reporting period	Last update date ID	State
FIR-DE-2023-158	1 [Current]	java.util.Random@9129ab1	Germany	MDR (REGULATION (EU) 2017/745 on medical devices)	BE-AR-000004907, BE-IM-000004851, BE-MF-000005207, BE-PR-000005149	1		2023-12-21	Registered
FIR-DE-2023-157	1 [Current]	java.util.Random@1bf596f8	Germany	MDR (REGULATION (EU) 2017/745 on medical devices)	BE-PR-000005149			2023-12-21	Registered
FIR-DE-2023-156	1 [Current]	java.util.Random@779d7f#4	Germany	MDR (REGULATION (EU) 2017/745 on medical devices)	BE-MF-000005207			2023-12-21	Registered
FIR-DE-2023-155	1 [Current]	java.util.Random@13638ddf	Germany	MDR (REGULATION (EU) 2017/745 on medical devices)	BE-IM-000004851			2023-12-21	Registered

**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:

Playground

**Results option**

Include historical version ☒

Search Generate XML file Clear search

**Search results for Reports**

Active filters:

Enable search filters available for bulk XML download: X Report type: Final Inspection Report X Last update date from: 2023-06-06 X Include historical version: X [Clear](#)

[search](#)

Showing 1 to 20 of 499 entries Show 20 entries per page

Report ID IT	Version	CA ref. number IT	Reporting country IT	Applicable regulation	Registered EO(s)	Non- registered EO(s)	Reporting period	Last update date IT	State
FIR-RO-2023-013	1 [Current]	*(&\$%^&*)	Romania	IVDR (REGULATION (EU) 2017/746 on in vitro diagnostic medical devices), MDR (REGULATION (EU) 2017/745 on medical devices)	BM-MF-000000842			2023-11-29	Registered
FIR-DE-2023-108	1 [Current]	andom2	Germany	MDR (REGULATION (EU) 2017/745 on medical devices)	BE-IM-000004851			2023-11-28	Registered
FIR-DE-2023-107	2 [Current]	java.util.Random@37ad818e	Germany	IVDR (REGULATION (EU) 2017/746 on in vitro diagnostic medical devices)	BE-AR-000004907			2023-11-28	Registered
FIR-DE-	1 [Historic]	java.util.Random@37ad818e	Germany	IVDR (REGULATION (EU) 2017/746 on in vitro diagnostic medical devices)	BE-AR-000004907			2023-11-28	Registered

**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.

Playground

