



EUDAMED user guide

Vigilance for EOs

Playground v 3.11.0
2025

ground

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Playground

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

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

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

Playground

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

Prerequisite to access EUDAMED:

[EU Login \(ECAS\) account](#)

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

Access the [EUDAMED Playground environment](#).

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

User profiles in the Vigilance module:

Profiles in Vigilance applicable for all Actor types:

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

Useful EUDAMED symbols and their meaning:

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


Date of incident

* Date of incident (Start Date)



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

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

Actor ID/ SRN 



NOTE

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



INFOGRAPHIC: [Vigilance reports description](#)



Playground

3 MIR

3.1 Register a new MIR



NOTICE

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

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

3.1.1 Step 0: Create initial MIR dossier

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

CURRENT ACTOR: Manufacturer, BE-MF-000000123, John's EU MF [Belgium] [Notifications](#)

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	User management	UDI-DIs/Device	Vigilance
Manage your actor data Manage your email notifications Machine to machine data delivery preferences	Assess user access requests Manage your users	Register a new Basic UDI-DI Register a legacy device Manage your Basic UDI-DIs / EUDAMED Dis Manage your device details	Manage Vigilance reports Register a new Vigilance Form

Vigilance

[Manage Vigilance reports](#)

[Register a new Vigilance Form](#)

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



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



The system will automatically retrieve your Actor ID/ SRN.

**TIP**

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

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

Playground

Vigilance Templates

* Select the template type for the new dossier

MIR (Manufacturer Incident Report) ▼

* Manufacturer

BE-MF-000000141 ▼

* Is this MIR related to a PSR?

Please choose a value ▼

Manufacturer

Actor ID/SRN: BE-MF-000000141

Organisation name: ManuEU_Vig

Address: street
2563
Ghent Belgium

Create Form

Playground

**TIP**
PSR MIR

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

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

Vigilance Templates

* Select the template type for the new dossier

MIR (Manufacturer Incident Report)

* Manufacturer

CN-MF-000003287

* Is this MIR related to a PSR?

Yes

* Periodic Summary Report ID

Manufacturer

Actor ID/SRN: CN-MF-000003287

Organisation name: D'Amore-Mann

Address:
518003
Shenzhen China

Create Form

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

[Back to list](#)

Report Primary Details

Administrative Information

Device Information

Report Primary Details

Form Type

MIR(Manufacturer Incident Report)

Periodic Summary Report ID

[PSR-2024-000466](#)

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

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

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

CURRENT ACTOR: Manufacturer, AF-MF-000000122, John's NonEU MF [Afghanistan]

Vigilance Templates

Select the template type for the new dossier

MIR (Manufacturer Incident Report) ▼

Manufacturer

AF-MF-000000122 ▼

Manufacturer's reference number for this incident

MFR_MIR_001

Country where the incident occurred

Country of incident ▼

Manufacturer

SRN:	AF-MF-000000122
Organisation name:	John's NonEU MF
Address:	Test, 2121 Test Test Afghanistan

Create Form

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

CURRENT ACTOR: Manufacturer, AF-MF-000000122, John's NonEU MF [Afghanistan]

Vigilance Templates

Select the template type for the new dossier

MIR (Manufacturer Incident Report) ▼

Manufacturer

AF-MF-000000122 ▼

Manufacturer's reference number for this incident

MFR_MIR_001

Country where the incident occurred

Austria ▼

Competent authority

Competent Authority ▼

- Competent Authority
- AT-CA-001

SRN:	AF-MF-000000122
Organisation name:	John's NonEU MF
Address:	Test, 2121 Test Test Afghanistan

Create Form

The system will automatically retrieve the CAs responsible for Vigilance.

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

CURRENT ACTOR: Manufacturer, BE-MF-000000123, John's EU MF [Belgium]

Vigilance Templates

* Select the template type for the new dossier

MIR (Manufacturer Incident Report) ▼

* Manufacturer

BE-MF-000000123 ▼

* Manufacturer's reference number for this incident

AT-CA-001

* Country where the incident occurred

Austria ▼

* Competent authority

AT-CA-001 ▼

Manufacturer

SRN:	BE-MF-000000123
Organisation name:	John's EU MF
Address:	Belgium

Competent Authority

SRN:	AT-CA-001
Organisation name:	Federal Ministry of Health (BMF) Dept. III/3 Pharmaceuticals & Medical Devices
Address:	Austria

[Create Form](#)

**IMPORTANT**

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

3.1.2 Step 1: Report primary details

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

Playground

EUDAMED Ref No: MIR-2024-06-000510

Version : 1 [Draft] | Last update : 2024-06-27

[Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

Device Information

Incident Information

Manufacturer Analysis

General Comments

Form Type
MIR(Manufacturer Incident Report)

Manufacturer's reference number for this incident
000

Country where the incident occurred
Germany

Competent Authority

Actor ID/SRN: DE-CA-003

Organisation name: Deutsches Institut für Medizinische Dokumentation und Information

Address: Waisenhausgasse 36-38a
D-50676 Köln Germany

Manufacturer

Actor ID/SRN: CN-MF-000003287

Organisation name: D'Amore-Mann

Address: 518003
Shenzhen China

Please ensure the information provided is correct.

3.1.3 Step 2: Administrative information

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

[Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

Device Information

Incident Information

Manufacturer Analysis

General Comments

Report Type
MIR(Manufacturer Incident Report)

Manufacturer's reference number for this incident
MFR_MIR_001

Country where the incident occurred
Austria

Competent Authority

SRN: AT-CA-001

Organisation name: Federal Ministry of Health (BMF) Dept. III/3 Pharmaceuticals & Medical Devices

Address: A-1030 Vienna
Austria

Manufacturer

SRN: AF-MF-000000122

Organisation name: John's NonEU MF

Address: Test, 2121 Test
Test
Afghanistan

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

CURRENT ACTOR: Manufacturer, AF-MF-000000122, John's NonEU MF [Afghanistan]

EUDAMED Ref No: MIR-2022-03-000107

Version : 1 [Draft] | Last update: 2022-03-14

[Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

Device Information

Incident Information

Manufacturer Analysis

General Comments

Administrative Information

Status

☒ Initial

☐ Follow up

☐ Combined initial and final

Reference number assigned by NCA for this incident

3. Provide all the relevant dates:

Date of incident

* Date of incident (Start Date)

* Date of incident (End date)

* Manufacturer awareness date of incident

* Manufacturer awareness date of reportability

* Expected date of the next report



NOTE

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

4. Select the classification of the incident:

Classification of Incident

☒ Serious public health threat

☐ Death

☐ Unanticipated serious deterioration in state of health

☐ All other reportable incidents

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

Contact information of the report

Manufacturer contact details

— Manufacturer Contact Details

* Contact First Name	* Contact Last Name
<input type="text"/>	<input type="text"/>
* E-mail	* Phone number
<input type="text"/>	<input type="text"/>

**TIP**

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

**NOTE**

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

Authorised Representative

Actor ID/ SRN

BE-AR-000000121 - Test AR BE Details

Contact First Name	Contact Last Name
<input type="text"/>	<input type="text"/>
Email	Phone Number
<input type="text"/>	<input type="text"/>

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

Report Primary Details

Administrative Information

Device Information

Incident Information

Manufacturer Analysis

General Comments

References to other Vigilance reports

References to other MIR Reports

If this incident involves multiple devices from the same manufacturer, please list the respective reference numbers of the other MIR forms you have submitted

Please select:

References to other MIR reports NON- registered in EUDAMED

Manufacturer's MIR reference number	NCA's local MIR reference number
<input type="text"/>	<input type="text"/>

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

References to other Vigilance reports

References to other MIR Reports

If this incident involves multiple devices from the same manufacturer, please list the respective reference numbers of the other MIR forms you have submitted

123

testAutomation

References to other MIR reports NON- registered in EUDAMED

Manufacturer's reference number	NCA's local reference number
<input type="text"/>	<input type="text"/>

Add

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

References to other MIR reports NON- registered in EUDAMED

Manufacturer's reference number	NCA's local reference number
534536353	<input type="text"/>

Add

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

Administrative Information

Device Information

Incident Information

Manufacturer Analysis

General Comments

References to other FSCA Reports

Manufacturer's reference number

Please select.

References to other FSCAs - not registered in EUDAMED

Manufacturer's FSCA reference number	NCA's local FSCA reference number
<input type="text"/>	<input type="text"/>

Add

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

PMCF/PMPF Investigation

Reference to PMCF/PMPF investigation

☒ Yes

☐ No

Clear

* Please provide the identifier of the PMCF/PMPF investigation



TIP

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

3.1.4 Step 3: Device information

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

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

Case A: Device with identifier registered in EUDAMED

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

Playground

Device Information

* Does the device have a known Identifier?
 → Displayed only for 'Initial' and 'Follow-up' MIRs

* Device identifier

Dataset of the device is not complete. Please provide the basic device data [here](#). → Warning displayed only for NRD devices, if dataset not complete

UDI-DI/EUDAMED ID:	test_status2243535566 [KCBSA]	<input type="button" value="Change"/>
Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)	
Risk Class:	Class IIIa	
Basic UDI-DI/Eudamed-DI:	103514777700000990P6 [GS1]	
Unit of use UDI-DI:		
Model:		
Device trade name:		
Reference/Catalogue number:	2341243	
Medical device terminology:	EMDN	
Nomenclature code(s):	A0101010202 : HYPODERMIC PEN NEEDLES, W/O SAFETY SYSTEMS	
Device type		
Implantable:	Yes	
Active Device:	No	
Intended to administer or remove a medicinal product:	No	
Sterile:	No	
Measuring functions:	No	
Reusable surgical instruments:	No	
Instrument:	No	
System:	No	
Procedure Packs:	No	
Non-medical purpose:	No	

GTIN number → Displayed only for special device types

→ Displayed only for devices with complete dataset

The system will retrieve the device's details.



NOTE

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

Administrative Information

Device Information

Incident Information

Manufacturer Analysis

General Comments

Medical device terminology: EMDN

Nomenclature code(s): B02010201 : LABORATORY ERYTHROCYTES (RBC) LEUKOREDUCTION FILTERS, A0201020101 : INFUSION AND IRRIGATION SYRINGES, 2-PIECE LUER CONE, 2-PIECE WITH NEEDLE, SINGLE-USE

GTIN number

Device Nomenclature Code

* Description of the device and its intended purpose

- Describe the device and its intended purpose:

Device Information

Incident Information

Manufacturer Analysis

* Description of the device and its intended purpose

- Fill in the *UDI Production Identifier* section:


4. Fill in the *Device dates* section:

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


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

Certificate Identification

– Certificate Identification

Notified body (NB) ID number 

Please select...

Notified body (NB) certificate number 


Add

**NOTE**

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

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


Was the device implanted at the time of serious incident?

Yes  Clear

Date when the device was implanted


Exact date ✓ Clear

Implant date



Implant facility

Device was explanted?

Please select... 

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

Market Distribution

Country where the device is made available on the market

[Check all](#) [Uncheck all](#)

<input type="checkbox"/> Austria	<input type="checkbox"/> Germany	<input type="checkbox"/> Poland	<input type="checkbox"/> Türkiye
<input type="checkbox"/> Belgium	<input type="checkbox"/> Greece	<input type="checkbox"/> Portugal	<input type="checkbox"/> Northern Ireland
<input type="checkbox"/> Bulgaria	<input type="checkbox"/> Hungary	<input type="checkbox"/> Romania	
<input type="checkbox"/> Croatia	<input type="checkbox"/> Ireland	<input type="checkbox"/> Slovakia	
<input type="checkbox"/> Cyprus	<input type="checkbox"/> Italy	<input type="checkbox"/> Slovenia	
<input type="checkbox"/> Czechia	<input type="checkbox"/> Latvia	<input type="checkbox"/> Spain	
<input type="checkbox"/> Denmark	<input type="checkbox"/> Lithuania	<input type="checkbox"/> Sweden	
<input type="checkbox"/> Estonia	<input type="checkbox"/> Luxembourg	<input type="checkbox"/> Iceland	
<input type="checkbox"/> Finland	<input type="checkbox"/> Malta	<input type="checkbox"/> Liechtenstein	
<input type="checkbox"/> France	<input type="checkbox"/> Netherlands	<input type="checkbox"/> Norway	

Other countries (outside EEA, TR, XI)

Please select...

[Add](#)

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

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

EUDAMED Ref No: MIR-2024-06-000510

Version : 1 [Draft] | Last update : 2024-06-27

[Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

Device Information

Incident Information

Manufacturer Analysis

General Comments

Device Information

Does the device have a known identifier?

No [Clear](#)

Applicable legislation

Please select...

Risk Class

Please select...

Device type

Please select...

[Add](#)



NOTE

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

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



NOTE

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

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

Device Information

Incident Information

Manufacturer Analysis

General Comments

Implantable?

No Clear

Model

Medical device name (brand/trade/proprietary or common name)

Medical device terminology

Please select...

Catalogue/reference number

Device Nomenclature Code

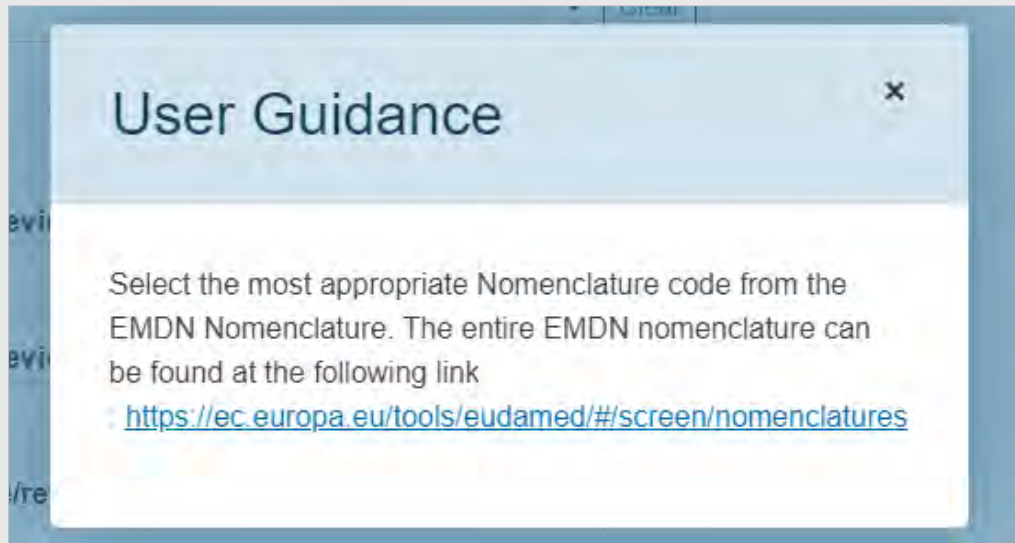
Please select...

Nomenclature text

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

**TIP**

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



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

5. Describe the device and its intended purpose:

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

Device Information
Incident Information
Manufacturer Analysis
General Comments

Does the device fulfil any of the following cases:

- for this device a scientific opinion has been asked in accordance with Article 52(9) MDR or Article 52(10) MDR
- for companion diagnostic a competent authority or European Medicines Agency (EMA) was consulted in accordance with section 5.2 of Annex IX IVDR or section 3.k of Annex X IVDR.

Yes

* Competent authority name or European Medicines Agency which delivered the scientific opinion or was consulted by the notified body

* Name(s) of the medicinal substance(s) / product(s), tissue(s), cell(s) of human origin or their derivative(s) associated with the device

* Name of the competent authority or EMA which delivered the scientific opinion or was consulted by the Notified Body



TIP

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

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

Device Information
Incident Information
Manufacturer Analysis
General Comments

UDI Production Identifier

UDI PI

Serial number

Lot/batch number

Software version

Firmware version

Device manufacturing date

Device expiry date

8. Fill in the *Device dates* section:

Device Information
Incident Information
Manufacturer Analysis
General Comments

Device dates

Please indicate the date of one of the following

	Year	Month
Select Device Date	Device Year	Device Month

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

Certificate Identification

[Certificate Identification](#)

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

Certificate Identification

– Certificate Identification

Notified body (NB) ID number

Please select...

Notified body (NB) certificate number

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

Market Distribution

Country where the device is made available on the market

[Check all](#) [Uncheck all](#)

<input type="checkbox"/> Austria	<input type="checkbox"/> Germany	<input type="checkbox"/> Poland	<input type="checkbox"/> Türkiye
<input type="checkbox"/> Belgium	<input type="checkbox"/> Greece	<input type="checkbox"/> Portugal	<input type="checkbox"/> Northern Ireland
<input type="checkbox"/> Bulgaria	<input type="checkbox"/> Hungary	<input type="checkbox"/> Romania	
<input type="checkbox"/> Croatia	<input type="checkbox"/> Ireland	<input type="checkbox"/> Slovakia	
<input type="checkbox"/> Cyprus	<input type="checkbox"/> Italy	<input type="checkbox"/> Slovenia	
<input type="checkbox"/> Czechia	<input type="checkbox"/> Latvia	<input type="checkbox"/> Spain	
<input type="checkbox"/> Denmark	<input type="checkbox"/> Lithuania	<input type="checkbox"/> Sweden	
<input type="checkbox"/> Estonia	<input type="checkbox"/> Luxembourg	<input type="checkbox"/> Iceland	
<input type="checkbox"/> Finland	<input type="checkbox"/> Malta	<input type="checkbox"/> Liechtenstein	
<input type="checkbox"/> France	<input type="checkbox"/> Netherlands	<input type="checkbox"/> Norway	

Other countries (outside EEA, TR, XI)

Please select...

3.1.5 Step 4: Incident information

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

EUDAMED Ref No: MIR-2024-06-000445

Version : 1 [Draft] | Last update : 2024-06-17

[Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

Device Information

Incident Information

Manufacturer Analysis

General Comments

* Nature of Incident

zzzzz

+ Medical device problem information

+ Clinical Information

+ Initial Reporter

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

Incident Information

Manufacturer Analysis

General Comments

IMDRF Annex A: Medical Device Problem terms and codes

+ Choice 1 (most relevant) : A180306 - Residue After Decontamination [A18/A1803/A180306] [Change](#)

[Add](#)

If exceptionally no relevant IMDRF code is available or specific enough, then provide additional information below



TIP
Find the correct IMDRF codes

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

Incident Information

Manufacturer Analysis

General Comments

Medical device problem information

Choice 1 (most relevant) : A180303 - Flushing Problem [A18/A1803/A180303] [Change](#)

Please start typing to show results

*Annex A: Medical Device Problem [?](#)

A180303 [Clear](#)

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

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

Administrative Information

Device Information

Incident Information

Manufacturer Analysis

General Comments

Number of patients involved

* What is the current location of the Device

☐ Healthcare facility/carer

☐ Patient/user

☐ In transit to manufacturer

☐ Distributor

☐ Discarded

☐ Remains implanted

☐ Manufacturer

☐ Unknown

☐ Other

Operator of device at the time of the incident

☐ Healthcare professional

☐ Patient/lay user

☐ Other

Usage of device (as intended)

☐ Initial use

☐ Reuse of a reusable medical device

☐ Reuse of a single use medical device

☐ Re-serviced/refurbished/fully refurbished

☐ Problem noted prior use

☐ Other

Remedial actions taken by healthcare facility, patient or user subsequent to the incident

4. Enter the remedial actions:

Remedial actions taken by healthcare facility, patient or user subsequent to the incident

+ Clinical Information

+ Initial Reporter

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

Playground

Device Information
Incident Information
Manufacturer Analysis
General Comments

IMDRF 'Health Effect' terms and codes (Annex E,F)

+
Choice 1 (most relevant) : E172005 - Radiodermatitis [E17|E1720|E172005] [Change](#)

Add

If exceptionally no relevant IMDRF code is available or specific enough, then provide additional information below

+
Choice 1 (most relevant) : F04 - Delay to Diagnosis [F04] [Change](#)

Add

If exceptionally no relevant IMDRF code is available or specific enough, then provide additional information below

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

Administrative Information
Device Information
Incident Information
Manufacturer Analysis
General Comments

Age of patient at the time of the incident

Patient is older than 1 year old
Please select...

Sex
☐ Female
☐ Male
☐ Other
☐ Not specified
Clear

Body weight (kg)

Patient height (cm)

List any of the patient's prior health condition or medication that may be relevant to this incident

+ Initial Reporter

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

The screenshot shows the 'Initial Reporter' section of the EUDAMED form. On the left, a sidebar contains 'Incident Information' (highlighted), 'Manufacturer Analysis', and 'General Comments'. The main area is titled 'Initial Reporter' and contains two sections: '* Role of initial reporter' with radio button options for 'Healthcare professional', 'Patient', 'Lay user', and 'Other'; and '* Healthcare facility information applicable' with a dropdown menu currently showing 'Please select...'.

3.1.6 Step 5: Manufacturer analysis

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

This screenshot shows the EUDAMED form with the reference number 'EUDAMED Ref No: MIR-2024-07-000521'. The status bar indicates 'Version : 1 [Draft]' and 'Last update : 2024-07-01'. A sidebar on the left lists 'Report Primary Details', 'Administrative Information', 'Device Information', 'Incident Information', 'Manufacturer Analysis' (highlighted), and 'General Comments'. The main content area shows three expandable sections: 'Manufacturer's preliminary comments' (expanded), 'Cause investigation and conclusion', and 'Similar serious incidents (for Final serious incidents)'. The 'Submit' button is in the top right corner.

2. Fill in all fields as required:

This screenshot shows the 'Manufacturer's preliminary comments' section expanded. The sidebar on the left is the same as in the previous screenshot. The main area contains three input fields: a text area for 'Preliminary results and conclusions of manufacturer's investigation' (containing 'dd'), a radio button selection for '* Suspicion of a relationship between the incident and the medicinal substance(s) / product(s), tissue(s), cell(s) of human origin or their derivative(s) associated with the device?' (with 'Yes' selected), and a text area for 'Initial actions (corrective and/or preventive) implemented by the manufacturer'. At the bottom, there is a question: 'What further investigations do you intend in view of reaching final conclusions?'.



TIP

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

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

EUDAMED Ref No: MIR-2024-06-000510

Version : 1 [Draft] | Last update : 2024-06-27

[Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

Device Information

Incident Information

Manufacturer Analysis

General Comments

+ Manufacturer's preliminary comments

+ **Cause investigation and conclusion**

+ Similar serious incidents (for Final serious incidents)

- Fill in all fields as required:

[Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

Device Information

Incident Information

Manufacturer Analysis

General Comments

- Manufacturer's preliminary comments

* Preliminary results and conclusions of manufacturer's investigation

dd

* Suspicion of a relationship between the incident and the medicinal substance(s) / product(s), tissue(s), cell(s) of human origin or their derivative(s) associated with the device?

☒ Yes

☐ No

Initial actions (corrective and/or preventive) implemented by the manufacturer

What further investigations do you intend in view of reaching final conclusions?

- Fill in the *IMDRF terms and codes Annex* section:

Playground

The screenshot shows the 'Cause Investigation' section of the EUDAMED interface. On the left, a sidebar contains 'Incident Information', 'Manufacturer Analysis' (highlighted), and 'General Comments'. The main area is titled 'IMDRF 'Cause Investigation' terms and codes (Annex B, C, D)'. It contains two sections: 'Annex B: Cause Investigation - Type of Investigation' and 'Annex C: Cause Investigation - Investigation Findings'. Each section has a search bar with a dropdown menu, an 'Add' button, and a text area for additional information. A note states: '* If exceptionally no relevant IMDRF code is available or specific enough, then provide additional information below'.



TIP

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

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

The screenshot shows the 'Cause Investigation' section with the 'Similar serious incidents (for Final serious incidents)' link highlighted. A hand icon points to the plus sign next to the link.

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

The screenshot shows the 'Similar serious incidents (for Final serious incidents)' form. The left sidebar contains 'Report Primary Details', 'Administrative Information', 'Device Information', 'Incident Information', 'Manufacturer Analysis' (highlighted), and 'General Comments'. The main area has a list of sections: '+ Manufacturer's preliminary comments', '+ Cause investigation and conclusion', and '- Similar serious incidents (for Final serious incidents)'. The first question is 'Are similar serious incidents identified based on IMDRF codes?'. Below the question is a text input field and two buttons: 'Yes' and 'No'.

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

Similar Incidents (for Final (Reportable incident))

Are Similar Incidents identified based on IMDRF Codes?

Yes

Identification of similar incidents using IMDRF Adverse Event Reporting terms and codes

☒ IMDRF code relating to most relevant 'Medical device problem' (Annex A)

☐ IMDRF code relating to most relevant 'Investigation finding' (Annex C, 'Cause investigation')

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

Administrative Information

Device Information

Incident Information

Manufacturer Analysis

General Comments

Are similar serious incidents identified based on IMDRF codes?

No

* Enter description of what similar serious incidents are based on and the rationale why the above IMDRF codes were not used

Use of in-house terms/codes for identifying similar incidents (only for transition period)

Most relevant medical Device problem

Code

Term

Most relevant root cause evaluation

Code

Term

Enter description of what similar serious incidents are based on and the rationale why the above codes were not used

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

Incident Information
Manufacturer Analysis
General Comments

Number of similar serious incidents and devices on the market

Indicate on which basis similar serious incidents were identified regarding the device or device variant

☐ Model
☐ Software
☐ Lot/Batch
☐ Product platform
☐ Other variant

Clear

Indicate to what criteria the number of devices on the market (also known as denominator data) is based on

☐ Devices placed on the market or put into service
☐ Units distributed within each time period
☐ Number of tests performed
☐ Number of episodes of use (for reusable devices)
☐ Active installed base
☐ Units distributed from the date of declaration of conformity/CE mark approval to the end date of each time period
☐ Number of devices implanted
☐ Other

Clear

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

Incident Information
Manufacturer Analysis
General Comments

Number of similar serious incidents (SI) and devices on the market for the indicated time periods

Time period (N) - year to date = MIR year

Start date

End date

Number of similar serious incidents (Country of SI)

Number of similar serious incidents (EEA+TR+XI)

Number of similar serious incidents (World)

Number of devices on the market (Country of SI)

Number of devices on the market (EEA+TR+XI)

Number of devices in on the market (World)

Time period (N-1) - calendar year, one year before MIR

☐ Data for Time Period N-1 will be entered

Time period (N-2) - calendar year, two years before MIR

☐ Data for Time Period N-2 will be entered

Time period (N-3) - calendar year, three years before MIR

☐ Data for Time Period N-3 will be entered

Comments on how similar serious incidents and associated number of devices on the market were determined

3.1.7 Step 6: General comments / Submission Comments

Type in the general comments:

EUDAMED Ref No: MIR-2024-06-000510

Version : 1 [Draft] | Last update : 2024-06-27

[Back to list](#) [Submit](#)

Report Primary Details
Administrative Information
Device Information
Incident Information
Manufacturer Analysis
General Comments

General comments

Submission

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

EUDAMED Ref No: MIR-2024-06-000445

Version : 1 [Draft] | Last update : 2024-06-18

[Back to list](#) [Submit](#)

Report Primary Details
Administrative Information
Device Information
Incident Information
Manufacturer Analysis
General Comments

Device Information

Device Information

Does the device have a known identifier?
Yes [Clear](#)

UDI-DI/EUDAMED DI

UDI-DI/EUDAMED ID:	78533221569816 [GS1]	Change
Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)	
Risk Class:	Class Ila	
Basic UDI-DI/Eudamed-DI:	78533221569815WH [GS1]	
Unit of use UDI-DI:	-	
Model:	-	
Device trade name:	-	
Reference/Catalogue number:	225	
Medical device terminology:	EMDN	
Nomenclature code(s):	A019015 - PERI- AND NEO-NATAL EPICRANIAL NEEDLES	

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

Dossier MIR-2024-06-000445 : Draft

After submission, the MIR form will have the state REGISTERED and will be visible to the Competent Authorities. The publicly available information from the MIR form will also be visible on the public website of EUDAMED. You may view your data immediately after the submission, or by accessing the dossier in "Search and manage Vigilance items page"

Progress bar stages:

- Draft With Submission (Active)
- Draft With Submission
- Registered Submitted to CA

Attachment (PDF)

Choose file

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

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

CURRENT ACTOR: Manufacturer BE-MF-000000141, ManuEU_Vig [Belgium]

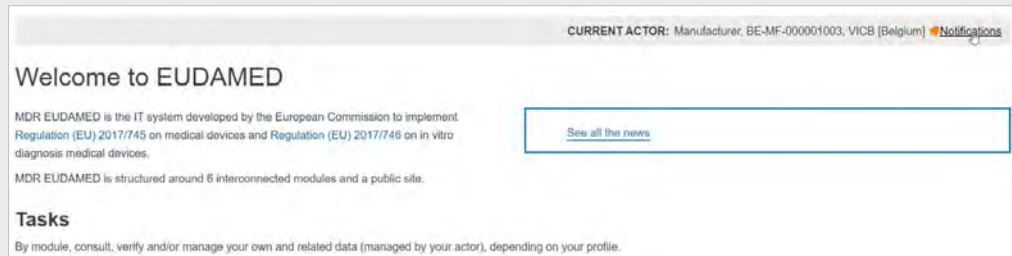
EUDAMED Ref No: MIR-2024-06-000445

Version: 1 [Current] | Last update: 2024-06-18

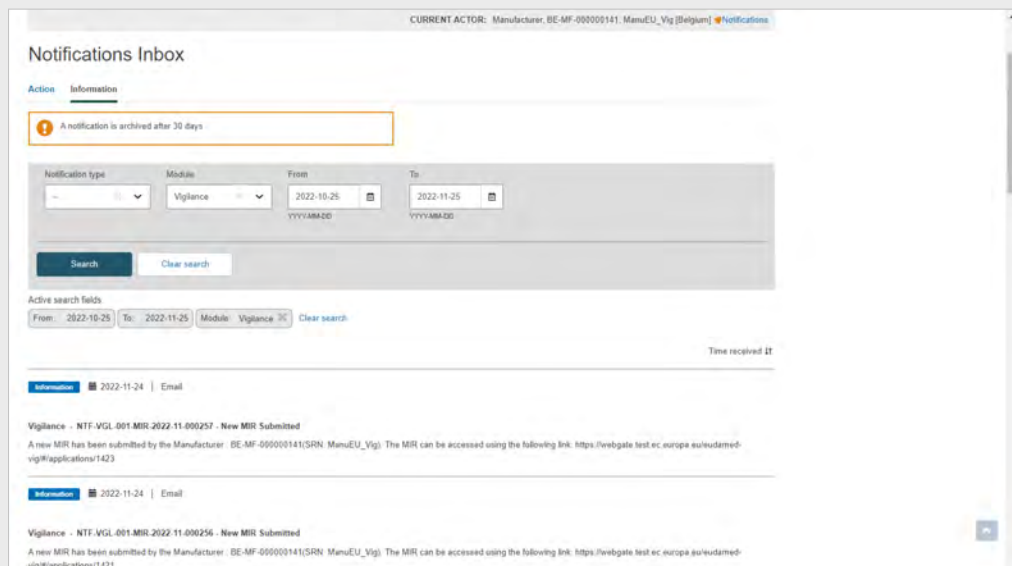
You have now completed the MIR registration process.

**NOTE**

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



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



Notifications are also sent by email.

3.2 Manage MIR

3.2.1 Action history overview

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

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

CURRENT ACTOR: Manufacturer, BE-MF-00000141, ManuEU_Vig [Belgium]

EUDAMED Ref No: MIR-2024-06-000445

Version : 2 [Draft] | Last update: 2024-06-18

[Back to list](#) Submit

Report Primary Details
Administrative Information
Device Information
Incident Information
Manufacturer Analysis
General Comments
Action history overview

Report Primary Details

Form Type
MIR(Manufacturer Incident Report)

Manufacturer's reference number for this incident
3232

Country where the incident occurred
Belgium

Competent Authority

Actor ID/SRN:	BE-CA-009
Organisation name:	DKUMAR Actor
Address:	StreetNumber Street 123 12345 CityName Belgium

Manufacturer



TIP Looking for a report?

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

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

Manufacturer Analysis
General Comments
Action history overview

UDI-DI/EUDAMED DI

UDI-DI/EUDAMED ID: 78533221569816 [GS1]

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

Risk Class: Class IIa

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

EUDAMED Ref No: MIR-2024-06-000445

Version : 2 [Draft] | Last update: 2024-06-18

[Back to list](#) Submit

Report Primary Details
Administrative Information
Device Information
Incident Information
Manufacturer Analysis
General Comments
Action history overview

2024-06-18 16:54:49
Version: 1

State : Registered
Report Status: Initial

**TIP**

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

3.2.2 Update MIR (create new version)

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

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

The MIR sections will become editable.

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

**TIP**

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

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

CURRENT ACTOR: Manufacturer, BE-MF-000000141, ManuEU_Vig [Belgium]

EUDAMED Ref No: MIR-2024-06-000446

Version : 2 [Draft] | Last update : 2024-06-18

[Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

Device Information

Incident Information

Manufacturer Analysis

General Comments

Action history overview

Administrative Information

* Status

☐ Initial

☐ Follow up

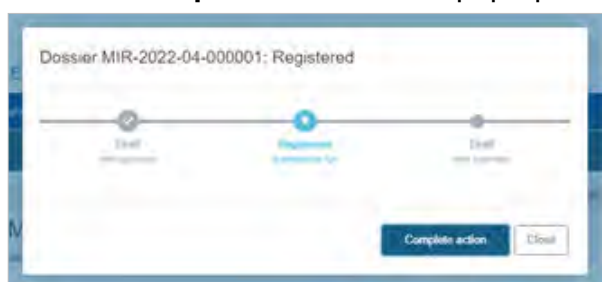
☒ Combined initial and final

☐ Final (Reportable incident)

☐ Final (Non-Reportable incident)

Reference number assigned by NCA for this incident

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



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



NOTE

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

CURRENT ACTOR: Manufacturer, BE-MF-000000141, ManuEU_Vig [Belgium] [Notifications](#)

Notifications Inbox

[Action](#) [Information](#)

A notification is archived after 30 days

Notification type: Module: From: 2022-11-06 To: 2022-12-06

Search

Active search fields: From: 2022-11-06 To: 2022-12-06

Time received if

Information 2022-12-06 | Email

Vigilance - NTF-VGL-002-MIR-2022-11-000219 - BE-MF-000000141[EUDAMED Reference: MIR-2022-11-000219]: New MIR version has been submitted

A new MIR has been submitted by the Manufacturer: ManuEU_Vig (SRN: BE-MF-000000141)

MIR EUDAMED Reference: (EUDAMED Reference: MIR-2022-11-000219)

The MIR can be accessed using the following link: <https://webgate.test.ec.europa.eu/eudamed-vig/#/applications/1328>

Information 2022-12-06 | Email

Notifications are also sent by email.

4 FSCA

4.1 Register a new FSCA

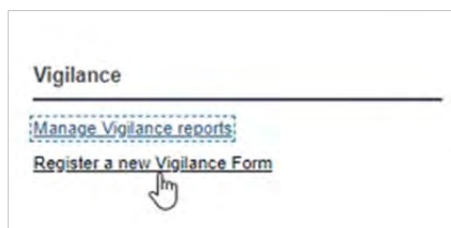


NOTE

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

4.1.1 Step 0: Create initial FSCA dossier

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



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

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



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



The system will automatically retrieve your Actor ID/SRN.

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

CURRENT ACTOR: Manufacturer, AF-MF-000000122, John's NonEU MF [Afghanistan]

Vigilance Templates

Select the template type for the new dossier

FSCA (Field Safety Corrective Action) ▼

Manufacturer

AF-MF-000000122 ▼

Manufacturer reference

FSCA_14.03_001

Coordinating Competent Authority country

Coordinating Competent Authority Country ▼

Manufacturer

SRN: AF-MF-000000122

Organisation name: John's NonEU MF

Address: Test, 2121 Test
Test
Afghanistan

Create Form

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

Vigilance Templates

Select the template type for the new dossier

FSCA (Field Safety Corrective Action) ▼

Manufacturer

AF-MF-000000122 ▼

Manufacturer reference

FSCA_14.03_001

Coordinating Competent Authority country

Austria ▼

Coordinating Competent Authority

AF-CA-001 ▼

Manufacturer

SRN: AF-MF-000000122

Organisation name: John's NonEU MF

Address: Test, 2121 Test
Test
Afghanistan

Create Form

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

Manufacturer

SRN:	AF-MF-000000122
Organisation name:	John's NonEU MF
Address:	Test, 2121 Test Test Afghanistan

[Create Form](#)

4.1.2 Step 1: Report primary details

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

CURRENT ACTOR: Manufacturer, AF-MF-000000122, John's NonEU MF [Afghanistan]

EUDAMED Ref No: FSCA_0-2022-03-000026

Version: 1 [Draft] | Last update: 2022-03-14

[Back to list](#) [Submit](#)

Report Primary Details

- Administrative information
- Device Information
- Corrective Action Details
- FSCA Categorisation
- Comments

Report Primary Details

Report Type
FSCA (Field Safety Corrective Action)

Manufacturer reference
FSCA_14.03_001

Coordinating Country for FSCA
Austria

Coordinating Competent Authority

SRN:	AT-CA-001
Organisation name:	Federal Ministry of Health (BMF) Dept. III/3 Pharmaceuticals & Medical Devices
Address:	A-1030 Vienna Austria

Manufacturer

SRN:	AF-MF-000000122
Organisation name:	John's NonEU MF
Address:	Test, 2121 Test Test Afghanistan

Please ensure the information provided is correct.

4.1.3 Step 2: Administrative information

- Click on the *Administrative information* section from the menu on the left:

EUDAMED Ref No: FSCA-2024-09-000870

Version : 1 [Draft] | Last update : 2024-09-12

[Back to list](#) [Submit](#)

Report Primary Details

Administrative information

Device Information

Corrective Action Details

FSCA Categorisation

Comments

Country specific details

* FSCA Status

☐ Initiated

☐ In progress

☐ Action completed

* Affected Countries

Please select...

[Add](#)

* When was the decision taken to perform this FSCA?

What is the FSCA based on?

Actual incident(s)

* Actual incidents

☐ Yes ☐ No

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

Report Primary Details

Administrative information

Device Information

Corrective Action Details

FSCA Categorisation

Comments

Country specific details (Germany)

* FSCA Status

☒ Initiated

☐ In progress

☐ Action completed

* Affected Countries

Germany

[Remove](#)

[Add](#)



TIP

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

* Affected Countries

Germany [Clear](#)

Belgium [Clear](#)

[Add](#) [Remove](#)

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

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

* When was the decision taken to perform this FSCA?

< Jun 2023 >

Mo Tu We Th Fr Sa Su based on?

29	30	31	1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	1	2
3	4	5	6	7	8	9

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

Playground

Administrative information

Device Information

Corrective Action Details

FSCA Categorisation

Comments

Country specific details (Germany)

What is the FSCA based on?

Actual incident(s)

* Actual incidents
☐ Yes ☐ No

QA internal testing

Device malfunction found in internal (QA) testing
☐ Yes ☐ No

MTR (Trend)

Reference to Trend
☐ Yes ☐ No

PSUR

Reference to PSUR
☐ Yes ☐ No

PMCF/PMPF Investigation

Reference to PMCF/PMPF investigation
☒ Yes
☐ No

Clear

* Please provide the identifier of the PMCF/PMPF investigation

Other

Other references

Playground

**TIP**

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

The screenshot shows the 'Administrative information' tab selected on the left. The main section is titled 'What is the FSCA based on?'. It has two sub-sections: 'Device Information', 'Corrective Action Details', 'FSCA Categorisation', 'Comments', and 'Country specific details (Germany)' on the left; and 'Actual incident(s)' on the right. Under 'Actual incident(s)', there is a radio button for '* Actual incidents' with 'Yes' selected and 'No' as an option. Below this is a dropdown menu for 'Reference to actual incident (MIR)' with the text 'Please select...'.

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

The screenshot shows the 'QA internal testing' section. It has a heading 'QA internal testing' and a sub-section 'Device malfunction found in internal (QA) testing' with a radio button for 'Yes' selected and 'No' as an option. Below this is a text input field for '* Device malfunction details' with an 'Add' button.

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

The screenshot shows the 'Contact information of the report' section. It has a sub-section 'Manufacturer contact details' with a heading 'Manufacturer Contact Details'. Below this are four text input fields: '* Contact First Name', '* Contact Last Name', '* E-mail', and '* Phone Number'. At the bottom, there is a section '* Contact details for this report' with two radio buttons: 'Same as manufacturer' and 'Other (e.g. subcontractor)'.

4.1.4 Step 3: Device information

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

The screenshot shows the 'Device Information' tab selected on the left. The main section is titled 'Actual incident(s)'. It has a sub-section 'Actual incidents' with a radio button for 'Yes' selected and 'No' as an option. Below this is a text input field for 'EUDAMED Ref No : MIR-2022-03-000107 | Manufacturer reference number' with an 'Add' button.

2. Select the regulatory scope:

EUDAMED Ref No: FSCA-2024-09-000874

Version : 1 [Draft] | Last update: 2024-09-11

[Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

Device Information

Regulatory scope type
Please select...

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

EUDAMED Ref No: FSCA-2024-09-000874

Version : 1 [Draft] | Last update: 2024-09-11

[Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

Device Information

Corrective Action Details

FSCA Categorisation

Regulatory scope type
MD (MDR, MDD, AIMDD) [Clear](#)

Device Information

+ [Device details](#)

[Add](#)

4. Provide the *Device Identifier*:

Device Information

Corrective Action Details

FSCA Categorisation

Comments

Country specific details

Device Information

- [Device details](#)

Device Identifier [?](#)

12345IVDRYG [Clear](#)

Start typing to search...

UDI-DI/EUDAMED ID:	12345IVDRYG (HIBCC)	Change
Applicable legislation:	IVDR (REGULATION (EU) 2017/746 on in vitro diagnostic medical devices)	
Risk Class:	Class D	
Basic UDI-DI/Eudamed-DI:	312312Test123123NN [GS1]	

**NOTE**

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

Administrative Information

Device Information

Incident Information

Manufacturer Analysis

General Comments

Medical device terminology: EMON

Nomenclature code(s): B02010201 : LABORATORY ERYTHROCYTES (RBC) LEUKOREDUCTION FILTERS A020102010101 : INFUSION AND IRRIGATION SYRINGES, 2-PIECE LUER CONE, 2-PIECE WITH NEEDLE, SINGLE-USE

GTIN number

Device Nomenclature Code [?](#)

Please select...

Description of the device and its intended purpose [?](#)

sdasd

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

Administrative information

Device Information

Corrective Action Details

FSCA Categorisation

Comments

Country specific details

Device nomenclature codes

Code:

*Device Nomenclature Code

Please select...

Nomenclature text

Not provided

Add

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

Administrative information

Device Information

Corrective Action Details

FSCA Categorisation

Comments

Country specific details

Device nomenclature codes

Code:

*Device Nomenclature Code

D01010101 Clear

Nomenclature text

D01010101: Glutaraldehyde, basic solution for the disinfection of medical devices

Add

6. Describe the device and its intended purpose:

Administrative information

Device Information

Corrective Action Details

FSCA Categorisation

* Description of the device and its intended purpose

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

Device Information

Corrective Action Details

FSCA Categorisation

Comments

Country specific details

* Competent authority name or European Medicines Agency which delivered the scientific opinion or was consulted by the notified body

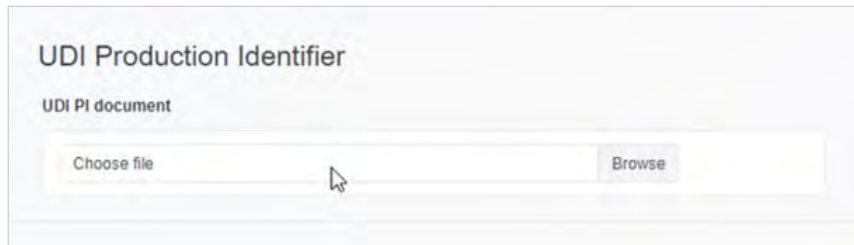
* Name(s) of the medicinal substance(s) / product(s), tissue(s), cell(s) of human origin or their derivative(s) associated with the device



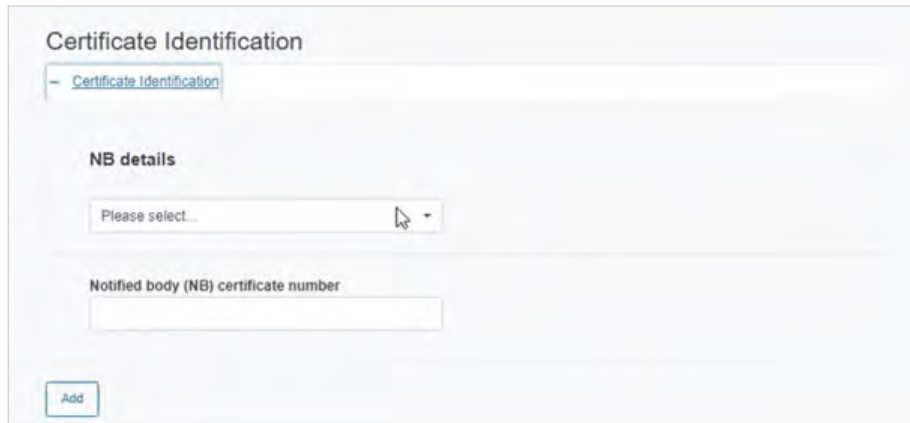
IMPORTANT

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

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

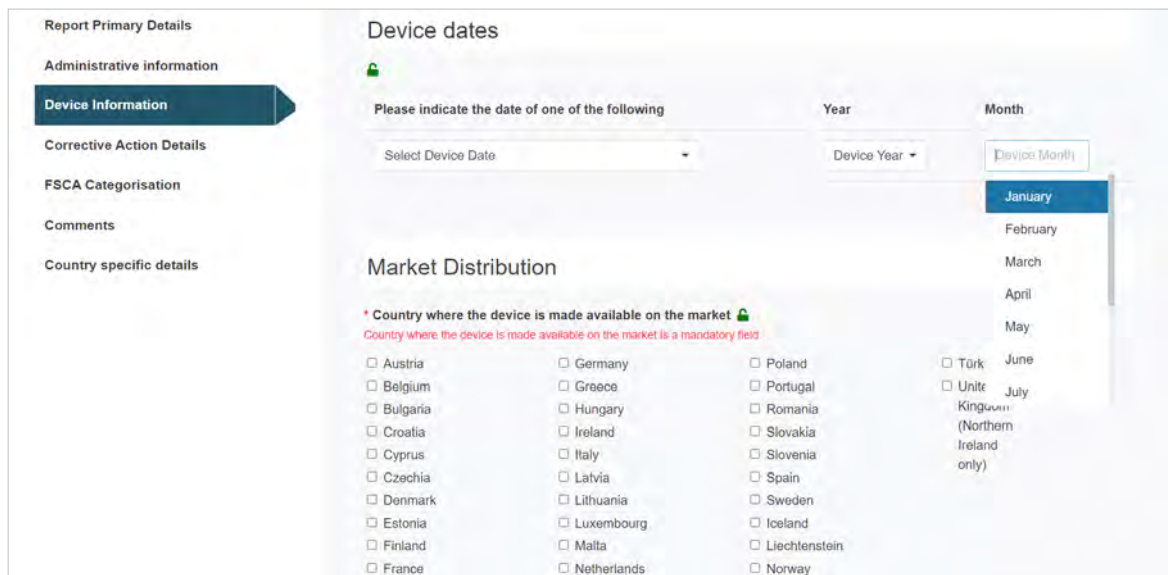


9. Click on the plus sign next to *Certificate Identification* and complete the appearing fields:



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

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



Device dates

Please indicate the date of one of the following

Select Device Date

Device Year

Device Month

Market Distribution

* Country where the device is made available on the market

Country where the device is made available on the market is a mandatory field

<input type="checkbox"/> Austria	<input type="checkbox"/> Germany	<input type="checkbox"/> Poland
<input type="checkbox"/> Belgium	<input type="checkbox"/> Greece	<input type="checkbox"/> Portugal
<input type="checkbox"/> Bulgaria	<input type="checkbox"/> Hungary	<input type="checkbox"/> Romania
<input type="checkbox"/> Croatia	<input type="checkbox"/> Ireland	<input type="checkbox"/> Slovakia
<input type="checkbox"/> Cyprus	<input type="checkbox"/> Italy	<input type="checkbox"/> Slovenia
<input type="checkbox"/> Czechia	<input type="checkbox"/> Latvia	<input type="checkbox"/> Spain
<input type="checkbox"/> Denmark	<input type="checkbox"/> Lithuania	<input type="checkbox"/> Sweden
<input type="checkbox"/> Estonia	<input type="checkbox"/> Luxembourg	<input type="checkbox"/> Iceland
<input type="checkbox"/> Finland	<input type="checkbox"/> Malta	<input type="checkbox"/> Liechtenstein
<input type="checkbox"/> France	<input type="checkbox"/> Netherlands	<input type="checkbox"/> Norway

☐ Türkiye
☐ United Kingdom (Northern Ireland only)
☐ June
☐ July
☐ August
☐ September
☐ October
☐ November
☐ December

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

Market Distribution

Country where the device is made available on the market

Check all Uncheck all

<input type="checkbox"/> Austria	<input type="checkbox"/> Germany	<input type="checkbox"/> Poland	<input type="checkbox"/> Türkiye
<input type="checkbox"/> Belgium	<input type="checkbox"/> Greece	<input type="checkbox"/> Portugal	<input type="checkbox"/> United Kingdom (Northern Ireland only)
<input type="checkbox"/> Bulgaria	<input type="checkbox"/> Hungary	<input type="checkbox"/> Romania	
<input type="checkbox"/> Croatia	<input type="checkbox"/> Ireland	<input type="checkbox"/> Slovakia	
<input type="checkbox"/> Cyprus	<input type="checkbox"/> Italy	<input type="checkbox"/> Slovenia	
<input type="checkbox"/> Czechia	<input type="checkbox"/> Latvia	<input type="checkbox"/> Spain	
<input type="checkbox"/> Denmark	<input type="checkbox"/> Lithuania	<input type="checkbox"/> Sweden	
<input type="checkbox"/> Estonia	<input type="checkbox"/> Luxembourg	<input type="checkbox"/> Iceland	
<input type="checkbox"/> Finland	<input type="checkbox"/> Malta	<input type="checkbox"/> Liechtenstein	
<input type="checkbox"/> France	<input type="checkbox"/> Netherlands	<input type="checkbox"/> Norway	

Others

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

Associated Devices or Device Accessories

Use of accessories

Use of associated devices or other devices

4.1.5 Step 4: Corrective action details

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

Playground

EUDAMED Ref No: FSCA-2025-04-000068

Version : 1 [Draft] | Last update : 2025-04-10

[< Back to list](#)

Report Primary Details

Administrative information

Device Information

Corrective Action Details

FSCA Categorisation

Comments

Country specific details (Austria)

Corrective Action

+ Corrective Action

Subactions

+ Subaction details [1]

[Add](#)

NOTE

Corrective action vs Sub-action details

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

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

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

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

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

CURRENT ACTOR: Manufacturer, AF-MF-000000122, John's NonEU MF (Afghanistan)

EUDAMED Ref No: FSCA_0-2022-03-000026

Version : 1 [Draft] | Last update: 2022-03-14

[Back to list](#) Submit

Report Primary Details

Administrative information

Device Information

Corrective Action Details

FSCA Categorisation

Comments

[Corrective Action](#)

[Subaction details](#)

[Add](#)

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

EUDAMED Ref No: FSCA_0-2022-03-000026

Version : 1 [Draft] | Last update: 2022-03-14

[Back to list](#) Submit

Report Primary Details

Administrative information

Device Information

Corrective Action Details

FSCA Categorisation

Comments

Country specific details

Country specific details

Country specific details

Corrective Action

* Background information and or technical problem leading to the FSCA

Test

* Summarized health hazard information (in reference to users/patients/others)

Test

* Probability of problem arising

Test

Is the root cause known

☒ Yes ☐ No

* Description on how affected devices were identified

Test

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

Playground

* Manufacturer Action Required

Product Removal : Partial Recall (Lot/Batch/Model)

Product Removal : Full Recall

IFU or labelling change

Software Upgrade

On-site modification/inspection by

Customer information only

Other

to be taken by the manufacturer, distributor, and/or user

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

* User Action Required

Quarantine Device Clear

Return Device Clear

Add

Remove

Remove

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

* Justification of the action(s) (corrective / preventive) to be taken by the manufacturer, distributor, and/or user

Test

Details of required patient level follow-up / review of patients' previous results or a justification why none is required

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

Customer list (uploaded document)

Choose file Browse

Add document

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

Other important documents to the FSCA (Uploaded documents)

Choose file Browse

Add document

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

+ [Corrective Action](#)

+ [Subaction details](#)

Add

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

- Subaction details

* Short action description

Subaction to be finalized on

Progress (%)

Subaction actually finalised on



IMPORTANT

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

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

Important documents for this subaction

Choose file Browse

Add document

Important documents for this subaction

MIR_form_v7.3_0_PMSV_WG_agreement.pdf

Add document

4.1.6 Step 5: FSCA categorisation

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

EUDAMED Ref No: FSCA-2024-09-000870

Version: 1 [Draft] | Last update: 2024-09-11

[Back to list](#) [Submit](#)

Report Primary Details

Administrative information

Device Information

Corrective Action Details

FSCA Categorisation

Comments

Country specific details

IMDRF Annex A: Medical Device Problem terms and codes

Enter choice 1 (most relevant)

*Annex A: Medical Device Problem

Please select...

Add

If exceptionally no relevant IMDRF code is available or specific enough, then provide additional information below

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

Playground

Report Primary Details
Administrative information
Device Information
Corrective Action Details
FSCA Categorisation
Comments
Country specific details

IMDRF 'Cause Investigation' terms and codes (Annex B, C, D)

+ Choice 1 (most relevant) : B07 - Testing of Raw/Starting Materials [B07] [Change](#)

Add

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain

test explanation

+ Choice 1 (most relevant) : C0209 - Signal Loss [C02|C0209] [Change](#)

Add

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain

test

+ Choice 1 (most relevant) : D0101 - Design Inadequate for Purpose [D01|D0101] [Change](#)

Add

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain

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

FSCA Categorisation
Comments
Country specific details

IMDRF 'Health Effect' terms and codes (Annex E, F)

+ Choice 1 (most relevant) : E172004 - Eczema [E17|E1720|E172004] [Change](#)

Add

If exceptionally no relevant IMDRF code is available or specific enough, then provide additional information below

+ Choice 1 (most relevant) : F0101 - Therapeutic Response Decreased [F01|F0101] [Change](#)

Add

If exceptionally no relevant IMDRF code is available or specific enough, then provide additional information below

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

FSCA Categorisation

Comments

Country specific details

IMDRF Component codes (Annex G)

+ Choice 1 (most relevant) : G0405203 - Clamp [G04|G04052|G0405203] [Change](#)

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain

4.1.7 Step 6: Comments

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

Report Primary Details

Administrative information

Device Information

Corrective Action Details

FSCA Categorisation

Comments

Country specific details (Belgium)

Country specific details (Austria)

Country specific details (Greece)

2. Type any general comments relevant to this FSCA:

EUDAMED Ref No: FSCA_0-2022-03-000026

Version: 1 (Draft) | Last update: 2022-03-14

[Back to list](#)

Report Primary Details

Administrative information

Device Information

Corrective Action Details

FSCA Categorisation

Comments

Country specific details (Belgium)

Country specific details (Austria)

Country specific details (Greece)

General comments

Test

4.1.8 Step 7: Country-specific details / Submission

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

CURRENT ACTOR: Manufacturer, AF-MF-000000122, John's NonEU MF [Afghanistan]

EUDAMED Ref No: FSCA_0-2022-03-000026

Version : 1 [Draft] | Last update: 2022-03-14

[Back to list](#) Submit

Report Primary Details

Administrative information

Device Information

Corrective Action Details

FSCA Categorisation

Comments

Country specific details (Belgium)

Country specific details (Austria)

Country specific details (Greece)

Administrative information

FSCA Status

☒ Initial

☐ Follow up

☐ Final

*Affected Countries

Austria Clear

Belgium Clear

Greece Clear

Remove

Remove

Remove

Add

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

CURRENT ACTOR: Manufacturer, AF-MF-000000122, John's NonEU MF [Afghanistan]

EUDAMED Ref No: FSCA_0-2022-03-000026

Version : 1 [Draft] | Last update: 2022-03-14

[Back to list](#) Submit

Report Primary Details

Administrative information

Device Information

Corrective Action Details

FSCA Categorisation

Comments

Country specific details (Belgium)

Country specific details (Austria)

Country specific details (Greece)

Country for which Country specific details are provided

Belgium

Competent Authority

Please select...

*NCA number for the FSCA

Contact person for this country

→ Contact Person for this Country

Contact First Name

Contact Last Name

Email

Phone number

*Number of devices affected

Comments

2. Select the appropriate Competent Authority for this country:

CURRENT ACTOR: Manufacturer, AF-MF-000000122, John's NonEU MF (Afghanistan)

EUDAMED Ref No: FSCA_0-2022-03-000026

Version: 1 [Draft] | Last update: 2022-03-14

[Back to list](#) **Submit**

Report Primary Details

Administrative Information

Device Information

Corrective Action Details

FSCA Categorisation

Comments

Country specific details (Belgium)

Country specific details (Austria)

Country specific details (Greece)

Country for which Country specific details are provided
Belgium

Competent Authority

BE-CA-009 - Test FDG CA cips mail

BE-CA-008 - CA TEST 002

BE-CA-001 - Agence Fédérale des Médicaments et des Produits de Santé/Federale Agentschap voor Geneesmiddelen en Gezondheidsproducten

BE-CA-999 - DG SANTE CA

GB-CA-001 - Medicines and Healthcare products Regulatory Agency

CH-CA-001 - Schweizerisches Heilmittelinstitut/ Swiss Agency for Therapeutic Products

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

FSCA Categorisation

Comments

Country specific details (Belgium)

Country specific details (Austria)

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

Address: B-1060 Brussels
Belgium

***NCA number for the FSCA**

NCA_23211412

- Provide the contact person's details for the specified country:

Contact person for this country

– Contact Person for this Country

Contact First Name

Test

Email

Test@test.com

Contact Last Name

Test

Phone number

341242342

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

***Number of devices affected**

12

Comments

Test

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

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

8. Follow the same process for all sub-actions listed inside this country's *Country-specific details* section.
9. Click on each *Country-specific details* section and repeat the process for each country added:

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

CURRENT ACTOR: Manufacturer, AF-MF-000000122, John's NonEU MF [Afghanistan]

EUDAMED Ref No: FSCA_0-2022-03-000026

Version: 1 [Draft] | Last update: 2022-03-14

[Back to list](#) [Submit](#)

Report Primary Details

Administrative information

Device Information

Corrective Action Details

FSCA Categorisation

Comments

Country specific details (Belgium)

Country specific details (Austria)

Country specific details (Greece)

Country for which Country specific details are provided
Belgium

Competent Authority

Actor ID/SRN: BE-CA-001 [Change](#)

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

Address: B-1060 Brussels
Belgium

NCA number for the FSCA
NCA_23211412

Contact person for this country

— Contact Person for this Country

Contact First Name: Test

Contact Last Name: Test

Email: Test@test.com

Phone number: 341242342

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

Dossier FSCA-2022-04-000004: Draft

This FSCA report version will have the state "Submitted". The related FSN(s) should be registered in order to have the FSCA report in state Registered. Competent Authorities will be notified and will have access to the FSCA report.

Submitted (Completed) Draft (Current) Registered (Completed)

[Complete action](#) [Close](#)

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

**NOTE**

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

4.2 Update FSCA (create new version)

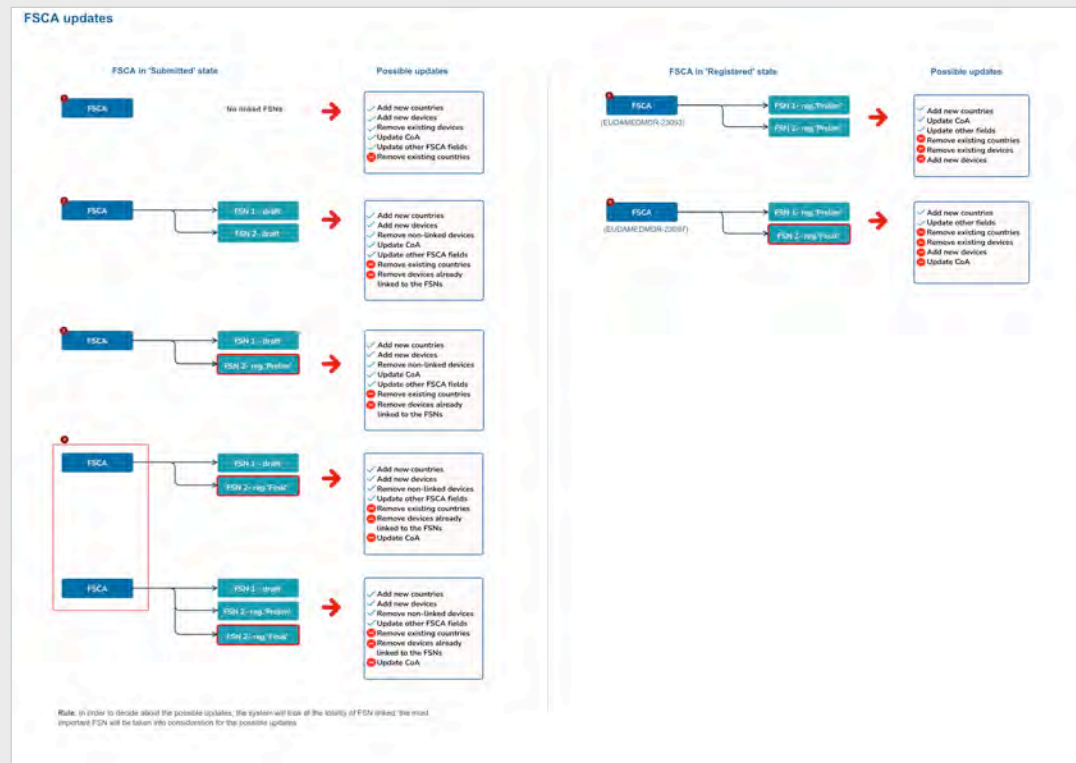
Once an FSCA is submitted, it can be updated through the creation of a new version.



NOTE

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

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



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

EUDAMED Ref No: FSQA-2023-09-002832

Version: 2 [Current] | Last update: 2023-09-13

[Back to list](#) [Create new version](#)

Report Primary Details

Administrative information

Form Type
FSQA (Field Safety Corrective Action)

Device Information

Manufacturer reference
0512

Coordinating Country for FSQA
Austria

Coordinating Competent Authority

FSQA Categorisation

Comments

Country specific details (Austria)

Country specific details (Belgium)

Report history overview

SRN: AT-CA-042

Organisation name: NEKVIE

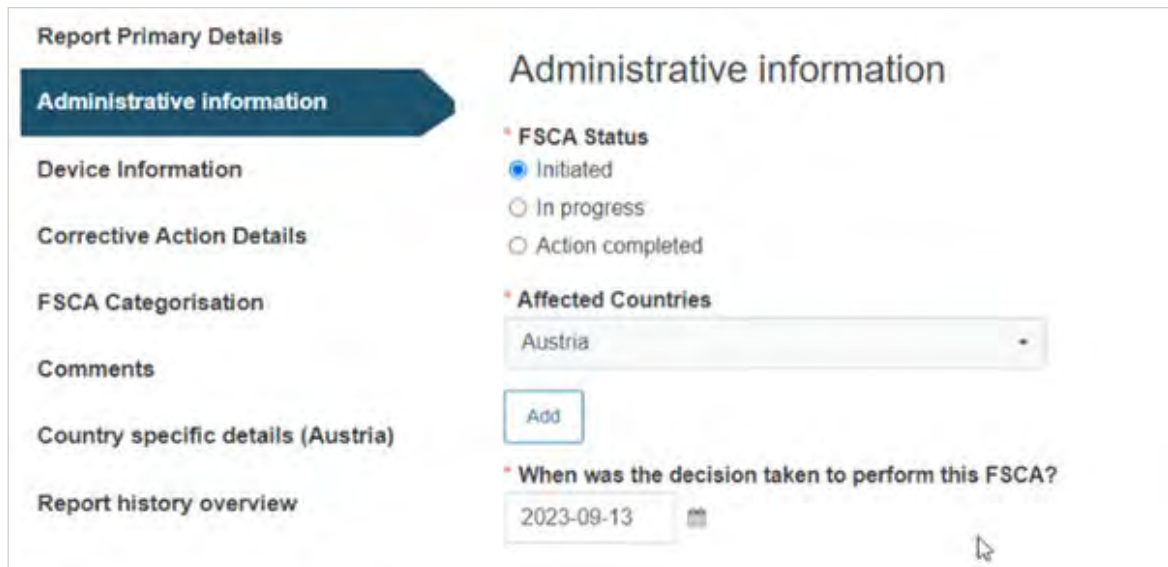
Address: 56523 Struitt
6523 3510125
Vervik, Austria

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



The applicable FSCA sections will become accessible for updates.

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



**IMPORTANT**

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

EUDAMED Ref No: FSCA-2024-03-000063

Version: 1 [Current] | Last update: 2024-03-15

[Back to list](#)

Report Primary Details

Administrative information

Device Information

Corrective Action Details

FSCA Categorisation

Comments

Country specific details (Belgium)

Report history overview

Regulatory scope type

MD (MDR, MDD, AIMDD)

Device Information

Device details

Applicable legislation

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

Is it a custom-made device?

No

Device

UDI-DI/EUDAMED ID

This device is linked to the following FSN(s)

FSN-2024-03-000038

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

EUDAMED Ref No: FSCA-2023-09-002832

Version: 3 [Draft] | Last update: 2023-09-14

[Back to list](#) [Submit](#)

Report Primary Details

Administrative information

Device Information

Corrective Action Details

FSCA Categorisation

Comments

Country specific details (Austria)

Country specific details (Belgium)

Report history overview

Report Primary Details

Form Type

FSCA (Field Safety Corrective Action)

Manufacturer reference

0513

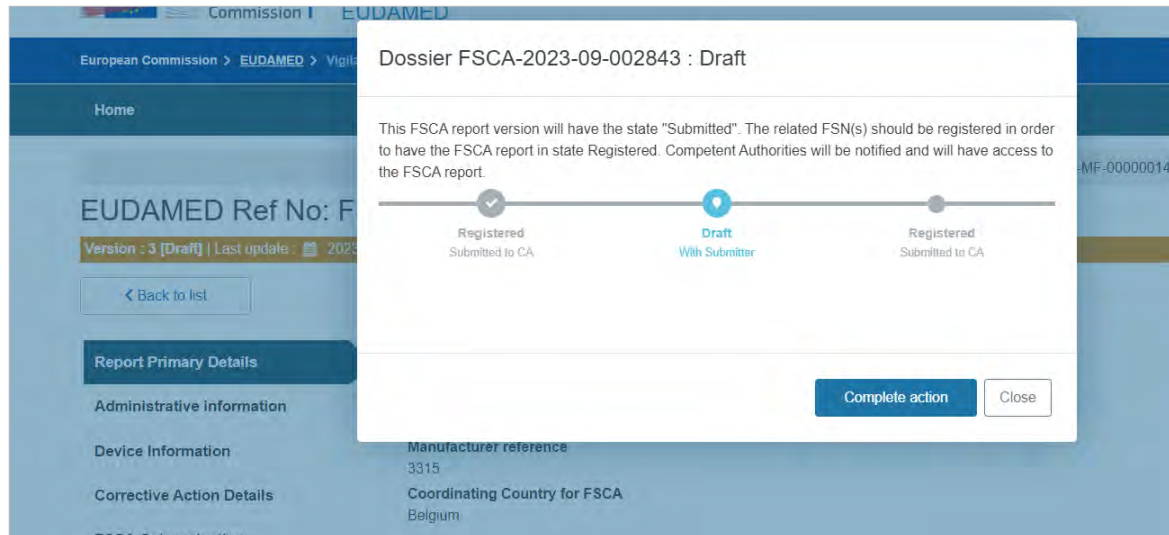
Coordinating Country for FSCA

Austria

Coordinating Competent Authority

SRN:	AT-CA-042
Organisation name:	NEKVE
Address:	56523 Strud 0523 0518135 Vienna Austria

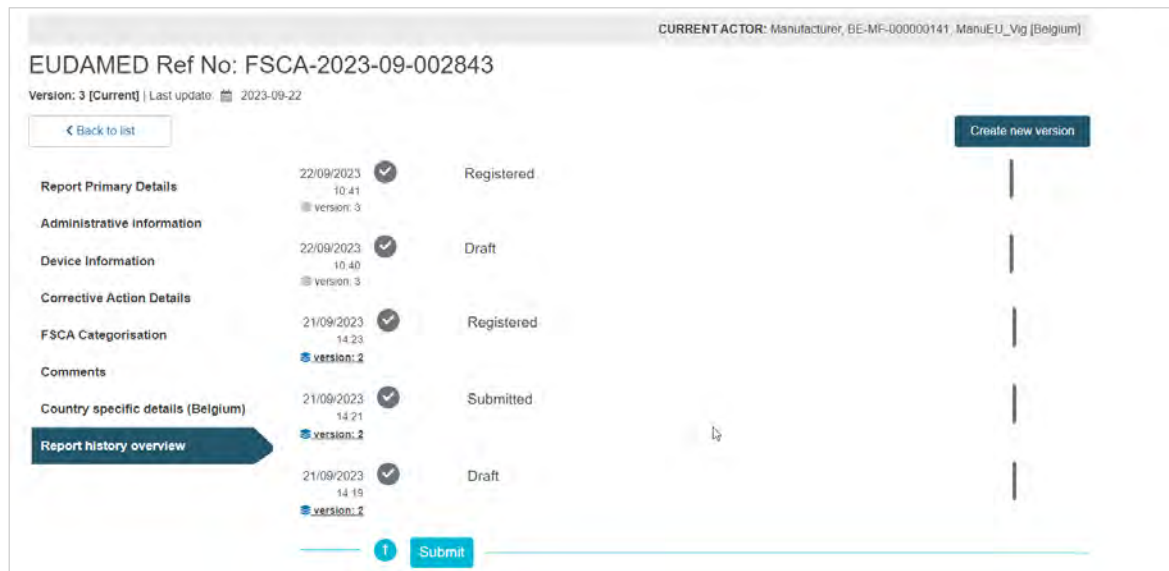
5. Click on **Complete action** in the pop-up window to finalise the action:



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



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





NOTE

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

Information 📅 2023-09-21 | Email

Vigilance - VGL-008 - BE-MF-000000141(Eudamed Reference: FSCA-2023-09-002843) New FSCA version submitted

A new FSCA version has been submitted by the Manufacturer : ManuEU_Vig (SRN: BE-MF-000000141)

The FSCA can be accessed using the following link: <https://webgate.test.ec.europa.eu/eudamed/vig/#/applications/14328>

Playground

5 FSN

5.1 Register a new FSN



NOTE

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



VIDEO: Register a new FSN



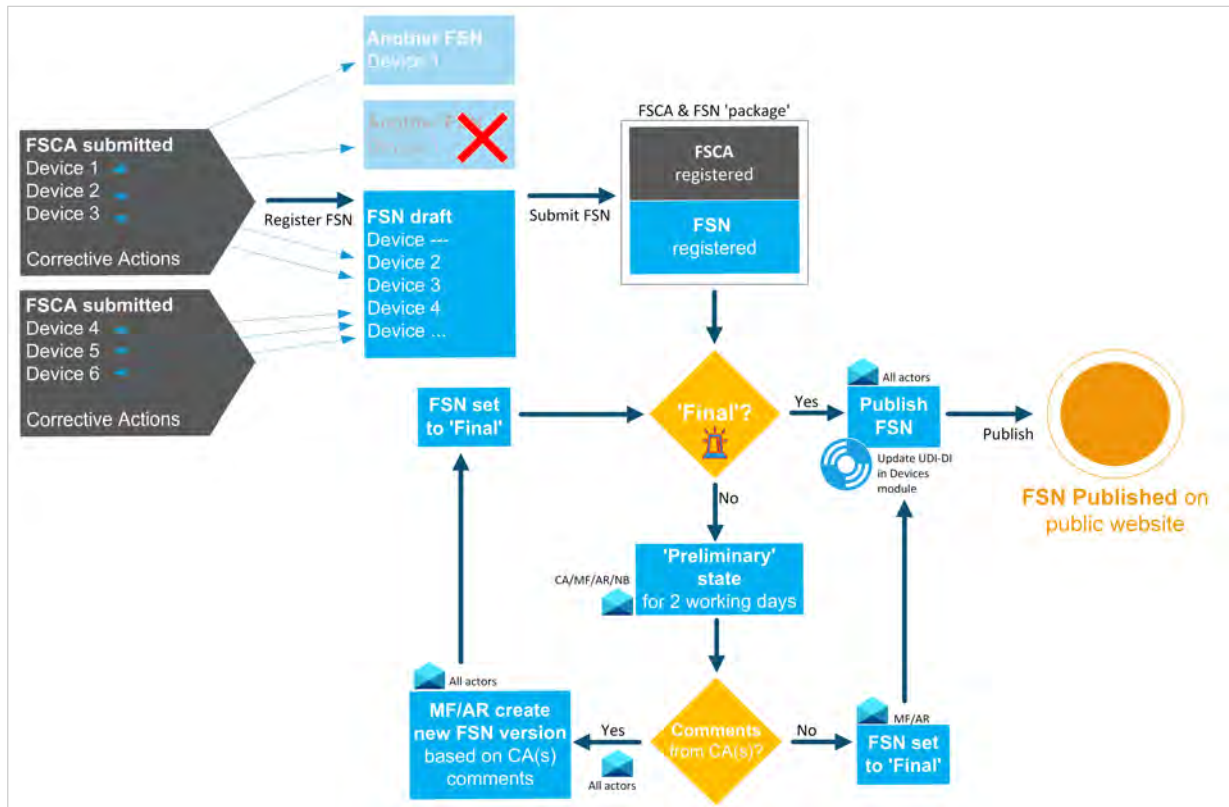
NOTICE

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

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

General process flow for an FSN

Playground



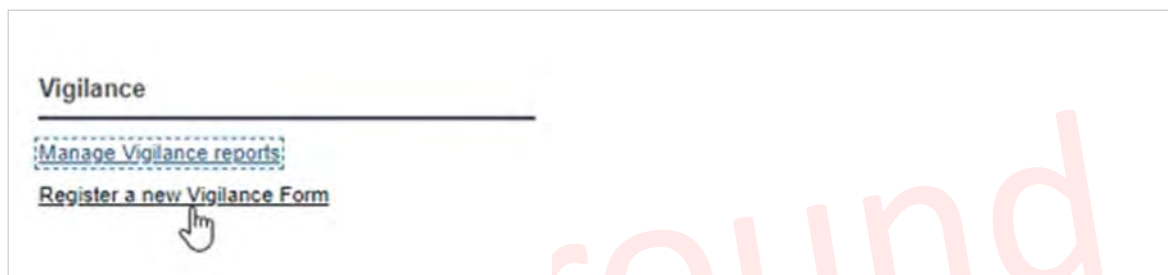
5.1.1 Step 0: Create initial FSN dossier



IMPORTANT

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

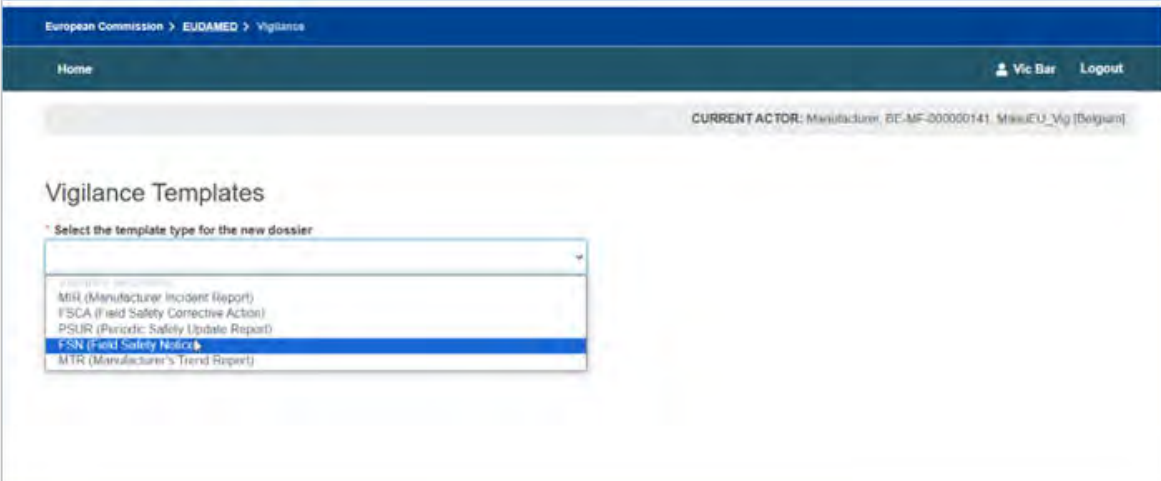
- From the EUDAMED dashboard, click on *Register a new Vigilance Form* under the *Vigilance* section:



IMPORTANT

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

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



European Commission > EUDAMED > Vigilance

Home Vic Bar Logout

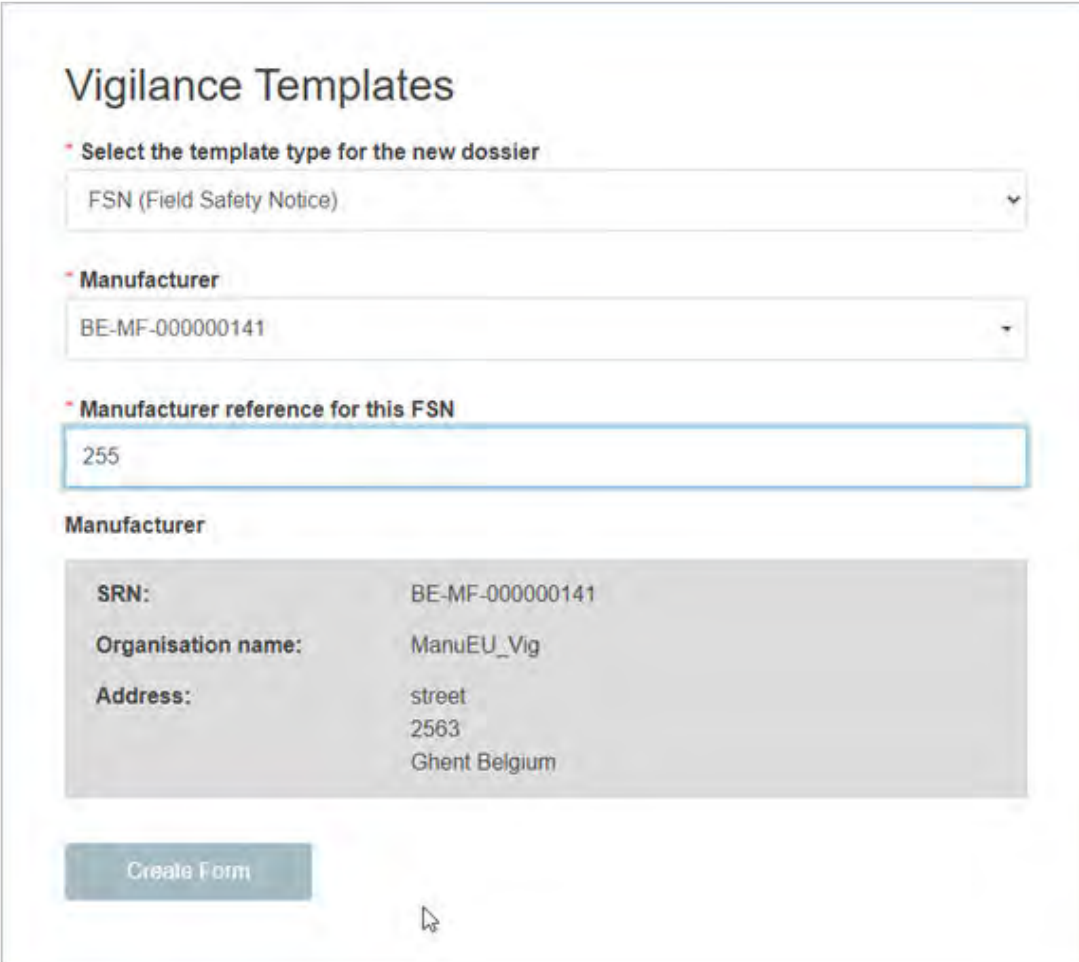
CURRENT ACTOR: Manufacturer, BE-MF-000000141, ManuEU_Vig [Belgium]

Vigilance Templates

* Select the template type for the new dossier

- MIR (Manufacturer Incident Report)
- FSCA (Field Safety Corrective Action)
- PSUR (Periodic Safety Update Report)
- FSN (Field Safety Notice)**
- MTR (Manufacturer's Trend Report)

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



Vigilance Templates

* Select the template type for the new dossier

FSN (Field Safety Notice)

* Manufacturer

BE-MF-000000141

* Manufacturer reference for this FSN

255

Manufacturer

SRN:	BE-MF-000000141
Organisation name:	ManuEU_Vig
Address:	street 2563 Ghent Belgium

Create Form

4. Provide the *Manufacturer's reference for this FSN* (uniquely used for this specific FSN).
5. Click on **Create Form**.

5.1.2 Step 1: Report primary details

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

EUDAMED Ref No: FSN-2023-09-000154

Version: 1 [Draft] | Last update: 2023-09-13

[Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

FSCA(s) & device(s)

Report Primary Details

Form Type
FSN (Field Safety Notice)

Manufacturer reference for this FSN
255

Manufacturer

SRN:	DE-MF-00000141
Organisation name:	ManuEU_Vg
Address:	street 2553 Ghent Belgium

5.1.3 Step 2: Administrative information

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

EUDAMED Ref No: FSN-2023-09-000154

Version: 1 [Draft] | Last update: 2023-09-13

[Back to list](#)

Report Primary Details

Administrative Information

FSCA(s) & device(s)

FSN Information

* Urgent FSN?

☒ Yes

☐ No

* Type of FSN

[Final](#)

EUDAMED Ref No: FSN-2023-09-000154

Version : 1 [Draft] | Last update: 2023-09-13

[← Back to list](#)

Report Primary Details

Administrative Information

FSCA(s) & device(s)

FSN Information

* Urgent FSN?

☐ Yes

☒ No

* Type of FSN



IMPORTANT

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

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

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

- The FSN date is mandatory only for *Final* FSN:

FSN Information

* Urgent FSN?

☒ Yes

☐ No

* Type of FSN

Final

* FSN Date



TIP
FSN date

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

5.1.4 Step 3: FSCAs and devices

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

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



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

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

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

Report Primary Details

Administrative Information

Reference to FSCA(s)

EUDAMED Ref No : FSCA-2023-08-002652 | Manufacturer reference number : 123 Remove

FSCA(s) & device(s) Add

Information on affected device(s)

FSCA-2023-08-002652

☒ 10251400044447

Custom-made device	No
Basic UDI-DI/EUDAMED DI	1025147777788888999MB
Model	
Device name	
UDI-DI/EUDAMED ID	10251400044447
Device trade name	
Catalogue/Reference Number	
Production Identifier	
FSN Reference	

☐ 10151400044440

Custom-made device	No
Basic UDI-DI/EUDAMED DI	1015147777788888999KG
Model	
Device name	
UDI-DI/EUDAMED ID	10151400044440
Device trade name	
Catalogue/Reference Number	
Production Identifier	
FSN Reference	

- Using the checkbox, select the affected devices.



TIP

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

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

Playground



Report Primary Details

Administrative Information

FSCA(s) & device(s)

Country specific details (Austria)

* Affected Countries

Austria

Add

Remove

Corrective action(s)

Corrective action(s) [FSCA-2023-08-002652]

EUDAMED Report ID
FSCA-2023-08-002652

Manufacturer Action Required
On-site modification/inspection by IFU or labelling change

User Action Required
Identify Device

Estimated date for completion
2023-09-28

The system will retrieve the corrective actions.

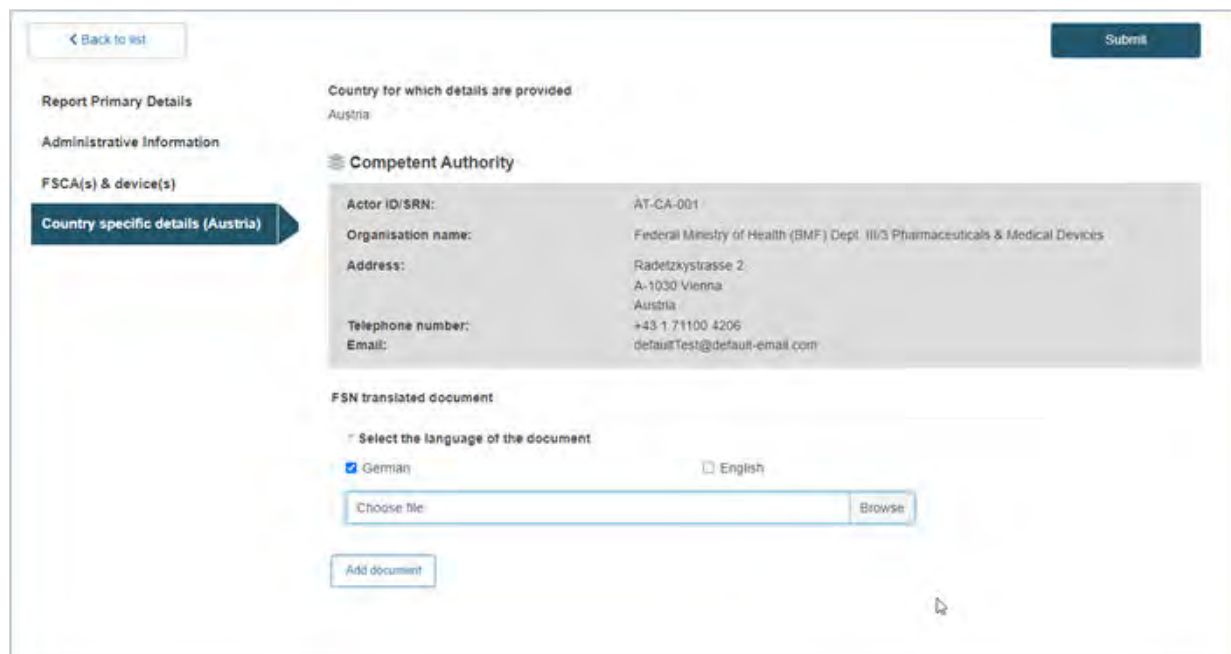


NOTE

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

5.1.5 Step 4: Country-specific details

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



Back to list

Submit

Report Primary Details

Administrative Information

FSCA(s) & device(s)

Country specific details (Austria)

Country for which details are provided

Austria

Competent Authority

Actor ID/SRN:	AT-CA-001
Organisation name:	Federal Ministry of Health (BMF) Dept. III/3 Pharmaceuticals & Medical Devices
Address:	Radetzkystrasse 2 A-1030 Vienna Austria
Telephone number:	+43 1 71100 4206
Email:	defaultTest@default-email.com

FSN translated document

Select the language of the document

☒ German ☐ English

Choose file: Browse

Add document

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

**TIP**

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

- Click on **Browse** to upload the document:

FSN translated document

Select the language of the document

☒ German ☐ English

baragvi_CS2736_2023_8 (3).pdf Delete

Add document

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

5.1.6 Step 5: FSN submission

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

[Back to list](#) Submit

Report Primary Details

Administrative Information

FSCA(s) & device(s)

Country specific details (Austria)

Country for which details are provided
Austria

Competent Authority

Actor ID/SRN: AT-CA-001

Organisation name: Federal Ministry of Health (BMF) Dept. III/3 Pharmaceuticals & Medical Devices

Address: Radetzkystrasse 2
A-1030 Vienna
Austria

Telephone number: +43 1 71100 4206

Email: defaultTest@default-email.com

FSN translated document

Select the language of the document

☒ German ☐ English

Choose file: Browse

Add document

**TIP**

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

1. **Preliminary FSN:** After submission, the *preliminary* FSN will be in *registered* state and visible to the Competent Authorities. CAs will be notified and will have **two days** to provide comments.
2. **Final FSN:** After submission, the *final* FSN will be in *registered* state and will also be publicly available on the public EUDAMED website. A sub-status for the referenced device(s) will be triggered (visible) in the EUDAMED Devices module.

**IMPORTANT**

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

Dossier FSN-2023-09-000154 : Draft

After submission, the FSN will have the state REGISTERED and will be visible to the Competent Authorities. You may view your data immediately after the submission, or by accessing the dossier in "Search and manage Vigilance items" page.



Complete action

Close

Notification after submission

After submission, notifications will be issued as follows:

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

5.2 Manage FSN

5.2.1 Step 6: View & follow-up CA Comments

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

**IMPORTANT**

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

Action 2023-09-17 | Email

Vigilance - VGL-020 - BE-MF-000000141(Eudamed Reference: FSN-2023-09-000151) No comments for the 'Preliminary' FSN Submitted

The FSN N/A has been previously submitted by the Manufacturer : ManuEU_Vig (SRN : BE-MF-000000141)

No comments received from the referenced Competent Authorities after the 'Preliminary' FSN submission, within the established term.

After 15 Sep 2023 02:00:00, the manufacturer/AR can make the FSN as 'Final' and to publish it on the Public website.

The FSN can be accessed using the following link: <https://webgate.test.ec.europa.eu/eudamed/vig/#/applications/14309>

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

**TIP**

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

5.2.2 Action history overview

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

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

EUDAMED Ref No: FSN-2023-09-000159

Version: 1 [Current] | Last update: 2023-09-21

[Back to list](#) [Create new version](#)

Report Primary Details

Administrative Information

FSCA(s) & device(s)	21/09/2023 14:23	Registered
Country specific details (Belgium)	version: 1	Submission date: 21/09/2023 14:23

CA Comments

[Report history overview](#)

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

5.2.3 Update FSN (create new version)



IMPORTANT

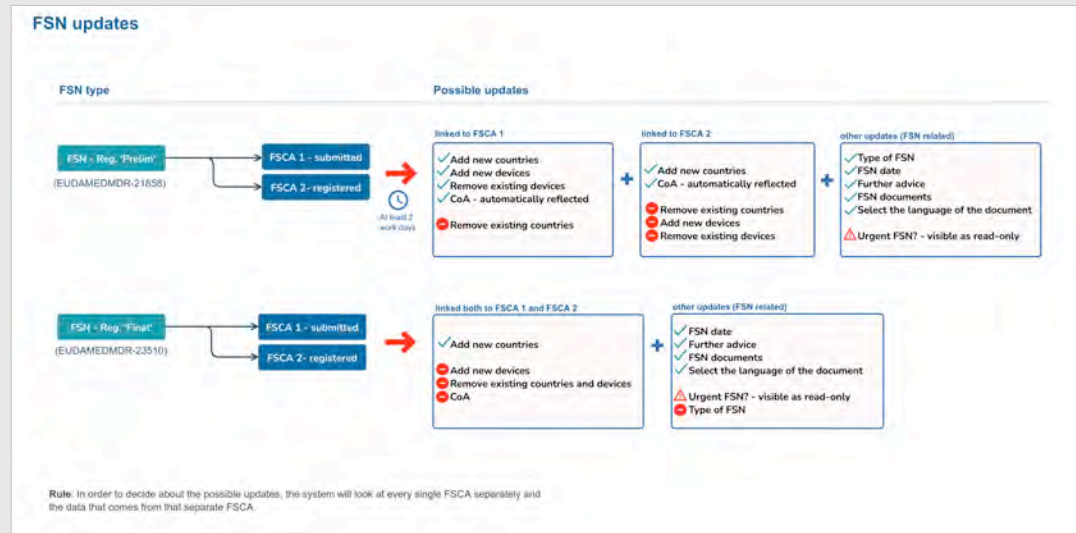
A new FSN version can only be created if:

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

**TIP**

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

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



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

EUDAMED Ref No: FSN-2023-09-000144

Version: 1 [Current] | Last update: 2023-09-14

[Back to list](#) **Create new version**

Report Primary Details

- Administrative Information
- FSCA(s) & device(s)
- Country specific details (Denmark)
- CA Comments
- Report history overview

Report Primary Details

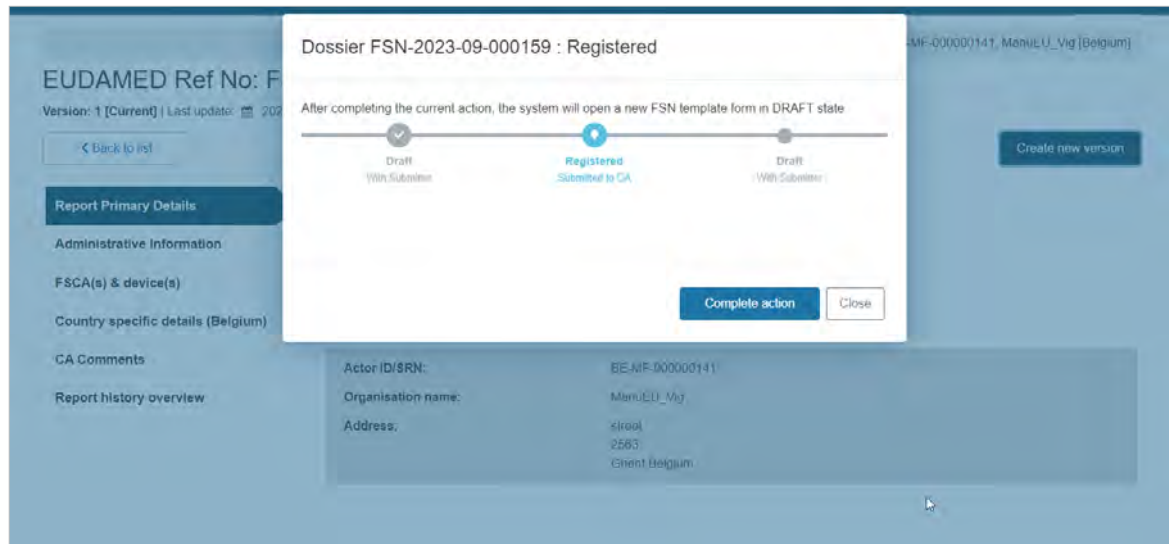
Form Type
FSN (Field Safety Notice)

Manufacturer reference for this FSN
23542354

Manufacturer

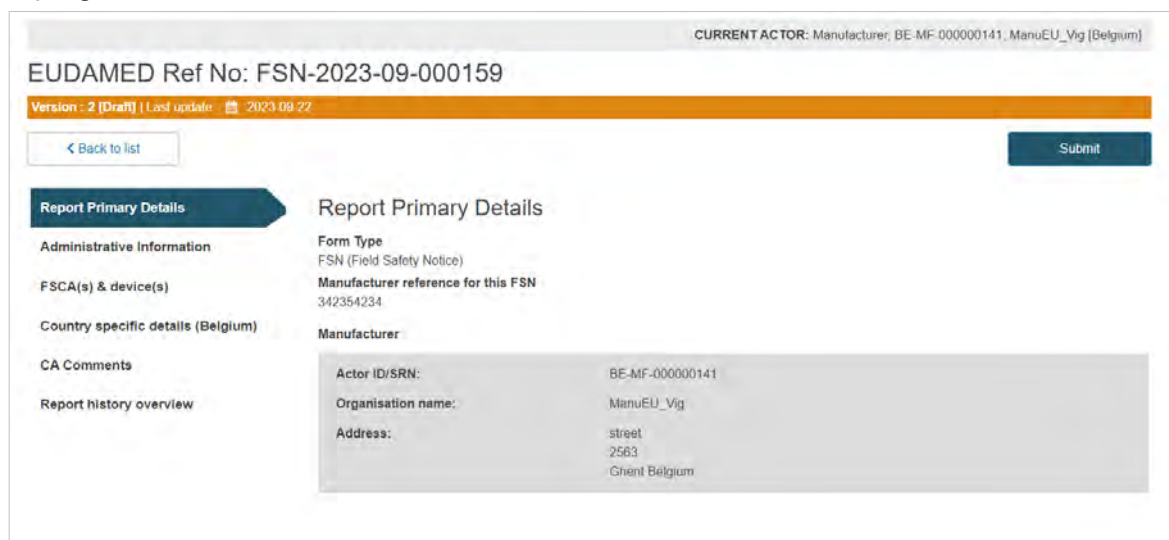
SRN:	BE.MF-000000141
Organisation name:	ManuEU_Vig
Address:	street 2563 Ghent Belgium

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

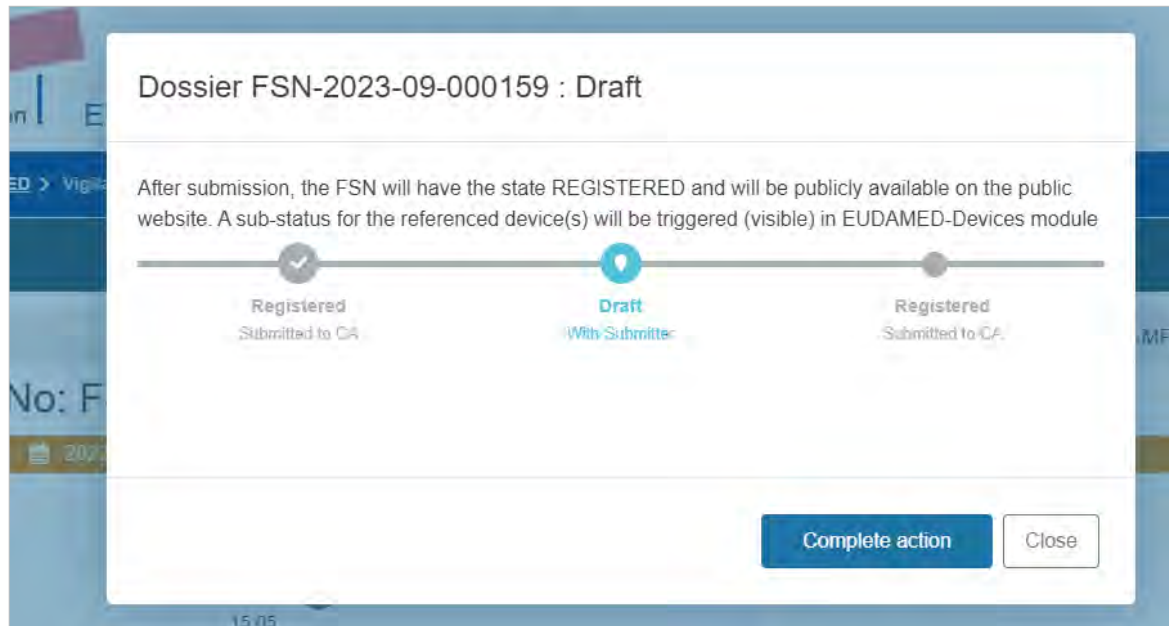


The applicable FSN sections will become editable.

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



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



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



NOTE

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

Information
2023-09-25 | Email

Vigilance - VGL-019 - BE-MF-000000141(Eudamed Reference: FSN-2023-09-000159) A new FSN version has been submitted

A new FSN version (2) has been submitted for the Manufacturer : ManuEU_Vig (Actor ID/SRN : BE-MF-000000141)

FSN EUDAMED Reference : FSN-2023-09-000159

The FSN can be accessed using the following link: <https://webgate.test.ec.europa.eu/eudamed/vig/#/applications/14548>

Playground

6 PSUR

6.1 Register a new PSUR



NOTE

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

6.1.1 Step 0: Create initial PSUR dossier

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



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

2. Select the PSUR template from the dropdown list:



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



The system will automatically retrieve your Actor ID/SRN.

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

CURRENT ACTOR: Manufacturer, AF-MF-000000122, John's NonEU MF [Afghanistan]

Vigilance Templates

Select the template type for the new dossier

PSUR (Periodic Safety Update Report)

Manufacturer

AF-MF-000000122

Manufacturer reference

PSUR_14_03_01

Manufacturer

SRN:	AF-MF-000000122
Organisation name:	John's NonEU MF
Address:	Test, 2121 Test Test Afghanistan

[Create Form](#)

6.1.2 Step 1: Report primary details

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

CURRENT ACTOR: Manufacturer, AF-MF-000000122, John's NonEU MF [Afghanistan]

EUDAMED Ref No: PSUR-2022-03-000010

Version: 1 [Draft] | Last update: 2022-03-14

[Back to list](#) [Submit](#)

Report Primary Details

PSUR details

Report Type

PSUR (Periodic safety update report)

Manufacturer reference

PSUR_14_03_01

Manufacturer

SRN:	AF-MF-000000122
Organisation name:	John's NonEU MF
Address:	Test, 2121 Test Test Afghanistan

6.1.3 Step 2: PSUR details / Submission

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

CURRENT ACTOR: Manufacturer, BE-MF-000000141, ManuEU_Vig [Belgium]

EUDAMED Ref No: PSUR-2024-09-000364

Version : 1 [Draft] | Last update : 2024-09-10

[Back to list](#) [Submit](#)

Report Primary Details

PSUR details

* PSUR version number assigned by the Manufacturer

Contact information of the report

Manufacturer contact details

Manufacturer Contact Details

* Contact First Name

* Contact Last Name

* E-mail

* Phone Number

* Competent Authority

Please select...

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

EUDAMED Ref No: PSUR-2024-09-000364

Version : 1 [Draft] | Last update : 2024-09-10

[Back to list](#) [Submit](#)

Report Primary Details

PSUR details

* PSUR version number assigned by the Manufacturer

v_123

Contact information of the report

Manufacturer contact details

Manufacturer Contact Details

* Contact First Name

John

* Contact Last Name

Smith

* E-mail

johnsmith@gmail.com

* Phone Number

004400000000

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

Report Primary Details

PSUR details

* Competent Authority

Actor ID/SRN: BE-CA-170 [Change](#)

Organisation name: DCM_CADEV

Address: 242323
Brux
Belgium

Telephone number:

Email: cc@pdr.com

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

PSUR details

Notified Body information

*** Notified Body**

Actor ID/SRN:	0373	Change
Organisation name:	ISTITUTO SUPERIORE DI SANITA'	
Address:	Viale Regina Elena, 299 00161 - ROMA 00161 - ROMA Italy	
Telephone number:	+39 06 49906146	
Email:	roberta.marcoaldi@iss.it	

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

PSUR details

Leading Basic UDI-DI

*** Basic UDI-DI**

708242222222K2 [Clear](#)

Start typing to search...

Basic UDI-DI/Eudamed-DI:	708242222222K2 [GS1] Change
Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Risk Class:	Class IIb
Model:	
Device name:	vb4e
Implantable:	Yes

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

Report Primary Details

PSUR details

Implantable: Yes

Certificate Identification

[+ Certificate Identification](#)

[Add](#)

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

PSUR details

Certificate Identification

[- Certificate Identification](#)

*** Notified body (NB) certificate number**

07082024 [Clear](#)

*** Notified body (NB) ID number**

Actor ID/SRN:	2797
Organisation name:	BSI Group The Netherlands B.V.
Address:	Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Amsterdam Netherlands
Telephone number:	+31 (0)20 346 07 80
Email:	info.nl@bsigroup.com

[Add](#)

**TIP**

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

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

Report Primary Details

PSUR details

Additional devices

Additional devices

* Basic UDI-DI/EUDAMED DI

Basic UDI-DI/Eudamed-DI: 808242222222LD [GS1] [Change](#)

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

Risk Class: Class IIb

Model:

Device name: vbEP

Implantable: Yes

Certificate Identification

Certificate Identification

*Notified body (NB) certificate number

808 [Clear](#)

Notified body (NB) ID number

Actor ID/SRN: 2797

Organisation name: BSI Group The Netherlands B.V.

Address: Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Amsterdam Netherlands

Telephone number: +31 (0)20 346 07 80

Email: info.nl@bsigroup.com

[Add](#)

9. Fill in the PSUR collection dates:

PSUR submission information

* Collection Start date

* Collection end date

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

PSUR Document

PSUR Document

[Browse](#)

11. Submission

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

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

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



NOTE

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

6.1.4 Report version details

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



IMPORTANT

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



NOTE

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

6.2 NB evaluation

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

1. Click on **Provide Evaluation:**

CURRENT ACTOR: Notified Body, NB-1005, PRÜFSTELLE FÜR MEDIZINPRODUKTE GRAZ [Austria]

EUDAMED Ref No: PSUR-2022-09-000155

Version: 1 [Current] | Last update: 2022-09-02

[← Back to list](#) [Provide Evaluation](#)

Report Primary Details

PSUR details

Report version details

Report history overview

Report Primary Details

Form Type
PSUR (Periodic safety update report)

Manufacturer reference
sdbde

Manufacturer


SRN:	BE-MF-00000941
Organisation name:	manufacture/ approve
Address:	street 234234 belgium Belgium

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

Playground

Dossier PSUR-2022-11-000205 : Registered

The PSUR version will be stored with the status "Evaluated" and the information regarding the evaluation outcome will be visible in the 'NB evaluation' page:



NB evaluation

Notified Body contact person details

Contact First Name

Vic

Contact Last Name

Barajan

Email

vb@pcnet.ro

Phone number

PSUR evaluation

Evaluation reference number

223

Evaluation decision

☒ NB agrees to the manufacturer's PSUR conclusions

☐ NB does not agree to the manufacturer's PSUR conclusions

Evaluation document

Document

Additional information and/or actions requested by the Notified Body

**NOTE**

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

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

EUDAMED Ref No: PSUR-2022-12-000215
Version: 2 [Current] | Last update: 2022-12-08

[← Back to list](#)

Report Primary Details
PSUR details
Report version details
NB evaluation
Report history overview

NB evaluation

Notified Body contact person details

Contact First Name
wqe

Contact Last Name
qwe

Email
ewe@r.ro

Phone number

PSUR evaluation

Evaluation reference number

Evaluation decision
NB agrees to the manufacturer's PSUR conclusions

Evaluation document

Additional information and/or actions requested by the Notified Body

NB Evaluation timing

Submission date
2022-12-08

Scheduled date
2023-03-08

Timeliness
-90

**NOTE**

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

Information
2022-12-06
Email

Vigilance - VGL-011 - NB-1035(Eudamed Reference: PSUR-2022-11-000209) New evaluation provided for a registered PSUR Report, not overpassing the process Timeliness

A new evaluation for PSUR Report has been provided by the Notified Body PRÜFSTELLE FÜR MEDIZINPRODUKTE GRAZ (SRN: NB-1035);

Leading Device of the PSUR: 000001JR

Additional Device(s) being part of the PSUR:

The PSUR can be accessed using the following link: <https://intragate.development.ec.europa.eu/eudamed-vig/#/applications/2594>

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

Information
2022-12-06
Email

Vigilance - VGL-012 - NB-1035(Eudamed Reference: PSUR-2022-12-000214) New evaluation provided for a registered PSUR Report, overpassing the process Timeliness

A new evaluation has been provided for a registered PSUR Report, overpassing the process Timeliness with 37 days has been provided by the Notified Body PRÜFSTELLE FÜR MEDIZINPRODUKTE GRAZ (SRN: NB-1035);

Leading Device of the PSUR: 88805558880555122587NQ

Additional Device(s) being part of the PSUR:

The PSUR can be accessed using the following link: <https://intragate.development.ec.europa.eu/eudamed-vig/#/applications/2604>

Playground

7 MTR

7.1 Register a new MTR



NOTE

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

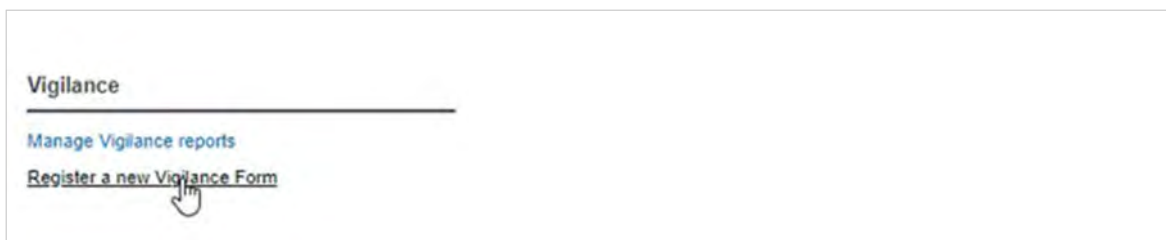


VIDEO: Create Manufacturer Trend Report

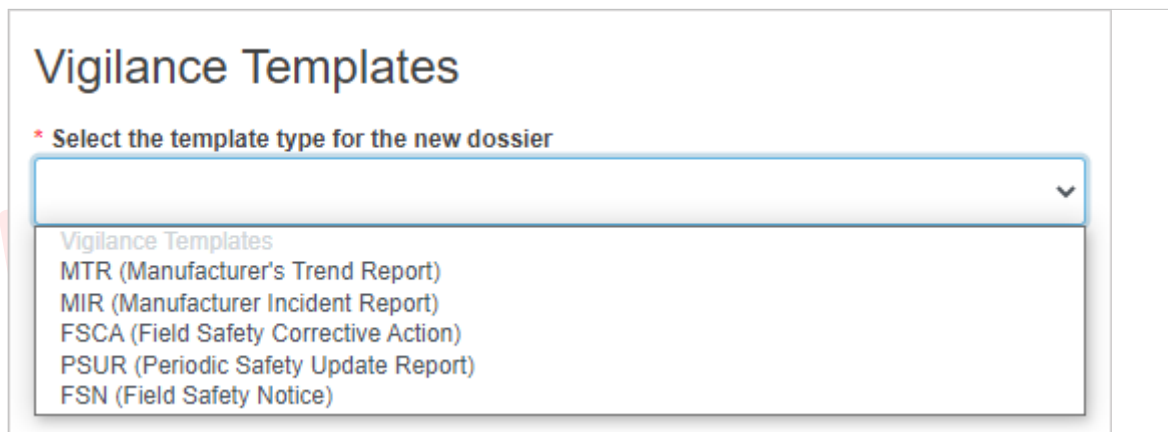


7.1.1 Step 0: Create initial MTR dossier

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



2. Select the MTR template from the dropdown list:



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

Vigilance Templates

* Select the template type for the new dossier

MTR (Manufacturer's Trend Report)

* Manufacturer

BE-MF-000000941 [manufacturer approval]

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

Vigilance Templates

* Select the template type for the new dossier

MTR (Manufacturer's Trend Report)

* Manufacturer

BE-MF-000000941

* Manufacturer's reference number for MTR

5622

* Competent Authority

BE-CA-001 - [Agence Fédérale des Médicaments et des Produits de]

Manufacturer

SRN:	BE-MF-000000941
Organisation name:	manufacturer approval
Address:	strett 234234 belgium Belgium

Competent Authority

SRN:	BE-CA-001
Organisation name:	Agence Fédérale des Médicaments et des Produits de Santé Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten
Address:	1060 B-1060 Brussels Belgium

Create Form

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



IMPORTANT

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

7.1.2 Step 1: Report primary details

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

EUDAMED Ref No: MTR-2022-11-000004

Version : 1 [Draft] | Last update : 2022-11-12

[Back to list](#) [Edit](#) [Submit](#)

Report Primary Details

Administrative Information

Form Type
MTR (Manufacturer's Trend Report)

Manufacturer reference
123213

Competent Authority

SRN: BE-CA-001

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

Address: 1060
B-1060 Brussels Belgium

Manufacturer

SRN: BE-MF-000000941

Organisation name: manufacturer approval

Address: street
234234
belgium Belgium

7.1.3 Step 2: Administrative information

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

EUDAMED Ref No: MTR-2024-09-000431

Version : 1 [Draft] | Last update : 2024-09-13

[Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

Type of report

☐ Initial

☐ Follow up

☐ Combined initial and final

☐ Final

Expected date of the next report

Date information for Trend

*** Date the trend was identified**

*** Time period of trend analysis (Start Date)**

*** Time period of trend analysis (End Date)**





*** Regulatory scope type**

MD (MDR, MDD, AIMDD) [Clear](#)

2. Choose the type of the report:

<p>* Type of report</p> <p><input type="radio"/> Initial</p> <p><input type="radio"/> Follow up</p> <p><input type="radio"/> Combined initial and final</p> <p><input type="radio"/> Final</p>	
---	--

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

<p>* Expected date of the next report</p> <p>2023-03-31 </p> <p>Date information for Trend</p> <p>* Date the trend was identified</p> <p>2023-03-01 ✓ </p> <p>* Time period of trend analysis (Start Date)</p> <p><input type="text"/> </p> <p>* Time period of trend analysis (End Date)</p> <p><input type="text"/> </p>	
---	--

4. Select the applicable legislation:

<p>* Regulatory scope type</p> <p><input type="text"/></p> <p>MD (MDR, MDD, AIMDD) increased</p> <p>IVD (IVDR, IVDD) a mandatory field</p>	
---	--

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

<p>* Basis for the report - type</p> <p><input checked="" type="radio"/> Incidents</p> <p><input type="radio"/> Expected undesirable side effect</p> <p>* Basis to the report - what increased</p> <p><input checked="" type="checkbox"/> Frequency</p> <p><input type="checkbox"/> Severity</p>	
--	--

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

Administrative Information	<p>Reference to PMCF/PMPF investigation</p> <p><input checked="" type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p>* Please provide the EUDAMED ID of that PMCF/PMPF investigation</p> <input style="width: 100%;" type="text"/>
Device Information	
Description of Trend	

7. Select the affected country(-ies):

Affected Countries

*** Member State(s) in which incidents, expected undesirable side affects, expected erroneous results (IVD) occurred**
 Member State(s) in which incidents, expected undesirable side affects, expected erroneous results (IVD) occurred is a mandatory field

[Check all](#) [Uncheck all](#)

<input type="checkbox"/> Austria	<input type="checkbox"/> France	<input type="checkbox"/> Latvia	<input type="checkbox"/> United Kingdom (Northern Ireland only)
<input type="checkbox"/> Belgium	<input type="checkbox"/> Greece	<input type="checkbox"/> Malta	<input type="checkbox"/> Sweden
<input type="checkbox"/> Bulgaria	<input type="checkbox"/> Croatia	<input type="checkbox"/> Netherlands	<input type="checkbox"/> Slovenia
<input type="checkbox"/> Cyprus	<input type="checkbox"/> Hungary	<input type="checkbox"/> Norway	<input type="checkbox"/> Slovakia
<input type="checkbox"/> Czechia	<input type="checkbox"/> Ireland	<input type="checkbox"/> Poland	<input type="checkbox"/> Türkiye
<input type="checkbox"/> Germany	<input type="checkbox"/> Iceland	<input type="checkbox"/> Portugal	
<input type="checkbox"/> Denmark	<input type="checkbox"/> Italy	<input type="checkbox"/> Romania	
<input type="checkbox"/> Estonia	<input type="checkbox"/> Liechtenstein		
<input type="checkbox"/> Spain	<input type="checkbox"/> Lithuania		
<input type="checkbox"/> Finland	<input type="checkbox"/> Luxembourg		

Other countries (outside EEA, TR, XI)

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

Administrative Information	Contact information of the report	
Device Information	Manufacturer contact details	
Description of Trend	<div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> <p style="color: #007bff; font-size: 0.8em; margin: 0;">Manufacturer Contact Details</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <p>* Contact First Name</p> <input style="width: 95%;" type="text"/> </div> <div style="width: 48%;"> <p>* Contact Last Name</p> <input style="width: 95%;" type="text"/> </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div style="width: 48%;"> <p>* E-mail</p> <input style="width: 95%;" type="text"/> </div> <div style="width: 48%;"> <p>* Phone Number</p> <input style="width: 95%;" type="text"/> </div> </div> </div> <p>* Contact details for this report</p> <p><input type="radio"/> Same as manufacturer</p> <p><input type="radio"/> Other (e.g. subcontractor)</p>	

7.1.4 Step 3: Device information

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

EUDAMED Ref No: MTR-2024-09-000436

Version : 1 [Draft] | Last update : 2024-09-10

Back to list

Submit

Report Primary Details

Administrative Information

Device Information

Description of Trend

Device Information

Type of device scope

☐ Category/Type/Group from Medical device nomenclature (EMDN)
 ☐ Basic UDI-DI(s)/Eudamed DI(s)
 ☐ Device Identifier(s) /Reference/Catalogue number(s)/Name(s)
 ☐ Device Identifier/Reference/Catalogue number/Name(s) and UDI-PI(s)/ Serial/Lot/Batch number(s)

Notified body (NB) ID number

Please select...

Add

Select the type of the device scope.



TIP

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

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

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

EUDAMED Ref No: MTR-2024-09-000431

Version : 1 [Draft] | Last update : 2024-09-11

Back to list

Submit

Report Primary Details

Administrative Information

Device Information

Description of Trend

Device Information

Type of device scope

☒ Category/Type/Group from Medical device nomenclature (EMDN)
 ☐ Basic UDI-DI(s)/Eudamed DI(s)
 ☐ Device Identifier(s) /Reference/Catalogue number(s)/Name(s)
 ☐ Device Identifier/Reference/Catalogue number/Name(s) and UDI-PI(s)/ Serial/Lot/Batch number(s)

Applicable legislation

Applicable legislation is a mandatory field

☐ AIMDD (90/35/EEC - Active implantable medical devices)
 ☐ MDD (Directive 93/42/EEC on medical devices)
 ☐ MDR (Regulation (EU) 2017/745 on medical devices)

Device nomenclature codes

+ Code

Add

Notified body (NB) ID number

Please select...

Add

1. Select the applicable legislation:

*** Applicable legislation**

Applicable legislation is a mandatory field

☐ AIMDD (90/35/EEC - Active implantable medical devices)

☐ MDD (Directive 93/42/EEC on medical devices)

☐ MDR (Regulation (EU) 2017/745 on medical devices)

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

Device nomenclature codes

Code: [A020101: Loss-of-resistance syringes]

* Device Nomenclature Code

A020101 Clear

* Nomenclature text

A020101: Loss-of-resistance syringes

Add

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

3. Select the Notified Body ID number:

* Notified body (NB) ID number

0051 Clear

Actor ID/SRN:	0051	Change
Organisation name:	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	
Address:	Via Quintiliano, 43 20138 - MILANO Italy	
Telephone number:	+39 02 50731	
Email:	info@imq.it	

Add

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

EUDAMED Ref No: MTR-2024-09-000436

Version : 1 [Draft] | Last update : 2024-09-10

Back to list

Submit

Report Primary Details

Administrative Information

Device Information

Description of Trend

Device Information

Type of device scope

Category/Type/Group from Medical device nomenclature (EMDN)

Basic UDI-DI(s)/Eudamed DI(s)

Device Identifier(s) /Reference/Catalogue number(s)/Name(s)

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

Device details

Basic UDI-DI/EUDAMED DI

Start typing to search...

Add

Notified body (NB) ID number

Please select...

Add

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

Device details

Basic UDI-DI/EUDAMED DI

103514777788888999P6

Clear

Start typing to search...

Basic UDI-DI/Eudamed-DI:

103514777788888999P6 [GS1]

Change

Applicable legislation:

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

Risk Class:

Class IIa

Model:

Device name:

vicb103

Implantable:

Yes

Add

2. Select the Notified Body ID number:

MTR

99

*** Notified body (NB) ID number**

0051 Clear

Actor ID/SRN:	0051	Change
Organisation name:	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	
Address:	Via Quintiliano, 43 20138 - MILANO Italy	
Telephone number:	+39 02 50731	
Email:	info@imq.it	

Add

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

EUDAMED Ref No: MTR-2024-09-000436

Version : 1 [Draft] | Last update : 2024-09-10

[Back to list](#) Submit

Report Primary Details

Administrative Information

Device Information

Description of Trend

Device Information

* Type of device scope

- ☐ Category/Type/Group from Medical device nomenclature (EMDN)
- ☐ Basic UDI-DI(s)/Eudamed DI(s)
- ☒ Device Identifier(s) /Reference/Catalogue number(s)/Name(s)
- ☐ Device Identifier/Reference/Catalogue number/Name(s) and UDI-PI(s)/ Serial/Lot/Batch number(s)

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

Report Primary Details

Administrative Information

Device Information

Description of Trend

Device Information

* Type of device scope

- ☐ Category/Type/Group from Medical device nomenclature (EMDN)
- ☐ Basic UDI-DI(s)/Eudamed DI(s)
- ☒ Device Identifier(s) /Reference/Catalogue number(s)/Name(s)
- ☐ Device Identifier/Reference/Catalogue number/Name(s) and UDI-PI(s)/ Serial/Lot/Batch number(s)

Device details

[Device identifier \(UDI-DI/EUDAMED ID\)](#)

*Device Identifier ?

Start typing to search ...



NOTE

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

Device Information

GTIN number

2. Select the Notified Body ID number:

*** Notified body (NB) ID number**

0051 Clear

Actor ID/SRN:	0051	Change
Organisation name:	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	
Address:	Via Quintiliano, 43 20138 - MILANO Italy	
Telephone number:	+39 02 50731	
Email:	info@imq.it	

Add

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

Report Primary Details

Administrative Information

Device Information

Description of Trend

Device Information

*** Type of device scope**

- ☐ Category/Type/Group from Medical device nomenclature (EMDN)
- ☐ Basic UDI-DI(s)/Eudamed DI(s)
- ☐ Device Identifier(s) /Reference/Catalogue number(s)/Name(s)
- ☒ Device Identifier/Reference/Catalogue number/Name(s) and UDI-PI(s)/ Serial/Lot/Batch number(s)

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

Device Information

Description of Trend

Device details

— Device identifier (UDI-DI/EUDAMED ID)

*** Device Identifier** [?](#)

Start typing to search

*** Will you provide the Production Identifiers for this UDI-DI/Device manually or will you provide them in a file(if up to 5 provide manually, if more upload a document)?**

- ☐ File Upload
- ☐ Manual Entry

**NOTE**

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

Device Information

GTIN number

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

Administrative Information

Device Information

Description of Trend

* Will you provide the Production Identifiers for this UDI-DI/Device manually or will you provide them in a file(if up to 5 provide manually, if more upload a document)?

☒ File Upload

☐ Manual Entry

* UDI-PI document

Choose file Browse

Alternatively, enter the UDI-PI manually:

Administrative Information

Device Information

Description of Trend

* Will you provide the Production Identifiers for this UDI-DI/Device manually or will you provide them in a file(if up to 5 provide manually, if more upload a document)?

☐ File Upload

☒ Manual Entry

Production Identifier

Production Identifier

Production Identifier Type

3. Select the Notified Body ID number:

* Notified body (NB) ID number

0051

Actor ID/SRN:	0051	Change
Organisation name:	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	
Address:	Via Quintiliano, 43 20138 - MILANO Italy	
Telephone number:	+39 02 50731	
Email:	info@imq.it	

7.1.5 Step 4: Description of Trend

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

Playground

Report Primary Details

Administrative Information

Device Information

Description of Trend

Description of Trend

* Background information on the trend, including probability of problem arising and the predicted risk to users

Coded information on trend

IMDRF Medical device problem codes (Annex A) or in-house codes

* IMDRF code(s) applicable?
☐ Yes ☐ No

Greatest hazard presented to the patient/user that the FSCA is intended to mitigate (IMDRF 'Health Effect' terms and codes (Annex E, F))

* IMDRF code(s) applicable?
☐ Yes ☐ No

Summary of the root cause analysis

Actions to be taken or already implemented to reduce the risks for the users/patients

Trend report document

Choose file Browse

General Comments

1. Enter the background information:

Description of Trend

* Background information on the trend, including probability of problem arising and the predicted risk to users

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

Coded information on trend

IMDRF Medical device problem codes (Annex A) or in-house codes

* IMDRF code(s) applicable?
☒ Yes ☐ No

— Enter choice 1 (most relevant):

* IMDRF "Medical Device problem" codes (Annex A) ?

|

A160102 - No Audible Alarm

A160103 - Low Audible Alarm

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

Coded information on trend

IMDRF Medical device problem codes (Annex A) or in-house codes

* IMDRF code(s) applicable?
☐ Yes ☒ No

In-house codes

* Code	* Term

Add

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

Playground

IMDRF 'Health Effect' terms and codes (Annex E, F) or in-house codes/MedDRA codes

* IMDRF code(s) applicable?
☒ Yes ☐ No

— Choice 1 (most relevant) E1719 - Skin Infection [E19|E1719] [Change](#)

* IMDRF Health Effects - Clinical Signs and Symptoms or Conditions Medical device problem codes (Annex E) [?](#)

E1719

[Add](#)

— Choice 1 (most relevant) F0102 - Therapeutic Response Increased [F01|F0102] [Change](#)

* IMDRF Health Effects - Health Impact (Annex F) [?](#)

F0102

[Add](#)

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

IMDRF 'Health Effect' terms and codes (Annex E, F) or in-house codes/MedDRA codes

* IMDRF code(s) applicable?
☐ Yes ☒ No

In-house/MedDRA codes

* Code	* Term
<input type="text"/>	<input type="text"/>

[Add](#)

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

Summary of the root cause analysis

Actions to be taken or already implemented to reduce the risks for the users/patients

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

Trend report document

Choose file Browse

6. Enter any general comments:

General Comments

7.1.6 Step 5: MTR submission

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

Home Vic Bar Logout

CURRENT ACTOR: Manufacturer, BE-MF-000000141, ManuEU_Vig [Belgium]

EUDAMED Ref No: MTR-2023-03-000198

Version : 1 [Draft] | Last update : 2023-03-23

[Back to list](#) Submit

Report Primary Details

Administrative Information

Device Information

Description of Trend

Description of Trend

* Background information on the trend, including probability of problem arising and the predicted risk to users

cardiac disease increase

Coded information on trend

IMDRF Medical device problem codes (Annex A) or in-house codes

* IMDRF code(s) applicable?

☒ Yes ☐ No

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

Playground

Dossier MTR-2023-03-000227 : Draft

After submission, the MTR form will have the state REGISTERED and will be visible to the Competent Authority. The publicly available information from the MTR form will be also visible on the Public website of EUDAMED. You may view your data immediately after the submission, or by accessing the dossier in "Search and manage Vigilance items" page.

Complete action Close

You have now completed the MTR registration process.



NOTE

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

Information
2023-03-20 | Email

Vigilance - VGL-014 - BE-MF-000000941(Eudamed Reference: MTR-2023-03-000030) A new MTR version has been submitted

A new MTR version has been submitted by the Manufacturer : manufacturer approval (SRN: BE-MF-000000941).

MTR EUDAMED Reference : MTR-2023-03-000030

The MTR can be accessed using the following link: <https://intragate.development.ec.europa.eu/eudamed-vig/#/applications/2692>

Information
2023-03-20 | Email

Vigilance - VGL-013 - BE-MF-000000941(Eudamed Reference: MTR-2023-03-000030) New MTR Submitted

A new MTR has been submitted by the Manufacturer : manufacturer approval (SRN: BE-MF-000000941).

The MTR can be accessed using the following link: <https://intragate.development.ec.europa.eu/eudamed-vig/#/applications/2692>

8 PSR

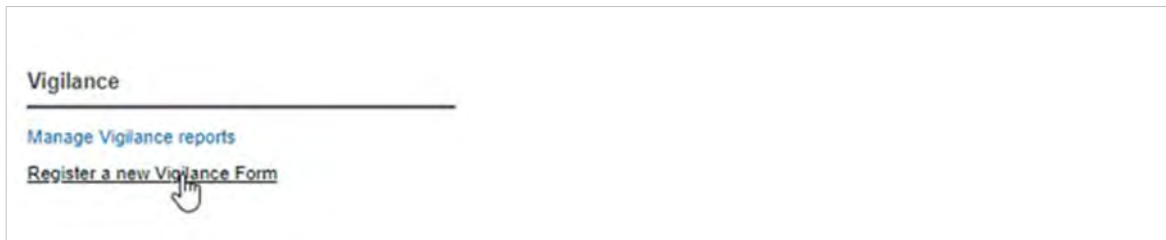
8.1 Register a new PSR

**NOTE**

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

8.1.1 Step 0: Create initial PSR dossier

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



2. Select the PSR template from the dropdown list:

Playground

Vigilance Templates

* Select the template type for the new dossier

PSR (Periodic Summary Report) ▼

* Manufacturer

NL-MF-000000041 ▼

* Manufacturer reference

123

Manufacturer

Authorised Representative Actor ID/SRN:	NL-MF-000000041
Organisation name:	Medical Device Manufacturer
Address:	30 Grootebeearlaan NL-8000 Amersfoort Netherlands

Create Form

3. Select the manufacturer from the *Manufacturer* field.
The system will automatically display your Actor information.
4. Enter the unique *Manufacturer reference*.
5. Click on **Create Form** to complete this initial step.



IMPORTANT

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

8.1.2 Step 1: Report primary details

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

EUDAMED Ref No: PSR-2023-000070

Version : 1 [Draft] | Last update : 2023-12-13

[Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

PSR Information

Device Information

Manufacturer PSR Analysis

General Comments

Report Primary Details

Form Type
PSR (Periodic Summary Report)

Manufacturer Reference
1234

Manufacturer

Authorised Representative Actor ID/SRN: NL-MF-000000041

Organisation name: Medical Device Manufacturer

Address: 30 Grootevismaan
NL-6000
Amsterdam Netherlands

8.1.3 Step 2: Administrative information

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

EUDAMED Ref No: PSR-2023-000070

Version : 1 [Draft] | Last update : 2023-12-13

[Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

PSR Information

Device Information

Manufacturer PSR Analysis

General Comments

Coordinating Competent Authority Country
Belgium [Close](#)

Coordinating Competent Authority

Authorised Representative Actor ID/SRN: BE-CA-001 [Change](#)

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

Address: EUROSTATION building block 2 place Victor Horta 40/ 40
B-1060 Brussels
Belgium

Telephone number: 00 32 2 528 40 00

Email: meddev@tagg.afmps.be



NOTE

Coordinating Competent Authority must be either:

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

- Fill in the Manufacturer contact details in the next section:

Administrative Information

PSR Information

Device Information

Manufacturer PSR Analysis

General Comments

Contact information of the report

Manufacturer contact details

— [Manufacturer Contact Details](#)

* Contact First Name
John

* Contact Last Name
Dee

* E-mail
jd@jd.com

* Phone Number
123456

* Contact details for this report
☐ Same as manufacturer
☒ Other (e.g. subcontractor)

— [Contact details for this report](#)

* Contact First Name
Jack

* Contact Last Name
Smith

* Email
js@js.com

* Phone Number
56789

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

Administrative Information

PSR Information

Device Information

Manufacturer PSR Analysis

General Comments

Contact information of the report

Manufacturer contact details

— [Manufacturer Contact Details](#)

* Contact First Name
John

* Contact Last Name
Dee

* E-mail
a@f.com

* Phone Number
1234

Authorised Representative

* Actor ID/ SRN

Authorised Representative Actor ID/SRN:	BE-AR-000000121	Change
Organisation name:	Test AR BE	
Address:	test 56 complement 1111 Test Belgium	
Telephone number:		
Email:	test@test.com	

— [Authorised representative Contact Details](#)

* Contact First Name
Britanny

* Contact Last Name
Smith

* Email
b@b.com

* Phone Number
4567

* Contact details for this report
☐ Same as manufacturer
☒ Same as authorised representative
☐ Other (e.g. subcontractor)

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

8.1.4 Step 3: PSR information

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

EUDAMED Ref No: PSR-2023-000070

Version : 1 [Draft] | Last update : 2023-12-13

[← Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

PSR information

Device Information

Manufacturer PSR Analysis

General Comments

PSR information

PSR type

- ☒ Incidents described in an FSCA
- ☒ Device specific Vigilance Guidance (DSVG)?
- ☐ Common and well documented incidents
- ☐ Root cause

Incidents described in an FSCA - Details

Is the FSCA registered in EUDAMED ?

☒ Yes

☐ No

EUDAMED Ref No : FSCA-2023-12-003108 | Manufacturer reference number : [My FSCA1](#) [Change](#)

[Add](#)

Device specific Vigilance Guidance (DSVG)? - Details

Please provide the relevant reference name

**NOTE**

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

PSR information

Device Information

Manufacturer PSR Analysis

General Comments

*** PSR type**

☒ Incidents described in an FSCA

☐ Device specific Vigilance Guidance (DSVG)?

☐ Common and well documented incidents

☐ Root cause

Incidents described in an FSCA - Details

*** Is the FSCA registered in EUDAMED ?**

☐ Yes

☒ No

*** Manufacturer's FSCA reference**

MF 123

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

EUDAMED Ref No: PSR-2023-000070

Version : 1 [Draft] | Last update : 2023-12-13

[Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

PSR information

Device Information

Manufacturer PSR Analysis

General Comments

*** PSR type**

☒ Incidents described in an FSCA

☒ Device specific Vigilance Guidance (DSVG)?

☐ Common and well documented incidents

☐ Root cause

Incidents described in an FSCA - Details

*** Is the FSCA registered in EUDAMED ?**

☐ Yes

☒ No

EUDAMED Ref No : FSCA-2023-12-003108 | Manufacturer reference number : My FSCA1 [Change](#)

*** Device specific Vigilance Guidance (DSVG)? - Details**

Please provide the relevant reference name

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

Report Primary Details

Administrative Information

PSR information

Device Information

Manufacturer PSR Analysis

General Comments

PSR related IMDRF code(s)

Please provide the IMDRF code(s) on which this specific PSR is based ?

IMDRF Medical device problem codes (Annex A)

+ Choice 1 (most relevant) A180304 - Problem with Removal of Enzymatic Cleaner [A18/A1803/A180304] [Change](#)

[Add](#)

IMDRF Cause investigation: Investigation findings (Annex C)

- Enter choice 1 (most relevant)

IMDRF Cause investigation: Investigation findings (Annex C) ?

Please select...

[Add](#)

IMDRF Cause investigation: Investigation conclusion (Annex D)

- Enter choice 1 (most relevant)

IMDRF Cause investigation: Investigation conclusion (Annex D) ?

Please select...

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

PSR information

Device Information

Manufacturer PSR Analysis

General Comments

PSR analysis update report frequency of reporting (months) ?

3 [Clear](#)

Participating countries and their corresponding CA

+ Competent authority

[Add](#)



NOTE

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

PSR information

Device Information

Manufacturer PSR Analysis

General Comments

PSR analysis update report frequency of reporting (months) ?

5 [Clear](#)

Rationale for selecting the frequency of reporting

the rationale is:

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

Participating countries and their corresponding CA

- Competent authority

* **Country**
 Belgium Remove

* **Corresponding competent authority**

Authorised Representative Actor ID/SRN:	BE-CA-001	Change
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 Belgium	
Telephone number:	00 32 2 528 40 00	
Email:	meddev@fagg-afmps.be	

Add

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

Participating countries and their corresponding CA

+ Competent authority [Belgium] Remove

+ Competent authority [Germany] Remove

+ Competent authority [Lithuania] Remove

Add

8.1.5 Step 4: Device information

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

EUDAMED Ref No: PSR-2024-000533

Version : 1 [Draft] | Last update : 2024-08-10

[Back to list](#) Submit

Report Primary Details

Administrative Information

PSR information

Device Information

Initial Manufacturer PSR Analysis

General Comments

Regulatory scope type

MD (MDR, MOD, AIMDD) / NICK

IVD (IVDR, IVDD)

* **Type of device scope**

☒ Category/Type/Group from Medical device nomenclature (EMDN)

☐ Basic UDI-DI(s)/Eudamed DI(s)

☐ Device Identifier(s) /Reference/Catalogue number(s)/Name(s)

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

- Select the type of device scope:

Device Information	
Initial Manufacturer PSR Analysis	<p>* Type of device scope</p> <p><input checked="" type="radio"/> Category/Type/Group from Medical device nomenclature (EMDN)</p> <p><input type="radio"/> Basic UDI-DI(s)/Eudamed DI(s)</p> <p><input type="radio"/> Device Identifier(s) /Reference/Catalogue number(s)/Name(s)</p> <p><input type="radio"/> Device Identifier/Reference/Catalogue number/Name(s) and UDI-PI(s)/ Serial/Lot/Batch number(s)</p>
General Comments	

**NOTE**

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

GTIN number

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

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

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

PSR information	Device Information
Device Information	<p>* Type of device scope</p> <p><input checked="" type="radio"/> Category/Type/Group from Medical device nomenclature (EMDN)</p> <p><input type="radio"/> Basic UDI-DI(s)/Eudamed DI(s)</p> <p><input type="radio"/> UDI-DI(s)/ Eudamed ID(s)/ Device name</p> <p><input type="radio"/> UDI-DI and UDI-PI(s)/ Eudamed ID/Device name and Lot/Batch number(s)</p> <p>* Applicable legislation</p> <p style="color: red; font-size: small;">Applicable legislation is a mandatory field</p> <p><input type="checkbox"/> AIMDD (90/35/EEC - Active implantable medical devices)</p> <p><input type="checkbox"/> MDD (Directive 93/42/EEC on medical devices)</p> <p><input type="checkbox"/> MDR (Regulation (EU) 2017/745 on medical devices)</p>
Manufacturer PSR Analysis	
General Comments	

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

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

Playground

The screenshot shows a web form for 'Device Information'. On the left, there are three tabs: 'Device Information' (active), 'Manufacturer PSR Analysis', and 'General Comments'. The main content area is titled 'AIMDD (Directive 90/385/EEC - Active implantable medical devices)'. Under the heading '* Applicable legislation', three options are listed:
☒ AIMDD (90/35/EEC - Active implantable medical devices)
☐ MDD (Directive 93/42/EEC on medical devices)
☐ MDR (Regulation (EU) 2017/745 on medical devices)
Below this, the heading '* Risk Class' is followed by the text 'Risk Class is a mandatory field'. There are two checkboxes:
☐ Active implant
☐ Code
Further down, there is a dropdown menu for '* Device Nomenclature Code' with the text 'Please select...' and a large text area for '* Nomenclature text'.

Example with MDD as applicable legislation:

This screenshot shows the same form as above, but with 'MDD (Directive 93/42/EEC on medical devices)' selected under '* Applicable legislation'. The heading for the main section is now 'MDD (93/42/EEC on medical devices)'. The 'Risk Class' section now lists four checkboxes:
☐ CLASS I
☐ CLASS IIa
☐ CLASS IIb
☐ CLASS III
The 'Code' checkbox remains. The 'Device Nomenclature Code' dropdown and 'Nomenclature text' area are also present. At the bottom of the form, there is an 'Add' button.

Example with MDR as applicable legislation:

Playground

Device Information

Manufacturer PSR Analysis

General Comments

Applicable legislation

☐ AIMDD (90/35/EEC - Active implantable medical devices)
 ☐ MDD (Directive 93/42/EEC on medical devices)
 ☒ MDR (Regulation (EU) 2017/745 on medical devices)

MDR (Regulation (EU) 2017/745 on medical devices)

Risk Class

Risk Class is a mandatory field

☐ CLASS I
 ☐ CLASS IIa
 ☐ CLASS IIb
 ☐ CLASS III

Device type

☐ Implantable
 ☐ Active Device
 ☐ Intended to administer or remove a medicinal product
 ☐ Sterile conditions
 ☐ Measuring functions
 ☐ Reusable surgical instruments
 ☐ Software
 ☐ Systems
 ☐ Procedure Packs
 ☐ Non-medical purpose

Code

Device Nomenclature Code

Please select...

Nomenclature text

Add

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

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

Enter the Basic UDI-DI/EUDAMED DI:

Playground

Administrative Information

PSR information

Device Information

Manufacturer PSR Analysis

General Comments

Device Information

* Type of device scope

- ☐ Category/Type/Group from Medical device nomenclature (EMDN)
- ☒ Basic UDI-DI(s)/Eudamed DI(s)
- ☐ UDI-DI(s)/ Eudamed ID(s)/ Device name
- ☐ UDI-DI and UDI-PI(s)/ Eudamed ID/Device name and Lot/Batch number(s)

* Basic UDI-DI/EUDAMED DI

Basic UDI-DI/Eudamed-DI:	12345-1b-ac-23 Q4 3-2-GP (GS1)	Change
Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)	
Risk Class:	Class IIB	
Model:	12345-1b-ac-23 Q4 3-2-GP	
Device name:		
Implantable:	No	

Basic UDI-DI/Eudamed-DI:	12345-ASB-DF-M5 (GS1)	Change
Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)	
Risk Class:	Class IIIa	
Model:		
Device name:		
Implantable:	No	

[Add](#)

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

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

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

PSR information

Device Information

Initial Manufacturer PSR Analysis

General Comments

Device Information

* Type of device scope

- ☐ Category/Type/Group from Medical device nomenclature (EMDN)
- ☐ Basic UDI-DI(s)/Eudamed DI(s)
- ☒ **Device Identifier(s) /Reference/Catalogue number(s)/Name(s)**
- ☐ Device Identifier/Reference/Catalogue number/Name(s) and UDI-PI(s)/ Serial/Lot/Batch number(s)

Device details

+ Device identifier (UDI-DI/EUDAMED ID)

*Device Identifier ?

Start typing to search ...

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

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

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

PSR information

- Device Information**
- Initial Manufacturer PSR Analysis
- General Comments

Device Information

*** Type of device scope**

- ☐ Category/Type/Group from Medical device nomenclature (EMDN)
- ☐ Basic UDI-DI(s)/Eudamed DI(s)
- ☐ Device Identifier(s) /Reference/Catalogue number(s)/Name(s)
- ☒ Device Identifier/Reference/Catalogue number(s) and UDI-PI(s) Serial/Lot/Batch number(s)

Device details

Device identifier (UDI-DI/EUDAMED ID)

***Device Identifier** ?

Start typing to search...

- Next, upload the UDI-PI:

Device Information

- Initial Manufacturer PSR Analysis
- General Comments

*** Will you provide the Production Identifiers for this UDI-DI/Device manually or will you provide them in a file(if up to 5 provide manually, if more upload a document)?**

- ☒ File Upload
- ☐ Manual Entry

*** UDI-PI document**

Choose file Browse

Alternatively, enter the *Production Identifier* information manually:

Device Information

- Initial Manufacturer PSR Analysis
- General Comments

*** Will you provide the Production Identifiers for this UDI-DI/Device manually or will you provide them in a file(if up to 5 provide manually, if more upload a document)?**

- ☐ File Upload
- ☒ Manual Entry

Production Identifier

*** Production Identifier**

Production Identifier is a mandatory field

*** Production Identifier Type**

Select a Production Identifier Type Remove

Select a Production Identifier Type Remove

Add

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

Device Information

Manufacturer PSR Analysis

General Comments

Notified body (NB) ID number

+ Certificate Identification Remove

- Certificate Identification Remove

* **Notified body (NB) ID number**

Authorised Representative Actor ID/SRN:	0051	
Organisation name:	IMQ (ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.)	
Address:	Via Quintiliano, 43 20138 - MILANO 20138 - MILANO	
Telephone number:	Italy +39 02 50731	
Email:	info@imq.it	

* **Notified body (NB) certificate number**

967

Add

Click **Add** for multiple entries.

8.1.6 Step 5: Initial Manufacturer PSR analysis

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

EUDAMED Ref No: PSR-2023-000070

Version: 1 (Draft) | Last update: 2023-12-13

< Back to list Submit

Manufacturer PSR Analysis

Initial problem statement and background

* Preliminary results and conclusions of manufacturer's investigation

texts

* What further investigations do you intend in view of reaching final conclusions?

texts

Initial cause investigation and conclusion/outcome

* Description of the manufacturer's evaluation concerning possible root causes/causative factors and conclusion/outcome

texts

* Is root cause confirmed?

Yes Close

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

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

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

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

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

Manufacturer PSR Analysis

General Comments

* Comments on how similar incidents and associated number of devices on the market were determined

Number of similar incidents and devices on the market for the indicated time periods
Time period (N) - year to date = PSR year

* Start date
2023-08-01

* End date
2023-12-31

* Number of similar incidents (EEA+TR+XI)
15

* Number of similar incidents (World)
35

* Number of devices on the market in EEA+TR+XI
1200

* Number of devices on the market at world level
2500

**NOTE**

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

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

Manufacturer PSR Analysis

General Comments

Time period (N-1) - calendar year one year before PSR

☐ Data for Time Period N-1 will be entered

Time period (N-2) - calendar year two years before PSR

☐ Data for Time Period N-2 will be entered

Time period (N-3) - calendar year three years before PSR

☐ Data for Time Period N-3 will be entered

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

Manufacturer PSR Analysis

General Comments

Time period (N-1) - calendar year one year before PSR

☒ Data for Time Period N-1 will be entered

* Start date
2022-01-14

* End date
2022-12-24

* Number of similar incidents (EEA+TR+XI)
11

* Number of similar incidents (World)
20

* Number of devices on the market in EEA+TR+XI
750

* Number of devices on the market at world level
1350


8.1.7 Step 6: General comments

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



8.1.8 Step 7: PSR Submission

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



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

Dossier PSR-2023-000074 : Draft

Are you sure you want to submit this PSR request? After submission, the PSR will have the state **UNDER APPROVAL** and will be notified and visible to the Competent Authorities. You may view your data immediately after the submission, or by accessing the dossier in "Search and manage Vigilance items" page. The Competent Authorities will have 7 calendar days to approve or not this PSR.

Complete action Close

**NOTE**

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

Action 2023-11-24 | Email

Vigilance - VGL-023 - AM-MF-000004569(Eudamed Reference: PSR-2023-000007) New PSR Submitted

A new PSR has been submitted by the Manufacturer NON_EU_MF_4.1_shriya (SRN : AM-MF-000004569) You can approve or reject this PSR in EUDAMED After 01 Dec 2023 01:00:00, if you did not submit your decision in EUDAMED, this is considered as a rejection.

The PSR can be accessed using the following link: <https://webgate.test.ec.europa.eu/eudamed/vig/#/applications/15066>

8.2 Manage PSR

8.2.1 Related PSRPs

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

EUDAMED Ref No: PSR-2024-000205

Version: 5 [Current] | Last update: 2024-03-22

[Back to list](#) [Close PSR](#)

Report Primary Details

Administrative Information

PSR Information

Device Information

Initial Manufacturer PSR Analysis

General Comments

Related PSRPs

CA Status & History

PSRPs submitted in the PSR

EUDAMED Ref No: PSRP-2024-000205-2024-03-22-09 | Manufacturer reference number: [98](#)

EUDAMED Ref No: PSRP-2024-000205-2024-03-22-07 | Manufacturer reference number: [356](#)

**TIP**

Each linked PSRP can be accessed via the hyperlink provided.

8.2.2 CA Status & History

**NOTE**

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

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

EUDAMED Ref No: PSR-2024-000356

Version: 15 [Current] | Last update: 2024-04-26

[Back to list](#) [Close PSR](#) [Change the Coordinating Competent Authority](#) [Extend the device scope](#) [Change the frequency of reporting](#)

[Add Competent Authority\(ies\)](#) [Update other fields](#)

Report Primary Details

Administrative Information

PSR Information

Device Information

Initial Manufacturer PSR Analysis

General Comments

Related PSRPs

CA Status & History

Summary

Period: 26/04/2024 13:25 - 26/04/2024 15:25 | version: 15

Period: 26/04/2024 11:20 - 26/04/2024 13:20 | version: 14

Approval: Add Competent Authority(ies) / Approved / 26/04/2024 13:20

Submitted on 26/04/2024 13:12 with the comment Add CA BE with the document.

[Add CA BE.pdf](#)

Add Competent Authority(ies) 26/04/2024 13:10

Period: 26/04/2024 09:20 - 26/04/2024 11:20 | version: 13

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

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

EUDAMED Ref No: PSR-2024-000356

Version: 15 [Current] | Last update: 2024-04-26

[Back to list](#)
[Close PSR](#)
[Change the Coordinating Competent Authority](#)
[Extend the device scope](#)
[Change the frequency of reporting](#)

[Add Competent Authority\(ies\)](#)
[Update other fields](#)

[Details](#)

Report Primary Details

Administrative Information

PSR Information

Device Information

Initial Manufacturer PSR Analysis

General Comments

Related PSRs

CA Status & History

Period: 26/04/2024 13:25 - 26/04/2024 15:25 version: 15

Type	Actor	Name	Comment	Document
CA	LT-CA-024	Valstybinė akreditavimo sveikatos priežiūros veiklai tarnyba prie Sveikatos apsaugos ministerijos		
CCA	LT-CA-024	Valstybinė akreditavimo sveikatos priežiūros veiklai tarnyba prie Sveikatos apsaugos ministerijos		
CA	BE-CA-001	Agence Fédérale des Médicaments et des Produits de Santé / Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten	CA BE ok participate	CA BE ok participate.pdf

8.2.3 PSR Approval or Refusal – first version



NOTE

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

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

**NOTE****Approved status**

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

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

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

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

Notification example: PSR approval by the CCA:

Vigilance - VGL-027 - NL-MF-000000041(EUDAMED Reference: PSR-2023-000027) Coordinating Competent Authority approves PSR (first version)
 PSR PSR-2023-000027 has been approved by the Coordinating Competent Authority Agence Fédérale des Médicaments et des Produits de Santé/Federale Agent
 Gezondheidsproducten (Actor ID/SRN : BE-CA-001)
 The PSR can be accessed using the following link: <https://webgate.test.ec.europa.eu/eudamed/vig/#/applications/15287>

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

Information 2023-11-29 | Email
 Vigilance - VGL-029 - NL-MF-000000041(EUDAMED Reference: PSR-2023-000029) A PSR has been refused
 PSR (first version) PSR-2023-000029 has been refused by the Coordinating Competent Authority (CCA) Agence Fédérale des Médicaments et des Produits de Santé/Federale Agent
 Geneesmiddelen en Gezondheidsproducten (Actor ID/SRN BE-CA-001) as a final decision (no further action on this PSR is possible).
 The Refused PSR can be accessed using the following link: <https://webgate.test.ec.europa.eu/eudamed/vig/#/applications/15321>

8.2.4 PSR Withdrawal – first version



NOTE

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

1. Access the relevant PSR via the *Search and Manage Vigilance items* page.
2. Inside the PSR main page, click on **Withdraw** at the top right corner:

CURRENT ACTOR: Manufacturer, NL-MF-000000041, Medical Device Manufacturer [Netherlands]

EUDAMED Ref No: PSR-2024-000479

Version: 1 [Current] | Last update: 2024-07-08

[Back to list](#) [Withdraw PSR](#)

Report Primary Details

Administrative Information

PSR version state
Under approval

Form Type
PSR (Periodic Summary Report)

Manufacturer reference
333

Manufacturer

Actor ID/SRN: NL-MF-000000041
Organisation name: Medical Device Manufacturer
Address: 30 Grootebeertaan
NL-8000
Amersfoort Netherlands

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

Dossier PSR-2023-000068 : Under approval

After completing the current action, the PSR status will be set to WITHDRAWN and no further actions are allowed for this PSR

Draft
Web_Supplier

Under approval
Under Approval

Withdrawn
Application/notification is withdrawn

[Complete action](#) [Close](#)

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



NOTE

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

CURRENT ACTOR: Manufacturer, NL-MF-000000041, Medical Device Manufacturer (Netherlands)

EUDAMED Ref No: PSR-2024-000479

Version: 1 [Current] | Last update: 2024-07-08

< Back to list

Report Primary Details

Administrative Information

PSR Information

Device Information

Initial Manufacturer PSR Analysis

General Comments

Related PSRPs

CA Status & History

Summary

Version 1

Approval, Initial version / Withdrawn / 08/07/2024 15:07

Submitted on 08/07/2024 15:05

8.2.5 Update PSR (create new version)



NOTE

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

Important:

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

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

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

**NOTE**

There are five possible types of updates in a PSR:

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

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

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

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

CURRENT ACTOR: Manufacturer, NL-MF-000000041, Medical Device Manufacturer [Netherlands]

Search and Manage Vigilance items Create Vigilance Form +

Search

Search criteria	Value
Form Type ×	PSR (Periodic Summary Report) ×

Add

Search Clear search

My Vigilance Items

Showing 1 to 6 of 6 entries SHOW 20 ENTRIES PER PAGE

EUDAMED Report ID	Form Type	Manufacturer SRN	Submission date	Status	State	Action
PSR-2024-000206	PSR (Periodic Summary Report)	NL-MF-000000041	2024-03-21	Approved	Approved	
PSR-2024-000205	PSR (Periodic Summary Report)	NL-MF-000000041	2024-03-21	Active	Active	
PSR-2024-000204	PSR (Periodic Summary Report)	NL-MF-000000041	2024-03-21	Active	Active	
PSR-2024-000203	PSR (Periodic Summary Report)	NL-MF-000000041	2024-03-21	Active	Active	

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

CURRENT ACTOR: Manufacturer, NL-MF-000000041, Medical Device Manufacturer [Netherlands]

EUDAMED Ref No: PSR-2024-000202

Version: 5 [Current] | Last update: 2024-03-22

[Back to list](#)
[Close PSR](#)
[Change the Coordinating Competent Authority](#)
[Extend the device scope](#)
[Change the frequency of reporting](#)

[Add Competent Authority\(ies\)](#)
[Update other fields \(no approval needed\)](#)

Report Primary Details
Administrative Information
 PSR information
 Device Information
 Initial Manufacturer PSR Analysis
 General Comments
 Related PSRPs
 CA Status & History

Report Primary Details

PSR dossier status: Active

Form Type: PSR (Periodic Summary Report)

Manufacturer reference: 3

Manufacturer:

Actor ID/SRN:	NL-MF-000000041
Organisation name:	Medical Device Manufacturer
Address:	30 Grootebeertaan NL-8000

In the present example the CCA is updated.

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

Dossier PSR-2024-000202 : Active

Approved (checked)
 Active (selected)
 Draft (With Subscriber)

[Complete action](#)
[Close](#)

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

Report Primary Details
Administrative Information
 PSR information
 Device Information
 Initial Manufacturer PSR Analysis

Administrative Information

*Coordinating Competent Authority Country

Austria
 Belgium

Authority Country is a mandatory field

nation of the report

- Click on **Submit** at the top right of the screen:

EUDAMED Ref No: PSR-2024-000202

Version: 6 [Draft] | Last update: 2024-03-22

[Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

PSR Information

Coordinating Competent Authority Country

Germany [Clear](#)

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

Dossier PSR-2024-000202 : Draft

Are you sure you want to submit this PSR update to change the Coordinating Competent Authority? After submission, the PSR update will have the state UNDER APPROVAL and the relevant actors will be notified. You may view your data immediately after submission, or by accessing the dossier in the "Search and manage Vigilance items" page. The new Coordinating Competent Authority will have 7 calendar days to react.

Timeline: **Draft** (7 days) → Under approval (7 days) → Approved

Comments

Attachment (PDF)

[Choose File](#) [Remove](#)

[Complete action](#) [Close](#)

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



NOTE

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

8.2.6 Approval or Refusal of PSR update



NOTE

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

All following updates require approval:

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



TIP

Approved state of PSR following an update

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

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

8.2.7 Participating CA opt-out of PSR



NOTE

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

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

All Actors involved in a PSR will be notified.

8.2.8 Close PSR



NOTE

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

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

CURRENT ACTOR: Manufacturer, NL-MF-000000041, Medical Device Manufacturer [Netherlands]

EUDAMED Ref No: PSR-2024-000068

Version: 1 [Current] | Last update: 2024-02-01

[Back to list](#) [Close PSR](#)

Report Primary Details

Administrative Information

PSR information

Report Primary Details

PSR dossier status
Active

Form Type
PSR (Periodic Summary Report)

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

Dossier PSR-2024-000068 : Active

After completing the current action, the PSR status will be set to PENDING CLOSURE and no further updates are possible for this PSR. MIR can still be linked until end of current period and a last PSRP must still be provided after the end of the current period. When the last PSRP is submitted or no PSRP is submitted at the end of the period, the PSR status will be set to CLOSED

Approved recovered Active Pending closure

[Complete action](#) [Close](#)

**TIP**

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

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

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

Following closure, all involved Actors will receive information notifications.

Playground

9 PSRP

9.1 Register a new PSRP

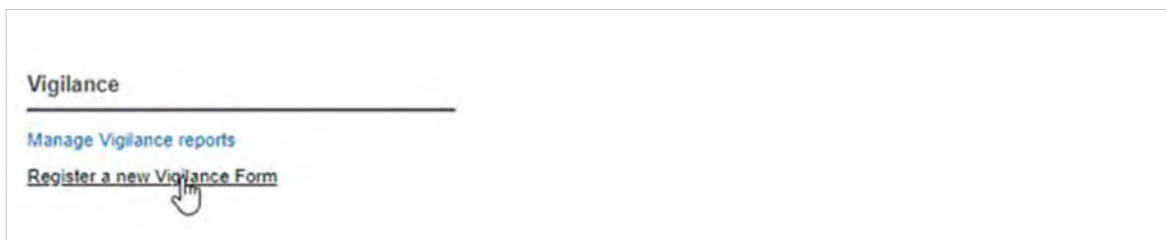
9.1.1 Step 0: Create initial PSRP dossier

**NOTE**

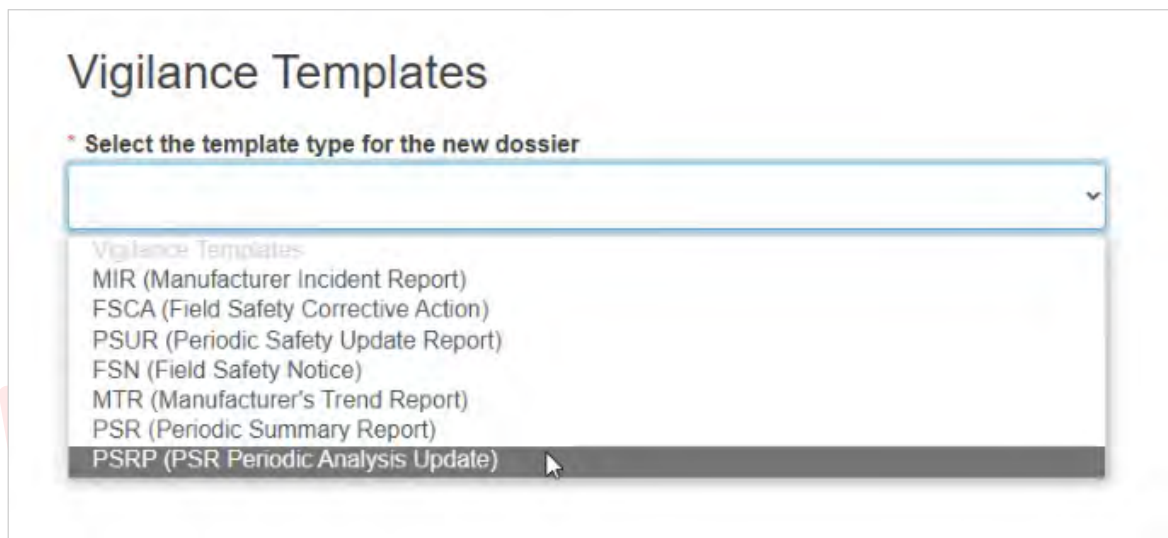
A **PSRP (PSR Periodic Analysis Update)** must be linked to an *active* PSR and serves as a tool for periodic reporting updates after the PSR period has elapsed.

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

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



2. Select the PSRP template from the dropdown list:



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

Vigilance Templates

* Select the template type for the new dossier

PSRP (PSR Periodic Analysis Update) ▼

* Manufacturer

NL-MF-000000041 [Medical Device Manufacturer]

The system will automatically retrieve your Actor information.

4. Enter the unique *Manufacturer reference*.
5. Select the PSR ID you wish to link the PSRP to:

Vigilance Templates

* Select the template type for the new dossier

PSRP (PSR Periodic Analysis Update) ▼

* Manufacturer

NL-MF-000000041 ▼

* Manufacturer reference

111

* Periodic Summary Report ID

|

PSR-2024-000058	
PSR-2024-000066	NL-MF-000000041
PSR-2024-000067	Medical Device Manufacturer
PSR-2024-000069	30 Grootebeearlaan
PSR-2024-000068	NL-8000
	Amersfoort Netherlands

Create Form

**TIP**

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

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

**IMPORTANT**

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

9.1.2 Step 1: Report primary details

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

The screenshot shows the 'Report Primary Details' form. At the top left is a '< Back to list' button, and at the top right is a 'Submit' button. On the left side, there is a sidebar with three menu items: 'Report Primary Details' (highlighted with a blue arrow), 'Administrative Information', 'Manufacturer PSRP Analysis', and 'General Comments'. The main content area is titled 'Report Primary Details' and contains the following information:

- Form Type**: PSRP (PSR Periodic Analysis Update)
- Periodic Summary Report ID**: PSR-2024-000067
- PSRP period**:
 - Period start date: 2024-02-02
 - Period end date: 2024-02-02
- Manufacturer reference**: 111
- Manufacturer**:
 - Actor ID/SRN: NL-MF-000000041
 - Organisation name: Medical Device Manufacturer
 - Address: 30 Grootebeerslaan, NL-8000, Amersfoort Netherlands

9.1.3 Step 2: Administrative information

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

Version : 1 [Draft] | Last update : 2024-02-02

[Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

Manufacturer PSRP Analysis

General Comments

Contact information of the report

Manufacturer contact details

Manufacturer Contact Details

Contact First Name: fbdgb

Contact Last Name: bfgb

E-mail: a@b.com

Phone Number: 44

Contact details for this report
Same as manufacturer

9.1.4 Step 3: Manufacturer PSRP analysis

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

[Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

Manufacturer PSRP Analysis

General Comments

Manufacturer Analysis

Problem statement and background

Preliminary results and conclusions of manufacturer's investigation

dbdssbq

What further investigations do you intend in view of reaching final conclusions?

bnbgfsn

Cause investigation and conclusion/outcome

Description of the manufacturer's evaluation concerning possible root causes/causative factors and conclusion/outcome

ntsgn

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

**TIP**

If necessary, consult the user guide's [Initial Manufacturer PSR analysis \[121\]](#) section.

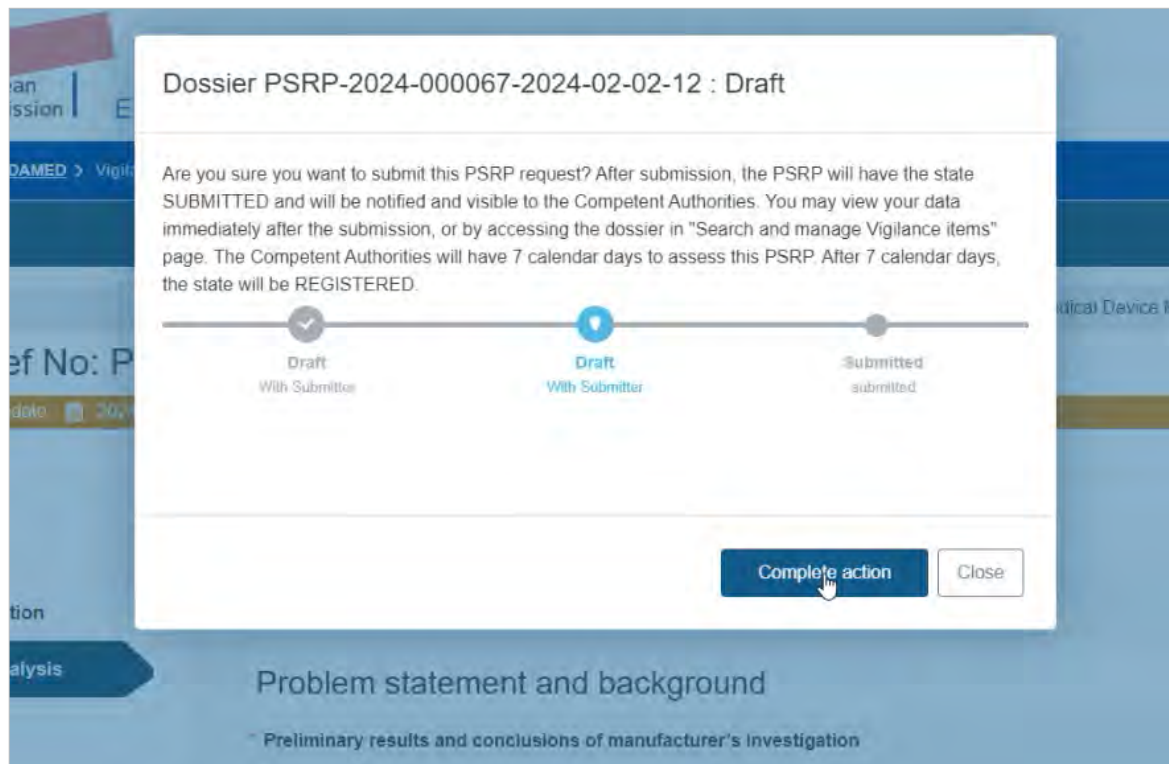
2. Fill in the *Periodic PSR Analysis Update* section:

3. Fill in the *Comments* field:

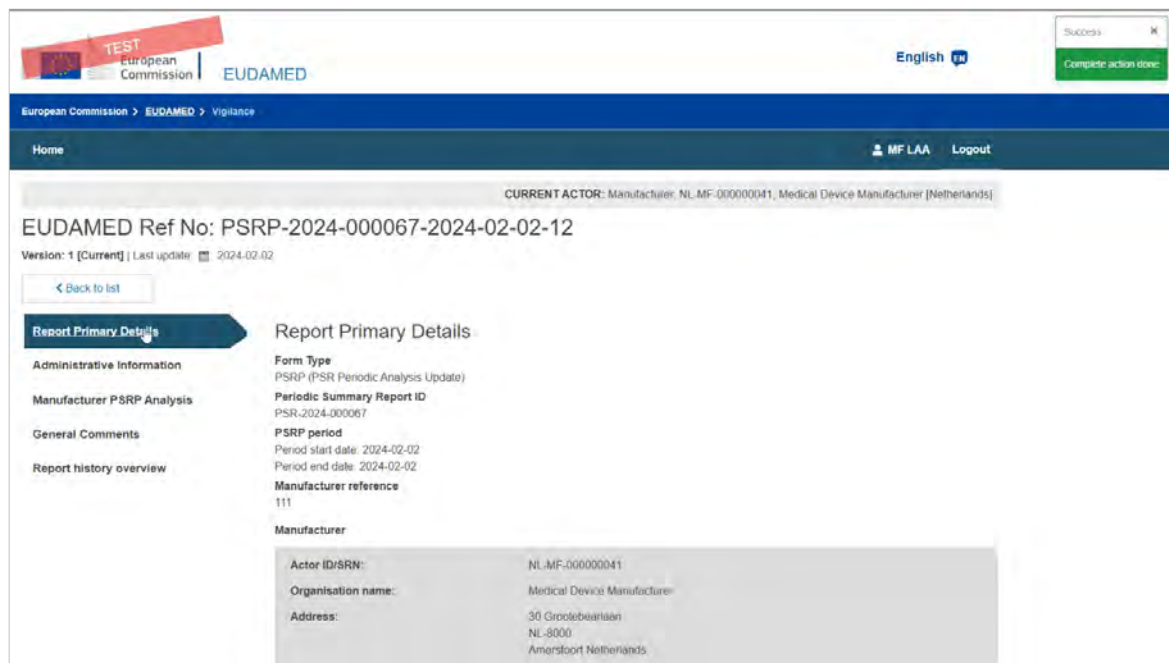
9.1.5 Step 4: General comments / Submission

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

2. After having verified that all information included in all previous steps is correct, click on **Submit**.
3. Click on **Complete action** in the pop-up window to finalise the submission or **Close** to go back:



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



9.2 Manage PSRP

9.2.1 Related incidents submitted (under development)

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

CURRENT ACTOR: Manufacturer, BE-MF-000000081, Medex [Belgium]

EUDAMED Ref No: PSRP-2024-000206-2024-04-09-13

Version: 1 [Current] | Last update: 2024-04-09

[← Back to list](#)

Report Primary Details

Administrative Information

Manufacturer PSRP Analysis

General Comments

Related incidents submitted

Action history overview

Related incidents submitted ⓘ

No result found

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

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



NOTE

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

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

9.2.3 Update PSRP (create new version)



NOTE

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

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

My Vigilance Items						
Showing 1 to 20 of 70 entries			SHOW: 20 ENTRIES PER PAGE			
EUDAMED Report ID	Form Type	Manufacturer SRN	Submission date	Status	State	Action
PSR-2024-000223	PSR (Periodic Summary Report)	BE-MF-000000081			Draft	Delete
MIR-2024-04-000028	MIR (Manufacturer Incident Report)	BE-MF-000000081			Draft	Delete
MIR-2024-04-000027	MIR (Manufacturer Incident Report)	BE-MF-000000081			Draft	Delete
MIR-2024-04-000026	MIR (Manufacturer Incident Report)	BE-MF-000000081			Draft	Delete
PSR-2024-000222	PSR (Periodic Summary Report)	BE-MF-000000081			Draft	Delete
PSR-2024-000221	PSR (Periodic Summary Report)	BE-MF-000000081			Draft	Delete
PSR-2024-000220	PSR (Periodic Summary Report)	BE-MF-000000081			Draft	Delete
PSR-2024-000219	PSR (Periodic Summary Report)	BE-MF-000000081	2024-04-09	Active	Active	
PSRP-2024-000206-2024-04-09-13	PSRP (PSR Periodic Analysis Update)	BE-MF-000000081	2024-04-09		Registered	
PSRP-2024-000210-2024-04-09-10	PSRP (PSR Periodic Analysis Update)	BE-MF-000000081			Draft	Delete

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

EUDAMED Ref No: PSRP-2024-000202-2024-03-27-17

Version: 2 [Current] | Last update: 2024-04-09

[Back to list](#)
[Create new version](#)

Report Primary Details

Administrative Information

Manufacturer PSRP Analysis

General Comments

Related incidents submitted

Action history overview

Report Primary Details

Form Type

PSRP (PSR Periodic Analysis Update)

Periodic Summary Report ID

[PSR-2024-000202](#)

PSRP period

Period start date: 2024-03-22 22:16

Period end date: 2024-03-27 17:00

Manufacturer reference

1003

Manufacturer

Actor ID/SRN:

BE-MF-000000081

Organisation name:

Madex

Address:

2352456 TEST MF STREET

235246 1000

Brussels Belgium

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

EUDAMED Ref No: P

Version: 2 [Current] | Last update: 202

[Back to list](#)
[Create new version](#)

Report Primary Details

Administrative Information

Manufacturer PSRP Analysis

General Comments

Related incidents submitted

Action history overview

Dossier PSRP-2024-000202-2024-03-27-17 : Registered

After completing the current action, the system will initiate a new PSRP version in DRAFT state

Draft

Registered

Draft

Complete action

Close

The applicable sections will become accessible for updates.

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

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

EUDAMED Ref No: PSRP-2024-000202-2024-03-27-17

Version : 3 [Draft] | Last update : 2024-04-05

[Back to list](#) [Submit](#)

Report Primary Details

Administrative Information

Manufacturer PSRP Analysis

General Comments

Related incidents submitted

Action history overview

Report Primary Details

Form Type
PSRP (PSR Periodic Analysis Update)

Periodic Summary Report ID
[PSR-2024-000202](#)

PSRP period
Period start date: 2024-03-22 22:16
Period end date: 2024-03-27 17:00

Manufacturer reference
1003


Manufacturer

Actor ID/SRN:	BE-MF-000000081
Organisation name:	Medex
Address:	2352468 TEST MF STREET 235246 1000 Brussels Belgium

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

Dossier PSRP-2024-000202-2024-03-27-17 : Registered

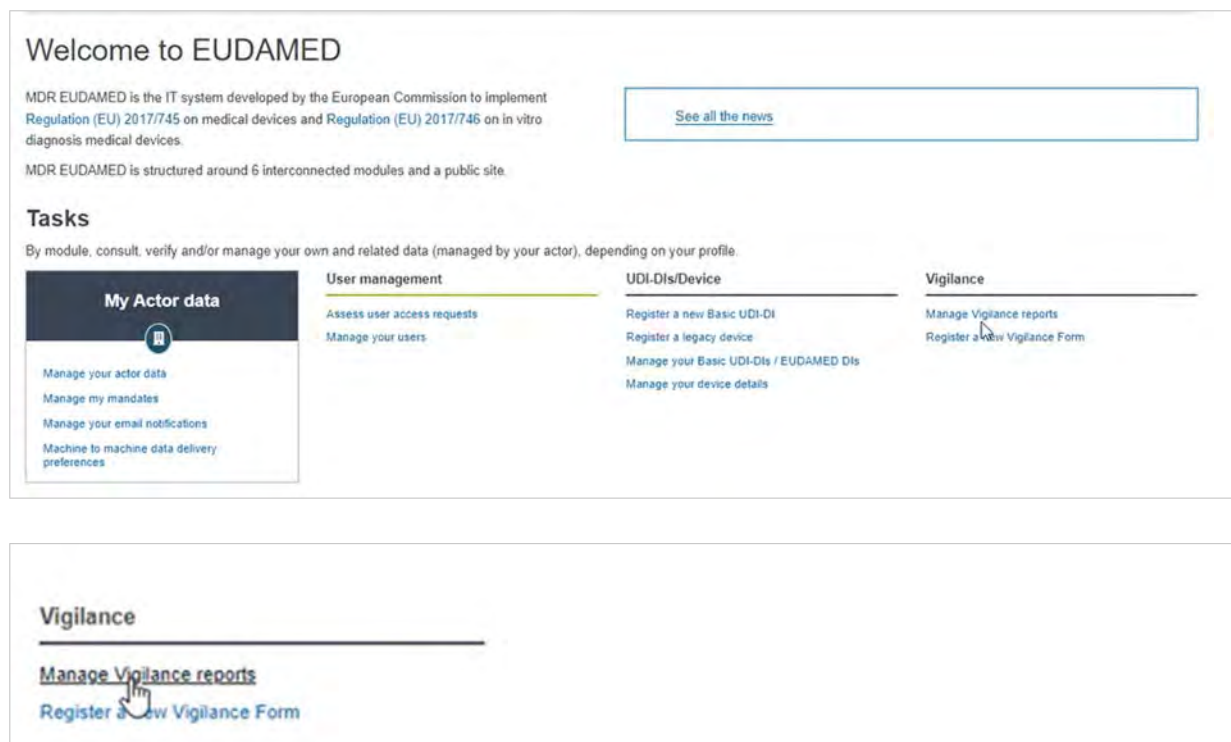
After completing the current action, the system will initiate a new PSRP version in DRAFT state



Complete action [Close](#)

10 Manage Vigilance & Post-Market Surveillance reports

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



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

CURRENT ACTOR: Manufacturer, AF-MF-000000122, John's NonEU MF (Afghanistan)

Search and Manage Vigilance items

Create Vigilance Form +

Search

Search criteria: Value:

Add

Search

My Vigilance Items 01 APPLICATION APPLICATIONS_LISTED

EUDAMED Report ID	Report Type	Manufacturer SRN	Report Submission Date	Status	State	Action
Column filter	Column filter	Column filter	Column filter	Column filter	Column filter	
FSCA_0-2022-03-000025	FSCA (Field Safety Corrective Action)	AF-MF-000000122	2022-03-14 11:02:57		Draft	Delete
MIR-2022-03-000106	MIR (Manufacturer Incident Report)	AF-MF-000000122	2022-03-11 03:28:05		Draft	Delete
MIR-2022-03-000105	MIR (Manufacturer Incident Report)	AF-MF-000000122	2022-03-11 03:01:23		Draft	Delete
MIR-2022-03-000104	MIR (Manufacturer Incident Report)	AF-MF-000000122	2022-03-11 02:30:57	Initial	Draft	Delete
PSUR-2022-03-000009	PSUR (Periodic Safety Update Report)	AF-MF-000000122	2022-03-11 01:54:56		Registered	
MIR-2022-03-000103	MIR (Manufacturer Incident Report)	AF-MF-000000122	2022-03-11 01:52:47		Draft	Delete
FSCA_0-2022-03-000021	FSCA (Field Safety Corrective Action)	AF-MF-000000122	2022-03-11 01:40:25		Draft	Delete

10.1 Create Vigilance & Post-Market Surveillance form

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

CURRENT ACTOR: Manufacturer, AF-MF-000000122, John's NonEU MF (Afghanistan)

Search and Manage Vigilance items

Create Vigilance Form +

Search

Search criteria: Value:

Add

Search

My Vigilance Items 01 APPLICATION APPLICATIONS_LISTED

EUDAMED Report ID	Report Type	Manufacturer SRN	Report Submission Date	Status	State	Action
Column filter	Column filter	Column filter	Column filter	Column filter	Column filter	
FSCA_0-2022-03-000025	FSCA (Field Safety Corrective Action)	AF-MF-000000122	2022-03-14 11:02:57		Draft	Delete

10.2 Delete Vigilance & Post-Market Surveillance draft report

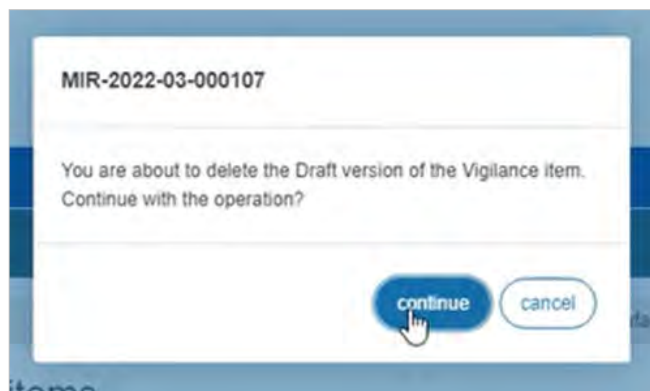
Newly created versions in state *draft* (not yet submitted) can be deleted from *My Vigilance items*.

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

My Vigilance Items 82 APPLICATION APPLICATIONS LISTED

EUDAMED Report ID	Report Type	Manufacturer SRN	Report Submission Date	Status	State	Action
MIR-2022-03-000107	MIR (Manufacturer Incident Report)	AF-MF-000000122	2022-03-14 02:25:48	Initial	Draft	Delete
FSCA_0-2022-03-000025	FSCA (Field Safety Corrective Action)	AF-MF-000000122	2022-03-14 11:02:57		Draft	Delete

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



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

CURRENT ACTOR: Manufacturer, AF-MF-000000122, John's NonEU MF [Afghanistan]

Search and Manage Vigilance items Create Vigilance Form +

Search

Search criteria Value

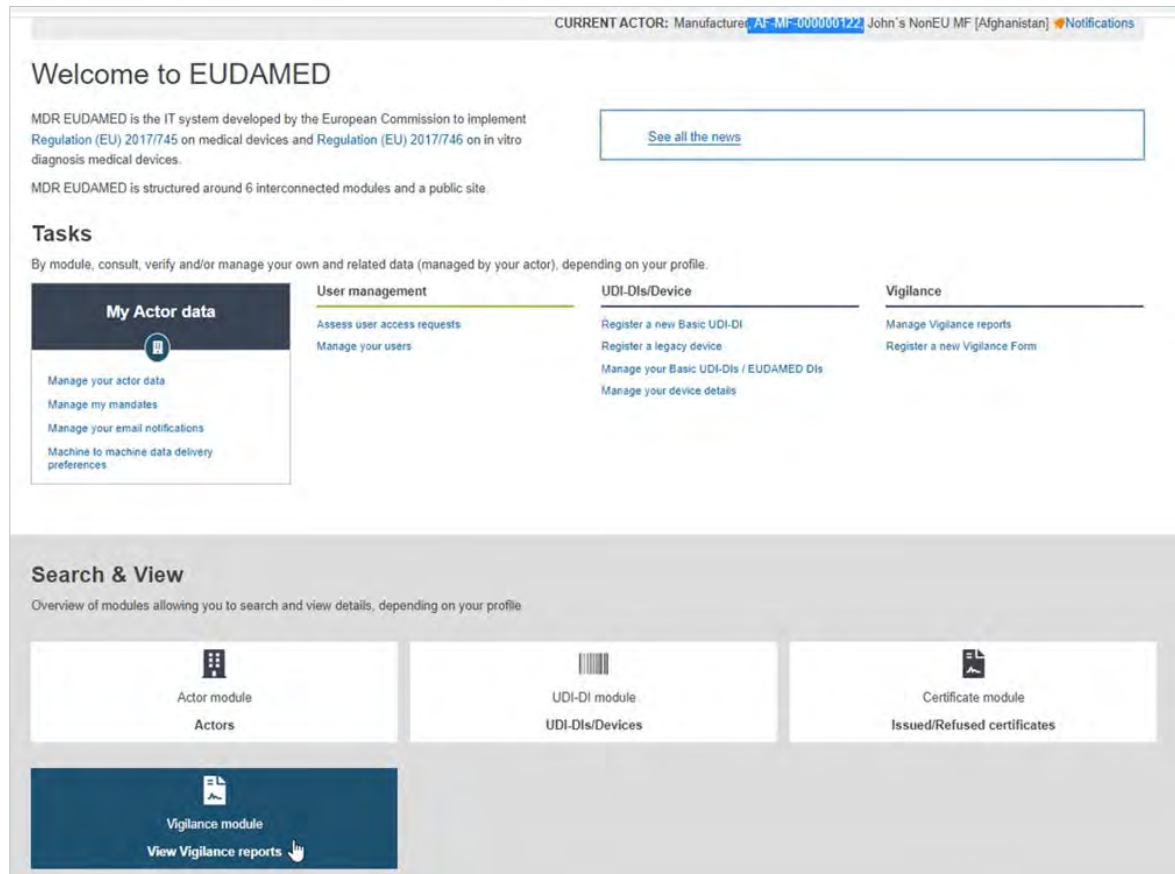
My Vigilance Items 81 APPLICATION APPLICATIONS LISTED

EUDAMED Report ID	Report Type	Manufacturer SRN	Report Submission Date	Status	State	Action
FSCA_0-2022-03-000025	FSCA (Field Safety Corrective Action)	AF-MF-000000122	2022-03-14 11:02:57		Draft	Delete
MIR-2022-03-000106	MIR (Manufacturer Incident Report)	AF-MF-000000122	2022-03-11 03:28:05		Draft	Delete

10.3 Search & View Vigilance & Post-Market Surveillance reports

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

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



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



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

CURRENT ACTOR: Manufacturer, AF-MF-000000122, John's NonEU MF [Afghanistan]

Search and Manage Vigilance items

Search

Please select...

Form Type

- EUDAMED Report ID
- Report Submission Date
- State
- application.manufacturerSrn
- application.authorisedRepresentativeSrn
- Country
- Actor ID/SRN
- Eudamed 2 CIV ID

11 ITEMS LISTED

Manufacturer SRN	Report Submission Date	Status	State	Action	
Column filter	Column filter	Column filter	Column filter		
AF-MF-000000122	2022-04-05	Initial	Draft	Delete	
MIR-2022-04-000187	MIR (Manufacturer Incident Report)	AF-MF-000000122	2022-04-05	Draft	Delete

**TIP**

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

Search and Manage Vigilance items

Search

Search criteria	Value	
Form Type	FSCA (Field Safety Corrective Action)	Remove
Country	Belgium	Remove

[Add](#)

[Search](#) [Clear search](#)

- Click on the **Search** button.

View Vigilance & Post-Market Surveillance report

**NOTE**

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

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

CURRENT ACTOR: Manufacturer, AF-MF-000000122, John's NonEU MF [Afghanistan]

Search and Manage Vigilance items

[Create Vigilance Form](#) +

Search

Search criteria Value

My Vigilance Items 01 APPLICATION APPLICATIONS_LISTED

EUDAMED Report ID	Report Type	Manufacturer SRN	Report Submission Date	Status	State	Action
<input type="text" value="Column filter"/>	<input type="text" value="Column filter"/>	<input type="text" value="Column filter"/>	<input type="text" value="Column filter"/>	<input type="text" value="Column filter"/>	<input type="text" value="Column filter"/>	
FSCA-0-2022-03-000025	FSCA (Field Safety Corrective Action)	AF-MF-000000122	2022-03-14 11:02:57		Draft	Delete
MIR-2022-03-000106	MIR (Manufacturer Incident Report)	AF-MF-000000122	2022-03-11 03:28:05		Draft	Delete
MIR-2022-03-000105	MIR (Manufacturer Incident Report)	AF-MF-000000122	2022-03-11 03:01:23		Draft	Delete
MIR-2022-03-000104	MIR (Manufacturer Incident Report)	AF-MF-000000122	2022-03-11 02:30:57	Initial	Draft	Delete

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

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

[Back to list](#)

Report Primary Details

Report Type
MIR(Manufacturer Incident Report)

Manufacturer's reference number for this incident
MFR_MIR_001

Country where the incident occurred
Austria

Competent Authority

SRN:	AT-CA-001
Organisation name:	Federal Ministry of Health (BMF) Dept. III/3 Pharmaceuticals & Medical Devices
Address:	A-1030 Vienna Austria

Manufacturer

SRN:	AF-MF-000000122
Organisation name:	John's NonEU MF
Address:	Test, 2121 Test Test Afghanistan

Report Primary Details

Administrative Information

Device Information

Incident Information

Manufacturer Analysis

General Comments

