



# **EUDAMED user guide**

# Actor module for Economic Operators

Production v 2.25.2  
2026



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# 1 Introduction

The ACT module of EUDAMED is used to manage the mandatory registration of economic operators of medical devices across EU/EEA according to requirements in MDR/IVDR. Access to EUDAMED is granted following a validation by the competent authority of the economic operator Actor registration request.

For the actors that also must register devices or systems and procedure packs (SPPs) in EUDAMED, the registration in the ACT module needs to be validated and their Actor ID/SRN issued before they can register their medical devices.

The Actor module information in EUDAMED is publicly available for searching and viewing, except the contact details for Competent Authorities.

This user guide specifically guides you to actor registration if you are a:

- Manufacturer
- Authorised Representative
- Importer
- System/Procedure pack producer

These roles, collectively referred to as economic operators, are defined by article 2 in MDR and IVDR. Actors who are active in more than one role need a separate registration per role.

This User Guide describes how to register each actor (organization), user (person) and how to assign profiles for each user.

The scope is how economic operators can use the actor registration module – concept, registration, management, access and mandates.

1



## **EVOLVING USER INTERFACE**

The visual components of the EUDAMED user interface, including field labels, menu options and screen layout, are still subject to change and may therefore slightly differ from what you see in this manual.

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

## 1.1 Overview

EUDAMED is the IT system developed by the European Commission to implement the EU medical devices regulations:

[Regulation \(EU\) 2017/745](#) on medical devices

[Regulation \(EU\) 2017/746](#) on *in vitro* diagnostic medical devices

EUDAMED restricted website is structured around **six interconnected modules**:

- Actor registration – user registration and management
- UDI/Devices – registration of devices and UDI database for device data and unique device identifiers (UDI)
- Notified Bodies and Certificates
- Clinical Investigation and performance studies
- Vigilance and post-market surveillance
- Market surveillance

Some of the information in EUDAMED is publicly available through EUDAMED Public.

## 1.2 Basic terms and principles

This section describes a number of basic terms and principles:

- Access through personal login
- Actors
- Basic concepts
- User profiles and access grants/rights
- Starting and ending a EUDAMED session

### 1.2.1 Access EUDAMED through personal login

To use EUDAMED, you must have an EU Login account associated with your professional/personal email address. Private / shared mailboxes are not allowed for security reasons.



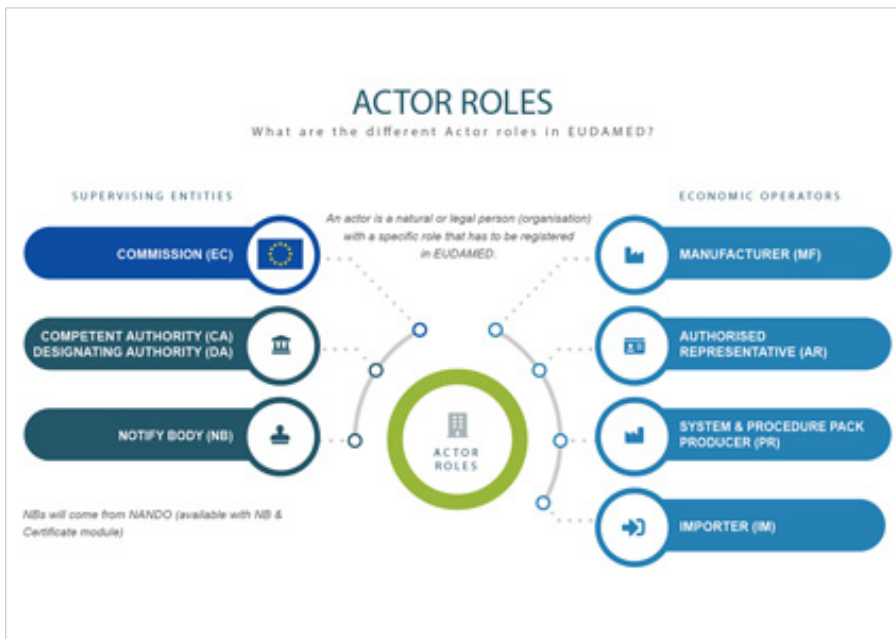
**IMPORTANT**

EU Login is the central European Commission Authentication Service allowing users to access a wide range of Commission information systems and services, using a single personal username and password.

Read more: [Introduction to EU Login](#)

## 1.2.2 EUDAMED Actors

**INFOGRAPHIC: Actor ID/SRN and Actor roles**



### List of actors

Actors involved in EUDAMED are:

#### Supervising bodies

- European Commission
- Competent Authorities (CA)
- Designating Authorities (DA)
- Notified Bodies (NB).

#### Economic operators

- Manufacturers
- System and procedure pack producers
- Authorised Representatives

- Importers

## EUDAMED access - based on three levels

EUDAMED access is personal and given to each individual user based on three levels:

- Actor - your organisation (in a certain Actor role)
- User - you as an individual
- Profile - the tasks you are allowed to do (per module)

### 1.2.3 User rights and profiles

Each user may have multiple accounts but can access EUDAMED with only one account at a time.

Each EUDAMED account is associated with one of the following actor types:

- Manufacturer
- Authorised Representative
- System/Procedure Pack Producer
- Importer

Each of these actor types has a set of roles that are specific to each module in EUDAMED. The actions and rights connected to each role are defined by the user profile of that user (i.e. *Viewer*, *Verifier*, *Linker*, *LAA* etc.) so user profiles are module specific.

Your user profile is determined by your actor role (see table). For example, in *Actors* module, the *Verifier* profile is only enabled for *Authorised Representative* actors. The *Linker* is enabled only for *Importer* actors, which allows them to create links with non-EU manufacturers.

### User profiles in the actor module

User profile	Actor	Rights
Viewer	All	May only view registered actors and own actor details
Verifier	Authorised Representative	View + verify non-EU manufacturer registration requests and verify/terminate associated mandates
Mandate manager	Non-EU manufacturer	View + submit/manage mandates with authorised representative(s)
Linker	Importer	View + link importer with non-EU manufacturer(s)
Local User Administrator (LUA)	All	Verify/manage mandates/ link (depending on actor role) + manage users and user access requests
Local Actor Administrator (LAA)	All	LUA + manage actor data and notification email addresses

### Hierarchy of user profiles

Profiles are hierarchical, i.e. higher-level profiles contain all lower-level grants/rights.

– e.g. *LAA* is the highest profile and contains the rights of all the profiles beneath it in the hierarchy.

## User profiles per actor role and their hierarchy

Authorised representative	Manufacturer	System and procedure pack producer	Importer
LAA	LAA	LAA	LAA
LUA	LUA	LUA	LUA
Verifier	Mandate manager	–	Linker
Viewer (default)	Viewer (default)	Viewer (default)	Viewer (default)

## Tasks in Actor registration

The following tasks can be handled in the ACT module:

- Registering a new Actor (organisation) and managing Actor details
- Registering a new user belonging to an existing Actor
- Managing profiles for a user

## 1.2.4 Starting and ending a EUDAMED session

1. Go to [EUDAMED](#).

The screenshot shows the EUDAMED website interface. At the top, there is the European Commission logo and the EUDAMED title. Below this is a navigation bar with 'European Commission' and 'EUDAMED'. The main heading is 'Welcome to EUDAMED - European Database on Medical Devices'. The page contains several sections:

- Welcome message:** Explains that EUDAMED is the IT system established by Regulation (EU) 2017/745 and Regulation (EU) 2017/746 on medical devices and in vitro diagnosis medical devices. It states that EUDAMED provides a living picture of the lifecycle of medical devices and aims to enhance transparency and coordination.
- Modules:** Lists six modules related to actor registration, UDI, device registration, notified bodies, clinical investigations, and performance studies.
- Sign in to EUDAMED:** A section with a button 'Enter with EU Login' and a link 'No EU Login account? Create your EU Login account'.
- Release note (2026-02-19):** Announces 'v2.22.2 PRODUCTION Hotfix released' and provides details about the hotfix and the XSD schema version (3.0.25).
- Warning (2026-03-11):** Announces 'XSD schemas next version' and states that the release will affect the XSD version number of the DTX services, requiring adaptation before using the M2M service or Bulk upload service.
- Warning (2025-11-27):** Announces that the notice declaring the functionality of the first four modules has been published in the OJEU, initiating a 6-month transition period.

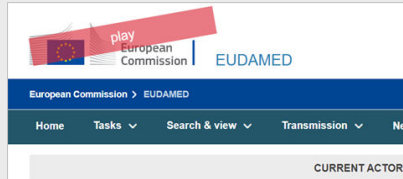


**NOTE**

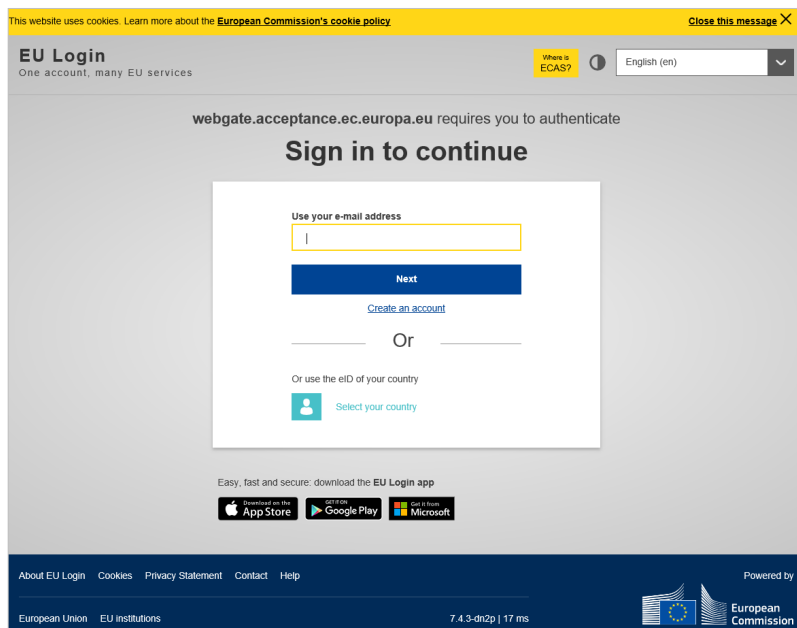
**Playground environment**

EUDAMED is also available in a **Playground environment** for training and testing purposes. All the information in this environment is considered as dummy, including the Actor ID/SRN, and will never be moved to the production environment.

The **Playground** environment contains a red *Play* banner across the logo at the top left of the screen. Access to the Playground requires a separate registration.



2. Click **Enter with EU login**. Alternatively, select **Create your EU Login account** if you do not have one yet.
3. Type your EU Login email address and click **Next**:



4. Enter your password and click **Sign in**:

# Sign in to continue

Welcome back





(European Commission)

[Sign in with a different e-mail address?](#)

Password

[Lost your password?](#)

Choose your verification method

	<p><b>Password</b> Authenticate to EU Login with only your password.</p>	
---	--	---

Sign in



**NOTE**  
**EU Login issues?**

- ▶ Forgot your password? Click [Lost your password?](#) on this screen:

**Sign in to continue**

Welcome back

[Redacted Name]  
(European Commission)

[Sign in with a different e-mail address?](#)

Password

[Redacted Password]

[Lost your password?](#)

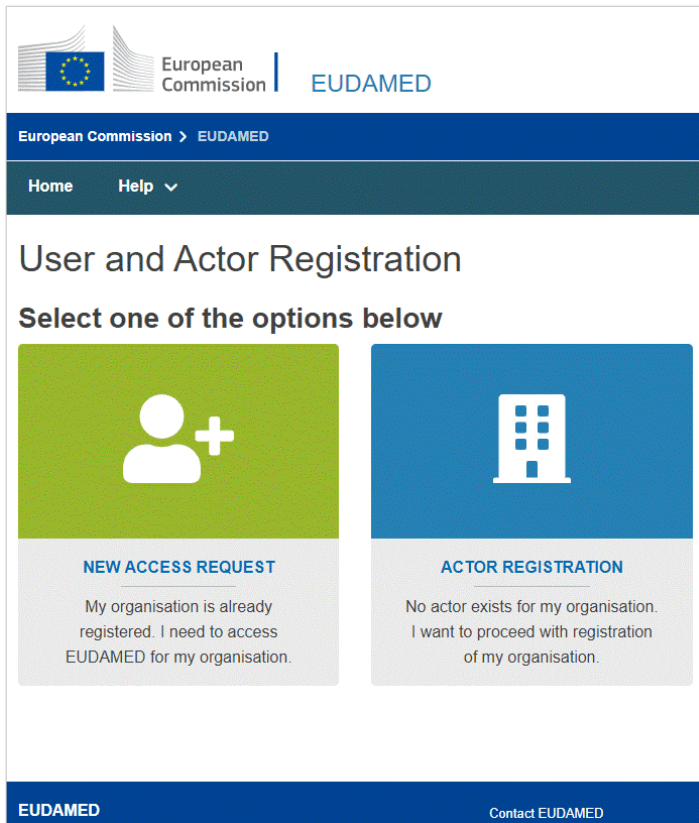
Choose your verification method

**Password**  
Authenticate to EU Login with only your password.

**Sign in**

- ▶ Change your password: Go to [Change password](#)
- ▶ View/edit your account: Go to [My Account](#)

5. Enter your EU Login password and click **Sign in**.  
If your personal login is not yet linked to any pending/registered Actor (organisation) account(s), EUDAMED opens the *User and Actor Registration* page:



**NOTE**

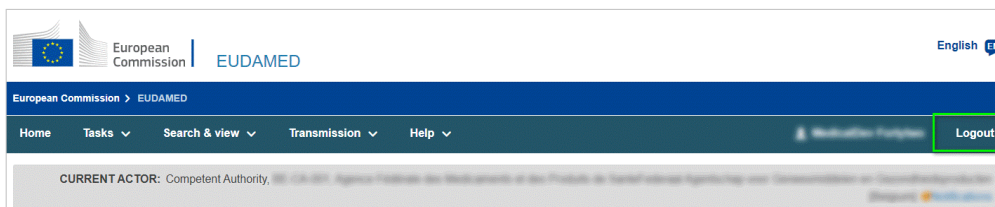
**Next steps:**

► Want to register your organisation as an actor in EUDAMED? See [Registering as an Economic Operator \[13\]](#)

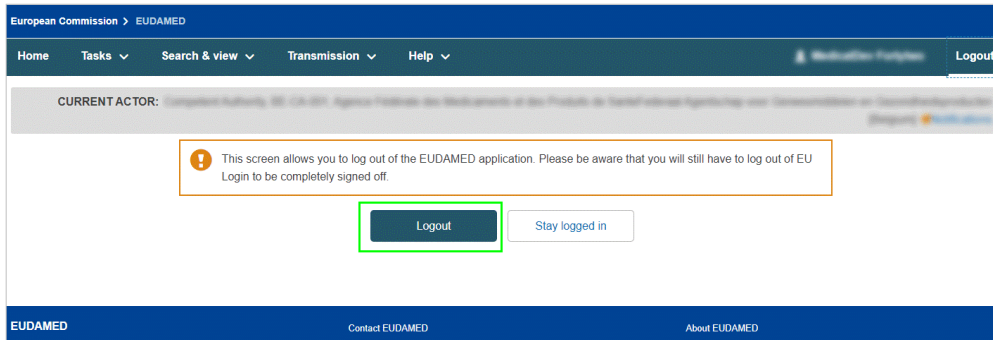
► Need access as a user for a registered economic operator? See [Requesting access as a user for a registered Economic Operator \[61\]](#)

## Ending a EUDAMED session

1. Click **Logout** at the top right of the screen:



2. Confirm with the **Logout** button:



3. Answer the EU Login confirmation message by clicking **Log me out**.

## 2 Managing actors and user accounts

The **Actors** module ensures that all actors and users using EUDAMED have been authenticated.

There are two levels of registration to gain access to EUDAMED:

- Registration of an Actor (organisation)
- Registration of a user (person) belonging to an Actor (organisation)

### Request registration for an Economic Operator (organisation)

Authentication for a new Actor is done by the relevant Competent Authority in that country.

Register your Actor in EUDAMED with the appropriate actor role.

- The person who performs the Actor registration automatically becomes the first *Local Actor Administrator (LAA)* for that actor once the registration is validated.
- Depending on the role, an Actor ID or Single Registration Number (SRN) is generated by EUDAMED and issued by the Competent Authority after validating the registrations request. Incorrect or incomplete requests will not be validated and no Actor ID/SRN will be generated until a complete and correct request has been provided and validated.

### Request access as a user (person) of a registered Economic Operator (organisation)

Authentication for a new user of an existing Actor is done by the Actor's users with the appropriate profile (Local User Administrator or Local Actor Administrator).

If your Actor is already registered in EUDAMED, you can request access as a user of that actor. Once an LAA/LUA from your actor has approved your request, your account will be granted the appropriate user profile for that actor.

**IMPORTANT**

It is good practice having at least two LAA for each Actor, as a fail-safe mechanism if one should be unavailable. Furthermore, an actor must have at least one active LAA at all times, making it impossible to terminate the last LAA for an actor.

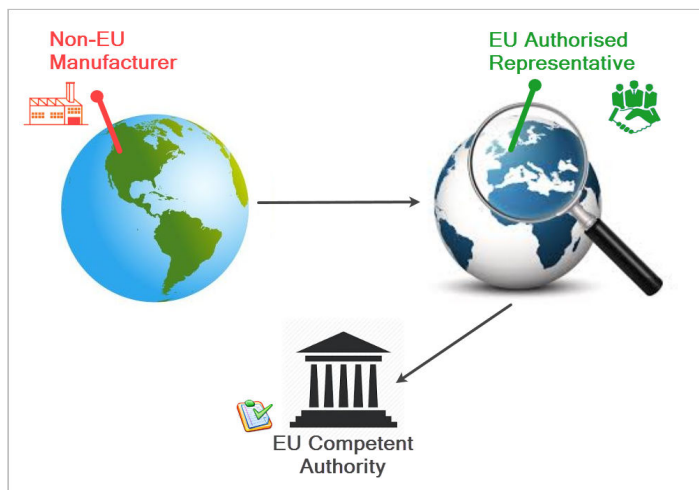
## 2.1 Managing actors

*Economic Operator* is defined by MDR and IVDR. The following Economic Operators are Actors who must be registered in EUDAMED:

- Manufacturer (MF: EU Manufacturers\* & Non-EU Manufacturers\*\*)
- Authorised Representative (AR)
- System/Procedure Pack Producer (SPPP)
- Importer (IM)

\* **EU manufacturers:** If you are established in the EU/EEA, your registration will be assessed by the relevant **Competent Authority (CA)** of the country where you are established.

\*\* **Non-EU manufacturers:** If you are not established in the EU/EEA, you need to appoint an **Authorised Representative** within the Union. Your registration will be verified by the **Authorised Representative** you indicate in your Actor registration request, before being assessed by the Competent Authority responsible for that AR. The AR you indicate in the registration request must be already registered in EUDAMED.



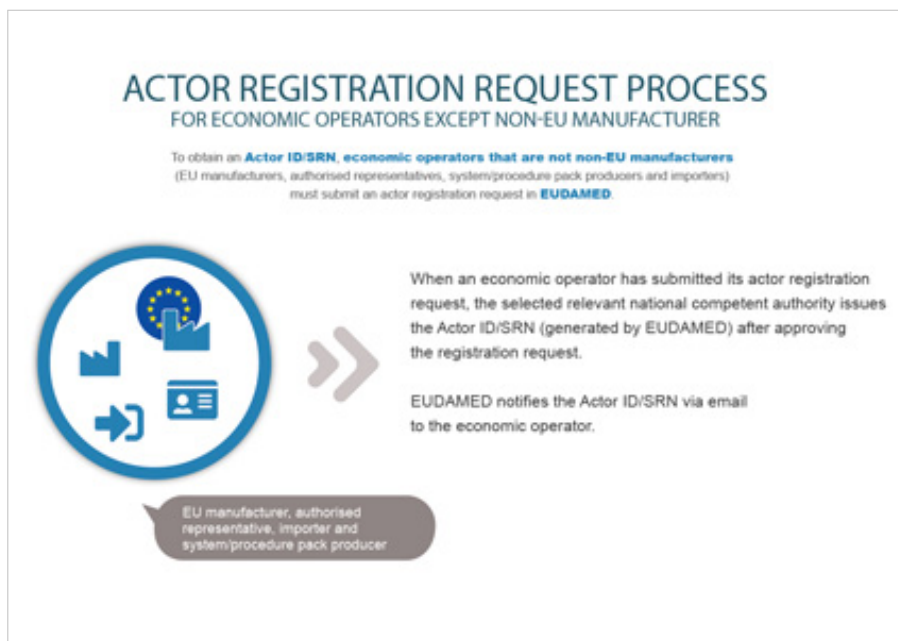
The difference in registration process between the two types of MFIs highlighted in the following pages.

**NOTE****Multiple roles**

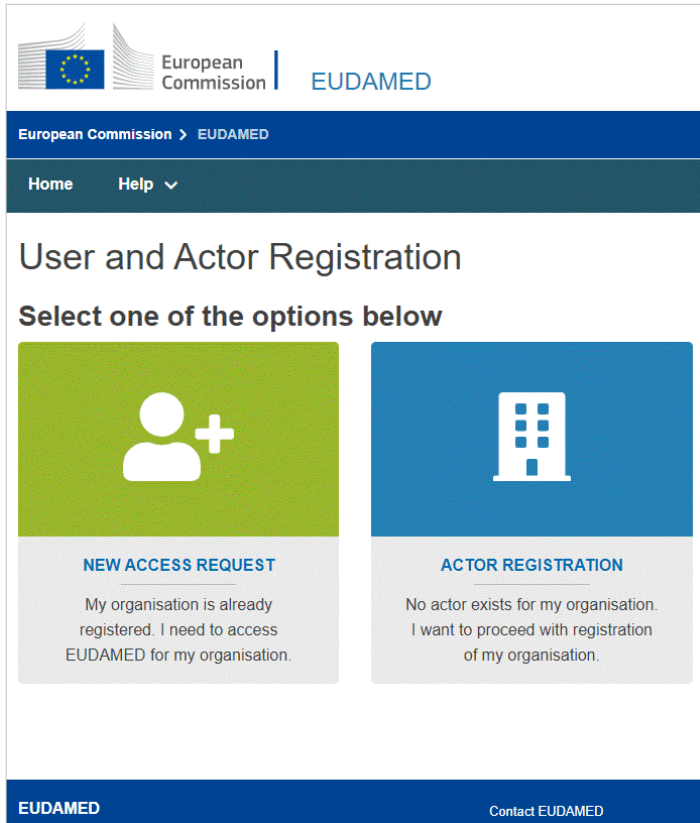
If your organisation has more than one Actor role (e.g. your organisation is a manufacturer and an importer at the same time), you must make a separate actor registrations for each role.

## 2.1.1 Register as an Economic Operator

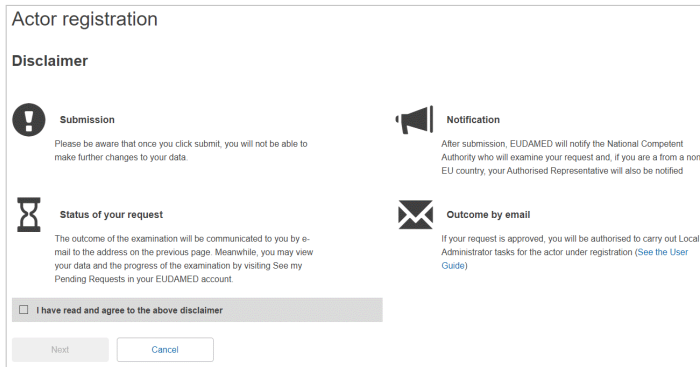
### INFOGRAPHIC: Actor registration request process



1. Log into EUDAMED with your EU Login account (See Section [Starting and ending a EUDAMED session \[2\]](#)). You will land on the *User and Actor Registration* page:



2. Select the Actor Registration widget on the *User and Actor Registration* page. A disclaimer is displayed before you are able to continue:



3. Read the disclaimer, select the *I have read the disclaimer* checkbox and click **Next**. You are prompted to enter the information about your actor:

## Actor registration

**!** Please note that you have to submit an actor registration request for each actor role your company may have:

- Authorised representative - AR
- Importer - IM
- Manufacturer - MF
- System/procedure pack producer - PR

### Create new actor

Enter your organisation data to register your actor

\* Role:

\* Country:

\* Actor / organisation name:

**Next**

- The process summary highlights the completed, current, and the remaining stages of the actor registration process.



- Select the role and country, enter the name of your actor (organisation) exactly as given in your national trade register and click **Next**.

**Actor registration**

1 Actor identification    2 Actor address    3 Contact details    4 Regulatory Persons    5 Registering Local Actor Administrator    6 Competent Authority

**Actor identification**

\* Role:  
Manufacturer

\* Country:  
Belgium

\* Organisation name:  
Sample MF

\* Select organisation language:  
--

+ [Add organisation name in another language](#)

Abbreviated organisation name:

Select abbreviated organisation name language:  
--

+ [Add abbreviated organisation name in another language](#)

**VAT information**

Yes  No  VAT information is required unless you select the option - No

\* VAT number:

[EORI number](#):

National trade register:

Organisation identification document  
Browse

Save registration    Save & Next >



**NOTE**

It is recommended to upload an Organisation Identification document even though it is not mandatory. Some CAs may request this document for validation. If you do decide to upload one, make sure the file is in PDF format and that it does not exceed 10MB.

6. Enter the information for the mandatory fields (marked with\*), and additional fields, needed to identify your Economic Operator: VAT, EORI and National Trade Register Number are mandatory if available. You can upload any document that may be useful for validating your request – but only in PDF format and not exceeding 10MB. Click **Save & Next**.

- a. You will be prompted by the *Actor address* details screen:

**Actor address**

Street information, if applicable  
 Yes  No Street information is required unless you select the option - No

\* Street:  Street number:

Address line 2:

PO box:

Latitude:  Longitude:   
Latitude format example: -15.4543 Longitude format example: 178.34354353

\* City name:  \* Postal code:

\* Country:  
 Belgium



**NOTE**

Non-EU Manufacturers will be prompted by the *Actor address* details screen after entering the *Authorised Representative* details.

7. Enter your actor's address details and click **Save & Next**.  
 You will be prompted by the *Contact Details* screen:

**Actor registration**

1 Actor identification
2 Actor address
3 Contact details
4 Regulatory Persons
5 Registering Local Actor Administrator
6 Competent Authority

**Actor contact details**

**Contact details for Competent Authorities**  
 Note: These details will be visible only to competent authorities

First name:  Last name:

\* Email:

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

**Public contact details**  
 Note: These details will be visible to the public

\* Email:

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

Web site:

- Enter the email addresses and other useful information regarding the contact points in your Actor. There are separate fields in which to enter contacts relevant to competent authorities, and those to be displayed to the public, and click **Save & Next**.

Manufacturers and Authorised Representatives must enter the Person Responsible for Regulatory Compliance details (one or several):

✔  
**Actor identification**

✔  
**Actor address**

✔  
**Contact details**

4  
**Regulatory Persons**

5  
**Registering Local Actor Administrator**

6  
**Competent Authority**

### Person Responsible for Regulatory Compliance

**Regulatory Persons**

\* First name:

\* Last name:

\* Email:

\* Telephone number:

Telephone format example: +32 x.xxx.xx.xx

Responsible for:

**Person Responsible for Regulatory Compliance**

Same address as the Actor organisation address

**Street information, if applicable**

Yes  No  i Street information is required unless you select the option - No

\* Street:  Street number:

Address line 2:

PO box:

Latitude:  Longitude:

Latitude format example: -15.4543 Longitude format example: 178.34354353

\* City name:  \* Postal code:

\* Country:

+ [Add a new Regulatory Person](#)

Save registration

Save & Next >

9. Enter your actor details and click **Save & Next**.

✔  
Actor identification

✔  
Actor address

✔  
Contact details

✔  
Regulatory Persons

5  
Registering Local Actor Administrator

6  
Competent Authority

### Registering Local Actor Administrator

**EU Login personal data** ⓘ

First name:

Last name:

Email:

**EUDAMED personal data** ⓘ

\* First name:

\* Last name:

**EUDAMED email of the user for the actor** ⓘ

\* Email:

**\* Signed declaration:**

⚠ Please use the declaration template below. Only signed declarations following this template will be considered

[Download signed declaration template](#)

Browse

**\* Are you a sub-contractor for this actor?:**

No

Yes

Save registration
Save & Next >



**NOTE**

The person that is registered as PRRC cannot access, change or delete their own contact information in EUDAMED. Only the organisation's LAA (see below) can change Actor information. The LAA should ensure that all information is kept up to date.



**NOTE**

**Local Actor Administrator (LAA)**

The person who first enters the details of an actor in EUDAMED automatically becomes the first LAA for that Actor, once the CA has validated the actor registration.

Additional LAAs may be added later. This only requires validation by the Actor's LAA.

As LAA, you can manage all the details for your Actor in EUDAMED (e.g. name, address, contact details, etc.) as well as user access requests for it (see [Validating user access requests \[69\]](#)).

It is good practice having more than one LAA (with at least one belonging to the actor itself, rather than all from a sub-contractor).



**NOTE**

Please make sure that your Actor has always an active LAA. If the last or only LAA leaves the organisation or loses their EUDAMED login, please contact EUDAMED support.

10. Check and complete the information on the page. Upload the signed declaration – PDF format only and not exceeding 10MB – using the **Browse** button. Please refer to the [template for the signed declaration](#).

**\* Are you a sub-contractor for this actor?:**

No

Yes

**\* Company name:**

**\* Telephone number:**

  
Telephone format example: +32 x xxx xx xx

**\* Company email address:**

**Street information, if applicable**

Yes  No  Street information is required unless you select the option - No

**\* Street:**  **Street number:**

**Address line 2:**

**PO box:**

**Latitude:**  **Longitude:**

Latitude format example: -15.4543 Longitude format example: 178.34354353

**\* City name:**  **\* Postal code:**

**\* Country:**



**NOTE**

If you specify that you are a *sub-contractor*, an additional section at the bottom of the page will prompt you to provide your sub-contracting company details.

11. Click **Save & Next** to move to the last step. Select the Competent Authority that will be responsible for your actor request validation. You can add any extra information that might be relevant for the Competent Authority:

✓ Actor identification   
 ✓ Actor address   
 ✓ Contact details   
 ✓ Regulatory Persons   
 ✓ Registering Local Actor Administrator   
 6 Competent Authority

### Competent Authority

\* Select the competent authority which will validate this actor:

--

**Any other information of significance for the competent authority**

Additional Information:

Save registration    Preview    Submit actor registration >

- If there is a choice between multiple Competent Authorities, select the most appropriate one from the list. (A help file will be available for Actors established in Germany, to assist with the Competent Authority selection). If there is only one authority that can be selected, the details will be automatically displayed. To view a summary of your completed registration form, click **Preview**:

✓ Actor identification   
 ✓ Authorised Representative   
 ✓ Actor address   
 ✓ Contact details   
 ✓ Regulatory Persons   
 ✓ Registering Local Actor Administrator   
 ✓ Competent Authority

### Competent Authority

**Name:** Agence Fédérale des Médicaments et des Produits de Santé/Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten

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

**Country:** Belgium

**Email:** meddev@fagg-afmps.be

**Telephone number:** 00 32 2 528 40 00

**Any other information of significance for the competent authority**

Additional Information:


Save registration    Preview    Submit actor registration >

- Review the information on the form, and then click **Submit actor registration** at the bottom of the page. A confirmation window will appear:

[✕ Close](#)

## Submit your actor registration request

You are about to submit your actor registration request to the relevant national Competent Authority.

 The assessment and validation of your actor registration request is the responsibility of the national competent authority. If you are a "non-EU Manufacturer", the Authorised Representative indicated in your actor registration request will verify the actor registration prior to the national competent authority assessment.


You will receive a notification with the assessment outcome to the email provided in your actor registration request. Follow your application status on 'See my pending requests' in your 'My account' page.

Confirm
Cancel

14. Read the information and click **Confirm**.

- Your registration request is saved and appears with a *Submitted* state in your *Pending requests* list.
- Your registration request has an application ID and is submitted to the selected competent authority:

### Actor registration



**Congratulations. You have successfully submitted your actor registration request.**

Your application ID is APP000000021

### What do you want to do now?

[View the request you just created](#)

[View all of your requests](#)

[Create another request](#)

15. You will be notified when your Actor registration request is approved or not approved. Follow your application status on *See my pending requests* in your *My account* page.



#### NOTE

The validation of the Actors registration requests is under the responsibility of the different national competent authorities (CA).

If the information you provided is incorrect or insufficient, you will get a notification through the system with a request for additional information from your CA. The CA may also deny access, e.g. if fraud is suspected.

If you are a non-EU Manufacturer, the Authorised Representative indicated in your actor registration request must verify your request prior to the national competent authority validation.

A list of national Competent Authorities can be found on the [EUDAMED website](#).

## If your registration is approved

An Actor ID or Single Registration Number (SRN) is generated by EUDAMED and issued by the Competent Authority.

1. The next time you enter EUDAMED, you will be prompted to accept your rights and obligations as the Local Actor Administrator (LAA) for your actor. You can download the disclaimer by clicking on **Download disclaimer** in the orange box:

2. After reading, click on *I accept the user rights and obligations* and then click **Next**. You will be prompted to validate your email address for the Actor module:



**NOTE**

This screen will only appear once, after the validation of the first LAA of an Actor.

**If your registration is not approved**

1. If your request is not approved, it will remain in your pending requests list. The next time you enter EUDAMED, your start page will be *My pending requests*, listing your registration requests and their states:

Application ID	Role IT	Name IT	City IT	Date of request ff	State	Actions
APP000000041	Manufacturer	[redacted]	[redacted]	2020-08-19	Correction Requested	...

2. Click the three-dot action button beside your request. You can view and edit your registration request if it has a *Correction requested* state.



## IMPORTANT

Requests with a **Refused** state cannot be edited or resubmitted. The reason given by the competent authority for the rejection is displayed. This information will not be publicly available.

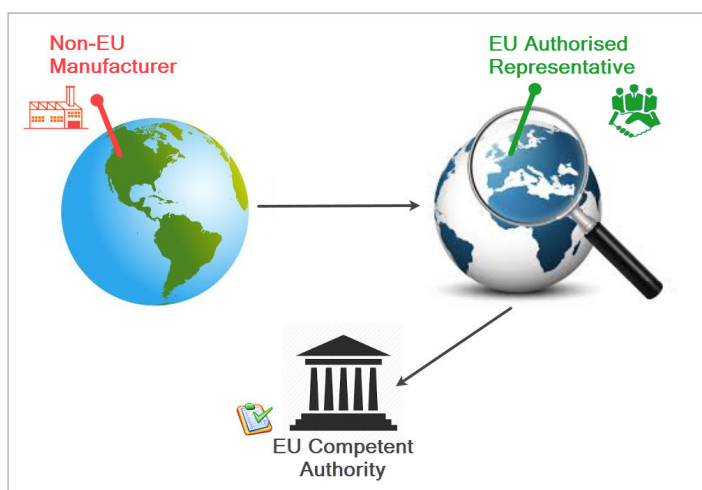
The screenshot shows a multi-step registration process with six steps: 1. Actor identification, 2. Actor address, 3. Contact details, 4. Regulatory Persons, 5. Registering Local Actor Administrator, and 6. Competent Authority. The 'Actor identification' step is active, showing fields for Role (Manufacturer), Country (Belgium), Organisation name, and Select organisation language (All languages). There are also fields for Abbreviated organisation name and Select abbreviated organisation name language. A 'Previous assessment(s)' panel is visible on the right, showing an application ID and a date of submission (2020-08-19). A green box highlights the 'Reason for rejection' field, which contains the text 'I think this is a duplicate'.

- For requests flagged as *Correction requested*, edit and resubmit them for validation as appropriate.

## 2.1.2 Register as a non-EU manufacturer

If you are a non-EU manufacturer, the procedure for registering differs from that for EU manufacturers explained in [Registering as an Economic Operator \[13\]](#).

You must identify an Authorised Representative (AR) with whom you have a mandate, according to the requirements in article 11 of MDR or IVDR. The AR must be already registered in EUDAMED before you can submit your registration request. If you have multiple ARs, indicate the Actor ID/SRN of your main AR. Your AR must verify your registration details before the request is submitted to the competent authority for validation. Only after this, you will gain access to your account and Single Registration Number (SRN).




### To register a non-EU manufacturer


- Log in to EUDAMED with your EU Login account. (See section [Starting and ending a EUDAMED session \[5\]](#)).


2. Select the **Actor registration** box on the *User and Actor Registration* page. You are presented with an online disclaimer:


Actor registration

**Disclaimer**

 **Submission**  
Please be aware that once you click submit, you will not be able to make further changes to your data.

 **Status of your request**  
The outcome of the examination will be communicated to you by e-mail to the address on the previous page. Meanwhile, you may view your data and the progress of the examination by visiting [See my Pending Requests](#) in your EUDAMED account.

 **Notification**  
After submission, EUDAMED will notify the National Competent Authority who will examine your request and, if you are from a non-EU country, your Authorised Representative will also be notified.

 **Outcome by email**  
If your request is approved, you will be authorised to carry out Local Administrator tasks for the actor under registration ([See the User Guide](#)).

I have read and agree to the above disclaimer

3. Enter the required data:
  - a. Identify your authorised representative:

Do you know the Single Registration Number (SRN)?	Yes	Select <b>I know the SRN</b> , click <b>Find</b> and select the number.
	No	Deselect <b>I know the SRN</b> , select the country and enter the name of the Authorised Representative. Click <b>Find</b> and select the correct result.



**NOTE**

If you do not find your authorised representative from the search page, please contact them to confirm their Actor ID/SRN. They may not have registered yet or may have registered with a different name.

- b. Enter the validity start and end-dates of the written mandate with the Authorised Representative.
  - c. In the **Upload summary mandate document** section, click **Browse**, select the location of the summary mandate (**PDF only and not surpassing 10MB in size**), and click **Open**. The file will appear under *Upload summary mandate document*. You can remove it by clicking the X next to the name of the file.

d. Click **Save & Next**.

**Actor address**

Street information, if applicable  
 Yes  No  Street information is required unless you select the option - No

\* Street:  Street number:

Address line 2:

PO box:

Latitude:  Longitude:   
Latitude format example: -15.4543 Longitude format example: 178.34354353

\* City name:  \* Postal code:

\* Country:  
 Australia



**NOTE**

You don't have to upload the full mandate text. It's enough to upload a summary mandate ([click here for the template](#)). This information is not publicly available.

4. Check and complete the information on the page. Upload the signed declaration – **in PDF format only and not exceeding 10MB** – using the **Browse** button. Click **Save & Next**.

In the final step, the Competent Authority that will validate your registration request (i.e. the CA responsible for your Authorised Representative) is identified, with contact information.

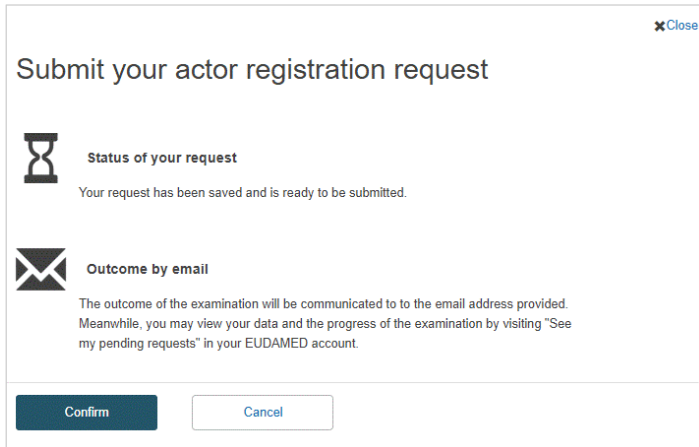
**Competent Authority**

**Name:** Agence Fédérale des Médicaments et des Produits de Santé/Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten  
**Address:** EUROSTATION building block 2place Victor Horta 40/ 40, B-1060 Brussels, Belgium  
**Country:** Belgium  
**Email:** meddev@fagg-afmps.be  
**Telephone number:** 00 32 2 528 40 00

**Any other information of significance for the competent authority**  
 Additional Information:

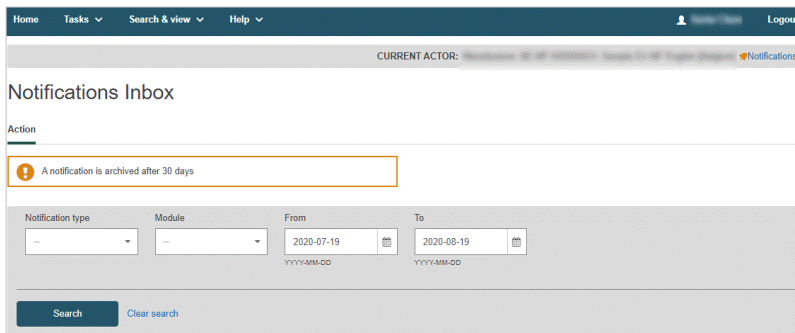
5. Enter any additional information you wish to pass on to the Competent Authority, and then click **Preview**. A summary of your completed registration form is displayed.

- Review the information on the form, and then click **Submit actor registration** at the bottom of the page. A confirmation window will appear:



- Read the information in the window and click **Confirm**.
  - Your registration request is saved and appears with a *Submitted* state in your *Pending requests* list.
  - Your registration request has a unique application ID and is submitted first to your Authorised Representative for verification and then to the Competent Authority for validation.

You will be notified when your Actor registration request is approved or rejected.



## What next?

You can track the status of your submitted application by selecting the **Home** menu. The state will change to *Verified* once it has been verified by your Authorised Representative:

My pending requests

You can view the status of your requests below

**EU Login details**

Name: [redacted]

Username: [redacted]

Email: [redacted]

**EUDAMED details**

Name: [redacted]

**My access requests for an existing actor**

Role ID	Name ID	City ID	Date of request	State	Actions
Manufacturer	[redacted]	[redacted]	2020-04-09	Submitted	...
Authorised Representative	[redacted]	[redacted]	2020-04-01	Draft	...

[New access request](#)

**My actor registration requests**

Application ID	Role ID	Name ID	City ID	Date of request	State	Actions
APP00000	Manufacturer	[redacted]	[redacted]	-	Draft	...
APP00000	Manufacturer	[redacted]	[redacted]	2020-08-19	Verified	...
[redacted]	SpecialProcedurePartHolder	[redacted]	[redacted]	[redacted]	Correction Requested	...
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Submitted	...

[New actor registration request](#)

The Competent Authority will then assess the actor registration request. An Actor ID or Single Registration Number (SRN) is generated by EUDAMED and issued by the Competent Authority after its approval.

If your Competent Authority cannot validate your application, it will be returned to your Authorised Representative for correction or completion, according to their instructions.

## 2.1.3 Verify non-EU manufacturer registrations

### *Specific to AR Verifier*

The Authorised Representative (AR) must verify the information provided by the non-EU manufacturer, as well as the summary mandate details.

Information on Actor registration in EUDAMED for Authorised Representative can be found in [Managing Actors \[12\]](#)

Information on how to create a user account and set profiles for an AR Actor is found in [User rights and profiles \[4\]](#)

### **To verify a non-EU manufacturer registration request as an AR**

### **To verify a non-EU manufacturer registration request as an AR**

1. The AR must log in to EUDAMED with a Verifier, LAA or LUA profile (for the Authorised Representative). If there are pending registration requests from non-EU manufacturers who have selected you as their AR, you will see the following on your dashboard:

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

**My Actor data**  
Manage your actor data  
Manage your email notifications  
Machine to machine data delivery preferences

**User management**  
Assess user access requests  
Manage your users

**Actor management**  
Verify actor registration requests 🔔 1  
Manage your mandates

- Click *Verify actor registration requests* in the *Actor management* section of the dashboard. The *Actor registration management* page lists all pending non-EU manufacturer registration requests waiting to be verified by your actor (if any):

Actor registration management

Filter ▾

Active filters:  
State of request: Submitted [Clear all filters](#)

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

Application ID	Role	Name	Postal code	City	Country	Date of request	State	Actions
APP000000	Manufacturer					2020-04-03	Submitted	

- Click **Assess** in the *Actions* column to review and assess the desired registration request. All details of the selected registration request, as submitted by the non-EU manufacturer, are displayed in read-only mode.

**TIP**  
Select the correct registration request from the list available.

- Review the information. A warning message will flag possible duplicates:

Assess actor registration request

Application ID: APP000000382 Date of request: 2020-04-03

Potential duplicates were detected during this registration request. [View list of duplicates](#)

- In the *Assessment* section, slide the toggle left to **Approved** or right to **Not approved**.

**NOTE**  
It is not possible to return the status to neutral once you have shifted the toggle bar in any direction. In order to leave an assessment without completing it, click **Go back to the list** at the top of the page.

If you **choose not to approve** the request, select one of the following reasons and provide a justification in free text for your decision. The request will be returned to the applicant, with your reason and justification.


**Assessment outcome:**


Approved  Not approved


**Type of reasons**

Incomplete or incorrect

Wrong Competent Authority and/or Authorised Representative

Duplicate 

Request not applicable 

Fraud suspected 

\* Justification:

Enter justification here


**Complete assessment**

<b>Incomplete or incorrect</b>	Some information that you deem important is either missing or looks incorrect. The requesting user will have a chance to correct or complete the request following your instructions and re-submit the request.
<b>Wrong Competent Authority and/or Authorised Representative</b>	You are not the correct Authorised Representative for this request. The requesting user will have a chance to select another and re-submit.
<b>Duplicate</b>	Informs the requesting user that this actor already exists.
<b>Request not applicable</b>	The request will be rejected and cannot be re-submitted.
<b>Fraud Suspected:</b>	The requesting user will be informed that registration was not successful. The reason and justification provided will not be shared with the requesting user but will be visible for competent authorities.

- Click **Complete assessment** at the bottom of the page, and then **Confirm** in the subsequent confirmation pop-up. You are informed that the non-EU manufacturer's registration request has been assessed.

If approved, its status now changes to *Verified*. This means the request has been submitted to the relevant Competent Authority for validation:

Actor registration management

 **Congratulations. You have successfully assessed the actor registration.**

The application ID is  

The assessment status is Verified

## 2.1.4 Search and view registered actors

Once an Economic Operator has been validated by the relevant Competent Authority and its Actor ID/SRN is issued, its details (except those only for the Competent Authorities) become visible to all users in EUDAMED and will be publicly available on the EUDAMED public website.





### To search and view Actors

As a logged in user for an Actor in EUDAMED, you can search and view Actor information entered in EUDAMED by all Actors, as described below.

You can also search and view Actor information from EUDAMED Public. The information available through EUDAMED Public is limited.

1. Log in to EUDAMED first. A dashboard for search & view is available on your starting page. Click on the **Actors** block on the dashboard or select **Search & view > Actors** in the menu bar. The actor *Search & view* page appears:

**Search & View**  
Overview of modules allowing you to search and view details, depending on your profile

 Actor module <a href="#">Actors</a>	 UDI-DI module <a href="#">UDI-DIs/Devices</a>	 NB & Certificates module <a href="#">Issued/Refused certificates</a>
 Vigilance module <a href="#">View Vigilance reports</a>		
















**NOTE**

The options in the search section might change depending on the profile that was set for your user.

E.g.: Search options for CA differ from the ones above:

**Search & View**  
Overview of modules allowing you to search and view details, depending on your profile

 Actor module <a href="#">Actors</a>	 Actor module <a href="#">Search for refused registration requests</a>	 UDI-DI module <a href="#">UDI-DIs/Devices</a>
 NB & Certificates module <a href="#">Issued/Refused certificates</a>	 NB & Certificates module <a href="#">Search for applications</a>	 NB & Certificates module <a href="#">Search for CEGP</a>
 NB & Certificates module <a href="#">Suspension/withdrawal request</a>	 NB & Certificates module <a href="#">Nominated experts list</a>	 Vigilance module <a href="#">View Vigilance reports</a>
 Clinical Investigation & Performance study module <a href="#">CI/PS application &amp; PMCF/PMCF notification</a>	 NB & Certificates module <a href="#">Search for MS summary reports on NB</a>	 Market Surveillance module <a href="#">Reports</a>
		

**Search & view**

**Actors**

Enable search filters available for bulk XML download

Name  Actor ID/SRN  VAT number  Role

Country  Competent Authority

**Results option**

Include historical version

- Enter your search criteria (Name, Actor ID/SRN or other identifying details) and click **Search**. All actors matching your search criteria will be listed in the search results section:

**Search results for actors**

Role: Manufacturer  Country: Belgium  [Clear all filters & create new search](#)

Showing 1 to 14 of 14 entries Show  entries per page

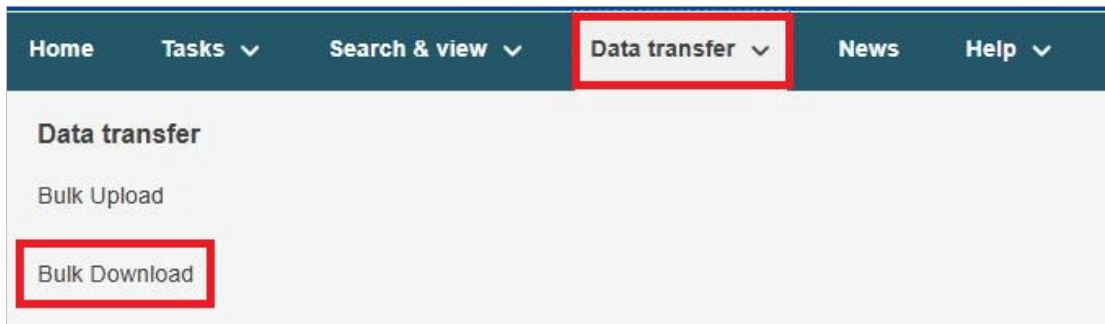
Actor ID <input type="button" value="x"/>	Role <input type="button" value="x"/>	Name <input type="button" value="x"/>	Country <input type="button" value="x"/>	Date of registration <input type="button" value="x"/>
BE-MF-0000 <input type="button" value="x"/>	Manufacturer	<a href="#">[Redacted]</a>	Belgium	2020-05-27
BE-MF-0000 <input type="button" value="x"/>	Manufacturer	<a href="#">[Redacted]</a>	Belgium	2020-07-24
BE-MF-0000 <input type="button" value="x"/>	Manufacturer	<a href="#">[Redacted]</a>	Belgium	2020-06-22

- To view the details for any actor, click the entry in the results list. All publicly available information on that Actor is displayed.
- To search and download actor data as an XML file:

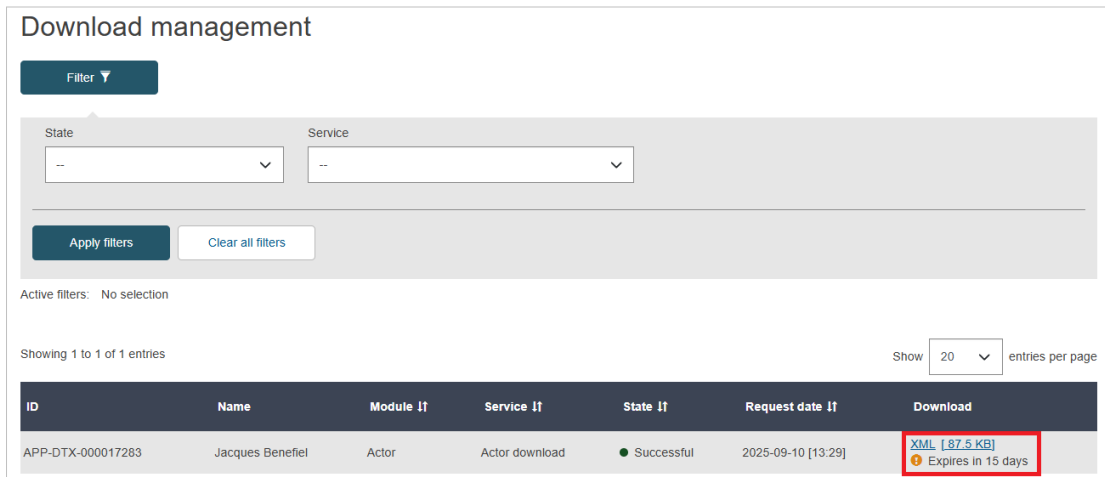
**NOTE**

Note that the search results can only be downloaded as XML format.

- Activate the toggle **Enable search filters available for bulk XML download**
- Enter your search criteria and click **Search**
- All actors matching your search criteria will be listed in the search results section
- Click the button **Generate XML file** and confirm
- Download the XML file of the results list from the *Downloads management* page.
  - Go to the **Data transfer** page and click on **Bulk download**:



- In the new window, click on **XML** to download the file to your local machine:



**NOTE**

There are limitations on what search criteria you can use for bulk downloads, so certain filters will be disabled when this toggle is active.

For more information on search criteria, see the [DTX service definition](#).

**To search for Actors' historical versions**

A historical version of an Actor means a version of the Actor details that is no longer up to date and has been changed since. A new historical version is created when a new version for the Actor is requested by the user.

1. Activate the toggle **Include historical version** under *Results option*.

**Search & view**

**Actors**

Enable search filters available for bulk XML download

Name  Actor ID/SRN  VAT number  Role

Country  Competent Authority

**Results option**

Include historical version

Active filters:

2. Enter your search criteria and click **Search**.
3. All actors' versions matching your search criteria will be listed in the search results section.
4. In the list of search results, each entry indicates whether it is the current version [Current] or a historical version [History], alongside the version number information:

Showing 1 to 20 of 593 entries Show  entries per page

Actor ID/SRN <sup>1</sup>	Version number <sup>1</sup>	Role <sup>1</sup>	Name <sup>1</sup>	Country <sup>1</sup>	Date of registration <sup>1</sup>
UY-MF-000006427	2 [Current]	Manufacturer	VIVUNT PHARMA S.A.S. [All languages]	Uruguay	2024-04-25
UY-MF-000006427	1 [History]	Manufacturer	VIVUNT PHARMA S.A.S. [All languages]	Uruguay	2024-04-25
UY-MF-000005447	1 [Current]	Manufacturer	MEGA LABS S.A. [All languages]	Uruguay	2024-01-17
US-MF-000007907	1 [Current]	Manufacturer	ABQ Pharmaceuticals [EN]	United States	2024-08-30
US-MF-000007349	1 [Current]	Manufacturer	actor sdxidu [EN]	United States	2024-07-09
US-MF-000007348	1 [Current]	Manufacturer	actor cynylq [EN]	United States	2024-07-09
US-MF-000007347	1 [Current]	Manufacturer	actor bhvsyc [EN]	United States	2024-07-09
US-MF-000007167	1 [Current]	Manufacturer	TEST MF NON-EU ELS [All languages]	United States	2024-06-27
US-MF-000005407	1 [Current]	Manufacturer	La Vie En Rose [All languages]	United States	2024-01-15
US-MF-000005389	1 [Current]	Manufacturer	La Vie En Rose [All languages]	United States	2024-01-15
US-MF-000005068	2 [Current]	Manufacturer	DROGUERIA AMERICANA S.A. [All languages]	United States	2023-12-01
US-MF-000005068	1 [History]	Manufacturer	Ohio Pharmaceuticals [All languages]	United States	2023-12-01
US-MF-000004107	2 [Current]	Manufacturer	Ohio Pharmaceuticals [All languages]	United States	2023-08-04

## View Actor data – historical versions

 **VIDEO: View historical version of an actor**



To see the historical version(s) of an actor:

1. Click the relevant entry in the results list:

Showing 1 to 20 of 122 entries Show  entries per page

Actor ID/SRN	Version number	Role	Name	Country	Date of registration
[Redacted]	1 [Current]	Manufacturer	[Redacted]	Belgium	2023-06-19
[Redacted]	1 [Current]	Manufacturer	[Redacted]	Belgium	2023-06-15
[Redacted]	1 [Current]	Manufacturer	[Redacted]	Belgium	2023-05-24
[Redacted]	1 [Current]	Manufacturer	[Redacted]	Belgium	2023-05-12
[Redacted]	1 [History]	Manufacturer	[Redacted]	Belgium	2023-05-05
[Redacted]	2 [Current]	Manufacturer	[Redacted]	Belgium	2023-05-05
[Redacted]	1 [Current]	Manufacturer	[Redacted]	Belgium	2023-05-04
[Redacted]	1 [Current]	Manufacturer	[Redacted]	Belgium	2023-04-25
[Redacted]	1 [Current]	Manufacturer	[Redacted]	Belgium	2023-04-21
[Redacted]	1 [Current]	Manufacturer	[Redacted]	Belgium	2023-04-20
[Redacted]	1 [Current]	Manufacturer	[Redacted]	Belgium	2023-04-19
[Redacted]	1 [Current]	Manufacturer	[Redacted]	Belgium	2023-04-19
[Redacted]	1 [Current]	Manufacturer	[Redacted]	Belgium	2023-04-14
[Redacted]	1 [Current]	Manufacturer	[Redacted]	Belgium	2023-04-13
[Redacted]	1 [Current]	Manufacturer	[Redacted]	Belgium	2023-04-12
[Redacted]	1 [Current]	Manufacturer	[Redacted]	Belgium	2023-04-05

2. Inside the current version, you can navigate between the versions (if more than one) using the **See version history** button:

### Actor Data

Version 3 [Current] [See version history](#) Last update date: 2023-03-30

#### Actor identification

Role: [Redacted]

Actor ID/SRN: [Redacted]

Country: [Redacted]

Actor / Organisation name: [Redacted]

Abbreviated name: [Redacted]

VAT information:

VAT number: [Redacted]

[EORI number](#)

National trade register number: [Redacted]

Last confirmation date of actor data accuracy: -

3. A list of the different versions will display:



- Clicking on one of the list items will open up that version and will also provide navigation buttons to allow easy switching between the versions:



**NOTE**  Person Responsible for Regulatory Compliance data will not be displayed for historical versions or inactive Manufacturers and Authorised Representatives, due to personal data protection rules (GDPR):

**Regulatory Persons**

Due to personal data protection rules (GDPR), this data is not available

## 2.1.5 Link a non-EU manufacturer to an importer

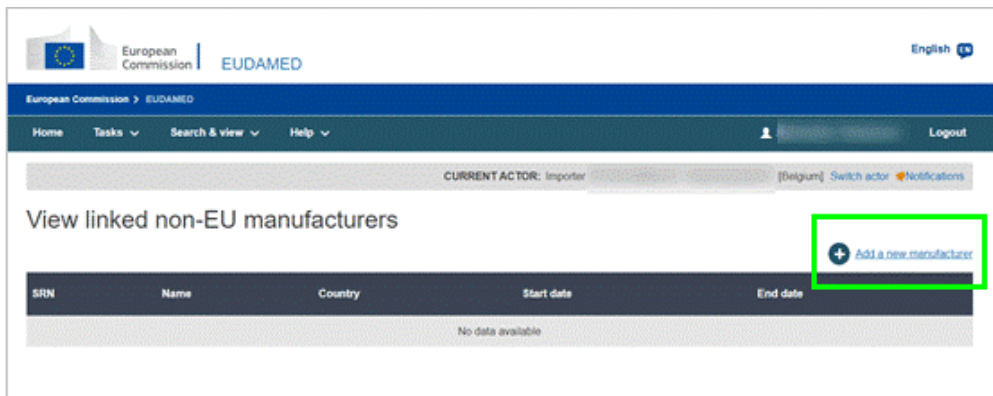
Section specific to importers with *Linker*, *LAA* or *LUA* profiles

To link a non-EU manufacturer to your importer:

- Open the Dashboard:



2. Click *Link to non-EU manufacturer* in section *My Actor*. You will arrive at the page displaying linked non-EU manufacturers (if there are no linked manufacturers, this list will be empty):



3. Click *Add a new manufacturer*.
4. If you know the Actor ID/SRN, enter it and click **Find** to select the manufacturer.

Link a non-EU manufacturer with your importer

I know the SRN

SRN:

Find

5. If you don't know the Actor ID/SRN, uncheck *I know the Actor ID/SRN*. Two new fields will appear:

Link a non-EU manufacturer with your importer

I know the SRN

Country:

Actor / organisation name:

**Find**

- Enter the country and actor/organisation name, and click **Find**. You will see a list of results based on your search criteria:

Link a non-EU manufacturer with your organisation

I know the SRN

Country:

Actor / organisation name:

**Find**

**Result**  
 Select your actor from the list below

<a href="#">View details</a>	Afghanistan - Manufacturer - Actor code: AF-MF- <a href="#">XXXXXXXXXX</a>	▲
<a href="#">View details</a>	Afghanistan - Manufacturer - Actor code: AF-MF- <a href="#">XXXXXXXXXX</a>	▲

- Select the actor you want from the list. You will see the detail page for that actor:

**Find**

**Result**  
 Select your actor from the list below

<a href="#">View details</a>	Afghanistan - Manufacturer - Actor code: AF-MF- <a href="#">XXXXXXXXXX</a>	▲
<a href="#">View details</a>	Afghanistan - Manufacturer - Actor code: AF-MF- <a href="#">XXXXXXXXXX</a>	▼

**SRN:**  
 AF-MF-[XXXXXXXXXX](#)

**Role:**  
 Manufacturer

**Country:**  
 Afghanistan

**Organisation name:**  
[XXXXXXXXXX](#)

**Address:**  
[XXXXXXXXXX](#)

**Email:**  
[XXXXXXXXXX](#)

**Telephone number:**  
 -

**Add link with this manufacturer**

- Click Add link with this manufacturer. You are prompted to enter the relevant dates:

**Add link with this manufacturer**

Enter the start date to link with this manufacturer

\* Start date:   
YYYY-MM-DD

End date:   
YYYY-MM-DD

**Confirm** **Cancel**

9. Enter a start-date (and end-date if known), then click **Confirm**.

## 2.1.6 Updating Actor details

### Section specific to Local Actor Administrators (LAA)

Once an Actor has been validated by its Competent Authority and obtained an Actor ID/SRN, changes to the Actor details can only be made by a Local Actor Administrator of this Actor.

### Update your details

1. Log in to EUDAMED with a *Local Actor Administrator* profile for the actor in question.
2. In your dashboard, select *Manage your actor data* under *My Actor data*:

**Tasks**  
According to [your profile per module](#), consult, verify and/or manage your own and related data (managed by your actor)

**My Actor data**

- [Manage your actor data](#)
- [Manage your email notifications](#)
- [Access point management](#)

**User management**

- [Assess user access requests](#)
- [Manage your users](#)

**UDI-DIs/Device**

- [Your Basic UDI-DIs / EUDAMED DIs](#)
- [Your UDI-DIs / EUDAMED IDs](#)

3. You can browse through the sections to review the information currently available about the actor:

Manufacturer, DK-MF-000003547, Nielsen-Beck [Denmark]

**My Actor data** Actions

Version 1 [Current] | Last update date: 2023-06-13

**Actor identification**

Role:	Manufacturer
Actor ID/SRN:	DK-MF-000003547
Country:	Denmark
Actor / Organisation name:	Nielsen-Beck [EN]
Abbreviated name:	NIELBECK [EN]
VAT information:	Yes
VAT number:	D-023-57BCC
EORI number	D-023-68854-U
National trade register number:	D-023-677653422
Organisation identification document:	<a href="#">Dummy Doc - Organisation Identification [PDF 104.72 KB]</a>
Last confirmation date of actor data accuracy:	-

**Actor address**

Street information, if applicable:	Yes
Street:	Alexandriagade
Street number:	40
Address line 2:	-
PO box:	-
Latitude:	-
Longitude:	-

4. If you need to change some information, proceed as follows:

a. Click on **Actions**:

Manufacturer, DK-MF-000003547, Nielsen-Beck [Denmark]

My Actor data

Competent Authority

Notification email

**My Actor data**

Version 1 [Current] | Last update date: 2023-06-13

**Actor identification**

Role:	Manufacturer
Actor ID/SRN:	DK-MF-000003547
Country:	Denmark
Actor / Organisation name:	Nielsen-Beck [EN]
Abbreviated name:	NIELBECK [EN]
VAT information:	Yes
VAT number:	D-023-57BCC
EORI number:	D-023-68854-U
National trade register number:	D-023-677653422
Organisation identification document:	<a href="#">Dummy Doc - Organisation Identification [PDF 104.72 KB]</a>
Last confirmation date of actor data accuracy:	-

Actions -

- Create new version
- Change competent authority
- Change Tax and Trade IDs
- Set status to Inactive
- Confirm data accuracy

b. Click *Create new version* and answer **Yes** to the confirmation message:

✕Close

**Create new version**

Are you sure you want to create a new version for this current actor?

Yes Cancel

c. Make all required changes in the corresponding tabs.

- d. When you are done, click **Register new version** and answer the confirmation message:

Create new version of my actor data

**Manufacturer, Nielsen-Beck [Denmark]**

Version 2 [Draft]

Save
Register new version
Delete draft version

**Actor identification**

<b>Role:</b>	Manufacturer
<b>Country:</b>	Denmark

\* Actor / Organisation name:  \* Select the language: English X ▾

[+ Add name in another language](#)

Abbreviated name:  Select the language: English X ▾

[+ Add abbreviated name in another language](#)

[✕Close](#)

**Once registered, this draft will become the latest version of this actor**

Moreover, if you select the option below, the 'Last confirmation date of actor data accuracy' will be updated for this actor.

I confirm the actor data accuracy

Do you confirm?

Confirm
Cancel

The changes apply immediately. The new version number displays, and the current version is identified:

Manufacturer, DK-MF-000003547, Nielsen-Beck [Denmark]

My Actor data

Competent Authority

Notification email

**My Actor data**

Version 2 [Current] [See version history](#) | Last update date: 2025-09-02

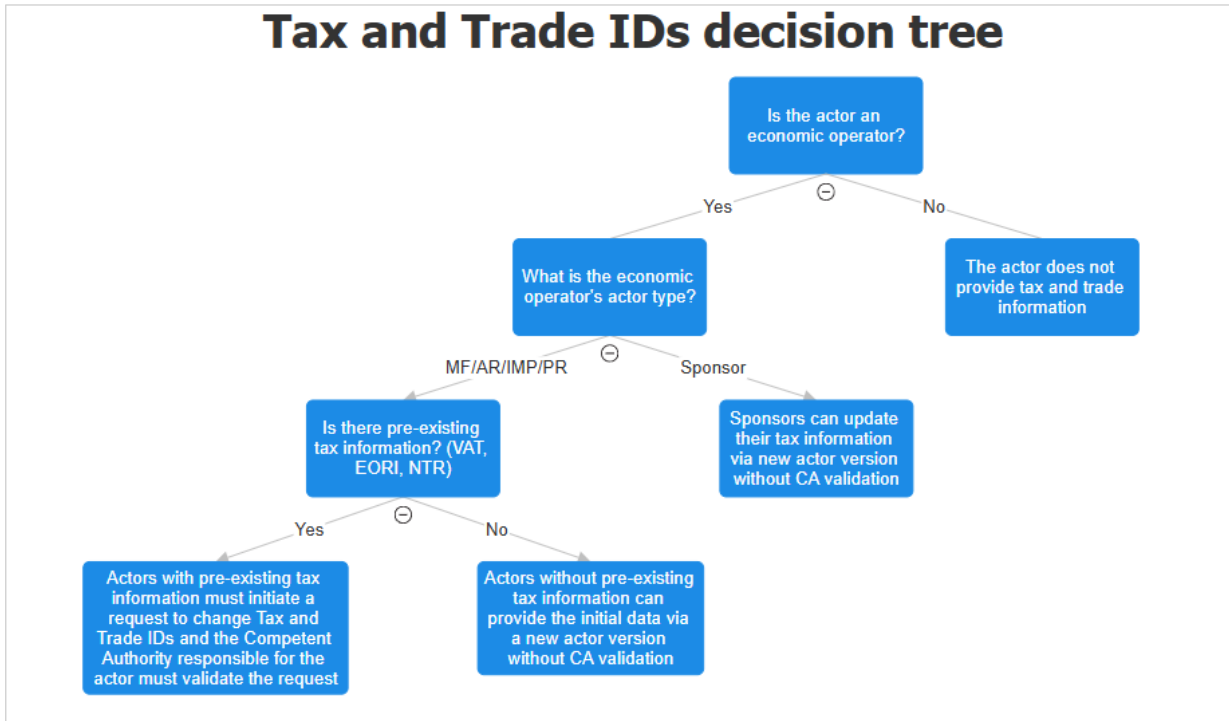
**Actor identification**

<b>Role:</b>	Manufacturer
<b>Actor ID/SRN:</b>	DK-MF-000003547
<b>Country:</b>	Denmark
<b>Actor / Organisation name:</b>	Nielsen-Beck [EN]
<b>Abbreviated name:</b>	NIELBECK [EN]
<b>VAT information:</b>	Yes
<b>VAT number:</b>	D-023-57BCC
<b>EORI number:</b>	D-023-68854-U
<b>National trade register number:</b>	D-023-677653422
<b>Organisation identification document:</b>	<a href="#">Dummy Doc - Organisation Identification [PDF 104.72 KB]</a>
<b>Last confirmation date of actor data accuracy:</b>	-

Actions ▾

## Change VAT/EORI/NTR

Before you change your VAT/EORI/NTR, be aware that depending on your role and profile, some options may not be available for you. To know more, you can take a look at this workflow chart:





**NOTE**

If your current Actor has any pending requests (new Actor version, Competent Authority change request, Set status to Inactive or Confirm data accuracy request), you will not be able to update your VAT/EORI/NTR information.

If you currently don't have a VAT/EORI/NTR information registered, you can also add it through the option below, or through the **Create new version** page:

CURRENT ACTOR: Manufacturer, DK-MF-000003547, Nielsen-Beck [Denmark] [Notifications](#)

Manufacturer, DK-MF-000003547, Nielsen-Beck [Denmark]

My Actor data

[Competent Authority](#)

[Notification email](#)

**My Actor data**

Version 3 [Current] | [See version history](#) | Last update date: 2025-09-02

**Actor identification**

Role:	Manufacturer
Actor ID/SRN:	DK-MF-000003547
Country:	Denmark
Actor / Organisation name:	Nielsen-Beck [EN]
Abbreviated name:	NIELBECK [EN]
VAT information:	Yes
VAT number:	D-023-57BCC
EORI number:	D-023-68854-U
National trade register number:	D-023-677653423
Organisation identification document:	<a href="#">Dummy Doc - Organisation Identification [PDF 104.72 KB]</a>
Last confirmation date of actor data accuracy:	-

**Actions -**

- [Create new version](#)
- [Change competent authority](#)
- [Change Tax and Trade IDs](#)
- [Set status to Inactive](#)
- [Confirm data accuracy](#)

1. Click on the **Actions** button and then on **Change Tax and Trade IDs**:

Manufacturer, DK-MF-000003547, Nielsen-Beck [Denmark]

My Actor data

[Competent Authority](#)

[Notification email](#)

**My Actor data**

Version 2 [Current] | [See version history](#) | Last update date: 2025-09-02

**Actor identification**


Role:	Manufacturer
Actor ID/SRN:	DK-MF-000003547
Country:	Denmark
Actor / Organisation name:	Nielsen-Beck [EN]
Abbreviated name:	NIELBECK [EN]
VAT information:	Yes
VAT number:	D-023-57BCC
EORI number:	D-023-68854-U
National trade register number:	D-023-677653422
Organisation identification document:	<a href="#">Dummy Doc - Organisation Identification [PDF 104.72 KB]</a>
Last confirmation date of actor data accuracy:	-

**Actions -**

- [Create new version](#)
- [Change competent authority](#)
- [Change Tax and Trade IDs](#)
- [Set status to Inactive](#)
- [Confirm data accuracy](#)

2. On the new page, scroll down a bit till you see the VAT/EORI/NTR section:

VAT information:

Yes  No  VAT information is required unless you select the option - No

\* VAT number:

[EORI number:](#)

National trade register number:

3. Change any details you wish in the fields related to your desires
4. When you are done, provide the **Reason for change** at the bottom of the page:

\* Reason for change:

**Submit request**

5. Click on **Submit request**
6. A pop-up message will appear asking you to confirm your request, click on **Confirm**:

[✕Close](#)

## Change of Tax and Trade IDs request



Your request to change Tax and Trade IDs will be submitted for validation.

- If validated, you will receive a notification and your Actor data will automatically be updated.
- While awaiting validation, you will not be able to create a new Actor's data version.
- If rejected, you will be notified with further instructions.

Are you sure you want to proceed?

Confirm

Cancel



**NOTE**

While the request is pending, no other changes to the Actor details will be authorised:

Manufacturer, DK-MF-000003547, Nielsen-Beck [Denmark]

My Actor data

Competent Authority

Notification email

**My Actor data**

Version 2 [Current] | [See version history](#) | Last update date: 2025-09-02

**i** You requested a change of Tax and Trade IDs. Your request to change the Tax and Trade IDs has been submitted for validation. When validated, you will receive a notification and your Actor data will be updated. [See your request](#)

**Actor identification**

Role:	Manufacturer
Actor ID/SRN:	DK-MF-000003547
Country:	Denmark
Actor / Organisation name:	Nielsen-Beck [EN]
Abbreviated name:	NIELBECK [EN]
VAT information:	Yes
VAT number:	D-023-57BCC
EORI number:	D-023-68854-U
National trade register number:	D-023-677653422
Organisation identification document:	<a href="#">Dummy Doc - Organisation Identification</a> [PDF 104.72 KB]
Last confirmation date of actor data accuracy:	-

You can look at your Actor details after the submission of your request, you will notice your current Tax and Trade IDs information, and the updated version you requested for:

**Tax and Trade IDs**

**Current Tax and Trade IDs**

VAT information:	Yes
VAT number:	D-023-57BCC
<a href="#">EORI number:</a>	D-023-68854-U
National trade register number:	D-023-677653422

**Requested Tax and Trade IDs**

VAT information:	Yes
VAT number:	D-023-57BCC
<a href="#">EORI number:</a>	D-023-68854-U
National trade register number:	D-023-677653423
Reason for change:	For testing purposes

- Once the request was validated by your Competent Authority, a notification will be sent, to see if it arrived, click on **Notifications** and then on the **Information** tab:

CURRENT ACTOR: Manufacturer, DK-MF-00003547, Nielsen-Beck [Denmark] Notifications

### Notifications Inbox

Action Information

! A notification is archived after 30 days

Notification type: -- x v    Module: -- x v    From: 2025-08-02 YYYY-MM-DD    To: 2025-09-02 YYYY-MM-DD

Search Clear search

Active search fields: From: 2025-08-02 To: 2025-09-02 [Clear search](#)

Showing 1 to 1 of 1 entries Time received 1h

Information 2025-09-02 | Email

**Actor - ACT-045-DK-MF-00003547-20250902 : A change of tax and trade IDs has been approved**

A change of tax and trade IDs has been approved for your actor DK-MF-00003547  
 You can access your updated Actor data here <https://webgate.test.ec.europa.eu/eudamed/secure/links/c991b96c-5b40-44e9-9c79-1f7ff0c85e19>

## Delete an actor's draft

To delete a version in draft, on the homepage, click on *Manage your actor data*:

### Tasks

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

#### My Actor data

- [Manage your actor data](#)
- [Manage your email notifications](#)
- [Machine to machine preferences](#)

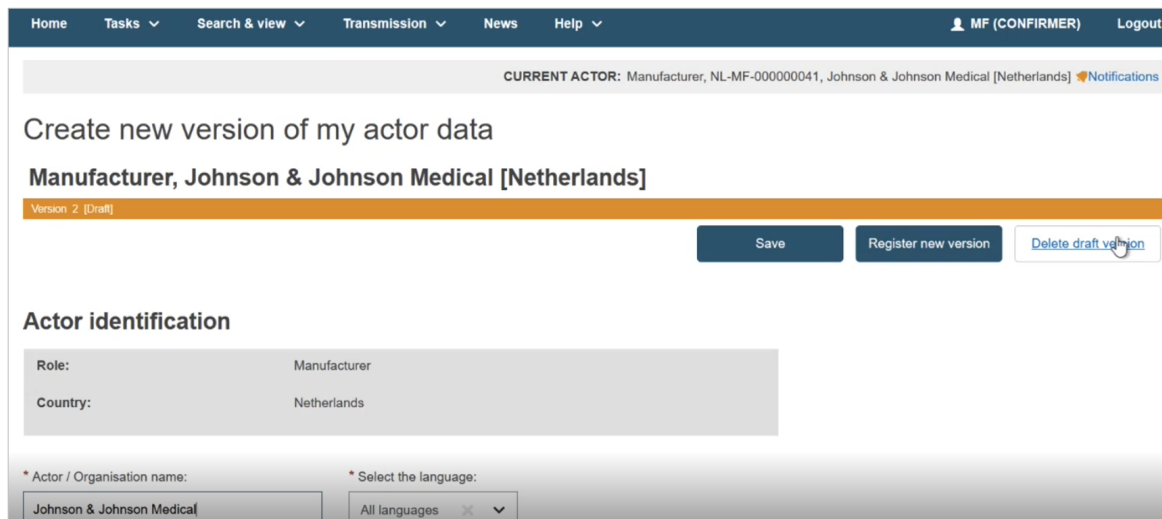
#### User management

- [Assess user access requests](#)
- [Manage your users](#)

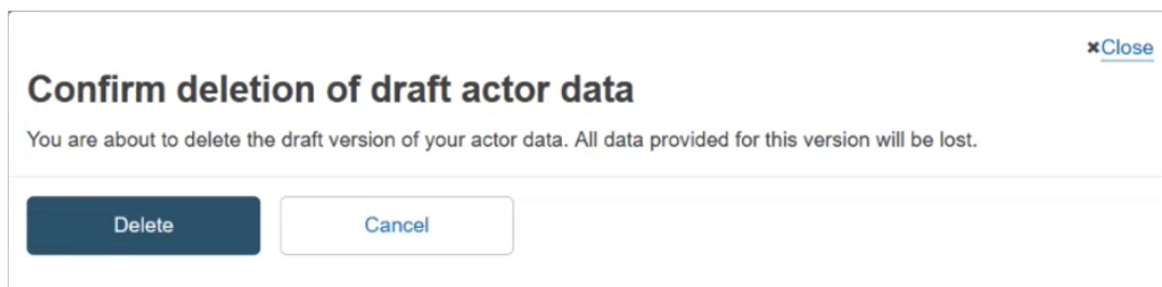
#### UDI-DIs/Device

- [Register a new Basic UDI-DI](#)
- [Register a legacy device](#)
- [Manage your Basic UDI-DIs / EUDAMED Dis](#)
- [Manage your device details](#)

1. You can delete the draft by clicking on **Delete draft version**. Click **Yes**, and you will be redirected to the following window:



2. A pop-up message asking you to confirm your decision:



3. Once you click on **Delete**, the draft is deleted.

## 2.1.7 Confirm Actor data accuracy

### VIDEO: Confirm actor data accuracy



Economic Operators registered in EUDAMED, are required by regulation [MDR Article 31§5](#)/ [IVDR Article 28§5](#) to confirm their data accuracy.


This action can only be done by an LAA either by creating a new version of the Actor or directly confirming the current data.

#### Method 1: Confirm the current data

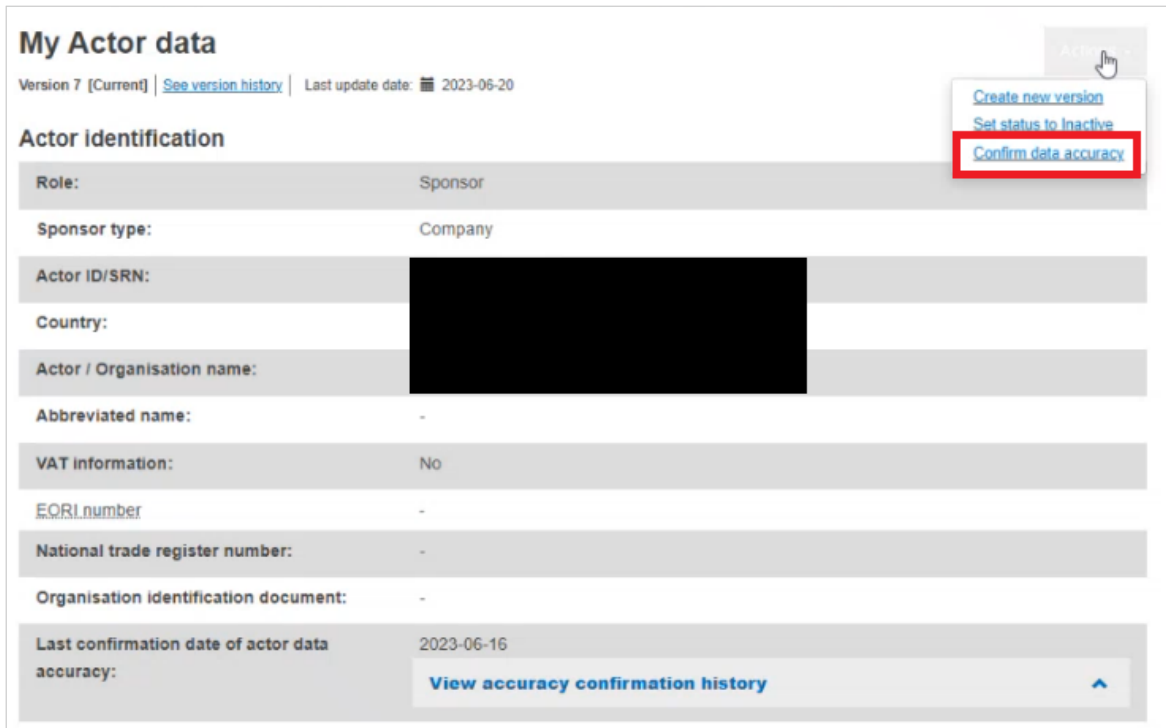
To confirm your Actor data accuracy for the current version, on the homepage of EUDAMED click on *Manage your actor data*:

## Tasks

According to [your profile per module](#), consult, verify and/or manage your own and related data (managed by your actor)

<b>My Actor data</b>  <a href="#" style="border: 2px solid red; padding: 2px;">Manage your actor data</a> <a href="#">Manage your email notifications</a> <a href="#">Access point management</a>	<b>User management</b> <a href="#">Assess user access requests</a> <a href="#">Manage your users</a>	<b>UDI-DIs/Device</b> <a href="#">Register a new Basic UDI-DI</a> <a href="#">Register a legacy device</a> <a href="#">Manage your Basic UDI-DIs / EUDAMED DIs</a> <a href="#">Manage your device details</a>
--	--	---

1. In the new window, click **Actions** on the side and then on **Confirm data accuracy**:



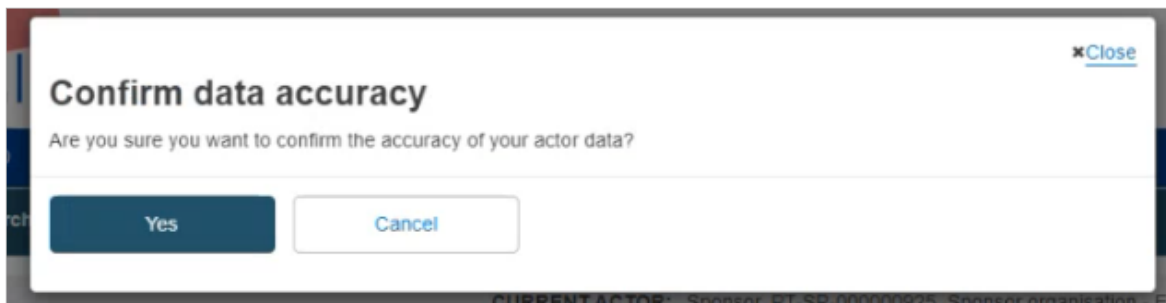
**My Actor data**  
 Version 7 [Current] | [See version history](#) | Last update date: 2023-06-20

**Actor identification**

Role:	Sponsor
Sponsor type:	Company
Actor ID/SRN:	[REDACTED]
Country:	[REDACTED]
Actor / Organisation name:	[REDACTED]
Abbreviated name:	-
VAT information:	No
EORI number:	-
National trade register number:	-
Organisation identification document:	-
Last confirmation date of actor data accuracy:	2023-06-16

[View accuracy confirmation history](#)

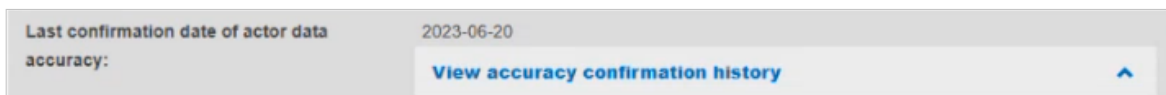
2. A pop-up message will appear asking you to confirm your actor data accuracy:



**Confirm data accuracy** ✕Close

Are you sure you want to confirm the accuracy of your actor data?

3. Click **Yes** to confirm or **Cancel** to go back.
4. Once you have clicked **Yes**, you will notice the latest *accuracy confirmation* date has changed to the latest one:



**My Actor data**  
 Version 7 [Current] | [See version history](#) | Last update date: 2023-06-20

**Actor identification**

Role:	Sponsor
Sponsor type:	Company
Actor ID/SRN:	[REDACTED]
Country:	[REDACTED]
Actor / Organisation name:	[REDACTED]
Abbreviated name:	-
VAT information:	No
EORI number:	-
National trade register number:	-
Organisation identification document:	-
Last confirmation date of actor data accuracy:	2023-06-20

[View accuracy confirmation history](#)

- Click *View accuracy confirmation history* to see the previous confirmation accuracy date and the corresponding Actor versions:

**View accuracy confirmation history**
▼

- 2025-10-21
- 2025-10-21
- 2025-09-09 Version 7
- 2025-08-28 Version 6
- 2025-07-11 Version 4
- 2025-06-05 Version 3
- 2025-06-05 Version 3
- 2025-06-05 Version 3



**NOTE**

If the Actor version corresponding to the confirmation date is the current one, only the date of the data confirmation will be displayed, without the version next to it.

**My Actor data**

Version 8 [Current] [See version history](#) | Last update date: 2025-09-09

Actions ▼

**Actor identification**

Role:	
Actor ID/SRN:	
Country:	
Actor / Organisation name:	
Abbreviated name:	
VAT information:	
VAT number:	
EORI number:	
National trade register number:	
Organisation identification document:	
Last confirmation date:	2025-10-22

**View accuracy confirmation history**
▼

- 2025-10-21
- 2025-10-21
- 2025-09-09 Version 7
- 2025-08-28 Version 6
- 2025-07-11 Version 4
- 2025-06-05 Version 3
- 2025-06-05 Version 3
- 2025-06-05 Version 3

**Method 2: Create new version**

- On the homepage of EUDAMED, click on *Manage your actor data*:

**Tasks**

According to [your profile per module](#), consult, verify and/or manage your own and related data (managed by your actor)

My Actor data	User management	UDI-DIs/Device
<a href="#">Manage your actor data</a> <a href="#">Manage your email notifications</a> <a href="#">Access point management</a>	<a href="#">Assess user access requests</a> <a href="#">Manage your users</a>	<a href="#">Register a new Basic UDI-DI</a> <a href="#">Register a legacy device</a> <a href="#">Manage your Basic UDI-DIs / EUDAMED DIs</a> <a href="#">Manage your device details</a>

- In the new window, click on **Actions** and then click on *Create new version*:

**My Actor data**

Version 8 [Current] | [See version history](#) | Last update date: 2025-09-09

**Actor identification**

Role:	
Actor ID/SRN:	
Country:	
Actor / Organisation name:	
Abbreviated name:	
VAT information:	
VAT number:	
EORI number:	
National trade register number:	
Organisation identification document:	
Last confirmation date:	2025-10-22

[View accuracy confirmation history](#)

**Actions**

- [Create new version](#)
- [Change competent authority](#)
- [Change Tax and Trade IDs](#)
- [Set status to Inactive](#)
- [Confirm data accuracy](#)

- Once you are done updating the details of the new version, click on **Register new version**:

Create new version of my actor data

Version 8 [Draft]

[Save](#) [Register new version](#) [Delete draft version](#)

**Actor identification**

Role:	
Country:	
Sponsor type:	

- The pop-up message will ask you to confirm the new version. You can check the tick-box which will confirm the Actor data accuracy after clicking **Confirm**:

[✕Close](#)

**Once registered, this draft will become the latest version of this actor**

Moreover, if you select the option below, the 'Last confirmation date of actor data accuracy' will be updated for this actor.

I confirm the actor data accuracy

Do you confirm?

Confirm
Cancel

5. This can be seen in the *Accuracy confirmation history* part of *My Actor data*:

### My Actor data

Actions ▾

Version 9 [Current] | [See version history](#) | Last update date: 📅 2025-10-22

#### Actor identification

Role:	
Actor ID/SRN:	
Country:	
Actor / Organisation name:	
Abbreviated name:	
VAT information:	
VAT number:	
EORI number:	
National trade register number:	
Organisation identification document:	
Last confirmation date:	2025-10-22

**View accuracy confirmation history**
▾

- 2025-10-22
- 2025-10-22 Version 8
- 2025-10-21 Version 8
- 2025-10-21 Version 8
- 2025-09-09 Version 7
- 2025-08-28 Version 6
- 2025-07-11 Version 4
- 2025-06-05 Version 3
- 2025-06-05 Version 3
- 2025-06-05 Version 3



**NOTE**

Note that the act of creating an Actor is not a confirmation of its data accuracy. If this action is performed right after the Actor is created, the accuracy confirmation date will also match the date the creation of the Actor took place.

## 2.1.8 Activate/inactivate your Actor

*This section is for LAA profile only*

Actors must be registered in EUDAMED with the status “active” when they place devices on the Union market. If an actor no longer is placing devices on the Union market, they can set their status as inactive. An inactive actor must reset the status to active again, before resuming to place devices on the Union market.

As an LAA of an Active Actor (*Active* being the default status of your Actor upon registration) you can indicate that your Actor is no longer Active from *My Actor data* > *Manage your actor data*:



**NOTE**

An actor CANNOT change its status to *Inactive* if they have Actor data in draft, OR if they have submitted a *Change of Competent Authority request*.

**Set your status to *Inactive***

1. On the right side of the screen, click on **Actions**:

2. Click on *Set status to Inactive*:



**NOTE**

By changing your status from *Active* to *Inactive*, a new Actor data version will be created reflecting your new status.

- In the new window, toggle the button from *Active* to *Inactive*:

### Change actor status

**Manufacturer, BB-MF-00001065, ARMEN 2.7 BARBADOS MANUFACTURERs [Barbados]**

Change the status of your actor

Active  Inactive

\* From date:

YYYY-MM-DD

\* Reason:

Register new status
Cancel

- Select the date from when this actor is no longer *Active*:

\* From date:

YYYY-MM-DD

\* From date:

2022-11-24

Nov 2022 ▾							< Today >
Mo	Tu	We	Th	Fr	Sa	Su	
31	01	02	03	04	05	06	
07	08	09	10	11	12	13	
14	15	16	17	18	19	20	
21	22	23	24	25	26	27	
28	29	30	01	02	03	04	



**NOTE**

Selecting a date in the future is not allowed.

\* From date:

2022-11-26

YYYY-MM-DD

✘ The date should not be in the future

- In the *Reason* box, write the reason why the actor is inactive:

\* Reason:

- Once you are done, click on **Register new status**:

Register new status
Cancel

- In the new pop-up window, click on **Confirm**. Upon confirmation, your new status will be reflected in *My actor data* page and in other screens next to your Actor ID/SRN:

[✕Close](#)

### Change actor status

You are about to set your Actor's status to Inactive

i A new Actor data version will be generated to reflect the new status. Your Competent Authority will be notified and your Inactive status will be displayed in both public and private EUDAMED searches.

Please confirm your status change.

Confirm
Cancel

**NOTE**

Setting your status back to *Active*, can be done at any time from *Manage your Actor data*.

**NOTE**

When your status is already *Active*, you will not see any *Status bar* in your Actor data.

**NOTE**

Your status as *Active/Inactive* will be displayed in EUDAMED Public as well as in EUDAMED Restricted.

**NOTE**

Inactivated users will stop receiving notifications via their email inbox.

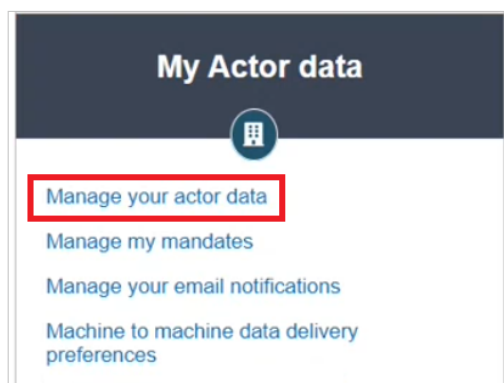
## 2.1.9 Change a Competent Authority for registered actors

The change of responsible Competent Authority (CA) can be necessary in some specific cases as follows:

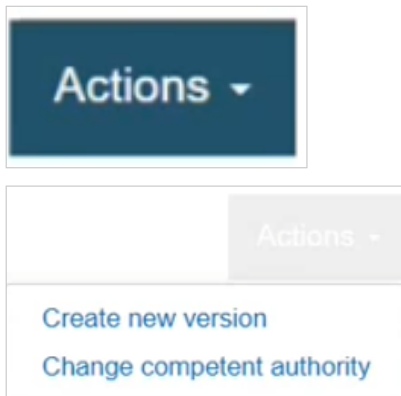
- An EU Economic Operator that moves within the same country;
- A non-EU manufacturer that changes its Authorised Representative or its Authorised Representative changes the responsible Competent Authority;
- A non-EU SPP producer that changes the market distribution of their SPPs.

For the non-EU manufacturers, their responsible CA must be at any moment one of the responsible CA(s) of the AR(s) with which they have an active mandate.

1. On the homepage of EUDAMED, click on *Manage your actor data*:



2. In the new page, click on **Actions** and then choose *Change competent authority*:



**NOTE**

If a request for *Change competent authority* has already been submitted, no further editing of the actor data is allowed till the change is either accepted or rejected.

If a draft has already been created, the competent authority cannot be changed.



**NOTE**

You will notice the change request in your actor data. The section *Competent Authority*, will display two parts, *Current competent authority* and *New competent authority*:

- In the new window, you will notice an almost exact copy of your actor data form, with one exception. At the bottom of the page, the section *Select a new Competent Authority* displays. Choose your new competent authority from the dropdown list:

## Competent authority change request

### Manufacturer, BE MF for DEMOs [Belgium]

#### Actor identification

Role:	Manufacturer
Country:	Belgium

\* Actor / Organisation name:

+ [Add name in another language](#)

Abbreviated name:

+ [Add abbreviated name in another language](#)

\* Select the language:


All languages
✕
▼

Select the language:

--
✕
▼

**Competent Authority**

 You requested a change of Competent Authority. You must select the new Competent Authority and provide a reason in order to submit your request.

**Current competent authority**

Eudamed Actor ID: [REDACTED]  
 Role: [REDACTED]  
 Country: [REDACTED]  
 Actor / Organisation name: [REDACTED]  
 Address: [REDACTED]  
 Email: [REDACTED]  
 Telephone number: [REDACTED]

\* Select a new Competent Authority:

-- X v

- DG SANTE CA
- Schweizerisches Heilmittelinstitut/ Swiss Agency for Therapeutic Products
- New Release Test Playground Org
- ARMEN BE CA
- Agence Fédérale des Médicaments et des Produits de Santé/Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten



## NOTE

For non-EU manufacturers, the dropdown displays the list of the the CAs responsible for the Authorised Representative(s) they have an active mandate with.



## NOTE

When an Authorised Representative changes their responsible CA, every non-EU manufacturer who is linked to that Authorised Representative will be notified (both via *Notifications* and email). The notification will be triggered once the new CA has approved the request from the Authorised Representative to change the responsible CA.

Showing 1 to 20 of 6129 entries Time received v

---

**Information** 2025-12-17 | Email

Actor - ACT-047-FR-AR-000007027-20251217 : Authorised Representative Thomas Et Fils FR-AR-000007027 has a new responsible Competent Authority

The Authorised Representative Thomas Et Fils FR-AR-000007027 with which you have an active mandate has a new responsible Competent Authority Qualité DeChamps FR-CA-145. <https://webgate.test.ec.europa.eu/eudamed/secure/links/97665877-7f0b-4d0b-885f-4827b8f0acb>

This could mean you must change the responsible Competent Authority as well if there is no other Authorised representative with which you have an active mandate that has the same responsible Competent Authority as you.

---

**Information** 2025-12-17 | Email

Actor - ACT-047-FR-AR-000007027-20251217 : Authorised Representative Thomas Et Fils FR-AR-000007027 has a new responsible Competent Authority

The Authorised Representative Thomas Et Fils FR-AR-000007027 with which you have an active mandate has a new responsible Competent Authority Bernhard LLC FR-CA-130. <https://webgate.test.ec.europa.eu/eudamed/secure/links/902f3408-903b-4d5a-bb8c-b0bf411cf0b7>

This could mean you must change the responsible Competent Authority as well if there is no other Authorised representative with which you have an active mandate that has the same responsible Competent Authority as you.

---

**Information** 2025-12-17 | Email

Actor - ACT-008-MD-CN-FR-000005882: Accord a new mandate by AR

- Once you have selected a new competent authority, enter the reason for the change in the *Reason for change CA* field:

\* Select a new Competent Authority:

R ✕ ▼

**Eudamed Actor ID:**

**Role:**

**Country:**

**Actor / Organisation name:**

**Address:**

**Email:**

**Telephone number:**


\* Reason for change CA:

5. Click on **Submit request**:

6. A pop-up message will appear, click **Confirm** or **Cancel** to go back:

[✕Close](#)


**Competent authority change request**

 Your request to change the Competent Authority will be submitted for validation.

- If validated, you will receive a notification and your Actor data will automatically be updated.
- While awaiting validation you will not be able to create a new actor's data version.
- If rejected, you will be notified, with further instruction.

Are you sure you want to proceed?


7. A success message will appear, non-EU manufacturers need to wait for the concerned Authorised Representative to assess the CA change request:

 You requested a change of competent authority. Your request to change the competent authority has been submitted for validation. When validated, you will receive a notification and your Actor data will be updated.  
[See your request](#)


**To see your pending/rejected competent authority change requests:**

1. On the homepage of EUDAMED, click on *Manage your actor data*:
2. If you have any pending/rejected requests, they will be accessible via the link found in the notice message.

Pending request message:

 You requested a change of competent authority. Your request to change the competent authority has been submitted for validation. When validated, you will receive a notification and your Actor data will be updated.  
[See your request](#)

Rejected request message:

 Your request to change your competent authority has been rejected. Click [here](#) to see your request and the reason for the rejection.

3. Once you have clicked on the link, you will arrive to an overview of your change request:

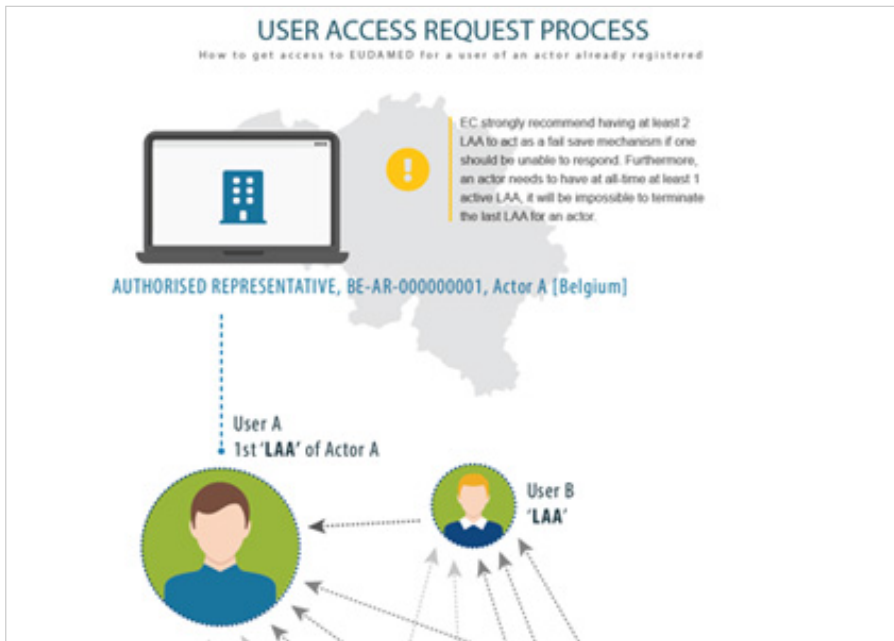
Reason for rejection and other details:

<b>Application ID:</b>	██████████
<b>Assessment outcome:</b>	Rejected
<b>Assessor CA Actor ID:</b>	██████████
<b>Reason for rejection:</b>	This request is rejected because .....
<b>Date of rejection:</b>	2023-03-31

## 2.2 Users and user access management

### 2.2.1 Request access as a user to a registered actor

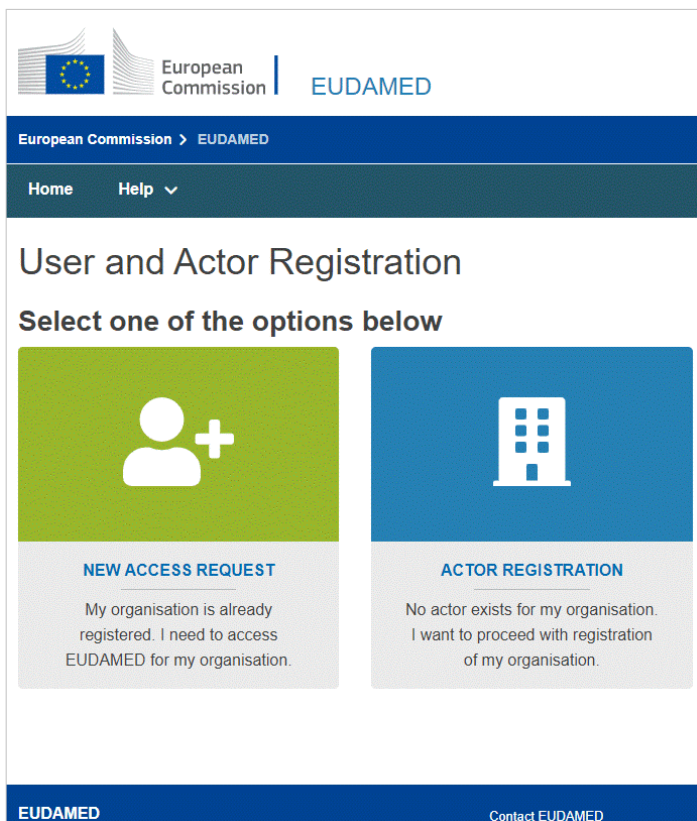
 **INFOGRAPHIC:** [User access request process](#)



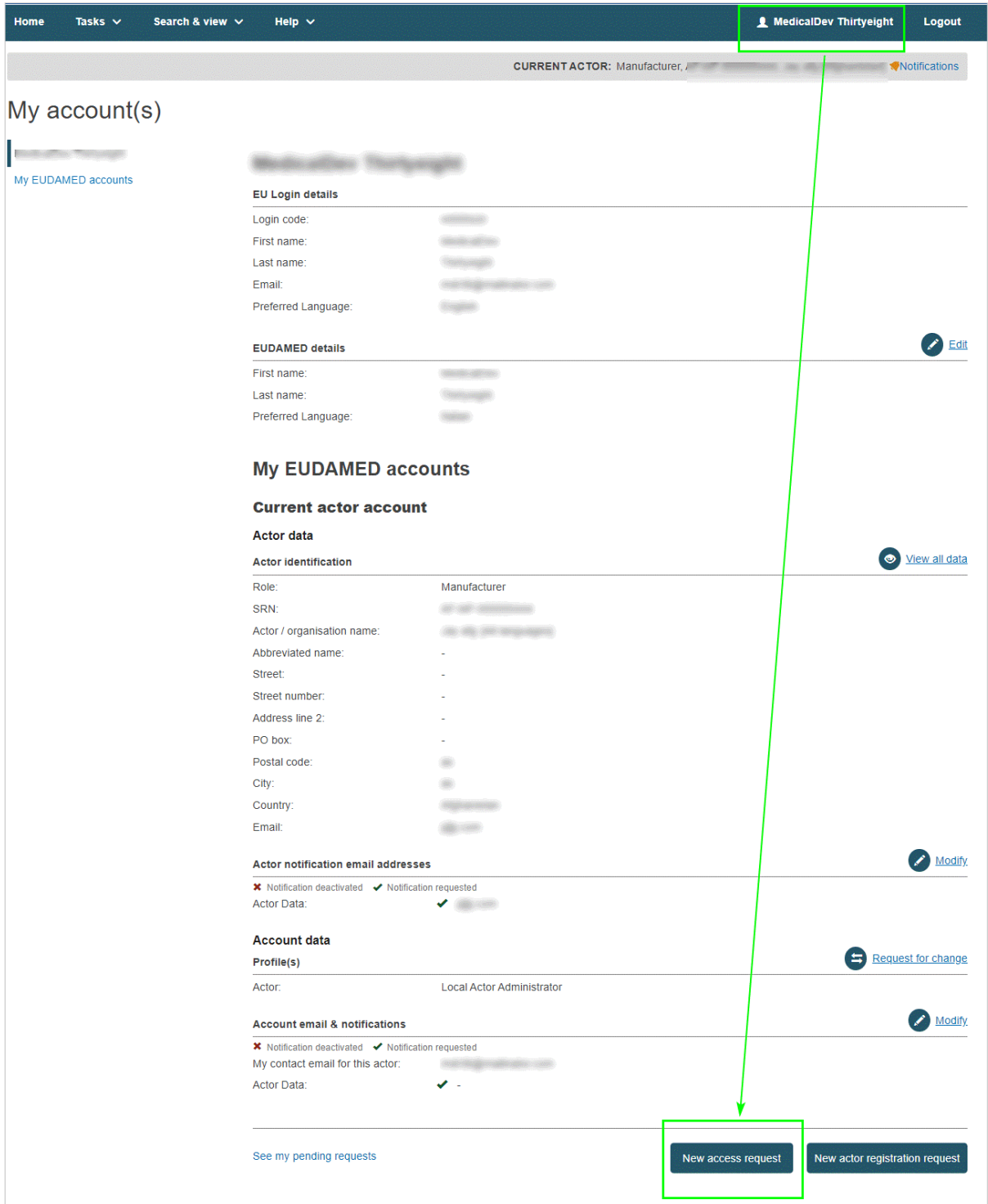
When an actor is already registered in EUDAMED, a person who needs to act on their behalf, must request access and choose (an) appropriate user profile for each of the relevant EUDAMED module(s) that are available to them.

**To request access as a user**

1. Log in to EUDAMED.
2. If you don't have user access for a registered actor yet, click the **New access request** box, in the *User and Actor Registration* page:



- Alternatively, if you are logged in with a EUDAMED user account and you need to request access for a a different actor, click your name at the top right of the page, and then click **New access request** at the bottom of your EUDAMED user account detail page:



An actor search page prompts you to select the actor on whose behalf you want to act in EUDAMED:

**New access request**

**!** The Local User Administrator of the organisation for which you are requesting access is empowered to validate the user requests and manage the user accounts of an organisation.

**Search existing actor**  
Enter your actor data to check if an actor already exists for your company

I know the actor's Single Registration Number (SRN) or EUDAMED Actor ID

\* Role:  
--

\* Country:  
--

\* Actor / organisation name:  
[Text input field]

Find

4. If you know the Actor ID/SRN(e.g. BE-MF-000000001), check *I know the actor's Single Registration Number (SRN) or EUDAMED Actor ID*.
5. If you don't know the Actor ID/SRN, you can find the actor by searching with: *role*, *country* and *name* (or part of it).
6. Click **Find**. The list of matching actors is displayed in the *Result* section.

**New access request**

**!** The Local User Administrator of the organisation for which you are requesting access is empowered to validate the user requests and manage the user accounts of an organisation.

**Search existing actor**  
Enter your actor data to check if an actor already exists for your company

I know the Actor's Single Registration Number (SRN)

\* Role:  
Manufacturer

\* Country:  
Belgium

\* Actor / organisation name:  
bel

Find

**Result**  
Select your actor from the list below

BE-MF-000000001 - Manufacturer - Actor code: BE-MF-000000001

SRN:  
BE-MF-000000001

Role:  
Manufacturer

Country:  
Belgium

Organisation name:  
[Redacted]

Address:  
[Redacted]

Email:  
[Redacted]

Telephone number:  
-

Request access to this actor



**NOTE**

If you can't find your actor from the search page, please contact them to confirm their Actor ID/SRN. They may have registered with a different name or may have not completed the registration yet.

If you search for a registered actor to which you already have access, the system will display a warning message, preventing you from proceeding further.

**New access request**

**!** The Local Actor/User Administrator of the organisation for which you are requesting access is empowered to validate the user requests and manage the user accounts of an organisation.

**Search existing actor**

Enter your actor data to check if an actor already exists for your company

I know the actor's EUDAMED Actor ID/Single Registration Number (SRN)

\* Actor code:

**Find**

**Result**

Select your actor from the list below

**Manufacturer, BE-MF-00000924, ARMEN 2.4 EU MANUFACTURER [Belgium]**

**!** You are already a registered user of the actor you have selected, and therefore cannot request new access.

If you wish to:

- Change your profile : Click "Request for change" next to your profile on the "My account" page and follow the steps. A separate LA/LUA must approve this access request. See the Actor module user guide for economic operators section 2.2.5 for more details.
- Create a new user: You must first access EUDAMED using a different EU Login (see <https://webgate.ec.europa.eu/cas/help.html> for more on how to create an EU Login), then use this to submit a new access request for this actor. See Actor module user guide for economic operators section 2.2.1 for more details.

However, if you search for an actor for which you initiated a *Draft* user access request, or for which a *Submitted* user access request exists, there will be no warning. To view this user access request, click your name at the top right of the page and then select *See my pending requests* at the bottom of your EUDAMED user account detail page.

7. Select the desired actor in the *Result* panel, and then click **Request access to this actor**. *Step 1* of a three-step process appears:

**New access request**

**Selected actor information**

SRN: [redacted]

Role: Manufacturer

Country: Belgium

Organisation name: [redacted]

Address: [redacted]

Email: [redacted]

Telephone number: [redacted]

**Select another actor**

1 My personal data
 2 My user manager
 3 My profile(s)

**My contact email for this actor** ?

\* Email:

\* Are you a sub-contractor for this actor?:

No

Yes

**Save**

**Save & Next** ▶

**Cancel**

8. Complete *Step 1*:
  - a. Enter your contact/notification email address related to this request.
  - b. Indicate whether you are a sub-contractor for the selected actor. If you select **Yes**, you will be prompted to enter details of the sub-contractor.

- Click **Save & Next**. *Step 2* appears. Here you must identify a manager in your organisation who can authorise your request:

New access request

**Information of the actor selected**

Actor code:  
IT-MF-00(000000)

Role:  
Manufacturer

Country:  
Italy

Actor/Organisation name:  
Bentley Systems, Inc.

Address:  
Via Salsola, 41, Cadriano-Granarolo Delfino

Email:  
contact@bentley.it

Phone:  
+39051234567

1 **My personal data** ✓
2 **My user manager**
3 **My profile(s)**

**User manager**

\* First Name:

\* Last Name:

\* Function/Position:

- Enter the name and function/position of your manager, and then click **Save & Next**. *Step 3* shows a list of possible user profiles for each module:

New access request

**Information of the actor selected**

SRN:  
0000000000

Role:  
Organisation Authority

Country:  
Belgium

Organisation name:  
Bentley Systems, Inc.

Address:  
Bentley Systems, Inc.

Email:  
contact@bentley.com

Phone number:  
+31201234567

1 **My personal data** ✓
2 **My user manager** ✓
3 **My profile(s)**

**My profile(s) for this actor**

Each profile is associated with a specific set of grants. Higher profiles include - and extend - the grants of the lower ones.

**Choose the profile(s) you need**

Actor 3

Local Actor Administrator

Local User Administrator

Validator

Viewer

**Active until**

End date:

YYYY-MM-DD



**NOTE**

The profiles available depend on the actor role.

The default minimum profiles for your actor are pre-selected.

- Select the user profile(s) you will need.

**NOTE****User profiles**

► **Local Actor Administrator (LAA)** can manage all actor details (name, address, contact details, etc.) and has all the rights of a Local User Administrator.

► **Local User Administrator (LUA)** can validate user access requests for the same actor (see [Validating user access requests \[69\]](#)).

► **Viewer** can view registered actors.

The other profiles available depend on the role of the actor in question.

12. If you want to save the request as a draft before submitting it, click **Save**.
13. If you want to see a preliminary summary of your request before submitting it, click **Preview** at the bottom of the page. A summary of your access request is displayed.
14. Review the information and click **Submit** at the bottom of the preview page. A confirmation page appears:

15. Click **Submit my request**. You are informed that your access request has been successfully submitted.  
A Local Actor Administrator or Local User Administrator belonging to the Actor will review and validate your request. You will be notified when your access request is approved or refused.
  - If **refused**, you can click the *View access request* link under the three dots, next to the pending request, to read the reason provided by the LAA/LUA. You can then change and re-submit as appropriate.

My pending/refused requests

You can view the status of your requests below

**EU Login details**

Name: [REDACTED]

Username: [REDACTED]

Email: [REDACTED]

**EUDAMED details**

Name: [REDACTED]

**My access requests for an existing actor**

Role ID	Name ID	City ID	Date of request ID	State	Actions
Manufacturer	Medical Device Manufacturer	Amersfoort	2024-03-22	Refused	<a href="#">View access request</a>

[New access request](#)

You do not have any pending actor registration requests for the moment

[New actor registration request](#)

Last name: [REDACTED]

Function/position: [REDACTED]

Validity date for the EUDAMED account

End date: -

**STEP 3 Profile(s)**

Certificate:	Viewer
UDI/Device:	Viewer
Actor:	Local User Administrator
Actor:	Viewer

**Assessment of user data**

Outcome:	Refused request
Remarks:	Here some remarks.

- If **approved**, the next time you log in to EUDAMED a disclaimer will show. You will only see the disclaimer the first time you log in for each actor connected to your account. Read the disclaimer and check *I accept the user rights and obligations*:

Home Tasks Search & view Help

**User rights and obligations disclaimer**

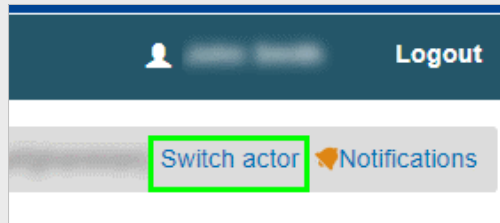
⚠ Actor/organisation name - [REDACTED] - [Download disclaimer](#)

I accept the user rights and obligations

[Next](#)

**NOTE****Working for multiple actors?**

If you have multiple EUDAMED user accounts for different actors, after having logged in you may switch to another actor for which you may act on behalf by clicking **Switch actor** at the top right of the screen:



16. Your details will be visible on the *My account(s)* page: click your name in the upper toolbar to open this:

Home Tasks Search & view Help

CURRENT ACTOR: [Switch actor](#) Notifications

### My account(s)

My EUDAMED accounts

**EU Login details**

Login code:   
 First name:   
 Last name:   
 Email:   
 Preferred Language:

**EUDAMED details** [Edit](#)

First name:   
 Last name:   
 Preferred Language:

**My EUDAMED accounts**

**Current actor account**

**Actor data**

**Actor identification** [View all data](#)

Role: Manufacturer   
 SRN:   
 Actor / organisation name:   
 Abbreviated name: -   
 Street:   
 Street number:

**NOTE**

To view the full details for the actor, click **View all data**. If you have several EUDAMED user accounts, this page may contain these other sections (in addition to *Current actor account*):

- ▶ *My other accounts*
- ▶ *Terminated accounts*

## 2.2.2 Validate user access requests

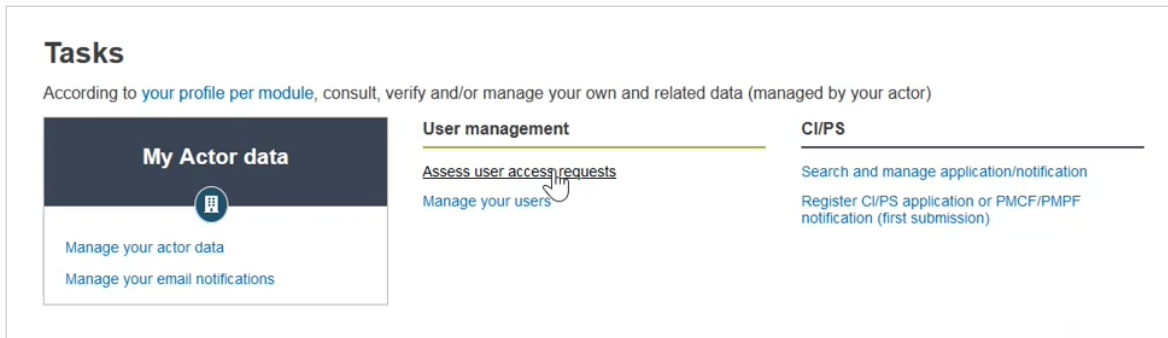
*Section for Local Actor Administrators and Local User Administrators*

Anyone with an EU Login account can request access to a registered Actor, but only a user with a *Local User Administrator (LUA)* or a *Local Actor Administrator (LAA)* profile can validate these requests.

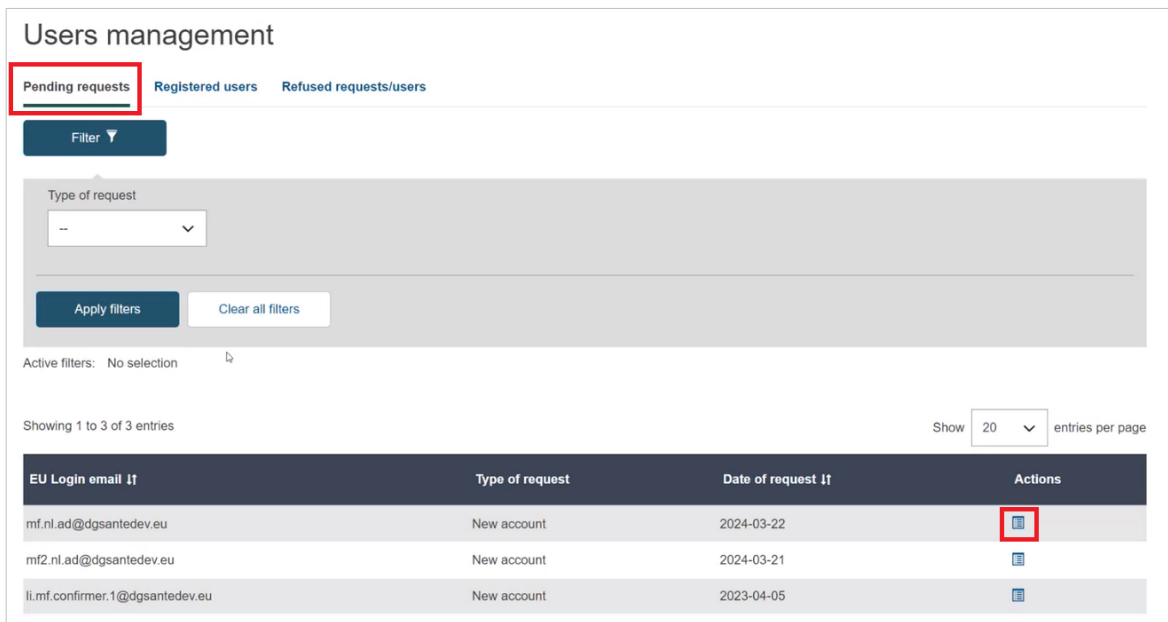
The Actor's LAAs and LUAs will be notified of all new or updated incoming users access requests.

**To validate an access request**

1. Log in to EUDAMED.
2. From your dashboard, select *Assess user access requests* (in the *User management* section):



The *Pending requests* tab on the *Users management* page lists all pending user access requests for your Actor:



3. Click **Assess access request** in the *Actions* column to view and assess a request from the list. Part 1. of the access request is displayed:

Assessment - part 1: User Data

**Actor identification**  
 Organisation name: -  
 SRN: AL-  
 Address: -  
 Telephone number: -  
 Email: -

**User information**

**EU Login ID**  
 ID: -

**Contact email for the actor**  
 Email: -

**Are you a sub-contractor for this actor?**  
 Sub-contractor:  No

**User manager**  
 \* First name: -  
 \* Last name: -  
 \* Function/position: -

**Validity date for the EUDAMED account**  
 End date: -


4. Review the information in Part 1. of the request.
5. In the *Assessment* section, slide the toggle left to **Approve** the request, or right to **Reject**.
  - If you select **Approve**, click **Next step**.
  - If you select **Reject**, you must add a comment and select one of the following reasons:


Incomplete and/or details to correct:	Some information is either missing or looks incorrect. The requesting user will have a chance to correct or complete the request following your instructions and re-submit the request.
Refused request:	The request will be refused, and the requesting user is not invited to re-submit.

Approve  Reject

**\* Type of reasons:**

Incomplete and/or details to correct

Refused request 

 Please be aware that you must inform us at SANTE-EUDAMED-SUPPORT@ec.europa.eu if you suspect that this is a fraudulent access request

**\* Remarks:**

This ends the steps you need to follow to reject a request (ignore steps 6-8 below). The rejected request is listed in the *Refused requests/users* tab:

Users management

[Pending requests](#) [Registered users](#) [Refused requests/users](#)

Showing 1 to 3 of 3 entries Show  entries per page

EU Login email ID	Type of request	Date of request ID
mf.nl.ad@dgsantedev.eu	New account	2024-03-22
mf2.nl.ad@dgsantedev.eu	New account	2024-03-21
mf2.nl.ad@dgsantedev.eu	New account	2024-03-21

6. If you decided to approve, click **Next step**.

**Assessment of user data**

Outcome:

Approve  Reject

A table is shown with the user profiles for all available modules. The *Viewer* profile is automatically granted to each user for the Actors, UDI/Devices and NBs & Certificates modules:

**Requested Profiles**

Profiles(s) for this actor

For each module, select the 'Approve' button to approve a profile or the 'Reject' button to reject a profile. The user has access by default to his/her own actor data.

[Approve all](#) [Reject all](#)

CI/PS:	Confirmer	Approve	Reject
		<input type="checkbox"/>	<input type="checkbox"/>



**NOTE**  
**Profile availability**

The profiles available in the table depend on the actor role – e.g. if the user is requesting access for an authorised representative, the additional profile of *Verifier* will be available.

- For each module in the table, click either **Accept** or **Reject**, and when you are done, click **Complete assessment**.  
A summary is displayed of the user profile you have approved.
- To confirm this user profile, click **Confirm** in the summary dialog box.  
You are informed that the access request has been properly assessed:
  - The status of the request will become *validated*.
  - The user is notified that their access request has been validated.

## 2.2.3 Terminate a user account

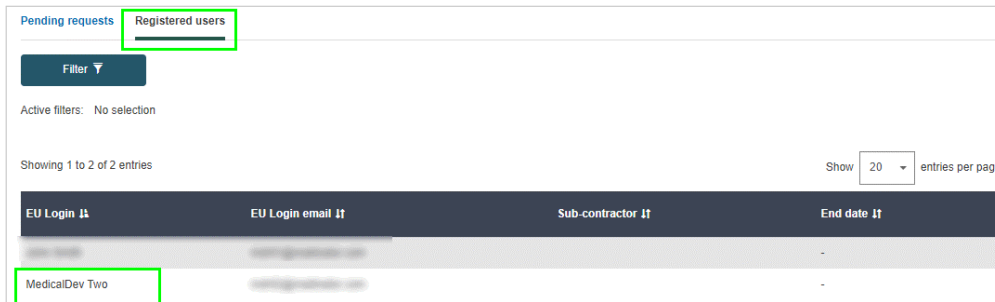
### *Specific to Local Actor Administrators and Local User Administrators*

When a EUDAMED-registered user leaves an organisation, changes their job function or is otherwise no longer involved in EUDAMED, should not have access anymore for this actor, the Local Actor Administrator (LAA) or Local User Administrator (LUA) can deactivate their account by marking it as *Terminated*.

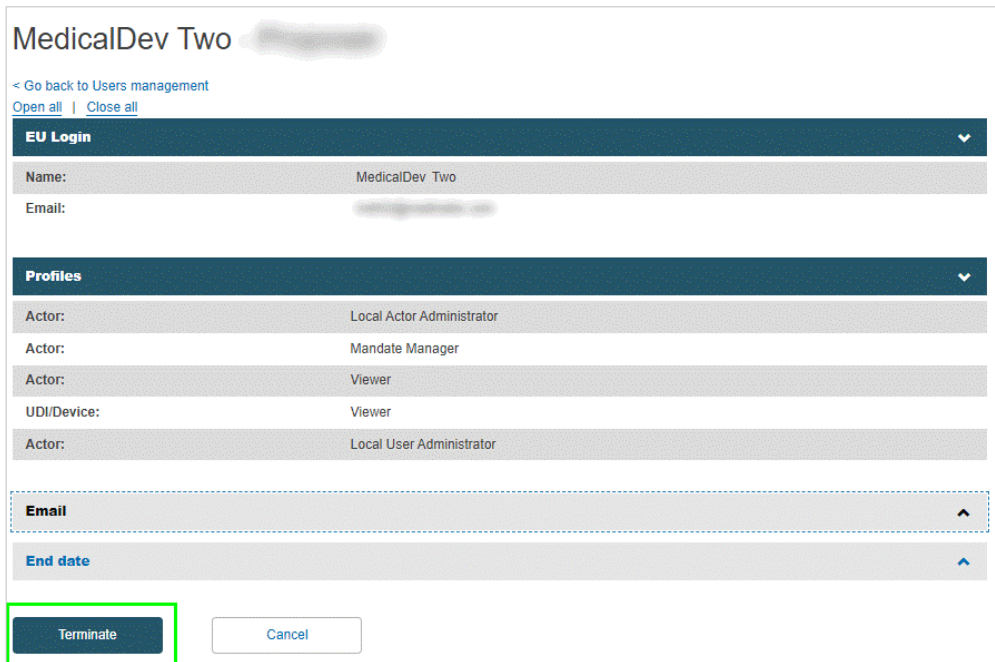
An actor user with a terminated account can no longer act on behalf of this actor. If they need to regain the role at any time in the future they will have to submit a new access request for that actor.

#### To terminate a user account

- Log in to EUDAMED.
- Select *Manage your users* in the *User management* section of your dashboard.
- On the *User management* page, select the *Registered users* tab, and then click on the user in question:



4. Click **Terminate** at the bottom of the page:



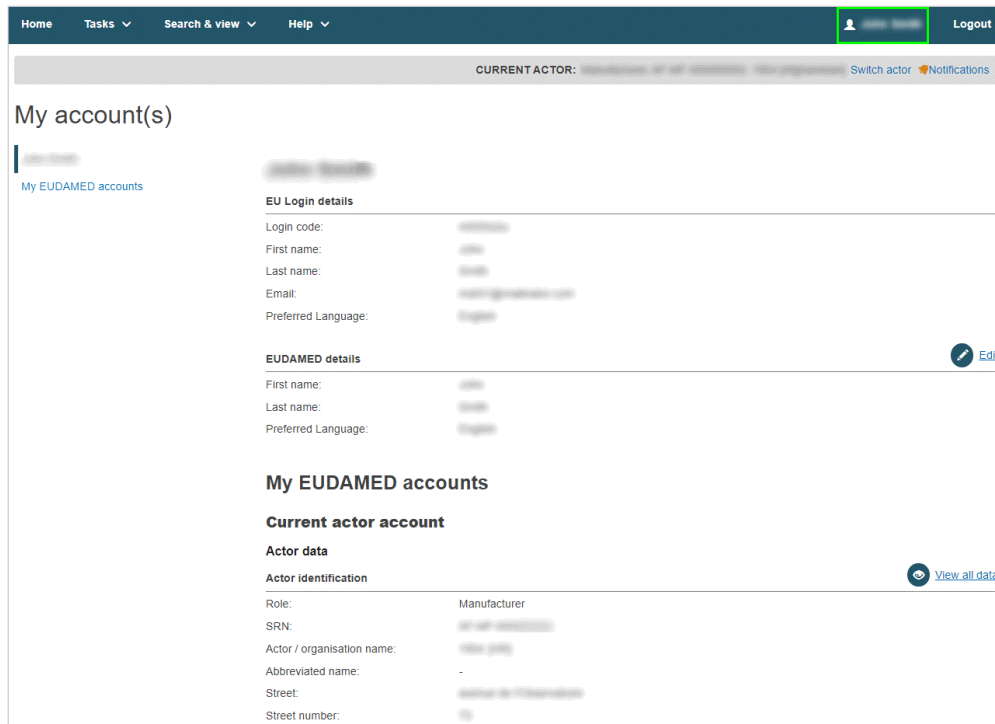
5. Confirm that you wish to complete the action. The user instantly loses access to this actor.

## 2.2.4 Edit your user account

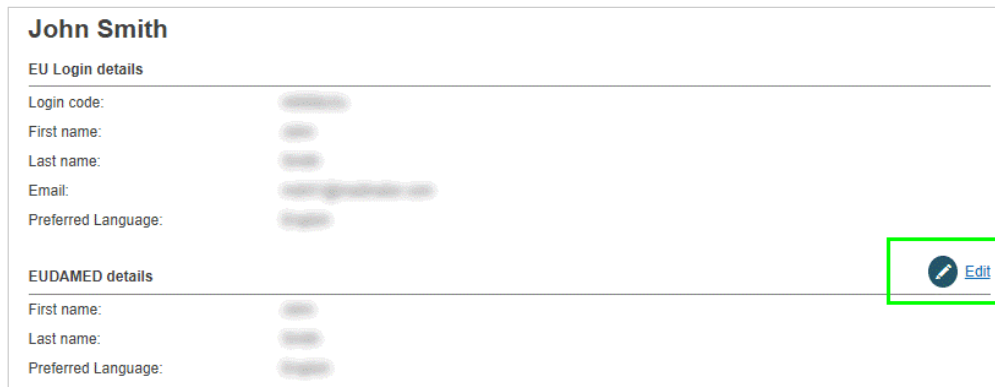
After your user access request is approved, you can still change your account information.

**To edit your user account:**

1. Log in to EUDAMED and click on your name in the upper toolbar. The page *My account(s)* appears:



- To change any editable data in the EUDAMED details, click **Edit**:  
**EU Login details / EUDAMED details**



Use the **Edit** button in this section if you want to change your first name, last name and/or preferred language.

**Current actor account: actor data**

**My EUDAMED accounts**

**Current actor account**

**Actor data**

Actor identification [View all data](#)

Role: [redacted]  
 SRN: [redacted]  
 Actor / organisation name: [redacted]  
 Abbreviated name: -  
 Street: -  
 Street number: -  
 Address line 2: -  
 PO box: -  
 Postal code: [redacted]  
 City: [redacted]  
 Country: [redacted]  
 Email: [redacted]

Actor notification email addresses [Modify](#)

✘ Notification deactivated ✔ Notification requested  
 Actor Data: ✔ [redacted]

A LAA has the **Modify** button in this section. Using this button, the receiving email address for notifications can be changed, including those for the different EUDAMED modules.



**NOTE**

**Local Actor Administrator only**

- ▶ The *Actor data* section can only be modified by a Local Actor Administrator.
- ▶ The **Modify** button is not active here for any other user profile.

**Current user actor account for this actor: Account data**

**Account data**

Profile(s) [Request for change](#)

Actor: Administrator  
 UDI/Device: Viewer

Account email & notifications [Modify](#)

✘ Notification deactivated ✔ Notification requested  
 My contact email for this actor: [redacted]  
 Actor Data: ✔ -

Use the **Request for change** button in this section if you want to request a different profile for one or more EUDAMED modules for the current actor.  
 Use the **Modify** button if you want to change the account email and/or the notification preferences for the current actor.

3. Make any required changes.
4. Click **Save**.
5. If you are registered with more than one actor, they are listed in the *My other account(s)* box:

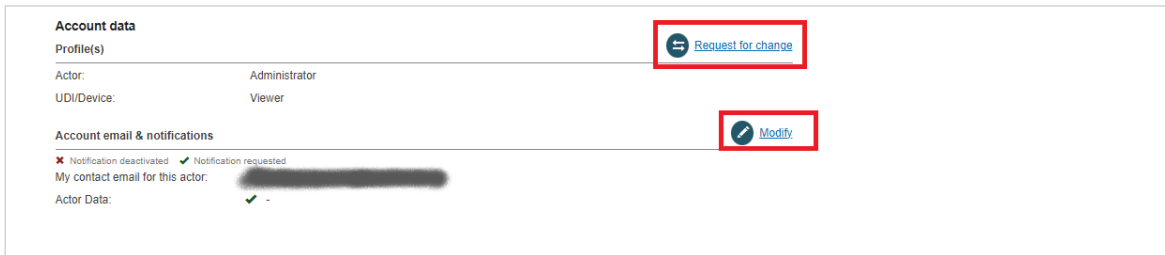
**My other account(s)**



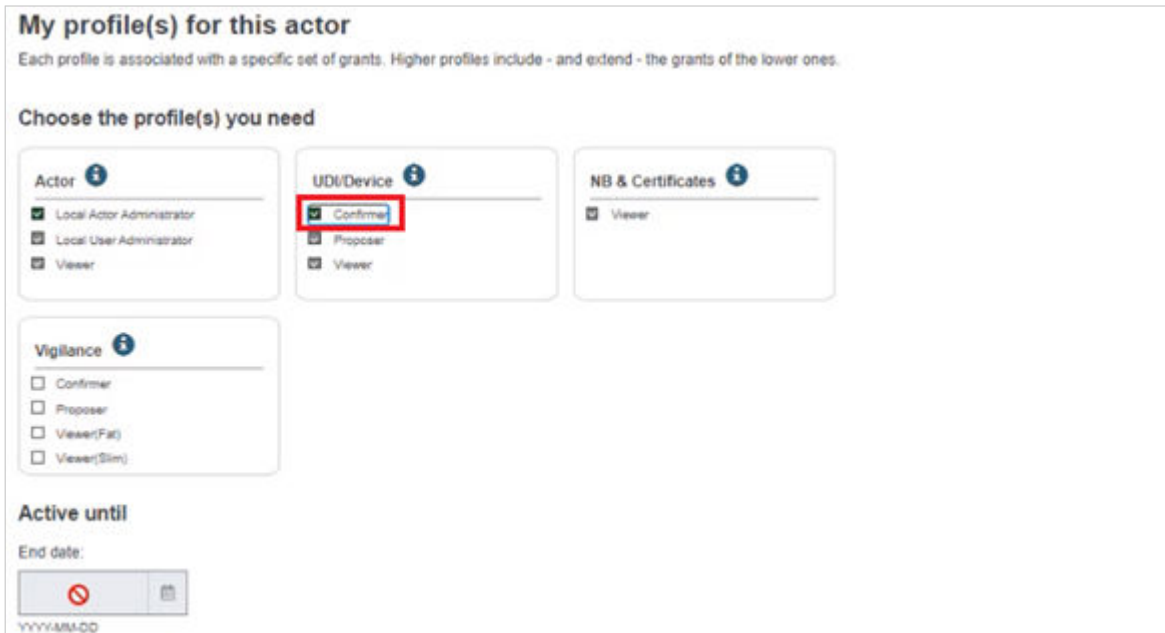
Click the right-pointing arrow next to one of the actors in the list to show their details. You can switch between actor accounts.

## 2.2.5 Upgrade your user profile

1. Log in to EUDAMED and click your name in the upper toolbar to reach the *My account* page.



2. Click *Request for change* next to your profiles and follow the steps to select the profiles for the module you require. If this button is missing, it means you have already submitted a request that is still under assessment – if this is the case, you can view your pending requests via the *See my pending requests* link at the bottom of the page.



3. An LAA/LUA must approve this request before these profiles are assigned to you.

**IMPORTANT**

- ▶ An LAA/LUA cannot approve their **own** requests. This means that for any actor with only ONE user, a **second user** with LAA/LUA profile will be needed to approve any profile upgrade requests.
- ▶ It is good practice for each actor to have **at least two** users with an LAAprofile.
- ▶ EUDAMED requires that an actor retains one LAA, so you will be unable to terminate the last user's LAAprofile.

4. If you are the only user from your actor, you will need to grant access to a new user, assigning an LAA/LUA profile via the process outlined in *Sections Requesting access as a user to an existing different actor* and *Validating Economic Operator access requests*.
5. Once you have approved access for this second LAA/LUA, this user will then be able to approve your request to upgrade your profile.

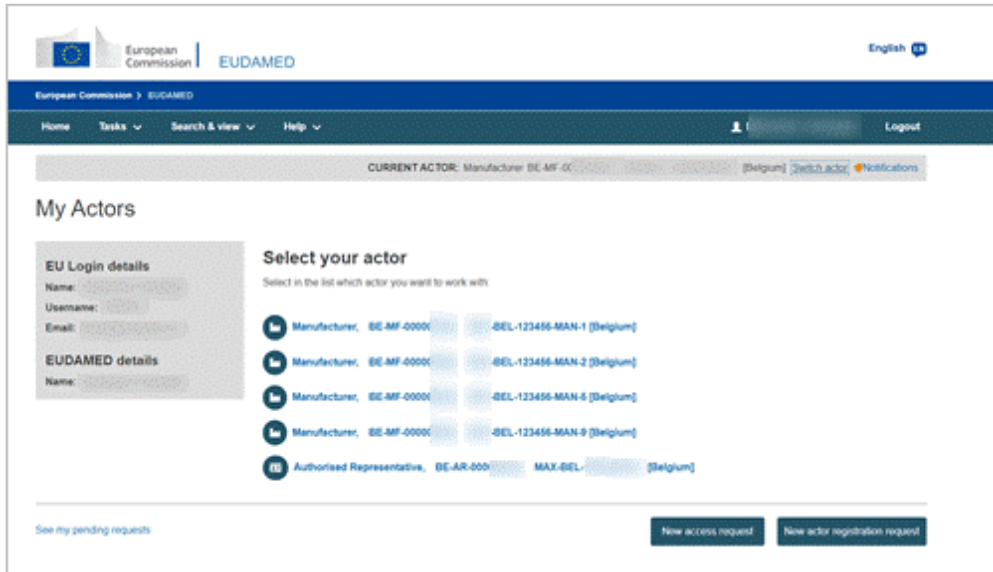
## 2.2.6 Switch between actors

If you have multiple EUDAMED user accounts for the same EU Login account, you can switch easily between them (and the different actors associated with them).

1. Go to the Dashboard:

2. Click on **Switch actor** at the top right:

3. Select an actor from the list shown:



## 2.3 Manage mandates

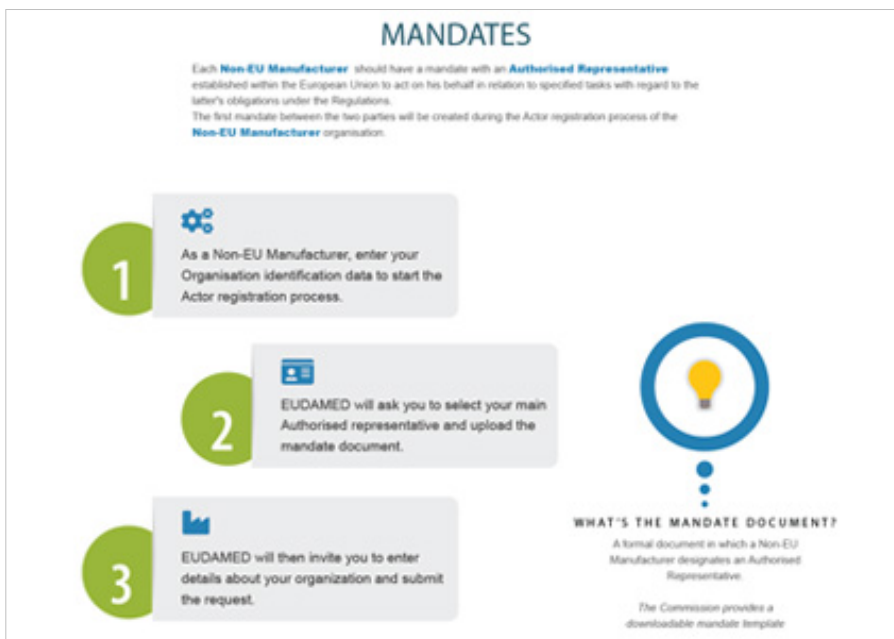
### *Specific to non-EU manufacturers and authorised representatives*

When registering in EUDAMED, non-EU manufacturers are required to provide information on their mandate with an authorised representative.

If they have mandate(s) with other authorised representative(s), these must also be individually registered in EUDAMED, those mandates need to be verified by the concerned authorised representative.

Additionally, the Authorised Representative or the non-EU manufacturer can decide to **terminate** the mandate at any moment.

### **INFOGRAPHIC: Mandates for AR/Non-EU Non-EU MF**



## 2.3.1 Add a new mandate

### *Specific to non-EU manufacturer*

#### To add a mandate

1. Log in to EUDAMED and select *Manage my mandates* under the *My Actor data* section of your dashboard. The list of mandates that have already been created is displayed, with information on their current state.

View my mandates

Manufacturer, AF-MF-0000 (00000, 1000 (registered))

Showing 1 to 6 of 6 entries Show  entries per page

Mandate ID	AR name	AR SRN	End date	State
MD-AF-BE-00000	AR name	BE-AR-00000	2020-06-08	Registered (Expired)
MD-AF-BE-00000	AR name	BE-AR-00000	2030-04-04	Terminated (MF)
MD-AF-BE-00000	AR name	BE-AR-00000	-	Registered
MD-AF-BE-00000	AR name	BE-AR-00000	-	Rejected



#### NOTE

Manage my mandates is available only to users with a *Mandate manager* or higher (e.g. LAA/LUA) profile for a registered non-EU manufacturer.

2. Select *Add a new mandate* at the top right of the list. The *Add a new mandate* page appears:

### Add a new mandate

**Manufacturer information**

Organisation name:

SRN:

Address:

Telephone number:

Email:

**Select an authorised representative**

I know the SRN

\* SRN:

**Mandate validity dates**

\* From:

YYYY-MM-DD

To:

YYYY-MM-DD

\* Upload mandate summary document

---

3. If you know the Actor ID/SRN for the Authorised Representative, enter it here, click **Find** and select from the results.
4. If you don't know the Actor ID/SRN, uncheck *I know the Actor ID/SRN*, enter the country and authorised representative name, click **Find** and select from the results.



#### NOTE

If you don't find your Authorised Representative from the search page, please contact them to confirm their Actor ID/SRN.

5. Specify the mandate's validity start-date (mandatory) and end-date (optional), if applicable.
6. Click **Browse**, under *Upload mandate summary document*, to upload your summary mandate document – in **PDF format only and not exceeding 10MB**:
  - A summary extract of the official signed mandate is enough, stating just:
    - Start and end dates.
    - Names and addresses of the Manufacturer and Authorised Representative.
    - List of generic device groups covered by the mandate.

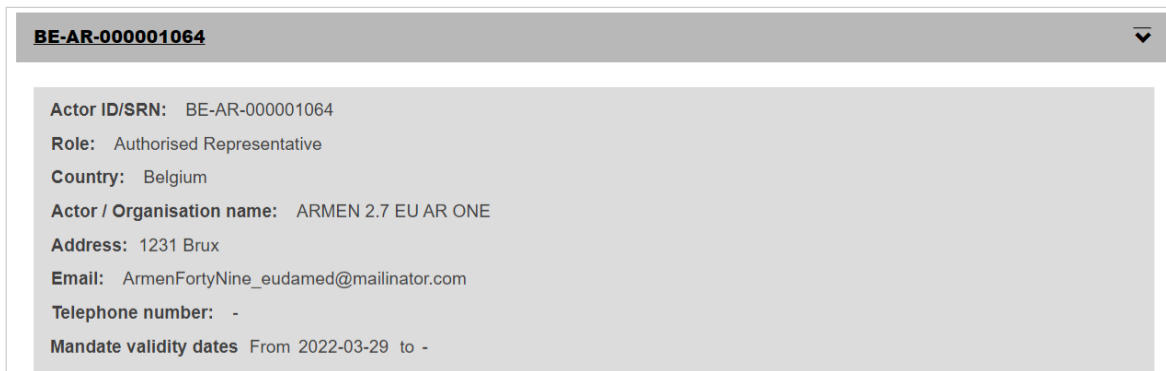
- [Click here for the mandate summary template.](#)

7. Click **Submit**.

The new mandate now appears in your mandate list, with the state *Submitted*. It must now be verified by the relevant Authorised Representative:



8. If you click on it, you will get an overview of your update, everything is visible from the *Authorised representative(s) mandates*, identified by the Actor ID/SRN of the Authorised representative, which will show as a clickable accordion:

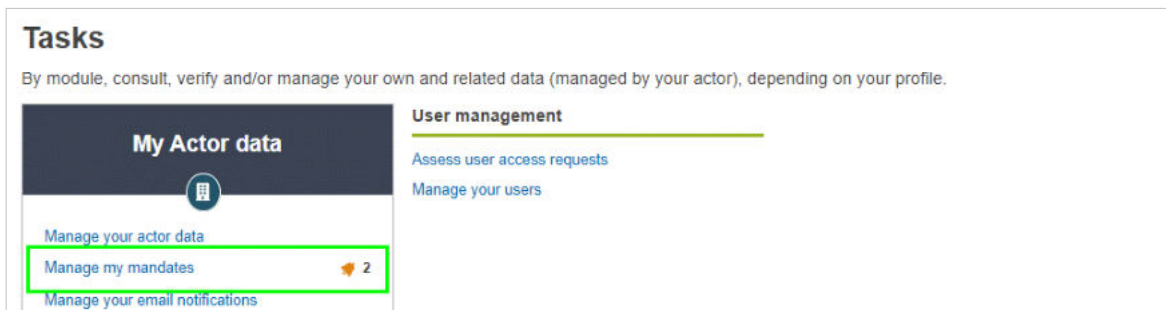


## 2.3.2 Create a new mandate version

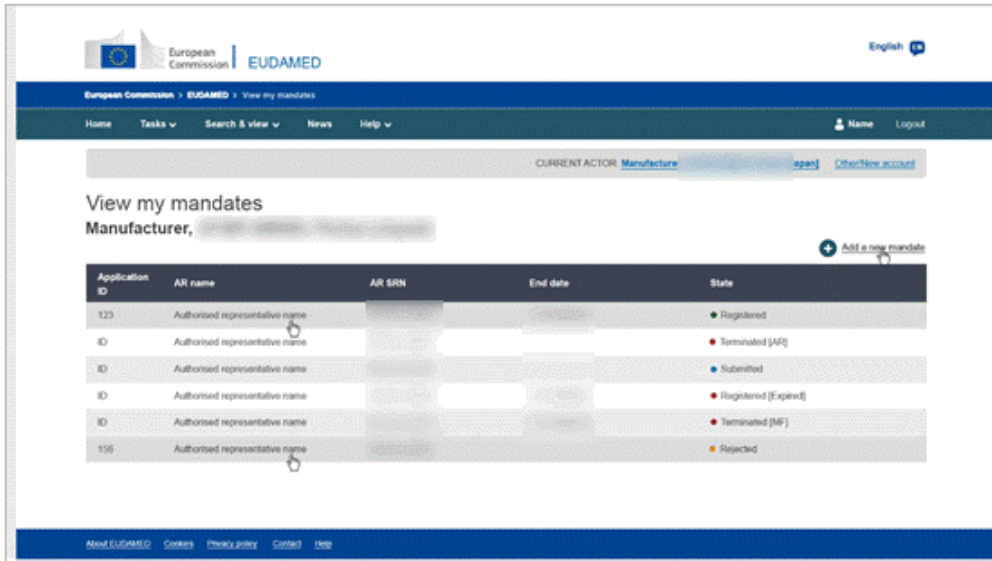
### Specific to Non-EU manufacturers

#### To create a new mandate version

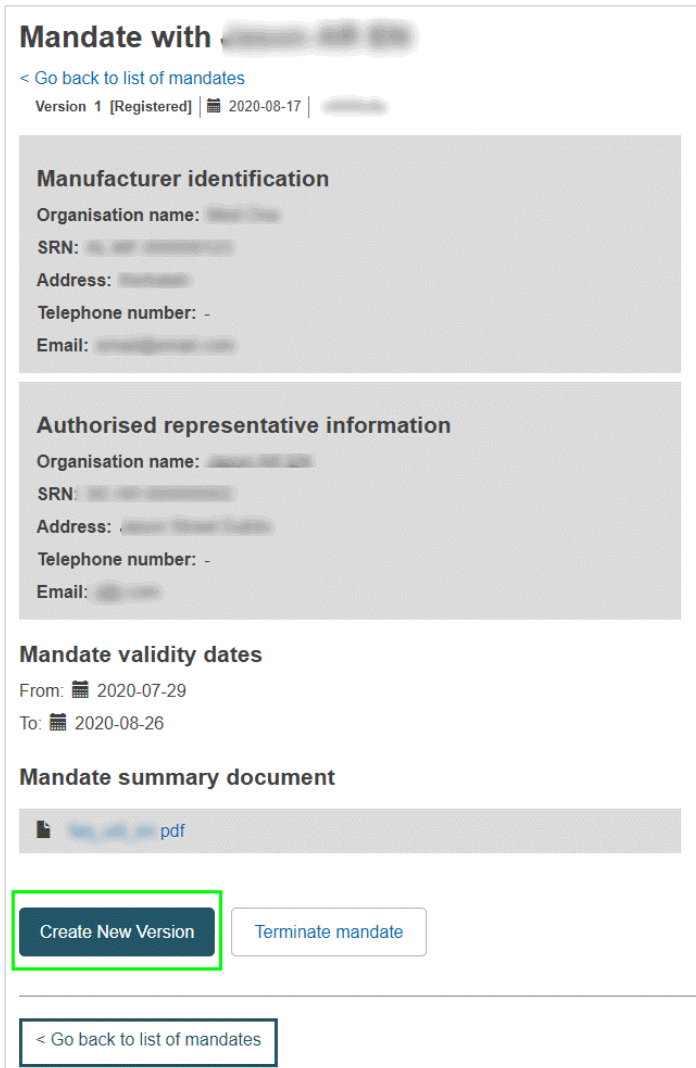
1. Log in to EUDAMED and select *Manage my mandates* in the *My Actor data* section of your dashboard:



2. Select the mandate from the list:



3. In the new window, where you can see details of the mandate, select **Create new version** at the bottom of the page:



- Upload the new mandate summary document (**in PDF only and not exceeding 10MB**) and change the validity dates accordingly.

### 2.3.3 Verify mandates

*Specific to authorised representatives with a Verifier or higher profile*

#### To verify a mandate

- Log in to EUDAMED and select *Manage your mandates* in the *Actor management* section of your dashboard:

The screenshot shows the 'Tasks' section of the EUDAMED dashboard. It is divided into three main areas: 'My Actor data', 'User management', and 'Actor management'. Under 'My Actor data', there are links for 'Manage your actor data', 'Manage your email notifications', and 'Machine to machine data delivery preferences'. Under 'User management', there are links for 'Assess user access requests' and 'Manage your users'. Under 'Actor management', there are links for 'Verify actor registration requests' and 'Manage your mandates', which is highlighted with a green box. A notification icon with the number '3' is visible next to 'Manage your mandates'.

If any registered manufacturer(s) have uploaded new mandates designating your actor as the associated Authorised Representative, they are listed in the *Pending mandates* tab:

The screenshot shows the 'Mandate management' interface. It has two tabs: 'Pending mandates' (highlighted with a green box) and 'Registered mandates'. Below the tabs is a 'Filter' button and a section for 'Active filters' showing 'Status: Submitted' and a 'Clear all filters' button. Below that, it says 'Showing 1 to 3 of 3 entries' and 'Show 20 entries per page'. A table displays the following data:

Mandate ID ↑	MF name ↓	MF SRN ↑	Country ↑	State ↑	End date ↑
MD-AF-BE-0000		AF-MF-00000	Afghanistan	Submitted	2020-04-04
		AF-MF-00000	Afghanistan	Submitted	2020-08-27

- Click on the mandate you want to verify in the *Pending mandates* list. The details of the concerned mandate are displayed. The mandate summary PDF is available under *Mandate summary document*:

**Mandate validity dates**  
 From: 📅 2020-08-05  
 To: 📅 2020-08-27

**Mandate summary document**

[Mandate Summary Document.pdf](#)

**Decision**

Approve  Reject

Remarks:

3. Review the mandate, and then slide the toggle at the bottom of the page left to **Approve** the mandate, or right to **Reject** it.
4. Enter some comments if necessary, or a justification for the rejection, in the *Remarks* field.
5. Click **Apply**.

## 2.3.4 Terminate a mandate

### *Specific to authorised representatives and non-EU manufacturers*

The Authorised Representative or the non-EU manufacturer may terminate a mandate. Either the Authorised Representative or the non-EU manufacturer can mark a mandate as *Terminated* in EUDAMED. The procedures are very similar.

#### **If you are an Authorised Representative**

##### **To terminate a mandate**

1. Select *Manage your mandates* under the *Actor management* section.

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

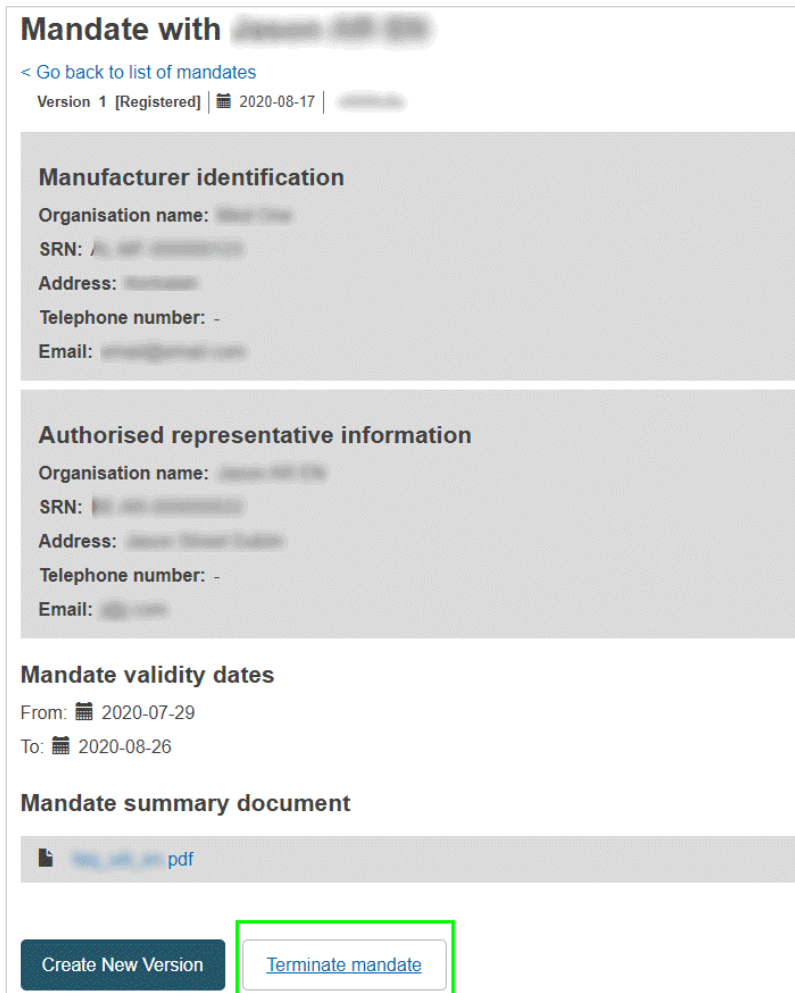
<div style="background-color: #333; color: white; padding: 5px; text-align: center; font-weight: bold; margin-bottom: 5px;">My Actor data</div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> <a href="#">Manage your actor data</a> </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> <a href="#">Manage your email notifications</a> </div> <div style="border: 1px solid #ccc; padding: 5px;"> <a href="#">Machine to machine data delivery preferences</a> </div>	<p><b>User management</b></p> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> <a href="#">Assess user access requests</a> </div> <div style="border: 1px solid #ccc; padding: 5px;"> <a href="#">Manage your users</a> </div>	<p><b>Actor management</b></p> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> <a href="#">Verify actor registration requests</a> </div> <div style="border: 1px solid #ccc; padding: 5px; border: 2px solid green;"> <a href="#">Manage your mandates</a> </div> <div style="text-align: right; margin-top: 5px;"> <span style="color: orange;">🔥</span> 3             </div>
--	---	--

The *Mandate Management* page appears. The mandates are split into two tabs: *Pending mandates* and *Registered mandates*.

2. Select the *Registered mandates* tab. A list of all registered mandates to which you are associated is displayed:



3. Click on the registered mandate that is to be terminated. The details of the selected mandate are displayed:



4. Click **Terminate mandate** at the bottom of the page.
5. Use the calendar icon to select the termination date (cannot be set in the future).

**NOTE**

If you try to set a date in the future, an error message will display when clicking on **Confirm**, stating that the termination date must be equal or before the current date.

6. Click **Confirm**.

**If you are a non-EU manufacturer****To terminate a mandate**

1. Select *Manage my mandates* under the *My Actor* data section. The list of your existing mandates is displayed:

View my mandates

Manufacturer, AF-MF-XXXXXXXXXX XXXXXX XXXXXX

[+ Add a new mandate](#)

Showing 1 to 7 of 7 entries Show  entries per page

Mandate ID <a href="#">↕</a>	AR name <a href="#">↕</a>	AR SRN <a href="#">↕</a>	End date <a href="#">↕</a>	State <a href="#">↕</a>
MD-AF-BE-00000 <a href="#">↕</a>	<a href="#">XXXXXXXXXX</a>	BE-AR-0000 <a href="#">↕</a>	2020-06-08	Registered (Expired)
MD-AF-BE-00000 <a href="#">↕</a>	<a href="#">XXXXXXXXXX</a>	BE-AR-0000 <a href="#">↕</a>	2030-04-04	Terminated [MF]
MD-AF-BE-00000 <a href="#">↕</a>	<a href="#">XXXXXXXXXX</a>	BE-AR-0000 <a href="#">↕</a>	-	Registered

2. Click on the registered mandate that is to be terminated. The details of the selected mandate are displayed.
3. Click **Terminate mandate** at the bottom of the mandate detail page.
4. Use the calendar icon to select the termination date (cannot be set in the future).

**NOTE**

If you try to set a date in the future, an error message will display when clicking on **Confirm**, stating that the termination date must be equal or before the current date.

5. Click **Confirm**.
6. You can see the terminated mandate by clicking on *My actor data*, and clicking on *Authorised representative* on the left side or by scrolling the page:

Manufacturer, BB-MF-00000 [Barbados]

My Actor data

- Authorised Representative
- Competent Authority
- Notification email
- Linked importers

### My Actor data

Version 2 [Current] | Last update date: 2022-09-16 | n0005f47

Your request to change your competent authority has been rejected. [Click here to see your request and the reason for the rejection.](#)

#### Actor identification

Role:	Manufacturer
Actor ID/SRN:	BB-MF-000001065
Country:	Barbados
Actor / Organisation name:	ARMEN 2.7 BARBADOS MANUFACTURER [All languages]
Abbreviated name:	-
VAT information:	No
EORI number:	-
National trade register number:	-
Organisation identification document:	-

Actions -

The terminated mandate will appear in an accordion, click on the Authorised Representative Actor ID/SRN to expand it, the termination date will be shown at the bottom of the accordion:

**BE-AR-000001063 (Terminated)**
▼

**Actor ID/SRN:** BE-AR-000001063

**Role:** Authorised Representative

**Country:** Belgium

**Actor / Organisation name:** ARMEN 2.7 EU AR TWO

**Address:** 1112 BRUXELLES

**Email:** ArmenFortyNine\_eudamed@mailinator.com

**Telephone number:** -

**Mandate validity dates** From 2022-03-29 to -

**Termination date:** 2022-08-31

