



EUDAMED user guide

Actor module for Economic Operators

Production v 2.15.1
2025



Table of Contents

1. Introduction	1
1.1. Overview	1
1.2. Application basics	1
1.2.1. Start and end a EUDAMED session	2
1.2.2. Actors and definitions	7
Actors	7
1.2.3. User rights and profiles	8
Hierarchy of user profiles	8
2. Managing actors and user accounts	10
2.1. Managing actors	10
2.1.1. Register as an Economic Operator	11
2.1.2. Register as a non-EU manufacturer	22
2.1.3. Verify non-EU manufacturer registrations	26
2.1.4. Search and view registered actors	28
View Actor data – historical versions	31
2.1.5. Link a non-EU manufacturer to an importer	32
2.1.6. Updating Actor details	35
Delete an actor's draft	36
2.1.7. Confirm Actor data accuracy	37
2.1.8. Activate/deactivate your Actor	41
2.1.9. Change a Competent Authority for registered actors	44
2.2. Users and user access management	48
2.2.1. Request access as a user to a registered actor ..	48
2.2.2. Validate user access requests	56
2.2.3. Terminate a user account	60
2.2.4. Edit your user account	61
2.2.5. Upgrade your user profile	64
2.2.6. Switch between actors	65
2.3. Manage mandates	66
2.3.1. Add a new mandate	67
2.3.2. Create a new mandate version	69
2.3.3. Verify mandates	71
2.3.4. Terminate a mandate	72

1 Introduction

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.

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 – user registration and management
- UDI database and registration of devices
- Notified Bodies and Certificates
- Clinical Investigation and performance studies
- Vigilance and post-market surveillance
- Market surveillance

A **public site** is also available.

1.2 Application basics

This section describes a number of basic principles:

- Starting and ending a EUDAMED session
- Basic concepts

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

- User profiles and access grants/rights.

1.2.1 Start and end a EUDAMED session

To use EUDAMED, you must have an EU Login account associated with your professional email address. Private / shared mailboxes are excluded for security reasons.



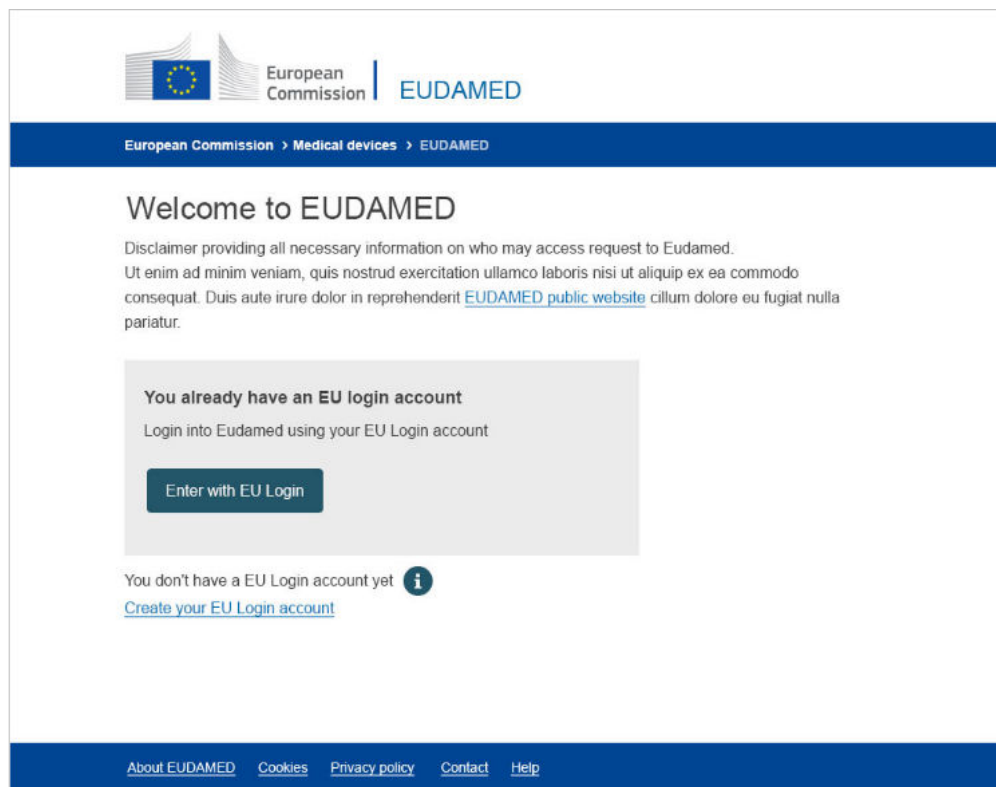
IMPORTANT

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 username and password.

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

To start EUDAMED:

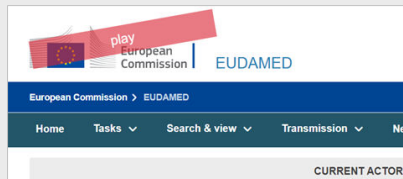
1. Go to [EUDAMED](#).



**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

[Redacted]
(European Commission)

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

Password

[Lost your password?](#)

Choose your verification method



Password

Authenticate to EU Login with only your password.



Sign in

**NOTE**
EU Login issues?

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

Sign in to continue

Welcome back

[Redacted Email Address]
(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.

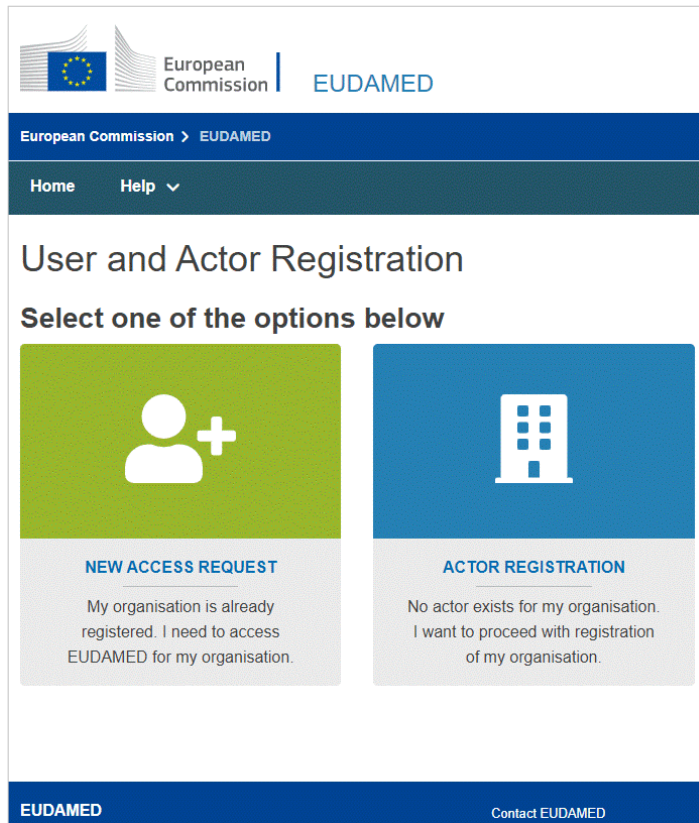


Sign in

► 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 you do not have any pending/registered account(s), EUDAMED opens the *User and Actor Registration* page:



European Commission | EUDAMED

European Commission > EUDAMED

Home Help ▾

User and Actor Registration

Select one of the options below



NEW ACCESS REQUEST

My organisation is already registered. I need to access EUDAMED for my organisation.



ACTOR REGISTRATION

No actor exists for my organisation. I want to proceed with registration of my organisation.

EUDAMED [Contact EUDAMED](#)



NOTE

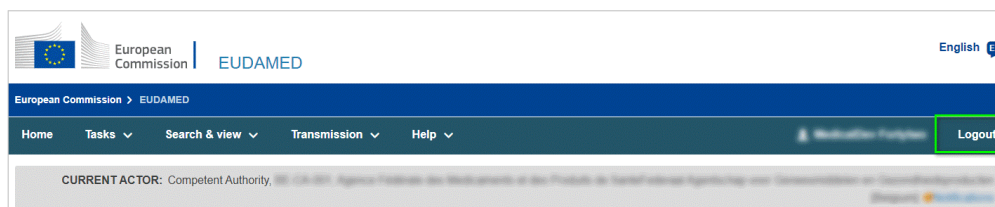
Next steps:

► Want to register your organisation as an actor in EUDAMED? See [Registering as an Economic Operator \[11\]](#)

► Need access as a user for a registered economic operator? See [Requesting access as a user for a registered Economic Operator \[48\]](#)

To quit EUDAMED:

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



European Commission | EUDAMED

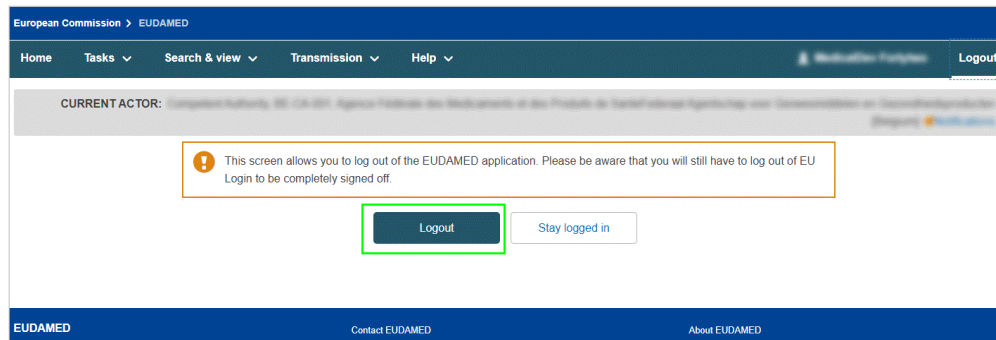
English EN

European Commission > EUDAMED

Home Tasks ▾ Search & view ▾ Transmission ▾ Help ▾ [Media/Press Page](#) **Logout**

CURRENT ACTOR: Competent Authority

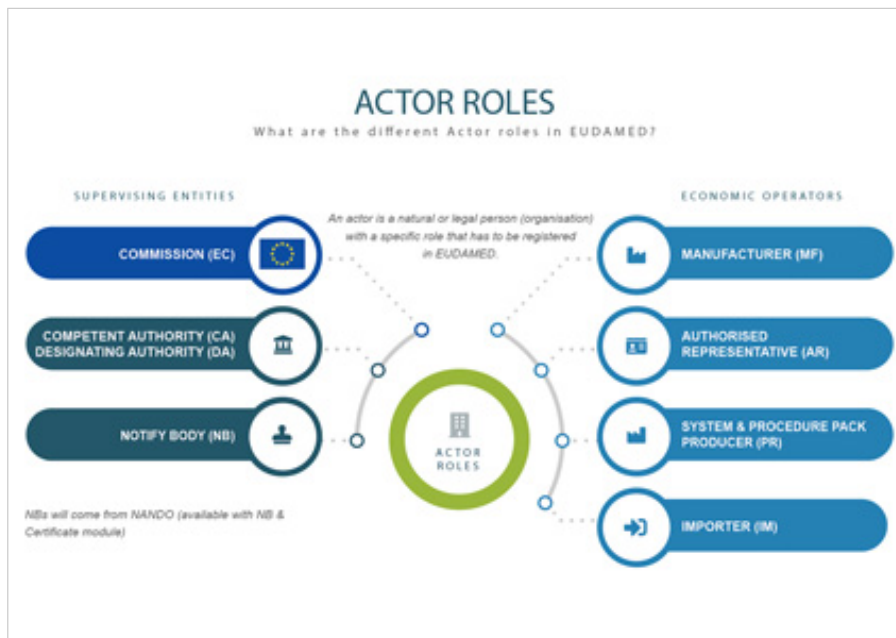
2. Confirm with the **Logout** button:



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

1.2.2 Actors and definitions

INFOGRAPHIC: Actor ID/SRN and Actor roles



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.

Sponsors

- Sponsors of clinical investigations/performance studies.

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 actors:

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

Each of these actors 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)

2 Managing actors and user accounts

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

There are two ways to gain access to EUDAMED:

Request registration for an economic operator

Register your Actor in EUDAMED with the appropriate actor role.

- The person who performs the Actor registration automatically becomes *Local Actor Administrator (LAA)* for that actor once the registration is validated.
- An Actor ID or Single Registration Number (SRN) is generated by EUDAMED and issued by the Competent Authority after validating the registrations request.

Request access as a user of a registered Economic Operator

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, 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.

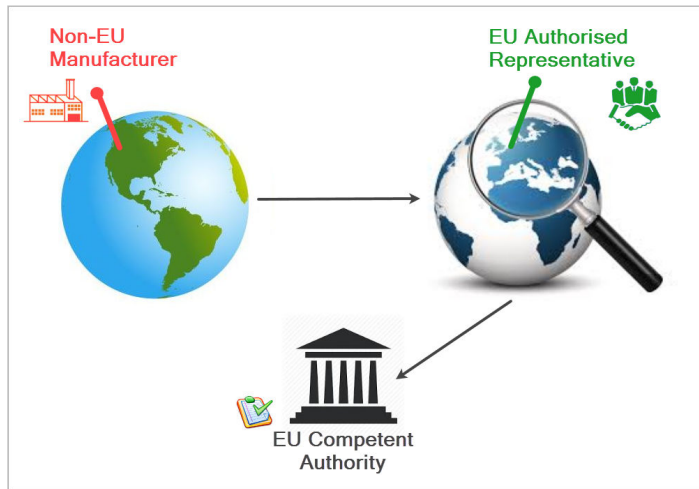
2.1 Managing actors

Economic Operator means one of the following:

- 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, your registration will be assessed by the **Competent Authority (CA)** of the country where you are established.

**** Non-EU manufacturers:** If you are not established in the EU, 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 difference in registration process between the two types of MFIs highlighted in the following pages.



NOTE

Multiple roles

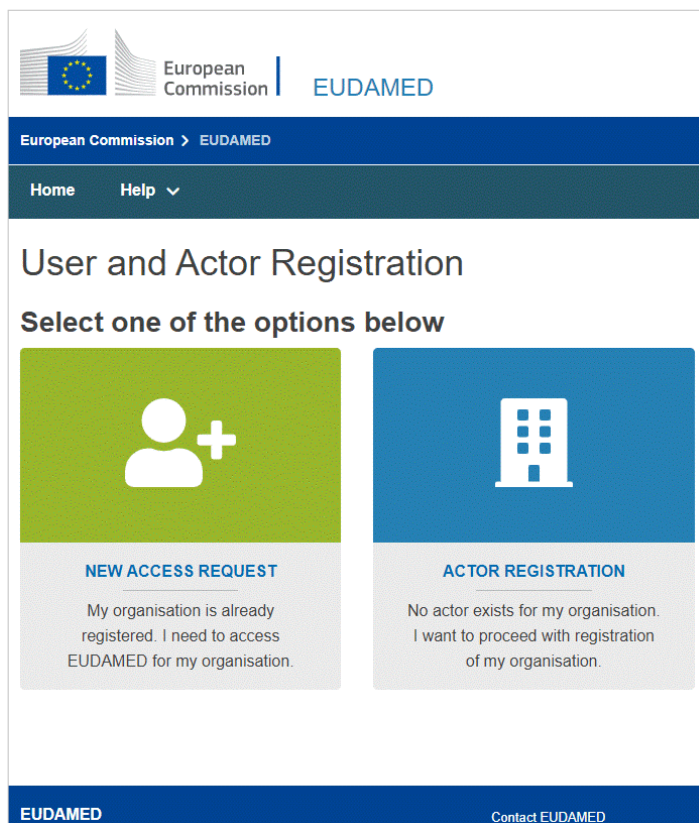
If your organisation has more than one Actor role (i.e. your organisation is a manufacturer and an importer at the same time), you must make separate actor registrations for each.

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:

Actor registration

Disclaimer



Submission

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



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.



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.



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

Next Cancel

- 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:

Manufacturer

* Country:

Ireland

* Actor / organisation name:

Sample MF

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 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. If you do decide to upload one, make sure the file is in PDF format and that it does not exceed 10MB.

- Enter the information for the mandatory fields, 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 identification 2 Actor address 3 Contact details 4 Regulatory Persons 5 Registering Local Actor Administrator 6 Competent Authority

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

Save registration **Save & Next >**



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

✓ Actor identification
✓ 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:

8. 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**.

Only for a non-EU manufacturer or Authorised Representative, you will be prompted by the Person Responsible for Regulatory Compliance, so that you can identify one or more regulatory person(s) within your Actor:

✓ 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 ☐ Street information is required unless you select the option - No

* Street:

Street number:

Address line 2:

PO box:

Latitude:

Latitude format example: -15.4543

Longitude:

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

Local Actor Administrator (LAA)

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

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 \[56\]](#)).

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).

- 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 xxx xxx

*** Company email 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:**



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.

- 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:

Competent Authority

* Select the competent authority which will validate this actor:

Any other information of significance for the competent authority

Additional Information:

12. 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**:

Competent Authority

Name: Agence Fédérale des Médicaments et des Produits de Santé/Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten
Address: EUROSTATION building block 2/place Victor Horta 40/ 40, B-1060 Brussels, Belgium
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 >

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

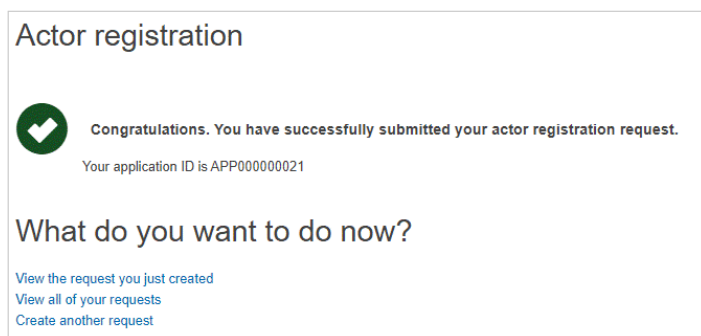
Submit your actor registration request

You now will have the possibility to evaluate user access requests and grant permissions to the relevant users so that they can initiate/submit/view the relevant information in EUDAMED

Are you sure you want to submit your request?

Confirm Cancel

14. Read the information and click **Submit**.
- 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:



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).

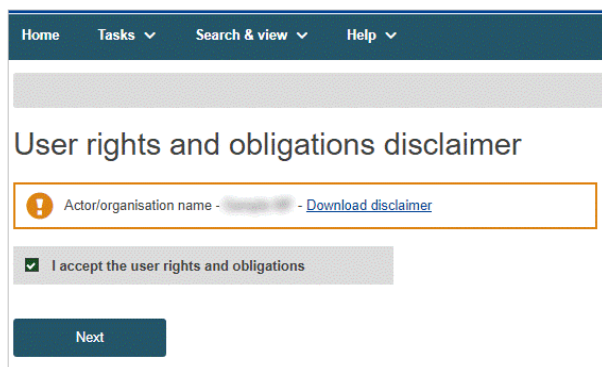
If you are a non-EU Manufacturer, the Authorised Representative indicated in your actor registration request will verify it prior to the national competent authority assessment.

A list of national contact points 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.

- 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:



- 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:

Actor notification email address

Actor Data:

* Email:

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:

My pending requests

You can view the status of your requests below

EU Login details

Name:

Username:

Email:

EUDAMED details

Name:

You do not have any pending access requests for the moment

My actor registration requests

Application ID	Role ID	Name ID	City ID	Date of request ID	State	Actions
APP000000041	Manufacturer	Registration	Belgium	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.

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:

* Select organisation language: All languages

Add organisation name in another language

Abbreviated organisation name:

Select abbreviated organisation name language:

Add abbreviated organisation name in another language

WKT information

Previous assessment(s)

Application ID:

Date of submission: 2020-08-19

2020-08-19

Reason for rejection: Duplicate

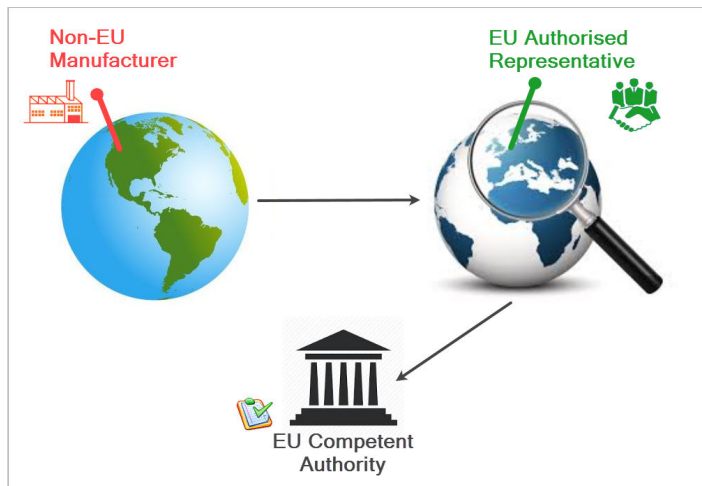
I think this is a duplicate

3. 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 \[11\]](#).

You must identify an Authorised Representative (AR) with whom you have a mandate. If you have multiple ARs, indicate which is the main representative by its Actor ID/Single Registration Number (SRN). Your AR must verify your registration details before the request is submitted to the competent authority for validation. To do this, the AR must be registered in EUDAMED.



To register a non-EU manufacturer

1. Log in to EUDAMED with your EU Login account.
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.

Notification

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

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.

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

Next Cancel

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

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

Save registration **Save & Next >**

**NOTE**

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

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 Medicaments et des Produits de Santé/Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten
 Address: EUROSTATION building block 2/place Victor Horta 40/ 40, B-1060 Brussels, Belgium
 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 >

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

Submit your actor registration request

Status of your request
 Your request has been saved and is ready to be submitted.

Outcome by email
 The outcome of the examination will be communicated to the email address provided. Meanwhile, you may view your data and the progress of the examination by visiting "See my pending requests" in your EUDAMED account.

Confirm Cancel

7. 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 access requests for an existing actor

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

My actor registration requests

Application ID	Role ID	Name ID	City ID	Date of request ID	State	Actions
APP000001	Manufacturer	Manufacturer	City	-	Draft	...
APP000001	Manufacturer	Manufacturer	City	2020-08-19	Verified	...
APP000001	Manufacturer	Manufacturer	City	2020-08-19	Correction Requested	...
APP000001	Manufacturer	Manufacturer	City	2020-08-19	Submitted	...

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.

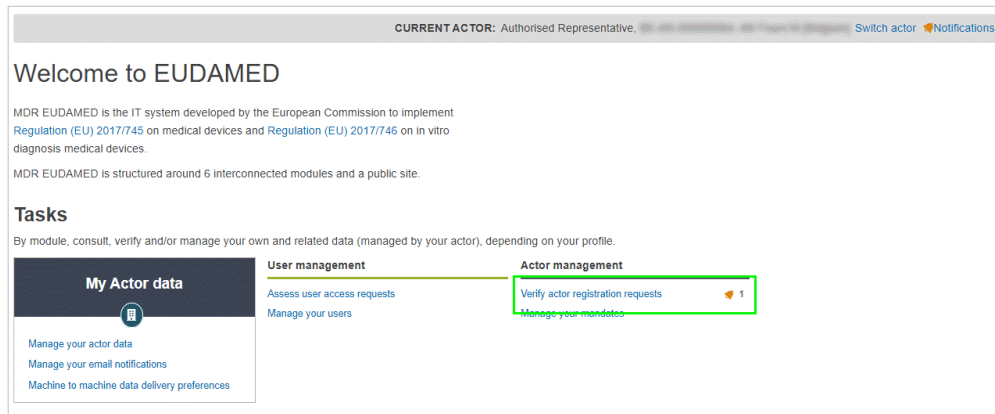
2.1.3 Verify non-EU manufacturer registrations

Specific to AR Verifier

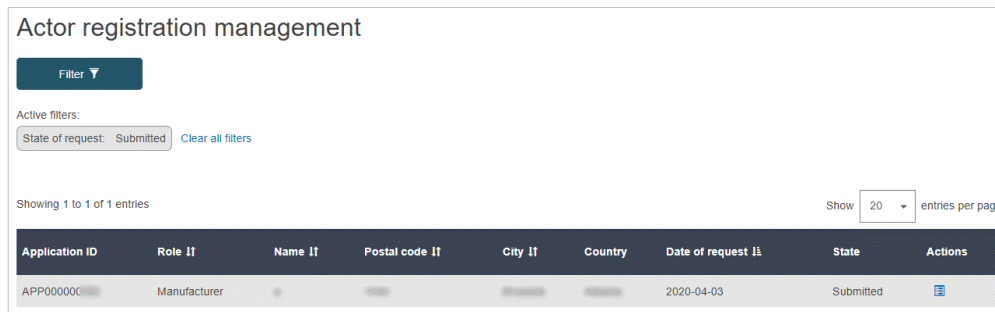
The Authorised Representative must verify the information provided by the non-EU manufacturer, as well as the summary mandate details.

To verify a non-EU manufacturer registration request

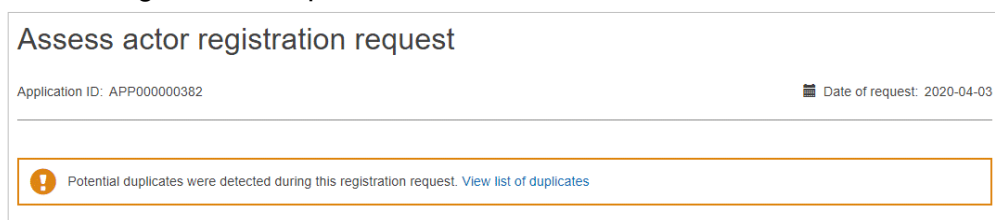
1. The AR must log in to EUDAMED with a Verifier, LAA or LUA profile (for the Authorised Representative). If there are pending registration requests from non-EU manufacturers, you will see the following link in your dashboard:



2. 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):



3. 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.
4. Review the information. A warning message will flag possible duplicates. Select the correct registration request from the list available:



5. In the *Assessment* section, slide the toggle left to **Approved** or right to **Not approved**.
If you **choose not to approve** the request, justify your decision with one of the following reasons:

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

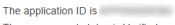
Incomplete or incorrect	Some information that you deem important is either missing or looks incorrect. The requesting user will have a chance to correct or complete the request following your instructions and re-submit the request.
Wrong Competent Authority and/or Authorised Representative	You are not the correct Authorised Representative for this request. The requesting user will have a chance to select another and re-submit.
Duplicate	Inform the requesting user that this actor already exists.
Request not applicable	The request will be rejected and cannot be re-submitted.
Fraud Suspected:	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

- 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](#)
[Actors](#)


[Actor module](#)
[Search for refused registration requests](#)


[UDI-DI module](#)
[UDI-DIs/Devices](#)

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 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 <i>IT</i>	Role <i>IT</i>	Name <i>IT</i>	Country <i>IT</i>	Date of registration <i>IT</i>
BE-MF-0000	Manufacturer	BE-MF-0000	Belgium	2020-05-27
BE-MF-0000	Manufacturer	BE-MF-0000	Belgium	2020-07-24
BE-MF-0000	Manufacturer	BE-MF-0000	Belgium	2020-06-22

- To view the details for any actor, click the entry in the results list.
- To search and download actors data:
 - 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.

Please see the data exchange guide for further information, available in the [Data exchange section](#).

**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

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:

Include historical version: Role: Manufacturer [Clear search](#)

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 ¹	Version number ¹	Role ¹	Name ¹	Country ¹	Date of registration ¹
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 sdxydu [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 20 entries per page

Actor ID/SRN	Version number	Role	Name	Country	Date of registration
	1 [Current]	Manufacturer		Belgium	2023-06-19
	1 [Current]	Manufacturer		Belgium	2023-06-15
	1 [Current]	Manufacturer		Belgium	2023-05-24
	1 [Current]	Manufacturer		Belgium	2023-05-12
	1 [History]	Manufacturer		Belgium	2023-05-05
	2 [Current]	Manufacturer		Belgium	2023-05-05
	1 [Current]	Manufacturer		Belgium	2023-05-04
	1 [Current]	Manufacturer		Belgium	2023-04-25
	1 [Current]	Manufacturer		Belgium	2023-04-21
	1 [Current]	Manufacturer		Belgium	2023-04-20
	1 [Current]	Manufacturer		Belgium	2023-04-19
	1 [Current]	Manufacturer		Belgium	2023-04-19
	1 [Current]	Manufacturer		Belgium	2023-04-14
	1 [Current]	Manufacturer		Belgium	2023-04-13
	1 [Current]	Manufacturer		Belgium	2023-04-12
	1 [Current]	Manufacturer		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:	
Actor ID/SRN:	
Country:	
Actor / Organisation name:	
Abbreviated name:	
VAT information:	
VAT number:	
EORI number:	
National trade register number:	
Last confirmation date of actor data accuracy:	-

3. A list of the different versions will display:

[◀ Go back to the current version](#)

Version 2 - Last update date: 2023-03-30

Version 1 - Last update date: 2023-03-30

4. 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:

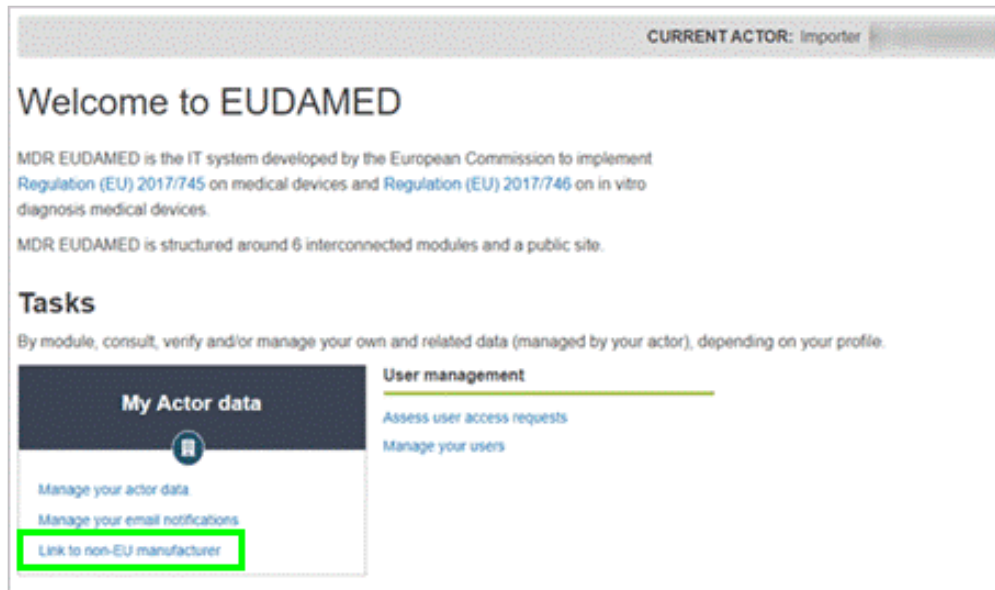
[≡ See all version history \(7\)](#) [◀ Previous version \[v5\]](#) | [Next version \[v7\] ▶](#)

2.1.5 Link a non-EU manufacturer to an importer

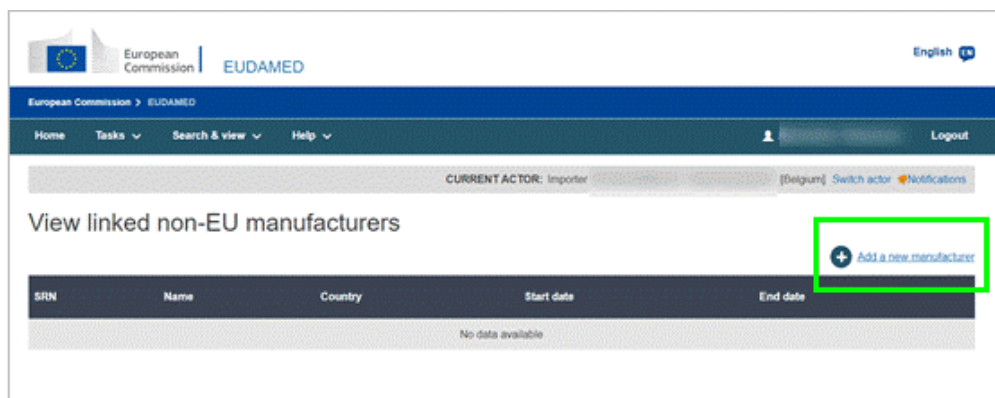
Section specific to importers with *Linker*, *LAA* or *LUA* profiles

To link a non-EU manufacturer to your importer:

1. Open the Dashboard:



- 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):



- Click *Add a new manufacturer*.
- 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

- 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

6. 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

View details	Afghanistan - Manufacturer - Actor code: AF-MF- XXXXXXXXXX	⬆
Remove from proposed linked names	Afghanistan - Manufacturer - Actor code: AF-MF- XXXXXXXXXX	⬆

7. 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

View details	Afghanistan - Manufacturer - Actor code: AF-MF- XXXXXXXXXX	⬆
Remove from proposed linked names	Afghanistan - Manufacturer - Actor code: AF-MF- XXXXXXXXXX	⬇

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

Role:
Manufacturer

Country:
Afghanistan

Organisation name:
[XXXXXXXXXX](#)

Address:
[XXXXXXXXXX](#)

Email:
[XXXXXXXXXX](#)

Telephone number:
-

Add link with this manufacturer

8. 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:  End date: 

YYYY-MM-DD YYYY-MM-DD

Confirm **Cancel**

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

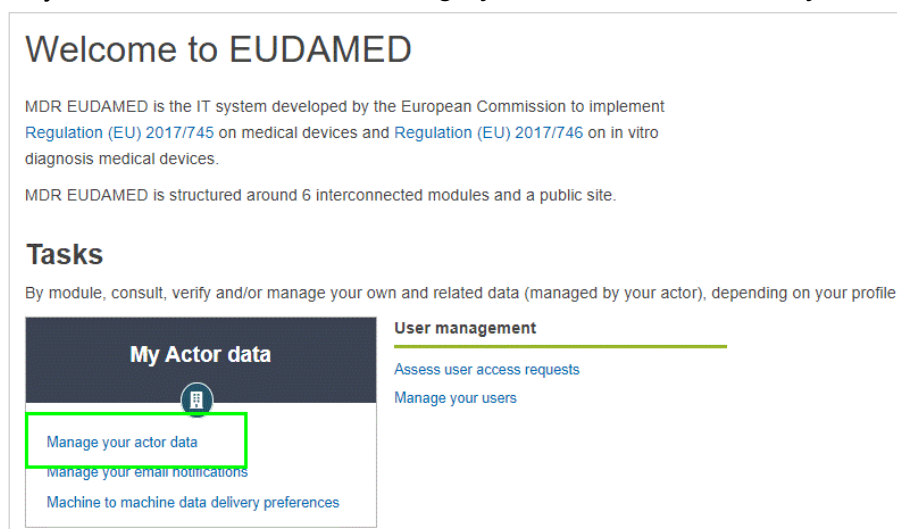
2.1.6 Updating Actor details

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.

To update actor details

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



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



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

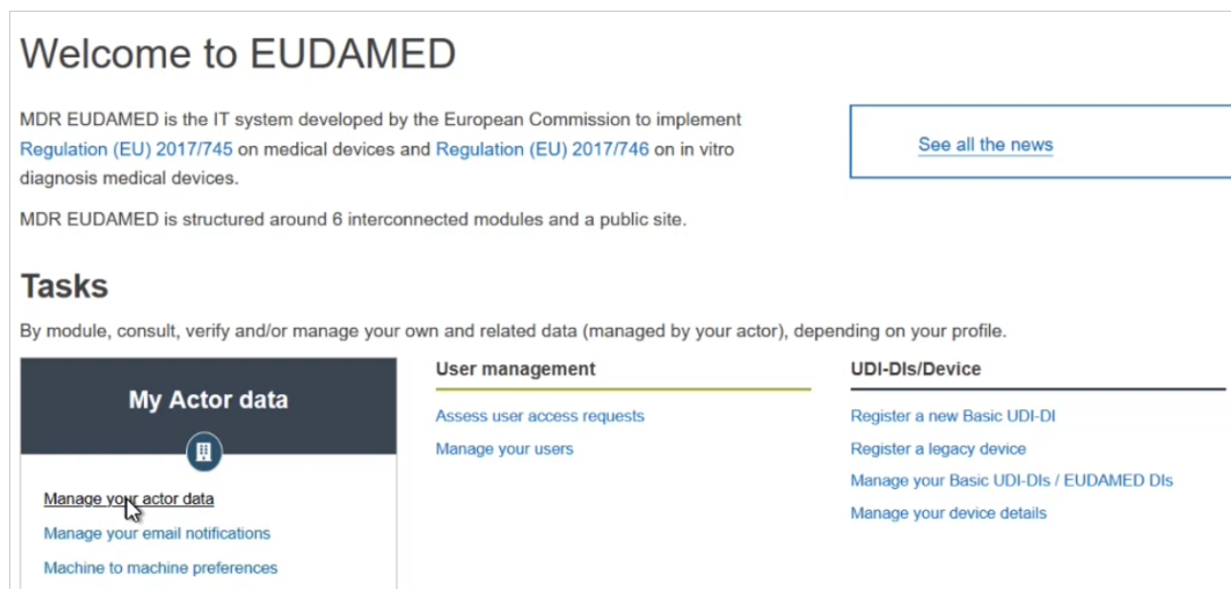
- a. Click on **Actions**.
- b. Click *Create new version* and answer **Yes** to the confirmation message.
- c. Make all required changes in the corresponding tabs.
- d. When you are done, click **Register new version** and answer the confirmation message.

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



Delete an actor's draft

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



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

Home Tasks Search & view Transmission News Help MF (CONFIRMER) Logout

CURRENT ACTOR: Manufacturer, NL-MF-000000041, Johnson & Johnson Medical [Netherlands] Notifications

Create new version of my actor data

Manufacturer, Johnson & Johnson Medical [Netherlands]

Version 2 [Draft]

Save Register new version Delete draft version

Actor identification

Role: Manufacturer

Country: Netherlands

* Actor / Organisation name: Johnson & Johnson Medical

* Select the language: All languages

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

Close

Confirm deletion of draft actor data

You are about to delete the draft version of your actor data. All data provided for this version will be lost.

Delete Cancel

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)

My Actor data

[Manage your actor data](#)

[Manage your email notifications](#)

User management

[Assess user access requests](#) 2

[Manage your users](#)

CI/PS

[Search and manage application/notification](#)

[Register CI/PS application or PMCF/PMPE notification](#)

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](#)

Actions

[Create new version](#)

[Set status to inactive](#)

[Confirm data accuracy](#)

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

Confirm data accuracy

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

[Close](#)

[Yes](#) [Cancel](#)

CURRENT ACTOR: Sponsor FI-SP-00000925 Sponsor organisation: F

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

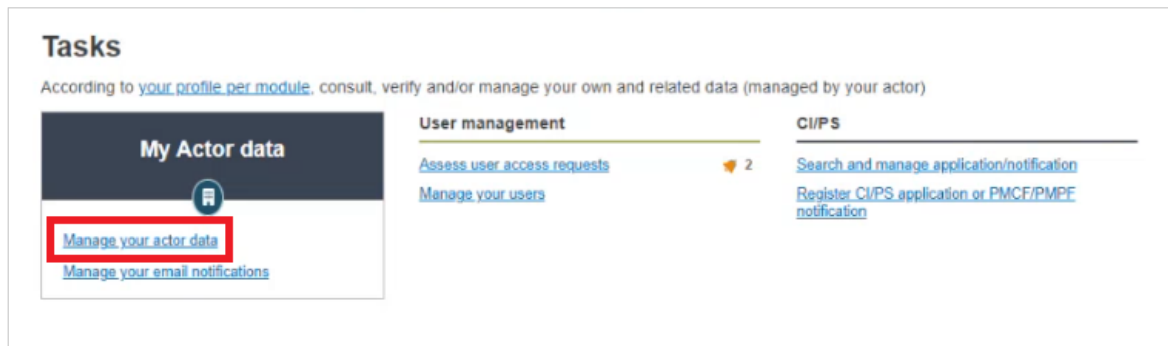
[View accuracy confirmation history](#)

5. You can also click on the drop-down list to display the rest of the preceding dates the Actor details were last accuracy confirmed:



Method 2: Create new version

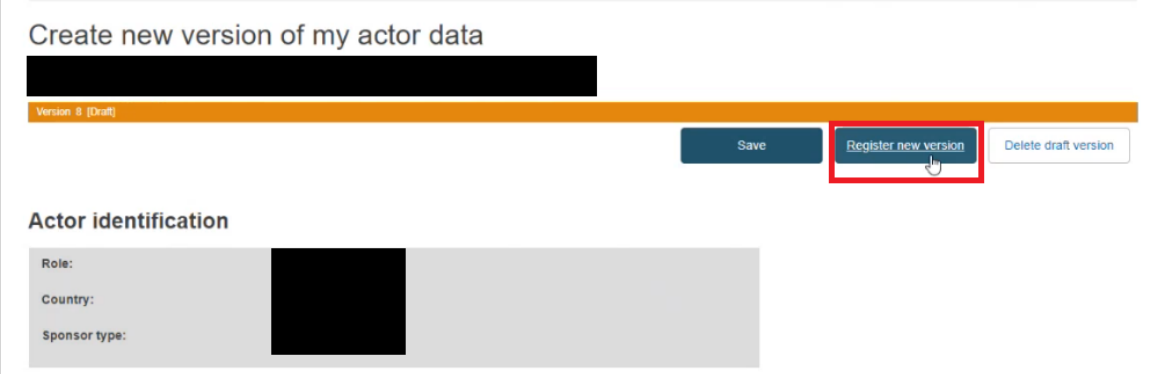
1. On the homepage of EUDAMED, click on *Manage your actor data*:



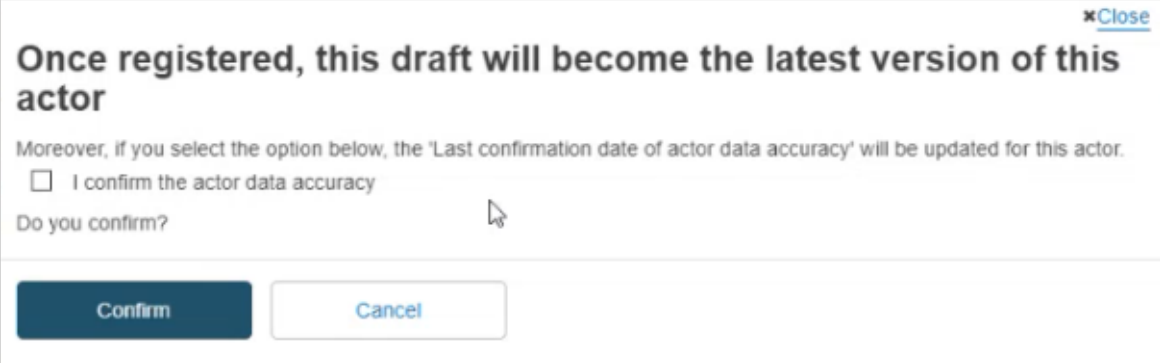
2. In the new window, click on **Actions** and then click on *Create new version*:



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



- 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**:



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

My Actor data

Version 8 [Current] | [See version history](#) | Last update date: 2023-06-20

Actions

Actor identification

Role:

Sponsor type:

Actor ID/SRN:

Country:

Actor / Organisation name:

Abbreviated name:

VAT information:

EORI number

National trade register number:

Organisation identification document:

Last confirmation date of actor data accuracy:

2023-06-20

View accuracy confirmation history

2023-06-20

2023-06-20

2023-06-16

2023-06-16

2023-06-14

2023-06-14

2023-06-14

**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/deactivate your Actor

This section is for LAA profile only

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*:

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 my mandates

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

**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**:

Manufacturer, BB-MF-000001065, ARMEN 2.7 BARBADOS MANUFACTURERS [Barbados]

My Actor data My Actor data Actions

Authorised Representative Version 10 [Current] Last update date: 2022-11-18 | n0005f4f

2. Click on *Set status to Inactive*:

Actions

Create new version

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.

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

Change actor status

Manufacturer, BB-MF-000001065, ARMEN 2.7 BARBADOS MANUFACTURERS [Barbados]

Change the status of your actor

Active ☒ Inactive

* From date:

YYYY-MM-DD

* Reason:

Register new status Cancel

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

* From date:



YYYY-MM-DD

* From date:



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:



YYYY-MM-DD

 The date should not be in the future

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

* Reason:

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

7. 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.



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.

2.1.9 Change a Competent Authority for registered actors

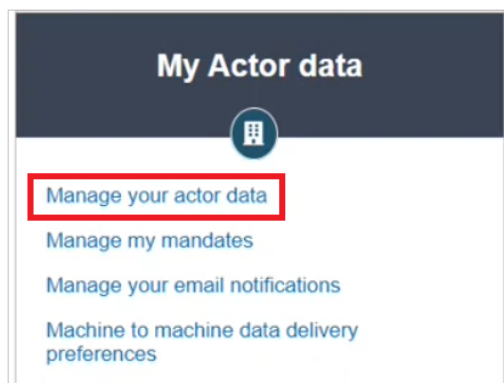
The change of responsible Competent Authority (CA) can be necessary in some specific cases as follows:

- 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;

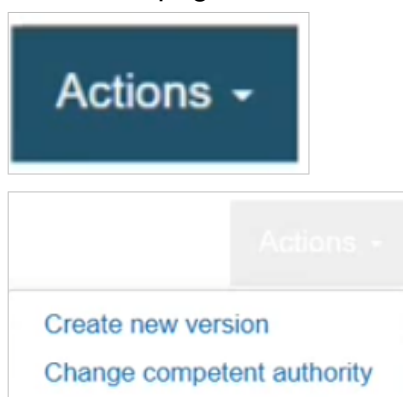
- A non-EU SPP producer that changes the market distribution of their SPPs.

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*:

3. 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:**

*** Select the language:**

[Add name in another language](#)

Abbreviated name:

Select the language:

[Add abbreviated name in another 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:

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
 Agentschap voor Geneesmiddelen en Gezondheidsproducten



NOTE

For non-EU manufacturers, the results in the dropdown list are determined by the responsible Competent Authorities of the Authorised Representative(s) they have an active mandate with.

- 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**:

Submit request Cancel

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

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?

Confirm Cancel

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:

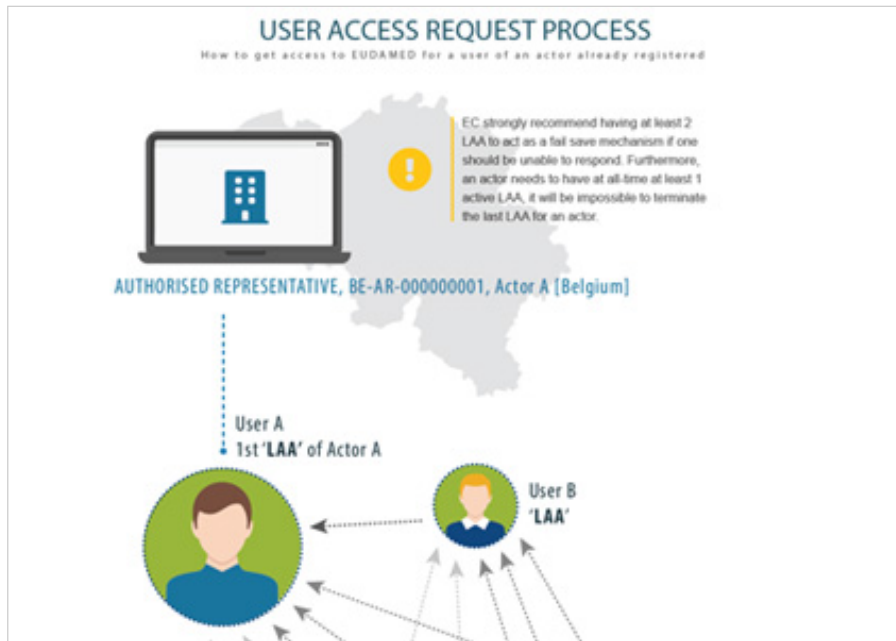
Reason for rejection and other details:

Application ID:	[REDACTED]
Assessment outcome:	Rejected
Assessor CA Actor ID:	[REDACTED]
Reason for rejection:	This request is rejected because
Date of rejection:	2023-03-31

2.2 Users and user access management

2.2.1 Request access as a user to a registered actor

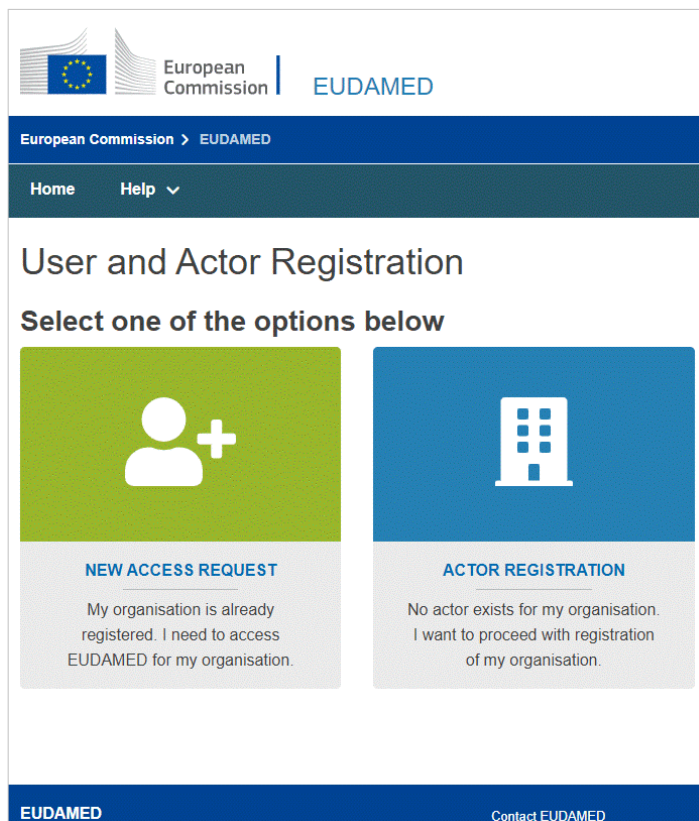
 **INFOGRAPHIC:** [User access request process](#)



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:



3. Alternatively, if you are logged in with a EUDAMED user account and you need to request access for 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:

The screenshot displays the EUDAMED user account detail page. At the top right, the user's name 'MedicalDev Thirtyeight' is highlighted with a green box. A green arrow points from this box to a 'New access request' button located at the bottom of the page, which is also highlighted with a green box. The page includes a navigation bar with 'Home', 'Tasks', 'Search & view', and 'Help'. Below the navigation bar, the current actor is identified as 'Manufacturer, /'. The main content area is titled 'My account(s)' and contains several sections: 'EU Login details', 'EUDAMED details', 'My EUDAMED accounts', 'Current actor account', 'Actor data', 'Actor identification', 'Actor notification email addresses', 'Account data', and 'Account email & notifications'. Each section contains various fields and links for managing the account and actor information.

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:

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:
BEL-000000001

Address:
Rue de la Loi 105

Email:
info@bel-000000001.be

Telephone number:
+32 2 123 45 67

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:

BE-MF-000000924

Find

Result

Select your actor from the list below

Manufacturer, BE-MF-000000924, 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 LAA/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.

- 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:

Role:

Manufacturer

Country:

Belgium

Organisation name:

Address:

Email:

Telephone number:

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

- Complete *Step 1*:
 - Enter your contact/notification email address related to this request.
 - 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.

9. 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:
S&P SRL - SPINA ITALIA

Address:
Via Buzzati, 41, Cadriano-Gerardo Delfante

Email:
contact@spina.it

Phone:
+390523638002

1

My personal
data

2

My user
manager

3

My profile(s)

User manager

* First Name:

* Last Name:

* Function/Position:

Save

Save & Next▶

Cancel

New access request

Information of the actor selected

SRN:
[redacted]

Role:
[redacted]

Country:
Belgium

Organisation name:
[redacted]

Address:
[redacted]

Email:
[redacted]

Phone number:
[redacted]

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 ⓘ

- ☐ Local Actor Administrator
- ☐ Local User Administrator
- ☐ Validator
- ☒ Viewer

Active until

End date: 

YYYY-MM-DD

Save

Submit ▶

Preview

Cancel



NOTE

The profiles available depend on the actor role.

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

**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 \[56\]](#)).

► **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	View access request

[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

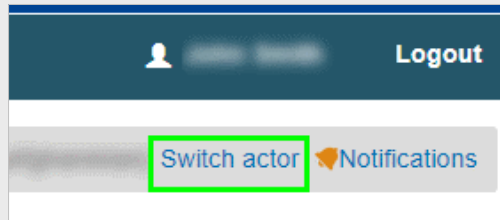

Actor/organisation name - [REDACTED] - [Download disclaimer](#)

☒ I accept the user rights and obligations

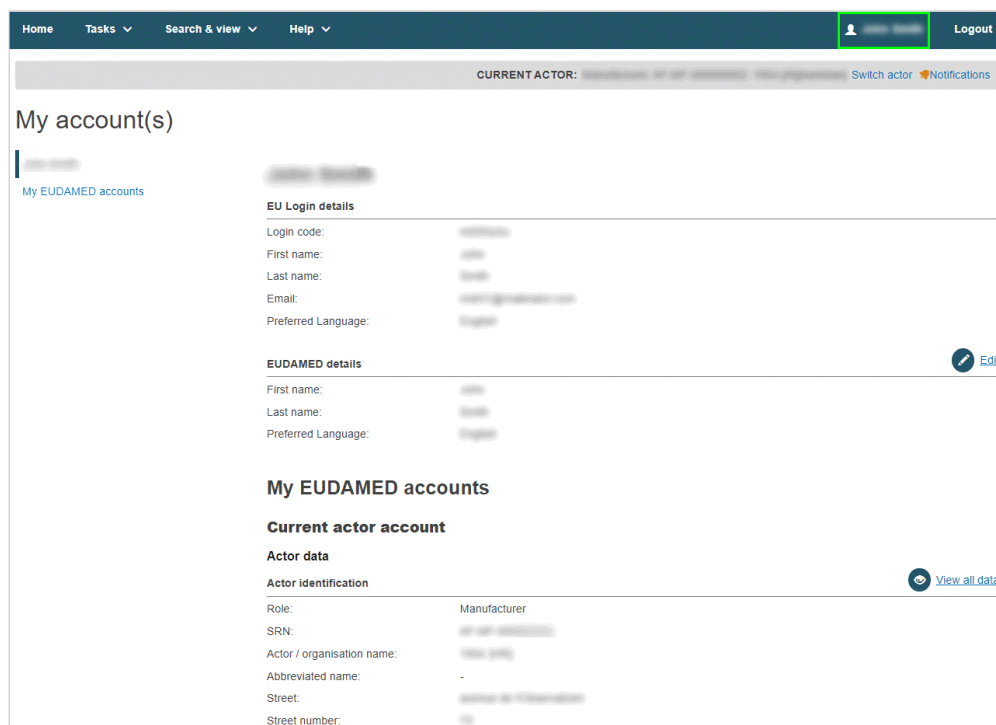
[Next](#)

**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:

**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

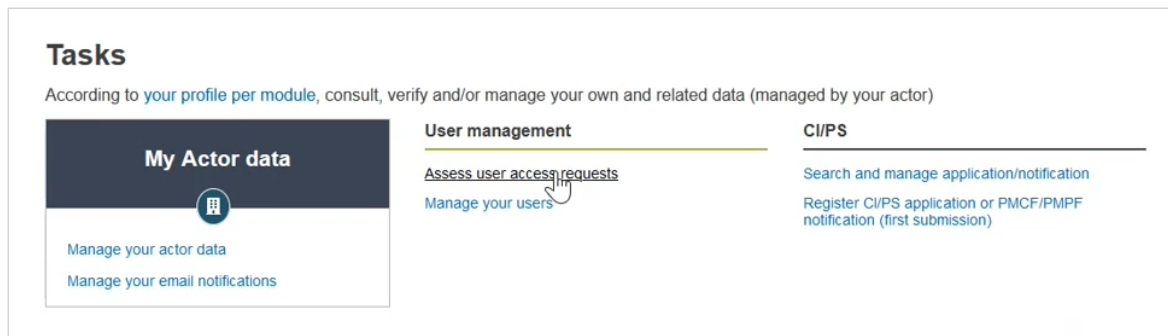
Section for Local Actor Administrators and Local User Administrators

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.

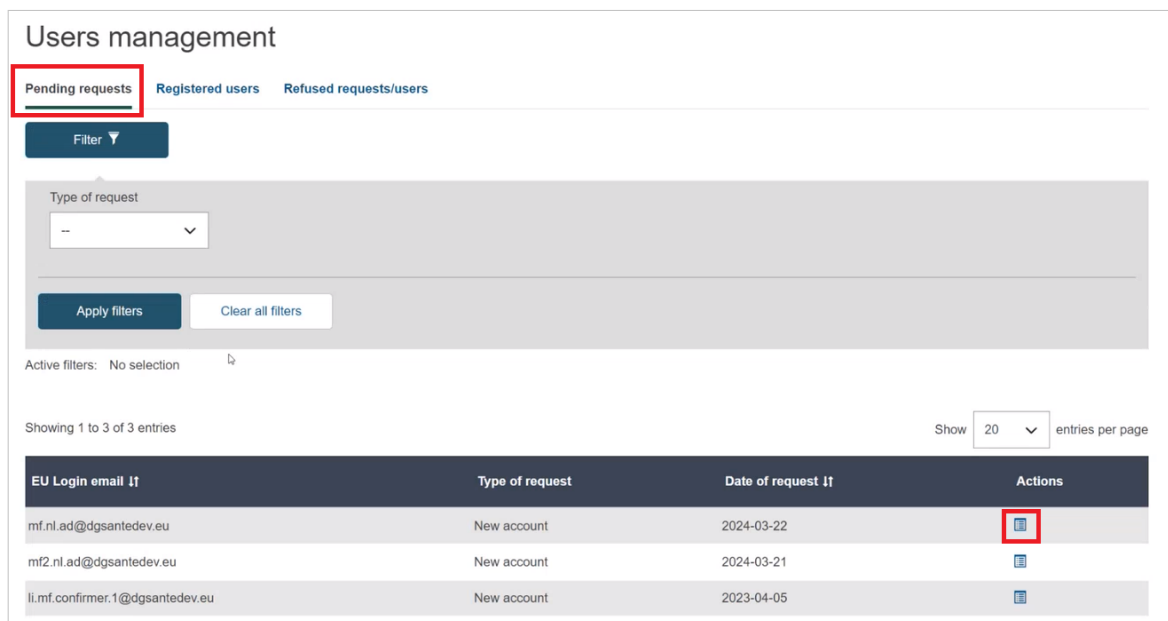
The Actor's LAAs and LUAs will be notified of all new or updated incoming users access requests.

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:**

Reject **Cancel**

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 20 entries per page

EU Login email ID	Type of request	Date of request ID
mf1.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

Next step **Cancel**

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](#)

C/IPS:	Confirmer	✓ Approve	✗ Reject
			

[Complete assessment](#) [Cancel](#)



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:

Pending requests Registered users

Filter

Active filters: No selection

Showing 1 to 2 of 2 entries

Show 20 entries per page

EU Login ID	EU Login email ID	Sub-contractor ID	End date ID
MedicalDev Two			

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

MedicalDev Two

< Go back to Users management

Open all | Close all

EU Login

Name: MedicalDev Two

Email:

Profiles

Actor: Local Actor Administrator

Actor: Mandate Manager

Actor: Viewer

UDI/Device: Viewer

Actor: Local User Administrator

Email

End date

Terminate Cancel

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:

The screenshot shows the EUDAMED user interface. At the top, there is a navigation bar with links for Home, Tasks, Search & view, and Help. On the right, there is a user profile icon and a Logout button. Below the navigation bar, a banner indicates the current actor: "CURRENT ACTOR: [Actor Name]".

The main content area is titled "My account(s)". It contains a section for "My EUDAMED accounts" which lists the user's accounts. The first account is "John Smith".

Under "John Smith", there are two main sections:

- EU Login details:** This section contains fields for Login code, First name, Last name, Email, and Preferred Language. An "Edit" button is located to the right of this section.
- EUDAMED details:** This section contains fields for First name, Last name, and Preferred Language. An "Edit" button is located to the right of this section.

Below these sections is a section titled "My EUDAMED accounts" which includes a subsection for the "Current actor account". This subsection contains "Actor data" and "Actor identification" details, including Role, SRN, Actor / organisation name, Abbreviated name, Street, and Street number. A "View all data" button is located to the right of this section.

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

This is a close-up screenshot of the "John Smith" account details. It shows the "EU Login details" and "EUDAMED details" sections. The "Edit" button in the "EUDAMED details" section is highlighted with a green box.

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)

My other account(s)	
Authorised Representative, IT-00 000000001, Regname=... [Italy]	>
Importer, IT-00 000000001, Esportatore=... [Italy]	>

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.

Account data

Profile(s)

Actor: Administrator

UDI/Device: Viewer

Request for change

Account email & notifications

My contact email for this actor: [REDACTED]

Actor Data: [REDACTED]

Modify

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.

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

- ☒ Local Actor Administrator
- ☐ Local User Administrator
- ☐ Viewer

UDI/Device

- ☒ Confirmer
- ☐ Proposer
- ☐ Viewer

NB & Certificates

- ☒ Viewer

Vigilance

- ☐ Confirmer
- ☐ Proposer
- ☐ Viewer(Fat)
- ☐ Viewer(Slim)

Active until

End date:





YYYY-MM-DD

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

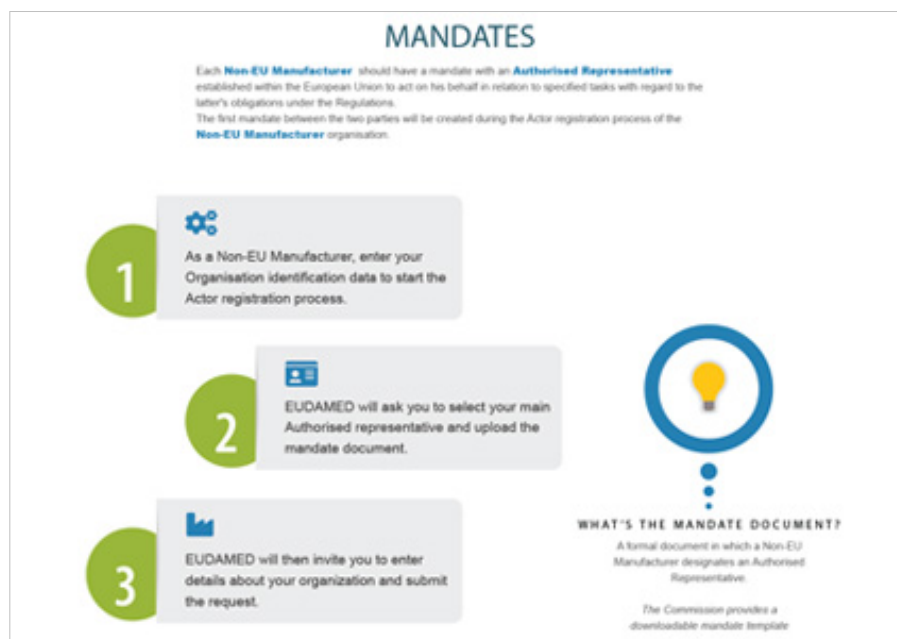
Specific to non-EU manufacturers and authorised representatives

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 (placeholder))

Showing 1 to 6 of 6 entries

Show 20 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:

View my mandates

Manufacturer, *MD-AF-000000, 1234 (placeholder)*

Showing 1 to 7 of 7 entries

Show 20 entries per page

Mandate ID <i>IT</i>	AR name <i>IT</i>	AR SRN <i>IT</i>	End date <i>IT</i>	State <i>IT</i>
MD-AF-BE-00000	AR-00000	BE-AR-00000	-	Registered
MD-AF-BE-00000	AR-00000	BE-AR-00000	-	Submitted

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:

BE-AR-000001064
Actor ID/SRN: BE-AR-000001064 Role: Authorised Representative Country: Belgium Actor / Organisation name: ARMEN 2.7 EU AR ONE Address: 1231 Brux Email: ArmenFortyNine_eudamed@mailinator.com Telephone number: - Mandate validity dates From 2022-03-29 to -

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:

Welcome to EUDAMED

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

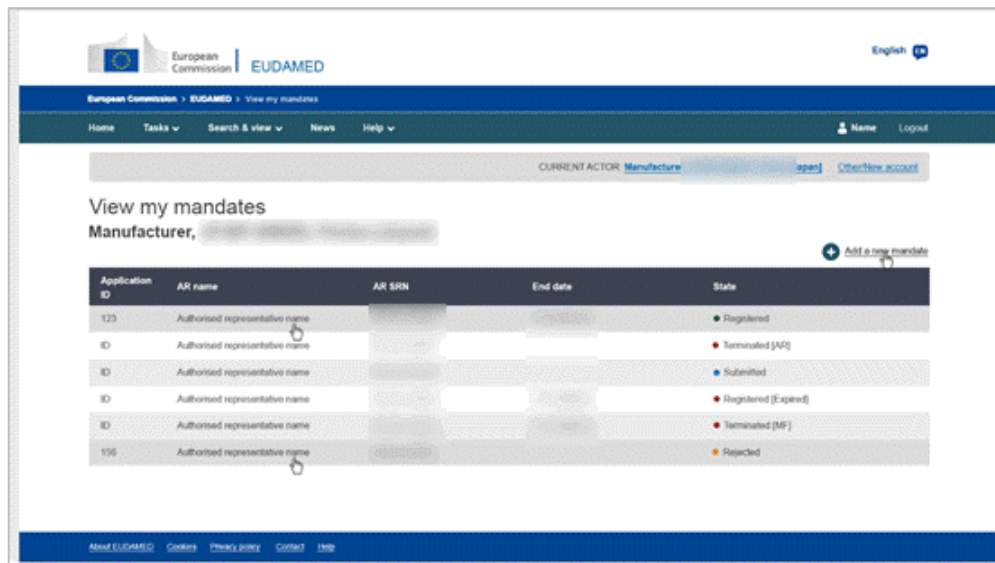
MDR EUDAMED is structured around 6 interconnected modules and a public site.

Tasks

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

My Actor data	User management
Manage your actor data Manage my mandates  Manage your email notifications	Assess user access requests Manage your users

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:

Mandate with [redacted]

[< Go back to list of mandates](#)

Version 1 [Registered] | 2020-08-17 | [redacted]

Manufacturer identification

Organisation name: [redacted]
 SRN: [redacted]
 Address: [redacted]
 Telephone number: -
 Email: [redacted]

Authorised representative information

Organisation name: [redacted]
 SRN: [redacted]
 Address: [redacted]
 Telephone number: -
 Email: [redacted]

Mandate validity dates

From: 2020-07-29
 To: 2020-08-26

Mandate summary document

[redacted] pdf

Create New Version [Terminate mandate](#)

[< Go back to list of mandates](#)

4. 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

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

Welcome to EUDAMED

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

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

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
- 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:

Mandate management

Pending mandates Registered mandates

Filter

Active filters: Status: Submitted Clear all filters

Showing 1 to 3 of 3 entries

Show 20 entries per page

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

2. 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:

[Apply](#) [Cancel](#)

[< Go back to list of mandates](#)

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.

Welcome to EUDAMED

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

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

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
- Manage your mandates** 🔔 3

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

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

CURRENT ACTOR: Authorised Representative, IT-AR-123456789, Registered in [Italy] [Switch actor](#) [Notifications](#)

Mandate Management

[Pending mandates](#) [Registered mandates](#)

[Filter](#)

Active filters: No selection

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

Mandate ID ↑↓	MF name ↑↓	MF SRN ↑↓	Country ↑↓	Start date ↑↓	End date ↑↓
MD-CHT-0123456789	Zurich	CH-0123456789	Côte d'Ivoire	2019-07-01	-

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

Mandate with [redacted]

[< Go back to list of mandates](#)

Version 1 [Registered] | 2020-08-17 | [redacted]

Manufacturer identification

Organisation name: [redacted]
 SRN: [redacted]
 Address: [redacted]
 Telephone number: -
 Email: [redacted]

Authorised representative information

Organisation name: [redacted]
 SRN: [redacted]
 Address: [redacted]
 Telephone number: -
 Email: [redacted]

Mandate validity dates

From: 2020-07-29
 To: 2020-08-26

Mandate summary document

[redacted].pdf

[Create New Version](#) [Terminate mandate](#)

- Click **Terminate mandate** at the bottom of the page.
- Use the calendar icon to select the termination date.
- Click **Confirm**.

If you are a non-EU manufacturer

To terminate a mandate

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

View my mandates

Manufacturer, AF-MF-[redacted] [+ Add a new mandate](#)

Showing 1 to 7 of 7 entries Show 20 entries per page

Mandate ID	AR name	AR SRN	End date	State
MD-AF-BE-00000	[redacted]	BE-AR-0000	2020-06-08	Registered (Expired)
MD-AF-BE-00000	[redacted]	BE-AR-0000	2030-04-04	Terminated [MF]
MD-AF-BE-00000	[redacted]	BE-AR-0000	-	Registered

- 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.
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 [Redacted]
[Barbados]

My Actor data

Authorised Representative

Competent Authority

Notification email

Linked importers

My Actor data

Version 2 [Current] | Last update date: 2022-09-16 | n000547

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

