



EUDAMED user guide

Economic Operators – Actor module

Production v 2.12
September 2023



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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 2017/745](#) on medical devices

[Regulation 2017/746](#) on *in vitro* diagnosis devices

EUDAMED is structured around **six interconnected modules** and a **public site**:

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

1.2 Application basics

This section describes a number of basic principles that you will acquire very quickly as you become familiar with EUDAMED. These include:

- Starting and ending a EUDAMED session
- Understanding the basic concepts

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

- Understanding user profiles and access grants/rights

1.2.1 Starting and ending a EUDAMED session

To use EUDAMED, you must have an **EU Login account** – linked to your **work email** address – private/shared mailboxes are not allowed for security reasons.



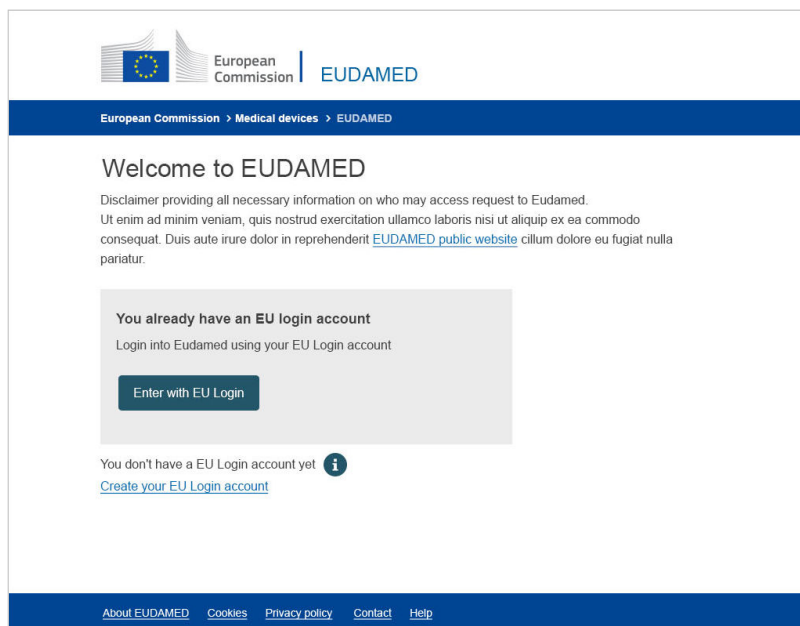
NOTE

Playground environment

EUDAMED is also available in a [Playground environment](#), intended to enable you to experiment with the application. All the information in this environment is dummy (including the Actor ID/SRN) and will never be moved to the production environment. Access to the Playground requires a separate registration.

To start EUDAMED:

1. Go to the [EUDAMED](#) Welcome page.



2. Click **Enter with EU Login**. (OR select **Create your EU Login account** if you do not have one yet). The first part of *EU Login – Sign-in* page prompts you to enter your email address:

This website uses cookies. Learn more about the [European Commission's cookie policy](#). Close this message

EU Login
One account, many EU services

Where is ECAS? English (en)

webgate.acceptance.ec.europa.eu requires you to authenticate

Sign in to continue

Use your e-mail address

Next

[Create an account](#)

Or

Or use the eID of your country

[Select your country](#)

Easy, fast and secure: download the EU Login app

About EU Login Cookies Privacy Statement Contact Help

European Union EU institutions 7.4.3-dn2p | 17 ms

Powered by European Commission

- Enter your (work) email address or username and click **Next**. The second part of the *EU Login – Sign-in* page prompts you to enter your password:

Sign in to continue

Welcome back

[Redacted Name]
(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

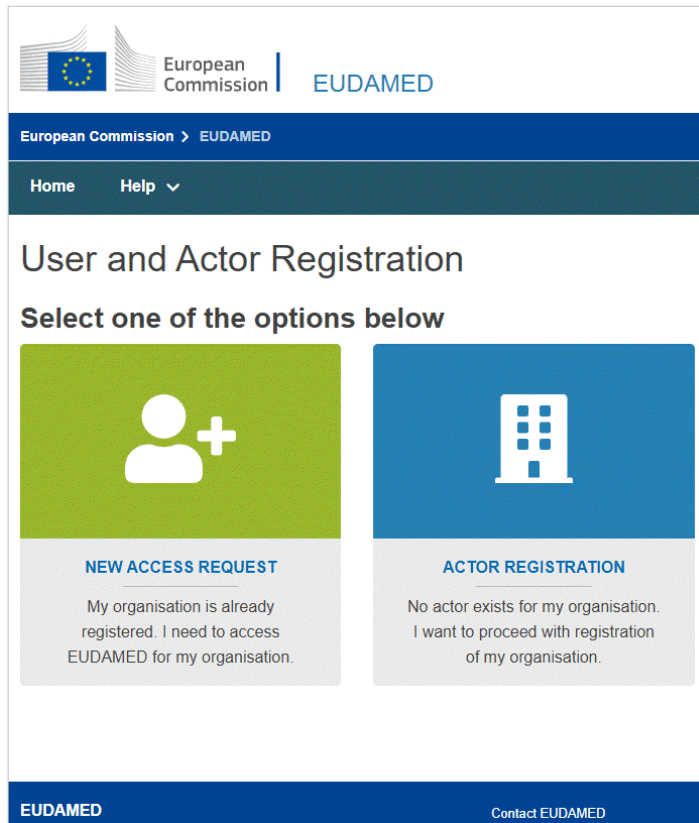
Password
Authenticate to EU Login with only your password.

Sign in

► Change your password: Go to [Change password](#)

► View/edit your account: Go to [My Account](#)

4. 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:



NOTE

Next steps:

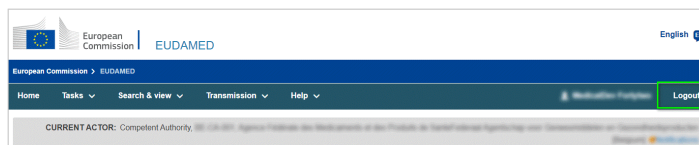
► Want to register your organisation as an actor in EUDAMED? See [Registering as an Economic Operator \[10\]](#)

► Need access as a user for a registered economic operator? See [Requesting access as a user for a registered Economic Operator \[50\]](#)

Logging out of EUDAMED:

At any time, you can **Logout** by clicking the **Logout** button in the top right corner of the screen. There is a two-step logout process, the latter being the confirmation step!

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



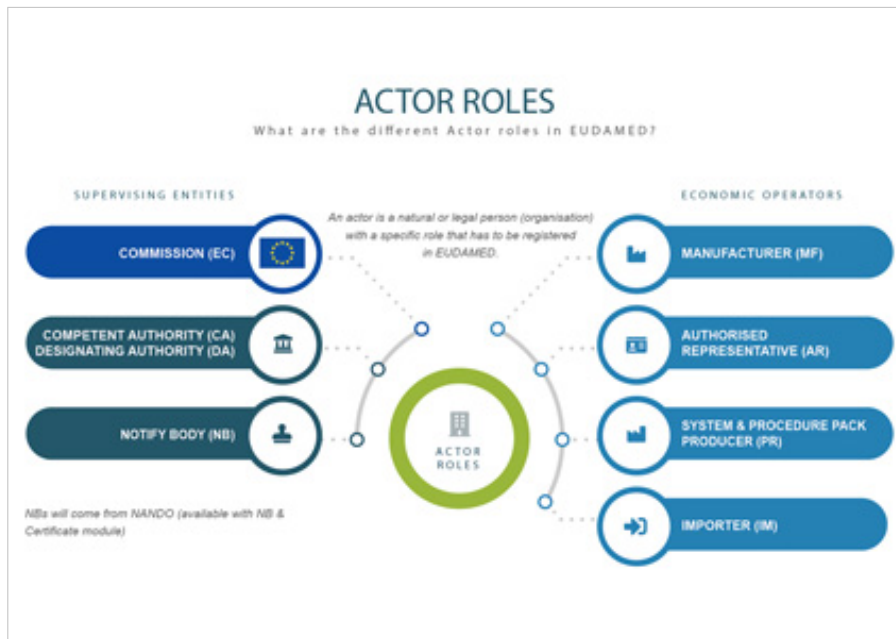
2. After you confirm the **Logout** from EUDAMED, you will be prompted with a *Log me out* confirmation page from the EU Login domain.

**IMPORTANT**

Private/shared mailboxes are not allowed, for security reasons. Read more here: [Introduction to EU Login – help](#).

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), including Designating Authorities (DA)
- Notified Bodies (NB)

Economic operators

- Manufacturers - see Article 2(30) or Article 2(30) of [Regulation 2017/745](#)
- System and procedure pack producers – any individual or organisation who places procedure packs and/or systems on the EU market
- Authorised Representatives – see Article 2(32) of [Regulation 2017/745](#)
- Importers – see Article 2(33) of [Regulation 2017/745](#)

Sponsors

- see Article 2(49) of [Regulation 2017/745](#)

Definitions

- Medical device – see Article 2(1) of [Regulation 2017/745](#)
- *In vitro* diagnostic medical device – see Article 2(2) of [Regulation 2017/746](#)
- Person responsible for regulatory compliance – see Article 15(1) and (3) of [Regulation 2017/745](#)
- Single Registration Number (SRN) – see Article 31(2) of [Regulation 2017/745](#)

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 (see table). For example, in 'Actors module', the *Verifier* profile is only enabled for 'Authorised Representative' actors. The *Linker* profile is a specific profile which is enabled only for 'Importer' actors, which allows them to create links with non-EU manufacturers in this module.

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 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	Viewer	Viewer	Viewer

2 Managing actors and user accounts

The **Actors** module ensures that all actors using EUDAMED, including **Economic Operators** (EO), 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.

It is good practice having at least two LAAs, 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.

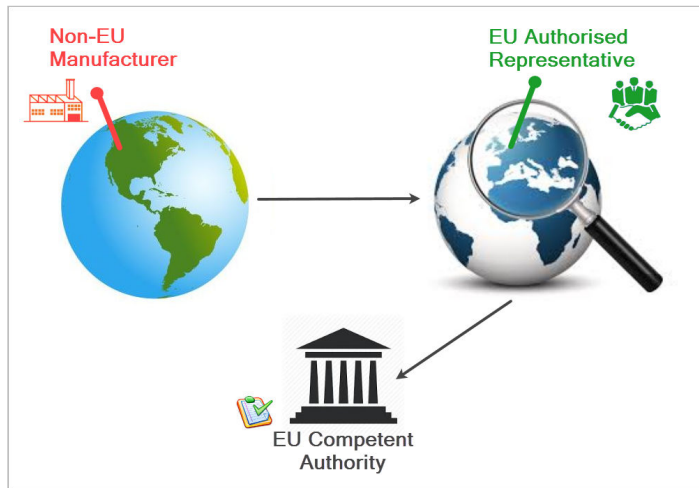
2.1 Managing actors

Economic Operator means one of the following:

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

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

** **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 your AR.



The difference in registration process between the two types of MF will be highlighted in the following pages.

Anyone with an EU Login account can register actor details in EUDAMED (if the actor is not already registered). Once completed, the registration form can be submitted directly for validation or saved as a draft.

By default, this user will become the **Local Actor Administrator** once the registration is validated.



NOTE

Multiple roles

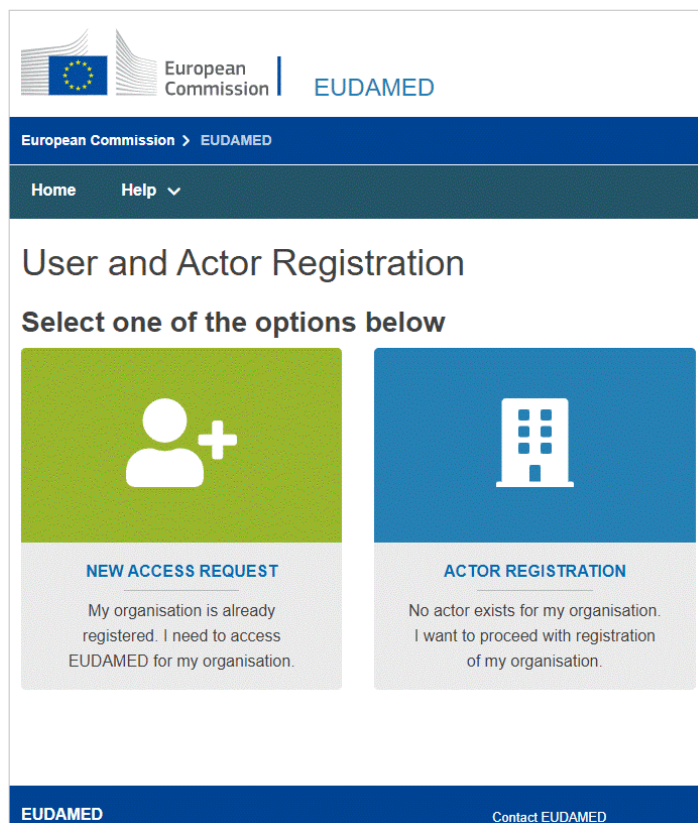
If your organisation has more than one role (i.e. your organisation is a manufacturer and an importer at the same time), you must make separate actor registrations for each.

2.1.1 Registering 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 only and that it does not surpass 3MB in size.

6. Enter the mandatory information 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 surpassing 3MB in size. Click **Save & Next**.

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

1 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

After entering all the required *Authorised Representative* data, in the case of a *non-EU manufacturer*, you also will be prompted by an *Actor address* details screen.

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:

Longitude:

Latitude format example: -15.4543

Longitude format example: 178.34354353

* City name:

* Postal code:

* Country:

+ Add a new Regulatory Person

Save registration

Save & Next >

**NOTE****Regulatory person contact**

The person in your actor who is responsible for ensuring regulatory compliance. See [Article 15 of Regulation 2017/745](#).

- 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 \[58\]](#)).

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 surpassing 3MB in size – using the **Browse** button.

*** 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 ☐ 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:**

Save registration **Save & Next >**



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, providing Competent Authority details. You can add any extra information you think might be relevant:

Competent Authority

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

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

Save registration **Preview** **Submit actor registration >**

- If there is a choice between multiple Competent Authorities, select the most appropriate one from the list. (A help file will be available for Actors established

in Germany, to assist with the Competent Authority selection). If there is only one authority that can validate your registration, details will be pre-populated. To view a summary of your completed registration form, click **Preview**:

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

Competent Authority

Name: Agence Fédérale des Médicaments et des Produits de Santé/Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten
Address: EUROSTATION building block 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 >

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

✕Close

Submit your actor registration request

! You 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

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

Actor registration

✓ Congratulations. You have successfully submitted your actor registration request.
 Your application ID is APP000000021

What do you want to do now?

[View the request you just created](#)
[View all of your requests](#)
[Create another request](#)

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

**NOTE**

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

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. Therefore, you may wish to contact your relevant Authorised Representative or National Competent Authority.

A list of national contact points can be found on the EUDAMED website: <https://ec.europa.eu/tools/eudamed/#/screen/competent-authorities>

If your registration is approved

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

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

2. 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:

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: [Registration Requirements](#)

Username: [username](#)

Email: [email@eudamed.eu](#)

EUDAMED details

Name: [Name](#)

You do not have any pending access requests for the moment

[New access request](#)

My actor registration requests

Application ID	Role ID	Name ID	City ID	Date of request ID	State	Actions
APP000000041	Manufacturer	Request ID	City	2020-08-19	Correction Requested	...

[New actor registration request](#)

- 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.

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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](#)

WET information

Previous assessment(s)

Application ID: [application ID](#) Date of submission: 2020-08-19

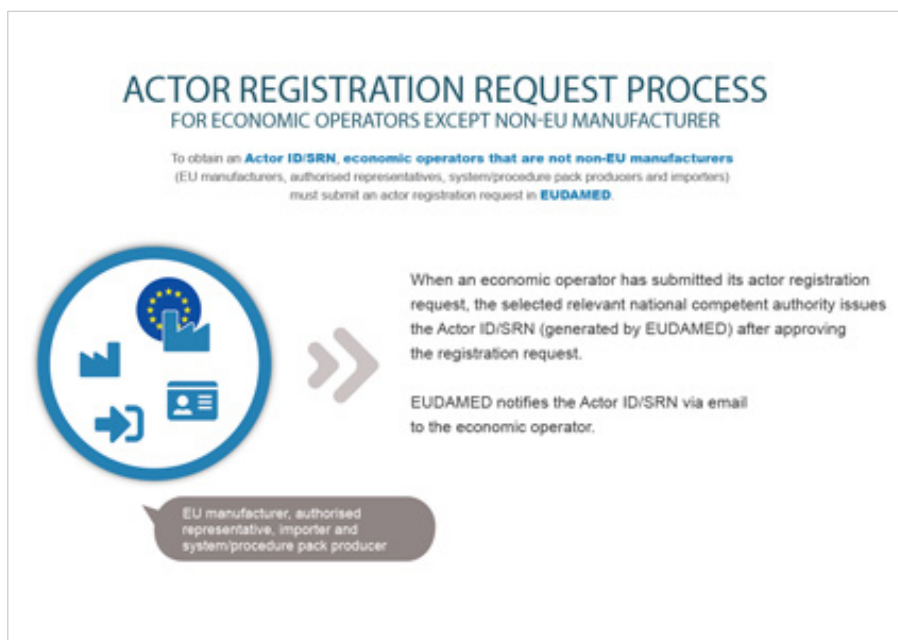
2020-08-19 [View](#)

Reason for rejection Duplicate
I think this is a duplicate

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

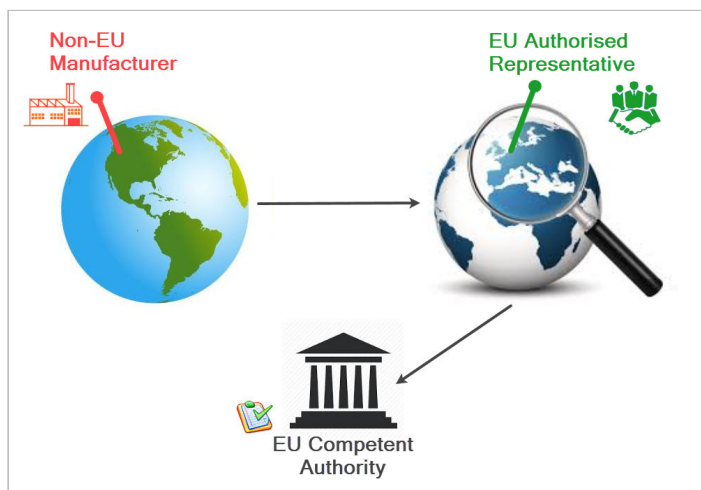
2.1.2 Registering as a non-EU manufacturer

 **INFOGRAPHIC:** [Actor registration request process](#)



If you are a non-EU manufacturer, the procedure for registering differs from that explained in [Registering as an Economic Operator \[10\]](#).

You must identify the 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 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 3MB 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 surpassing 3MB in size** – using the **Browse** button. Click **Save & Next**.

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

Competent Authority

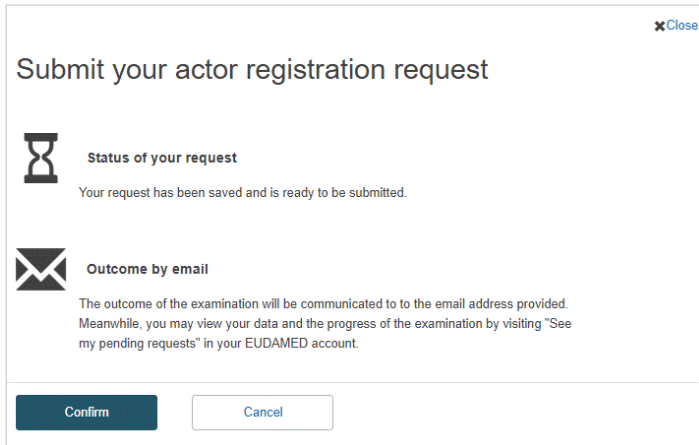
Name: Agence Fédérale des Médicaments et des Produits de Santé/Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten
Address: EUROSTATION building block 2/place Victor Horta 40/ 40, B-1060 Brussels, Belgium
Country: Belgium
Email: meddev@fagg-afmps.be
Telephone number: 00 32 2 528 40 00

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.

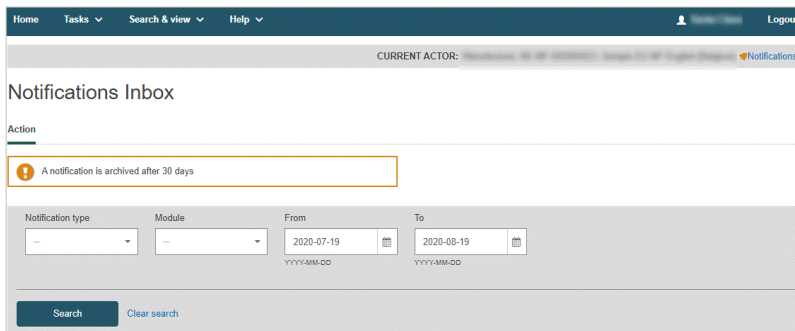
6. Review the information on the form, and then click **Submit actor registration** at the bottom of the page. A confirmation window will appear:



A confirmation window titled "Submit your actor registration request" with a close button (X Close) in the top right corner. The window contains two sections: "Status of your request" with an hourglass icon and the text "Your request has been saved and is ready to be submitted." and "Outcome by email" with an envelope icon and the text "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." At the bottom, there are two buttons: "Confirm" (dark blue) and "Cancel" (light blue).

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.



A screenshot of the "Notifications Inbox" interface. The top navigation bar includes "Home", "Tasks", "Search & view", "Help", and a user profile with "Logout". Below the navigation bar, it says "CURRENT ACTOR: [Name]". The main section is titled "Notifications Inbox" and has an "Action" tab. A message box states "A notification is archived after 30 days". Below this is a search filter section with "Notification type" and "Module" dropdowns, and "From" and "To" date pickers. The date range is set from "2020-07-19" to "2020-08-19". At the bottom, there are "Search" and "Clear search" buttons.

What next?

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

My pending requests

You can view the status of your requests below

EU Login details

Name: [redacted]

Username: [redacted]

Email: [redacted]

EUDAMED details

Name: [redacted]

My access requests for an existing actor

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

[New access request](#)

My actor registration requests

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

[New actor registration request](#)

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

2.1.3 Verifying non-EU manufacturer registrations

[Specific to AR Verifier]

Although the national competent authorities are responsible for validating a non-EU manufacturer's registration request, an additional preliminary step is required from the Authorised Representative: they must verify the information provided by the manufacturer, as well as the summary mandate details.

To verify a non-EU manufacturer registration request

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

CURRENT ACTOR: Authorised Representative. [Switch actor](#) [Notifications](#)

Welcome to EUDAMED

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

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

Tasks

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

My Actor data

Manage your actor data

Manage your email notifications

Machine to machine data delivery preferences

User management

Assess user access requests

Manage your users

Actor management

Verify actor registration requests 1

Manage your mandates

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

Actor registration management

Filter ▼

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

Showing 1 to 1 of 1 entries

Show 20 entries per page

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

- Click **Assess** in the *Actions* column to review and assess the desired registration request in the list. All details of the selected registration request, as submitted by the non-EU manufacturer, are displayed.
- Review the information. A warning message will flag possible duplicates, so select the correct registration request from the list available:

Assess actor registration request

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

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

- In the *Assessment* section, slide the toggle left to **Approved** or right to **Not approved**.
If you **choose to approve** the request, you may enter additional notes.
If you **choose not to approve** the request, you will be prompted to the **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 its Competent Authority and an Actor ID/SRN is issued, its details (except those only for the Competent Authority) 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**. The actor *Search & view* page appears:

Search & view

Actors

Enable search filters available for bulk XML download ☐

Name

Actor ID/SRN

VAT number

Role × ▼

Country × ▼

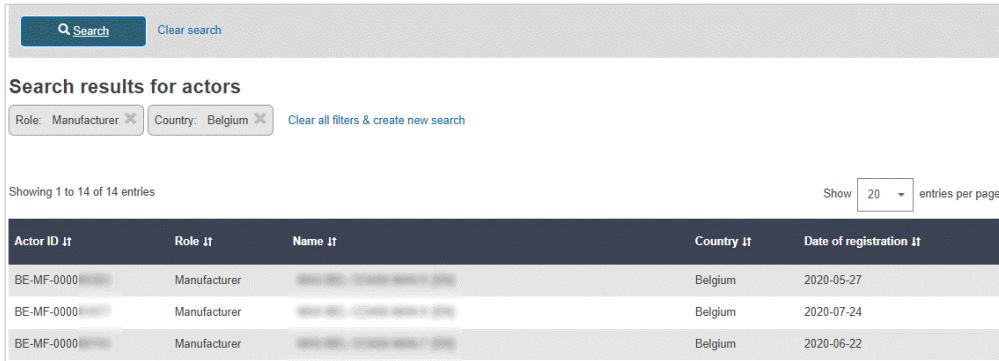
Competent Authority × ▼

Results option

Include historical version ☐

Search Generate XML file Clear search

- Enter your search criteria in the *Search & view* page and click **Search**. All actors matching your criteria are 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 20 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-0000-0000-0000-0000	Belgium	2020-05-27
BE-MF-0000	Manufacturer	BE-MF-0000-0000-0000-0000	Belgium	2020-07-24
BE-MF-0000	Manufacturer	BE-MF-0000-0000-0000-0000	Belgium	2020-06-22

- To view the details for any actor, click the entry in the results list.
- To download your search result in bulk (XML) format, activate the toggle 'Only enable search filters available for bulk XML download of economic operators'. Once your search is complete, click the button **Generate XML file** and confirm. You can now view the status and download the XML file containing the results list from the Downloads management page. Please see the data exchange guide for further information, available [here](#).

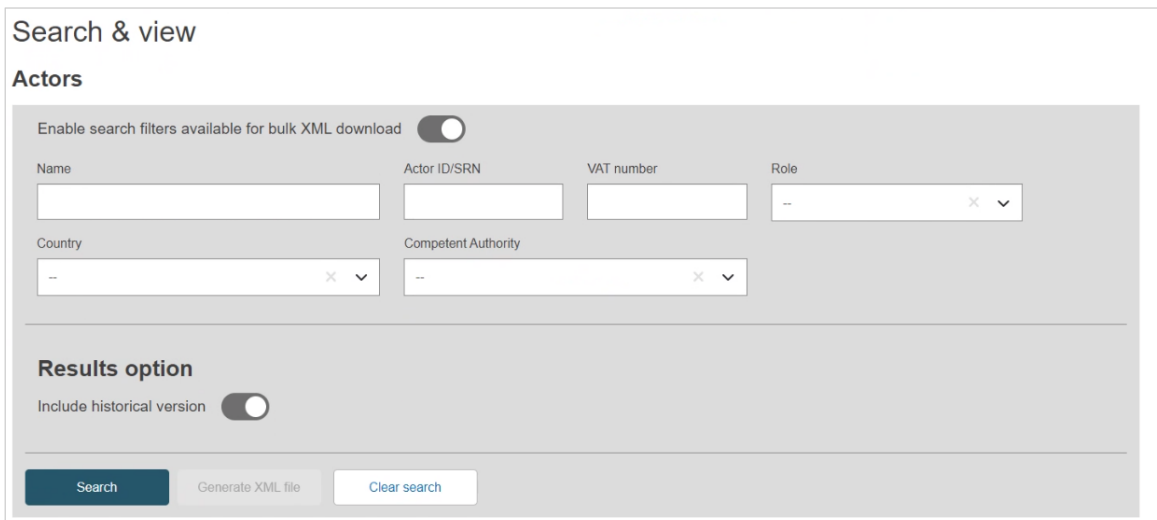
**NOTE**

There are limitations on what search criteria you can use for bulk downloads, so certain filters will be disabled when this toggle is active. Please see the DTX service definition for more information on search criteria.

Search and view actors for non-EU Manufacturer/Authorised representative

Search for Non-EU Manufacturer

- Click on the **Actors** block on the dashboard or select **Search & view > Actors**. The actor *Search & view* page appears:



Search & view

Actors

Enable search filters available for bulk XML download ☐

Name Actor ID/SRN VAT number Role

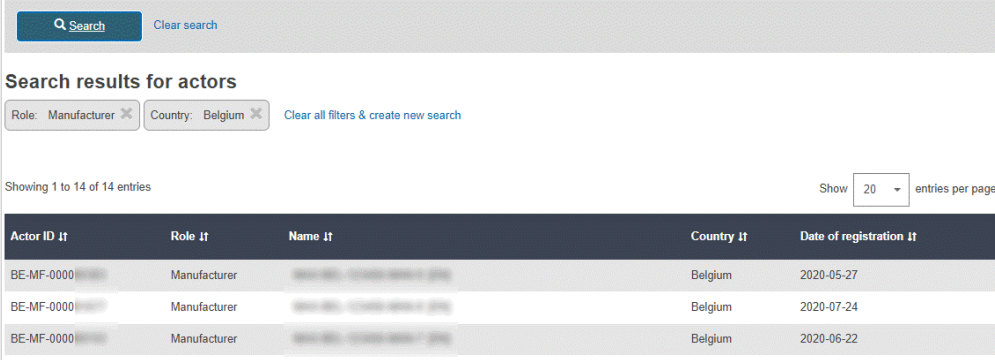
Country Competent Authority

Results option

Include historical version ☐

Search Generate XML file Clear search

- Enter your search criteria in the *Search & view* page and click **Search**. All actors matching your criteria are 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 20 entries per page

Actor ID	Role	Name	Country	Date of registration
BE-MF-0000	Manufacturer	BE-MF-0000-0000-0000-0000	Belgium	2020-05-27
BE-MF-0000	Manufacturer	BE-MF-0000-0000-0000-0000	Belgium	2020-07-24
BE-MF-0000	Manufacturer	BE-MF-0000-0000-0000-0000	Belgium	2020-06-22

- To view the details for any actor, click the entry in the results list.
- Once you have clicked on one of the results from the list, the selection will open in a new page.
- By using the side menu, you can navigate between the different information related to the actor.
- Each section of data will be displayed within an accordion, this accordion can be expanded by clicking on the title of said accordion or by clicking on the same title in the side menu.
- Different information can be found in each section, clicking on 'Actor information' will display the basic details of the actor you selected.
- Clicking on 'Authorised representative(s) mandates' will display all current and past mandates as well as their details:
 - Mandate title:** an automatically generated title by the system for the mandate
 - Actor ID/SRN:** the ID for the actor related to the mandate
 - Name, address, country, email and phone number:** the basic information for the Authorised representative who accepted/rejected the mandate
 - Mandate validity date:** displays when the mandate was created till its expiration date

Search for Authorised representative

- Click on the **Actors** block on the dashboard or select **Search & view > Actors**. The actor *Search & view* page appears:

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 ☐

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

2. Enter your search criteria in the *Search & view* page and click **Search**. All actors matching your criteria are 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 20 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

3. To view the details for any actor, click the entry in the results list.
4. Once you have clicked on one of the results from the list, the selection will open in a new page.
5. By using the side menu, you can navigate between the different information related to the actor.
6. Each section of data will be displayed within an accordion, this accordion can be expanded by clicking on the title of said accordion or by clicking on the same title in the side menu.
7. Different information can be found in each section, clicking on 'Actor information' will display the basic details of the actor you selected.
8. Clicking on **Non-EU manufacturers** will display a link, clicking on this link will redirect you to the list of Non-EU manufacturers linked to the same Authorised Representative.
9. Clicking on **Competent Authority** will display the details for the Competent Authority that is in charge of the actor.

10. *Devices* will also display a link, clicking that link will redirect you to a list of devices registered under this actor.

View Actor data – historical versions

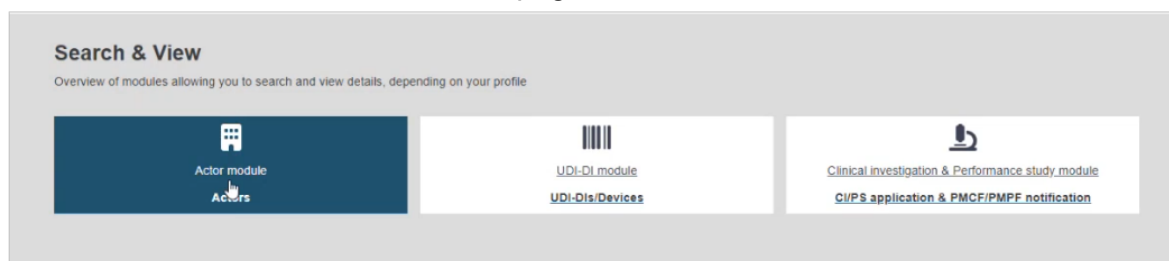
VIDEO: View historical version of an actor



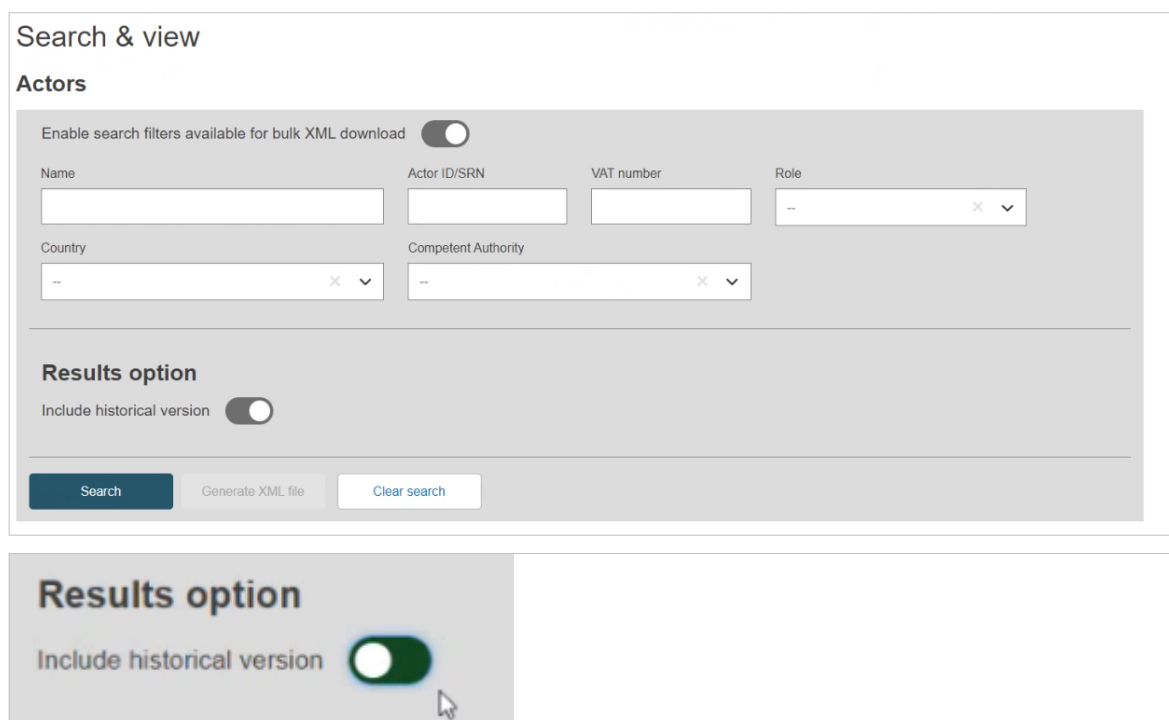
You have the option of searching for an Actor and have the search show the historical version of said actor.

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

1. Click on **Search & View** on the homepage tile or on the menu:



2. In the next window, when entering all the search criteria, tick the *Include historical version* button:


 The form is titled "Search & view" and "Actors". It includes a toggle for "Enable search filters available for bulk XML download". Search criteria fields include "Name", "Actor ID/SRN", "VAT number", "Role" (dropdown), "Country" (dropdown), and "Competent Authority" (dropdown). A "Results option" section contains the "Include historical version" toggle, which is shown as turned on in a separate callout. At the bottom are buttons for "Search", "Generate XML file", and "Clear search".

3. After clicking on **Search**, a list with results relating to your search will appear, you will notice one of the columns is *Version number*:

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

4. You will notice two types of versions, *Current* and *History*:



5. Clicking on one of the search item will open up the historical or the current version you have selected.
6. Also, once inside the current version, you have the option of navigating between the versions 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:	-

- A list of the different versions for said Actor data will display:



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

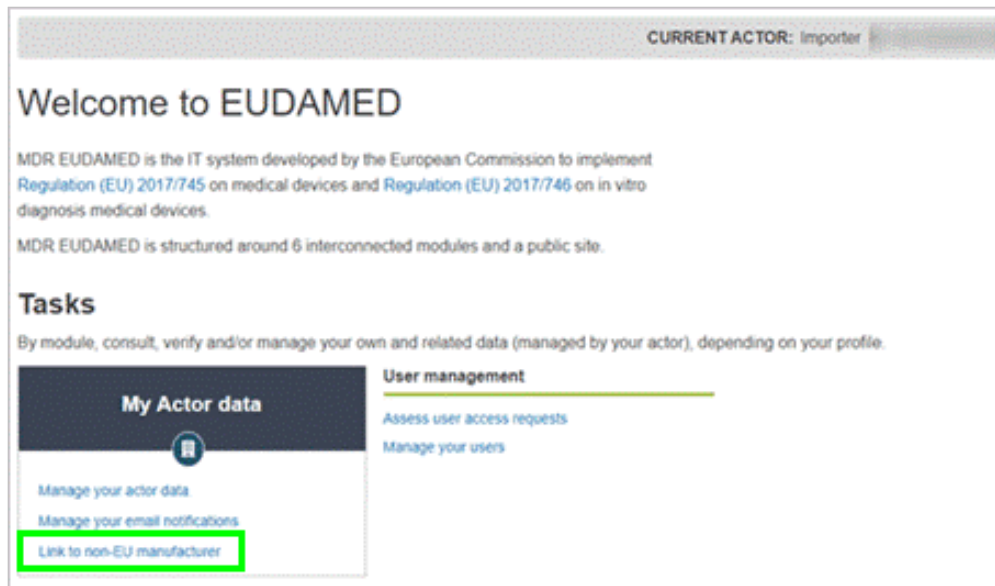


2.1.5 Linking a non-EU manufacturer to an importer

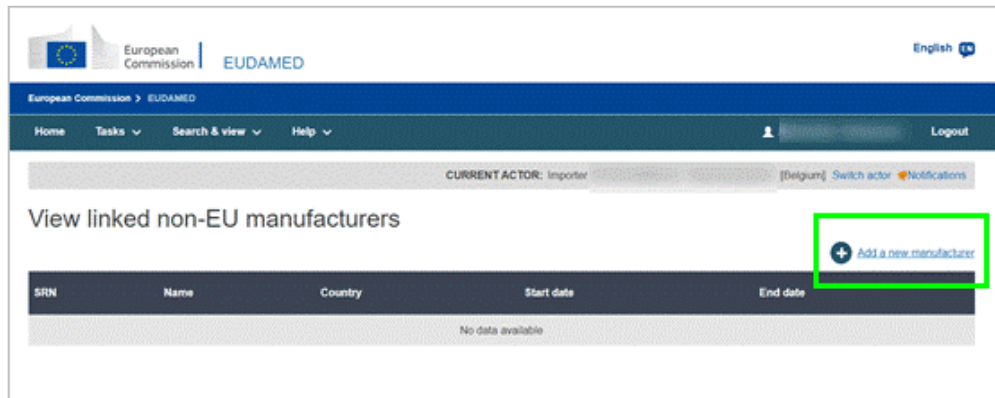
[Section specific to importers with 'Linker' profile]

To link a non-EU manufacturer to your importer:

- Go to the Dashboard:



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



3. Click **Add a new manufacturer**. You will be invited to select the non-EU manufacturer:

Link a non-EU manufacturer with your importer

☒ I know the SRN

SRN:

Find

4. If you know the Actor ID/SRN, enter it here and click **Find** to select the manufacturer.
5. If you don't know the Actor ID/SRN, uncheck **I know the Actor ID/SRN**. Two new fields will appear:

Link a non-EU manufacturer with your importer

☐ I know the SRN

Country:

Australia

Actor / organisation name:

Find

6. Enter the country and actor/organisation name, then 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:

Afghanistan

Actor / organisation name:

Find

Result

Select your actor from the list below

Search results: Afghanistan - Manufacturer - Actor code: AF-MF	^
Search results: Afghanistan - Manufacturer - Actor code: AF-MF	^

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

Afghanistan - Manufacturer - Actor code: AF-MF-

SRN:

AF-MF:

Role:

Manufacturer

Country:

Afghanistan

Organisation name:

Address:

Email:

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

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

2.1.6 Updating actor details

[Section specific to Local Actor Administrators (LAA)]

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

To update actor details

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

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

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

CURRENT ACTOR: Manufacturer, AL-MF-000001322, Non-EU MF for DEMOs [Albania] [Switch actor](#) [Notifications](#)

Manufacturer, AL-MF-000001322, Non-EU MF for DEMOs [Albania]

My Actor data

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

My Actor data

Version 8 [Current] | Last update date: 2022-12-09 | e00054f

Actor identification

Role:	Manufacturer
Actor ID/SRN:	AL-MF-000001322
Country:	Albania
Actor / Organisation name:	Non-EU MF for DEMOs [All languages]
Abbreviated name:	-
VAT information:	No
EQRI number:	-
National trade register number:	-
Organisation identification document:	-

Actor address

[Create new version](#)
[Change competent authority](#)
[Set status to inactive](#)

- If you need to change some information, proceed as follows:
 - Click **Create new version** and answer **Yes** to the confirmation message.
 - Make all required changes in the corresponding tabs.
 - 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:

Manufacturer, BE-MF-000001322, BE-MF-000001322 [Belgium]

My Actor data

- Competent Authority
- Version 2 [Current] | Last update date: 2020-08-20 | e00054f

Deleting an actor's draft

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

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.

[See all the news](#)

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

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 will disappear from the list.

2.1.7 Confirm Actor data accuracy

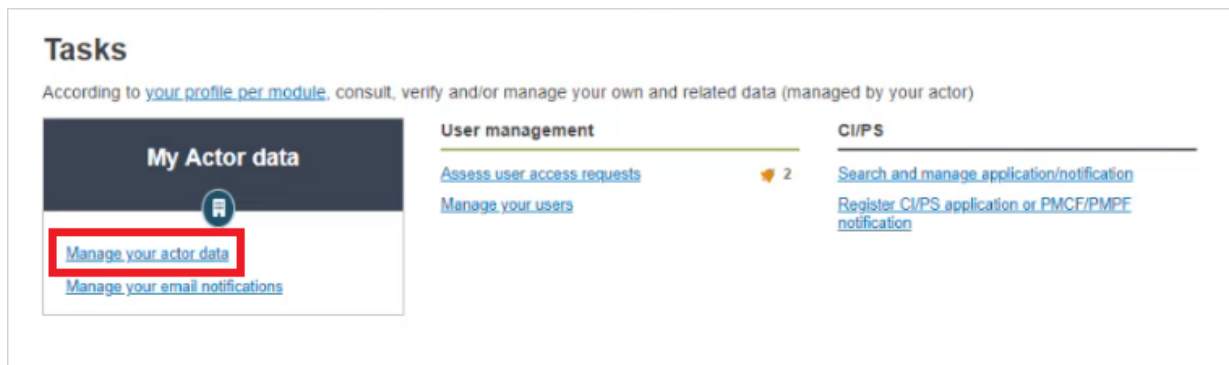
VIDEO: Confirm actor data accuracy



[As an LAA] Method 1: Confirm data accuracy button

As an Economic Operator in EUDAMED, you are required by regulation [MDR Article 31§5](#)/ [IVDR Article 28§5](#) to confirm your data accuracy (either when updating your Actor details/creating a new version or by choice). The idea of confirming your data makes sure that everyone who views your Actor profile will be aware of the latest updates made to said profile and they will be sure what they are viewing is up to date.

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



1. In the new window, click on the **Actions** button on the side and then on **Confirm data accuracy** on the drop-down list that appears:

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](#)

Actor status: [Create new version](#) [Set status to inactive](#) [Confirm data accuracy](#)

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

Confirm data accuracy ✕Close

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

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

CURRENT ACTOR: Sponsor PT-SP-000000925 Sponsor organisation: E

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

Last confirmation date of actor data accuracy:	2023-06-20
--	------------

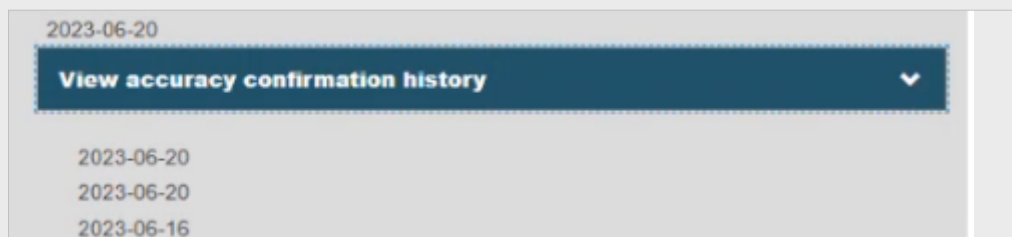
[View accuracy confirmation history](#)

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



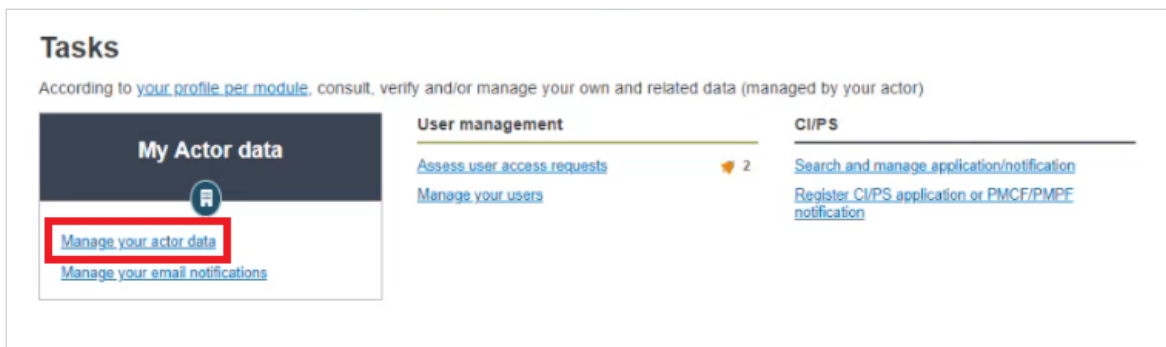
NOTE

Note that EUDAMED allows the user to perform this action at any given moment:



[As an LAA] Method 2: Create new version

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



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



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

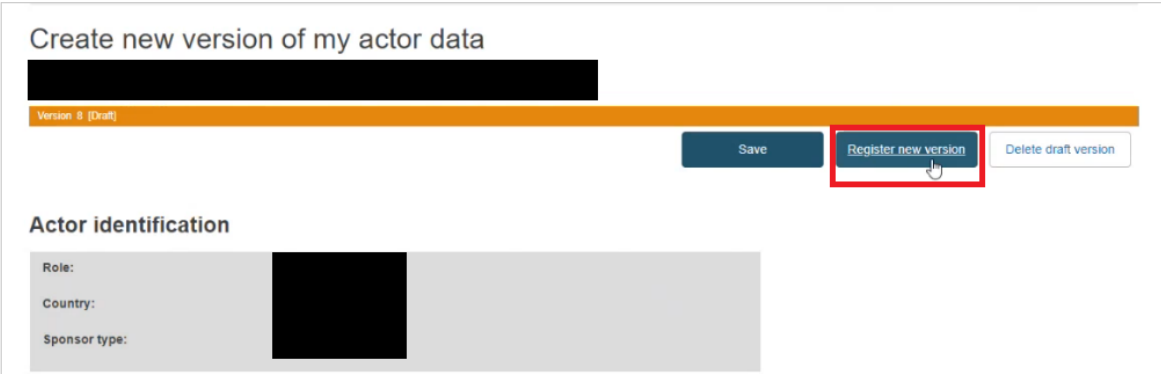
Actor identification

Role: [Redacted]
Sponsor type: [Redacted]
Actor ID/SRN: [Redacted]
Country: [Redacted]
Actor / Organisation name: [Redacted]
Abbreviated name: [Redacted]
VAT information: [Redacted]
[EORI number](#)
National trade register number: [Redacted]
Organisation identification document: [Redacted]
Last confirmation date of actor data accuracy: [Redacted]

[View accuracy confirmation history](#)

Actions:
[Create new version](#)
[Set status to inactive](#)
[Confirm data accuracy](#)

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



Create new version of my actor data

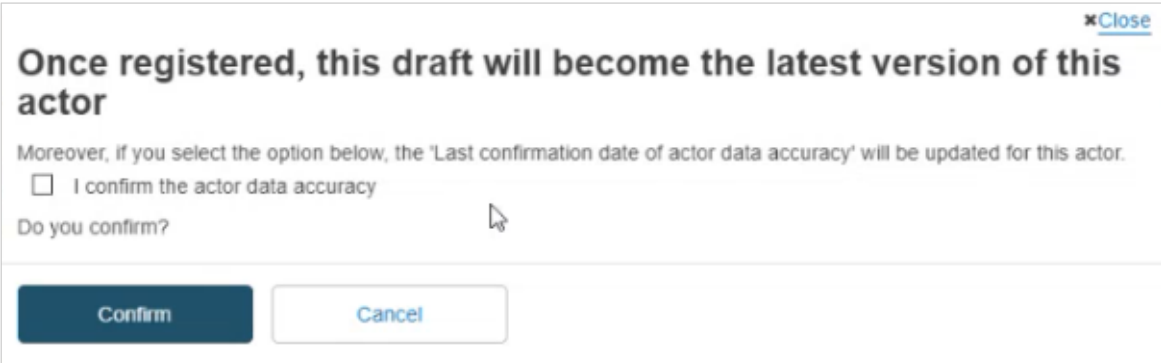
Version 8 [Draft]

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

Actor identification

Role: [Redacted]
Country: [Redacted]
Sponsor type: [Redacted]

- The pop-up message that will show up will ask you to confirm the new version. You will also notice the tick-box you can check, this will confirm the Actor data accuracy:



[Close](#)

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

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

☐ I confirm the actor data accuracy

Do you confirm?

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

- This action will then be logged and 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

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 profiles only]

If you are the 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 if they have an 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**:

Register new status

Cancel

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 SRN:

[✕Close](#)

Change actor status

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

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

Please confirm your status change.

Confirm

Cancel



NOTE

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



NOTE

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

2.1.9 Changing a competent authority for registered actors

[Specific to EO]

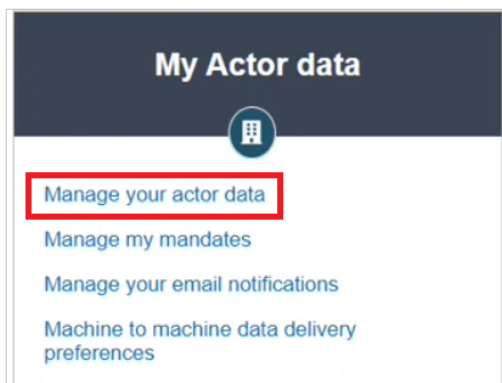
The change of responsible Competent Authority (CA) can be necessary in some specific cases. EUDAMED will only allow to select a new responsible CA for those specific cases and among the possible CAs that the system will present.

The change can be triggered by either:

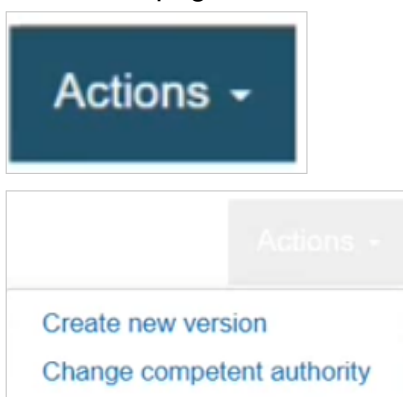
- For an EU economic operator, a move of location inside the same country;
- For a non-EU manufacturer, a change of Authorised Representative or a change of responsible Competent Authority for their Authorised Representative;
- For a non-EU SPP producer, a change in the market distribution of their SPPs;

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. To do so, on the homepage of EUDAMED, click on **Manage your actor data**:



2. In the new page, click on **Action** 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:

 [Add name in another language](#)

Abbreviated name:

 [Add abbreviated name in another language](#)


* Select the language:

All languages
✕
▼

Select the language:

--
✕
▼

Competent Authority

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

Current competent authority

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

* Select a new Competent Authority:

--
✕
▼

DG SANTE CA

Schweizerisches Heilmittelinstitut/ Swiss Agency for Therapeutic Products

New Release Test Playground Org

ARMEN BE CA

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



NOTE

For non-EU manufacturers, the 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 of CA in the free text box below:

* 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 on **Confirm** to continue with your current action or **Cancel** to go back:

✕Close

Competent authority change request

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


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

Are you sure you want to proceed?

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:





NOTE

Only active mandates will be displayed in the 'Authorised representative(s) mandates' section:

Authorised Representative(s) mandates	
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 Bruux
Email:	ArmenFortyNine_eudamed@mailinator.com
Telephone number:	-
Mandate validity dates	From 2022-03-29 to -

Reason for rejection and other details:

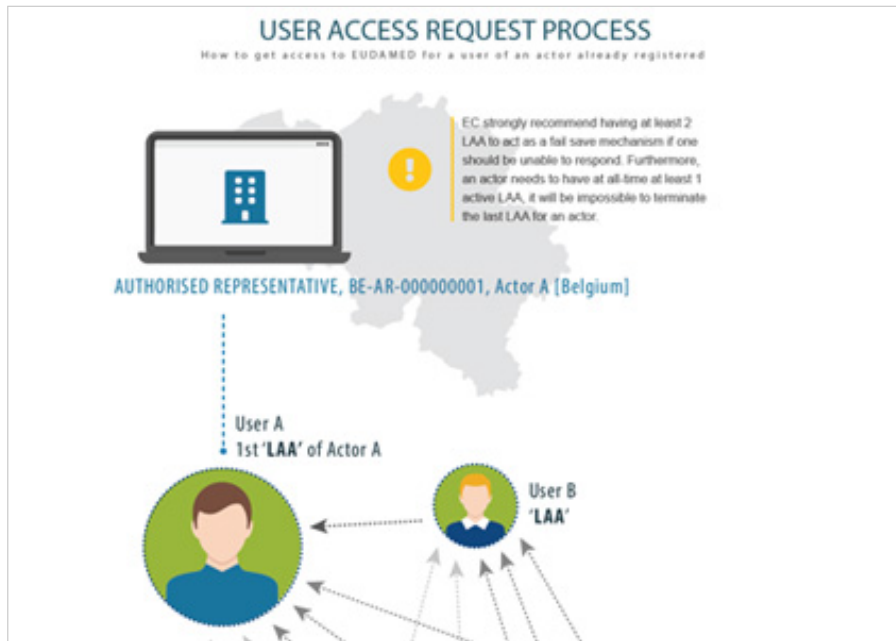
Application ID:	
Assessment outcome:	Rejected
Assessor CA Actor ID:	
Reason for rejection:	This request is rejected because
Date of rejection:	2023-03-31

2.2 Users and user access management

2.2.1 Requesting access as a user to an existing different actor



INFOGRAPHIC: [User access request process](#)

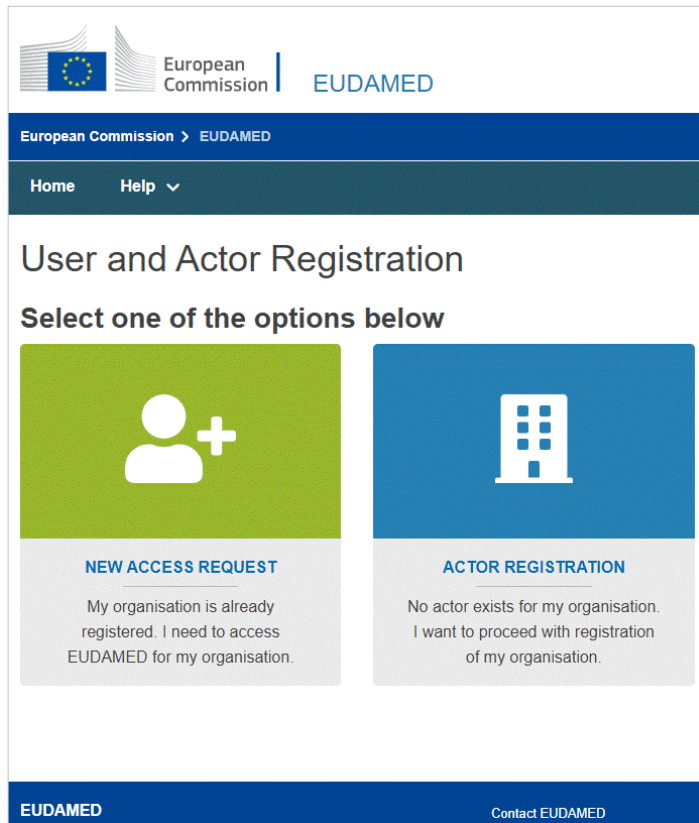


This chapter introduces how to request a new user's access to an Actor that is different than the one you already have access to.

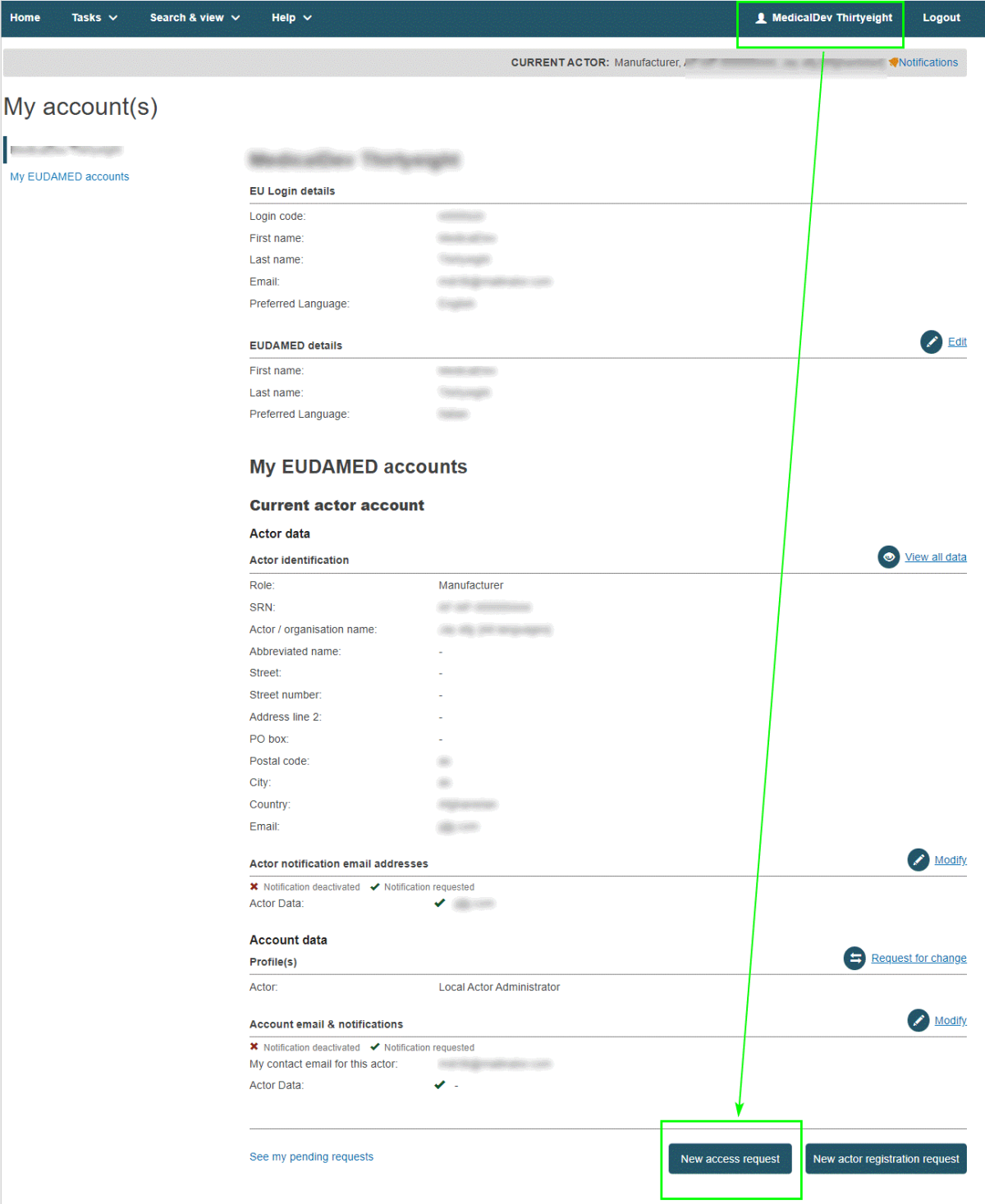
When an actor is already registered in EUDAMED, a person who needs to act on their behalf, must request access and choose (an) appropriate user profile for each of the relevant EUDAMED module(s) that are available to them.

To request access as an actor 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, 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:



Home Tasks Search & view Help

MedicalDev Thirtyeight Logout

CURRENT ACTOR: Manufacturer, [redacted] Notifications

My account(s)

My EUDAMED accounts

EU Login details

Login code: [redacted]
 First name: [redacted]
 Last name: [redacted]
 Email: [redacted]
 Preferred Language: [redacted]

EUDAMED details

First name: [redacted]
 Last name: [redacted]
 Preferred Language: [redacted]

[Edit](#)

My EUDAMED accounts

Current actor account

Actor data

Actor identification

Role: Manufacturer
 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]

[View all data](#)

Actor notification email addresses

✗ Notification deactivated ✓ Notification requested
 Actor Data: ✓ [redacted]

[Modify](#)

Account data

Profile(s)

Actor: Local Actor Administrator

[Request for change](#)

Account email & notifications

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

[Modify](#)

[See my pending requests](#)

[New access request](#) [New actor registration request](#)

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



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 know the Actor ID/SRN (e.g. BE-MF-000000001), you can use it to find the actor by selecting **I know the actor's Single Registration Number (SRN) or EUDAMED Actor ID**.
- 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).
- Click **Find**. The list of matching actors is displayed in the *Result* section on the right-hand side.

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:

* Country:

* Actor / organisation name:

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

Address: Belgium

Email: bel@bel.be

Telephone number: -

Request access to this actor

**NOTE**

You cannot request access to an actor you are already registered with, the system will not be able to locate it.

7. Click 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:
IT-MF-00123456789

Role:
Manufacturer

Country:
Belgium

Organisation name:
ABC DEF GHI

Address:
123 Street, Belgium

Email:
info@abcdefghi.com

Telephone number:
+32 123 456 789

Select another actor

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

My contact email for this actor ⓘ

* Email:

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

☐ No

☐ Yes

Save Save & Next > Cancel

8. Complete *Step 1* of the user access request process:
 - a. Enter your contact/notification email address related to this request.
 - b. Indicate whether you are a sub-contractor for the selected actor. If you select **Yes**, you will be prompted to enter details of your company.
9. Click **Save & Next**. *Step 2* appears. Here you must identify a manager in your organisation who has the necessary authority to support your request:

New access request

Information of the actor selected

Actor code:
IT-MF-00123456789

Role:
Manufacturer

Country:
Italy

Actor/Organisation name:
ABC DEF GHI

Address:
Via Buco, 41, Cadriano-Gemello Delfino

Email:
contact@abcdefghi.it

Phone:
+39 0123 456789

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

User manager

* First Name:

* Last Name:

* Function/Position:

Save Save & Next > Cancel

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

New access request

Information of the actor selected

SRN:
[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:
[calendar icon]

YYYY-MM-DD

Save

Submit ▶

Preview

Cancel

**NOTE**

The profiles available depend on the actor role, e.g. you can only choose *Verifier* if your Actor is an *Authorised Representative*.

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

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

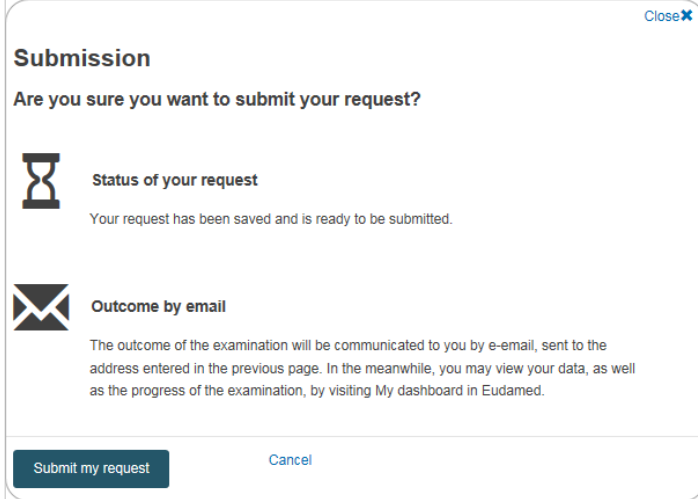
**NOTE****User profiles**

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

► **Local User Administrator (LUA)** can validate user access requests for the same actor (see [Validating user access requests \[58\]](#)).


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:



Submission Close

Are you sure you want to submit your 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 you by e-mail, sent to the address entered in the previous page. In the meanwhile, you may view your data, as well as the progress of the examination, by visiting My dashboard in Eudamed.


[Submit my request](#) [Cancel](#)

15. Click **Submit my request**. You are informed that your access request has been successfully submitted.

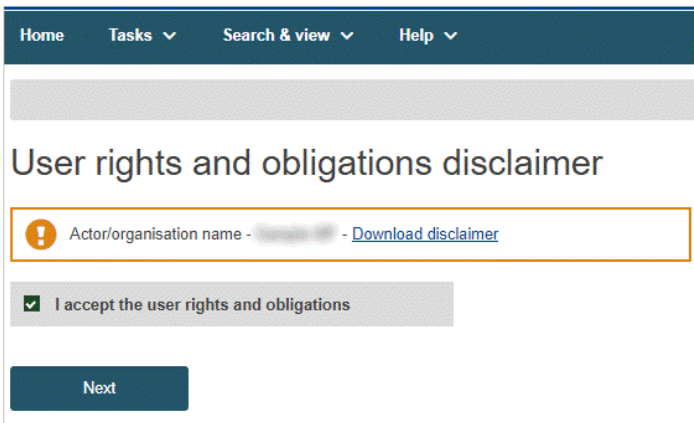
A Local Actor Administrator or Local User Administrator belonging to the Actor will review and validate your request. You will be notified when your access request is approved or rejected.

- If **not approved**, you can click the action button next to the pending request to read the reason provided by the LAA/LUA. You can then change and re-submit as appropriate.

My access requests for an existing actor


Role	Name	City	Date of the request	State	Actions
Authorised Representative	Megamedics	Sorrento	2019-12-06	Reopened	

- 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:



Home Tasks Search & view Help

User rights and obligations disclaimer

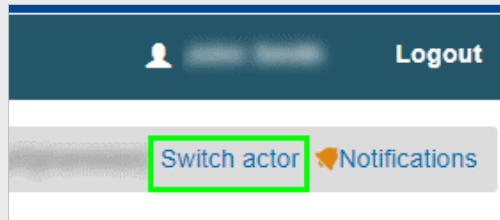
 Actor/organisation name - xxxxxx - [Download disclaimer](#)

☒ I accept the user rights and obligations

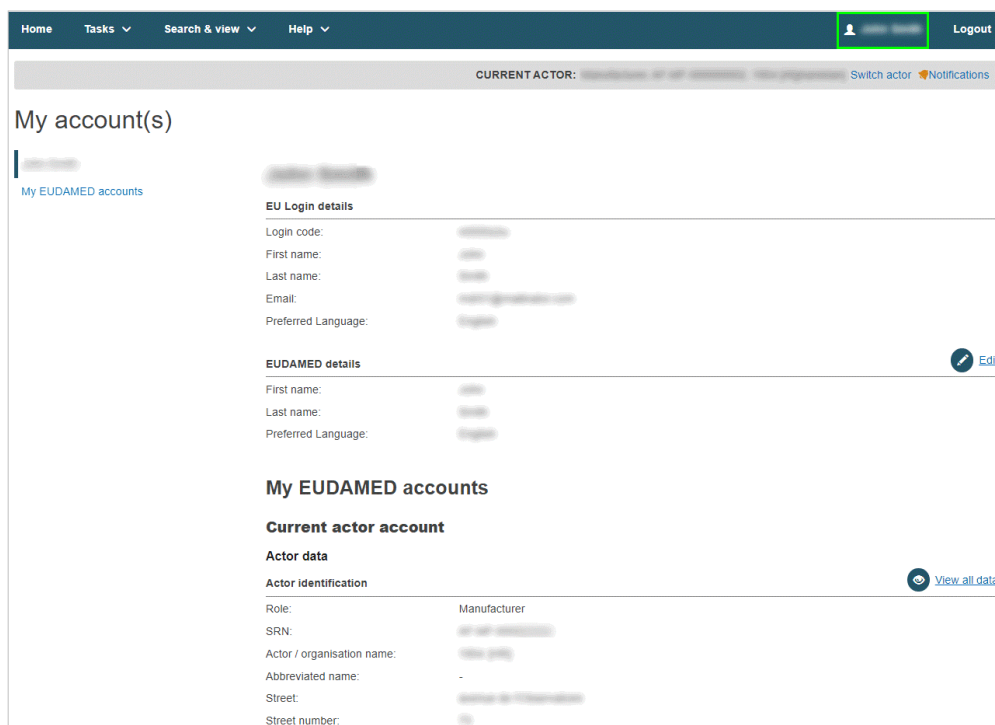
[Next](#)

**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 application:



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 Validating Economic Operator access requests

[Section for Local User Administrators]

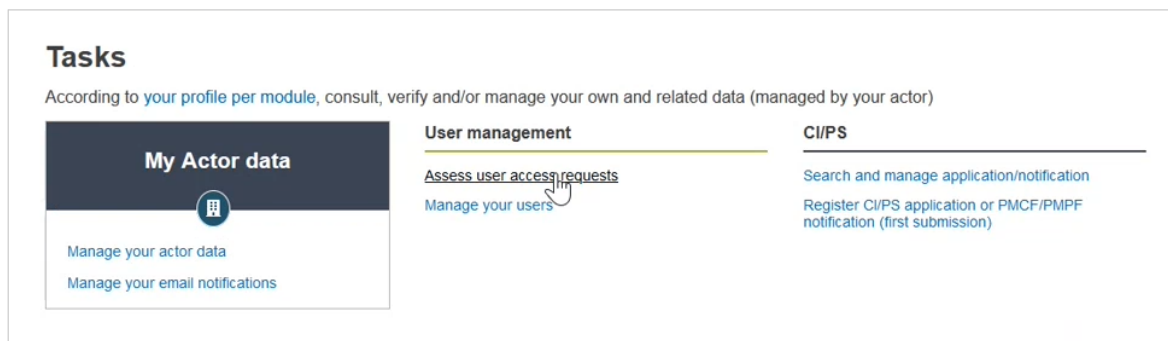
Anyone with an EU Login account can request access to a registered Actor, but only a user with a *Local User Administrator* (LUA) or a *Local Actor Administrator* (LAA) profile can validate these requests. The person who registers an actor in EUDAMED automatically receives an *LAA* profile for this Actor. This includes the *LUA* rights for managing new user access requests.

As an LAA or LUA for the actor, you will be notified of all new or updated incoming access requests.

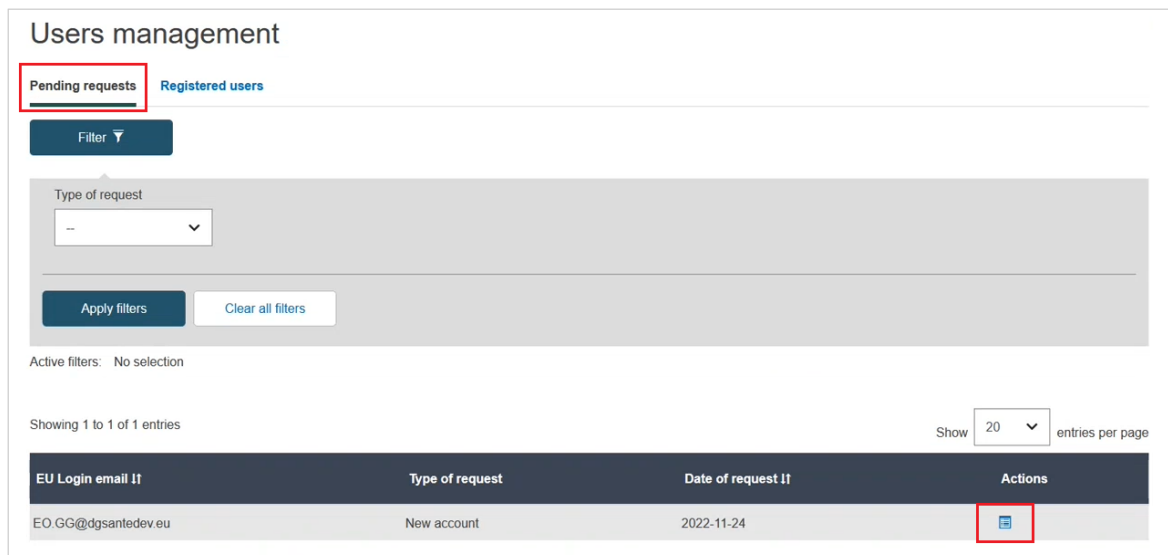
Users cannot access EUDAMED until their access request is approved.

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 *User 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**, the **Next step** button remains available at the bottom of the page (go to *Step 6*).
 - 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:**

The rejected request disappears from your pending requests list. This ends the steps you need to follow for this request (ignore steps 6-8 below).

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

Assessment of user data

Outcome:

Approve ☒ Reject


A table is shown with the user profiles for all available modules. The *Viewer* profile is automatically granted to each user:

Requested Profiles

Profiles(s) for this actor

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

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

CI/PS:	Confirmer	✓ Approve	✗ Reject
			



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.

7. 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.
8. 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 update to *validated*.
 - The user details are moved to the *Registered users* tab, on the *Users management* page.
 - The user is notified that their access request has been validated.

2.2.3 Terminating 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, 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 the organisation or manage data. 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

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

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

4. Review the user's details and 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: [blurred]

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 disappears from the *User management* module.

2.2.4 Editing your user account

After your user access request is approved, you can still change your account information, e.g. after any personal or professional changes. But you cannot edit any of the information relating to your actor (unless you are a Local Actor Administrator).

To edit your user account

1. Log in to EUDAMED and click on your name in the upper toolbar. The *My account(s)* page 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. An eye icon and a "View all data" link are present next to the actor identification details.

- To change any editable data, click the **Edit** button (or if you are a LAA, the **Modify** button), if one is available next to the section in question:

EU Login details / EUDAMED details

This is a close-up view of the "John Smith" account details. It shows the "EU Login details" and "EUDAMED details" sections. The "Edit" button next to 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]

Use the **Modify** button in this section if you want to change the receiving email address for notifications regarding 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 actor account: Account data

Account data

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

Actor: Local Actor Administrator
 UDI/Device: Viewer

Account's email & notifications  [Modify](#)

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

Use the **Request for change** button in this section if you want to request a different profile for one or more EUDAMED modules for the current actor.

Use the **Modify** button if you want to change the account email and/or the notification preferences for the current actor.

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

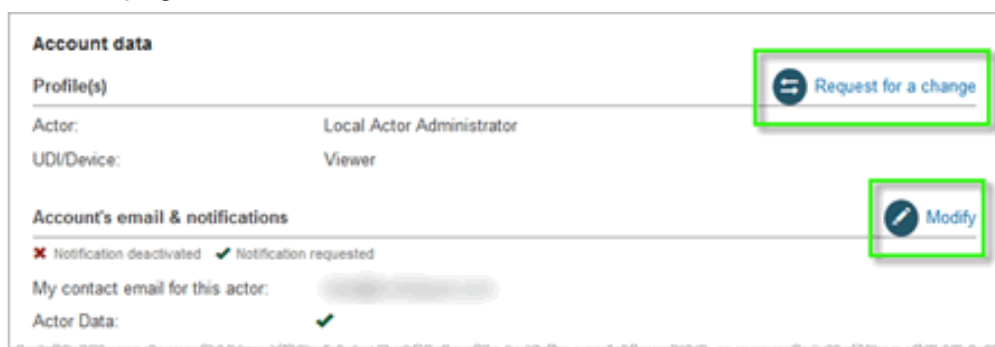


Click the right-pointing arrow next to one of the actors in the list to show their details. You can switch between actor accounts.

2.2.5 Upgrading your user profile

To request to change/upgrade your profile

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



2. Click **Request for change** next to your profiles and follow the steps to select the profiles for the module you require. If this button is missing, it means you have already submitted a request.
3. An LAA/LUA will need to approve this request before these profiles will be assigned to you.



IMPORTANT

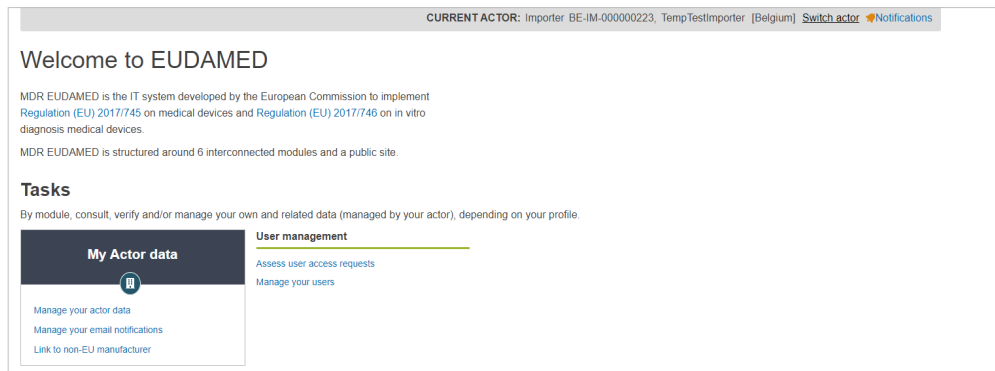
- An LAA/LUA cannot approve their **own** requests. This means that for any actor with only ONE user, a **second user** with LAA/LUA profile will be needed to approve any profile upgrade requests.
- It is good practice for each actor to have **at least two** users with an LAA profile.
- EUDAMED requires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

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.

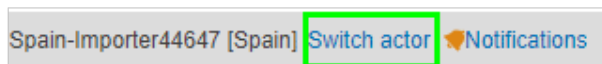
2.2.6 Switching between actors

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).

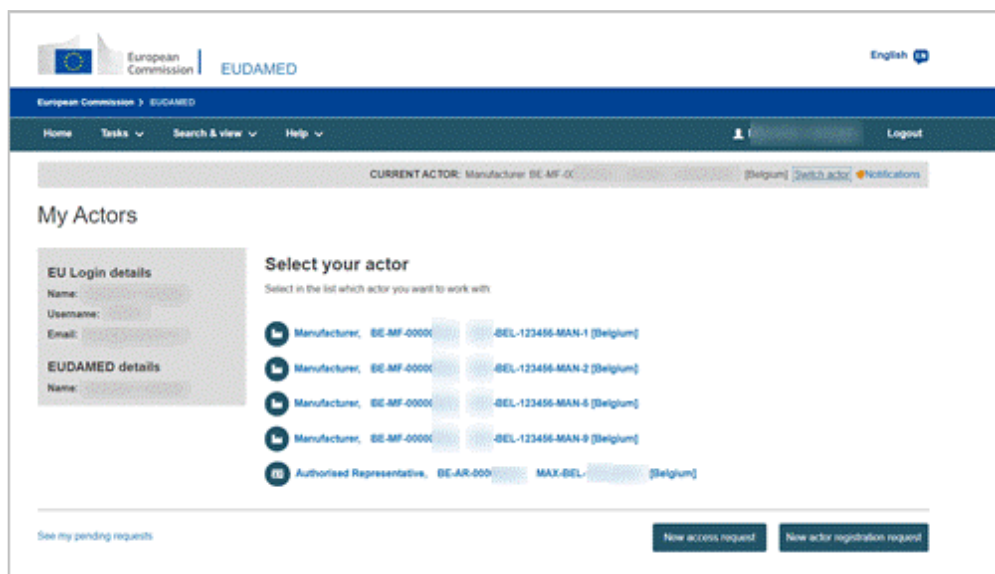
1. Go to the Dashboard:



2. Click on **Switch actor** at the top right (you can also do this after selecting an actor):



3. Select an actor from the list shown:



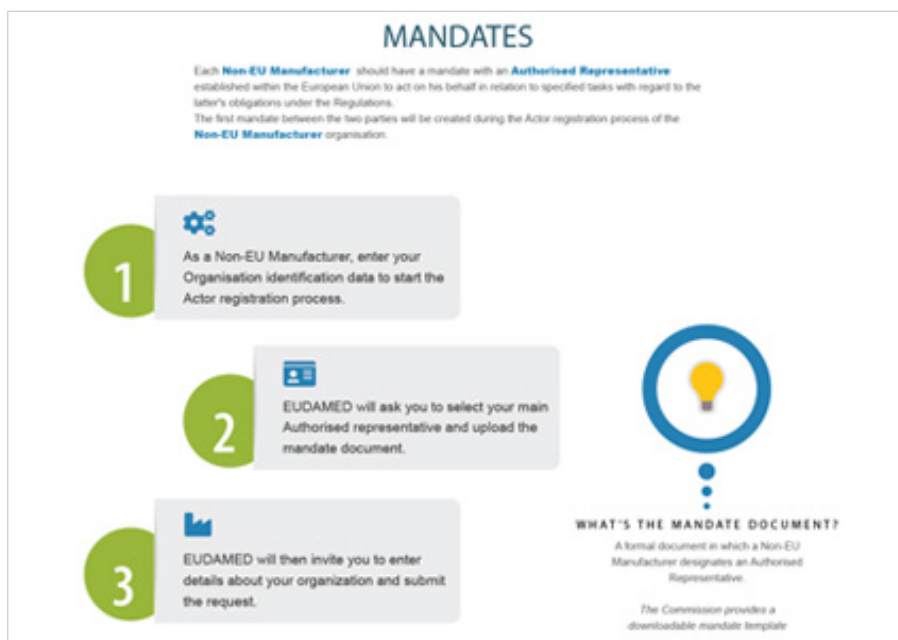
2.3 Managing mandates

[Specific to non-EU manufacturers]

If a registered non-EU manufacturer subsequently uploads mandates with other authorised representatives, these must be **verified** by those authorised representatives.

The duration of a mandate may be determined by its validity end date. Alternatively, the Authorised Representative or the non-EU manufacturer can decide to **terminate** before this date.

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



2.3.1 Adding a new mandate

[Specific to non-EU manufacturer]

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 registered in EUDAMED.

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 (Authorised))

Showing 1 to 6 of 6 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 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**

**NOTE**

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

- If you know the Actor ID/SRN for the Authorised Representative, enter it here, click **Find** and select from the results.
- 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.
- Specify the mandate's validity start-date (mandatory) and end-date (optional).
- Click **Browse**, under *Upload mandate summary document*, to select and upload your summary mandate document – in **PDF format only and not surpassing 3MB in size**:
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.

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

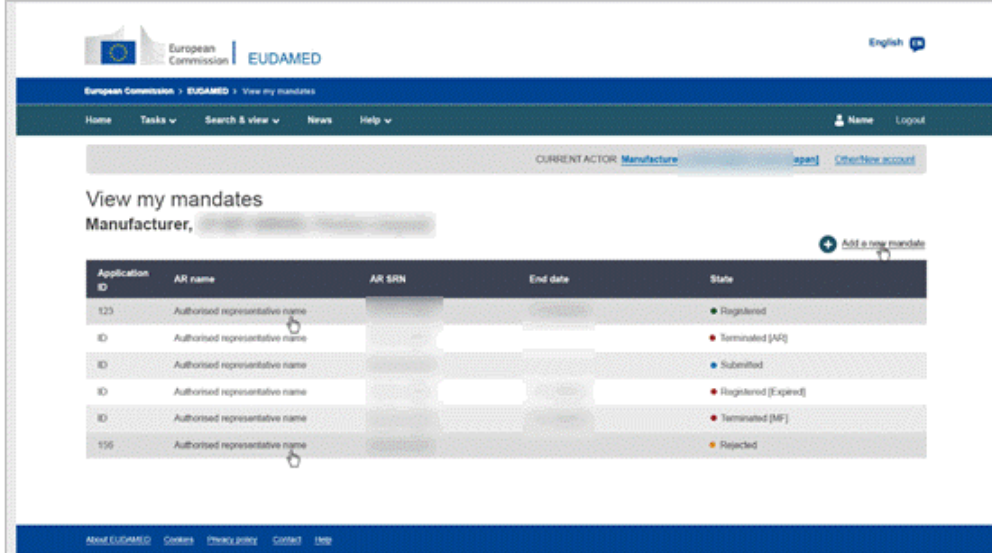


- Manage your actor data
- Manage my mandates  2
- Manage your email notifications

User management

- Assess user access requests
- Manage your users

- Select the target mandate from the list on the next page:



View my mandates

Manufacturer,

Application ID	AR name	AR SRN	End date	State
123	Authorized representative name			Registered
ID	Authorized representative name			Terminated (AR)
ID	Authorized representative name			Submitted
ID	Authorized representative name			Registered (Expired)
ID	Authorized representative name			Terminated (MF)
156	Authorized representative name			Rejected

- 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](#)

5. Upload the new mandate summary document (**In PDF only and not surpassing 3MB in size**) and change the validity dates accordingly.

2.3.3 Verifying mandates

[Specific to authorised representatives with a Verifier 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**



NOTE

The mandate management features are available only to authorised representative users with a *Verifier* profile, or higher (e.g. *LAA/LUA*).

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

- Click on the mandate you want to verify in the *Pending mandates* list. The details of the received 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](#)

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

2.3.4 Terminating a mandate

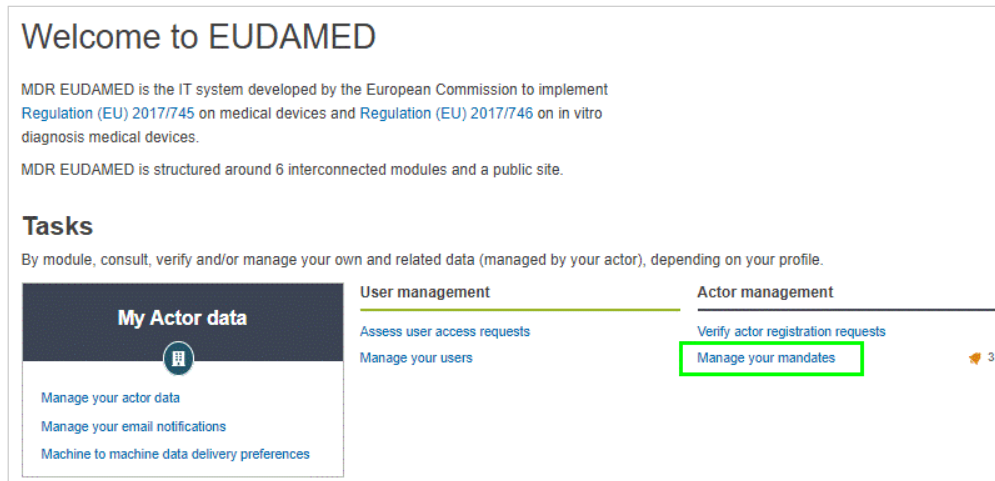
[Specific to authorised representatives and non-EU manufacturers]

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

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



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 your registered mandates is displayed:



- 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 and state of 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 <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	[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 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 | n0005147

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 its name 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

