

EUDAMED: Economic Operator user guide

How economic operators can use the actor registration module –
concept, registration, management, access and mandates.

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1 Introduction

How economic operators can use the actor registration module – concept, registration, management, access and mandates.¹

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



NOTE

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 they may therefore slightly differ from what you see in this manual.

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 Help Centre](#).

- Understanding user profiles and access grants/rights

1.2.1 Accessing EUDAMED portal

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.



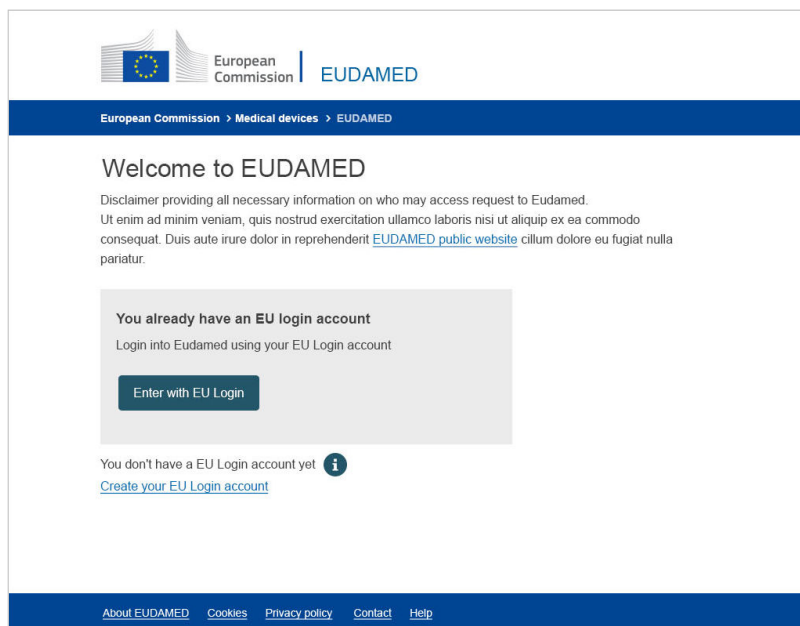
NOTE

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 screenshot shows the EU Login 'Sign in to continue' page. At the top, a yellow banner states 'This website uses cookies. Learn more about the European Commission's cookie policy' with a 'Close this message' link. The page header includes 'EU Login' with the tagline 'One account, many EU services', a 'Where is ECAS?' button, and a language selector set to 'English (en)'. The main heading is 'Sign in to continue' with the URL 'webgate.acceptance.ec.europa.eu requires you to authenticate'. The central form prompts the user to 'Use your e-mail address' with an input field containing a single character. Below the input field is a blue 'Next' button, a link to 'Create an account', and an 'Or' separator. Further down, it says 'Or use the eID of your country' with a user icon and a 'Select your country' link. At the bottom of the form area, it promotes the 'EU Login app' with download links for the App Store, Google Play, and Microsoft. The footer contains links for 'About EU Login', 'Cookies', 'Privacy Statement', 'Contact', and 'Help', along with 'European Union' and 'EU institutions' logos, a performance indicator '7.4.3-dn2p | 17 ms', and the 'Powered by European Commission' logo.

3. 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:

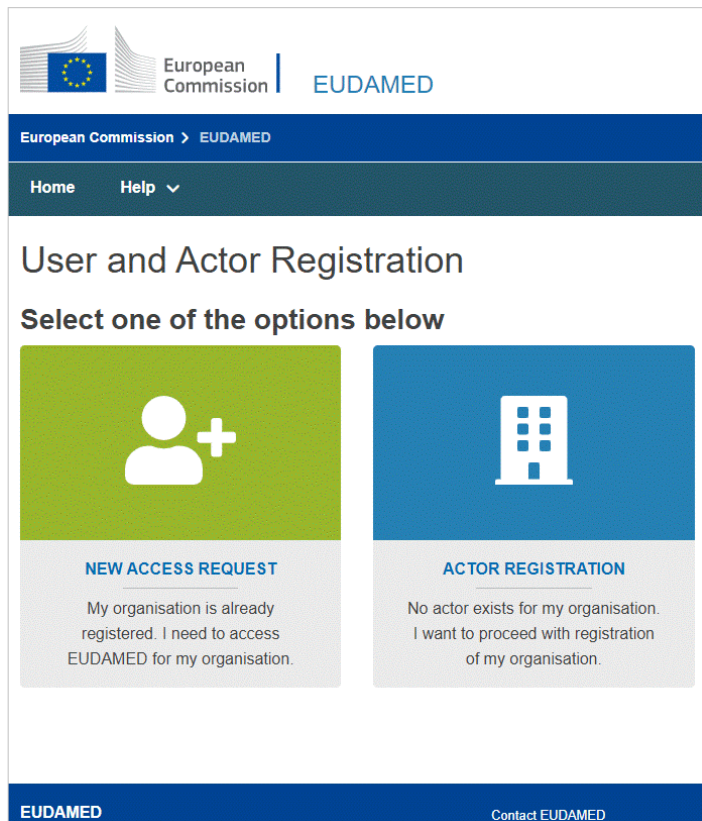
This screenshot shows the EU Login 'Sign in to continue' page for 'eudamed'. The layout is similar to the previous one, but the URL is 'eudamed requires you to authenticate'. The central form displays a 'Welcome back' message for a user with the email 'j.smith@ec.europa.eu' (External). It includes a link to 'Sign in with a different e-mail address?'. The 'Password' field is empty, with a 'Lost your password?' link below it. A 'Choose your verification method' dropdown menu is set to 'Password'. Below the dropdown is a computer icon and a blue 'Sign in' button. The footer is identical to the first screenshot, showing the 'EU Login app' promotion and various site links.



NOTE EU Login issues?

- Forgot your password? Click **Lost your password?** on this screen.
- 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

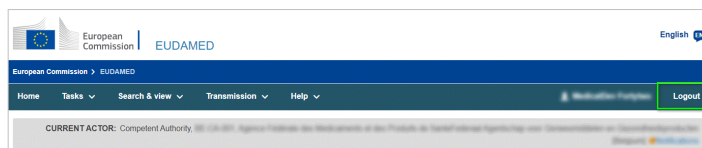
Next steps:

- Want to register your organisation as an actor in EUDAMED? [See section 2.1.1 \[9\]](#)
- Need access as a user for a registered economic operator? [See section 2.2.1 \[34\]](#)

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:



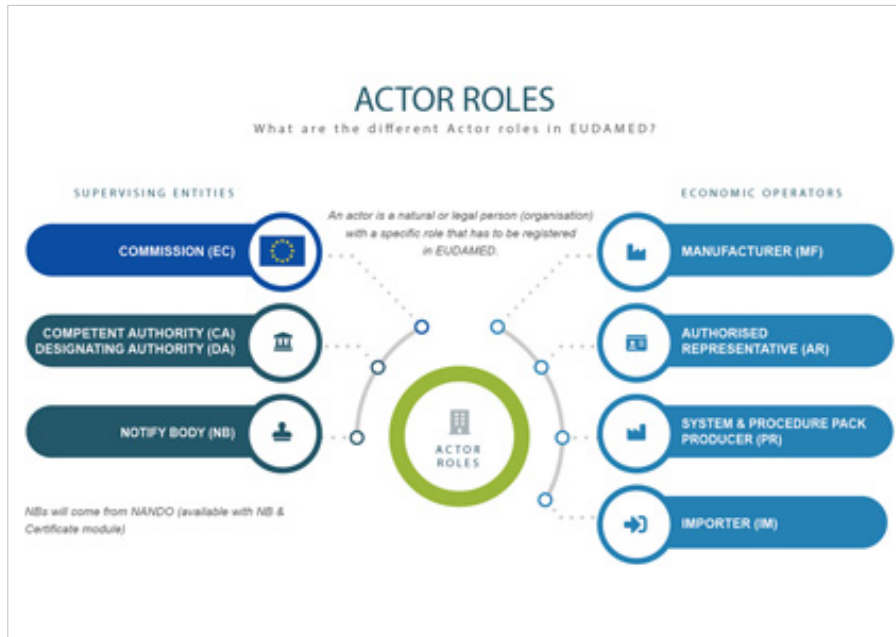
2. After you confirm the **Logout** from EUDAMED, you will be prompted with a *Log me out* confirmation page from the EU Login domain.

**IMPORTANT**

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

1.2.2 Actors and definitions

 The image opens an infographic illustrating the process.



Actors

Actors involved in EUDAMED are:

Supervising bodies

- European commission
- Competent authorities (CAs), including designating authorities
- Notified bodies (NBs)

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.

Table 1 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.

Table 2 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. This can be an individual or an organisation – both can be considered an 'actor' in EUDAMED.

- The person who performs the 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.

Request access as a user of a registered economic operator

If your organisation (or person) is already registered as an actor in EUDAMED, you can request access as a user of that actor. Once one of the administrators in your actor (an LAA or LUA) has approved your request, your account will be granted the appropriate user profile for that actor.

The first user becomes the LAA by default, with the fullest set of user rights. The user can also switch actors and act as the LAA for other actors. EC strongly recommends 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

If you are an economic operator who needs to be officially recognised as an actor in EUDAMED, you must register your details using the **Actors** module.

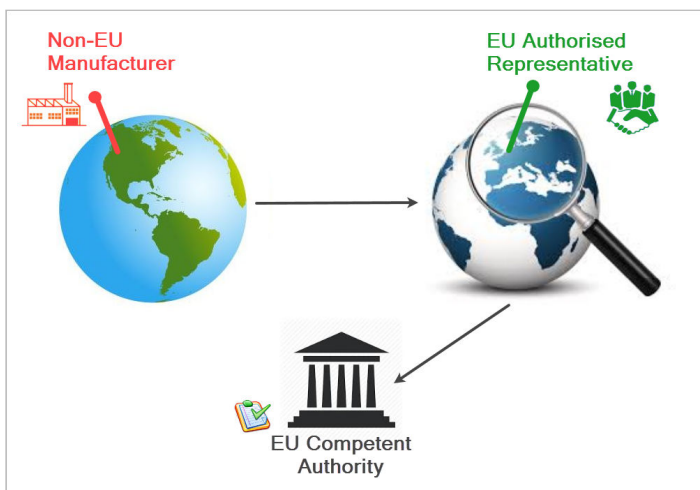
'Economic Operator' means one of the following:

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

- Importer (IM)

* **EU manufacturers:** If you are officially registered ('established') in the EU, your registration will be directly assessed by the **Competent Authority** in that country.

** **Non-EU manufacturers:** If you are not registered in the EU, your registration must be verified by an **Authorised Representative** within the EU, before being assessed by a Competent Authority from the same country as the AR who verified your application for EUDAMED registration.



The difference in registration process between the two types of MFs, 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.

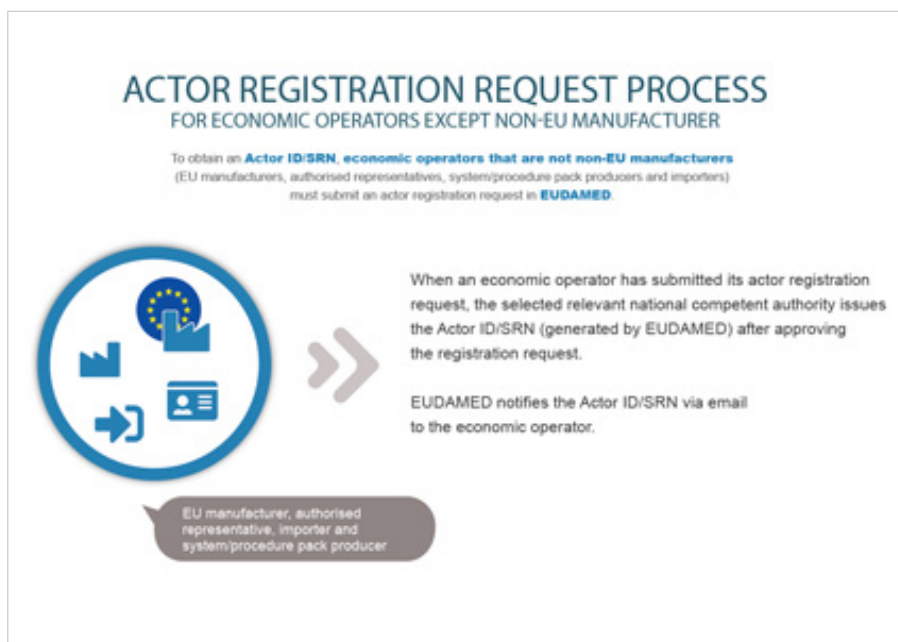


NOTE **Multiple roles**

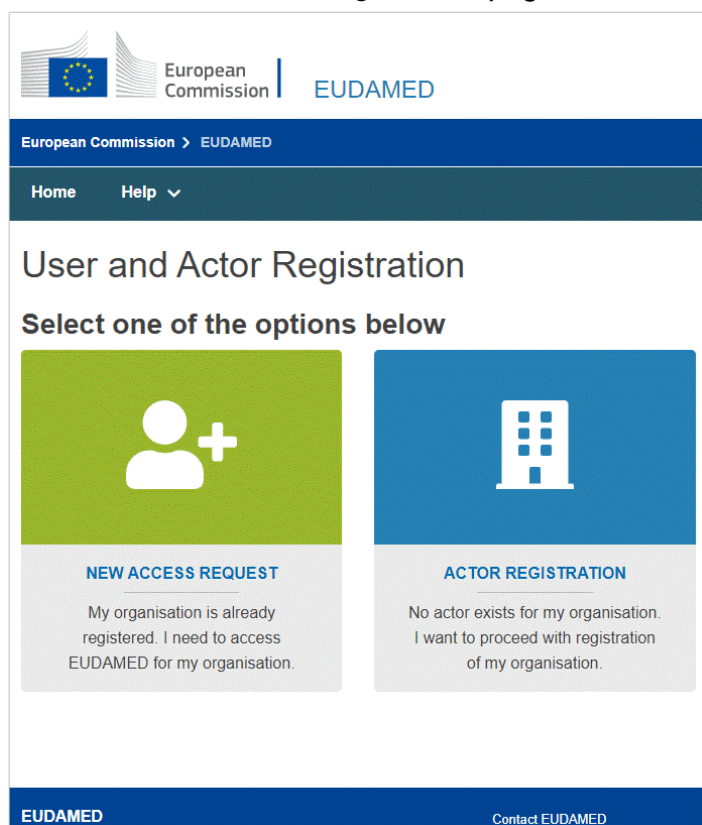
If your organisation has more than one role (i.e. your organisation is a manufacturer and an importer at the same time), you must make separate actor registrations for each.

2.1.1 Register as an economic operator

 The image opens an infographic illustrating the process.



1. Log into EUDAMED with your EU Login account (see [Section 1.2.1 \[2\]](#)). 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 generic information about the organisation to avoid duplicates:

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 your EUDAMED action.



- Select the role and country, enter the name of your organisation (actor) and click **Next**. A six- or seven-step process will guide you through you actor registration.

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 >

6. Enter the mandatory information fields, and additional fields, needed to identify your economic operator: VAT, EORI and National Trade Register Number etc. These cannot be updated via the User Interface and data exchange. However, it is possible to address the SANTE EUDAMED SUPPORT with requests to change one of these items. The request will be assessed, and possibly performed, on a case-by-case basis depending on the justification for such change. You can upload any document that may be useful for validating your request – but only in PDF format.

EORI number: All businesses and individuals trading in the EU need an EORI. You can validate your number in the [EORI database](#). If you have no EORI, contact the [customs authorities](#) in the country where you are registered. Its provision is optional however.

Click **Save & Next**.

1. If you register as a *Non-EU Manufacturer*, you will be prompted by an *Authorized Representative* selector screen:

The screenshot shows a multi-step registration process. At the top, a progress bar indicates seven steps: 1. Actor Identification (completed), 2. Authorised Representative (current step), 3. Actor address, 4. Contact details, 5. Regulatory Persons, 6. Registering Local Actor Administrator, and 7. Competent Authority.

Authorised Representative

Select an authorised representative

☒ I know the SRN

* SRN:

Find

Mandate validity dates

* From: To:

YYYY-MM-DD YYYY-MM-DD

* Upload summary mandate document:

Browse

Save registration Save & Next >



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 under a different name.

You don't have to upload the full mandate text. It's enough to upload a summary/ extract with the start/end dates, details of the manufacturer and authorised representative, and list of generic device groups covered by the mandate.

2. Alternatively, for *EU Manufacturer* or any other type of actors (AR, PR, IM), you will be prompted by the *Actor address* details screen:

Actor address

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

* Street: Street number:

Address line 2:

PO box:

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

* City name: * Postal code:

* Country:
 Belgium

Save registration **Save & Next >**



NOTE

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

7. Enter the address details for your economic operator (you can select No if you prefer not to enter street-level information), 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:

Save registration

Save & Next >

- Enter the email addresses and other useful information regarding the contact points in your organisation. 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**.

You will be prompted by the *Regulatory Persons* screen, so that you to identify one or more regulatory person(s) within your organisation:

✓
Actor
identification

✓
Actor address

✓
Contact
details

4
Regulatory
Persons

5
Registering
Local Actor
Administrator

6
Competent
Authority

Person Responsible for Regulatory Compliance

Regulatory Persons

* First name:

* Last name:

* Email:

* Telephone number:

Telephone format example: +32 x xxx xx xx

Responsible for:

Person Responsible for Regulatory Compliance

☐ Same address as the Actor organisation address

Street information, if applicable

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

* Street:

Street number:

Address line 2:

PO box:

Latitude:

Latitude format example: -15.4543

Longitude:

Longitude format example: 178.34354353

* City name:

* Postal code:

* Country:

[+ Add a new Regulatory Person](#)

Save registration

Save & Next >



NOTE

Regulatory person contact

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

9. Enter the details of this person and specify their area(s) of responsibility. To add another person with this role, select 'Add a new Regulatory person', 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 registration has been accepted.

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 [Section 2.2.2 \[41\]: Validating user access requests](#)).

It is good practice for each actor to identify at least two LAAs (with at least one belonging to the actor itself, rather than all sub-contractor contacts).

10. Check and complete the information on the page. Upload the signed declaration – in PDF format only – 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 xx

*** Company email address:**

Street information, if applicable

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

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

Address line 2:

PO box:

Latitude: **Longitude:**

Latitude format example: -15.4543 Longitude format example: 178.34354353

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

*** Country:**



NOTE

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

- Click **Save & Next** to move to the last step, providing 'Competent Authority' details. You can add any extra information you think it 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:

- If there are multiple competent authorities that could validate your request, select the most appropriate one from the list. (A help file will be available for German

authorities, to assist with 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**.

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:

Submit your actor registration request

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

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

Confirm Cancel

- Read the information here and then click **Confirm**.
 - Your registration request is immediately saved and appears with a 'Submitted' state in your 'Pending requests' list.
 - It is given a unique application ID and 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 application is approved or rejected.

**NOTE**

The validation of the Actors registration requests are under the responsibility of the different national Competent Authorities (CAs).

We only provide a technical Support for EUDAMED application. (For non-EU requests, verification of non-EU actor registration requests are completed by authorised representatives and) validation of requests are completed by the responsible CA. 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 (except non-EU manufacturers)

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 rejected (except non-EU manufacturers)

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: [redacted]

Username: [redacted]

Email: [redacted]

EUDAMED details

Name: [redacted]

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	[redacted]	[redacted]	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

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: [text input]

* Select organisation language: All languages [dropdown]

+ Add organisation name in another language

Abbreviated organisation name: [text input]

Select abbreviated organisation name language: [dropdown]

+ Add abbreviated organisation name in another language

Previous assessment(s)

Application ID: [redacted] Date of submission: 2020-08-19

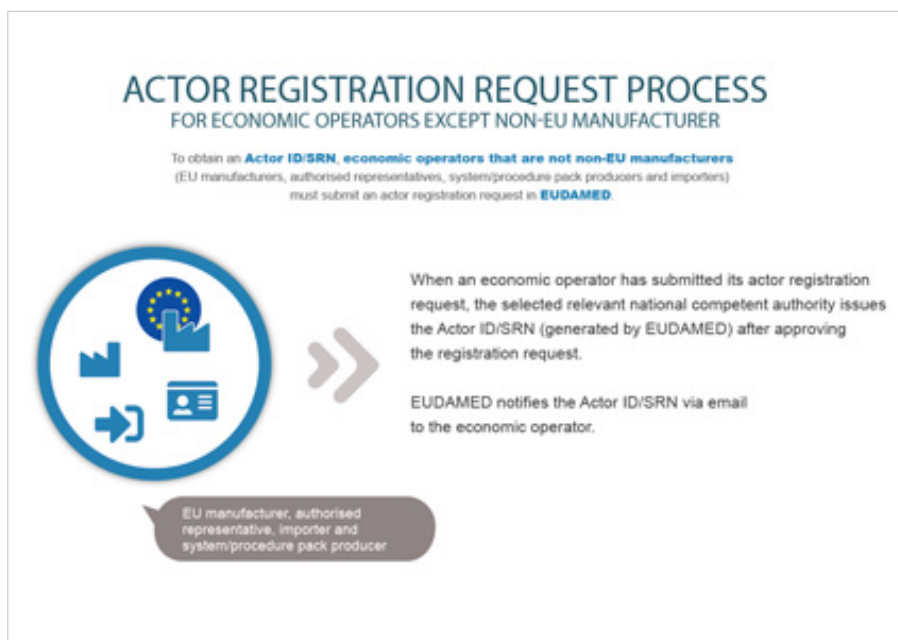
2020-08-19

Reason for rejection: Duplicate
I think this is a duplicate

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

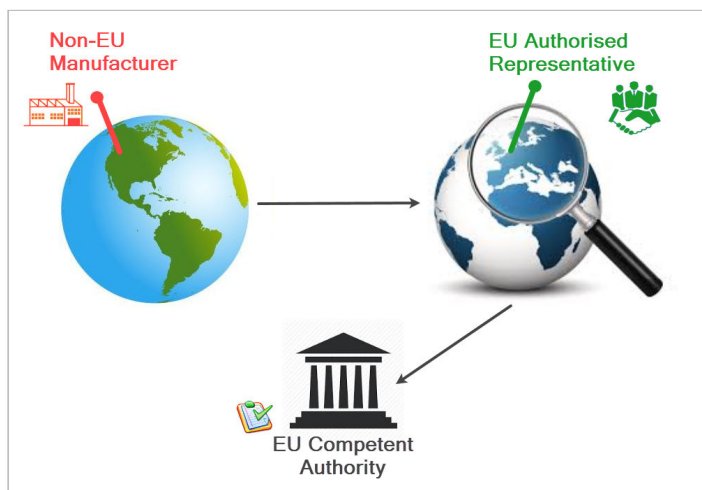
2.1.2 Registering as a non-EU manufacturer

 The image opens an infographic illustrating the process.



If you are a manufacturer who is **not registered (i.e. established) in the EU**, the procedure for registering differs from that explained in [Section 2.1.1 \[9\]](#).

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:

1. 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	Unselect 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.

- Enter the validity start and end-dates of the written mandate your organisation has provided the authorised representative.
- In the **Upload summary mandate document** section, click **Browse**, select the location of the signed mandate (**PDF only**), 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.

4. 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/extract with the start/end dates, details of the manufacturer and authorised representative and list of generic device groups covered by the mandate.

4. Check and complete the information on the page. Upload the signed declaration – in **PDF format only** – using the **Browse** button.

Click **Save & Next**.

In the final step, the competent authority that will validate your registration request (i.e. the body that is responsible for your authorised representative) is identified, with contact information.

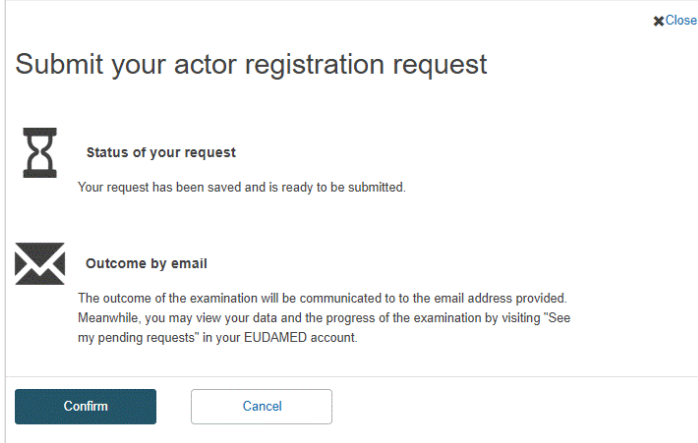
Competent Authority

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. If necessary, enter any additional information you wish to pass on to the competent authority, and then click **Preview**. A summary of your completed registration form is displayed.
6. Review the information on the form, and then click **Submit actor registration** at the bottom of the page. A confirmation window will appear:



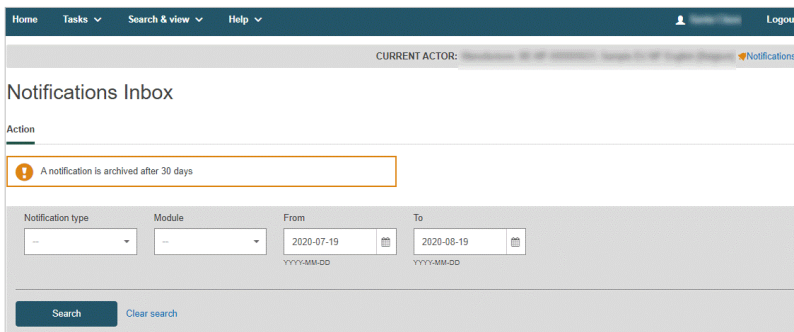
Submit your actor registration request

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

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

Confirm **Cancel**

7. Read the information in the window and click **Confirm**.
 - Your registration request is immediately saved with a *Submitted* state in your *Pending requests* list.
 - It is given a unique application ID and submitted to your authorised representative for verification (and after that, to the competent authority for validation).
 - You receive a notification email (you can view this at all times via the Notifications option, once your account has been fully registered).




Home Tasks Search & view Help

CURRENT ACTOR: [View profile](#) [View all notifications](#) [Logout](#) [Notifications](#)

Notifications Inbox

Action

 A notification is archived after 30 days

Notification type	Module	From	To
--	--	2020-07-19	2020-08-19
		YYYY-MM-DD	YYYY-MM-DD

Search **Clear search**

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 IT	Name IT	City IT	Date of request IT	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 IT	Name IT	City IT	Date of request IT	State	Actions
APP00000	Manufacturer	[redacted]	[redacted]	-	Draft	...
APP00000	Manufacturer	[redacted]	[redacted]	2020-08-19	Verified	...
[redacted]	Specialised Health Products	[redacted]	[redacted]	2020-07-12	Correction Requested	...
[redacted]	Manufacturer	[redacted]	[redacted]	2020-07-12	Submitted	...

[New actor registration request](#)

The competent authority will then validate the information, and the details of your organisation will be displayed, once they are approved.

2.1.3 Verifying non-EU manufacturer registrations

[Specific to AR Verifier]

Although the body responsible for validating a non-EU manufacturer's registration request is the relevant competent authority, an additional preliminary step is required from the authorised representative: they must verify the information provided by the manufacturer, including the uploaded document containing the (summary) mandate details.



NOTE

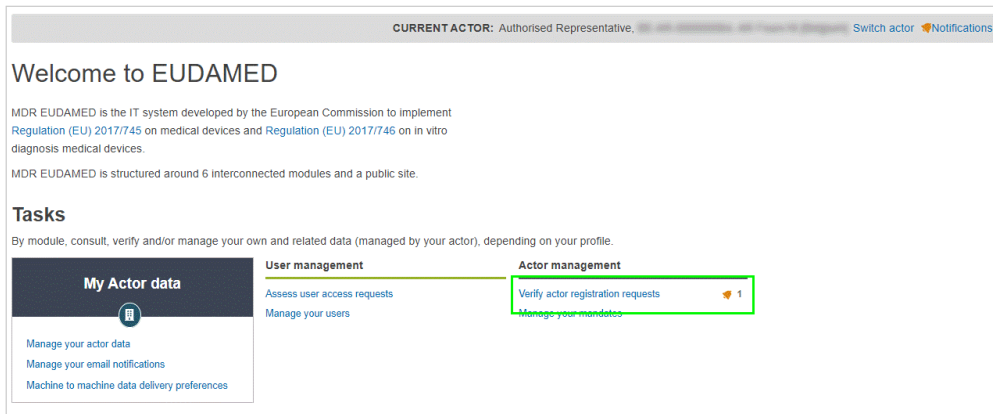
Verifier profile

Requests made by non-EU manufacturers can be verified only by users belonging to the relevant authorised representative who have a *Verifier* profile (i.e. *AR Verifiers*).

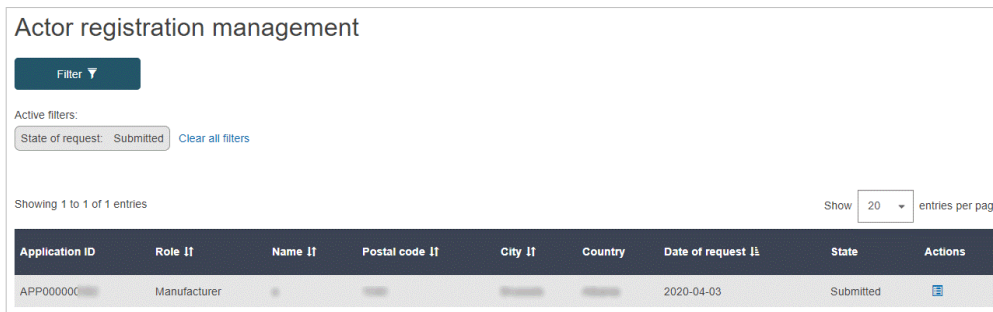
By default, the Local Actor Administrator and Local User Administrator representatives also have these rights.

To verify a non-EU manufacturer registration request

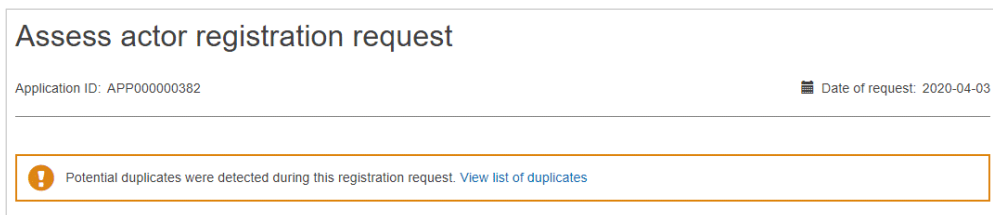
1. Log in to EUDAMED with a *Verifier*, *LAA* or *LUA* profile (for the authorised representative). If there are outstanding registration requests from non-EU manufacturers, you will see the following link in your dashboard:



- 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):



- 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 in the form. A warning message will flag possible duplicates, so select the correct registration request from the list available:



- 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	Informs 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 (other than those specified 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:

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:

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

3. To view the details for any actor, click the entry in the results list.
4. 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** 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 from the **Help > Documents** menu.

**NOTE**

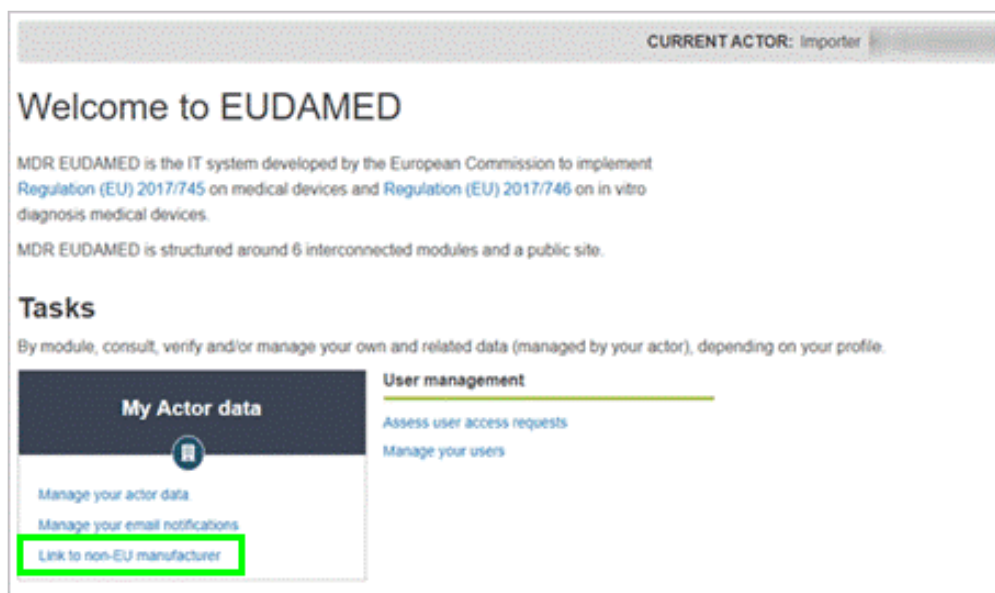
There are limitations on what search criteria you can use for bulk downloads, so certain filters will be disabled when this toggle is active. Please see the DTX service definition for more information on search criteria.

2.1.5 Linking a non-EU manufacturer to an importer

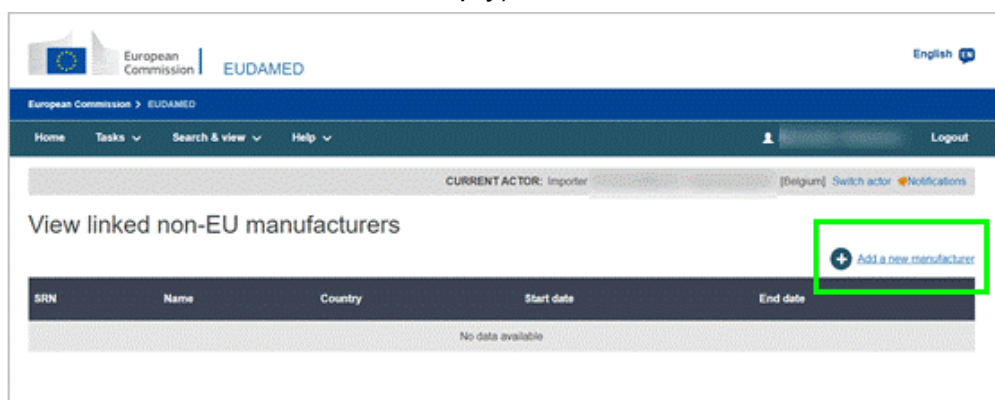
[Section specific to importers with 'Linker' profile]

To link a non-EU manufacturer to your importer:

1. 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):



- 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

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

Link a non-EU manufacturer with your importer

☐ I know the SRN

Country:

Actor / organisation name:

Find

- Enter the country and actor/organisation name, 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:

Actor / organisation name:

Find

Result

Select your actor from the list below

View details about actor	Afghanistan - Manufacturer - Actor code: AF-MF-	View details about actor
View details about actor	Afghanistan - Manufacturer - Actor code: AF-MF-	View details about actor

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

Find

Result

Select your actor from the list below

View details about actor	Afghanistan - Manufacturer - Actor code: AF-MF-	View details about actor
View details about actor	Afghanistan - Manufacturer - Actor code: AF-MF-	View details about actor

SRN:
 AF-MF-
Role:
 Manufacturer
Country:
 Afghanistan
Organisation name:

Address:

Email:

Telephone number:
 -

Add link with this manufacturer

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

Add link with this manufacturer

Enter the start date to link with this manufacturer

* Start date:

End date:

Confirm **Cancel**

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

2.1.6 Updating actor details

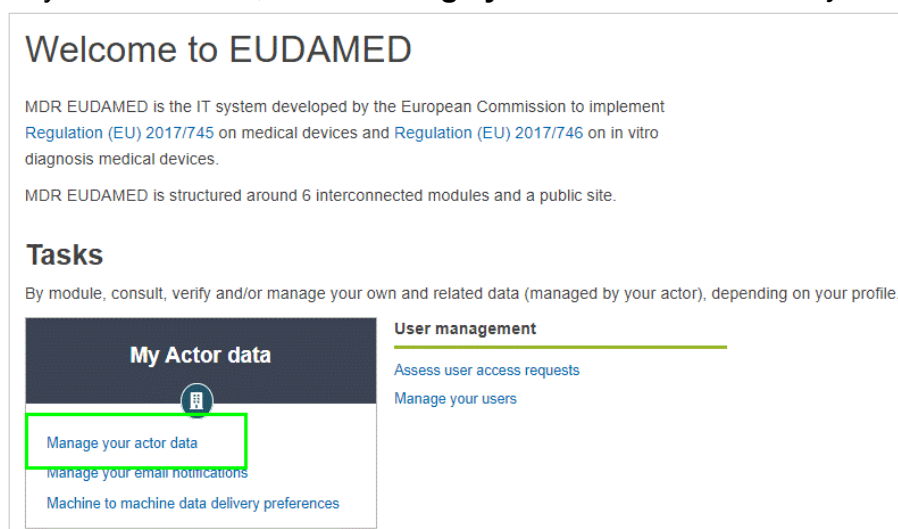
[Section specific to Local Actor Administrators (LAA)]

Once an economic operator has been validated by its competent authority and obtained an Actor ID/SRN, changes to registration details can only be made by the Local Actor Administrator.

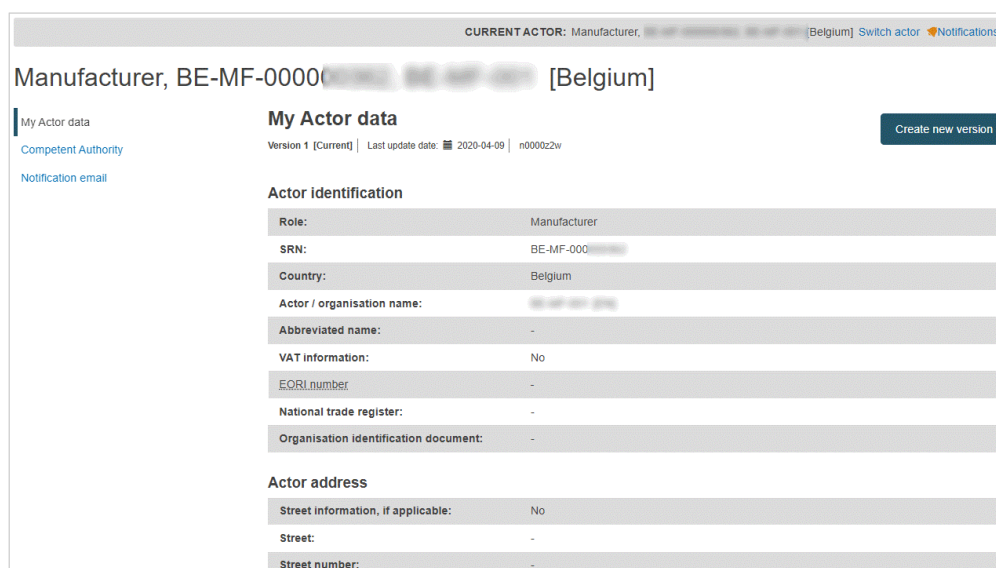
Apart from changes to mandates and notification email addresses, every change creates a new numbered version of the actor. Information is not deleted, and previous versions can be consulted at any time.

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*:



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



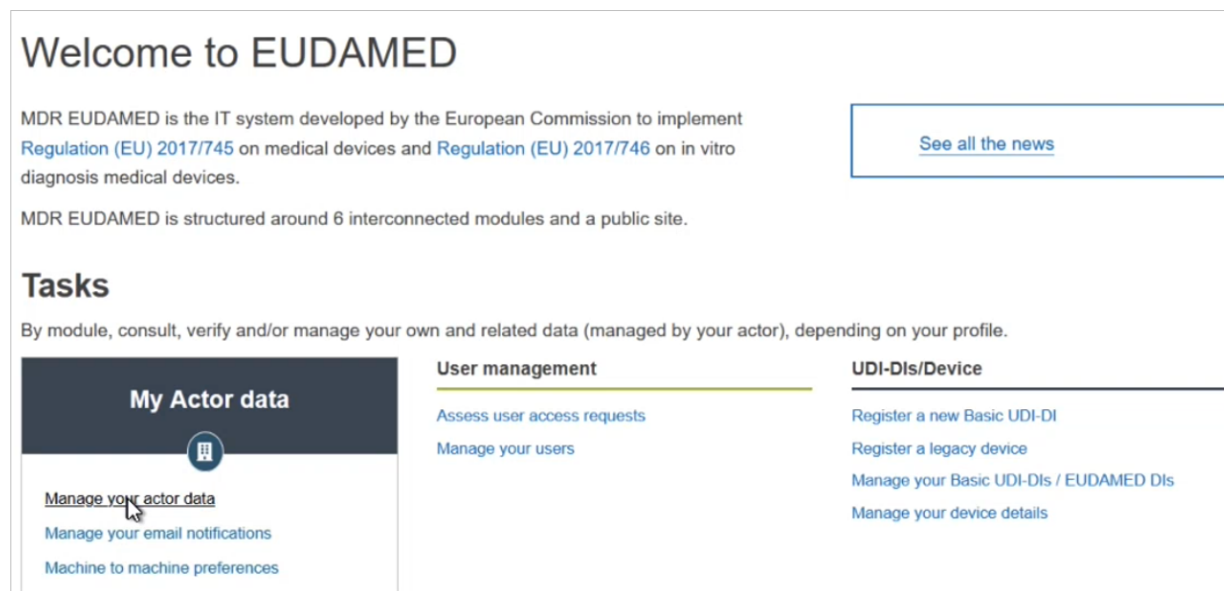
4. If you need to change some information, proceed as follows:
 1. Click **Create new version** and answer **Yes** to the confirmation message.
 2. Make all required changes in the corresponding tabs.
 3. When you are done, click **Register new version** and answer the confirmation message.

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

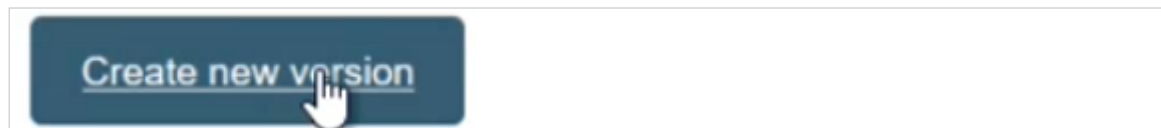


Deleting an actor's draft

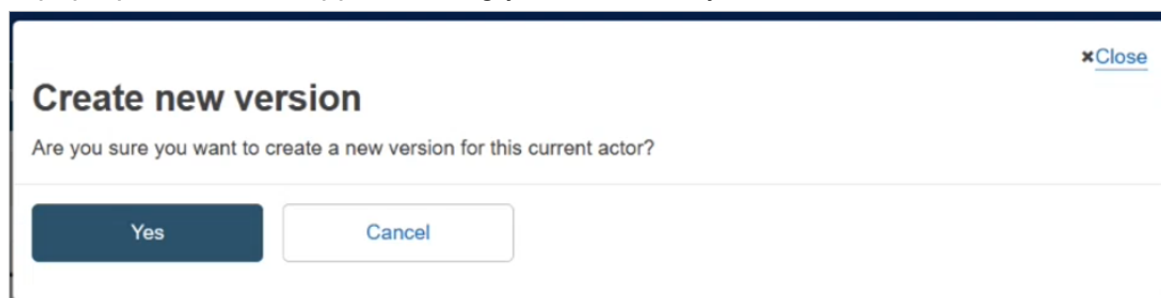
In order to delete a draft created by your own actor, on the homepage, click on **Manage your actor data**:



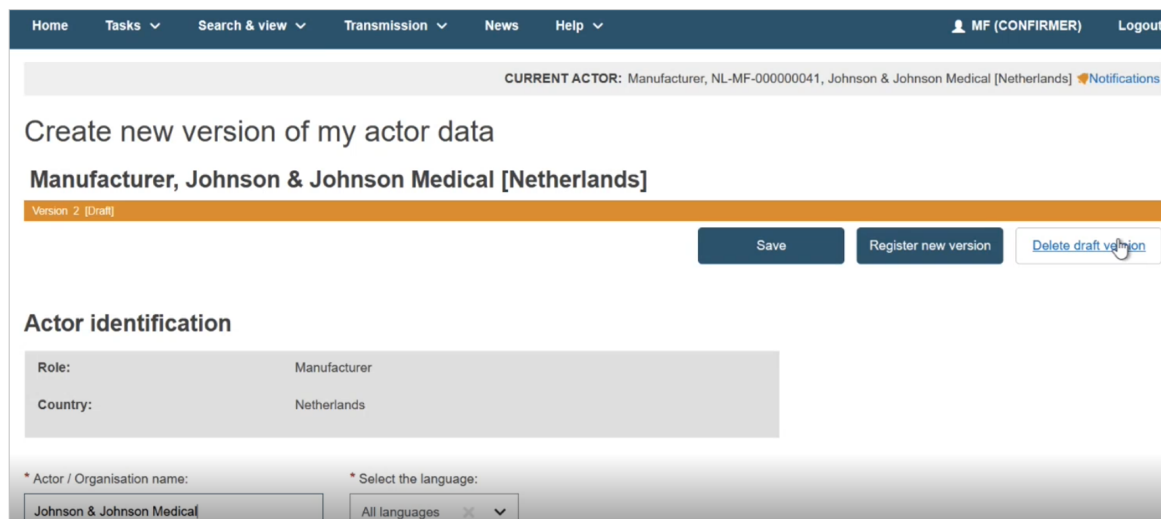
1. In the new window that opens up, click on **Create new version**:



2. A pop-up window will appear asking you to confirm your decision:



3. Once you have clicked on **Yes**, 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

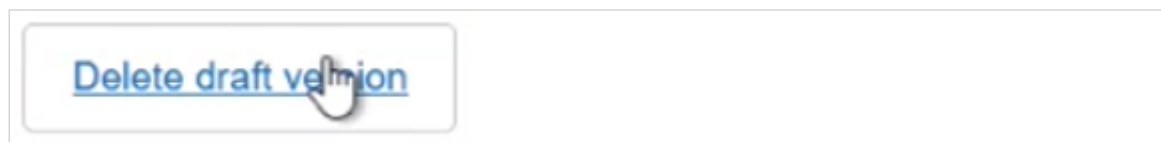
Role: Manufacturer

Country: Netherlands

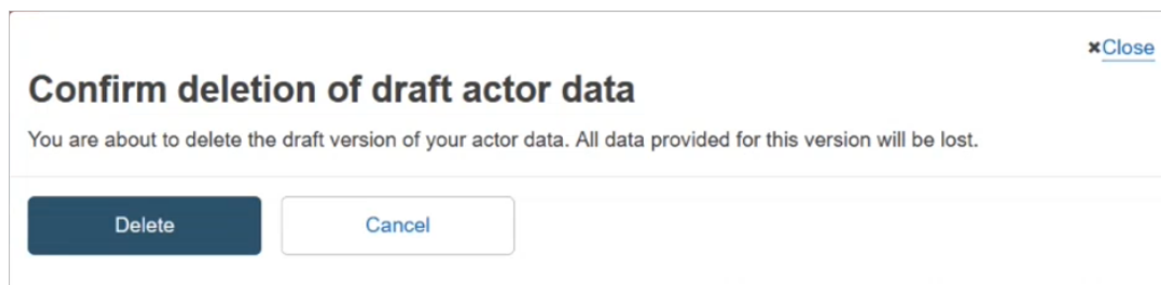
* Actor / Organisation name: Johnson & Johnson Medical

* Select the language: All languages

4. In here, you can save the changes you made or you can delete the draft, in order to delete it, click on **Delete draft version**:



5. Clicking on this will prompt another 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.

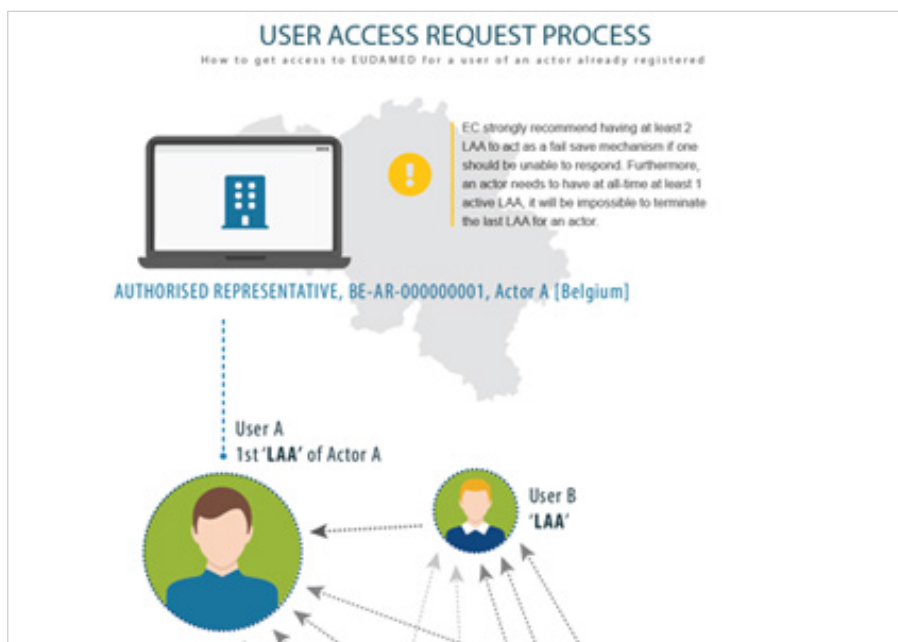
Delete Cancel

6. Once you click on **Delete** the draft will disappear from the list.

2.2 Users and user access management

2.2.1 Requesting access as a user for a registered economic operator

 The image opens an infographic that illustrates the process.



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

To request access as an economic operator 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:

European Commission | EUDAMED

European Commission > EUDAMED

Home Help ▾

User and Actor Registration

Select one of the options below

NEW ACCESS REQUEST

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

ACTOR REGISTRATION

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

EUDAMED Contact EUDAMED

- 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:

The screenshot displays the EUDAMED user account detail page. At the top, a dark blue navigation bar contains links for Home, Tasks, Search & view, and Help. On the right side of this bar, the user's name 'MedicalDev Thirtyeight' is displayed next to a 'Logout' button. Below the navigation bar, a grey banner indicates the 'CURRENT ACTOR: Manufacturer, /'. The main content area is titled 'My account(s)' and includes a link to 'My EUDAMED accounts'. The page is divided into several sections: 'EU Login details' (showing login code, first/last name, email, and preferred language), 'EUDAMED details' (showing first/last name and preferred language), 'My EUDAMED accounts' (with a sub-section for 'Current actor account'), 'Actor data' (including actor identification and address details), 'Actor notification email addresses', 'Account data' (showing profile(s) and actor information), and 'Account email & notifications'. At the bottom of the page, there are two buttons: 'New access request' and 'New actor registration request'. A green box highlights the 'New access request' button, and a green arrow points from the user's name in the top right navigation bar to this button.

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.

New access request

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

Search existing actor

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

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

* Role:

* 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:
Rue de la Paix

Email:
info@bel

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.

- 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:
[redacted]

Role:
Manufacturer

Country:
Belgium

Organisation name:
[redacted]

Address:
[redacted]

Email:
[redacted]

Telephone number:
-

Select another actor

1

My personal data

2

My user manager

3

My profile(s)

My contact email for this actor

* Email:

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

Save

Save & Next >

Cancel

8. Complete *Step 1* of the user access request process:
 1. Enter your contact/notification email address related to this request.
 2. 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 direct superior who can support your request:

New access request

Information of the actor selected

Actor code:
IT-MF-DO(00000000)

Role:
Manufacturer

Country:
Italy

Actor/Organisation name:
S&P SRL - Strada 102/A

Address:
Via Suzzani, 41, Cadriano-Grandate Dell'Inferno

Email:
contact@spid.it

Phone:
+390323000002

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:

Role:

Country:

Organisation name:

Address:

Email:

Phone number:

My personal data ✓

My user manager ✓

My profile(s) 3

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 1

☐ Local Actor Administrator

☐ Local User Administrator

☐ Validator

☒ Viewer

Active until

End date:

YYYY-MM-DD

Save

Submit ▶

Preview

Cancel



NOTE

The profiles available depend on the actor role, 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

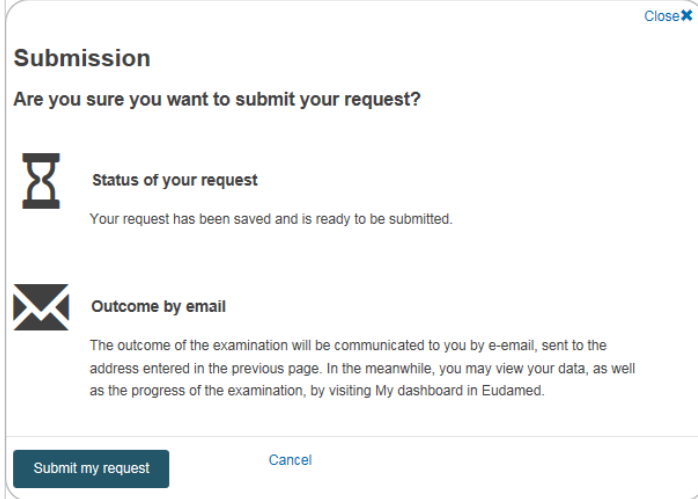
Local Actor Administrator profiles are strictly reserved for people who will be responsible for maintaining the actor's details in EUDAMED, and/or validating, updating or deleting access requests:

► **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 [Section 2.2.2 \[41\]](#), Validating user access requests).


The other profiles available depend on the role of the actor in question (except for *Viewer*, which is a non-interactive profile).


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.

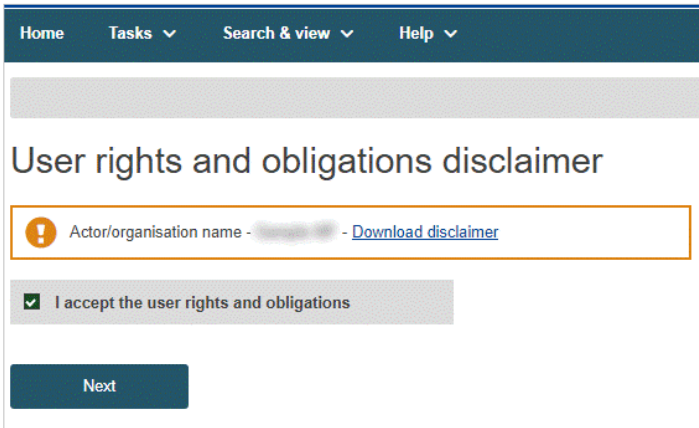
A Local Actor Administrator or Local User Administrator belonging to the actor will review and validate your request. You will be notified when your access request is approved or rejected.

- If **rejected**, 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	Megamatics	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

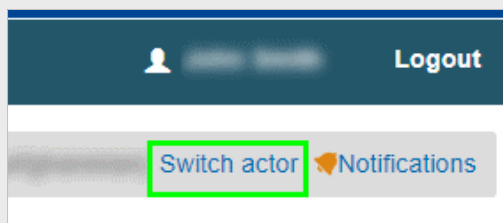
 Actor/organisation name - xxxxxx - [Download disclaimer](#)

☒ I accept the user rights and obligations

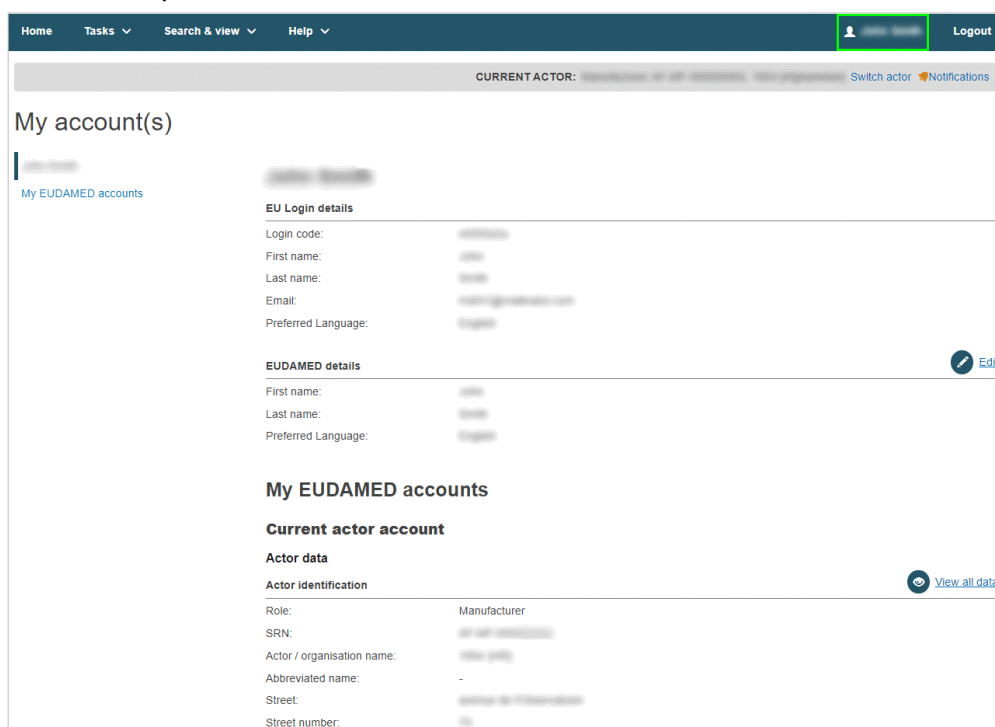
[Next](#)

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

If you have multiple EUDAMED user accounts (and therefore also rights to act on behalf of and/or access multiple actors in EUDAMED), you must select the correct actor 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*

Validating Economic Operators access requests

[Section for Local Actor Administrators and Local User Administrators]

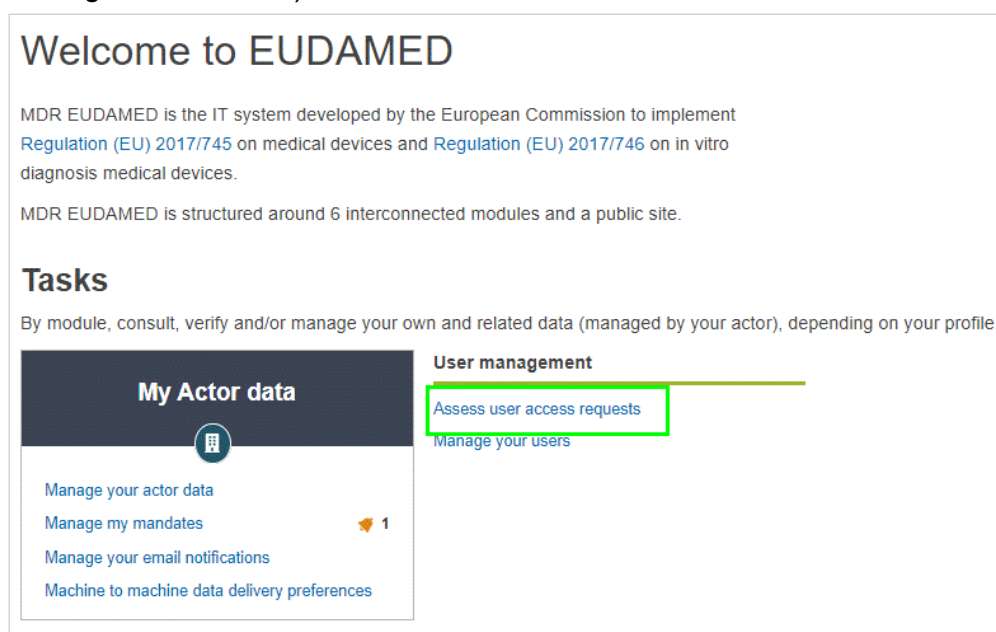
Anyone with an EU Login account can request access to a registered actor, but only a user with a *Local User Administrator* (LUA) or a *Local Actor Administrator* (LAA) profile can validate these requests. The first person who registers an actor in EUDAMED automatically receives a LAA profile. This includes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

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

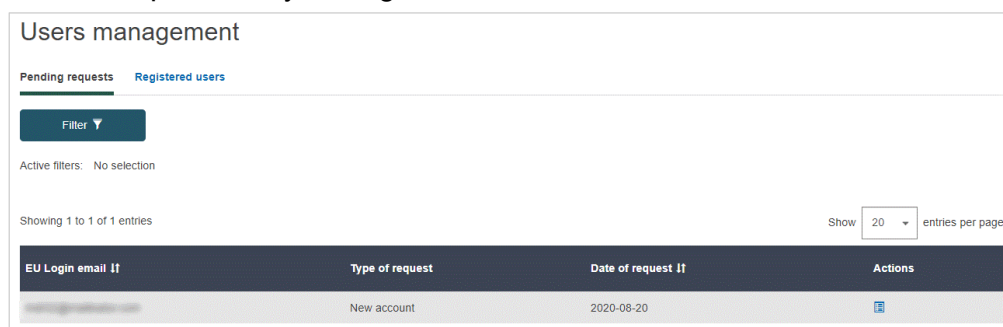
Users cannot access EUDAMED until their access request is approved.


To validate an access request

1. Log in to EUDAMED using your *LAA* or *LUA* profile for the organisation in question.
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 organisation:



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 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.
Refused request:	The request will be refused, and the requesting user is not invited to re-submit.


Assessment of user data

Outcome:


Approve ☒ Reject

* **Type of reasons:**

☐ Incomplete and/or details to correct

☐ Refused 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**.

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

Assessment : Profiles

[< Go back to Assessment part 1](#)

Default profiles

 Actor: the 'Viewer' profile is granted by default because the user has always access to his own data.

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](#)

UDI/Device:	Viewer	<input checked="" type="checkbox"/> Approved	
Actor:	Local Actor Administrator	<input checked="" type="checkbox"/> Approved	<input checked="" type="checkbox"/> 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.

2.2.2 Terminating a user account

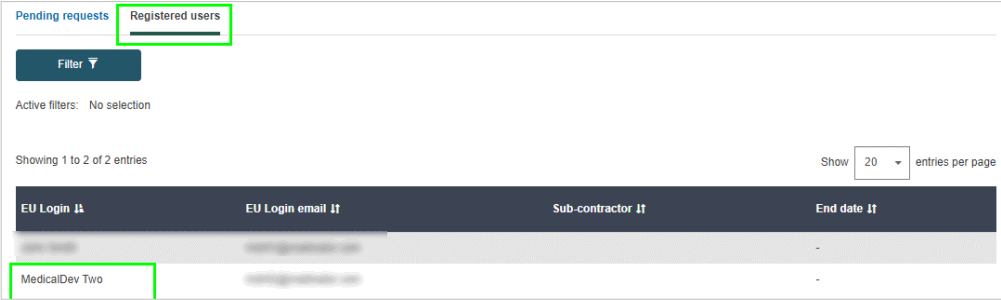
[Specific to Local Actor Administrators and Local User Administrators]

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*.

A terminated account can no longer act on behalf of, or manage, data for the associated actor. If they need regain the role at any time in the future, they will have to submit a new access request for that actor in the system.

To terminate a user account

1. Log in to EUDAMED with your *LAA/LUA* profile.
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 ID	EU Login email ID	Sub-contractor ID	End date ID
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.

2.2.3 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. A "View all data" button is located to the right of the "Actor identification" section.

- 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 "EU Login details" section includes fields for Login code, First name, Last name, Email, and Preferred Language. The "EUDAMED details" section includes fields for First name, Last name, and Preferred Language. An "Edit" button, represented by a pencil icon, is highlighted with a green box in the bottom right corner of the "EUDAMED details" section.


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)



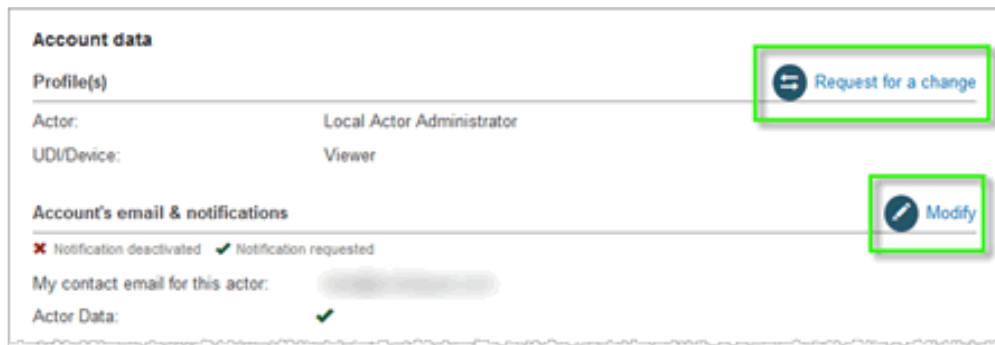
Click the right-pointing arrow next to one of the actors in the list to show their details. You can switch between actor accounts.

2.2.4 Upgrading your user profile

After a new module has been released, for security reasons you will automatically receive the lowest profile for these modules, e.g. *Viewer*. Unless you upgrade to a profile with more rights and permissions, e.g. *Confirmer*, you will not be able to perform any actions in these modules.

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. Your LAA / LUA will need to approve this request before these features will be available to you.



IMPORTANT Rules for LAAs / LUAs

- ▶ A 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 a LAA profile.
- ▶ EUDAMED requires that an actor retains one LAA, so you will be unable to remove the last user's LAA profile.

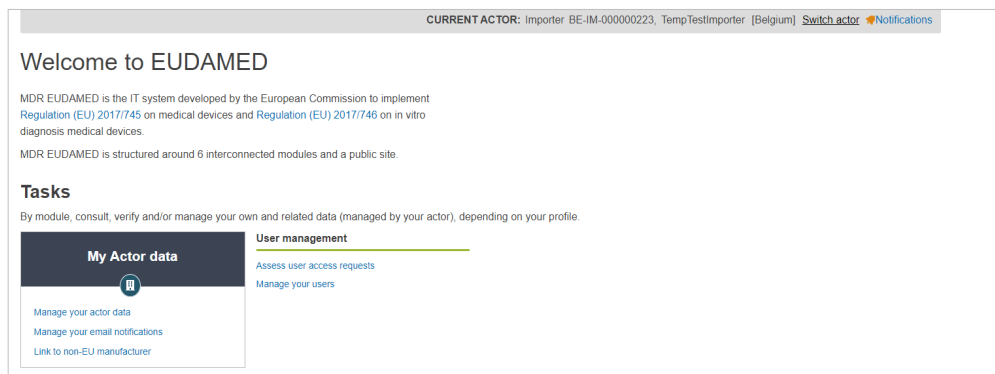
4. If you are the only user from your actor, you will need to grant access to a new user, assigning a LAA / LUA profile via the process outlined in sections 2.2.1 and 2.2.2.

- Once you have approved access for this second LAA / LUA, this user will then be able to approve your request to upgrade your profile.

2.2.5 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).

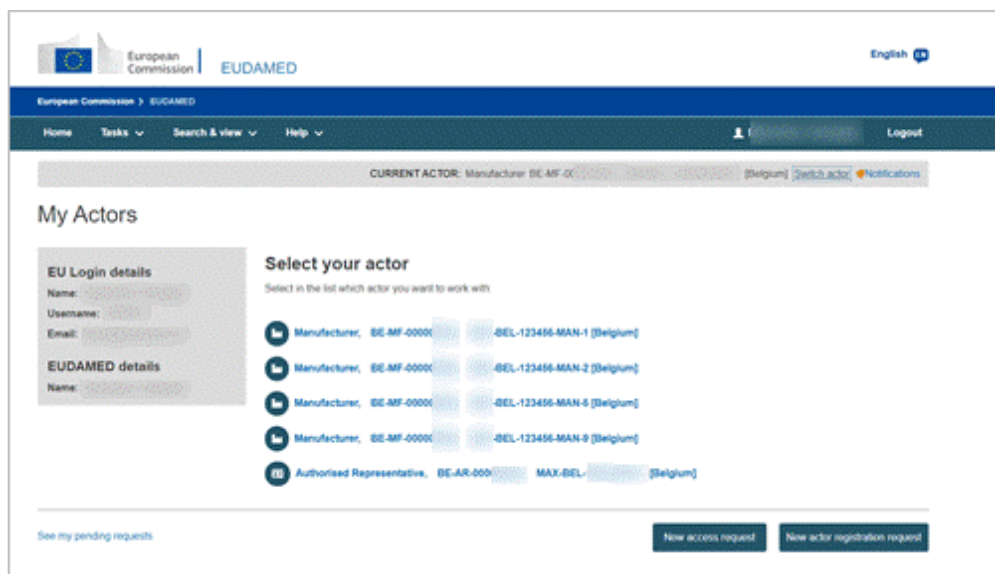
- Go to the Dashboard:



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



- Select an actor from the list shown:

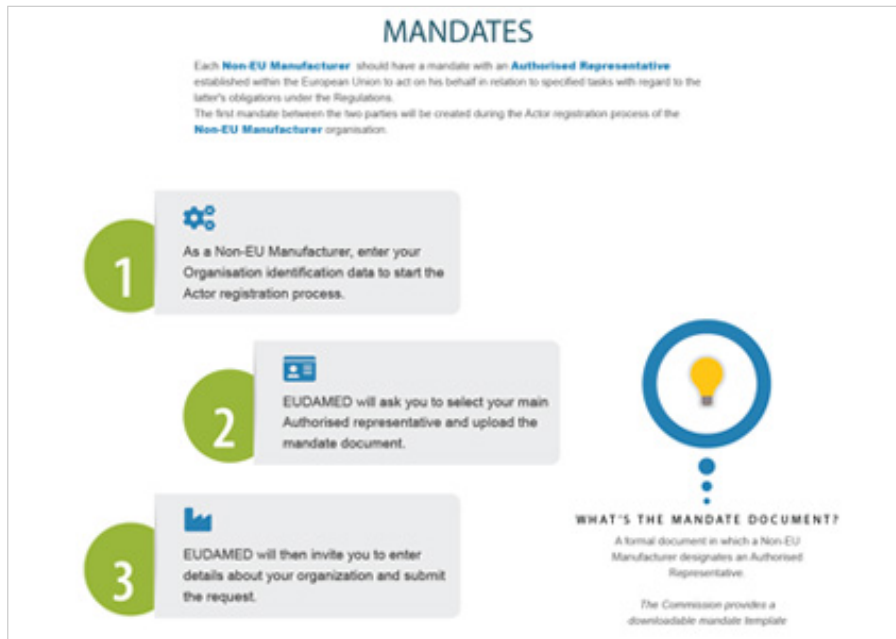


2.3 Managing mandates

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 manufacturer can decide to **terminate** before this date.

 The image opens an infographic illustrating the process.



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 the mandate they have agreed with an EU authorised representative. If they have agreed mandates with other authorised representatives, 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	AR name	AR SRN	End date	State
MD-AF-BE-00000	AR name	BE-AR-00000	2020-06-08	Registered (Expired)
MD-AF-BE-00000	AR name	BE-AR-00000	2030-04-04	Terminated [MF]
MD-AF-BE-00000	AR name	BE-AR-00000	-	Registered
MD-AF-BE-00000	AR name	BE-AR-00000	-	Rejected



NOTE

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

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

Add a new mandate

Manufacturer information

Organisation name:
 SRN:
 Address:
 Telephone number:
 Email:

Select an authorised representative

☒ I know the SRN

* SRN:

Mandate validity dates

* From:
 YYYY-MM-DD

To:
 YYYY-MM-DD

* Upload mandate summary document

**NOTE**

If you don't 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.

- 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 SRN, uncheck **I know the 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**:
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.

7. Click **Submit**.

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

View my mandates

Manufacturer, **MD-AF-000000, 1234 (placeholder)** [+ 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	MD-AF	BE-AR-00000	-	Registered
MD-AF-BE-00000	MD-AF	BE-AR-00000	-	Submitted

2.3.2 Create a new mandate version

[Specific to Non-EU manufacturers]

To create a new mandate version

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

Welcome to EUDAMED


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

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

Tasks

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

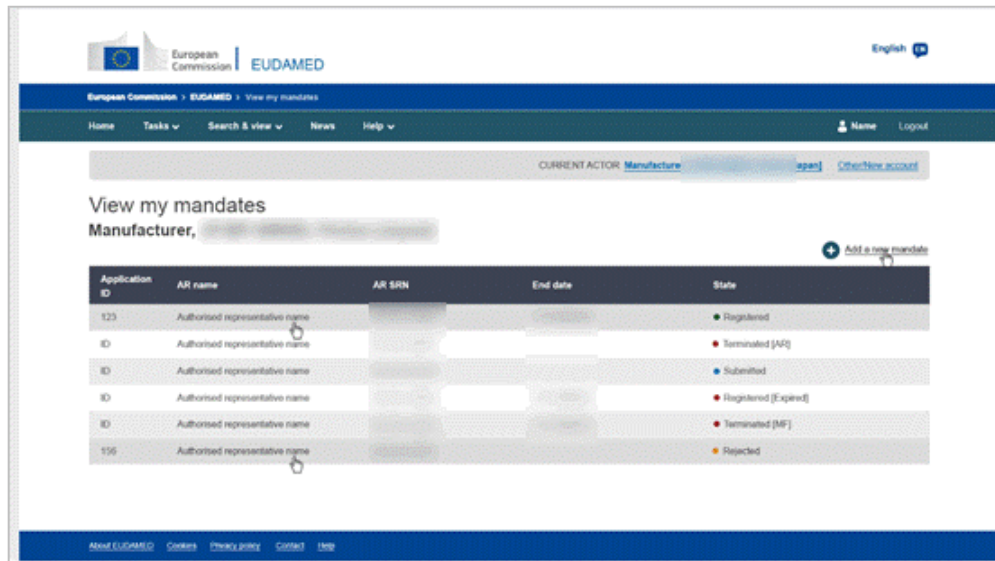
My Actor data

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

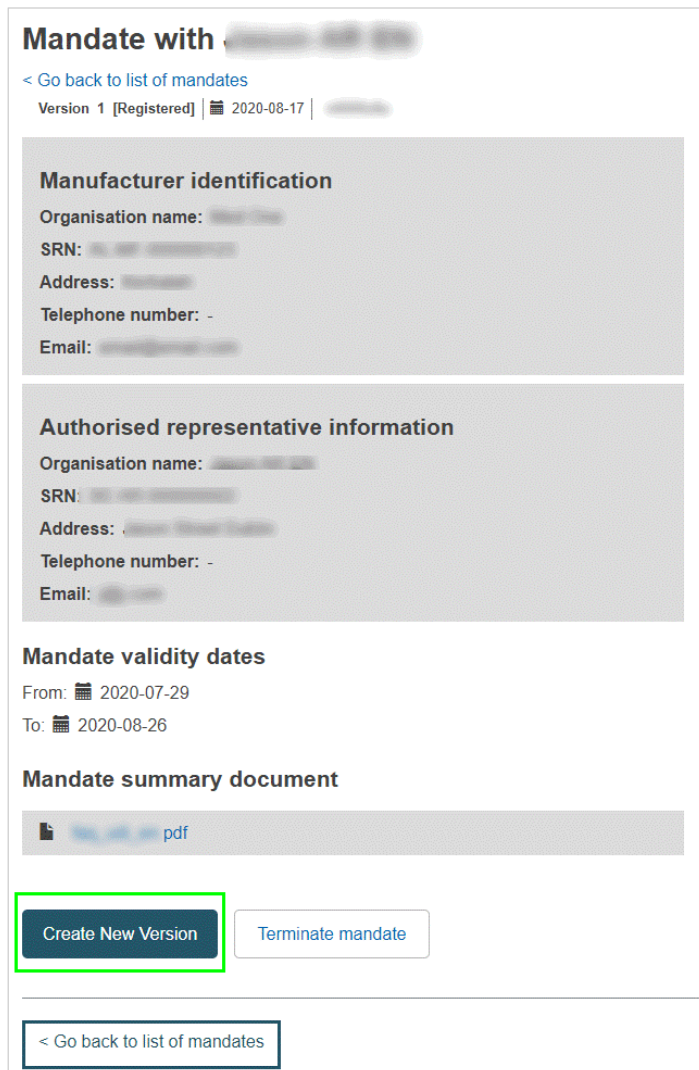
User management

- Assess user access requests
- Manage your users

3. Select the target mandate from the list on the next page:



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



- Upload the new mandate summary document and change the validity dates accordingly.

2.3.3 Verifying mandates

[Specific to authorised representatives with a Verifier profile]

To verify a mandate

- 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
 [PDF icon] .pdf

Decision
 Approve ☒ Reject

Remarks:
 [Text box]

Apply Cancel

< Go back to list of mandates

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

2.3.4 Terminating a mandate

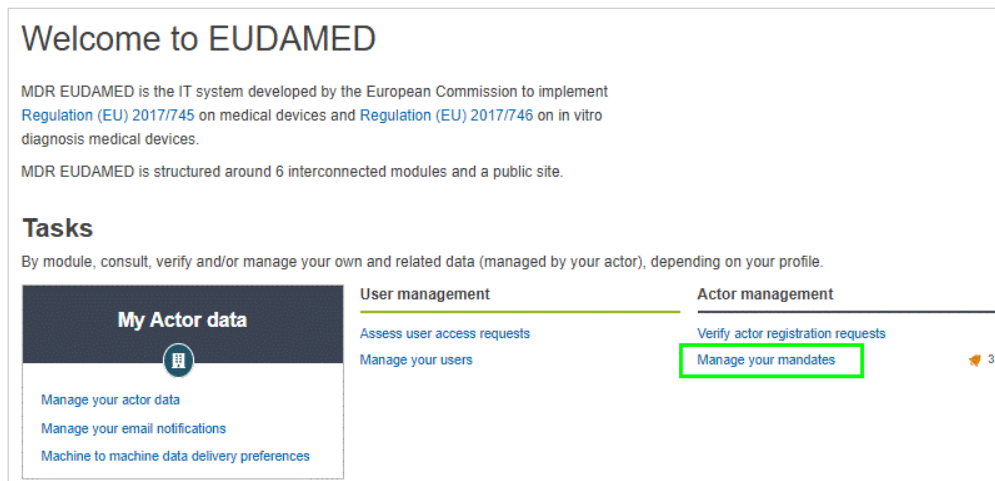
[Specific to authorised representatives and non-EU manufacturers]

A mandate is normally valid until its end-date, as specified in the written agreement (mandate). However, the authorised representative or manufacturer may decide to terminate a mandate at any point. Either the authorised representative or the manufacturer can mark a mandate as Terminated in EUDAMED. The procedures are very similar.

If you are an unauthorised representative

To terminate a mandate

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



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

- Log in to EUDAMED and select **Manage my mandates** under the *My Actor* data section of your Dashboard. 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	AR name	AR SRN	End date	State
MD-AF-BE-00000	[redacted]	BE-AR-0000	2020-06-08	Registered (Expired)
MD-AF-BE-00000	[redacted]	BE-AR-0000	2030-04-04	Terminated [MF]
MD-AF-BE-00000	[redacted]	BE-AR-0000	-	Registered

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

3. Click **Terminate mandate** at the bottom of the mandate detail page.
4. Use the calendar icon to select the termination date.
5. Click **Confirm**

