

Guide to Using **EUDAMED**

*Actor registration module
for economic operators*

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1. Introduction

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 **6 interconnected modules** and a **public site**:

- Actor and 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

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.

1.2 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
- Understanding user profiles and access grants/rights

1.2.1 Starting and ending a EUDAMED session

‘Playground’ environment

EUDAMED is also available in a Playground environment, serving exclusively to experiment with the application: <https://webgate.training.ec.europa.eu/eudamed-play>

All information of this environment is dummy (including the Actor ID/SRN) and will never be moved to the production environment. The Playground access needs a separate registration.

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 – read more here <https://webgate.ec.europa.eu/cas/help.html>).

◆ To start EUDAMED

1. Go to <https://webgate.ec.europa.eu/eudamed>

Result: The *Welcome to EUDAMED* page appears:

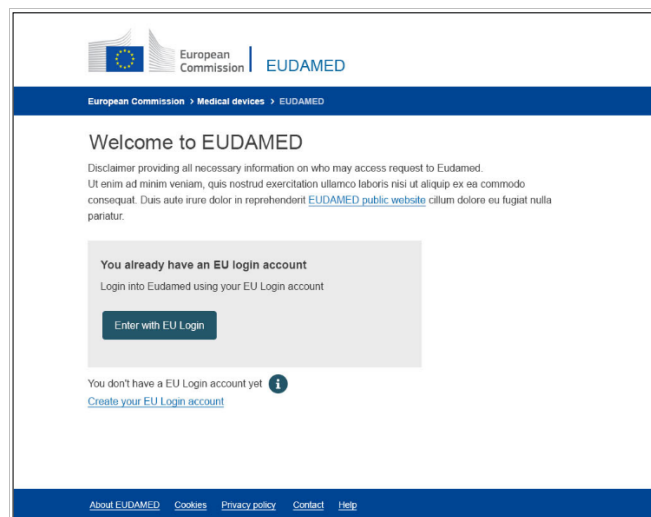


Figure 1 – EUDAMED Welcome page

2. Click **Enter with EU Login**.

(alternatively, select **Create your EU Login account** if you do not have one yet).

Result: The first part of the *EU Login – Sign in* page prompts you to enter your **email address**:

This screenshot shows the 'EU Login' sign-in page. At the top, there's a yellow banner with a cookie policy notice. Below it, the 'EU Login' logo and tagline 'One account, many EU services' are visible. The main heading is 'Sign in to continue'. A form prompts the user to 'Use your e-mail address' with a text input field and a 'Next' button. There are links for 'Create an account' and 'Or use the eID of your country' with a 'Select your country' button. At the bottom, it encourages downloading the EU Login app from the App Store, Google Play, or Microsoft.

Figure 2 – EU Login: Sign in page 1: email address

3. Enter your (work) email address or username and click **Next**.

Result: The 2nd part of the *EU Login – Sign in* page prompts you to enter your **password**:

EU Login issues?

■ **Forgot your password?**

Click 'Lost your password?' on this screen.

■ **Change your password**

Go to
<https://webgate.ec.europa.eu/cas/change/changePassword.cgi>

■ **View/edit your account**

Go to
<https://webgate.ec.europa.eu/cas/userdata/myAccount.cgi?>

This screenshot shows the second part of the 'EU Login' sign-in process. It features a 'Welcome back' message with a blurred email address and '(External)' label. There are links for 'Sign in with a different e-mail address?' and 'Lost your password?'. A 'Password' input field is present, followed by a 'Choose your verification method' dropdown menu set to 'Password'. A 'Sign in' button is at the bottom. The page also includes a cookie policy notice and app download links for the App Store, Google Play, and Microsoft.

Figure 3 – EU Login: Sign in page 2: password

4. Enter your EU Login password and click **Sign in**.

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

Next steps

- **Want to register your organisation as an actor in EUDAMED?**
See section 2.1.1
- **Need access as a user, for a registered economic operator?**
See section 2.2.1

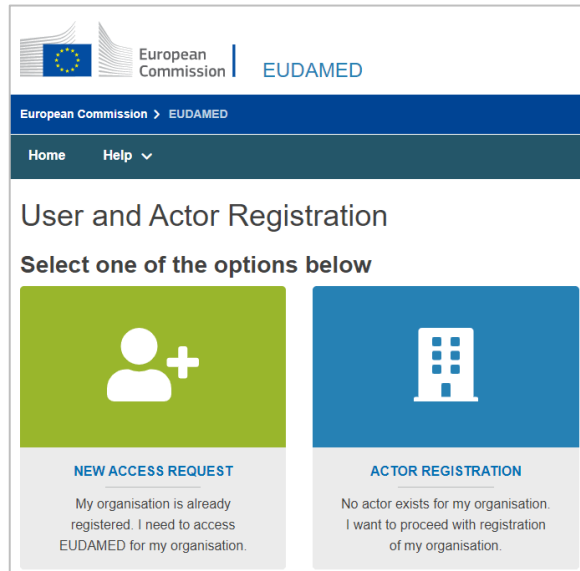


Figure 4 – EUDAMED User and Actor Registration page

◆ To quit EUDAMED

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

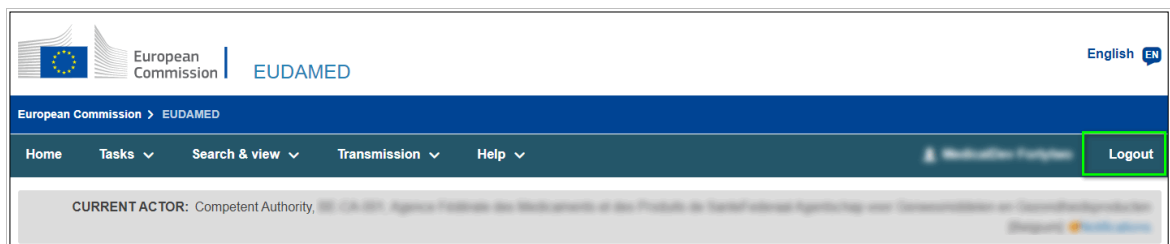


Figure 5 – Logging out

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

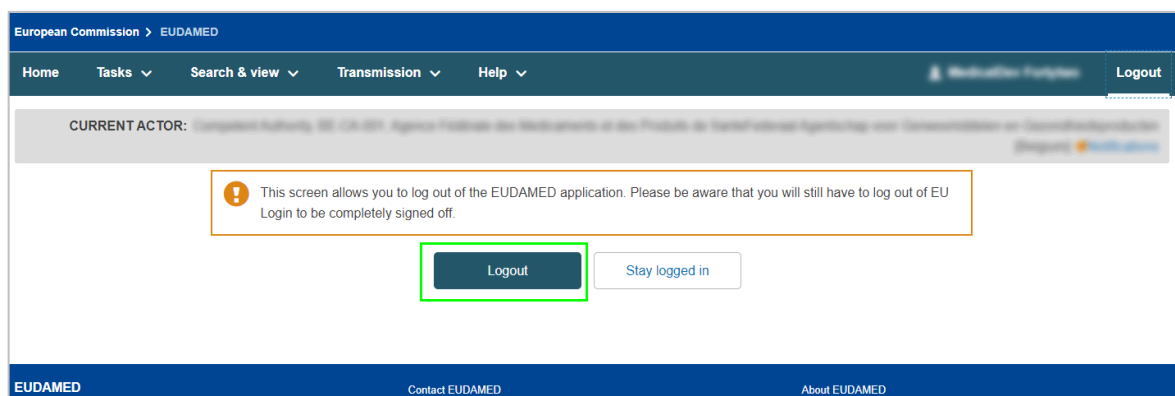


Figure 6 – Logout confirmation

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

1.2.2 Basic concepts

Actor

Actors involved in EUDAMED are:

- **Supervising bodies**
 - European Commission
 - Competent authorities (CAs), including designating authorities
 - Notified bodies (NBs)
- **Economic operators**
 - Manufacturers
 - System and procedure pack producers
 - Authorised representatives
 - Importers
- **Sponsors**

Definitions

- **Manufacturer** – see Article 2(30) of [Regulation 2017/745](#)
- **Authorised representative** – see Article 2(32) of [Regulation 2017/745](#)
- **Importer** – see Article 2(33) of [Regulation 2017/745](#)
- **Sponsor** – see Article 2(49) of [Regulation 2017/745](#)
- **System/procedure pack producer** – any individual or organisation who places procedure packs and/or systems on the EU market
- **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 & profiles

Each user has 1 or more account(s) but may access EUDAMED with only 1 account at a time.

Each EUDAMED account is associated one of the following actors:

- **manufacturer**
- **authorised representative**
- **system/procedure pack producer**
- **importer**

Each of these actors has a specific role, set out in user profiles for each module of the system that they need to use. The profile describes the specific actions they can perform in that module (user profiles are module-specific).

Your user profile is determined by your actor (see table). E.g. in the actor module, the 'Verifier' profile is only available to authorised representatives.

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 lower profiles.

User profiles per actor & their hierarchy

Authorised representative	Manufacturer	System & procedure pack producer	Importer
LAA	LAA	LAA	LAA
LUA	LUA	LUA	LUA
Verifier	Mandate manager	-	Linker
Viewer	Viewer	Viewer	Viewer

2. Managing actors & user accounts

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The **Actors** module ensures that all actors using EUDAMED, including economic operators, have been authenticated.

There are 2 ways to gain access to EUDAMED:

1 – REQUEST REGISTRATION FOR AN ECONOMIC OPERATOR

Register your actor in EUDAMED with the appropriate actor role (an organisation with a specific actor role is considered an actor in EUDAMED).

- the person who performs the registration automatically becomes Local Actor Administrator 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.

2 – REQUEST ACCESS AS A USER OF A REGISTERED ECONOMIC OPERATOR

If your organisation 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 required user profile for that actor.

2.1 Managing actors

2.1.1 Registering as an economic operator

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
- authorised representative
- system/procedure pack producer
- importer

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. This user will become the **Local Actor Administrator** once the registration is validated.

EU manufacturers

If you are officially registered ('established') in the EU, your details will be assessed by the competent authority in that country.

Non-EU manufacturers

If you are not registered in the EU, you must, when registering in EUDAMED, identify your **registered authorised representative** on EU territory.

Your details will first be sent to them for verification (and then to the competent authority).

These 2 different registration procedures, i.e. for economic operators (except non-EU manufacturers) and non-EU manufacturers, will be described in the following pages.

Multiple roles

If your organisation has more than one role (2 or more of the 4 types of economic operator), you must make separate actor registrations for each.

2.1.1.1 Registering as an economic operator (except non-EU manufacturers)

◆ To register your organisation

1. Log in to EUDAMED with your EU Login account (see 1.2.1).

Result: EUDAMED opens with the *User and Actor Registration* page:

Figure 7 – EUDAMED User and Actor Registration page

2. Select the **ACTOR REGISTRATION** box on the “User and Actor Registration” page.

Result: You are presented with a disclaimer:

Figure 8 – Actor registration: disclaimer page

3. Read the disclaimer, select the **I have read the disclaimer** checkbox and click **Next**.

Result: You are prompted to enter general 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:

* Country:

* Actor / organisation name:

[Next](#)

Figure 9 – Actor registration: initial page, 'Create new actor'

4. Select the role and country, enter the name of your organisation (actor) and click **Next**.

Result: Screen ① of the actor registration process appears:

① Actor identification

② Actor address

③ Contact details

④ Regulatory Persons

⑤ Registering Local Actor Administrator

⑥ Competent Authority

Actor identification

* Role:
Manufacturer

* Country:
Belgium

* Organisation name:

* Select organisation language:

+ [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 >](#)

Figure 10 – Actor registration: step 1, 'Actor identification'

5. Enter all the information needed to identify your economic operator: VAT, EORI and national trade register. Please note that these three fields **cannot be updated** once the Actor ID/SRN is issued as they identify a legal entity, and if any of them change you must request a new actor registration. 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. Check if you have one in the [EORI database](#). If not, contact the [customs authorities](#) in the country where you

are registered.

Click **Save & Next**.

Result: Step 2 appears:

The screenshot shows the 'Actor address' step of the registration process. At the top, a progress bar indicates the sequence of steps: 1. Actor identification (completed), 2. Actor address (current step), 3. Contact details, 4. Regulatory Persons, 5. Registering Local Actor Administrator, and 6. Competent Authority. The main form area is titled 'Actor address' and contains several sections. The first section, 'Street information, if applicable', has a toggle switch set to 'Yes' and a note stating 'Street information is required unless you select the option - No'. Below this are input fields for 'Street', 'Street number', and 'Address line 2'. The next section is 'PO box' with an input field. This is followed by 'Latitude' and 'Longitude' fields, with format examples provided: '-15.4543' for latitude and '176.34354353' for longitude. The 'City name' and 'Postal code' fields are also present, along with a 'Country' dropdown menu currently set to 'Belgium'. At the bottom of the form are two buttons: 'Save registration' and 'Save & Next >'.

Figure 11 – Actor registration: step 2, 'Actor address'

6. 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**.

Result: Step 3 appears:

The screenshot displays the 'Contact details' step of the registration process. The progress bar at the top shows steps 1 through 6, with step 3, 'Contact details', being the active step. The form is titled 'Actor contact details' and is divided into two main sections. The first section, 'Contact details for Competent Authorities', includes a note that these details are visible only to competent authorities. It contains input fields for 'First name', 'Last name', '* Email', and 'Telephone', with a telephone format example of '+32 x xxx xx xx'. The second section, 'Public contact details', includes a note that these details are visible to the public. It contains input fields for '* Email', 'Telephone', and 'Web site', with a telephone format example of '+32 x xxx xx xx'. At the bottom of the form are two buttons: 'Save registration' and 'Save & Next >'.

Figure 12 – Actor registration: step 3, 'Contact Details'

7. Enter the email addresses and other useful information about the contact points in your organisation.

There are separate areas for the contacts that should be used by competent authorities and those open to the public.

Click **Save & Next**.

Result: Step 4 prompts you to identify 1 or more regulatory person(s) within your organisation.

The screenshot shows the 'Person Responsible for Regulatory Compliance' form in the EUDAMED Actor module. At the top, a progress bar indicates the current step is 4, 'Regulatory Persons', with previous steps (1-3) completed and subsequent steps (5-6) pending. The form is divided into two main sections. The first section, 'Regulatory Persons', contains fields for:

- * First name: [text input]
- * Last name: [text input]
- * Email: [text input]
- * Telephone number: [text input]
- Telephone format example: +32 x xxx xx xx
- Responsible for: [text input]

 The second section, 'Person Responsible for Regulatory Compliance', includes:

- A checkbox: ☐ Same address as the Actor organisation address
- A sub-section 'Street information, if applicable' with a toggle for 'Yes' (selected) and 'No'. A note states: 'Street information is required unless you select the option - No'.
- Fields for: * Street, Street number, Address line 2, PO box, Latitude, Longitude, * City name, * Postal code, and * Country (dropdown).
- Latitude format example: -15.4543, Longitude format example: 178.34354353
- A link: '+ Add a new Regulatory Person'
- Buttons at the bottom: 'Save registration' and 'Save & Next >'.

Figure 13 – Actor registration: step 4, 'Regulatory persons'

Regulatory person

The person in your organisation who is responsible for ensuring it complies with the regulations. See Article 15 of [Regulation 2017/745](#).

8. Enter the details of this person and specify the area(s) they are responsible for.

To add another person with this role, select **Add a new Regulatory person**.

Click **Save & Next**.

Result: Step 5 prompts you to confirm you will be the Local Actor Administrator for the organisation:

The screenshot shows a multi-step registration process. At the top, a progress bar indicates six steps: 1. Actor identification, 2. Actor address, 3. Contact details, 4. Regulatory Persons, 5. Registering Local Actor Administrator (current step), and 6. Competent Authority. The main heading is 'Registering Local Actor Administrator'. Below it, there are three sections: 'EU Login personal data' with fields for First name, Last name, and Email; 'EUDAMED personal data' with fields for First name and Last name; and 'EUDAMED email of the user for the actor' with an Email field. A 'Signed declaration' section contains a warning box with an exclamation mark icon and the text: 'Please use the declaration template below. Only signed declarations following this template will be considered'. Below this is a link 'Download signed declaration template' and a 'Browse' button. At the bottom, there is a question '* Are you a sub-contractor for this actor?' with radio buttons for 'No' and 'Yes'. Two buttons at the bottom are 'Save registration' and 'Save & Next >'.

Figure 14 – Actor registration: step 5, 'Registering Local Actor Administrator'

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: Validating user access requests).

*It is good practice for each actor to have **at least 2** LAAs (and at least one of them should not belong to a sub-contractor).*

9. Check and complete the information on the page.

Upload the signed declaration – **in PDF format only** – using the **Browse** button.

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

* 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:

[Save registration](#) [Save & Next >](#)

Figure 15 – Actor registration: Step 5, 'Are you a sub-contractor for this actor?'

10. Enter the sub-contractor details and click **Save & Next** to move to the last step.

Result: Step **6** appears:

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 >](#)

Figure 16 – Actor registration: Step 6, 'Competent Authority'

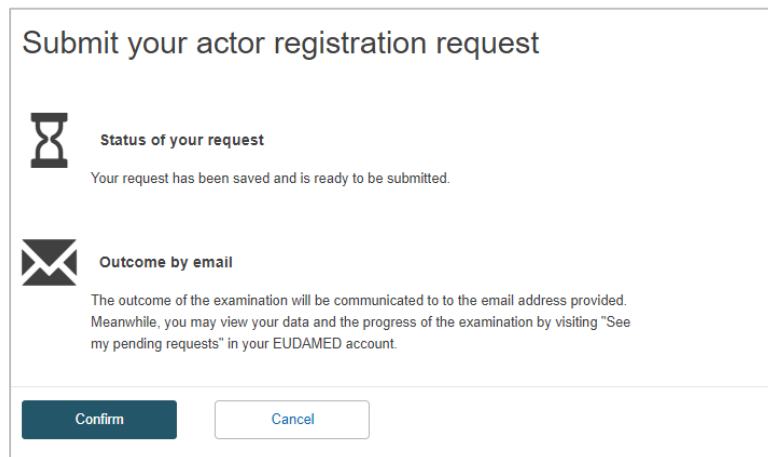
11. Select the competent authority that will validate your registration request (if it is not already pre-completed).

You can add any extra information you think might be relevant for the competent authority.


12. To view a summary of your completed registration form, to review the information before submitting, click **Preview**.


13. Review the information on the form, and then click **Submit actor registration** at the bottom of the page.

Result: 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.

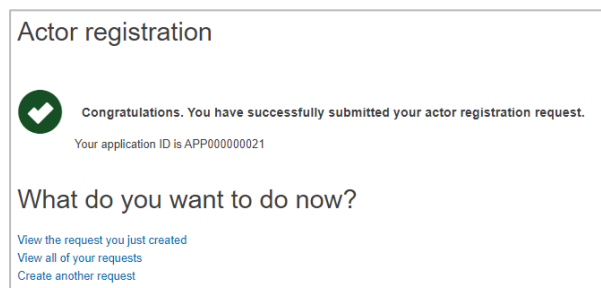
[Confirm](#) [Cancel](#)

Figure 17 – Submission confirmation


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

Results:

- 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 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](#)

Figure 18 – Confirming you want to submit

15. You will be notified when your application is approved or rejected.

♦ **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.

Result: You can download the disclaimer by clicking on **Download disclaimer** in the orange box:

Figure 19 – Confirming your registration: disclaimer

2. Click on **I accept the user rights and obligations** and then click **Next**.

Result: You will be prompted to validate your email address for the Actor module:

Figure 20 – Validating your email address

♦ **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'.

Result: The pending requests page shows the list of registration requests and their states:

Figure 21 – My pending requests page

2. Click the actions button next to your request. You can view and edit your registration request if it has the state "Correction requested".

⚠ **Requests with the in state "Refused" cannot be edited or resubmitted.**

Result: The reason given by the competent authority for the rejection is displayed:

Actor identification

* Role:
Manufacturer

* Country:
Belgium

* Organisation name:
[Text input field]

* Select organisation language:
All languages [Dropdown menu]

+ Add organisation name in another language

Abbreviated organisation name:
[Text input field]

Select abbreviated organisation name language:
[Dropdown menu]

+ Add abbreviated organisation name in another language

Previous assessment(s)

Application ID: [Text]

Date of submission: 2020-08-19

Reason for rejection: Duplicate
I think this is a duplicate

Figure 22 – Reason for rejection and resubmitting your request

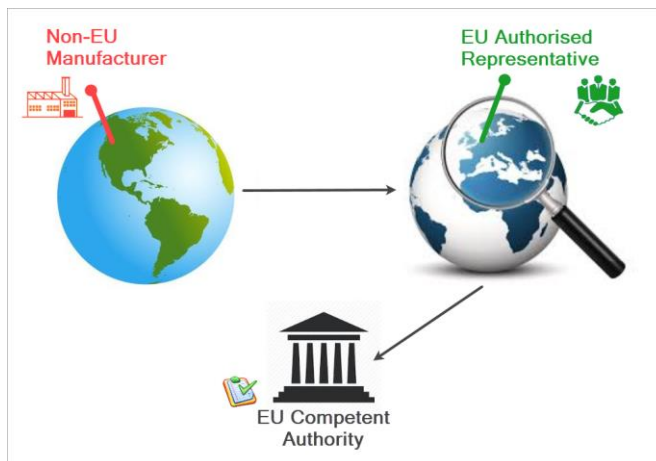
- For requests flagged as “*Correction requested*”, change and resubmit them for validation as appropriate.

2.1.1.2 Registering as a non-EU manufacturer

If you are a manufacturer who is **not registered ('established') in the EU**, the procedure for registering differs from that explained in section 2.1.1.1.

You must also identify the authorised representative who you have a mandate with (and if you have more than one, identify which is the main representative with an Actor ID/Single Registration Number (SRN)).

Your authorised representative will verify your registration details before the request is submitted to the competent authority for validation. To do this, they must have previously 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.

Result: You are presented with an online disclaimer:

Actor registration

Disclaimer

Submission

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

Notification

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

Status of your request

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

Outcome by email

If your request is approved, you will be authorised to carry out Local Administrator tasks for the actor under registration (See the User Guide)

☐ I have read and agree to the above disclaimer

Next

Cancel

Figure 23 – Actor registration: disclaimer page

3. Read the disclaimer, select the **I have read the disclaimer** checkbox and click **Next**.

Result: You are prompted to enter general information about the manufacturer, 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 actor data to register your organisation

* Role:
Manufacturer

* Country:
Belgium

* Actor / organisation name:
Sample MF

Next

Figure 24 – Registration: initial page, 'Create new actor'

- Select the role and country, enter the name of your manufacturer and click **Next**.

Result: Step 1 of the registration process appears:

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 >

Figure 25 – Registration: step 1, 'Actor identification'

- Enter all the information needed to identify the manufacturer. You can upload any document that may be useful for validating your request – but **only in PDF format**.

Click **Save & Next**.

Result: Step 2 appears:

Figure 26 – Non-EU registration: step 2, 'Authorised representative'

6. Enter the required data:

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.

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.

6.1 Identify your authorised representative:

Do you know the Actor ID/SRN?

Select **I know the Actor ID/SRN**, click **Find** and select the number.

Do you not know the Actor ID/SRN?

Unselect **I know the Actor ID/SRN**, select the country and enter the name of the authorised representative. Click **Find** and select the correct result.

6.2 Enter the start and end dates for the validity of the written mandate your organisation has given the authorised representative.

6.3 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.

6.4 Click **Save & Next**.

Result: Step 3 appears:

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 >](#)

Figure 27 – Non-EU registration wizard: step 3, 'Actor address'

7. Enter the address details for the manufacturer, and click **Save & Next**.

Result: Step 4 appears:

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 xxx xxx

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

* Email:

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

Web site:

[Save registration](#) [Save & Next >](#)

Figure 28 – Non-EU registration: step 4, 'Contact Details'

8. Enter the email address and other useful information about the contact points in the manufacturer.

There are separate areas for contacts that should be used by competent authorities and those open to the public.

Click **Save & Next**.

Result: Step 5 prompts you to identify 1 or more regulatory person(s) within your manufacturer.

The screenshot shows a multi-step registration process. The top navigation bar indicates the current step is 5, 'Regulatory Persons', with previous steps (Actor identification, Authorised Representative, Actor address, Contact details) completed and subsequent steps (6, 7) pending. The main form area is titled 'Person Responsible for Regulatory Compliance' and contains a sub-section 'Regulatory Persons'. This section includes input fields for 'First name', 'Last name', 'Email', and 'Telephone number', along with a 'Responsible for' text area. A 'Telephone format example' is provided below the telephone field. Below this, there is a detailed address section titled 'Person Responsible for Regulatory Compliance' with a checkbox for 'Same address as the Actor organisation address'. A toggle switch for 'Street information, if applicable' is set to 'Yes'. The address section includes fields for 'Street', 'Street number', 'Address line 2', 'PO box', 'Latitude', 'Longitude', 'City name', 'Postal code', and 'Country'. A 'Country' dropdown menu is shown with a flag icon. At the bottom of the form, there is a link to 'Add a new Regulatory Person' and two buttons: 'Save registration' and 'Save & Next'.

Figure 29 – Non-EU registration: step 5, 'Regulatory persons'

Regulatory person

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

9. Enter the details of the person and specify the area(s) they are responsible for.

To add another person with this responsibility, select **Add a new Regulatory person** at the bottom of the page.

Click **Save & Next**.

Result: Step 6 prompts you to confirm you will be the Local Actor Administrator (LAA) for the actor. (once approved, the person who first enters the details of an actor in EUDAMED automatically becomes the LAA):

The screenshot shows the 'Registering Local Actor Administrator' step (Step 6) of the EUDAMED registration process. The progress bar at the top indicates that steps 1 through 5 (Actor identification, Authorised Representative, Actor address, Contact details, and Regulatory Persons) are completed, while Step 6 is currently active and Step 7 (Competent Authority) is pending.

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](#)

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

☐ No ☐ Yes

Figure 30 – Non-EU registration: step 6, 'Registering Local Actor Administrator'

10. Check and complete the information on the page.

Upload the signed declaration – **in PDF format only** – using the **Browse** button.

Click **Save & Next**.

Result: The last step appears. It displays information about the competent authority that will validate your registration request (the one that is responsible for your authorised representative).

The screenshot shows the 'Competent Authority' step (Step 7) of the EUDAMED registration process. The progress bar at the top indicates that steps 1 through 6 are completed, and Step 7 is currently active.

Competent Authority

Name: Agence Fédérale des Médicaments et des Produits de Santé/Federale 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:

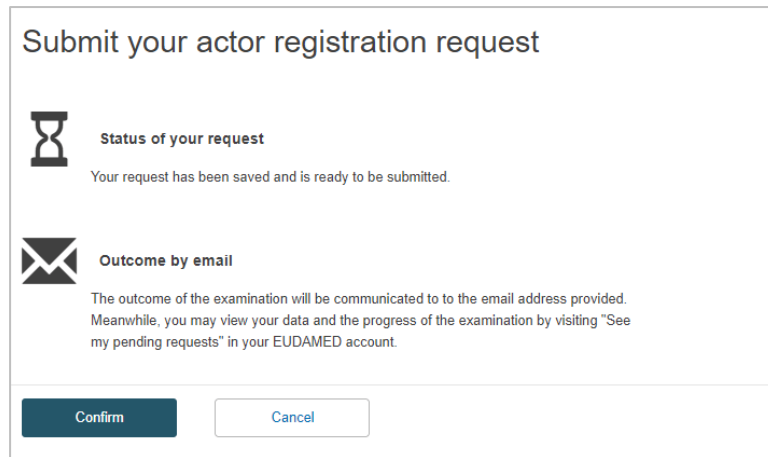
Figure 31 – Non-EU registration: Step 7, 'Competent Authority'

11. If necessary, enter any additional information you wish to pass on to the competent authority, and then click **Preview**.

Result: A summary of your completed registration form is displayed.

12. Review the information on the form, and then click **Submit actor registration** at the bottom of the page.

Result: 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.

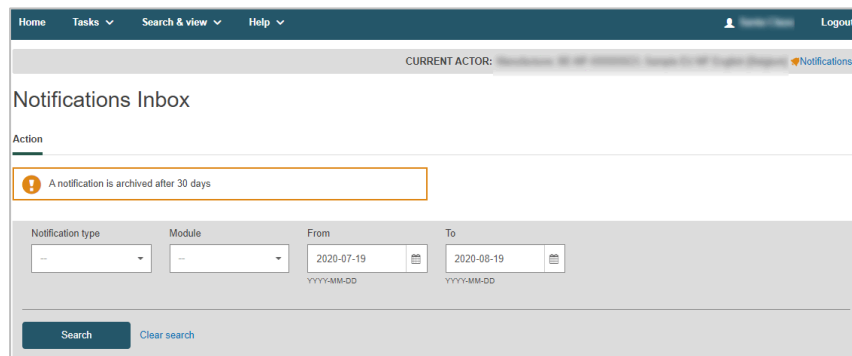
Confirm **Cancel**

Figure 32 – Non-EU registration: submission confirmation

13. Read the information in the window and click **Confirm**.

Results:

- 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 in your 'Notification Inbox' (*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: [User Name] Notifications

Notifications Inbox

Action

! A notification is archived after 30 days

Notification type: [Dropdown] Module: [Dropdown] From: 2020-07-19 To: 2020-08-19

Search Clear search

Figure 33 - Notifications inbox

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:

Username:

Email:

EUDAMED details

Name:

My access requests for an existing actor

Role ID	Name ID	City ID	Date of request ID	State	Actions
Manufacturer	<input type="text"/>	<input type="text"/>	2020-04-09	Submitted	...
Authorised Representative	<input type="text"/>	<input type="text"/>	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	<input type="text"/>	<input type="text"/>	-	Draft	...
APP00000	Manufacturer	<input type="text"/>	<input type="text"/>	2020-08-19	Verified	...
APP00000	Supplier/Producer/First Producer	<input type="text"/>	<input type="text"/>	2020-07-02	Correction Requested	...
APP00000	Manufacturer	<input type="text"/>	<input type="text"/>	2020-07-02	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.

2.1.2 Verifying non-EU manufacturer registrations

[Reserved for AR Verifiers]

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 with the (summary) mandate details.

'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 representative's Local Actor Administrator and Local User Administrator also have these rights.

♦ To verify a non-EU manufacturer's registration request

1. Log in to EUDAMED with a *Verifier*, *LAA* or *LUA* profile (for the authorised representative).

Result: If there are outstanding registration requests from non-EU manufacturers, you will see the following link in your dashboard:

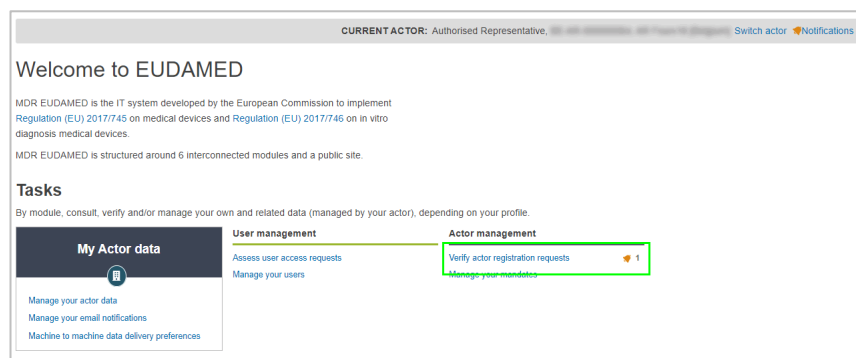


Figure 34 – 'Verify actor registration requests' link

2. Click **Verify actor registration requests** in the *Actor management* section of the dashboard.

Result: The *Actor registration management* page lists all pending non-EU manufacturer registration requests waiting to be verified by your actor (if any):

The screenshot shows the 'Actor registration management' page. It includes a filter dropdown, active filters (State of request: Submitted), and a table of pending requests. The table has columns for Application ID, Role ID, Name ID, Postal code ID, City ID, Country, Date of request ID, State, and Actions.

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

Figure 35 – Pending non-EU manufacturer registration request list

3. Click **Assess** in the *Actions* column to review and assess the desired registration request in the list.

Result: All details of the selected registration request, as submitted by the non-EU manufacturer, are displayed.

4. Review the information in the form. If there are possible duplicates, a warning will appear here and you may select the correct registration request:

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](#)

Figure 36 – Potential duplicates warning

5. In the *Assessment* section, move the toggle button 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 should select 1 of the following reasons:

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.

If you choose not to approve, you will be prompted to **justify your decision**:

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

Figure 37 – Assessing a non-EU manufacturer registration request

6. Click **Complete assessment** at the bottom of the page, and then **Confirm** in the subsequent confirmation popup.

Result: You are informed that the non-EU manufacturer's registration request has been properly assessed.

If approved, its status now changes to **VERIFIED**. This means the request has been submitted to the relevant competent authority for validation:

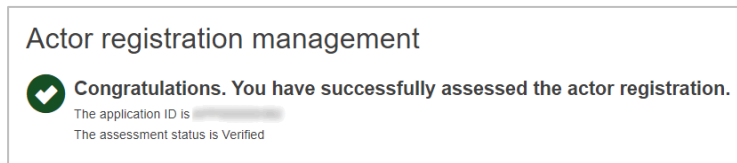


Figure 38 – A verified registration request

2.1.3 Viewing 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:

1. Click on the Actors block on the dashboard or select **Search & view > Actors** :

Result: The actor search & view page appears:

Figure 39 – Search & view (Actors)

2. Enter your search criteria in the *Search & view* page, and click **Search**.

Result: All actors matching your criteria are listed in the search results section:

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

Figure 40 – Search results page (Actors)

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 an XML file of the results list from the Downloads management page.

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

2.1.4 Linking a non-EU manufacturer to an importer

Reserved for importers with 'Linker' profile

To link a non-EU manufacturer to your importer:

1. Go to the dashboard:

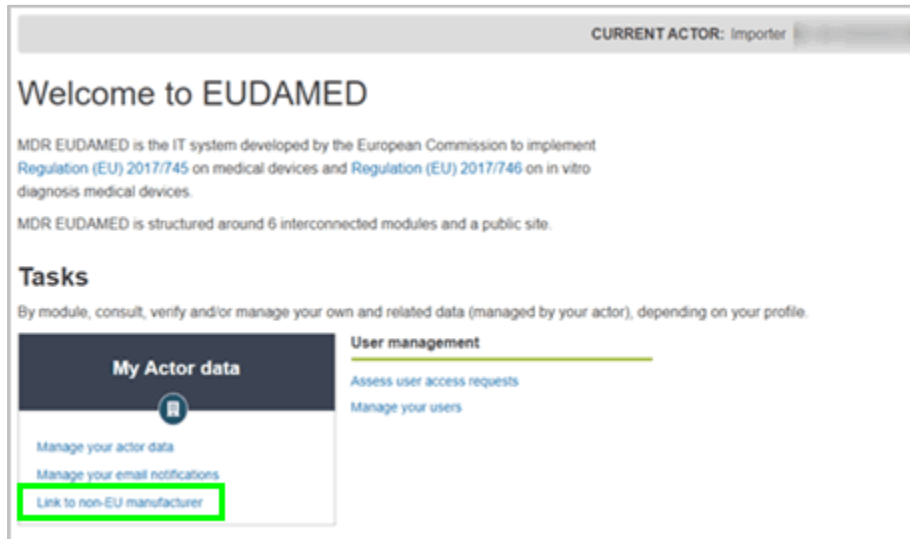


Figure 41 – Importer dashboard

2. Click **Link to non-EU manufacturer** in the *My Actor data* section:

Result: You will arrive at the page displaying linked non-EU manufacturers (if there are no linked manufacturers, this list will be empty).

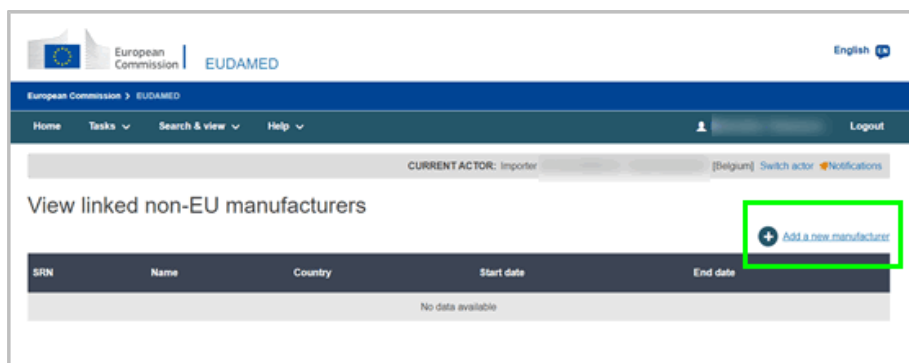
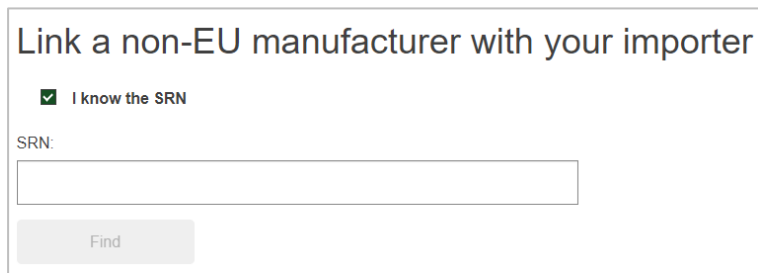


Figure 42 - Linked non-EU manufacturers list

3. Click **Add a new manufacturer**

Result: You will be invited to select the non-EU manufacturer.



Link a non-EU manufacturer with your importer

☒ I know the SRN

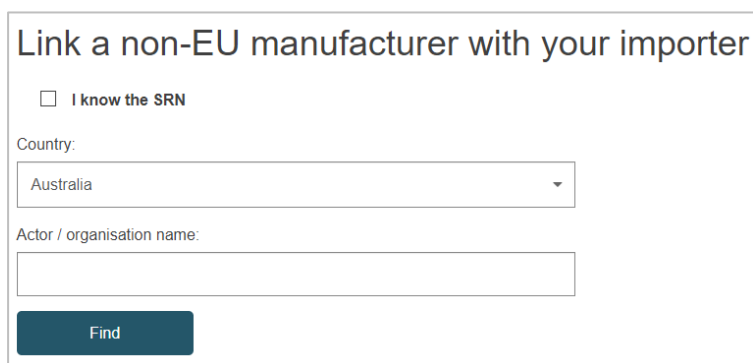
SRN:

Find

Figure 43 - Link to non-EU manufacturer page

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**.

Result: 2 new fields will appear:



Link a non-EU manufacturer with your importer

☐ I know the SRN

Country:

Australia

Actor / organisation name:

Find

Figure 44 - Link to non-EU manufacturer, box unchecked

6. Enter the country and actor/organisation name and click **Find**.

Result: You will see a list of results based on your search criteria:



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	^

Figure 45 - List of non-EU manufacturers that can be linked to your actor

7. Select the actor you want from the list.

Result: You will see the detail page for that actor:

The screenshot shows a web interface with a 'Find' button at the top. Below it, a 'Result' section prompts the user to 'Select your actor from the list below'. A dropdown menu is open, showing a selection for 'Afghanistan - Manufacturer - Actor code: AF-MF-'. Below the dropdown, the details for the selected manufacturer are displayed:

- SRN:
- AF-MF:
- Role: Manufacturer
- Country: Afghanistan
- Organisation name:
- Address:
- Email:
- Telephone number:

At the bottom of the details section, there is a button labeled 'Add link with this manufacturer'.

Figure 46 - Details of selected non-EU manufacturer

8. Click **Add link with this manufacturer:**

Result: You are prompted to enter the relevant dates:

The screenshot shows a dialog box titled 'Add link with this manufacturer'. It contains the instruction 'Enter the start date to link with this manufacturer'. There are two input fields: '* Start date:' and 'End date:'. Both fields have a calendar icon to their right. Below the input fields, the format 'YYYY-MM-DD' is indicated for both. At the bottom of the dialog, there are two buttons: 'Confirm' and 'Cancel'.

Figure 47 – Confirm link between a non-EU manufacturer and your actor

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

2.1.5 Updating actor details

[Reserved for Local Actor Administrators]

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 version of the actor. Previous versions will remain available for viewing 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':

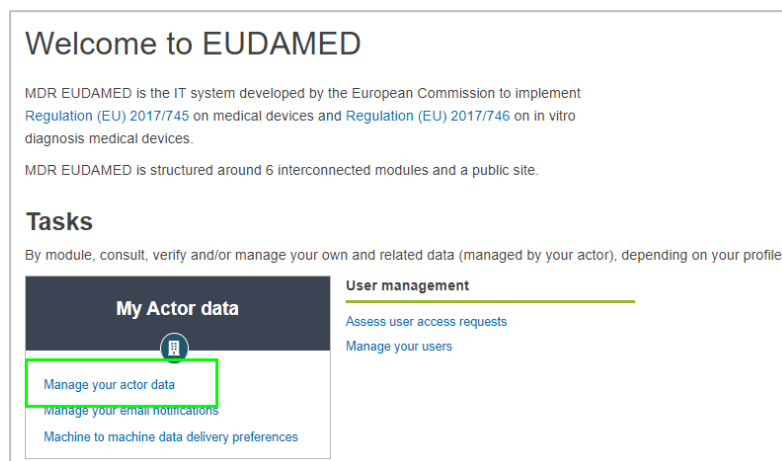


Figure 48 – 'Manage your actor data' link

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

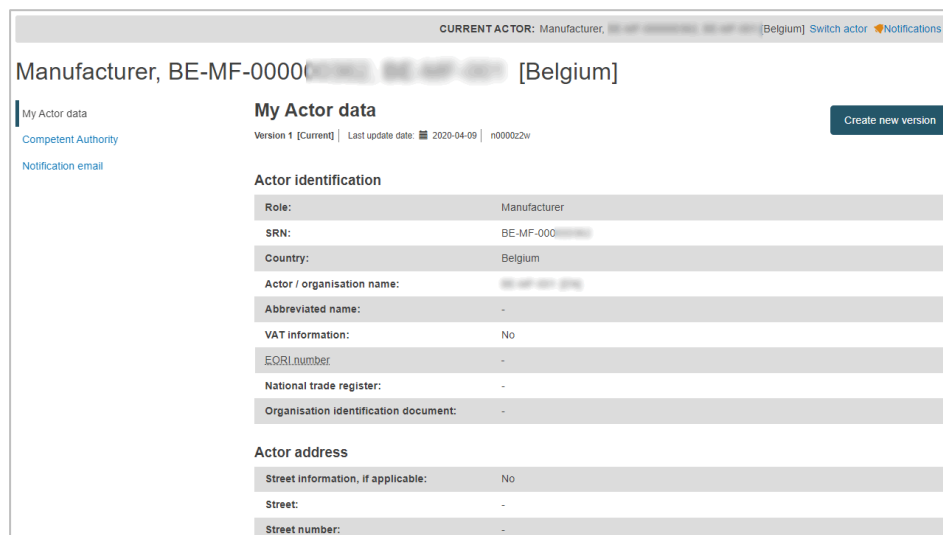


Figure 49 – Actor details

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

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

Result: The changes apply immediately.

The current version number is increased by 1:



Figure 50 – New actor version

2.2. Users & user access management

2.2.1 Requesting access as a user for a registered economic operator

When an actor is already registered in EUDAMED, anyone who needs to act on behalf of them in the system must request access and choose (an) appropriate user profile(s) in the different 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:

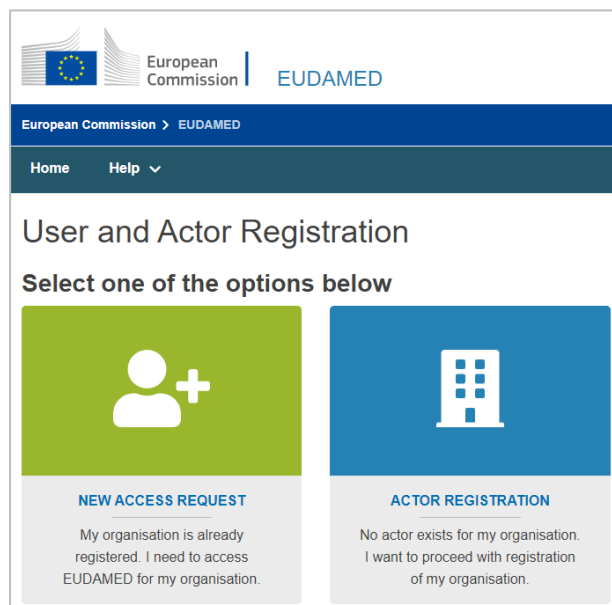


Figure 51 – EUDAMED User and Actor Registration page

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:

The screenshot shows the 'My account(s)' page for a user named 'MedicalDev Thirtyeight'. The page is divided into several sections: 'EU Login details', 'EUDAMED details', and 'My EUDAMED accounts'. Under 'My EUDAMED accounts', there is a 'Current actor account' section with 'Actor data' and 'Actor identification' details. Below this is the 'Actor notification email addresses' section, which shows a table with columns for 'Notification deactivated', 'Notification requested', and 'Actor Data'. 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 navigation bar to this button.

Figure 52 – EUDAMED user account detail page and new access request button

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

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 registration yet.

The 'New access request' page has a title bar and a warning message in an orange box: '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.' Below this is a 'Search existing actor' section with the instruction 'Enter your actor data to check if an actor already exists for your company'. There is a checkbox labeled 'I know the actor's Single Registration Number (SRN) or EUDAMED Actor ID'. Below the checkbox are three required fields: '* Role:', '* Country:', and '* Actor / organisation name:'. At the bottom of the search section is a 'Find' button.

Figure 53 – 'New Access Request'

4. 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**
5. If you don't know the Actor ID/SRN, you can find the actor by searching with: **role, country** and **name** (or part of it).
6. Click **Find**.

Result: The list of matching actors is displayed in the *Result* section on the right-hand side.

The screenshot shows the 'New access request' form. At the top, a message states: '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.' Below this, the 'Search existing actor' section contains a checkbox for 'I know the Actor's Single Registration Number (SRN)', a dropdown for 'Role' (set to 'Manufacturer'), a dropdown for 'Country' (set to 'Belgium'), and a text input for 'Actor / organisation name' (containing 'bel'). A 'Find' button is at the bottom of this section. The 'Result' section on the right shows a dropdown for 'Manufacturer - Actor code:' and a list of actor details: SRN (BE-000000001), Role (Manufacturer), Country (Belgium), Organisation name (EUDAMED), Address (Rue de la Loi 200, 1049 Brussels, Belgium), Email (eudamed@eudamed.eu), and Telephone number (-). A 'Request access to this actor' button is at the bottom of the result section.

Figure 54 – 'Request access to this actor'

7. Click the desired actor in the *Result* panel, and then click **Request access to this actor**

Result: Step 1 of a 3-step process appears:

The screenshot shows the 'New access request' form at step 1 of a 3-step process. The steps are: 1. My personal data, 2. My user manager, and 3. My profile(s). The 'Selected actor information' section on the left displays the same actor details as in Figure 54. The main section, 'My contact email for this actor', includes a text input for 'Email:' and a radio button selection for 'Are you a sub-contractor for this actor?'. The 'No' option is selected. At the bottom, there are three buttons: 'Save', 'Save & Next', and 'Cancel'.

Figure 55 – User access request: step 1

8. Complete step 1 of the user access request process:
 - a. Enter your contact/notification email address related to this actor

- 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**.

Result: 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-00123456789

Role: Manufacturer

Country: Italy

Actor/Organisation name: S.p.A. - 12345678901234567890

Address: Via Sussani, 47, Cadriano Grando Delfino

Email: contact@mf.it

Phone: +390212345678

User manager

* First Name:

* Last Name:

* Function/Position:

Buttons: Save, Save & Next, Cancel

Figure 56 – User access request: step 2

10. Enter the name and function/position of your manager, and then click **Save & Next**.

Result: Step ③ shows a list of possible user profiles for each module:

New access request

Information of the actor selected

SRN: IT-123456789

Role: Manufacturer

Country: Belgium

Organisation name: S.p.A. - 12345678901234567890

Address: Via Sussani, 47, Cadriano Grando Delfino

Email: contact@mf.it

Phone number: +390212345678

My profile(s) for this actor

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

Choose the profile(s) you need

Actor

☐ Local Actor Administrator

☐ Local User Administrator

☐ Validator

☒ Viewer

Active until

End date:

YYYY-MM-DD

Buttons: Save, Submit, Preview, Cancel

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

Figure 57 – User access request: step 3

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

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 Validating user access requests).

The other profiles available depend on the role of the actor in question (except for **Viewer**).

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.

Result: A summary of your access request is displayed.

14. Review the information and click **Submit** at the bottom of the preview page.

Result: A confirmation page appears:

15. Click **Submit my request**.

Result: 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.

Role	Name	City	Date of the request	State	Actions
Authorised Representative	Magnumedica	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 with your account:

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:

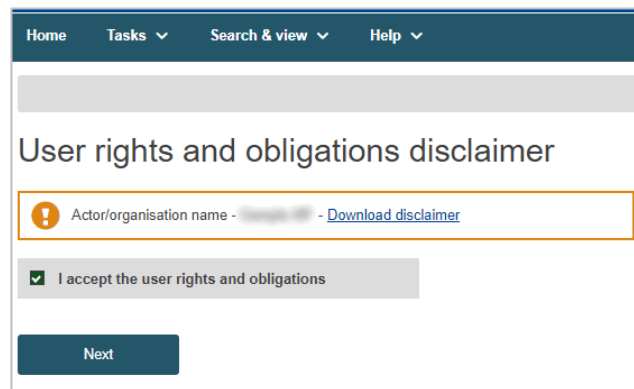
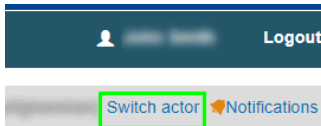
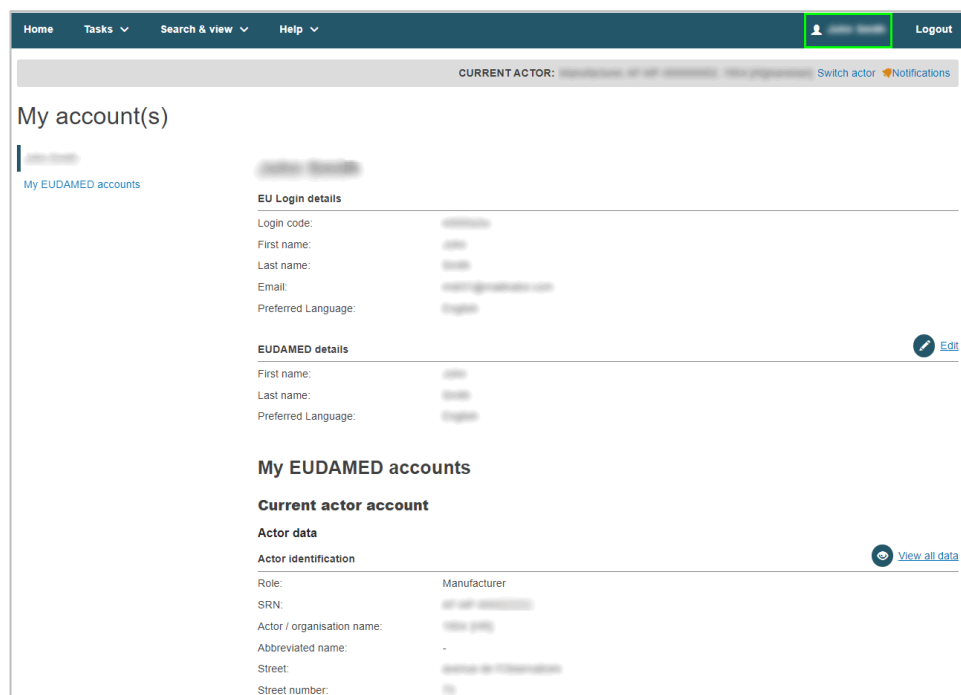


Figure 58 – User rights and obligations disclaimer

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



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 user access requests

[Reserved 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 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 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):

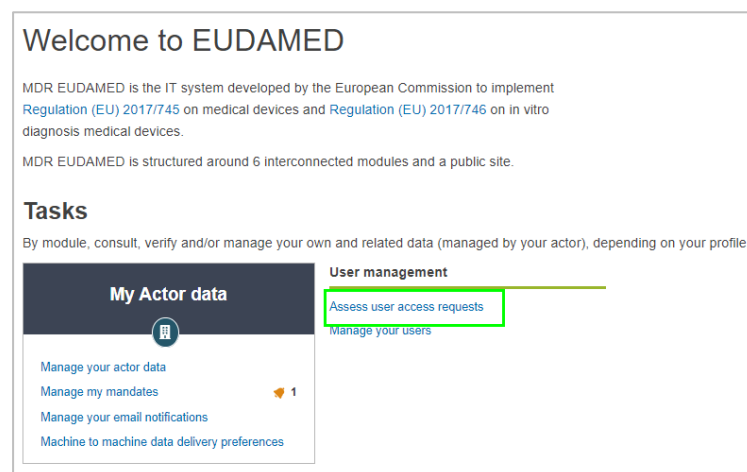


Figure 59 – 'Assess user access requests' on the dashboard

Result: The *Pending requests* tab on the *User management* page lists all pending user access requests for your organisation:

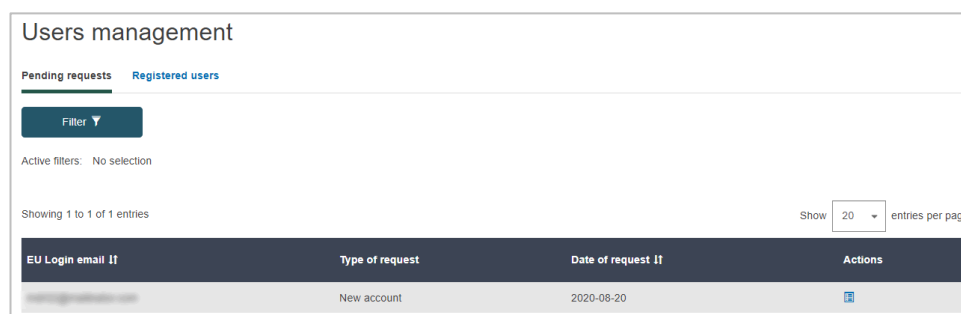



Figure 60 – Pending access requests to be validated

3. Click  (*Assess access request*) in the *Actions* column to view and assess a request from the list.

Result: 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:

User manager

* First name:

* Last name:

* Function/position:

Validity date for the EUDAMED account

End date:

Figure 61 – User access request assessment: part 1

4. Review the information in part 1 of the request.
5. In the *Assessment* section, move the toggle button 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 1 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:

Reject Cancel

Figure 62 – Validating an access request

Result: 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**.

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

Profile availability

The profiles available in the table depend on the role of actor.

E.g. if the user is requesting access for an authorised representative, the additional profile of 'Verifier' will be available.

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	Approved	
Actor:	Local Actor Administrator	Approved	Reject

Complete assessment Cancel

Figure 63 – Granting specific roles to a user

7. For each module in the table, click either **Accept** or **Reject**, and when you're done, click **Complete assessment**.

Result: A summary is displayed of the user profile you have approved.

8. To confirm this user profile, click **Confirm** in the summary dialog box.

Result: 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

[Reserved for LAAs/LUAs]

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 related actor. If they need to do this again 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:

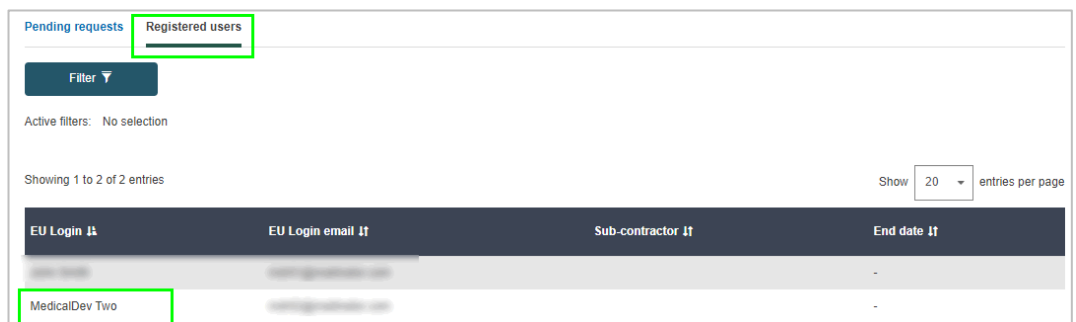


Figure 64 – Selecting one of your registered users

4. Review the user's details and click **Terminate** at the bottom of the page:

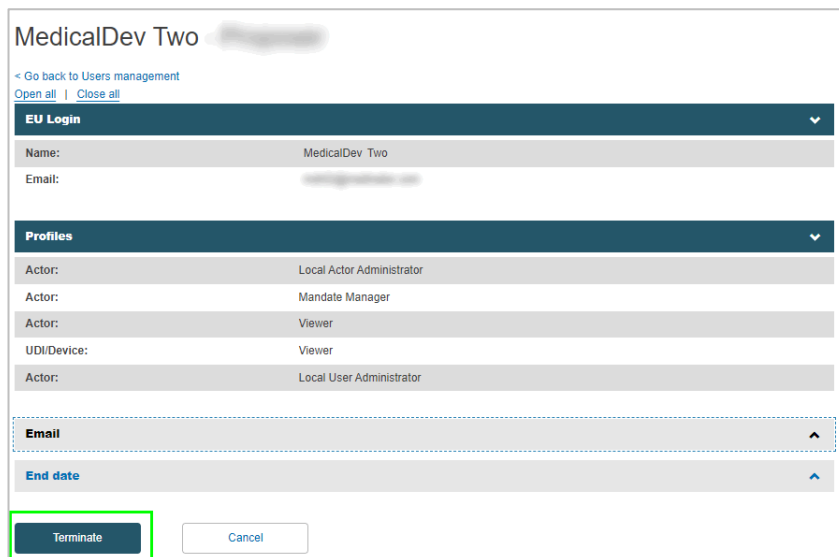


Figure 65 – 'Terminate' button

5. Answer the confirmation message.

Result: 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 can't 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 your name in the upper toolbar:

Result: The *My account(s)* page appears:

The screenshot shows the 'My account(s)' page in the EUDAMED Actor module. The page has a dark blue header with navigation links: Home, Tasks, Search & view, and Help. On the right of the header, there is a user profile icon (highlighted with a green box) and a Logout button. Below the header, a grey bar indicates the 'CURRENT ACTOR' and provides links to 'Switch actor' and 'Notifications'.

The main content area is titled 'My account(s)' and contains several sections:

- My EUDAMED accounts:** A section with a blue link 'My EUDAMED accounts'.
- EU Login details:** A table with fields: Login code, First name, Last name, Email, and Preferred Language.
- EUDAMED details:** A table with fields: First name, Last name, and Preferred Language. An 'Edit' button is visible to the right.
- My EUDAMED accounts:** A section header.
- Current actor account:** A section header.
- Actor data:** A section header.
- Actor identification:** A table with fields: Role, SRN, Actor / organisation name, Abbreviated name, Street, and Street number. A 'View all data' button is visible to the right.

Figure 66 – Viewing your user account

2. To change any editable data, click the **Edit** or **Modify** button, if one is available next to the section in question:

► **EU Login details / EUDAMED details**

John Smith

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](#)

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**

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.*

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

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

 [Modify](#)

Use the **Modify** button in this section if you want to change the receiving email address for notifications about the different EUDAMED modules.

► **Current actor account: Account data**

Use the **Request for change** button in this section if you want to request a different profile for 1 or more EUDAMED modules for the current actor

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

3. Make any required changes.
4. Click **Save**.
5. If you are registered with more than 1 actor:

► My other account(s)

Click the right-pointing arrow next to one of the actors in the list to show their details. Here you can switch to these other actors.

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).

1. Go to the dashboard:

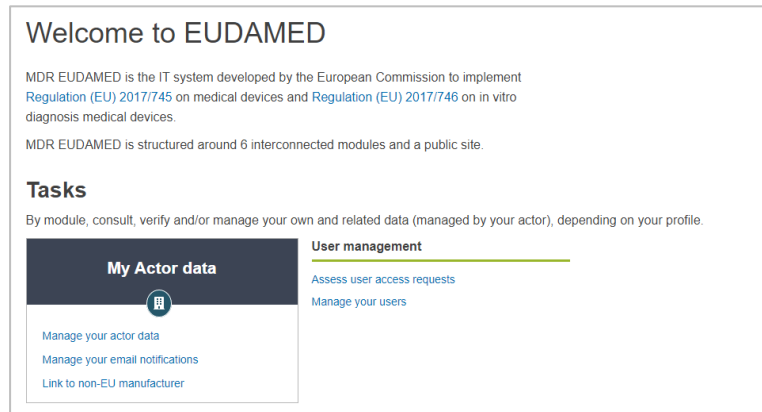


Figure 67 - Welcome page for actors

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



Figure 68 - Switch actor

3. Select an actor from the list shown:

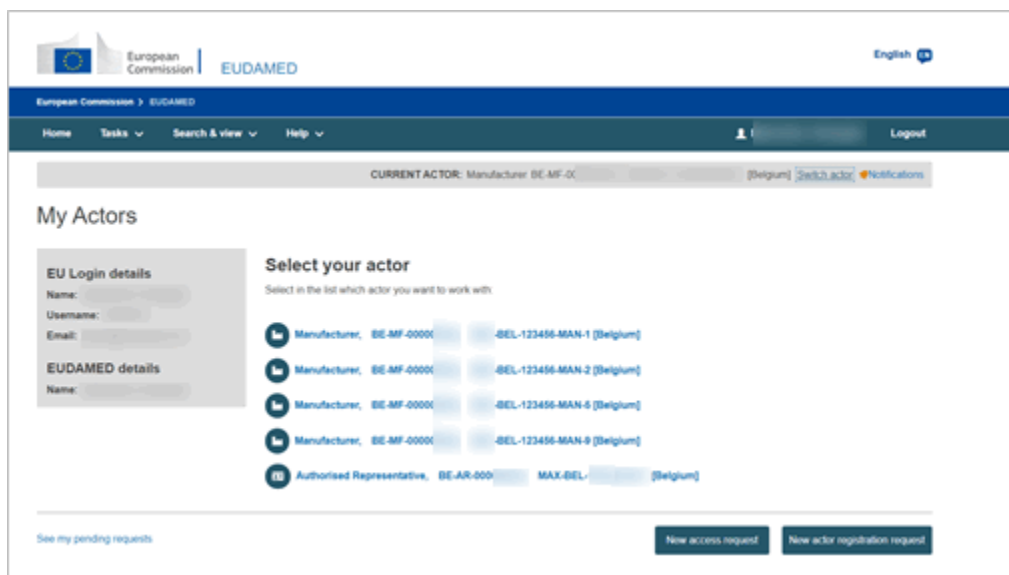


Figure 69 - Actor selection window

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.

2.3.1 Adding a new mandate

[Reserved for non-EU manufacturers]

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.

Result: The list of mandates that have already been created is displayed, with information on their current state.

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

View my mandates

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

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

[+ Add a new mandate](#)

Figure 70 – List of mandates

2. Select **Add a new mandate** at the top right of the list.

Result: 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:

Find

Mandate validity dates

* From: 

YYYY-MM-DD

To: 

YYYY-MM-DD

* Upload mandate summary document

Browse

SubmitCancel

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.

Figure 71 – Add a new mandate

3. If you know the Actor ID/SRN for the authorised representative, enter it here, click **Find** and select from the results.
4. If you don't know the SRN, uncheck **I know the Actor ID/SRN**, enter the country and authorised representative name, click **Find** and select from the results.
5. Specify the mandate's validity start date (mandatory) and end date (optional).
6. 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**.

Result: 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, **AF-BE-00000002, 1954 (Afghanistan)**

+

Add a new mandate

Showing 1 to 7 of 7 entries

Show

20

entries per page












Mandate ID 	AR name 	AR SRN 	End date 	Status 
MD-AF-BE-00000 	AF-BE 	BE-AR-00000 	-	<div><div>Registered</div></div>
MD-AF-BE-00000 	AF-BE 	BE-AR-00000 	-	<div><div>Submitted</div></div>

Figure 72 – A newly submitted mandate

2.3.2 Create a new mandate version

[Reserved for 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:

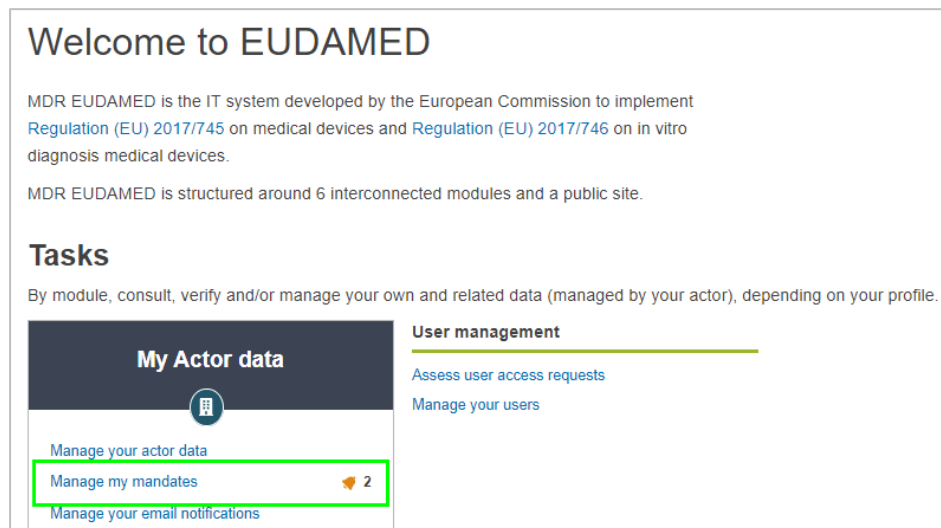


Figure 73 - Dashboard for non-EU manufacturers

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

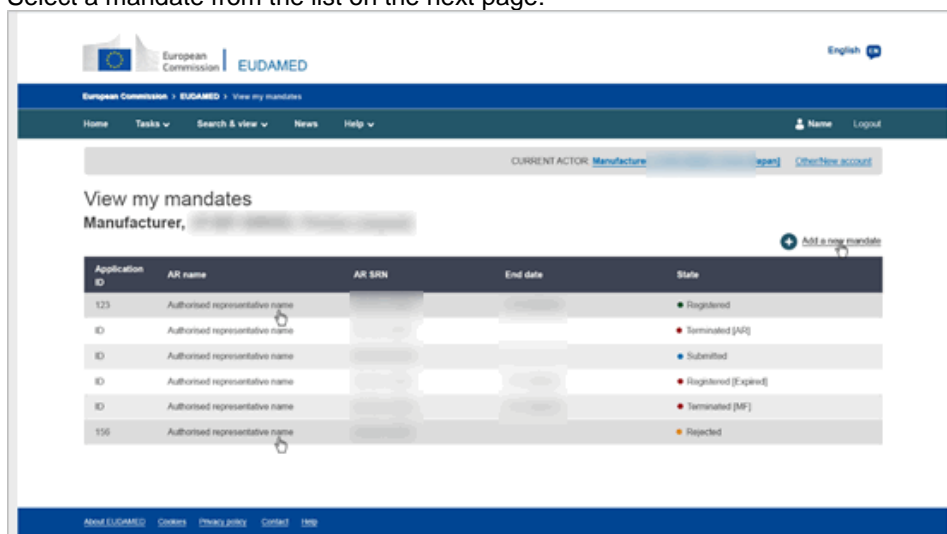


Figure 74 - Existing mandate list

4. 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

Figure 75 - Existing mandate window

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

2.3.3 Verifying mandates

[Reserved for 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:

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

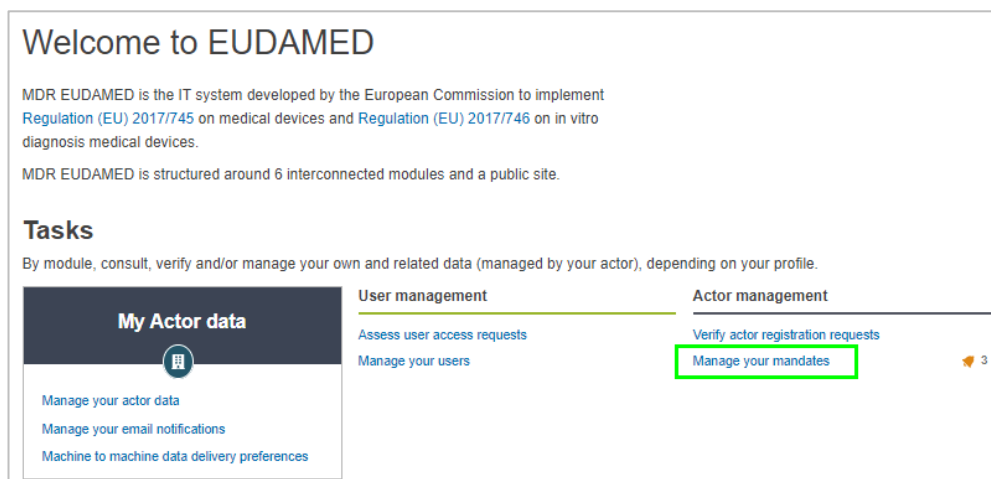


Figure 76 – 'Manage your mandates', in the dashboard for an authorised representative

Result: 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

Figure 77 – Pending mandates

2. Click on the mandate you want to verify in the *Pending mandates* list.

Result: 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

Figure 78 – Mandate details

3. Review the mandate, and then move the toggle button 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

[Reserved for 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 moment.

Either the authorised representative or the manufacturer can mark a mandate as *Terminated* in EUDAMED. The procedures are very similar.

If you are an authorised representative

◆ To terminate a mandate

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

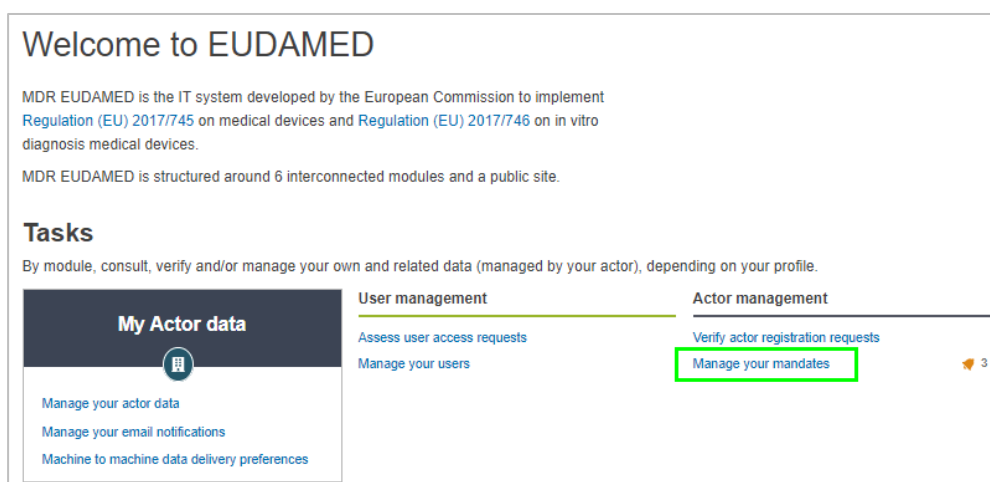


Figure 79 – 'Manage your mandates' (authorised representative)

Result: The *Mandate management* page appears. The mandates are split into 2 tabs: *Pending mandates* and *Registered mandates*.

2. Select the **Registered mandates** tab.

Result: A list of all your registered mandates is displayed:

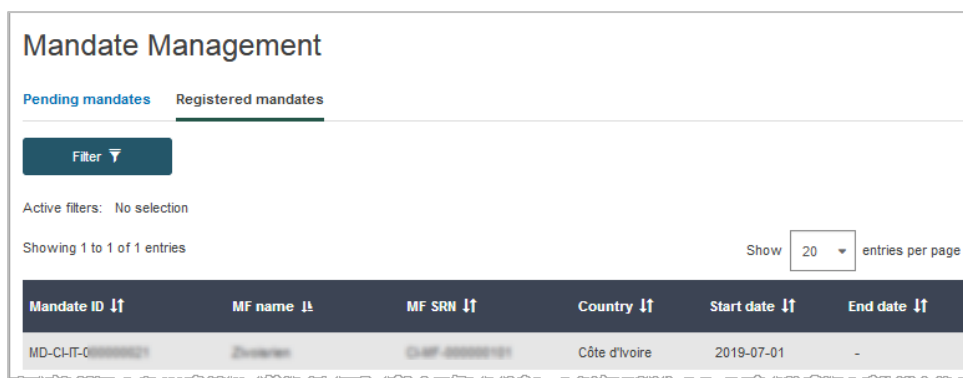


Figure 80 – List of mandates associated with an authorised representative

- Click on the registered mandate that will be terminated.

Result: 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

Figure 81 – A mandate associated with an authorised representative

- 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

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

Result: The list and state of existing mandates is displayed:

View my mandates

Manufacturer, AF-MF-XXXXXXXXXX, 1934 (highlighted)

+ Add a new mandate

Showing 1 to 7 of 7 entries Show 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 <i>it</i>	AR <i>it</i>	BE-AR-0000 <i>it</i>	2020-06-08	● Registered (Expired)
MD-AF-BE-00000 <i>it</i>	AR <i>it</i>	BE-AR-0000 <i>it</i>	2030-04-04	● Terminated [MF]
MD-AF-BE-00000 <i>it</i>	AR <i>it</i>	BE-AR-0000 <i>it</i>	-	● Registered

Figure 82 – List of mandates associated with a non-EU manufacturer

2. Click on the registered mandate that will be terminated.
- Result:* 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**.

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