EUDAMED user guide

Economic Operators – Actor module

Production v 2.10
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1 Introduction

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



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

1.1 Overview

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

Regulation 2017/745 on medical devices

Regulation 2017/746 on *in vitro* diagnosis devices

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

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

1.2 Application basics

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

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

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

- Understanding user profiles and access grants/rights

1.2.1 Accessing EUDAMED portal

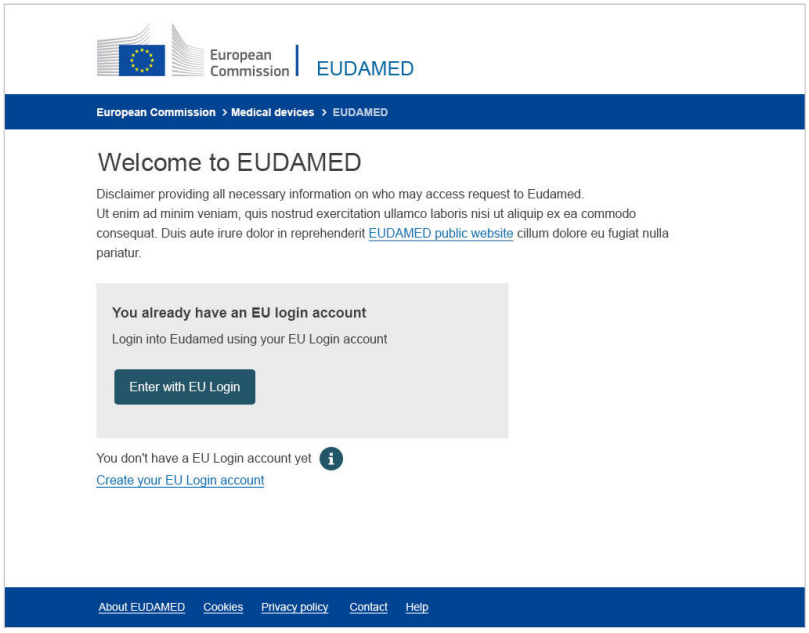
To use EUDAMED, you must have an **EU Login account** – linked to your **work email** address – private/shared mailboxes are not allowed for security reasons.

NOTE
Playground environment

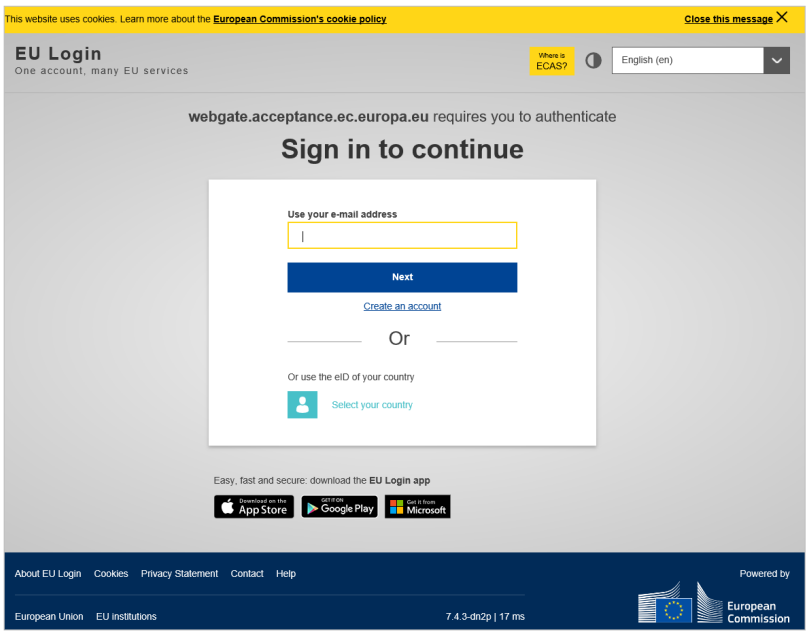
EUDAMED is also available in a Playground environment, intended to enable you to experiment with the application. All the information in this environment is dummy (including the Actor ID/SRN) and will never be moved to the production environment. Access to the Playground requires a separate registration.

To start EUDAMED:

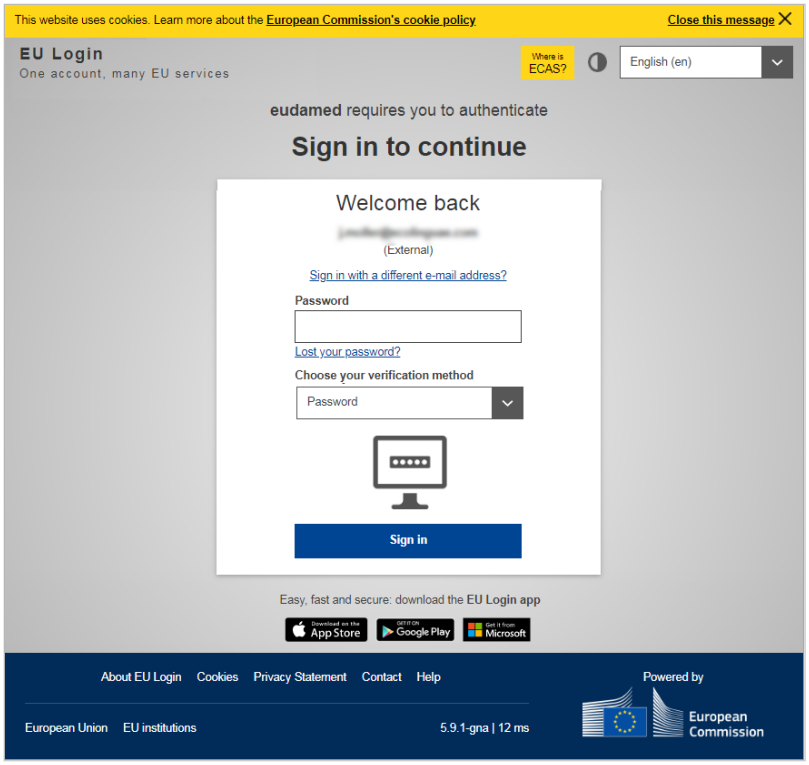
1. Go to the EUDAMED Welcome page.



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:



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:



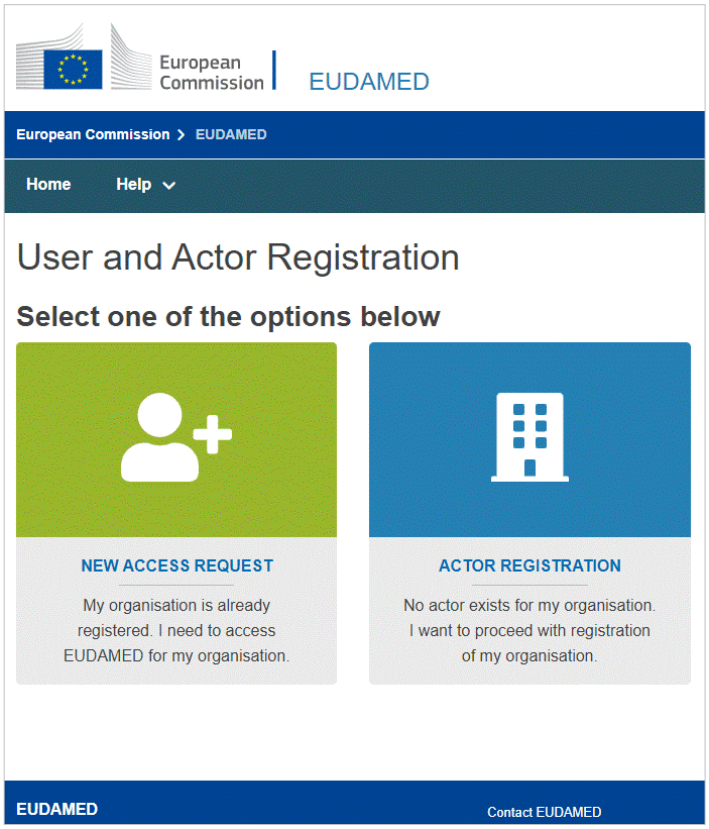
NOTE
EU Login issues?

► 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:

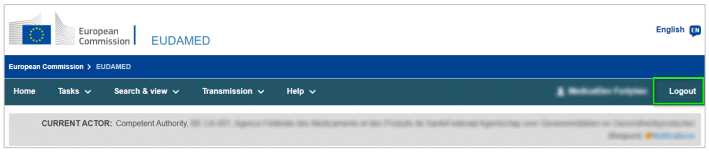
►Want to register your organisation as an actor in EUDAMED? See *Section 2.1.1* [9]

►Need access as a user for a registered economic operator? See *Section 2.2.1* [42]

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:

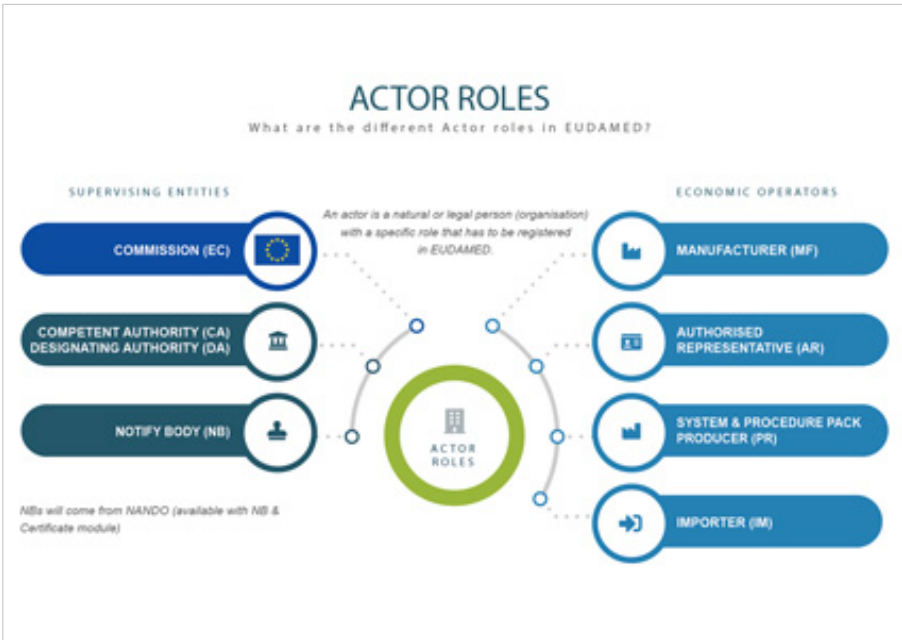


2. After you confirm the **Logout** from EUDAMED, you will be prompted with a *Log me out* confirmation page from the EU Login domain.

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

Economic operators

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

Sponsors

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

Definitions

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

1.2.3 User rights and profiles

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

Each EUDAMED account is associated with one of the following actors:

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

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

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

User profiles in the actor module

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

Hierarchy of user profiles

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

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

User profiles per actor and their hierarchy

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

2 Managing actors and user accounts

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

There are two ways to gain access to EUDAMED:

Request registration for an economic operator

Register your Actor in EUDAMED with the appropriate actor role.

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

Request access as a user of a registered Economic Operator

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

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

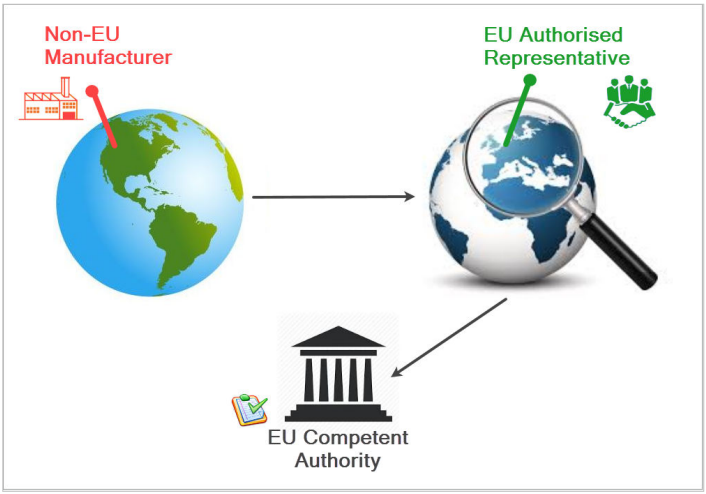
2.1 Managing actors

‘Economic Operator’ means one of the following:

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

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

** **Non-EU manufacturers**: If you are not established in the EU, your registration will be verified by the **Authorised Representative** you indicate in your actor registration request, before being assessed by the Competent Authority responsible for your AR.



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

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

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

NOTE
Multiple roles

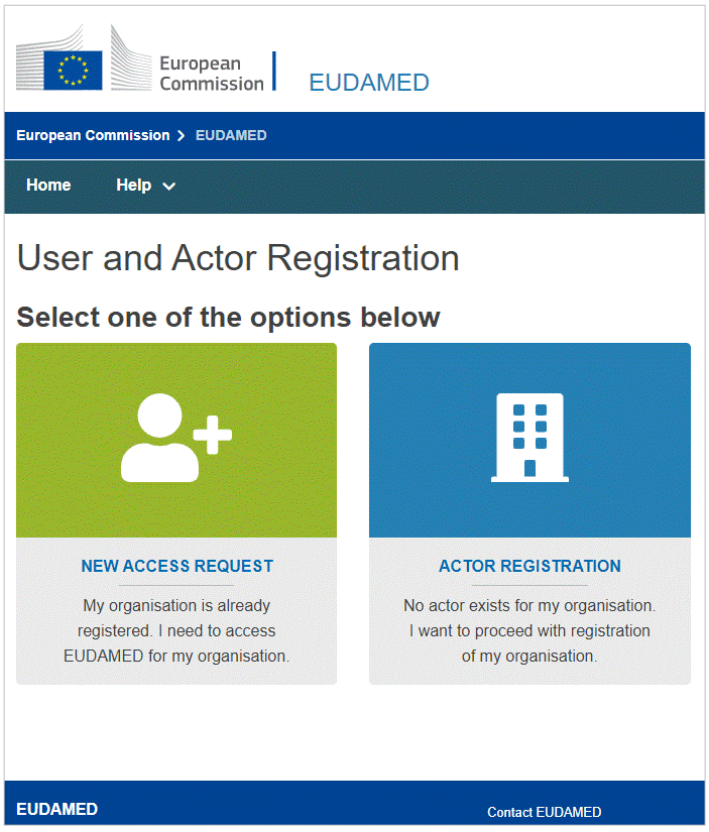
If your organisation has more than one role (i.e. your organisation is a manufacturer and an importer at the same time), you must make separate actor registrations for each.

2.1.1 Register as an Economic Operator

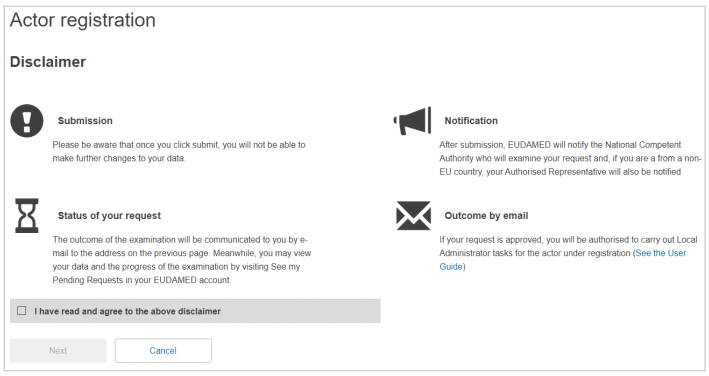
The image opens an infographic illustrating the process.



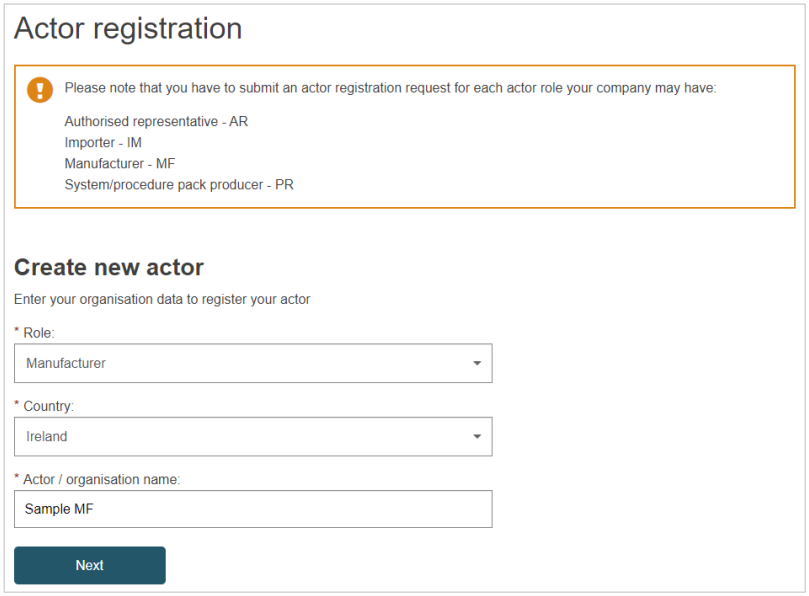
1. Log into EUDAMED with your EU Login account (see *Section 1.2.1* [2]). You will land on the *User and Actor Registration* page:



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



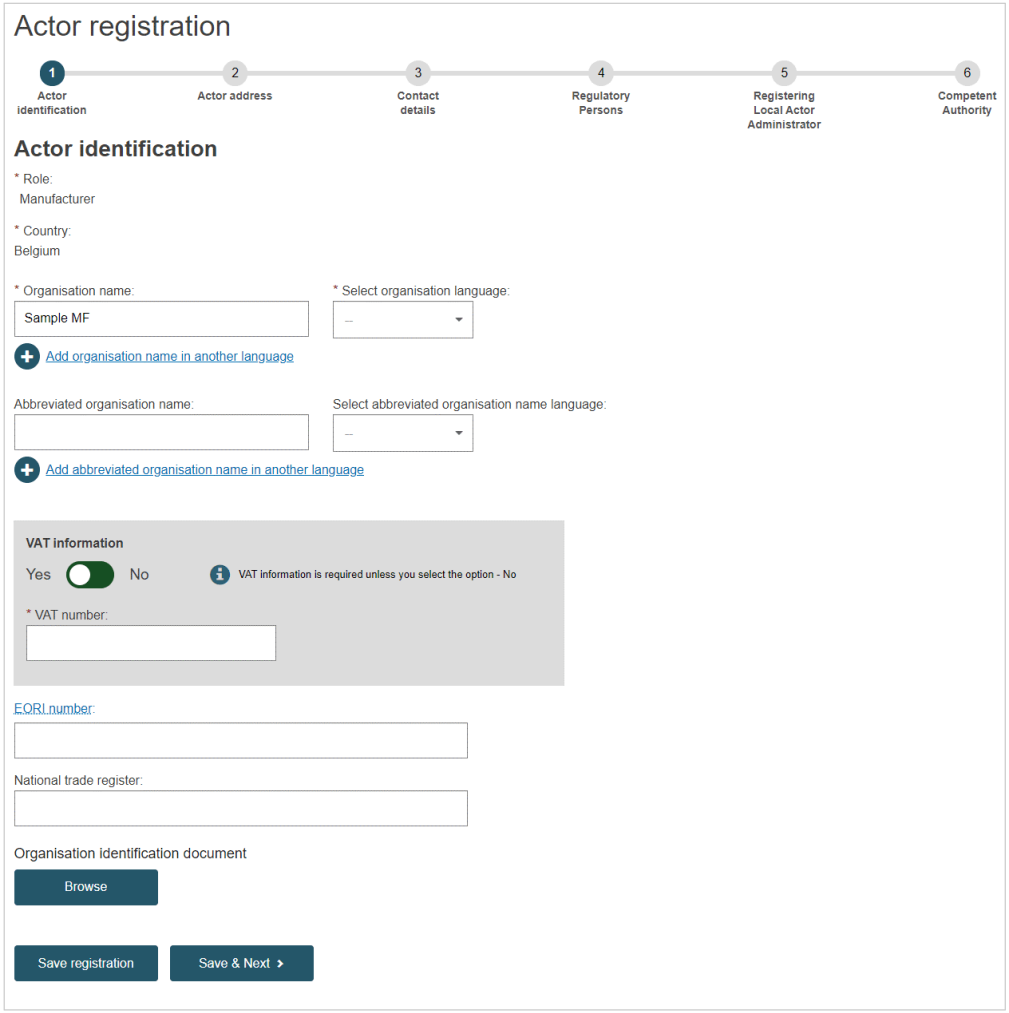
3. Read the disclaimer, select the "I have read the disclaimer" checkbox and click **Next**. You are prompted to enter the information about your actor:



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

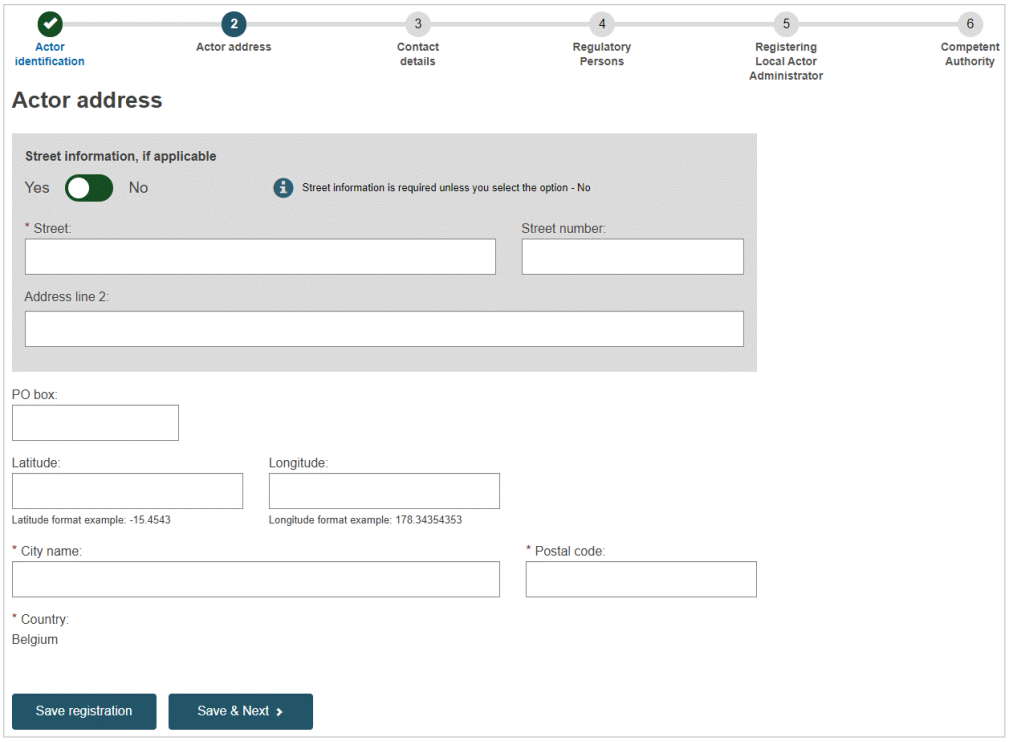


5. Select the role and country, enter the name of your actor and click **Next**.



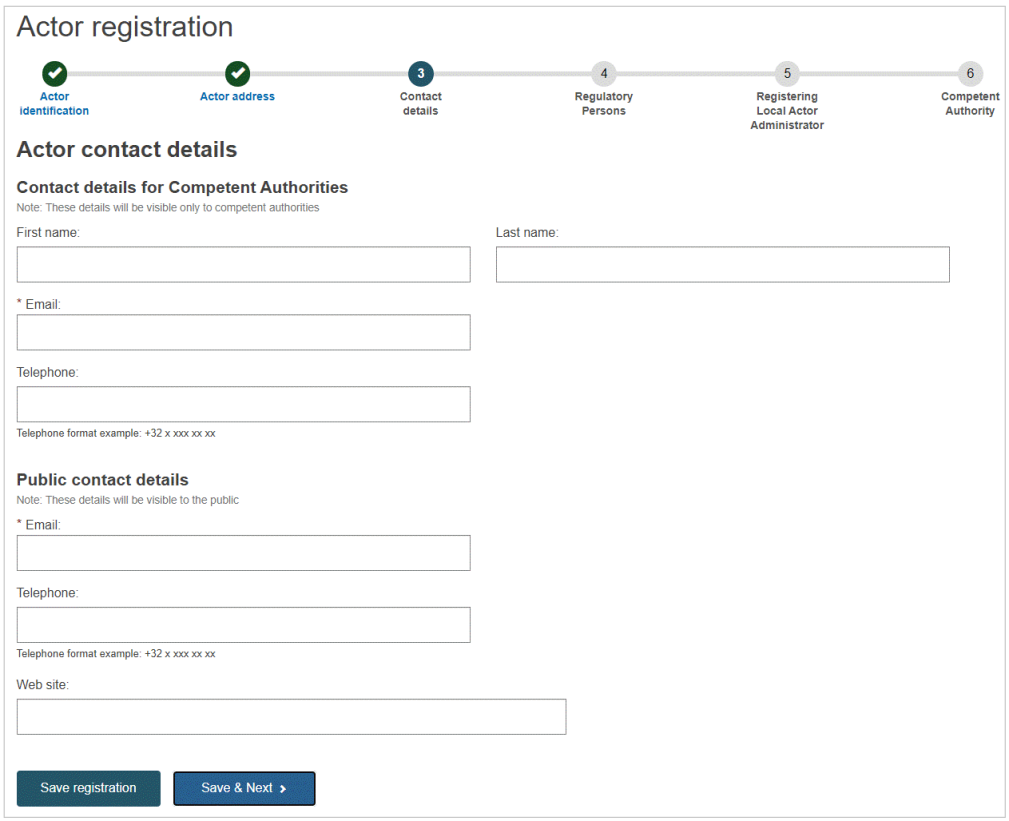
6. Enter the mandatory information fields, and additional fields, needed to identify your Economic Operator: VAT, EORI and National Trade Register Number are mandatory if available. You can upload any document that may be useful for validating your request – but only in PDF format.
   Click **Save & Next**.

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

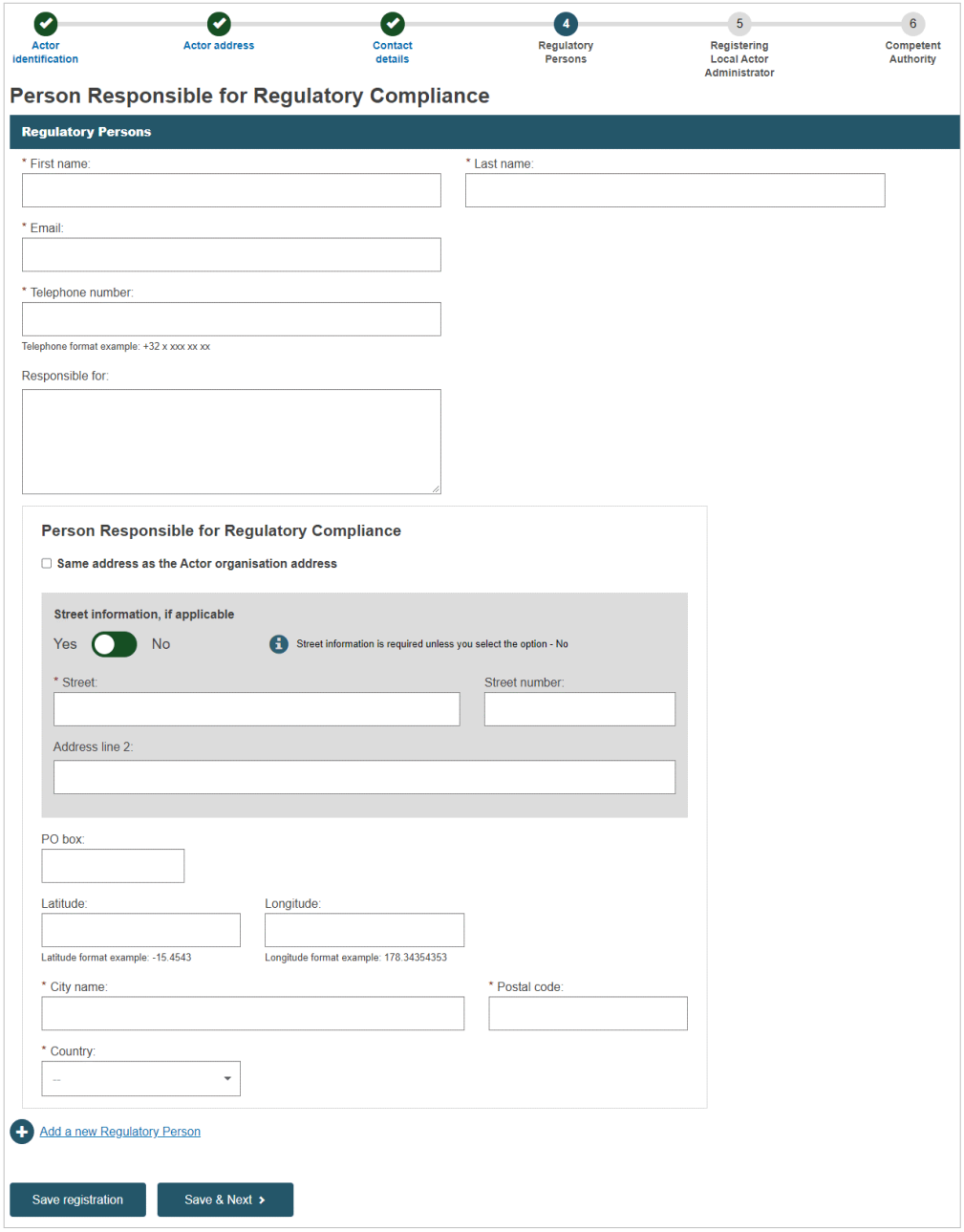


> **NOTE**
> After entering all the required *Authorised Representative* data, in the case of a *non-EU manufacturer*, you also will be prompted by an *Actor address* details screen.

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



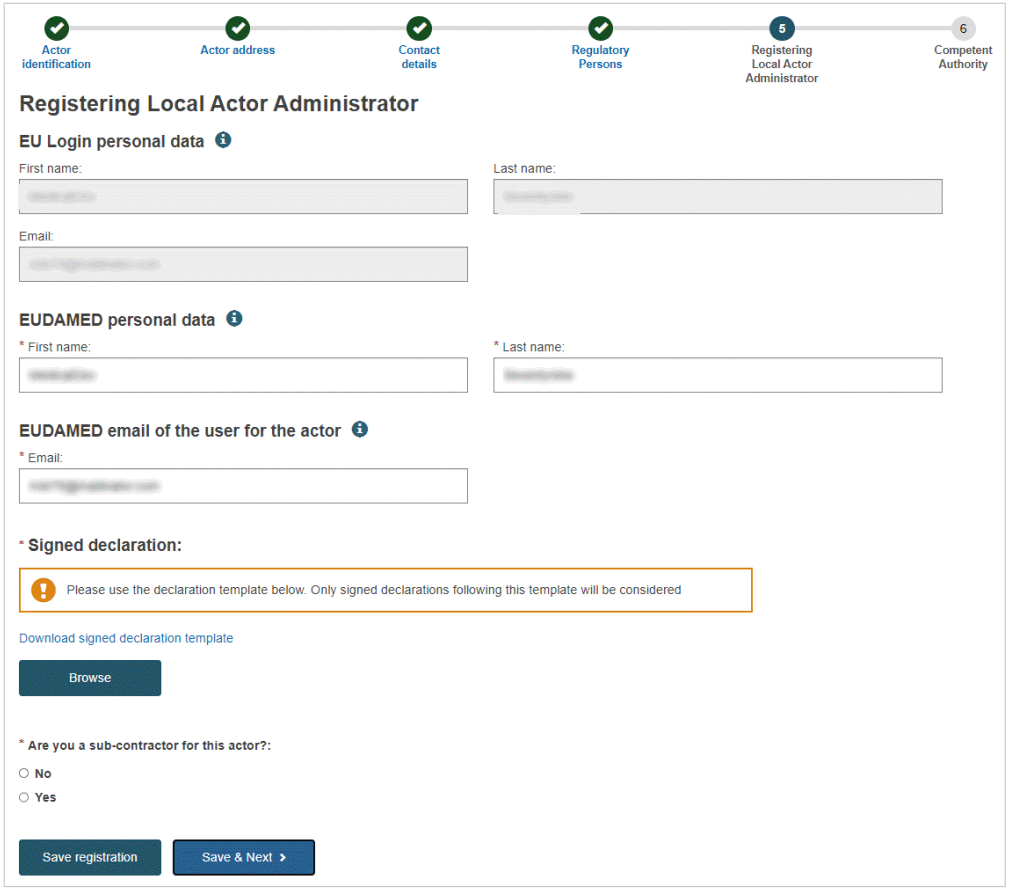
8. Enter the email addresses and other useful information regarding the contact points in your Actor. There are separate fields in which to enter contacts relevant to competent authorities, and those to be displayed to the public, and click **Save & Next**.
   Only for a non-EU manufacturer or Authorised Representative, you will be prompted by the Person Responsible for Regulatory Compliance, so that you can identify one or more regulatory person(s) within your Actor:



NOTE
Regulatory person contact

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

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



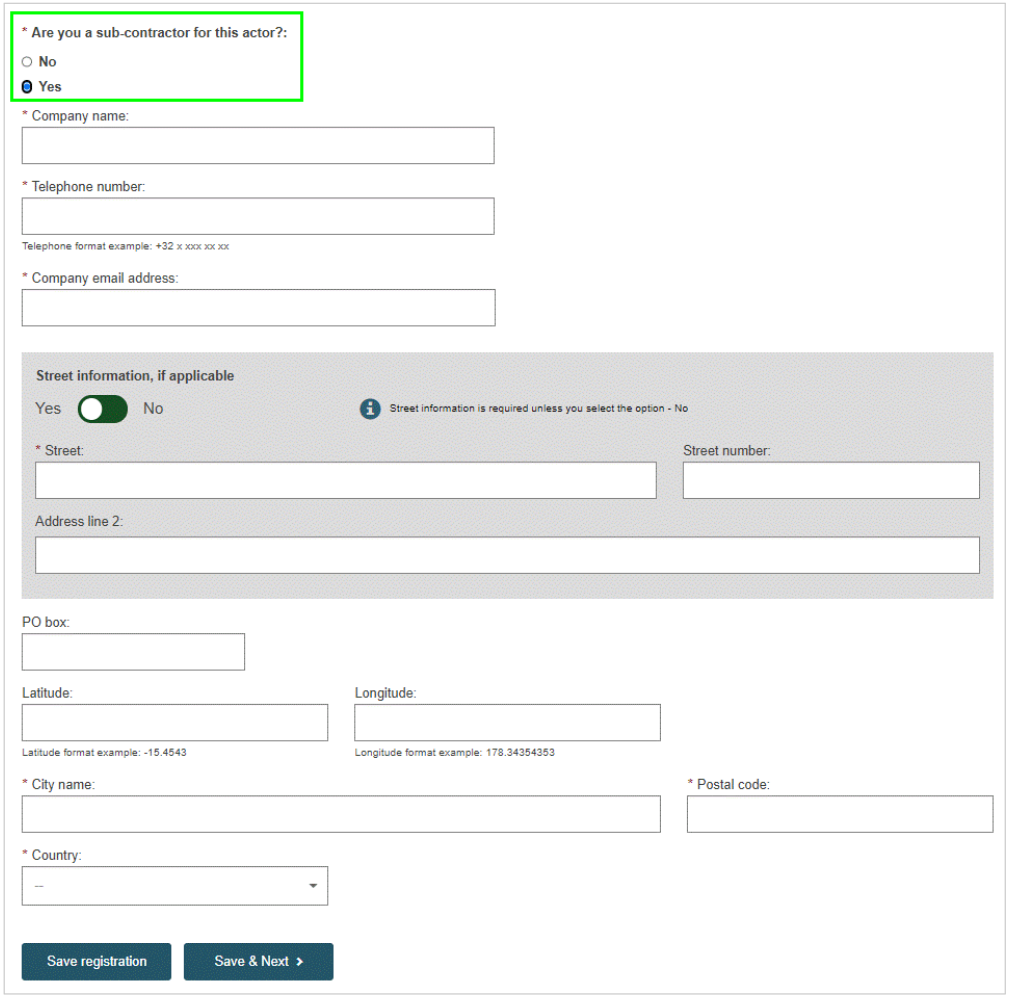
NOTE
Local Actor Administrator (LAA)

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

As LAA, you can manage all the details for your Actor in EUDAMED (e.g. name, address, contact details, etc.) as well as user access requests for it (see *Section 2.2.2 [50]*: *Validating user access requests*).

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

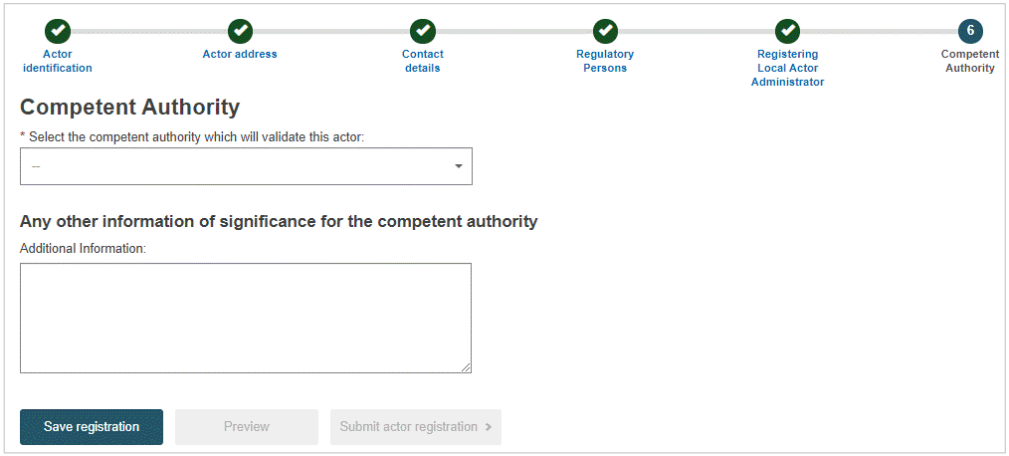
10. Check and complete the information on the page. Upload the signed declaration – in PDF format only – using the **Browse** button.



NOTE

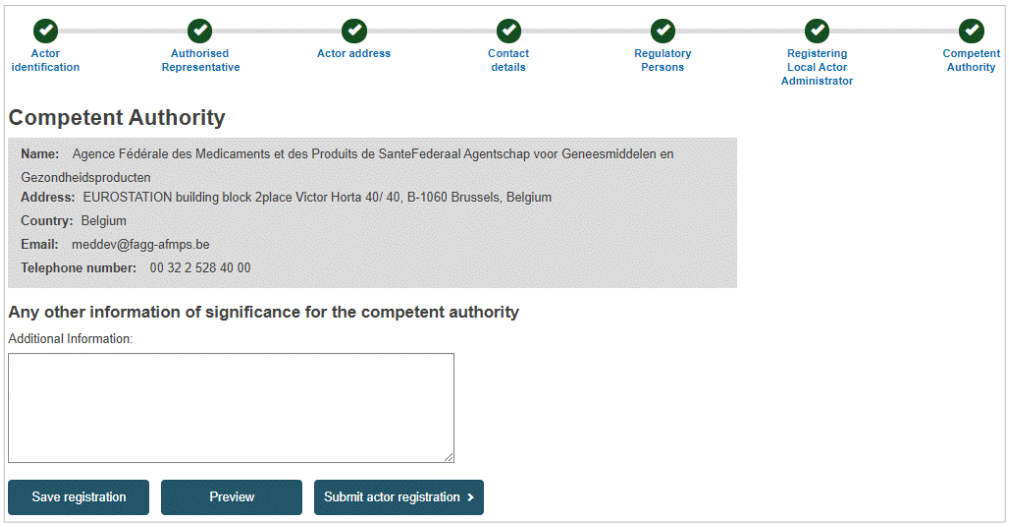
If you specify that you are a 'sub-contractor', an additional section at the bottom of the page will prompt you to provide your sub-contracting company details.

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

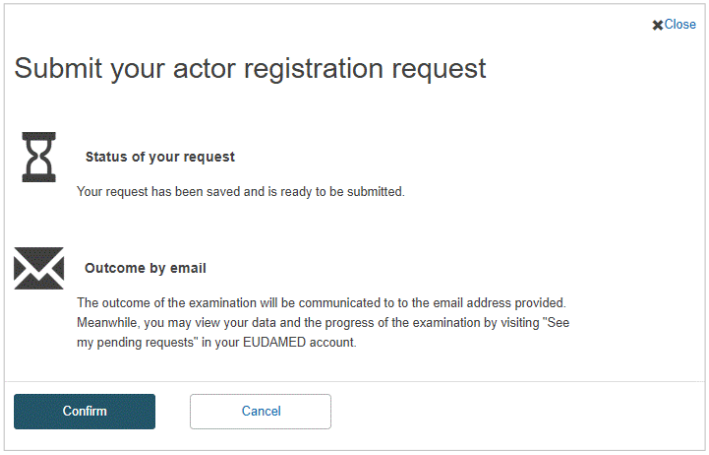


12. If there is a choice between multiple Competent Authorities, select the most appropriate one from the list. (A help file will be available for Actors established

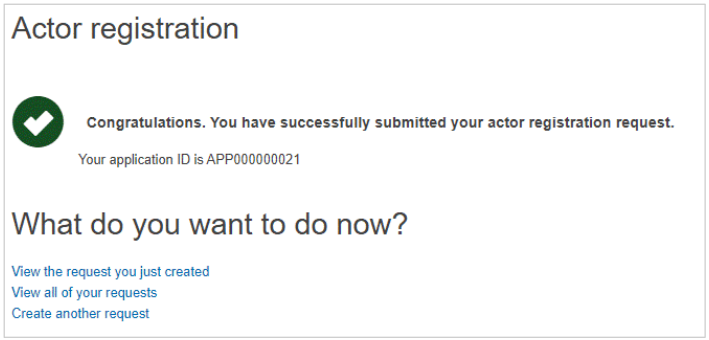
in Germany, to assist with the Competent Authority selection). If there is only one authority that can validate your registration, details will be pre-populated. To view a summary of your completed registration form, click **Preview**:



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



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



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

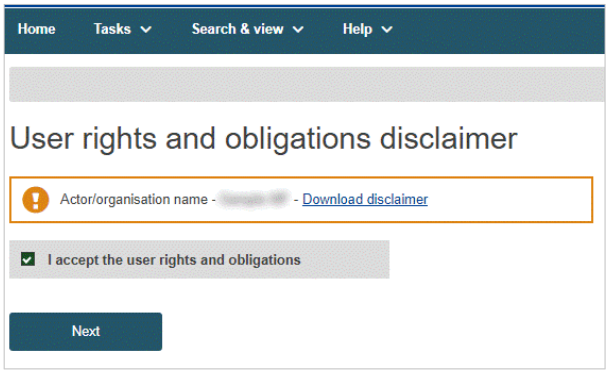
> **NOTE**
> The validation of the Actors registration requests is under the responsibility of the different national competent authorities (CAs).
>
> If you are a non-EU Manufacturer, the Authorised Representative indicated in your actor registration request will verify if prior to the national competent authority assessment. Therefore, you may wish to contact your relevant Authorised Representative or National Competent Authority.

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

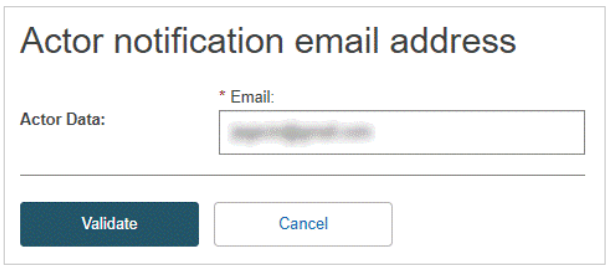
If your registration is approved

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

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

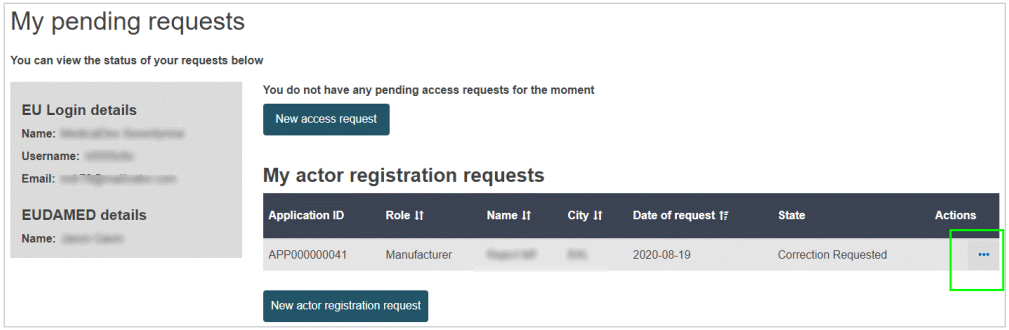


2. Click on **I accept the user rights and obligations** and then click **Next**. You will be prompted to validate your email address for the Actor module:



If your registration is not approved

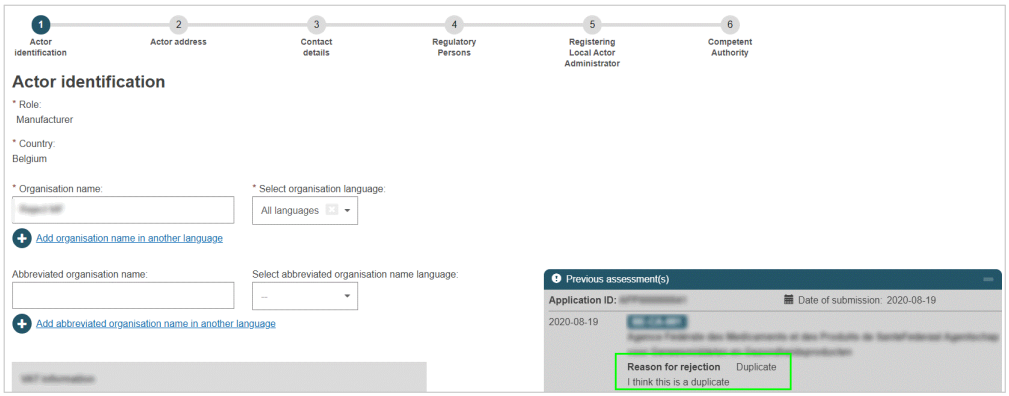
1. If your request is not approved, it will remain in your pending requests list. The next time you enter EUDAMED, your start page will be 'My pending requests', listing your registration requests and their states:



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

IMPORTANT

Requests with a 'Refused' state cannot be edited or resubmitted. The reason given by the competent authority for the rejection is displayed.



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

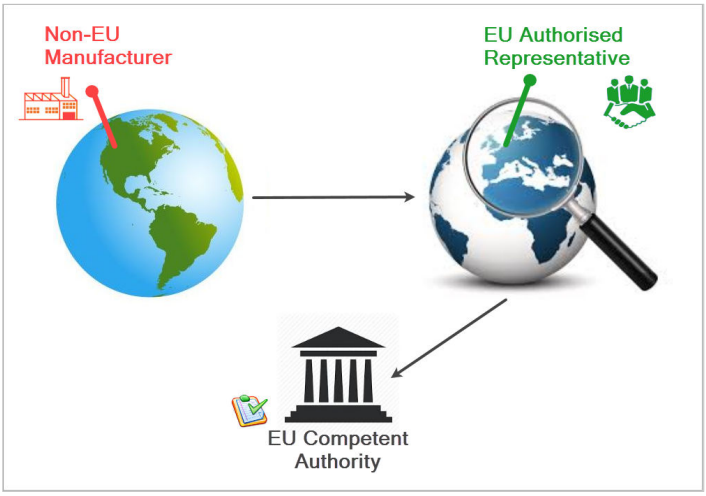
2.1.2 Registering as a non-EU manufacturer

The image opens an infographic illustrating the process.



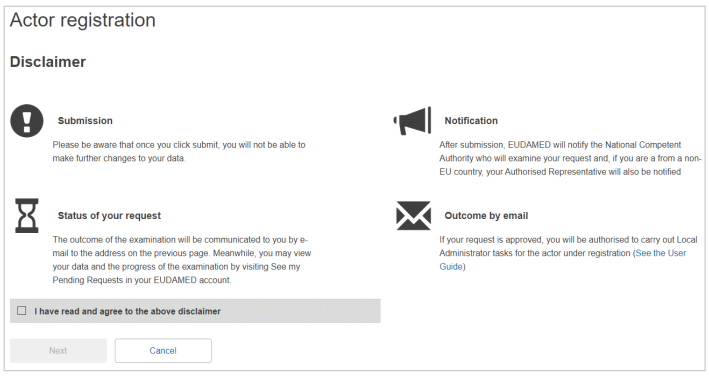
If you are a non-EU manufacturer, the procedure for registering differs from that explained in *Section 2.1.1 [9]*.

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:



3. Enter the required data:
   1. Identify your authorised representative:

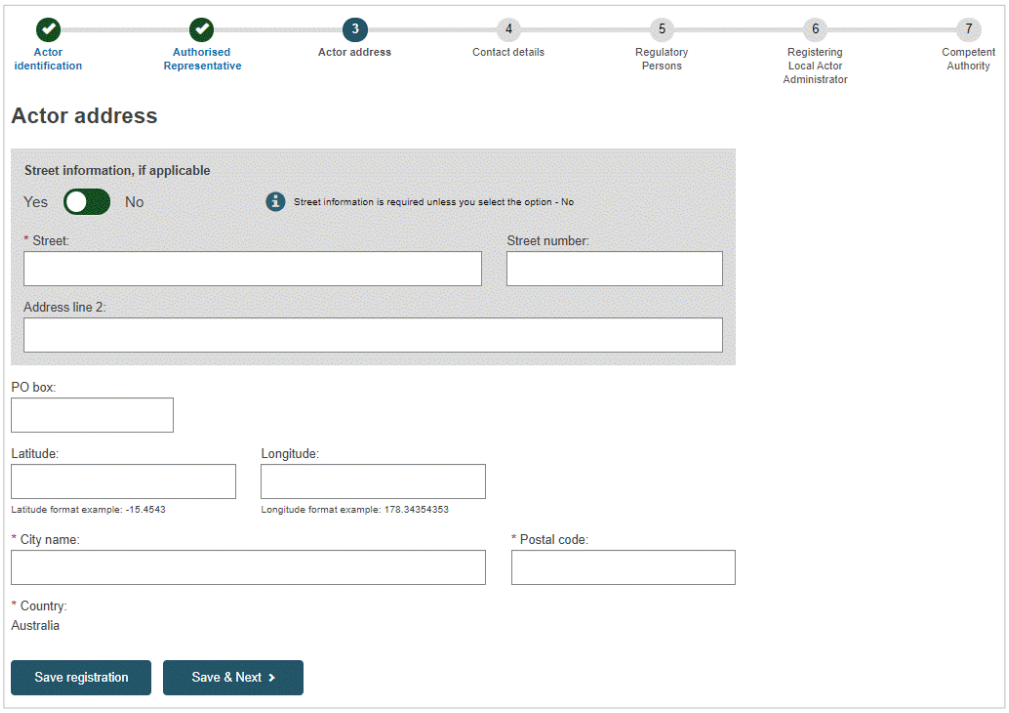
Do you know the Single Registration Number (SRN)?	Yes	Select **I know the SRN**, click **Find** and select the number.
	No	Unselect **I know the SRN**, select the country and enter the name of the Authorised Representative. Click **Find** and select the correct result.

> **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.

   2. Enter the validity start and end-dates of the written mandate with the Authorised Representative.

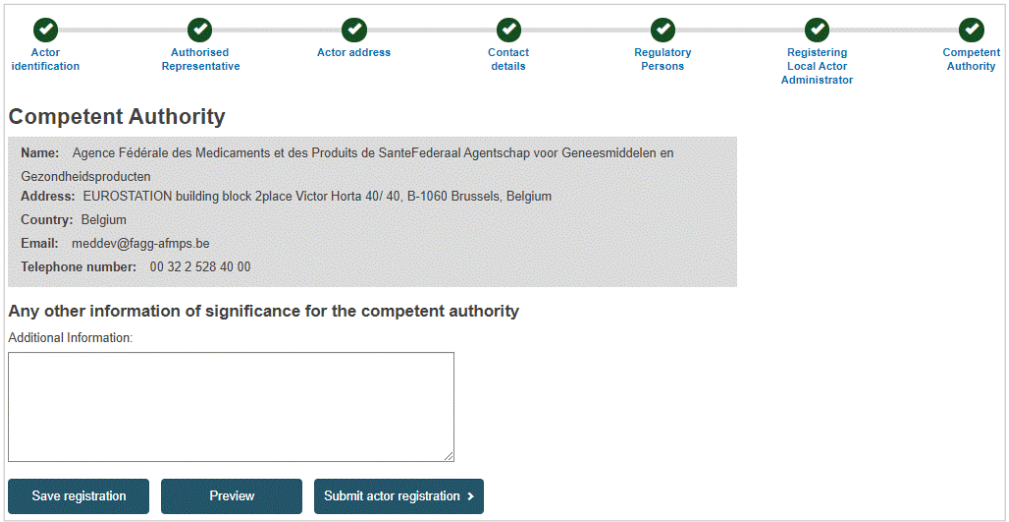
   3. In the **Upload summary mandate document** section, click **Browse**, select the location of the summary mandate (**PDF only**), and click **Open**. The file will appear under *Upload summary mandate document*. You can remove it by clicking the X next to the name of the file.

4. Click **Save & Next**.



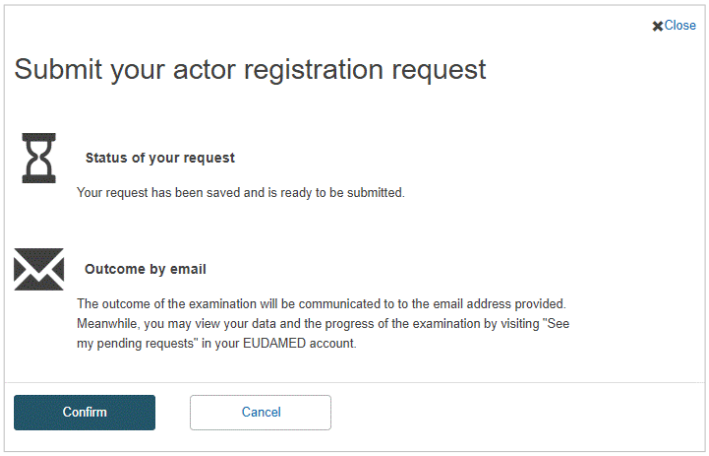
> **NOTE**
> You don't have to upload the full mandate text. It's enough to upload a summary mandate (click here for the template).

4. Check and complete the information on the page. Upload the signed declaration – **in PDF format only** – using the **Browse** button.
   Click **Save & Next**.
   In the final step, the Competent Authority that will validate your registration request (i.e. the CA responsible for your Authorised Representative) is identified, with contact information.



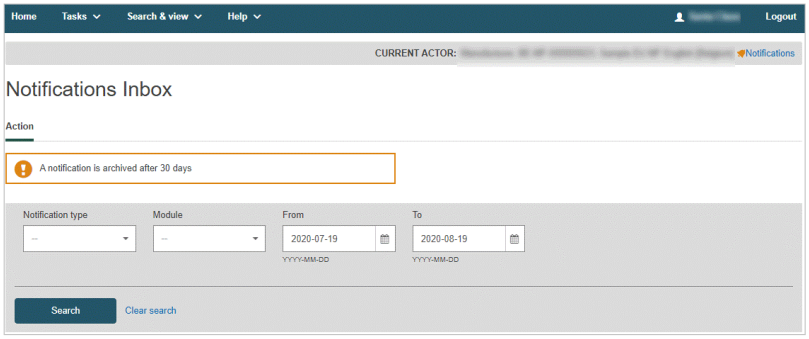
5. Enter any additional information you wish to pass on to the Competent Authority, and then click **Preview**. A summary of your completed registration form is displayed.

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



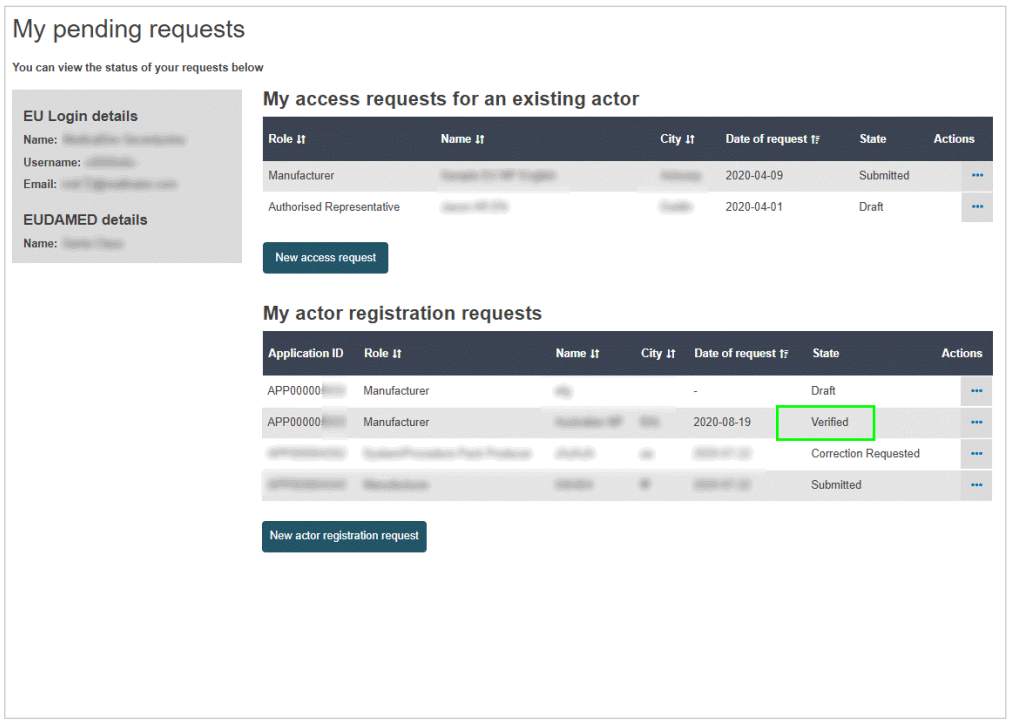
7. Read the information in the window and click **Confirm**.
   - Your registration request is saved and appears with a *Submitted* state in your *Pending requests* list.
   - Your registration request has a unique application ID and is submitted first to your Authorised Representative for verification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

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



What next?

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



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

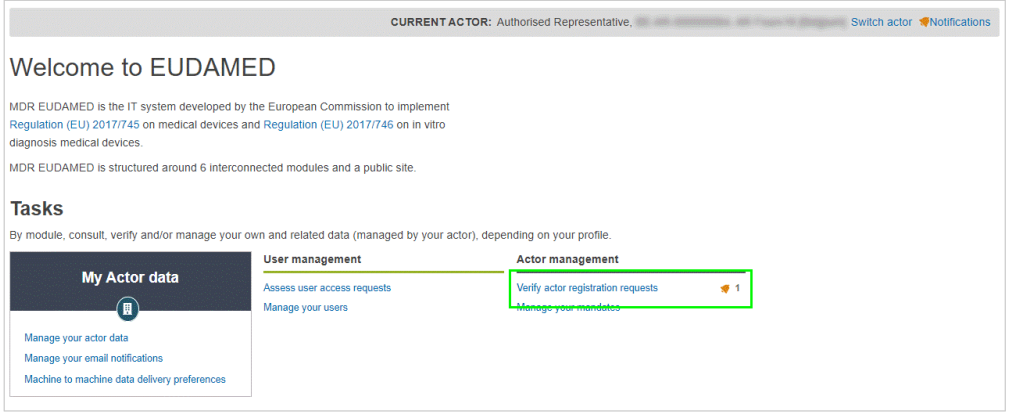
2.1.3 Verifying non-EU manufacturer registrations

[Specific to AR Verifier]

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

To verify a non-EU manufacturer registration request

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:

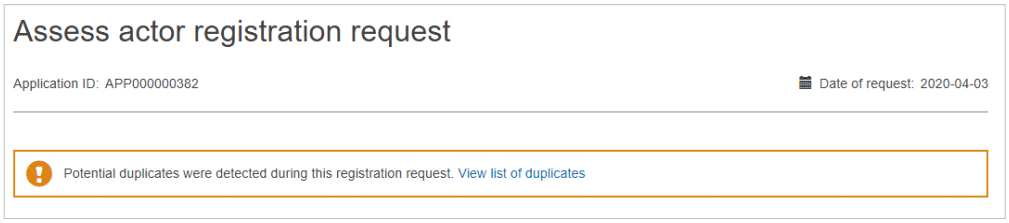


2. Click **Verify actor registration requests** in the *Actor management* section of the dashboard. The *Actor registration management* page lists all pending non-EU manufacturer registration requests waiting to be verified by your actor (if any):

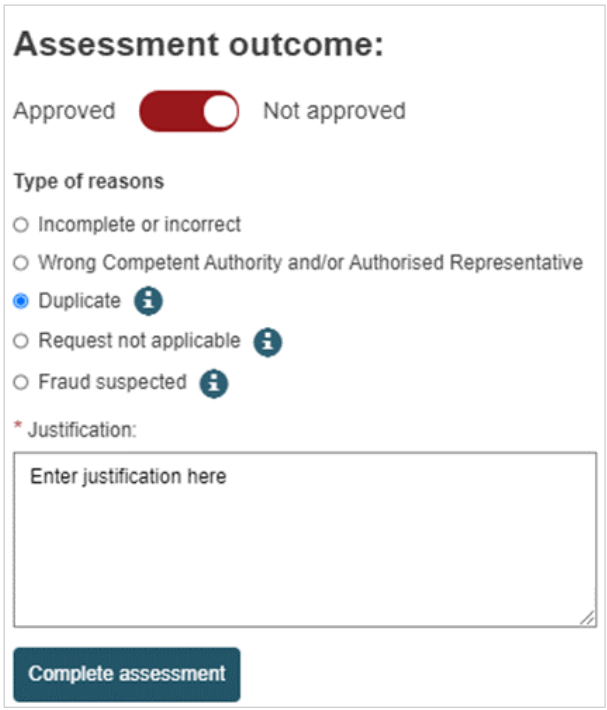


3. Click **Assess** in the *Actions* column to review and assess the desired registration request in the list. All details of the selected registration request, as submitted by the non-EU manufacturer, are displayed.

4. Review the information. A warning message will flag possible duplicates, so select the correct registration request from the list available:

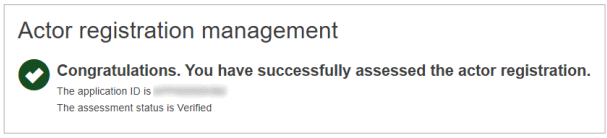


5. In the *Assessment* section, slide the toggle left to **Approved** or right to **Not approved**.
   If you **choose to approve** the request, you may enter additional notes.
   If you **choose not to approve** the request, you will be prompted to the **Justify your decision** with one of the following reasons:



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.

6. 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:

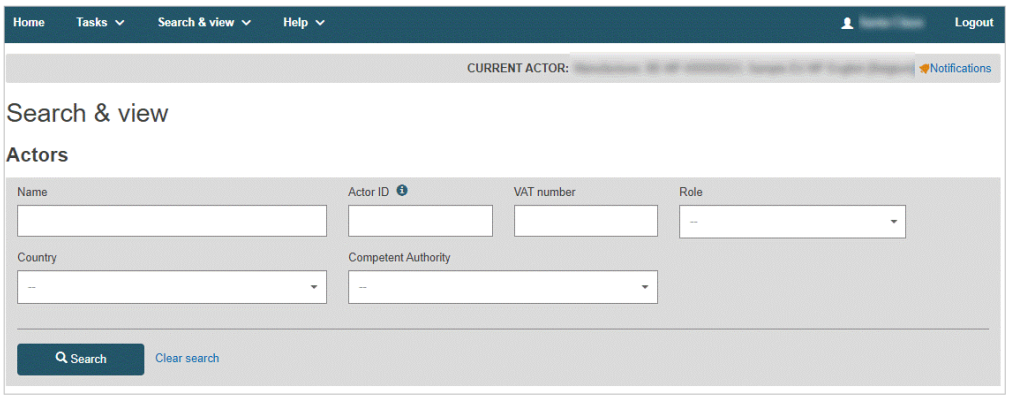


2.1.4 Search and view registered actors

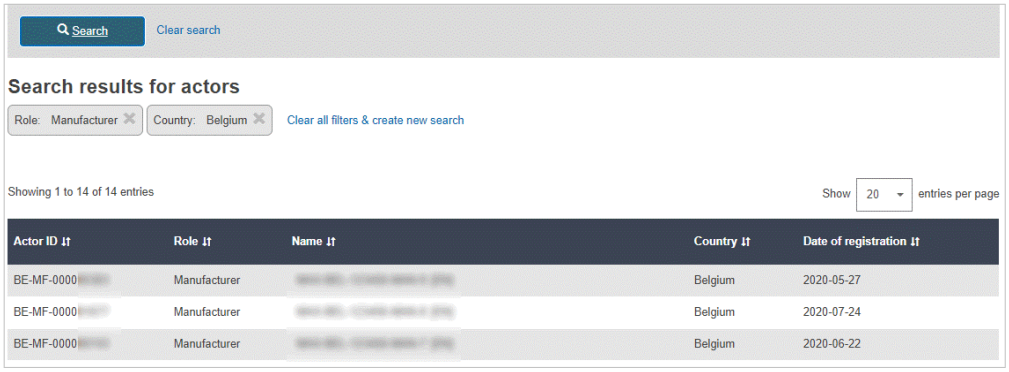
Once an economic operator has been validated by its Competent Authority and an Actor ID/SRN is issued, its details (except those only for the Competent Authority) become visible to all users in EUDAMED and will be publicly available on the EUDAMED public website.

To search and view actors:

1. 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:



3. To view the details for any actor, click the entry in the results list.

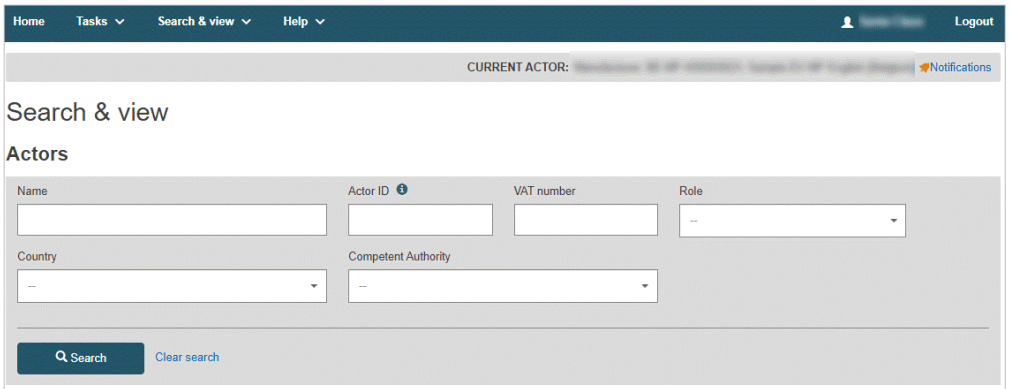
4. To download your search result in bulk (XML) format, activate the toggle 'Only enable search filters available for bulk XML download of economic operators'. Once your search is complete, click the button **Generate XML** and confirm. You can now view the status and download the XML file containing 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.

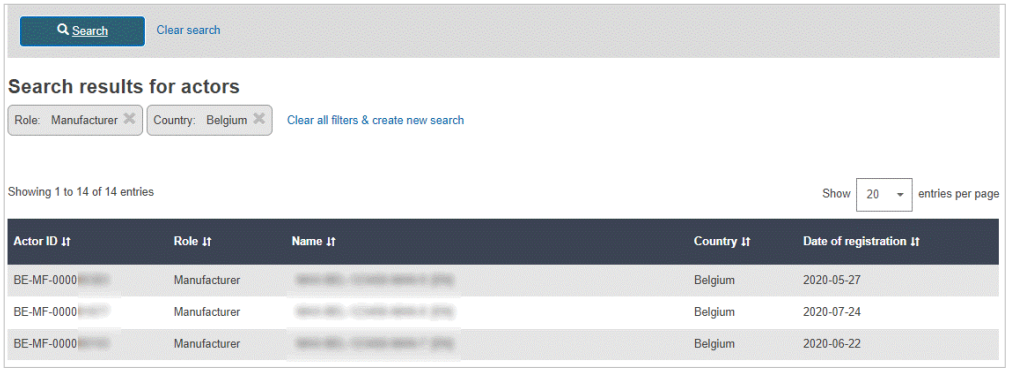
Search and view actors for non-EU Manufacturer/Authorised representative

Search for Non-EU Manufacturer

1. 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:



3. To view the details for any actor, click the entry in the results list.

4. Once you have clicked on one of the results from the list, the selection will open in a new page:

5. By using the side menu, you can navigate between the different information related to the actor:

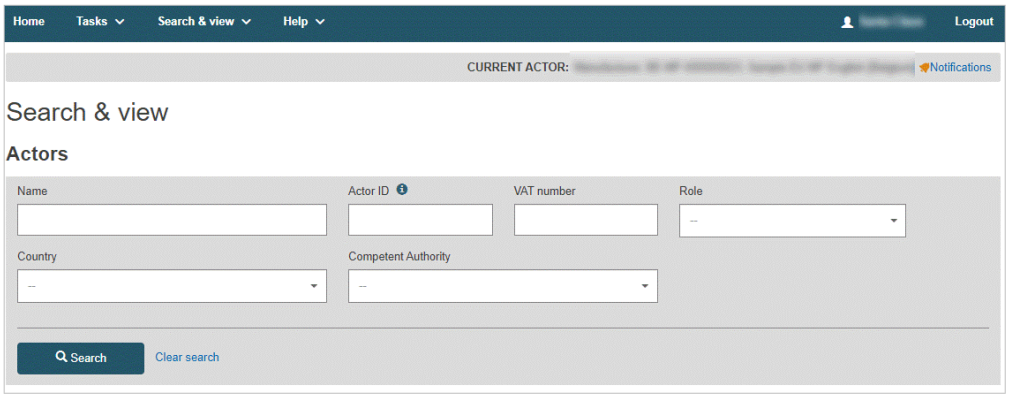
6. Each section of data will be displayed within an accordion, this accordion can be expanded by clicking on the title of said accordion or by clicking on the same title in the side menu:

7. Different information can be found in each section, clicking on 'Actor information' will display the basic details of the actor you searched up:

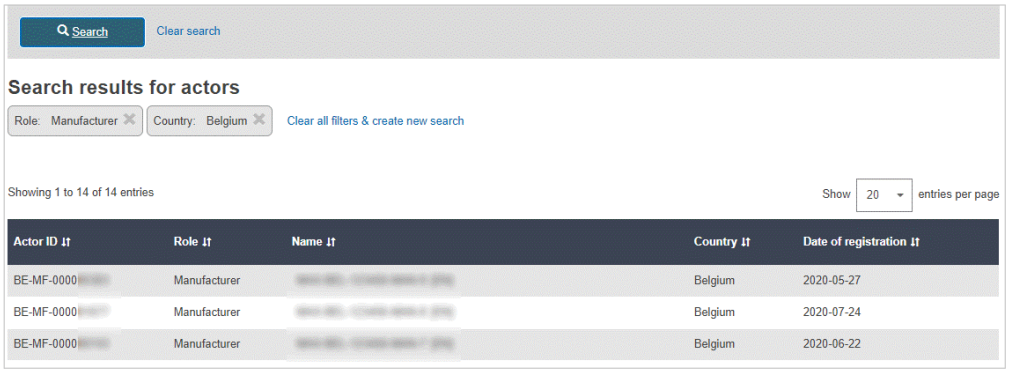
8. Clicking on 'Authorised representative(s) mandates' will display all current and past mandates as well as their details:
   Mandate title: an automatically generated title by the system for the mandate
   Actor ID/SRN: the ID for the actor related to the mandate
   Name, address, country, email and phone number: the basic information for the Authorised representative who accepted/rejected the mandate
   Mandate validity date: displays when the mandate was created till its expiration date

Search for Authorised representative

1. 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:



3. To view the details for any actor, click the entry in the results list.

4. Once you have clicked on one of the results from the list, the selection will open in a new page:

5. By using the side menu, you can navigate between the different information related to the actor:

6. Each section of data will be displayed within an accordion, this accordion can be expanded by clicking on the title of said accordion or by clicking on the same title in the side menu:

7. Different information can be found in each section, clicking on 'Actor information' will display the basic details of the actor you searched up:

8. Clicking on 'Non-EU manufacturers' will display a link, clicking on this link will redirect you to the list of Non-EU manufacturers linked to the same authorised representative:

9. Clicking on 'Competent Authority' will display the details for the Competent Authority that is in charge of the actor:

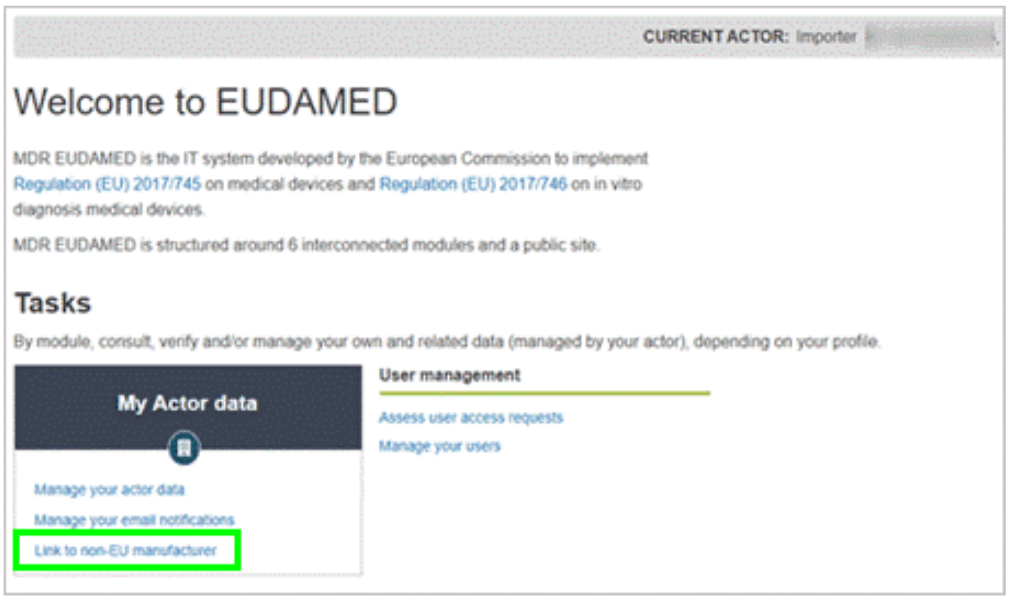
10. 'Devices' will also display a link, clicking that link will redirect you to a list of devices registered under this actor:

2.1.5 Linking a non-EU manufacturer to an importer

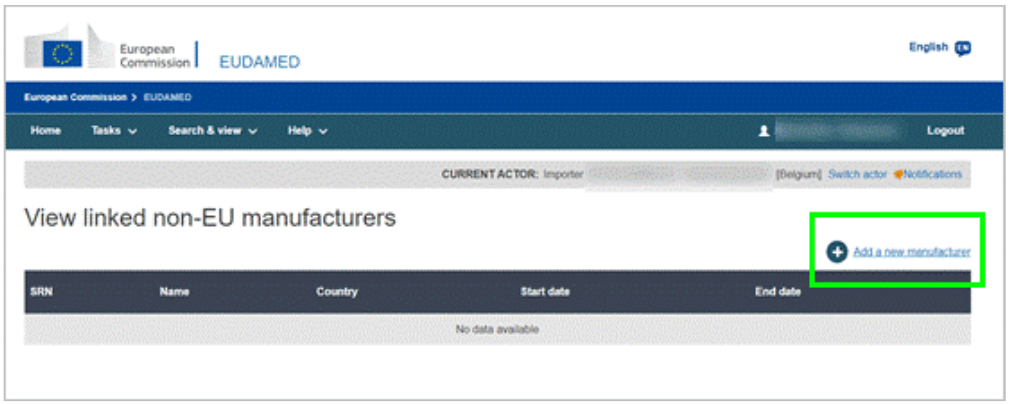
[Section specific to importers with 'Linker' profile]

To link a non-EU manufacturer to your importer:

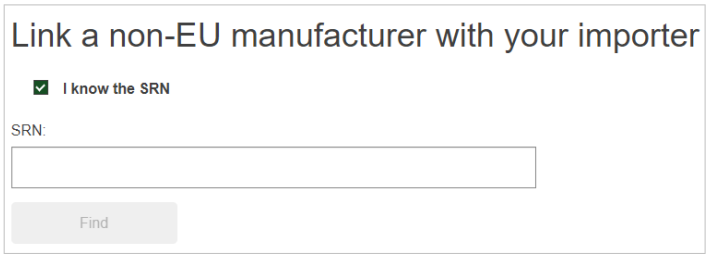
1. Go to the Dashboard:



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



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

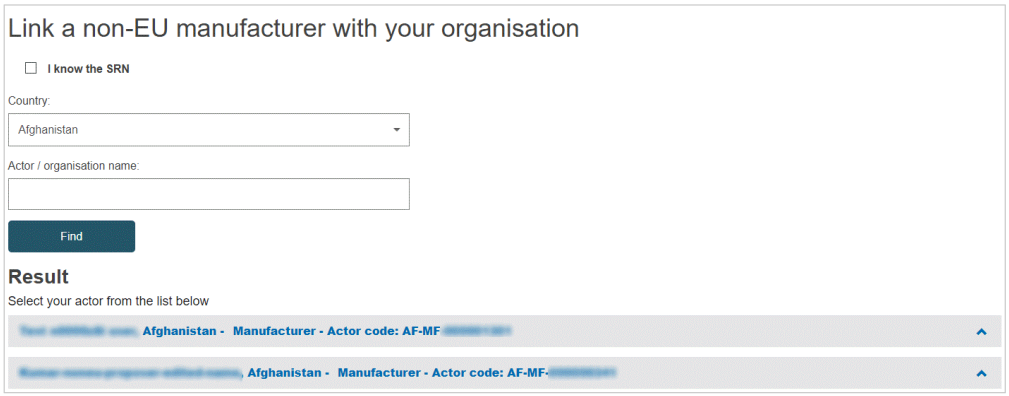


4. If you know the Actor ID/SRN, enter it here and click **Find** to select the manufacturer.

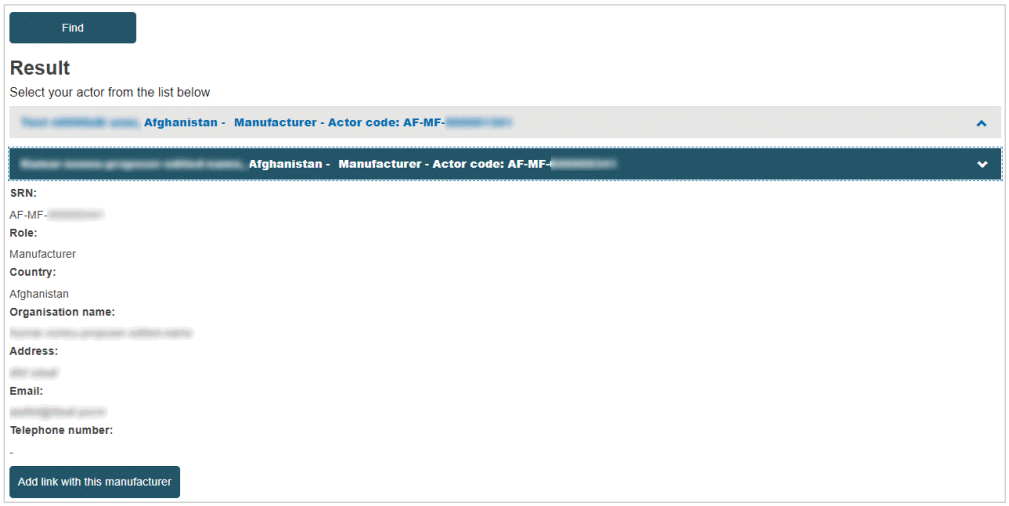
5. If you don't know the Actor ID/SRN, uncheck **I know the Actor ID/SRN**. Two new fields will appear:



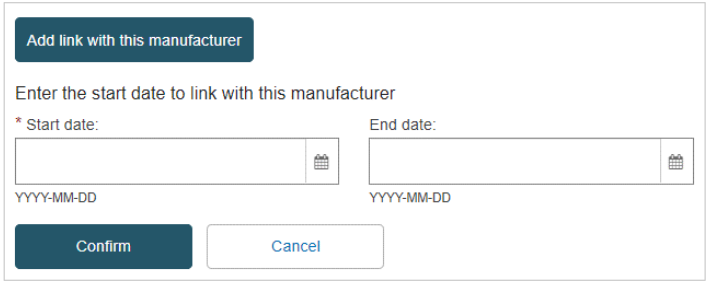
6. Enter the country and actor/organisation name, then click **Find**. You will see a list of results based on your search criteria:



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



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



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

2.1.6 Updating actor details

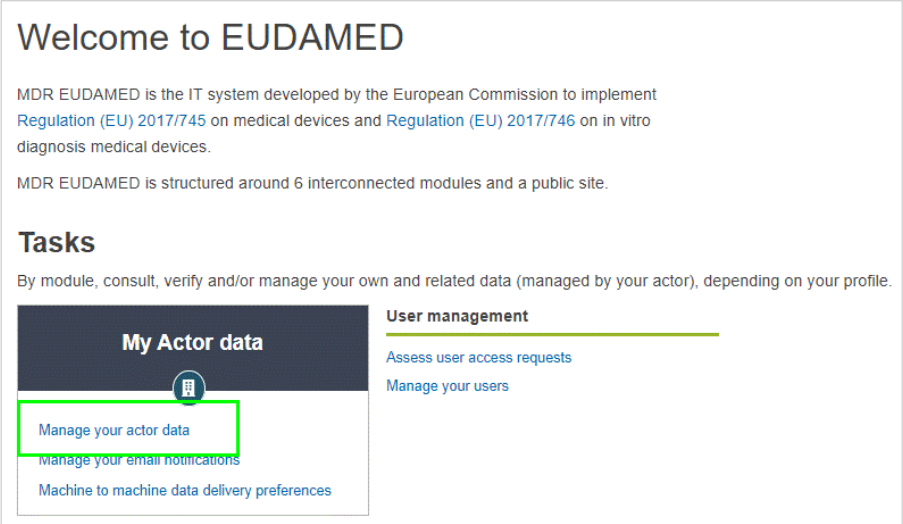
[Section specific to Local Actor Administrators (LAA)]

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

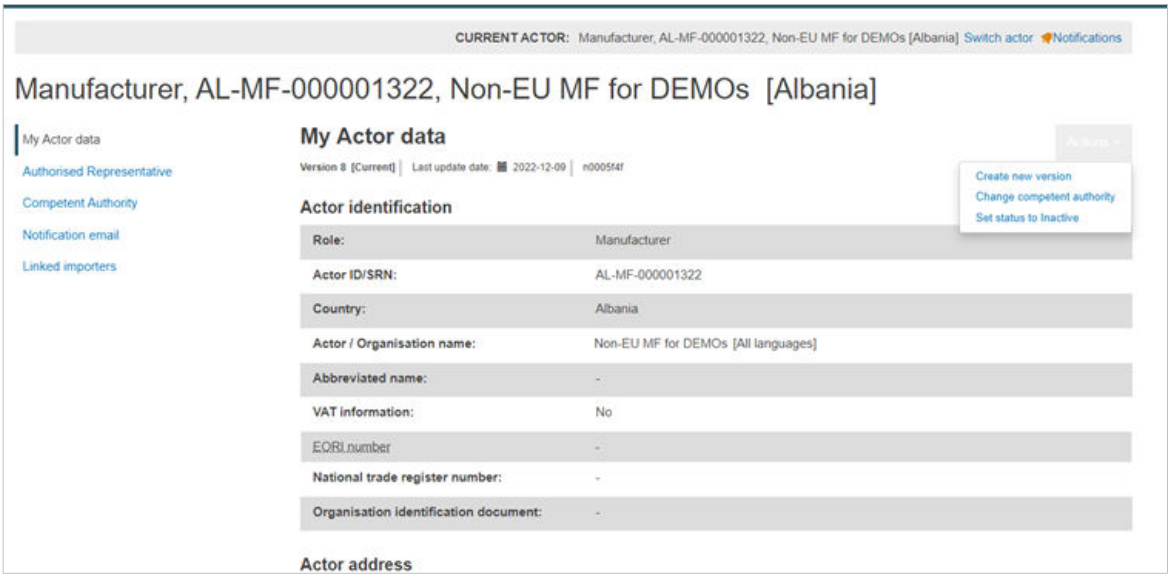
To update actor details

1. Log in to EUDAMED with a *Local Actor Administrator* profile for the actor in question.

2. In your dashboard, select **Manage your actor data** under *My Actor data*:



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:

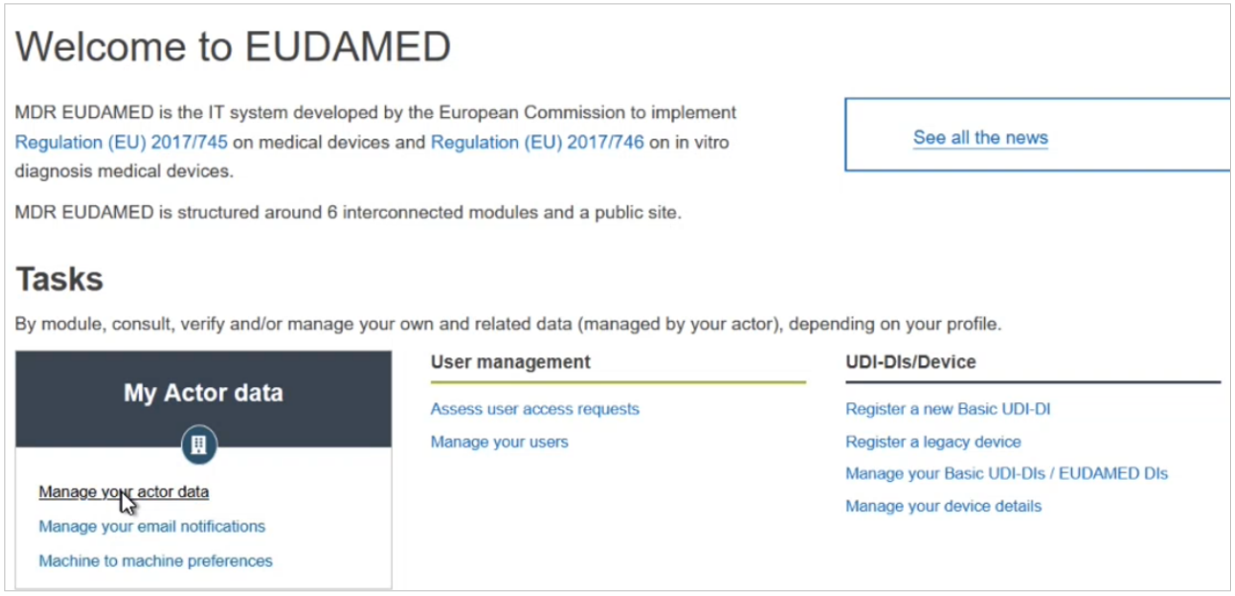
1. Click **Create new version** and answer **Yes** to the confirmation message.
2. Make all required changes in the corresponding tabs.
3. When you are done, click **Register new version** and answer the confirmation message.

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

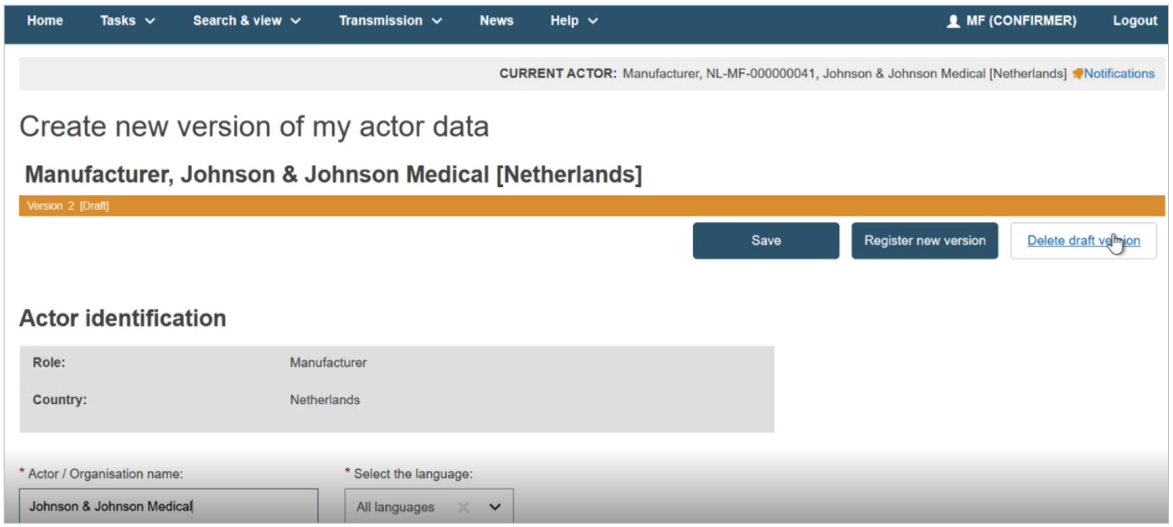


Deleting an actor's draft

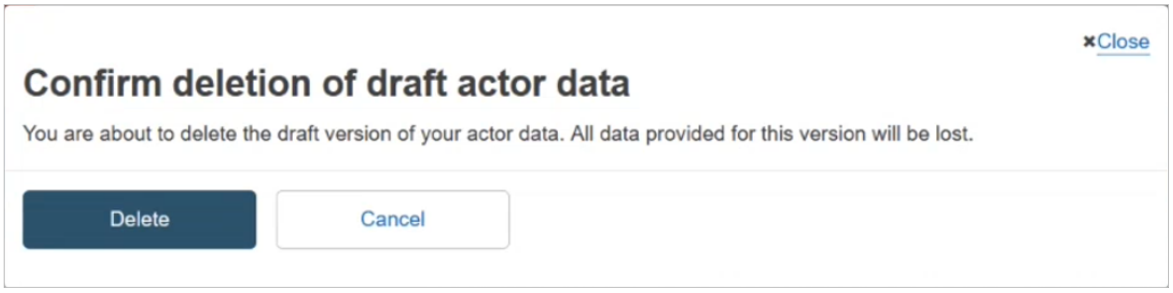
In order to delete a version in draft, on the homepage, click on **Manage your actor data**:



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



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

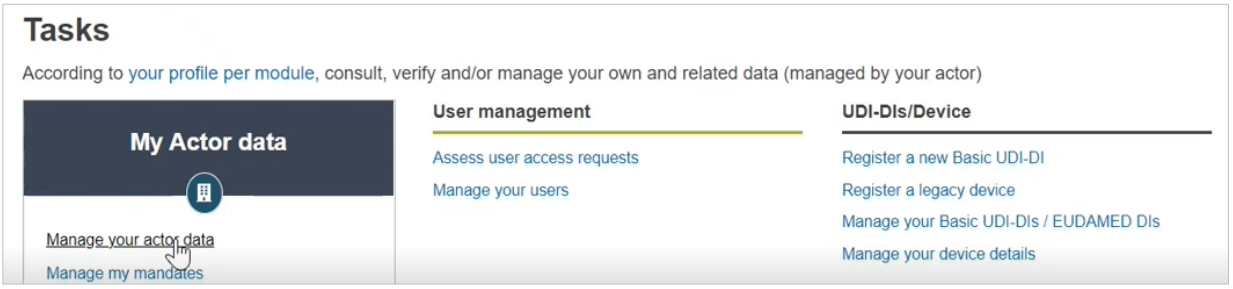


3. Once you click on **Delete**, the draft will disappear from the list.

2.1.7 Activate/deactivate your actor

[This section is for LAA profiles only]

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



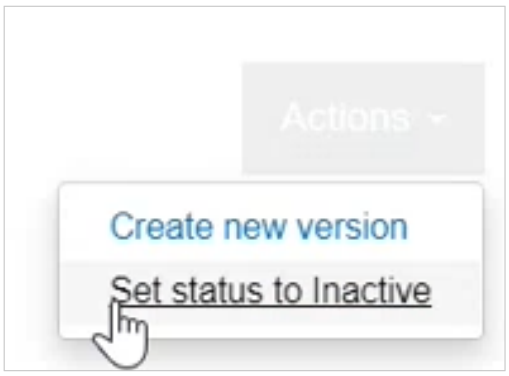
NOTE
An actor CANNOT change its status if they have an Actor data in draft OR if they have submitted a "Change of Competent Authority request".

Set your status to *Inactive*

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



2. Click on **Set status to Inactive**:

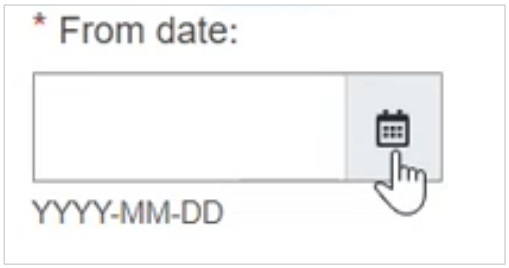


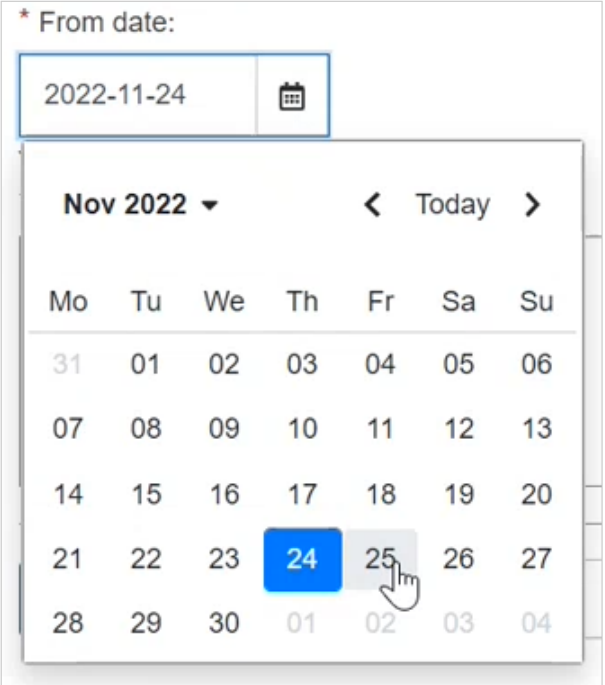
NOTE
By changing your status from *Active* to *Inactive*, a new Actor data version will be created reflecting your new status.

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

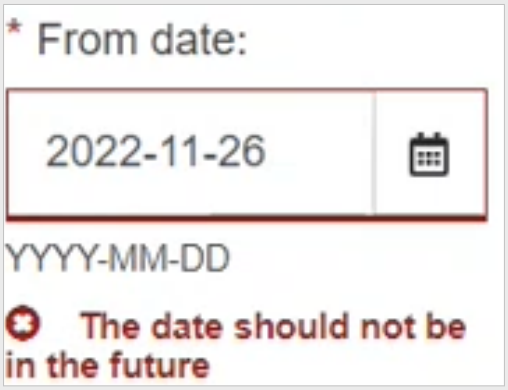


4. Select the date from when this actor is no longer *Active*:





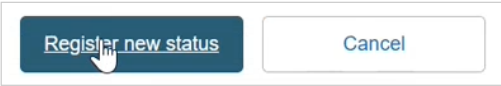
NOTE
Selecting a date in the future is not allowed.



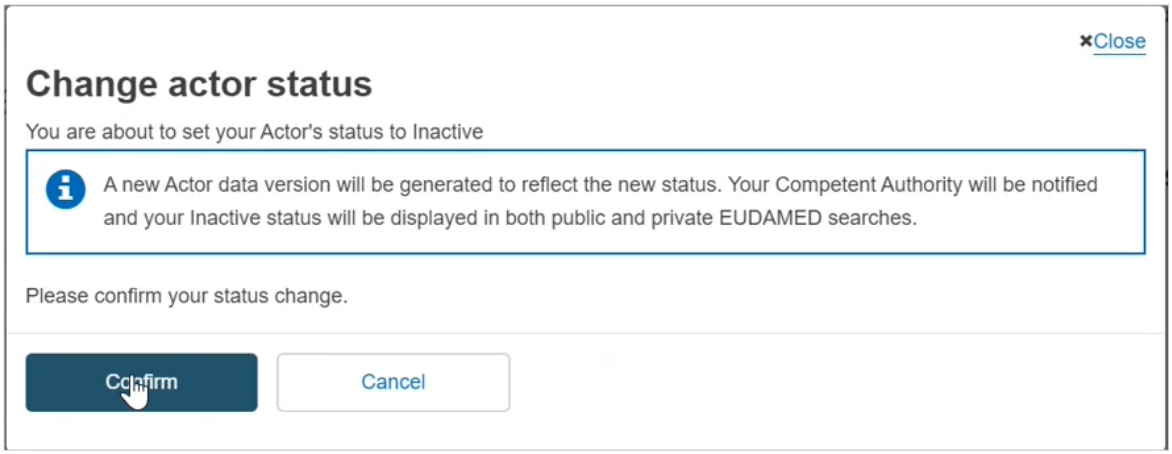
5. In the "Reason" box, write the reason why the actor is inactive:



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



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



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

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

2.1.8 Changing a competent authority for registered actors

[Specific to EO]

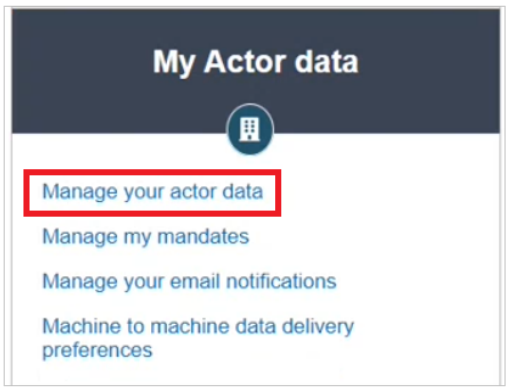
The change of responsible Competent Authority (CA) can be necessary in some specific cases. EUDAMED will only allow to select a new responsible CA for those specific cases and among the possible CAs that the system will present.

The change can be triggered by either:

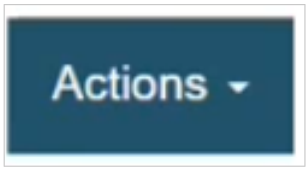
- For an EU economic operator, a move of location inside the same country;
- For a non-EU manufacturer, a change of Authorised Representative or a change of responsible Competent Authority for their Authorised Representative;
- For a non-EU SPP producer, a change in the market distribution of their SPPs;

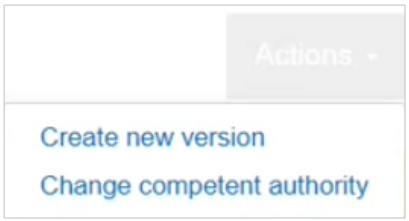
For the non-EU manufacturers, their responsible CA must be at any moment one of the responsible CA(s) of the AR(s) with which they have an active mandate.

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



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



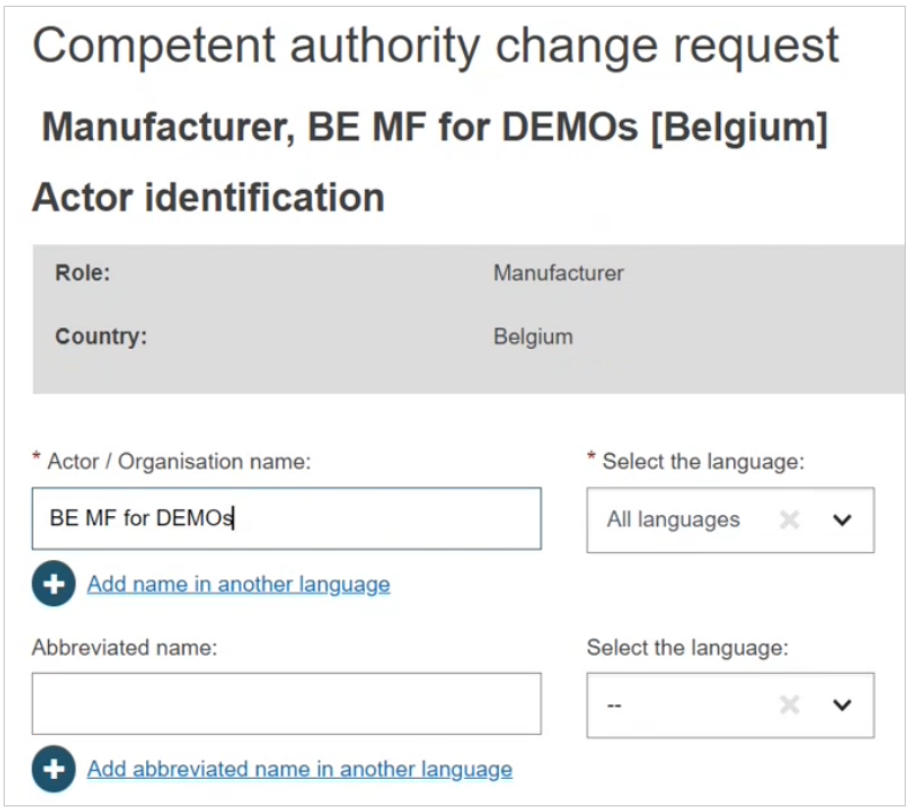


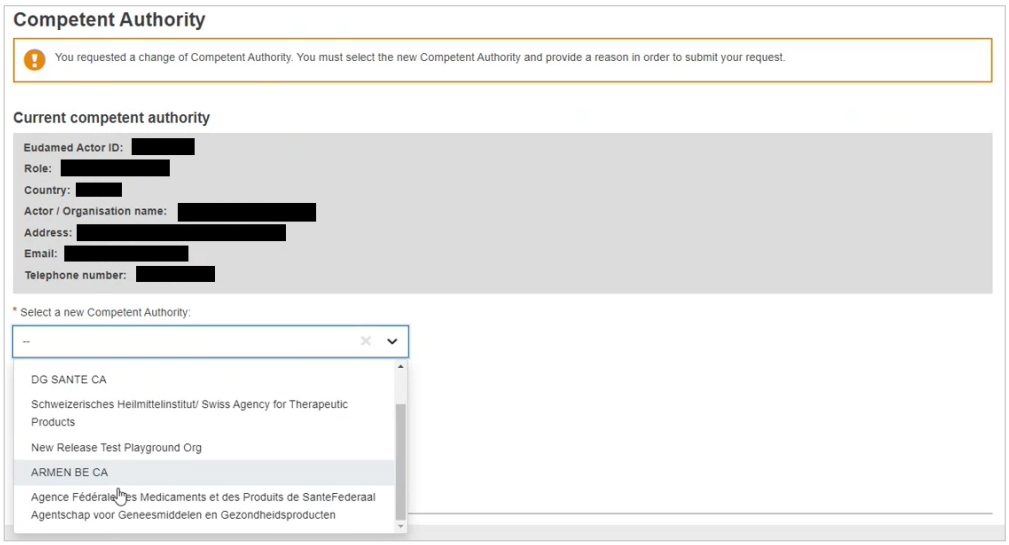
NOTE
If a request for "change competent authority" has already been submitted, no further editing of the actor data is allowed till the change is either accepted or rejected.

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

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

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

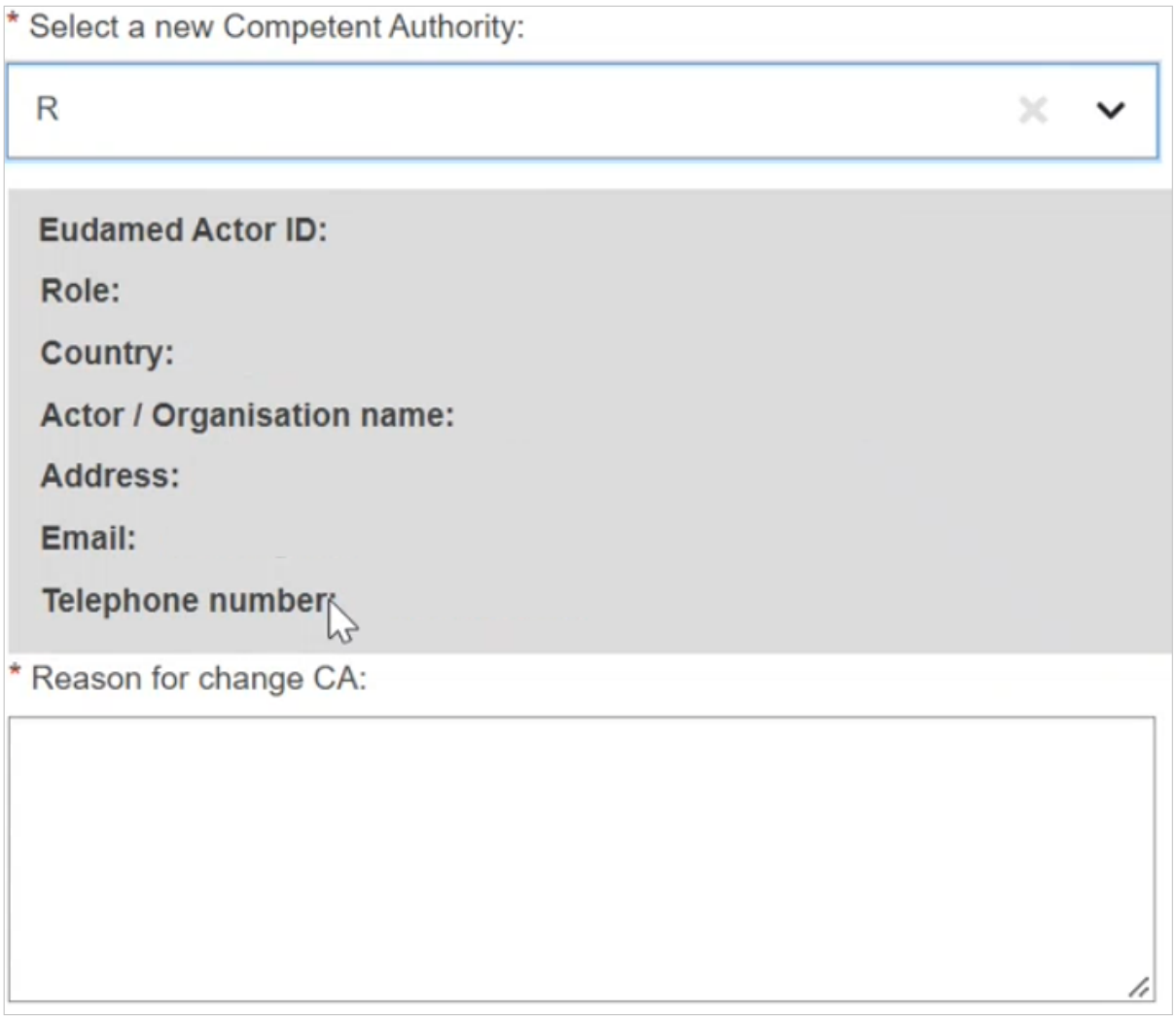




NOTE

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

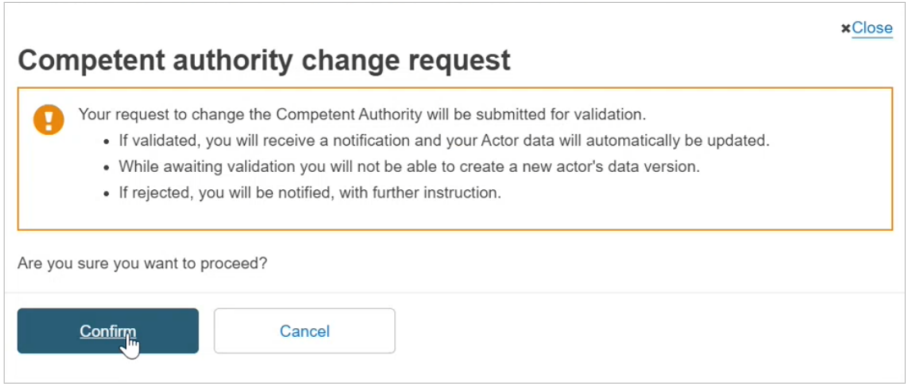
4. Once you have selected a new competent authority, enter the reason for the change of CA in the free text box below:



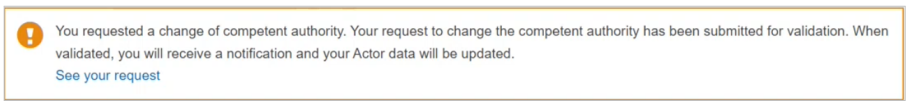
5. Click on **Submit request**:



6. A pop-up message will appear, click on **Confirm** to continue with your current action or **Cancel** to go back:



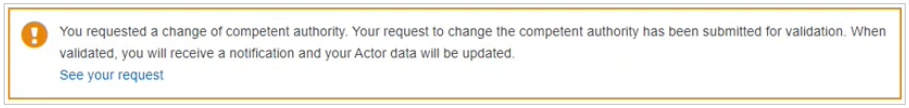
7. A success message will appear, non-EU manufacturers need to wait for the concerned Authorised Representative to assess the CA change request:



To see your pending/rejected competent authority change requests:

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

2. If you have any pending/rejected requests, they will be accessible via the link found in the notice message.
   Pending request message:



   Rejected request message:



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

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



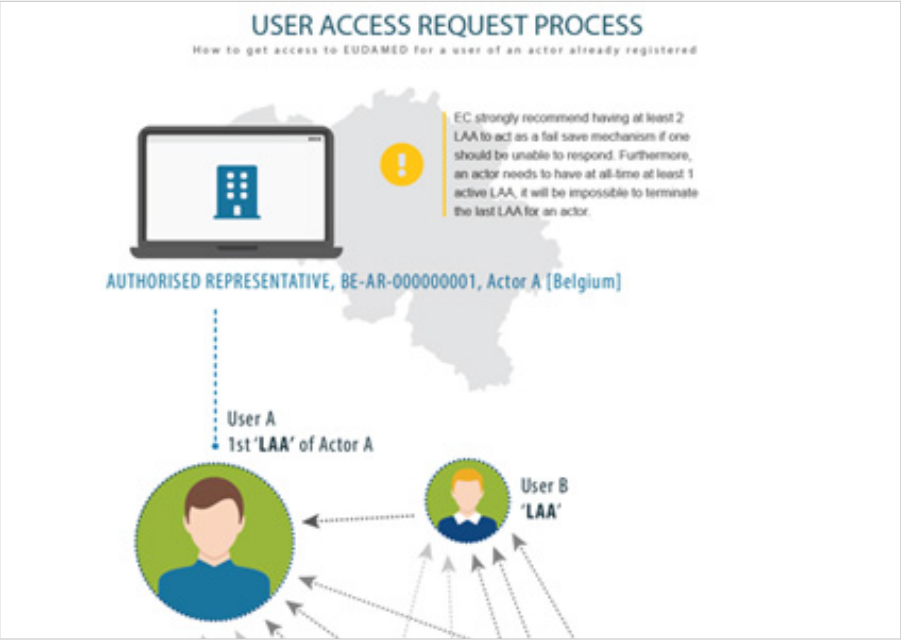
   Reason for rejection and other details:



2.2 Users and user access management

2.2.1 Requesting access as a user to an existing different actor

The image opens an infographic that illustrates the process.



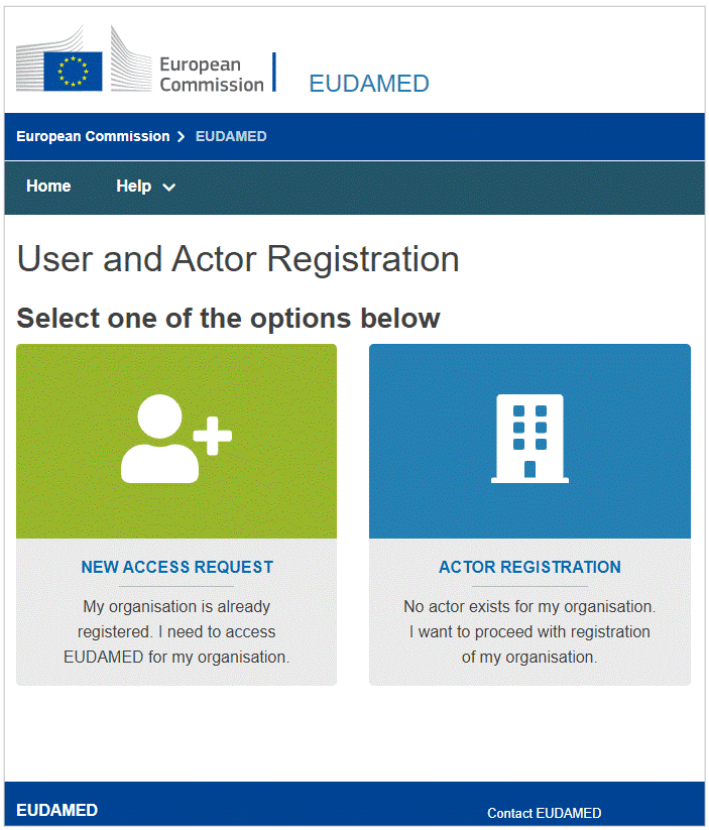
This chapter introduces how to request a new user's access to an Actor that is different than the one you already have access to.

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

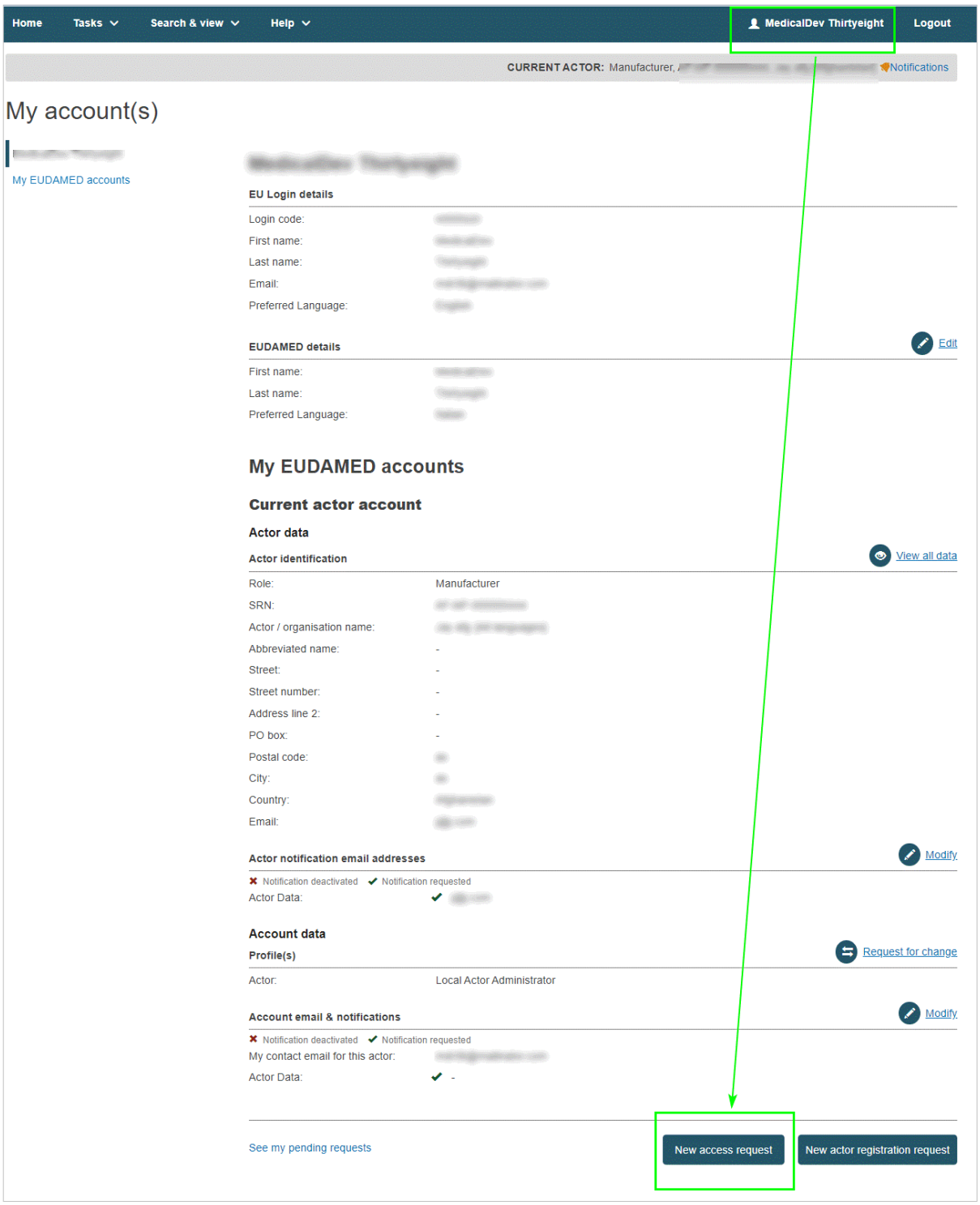
To request access as an actor user

1. Log in to EUDAMED

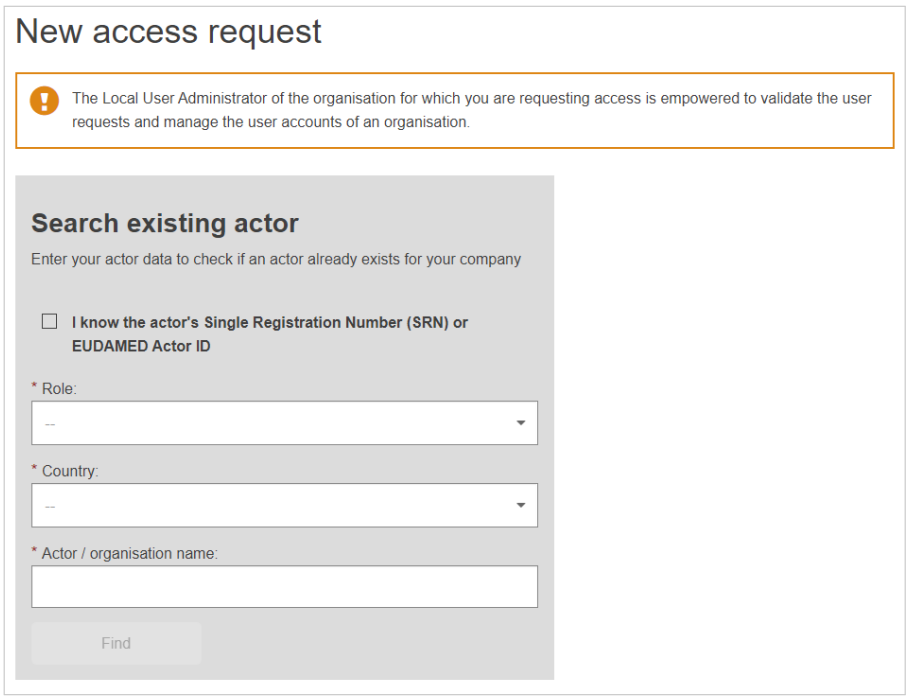
2. If you don’t have user access for a registered actor yet, click the **New access request** box, in the **User and Actor Registration** page:



3. Alternatively, if you are logged in with a EUDAMED user account, click your name at the top right of the page, and then click **New access request** at the bottom of your EUDAMED user account detail page:



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



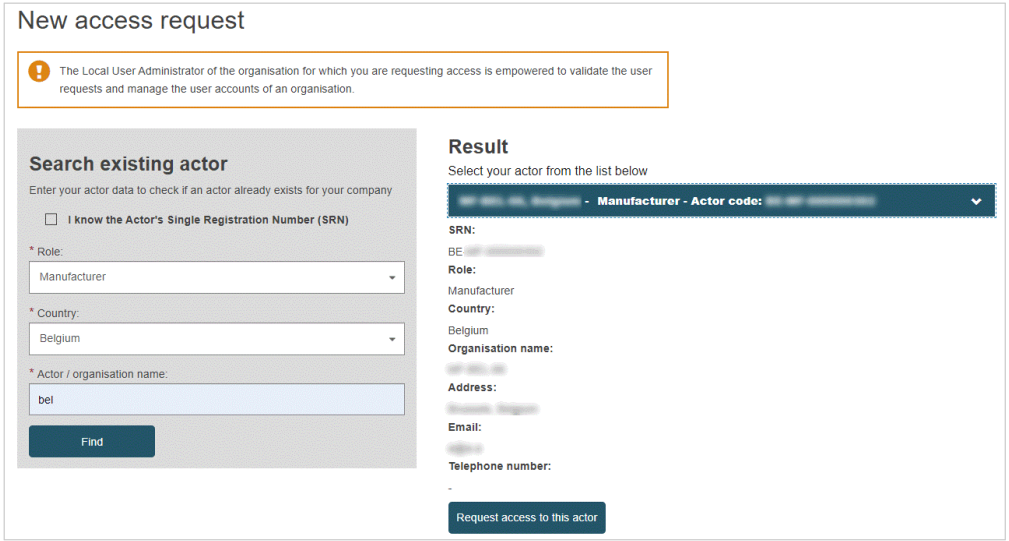
NOTE

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.

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**.

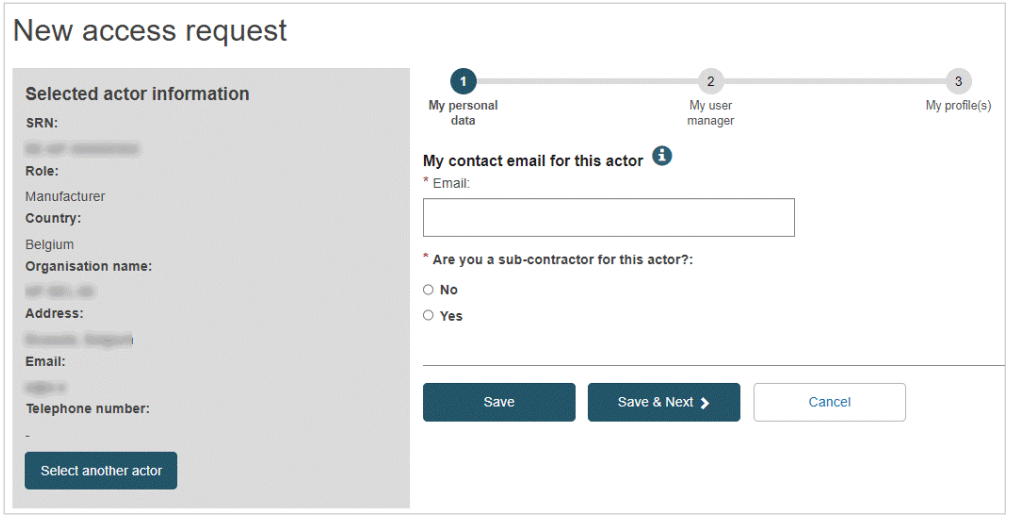
5. If you don't know the Actor ID/SRN, you can find the actor by searching with: **role**, **country** and **name** (or part of it).

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



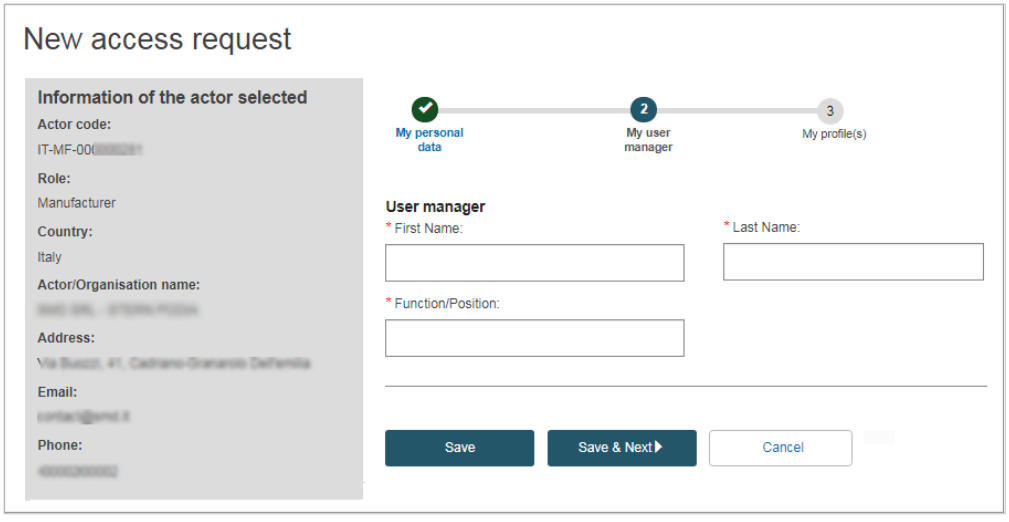
NOTE
You cannot request access to an actor you are already registered with, the system will not be able to locate it.

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

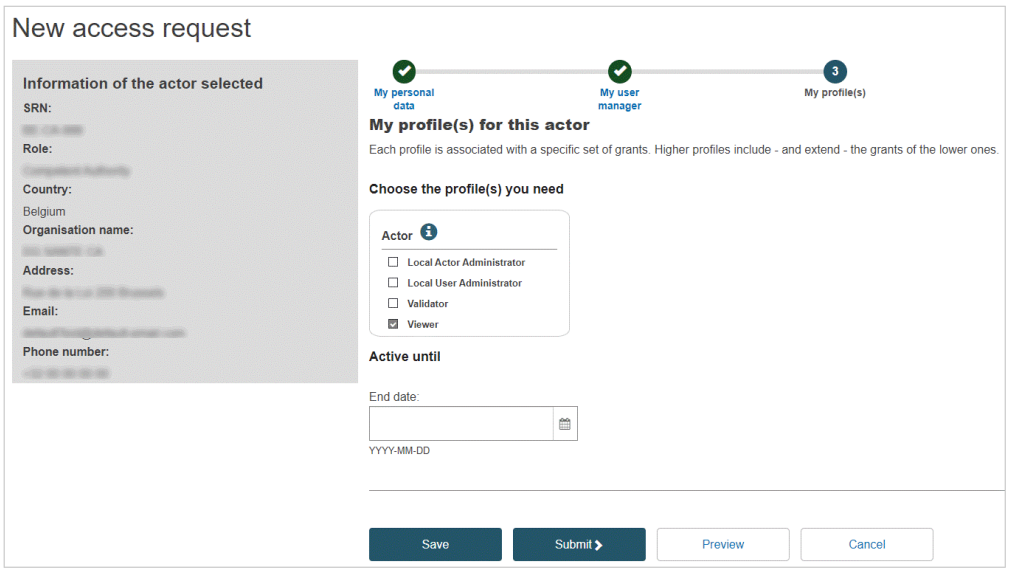


8. Complete *Step 1* of the user access request process:
   1. Enter your contact/notification email address related to this request.
   2. Indicate whether you are a sub-contractor for the selected actor. If you select **Yes**, you will be prompted to enter details of your company.

9. Click **Save & Next**. *Step 2* appears. Here you must identify a manager in your organisation who has the necessary authority to support your request:



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:



NOTE

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

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

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

NOTE

User profiles

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

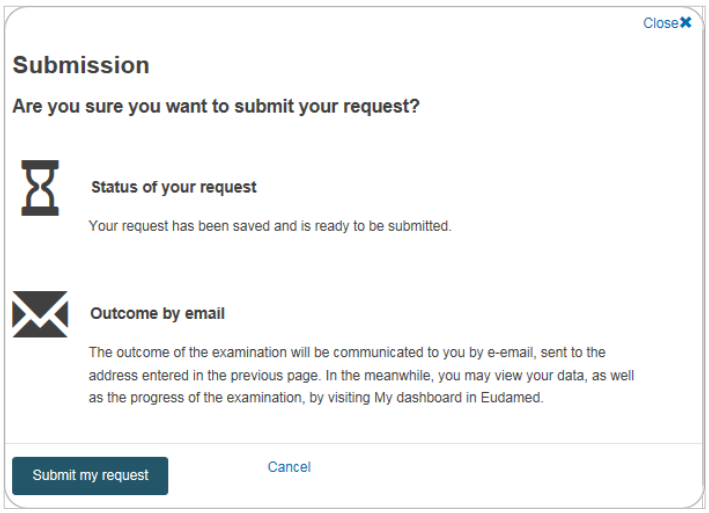
► **Local User Administrator (LUA)** can validate user access requests for the same actor (see *Section 2.2.2 [50]*, Validating user access requests).

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

12. If you want to save the request as a draft before submitting it, click **Save**.

13. If you want to see a preliminary summary of your request before submitting it, click **Preview** at the bottom of the page. A summary of your access request is displayed.

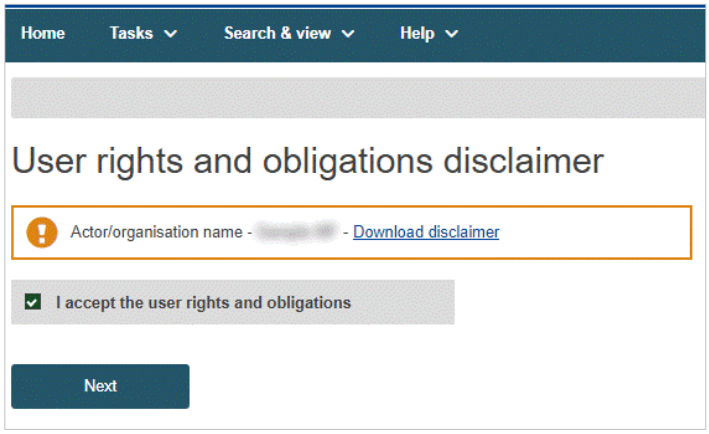
14. Review the information and click **Submit** at the bottom of the preview page. A confirmation page appears:



15. Click **Submit my request**. You are informed that your access request has been successfully submitted.
    A Local Actor Administrator or Local User Administrator belonging to the Actor will review and validate your request. You will be notified when your access request is approved or rejected.
    - If **not approved**, you can click the action button next to the pending request to read the reason provided by the LAA/LUA. You can then change and re-submit as appropriate.

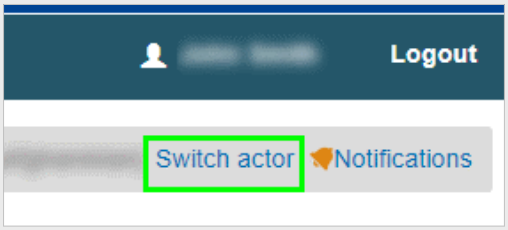


    - If **approved**, the next time you log in to EUDAMED a disclaimer will show. You will only see the disclaimer the first time you log in for each actor connected to your account:

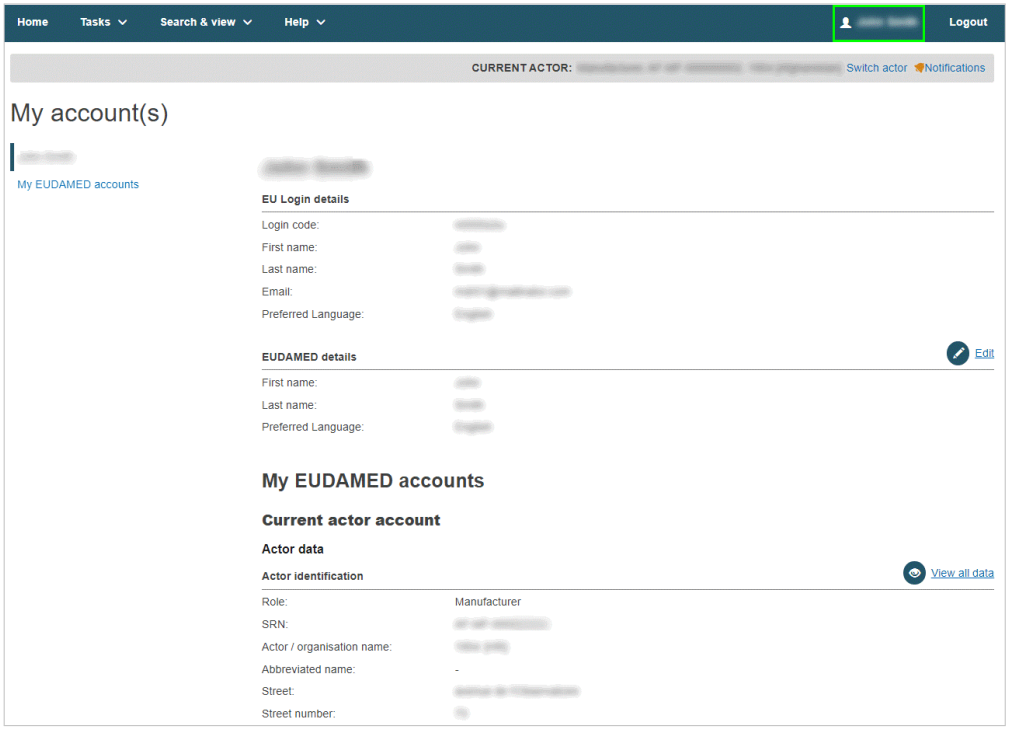


NOTE
Working for multiple actors?

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



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



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

► *My other accounts*

► *Terminated accounts*

2.2.2 Validating Economic Operator access requests

[Section for Local User Administrators]

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

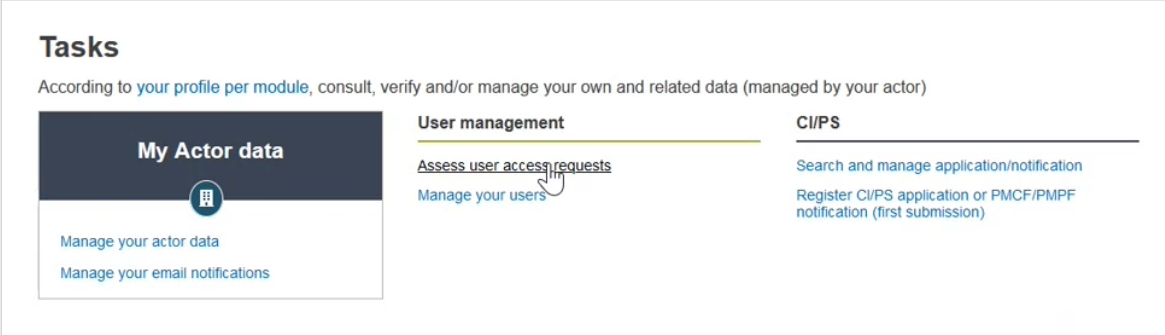
As an LAA or LUA for the actor, you will be notified of all new or updated incoming access requests.

Users cannot access EUDAMED until their access request is approved.

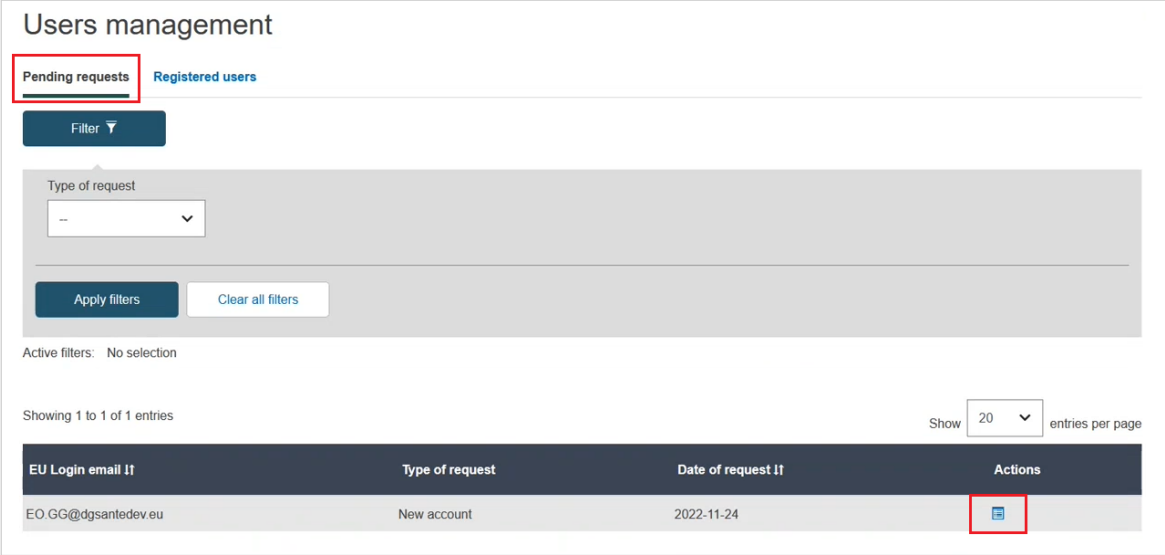
To validate an access request

1. Log in to EUDAMED.

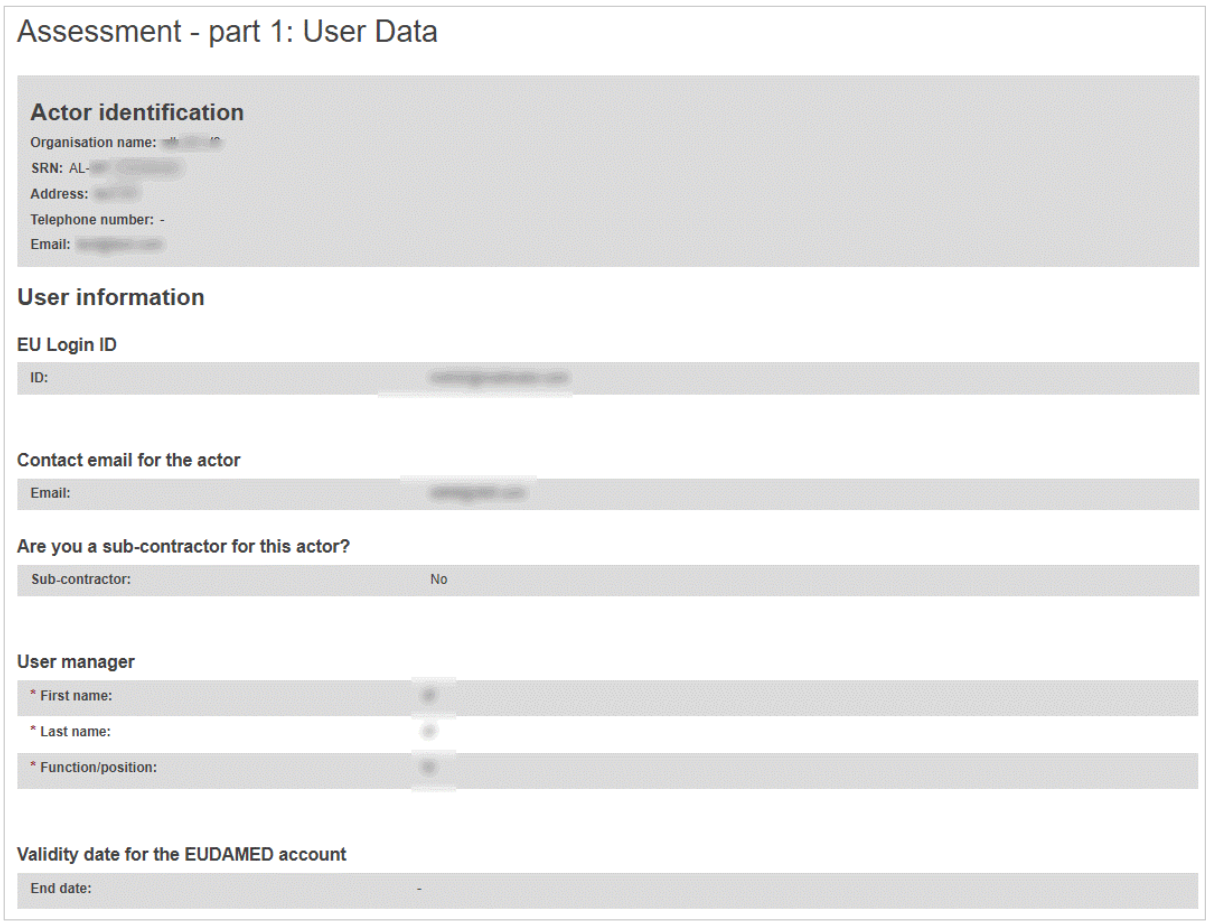
2. From your dashboard, select **Assess user access requests** (in the *User management* section):



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



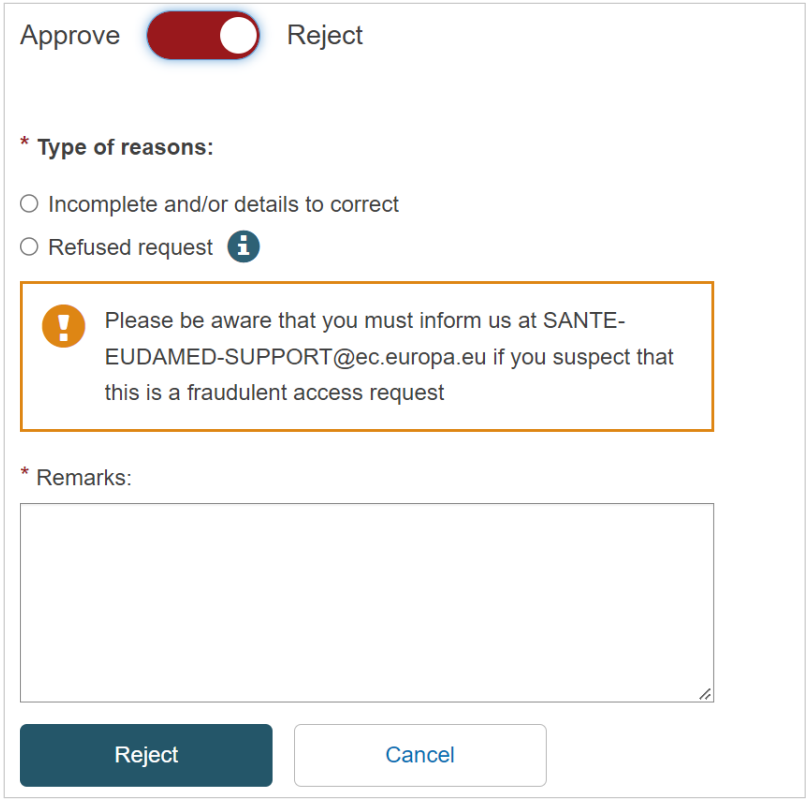
3. Click **Assess access request** in the *Actions* column to view and assess a request from the list. Part 1. of the access request is displayed:



4. Review the information in Part 1. of the request.

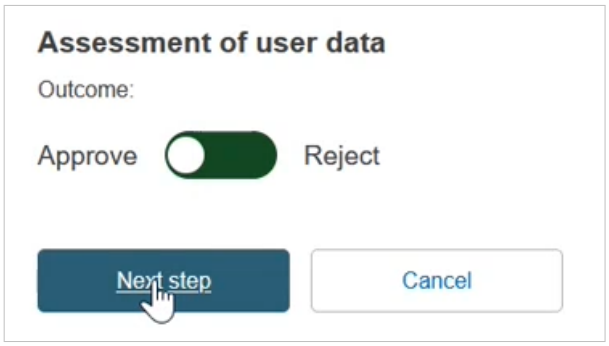
5. In the *Assessment* section, slide the toggle left to **Approve** the request, or right to **Reject**.
   - If you select **Approve**, the **Next step** button remains available at the bottom of the page (go to *Step 6*).
   - If you select **Reject**, you must add a comment and select one of the following reasons:

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



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:



NOTE
Profile availability

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

7. For each module in the table, click either **Accept** or **Reject**, and when you are done, click **Complete assessment**.
   A summary is displayed of the user profile you have approved.

8. To confirm this user profile, click **Confirm** in the summary dialog box.
   You are informed that the access request has been properly assessed:
   - The status of the request will update to *validated*.
   - The user details are moved to the *Registered users* tab, on the *Users management* page.
   - The user is notified that their access request has been validated.

2.2.3 Terminating a user account

[Specific to Local Actor Administrators and Local User Administrators]

When a EUDAMED-registered user leaves an organisation, changes their job function or is otherwise no longer involved in EUDAMED, the Local Actor Administrator (LAA) or Local User Administrator (LUA) can deactivate their account by marking it as *Terminated*.

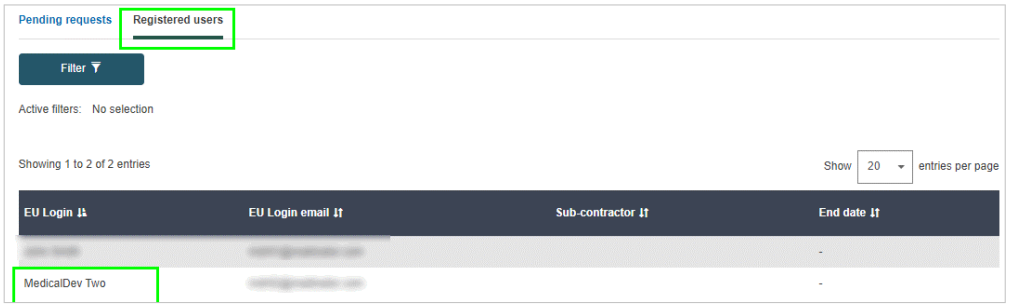
An actor user with a terminated account can no longer act on behalf of the organisation or manage data. If they need to regain the role at any time in the future they will have to submit a new access request for that actor.

To terminate a user account

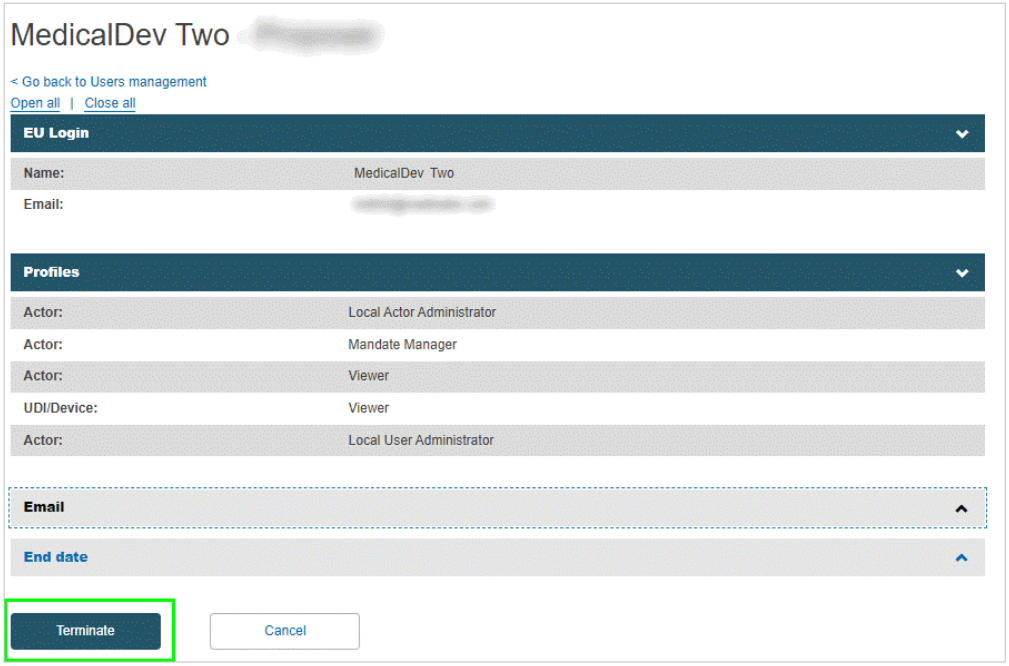
1. Log in to EUDAMED.

2. Select **Manage your users** in the *User management* section of your dashboard.

3. On the *User management* page, select the **Registered users** tab, and then click on the user in question:



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



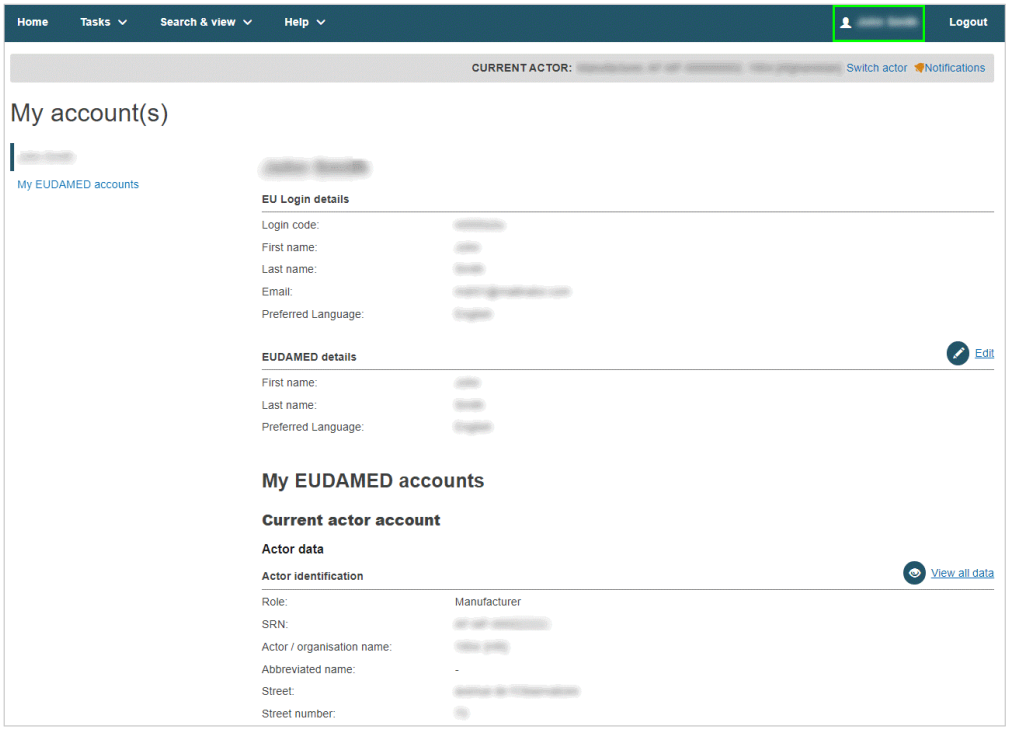
5. Confirm that you wish to complete the action. The user instantly disappears from the *User management* module.

2.2.4 Editing your user account

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

To edit your user account

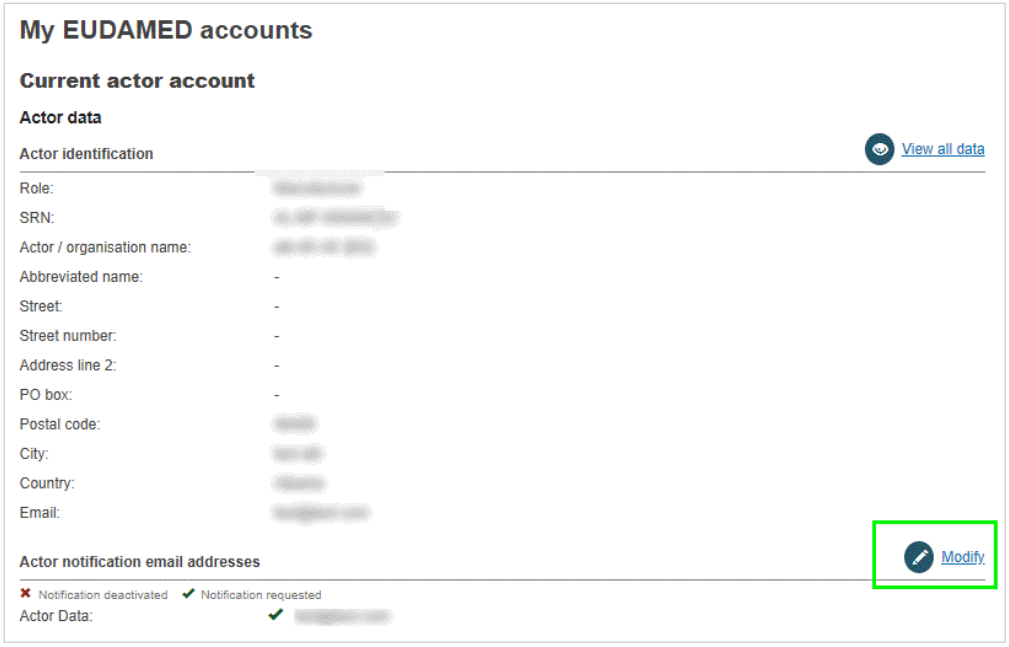
1. Log in to EUDAMED and click on your name in the upper toolbar. The *My account(s)* page appears:



2. 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



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



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



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

3. Make any required changes.

4. Click **Save**.

5. If you are registered with more than one actor, they are listed in the *My other account(s)* box:
   My other account(s)

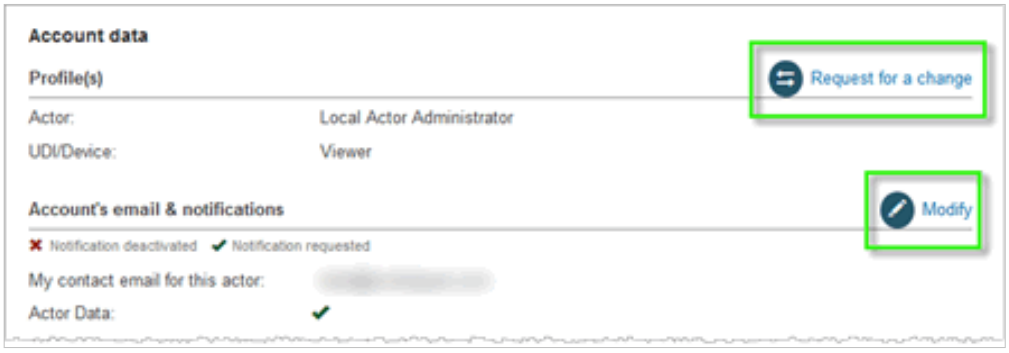


Click the right-pointing arrow next to one of the actors in the list to show their details. You can switch between actor accounts.

2.2.5 Upgrading your user profile

To request to change/upgrade your profile

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



2. Click **Request for change** next to your profiles and follow the steps to select the profiles for the module you require. If this button is missing, it means you have already submitted a request.

3. An LAA/LUA will need to approve this request before these profiles will be assigned to you.

IMPORTANT

► An LAA/LUA cannot approve their **own** requests. This means that for any actor with only ONE user, **a second user** with LAA/LUA profile will be needed to approve any profile upgrade requests.

► It is good practice for each actor to have **at least two** users with an LAA profile.

► EUDAMED requires that an actor retains one LAA, so you will be unable to terminate the last user's LAA profile.

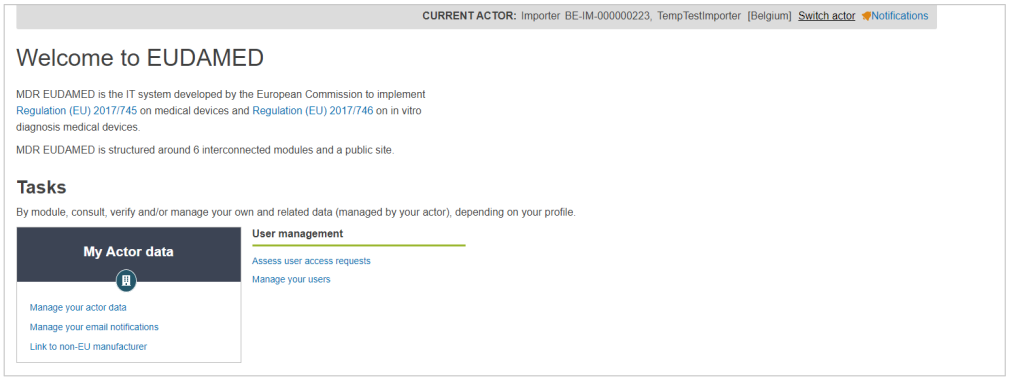
4. If you are the only user from your actor, you will need to grant access to a new user, assigning a LAA/LUA profile via the process outlined in sections 2.2.1 and 2.2.2.

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

2.2.6 Switching between actors

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

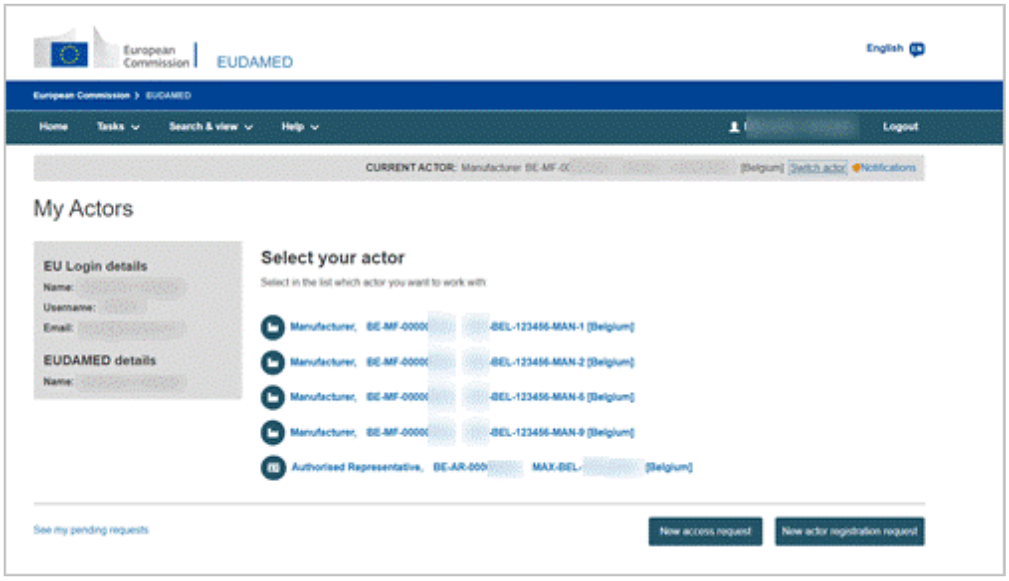
1. Go to the Dashboard:



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



3. Select an actor from the list shown:



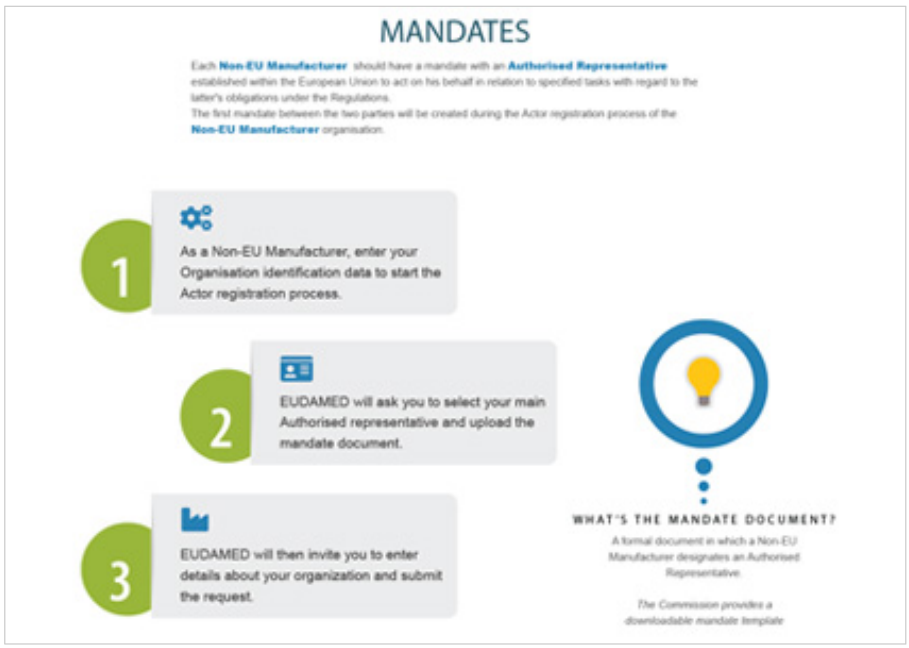
2.3 Managing mandates

[Specific to non-EU manufacturers]

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

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

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 their mandate with an authorised representative. If they have mandate(s) with other authorised representative(s), these must also be registered in EUDAMED.

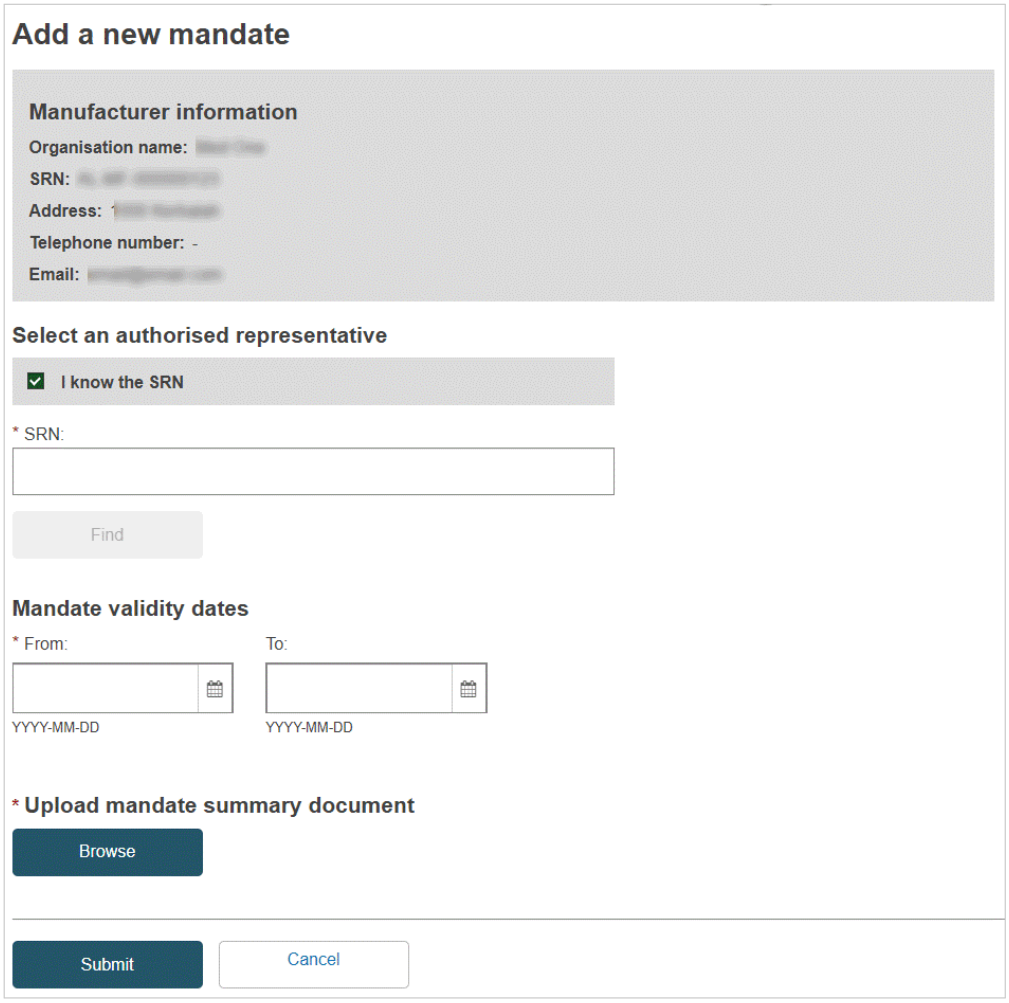
To add a mandate

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



> **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:



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

3. If you know the Actor ID/SRN for the Authorised Representative, enter it here, click **Find** and select from the results.

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

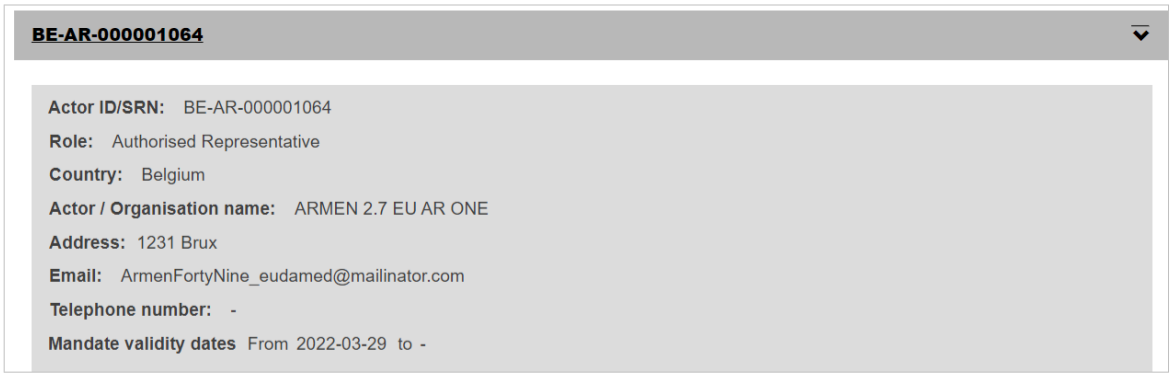
5. Specify the mandate's validity start-date (mandatory) and end-date (optional).

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.
   - Click here for the mandate summary template.

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



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



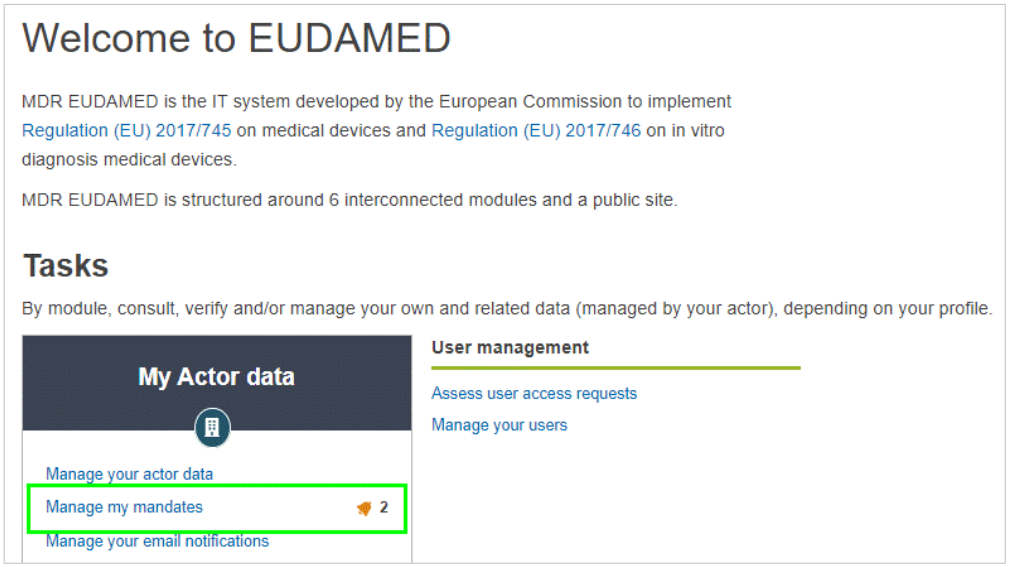
2.3.2 Create a new mandate version

[Specific to Non-EU manufacturers]

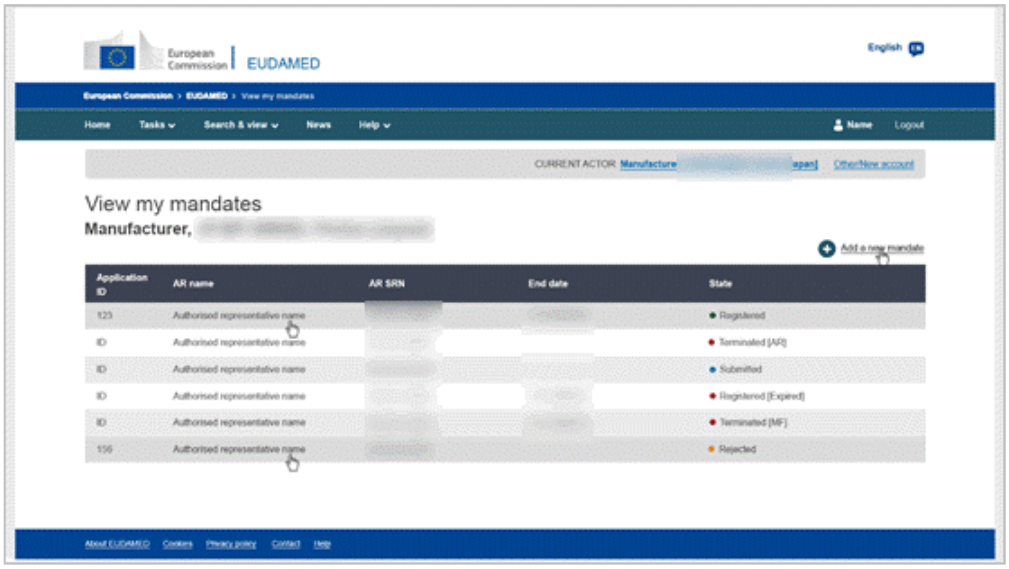
To create a new mandate version

1. Log in to EUDAMED

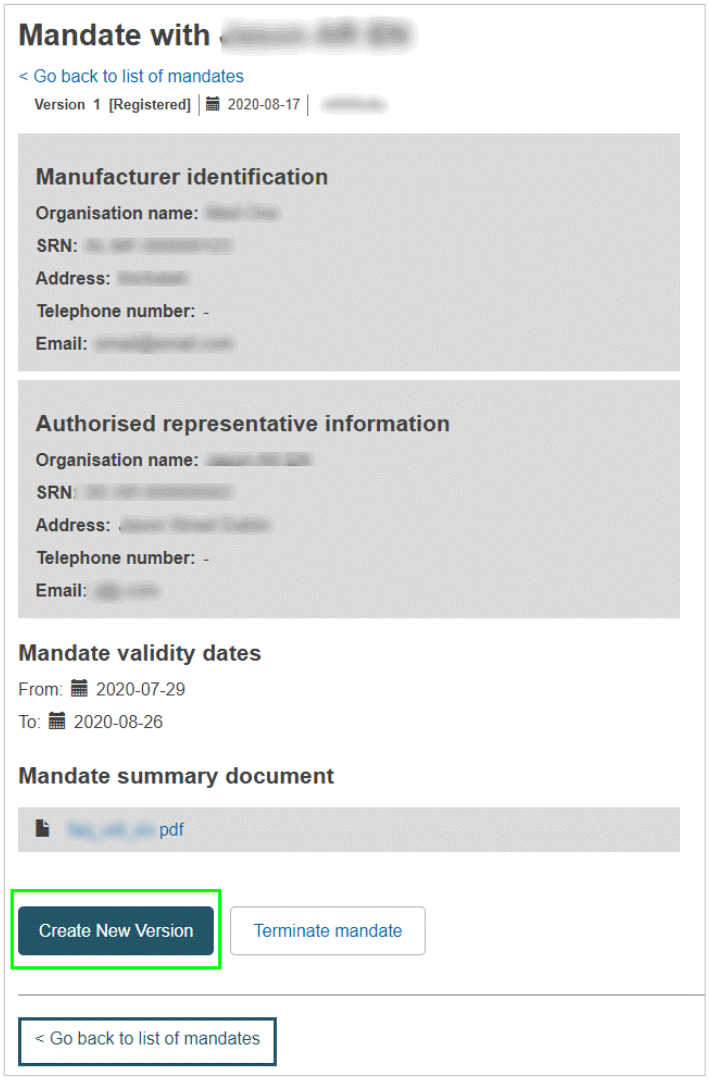
2. Select **Manage my mandates** in the *My Actor data* section of your dashboard:



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



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



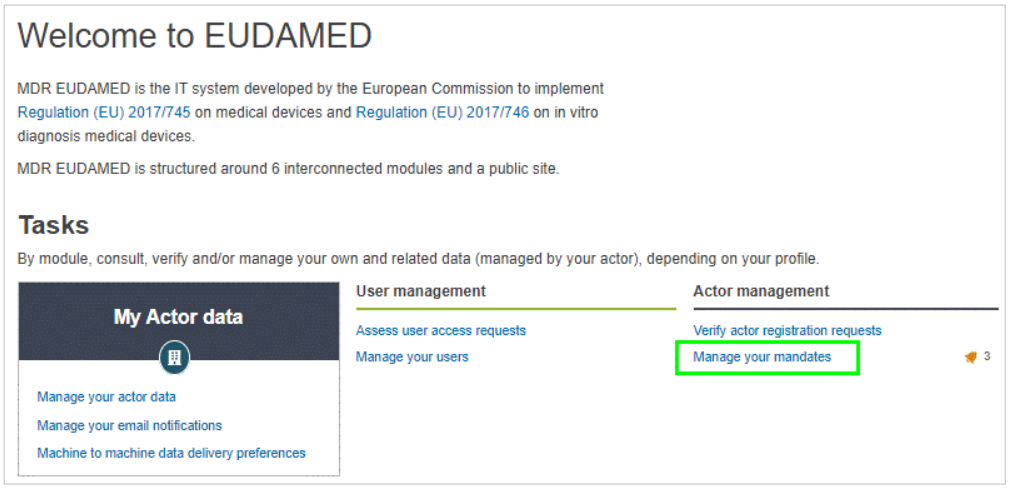
5. Upload the new mandate summary document and change the validity dates accordingly.

2.3.3 Verifying mandates

[Specific to authorised representatives with a Verifier profile]

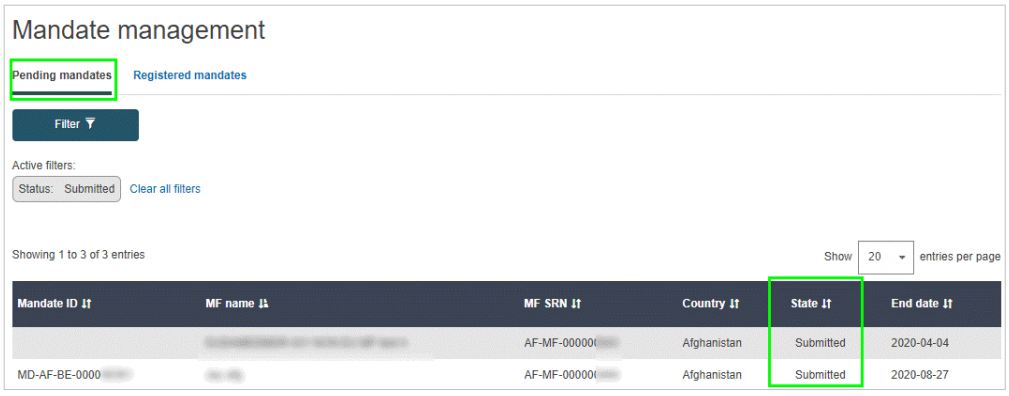
To verify a mandate

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

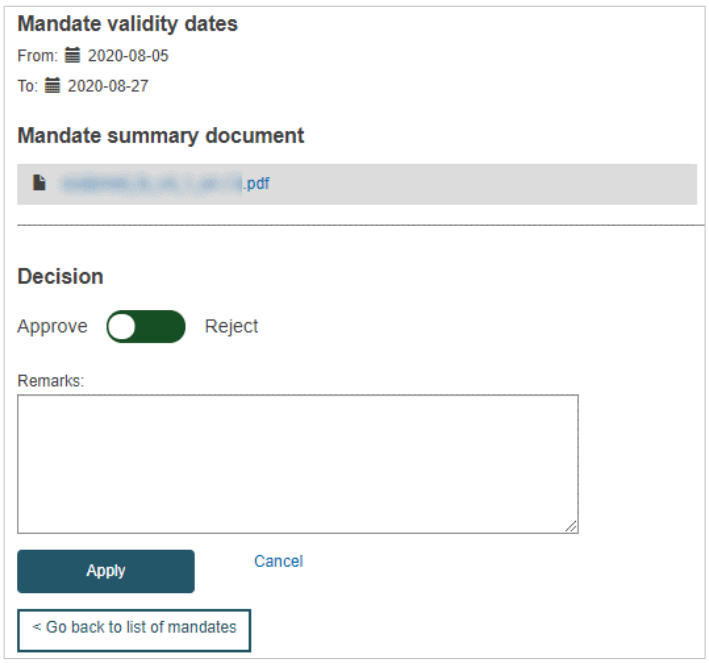


> **NOTE**
> The mandate management features are available only to authorised representative users with a *Verifier* profile, or higher (e.g. *LAA/LUA*).

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:



2. 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*:



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

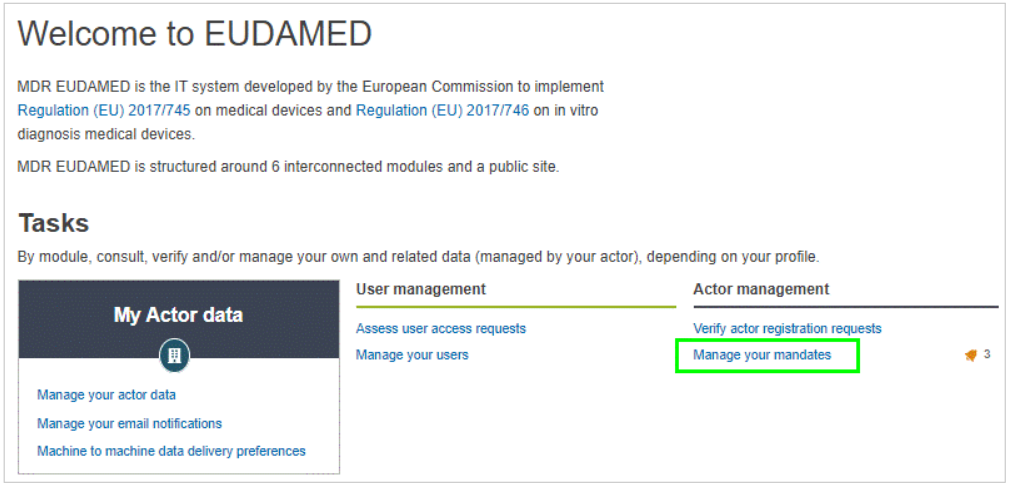
[Specific to authorised representatives and non-EU manufacturers]

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

If you are an Authorised Representative

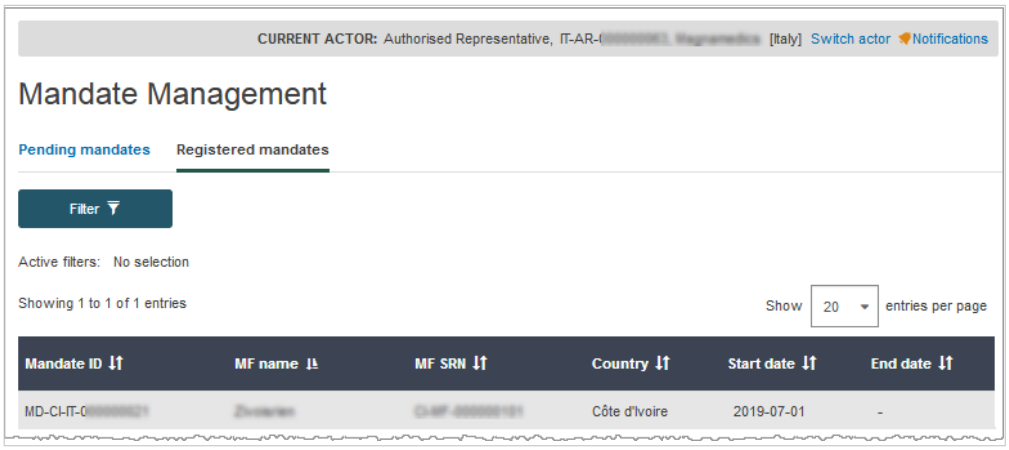
To terminate a mandate

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

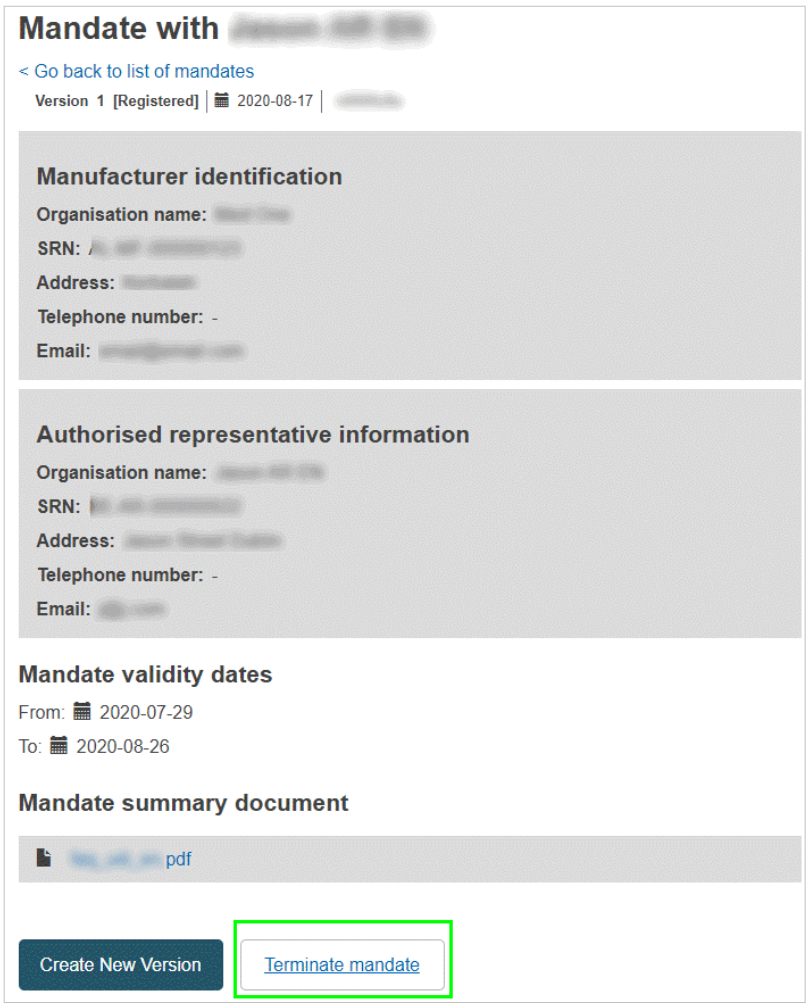


The *Mandate Management* page appears. The mandates are split into two tabs: **Pending mandates** and **Registered mandates**.

2. Select the **Registered mandates** tab. A list of all your registered mandates is displayed:



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

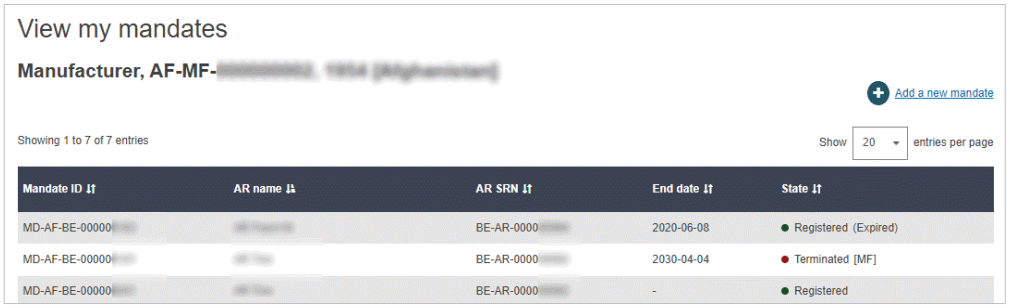


4. Click **Terminate mandate** at the bottom of the page.
5. Use the calendar icon to select the termination date.
6. Click **Confirm**

If you are a non-EU manufacturer

To terminate a mandate

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



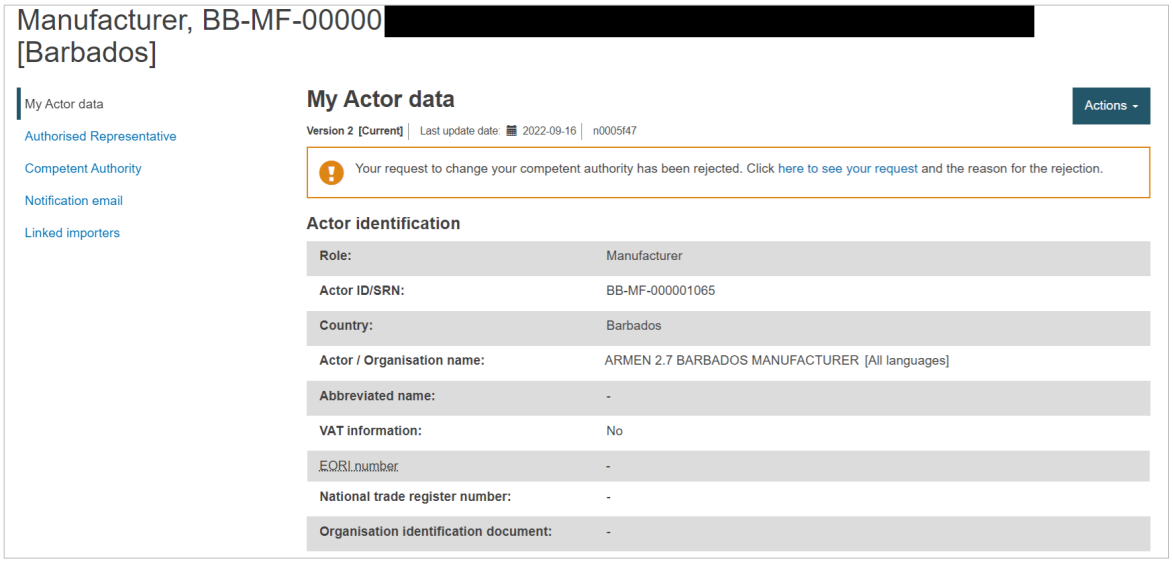
2. Click on the registered mandate that is to be terminated. The details of the selected mandate are displayed.

3. Click **Terminate mandate** at the bottom of the mandate detail page.

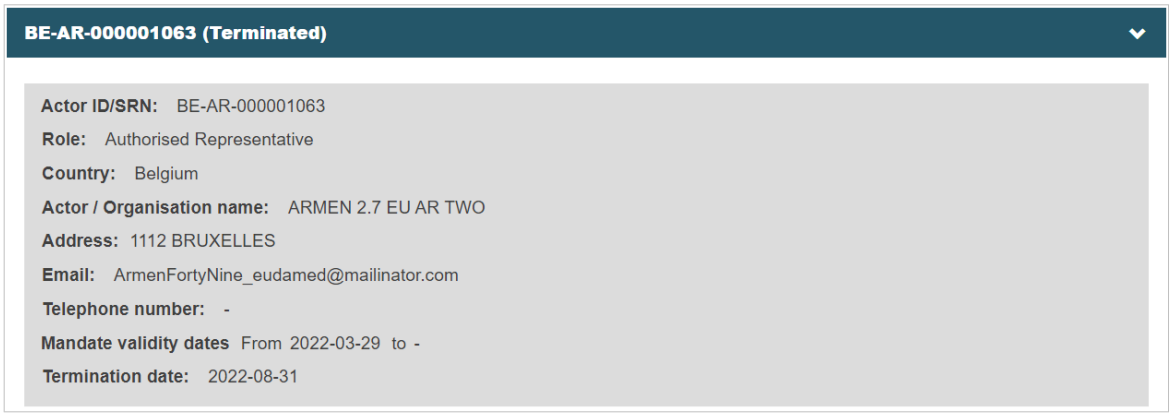
4. Use the calendar icon to select the termination date.

5. Click **Confirm**

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



The terminated mandate will appear in an accordion, click on its name to expand it, the termination date will be shown at the bottom of the accordion:




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