SANTE

Health and Food Safety

Guide to Using

EUDAMED

Actor registration module
for economic operators

Version 0.1 – September 2020

Last update: 01/09/2020

Contents

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 currently only available in a pre-production environment, serving exclusively as a playground for users to experiment with the application.*
>
> *All information entered in this environment is dummy (including the Single Registration Number (SRN)) and will NOT be moved to the production environment when the module goes live.*

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.acceptance.ec.europa.eu/eudamed_play/
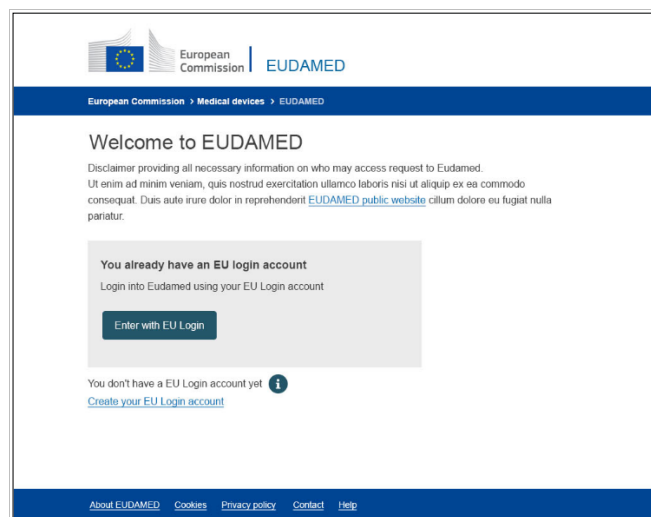
   Result: The *Welcome to EUDAMED* page appears:

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).

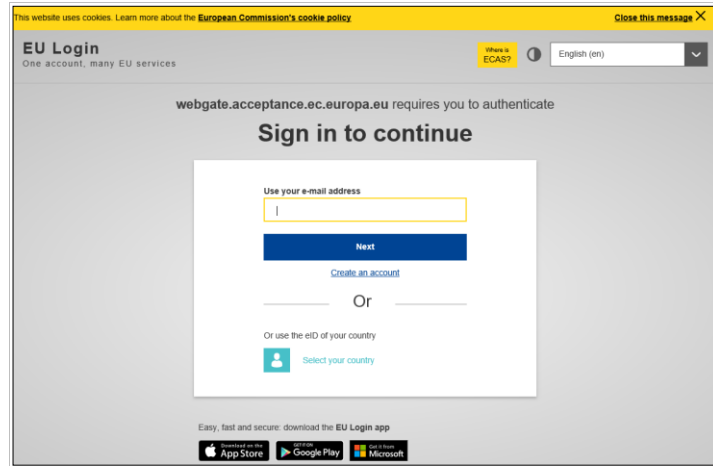   *Result:* The first part of the *EU Login – Sign in* page prompts you to enter your **email address**:

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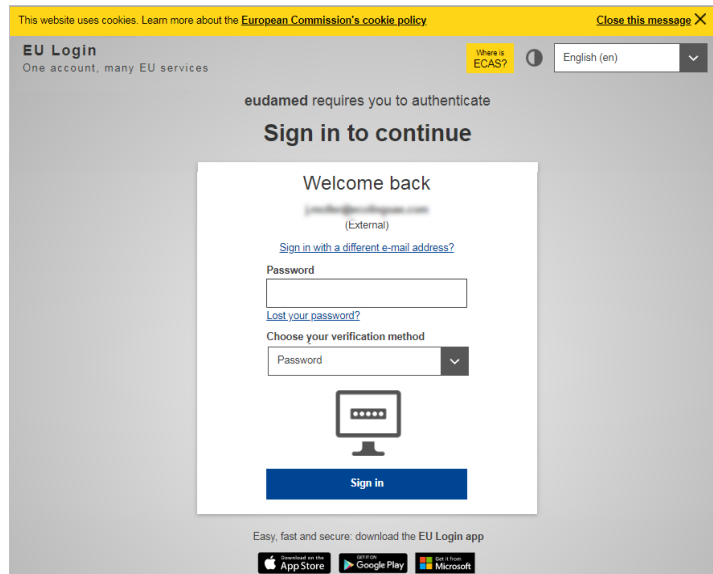*Go to* https://webgate.ec.europa.eu/cas/userdata/myAccount.cgi?

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:
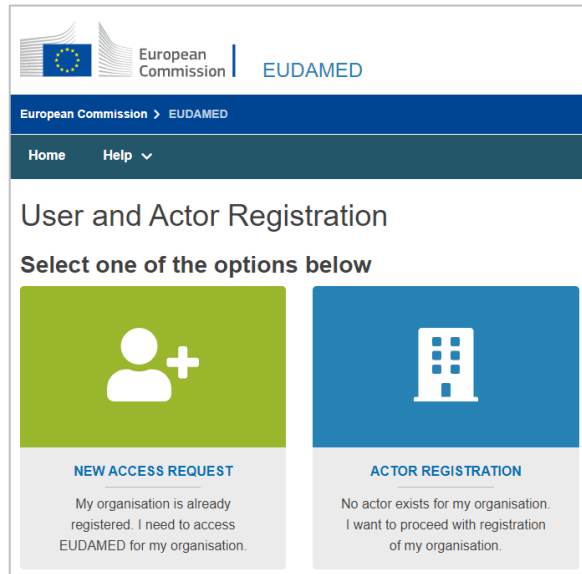
Figure 4 – EUDAMED User and Actor Registration page

♦ **To quit EUDAMED**

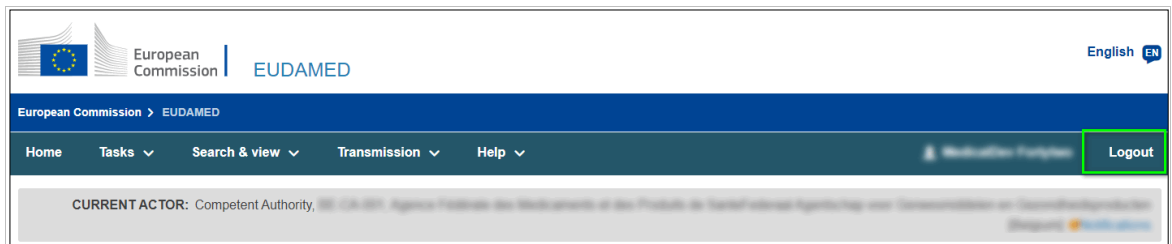1. Click **Logout** at the top right of the screen:

Figure 5 – Logging out
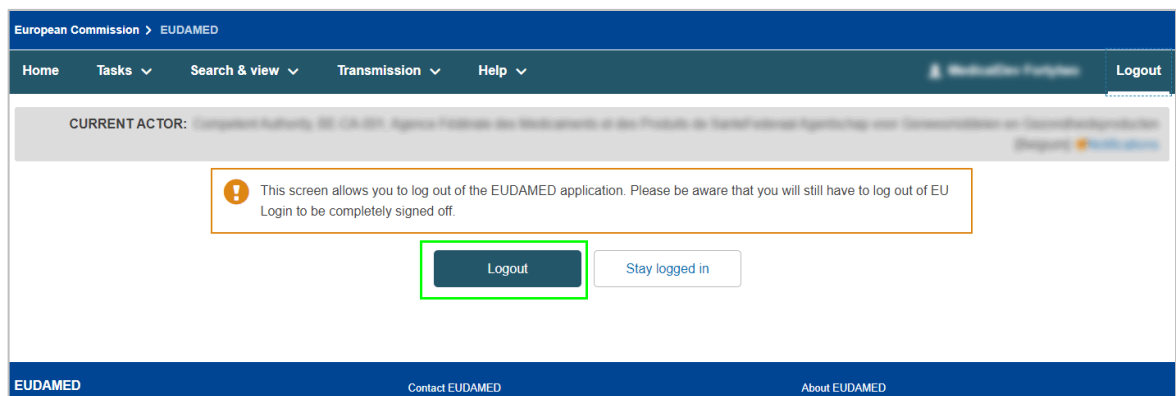
2. Confirm with the **Logout** button:

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

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).

– a 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 – and therefore as an actor on the EU market with a Single Registration Number (SRN) – 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**).

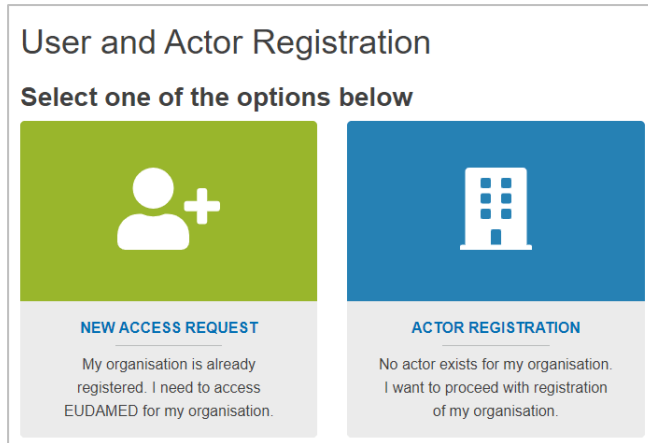   Result: EUDAMED opens with the *User and Actor Registration* page:

Figure 7 – EUDAMED User and Actor Registration page

2. Select the **ACTOR REGISTRATION** box on the "User and Actor Registration" page.
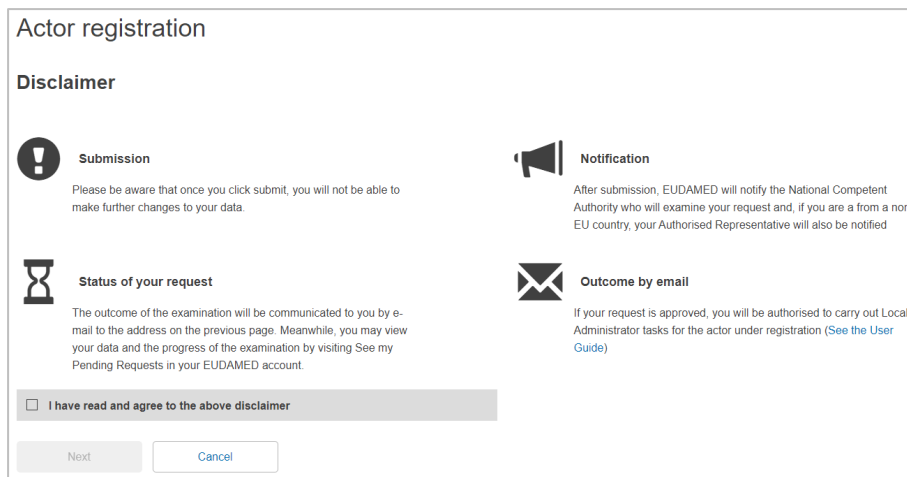
   Result: You are presented with a disclaimer:

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:

EUDAMED Actor module user guide – for economic operators

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 ❶ of the actor registration process appears:

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

5. Enter all the information needed to identify your economic operator: VAT, EORI and national trade number. 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 ❷ appears:

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 ❸ appears:

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 ❹ prompts you to identify 1 or more regulatory person(s) within your organisation.

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 ❺ prompts you to confirm you will be the Local Actor Administrator for the organisation:

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, VAT, 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:

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 ❻ appears:

Figure 16 – Actor registration: Step 6, 'Competent Authority'
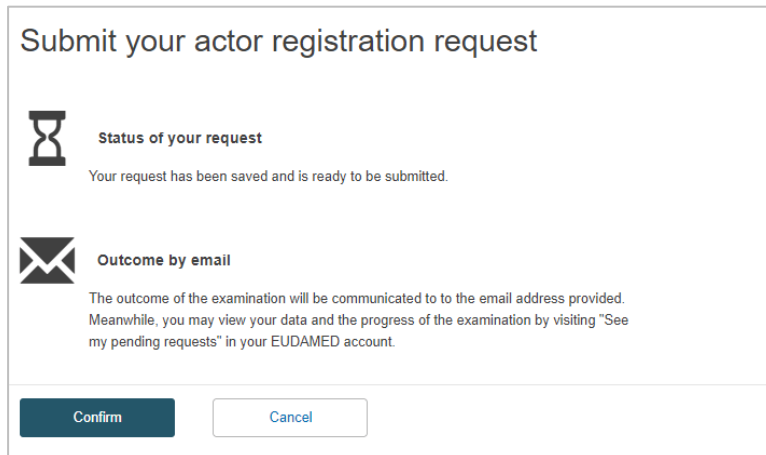
11. Select the competent authority that will validate your registration request (if it is not already pre-completed).

    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:

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:

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:
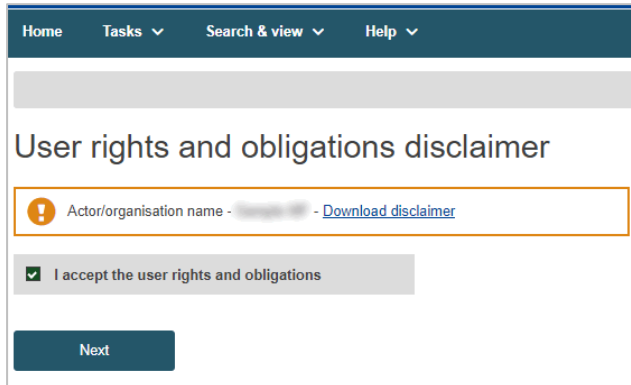

Figure 19 – Confirming your registration: disclaimer

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:
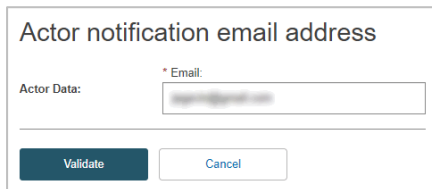
Figure 20 – Validating your email address

♦ **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:
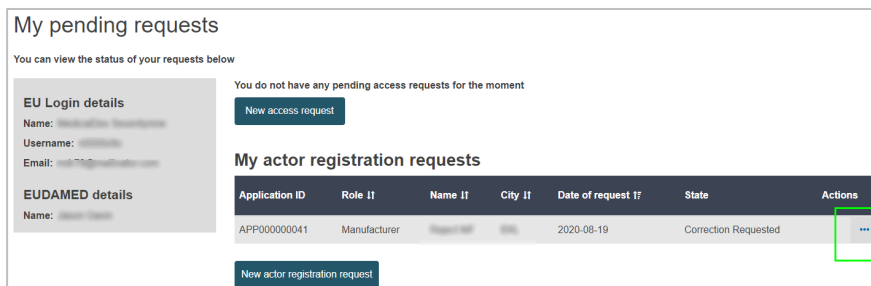

Figure 21 – My pending requests page

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:

*Figure 22 – Reason for rejection and resubmitting your request*

3. 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 a 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.
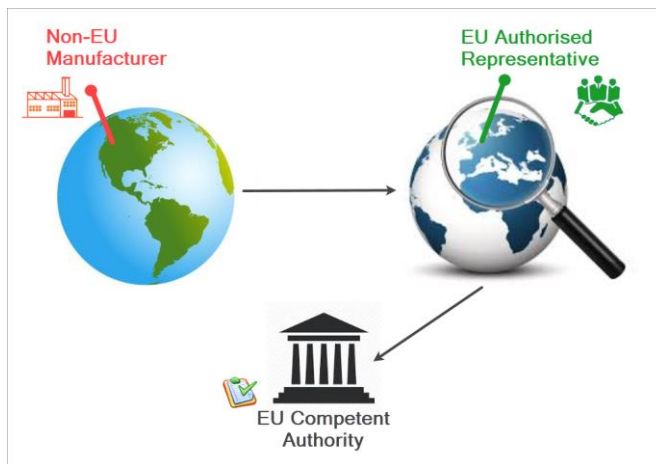
♦ **To register a non-EU manufacturer**

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:

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:

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

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

   Result: Step ❶ of the registration process appears:

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

5. 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 ❷ appears:

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

If you do not find your authorised representative from the search page, please contact them to confirm their 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. Enter the required data:

    6.1 Identify your authorised representative:

    Do you know the Single Registration Number (SRN)?
    Select **I know the SRN**, click **Find** and select the number.

    Do you not know the SRN?
    Unselect **I know the 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 ❸ appears:

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

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

   Result: Step ❹ appears:

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 ❺ prompts you to identify 1 or more regulatory person(s) within your manufacturer.

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 ❻ 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):

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).

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.
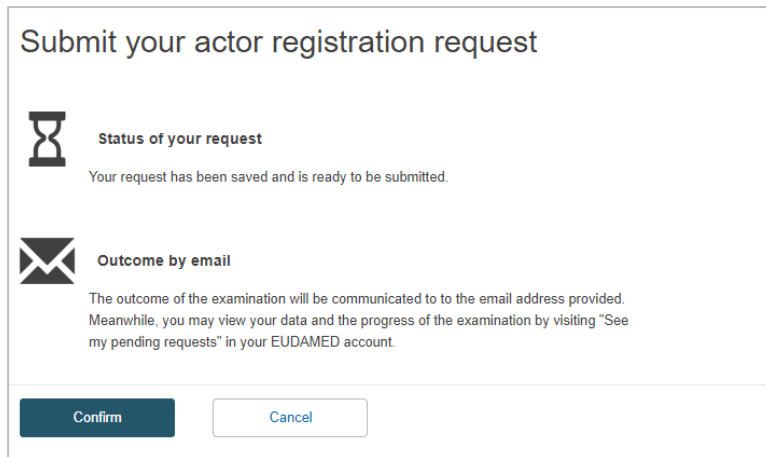
Result: A confirmation window will appear:

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 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*).
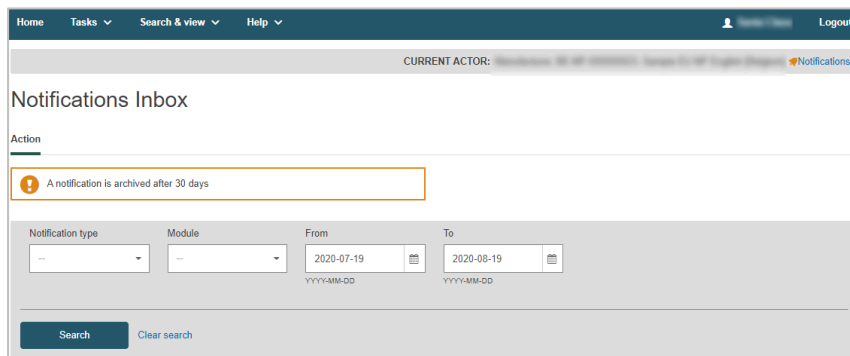
| Home | Tasks ⌄ | Search & view ⌄ | Help ⌄ | | | Logout |

CURRENT ACTOR: 〔...〕 📌Notifications

Notifications Inbox

Action

⚠ A notification is archived after 30 days

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

[Search]   Clear search

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:

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:
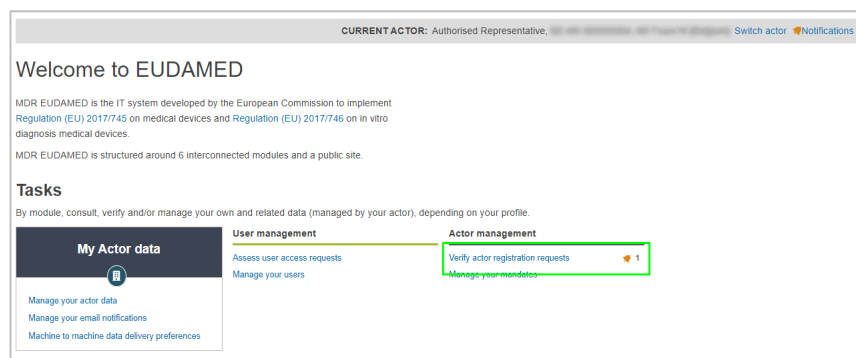

   Figure 34 – 'Verify actor registration requests' link

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):

   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:

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:	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.

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

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:
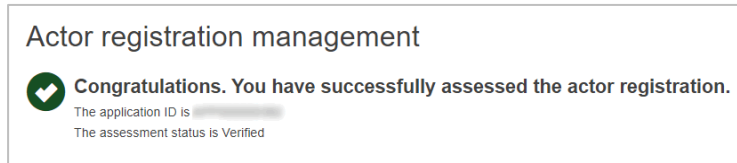

Figure 38 – A verified registration request

2.1.3 Viewing registered actors

Once an economic operator has been validated by its competent authority and a 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:

Figure 40 – Search results page (Actors)

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

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:
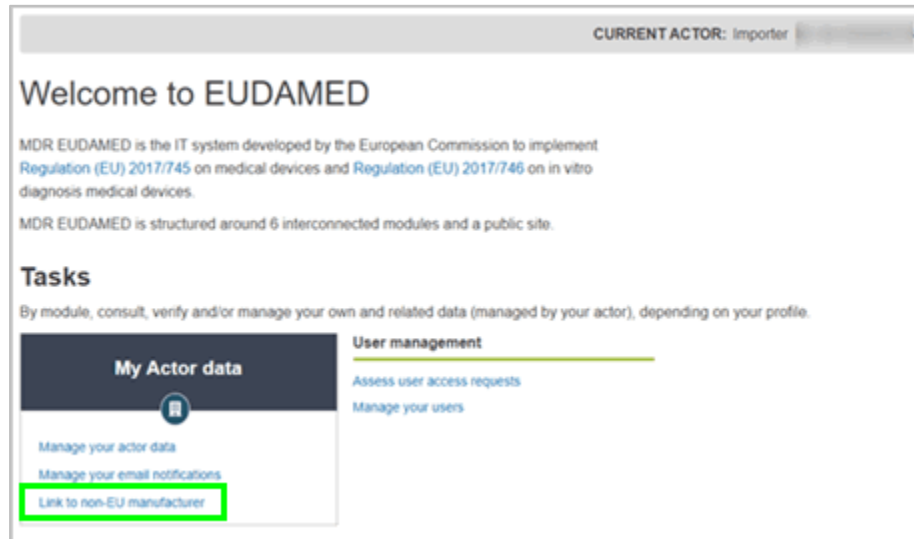
1. Go to the dashboard:

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).
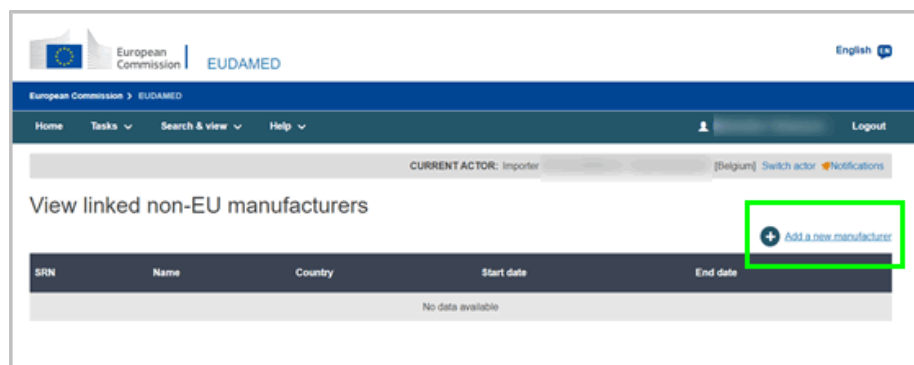

Figure 42 - Linked non-EU manufacturers list

3. Click **Add a new manufacturer**

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

Figure 43 - Link to non-EU manufacturer SRN page

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

5. If you don't know the SRN, uncheck **I know the SRN**.

   Result: 2 new fields will appear:

Figure 44 - Link to non-EU manufacturer, SRN 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:

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:

Figure 46 - Details of selected non-EU manufacturer

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

    Result: You are prompted to enter the relevant dates:

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 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':
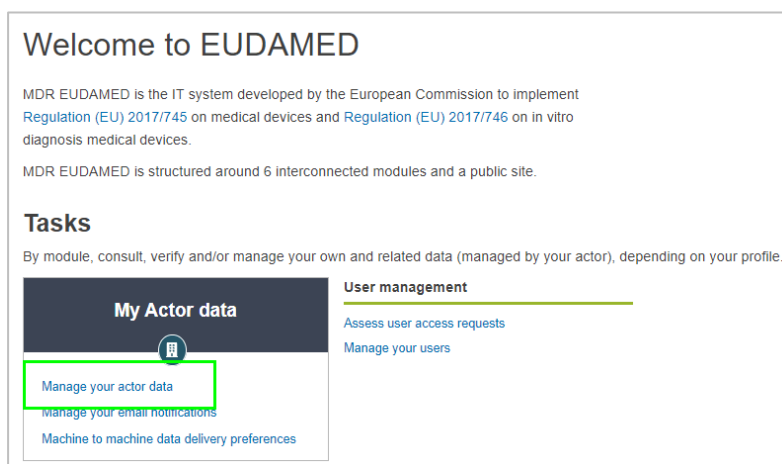
Figure 48 –'Manage your actor data' link

3. You can browse through the sections to review the information currently available about the actor:
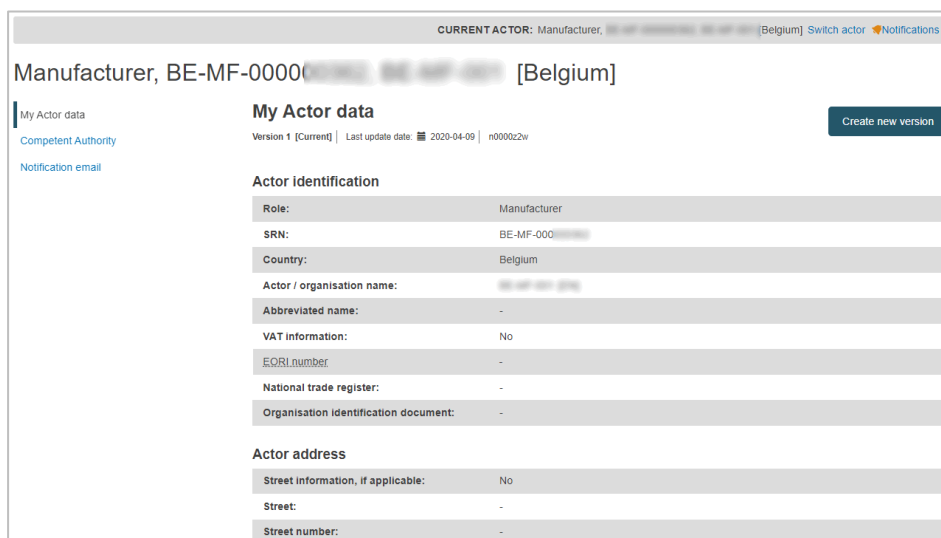
Figure 49 – Actor details

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:
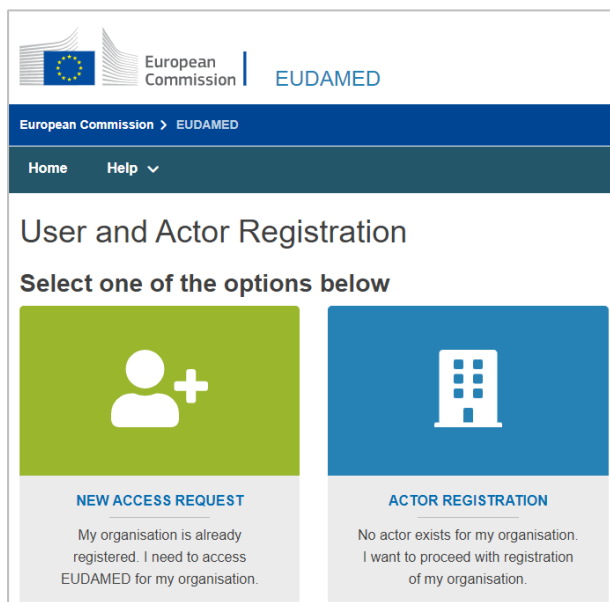

Figure 51 – EUDAMED User and Actor Registration page

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:

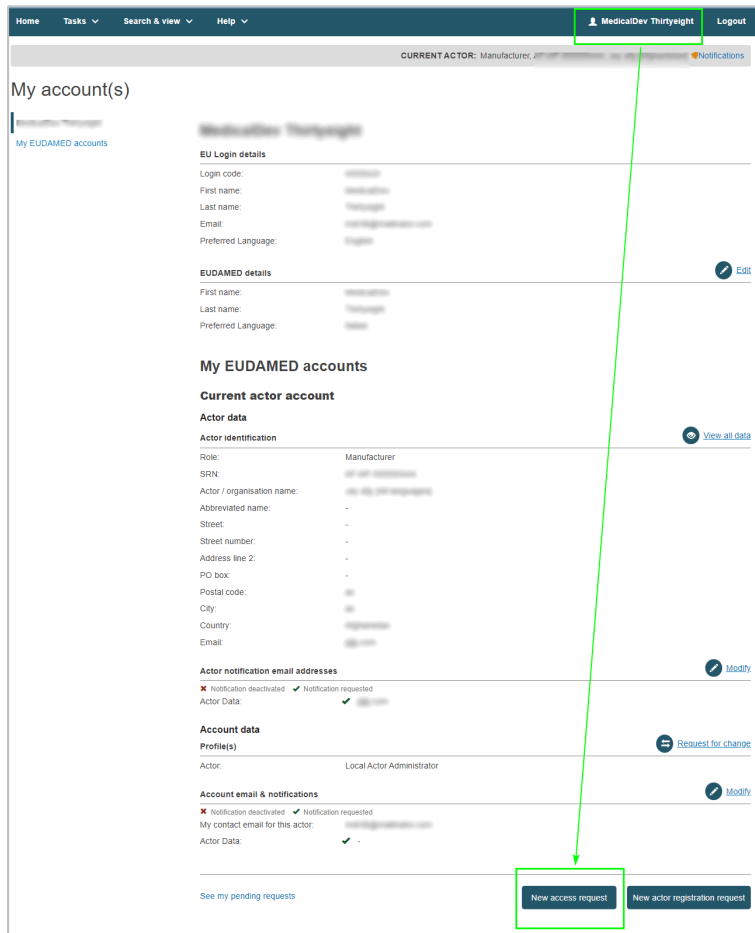*Figure 52 – EUDAMED user account detail page and new access request button*

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 SRN.

They may have registered with a different name or may have not completed registration yet.
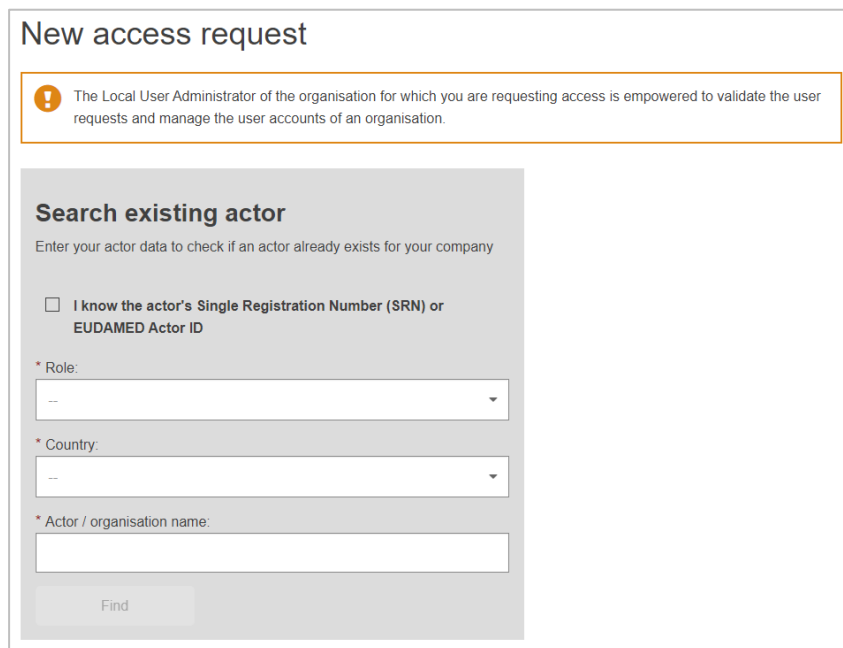

Figure 53 – 'New Access Request'

4. If you know the actor's Single Registration Number (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 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.

Figure 54 – 'Request access to this actor'

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

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

Figure 55 – User access request: step 1

8. Complete step ❶ 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 ❷ appears. Here you must identify a direct superior who can support your request:

Figure 56 – User access request: step 2

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

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

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, VAT, 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:

    Close ✖

    Submission

    Are you sure you want to submit your request?

    ⏳ **Status of your request**

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

    ✉ **Outcome by email**

    The outcome of the examination will be communicated to you by e-mail, sent to the address entered in the previous page. In the meanwhile, you may view your data, as well as the progress of the examination, by visiting My dashboard in Eudamed.

    [Submit my request]   Cancel

    ---

15. Click **Submit my request**.

    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.

    ### My access requests for an existing actor

Role ⬍	Name ⬍	City ⬍	Date of the request ⬍	State	Actions
Authorised Representative	Magnamedics	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:*
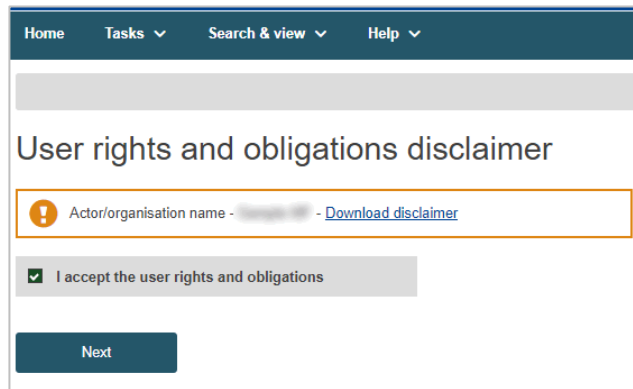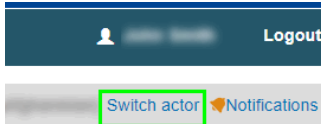

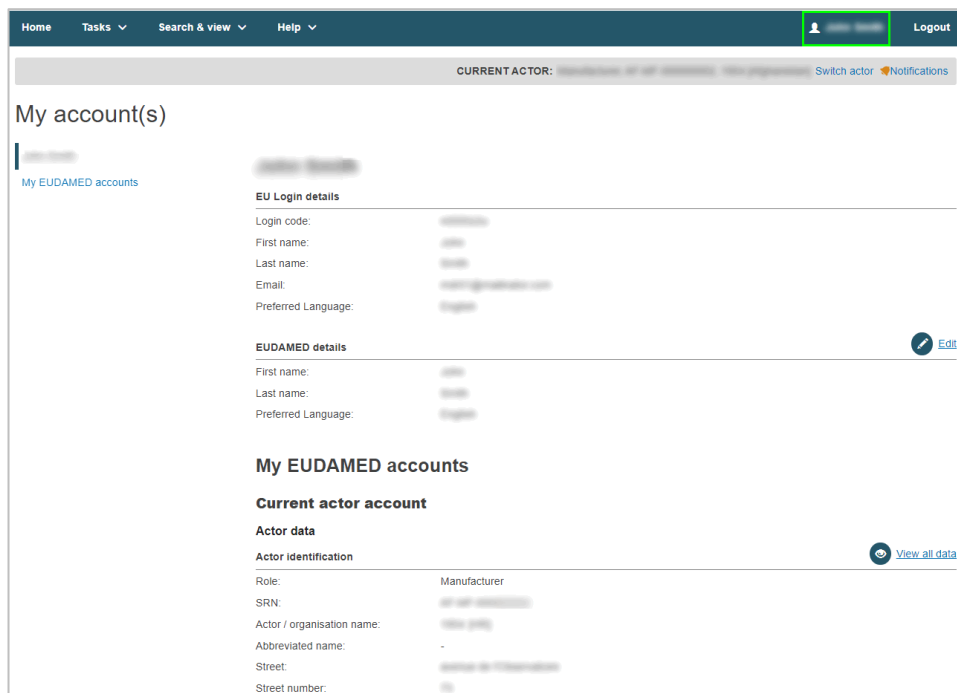*Figure 58 – User rights and obligations disclaimer*

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):
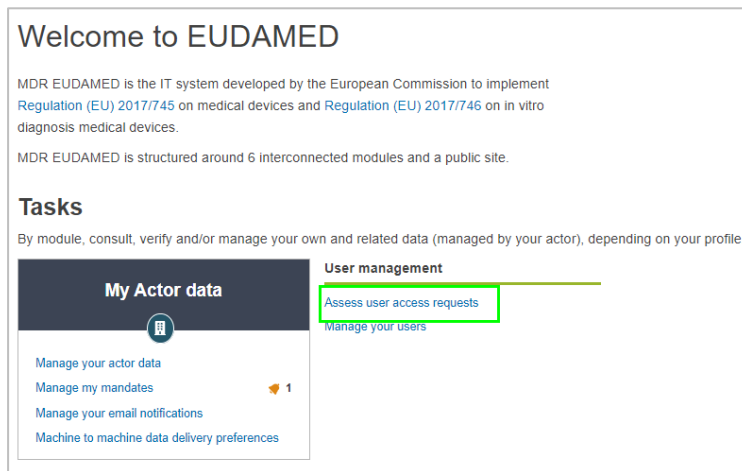

Figure 59 – 'Assess user access requests' on the dashboard

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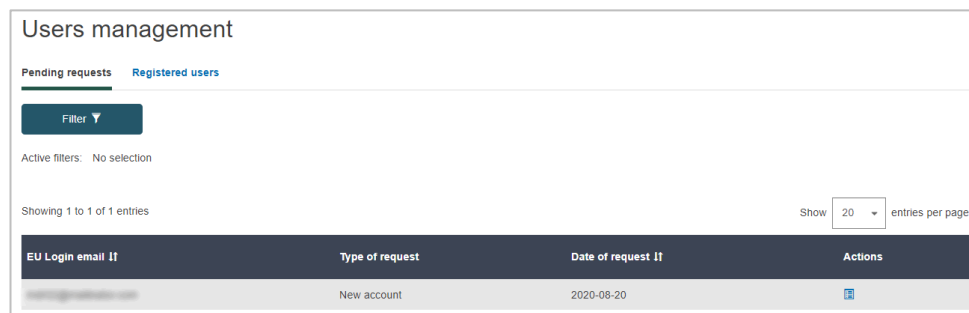

Figure 60 – Pending access requests to be validated

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:

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.

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.*

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.

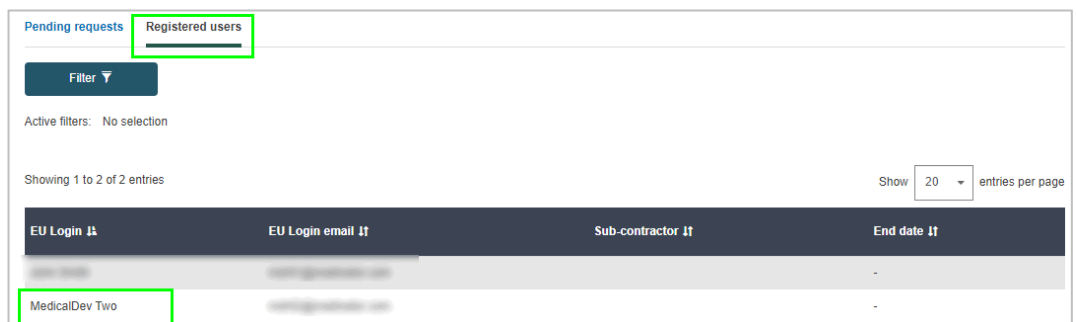3. On the *User management* page, select the **Registered users** tab, and then click on the user in question:

Figure 64 – Selecting one of your registered users

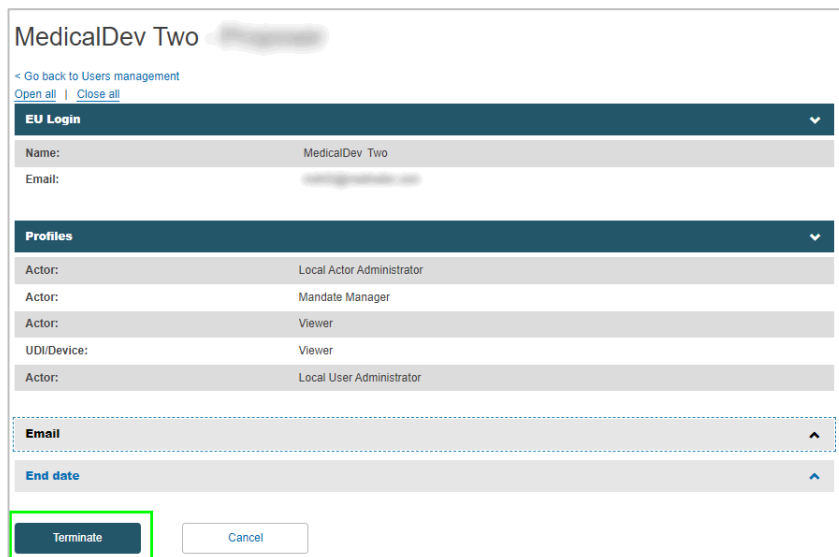4. Review the user's details and click **Terminate** at the bottom of the page:

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:

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:	
First name:	
Last name:	
Email:	
Preferred Language:	

   EUDAMED details   ✏ Edit

First name:	
Last name:	
Preferred Language:	

   Use the **Edit** button in this section if you want to change your first name, last name and/or preferred language.

   ▶ **Current actor account: actor data**

   My EUDAMED accounts

   Current actor account

   Actor data

   Actor identification   👁 View all data

Role:	
SRN:	
Actor / organisation name:	
Abbreviated name:	-
Street:	-
Street number:	-
Address line 2:	-
PO box:	-
Postal code:	
City:	
Country:	
Email:	

   Actor notification email addresses   ✏ Modify

   ✖ Notification deactivated   ✔ Notification requested

Actor Data:	✔

   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).
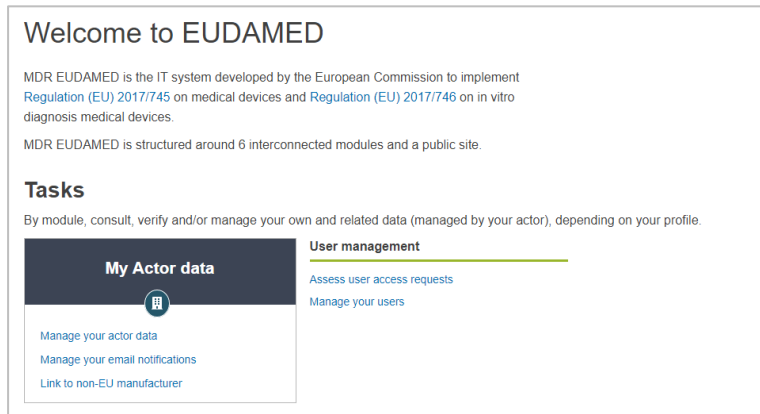
1. Go to the dashboard:

Figure 67 - Welcome page for actors

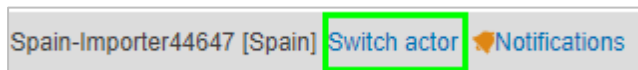2. Click on "Switch actor" at the top right (you can also do this after selecting an actor):

Figure 68 - Switch actor
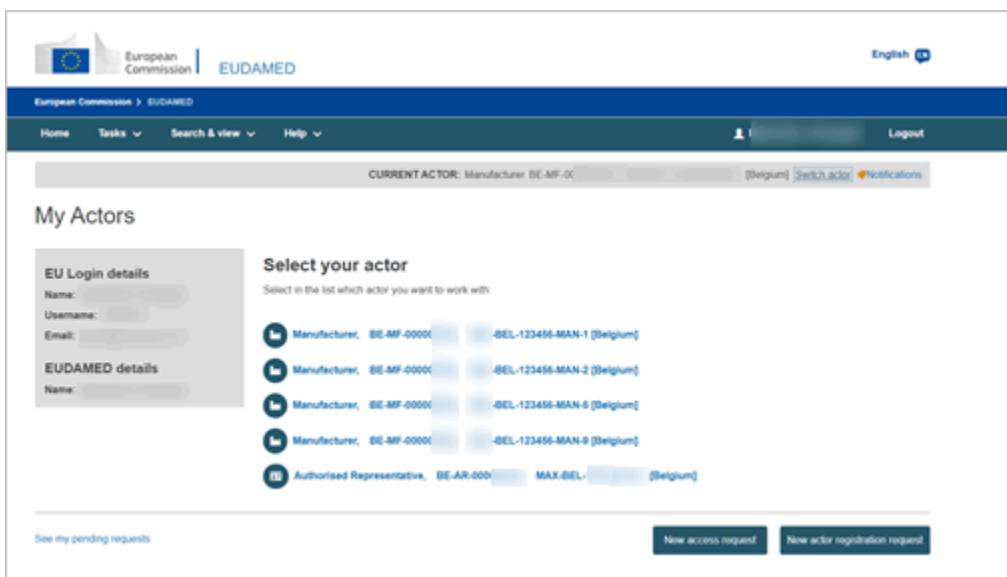
3. Select an actor from the list shown:

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**

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

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.

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

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: To:

[📅]   [📅]

YYYY-MM-DD   YYYY-MM-DD

* **Upload mandate summary document**

[Browse]

[Submit]   [Cancel]

If you don't find your authorised representative from the search page, please contact them to confirm their 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 Single Registration Number (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 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,

➕ Add a new mandate

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

Mandate ID ↕	AR name ↕	AR SRN ↕	End date ↕	State ⊤≣
MD-AF-BE-00000		BE-AR-00000	-	● Registered
MD-AF-BE-00000		BE-AR-00000	-	● Submitted

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.

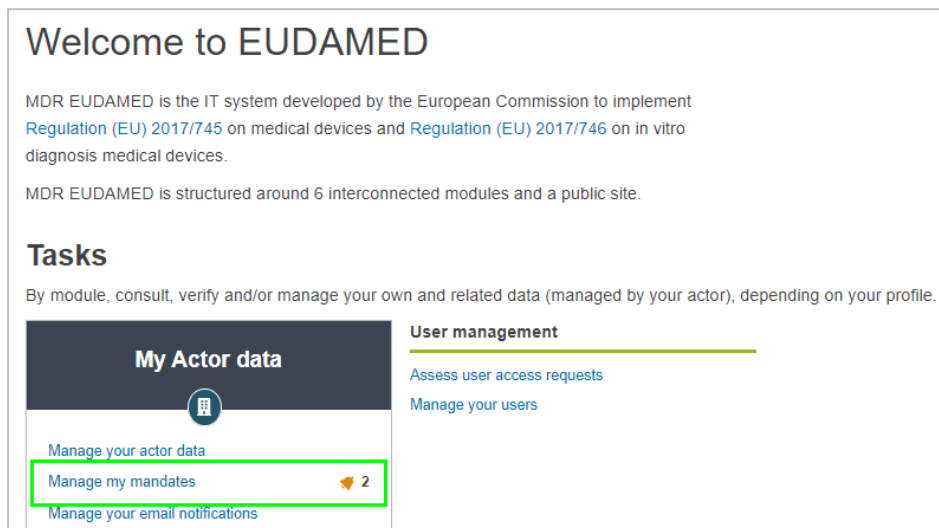2. Select **Manage my mandates** in the *My Actor data* section of your dashboard:

Figure 73 - Dashboard for non-EU manufacturers
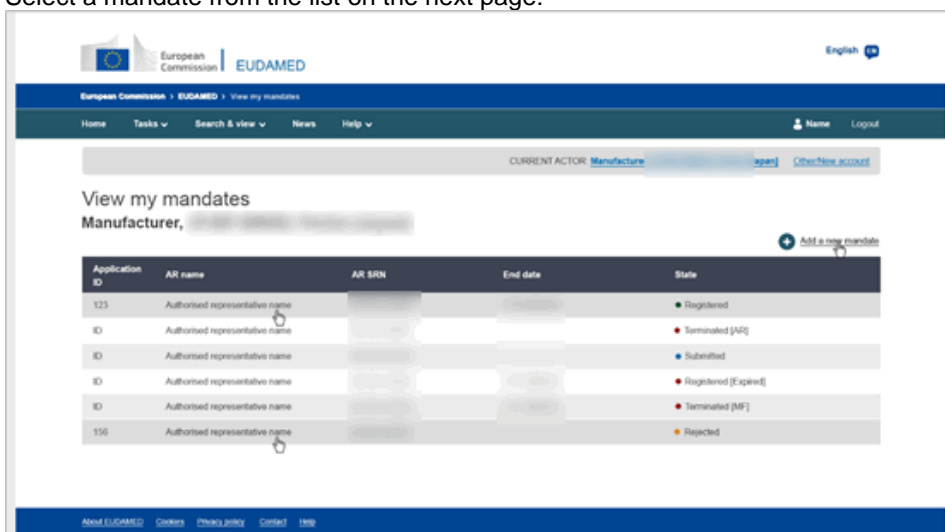
3. Select a mandate from the list on the next page:

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:

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:

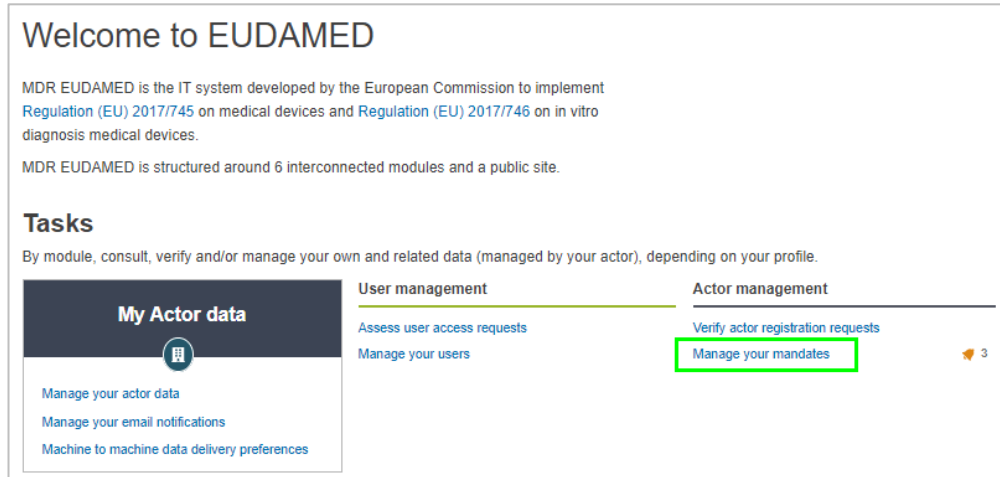*The mandate management features are available only to authorised representative users with a **Verifier** profile or higher (LAA/LUA).*

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:
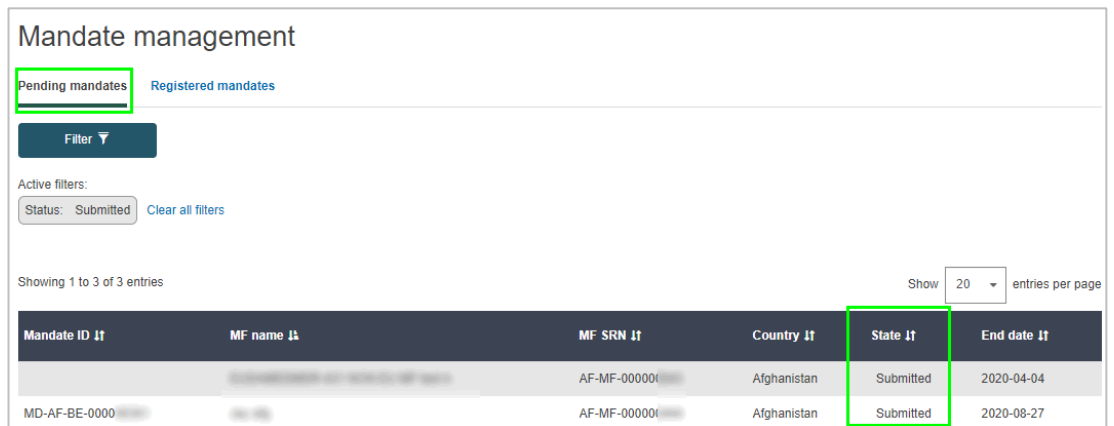
Figure 77 – Pending mandates

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*:

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

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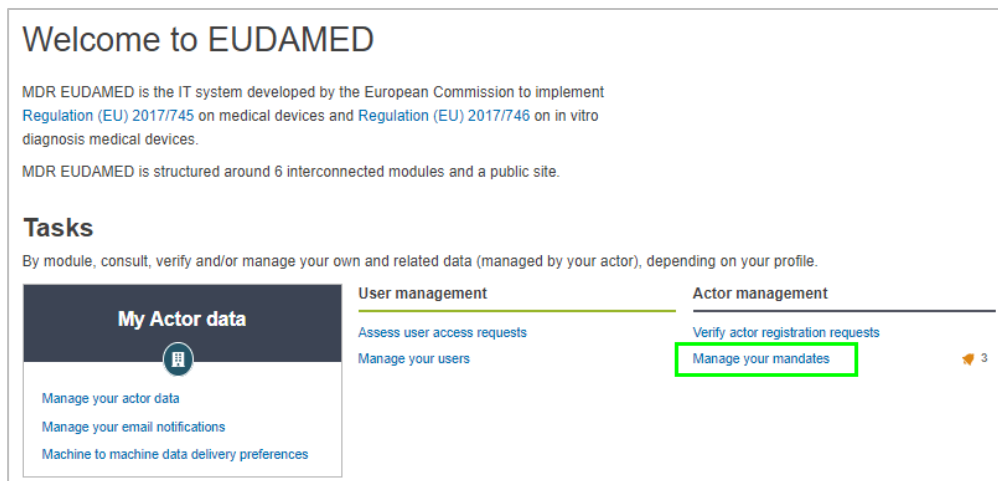
Figure 79 – 'Manage your mandates' (authorised representative)

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

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

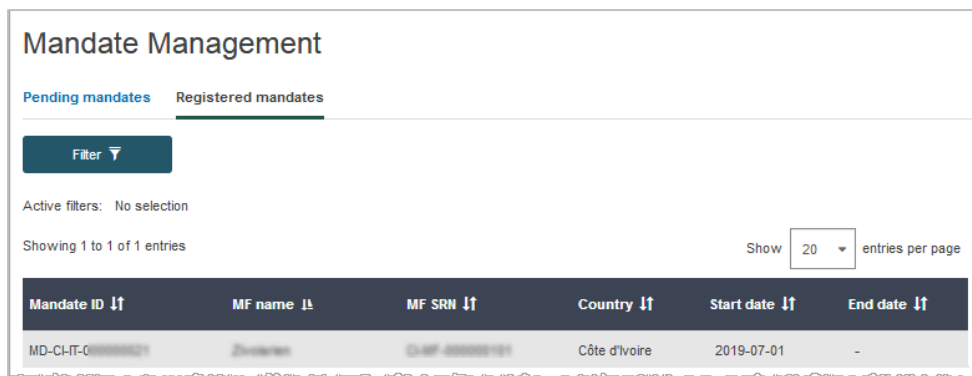*Result:* A list of all your registered mandates is displayed:

Figure 80 – List of mandates associated with an authorised representative

3. Click on the registered mandate that will be terminated.

   Result: The details of the selected mandate are displayed:

Figure 81 – A mandate associated with an authorised representative

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. 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-██████████, ████ [██████████]

   Add a new mandate

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

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

3. Index