SANTE

Health and Food Safety

Guide to accessing

EUDAMED

Actor registration module

for economic operators

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1. Introduction

1.1. Overview

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

- Regulation 2017/745 on medical devices
- Regulation 2017/746 on in vitro diagnosis devices

EUDAMED is structured around **6 interconnected modules** and a **public site**:

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

Evolving user interface

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

1.2 Application basics

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

- Starting and ending a EUDAMED session
- Understanding the basic concepts
- Understanding user profiles and access grants/rights

1.2.1 Starting and ending a EUDAMED session

'Playground' environment

EUDAMED *is 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:

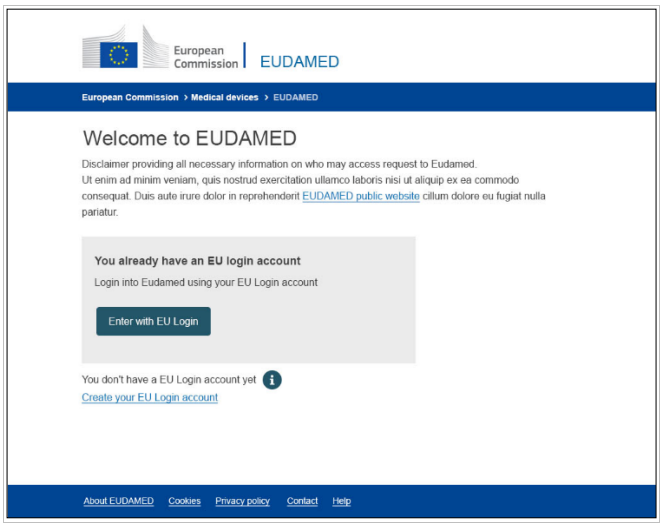


Figure 1 – EUDAMED Welcome page

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**:

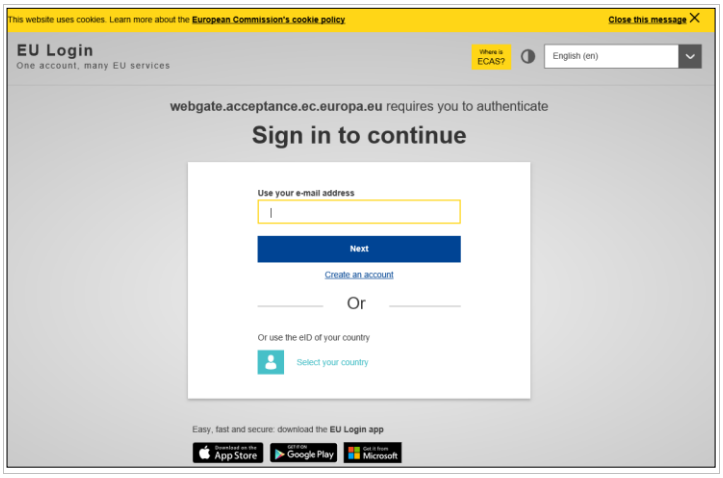


Figure 2 – EU Login: Sign in page 1: email address

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**:

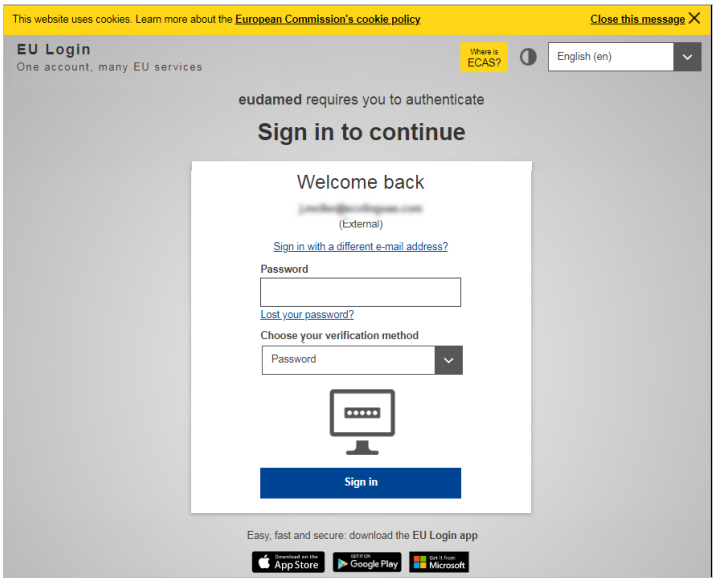


Figure 3 – EU Login: Sign in page 2: password

EU Login issues?

- ***Forgot your password?***
  Click 'Lost your password?' on this screen.
- ***Change your password***
  Go to https://webgate.ec.europa.eu/cas/changePassword.cgi
- ***View/edit your account***
  Go to https://webgate.ec.europa.eu/cas/userdata/myAccount.cgi?

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

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

Next steps

- ***Want to register your organisation as an actor in EUDAMED?***

  See section 2.1.1

- ***Need access as a user, for a registered economic operator?***

  See section 2.2.1

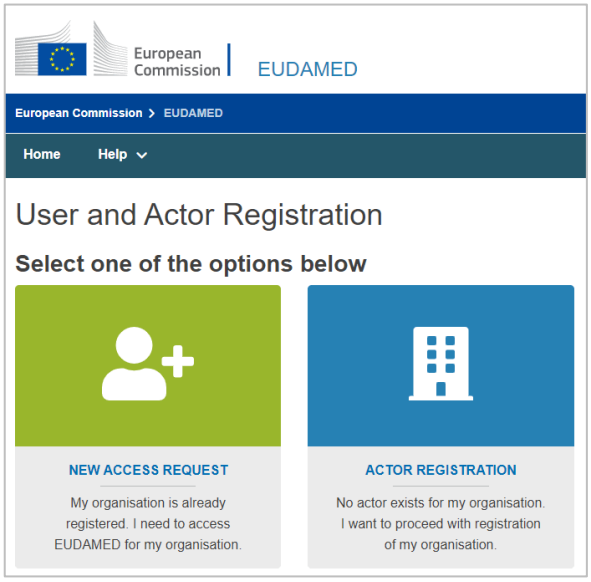


Figure 4 – EUDAMED User and Actor Registration page

♦ To quit EUDAMED

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

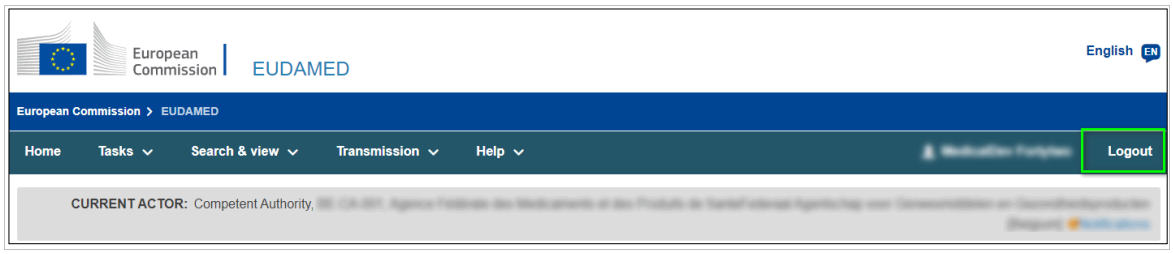


Figure 5 – Logging out

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

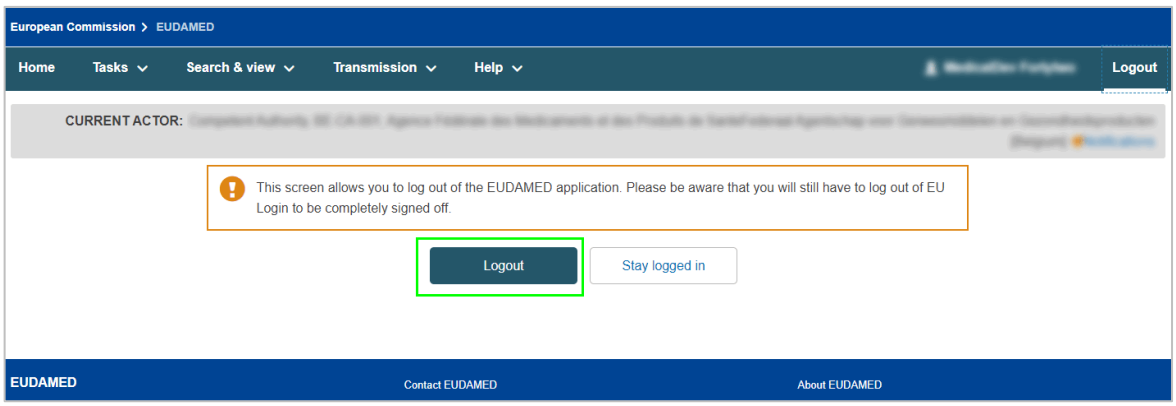


Figure 6 – Logout confirmation

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

1.2.2 Basic concepts

Actor

Actors involved in EUDAMED are:

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

Definitions

- **Manufacturer** – see Article 2(30) of Regulation 2017/745
- **Authorised representative** – see Article 2(32) of Regulation 2017/745
- **Importer** – see Article 2(33) of Regulation 2017/745
- **Sponsor** – see Article 2(49) of Regulation 2017/745
- **System/procedure pack producer** – any individual or organisation who places procedure packs and/or systems on the EU market
- **Medical device** – see Article 2(1) of Regulation 2017/745
- **In vitro diagnostic medical device** – see Article 2(2) of Regulation 2017/746
- **Person responsible for regulatory compliance** – see Article 15(1) and (3) of Regulation 2017/745
- **Single Registration Number (SRN) – see Article 31(2) of** Regulation 2017/745

1.2.3 User rights & profiles

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

Each EUDAMED account is associated one of the following actors:

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

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

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

User profiles in the actor module

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

Hierarchy of user profiles

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

E.g. LAA is the highest profile and contains the rights of all lower profiles.

User profiles per actor & their hierarchy

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

2. 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 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 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:

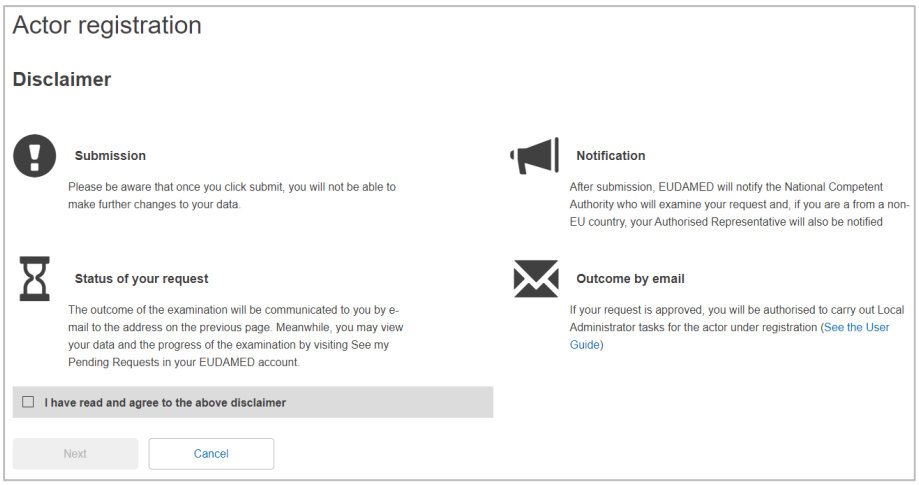


Figure 8 – Actor registration: disclaimer page

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:

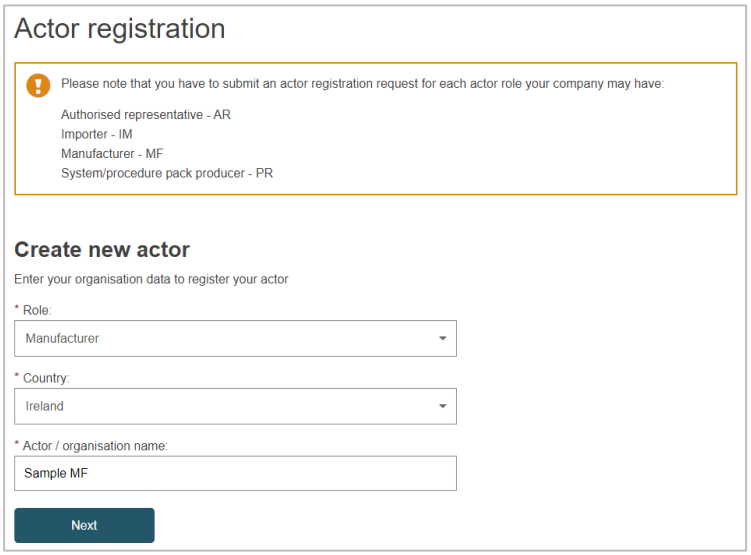


Figure 9 – Actor registration: initial page, 'Create new actor'

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:

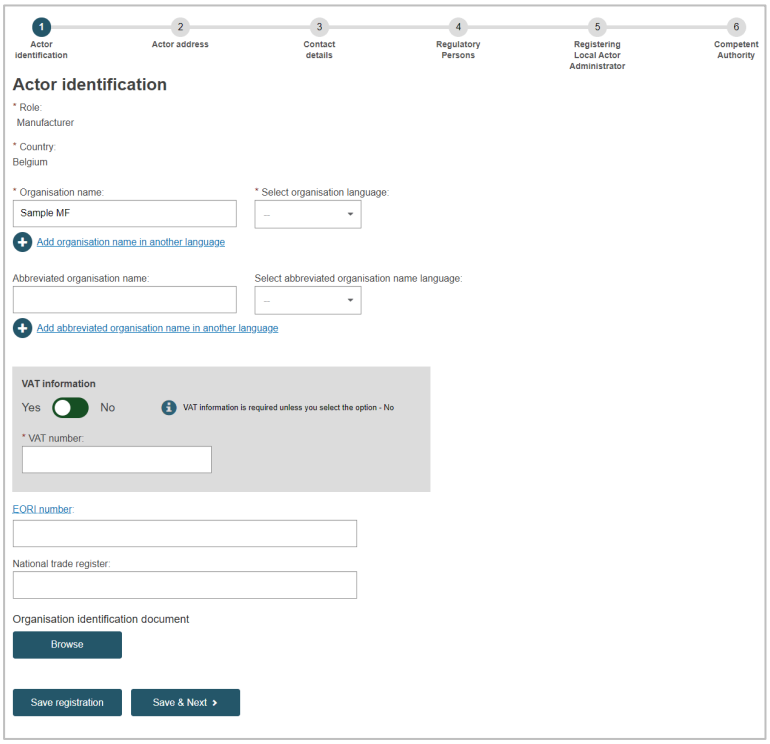


Figure 10 – Actor registration: step 1, 'Actor identification'

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:

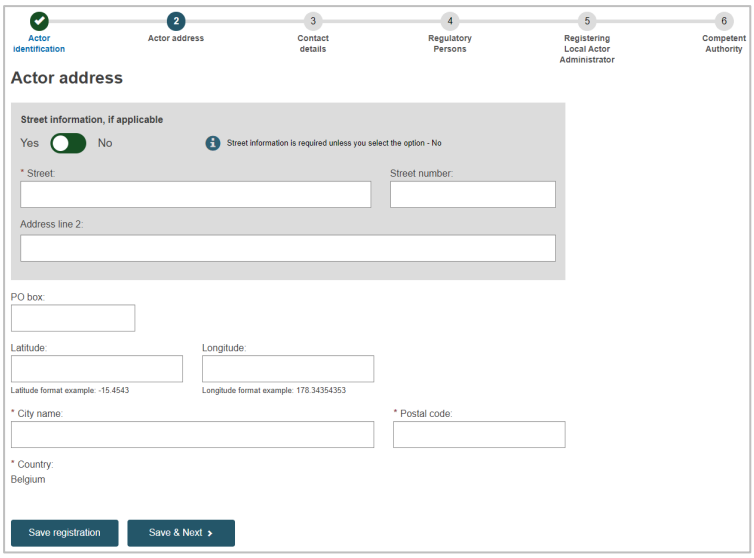


Figure 11 – Actor registration: step 2, 'Actor address'

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:

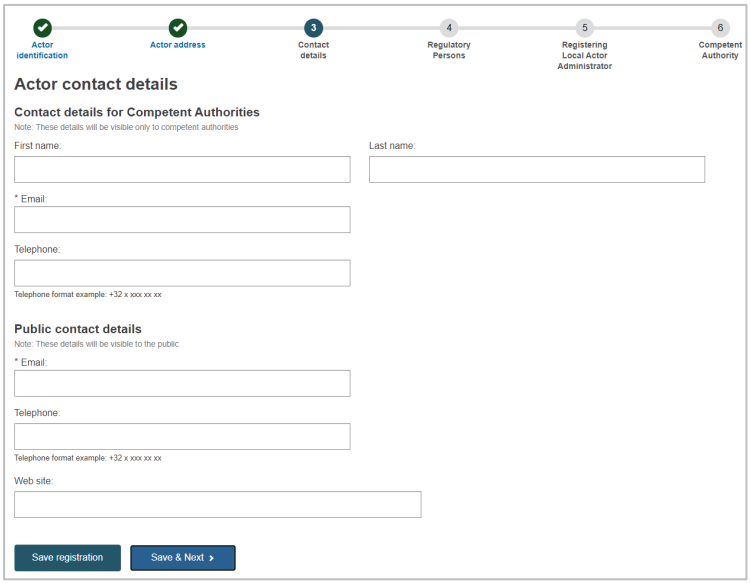


Figure 12 – Actor registration: step 3, 'Contact Details'

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.

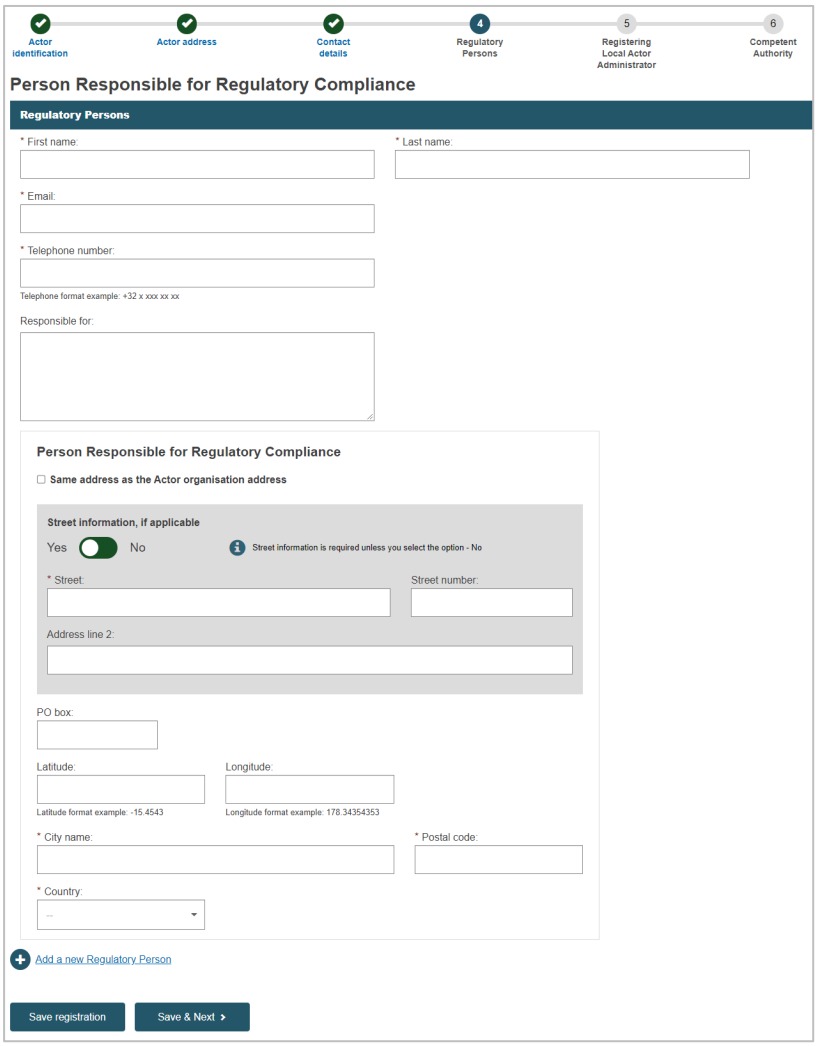


Figure 13 – Actor registration: step 4, 'Regulatory persons'

> ### 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:

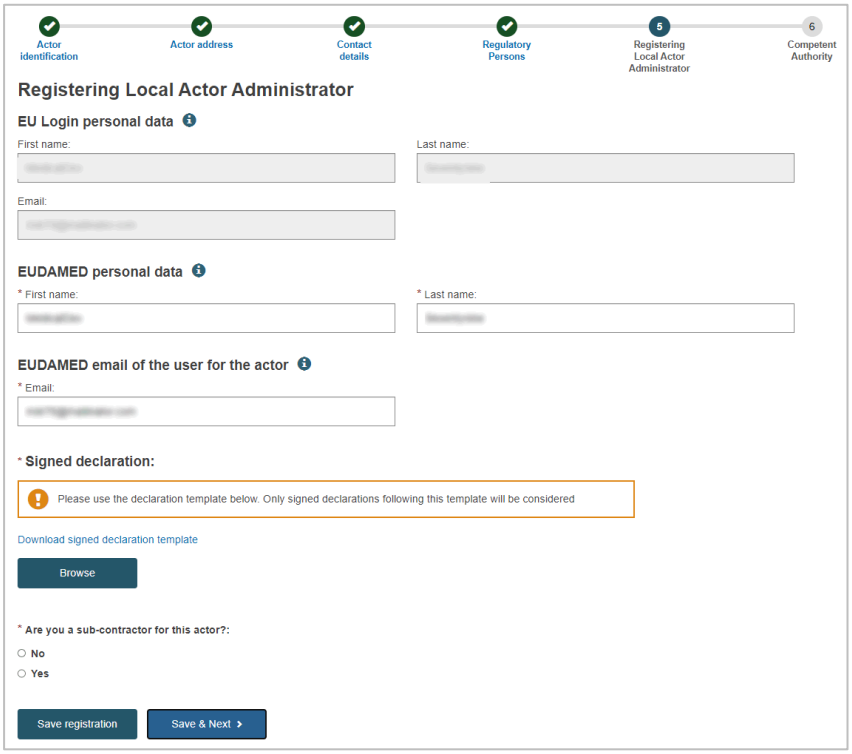


Figure 14 – Actor registration: step 5, 'Registering Local Actor Administrator'

> ***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:

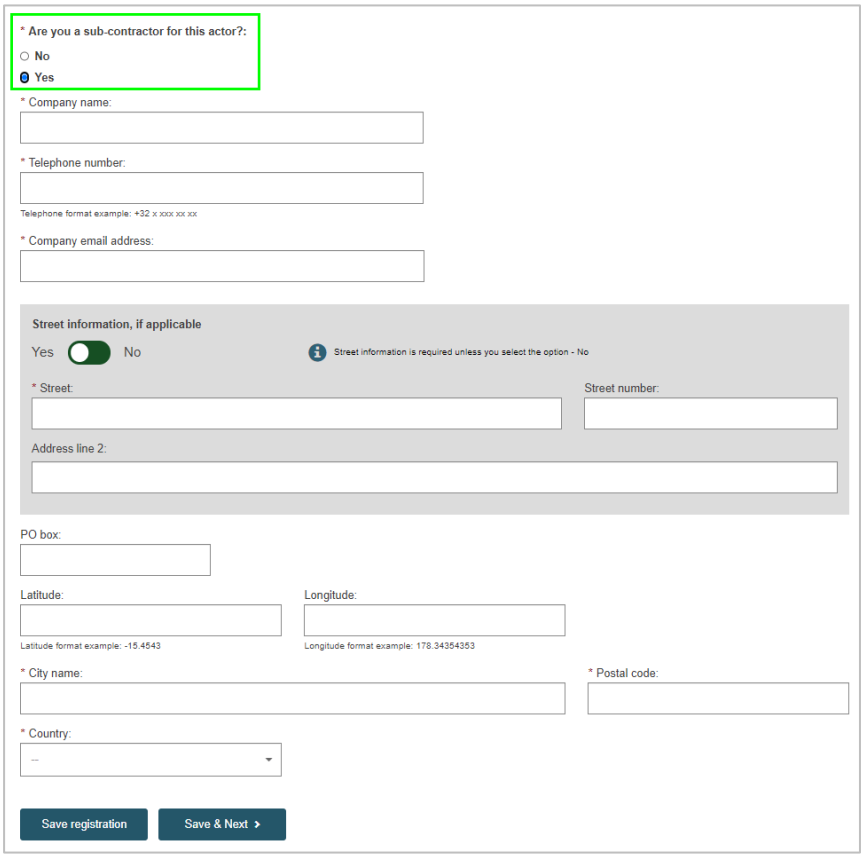


Figure 15 – Actor registration: Step 5, 'Are you a sub-contractor for this actor?'

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

    Result: Step 6 appears:

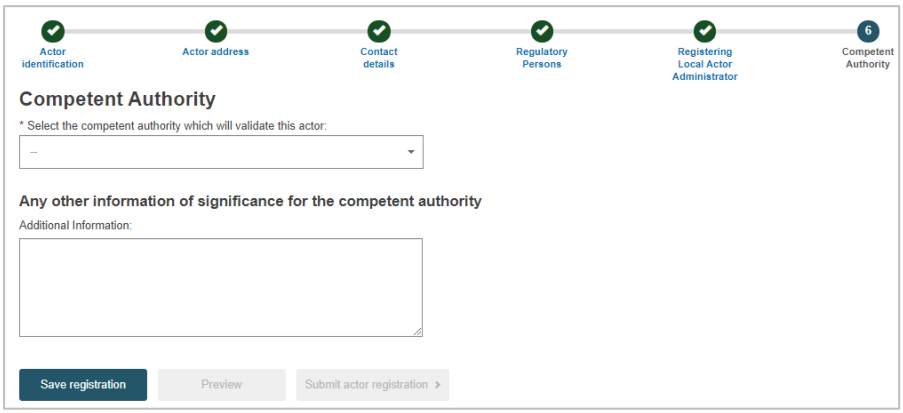


Figure 16 – Actor registration: Step 6, 'Competent Authority'

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:

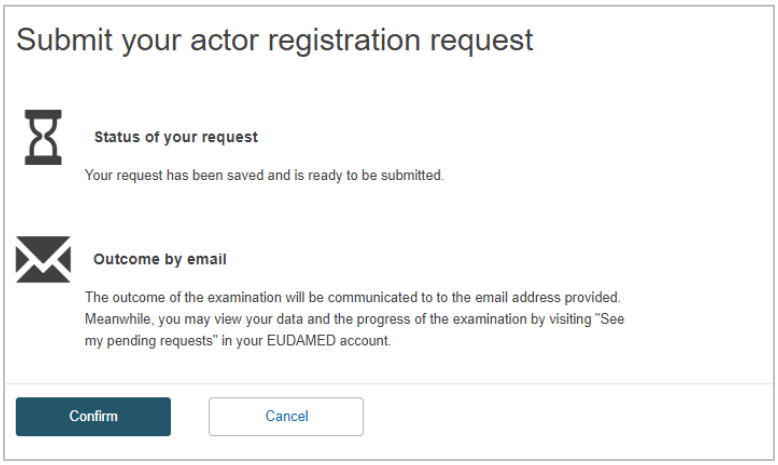


Figure 17 – Submission confirmation

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:

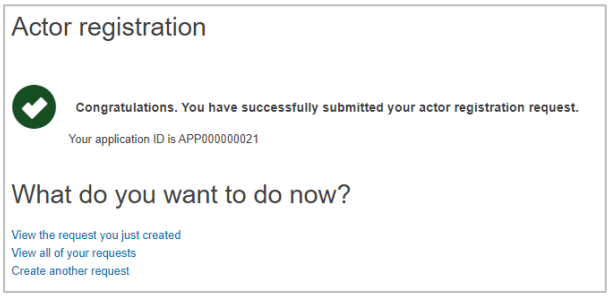


Figure 18 – Confirming you want to submit

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:

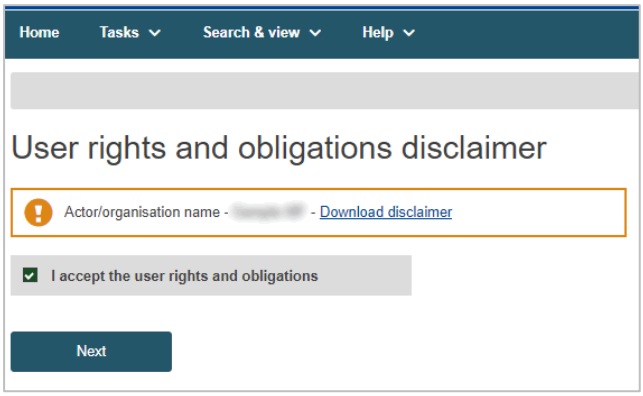


Figure 19 – Confirming your registration: disclaimer

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:

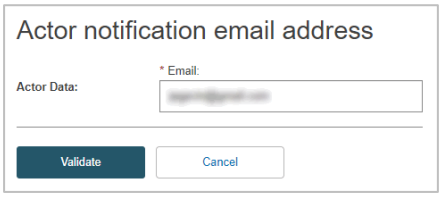


Figure 20 – Validating your email address

♦ **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:

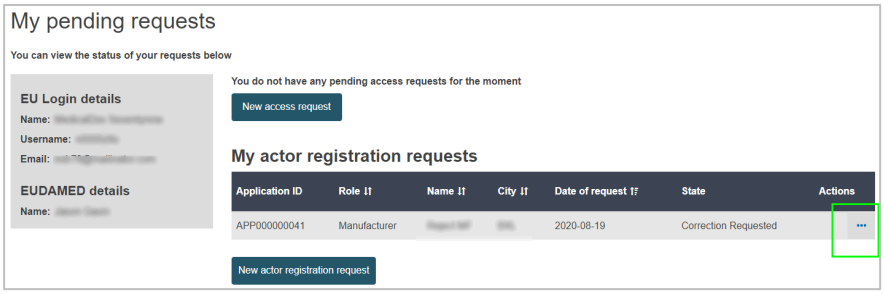


Figure 21 – My pending requests page

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:

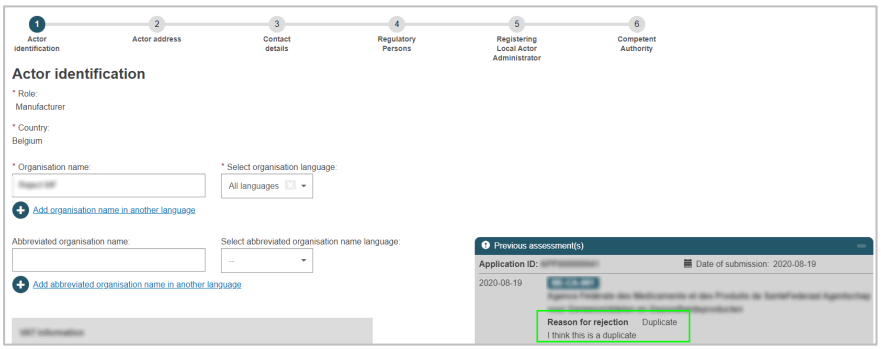


Figure 22 – Reason for rejection and resubmitting your request

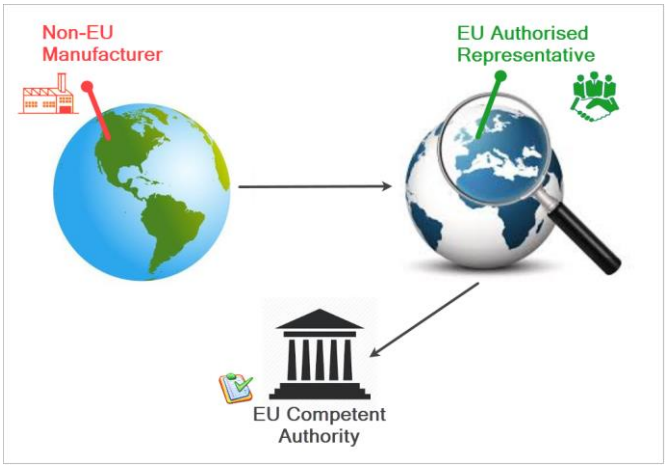
3. For requests flagged as "*Correction requested*", change and resubmit them for validation as appropriate.

2.1.2 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:

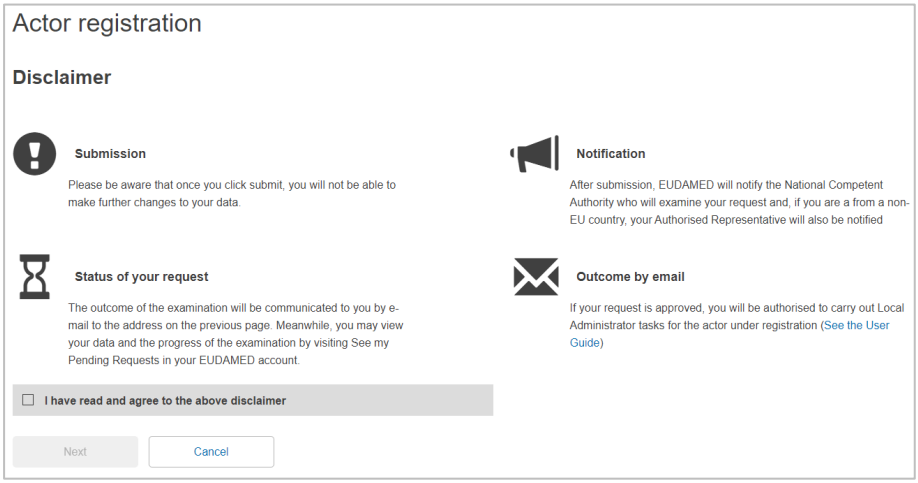


Figure 23 – Actor registration: disclaimer page

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:

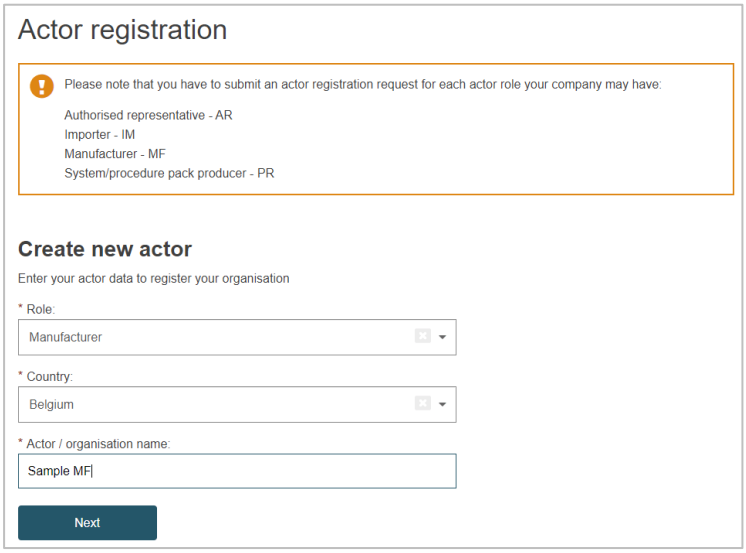


Figure 24 – Registration: initial page, 'Create new actor'

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

   Result: Step ❶ of the registration process appears:

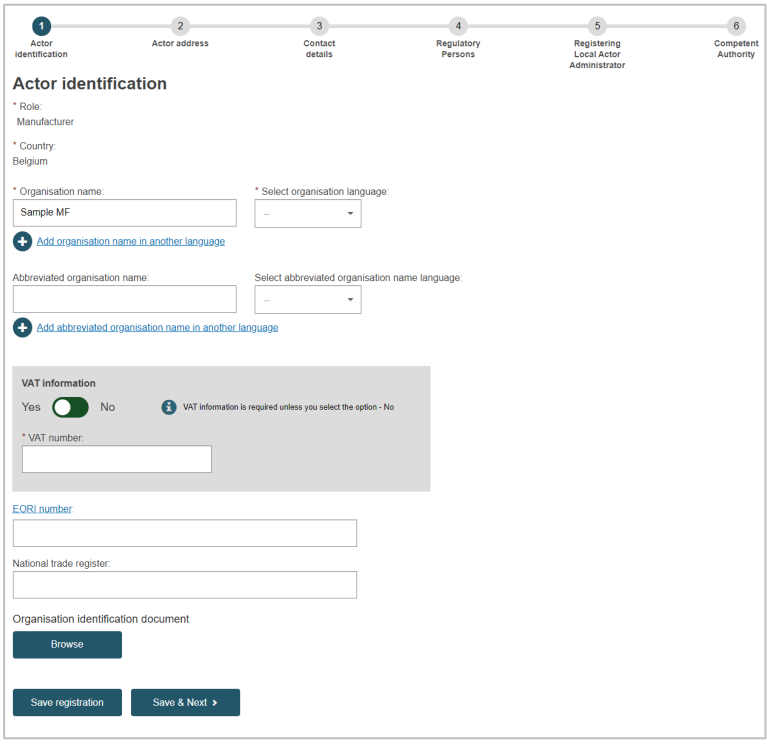


*Figure 25 – Registration: step 1, '*Actor identification'

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:

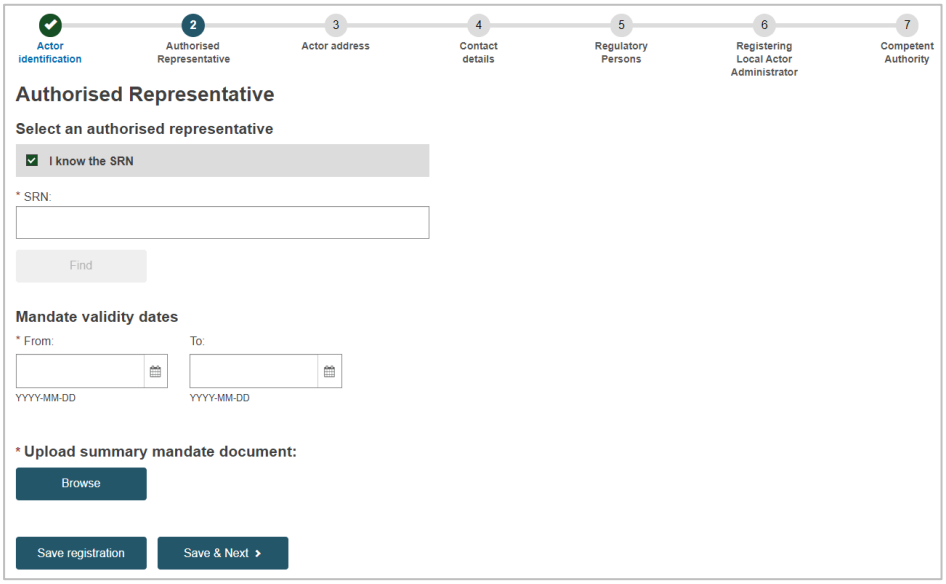


Figure 26 –Non-EU registration: step 2, 'Authorised representative'

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.

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.

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.

6.3 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:

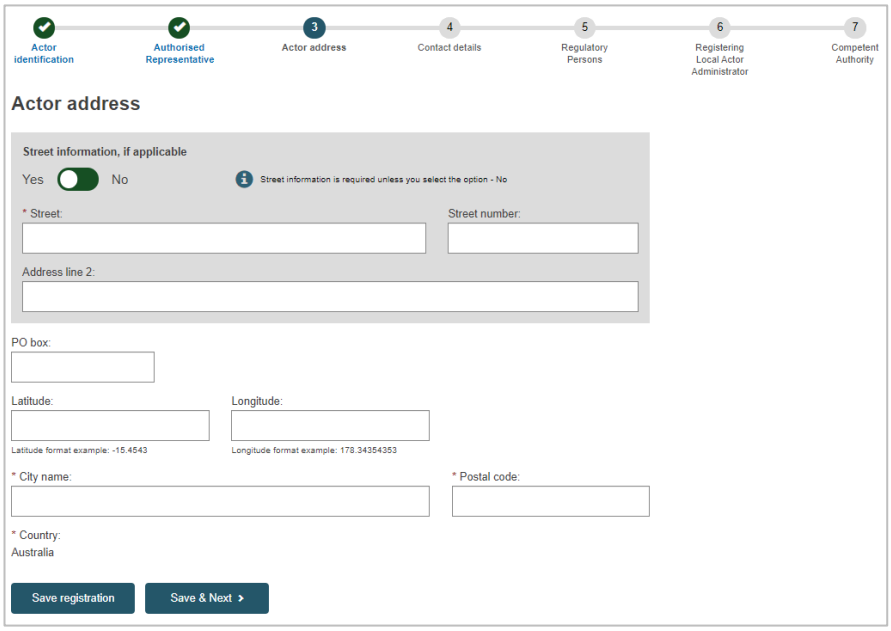


Figure 27 – Non-EU registration wizard: step 3, 'Actor address'

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

   Result: Step 4 appears:

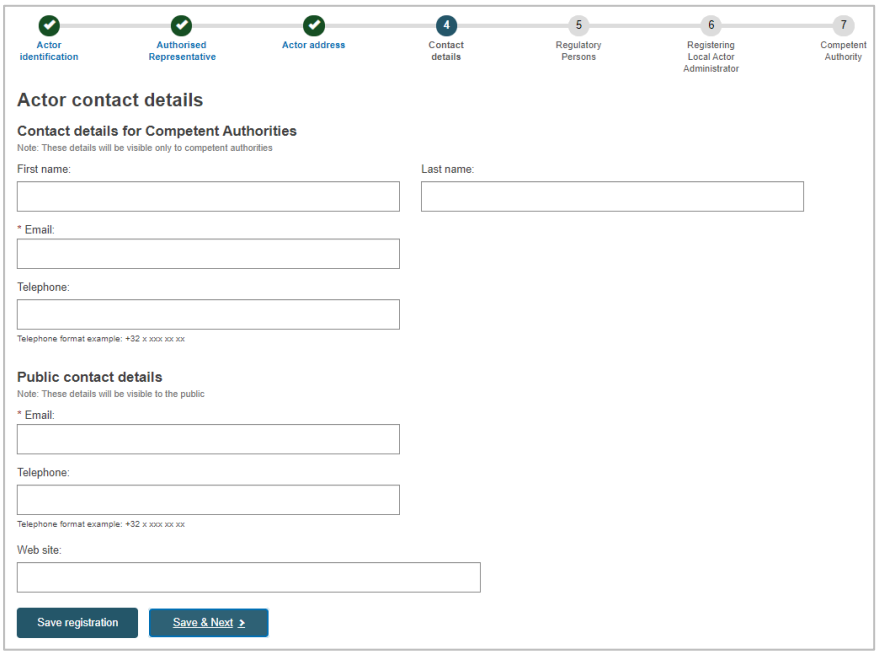


Figure 28 – Non-EU registration: step 4, 'Contact Details'

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

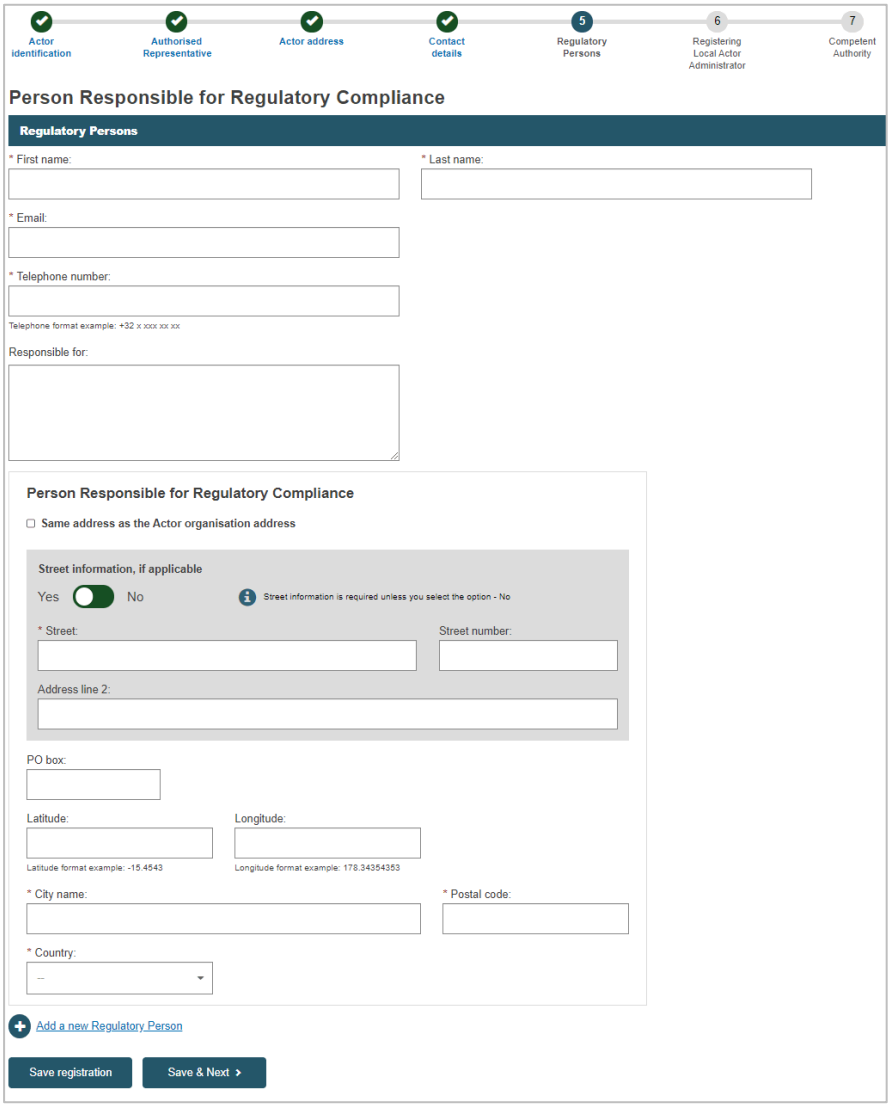


Figure 29 – Non-EU registration: step 5, 'Regulatory persons'

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

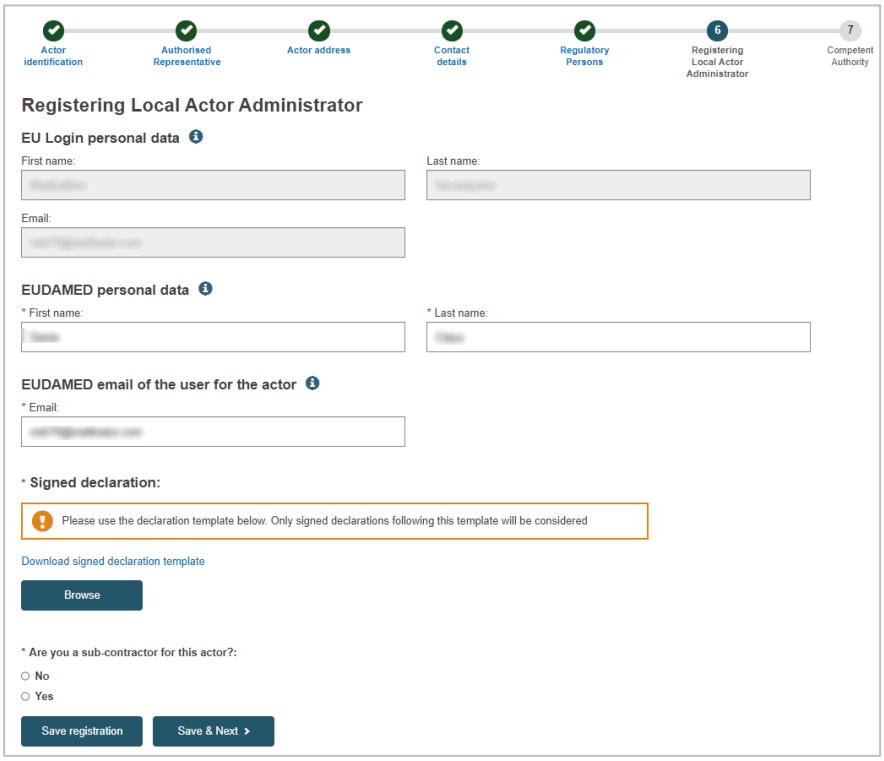


Figure 30 – Non-EU registration: step 6, 'Registering Local Actor Administrator'

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).

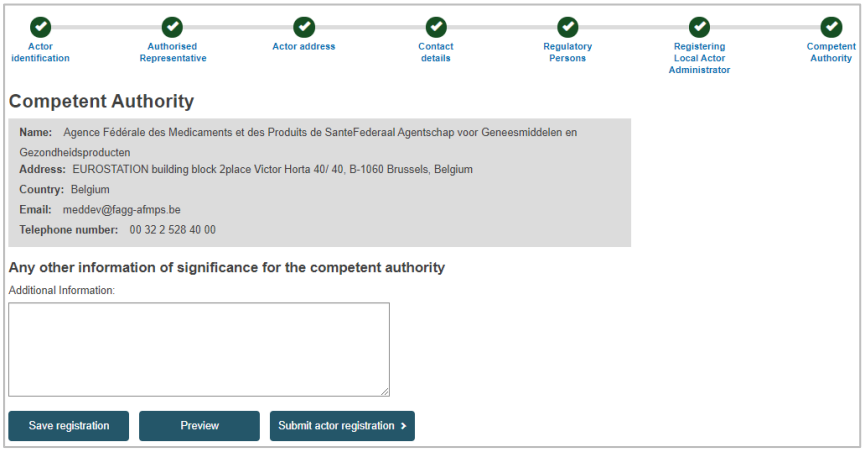


Figure 31 – Non-EU registration: Step 7, 'Competent Authority'

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:

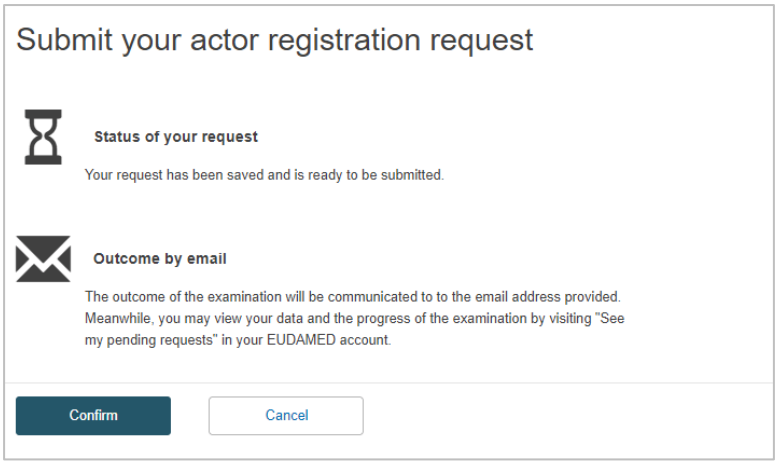


Figure 32 – Non-EU registration: submission confirmation

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*).

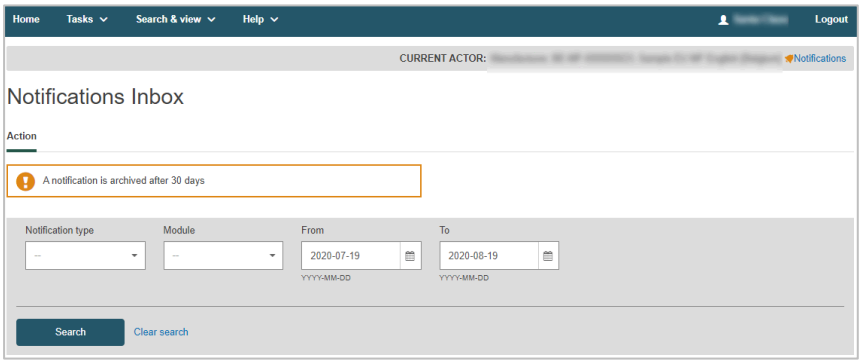
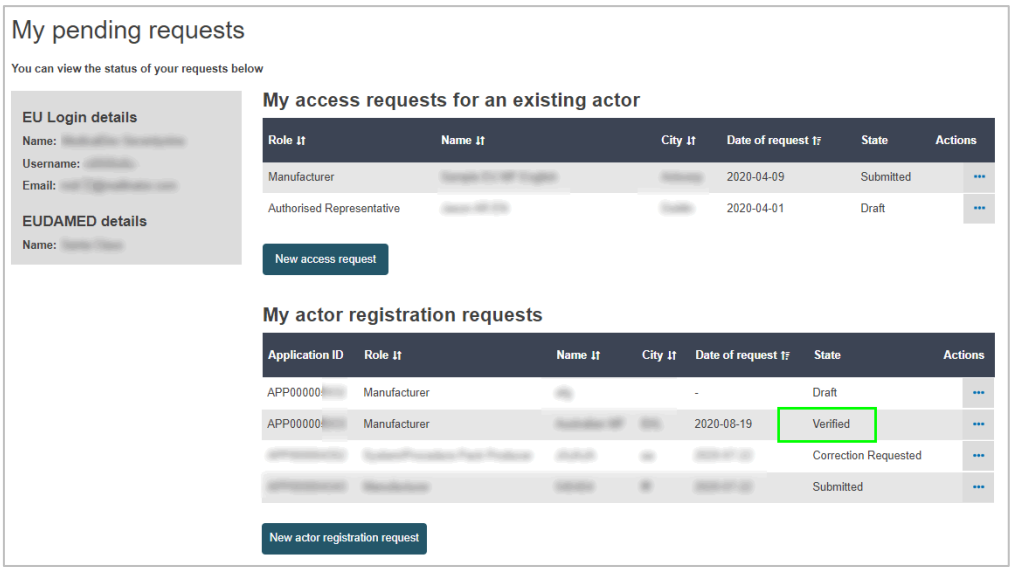


Figure 33 - Notifications inbox

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.

2.2. 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:

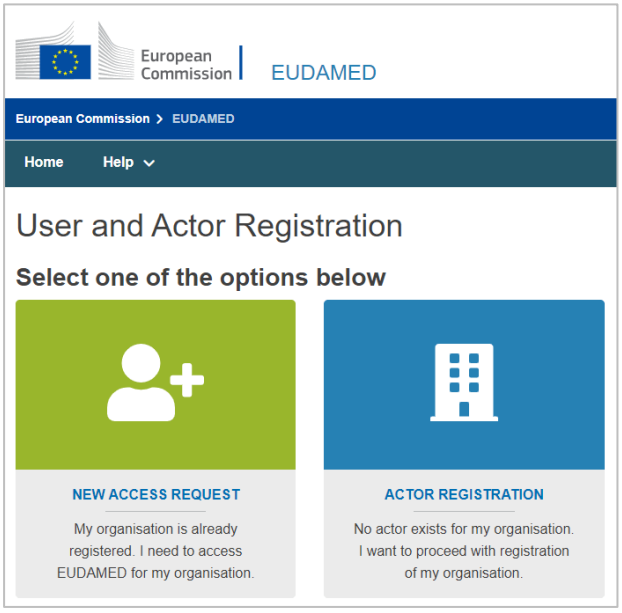


Figure 34 – EUDAMED User and Actor Registration page

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:

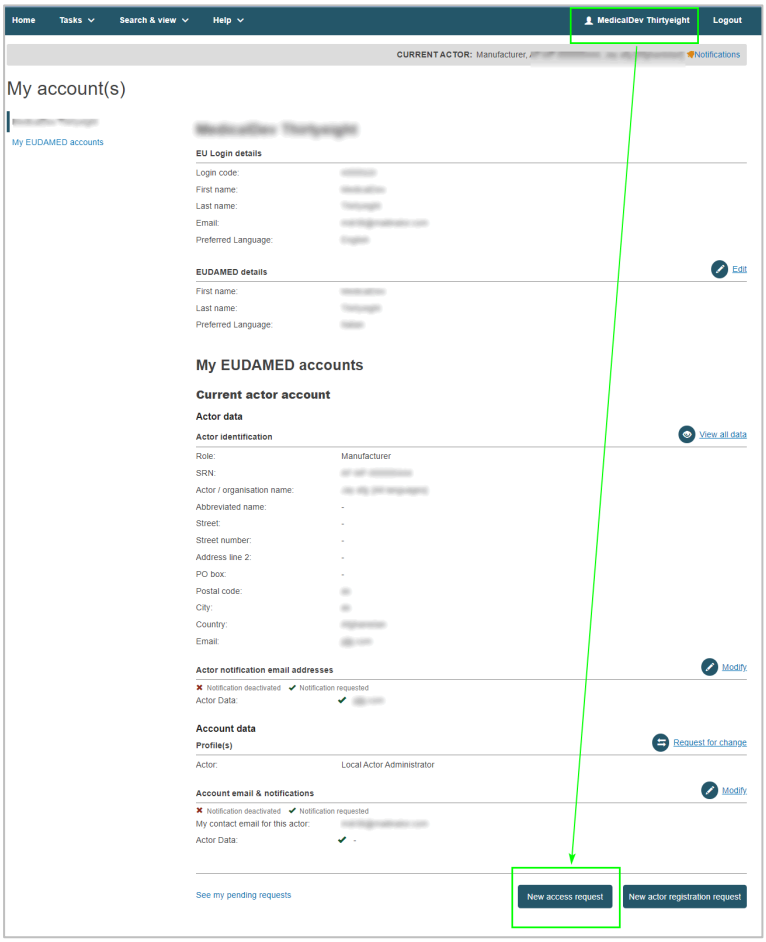


Figure 35 – EUDAMED user account detail page and new access request button

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.

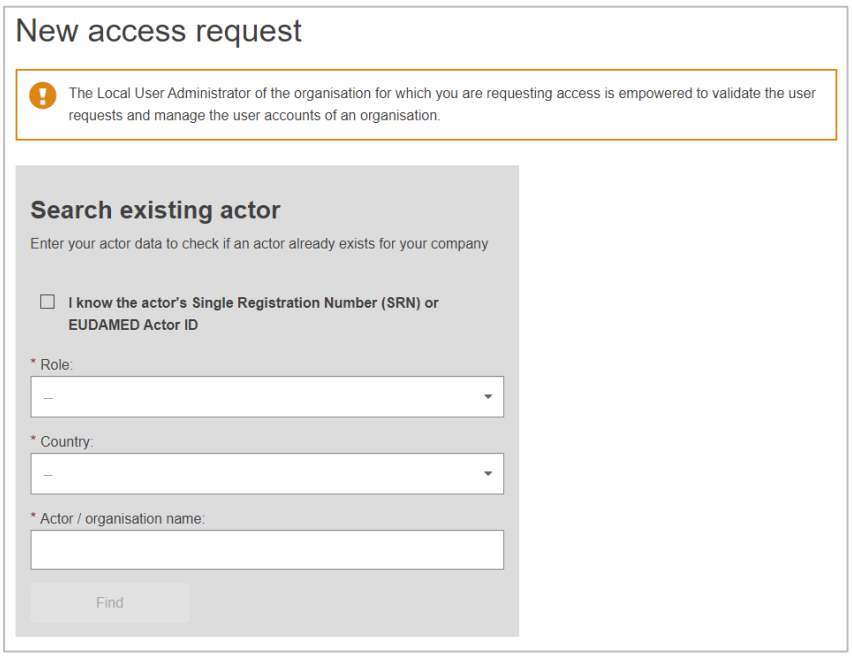


Figure 36 – 'New Access Request'

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.

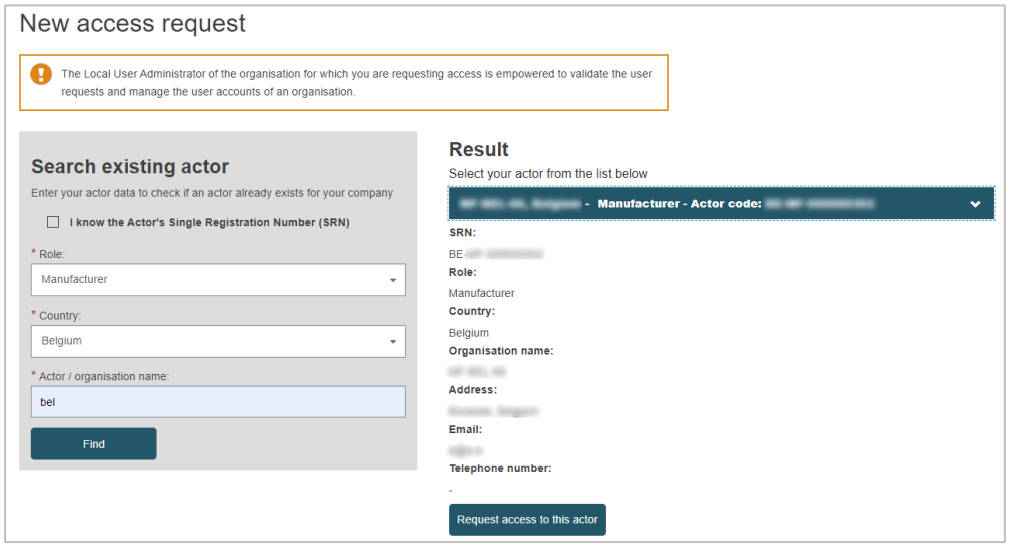


Figure 37 – 'Request access to this actor'

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

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

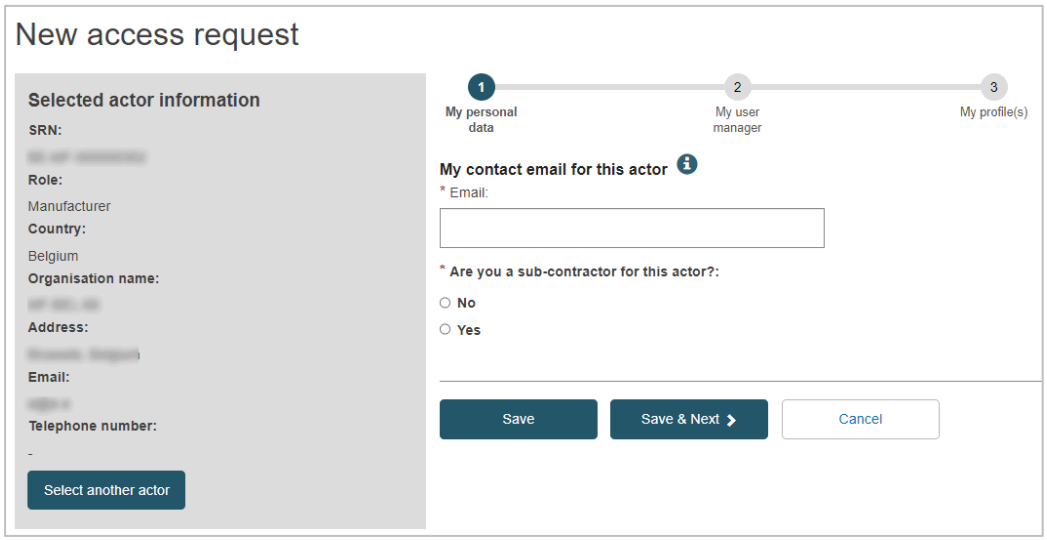


Figure 38 – User access request: step 1

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:

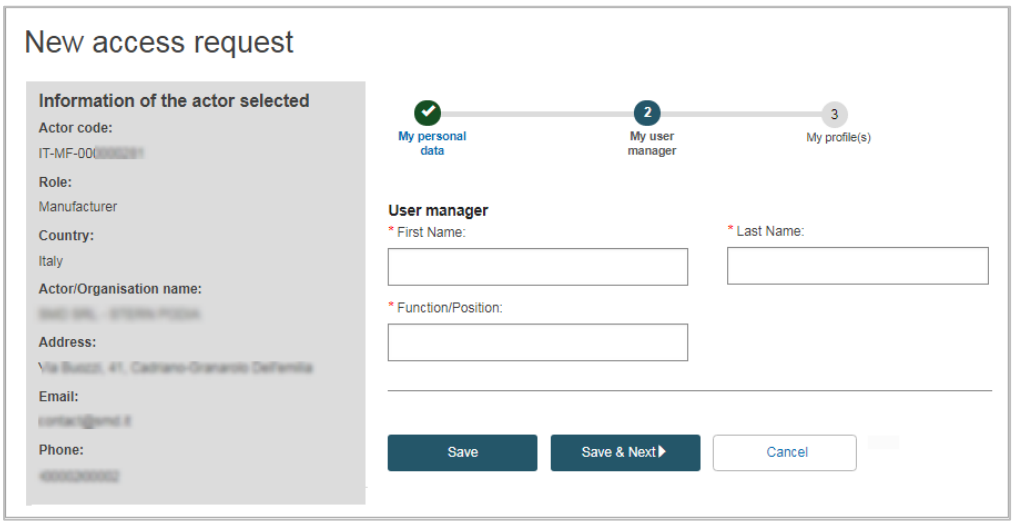


Figure 39 – User access request: step 2

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

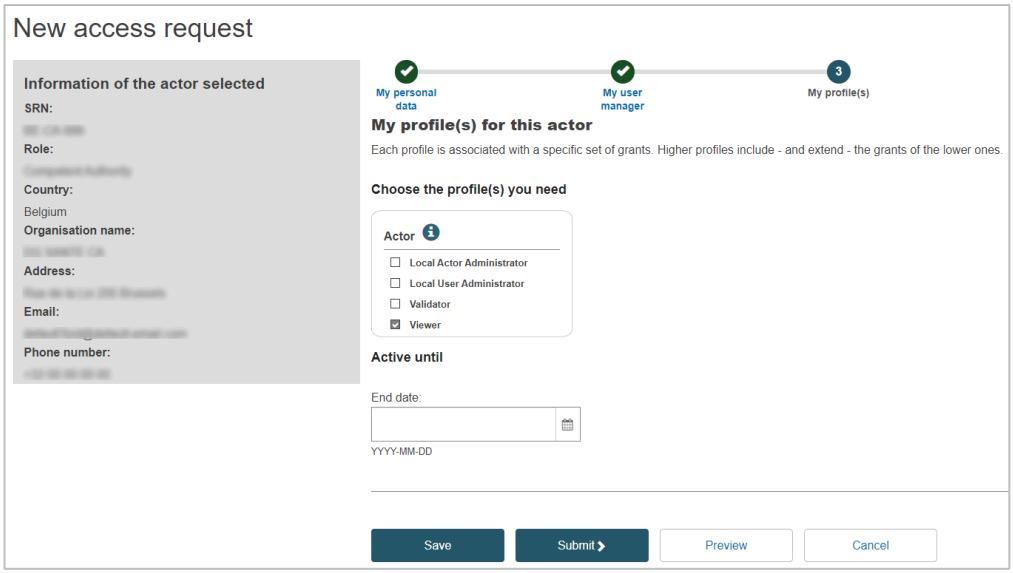


Figure 40 – User access request: step 3

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***).

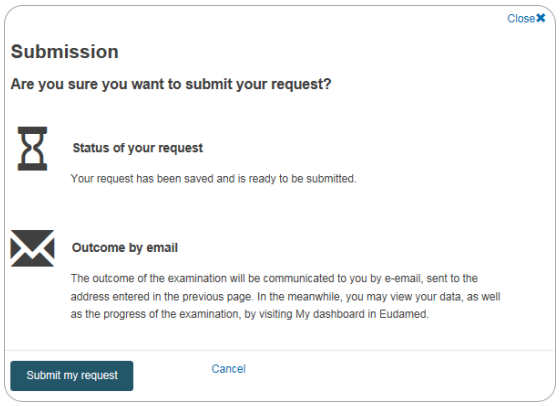
12. If you want to **save the request as a draft** before submitting it, click **Save**.

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:



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.

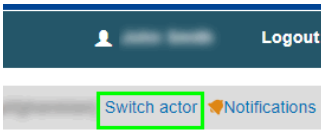
    ▸ If **rejected**, you can click the action button next to the pending request to read the reason provided by the LAA/LUA. You can then change and re-submit as appropriate.



    ▸ 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:



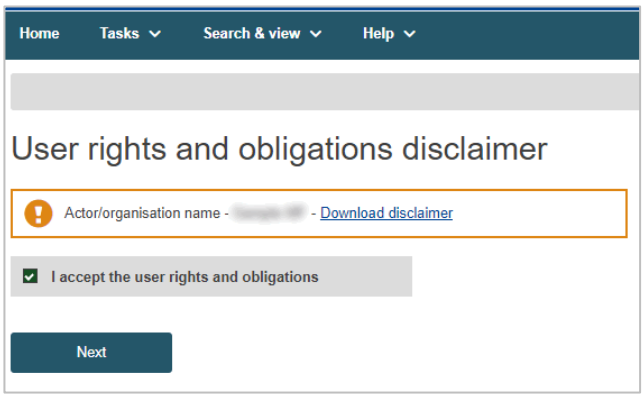
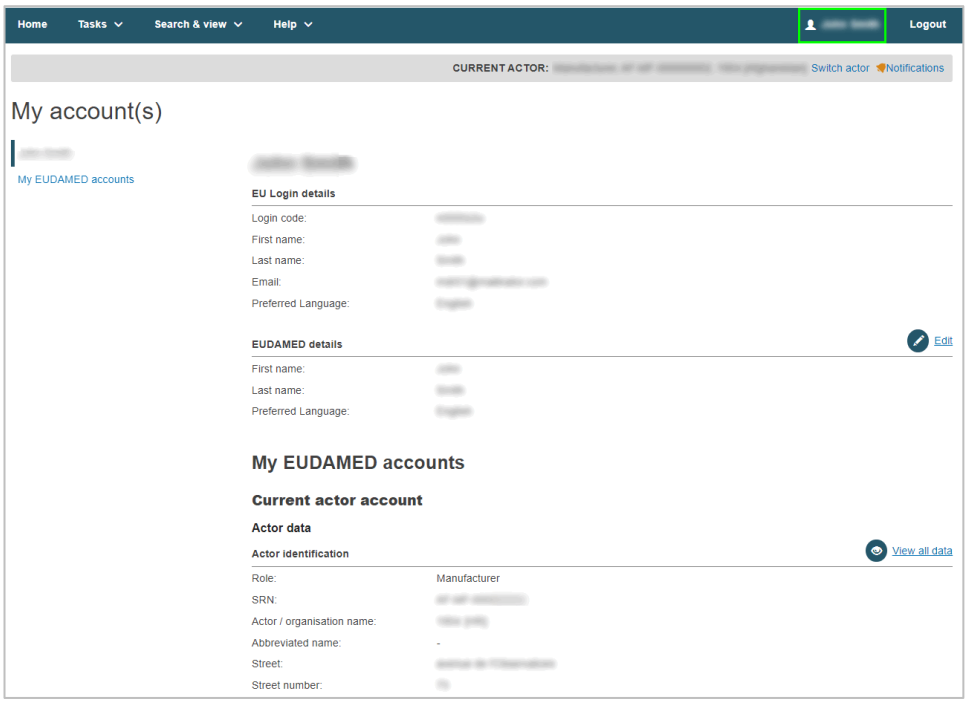


Figure 41 – User rights and obligations disclaimer

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*'

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