

Notified Bodies access – User guide

Production v2.8
July 2022

Table of Contents

1. Overview	1
2. Application basics	2
3. Starting and ending a EUDAMED session	3
4. User rights & profiles	8
5. User access requests	9

1. Overview

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

- [Regulation 2017/745](#) on medical devices
- [Regulation 2017/746](#) on in vitro diagnosis devices

EUDAMED is structured around **six interconnected modules** and a **public site**¹:

- 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



NOTE
Evolving user interface

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

¹For a wider understanding on how to use the platform, visit the [EUDAMED Help Centre](#).

2. Application basics

This section describes a number of basic principles that you will acquire 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

3. Starting and ending a EUDAMED session



NOTE

EUDAMED's Playground and Production environments

Please ensure that you are in the correct EUDAMED environment!

The test, or **Playground**, environment contains a red “**Play**” banner across the logo at the top of the screen. Any submissions to the playground are for testing only and should contain dummy data, and all actions, including user access requests **must** be repeated in the **Production environment**.

To use EUDAMED, you must have an **EU Login account** – linked to your **work email address**.



IMPORTANT

Private/shared mailboxes are not allowed for security reasons.

Read more: [Introduction to EU Login](#)

To start EUDAMED

1. Go to [EUDAMED](#)

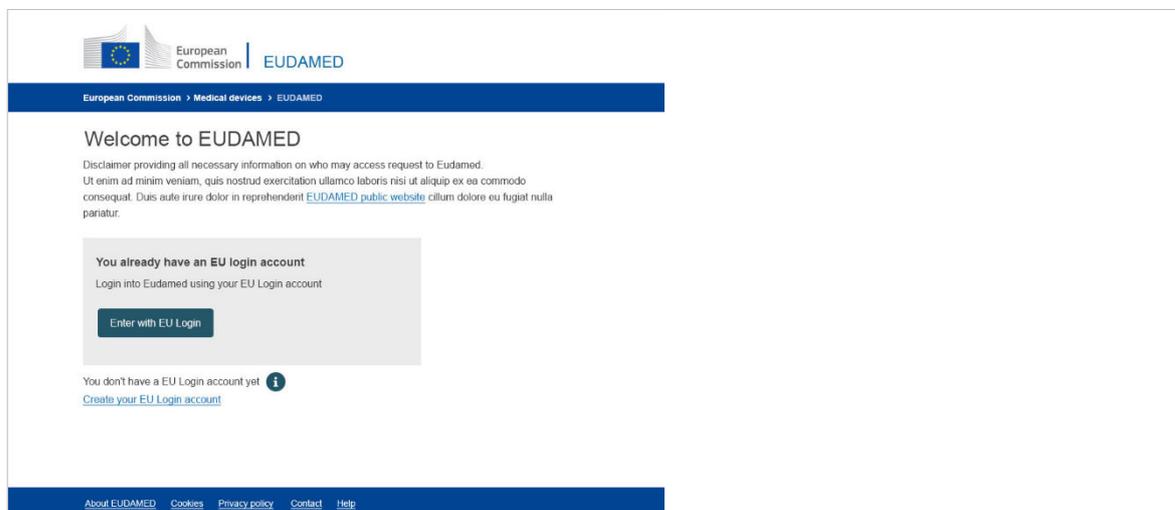


Figure 1 – EUDAMED Welcome page

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:

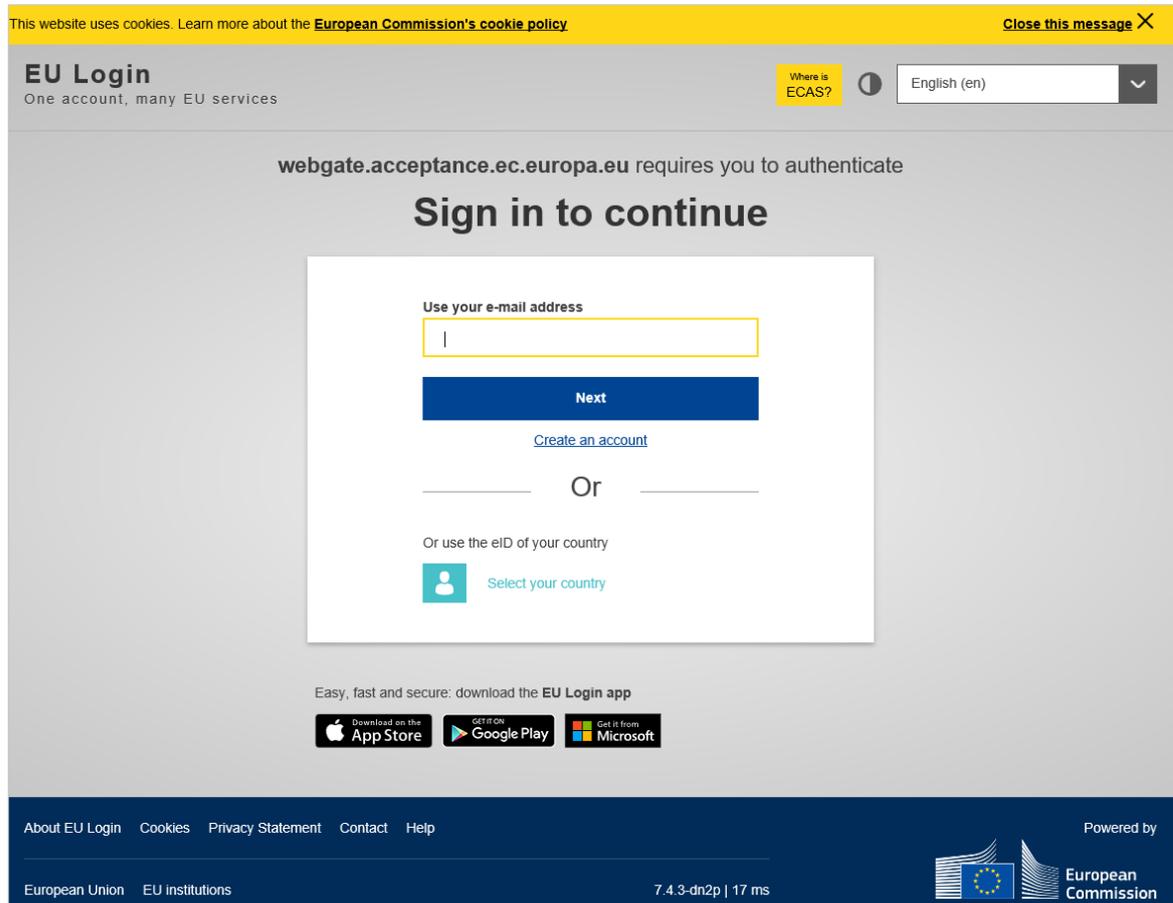


Figure 2 – EU Login: Sign in page one: email address

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

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

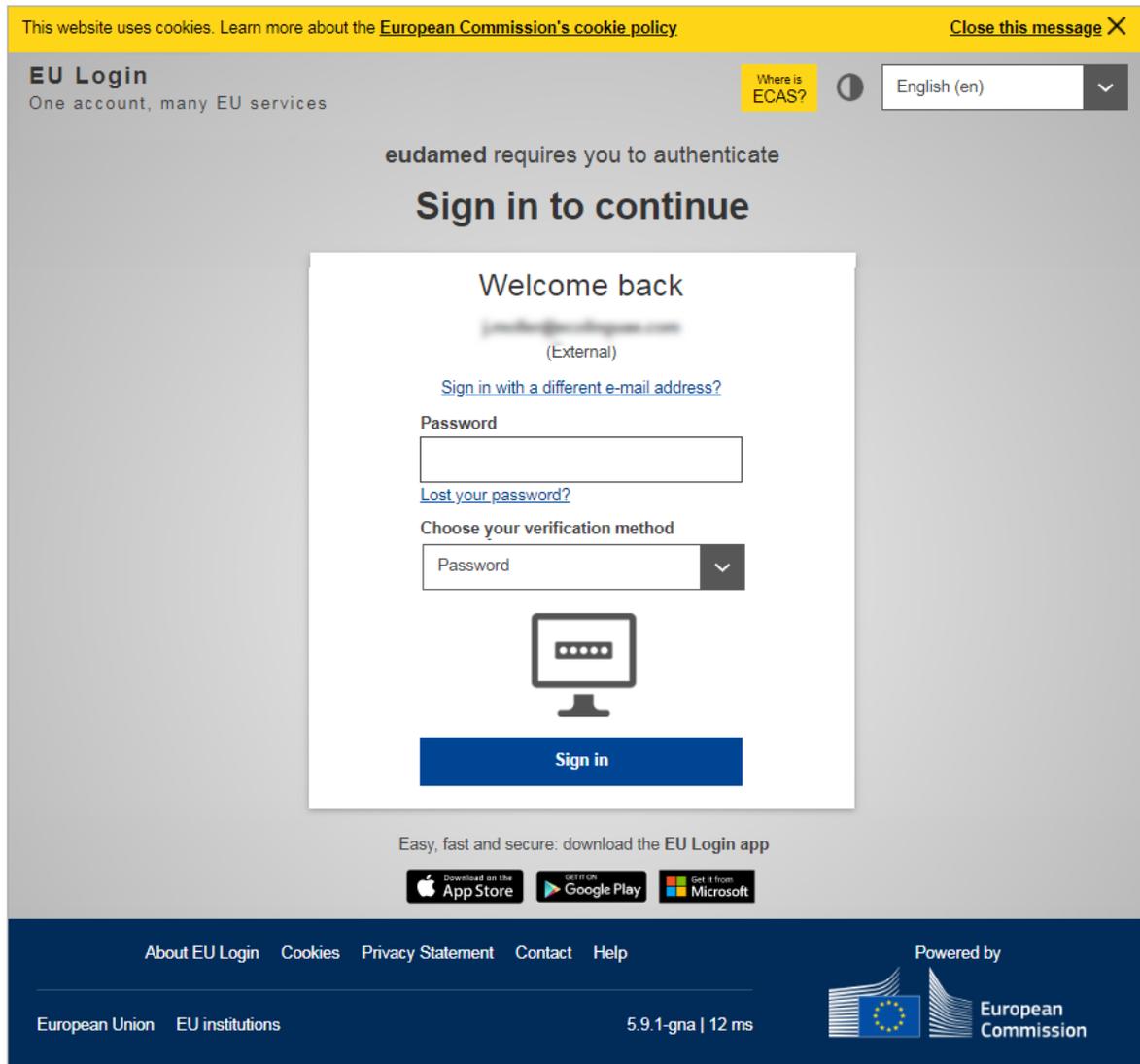


Figure 3 – EU Login: Sign in page two: password



NOTE

EU Login issues?

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

Change your password: Go to [Change password](#)

View/edit your account: Go to [My Account](#)

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

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

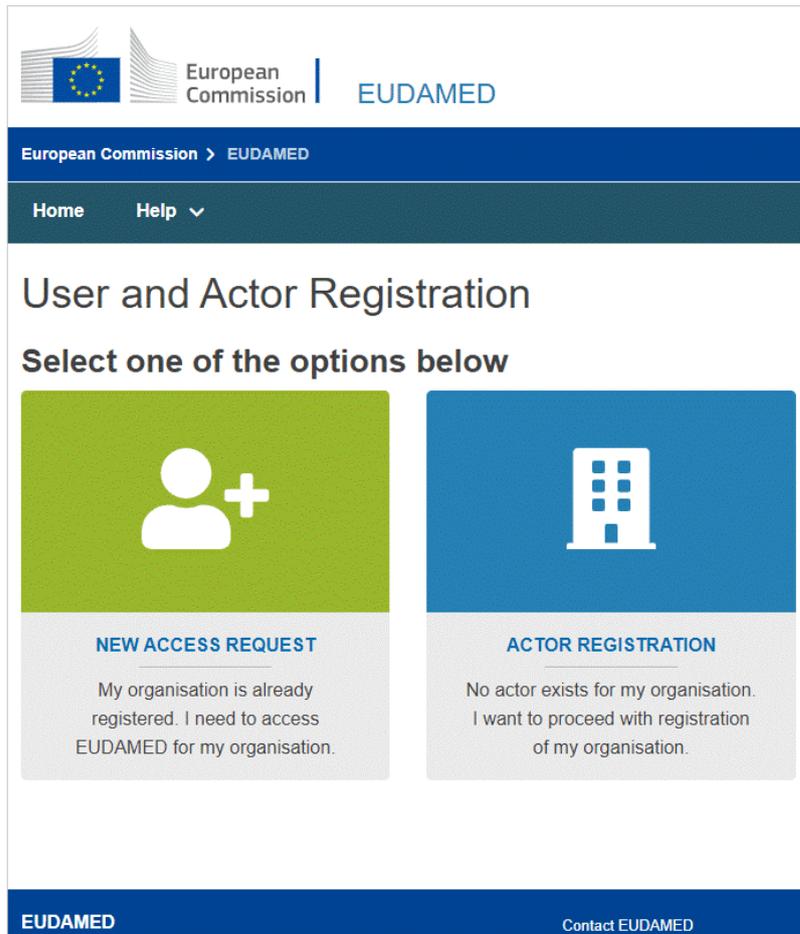


Figure 4 – EUDAMED User and Actor Registration page

To quit EUDAMED

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

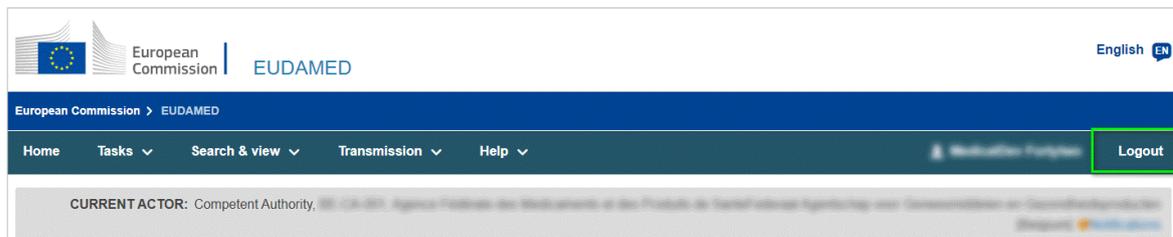


Figure 5 – Logging out

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

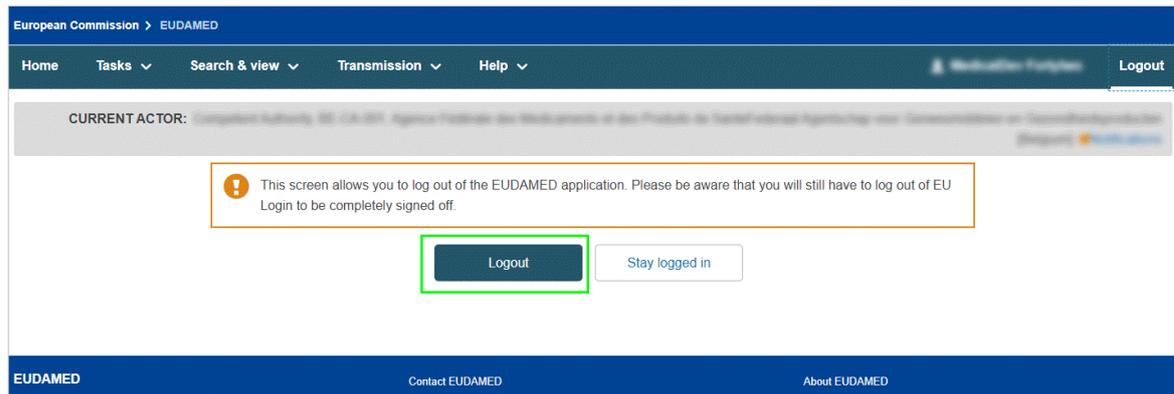


Figure 6 – Logout confirmation

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

4. User rights & profiles

EUDAMED users may have one or more account(s), but Notified Body users may **not** have a EUDAMED account with any other actor type.

Each actor type has a specific role, set out in user profiles for each module of the system that they need to use. The profiles are module-specific and describe the specific actions the user can perform in that module.

Profiles are hierarchical, i.e. higher level profiles contain all lower level grants/rights, e.g. the *Local Actor Administrator* (LAA) is the highest profile in the Actor module and contains the rights of all lower profiles.

Table 1. User profiles available to a Notified body in each module

User profile	Module	Rights
Viewer	All	May only view registered actors, own actor details, device and certificate information
Local User Administrator (LUA)	Actor	Manage users and user access requests
Local Actor Administrator (LAA)	Actor	LUA + manage actor data and notification email addresses
Proposer	Certificates	Enter, delete and update certificate module information in state <i>Draft</i>
Confirmer	Certificates	Proposer + submit and delete certificate module information in state <i>Registered</i>

Once the first LAA is approved by your designating authority, subsequent user access or profile change requests for the Notified Body will be approved by this user (not the designating authority). This responsibility can then be delegated to other LAA/LUAs in the Notified Body. It is good practice for each actor to have **at least two LAAs**.

Every validated user in EUDAMED is granted the profile *Viewer*, and can search and view registered certificates.

In order to register a certificate in EUDAMED, you must request access to the Notified Bodies & Certificates module as *Proposer* or *Confirmer*.

As a LAA cannot approve their own profile change requests, these requests must be approved by different LAA/LUA from the Notified Body.

5. User access requests

The **Actors** module ensures that all actors using EUDAMED have been authenticated.

All economic operators must submit actor registration requests to their competent authority before accessing EUDAMED. However, notified bodies do **not** need to register: details of all notified bodies will automatically be available in EUDAMED as they are synchronised with the New Approach Notified and Designated Organisations (NANDO) database.

To request access as a user acting on behalf of a Notified Body

1. Log in to EUDAMED as a new user. You will be greeted by the **user and actor registration** page.
2. Click the **Next access request** box.

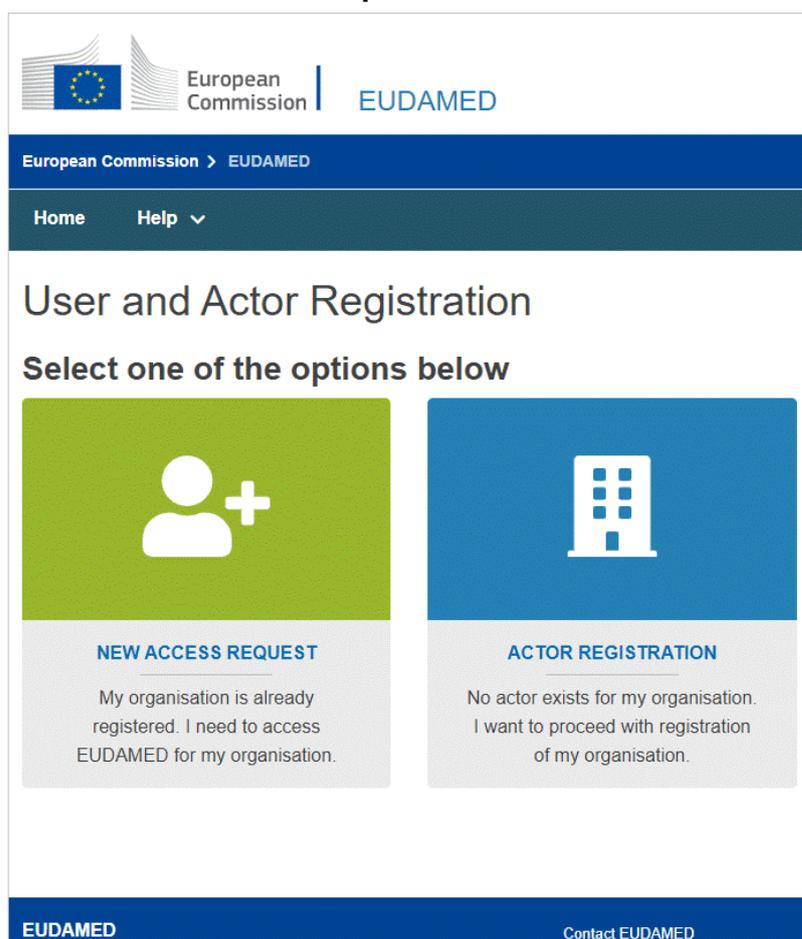


Figure 7 – EUDAMED User and Actor Registration page

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

New access request



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

Search existing actor

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

I know the actor's Single Registration Number (SRN) or EUDAMED Actor ID

* Role:

* Country:

* Actor / organisation name:

Find

Figure 8 – New Access Request



NOTE

Missing actor?

If you cannot find your notified body from the search page, please ensure your details are up to date on the NANDO database. The EUDAMED database is synchronised with NANDO once daily.

3. The Actor ID of a notified body is equal to its NANDO identifier. If you know this ID, you can use it to find the notified body by selecting **I know the actor's Single Registration Number (SRN) or EUDAMED Actor ID**.
4. If you do not know the notification body ID, you can find it by searching with **role**, and **country**.
5. Click **Find**.
Result: The list of matching actors is displayed in the *Result* section on the right-hand side.

New access request

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

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

I know the actor's Single Registration Number (SRN) or the EUDAMED Actor ID

* Role:
Notified Body

* Country:
Belgium

Actor / Organisation name:
[Empty field]

Find

Result
Select your actor from the list below

Notified Body, 0000 0000 Belgium 00 [Belgium]

NB ID: 0000
Role: Notified Body
Country: Belgium
Actor / Organisation name: 0000 Belgium 00
Address: Boulevard 00, Avenue 00, Belgium
Email: 00@00000000.com
Telephone number: 0000 000 0000

Request access to this actor

Create my actor

Figure 9 – Request access to this actor

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

Result: Step one of a three-step process appears:

New access request

Selected actor information

SRN:
[Empty field]

Role:
[Empty field]

Country:
Belgium

Organisation name:
[Empty field]

Address:
[Empty field]

Email:
[Empty field]

Telephone number:
[Empty field]

Select another actor

1 My personal data 2 My user manager 3 My profile(s)

My contact email for this actor ⓘ

* Email:
[Empty field]

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

Save **Save & Next >** **Cancel**

Figure 10 – User access request: step one

- Complete step one of the user access request process:
 - Enter your contact/notification email address related to this actor.
 - 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.
- Click **Save & Next**.
Result: Step two appears. Here you must identify a direct superior who can support your request:

Figure 11 – User access request: step two

- Enter the name and function/position of your manager, and then click **Save & Next**.
Result: Step three shows a list of possible user profiles for each module:

Figure 12 – User access request: step three



IMPORTANT Profile types

Profiles are specific for each module.

Please ensure that you select those that are suitable for each, e.g. *Local User Administrator* can approve user access requests for your actor, *Certificate confirmer* can submit new issued certificates, etc.

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



IMPORTANT User Profiles

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

- **Local Actor Administrator (LAA)** can manage the actor notification email addresses and has all the rights of a Local User Administrator. The first user for each notified body will be automatically granted the LAA profile.
- **Local User Administrator (LUA)** can validate user access requests.

As the details of the notified body (e.g. address) are taken from the NANDO database, these are not updatable in EUDAMED.

11. If you want to **save the request as a draft** before submitting it, click **Save**.
12. 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.
13. 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

14. Click **Submit my request**.
Result: You are informed that your access request has been successfully submitted.



NOTICE

Who will review my request?

If you are the **first** user to request access to a notified body, the designating authority responsible for this Notified Body will approve your request.

For subsequent user access requests, the LAA/LUA from your Notified Body will approve 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. You can then review and re-submit as appropriate.

Role	Name	City	Date of the request	State	Actions
Authorised Representative	Magnumatica	Sorrento	2019-12-05	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:

Home Tasks ▾ Search & view ▾ Help ▾

User rights and obligations disclaimer

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

I accept the user rights and obligations

Next

Figure 13 – User rights and obligations disclaimer

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

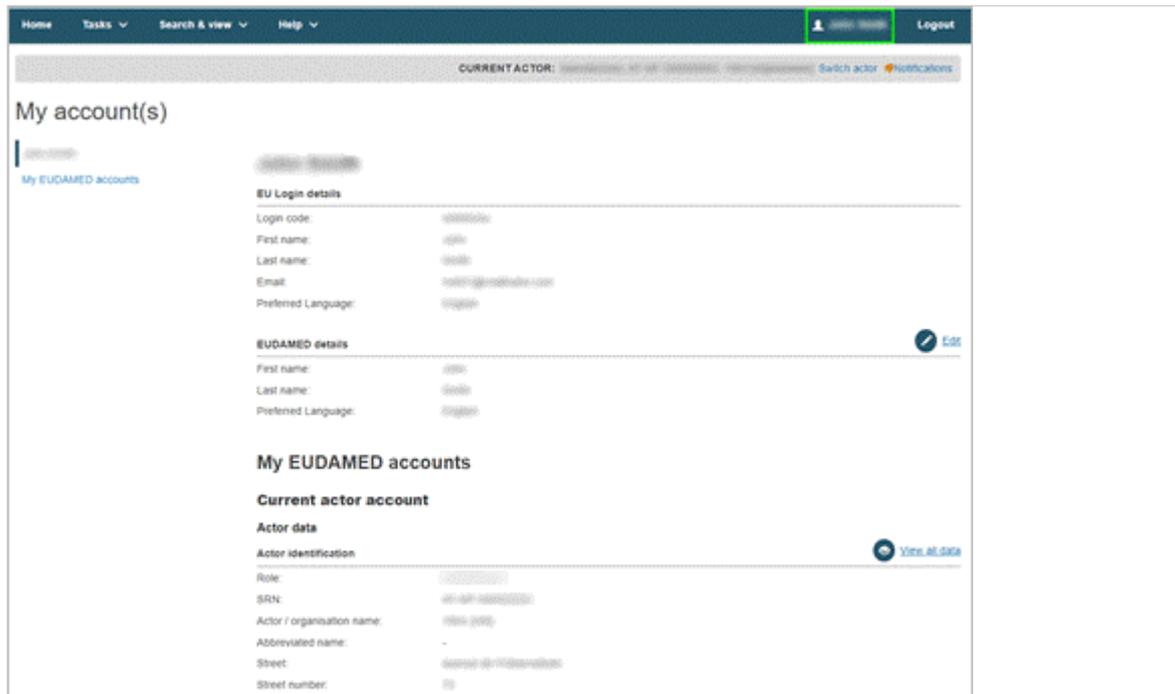


Figure 14 – User rights and obligations disclaimer



NOTE

To view the full details for the actor, click *View all data*.

