



EUDAMED access user guide

Notified Bodies

Production v 2.14
2024



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1 Overview

EUDAMED is the IT system implementing [Regulation 2017/745](#) on medical devices, and [Regulation 2017/746](#) on *in vitro* diagnosis devices.¹

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

2 Application basics

This section describes a number of basic principles that you will acquire as you become familiar with EUDAMED.

These include:

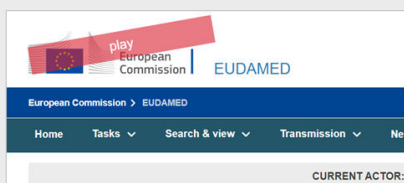
- Starting and ending a EUDAMED session
- Understanding the basic concepts
- Understanding user profiles and access grants/rights

3 Starting and ending a EUDAMED session



NOTE

EUDAMED is also available in a [Playground environment](#), intended to enable you to experiment with the application. All the information in this environment is dummy (including the Actor ID/SRN) and will never be moved to the production environment. Access to the Playground requires a separate registration. The website displays a red "Play" banner across the logo at the top left of the screen.



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



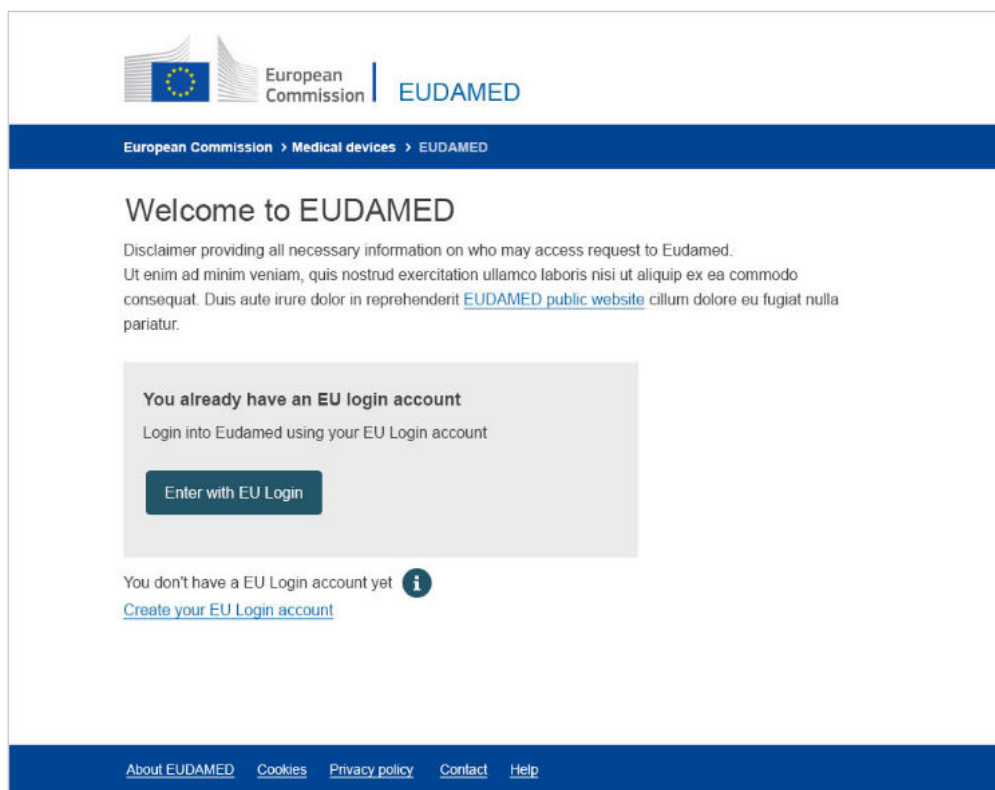
IMPORTANT

Private/shared mailboxes are not allowed for security reasons.

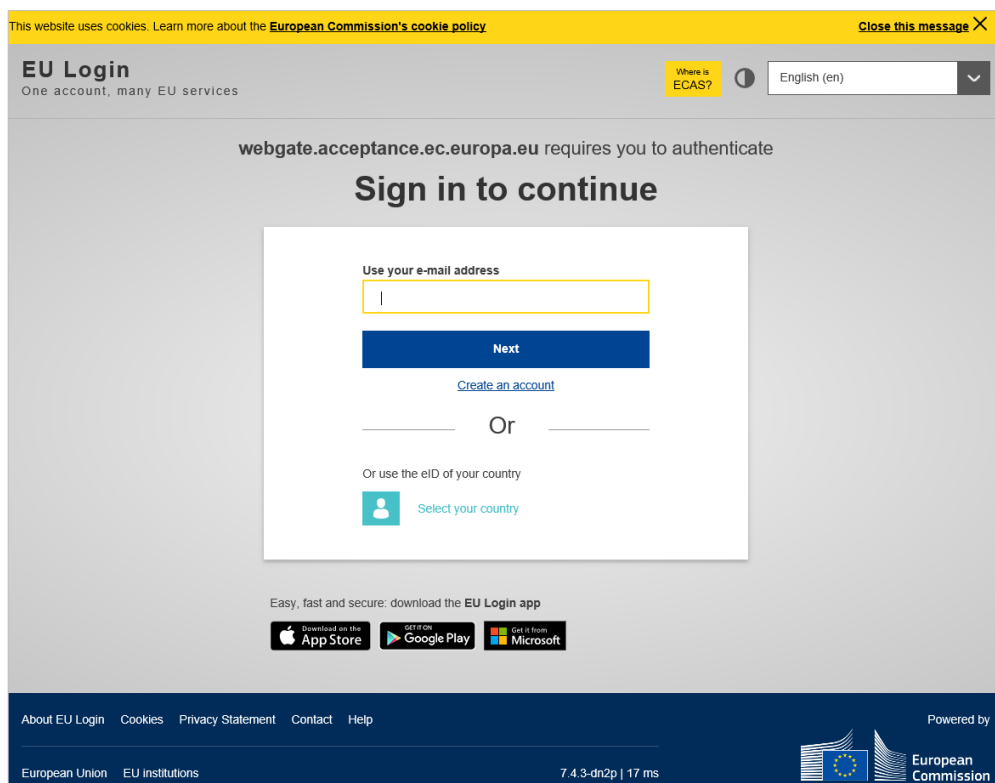
Read more: [Introduction to EU Login](#)

To start EUDAMED

1. Go to [EUDAMED](#).



2. Click **Enter with EU Login**.
Alternatively, select **Create your EU Login account** if you do not have one yet.
The *EU Login – Sign in* page prompts you to enter your email address:



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

This website uses cookies. Learn more about the [European Commission's cookie policy](#) Close this message X

EU Login
One account, many EU services

Where is ECAS? English (en)

eudamed requires you to authenticate


Sign in to continue

Welcome back
[j.smith@ec.europa.eu](#)
(External)
[Sign in with a different e-mail address?](#)

Password

[Lost your password?](#)

Choose your verification method
Password ▼




Sign in

Easy, fast and secure: download the EU Login app

[Download on the App Store](#) [GET IT ON Google Play](#) [Get it from Microsoft](#)

[About EU Login](#) [Cookies](#) [Privacy Statement](#) [Contact](#) [Help](#)

European Union EU institutions 5.9.1-gna | 12 ms

Powered by  European Commission



NOTE

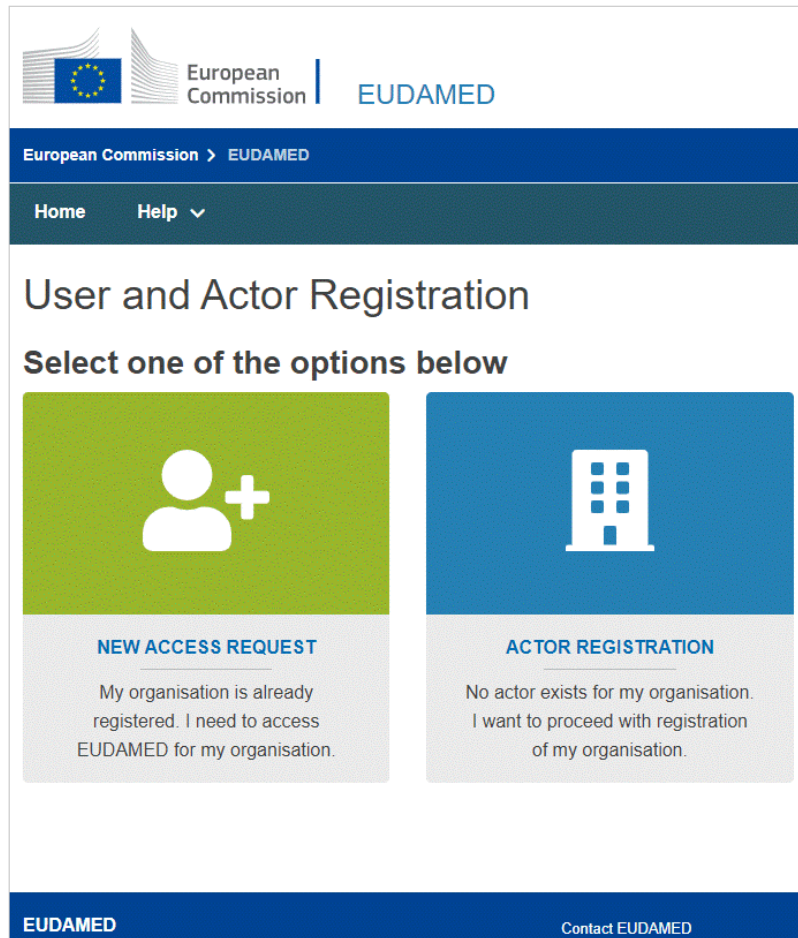
EU Login issues?

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

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

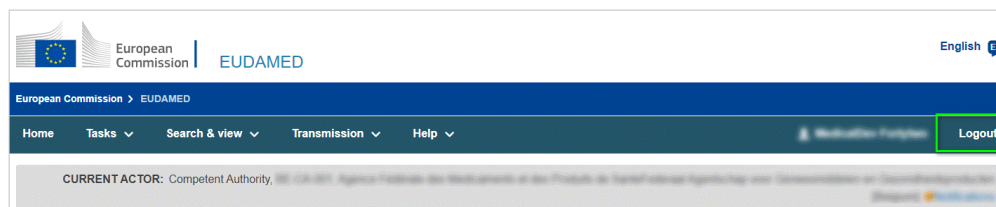
View/edit your account: Go to [My Account](#)

4. Enter your EU Login password and click **Sign in**.
EUDAMED opens the *User and Actor Registration* page:

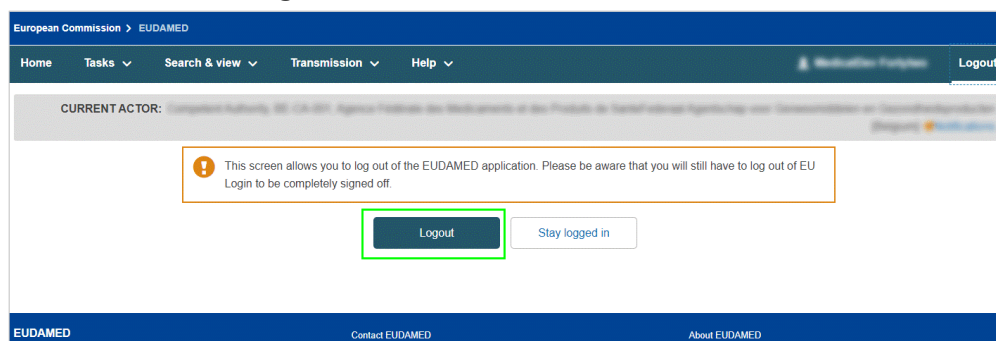


To quit EUDAMED

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



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



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

4 User rights & profiles

Notified Body users do **not** have a EUDAMED account with any other actor type; and can only enter data in the NBs & Certificates module.

Profiles are module-specific and 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.

User profiles available to a Notified Body

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

5 User access requests

Request access as a Notified Body user

The NB has to designate the person that will act as the first LAA and inform accordingly its Designating Authority.

The NB first LAA submits a user access request in EUDAMED selecting the NB he belongs to, and the concerned DA will receive a prompting notification to validate the NB first LAA.

Once the NB first LAA has been granted access to EUDAMED by its DA, all the other users of this NB can request access.



NOTE

To start entering certificates data the LAA profile is not enough, at least one user with confirmer profile is required.

1. Log in to EUDAMED as a new user. You will see the *User and Actor Registration* page. Click the **New access request** box:

European Commission | EUDAMED

European Commission > EUDAMED

Home Help ▾

User and Actor Registration

Select one of the options below

NEW ACCESS REQUEST

My organisation is already registered. I need to access EUDAMED for my organisation.

ACTOR REGISTRATION

No actor exists for my organisation. I want to proceed with registration of my organisation.

EUDAMED [Contact EUDAMED](#)

2. An actor search page prompts you to select the NB you belong to:

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

The Actor ID of a notified body is equal to its NANDO identifier. You can use it to find the Notified Body by selecting *I know the actor's Single Registration Number (SRN) or EUDAMED Actor ID*.

Click **Find**.

3. The matching NB is displayed in the *Result* section on the right-hand side:

The screenshot shows the 'New access request' form. On the left, under 'Search existing actor', there is a checkbox 'I know the actor's EUDAMED Actor ID/Single Registration Number (SRN)' which is checked. Below it, the 'Actor code' field contains '1639'. A 'Find' button is at the bottom of this section. On the right, the 'Result' section shows a dropdown menu with 'Notified Body, 1639, SGS Belgium NV [Belgium]' selected. Below this, the actor's details are listed: NB ID: 1639, Role: Notified Body, Country: Belgium, Actor / Organisation name: SGS Belgium NV, Address: Noorderlaan 87, BE-2030 Antwerpen, Belgium, Email: NB1639@sgs.com, and Telephone number: +32(0)3 545 48 60. A 'Request access to this actor' button is at the bottom of the details, and a 'Create my actor' link is below it.

4. Click **Request access to this actor**.

The screenshot shows the 'New access request' form with a progress bar at the top indicating three steps: 1. My personal data, 2. My user manager, and 3. My profile(s). The 'Selected actor information' section on the left displays the actor's details: SRN, Role, Country (Belgium), Organisation name, Address, Email, and Telephone number. A 'Select another actor' button is at the bottom of this section. The 'My contact email for this actor' section on the right has an 'Email' field and a question 'Are you a sub-contractor for this actor?' with 'No' and 'Yes' radio buttons. At the bottom, there are 'Save', 'Save & Next >', and 'Cancel' buttons.

5. Complete *Step 1* 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**.

6. *Step 2* appears. Here you must identify a direct superior who can support your request. Enter the name and function/position of your manager, and then click **Save & Next**:

New access request

Information of the actor selected

Actor code: [redacted]

Role: [redacted]

Country: Italy

Actor/Organisation name: [redacted]

Address: Via Balbo, 41, Cadriano-Gianico, Ferrara

Email: [redacted]

Phone: [redacted]

User manager

* First Name: [text box]

* Last Name: [text box]

* Function/Position: [text box]

Buttons: Save, Save & Next, Cancel

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

New access request

Selected actor information

NB ID: [redacted]

Role: Notified Body

Country: Belgium

Actor / Organisation name: [redacted]

Address: [redacted]

Email: [redacted]

Telephone number: [redacted]

My profile(s) for this actor

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

Choose the profile(s) you need

Actor

☐ Local Actor Administrator

☐ Local User Administrator

☒ Viewer

UDI/Device

☐ Confirmer

☒ Viewer

Certificate

☐ Confirmer

☐ Proposer

☒ Viewer

Active until

End date: [text box]


Buttons: Save, Submit, Preview, Cancel

8. Select the user profile(s) you need.
9. If you want to **save the request as a draft** before submitting it, click **Save**.
10. If you want to see a **preliminary summary** of your request before submitting it, click **Preview** at the bottom of the page. A summary of your access request is displayed.
11. Review the information and click **Submit** at the bottom of the preview page. The 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

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

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:

My access requests for an existing actor

Role	Name	City	Date of the request	State	Actions
Authorised Representative	Magnamedica	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:


Home

Tasks

Search & view

Help

User rights and obligations disclaimer



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

☒ I accept the user rights and obligations

Next

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

[Home](#) [Tasks](#) [Search & view](#) [Help](#) [User profile](#) [Logout](#)

CURRENT ACTOR: [Name: actor1, ID: 123456789, Email: actor1@eudamed.eu](#) [Switch actor](#) [Notifications](#)

My account(s)

[View all accounts](#)

My EUDAMED accounts

EU Login details	
Login code:	123456789
First name:	actor1
Last name:	actor1
Email:	actor1@eudamed.eu
Preferred Language:	English

EUDAMED details		Edit
First name:	actor1	
Last name:	actor1	
Preferred Language:	English	

My EUDAMED accounts

Current actor account

Actor data

Actor identification		View all data
Role:	ACTOR	
SRN:	123456789	
Actor / organisation name:	Name (org)	
Abbreviated name:	-	
Street:	Address 123456789	
Street number:	123	

