EUDAMED user guide

Actor validation for CAs

Production v 2.14.1
2024

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1 Introduction

EUDAMED is the IT system implementing Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnosis medical devices.

This guide describes the validation process for competent authorities.[1]

EVOLVING USER INTERFACE

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

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

2 Starting and ending a EUDAMED session

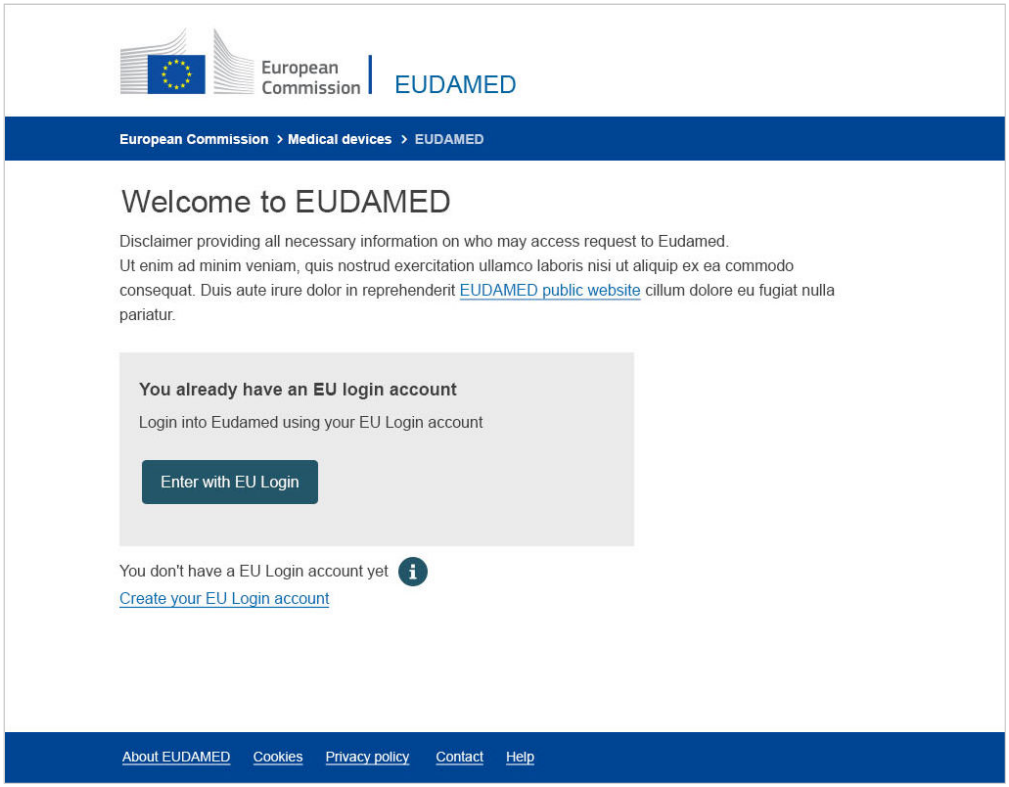
To use EUDAMED, you must have an EU Login account associated with your professional email address.

IMPORTANT
EU Login is the central European Commission Authentication Service allowing users to access a wide range of Commission information systems and services, using a single username and password.

Read more: Introduction to EU Login

To start EUDAMED

1. Go to EUDAMED

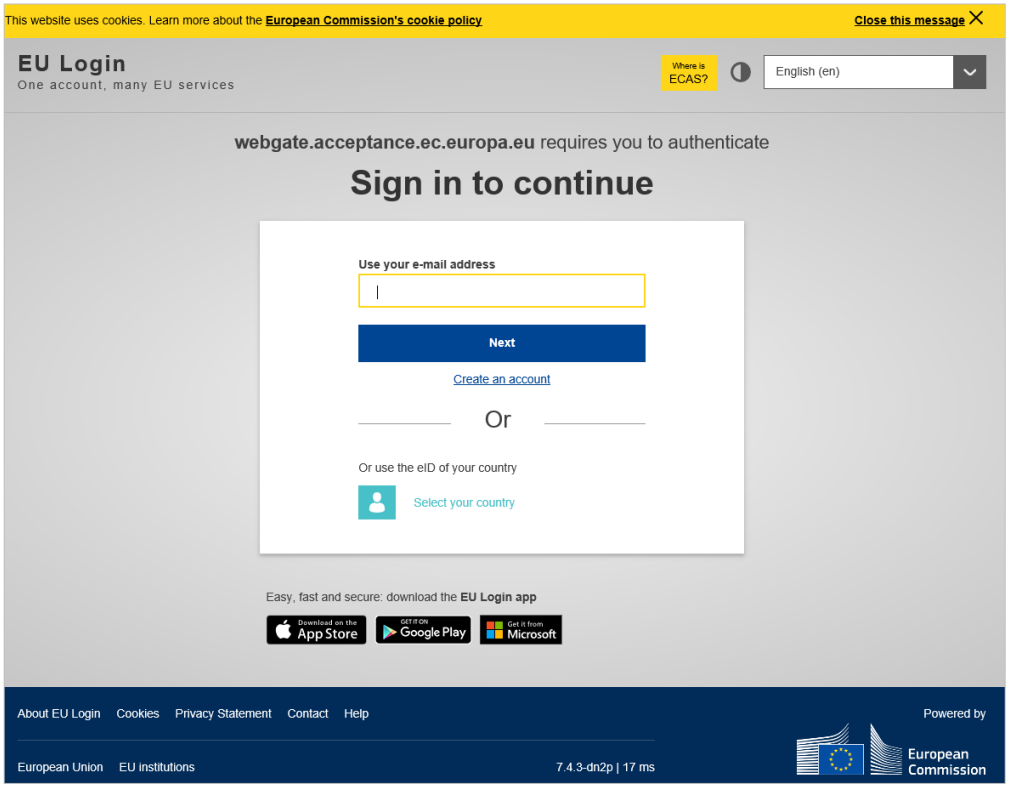


IMPORTANT
Production or Playground?

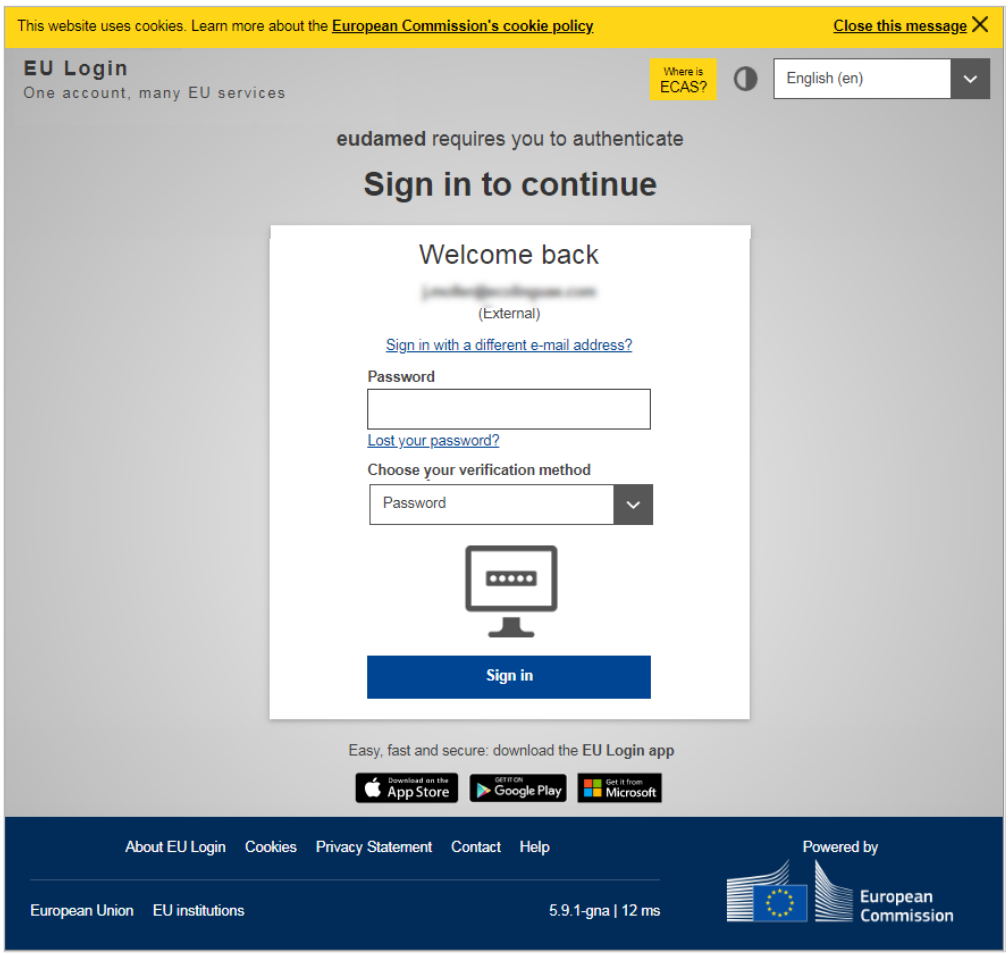
Please ensure that you are in the correct EUDAMED environment!

The *Playground* environment contains a red *Play* banner across the logo at the top left of the screen. Any submissions to the playground are for testing only and are considered dummy data. The *Production* environment needs a separate registration.

2. Click **Enter with EU Login**:
Alternatively, select **Create your EU Login account** if you do not have an EU Login account yet.

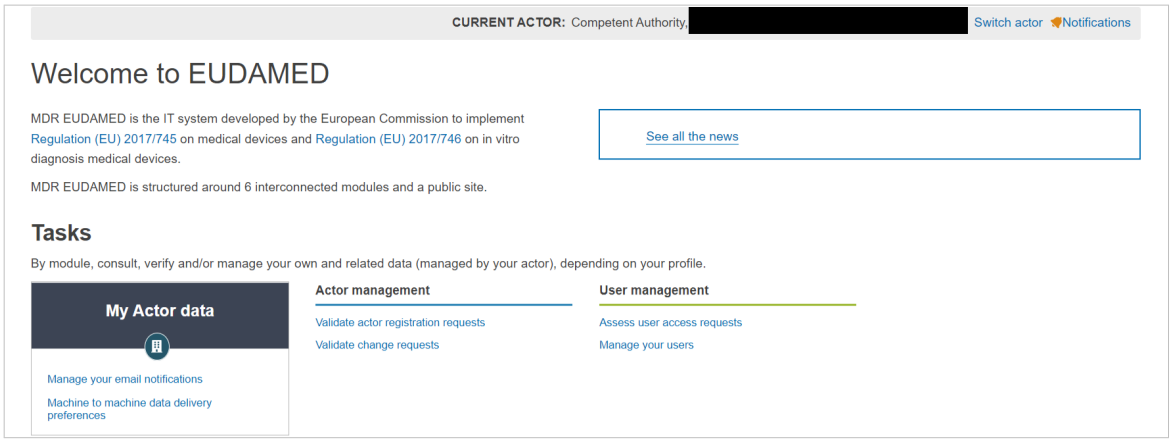


3. Type your EU Login email address and click **Next**, enter your password next:



4. Enter your EU Login password and click **Sign in**, the EUDAMED homepage will open:

> **NOTE**
> The dashboard content depends on the type of user profile you have – i.e the dashboard displayed below is the one of an LAA including the validator profile.

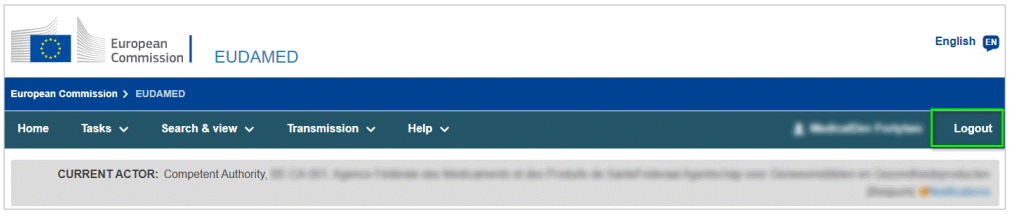


NOTE
Don’t see your homepage?

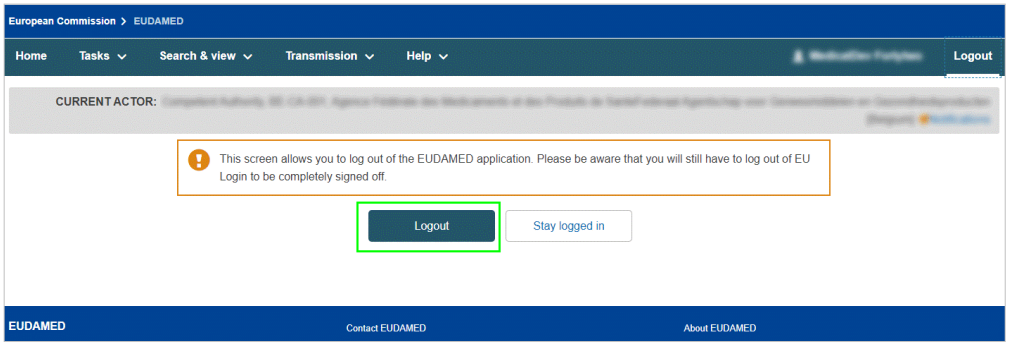
If your *Local Actor Administrator* has not yet granted you access to EUDAMED, see Section *User access management [6]*.

To quit EUDAMED:

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



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



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

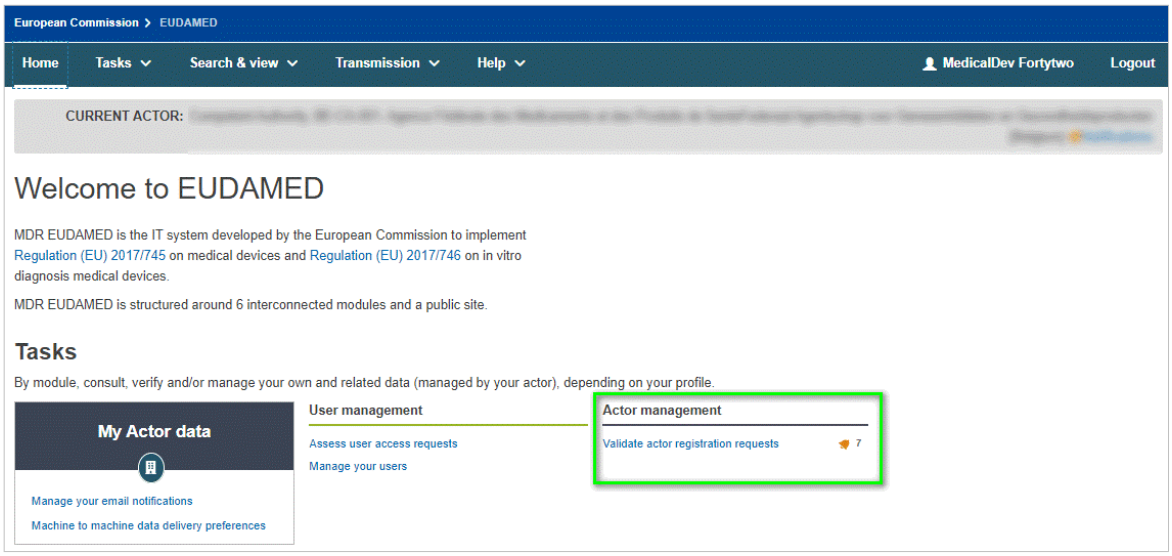
3 Validating actor registration access requests

Actor registration requests are displayed in the *Tasks* menu for validation.

To validate an actor registration request

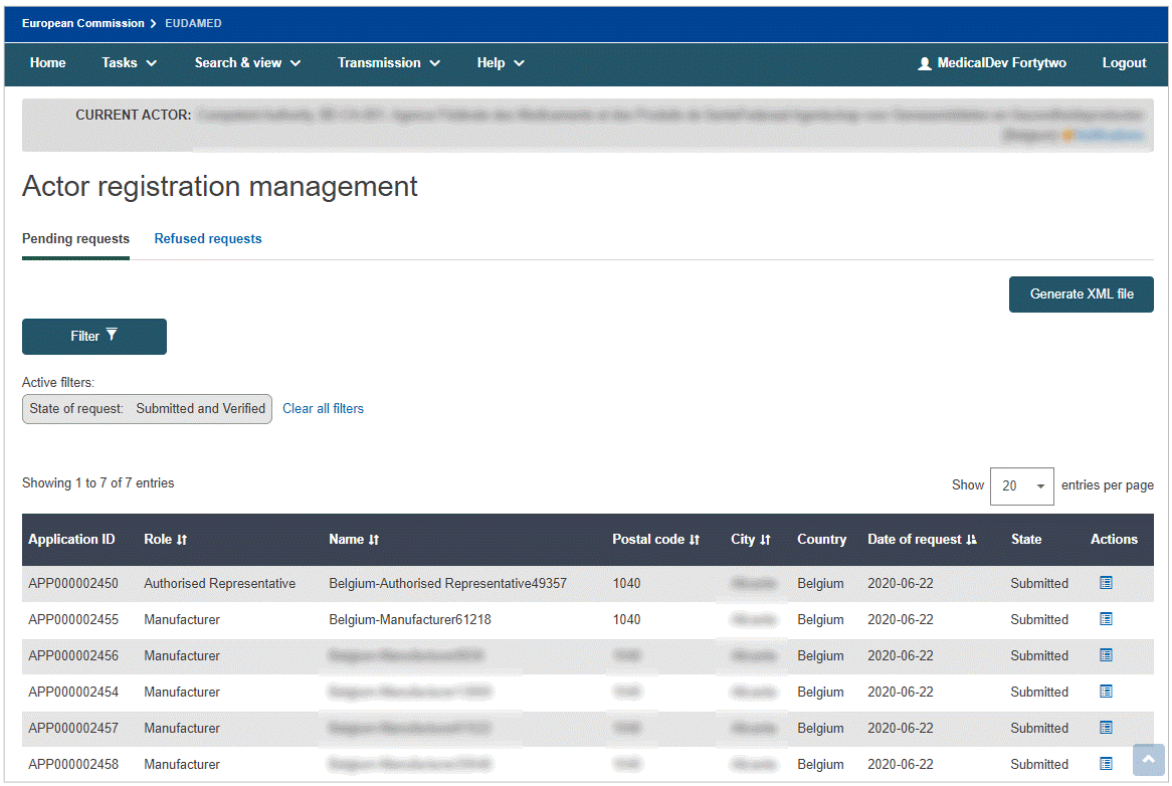
CA users with LAA, LUA or Validator profile can assess the actor registration requests

1. In the *Tasks* section of your dashboard, click **Validate actor registration requests**:



> **NOTE**
> The bell icon indicates that there are registration requests for your competent authority to validate, and how many.

An overview of all actor registration requests pending validation is displayed:



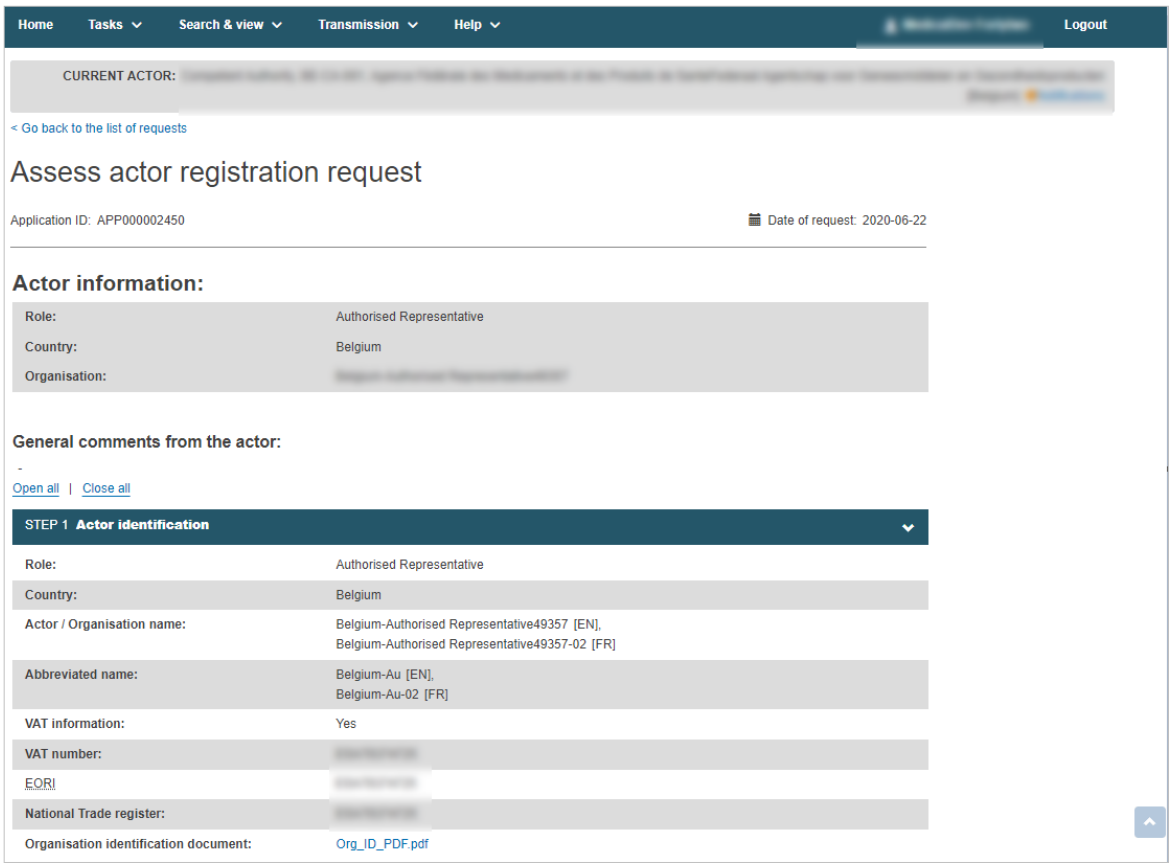
NOTE
Submitted* vs. *verified

Registration requests in your *pending requests* list may have *submitted* or *verified* states.

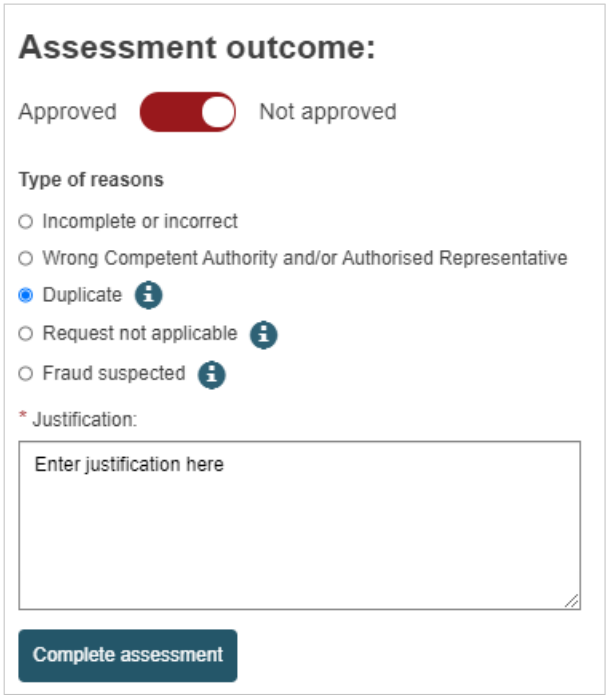
Verified requests pertain only to non-EU manufacturers (they are first verified by the Authorised Representative specified in the actor registration request before they become available for validation by the competent authority).

Submitted requests are from all other economic operators.

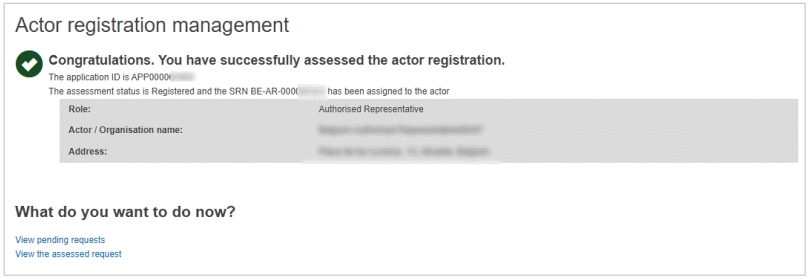
2. From the *Actions* column in your *pending requests* list, click **Assess** next to the actor you wish to validate.
   An overview of the information entered by the actor is displayed:



3. Check the information and scroll down to the *Assessment* section. Here you can switch the toggle to either *Approved* or *Not approved*, enter any assessment comments in the *Notes* text box and then click **Complete assessment**.



4. Confirm your decision whether or not to approve the request.
You will be informed that the actor registration request has been successfully assessed:



If you approved the request, its state is now *Registered* and EUDAMED generates an *Actor ID Single Registration Number (SRN)* for this actor.

The user who submitted the request is informed by email notification.

In the event of non-approval:

If you decide not to approve the request, you must select the reason why and provide a justification:

- *Incomplete or incorrect*, *wrong competent authority and/or authorised representative* and *duplicate*: will remove the request from the *pending requests* list and return it to the requester with a state of *Correction requested*. The user who submitted the request will be informed by email notification. The Actor user who submitted the request should then follow the instructions/comments that you entered in the justification box, update and re-submit the request.

- *Request not applicable*: will move the request from the *pending requests* to the *refused requests* tab with *Refused* state. The user who submitted the request will be informed by email notification. The user who submitted the request can view your justification, but the request cannot be re-submitted.

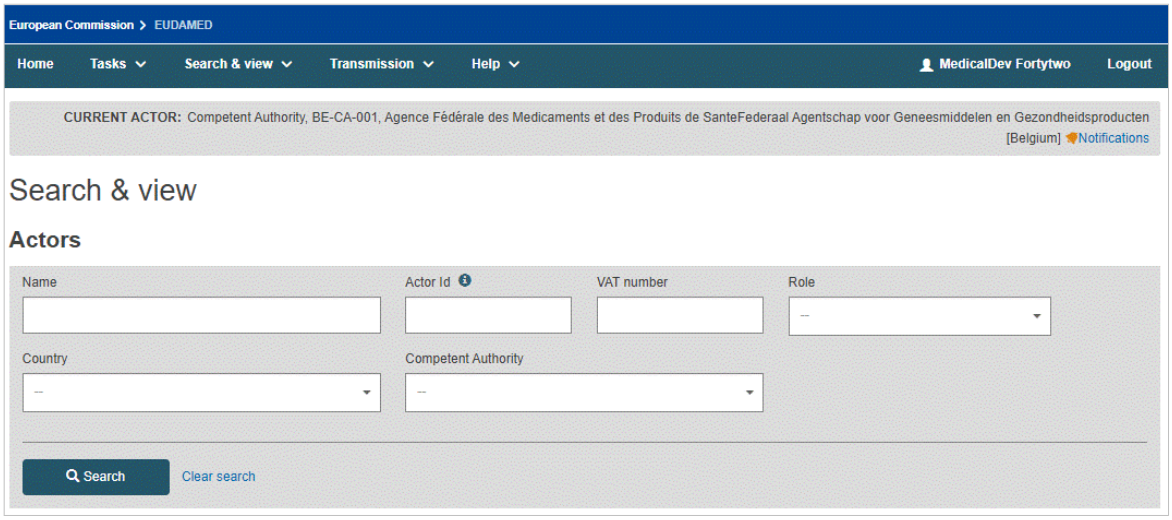
- *Fraud suspected*: will move the request from the *pending requests* to the *refused requests* tab with *Fraud suspected* as the reason for refusal. The user who submitted the request will be informed by email notification. The user who made the request cannot view the justification that you provided and the request cannot be re-submitted.

NOTE
In case of *Fraud suspected*, please contact the EUDAMED application support team at sante-eudamed-support@ec.europa.eu

3.1 Consulting registered actors

To search and consult actors

1. Click on the *Actors* block in the dashboard or select **Search & view > Actors**.
   The *Actor Search & view* page appears:



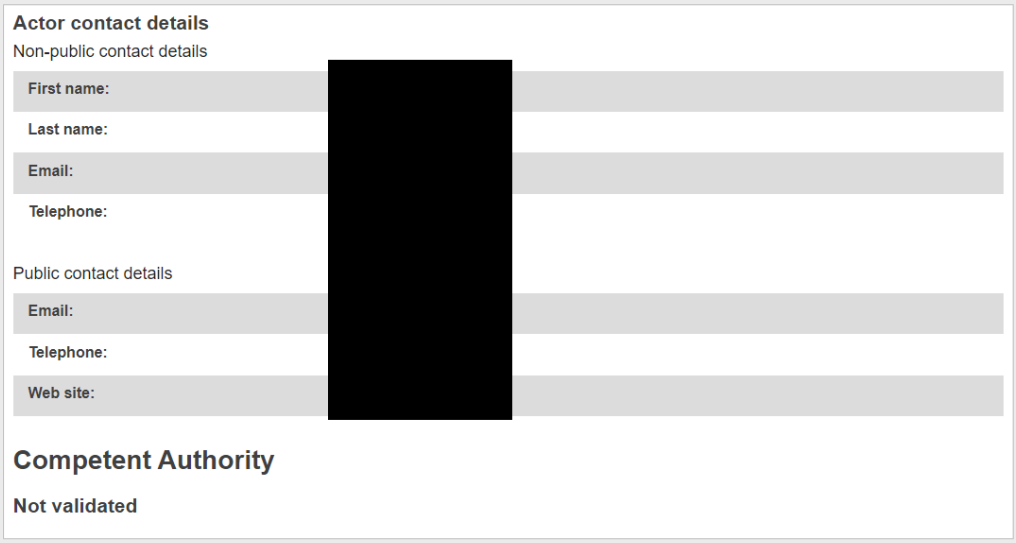
2. Enter your search criteria on the *Search & view* page, and then click **Search**. The actors matching your search criteria will be listed in the search section:

3. You can click on an actor in the list to view its details.

NOTE

When looking at a *Sponsor*'s details page, the *Competent Authority* section might be empty or populated depending on whether the *Sponsor* already has a submitted AND accepted CI/PS application.

Sponsor details without a *Competent Authority*:



Sponsor details with a *Competent Authority*:

4. You can also read the Declaration on information security responsibilities by clicking on the name of the document:

5. To download your search result in bulk (XML) format follow these steps:
   a. Activate the toggle *Only enable search filters available for bulk XML download of economic operators*

   b. Complete the search

   c. Click the button **Generate XML** and confirm

   d. Download the XML file of the results list from the *Downloads management* page.

NOTE
There are limitations on what search criteria you may use for bulk download, so certain filters will be disabled when this toggle is active.

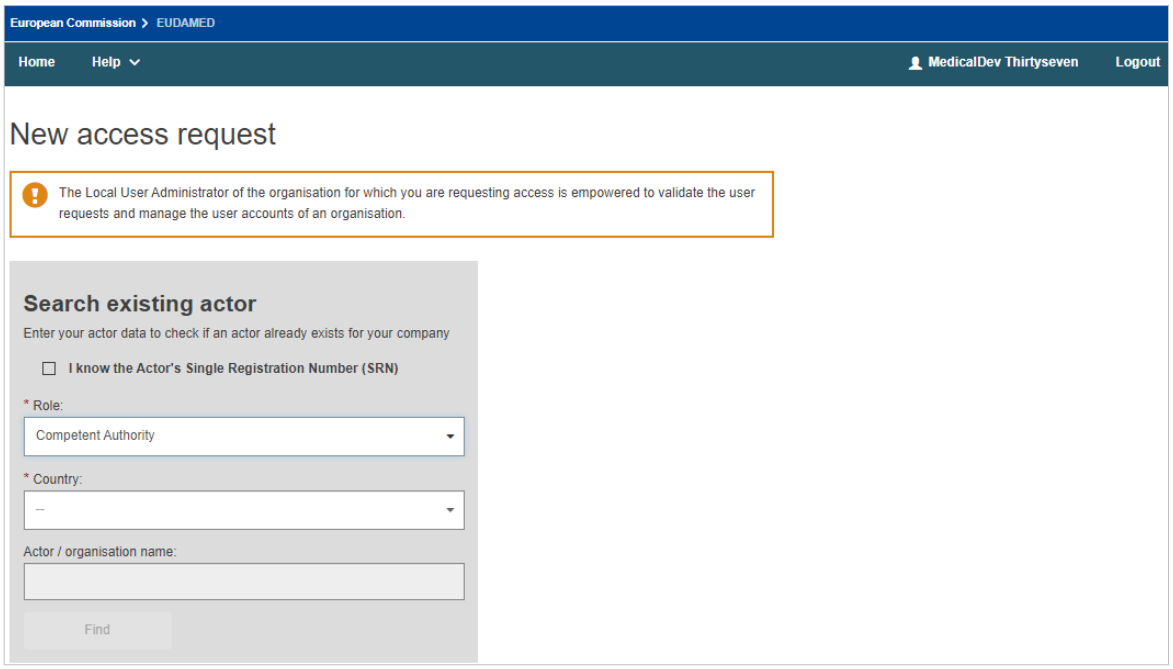
For more information on search criteria, see the DTX service definition.

4 Requesting access as a competent authority user

To request access as a competent authority user

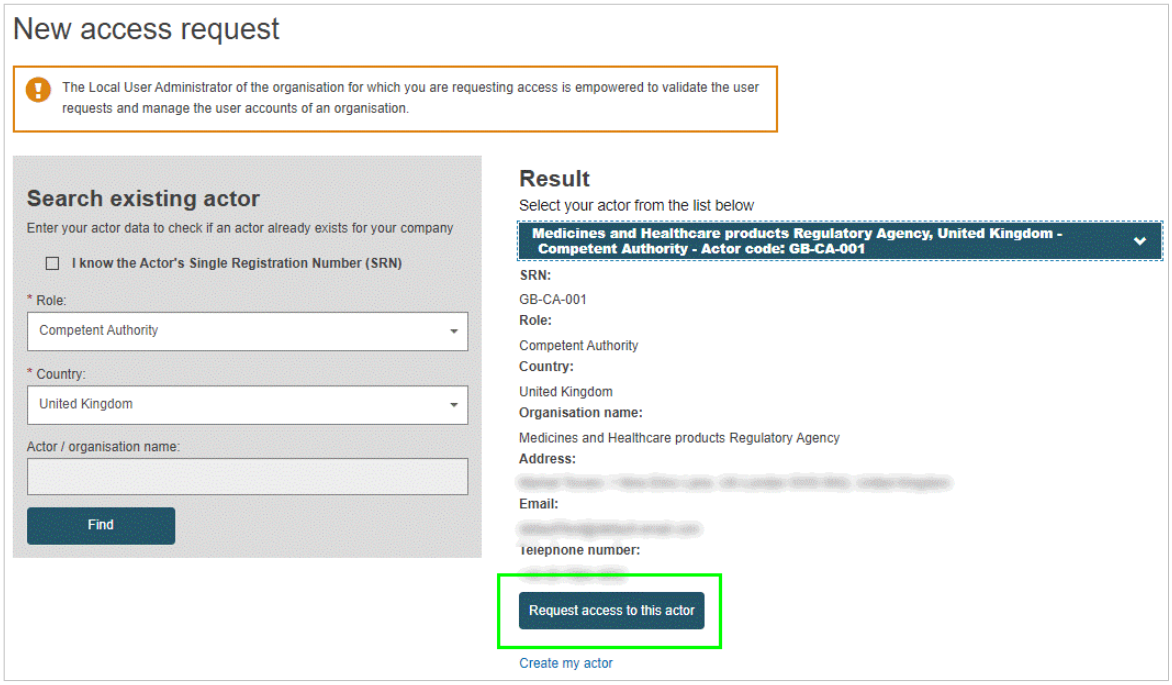
See *Section 6 Overview of Profile hierarchy [19]* for a description of the user profiles in the actor registration module.

1. Log into EUDAMED and select **New access request**. This will bring you to a page prompting you to select the Actor (Competent Authority) you belong to:



2. If you know your CA EUDAMED Actor ID, you can select *I know the Actor ID/Single Registration Number (SRN)* checkbox and enter it. Otherwise you can find it on the basis of its role (CA), country and name.

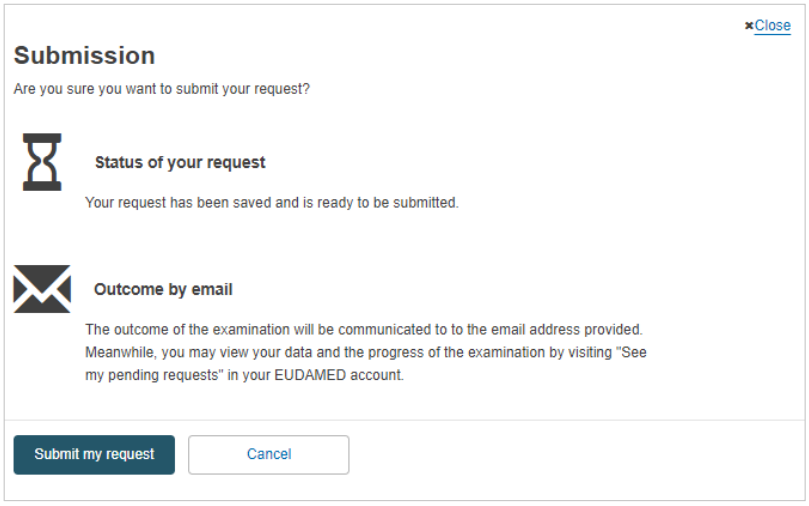
3. Click on the relevant competent authority in the result panel and then click **Request access to this actor**:



4. You will be prompted to enter the relevant details. Click **Save & Next** to move through the steps.

5. Select the user profile(s) that you need, click **Save**, **Preview**. If you are happy with the information, click **Submit**.

6. A confirmation message will appear. Click **Submit my request**.

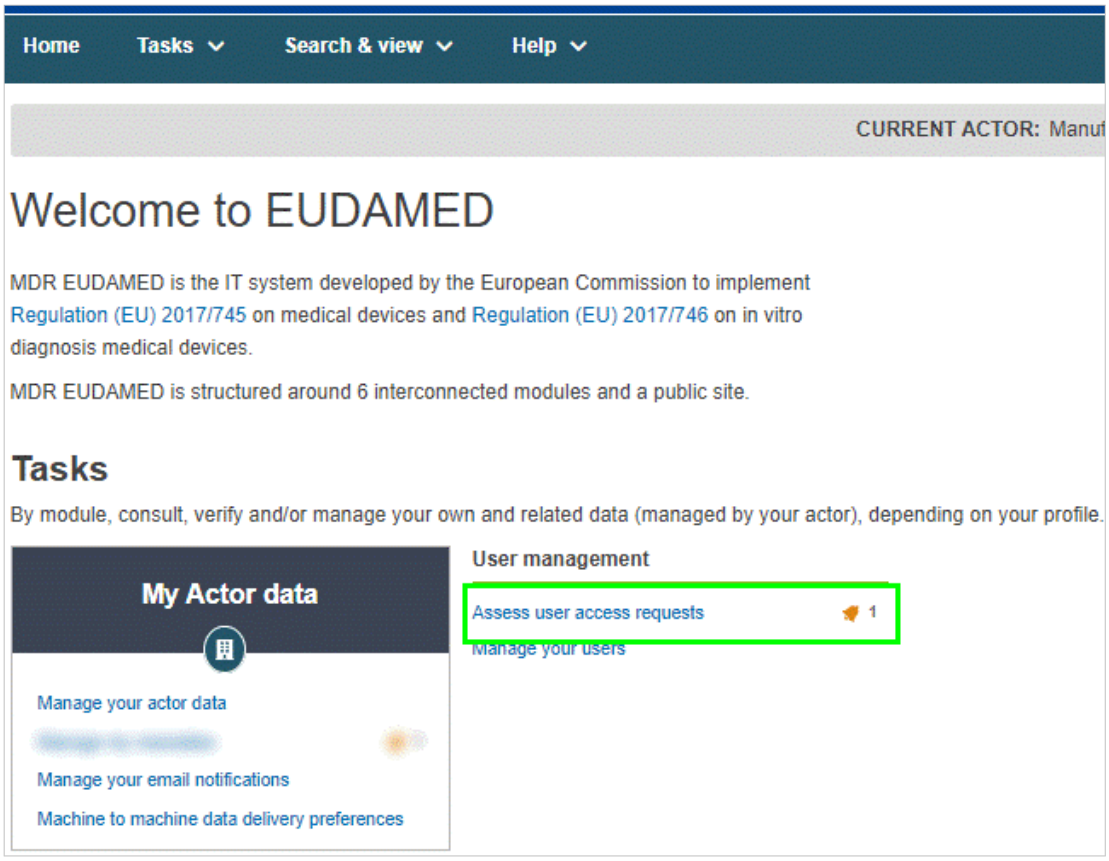


5 Validating user access requests as a CA

To validate user access requests

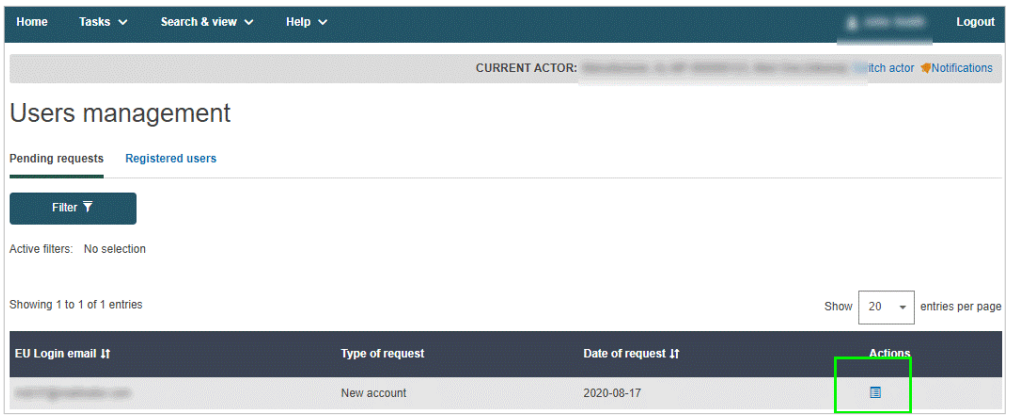
Users with LAA/LUA profile can assess user access requests

1. Select **Assess user access requests** from the *User management* section of the dashboard:

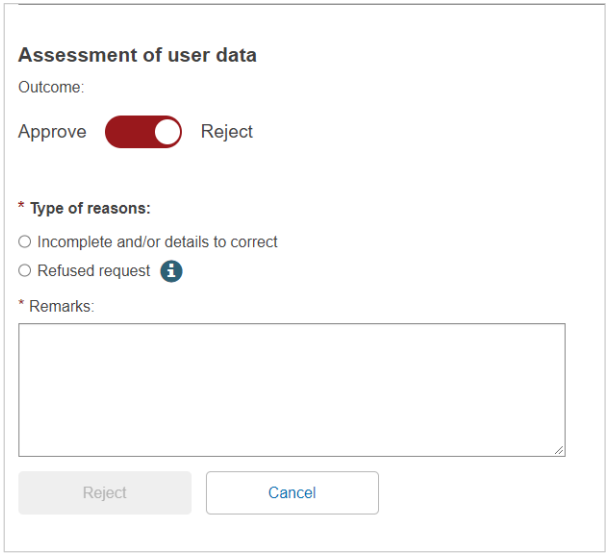


> **NOTE**
> See above for bell icon description.

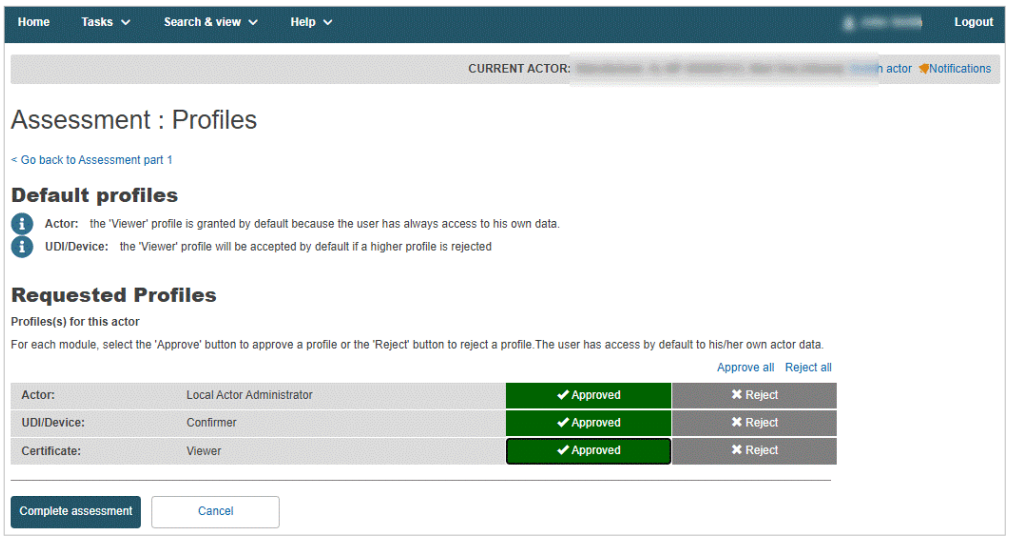
2. Click **Assess access request** to assess the pending request in the list:



3. Check the content of the request and move the toggle to *Approve* or *Reject* the request. If you select *Reject*, you must enter a comment and select one of the following reasons:
   - *Incomplete and/or details to correct:* The requesting user will have a chance to correct or complete the request following your instructions and to re-submit it.
   - *Refused request:* The request will be refused and cannot be re-submitted:



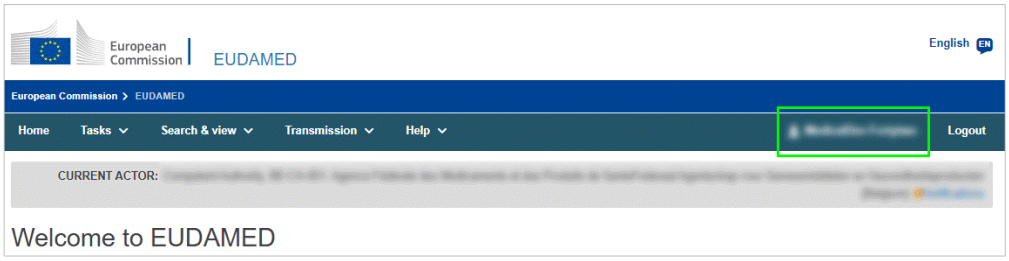
4. If you are approving the request, click **Next step** to assess each profile that the user is requesting. For each module in the grid, select either *Accept* or *Reject*, and then click **Complete assessment**:



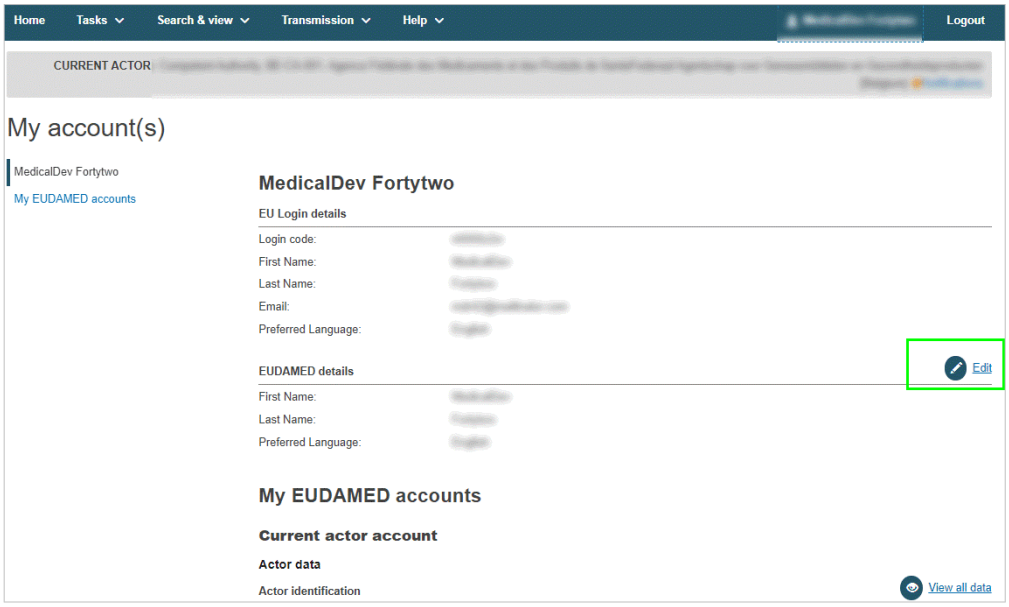
5. Click **Confirm** in the summary dialogue box to confirm the user's profile.

To edit your details as a competent authority user

1. Click on your name in the upper toolbar:



2. Click **Edit** next to the relevant section of your access profile:



3. Make the required changes and click **Save**.

A Competent Authority can request an XML file of his pending *Actor registration requests* via the *Actor registration management* page.

INFOGRAPHIC: Bulk upload-download process

Actor registration requests are displayed in the *Tasks* menu for validation.

6 Overview of profile hierarchy

Profiles, grants and rights in the EUDAMED Actor module

User profile	Grants/rights
Local Actor Administrator (LAA)	As for LUA + may manage actor notification email addresses
Local User Administrator (LUA)	As for validator + may manage user access requests and users (only to terminate access)
Validator	As for viewer + may validate actor registration requests for the competent authority
Viewer	May view in *Actor* module registered actors and own actor details only

Higher-level profiles have all lower-level grants/rights. For example, the LAA profile has the grants/rights of all lower profiles.

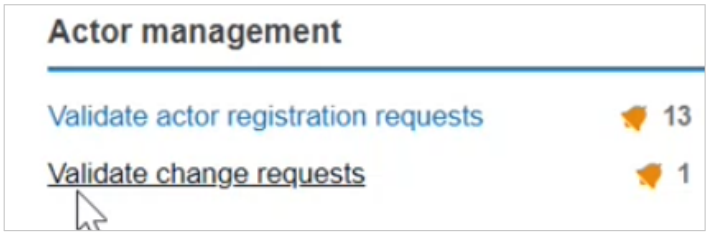
7 Validating change of Competent Authority requests

The change of responsible Competent Authority (CA) can be necessary in some specific cases as:

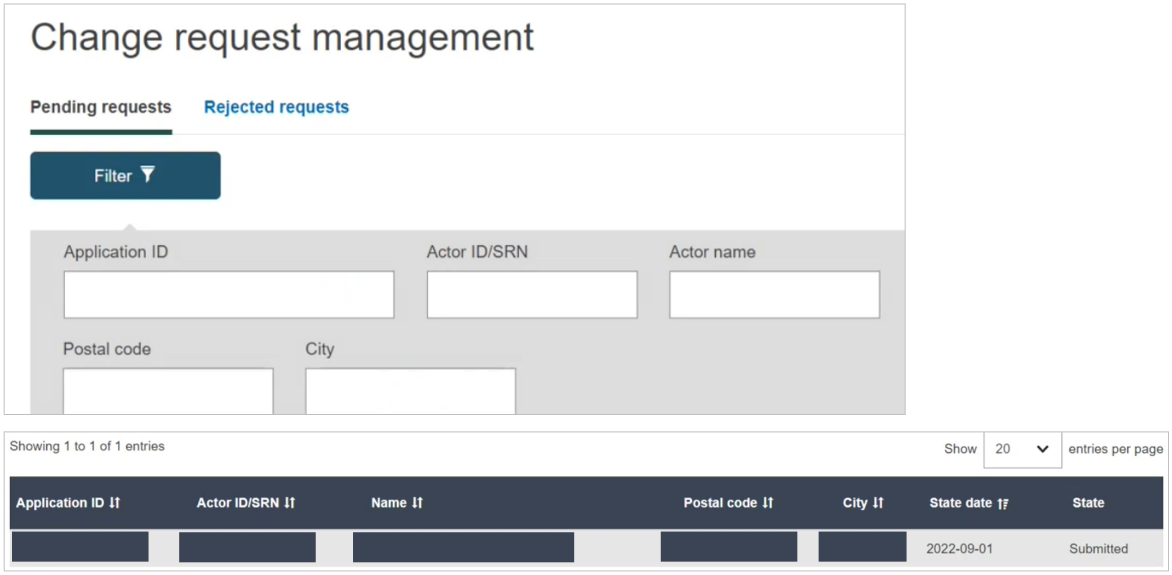
- An EU economic operator that moves inside the same country;
- A non-EU manufacturer that changes of Authorised Representative or changes of responsible Competent Authority for their Authorised Representative;
- A non-EU SPP producer that change the market distribution of their SPPs;

The new CA will be able to assess the request and accept or not to be the new CA.

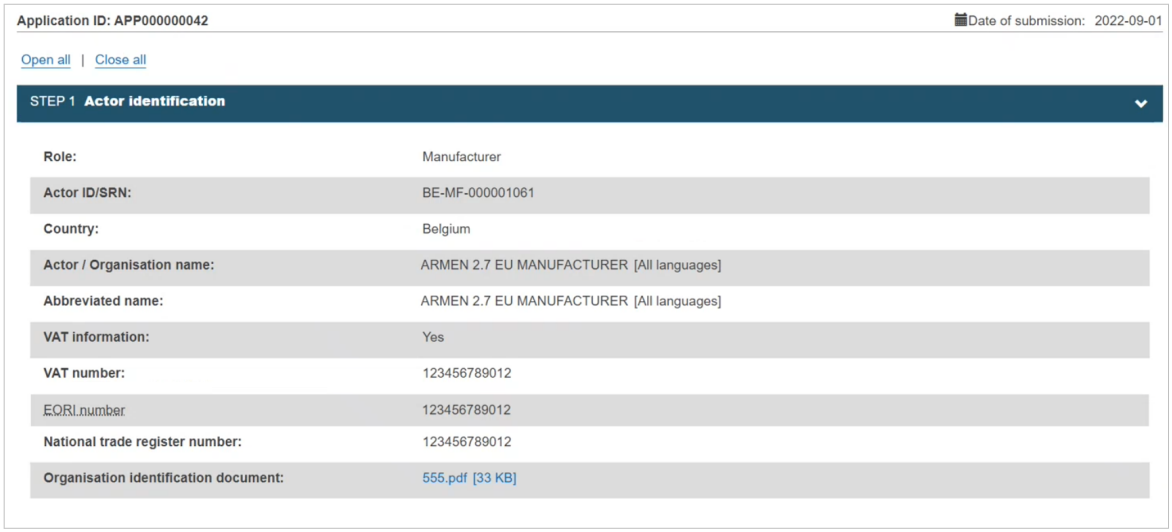
1. Select *Validate change requests* from the *Actor Management* section:



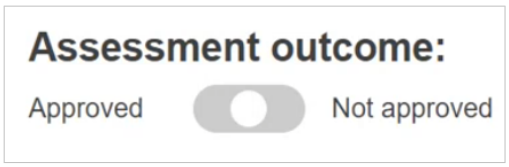
2. You will find the pending requests at the bottom of the page:



3. Click on it to open the change request, the new window will display all the details concerning the change request:



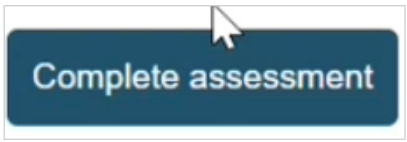
4. At the bottom of the page, you will have the *Assessment outcome* section, here you will decide whether you approve the change of competent authority request or whether you reject it:



5. If you click on **Approve**, the button will turn green:

6. If you click on **Not Approved**, the button will turn red and a mandatory free-text box will appear asking you to justify your decision for not approving the request:

7. To finish, you can click on **Complete assessment**:



8. A success message will appear:

9. If the request was accepted, the new CA will get a notification of the changes made, as well as the concerned Economic Operator and the old CA.

10. If the request was not approved, the concerned Economic Operator will get a notification with the reason for rejection.

8 Support

EUDAMED Information Centre

SANTE-EUDAMED-SUPPORT@ec.europa.eu

European
Commission