



EUDAMED user guide

Designating Authorities

Production v 2.14
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.¹

This guide describes:

- Validation process of the first NB LAA account
- Managing access requests of internal users
- Managing requests for suspension/withdrawal of certificates
- View nominated experts list
- Search & view for withdrawn/refused applications.



NOTE

EUDAMED is 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.



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

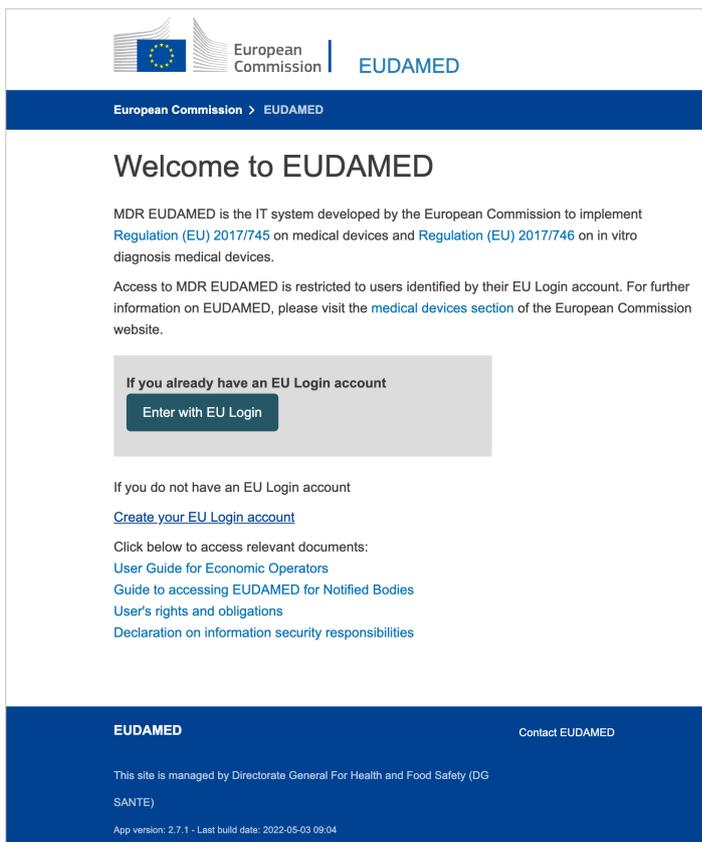
2 Getting started

Prerequisites to access EUDAMED:

To use EUDAMED, you must have an EU Login account associated with your professional email address.²

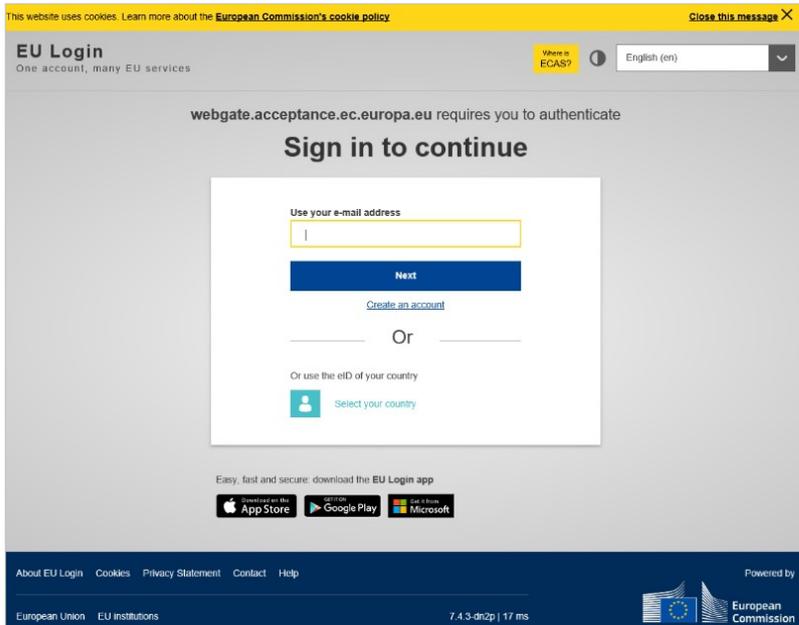
[EU Login \(ECAS\) account](#)

[EUDAMED Production landing page](#)

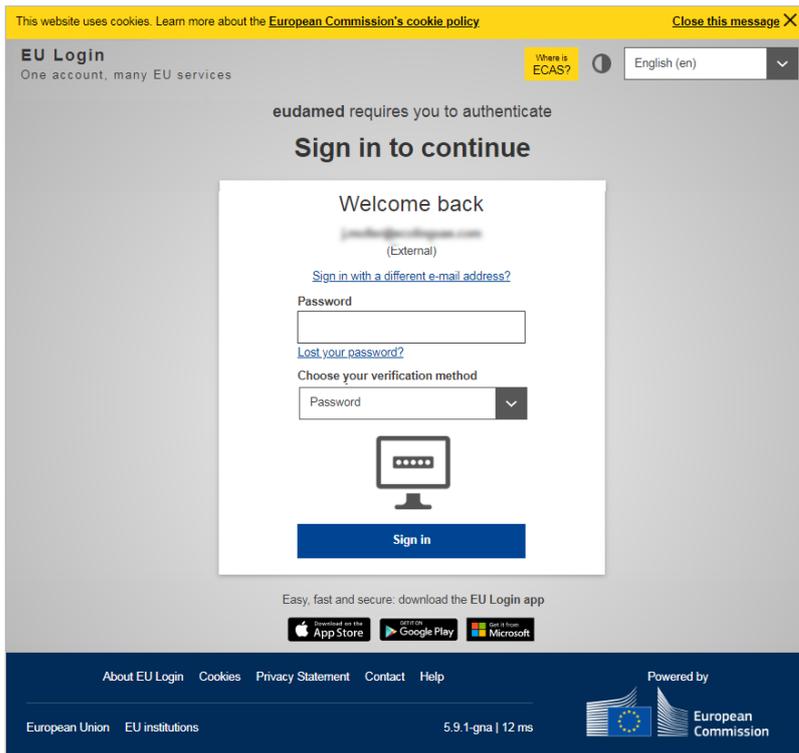


1. Click **Enter with EU Login** and enter your EU Login email address. (Alternatively, select **Create your EU Login account** if you do not yet have an EU Login account):

²EU 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 at: [EU Login \(ECAS\) account](#).

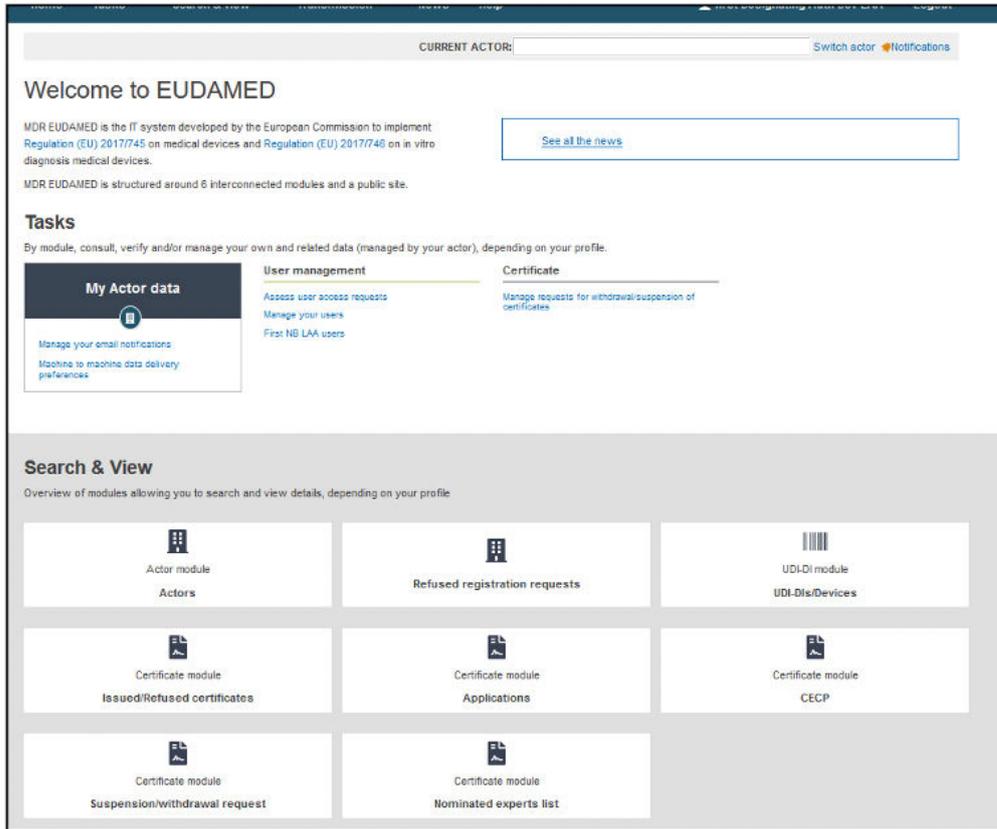


2. Once you have entered your EU Login email address, click **Next**. You are prompted to enter your EU Login password:



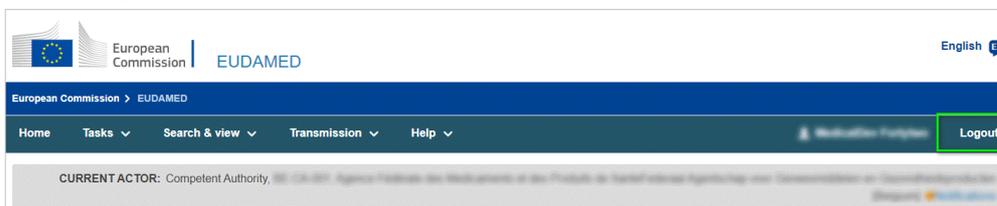
3. Enter your EU Login password and click **Sign in**. The EUDAMED homepage opens (i.e. your personal dashboard).

EUDAMED user guide

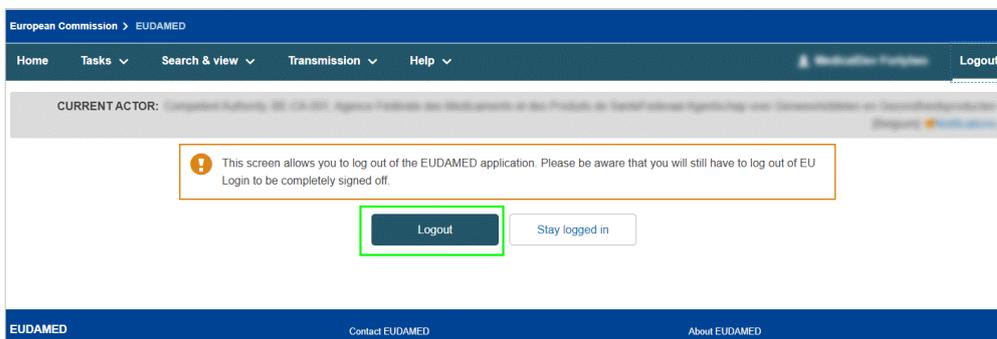


To quit EUDAMED:

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



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

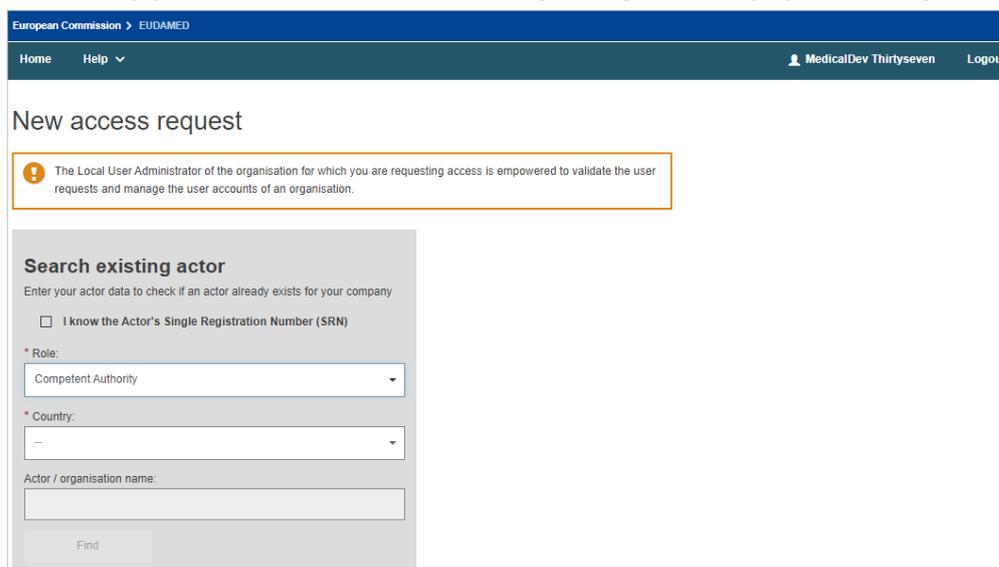


3. Answer the EU Login confirmation message by clicking **Logout**.

3 Requesting access as a designating authority user

To request access as a designating authority user

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



If you know your Designating Authority (DA) EUDAMED Actor ID, you can select *I know the Actor ID/Single Registration Number (SRN)* checkbox and enter it. Alternatively, you can search by selecting its *role* (Designating Authority), *country*, and clicking **Find**.

Click on the relevant authority in the *Result* panel and then click **Request access to this actor**.

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)

* Role:

* Country:

Actor / organisation name:

Find

Result

Select your actor from the list below

Medicines and Healthcare products Regulatory Agency, United Kingdom - Competent Authority - Actor code: GB-CA-001

SRN:
GB-CA-001

Role:
Competent Authority

Country:
United Kingdom

Organisation name:
Medicines and Healthcare products Regulatory Agency

Address:
[Redacted]

Email:
[Redacted]

Telephone number:
[Redacted]

Request access to this actor

Create my actor

2. You are asked to enter relevant details. Click **Save & Next** to move through the steps.
3. Select the user profile(s) that you need.
4. Click **Save, Preview** and when you are certain of the information, click **Submit**.
5. A confirmation message will appear – click **Submit my request**.

Submission ✕Close

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 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.

Submit my request

Cancel



IMPORTANT User Profiles

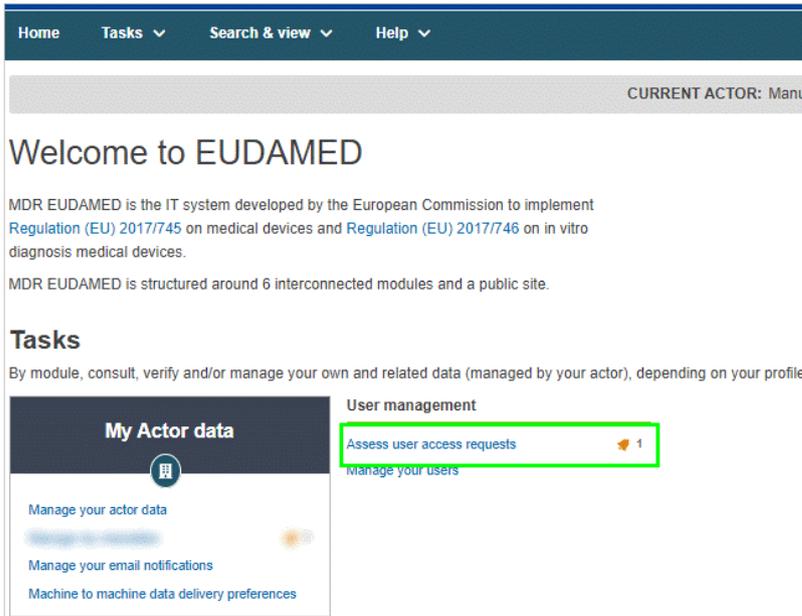
The Local Actor Administrator (LAA) can manage the actor notification email addresses and has all the rights of a Local User Administrator (LUA).

A DA LAA/LUA can validate user access requests for first NB LAAs and its Designating Authority users.

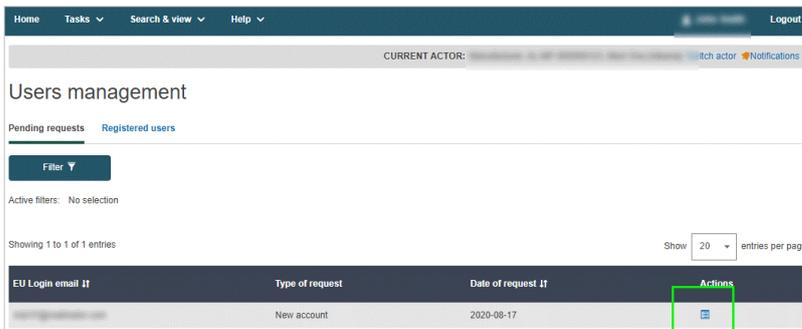
Validators can validate user access requests for first NB LAAs only.

How to validate user access requests as a designating authority Local Actor or User Administrator

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



2. Click on the menu icon to assess the pending request in the list.

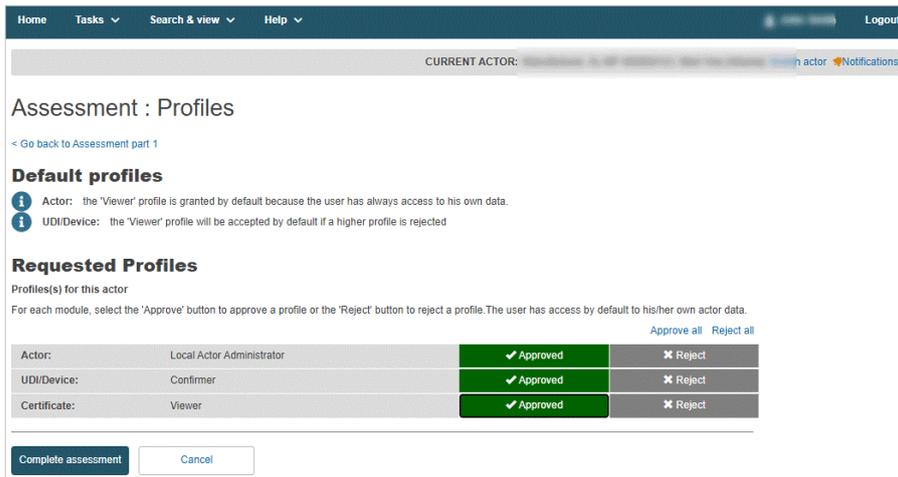


3. Review the content of the request and move the toggle to **Approve** or **Reject** the request. If you select *Reject*, you must enter a comment and select one of the following reasons:

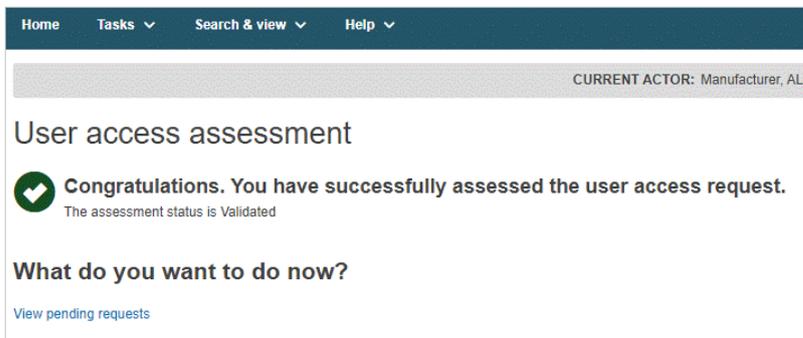
Incomplete and/or details to correct	Some information that you deem important is either missing or looks incorrect. The requesting user will have a chance to correct or complete the request following your instructions and to re-submit it.
Refused request	The request will be given the reason <i>Refused</i> , and the user will need to re-submit it.

The screenshot shows the 'Assessment of user data' form. It includes an 'Outcome' section with a toggle switch for 'Approve' (which is currently selected) and 'Reject'. Below this, there is a section for '* Type of reasons:' with radio buttons for 'Incomplete and/or details to correct', 'Refused request' (which is selected), and an information icon. There is also a text area for '* Remarks:' and two buttons at the bottom: 'Reject' and 'Cancel'.

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**.

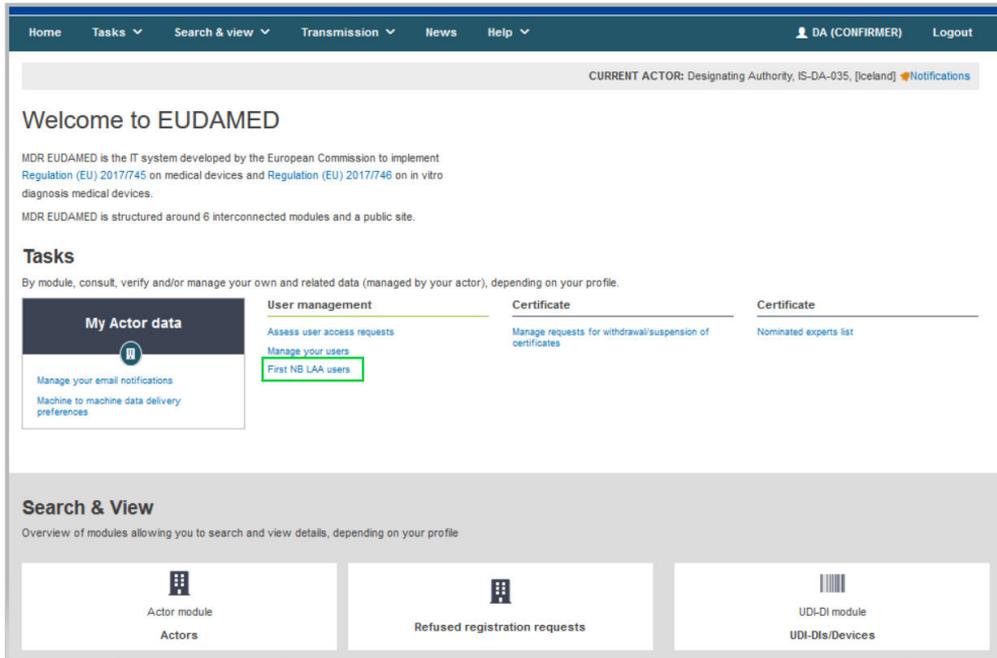


5. Click **Confirm** in the summary dialog box to confirm the user's profile.

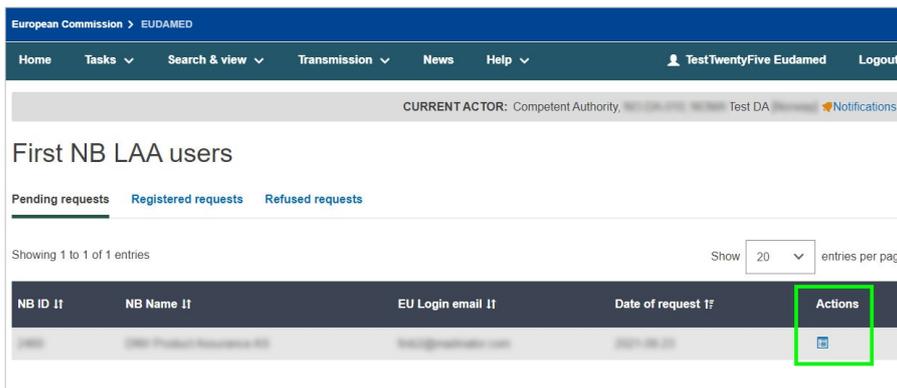


4 Assess and confirm first NB LAA user request

1. From your EUDAMED dashboard, click on *First NB LAA users*:



2. On the *Pending requests* tab, you will find a table containing the user request entry. Click on the list icon under the *Actions* column:



3. The *Assessment* page will open, which displays all the Actor Identification and NB user information:

European Commission > EUDAMED

Home Tasks Search & view Transmission News Help TestTwentyFive Eudamed Logout

CURRENT ACTOR: [redacted] Test DA Notifications

Assessment

Actor identification

Organisation name: [redacted]
 NB number: [redacted]
 Address: [redacted]
 Telephone number: [redacted]
 Email: [redacted]

User information

EU Login ID

ID: [redacted]

Contact email for the actor

Email: [redacted]

Are you a sub-contractor for this actor?

Sub-contractor: No

User manager

First name: [redacted]
 Last name: [redacted]
 Function/position: [redacted]

Validity date for the EUDAMED account

End date: -

Requested Profiles

Actor: LAA

Assessment of user data

Outcome:

Approve Refuse

Submit Cancel

- At the bottom of the page, toggle left or right to approve or refuse the request accordingly, and then press **Submit**.

Assessment of user data

Outcome:

Approve Refuse

Submit Cancel

- If you choose to refuse the request, you are required to provide your comments/justifications in the *Remarks* box provided below before submitting your assessment.

Assessment of user data

Outcome:

Approve Refuse

* Remarks:

Insert comment here

Submit Cancel

6. Once you have approved a request, it will appear under the *Registered requests* tab.

First NB LAA users

Pending requests Registered requests Refused requests

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

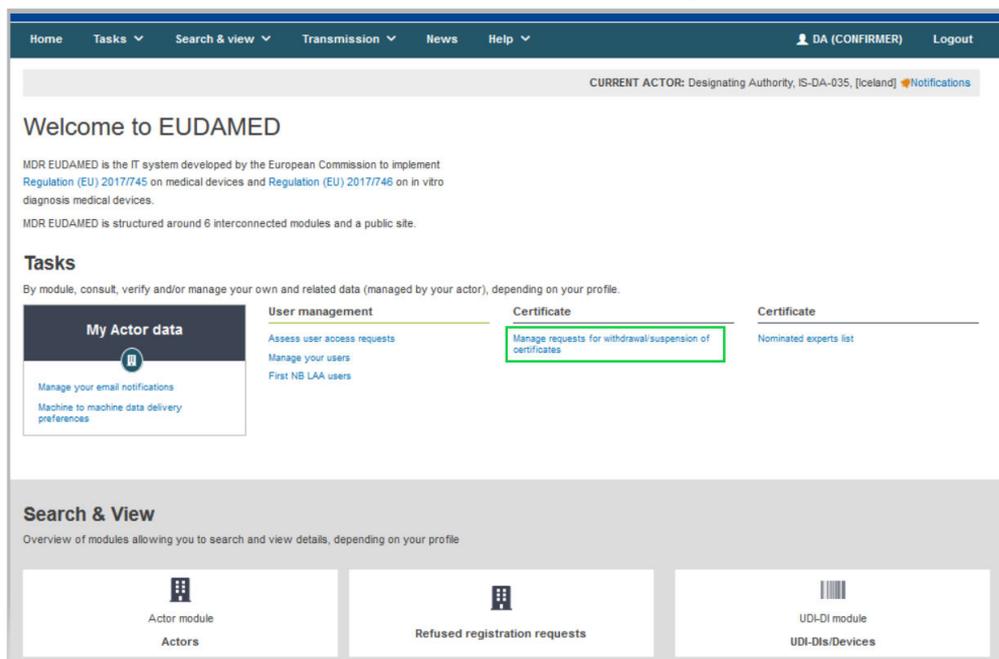
NB ID	NB Name	EU Login	EU Login email	Sub-contractor	End date

You have now completed the process for assessment of a NB first LAA.

5 Manage requests for suspension/withdrawal of certificates

5.1 Register a request for suspension/withdrawal of certificate(s)

1. From the homepage, click on *Manage requests for suspension/withdrawal of certificates* under the *Certificates* column on the right of the screen:



2. On the following suspension/withdrawal management page, select the Notified Body from the dropdown list (mandatory), complete any other search criteria and click on **Apply filters**:

EUDAMED user guide

Next the Certificates result list will appear:

Select all	Certificate number revision number	MF/PR Actor ID/SRN	Certificate type	Starting certificate validity date	Date of issue	Date of expiry	Status
<input checked="" type="checkbox"/>	RESTR-IV-426247 2	BE-MF-00000803	(IVDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-13	2021-12-13	2023-12-13	Restricted
<input type="checkbox"/>	REST-QAC_1141331 2	BE-MF-00000803	(MDR) EU quality assurance certificate (Annex XI Part A)	2021-12-13	2021-12-13	2023-12-13	Restricted
<input checked="" type="checkbox"/>	RESTR-QMS-MDR_1141 2	BE-MF-00000803	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-13	2021-12-13	2023-12-06	Restricted
<input type="checkbox"/>	REISSU-QMS-IV-141254 2	BE-MF-00000803	(IVDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-13	2021-12-13	2023-11-30	Restricted
<input checked="" type="checkbox"/>	MDR-QMS-SUPP-1111 2	BE-MF-00000803	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-13	2021-12-13	2023-12-13	Supplemented
<input checked="" type="checkbox"/>	REISSUE-IV-13134 1	BE-MF-00000803	(IVDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-13	2021-12-13	2023-12-13	Reissued
<input type="checkbox"/>	QAC-REISS-13142154 1	BE-MF-00000803	(MDR) EU quality assurance certificate (Annex XI Part A)	2021-12-13	2021-12-13	2023-12-13	Reissued

3. Select the relevant Certificates from the column on the left and click on *Request for Suspension* or *Request for Withdrawal* accordingly:

The next page displays selected certificates as well as the details of the selected Notified Body.

4. Fill in the mandatory fields, i.e. the Request date and Comments, and click on **Confirm**:

Request for suspension of certificates

Notified Body identification

Notified Body number: 2797
 Name: BSI Group The Netherlands B.V.
 Country: Netherlands

List of certificates

4 certificates selected

- RESTR-IV-426247 2
- RESTR-QMS-MDR_1141 2
- MDR-QMS-SUPP-111 2
- REISSUE-IV-13134 1

* Request date:

 YYYY-MM-DD

* Comments:

[Confirm](#) [Cancel](#)

The system has now successfully registered the request:

Request for suspension/withdrawal registration

You have successfully registered your request for suspension/withdrawal of certificates. The following actors are being notified: i) Competent authority of the Member State in which the manufacturer and/or the system and/or procedure pack producer has their registered place of business; ii) Designating authority you are acting on behalf.

What do you want to do now?

[View the request you just created](#)
[Go to the homepage](#)

An email notification is sent to the competent authority(ies) of the country of establishment of the manufacturer, or of its authorised representative(s), to inform them about that request for withdrawal/suspension of certificate(s).

5.2 Register a request for withdrawal/suspension for certificates not yet registered in EUDAMED

1. Follow the steps in [Register a request of Suspension/Withdrawal of Certificates \[12\]](#) to reach the certificates search result page (*Step 2*):

i In order to register a suspension/withdrawal of a certificate that is not registered in EUDAMED, you can click on the "Request for suspension" or Request for withdrawal" link without selecting a certificate from the list

Showing 1 to 20 of 234 entries Show entries per page

Select all	Certificate number revision number	MF/PR Actor ID/SRN II	Certificate type II	Starting certificate validity date II	Date of issue II	Date of expiry II	Status
<input type="checkbox"/>	0 certificates selected	Request for suspension	Request for withdrawal				
<input type="checkbox"/>	REINS-QMS-1232442 1	BE-MF-000000803	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-13	2021-12-13	2022-12-13	Reinstated
<input type="checkbox"/>	REINST-1111 1	BE-MF-000000803	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-13	2021-12-13	2023-12-13	Withdrawn
<input type="checkbox"/>	RESTR-IV-426247 2	BE-MF-000000803	(IVDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-13	2021-12-13	2023-12-13	Restricted
<input type="checkbox"/>	REST-QAC_1141331 2	BE-MF-000000803	(MDR) EU quality assurance certificate (Annex XI Part A)	2021-12-13	2021-12-13	2023-12-13	Restricted
<input type="checkbox"/>	RESTR-QMS-MDR_1141 2	BE-MF-000000803	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-13	2021-12-13	2023-12-06	Restricted
<input type="checkbox"/>	REISSU-QMS-IV-141254 2	BE-MF-000000803	(IVDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-13	2021-12-13	2023-11-30	Restricted
<input type="checkbox"/>	MDR-QMS-SUPP-111 2	BE-MF-000000803	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-13	2021-12-13	2023-12-13	Supplemented

(IVDR) EU quality management

- Pay attention to the **Information** Box in blue and follow the instructions provided:

i In order to register a suspension/withdrawal of a certificate that is not registered in EUDAMED, you can click on the "Request for suspension" or Request for withdrawal" link without selecting a certificate from the list

- Without selecting any specific certificate, click on **Request for Suspension** or **Request for Withdrawal** accordingly:

number MF/PR Actor ID/SRN Certificate type Start

[Request for suspension](#) [Request for withdrawal](#)

- A pop-up window will ask you to confirm if you wish to submit a request for suspension/withdrawal of certificates not yet registered in EUDAMED. Click on **Yes** to proceed:

Request for suspension/withdrawal of certificates *Close

Do you want to submit a request for suspension/withdrawal of certificates that are not yet registered in EUDAMED?

- On the next screen, fill in the required information like manufacturer or system or procedure pack producer identification.

Enter the Actor ID/SRN or the name of the actor (e.g. manufacturer):

When you select the actor, their details will be displayed in the same box.

In case the manufacturer is a non-EU one, the system will ask you to select among the possible authorised representative(s) for this manufacturer.

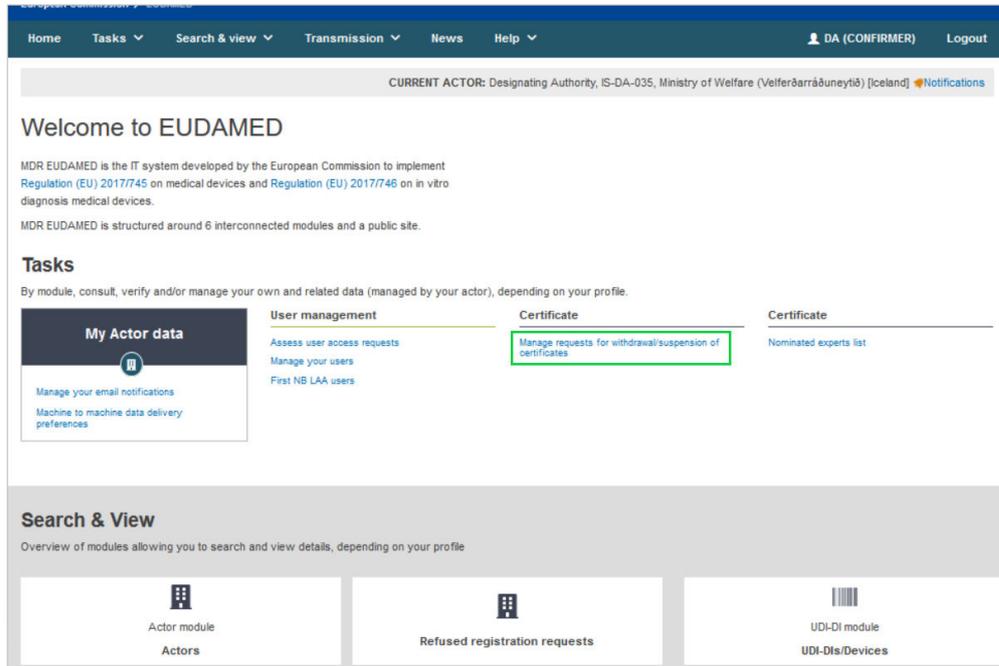
At least one certificate must be present within the request. You may add certificates by clicking on the *Add another Certificate* link.

Once the list of certificates, the request date and comments were provided click **Confirm**.

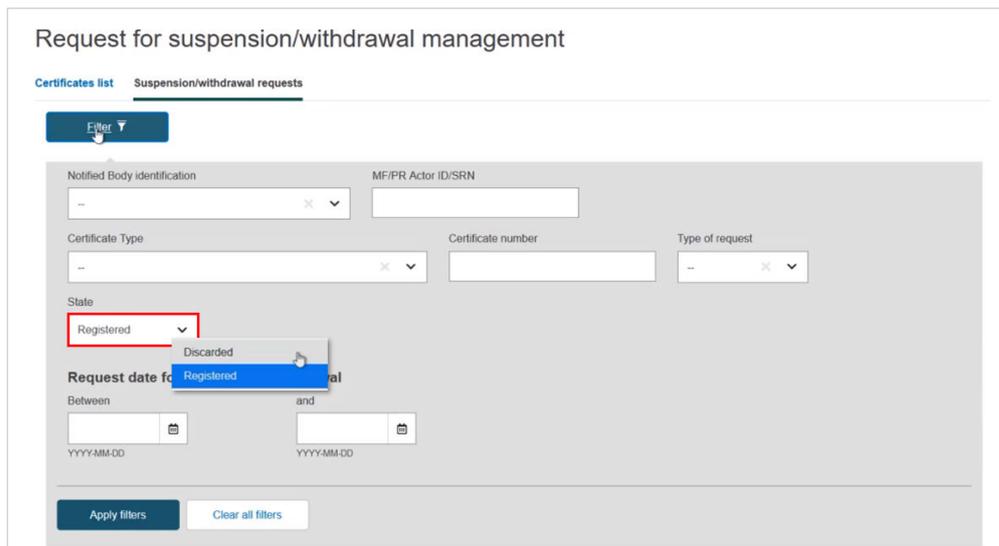
The system has now successfully registered the request:

5.3 View own requests for suspension/ withdrawal of certificates

- From the dashboard, click on *Manage requests for withdrawal/suspension of certificates* under the *Certificates* column on the right of the screen:



- On the next page, click on the tab on the top entitled *Suspension/Withdrawal requests*. The state dropdown is set to *Registered* by default, with the possibility of viewing *Discarded* requests:



- All requests registered by your DA will be displayed beneath the filter dialog. You can refine the results by completing any other search criteria and click on **Apply filters**. The list of results will appear below:

Request for suspension/withdrawal management

Certificates list Suspension/withdrawal requests

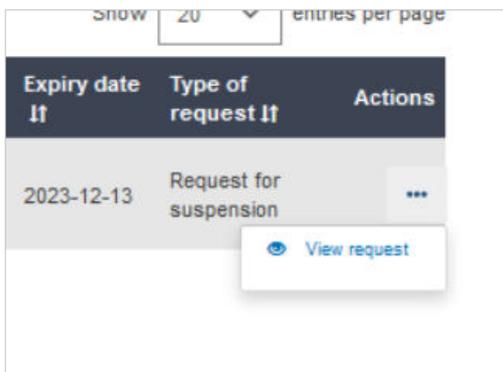
Filter

Active filters: State: Registered Clear all filters

Showing 1 to 20 of 39 entries Show 20 entries per page

NB number I1	Certificate number revision number	MF/PR Actor ID/SRN I1	Certificate type I1	Request date for suspension/withdrawal I1	Expiry date I1	Type of request I1	State	Actions
0051	645 564	BE-MF-000000281_BE-PR-000000301 -		2022-03-01	-	Request for withdrawal	Registered	...
0051	43543 54345	BE-MF-000000281		2022-03-02		Request for	Registered	...

- Click on the three dots ‘...’ under the Actions column for a specific entry, and a dropdown menu will show:



Once clicked, the view page of the corresponding request will be displayed:

Request ID: IT-DA-013-2021-1041

Go back to the request list

Discard

Request details

Request date: 2021-12-06

Decision: Request for withdrawal

Comments: 44565464

Notified Body identification

Notified Body number: NB-1039

Name: SGS Belgium NV

Country: Belgium

Certificate(s): test quality for steriliser reissued

5.4 Discarding requests for suspension/withdrawal of certificates

- Repeat Steps 2-4 from Section [View own requests for suspension/withdrawal of certificates \[17\]](#). You can discard a request by clicking the **Discard** button, which opens a confirmation pop-up:

CURRENT ACTOR: Designating Authority, IT-DA-013, Designating Auth Dev (Italy) [Switch actor](#) [Notifications](#)

Request ID: IT-DA-013-2022-1001

[Go back to the request list](#)

[Discard](#)

Request details

Request date: 2022-03-01

Decision: Request for withdrawal

Comments: 645

Notified Body identification

Notified Body number: 0051

Name: IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.

Country: Italy

Certificate(s): 645 564

Discarding a request for suspension withdrawal of certificates ✖Close

This request for suspension/withdrawal of certificates will be discarded (lost). The operation cannot be reverted. Do you want to finalise the operation?

- The new state of the request for suspension/withdrawal of certificates is confirmed. A notification is sent to the related competent authority(ies), when the discard operation is confirmed.

Request ID: IT-DA-013-2021-1038

[Go back to the request list](#)

This request has been discarded | Last update: 2022-03-04

Request details

Request date: 2021-12-07

Decision: Request for suspension

Comments: 7777777777

Notified Body identification

Notified Body number: NB-1039

Name: SGS Belgium NV

Country: Belgium

Certificate(s): spp+device+deviceGroup2 restricted

- Using the filter *State*, you can view a list of discarded certificates:

[Filter](#)

Active filters: [State: Discarded](#) [Clear all filters](#)

Showing 1 to 10 of 10 entries Show 20 entries per page

NB number II	Certificate number revision number	MF/PR Actor ID/SRN II	Certificate type II	Request date for suspension/withdrawal II	Expiry date II	Type of request II	State	Actions
2862	20220203 1	BE-MF-000000041	-	2022-03-01	-	Request for suspension	Discarded	...
0477	202202033	BE-MF-000000061, BE-PR-000000301	-	2022-03-01	-	Request for suspension	Discarded	...
0051	645 564	BE-MF-000000281, BE-PR-000000301	-	2022-03-01	-	Request for withdrawal	Discarded	...
0050	534543 5	GB-MF-000000202, BE-PR-000000301	-	2021-12-08	-	Request for withdrawal	Discarded	...
0050	534 14y	BE-MF-000000041, BE-PR-000000301	-	2021-12-07	-	Request for suspension	Discarded	...
NB-1039	spp+device+deviceGroup2 restricted	BE-PR-000000301	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-07	2024-01-01	Request for suspension	Discarded	...

5.5 Search and View requests for suspension/withdrawal of certificates

To view all requests for suspension/withdrawal, use the **Search & View requests for suspension/withdrawal of certificates** function.

1. From the dashboard click on *Suspension/withdrawal request* within the *Search & View* section:

The screenshot shows the EUDAMED dashboard. At the top, there is a 'Tasks' section with three columns: 'My Actor data', 'User management', and 'Certificate'. Below this is the 'Search & View' section, which contains a grid of modules. The 'Suspension/withdrawal request' module is highlighted with a green border.

2. On the next page you can specify filter criteria such as type of request, Notified Body identification, DA identification etc. and then click on the **Search** button:

The screenshot shows the 'Search & View' page for 'Requests for suspension/withdrawal of certificates'. The page has a header 'CURRENT ACTOR: Designating Authority, IS-DA-035, [Iceland] Notifications'. Below the header, there is a 'Search & View' section with the title 'Requests for suspension/withdrawal of certificates'. The 'Requests data' section contains several filter criteria: 'Searching for' (All requests), 'NB identification' (---), 'DA identification' (---), 'Certificate Type' (---), 'Economic operator Actor ID/SRN' (---), 'Economic operator name' (---), and 'Date of request' (Date of request - Between and Date of request - And). At the bottom, there are 'Search' and 'Clear search' buttons.

3. By clicking on a result entry, the request view page will be displayed:

Search results for requests for suspension/withdrawal of certificates

Active search fields:
 Searching for: All requests [Clear search](#)

Showing 1 to 2 of 2 entries Show entries per page

NB number ID	Certificate number revision	MF/PR Actor ID/SRN	DA ID ID	Certificate type ID	Date of request ID	Date of expiry ID	Request type ID
	ZXY 001	BE-PR-000000862	IS-DA-035	-	2021-12-06	-	Request for suspension
	REISSUE-IV-13134 1	BE-MF-000000803	IS-DA-035	(IVDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-13	2023-12-13	Request for suspension

- On the next page when clicking on a certificate within the *Certificate(s)* section, a new window will open displaying the certificate details:

CURRENT ACTOR: Designating Authority, IS-DA-035, [Iceland] [Notifications](#)

Request ID: IS-DA-035-2021-1000

[Go back to the request list](#)

Request details

Request details

Requested by (Designating authority): IS-DA-035

Request date: 2021-12-13

Decision: Request for suspension

Comments: my comments

Notified Body identification

Notified Body number: 

Name: 

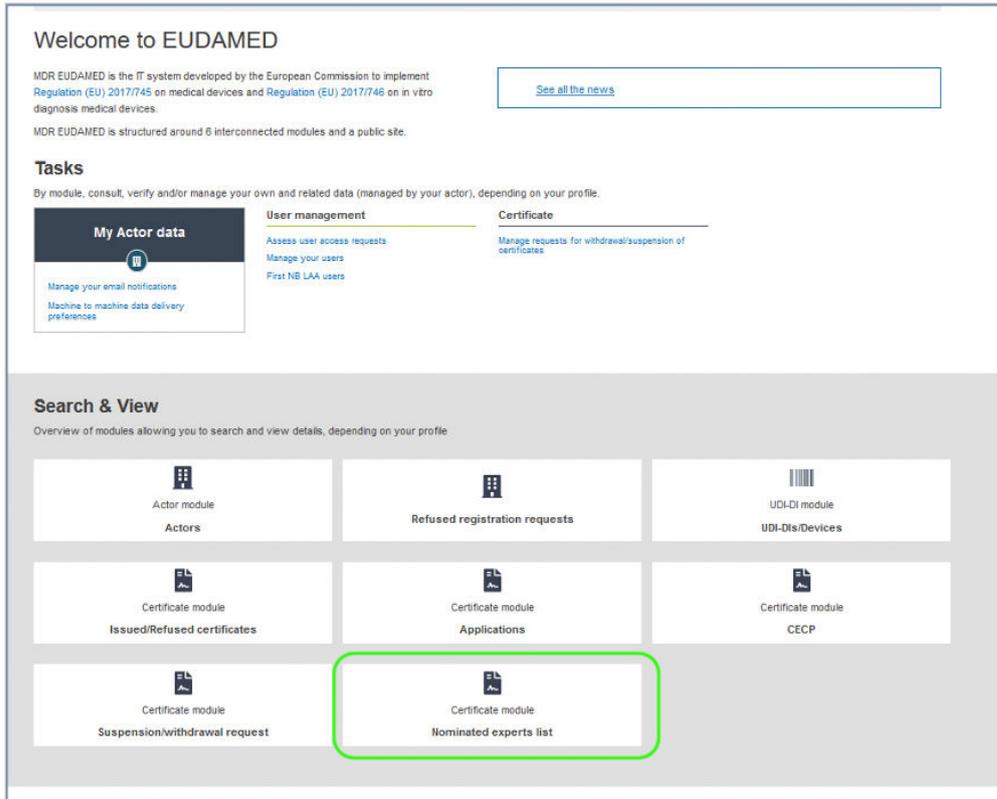
Country: 

Certificate(s):

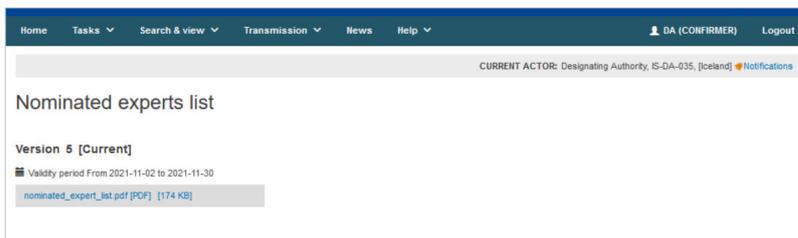
- [REISSUE-IV-13134 1](#)
- [MDR-QMS-SUPP-111 2](#)
- [RESTR-QMS-MDR_1141 2](#)
- [RESTR-IV-426247 2](#)

6 View nominated expert list

1. On the dashboard page, click on *Nominated experts list* under the *Certificate* section:

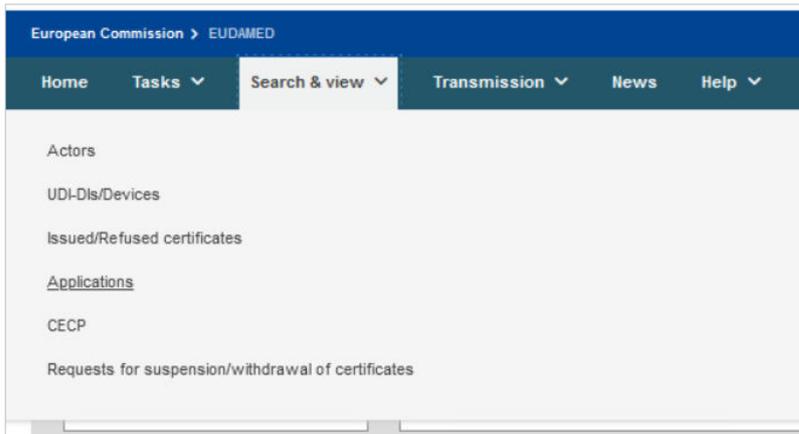


2. The next page contains the latest version of the nominated expert list document. Click on the document to start the download or view action accordingly:

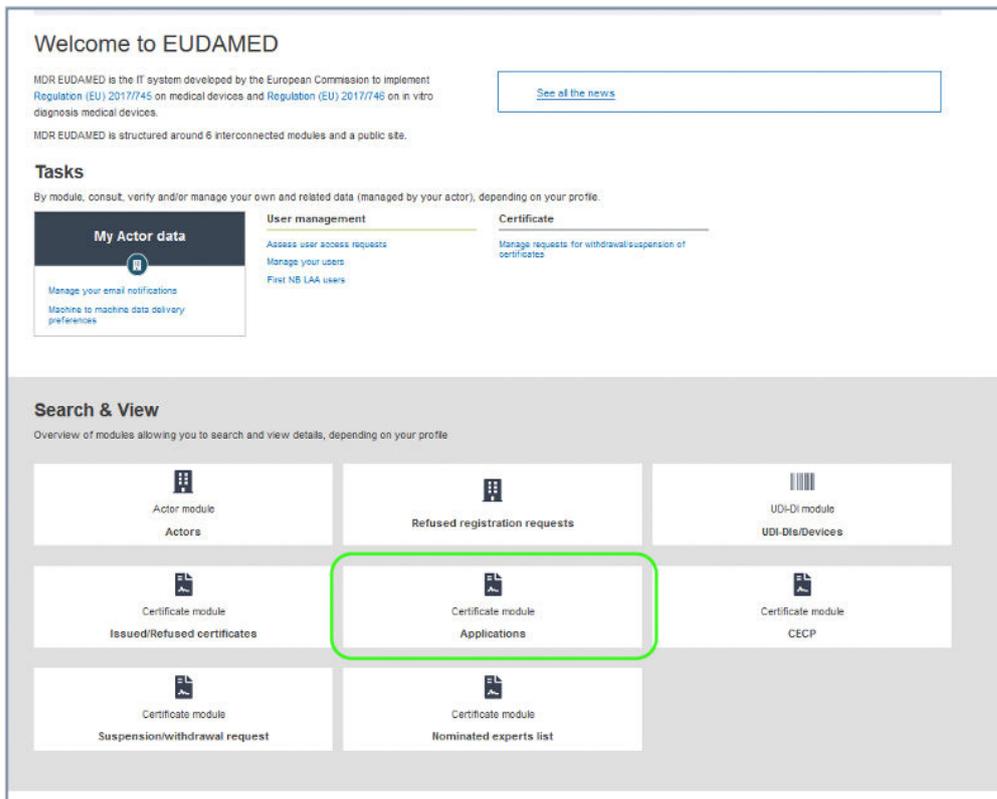


7 Search and view refused/withdrawn applications for conformity assessment

1. On the header menu, click on **Search & View**, then click on **Applications**:



Alternatively, use the *Search & View* section in the dashboard:



2. Next, the refused/withdrawn applications search page will be displayed:

Search and view refused/withdrawn applications for conformity assessment

Applications

Application data

Searching for: NB identification: Conformity assessment procedure:

Application reference number: Economic operator Actor ID/SRN: Economic operator name:

Decision date: Between and

Device data

Device identification: Enter the device identification value/text:

Risk class:

- Enter the search criteria and click on **Search**. A list of refused/withdrawn applications will be displayed:

Search results for refused/withdrawn applications

Active search fields: Searching for:

Showing 1 to 13 of 13 entries Show entries per page

NB number	MF/PR Actor ID/SRN	Actor ID/SRN AR	Application reference number	Conformity assessment procedure	Decision date	Decision
	BE-MF-000000803, BE-PR-000000804		STERI-WITH-1	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-14	Withdrawn application (by MF)
	BE-MF-000000803, BE-PR-000000804		STERI-REFU-1	(MDR) EU quality assurance certificate (Annex XI Part A)	2021-12-14	Application refusal (by NB)
	BE-MF-000000803, BE-PR-000000804		REF-APP-3426236	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-02	Application refusal (by NB)
	BE-MF-000000803, BE-PR-000000804		WITHD-234467	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-02	Withdrawn application (by MF)
	IN-MF-000000451	BE-AR-000000447	11398_1	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-11-11	Withdrawn application (by MF)
	IN-MF-000000451	BE-AR-000000447	11398_2	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-11-11	Application refusal (by NB)
	BR-MF-000000585, BE-PR-000000584	BE-AR-000000582	WITH-NOT-1314	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-11-08	Withdrawn application (by MF)

- Click on the desired result record to see its details:

Withdrawn application: STERI-WITH-1

[← Go back to the applications list](#)

Withdrawn application data

- Application data**
- [Application details](#)
- [Device\(s\)](#)
- [System Procedure Pack\(s\)](#)

Application data

Notified body

Notified Body number: ██████████
 Name: ██████████
 Country: ██████████

Application details

Decision Type:	Withdrawn application (by MF)
Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Conformity assessment procedure:	(MDR) EU quality management system certificate (Annex IX Chapter I)
Application reference number:	STERI-WITH-1
Decision date:	2021-12-14
Date of submission (by MF/Producer):	2021-12-14

Manufacturer identification

Organisation name: ██████████
 Actor ID/SRN: ██████████
 Address: ██████████
 Telephone number: -
 Email: ██████████

System and/or Procedure Pack Producer Identification

