

# EUDAMED user guide Actor module for Economic Operators

Production v 2.15 2025

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## **1** Introduction

How economic operators can use the actor registration module – concept, registration, management, access and mandates.<sup>1</sup>



### **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.

### **1.1 Overview**

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

Regulation (EU) 2017/745 on medical devices

Regulation (EU) 2017/746 on in vitro diagnostic medical devices

EUDAMED restricted website is structured around six interconnected modules:

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

A public site is also available.

### **1.2 Application basics**

This section describes a number of basic principles:

- · Starting and ending a EUDAMED session
- Basic concepts

<sup>&</sup>lt;sup>1</sup>For a wider understanding on how to use the platform, visit the EUDAMED Information Centre.

• User profiles and access grants/rights.

### 1.2.1 Start and end a EUDAMED session

To use EUDAMED, you must have an EU Login account associated with your professional email address. Private / shared mailboxes are excluded for security reasons.

### 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.

European Commission EUDAMED	
European Commission > Medical devices >> EUDAMED	
Welcome to EUDAMED Disclaimer providing all necessary information on who may access request to Eudamed. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit <u>EUDAMED public website</u> cillum dolore eu fugiat nulla pariatur.	
You already have an EU login account Login into Eudamed using your EU Login account Enter with EU Login	
You don't have a EU Login account yet 1	
About EUDAMED Cookies Privacy policy Contact Help	



#### NOTE Playground environment

EUDAMED is also available in a Playground environment for training and testing purposes. All the information in this environment is considered as dummy, including the Actor ID/SRN, and will never be moved to the production environment.

The *Playground* environment contains a red *Play* banner across the logo at the top left of the screen. Access to the Playground requires a separate registration.



- 2. Click Enter with EU login. Alternatively, select Create your EU Login account if you do not have one yet.
- 3. Type your EU Login email address and click Next:

This website uses cookies. Learn more about the European Commission's c	ookie policy			Close this message $ imes$
EU Login One account, many EU services	v E	Where is	•	English (en)
webgate.acceptance	e.ec.europa.eu requires you to a	auther	nticate	9
Sigr	n in to continue			
Or use the	e-mail address           Next           Create an account           Or           of your country           selled by our country           Select your country			
About EU Login Cookies Privacy Statement Contact Help				Powered by
European Union EU institutions	7.4.3-dn2p   17 ms			European Commission

4. Enter your password and click Sign in:

Sign in to continue	
Welcome back (European Commission) Sign in with a different e-mail address?	
Password	
Lost your password? Choose your verification method	
Password       Authenticate to EU Login with only your password.	
Sign in	

► Forgot your	es? password? Click <i>Lost your password?</i> on this screen:
	Sign in to continue
	Welcome back
	(European Commission) <u>Sign in with a different e-mail address?</u>
	Password
	Lost your password? Choose your verification method
	Password       Authenticate to EU Login with only your password.
	Sign in
_	
► Change your	password: Go to Change password

5. Enter your EU Login password and click **Sign in**. If you do not have any pending/registered account(s), 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:

European	Commission > EUD/	AMED								
Home	Tasks 🗸	Search & view 🗸	Transmission 🗸	Help 🗸					Budlins Fullythes	Logout
	CURRENT ACTOR:	Competing Roberts 8	E CA-BR Agence Feed	nga ina Mada y	nanta di San <sup>P</sup> adadi	a tenti sina			nas ar fasadhan Singari <mark>e</mark> n	an de la com
			allows you to log out of completely signed off.	the EUDAMED a	application. Please be	aware that you v	vill still have to log o	ut of EU		
				Logout	Stay logger	d in				
EUDAME	ED		Contact EUI	DAMED			About EUDAMED			

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

### 1.2.2 Actors and definitions

INFOGRAPHIC: Actor ID/SRN and Actor roles



### Actors

Actors involved in EUDAMED are:

### **Supervising bodies**

- European Commission
- Competent Authorities (CA)
- Designating Authorities (DA)
- Notified Bodies (NB).

### **Economic operators**

Manufacturers

#### Introduction

- · System and procedure pack producers
- Authorised Representatives
- Importers.

#### Sponsors

· Sponsors of clinical investigations/performance studies.

### 1.2.3 User rights and profiles

Each user may have multiple accounts but can access EUDAMED with only one account at a time.

Each EUDAMED account is associated with one of the following actors:

- Manufacturer
- · Authorised Representative
- System/Procedure Pack Producer
- Importer

Each of these actors has a set of roles that are specific to each module in EUDAMED. The actions and rights connected to each role are defined by the user profile of that user (i.e. *Viewer*, *Verifier*, *Linker*, *LAA* etc.) so user profiles are module specific.

Your user profile is determined by your actor role (see table). For example, in *Actors* module, the *Verifier* profile is only enabled for *Authorised Representative* actors. The *Linker* is enabled only for *Importer* actors, which allows them to create links with non-EU manufacturers.

### 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 the profiles beneath it in the hierarchy.

### User profiles per actor role and their hierarchy

Authorised representative	Manufacturer	System and procedure pack producer	Importer
LAA	LAA	LAA	LAA
LUA	LUA	LUA	LUA
Verifier	Mandate manager	-	Linker
Viewer (default)	Viewer (default)	Viewer (default)	Viewer (default)

# 2 Managing actors and user accounts

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

There are two ways to gain access to EUDAMED:

#### Request registration for an economic operator

Register your Actor in EUDAMED with the appropriate actor role.

- The person who performs the Actor registration automatically becomes *Local Actor Administrator (LAA)* for that actor once the registration is validated.
- An Actor ID or Single Registration Number (SRN) is generated by EUDAMED and issued by the Competent Authority after validating the registrations request.

#### Request access as a user of a registered Economic Operator

If your Actor is already registered in EUDAMED, you can request access as a user of that actor. Once an LAA/LUA from your actor has approved your request, your account will be granted the appropriate user profile for that actor.

### IMPORTANT

It is good practice having at least two LAA, as a fail-safe mechanism if one should be unavailable. Furthermore, an actor must have at least one active LAAat all times, making it impossible to terminate the last LAA for an actor.

### 2.1 Managing actors

Economic Operator means one of the following:

- Manufacturer (MF: EU Manufacturers\* & Non-EU Manufacturers\*\*)
- Authorised Representative (AR)
- System/Procedure Pack Producer (SPPP)
- Importer (IM)

\* **EU manufacturers**: If you are established in the EU, your registration will be assessed by the **Competent Authority** (CA) of the country where you are established. \*\* **Non-EU manufacturers**: If you are not established in the EU, your registration will be verified by the **Authorised Representative** you indicate in your actor registration request, before being assessed by the Competent Authority responsible for that AR.



The difference in registration process between the two types of MFis highlighted in the following pages.



### Multiple roles

If your organisation has more than one Actor role (i.e. your organisation is a manufacturer and an importer at the same time), you must make separate actor registrations for each.

### 2.1.1 Register as an Economic Operator

INFOGRAPHIC: Actor registration request process



1. Log into EUDAMED with your EU Login account (See Section *Starting and ending a EUDAMED session* [2]). You will land on the *User and Actor Registration* page:



2. Select the Actor Registration widget on the *User and Actor Registration* page. A disclaimer is displayed before you are able to continue:

Acto	or registration	
Disc	laimer	
0	Submission Please be aware that once you click submit, you will not be able to	Notification After submission, EUDAMED will notify the National Competent
	make further changes to your data.	Authority who will examine your request and, if you are a from a non- EU country, your Authorised Representative will also be notified
X	Status of your request	Outcome by email
	The outcome of the examination will be communicated to you by e- mail to the address on the previous page. Meanwhile, you may view your data and the progress of the examination by visiting See my Pending Requests in your EUDAMED account.	If your request is approved, you will be authorised to carry out Local Administrator tasks for the actor under registration (See the User Guide)
	nave read and agree to the above disclaimer	
	Next Cancel	

3. Read the disclaimer, select the *I have read the disclaimer* checkbox and click **Next**. You are prompted to enter the information about your actor:

Actor registration
Please note that you have to submit an actor registration request for each actor role your company may have:
Authorised representative - AR
Importer - IM
Manufacturer - MF
System/procedure pack producer - PR
Create new actor Enter your organisation data to register your actor
* Role:
Manufacturer 👻
* Country:
Ireland 👻
* Actor / organisation name:
Sample MF
Next

4. The process summary highlights the completed, current, and the remaining stages of the actor registration process.

0	0	0	4	5	6
Actor	Actor address	Contact details	Regulatory	Registering Local Actor	Competent
To entitle a contraction		Getairs	Persons	Administrator	Additionly

5. Select the role and country, enter the name of your actor and click **Next**.

Actor regis	stration				
1	2	3	4	5	6
Actor identification	Actor address	Contact details	Regulatory Persons	Registering Local Actor Administrator	Competent Authority
Actor identif	fication				
* Role: Manufacturer					
* Country: Belgium					
* Organisation name:		* Select organisation language:			
Sample MF		- •			
Add organisation	name in another language				
Abbreviated organisati	on name:	Select abbreviated organisation	name language:		
		- •			
Add abbreviated	organisation name in another lang	juage			
_					
VAT information					
Yes N	O 🚯 VAT information is re	equired unless you select the option - N	0		
* VAT number:	-				
EORI number:					
National trade register:	:				
Organisation identifi	cation document				
Browse					
Diowse					
Save registration					



#### NOTE

It is recommended to upload an Organisation Identification document even though it is not mandatory. If you do decide to upload one, make sure the file is in PDF format and that it does not exceed 10MB.

 Enter the information for the mandatory fields, and additional fields, needed to identify your Economic Operator: VAT, EORI and National Trade Register Number are mandatory if available. You can upload any document that may be useful for validating your request – but only in PDF format and not exceeding 10MB. Click Save & Next. a. You will be prompted by the Actor address details screen:

Actor identification	2 Actor address	3 Contact details	4 Regulatory Persons	5 Registering Local Actor Administrator	6 Competent Authority
Actor addres	s				
Street information, it	_				
Yes No	) Street	nformation is required unless you se	elect the option - No		
* Street:			Street number:		
Address line 2:					
O box:					
atitude:	Longitude:				
andde.	Longitude.				
atitude format example: -15.	4543 Longitude form	nat example: 178.34354353			
City name:			* Postal code:		
Country:					
lelgium					
Save registration	Save & Next ≯				
	NOTE				
	Non-EU Manufa	acturers will be	e prompted by t	he Actor addres	s details s

after entering the Authorised Representative details.

7. Enter your actor's address details and click **Save & Next**. You will be prompted by the *Contact Details* screen:

Actor Act identification	or address	3 Contact details	4 Regulatory Persons	5 Registering Local Actor Administrator	6 Competen Authority
Actor contact detai	ls				
Contact details for Compo lote: These details will be visible only to c		S			
irst name:			Last name:		
Email:					
elephone:					
elephone format example: +32 x xxx xx xx					
Public contact details					
lote: These details will be visible to the pu	ublic				
Email:					
elephone:					
elephone format example: +32 x xxx xx xx					
Veb site:					

8. Enter the email addresses and other useful information regarding the contact points in your Actor. There are separate fields in which to enter contacts relevant to competent authorities, and those to be displayed to the public, and click **Save & Next**.

Only for a non-EU manufacturer or Authorised Representative, you will be prompted by the Person Responsible for Regulatory Compliance, so that you can identify one or more regulatory person(s) within your Actor:

tification	Actor address	Contact details	4 Regulatory Persons	5 Registering Local Actor Administrator	6 Compete Authori
rson Res	ponsible for Regul	atory Complian	ce		
ïrst name:			* Last name:		
mail:					
elephone number					
ephone format exampl	18. +32 X XXX XX XX				
Person Res	ponsible for Regulatory	Compliance			
	as as the Actor organisation add				
	s as the Actor organisation add	1000			
Street informa	ation, if applicable				
Street information		eet information is required unless yo	ou select the option - No		
		eet information is required unless yo	u select the option - No Street number:		
Yes		eet information is required unless yo			
Yes	No 🚯 Stre	aet information is required unless yo			
Yes  * Street:	No 🚯 Stre	set information is required unless yo			
Yes  * Street:	No 🚯 Stre	set information is required unless yo			
Yes  * Street:	No 🚯 Stre	set information is required unless yo			
Yes  * Street: Address line 2	No 🚯 Stre	set information is required unless yo			
Yes  * Street: Address line 2	No 🚯 Stre				
Yes  * Street: Address line 2 PO box:	No 🕄 Stre				
Yes  * Street: Address line 2 PO box:	No Stre				
Yes  * Street: Address line 2 PO box: Latitude:	No Stre	e.			
Yes  * Street: Address line 2 PO box: Latitude: Latitude format exam	No Stre	e.	Street number:		
Yes  * Street: Address line 2 PO box: Latitude: Latitude format exam	No Stre	e.	Street number:		
Yes  * Street: Address line 2 PO box: Latitude: Latitude: Latitude format exam * City name:	No Stre	e.	Street number:		
Yes  * Street:  Address line 2  PO box: Latitude: Latitude: Latitude format exan  * City name: * City name: * Country:	NO Stre	e.	Street number:		
Yes  * Street: Address line 2 PO box: Latitude: Latitude: Latitude format exam * City name:	NO Stre	e.	Street number:		

9. Enter your actor details and click **Save & Next**.

Actor identification	Actor address	Contact details	Regulatory Persons	5 Registering Local Actor Administrator	6 Competent Authority
Registering L	ocal Actor Admin	istrator		Paninistator	
EU Login persona	II data 🚯				
First name:			_ast name:		
Email:					
I was a regime addressible a sea	,				
EUDAMED persor	nal data 📵				
* First name:			' Last name:		
			Concentration and the Concentration of the Concentr		
* Email:		•			
* Signed declarati	on:				
Please use the c	leclaration template below. Only	signed declarations following	g this template will be considered		
Download signed declara	tion tomplato				
Download signed declara					
Browse					
* Are you a sub-contrac	ctor for this actor?:				
○ No					
⊖ Yes					
Save registration	Save & Next >				



### NOTE

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 CA has validated the actor registration.

As LAA, you can manage all the details for your Actor in EUDAMED (e.g. name, address, contact details, etc.) as well as user access requests for it (see *Validating user access requests [56]*).

It is good practice having more than one LAA (with at least one belonging to the actor itself, rather than all from a sub-contractor).

 Check and complete the information on the page. Upload the signed declaration – PDF format only and not exceeding 10MB – using the **Browse** button.
 Please refer to the template for the signed declaration.

* Are you a sub-contractor for this actor?:     No     Yes     * Company name:     Telephone number:     Telephone format example: +32 x xxx xxx xxx		
* Company email address:		
Street information, if applicable Yes No	Street information is required unless you select the option	- No
*Street:		Street number:
Address line 2:		
PO box:		
Latitude:	Longitude:	
Latitude format example: -15.4543	Longitude format example: 178.34354353	
* City name:		* Postal code:
* Country:		
Save registration Save & Next >		



### NOTE

If you specify that you are a *sub-contractor*, an additional section at the bottom of the page will prompt you to provide your sub-contracting company details.

11. Click **Save & Next** to move to the last step. Select the Competent Authority that will be responsible for your actor request validation. You can add any extra information that might be relevant for the Competent Authority:

Actor identification	Actor address	Contact details	Regulatory Persons	Registering Local Actor Administrator	6 Competent Authority
Competent /	Authority				
- Any other inform	t authority which will validate this a	-	ity		
Additional Information:	:	ĥ			
Save registration	Preview	Submit actor registration »			

12. If there is a choice between multiple Competent Authorities, select the most appropriate one from the list. (A help file will be available for Actors established in Germany, to assist with the Competent Authority selection). If there is only one authority that can be selected, the details will be automatically displayed. To view a summary of your completed registration form, click **Preview**:

Actor identification	Authorised Representative	Actor address	Contact details	Regulatory Persons	Registering Local Actor Administrator	Competent Authority
Name: Agence Gezondheidsprod Address: EURO Country: Belgiur Email: meddev	Fédérale des Medicaments lucten STATION building block 2pla m	at des Produits de SanteFede		neesmiddelen en		
Any other info Additional Informatio	on:	nce for the competen				

13. Review the information on the form, and then click **Submit actor registration** at the bottom of the page. A confirmation window will appear:

Submit your actor registration request	× <u>Close</u>
You now will have the possibility to evaluate user access requests and grant permissions to the relevant user access requests and grant permissions to the rel	sers
Are you sure you want to submit your request?	
Confirm	

- 14. Read the information and click **Submit**.
  - Your registration request is saved and appears with a *Submitted* state in your *Pending requests* list.
  - Your registration request has an application ID and is submitted to the selected competent authority:

Actor registration
Congratulations. You have successfully submitted your actor registration request. Your application ID is APP00000021
What do you want to do now?
View the request you just created View all of your requests Create another request

15. You will be notified when your Actor registration request is approved or not approved. Follow your application status on *See my pending requests* in your *My account* page.



NOTE

The validation of the Actors registration requests is under the responsibility of the different national competent authorities (CA).

If you are a non-EU Manufacturer, the Authorised Representative indicated in your actor registration request will verify it prior to the national competent authority assessment.

A list of national contact points can be found on the EUDAMED website.

#### If your registration is approved

An Actor ID or Single Registration Number (SRN) is generated by EUDAMED and issued by the Competent Authority.

1. The next time you enter EUDAMED, you will be prompted to accept your rights and obligations as the Local Actor Administrator (LAA) for your actor. You can download the disclaimer by clicking on **Download disclaimer** in the orange box:



2. After reading, click on *I accept the user rights and obligations* and then click **Next**. You will be prompted to validate your email address for the Actor module:

Actor notification email address					
Actor Data:	* Email:				
Validate	Cancel				

#### If your registration is not approved

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*, listing your registration requests and their states:

My pending request							
You can view the status of your requests below           EU Login details         You do not have any pending access requests for the moment           Name:         New access request           Username:         My actor registration requests							
EUDAMED details	Application ID	Role I†	Name 11	City It	Date of request †₹	State	Actions
Name:	APP00000041	Manufacturer	lager 60	645	2020-08-19	Correction Requested	
	New actor registrat	ion request					

2. Click the three-dot action button beside your request. You can view and edit your registration request if it has a *Correction requested* state.

Q	-	s with a <i>R</i>		<b>te cannot be</b> ity for the reje		<b>or resubmitted.</b> T displayed.	he reasor
Actor identification Actor identifi Actor identifi Manufacturer * Country: Belaium	2 Actor address	3 Contact details	4 Regulatory Persons	5 Regel Actor Local Actor Administrator	6 Competent Authority		
* Organisation name:	name in another language	* Select organisation language All languages 🔝 👻	2				
Abbreviated organisatio	n name:	Select abbreviated organisatio	n name language:	Previous assessment(s)     Application ID:		Date of submission: 2020-08-19	
Add abbreviated o	rganisation name in another lang	Wage		2020-08-19 Reason for I think this is	rejection Duplicate	el des Produits de Santal-Astron Agenteches Manufactus	

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

### 2.1.2 Register as a non-EU manufacturer

If you are a non-EU manufacturer, the procedure for registering differs from that for EU manufacturers explained in *Registering as an Economic Operator [11]*.

You must identify an Authorised Representative (AR) with whom you have a mandate. If you have multiple ARs, indicate which is the main representative by its Actor ID/Single Registration Number (SRN). Your AR must verify your registration details before the request is submitted to the competent authority for validation. To do this, the AR must be 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. You are presented with an online disclaimer:



- 3. Enter the required data:
  - a. Identify your authorised representative:

Do you know the Single	Yes	Select I know the SRN, click Findand select the number.
Registration Number (SRN)?	No	Deselect I know the SRN, select the country and enter the name of the Authorised Representative. Click Findand select the correct result.

### NOTE

If you do not find your authorised representative from the search page, please contact them to confirm their Actor ID/SRN. They may not have registered yet or may have registered with a different name.

- b. Enter the validity start and end-dates of the written mandate with the Authorised Representative.
- c. In the Upload summary mandate document section, click Browse, select the location of the summary mandate (PDF only and not surpassing 10MB in size), 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.
- d. Click Save & Next.

0	0	3	4	5	6	7
Actor identification	Authorised Representative	Actor address	Contact details	Regulatory Persons	Registering Local Actor Administrator	Competent Authority
Actor addre	ess					
Street information	n, if applicable					
Yes 🚺 I	No	Street information is required un	less you select the option - No			
* Street:			Street number:			
Address line 2:						
PO box:						
Latitude:		Longitude:				
Latitude format example: -	15 4543	Longitude format example: 178.343543	53			
* City name:		congress former example. There is no is	* Postal code:			
* Country:				,		
Australia						
Save registration	Save & Ne	xt ≯				



NOTE

You don't have to upload the full mandate text. It's enough to upload a summary mandate (click here for the template).

 Check and complete the information on the page. Upload the signed declaration – in PDF format only and not exceeding 10MB – using the Browse button. Click Save & Next.

In the final step, the Competent Authority that will validate your registration request (i.e. the CA responsible for your Authorised Representative) is identified, with contact information.

Actor identification	Authorised Representative	Actor address	Contact details	Regulatory Persons	Registering Local Actor Administrator	Competent Authority
Competent	t Authority					
Gezondheidsprod Address: EURO Country: Belgiur Email: meddev(	ucten STATION building block 2pla n	et des Produits de SanteFed ace Victor Horta 40/ 40, B-10		neesmiddelen en		
Any other info	rmation of significa	nce for the competer	nt authority			
Additional Informatio	on:					
Save registratio	n Preview	Submit actor registr	ation >			

- 5. Enter any additional information you wish to pass on to the Competent Authority, and then click **Preview**. A summary of your completed registration form is displayed.
- 6. Review the information on the form, and then click **Submit actor registration** at the bottom of the page. A confirmation window will appear:

	Close
Submit your actor registration 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 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.	
Confirm Cancel	

- 7. Read the information in the window and click Confirm.
  - Your registration request is saved and appears with a *Submitted* state in your *Pending requests* list.
  - Your registration request has a unique application ID and is submitted first to your Authorised Representative for verification and then to the Competent Authority for validation.

You will be notified when your Actor registration request is approved or rejected.

Home Tasks 🗸	Search & view 🗸 🕴 F	lelp 🗸		Logout
			CURRENT ACTOR:	Notifications
Notification	s Inbox			
Action				
icuon				
A notification is a	rchived after 30 days			
Notification type	Module	From	То	
			2020-08-19	
	]	YYYY-MM-DD	YYYYY-MM-DD	
Search	Clear search			

### 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:

U Login details	My access reque	sts for an exis	sting acto	r			
ame:	Role It	Name 11		City 11	Date of reques	st †≓ State	Actions
sername: nail:	Manufacturer				2020-04-09	Submitted	
UDAMED details	Authorised Representative			6.00	2020-04-01	Draft	
ame:	New access request						
	My actor registra	tion requests					
	Application ID Role 11	-	Name It	City 11	Date of request 17	State	Action
	APP00000 Manufactur	rer	•	-	-	Draft	
	APP00000 Manufactur	rer	Subdisc (#		2020-08-19	Verified	
		andre fan heden			ana at p	Correction Requested	
	arrestored Bendered		695355		0.0	Submitted	
	New actor registration request						

The Competent Authority will then assess the actor registration request. An Actor ID or Single Registration Number (SRN) is generated by EUDAMED and issued by the Competent Authority after its approval.

### 2.1.3 Verify non-EU manufacturer registrations

### Specific to AR Verifier

The Authorised Representative must verify the information provided by the non-EU manufacturer, as well as the summary mandate details.

#### To verify a non-EU manufacturer registration request

 The ARmust log in to EUDAMED with a Verifier, LAA or LUA profile (for the Authorised Representative). If there are pending registration requests from non-EU manufacturers, you will see the following link in your dashboard:

	CURRENTACTO	R: Authorised Representative,	Switch actor			
Welcome to EUDAME	Ð					
MDR EUDAMED is the IT system developed by Regulation (EU) 2017/745 on medical devices and diagnosis medical devices.						
MDR EUDAMED is structured around 6 intercon	MDR EUDAMED is structured around 6 interconnected modules and a public site.					
Tasks						
By module, consult, verify and/or manage your o	wn and related data (managed by your actor),	depending on your profile.				
	User management	Actor management				
My Actor data	Assess user access requests	Verify actor registration requests	🐙 1			
	Manage your users	Manage your mandates				
Manage your actor data						
Manage your email notifications						
Machine to machine data delivery preferences						

 Click Verify actor registration requests in the Actor management section of the dashboard. The Actor registration management page lists all pending non-EU manufacturer registration requests waiting to be verified by your actor (if any):

Actor regis	stration ma	nageme	nt					
Filter 🔻								
Active filters: State of request: Su	Ibmitted Clear all filters	;						
Showing 1 to 1 of 1 en	tries						Show 20 -	entries per page
Application ID	Role Iî	Name 11	Postal code 11	City <u>I</u> ↑	Country	Date of request 🛓	State	Actions
APP000000	Manufacturer			(Bosmith)	-	2020-04-03	Submitted	

- 3. Click **Assess** in the *Actions* column to review and assess the desired registration request. All details of the selected registration request, as submitted by the non-EU manufacturer, are displayed in read-only mode.
- 4. Review the information. A warning message will flag possible duplicates. Select the correct registration request from the list available:

Assess actor registration request	
Application ID: APP000000382	Date of request: 2020-04-03
Potential duplicates were detected during this registration request. View list of duplicates	

5. In the *Assessment* section, slide the toggle left to **Approved** or right to **Not approved**.

If you **choose not to approve** the request, justify your decision with one of the following reasons:

Assessment of	utcome:	
Approved	Not approved	
Type of reasons		
O Incomplete or incorrect		
O Wrong Competent Autho	rity and/or Authorised Representative	
💿 Duplicate 🔒		
O Request not applicable	8	
O Fraud suspected	•	
* Justification:		
Enter justification here		
Complete assessment		
Incomplete or incorrect	Some information that you deem important is to correct or complete the request following y	either missing or looks incorrect. The requesting user will have a chance our instructions and re-submit the request.
Wrong Competent Authority and/or Authorised Representative	You are not the correct Authorised Represent another and re-submit.	ative for this request. The requesting user will have a chance to select
Duplicate	Informs the requesting user that this actor alm	eady exists.
Request not applicable	The request will be rejected and cannot be re	-submitted.
Fraud Suspected:	The requesting user will be informed that regine be shared with the requesting user but will be	istration was not successful. The reason and justification provided will not visible for competent authorities.

6. Click **Complete assessment** at the bottom of the page, and then **Confirm** in the subsequent confirmation pop-up. You are informed that the non-EU manufacturer's registration request has been assessed.

If approved, its status now changes to *Verified*. This means the request has been submitted to the relevant Competent Authority for validation:

Actor registration management
Congratulations. You have successfully assessed the actor registration. The application ID is The assessment status is Venified

### 2.1.4 Search and view registered actors

Once an economic operator has been validated by the relevant Competent Authority and its Actor ID/SRN is issued, its details (except those only for the Competent Authorities) become visible to all users in EUDAMED and will be publicly available on the EUDAMED public website.

### To search and view actors

 Click on the Actors block on the dashboard or select Search & view > Actors in the menu bar. The actor Search & view page appears:

	Search & View Overview of modules allowing you to search and view details, dep	ending on your profile	1111				
	Actor module	Actor module	UDI-DI module				
	Actors	Search for refused registration requests	UDI-DIs/Devices				
		<u></u>					
	Search & view Actors						
E	nable search filters available for bulk XML download						
Na	ame /	Actor ID/SRN VAT number	Role				
			X v				
Co	buntry (	Competent Authority					
	- × •	X V					
	Results option Include historical version						
	Search Generate XML file Clear s	search					

2. Enter your search criteria and click **Search**. All actors matching your search criteria will be listed in the search results section:

Q <u>Search</u>	Clear search			
Search result		Clear all filters & create new search		
Showing 1 to 14 of 14 er		Name It	Country It	Show 20 - entries per page
Actor ID 11 BE-MF-0000	Role 11 Manufacturer	Name it	Country If Belgium	Show 20 - entries per page Date of registration 11 2020-05-27
Actor ID 11	Role 11	Name If		Date of registration #

- 3. To view the details for any actor, click the entry in the results list.
- 4. To search and download actors data:
  - Activate the toggle Enable search filters available for bulk XML download
  - Enter your search criteria and click Search
  - · All actors matching your search criteria will be listed in the search results section
  - Click the button Generate XML file and confirm
  - Download the XML file of the results list from the *Downloads management* page.

Please see the data exchange guide for further information, available in the Data exchange section.



### NOTE

There are limitations on what search criteria you can use for bulk downloads, so certain filters will be disabled when this toggle is active. For more information on search criteria, see the DTX service definition.

#### To search for actors' historical versions

1. Activate the toggle **Include historical version** under *Results option*.

Search & view					
Actors					
Enable search filters	available for bulk XM	L download			
Name		Actor ID/SRN	VAT number	Role Manufacturer	× ~
Country	× ~	Competent Authority		× •	
Results option					
Search Genera	ite XML file	ar search			
ctive filters:	e: Manufacturer 🗶 <u>Cle</u>	ear search			

- 2. Enter your search criteria and click **Search**.
- 3. All actors' versions matching your search criteria will be listed in the search results section.
- 4. In the list of search results, each entry indicates whether it is the current version [Current] or a historical version [History], alongside the version number information:

Showing 1 to 20 of 593 e	entries			1	Show 20 V entries per pag
Actor ID/SRN 1칠	Version number 1월	Role 11	Name 11	Country It	Date of registration 11
UY-MF-000006427	2 [Current]	Manufacturer	VIVUNT PHARMA S.A.S. [All languages]	Uruguay	2024-04-25
UY-MF-000006427	1 [History]	Manufacturer	VIVUNT PHARMA S.A.S. [All languages]	Uruguay	2024-04-25
UY-MF-000005447	1 [Current]	Manufacturer	MEGA LABS S.A. [All languages]	Uruguay	2024-01-17
US-MF-000007907	1 [Current]	Manufacturer	ABQ Pharmaceuticals [EN]	United States	2024-08-30
US-MF-000007349	1 [Current]	Manufacturer	actor sdxydu [EN]	United States	2024-07-09
US-MF-000007348	1 [Current]	Manufacturer	actor cynylg [EN]	United States	2024-07-09
US-MF-000007347	1 [Current]	Manufacturer	actor bhvsyc [EN]	United States	2024-07-09
US-MF-000007167	1 [Current]	Manufacturer	TEST MF NON-EU ELS [All languages]	United States	2024-06-27
US-MF-000005407	1 [Current]	Manufacturer	La Vie En Rose [All languages]	United States	2024-01-15
US-MF-000005389	1 [Current]	Manufacturer	La Vie En Rose [All languages]	United States	2024-01-15
US-MF-000005068	2 [Current]	Manufacturer	DROGUERIA AMERICANA S.A. [All languages]	United States	2023-12-01
US-MF-000005068	1 [History]	Manufacturer	Ohio Pharmaceuticals [All languages]	United States	2023-12-01
US-MF-000004107	2 [Current]	Manufacturer	Ohio Pharmaceuticals [All languages]	United States	2023-08-04

### View Actor data – historical versions

### ▶ VIDEO: View historical version of an actor



To see the historical version(s) of an actor:

1. Click the relevant entry in the results list:

nowing 1 to 20 of 122	2 entries			Sho	w 20 🗸 entries per pa
lctor ID/SRN ∔≟	Version number	Role Iî	Name 11	Country 11	Date of registration 1
	1 [Current]	Manufacturer		Belgium	2023-06-19
	1 [Current]	Manufacturer		Belgium	2023-06-15
	1 [Current]	Manufacturer		Belgium	2023-05-24
	1 [Current]	Manufacturer		Belgium	2023-05-12
	1 [History]	Manufacturer		Belgium	2023-05-05
	2 [Current]	Manufacturer		Belgium	2023-05-05
	1 [Current]	Manufacturer		Belgium	2023-05-04
	1 [Current]	Manufacturer		Belgium	2023-04-25
	1 [Current]	Manufacturer		Belgium	2023-04-21
	1 [Current]	Manufacturer		Belgium	2023-04-20
	1 [Current]	Manufacturer		Belgium	2023-04-19
	1 [Current]	Manufacturer		Belgium	2023-04-19
	1 [Current]	Manufacturer		Belgium	2023-04-14
	1 [Current]	Manufacturer		Belgium	2023-04-13
	1 [Current]	Manufacturer		Belgium	2023-04-12
	1 [Current]	Manufacturer		Belgium	2023-04-05

2. Inside the current version, you can navigate between the versions (if more than one) using the **See version history** button:

Actor Data Aersion 3 [Current] See version history Last updat	date: 🗮 2023-03-30	
Actor identification		
Role:		
Actor ID/SRN:		
Country:		
Actor / Organisation name:		
Abbreviated name:		
VAT information:		
VAT number:		
EORI number		
National trade register number:		
Last confirmation date of actor data accuracy:	-	

3. A list of the different versions will display:

Go back to the current version	
/ersion 2 - Last update date: 2023-03-30	
/ersion 1 - Last update date: 2023-03-30	

4. Clicking on one of the list items will open up that version and will also provide navigation buttons to allow easy switching between the versions:



### 2.1.5 Link a non-EU manufacturer to an importer

Section specific to importers with Linker, LAAor LUA profiles

To link a non-EU manufacturer to your importer:

1. Open the Dashboard:

		CURRENT ACTOR: Importer
Welcome to EUDAM	ED	
MDR EUDAMED is the IT system developed b Regulation (EU) 2017/745 on medical devices diagnosis medical devices.		
MDR EUDAMED is structured around 6 interco	onnected modules and a publi	c sito.
Tasks		
By module, consult, verify and/or manage your	r own and related data (mana;	ed by your actor), depending on your profile.
	User management	
My Actor data	Assess user access request	k
	Manage your users	
Manage your actor data.		
Manage your email notifications		
Link to non-EU manufacturer		

2. Click *Link to non-EU manufacturer* in section *My Actor*. You will arrive at the page displaying linked non-EU manufacturers (if there are no linked manufacturers, this list will be empty):

European Commissio	EUDAMED		English 😱
European Commission > EUDAM	10		
Home Tasks 🗸 Se	arch & view 🗸 🛛 Help 🗸		1 Standardshiller Logout
		CURRENT ACTOR: Importer	[Beigium] Switch actor #Notifications
View linked no	n-EU manufacturers		Add a new menufacturer
SRN Nar	we Country	Start date	End date
		No data available	

- 3. Click Add a new manufacturer.
- 4. If you know the Actor ID/SRN, enter it and click **Find** to select the manufacturer.

Link a non-	-EU manufacturer with your importer
✓ I know the SRN	í
SRN:	
Find	

5. If you don't know the Actor ID/SRN, uncheck *I know the Actor ID/SRN*. Two new fields will appear:

Link a non-EU manufacturer with yo	ur importei
□ I know the SRN	
Country:	
Australia -	
Actor / organisation name:	
Find	

6. Enter the country and actor/organisation name, and click **Find**. You will see a list of results based on your search criteria:

Link a non-EU manufacturer with your organisation	
□ I know the SRN	
Country:	
Afghanistan -	
Actor / organisation name:	
Find	
Result	
Select your actor from the list below	
Afghanistan - Manufacturer - Actor code: AF-MF	^
, Afghanistan - Manufacturer - Actor code: AF-MF-	^

7. Select the actor you want from the list. You will see the detail page for that actor:

Find	
Result	
Select your actor from the list below	
Afghanistan - Manufacturer - Actor code: AF-MF-	•
Afghanistan - Manufacturer - Actor code: AF-MF-	•
SRN:	
AF-MF-	
Role:	
Manufacturer	
Country:	
Afghanistan	
Organisation name:	
Range rente program allest agree	
Address:	
Research and the second s	
Email:	
and a grant set of the	
Telephone number:	
-	
Add link with this manufacturer	

8. Click Add link with this manufacturer. You are prompted to enter the relevant dates:

Add link with this manuf	acturer		
Enter the start date to	link with this manufa	cturer	
* Start date:		End date:	
	<b>m</b>		Ê
YYYY-MM-DD		YYYY-MM-DD	1
Confirm	Cancel		
9. Enter a start-date (and end-date if known), then click Confirm.

# 2.1.6 Updating Actor details

Section specific to Local Actor Administrators (LAA)

Once an Actor has been validated by its Competent Authority and obtained an Actor ID/SRN, changes to the Actor details can only be made by a Local Actor Administrator of this Actor.

### To update actor details

- 1. Log in to EUDAMED with a Local Actor Administrator profile for the actor in question.
- 2. In your dashboard, select Manage your actor data under My Actor data:

Welcome to EUDAMED						
MDR EUDAMED is the IT system developed by the European Commission to implement Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices.						
MDR EUDAMED is structured around 6 interconnected modules and a public site.						
Tasks						
By module, consult, verify and/or manage your own and related data (managed by your actor), depending on your profile.						
User management						
My Actor data Assess user access requests						
Manage your users						
Manage your actor data						
Manage your email notifications						
Machine to machine data delivery preferences						

3. You can browse through the sections to review the information currently available about the actor:



4. If you need to change some information, proceed as follows:

- a. Click on Actions.
- b. Click *Create new version* and answer **Yes** to the confirmation message.
- c. Make all required changes in the corresponding tabs.
- d. When you are done, click **Register new version** and answer the confirmation message.

The changes apply immediately. The new version number displays, and the current version is identified:

Manufacturer, BE-MF- , BE-MF [Bel				
	My Actor data	My Actor	data	
	Competent Authority	Version 2 [Current]	Last update date: 🗮 2020-08-20	

# Delete an actor's draft

To delete a version in draft, on the homepage, click on Manage your actor data:

Welcome to EUDAM	ED							
	MDR EUDAMED is the IT system developed by the European Commission to implement Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices.							
MDR EUDAMED is structured around 6 interconnected modules and a public site.								
Tasks								
By module, consult, verify and/or manage you	r own and related data (managed by your actor), deper	ding on your profile.						
	User management	UDI-DIs/Device						
My Actor data Assess user access requests Register a new Basic UDI-DI								
	Manage your users	Register a legacy device						
Manago your actor data		Manage your Basic UDI-DIs / EUDAMED DIs						
Manage your actor data Manage your email notifications		Manage your device details						
Machine to machine preferences								

1. You can delete the draft by clicking on **Delete draft version**. Click **Yes**, and you will be redirected to the following window:

Home	Tasks 🗸	Search & view 🗸	Transmission 🗸	News	Help 🗸			👤 MF (Co	ONFIRMER)	Logout
				CUR	RENT ACTOR: Manufa	cturer, NL-MF-0000	00041, Johr	nson & Johnson Medical [Ne	etherlands]	otifications
Crea	te new	version of n	ny actor da	ta						
Manu	facturer,	Johnson & Jo	ohnson Medie	al [Ne	etherlands]					
Version 2 [	Draft]									
						Save		Register new version	Delete draft	veligion
Actor	identifica	ation								
Role:		Manu	facturer							
Country	:	Nethe	rlands							
* Actor / Or	ganisation name	9:	* Select the languag	Ð:						
Johnson	& Johnson Medi	ical	All languages	~ ~						

2. A pop-up message asking you to confirm your decision:

Confirm deletic		ctor data ctor data. All data provided for this	version will be lost.	× <u>Close</u>
Delete	Cancel			

3. Once you click on **Delete**, the draft is deleted.

# 2.1.7 Confirm Actor data accuracy

# VIDEO: Confirm actor data accuracy



Economic Operators registered in EUDAMED, are required by regulation MDR Article 31§5/ IVDR Article 28§5 to confirm their data accuracy.

This action can only be done by an LAAeither by creating a new version of the Actor or directly confirming the current data.

### Method 1: Confirm the current data

To confirm your Actor data accuracy for the current version, on the homepage of EUDAMED click on *Manage your actor data*:

	User management		CI/PS
Actor data	Assess user access requests	🧋 2	Search and manage application/notification
	Manage your users		Register CI/PS application or PMCF/PMPF notification
lata			

1. In the new window, click **Actions** on the side and then on **Confirm data accuracy**:

My Actor data Version 7 [Current] See version history Last update da Actor identification	te: 🗮 2023-06-20	Create new version Set status to Inactive Confirm data accuracy
Role:	Sponsor	
Sponsor type:	Company	
Actor ID/SRN:		
Country:		
Actor / Organisation name:		
Abbreviated name:		
VAT information:	No	
EORI number		
National trade register number:	· · · · · · · · · · · · · · · · · · ·	
Organisation identification document:	•	
Last confirmation date of actor data	2023-06-16	
accuracy:	View accuracy confirmation history	^

2. A pop-up message will appear asking you to confirm your actor data accuracy:



- 3. Click **Yes** to confirm or **Cancel** to go back.
- 4. Once you have clicked **Yes**, you will notice the latest *accuracy confirmation* date has changed to the latest one:

Last confirmation date of actor data	2023-06-20	
accuracy:	View accuracy confirmation history	^

5. You can also click on the drop-down list to display the rest of the preceding dates the Actor details were last accuracy confirmed:

View accuracy confirmation history	~
2023-06-20	
2023-06-16	
2023-06-16	
2023-06-14	
2023-06-14	
2023-06-14	
2023-06-14	

### Method 2: Create new version

1. On the homepage of EUDAMED, click on *Manage your actor data*:

	User management		CI/PS
My Actor data	Assess user access requests	🧳 2	Search and manage application/notification
	Manage your users		Register CI/PS application or PMCF/PMPF notification
our actor data			nouncation

2. In the new window, click on **Actions** and then click on *Create new version*:

Wy Actor data         Version 7 [Current]       See version history         Last update date:       2023-06-20	Create new version
Actor identification	Set status to Inactive Confirm data accuracy
Role:	
Sponsor type:	
Actor ID/SRN:	
Country:	
Actor / Organisation name:	
Abbreviated name:	
VAT information:	
EORI number	
National trade register number:	
Organisation identification document:	
Last confirmation date of actor data accuracy: View accuracy confirmation	on history

3. Once you are done updating the details of the new version, click on **Register new** version:

Create new version of r	ny actor data			
Version & [Draft]		Sav	re <u>Register new version</u>	Delete draft version
Actor identification				
Role: Country: Sponsor type:				

4. The pop-up message will ask you to confirm the new version. You can check the tick-box which will confirm the Actor data accuracy after clicking **Confirm**:

Once registere actor	ed, this draft will become the latest version of this
_	option below, the 'Last confirmation date of actor data accuracy' will be updated for this actor.
I confirm the actor da Do you confirm?	ita accuracy

5. This can be seen in the Accuracy confirmation history part of My Actor data:

My Actor data Aersion 8 [Current] See version history   Last updat	Action	<u>s</u> .•
ension o (currend) <u>See version instory</u>   Last updat	e date. 🔤 2023-00-20	
Actor identification		
Role:		
Sponsor type:		
Actor ID/SRN:		
Country:		
Actor / Organisation name:		
Abbreviated name:		
VAT information:		
EORI number		
National trade register number:		
Organisation identification document:		
Last confirmation date of actor data	2023-06-20	
accuracy:	View accuracy confirmation history 🗸 🗸	
		_
	2023-06-20 2023-06-20	
	2023-06-16	
	2023-06-16	
	2023-06-14	
	2023-06-14	
	2023-06-14	
	2023-06-14	



# NOTE

Note that the act of creating an Actor is not a confirmation of its data accuracy. If this action is performed right after the Actor is created, the accuracy confirmation date will also match the date the creation of the Actor took place.

# 2.1.8 Activate/deactivate your Actor

This section is for LAA profile only

As an LAA of an Active Actor (*Active* being the default status of your Actor upon registration) you can indicate that your Actor is no longer Active from *My Actor data* > *Manage your actor data*:

Tasks					
According to your profile per module, consult, verify and/or manage your own and related data (managed by your actor)					
	User management	UDI-DIs/Device			
My Actor data	Assess user access requests	Register a new Basic UDI-DI			
	Manage your users	Register a legacy device			
		Manage your Basic UDI-DIs / EUDAMED DIs			
Manage your actor data Manage my mandates		Manage your device details			



### NOTE

An actor CANNOT change its status to *Inactive* if they have Actor data in draft, OR if they have submitted a *Change of Competent Authority request*.

# Set your status to Inactive

1. On the right side of the screen, click on Actions:

Manufacturer, BB-MF-000001065, ARMEN 2.7 BARBADOS MANUFACTURERs [Barbados] My Actor data Authorised Representative

2. Click on Set status to Inactive:

Create r	new version
Set stat	us to Inactive



### NOTE

By changing your status from *Active* to *Inactive*, a new Actor data version will be created reflecting your new status.

3. In the new window, toggle the button from Active to Inactive:



4. Select the date from when this actor is no longer *Active*:

110	m da	ate:				
YYYY	-MM-I	DD				
From	date:					
2022	-11-24	-	Ē			
Nov	/ 2022	•		<	Today	>
	-	We	Th	5-	0.0	0
Mo	Tu	VVC		Fr	Sa	Su
<b>Mo</b>	01	02				
31	01 08	02	03	04	05	06 13
31 07	01 08 15	02 09	03 10	04 11	05 12	06 13 20

Selecting a date in the future	is not allow
* From date:	
2022-11-26	ä
YYYY-MM-DD	
O The date should in the future	not be

5. In the *Reason* box, write the reason why the actor is inactive:

Reason:		

6. Once you are done, click on Register new status:

Register new status	Cancel
---------------------	--------

7. In the new pop-up window, click on **Confirm**. Upon confirmation, your new status will be reflected in *My actor data* page and in other screens next to your Actor ID/SRN:

× Change actor status	lose
You are about to set your Actor's status to Inactive	
A new Actor data version will be generated to reflect the new status. Your Competent Authority will be notified and your Inactive status will be displayed in both public and private EUDAMED searches.	
Please confirm your status change.	
Cancel	



# NOTE

Setting your status back to *Active*, can be done at any time from *Manage your Actor data*.



### NOTE

When your status is already *Active*, you will not see any *Status bar* in your Actor data.

# 2.1.9 Change a Competent Authority for registered actors

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

- An EU Economic Operator that moves within the same country;
- A non-EU manufacturer that changes its Authorised Representative or its Authorised Representative changes the responsible Competent Authority;

• A non-EU SPP producer that changes the market distribution of their SPPs.

For the non-EU manufacturers, their responsible CA must be at any moment one of the responsible CA(s) of the AR(s) with which they have an active mandate.

1. On the homepage of EUDAMED, click on *Manage your actor data*:



2. In the new page, click on **Actions** and then choose *Change competent authority*:





# NOTE

If a request for *Change competent authority* has already been submitted, no further editing of the actor data is allowed till the change is either accepted or rejected.

If a draft has already been created, the competent authority cannot be changed.



# NOTE

You will notice the change request in your actor data. The section *Competent Authority*, will display two parts, *Current competent authority* and *New competent authority*:

3. In the new window, you will notice an almost exact copy of your actor data form, with one exception. At the bottom of the page, the section *Select a new Competent Authority* displays. Choose your new competent authority from the dropdown list:

	rity change request <sup>-</sup> for DEMOs [Belgium]
Role:	Manufacturer
Country:	Belgium
* Actor / Organisation name:	* Select the language:
BE MF for DEMOs	All languages 🗙 🗸
Add name in another language	
Abbreviated name:	Select the language:
	× •
Add abbreviated name in another	language
Competent Authority	
9 You requested a change of Competent Authority. You must select the new	Competent Authority and provide a reason in order to submit your request.
Current competent authority	
Eudamed Actor ID:	
* Select a new Competent Authority:	
DG SANTE CA Schweizerisches Heilmittelinstitut/ Swiss Agency for Therapeutic Products New Release Test Playnmund Orn	



ARMEN BE CA

# NOTE

Agence Fédéral en es Medicaments et des Produits de SanteFederaal Agentschap voor Geneesmiddelen en Gezondheidsproducten

For non-EU manufacturers, the results in the dropdown list are determined by the responsible Competent Authorities of the Authorised Representative(s) they have an active mandate with.

4. Once you have selected a new competent authority, enter the reason for the change in the *Reason for change CA* field:

R	× •
Eudamed Actor ID:	
Role:	
Country:	
Actor / Organisation name:	
Address:	
Email:	
Telephone number	
Reason for change CA:	

5. Click on Submit request:



6. A pop-up message will appear, click **Confirm** or **Cancel** to go back:

Competent authority change request	×Close
<ul> <li>Your request to change the Competent Authority will be submitted for validation.</li> <li>If validated, you will receive a notification and your Actor data will automatically be updated.</li> <li>While awaiting validation you will not be able to create a new actor's data version.</li> <li>If rejected, you will be notified, with further instruction.</li> </ul>	
Are you sure you want to proceed?	
Confirm	

7. A success message will appear, non-EU manufacturers need to wait for the concerned Authorised Representative to assess the CA change request:



### To see your pending/rejected competent authority change requests:

- 1. On the homepage of EUDAMED, click on Manage your actor data:
- 2. If you have any pending/rejected requests, they will be accessible via the link found in the notice message.

Pending request message:



3. Once you have clicked on the link, you will arrive to an overview of your change request:

Reason for rejection and other details:

Application ID:	
Assessment outcome:	Rejected
Assessor CA Actor ID:	
Reason for rejection:	This request is rejected because
Date of rejection:	2023-03-31

# 2.2 Users and user access management

# 2.2.1 Request access as a user to a registered actor

INFOGRAPHIC: User access request process



When an actor is already registered in EUDAMED, a person who needs to act on their behalf, must request access and choose (an) appropriate user profile for each of the relevant EUDAMED module(s) that are available to them.

### To request access as a 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:



3. Alternatively, if you are logged in with a EUDAMED user account and you need to request access for a a different actor, 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:

Home	Tasks 🗸	Search & view 🗸	Help 🗸		1	MedicalDev Thirtyeight	Logout
				CURRENT ACTOR: Manufacture	er, /	19 (19 (19 (19 (19 (19 (19 (19 (19 (19 (	lotifications
Mv a	ccount(	(s)					
iviy a	coound	.0)					
			Build all her Thirty				
My EUDA	MED accounts						
			EU Login details				
			Login code:	(Construction)			
			First name:				
			Last name:				
			Email:				
			Preferred Language:	Cogeno			
			EUDAMED details				🖉 Edit
			First name:				
			Last name:	(minimum)			
			Preferred Language:	())))))			
			My EUDAMED acc	ounts			
			Current actor accoun	t			
			Actor data				
			Actor identification				View all data
			Role:	Manufacturer			
			SRN:	at all deservices			
			Actor / organisation name:	(d) (d) (the trajectory)			
			Abbreviated name:	-			
			Street:	-			
			Street number:	-			
			Address line 2:	-			
			PO box:	-			
			Postal code:				
			City:				
			Country:				
			Email:				
			Actor notification email address	es			Modify
			× Notification deactivated  ✓ Notificat	ion requested			
			Actor Data:	✓ (())			
			Account data				
			Profile(s)			E Reques	st for change
			Actor:	Local Actor Administrator			
			Account email & notifications				Modify
			X Notification deactivated 🗸 Notificat	ion requested			
			My contact email for this actor:				
			Actor Data:	✓ -	1		
			See my pending requests		Now access rates	Now eater register	ion roquest
			oce my penuing requests	I	New access reque	New actor registrat	ion request
				L			

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

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

- 4. If you know the Actor ID/SRN(e.g. BE-MF-000000001), check *I know the actor's* Single Registration Number (SRN) or EUDAMED Actor ID.
- 5. If you don't know the Actor ID/SRN, you can find the actor by searching with: *role*, *country* and *name* (or part of it).
- 6. Click **Find**. The list of matching actors is displayed in the *Result* section.

requests and manage the user accounts of an organisation.	
Search existing actor	Result Select your actor from the list below
Enter your actor data to check if an actor already exists for your company I know the Actor's Single Registration Number (SRN)	- Manufacturer - Actor code:
* Role:	BE
Manufacturer	Role: Manufacturer
* Country:	Country:
Belgium	Belgium Organisation name:
* Actor / organisation name:	61 EL A
bel	Address:
Find	Email:
	Telephone number:



# NOTE

If you can't find your actor from the search page, please contact them to confirm their Actor ID/SRN. They may have registered with a different name or may have not completed the registration yet.

If you search for a registered actor to which you already have access, the system will display a warning message, preventing you from proceeding further.

The Local Actor/User Administrator of the organisation for which you a user requests and manage the user accounts of an organisation.	re requesting access is empowered to validate the
Search existing actor Interyour actor data to check if an actor already exists for your company I know the actor's EUDAMED Actor ID/Single Registration Number (SRN) Actor code: BE-MF-00000924 Find	Result Select your actor from the list below Manufacturer, BE-MF-000000924, ARMEN 2.4 EU MANUFACTURER (Belgium) ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓

However, if you search for an actor for which you initiated a *Draft* user access request, or for which a *Submitted* user access request exists, there will be no warning. To view this user access request, click your name at the top right of the page and then select *See my pending requests* at the bottom of your EUDAMED user account detail page.

7. Select the desired actor in the *Result* panel, and then click **Request access to this actor**. *Step 1* of a three-step process appears:

New access request			
Selected actor information	1 My personal data	2 My user manager	3 My profile(s)
Role: Manufacturer	My contact email for this * Email:	s actor 🕄	
Country: Belgium Organisation name:	* Are you a sub-contractor	for this actor?:	
Address:	O No O Yes		
Email: Telephone number:	Save	Save & Next 🗲	Cancel
- Select another actor			

- 8. Complete Step 1:
  - a. Enter your contact/notification email address related to this request.
  - b. Indicate whether you are a sub-contractor for the selected actor. If you select **Yes**, you will be prompted to enter details of the sub-contractor.

9. Click **Save & Next**. *Step 2* appears. Here you must identify a manager in your organisation who can authorise your request:

New access request			
Information of the actor selected Actor code: IT-MF-00( Role:	My personal data	2 My user manager	3 My profile(s)
Manufacturer Country: Italy	User manager * First Name:		* Last Name:
Actor/Organisation name: Address:	* Function/Position:		
Email:	Save	Save & Next ▶	Cancel
	Save	Save & Next	Cancer

10. Enter the name and function/position of your manager, and then click **Save & Next**. *Step 3* shows a list of possible user profiles for each module:

Information of the actor selected SRN:	My personal data	My user manager	3 My profile(s)
80.CA.889	My profile(s) for this a	ctor	
Role: Country:	Each profile is associated with a spe Choose the profile(s) you nee		es include - and extend - the grants of the lower ones
Belgium Organisation name: Address: Email: Phone number:	Actor  Active until		
	End date:	<b>**</b>	
	Save	Submit <b>&gt;</b> Pre	Cancel

The profiles available depend on the actor role.

The default minimum profiles for your actor are pre-selected.

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



- 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. A summary of your access request is displayed.
- 14. Review the information and click **Submit** at the bottom of the preview page. A confirmation page appears:



15. Click **Submit my request**. 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 refused.

• If **refused**, you can click the *View access request* link under the three dots, next to the pending request, to read the reason provided by the LAA/LUA. You can then change and re-submit as appropriate.

My pending/refused i	requests					
You can view the status of your requests below						
EU Login details	My acces	s requests for an exis	ting actor			
Name: Commentation	Role I1	Name It	City If	Date of request 4	State	Actions
Username: <b>Contractor</b> Email: <b>Contractor</b>	Manufacturer	Medical Device Manufacturer	Amersfoort	2024-03-22	Refused	
EUDAMED details		_			View	v access request
Name:	New access re-	quest			_	
	You do not have	any pending actor registration reques	ts for the moment			
	New actor re	gistration request				
Last name:						
Function/position:	•	-				
Punction/position.						
Validity date for the EUDAMED ac	count					
End date:						
STEP 3 Profile(s)			0			~
Certificate:		Viewer				
UDI/Device:		Viewer				
Actor:		Local User Administrator		ð		
Actor:						
Assessment of user data						
Outcome:		Refused request				
Remarks:						

• 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 connected to your account. Read the disclaimer and check *I accept the user rights and obligations*:

Home	Tasks 🗸	Search & view 🗸	Help 🗸	
User	rights a	and obligati	ions disclaimer	
🚹 Ac	tor/organisation	name -	ownload disclaimer	
I acc	cept the user rig	hts and obligations		
I	Next			



NOTE

# Working for multiple actors?

If you have multiple EUDAMED user accounts for different actors, after having logged in you may switch to another actor for which you may act on behalf by clicking **Switch actor** at the top right of the screen:



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

Home	Tasks 🗸	Search & view 🗸	Help 🗸		1	Logout
				CURRENT ACTOR:	Switch actor 📢	Notifications
My a	ccount(	s)				
1		,				
	8		(and the second			
My EUDAI	MED accounts		EU Login details			
			Login code:			
			First name:	600 C		
			Last name:	0.00		
			Email:	(net) geneticate can		
			Preferred Language:	Cogilia		
			EUDAMED details			🖉 Edit
			First name:			
			Last name:	0.00		
			Preferred Language:	Crights		
			My EUDAMED a	ccounts		
			Current actor acco	punt		
			Actor data			
			Actor identification		۲	View all data
			Role:	Manufacturer		
			SRN:	at all second and		
			Actor / organisation name:	(001: (00))		
			Abbreviated name:	-		
			Street:	desiries de l'Universitation		
			Street number:	0		



# NOTE

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

# 2.2.2 Validate user access requests

Section for Local Actor Administrators and Local User Administrators

Anyone with an EU Login account can request access to a registered Actor, but only a user with a *Local User Administrator* (LUA) or a *Local Actor Administrator* (LAA) profile can validate these requests.

The Actor's LAAs and LUAs will be notified of all new or updated incoming users access requests.

### To validate an access request

- 1. Log in to EUDAMED.
- 2. From your dashboard, select *Assess user access requests* (in the *User management* section):



The *Pending requests* tab on the *Users management* page lists all pending user access requests for your Actor:

Users management						
Pending requests Registered users Refused requests/users						
Filter 🔻						
Type of request						
Apply filters Clear all filters						
Active filters: No selection						
Showing 1 to 3 of 3 entries			Show 20 v entries per page			
EU Login email I†	Type of request	Date of request 11	Actions			
mf.nl.ad@dgsantedev.eu	New account	2024-03-22				
mf2.nl.ad@dgsantedev.eu	New account	2024-03-21				
li.mf.confirmer.1@dgsantedev.eu	New account	2023-04-05				

3. Click **Assess access request** in the *Actions* column to view and assess a request from the list. Part 1. of the access request is displayed:

Assessment - part 1:	User Data
Actor identification Organisation name: " ^ SRN: AL- Address: Telephone number: - Email:	
User information	
EU Login ID	
ID:	
Contact email for the actor	
Email:	
Are you a sub-contractor for this	actor?
Sub-contractor:	No
User manager	
* First name:	
* Last name:	0
* Function/position:	0
Validity date for the EUDAMED ac	count
End date:	

- 4. Review the information in Part 1. of the request.
- 5. In the *Assessment* section, slide the toggle left to **Approve** the request, or right to **Reject**.
  - If you select **Approve**, click **Next step**.
  - If you select **Reject**, you must add a comment and select one of the following reasons:

Incomplete and/or details to correct:	Some information is either missing or looks incorrect. The requesting user will have a chance to correct or complete the request following your instructions and re-submit the request.
Refused request:	The request will be refused, and the requesting user is not invited to re-submit.

Approve Reject
* Type of reasons:
○ Incomplete and/or details to correct
○ Refused request 🔒
Please be aware that you must inform us at SANTE- EUDAMED-SUPPORT@ec.europa.eu if you suspect that this is a fraudulent access request
* Remarks:
1
Reject Cancel

This ends the steps you need to follow to reject a request (ignore steps 6-8 below). The rejected request is listed in the *Refused requests/users* tab:

Users management			
Pending requests Registered users Refused requests/users			
Showing 1 to 3 of 3 entries			Show 20 v entries per pag
EU Login email 1†	Type of request	Date of request It	
mf.nl.ad@dgsantedev.eu	New account	2024-03-22	
mf.nl.ad@dgsantedev.eu mf2.nl.ad@dgsantedev.eu	New account	2024-03-22 2024-03-21	

### 6. If you decided to approve, click **Next step**.

Assessment of us	er data
Outcome:	
Approve	Reject
<u>Next step</u>	Cancel

A table is shown with the user profiles for all available modules. The *Viewer* profile is automatically granted to each user for the Actors, UDI/Devices and NBs & Certificates modules:

Requested Pro	ofiles	
Profiles(s) for this a	actor	
For each module, se	elect the 'Approve' button to approve a profile of	r the 'Reject' button to reject a profile. The user has access by default to his/her own actor data.
		Approve all Reject all
CI/PS:	Confirmer	✓ Approve
Complete assessm	Cancel	

# NOTE Profile availability

The profiles available in the table depend on the actor role – e.g. if the user is requesting access for an authorised representative, the additional profile of *Verifier* will be available.

7. For each module in the table, click either **Accept** or **Reject**, and when you are done, click **Complete assessment**.

A summary is displayed of the user profile you have approved.

- 8. To confirm this user profile, click **Confirm** in the summary dialog box. You are informed that the access request has been properly assessed:
  - The status of the request will become validated.
  - The user is notified that their access request has been validated.

# 2.2.3 Terminate a user account

# Specific to Local Actor Administrators and Local User Administrators

When a EUDAMED-registered user leaves an organisation, changes their job function or is otherwise no longer involved in EUDAMED, should not have access anymore for this actor, the Local Actor Administrator (LAA) or Local User Administrator (LUA) can deactivate their account by marking it as *Terminated*.

An actor user with a terminated account can no longer act on behalf of this actor. If they need to regain the role at any time in the future they will have to submit a new access request for that actor.

# To terminate a user account

- 1. Log in to EUDAMED.
- 2. Select *Manage your users* in the *User management* section of your dashboard.
- 3. On the *User management* page, select the *Registered users* tab, and then click on the user in question:

Pending requests Registered users	8		
Active filters: No selection Showing 1 to 2 of 2 entries			Show 20 👻 entries per page
EU Login 11	EU Login email 🎝	Sub-contractor 11	End date ↓†
			-
MedicalDev Two			-

4. Click **Terminate** at the bottom of the page:

MedicalDev Two	
< Go back to Users management <u>Open all   Close all</u>	
EV Login	•
Name:	MedicalDev Two
Email:	anti-prototo an
Profiles	×
Actor:	Local Actor Administrator
Actor:	Mandate Manager
Actor:	Viewer
UDI/Device:	Viewer
Actor:	Local User Administrator
Email	^
End date	^
Terminate	

5. Confirm that you wish to complete the action. The user instantly loses access to this actor.

# 2.2.4 Edit your user account

After your user access request is approved, you can still change your account information.

### To edit your user account:

1. Log in to EUDAMED and click on your name in the upper toolbar. The page *My account(s)* appears:

Home Tasks ∨	Search & view 🗸 🛛 Help 🗸		Logout
		CURRENT ACTOR:	Switch actor
My account(s	)		
	collection francism		
My EUDAMED accounts	EU Login details		
	Login code:		
	First name:	000	
	Last name:		
	Email:		
	Preferred Language:	colima	
	EUDAMED details		🖉 Edit
	First name:	<u></u>	
	Last name:	0.00	
	Preferred Language:	6980	
	My EUDAMED		
	Actor data		
			View all data
	Actor identification		
	Role:	Manufacturer	
	SRN:	ar ar contains	
	Actor / organisation name:	(BBR (999)	
	Abbreviated name:	-	
	Street:	desired at 10 met-allow	
	Street number:		

2. To change any editable data in the EUDAMED details, click **Edit**: **EU Login details / EUDAMED details** 

John Smith		
EU Login details		
Login code:	(Section 1)	
First name:		
Last name:	000	
Email:	and a second second second	
Preferred Language:		
EUDAMED details		🖉 Edit
First name:		
Last name:		
Preferred Language:		

Use the **Edit** button in this section if you want to change your first name, last name and/or preferred language.

Current actor account: actor data

Current actor accou	nt	
Actor data		-
Actor identification		View all dat
Role:	Press Contractor	
SRN:	Contraction and the	
Actor / organisation name:		
Abbreviated name:	-	
Street:	-	
Street number:	-	
Address line 2:	-	
PO box:	-	
Postal code:		
City:	dentality	
Country:	Official	
Email:	Server .	
Actor notification email addres	ses	Modif

A LAA has the **Modify** button in this section. Using this button, the receiving email address for notifications can be changed, including those for the different EUDAMED modules.



► The **Modify** button is not active here for any other user profile.

Current user actor account for this actor: Account data

Account data Profile(s)		Equest for change
Actor:	Administrator	
UDI/Device:	Viewer	
Account email & noti	fications	Modify.
	✓ Notification requested	Modify.

Use the **Request for change** button in this section if you want to request a different profile for one or more EUDAMED modules for the current actor.

Use the **Modify** button if you want to change the account email and/or the notification preferences for the current actor.

- 3. Make any required changes.
- 4. Click Save.
- 5. If you are registered with more than one actor, they are listed in the *My other account(s)* box:

My other account(s)



Click the right-pointing arrow next to one of the actors in the list to show their details. You can switch between actor accounts.

# 2.2.5 Upgrade your user profile

1. Log in to EUDAMED and click your name in the upper toolbar to reach the *My account* page.

Account data Profile(s)		Request for change
Actor:	Administrator	
UDI/Device:	Viewer	
Account email & notifi		Modify
X Notification deactivated		
My contact email for this	s actor:	

 Click Request for change next to your profiles and follow the steps to select the profiles for the module you require. If this button is missing, it means you have already submitted a request that is still under assessment – if this is the case, you can view your pending requests via the See my pending requests link at the bottom of the page.

Choose the profile(s) you		clude - and extend - the grants of the lower ones.
Actor	UDI/Device 6	NB & Certificates
Local Actor Administrator     Local User Administrator     Viewer	Confirmer Proposer	🖸 Varoer
Vigilance		
Confirmer Proposer Verwer(Fat) Verwer(Sim)		
Active until		
<b>O</b>		

3. An LAA/LUA must approve this request before these profiles are assigned to you.

# IMPORTANT An LAA/LUA cannot approve their own requests. This means that for any actor with only ONE user, a second user with LAA/LUA profile will be needed to approve any profile upgrade requests. It is good practice for each actor to have at least two users with an LAAprofile. EUDAMED requires that an actor retains one LAA, so you will be unable to terminate the last user's LAAprofile.

- 4. If you are the only user from your actor, you will need to grant access to a new user, assigning an LAA/LUA profile via the process outlined in Sections *Requesting access* as a user to an existing different actor and Validating Economic Operator access requests.
- 5. Once you have approved access for this second LAA/LUA, this user will then be able to approve your request to upgrade your profile.

# 2.2.6 Switch between actors

If you have multiple EUDAMED user accounts for the same EU Login account, you can switch easily between them (and the different actors associated with them).

1. Go to the Dashboard:



2. Click on **Switch actor** at the top right:



3. Select an actor from the list shown:

uniquean Commission ) EUCAARED	
Home Tasks 🗸 Search & v	lee v Help v Lagost
	CURRENT ACTOR: Manufacturer BE ARF 20 [Belgium] Settin ador: @Votifications
My Actors	
EU Login details Name: Usemane: Email:	Select your actor Select in the list which actor you want to work with BEL-123466-MAN-1 (Delphung) BEL-123466-MAN-1 (Delphung)
EUDAMED details	O         Manufacturer, EE MF-00001         BEL-123456-MAN-2 (Delgium)           O         Manufacturer, EE MF-00001         BEL-123456-MAN-4 (Delgium)
	Menufacturer, 8E-MF-0000

# 2.3 Manage mandates

# Specific to non-EU manufacturers and authorised representatives

When registering in EUDAMED, non-EU manufacturers are required to provide information on their mandate with an authorised representative.

If they have mandate(s) with other authorised representative(s), these must also be individually registered in EUDAMED, those mandates need to be verified by the concerned authorised representative.

Additionally, the Authorised Representative or the non-EU manufacturer can decide to **terminate** the mandate at any moment.



# INFOGRAPHIC: Mandates for AR/Non-EU Non-EU MF

# 2.3.1 Add a new mandate

Specific to non-EU manufacturer

# To add a mandate

1. Log in to EUDAMED and select *Manage my mandates* under the *My Actor data* section of your dashboard. The list of mandates that have already been created is displayed, with information on their current state.

View my mand	lates			
Manufacturer, AF	-MF-000(	Kighanistar)		Add a new mandate
Showing 1 to 6 of 6 entries				Show 20 - entries per page
Mandate ID 11	AR name 🏨	AR SRN IT	End date 11	State 11
MD-AF-BE-00000		BE-AR-00000	2020-06-08	Registered (Expired)
MD-AF-BE-00000		BE-AR-00000	2030-04-04	Terminated [MF]
MD-AF-BE-00000	100 100	BE-AR-00000	-	Registered
MD-AF-BE-00000		BE-AR-00000	-	Rejected



NOTE

Manage my mandates is available only to users with a *Mandate manager* or higher (e.g. LAA/LUA) profile for a registered non-EU manufacturer.

2. Select *Add a new mandate* at the top right of the list. The *Add a new mandate* page appears:

Add a new mandate
Manufacturer information Organisation name: SRN: Address: 1 Telephone number: - Email:
Select an authorised representative
I know the SRN
* SRN:
Find
Mandate validity dates
* From: To:
YYYY-MM-DD YYYY-MM-DD
* Upload mandate summary document Browse
Submit Cancel

- 3. If you know the Actor ID/SRNfor the Authorised Representative, enter it here, click **Find** and select from the results.
- 4. If you don't know the Actor ID/SRN, uncheck *I know the Actor ID/SRN*, enter the country and authorised representative name, click **Find** and select from the results.



NOTE

If you don't find your Authorised Representative from the search page, please contact them to confirm their Actor ID/SRN.

- 5. Specify the mandate's validity start-date (mandatory) and end-date (optional), if applicable.
- Click Browse, under Upload mandate summary document, to upload your summary mandate document – in PDF format only and not exceeding 10MB: A summary extract of the official signed mandate is enough, stating just:
  - · Start and end dates.
  - Names and addresses of the Manufacturer and Authorised Representative.
  - List of generic device groups covered by the mandate.

- Click here for the mandate summary template.
- 7. Click Submit.

The new mandate now appears in your mandate list, with the state *Submitted*. It must now be verified by the relevant Authorised Representative:

View my mand	ates			
Manufacturer,	<b>er</b> -200000002, 1954 (	Alghanistan]		Add a new mandate
Showing 1 to 7 of 7 entries				Show 20 - entries per page
Mandate ID 1†	AR name 1	AR SRN It	End date 11	State
MD-AF-BE-00000		BE-AR-00000	-	Registered
MD-AF-BE-00000		BE-AR-00000	-	<ul> <li>Submitted</li> </ul>

8. If you click on it, you will get an overview of your update, everything is visible from the *Authorised representative(s) mandates*, identified by the Actor ID/SRN of the Authorised representative, which will show as a clickable accordion:

BE-AR-000001064	$\overline{\mathbf{v}}$
Actor ID/SRN: BE-AR-000001064	
Role: Authorised Representative	
Country: Belgium	
Actor / Organisation name: ARMEN 2.7 EU AR ONE	
Address: 1231 Brux	
Email: ArmenFortyNine_eudamed@mailinator.com	
Telephone number: -	
Mandate validity dates From 2022-03-29 to -	

# 2.3.2 Create a new mandate version

# Specific to Non-EU manufacturers

### To create a new mandate version

1. Log in to EUDAMED and select *Manage my mandates* in the *My Actor data* section of your dashboard:



# 2. Select the mandate from the list:

uropean commits	ion > EUGAMED > You my mandates			
lome Task	a v Search & view v News	Help 🗸		🛔 Name Lopou
			CURRENTACTOR Manufacture	apan) OtherNew account
View my Manufacti	/ mandates urer,			O Add.o.may.mandah
Application ID	AR name	AR SRN	End date	State
125	Authorised representative name		Central	Registered
10	Authorised representative name			Terminated [AR]
D	Authorised representative name			Submitted
10	Authorised representative name			<ul> <li>Registered (Expired)</li> </ul>
ID.	Authorised representative name			Terminated [MF]
155	Authorised representative name			<ul> <li>Rejected</li> </ul>

3. In the new window, where you can see details of the mandate, select **Create new version** at the bottom of the page:

Mandate with
< Go back to list of mandates
Version 1 [Registered] 🗎 2020-08-17
Manufacturer identification
Organisation name:
SRN:
Address:
Telephone number: -
Email:
Authorised representative information
Organisation name:
SRN
Address:
Telephone number: -
Email:
Mandate validity dates
From 2020-07-29
To
Mandate summary document
🖺 🐂 pdf
Create New Version Terminate mandate
< Go back to list of mandates

4. Upload the new mandate summary document (in PDF only and not exceeding 10MB) and change the validity dates accordingly.

# 2.3.3 Verify mandates

Specific to authorised representatives with a Verifier or higher profile

### To verify a mandate

1. Log in to EUDAMED and select *Manage your mandates* in the *Actor management* section of your dashboard:

Welcome to EUDAM	ED				
MDR EUDAMED is the IT system developed by the European Commission to implement Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices.					
MDR EUDAMED is structured around 6 interco	nnected modules and a public site.				
Tasks By module, consult, verify and/or manage your	own and related data (managed by your actor), de				
My Actor data	My Actor data				
	Assess user access requests Manage your users	Verify actor registration requests Manage your mandates			
Manage your actor data					
Manage your email notifications					

If any registered manufacturer(s) have uploaded new mandates designating your actor as the associated Authorised Representative, they are listed in the *Pending mandates* tab:

Mandate ma	anagement				
Pending mandates	egistered mandates				
Filter 🔻					
Active filters: Status: Submitted CI	ear all filters				
Showing 1 to 3 of 3 entries	5			Show	20 👻 entries per page
Mandate ID 11	MF name 1	MF SRN 4	Country It	State 1†	End date ‡†
		AF-MF-000000	Afghanistan	Submitted	2020-04-04
MD-AF-BE-0000	(67)	AF-MF-000000	Afghanistan	Submitted	2020-08-27

2. Click on the mandate you want to verify in the *Pending mandates* list. The details of the concerned mandate are displayed. The mandate summary PDF is available under *Mandate summary document*:

Mandate validity dates
From: 🗮 2020-08-05
То: 🗰 2020-08-27
Mandate summary document
pdf
Decision
Approve Reject
Remarks:
//
Apply
< Go back to list of mandates

- 3. Review the mandate, and then slide the toggle at the bottom of the page left to **Approve** the mandate, or right to **Reject** it.
- 4. Enter some comments if necessary, or a justification for the rejection, in the *Remarks* field.
- 5. Click Apply.

# 2.3.4 Terminate a mandate

# Specific to authorised representatives and non-EU manufacturers

The Authorised Representative or the non-EU manufacturer may terminate a mandate. Either the Authorised Representative or the non-EU manufacturer can mark a mandate as *Terminated* in EUDAMED. The procedures are very similar.

# If you are an Authorised Representative

# To terminate a mandate

1. Select *Manage your mandates* under the *Actor management* section.

Welcome to EUDAMED				
MDR EUDAMED is the IT system developed by the European Commission to implement Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices.				
MDR EUDAMED is structured around 6 interconnected modules and a public site.				
Tasks				
By module, consult, verify and/or manage your own and related data (managed by your actor), depending on your profile.				
	User management	Actor management		
My Actor data	Assess user access requests	Verify actor registration requests		
	Manage your users	Manage your mandates 🚀		
Manage your actor data				
Manage your email notifications				
Manage your email nouncations				

The *Mandate Management* page appears. The mandates are split into two tabs: *Pending mandates* and *Registered mandates*.

2. Select the *Registered mandates* tab. A list of all registered mandates to which you are associated is displayed:

	CURRENT ACTOR: Aut	horised Representative, IT-A	R-(	[Italy] Switch acto	r <b></b> Notifications
Mandate Manag	gement				
Pending mandates Registe	red mandates				
Filter <b>▼</b>					
Active filters: No selection					
Showing 1 to 1 of 1 entries				Show 20 💌	entries per page
Mandate ID <b>↓</b> †	MF name ↓	mf srn ‡t	Country 🕴 Sta	rt date <b>↓†</b> Er	id date 👫
MD-CI-IT-0	Zvolarien	C-WF-000000101	Côte d'Ivoire 20	19-07-01 -	

3. Click on the registered mandate that is to be terminated. The details of the selected mandate are displayed:

Mandate with
< Go back to list of mandates
Version 1 [Registered] 🗎 2020-08-17
Manufacturer identification
Organisation name:
SRN: /
Address:
Telephone number: -
Email:
Authorised representative information
Organisation name:
SRN:
Address:
Telephone number: -
Email:
Mandate validity dates
From: 🗰 2020-07-29
То: 🗰 2020-08-26
Mandate summary document
🖹 🐜 🛶 pdf
Create New Version

- 4. Click **Terminate mandate** at the bottom of the page.
- 5. Use the calendar icon to select the termination date.
- 6. Click Confirm.

### If you are a non-EU manufacturer

### To terminate a mandate

1. Select *Manage my mandates* under the *My Actor* data section. The list of your existing mandates is displayed:

View my mandates				
Manufacturer, AF-MF-				
Showing 1 to 7 of 7 entries				Show 20 - entries per page
Mandate ID 11	AR name 👪	AR SRN 4	End date 11	State 1†
MD-AF-BE-00000	(0) 700010	BE-AR-0000	2020-06-08	<ul> <li>Registered (Expired)</li> </ul>
MD-AF-BE-00000		BE-AR-0000	2030-04-04	Terminated [MF]
MD-AF-BE-00000	68/100	BE-AR-0000	-	Registered

2. Click on the registered mandate that is to be terminated. The details of the selected mandate are displayed.

- 3. Click **Terminate mandate** at the bottom of the mandate detail page.
- 4. Use the calendar icon to select the termination date.
- 5. Click Confirm.
- 6. You can see the terminated mandate by clicking on *My actor data*, and clicking on *Authorised representative* on the left side or by scrolling the page:

Manufacturer, BB-MF- [Barbados]	00000	
My Actor data Authorised Representative Competent Authority	My Actor data         Version 2 [Current]       Last update date:	Actions -
Notification email Linked importers	Actor identification Role: Manufacturer	
	Actor ID/SRN:	BB-MF-000001065
	Country: Actor / Organisation name:	Barbados ARMEN 2.7 BARBADOS MANUFACTURER [All languages]
	Abbreviated name:	•
	VAT information:	No -
	National trade register number:	
	Organisation identification document:	-

The terminated mandate will appear in an accordion, click on the Authorised Representative Actor ID/SRN to expand it, the termination date will be shown at the bottom of the accordion:

BE-AR-000001063 (Terminated)	~
Actor ID/SRN: BE-AR-000001063	
Role: Authorised Representative	
Country: Belgium	
Actor / Organisation name: ARMEN 2.7 EU AR TWO	
Address: 1112 BRUXELLES	
Email: ArmenFortyNine_eudamed@mailinator.com	
Telephone number: -	
Mandate validity dates From 2022-03-29 to -	
Termination date: 2022-08-31	

