

### EUDAMED user guide Designating Authorities

Production v 2.14.1 2024

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### **1** Introduction

EUDAMED is the IT system implementing Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnosis medical devices.<sup>1</sup>

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- · Search & view for withdrawn/refused applications.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.



<sup>&</sup>lt;sup>1</sup>For 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.<sup>2</sup>

#### EU Login (ECAS) account

#### **EUDAMED** Production landing page



 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):

<sup>&</sup>lt;sup>2</sup>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 at: EU Login (ECAS) account.

This website uses cookies. Learn more about the European	Commission's cookie policy			$\frac{Close this message}{Close this message} \times$
EU Login One account, many EU services		Where is ECAS?	<b>0</b> E	nglish (en) 🗸
webgate.a	acceptance.ec.europa.eu	requires you to auther	nticate	
	Sign in to c	ontinue		
	Use your e-mail address	unt		
Easy, fast	and secure: download the EU Login app	p we osoft		Powerd by
European Union EU Institutions		7.4.3-dn2p   17 ms		European Commission

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

This website uses cookies. Learn more about	t the European Commission's cookie policy			Close this message X
EU Login		Where is ECAS?	•	English (en)
	eudamed requires you to authentic	ate		
	Sign in to continue	•		
	Welcome back			
	(External)			
	Sign in with a different e-mail address? Password			
	Lost your password?			
	Choose your verification method			
	Sign in			
	Easy, fast and secure: download the EU Login a	арр		
	Get If form Google Play	t		
About EU Login Cookies	Privacy Statement Contact Help	_		Powered by
European Union EU institutions	5.9.1-gna   12 ms	s		European Commission

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

	CURRENT	ACTOR:	Switch actor #Notifications
elcome to EUDAME	D		
R EUDAMED is the IT system developed by the ulation (EU) 2017/745 on medical devices and mosis medical devices.	e European Commission to implement d Regulation (EU) 2017/746 on in vitro	See all the news	
R EUDAMED is structured around 6 interconne	ected modules and a public site.		
acke			
module, consult, verify and/or manage your ov	wn and related data (managed by your acto	r), depending on your profile.	
	User management	Certificate	
My Actor data	Assess user access requests Manage your users First NB LAA users	Manage requests for withdrawal/suspension of certificates	_
Manage your email notifications Machine to machine data delivery			
preferences			
ecarch & View verview of modules allowing you to search and Actor module Actors	d view details, depending on your profile Refused r	egistration requests	UDI-Dis/Devices
Search & View verview of modules allowing you to search and Actor module Actors	d view details, depending on your profile Refused r	egistration requests	UDI-Dimodule UDI-Dimodule
erview of modules allowing you to search and Review of modules allowing you to search and Review and the search and Actors Continues and the	d view details, depending on your profile Refused r	egistration requests	UDI-Di module UDI-Di vices
erearch & View verview of modules allowing you to search and Actor module Actors Certificate module Issued/Refused certificates	d view details, depending on your profile Refused r Ce	egistration requests	UDI-DI indula UDI-DIs/Devices Certificate module CECP
Certificate module Certificate module Certificate module Certificate module Certificate module Certificate module Certificate module	d view details, depending on your profile Refused r Ce	egistration requests	UDI-DI module UDI-DIs/Devices
Search & View verview of modules allowing you to search and Actor module Actors Certificate module Issued/Refused certificates	d view details, depending on your profile Refused r Ce	egistration requests	UDI-DI medule UDI-DIs/Devices
Search & View verview of modules allowing you to search and Actor module Actors Certificate module Issued/Refused certificates Certificate module	d view details, depending on your profile Refused r Ce J	egistration requests	UDI-DI Indula UDI-DIs/Devices Certificate module CECP

#### To quit EUDAMED:

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

C	Europe Comm	ean ission EUDAN	1ED				English 📖
European	Commission > EU	IDAMED					
Home	Tasks 🗸	Search & view 🗸	Transmission 🗸	Help 🗸		A Madaatha Turghas	Logout
	CURRENT ACTO	R: Competent Authority,	B (AB) Agence (A	area as link area	e de <sup>r</sup> istal de landfaller	t Specific Tage and Terranoverlifting on Terrandom (Bergaret)	

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

European	Commission > EU	DAMED							
Home	Tasks 🗸	Search & view 🗸	Transmission	elp 🗸			-	ien Parlyten	Logout
	CURRENT ACTOP	R: Competent Authority 1	E CA-BT Agence Federate	ins inclusions	a ao Ponto in Sa	tel atras ignicing on	Concentration of the second	er Seconducts Begart <b>e</b> t	prodice fields
		This screet Login to be	n allows you to log out of the l e completely signed off.	EUDAMED applic	ation. Please be aware	that you will still have to log (	out of EU		
				.ogout	Stay logged in				
EUDAME	D		Contact EUDAME	D		About EUDAMED			

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.

European Commission > EUDAMED		
Home Help 🗸	<b>MedicalDev Thirtyseven</b>	Logout
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)		
* Rale: Competent Authority		
* Country:		
Actor / organisation name:		
Find		

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**.

The Local User Administrator of the organisation for which you are reque requests and manage the user accounts of an organisation.	sting access is empowered to validate the user
Poorch existing actor	Result
Search existing actor	Select your actor from the list below
Enter your actor data to check if an actor already exists for your company	Medicines and Healthcare products Regulatory Agency, United Kingdom - Competent Authority - Actor code: GB-CA-001
I know the Actor's Single Registration Number (SRN)	SRN:
* Role:	GB-CA-001
Competent Authority	Role:
Competent Additionary	Competent Authority
* Country:	Country:
Linited Kingdom	United Kingdom
	Organisation name:
Actor / organisation name:	Medicines and Healthcare products Regulatory Agency
	Address:
	Second Country (Mark Contry (Mark Country), 1992) (1992) (1992) (1992)
Find	Email:

- 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.
- Click Save, Preview and when you are certain of the information, click Submit. 4.
- 5. A confirmation message will appear – click **Submit my request**.

request?  st  ed and is ready to be submitted.  lation will be communicated to to the end (our data and the progress of the exam  ur EUDAMED account.  ancel  WPORTANT	amail address provided ministion by visiting "See						
at ed and is ready to be submitted. Instant will be communicated to to the e over data and the progress of the exam wire EUDAMED account.	smail address provided minaton by visiting "See						
nation will be communicated to to the e over data and the progress of the exam wr EUDAMED account.	amail address provided mination by visiting "See						
ser Profiles he Local Act ddresses an	r tor Administra d has all the l	tor (LAA ights of	۱) can ma a Local ۱	anage th Jser Adi	ne actor i ministrat	notificatior tor (LUA).	email
DA LAA/LU	A can validat wthority users	e user ao s.	ccess red	quests fo	or first N	IB LAAs ar	ıd its
alidators can	n validate use	r access	request	s for firs	t NB LA	As only.	
	he Local Act ddresses an DA LAA/LU esignating A /alidators car	he Local Actor Administra ddresses and has all the r DA LAA/LUA can validate besignating Authority users falidators can validate use	he Local Actor Administrator (LAA ddresses and has all the rights of DA LAA/LUA can validate user a besignating Authority users. /alidators can validate user access	he Local Actor Administrator (LAA) can ma ddresses and has all the rights of a Local U DA LAA/LUA can validate user access red besignating Authority users. /alidators can validate user access request	he Local Actor Administrator (LAA) can manage the ddresses and has all the rights of a Local User Ad DA LAA/LUA can validate user access requests for designating Authority users. /alidators can validate user access requests for firs	The Local Actor Administrator (LAA) can manage the actor ddresses and has all the rights of a Local User Administra DA LAA/LUA can validate user access requests for first N Designating Authority users. Validators can validate user access requests for first NB LA	he Local Actor Administrator (LAA) can manage the actor notification ddresses and has all the rights of a Local User Administrator (LUA). DA LAA/LUA can validate user access requests for first NB LAAs an Designating Authority users. /alidators 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** 

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



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

Home Tasks 🗸 Search & view 🗸 Help 🗸				Logout
	CURRENT ACTOR	Sectors ( # SECTOR In the last	itch actor	*Notifications
Users management				
Pending requests Registered users				
Filter 🔻				
Active filters: No selection				
Showing 1 to 1 of 1 entries		Sł	now 20 👻	entries per page
EU Login email #	Type of request	Date of request 11	Actions	
and protection on	New account	2020-08-17		

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.
Assessment of user data	
Approve Reject	
Type of reasons:     Incomplete and/or details to correct     Refused request	
* Remarks:	
Reject 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**.

Home Tasks 🗸	Search & view 🗸 🛛 Help 🗸		Log
		CURRENT ACTOR:	n actor Notificati
Assessmer	nt : Profiles		
< Go back to Assessmer	t part 1		
Default prof	iles		
Actor: the 'View	er' profile is granted by default because the user h	as always access to his own data.	
UDI/Device: the	'Viewer' profile will be accepted by default if a high	her profile is rejected	
Profiles(s) for this acto For each module, select	r r the 'Approve' button to approve a profile or the 'Re	eject" button to reject a profile.The user has access by defa	ault to his/her own actor data. Approve all Reject all
Actor:	Local Actor Administrator	✓ Approved	X Reject
UDI/Device:	Confirmer	✓ Approved	¥ Reject
Certificate:	Viewer	✓ Approved	¥ Reject
Complete assessment	Cancel		

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:

Home Tasks 🗸 Search & view 🗸 Transn	nission 🛩 News	Help 🗸		L DA (CONFIRMER)	Logout	
CURRENT ACTOR: Designating Authority, IS-DA-035, [Iceland] #Notificatio						
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 of User manage	Jata (managed by your actor ment	or), depending on your profile. Certificate	Certi	ificate		
My Actor data Assess user aco Manage your use Manage your email notifications	zss requests rs	Manage requests for withdrawal/su certificates	spension of Nomin	ated experts list		
Machine to machine data delivery preferences						
Search & View						
Overview of modules allowing you to search and view details, d	epending on your profile					
8						
Actor module Actors	Refused re	egistration requests		UDI-DI module UDI-DIs/Devices		

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:

European Co	mmission > EU	DAMED								
Home	Tasks 🗸	Search & view	✓ Transmission	~	News	Help 🗸		E TestTwenty	Five Eudamed	i Logout
					CURRENT	ACTOR: Compete	ent Authority,	Tes	t DA	Notifications
First I	NB LAA	users								
Pending red	quests Regi	stered requests	Refused requests							
Showing 1 to	o 1 of 1 entries							Show	20 🗸	entries per pag
NB ID 11	NB N	ame 11		3	EU Login em	ail 11	Date of re	quest†₹	Α	actions
1000	1000	Polici Anoraro	-45		heligeate		201-00.2			1
										_

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

European C	commission > EU	DAMED					
Home	Tasks 🗸	Search & view 🗸	Transmission 🗸	News	Help 🗸	TestTwentyFive Eudamed	Logout
				CURRENTA	CTOR:	Test DA 📢	otifications
Asso	esment						
7996	SSILICIT						
Acto Organis NB num Address Telepho Email:	r identific ation name: ber: s: ne number:	cation					
User i	nformatio	on					
EU Logi	in ID						
ID:			halignates				
Contact	email for th	e actor					
Email:			1000				
Are you	a sub-contr	actor for this acto	r?				
Sub-con	ntractor:		No				
User ma	anager						
First nar	me:						
Last nar	ne:						
Function	n/position:						
Validity	date for the	EUDAMED accou	nt				
Life date							
Bogur	tod Brafila						
Actor:	ted Profiles		LAA				
Assessi	ment of user	data					
Outcome:							
Approve		Refuse					
	ubmit	Cancel					

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

Assessment of u	ıser data
Outcome:	
Approve	Refuse
Submit	Cancel

5. 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 use Outcome:	er data
Approve	Refuse
* Remarks:	
Submit	Cancel

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

	The full Parks' losses them (without the				-
NB ID It	NR Name If	Ell Login It	Ell Login email It	Sub-contractor It	End date 15
Showing 1 to	1 of 1 entries			Show 20	✓ entries per page
Pending requ	uests Registered requests Refused requests				
First N	IB LAA users				

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:

Home Tas	ks ❤ Sear	ch & view 💙	Transmission 🗸	News	Help 🗸		L DA (CONFIRMER)	Logout
					CURREN	NT ACTOR: Designating	Authority, IS-DA-035, [iceland] 📢	otifications
Welcom	e to EUI	DAMED						
MDR EUDAMED is Regulation (EU) 20 diagnosis medical MDR EUDAMED is	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, consul My . Manage your emi Machine to machi preferences	; venty and/or ma Actor data ill notifications ne data delivery	Lage your own a	wn and related data (managed by your actor), depending on your profile. User management Certificate Certificate Assess user access requests Manage requests for withdrawal suspension of Manage your users First NB LAA users			Certificate Nominated experts list		
Search &	Search & View Overview of modules allowing you to search and view details, depending on your profile							
	Actor mode Actors	ule		Refused re	<b>iii</b> egistration requests		UDI-DI module UDI-DIs/Devices	

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**:

ropean Commission > EUDAMED		
lome Tasks 🗸 Search & view 🗸 Transr	nission 🗸 News Help 🗸	L DA (CONFIRMER) Logo
		CURRENT ACTOR: Designating Authority, IS-DA-035, [Iceland] «Notificatio
Request for suspension/witho	drawal management	
ertificates list Suspension/withdrawal requests		
Filter <b>T</b>		
* Notified Body identification	MF/PR Actor ID/SRN	
- × ×		
Certificate Type	Certificate number	Revision number
O Please provide value for mandatory parameter: Notified Bod	y	
Apply filters Clear all filters		
Active filters: No selection		
In order to register a suspension/withdrawal of a cert without selecting a certificate from the list	tificate that is not registered in EUDAMED, you can	n click on the "Request for suspension" or Request for withdrawal" link

Next the Certificates result list will appear:

ctive filt	ers:						
Notified	Body identification: 2797 - B	ISI Group The Netherlands B.V. 💥 C	lear all filters				
	n order to register a suspensi vithout selecting a certificate	on/withdrawal of a certificate that is no from the list	nt registered in EUDAMED, you can o	lick on the "Request for s	uspension" or R	equest for withdra	awal" link
howing	1 to 20 of 232 entries				SI	10W 20 ~	entries per pag
Select all	Certificate number revision number	MF/PR Actor ID/SRN 11	Certificate type If	Starting certificate validity date 11	Date of issue It	Date of expiry 11	Status
	4 certificates selec	ted e Request for suspension	Request for withdrawal				
	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
	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
	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
	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
Y	MDR-QMS-SUPP-111 2	BE-MF-00000803	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-13	2021-12-13	2023-12-13	Supplemente
<b>v</b>	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
	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
			(MDR) EU quality management				

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

Select	Certificate number	MF/PR Actor ID/SRN 11	Certificate type 11	Starting certificate	Date of	Date of	Status
an				validity date 11	ISSUETI	expiry #	
	4 certificates selec	ted   Request for suspension	Request for withdrawal				
	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
	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
	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
			(A (BB) EU				

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**:





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*):

owing	1 to 20 of 234 entries				Sh	ow 20 ¥	entries per pag
elect I	Certificate number revision number	MF/PR Actor ID/SRN 11	Certificate type 11	Starting certificate validity date 11	Date of issue It	Date of expiry lt	Status
	certificates selec	ted   Request for suspension	Request for withdrawal				
	REINS-QMS-1232442 1	BE-MF-00000803	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-13	2021-12-13	2022-12-13	Reinstated
	REINST-1111 1	BE-MF-00000803	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-13	2021-12-13	2023-12-13	Withdrawn
	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
	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
	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
	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
	MDR-QMS-SUPP-111 2	BE-MF-00000803	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-13	2021-12-13	2023-12-13	Supplemente
			(IVDR) EU quality management				

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



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



 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:



	CURRENT ACTOR: Designating Authority, IS-DA-035, [iceland] «Notifications
Request for suspension of certificates	
Notified Body identification	
Notified Body number:	
Name: Country:	
Manufacturer identification	
* Enter Actor ID/SRN or name:	
Q. Find	
System and/or Procedure Pack Producer Identification	
* Enter Actor DISRN or name: Q, Find	
List of certificates	
* Certificate Number: Revision number:	
Add another Certificate	
* Request date:	
YYYYAMADD	
* Comments.	
Confirm	

5. 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):

Q Find

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:

Home	Tasks 🗸	Search & view 🗸	Transmission 🗸	News	Help 🗸	first Designating Auth Dev LAA	Logout
				CUF	IRRENT ACTOR: D	lesignating Authority, IT-DA-013, Designating Auth Dev [Italy] Switch actor 🥠	otifications
Requ	est for	suspensior	n/withdrawa	ıl regi	istration		
	/ou have suc he Member S authority you	ccessfully registered y State in which the mai are acting on behalf.	your request for susp nufacturer and/or the	oension/w sys <mark>tem</mark> a	withdrawal of cer and/or procedur	tificates. The following actors are being notified: i) Competent au e pack producer has their registered place of business; ii) Design	thority of ating
What o	do you w	vant to do nov	v?				
View the rea	quest you just c	reated					
Go to the he	omepage						

### 5.3 View own requests for suspension/ withdrawal of certificates

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

Home	Tasks 🗸	Search & view 💙	Transmission 🗸	News	Help 🗸		L DA (CONFIRMER)	Logout
			CURR	ENT ACTOR:	Designating Authority, IS-DA-035, I	linistry of Welfare	(Velferðarráðuneytið) [Iceland] 📌N	otifications
MDR EUDAI Regulation diagnosis m MDR EUDAI	OME to MED is the IT sys (EU) 2017/745 or nedical devices. MED is structured	EUDAMED tem developed by the Eur n medical devices and Res d around 6 interconnected	opean Commission to imple julation (EU) 2017/746 on i modules and a public site	ement n vitro				
Manage y Machine t preference	Nome       Tasks       Search & view       Tree         Welcome to EUDAMED         ADR EUDAMED is the IT system developed by the European seguration (EU) 2017/745 on medical devices and Regulatio liagnosis medical devices.       And Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/745 end (EU) 2017/745 e	nd related data (managed r management ess user access requests age your users INB LAA users	by your actor	), depending on your profile. Certificate Manage requests for withdrawal/a certificates	uspension of	Certificate Nominated experts list		
Searcl	h & View	ing you to search and view	w details, depending on yo	ur profile				
	Ac	ctor module Actors		Refused reg	jistration requests		UDI-DI module UDI-DIs/Devices	

2. 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:

Filter T					
Notified Body identification	ME	PR Actor ID	I/SPN		
	× •				
				_	
Certificate Type			Certificate number	Type of request	
-	×	~		- ×	~
State					
State					
Registered V					
Discarded	5				
Request date for Registered	al				
Between	and	_			
<b></b>		Ö			
1000000000	YYYYMM.DD				

3. 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:

Reque	est for suspe	ension/withdrawal m	anagemen	t				
ertificates li	ist Suspension/withd	rawal requests						
Fill	er 🔻							
Active filters	5.							
State: Re	egistered Clear all filters							
Showing 1 t	to 20 of 39 entries					Show 20	<ul> <li>✓ entrie</li> </ul>	s per page
NB number ‡†	Certificate number revision number	MF/PR Actor ID/SRN []	Certificate type I†	Request date for suspension/withdrawal I1	Expiry date I1	Type of request 11	State	Actions
0051	645 564	BE-MF-000000281,BE-PR-000000301	-	2022-03-01	-	Request for withdrawal	Registered	
						Request for		

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

Expiry date It	Type of request l†	Actions
2023-12-13	Request for suspension	
	۲	View request

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 storiliser reissued	

### 5.4 Discarding requests for suspension/ withdrawal of certificates

1. 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	3-2022-1001	
Go back to the request list		
		Discard
Request details		
Request date:	2022-03-01	XCInce
Decision:	Request for withdrawal	Discarding a request for suspension withdrawal of certificates
Comments:	645	This request for suspension/withdrawal of certificates will be discarded (lost). The operation cannot be reverted. Do you want to finitise the operation?
Notified Body identification		
Notified Body number: 0051 Name: IMQ ISTITUTO ITALIANO DEL MARCH Country: Italy	IIO DI QUALITÀ S.P.A.	Yes No
Certificate(s):	645 564	

2. 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:	יוווזוווווווווווווווווווווווווווווווווו
Notified Body identification	
Notified Body number: NB-1039 Name: SQS Belgium NV Country: Belgium	
Certificate(s):	spp+device+deviceGroup2 restricted

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

Fit Active filters State: Di Showing 1	er <b>T</b> S: Scarded Clear all filters to 10 of 10 entries					Show 20	✓ entries	; per page
NB number ↓†	Certificate number revision number	MF/PR Actor ID/SRN 11	Certificate type If	Request date for suspension/withdr	Expiry awal if date if	Type of request 11	State	Actions
2862	20220203 1	BE-MF-00000041	-	2022-03-01	-	Request for suspension	Discarded	
0477	202202033	BE-MF-00000061,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 t4y	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:

	User management	Certificate		Certificate
Assess user aco Manage your use Manage your use Manage your use First NB LAA use preferences		sts Manage requests for withdrawal centificates	suspension of	Nominated experts list
earch & View erview of modules allowing you to search	n and view details, depending	) on your profile		
Actor module Actors		Refused registration requests		UDI-DI module UDI-DIs/Devices
Actor module Actors		Refused registration requests		UDI-DI module UDI-DIs/Devices
Actor module Actors		E Refused registration requests		UDI-DI module UDI-DIs/Devices
Actor module Actors		Refused registration requests		UDI-DI module UDI-DIs:/Devices
Actor module Actors	tes	Refused registration requests		UDI-DI module UDI-DIs:/Devices
Actor module Actors	tes	Refused registration requests		UDI-DI module UDI-DIs/Devices

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:

			CURRENT ACTOR	: Designating Authority, IS-DA-035, [Iceland] <i></i>	ations
Search & View					
equests for suspensi	ion/withdrawa	I of certificates			
Requests data					
Searching for	NB identificati	on	DA identification		
All requests	× -	× •	· _	× ×	
-	× •				
Date of request					
Date of request - Between Date	of request - And				
YYYY-MM-DD YYYY	Y-MM-DD				
Search	search				

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

ctive search fields: Searching for: All requests Clear search							
Showing 1 to 2	of 2 entries					Show 20	✓ entries per page
NB number It	Certificate number revision number	MF/PR Actor ID/SRN	DA ID 11	Certificate type 1	Date of request l1	Date of expiry 11	Request type If
NB number Lt	Certificate number revision number ZXY 001	MF/PR Actor ID/SRN BE-PR-000000862	DA ID 11 IS-DA-035	Certificate type 1†	Date of request It 2021-12-06	Date of expiry 4t	Request type If Request for suspension

4. 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] Interfections
Request ID: IS-DA-03	35-2021-1000	
▲ 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:	
	Certificate(s):	REISSUE-IV-13134 1 MDR-GMS-SUPP-111 2 RESTR-GMS-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:

7R EUD-AIRD is the IT system developed by the European Commission to implement guidation (EU) 2017/R46 on medical devices and Regulation (EU) 2017/R46 on in vitro agnosis medical devices.		See all the news				
DR EUDAMED is structured around 6 interc	R EUDAMED is structured around 6 interconnected modules and a public site.					
lasks						
y module, consult, verify and/or manage yo	ur own and related data (managed by your	actor), depending on your profile.				
	User management	Certificate				
My Actor data	Assess user access requests Manage your users First NB LAA users	Manage requests for withdrawal/suspens certificates	ion of			
Manage your email notifications Machine to machine data delivery						
a hara an	]					
Search & View verview of modules allowing you to search	and view details, depending on your profile	e 	100			
Search & View verview of modules allowing you to search	and view details, depending on your profile	B	1101			
Search & View verview of modules allowing you to search Actor module	and view details, depending on your profile	e El ed registration requests	1) UDI-DI module			
Search & View verview of modules allowing you to search Actor module Actors	and view details, depending on your profile Refuse	e	UDI-DI module UDI-DIs/Devices			
Search & View verview of modules allowing you to search Actor module Actors	and view details, depending on your profix	e ed registration requests	UDI-DI module UDI-DisiDevices			
Search & View verview of modules allowing you to search Actor module Actors Cotificate module	and view details, depending on your profile Refuse	e ed registration requests	UDI-Di module UDI-Dis/Devices			
Search & View verview of modules allowing you to search	and view details, depending on your profile Refuse	e ed registration requests	UDI-Di module UDI-Dis/Devices			
Search & View verview of modules allowing you to search	and view details, depending on your profile Refuse	e ed registration requests Certificate module Applications	UDI-DI module UDI-DI siDevices UDI-DisiDevices Certificate module CECP			
Search & View verview of modules allowing you to search Actor module Actors Certificate module Issued/Refused certificat ES	and view details, depending on your profile Refuse	e ed registration requests Certificate module Applications	UDI-DI module UDI-DisiDevices			
Search & View verview of modules allowing you to search	and view details, depending on your profile Refuse	e e e e e e certificate module Applications Certificate module Certificate module	UDI-Di module UDI-Di module UDI-DisiDevices			

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**:

European Commission > EUDAMED							
Home	Tasks 🗸	Search & view 💙	Transmission 🗸	News	Help 🗸		
Actors							
UDI-DIs/D	evices						
Issued/R	efused certificates	3					
Application	ons						
CECP							
Requests	s for suspension/v	vithdrawal of certificate	and the second se				

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

egulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro lagnosis medical devices.		See all the news	
OR EUDAMED is structured around 6 int	erconnected modules and a public site.		
asks			
module consult verify and/or manage	your own and related data (managed by you	r actor) depending on your profile	
indexe, condex, ronny and or manage	User management	Certificate	
My Actor data	Assess user access requests Manage your users	Manage requests for withdrawal/suspensi certificates	on of
Manage your email notifications	First NB LAA users		
Machine to machine data delivery			
earch & View erview of modules allowing you to see	rch and view details, depending on your prof	11e	
earch & View rerview of modules allowing you to ser Actor module	rch and view details, depending on your prof	tte III sed conistration converte	LIIII UDi-Di module
earch & View erview of modules allowing you to set Actor module Actors	rch and view details, depending on your prof	tte sed registration requests	UD+Df module UDH-Dfs/Devices
earch & View review of modules allowing you to see Actor module Actors	rch and view details, depending on your prof Refu	sed registration requests	UDI-DI module UDI-DIs/Devices
earch & View enview of modules allowing you to see Actor modulo Actors Actors	rch and view details, depending on your prof Refu	sed registration requests	UDI-DI module UDI-DI module UDI-DIs/Devices
earch & View enview of modules allowing you to see Actor module Actors Actors Certificate module LaguageBofugerd certifi	rch and view details, depending on your prof Refu	tte e sed registration requests Certificate module Applications	UDE-DI module UDE-DIs/Devices
earch & View review of modules allowing you to see Actor module Actors Certificate module Issued/Rofused certifi	rch and view defails, depending on your prof Refu	tte ed registration requests Certificate module Applications	UDE-DI module UDE-DIs/Devices UDE-Dis/Devices Certificale module CECP
earch & View erview of modules allowing you to see Actor module Actors Certificate module Issued/Rofused certif	rch and view defails, depending on your prof Refu	ite E sed registration requests Certificate module Applications	UDI-DI module UDI-Dis/Devices UDI-Dis/Devices Certificate module CECP
earch & View enview of modules allowing you to see	rch and view details, depending on your prof Refu	The Sed registration requests Certificate module Applications Certificate module Certificate module	UDI-DI module UDI-DI module UDI-DIs/Devices

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

Search and view refused/withdrawn applications for conformity assessment

Application data				
Searching for		NB identification	Conformity assessment procedure	
All	~	- * *		×
Application reference numbe	r	Economic operator Actor ID/SRN	Economic operator name	
Decision date				
Between	and	<u>80</u>		
YYYY-MM-DD	YYYY-MM-DD			
Device data				
Device identification		Enter the device identification value/text		
-	× •			
Risk class				
	× •			

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

Search Active searc Searching t	earch results for refused/withdrawn applications ctive search fields: Searching for: All Clear search						
Showing 1 to	o 13 of 13 entries			_	Show 20	✓ entries per page	
number It	MF/PR Actor ID/SRN 11	Actor ID/SRN AR 11	Application reference number 11	Conformity assessment procedure 11	date 1	Decision 11	
—	BE-MF-00000803, BE-PR-00000804		STERI-WITH-1	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-14	Withdrawn application (by MF)	
	BE-MF-00000803, BE-PR-00000804		STERI-REFU-1	(MDR) EU quality assurance certificate (Annex XI Part A)	2021-12-14	Application refusal (by NB)	
=	BE-MF-00000803, BE-PR-00000804		REF-APP-3426236	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-02	Application refusal (by NB)	
N	BE-MF-00000803, BE-PR-00000804		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)	
N	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)	
2	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)	

4. Click on the desired result record to see its details:

Withdrawn applica	ation: STERI-WITH-1	
Go back to the applications list		
Withdrawn application data		
Application data	Application data	
Application details	Notified body	
Device(s)	Notified Body number:	
System Procedure Pack(s)	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:	
	Telephone number: -	
	Email:	
	System and/or Procedure Pack Pr	oducer Identification

