

EUDAMED user guide Machine-to-machine data exchange

Production v 2.14.1 2024

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1 Glossary

Term	Description						
Access Point	The Access Point (AP) of CEF eDelivery implements the AS4 message exchange protocol according to the e-SENS profile. This ensures standardised, interoperable, secure and reliable data exchange. For more information, please refer to the CEF Digital Portal.						
AS4	The AS4 profile of eDelivery is the AS4 Usage Profile/ implementation guidelines defined by e-SENS based on the AS4 specification of OASIS, itself a profile of OASIS ebXML Messaging Services Version 3.0, which in turn is based on various Web Services specifications of OASIS.						
Bulk Upload (BLK)	The GUI-to-machine upload feature of the restricted website in EUDAMED						
Criteria	a pull request will contain search conditions; called criteria						
DTX	Data Exchange, a term used in EUDAMED that covers the Bulk Upload (GUI) and Machine-to-Machine (M2M) services						
Domibus	eDelivery AS4 solution by DIGIT. Implementation of eDelivery (Specification)						
eDelivery	AS4 Standard						
Entity Model	The Entity Data Model (EDM) is an extended version of the Entity-Relationship model which specifies the conceptual model of the data using various modelling technique. It also refers to a set of concepts that describe data structure, regardless of its stored form						
EU SEND	Allows for the use of a persistent encryption mechanism that can be applied to some parts of the message and to payloads within a message as well. Persistent encryption can be leveraged as an additional layer of security for Internet based messaging. A SaaS deployment of Domibus.						
Message Type	Pull, Push						
M2M	Machine-to-Machine						
Operation	PUT, GET, POST, PATCH						
Page	Responses are split into pages based on the PageSize provided with the request						
Pagination	The EUDAMED services offer the possibility to split responses into different pages to manage the message size						
PageNumber	In case of paginated response, the requester can orchestrate multiple page response and ask for a specific page on page to be provided in the response. The first page is page number '0'.						
PageSize	Required maximum number of entities on a specific response page						
PartyID	Party Identifier part of the sender/node/nodeID, identifies the AP that sent the payload						
Payload	It may contain the main service entity in case of a query by example						
Recipient	EUDAMED service						
Service	Operations made available on the M2M environment						
SOAP	Simple Object Access Protocol						
XML	Extensible Markup Language (XML) is a markup language that defines a set of rules for encoding documents in a format that is both human-readable and machine-readable						
XSD	An XML Schema Definition describes the structure of an XML document						

2 Introduction

2.1 Purpose

The current user guide aims at providing guidelines to the IT/Software development team of the public/private organisations, in order to successfully perform M2M data exchange. Moreover, this document assumes that the readers are familiar with the EUDAMED MDR general purpose and CEF eDelivery building block (EUSEND) of the Connecting Europe Facility (CEF).¹

2.2 Modes of data input

A user can register data in EUDAMED by using:

- The EUDAMED user interface. For any further assistance visit the EUDAMED Information Centre
- The XML bulk upload/download. For more information visit the Bulk uploadingdownloading page of the EUDAMED Information Centre
- The M2M data exchange.



NOTE

Not sure which way to use for registering data? Here is a tip:

- If you must register up to 100 devices, then use the EUDAMED user interface
- If you must register 100-1000 devices, then use the bulk upload/download
- If you must register more than 1000 devices, then use the M2M data exchange.

¹For a wider understanding on how to use the platform, including FAQs and process infographics, visit the EUDAMED Information Centre.

3 M2M data exchange architecture

The M2M data exchange allows the automatic data exchange between a public/private organisation (external system) and EUDAMED. To achieve this, the external system must convert its data into the XML format that EUDAMED supports. Moreover, the external system must install and configure a dedicated CEF eDelivery Access Point and a secure AS4-compliant communication protocol on its premises in order to establish a secure link with EUDAMED.

The EUDAMED M2M data exchange defines a set of building blocks that should be specified and implemented to enable the information exchange between public/private organisations and EUDAMED.



Organisation Backend: Represents a dedicated information exchange gateway. It implements a specific communication protocol, service and entity data exchanged between the organisations and EUDAMED, compliant with the EUDAMED service and data model.

Access Point: The organisation's AP will deliver the messages to the EUDAMED AP. The EUDAMED AP will acknowledge or respond to the organisation's requests. Both must be AS4-compliant. Domibus is used on the EUDAMED side.

EUDAMED Backend: Is responsible for the data exchange message requests, including the security, access control and reliability aspects, and for constructing the messageresponses.

4 Prerequisites

Before performing M2M data exchange, the following conditions must be met:

- 1. The public/private organisation must be registered as an Actor in EUDAMED (see EUDAMED Information Centre) and have an active user with Local Actor Administrator (LAA) profile.
- 2. A user with LAA profile acting on behalf of the Actor must know or obtain the Party ID that identifies the Access Point that will be used for data exchange with EUDAMED.
- 3. A user with LAA profile acting on behalf of the Actor must obtain a security key (token) for every module that the user intends to perform M2M data exchange (see Section Generate your security key [31] of the current guide).
- 4. A user with LAA profile acting on behalf of the Actor must have successfully completed the onboarding procedure in the Playground environment, because before having an AP in the Production environment all participants must apply for an AP in Playground in order to test the service (see Section M2M Onboarding of the Playground user guide).

5 M2M Onboarding

5.1 How to configure your M2M settings in EUDAMED



NOTE

If you wish to activate your M2M services in EUDAMED Production environment you must first apply for an Access Point (AP) in EUDAMED Playground environment, complete the onboarding and test the service.

5.1.1 Request the use of a new AP

▶ VIDEO: eDelivery access points





NOTE

Economic Operators can have **up to two** APs in *active/submitted/connectivity under validation* statuses while Competent Authorities, Designating Authorities and Notified Bodies can have **only one** AP in *active/submitted/connectivity under validation* statuses. See Annex 3 (AP statuses) [60] of the current guide for further information about the AP statuses.

1. Log into EUDAMED as a Local Actor Administrator (LAA). Under the *My Actor data* section click on the *Access point management* link:

EUDAMED user guide

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸			L Test DTHREE-TWO	Logout	
				CUR	RENT ACTOR	: Manufacturer, BE-MF-000002	2291, Test Maker	of Things in Belgium [Belgium] 🥠	otifications	
Welc MDR EUD/ Regulation diagnosis n MDR EUD/ Tasks According 1	AMED is the IT s (EU) 2017/745 (nedical devices AMED is structur to your profile pe	EUDAMEE ystem developed by the on medical devices an ed around 6 interconnect r module, consult, verify) European Commission I d Regulation (EU) 2017/ ted modules and a public and/or manage your owr Iser management ssess user access request	o implement 746 [2] on ir : site. n and related	i vitro 1 data (manag	ed by your actor) J DI-Dis/Device Your Basic UDI-Dis / EUDAMED Dis				
Manage y Manage y Access p	your actor data your email notificat	ions	lanage your users			Your UDI-DIS / EUDAMED IDS				
Searc	h & View									
Overview o	n modules allowi	ng you to search and vie	w details, depending on	your prome						
								= L ~		
	A	ctor module Actors			UDI-DI m UDI-DIs/D	odule evices		NB & Certificates module Issued/Refused certificates		

2. Click on the **Request a new M2M access** button:

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸		1 Test DTHREE-TWO	Logout
				CUR	RENT ACTOR:	Manufacturer, BE-MF-000002291, Test Maker of Thi	ngs in Belgium [Belgium] 🐢No	otifications
Acce	ss point	managem	ent					
Request a	a new M2M acces	<u>ss</u>						
Filt	ter 🔻							
Status	<u>^</u>							
Draft			×	~				
Ap	oply filters	Clear all filters						
Active filters Status: D	s: Draft Clear sea	rch						
Showing 11	to 1 of 1 entries						Show 20 🗸 entri	es per page
Access Pe	oint	Part	y ID	Status		Access Point Type	Actions	
Test bidon	1			Draft		OWN		

3. Agree to the disclaimer and click on the **Next** button:

Access point disclaimer	
Web services provided by DG SANTE to the Actor	hash and a start and a
For the purpose of accessing these web services a user account will be created with the relevant permissions. The	web services' account.
 Shall not be used for any other purpose than connecting the Actor web services client application. In particula 	ar it shall never be directly used by a human being.
The bush convises' account will be activated ofter the Actor client application has successfully passed the required	accentance texts in the ELIDAMED Accentance environment
The web services account will be activated after the Actor client application has successfully passed the required a	acceptance tests in the EODAMED Acceptance environment.
The responsibilities of the designated person in charge of managing the 'web services' account area:	
Requesting an initial web services account password	
Unon recention of initial access code	
 In case of compromise, 	
 After the handover of the person in charge of managing the 'web services' account. 	
 Setting a login/password pair in the web services client application. To that purpose the client application shall anyone. 	Il implement a mechanism that prevents the disclosure of the passwo
 Protecting the password from disclosure. 	
The web services client application may be developed internally or by a contractor. In any case:	
 Developers must comply with secure coding best practices. 	
 Code review must be completed by an independent party before going into production with a view to ensuring confidentiality of the stored credentials. 	g confidentiality and integrity of the exchanged data, as well as the
The production environment of the web services client application must be hosted by the Actor.	
Developers and testers shall not have access to the production environment.	
Sensitive data and credentials shall be accessible to a strictly limited number of system administrators, and all acce	ess logged.
Privileged accounts (system administrators) shall be managed according to ISO27002 best practices.	
I accept the terms of the displainer	

4. In the next screen select **No** to create a new AP and click on the **Next** button:

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸	L Test DTHREE-TWO Lo	gout
				CUR	RENT ACTOR:	Manufacturer, BE-MF-000002291, Test Maker of Things in Belgium [Belgium] #Notifical	tions
Mach	ine to N	Machine req	uest acce	SS			
Will you use	an existing Eud	damed Access Point?					
O Yes 💿 N	0						
Ne	N	Cancel					

5. Select the owner of the AP:

a. If you own the AP, you must select if you will share this AP or not. The Organisation details will be prefilled:

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸	L Test DTHREE-THRE	E Logout
				CURRE	NT ACTOR:	Manufacturer, DE-MF-000002295, Test Maker of Things in Germany [Germany]	 Notifications
Mach	nine to I	Machine red	quest acce	SS			
			1				
* Who	will be the ow	vner of the access poi	int?				
 Owne 	d by my actor						
O Owne	ed by a 3rd party	access point provider					
* May	this access po	oint be used by other	Actor(s)?				
O Yes	O No						
Organi	sation						
Organ	isation name: ID/SRN: DE-MI	Test Maker of Things in G F-000002295	iermany				
Addre	ss: 123456 Ber	din					
Telepl	hone number:	-					
Email	: DE.EO.DTHRI	EE-THREE@dgsantedev	eu				
* Access P	oint:						
* Access P	oint Country:						
-				0	\sim		
* Access P	oint City:						

b. If the AP is owned by a 3rd party company, the *May this access point be used by other Actor(s)?* field will be greyed out and you will be asked to upload the 3rd Party Agreement:

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸		L Test DTHREE-TWO	Logout
				CURF	RENT ACTOR:	Manufacturer, BE-MF-000002291, Test M	aker of Things in Belgium [Belgium] 🥠No	tifications
Mac	hine to l	Machine red	quest acce	SS				
* Who	will be the ow	mer of the access poi	int?					
 Owned 	ed by a 3rd party	access point provider						
* 3rd Party	/ Agreement:							
★ May	this access po	bint be used by other	Actor(s)?					
Organi	sation							
Stree	t information, if	applicable	A Street information is rea	wired unless v	ou select the optio	n Na		
* Stre	eet:			unco uncoo y	Str	eet number:		
Addre	ess line 2:							



3rd Party Agreement

The 3rd Party Agreement document is to confirm that a company (either a 3rd party provider or another Actor registered in EUDAMED having already an AP) agrees to act as 3rd party service provider for the Actor organisation that submits the request for the purposes of M2M DTX with EUDAMED.

This document will be used to assess the validation of the AP access/link request and must be provided for each environment where an AP access/link is requested (Playground and Production).

This document must identify clearly the two parties (Actor and 3rd party service provider) and must be signed by both parties for confirming the agreement from the 3rd party service provider toward the Actor.

You can download the 3rd Party Agreement template here.

You must upload a PDF file in the 3rd Party Agreement field.

Enter information related to the Organisation:

3rd Party Agreement:	
file uploaded successfully	
mahonle_CS18864_2022_5 [PDF 33.65 KB]	×
* May this access point be used by other Actor(s)? • Yes O No	
Organisation * Name	
TW Demo Third Party1	
Street information, if applicable	
Yes No Street information is required un	less you select the option - No
* Street:	Street number:
88	1
aa Address line 2:	1
aa Address line 2: PO box:	1
aa Address line 2: PO box: City name:	* Postal code:
aa Address line 2: PO box: City name: Liege	* Postal code: L123
aa Address line 2: PO box: City name: Liege * Country:	* Postal code: L123
aa Address line 2: PO box:	* Postal code: L123
aa Address line 2: PO box: * City name: Liege * Country: Belgium X Telephone:	* Postal code: L123
aa Address line 2: PO box:	* Postal code: L123
aa Address line 2: PO box:	* Postal code: L123
aa Address line 2: PO box:	* Postal code: L123

6. Enter the name of the AP in the *Access Point* field, the country and the city of the AP, then select **Yes** if you use this AP in other eDelivery application or **No** otherwise and click on the **Save & Next** button:

TW Demo 3rd Party AP 1	
Access Point Country:	
Belgium	× ¥
Access Point City:	
Liege	
* Is this an EC eDelive application(s)? O Yes O No	ery Access Point already set up for other

7. In the next screen fill in your technical and legal contact details:

Home Tasks ∨	Search & view 🗸	Data Transfer 🗸	News Help 🗸	L Test DTHREE-TWO Log
			CURRENT ACTOR	Manufacturer, BE-MF-000002291, Test Maker of Things in Belgium [Belgium] Notificat
lachine to	Machine rec	uest acces	SS	
		1		
* First name:				
I b				
* Last name:				
* Email:				
* Telephone:				
Felephone format example: +	32 x XXX XX XX			
Legal Contact				
* First name:				
* Last name:				
* Email:				
* Telephone:				
Felephone format example: +	32 x xxx xx xx			



NOTE

Technical contact: The technical person to contact for setting up the AP and for any related technical issues.

This person must belong to the organisation that owns the AP (if the owner is a 3rd party provider, the technical contact should belong to the 3rd party provider; if the owner is an Economic Operator, the technical contact should belong to the Economic Operator).

Legal Contact: The person to contact in case there is a non-technical issue with the way the AP is used (e.g., misuse) or for notifications in case of maintenance/bug etc. that impacts the use of the AP.

This person must belong to the Actor's organisation submitting the request.

8. Upload your Proof of testing:

* Business justification / Proof of testing:

Browse



NOTE

In the *Business justification / Proof of testing* field use the Business justification document if you are a Playground user and the Proof of testing document if you are a user of the Production environment. See the EUDAMED environments page for further information about the existing environments accessible to the users.

IMPORTANT Proof of testing

The Proof of testing is required to set-up an AP in Production. Its purpose is to confirm that the prerequisite of a successful AP access/link in Playground is fulfilled by getting concrete information on the successful data exchange in Playground in order to assess whether the Actor can have an active AP in Production.

There is no template. However, it should contain the information listed below in a single PDF document:

- 1. Your Actor's SRN/ID and Party ID in Playground.
- 2. The XML request and response files that prove successful upload and/or download via M2M in Playground environment.

In case you request the upload of Legacy/Regulation Device/SPP (Basic UDI and UDI-DI) service, please also provide:

- 1. The Basic UDI-DI and UDI-DI of a successfully registered device in Playground.
- 2. The XML request and response files that prove that you have successfully registered this specific device (see point 1 above) via M2M in Playground.

9. Select the services that you want to use this AP for and click on the **Submit** button:

mahonle_CS18864_2022_5 [PDF 33.65 KB]	×	
Actor	UDI/Device	Certificates/Notified Body
Manage security keys:	Manage security keys:	Manage security keys:
Actor download	 Upload of Legacy / Regulation Device/ SPP (Basic UDI and UDI-DI) 	SS(C)P Download
	Update Basic UDI	
	Download of Legacy/ Regulation Device/SPP	
	Upload UDI-DI for existing Basic UDI	
	Update UDI-DI	
	Update container package	
	Update market information	
Submit Cancel		



NOTE

You will be able to edit the selected services after the activation of your AP. Each service can be linked to **only** one AP. See section Generate your security key [31] of the current guide for more information.

10. Select **Yes** in the pop-up window to complete the AP registration:



If you select **Yes** your request will be stored as *submitted*. Otherwise, your request will be stored as *draft* (see Annex 3 (AP statuses) [60] of the current guide).

11. In the next screen you can see a confirmation message and the AP's Party ID. Click on the *Go back to Access Point Link dashboard* link to manage your AP:





NOTE

EUDAMED team at the Commission will either accept or reject your request. If your request is rejected then the status of your request will be *rejected* and you will be able to request again. Otherwise, the status of your request will be *connectivity under validation* (see Annex 3 (AP statuses) [60] of the current guide). Upon EUDAMED team's decision (request accepted/rejected), you will get a notification in your *Notifications Inbox*:

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News H	elp 🗸	1 Test DTHREE-TWO	Logout
				CURRENT	ACTOR: Manufacturer, BE-MF-00	0002291, Test Maker of Things in Belgium [Belgium] 🥠	lotifications
Notif	ications I	nbox					
A	notification is archiv	ed after 30 days					
Notifica	ation type	Module	From		То		
-	× •	-	× 🗸 2023	-02-16 🛗	2023-03-16 🛗		
	Search	Clear search					
Active sear	rch fields:						
From: 2	2023-02-16 To:	2023-03-16 Clear s	search				
						Tim	e received
Information Actor - Ad Your reque	CT-019.02-EUDAM	5 Email ED_000081: Machine machine access point eu/eu/amed/secure/li	to Machine Access Prilink has been approved	pint Link Approv Your access poir 8-b3b1-c1003e914	ed It link is now active and can be used	i	
Informatio	on 🗮 2023-03-1() Email					



5.1.2 Request the use of an existing AP

▷ VIDEO: Link to an existing AP





NOTE

Economic Operators can have **up to two** APs in *active/submitted/connectivity under validation* statuses while Competent Authorities, Designating Authorities and Notified Bodies can have **only one** AP in active/submitted/connectivity under validation statuses. See Annex 3 (AP statuses) [60] of the current guide for further information about the AP statuses.

1. Log into EUDAMED as a Local Actor Administrator (LAA). Under the *My Actor data* section click on the *Access point management* link:



2. Click on the Request a new M2M access button:

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸		L Test DTHREE-TWO	Logout
				CU	RRENT ACTOR:	Manufacturer, BE-MF-000002291, Test Maker of T	hings in Belgium (Belgium) 🐢	otifications
Acce	ss point	t managem	ent					
Request	a new M2M acce	ss						
Fil	ter 🔻							
Status								
Draft	t.		×	~				
A,	oply filters	Clear all filters						
Active filter	s:							
Status: I	Oraft Clear sea	rch						
Showing 1	to 1 of 1 entries						Show 20 🗸 entr	ies per page
Access P	oint	Part	y ID	Status		Access Point Type	Actions	
Test bidon	1			Draft		OWN		

3. Agree to the disclaimer and click on the **Next** button:

ome	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸	L Test DTHREE-TWO	Logou
				CURF	RENT ACTOR: Manuf	acturer, BE-MF-000002291, Test Maker of Things in Belgium [Belgium] @No	otifications
lach	nine to I	Machine re	quest acce	SS			
P Ac We Fo	ccess point discla leb services provi or the purpose of Is dedicated to Chall act he	imer ided by DG SANTE to the accessing these web set to the Actor.	e Actor rvices a user account wi	l be created	with the relevant perm	ssions. The 'web services' account:	
Th	 Shail hot be t 	account will be activated	Laffer the Actor client an	clor web ser	vices client application	In particular it shall never be directly used by a numan being.	
Th	 re responsibilities Requesting a Changing the Upon re In case After th Setting a logi anyone. Protecting the new be services c Developers n 	i of the designated perso n initial web services' ac access code when nece coeption of initial access of compromise, e handover of the person n/password pair in the wi- e password from disclost client application may be nust comply with secure -	on in charge of managing ccount password assary, i.e.: code, n in charge of managing eb services client applici ire. developed internally or 1 coding best practices.	the 'web servet the 'web servet ation. To that	vices' account area: vices' account. purpose the client app or. In any case:	lication shall implement a mechanism that prevents the disclosure of the pas	ssword to
	 Code review confidentiality 	must be completed by an y of the stored credential:	n independent party befo s.	ere going into	production with a view	to ensuring confidentiality and integrity of the exchanged data, as well as the	e
Th	ne production env	vironment of the web serv	vices client application m	ust be hoste	d by the Actor.		
De	evelopers and tes	sters shall not have acce	ss to the production env	ronment.			
Se	ensitive data and	credentials shall be acce	essible to a strictly limite	d number of	system administrators,	and all access logged.	
Pri	ivileged accounts	s (system administrators)) shall be managed acco	rding to ISO	27002 best practices.		

4. In the next screen select **Yes** to use an existing AP and click on the **Next** button:



5. Enter the Party ID of the Access Point that you want to use and click on the **Validate AP** button:

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸	L Test DTHREE-THREE Log	out
				CURRE	ENT ACTOR:	Manufacturer, DE-MF-000002295, Test Maker of Things in Germany [Germany] *Notificati	ons
Mach	nine to I	Machine rec	quest acces	SS			
* Enter the	Party Id of the A	ccess Point you want to u	ISE:				
EUDAME	D_000081						
Valio	late AP						
* 3rd Party	Agreement:						
Br	owse						
Save	& Next	Cancel					

6. You will be able to view information regarding the AP with the specified Party ID. You will not be able to edit that information:

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lome	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸	L Test DTHREE-THREE	
				CURRE	NT ACTOR:	Manufacturer, DE-MF-000002295, Test Maker of Things in Germany [Germany]	Notifi
1 l-							
lach	ine to ivi	achine ree	quest acce	SS			
Inter the I	Party Id of the Acce	ess Point you want to	use:				
UDAME	D_000081						
Valid	ate AP						
Tana							
Access	Point						
Access F	Point:	TW Demo 3rd Pa	irty AP				
Party ID:		EUDAMED_0000	181				
Access P	oint Country:	Belgium					
Access P	oint City:	Liege					
Organ	isation						
Org	anisation name:	TW Demo Third	Party1				
Stre	et information, if licable:	Yes					
Stre	eet:	aa					
Stre	eet number:	1					
Add	iress line 2:	-					
PO	box:	-					
City	name:	Liege					
Pos	tal code:	L123					
Cou	intry:	Belgium					
Tele	ephone:	*					
Ema	ail:	1@1.com					

7. Upload the 3rd Party Agreement and click on the **Save & Next** button:

Access Point	TAI Dome 2rd Darty AD 1	
Access Point:	TW Demo 3rd Party AP 1	
Party ID:	EODAMED_000081	
Access Point Country:	beigium	
Access Point City.	Liege	
Organisation		
Organisation name:	TW Demo Third Party1	
Street information, if applicable:	Yes	
Street:	aa	
Street number:	1	
Address line 2:		
PO box:		
City name:	Liege	
Postal code:	L123	
Country:	Belgium	
Telephone:	*	
Email:	1@1.com	

3rd Party Agreement

NOTE

The 3rd Party Agreement document is to confirm that a company (either a 3rd party provider or another Actor registered in EUDAMED having already an AP) agrees to act as 3rd party service provider for the Actor organisation that submits the request for the purposes of M2M DTX with EUDAMED.

This document will be used to assess the validation of the AP access/link request and must be provided for each environment where an AP access/link is requested (Playground and Production).

This document must identify clearly the two parties (Actor and 3rd party service provider) and must be signed by both parties for confirming the agreement from the 3rd party service provider toward the Actor.

You can download the 3rd Party Agreement template here.

You must upload a PDF file in the 3rd Party Agreement field.

8. In the next screen fill in your technical and legal contact details:

lome	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸	Test DTHREE-TWO	Logou
				CURF	RENT ACTOR:	Manufacturer, BE-MF-000002291, Test Maker of Things in Belgium [Belgium]	tifications
/lach	nine to	Machine re	quest acce	SS			
Technic	al Contact						
* First na	ame:						
1	*						
* Last na	ame:						
* Email:							
* Teleph	one:						
Telephone f	format example: +	32 x xxx xx xx					
Legal C	ontact						
* First na	ame:						
* Last na	ame:						
* Email:							
* Teleph	one:						
8							
Telephone f	format example: +	32 x xxx xx xx					



NOTE

Technical contact: The technical person to contact for setting up the AP and for any related technical issues.

This person must belong to the organisation that owns the AP (if the owner is a 3rd party provider, the technical contact should belong to the 3rd party provider; if the owner is an Economic Operator, the technical contact should belong to the Economic Operator).

Legal Contact: The person to contact in case there is a non-technical issue with the way the AP is used (e.g., misuse) or for notifications in case of maintenance/bug etc. that impacts the use of the AP.

This person must belong to the Actor's organisation submitting the request.

9. Upload your Proof of testing:

* Business justification / Proof of testing:

Browse



NOTE

In the *Business justification / Proof of testing* field use the Business justification document if you are a Playground user and the Proof of testing document if you are a user of the Production environment. See the EUDAMED environments page for further information about the existing environments accessible to the users.

IMPORTANT Proof of testing

The Proof of testing is required to set-up an AP in Production. Its purpose is to confirm that the prerequisite of a successful AP access/link in Playground is fulfilled by getting concrete information on the successful data exchange in Playground in order to assess whether the Actor can have an active AP in Production.

There is no template. However, it should contain the information listed below in a single PDF document:

- 1. Your Actor's SRN/ID and Party ID in Playground.
- 2. The XML request and response files that prove successful upload and/or download via M2M in Playground environment.

In case you request the upload of Legacy/Regulation Device/SPP (Basic UDI and UDI-DI) service, please also provide:

- 1. The Basic UDI-DI and UDI-DI of a successfully registered device in Playground.
- 2. The XML request and response files that prove that you have successfully registered this specific device (see point 1 above) via M2M in Playground.

10. Select the services that you want to use this AP for and click on the **Submit** button:





NOTE

You can only select services that are not assigned to another AP. Services assigned to another AP are greyed out. You will be able to edit the selected services after the activation of your AP. See section Generate your security key [31] of the current guide for more information.

11. Select **Yes** in the pop-up window to complete the AP registration process:

Are you sure you want to register this access point?										
Yes	No									



NOTE

If you select **Yes** your request will be stored as *submitted*. Otherwise, your request will be stored as *draft* (see Annex 3 (AP statuses) [60] of the current guide).

12. In the next screen you can see a confirmation message and the AP's Party ID. Click on the *Go back to Access Point Link dashboard link* to manage your AP:





NOTE

EUDAMED team at the Commission will either accept or reject your request. If your request is rejected then the status of your request will be *rejected* and you will be able to request again. Otherwise, the status of your request will be *active* (see Annex 3 (AP statuses) [60] of the current guide). Upon EUDAMED team's decision (request accepted/rejected), you will get a notification in your *Notifications Inbox*:

Home Tasks 🗸 Se	earch & view 🗸	Data Transfer 🗸 New	s Help 🗸		L Test DTHREE-TWO
		C	URRENT ACTOR: Manufact	turer, BE-MF-000002291, Test Mak	ker of Things in Belgium [Belgium] #Notifi
Notifications Ir	nbox				
Action Information					
A notification is archived	d after 30 days				
Notification type	Module	From	То		
- × •	-	× • 2023-02-16		6 🛱	
		YYYY-MM-DD	YYYY-MM-DD		
Active search fields: From: 2023-02-16 To: 2	023-03-16 Clear sea	rch			
					Time red
Information 🖬 2023-03-16	Email				
Actor - ACT-019.02-EUDAME	D_000081: Machine to	Machine Access Point Link	Approved		
Your request for a machine to m https://webgate.test.ec.europa.e	achine access point link u/eudamed/secure/links	k has been approved. Your ac s/ca0b44ef-cb1e-4bd8-b3b1-c	ccess point link is now active a c10f3e9167e3.	and can be used.	
Information = 2023-03-10	Email				



5.1.3 View your APs

1. Log into EUDAMED as a Local Actor Administrator (LAA). Click on the *Access point management* link under the *My Actor data* section to view your APs:

EUDAMED user guide

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸			L Test DTHREE-TWO	Logout
				CURF	RENT ACTOR	t: Manufacturer, BE-MF-000002	291, Test Maker	of Things in Belgium [Belgium] 🛷No	tifications
Welc	ome to	EUDAMED)						
MDR EUD/ Regulation	AMED is the IT s (EU) 2017/745 (ystem developed by the on medical devices an	European Commission to d Regulation (EU) 2017/	o implement 746 🛃 on in	vitro				
MDR EUD	AMED is structur	ed around 6 interconnec	ed modules and a public	: site.					
Tasks									
According	to your profile pe	r module, consult, verify	and/or manage your owr	and related	l data (manag	ed by your actor)			
	My Actor	data	lser management	UDI-DIs/Device					
		A	ssess user access requests lanage your users	5		Your Basic UDI-DIs / EUDAMED DIs Your UDI-DIs / EUDAMED IDs			
Manage	your actor data								
Manage Access n	your email notificat	ions							
Searc	h & View								
Overview o	of modules allowi	ng you to search and vie	w details, depending on	your profile					
		-						EL	
	H I				1				
	A	Actors			UDI-DIs/D	levices		Issued/Refused certificates	
									<u>^</u>

2. In the Access Point management page, you can view all your APs listed in the table:

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸			👤 Test D1	HREE-THRE	E Logout
				CURREN	TACTOR:	Manufacturer, DE-MF-	000002295, Test Make	er of Things in Germa	ny [Germany]	Notifications
Acce	ss point	managem	ent							
Request a	a new M2M acces	55								
Fill	ter 🔻									
Active filter	s: Active Clear set	arch								
Showing 1	to 1 of 1 entries							Show	20 🗸	entries per page
Access P	oint		Party ID			Status	Access Point Type		Actio	ns
TW Demo	3rd Party AP 1		EUDAMED_0000	81		Active	THIRD_PARTY			

3. To view further details about an AP, click on the *View* link under the three dots:

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸			L Test DTHREE-THREE	Logout
				CURREN	T ACTOR:	Manufacturer, DI	E-MF-000002295, Test Maker of Th	ings in Germany [Germany] 🐢	lotifications
Acce	ss poin	t managem	ient						
Request	a new M2M acce	ess							
Fil	ter 🔻								
Active filter	S:								
Status: A	Active Clear se	arch							
Showing 1	to 1 of 1 entries							Show 20 V ent	ries per page
Access P	oint		Party ID			Status	Access Point Type	Actions	
TW Demo	3rd Party AP 1	8.8.8.8.	EUDAMED_00008	0		Active	THIRD_PARTY		
								Vie	w J
								🖍 Edr	1

4. In the next screen you can only view details about the selected AP:

Ho	me Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸			1 Test DTHREE-THREE	Logout
				CURREN	T ACTOR:	Manufacturer, DE-MF-	000002295, Test Maker of T	hings in Germany [Germany] 🐢No	otifications
٨									
A	ccess point	managem	ent						
<	Go back to the list								
Acce	ess Point:	TW Demo 3rd Part	y AP 1			Status:	Active		
Part	y ID:	EUDAMED_00008	1			Access Point Type:	3rd Party		
Acce	ess Point Country:	Belgium							
Acce	ess Point City:	Liege			N				
3rd I	Party Agreement:	mahonle_CS18864	4_2022_5.pdf [33.65 KB]		6				
Busi	iness justification / of of testing:	mahonle_CS18864	4_2022_5.pdf [33.65 KB]						
0	rganisation								
	Organisation name:	TW Demo Third P	arty1						
	Street information, if applicable:	Yes							
	Street:	aa							
	Street number:	1							
	Address line 2:								
	PO box:	*							
	City name:	Liege							
	Postal code:	L123							
	Country:	Belgium							
	Telephone:								
	Email:	1@1.com							

Technical Contact		
First name:	Mickey	
Last name:	Mouse	
Email:	m.mouse@company.com	
Telephone number:	23456	
Legal Contact		
First name:	Donald	
Last name:	Duck	
Email:	d.duck@company.com	
Telephone number:	987654	
UDI/Device		
Manage security keys:		
 Upload of Legacy / Reg 	ulation Device/ SPP (Basic UDI	
and UDI-DI)		
✓ Update Basic UDI		
 Download of Legacy/ Re 	egulation Device/SPP	
 Upload UDI-DI for existi 	ng Basic UDI	
✓ Update UDI-DI		
 Update container packa 	ge	

5.1.4 Edit your APs

1. Log into EUDAMED as a Local Actor Administrator (LAA). Click on the *Access point management* link under the *My Actor data* section to view your APs:

EUDAMED user guide

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸			L Test DTHREE-TWO	Logout
				CURF	RENT ACTOR	t: Manufacturer, BE-MF-000002	291, Test Maker	of Things in Belgium [Belgium] 🛷No	tifications
Welc	ome to	EUDAMED)						
MDR EUD/ Regulation	AMED is the IT s (EU) 2017/745 (ystem developed by the on medical devices an	European Commission to d Regulation (EU) 2017/	o implement 746 🛃 on in	vitro				
MDR EUD/	AMED is structur	ed around 6 interconnec	ed modules and a public	: site.					
Tasks									
According	to your profile pe	r module, consult, verify	and/or manage your owr	and related	l data (manag	ed by your actor)			
	My Actor	data	lser management			UDI-DIs/Device			
		A	ssess user access requests lanage your users	5		Your Basic UDI-DIs / EUDAMED DIs Your UDI-DIs / EUDAMED IDs			
Manage	your actor data								
Manage Access n	your email notificat	ions							
Searc	h & View								
Overview o	of modules allowi	ng you to search and vie	w details, depending on	your profile					
		-						EL	
						1			
	A	Actors			UDI-DIs/D	levices		Issued/Refused certificates	
									<u>^</u>

2. In the Access Point management page, you can view all your APs listed in the table:

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸			👤 Test DT	HREE-THREE	Logout
				CURREN	T ACTOR:	Manufacturer, Dig-MF	000002295, Test Make	er of Things in Germar	ny [Germany] 🕇	Notifications
Acce	ss point	managem	ent							
Request	a new M2M acces	55								
Fill	ter 🔻									
Active filter: Status: A	s: Active Clear sea	arch								
Showing 1	to 1 of 1 entries							Show	20 🗸 e	ntries per page
Access P	oint		Party ID			Status	Access Point Type	Al en en en	Action	s
TW Demo	3rd Party AP 1		EUDAMED_0000	81		Active	THIRD_PARTY			

3. Click on the *Edit* link under the three dots to edit your AP's settings:

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸			Test DTHREE-THREE	Logout
				CURREN	NT ACTOR:	Manufacturer, DE	E-MF-000002295, Test Maker of Th	ings in Germany [Germany] 1	Notifications
Acce	ss poin	t managem	ent						
Request	a new M2M acce	ss							
Fit	ter 🔻								
Active filter	s:								
Status: 7	Active Clear se	arch							
Showing 1	to 1 of 1 entries							Show 20 🗸	entries per page
Access P	oint		Party ID			Status	Access Point Type	Action	IS
TW Demo	3rd Party AP 1		EUDAMED_0000	81		Active	THIRD_PARTY		
								٩	/iew
								1	Edit

4. In the next screen you can edit your AP details:

	CORRENTACTOR. Manuacturer, DE-MI-000002295, lest Maker of Things in Germany [Germany] *Notifications
lachine to Machine request acces	SS
* Eirst name:	
Mickey	
* Lact name	
Last halfe.	
Mouse	
Email.	
m.mouse@company.com	
* Telephone:	
23456	
Felephone format example: +32 x xxx xx	
egal Contact * First name: Donald	
* Last name:	
Duck	
* Email:	
d.duck@company.com	
* Telephone:	L2
987654	
Telephone format example: +32 x xxx xx xx	
susiness justification / Proof of testing:	
ile uploaded successfully	
mahonle_CS18864_2022_5 [PDF 33.65 KB]	×

5.1.5 Terminate your AP

1. Log into EUDAMED as a Local Actor Administrator (LAA). Click on the *Access point management* link under the *My Actor data* section to view your APs:

EUDAMED user guide

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸			L Test DTHREE-TWO	Logout
				CURF	RENT ACTOR	t: Manufacturer, BE-MF-000002	291, Test Maker	of Things in Belgium [Belgium] 🛷No	tifications
Welc	ome to	EUDAMED)						
MDR EUD/ Regulation	AMED is the IT s (EU) 2017/745 (ystem developed by the on medical devices an	European Commission to d Regulation (EU) 2017/	o implement 746 🛃 on in	vitro				
MDR EUD/	AMED is structur	ed around 6 interconnec	ed modules and a public	: site.					
Tasks									
According	to your profile pe	r module, consult, verify	and/or manage your owr	and related	l data (manag	ed by your actor)			
	My Actor	data	lser management			UDI-DIs/Device			
		A	ssess user access requests lanage your users	5		Your Basic UDI-DIs / EUDAMED DIs Your UDI-DIs / EUDAMED IDs			
Manage	your actor data								
Manage Access n	your email notificat	ions							
Searc	h & View								
Overview o	of modules allowi	ng you to search and vie	w details, depending on	your profile					
		-						EL	
						1			
	A	Actors			UDI-DIs/D	levices		Issued/Refused certificates	
									<u>^</u>

2. In the Access Point management page, you can view all your APs listed in the table:

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸			👤 Test D1	HREE-THRE	E Logout
				CURREN	TACTOR:	Manufacturer, DE-MF-	000002295, Test Make	er of Things in Germa	ny [Germany]	Notifications
Acce	ss point	managem	ent							
Request a	a new M2M acces	55								
Fill	ter 🔻									
Active filter	s: Active Clear set	arch								
Showing 1	to 1 of 1 entries							Show	20 🗸	entries per page
Access P	oint		Party ID			Status	Access Point Type		Actio	ns
TW Demo	3rd Party AP 1		EUDAMED_0000	81		Active	THIRD_PARTY			

3. Click on the *View* link under the three dots to view further details about your AP:

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸			1 Test DTHREE-THREE	Logout
				CURREN	IT ACTOR:	Manufacturer, DB	E-MF-000002295, Test Maker of Th	ings in Germany [Germany]	Notifications
Acce	ss poin	t managem	ient						
Request	a new M2M acce	ess							
Fil	ter 🔻								
Active filter	S:								
Status: /	Active Clear se	earch							
Showing 1	to 1 of 1 entries							Show 20 V	entries per page
Access P	oint		Party ID			Status	Access Point Type	Action	S
TW Demo	3rd Party AP 1		EUDAMED_00008	1		Active	THIRD_PARTY		
								•	/iew b
								1	Edit

4. In the next screen click on the **Terminate link** button to terminate your AP:

		CURRENT AC	TOR: Manufacturer, BE-MF-00	00000222, ARMEN EU MF	2 [Belgium] Switch actor #Notifications
Access point n	nanagement				Terminate Link
Access Point: Party ID: Access Point Country: Access Point City: 3rd Party Agreement: Business justification / Proof of testing:	Armen TEST 2 EUDAMED_000042 American Samoa A CITY test_file_size_is_1383KB.pdf [1.35 MB] test_file_size_is_1383KB.pdf [1.35 MB]		Status: Access Point Type:	Active Other Actor	
Organisation Organisation name:	ARMEN EU MF 1				
Street information, if applicable:	No				



NOTE

The status of your AP is now *terminated* (see Annex 3 (AP statuses) [60] of the current guide). You will not be able to use this AP anymore nor revert to the previous state.

5.1.6 Generate your security key



1. Log into EUDAMED as a Local Actor Administrator (LAA). Click on the Access point management link under the My Actor data section to view your APs:

Home Tasks 🗸 Search 8	& view 〜 🛛 Data Tran	sfer 🗸 News	Help 🗸			L Test DTHREE-TWO	Logout
		CUF	RENTACTOR	: Manufacturer, BE-MF-000002	291, Test Maker of Thing	gs in Belgium (Belgium) 🐗No	otifications
Welcome to EUD	AMED						
MDR EUDAMED is the IT system deve Regulation (EU) 2017/745 C on medica diagnosis medical devices	loped by the European Cor al devices and Regulation (nmission to implemen EU) 2017/746 🔀 on i	nt in vitro				
MDR EUDAMED is structured around 6	6 interconnected modules a	nd a public site.					
Tasks							
According to your profile per module, co	onsult, verify and/or manag	e your own and relate	ed data (manag	ed by your actor)			
My Actor data	User manager	nent		JDI-DIs/Device			
	Assess user acco Manage your use	ess requests ers		Your Basic UDI-DIs / EUDAMED DIs			
Manage your actor data							
Manage your email notifications							
Access point management							
Search & View							
Overview of modules allowing you to se	earch and view details, dep	ending on your profile	1				
						N	
Actor module	9		UDI-DI m	odule	NB	& Certificates module	
Actors			UDI-DIs/D	evices	Issue	ed/Refused certificates	

2. In the Access Point management page, you can view all your APs listed in the table:

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸			👤 Test D'	THREE-THR	EE Logout
				CURREN	IT ACTOR:	Manufacturer, DF-MF-0	000002295, Test Make	er of Things in Germa	ny [German	y] #Notifications
Acce	ss poin	t managem	ent							
Request	a new M2M acce	SS								
Fi	ter 🔻									
Status:	s: Active Clear se	arch								
Showing 1	to 1 of 1 entries							Show	20 🗸	entries per page
Access P	oint		Party ID			Status	Access Point Type		Act	ions
TW Demo	3rd Party AP 1		EUDAMED_0000	081		Active	THIRD_PARTY			

3. Click on the *Edit* link under the three dots to view your AP's settings:

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸			1	est DTHREE-TH	REE Logout	
				CURREN	TACTOR:	Manufacturer, Di	E-MF-000002295, Test Maker of T	hings in (Germany [Germar	y] #Notifications	
Acces	ss point	managem	ent								
Request a	new M2M acces	s									
Filte	er 🔻										
Active filters											
Status: A	clive Clear sea	rch								_	
Showing 1 to	o 1 of 1 entries							5	Show 20 V	entries per page	9
Access Po	int		Party ID			Status	Access Point Type		Ac	tions	
TW Demo 3	rd Party AP 1		EUDAMED_00008	1		Active	THIRD_PARTY				
									•	View	
										✓ Edit	and a state of the

4. In the displayed screen you can view and edit the details you entered regarding the selected AP. Moreover, you can now change the services attached to your AP and manage your security keys by clicking on the *Manage security keys* link:

Actor	UDI/Device	Certificates/Notified Body
Manage security keys:	Manage segurity keys:	Manage security keys:
Actor download	 Upload of Legacy / Regulation Device/ SPP (Basic UDI and UDI-DI) 	SS(C)P Download
	Update Basic UDI	
	Download of Legacy/ Regulation Device/SPP	
	Upload UDI-DI for existing Basic UDI	
	Update UDI-DI	
	Update container package	
	Update market information	

5. In the pop-up window click on the **Generate a security key** button to generate the security key for the selected module:

d duck@company.com * Telephone: 987654 Telephone format example: +32 x sox sox } No security key	security keys is available. Please generate a security key	* <u>Close</u>
* Business justification / Proof of testi	curity hay Cancel	
file uploaded successfully		
mahonle_CS18864_2022_5 (PDF 33.65 KB)	×	
Actor Manage security keys:	UDI/Device Manage security keys: Upload of Legacy / Regulation Device/ SPP (Basic UDI and UDI-DI) Update Basic UDI Download of Legacy/ Regulation Device/SPP Upload UDI-DI for existing Basic UDI Update UDI-DI Update container package Update market information	Certificates/Notified Body Manage security keys:
Submit Cancel		



The security keys are generated per module.

6. In the pop-up window you will be able to view the generated security key:

	d.duck@company.com	×Close
	* Telephone:	Manage security keys
	987654	No security key is available. Please generate a security key
	elephone format example: +32 x xxx xx x	Please copy the security key since you will not be able to view it again
* В	usiness justification / Proof of testi	La contra c
1 fi	ile uploaded successfully	E2CE0B12A047344403BD69ED460275568DFD960238E786B4D3185B8EE1A5DAFF3526F3AC98241D7574C600B0F35 676B91914BB3A2CD071A881F66602B19C52EBE1A01E8170960477FE373211EC37D3289AEFCAF7C1287054787FCA
П	nahonle_CS18864_2022_5 (PDF	27865005FF355B48E9945BBEA096989E864FFF029598D89A9027EE0F6399E7BFA2BD15ED4490C427B492C3498521
ł	Actor Manage security keys:	B584F4C1F59DA4AFEBE39F4BEATFED21FB3A743F215DDA610B10597544D1C661B1B58975ED38CC34396CBA9AA3 FC31771DDB336A8CA58837C88654831AF9FA1948CF4E705201CE50D8E3DBE699F7CC1C9C0F4E0CEF5FF5DB588 E9079F6FBB285ABFFE79AC6CCDB67FD1668907166025CAA3D2E5B4892EA9265CCD6CD00A2C351D63B1692E41B EEF
		Generate a security key Cancel
		Upload UDI-DI for existing Basic UDI
		Update UDI-DI
		Opdate container package Update market information
	Submit	ancel

IMPORTANT

Please copy the security key. You will not be able to view your security key after closing the pop-up window. If you lose your security key, you must regenerate it (see Section Regenerate your security key [34] of the current guide for further details).



5.1.7 Regenerate your security key

1. Log into EUDAMED as a Local Actor Administrator (LAA). Click on the *Access point management* link under the *My Actor data* section to view your APs:

Home Tasks 🗸 Search & view 🗸 Data	Transfer 🗸 News	Help 🗸	Logout				
	CUR	RENT ACTOR: Manufacturer, BE-MF-000002	2291, Test Maker of Things in Belgium [Belgium] #Notifications				
Welcome to EUDAMED							
MDR EUDAMED is the IT system developed by the Europea Regulation (EU) 2017/745 ² on medical devices and Regula diagnosis medical devices MDR EUDAMED is structured around 6 interconnected medi	n Commission to implement ation (EU) 2017/746 C on ir	t vitro					
Teeke	and a public site.						
According to your profile per module, consult, verify and/or m	anage your own and relate	d data (managed by your actor)					
User mai	nagement	UDI-DIs/Device					
My Actor data Assess us	er access requests	Your Basic UDI-DIs / EUDAMED DIs Your UDI-DIs / EUDAMED IDs					
Manage your actor data Manage your email notifications Access point management	NI 03013						
Search & View Overview of modules allowing you to search and view details, depending on your profile							
Actor module		UDI-DI module	NB & Certificates module				
Actors		UDI-DIs/Devices	Issued/Refused certificates				
				^]			

2. In the Access Point management page, you can view all your APs listed in the table:



3. Click on the *Edit* link under the three dots to view your AP's settings:

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸			L Test DTHREE-THREE	Logout
				CURREN	NT ACTOR:	Manufacturer, DE	-MF-000002295, Test Maker of Th	ings in Germany [Germany] 🚀	Notifications
Acce	ss poin	t managem	ent						
Request	a new M2M acce	ess							
Fil	ter 🔻								
Active filter	S:								
Status: A	Active Clear se	earch							
Showing 1	to 1 of 1 entries							Show 20 V en	tries per page
Access P	oint		Party ID			Status	Access Point Type	Actions	
TW Demo	3rd Party AP 1		EUDAMED_00008	31		Active	THIRD_PARTY		
								Vie	ew
								Ed	it M

4. In the displayed screen click on the *Manage security keys* link:

Actor	UDI/Device	Certificates/Notified Body
Manage security keys:	Manage semurity keys:	Manage security keys:
Actor download	 Upload of Legacy / Regulation Device/ SPP (Basic UDI and UDI-DI) 	SS(C)P Download
	Update Basic UDI	
	Download of Legacy/ Regulation Device/SPP	
	 Upload UDI-DI for existing Basic UDI 	
	Update UDI-DI	
	 Update container package 	
	Update market information	
Submit Cancel		

5. In the pop-up window click on the **Regenerate a security key** button to regenerate the security key for the selected module:

d duck@company.com * Telephone 987654 Telephone format example: +32 × xxx xx * Business justification / Proof of test Regenerate a se 1 file uploaded successfully	ecurity keys been already generated. Click on regenerate button to create a new one curty key	* <u>Close</u>
mahonle_CS18864_2022_5 [PDF 33.65 KB]	×	
Actor Manage security keys Actor download Submit Cancel	UDI/Device Manage security keys. Upload of Legacy / Regulation Device/ SPP (Basic UDI and UDI-DI) Update Basic UDI Download of Legacy/Regulation Device/SPP Upload UDI-DI for existing Basic UDI Update UDI-DI for existing Basic UDI Update container package Update market information	Certificates/Notified Body Manage security keys: SS(C)P Download

6. In the pop-up window you will be able to view the regenerated security key:

d.duck@company.com * Telephone:	× <u>Close</u>	
987654 Telephone format example: +32 x xox xox xo * Buisiness inistification / Proof of testi	A security key has been already generated. Click on regenerate button to create a new one Please copy the security key since you will not be able to view it again	
1 file uploaded successfully mahonie_CS18864_2022_5 (PDF Actor Manage security keys: Actor download	1FB70B7832103F7C108FDE4B375E30372678A51E6DF530C6A8321FEE446C8DC52984C9CCB5410002B94F0DC91E CAF2C6A1FBDE39F654D71504E853C7E0820466CE97DCA6BF17116565EAC6347D45BF889645417CD6053890CC38 4980873E0BD74F819672D5579F847001A425F6FFCB0C0F15F3C42BBB79DC81961D1712A7AA58122C04DA0FE212A 4F7F3376A0F79822933B55A6170AC3DD88F80C7D6C7C8BD31580AC04DCC2F85601E00C805E48B0328B61898EDB 8865C2E39E96A19EB1DB60D04DD016CBE7CE58E27959881F66A3589F47B1D661A35C9C2BC8618591274AA99333 49C91D3826103B7066C2B11D1C2DE66942724AEB301B5C14A94F2842EF9C03AD816A1088E420A077F8C7A33C52E 45 Regenerate a security key Cancel	lody
Submit	Upload UDI-DI for existing Basic UDI Update UDI-DI Update container package Update market information Cancel	



IMPORTANT

Please copy the regenerated security key. You will not be able to view your security key after closing the pop-up window. If you lose your security key, you must regenerate it.



NOTE

When a security key is regenerated, all new XML files must include the new security key for that module, otherwise they will be rejected.

5.2 How to configure your AP

After submitting your request (the status of the request should be *connectivity under validation*) for M2M services, you must follow the steps listed below in order to complete the onboarding:

- 1. Download the Technical Onboarding template here.
- 2. Fill in the Technical Onboarding template given the instructions described in the document.
- 3. Send the filled in document via email to the EUDAMED support team.

EUDAMED support team will process your request and will send you an email message consisting of further useful information that will help you configure your AP and complete the onboarding.



NOTE

Only after completing the steps described in the email message that you will receive by EUDAMED support team your AP will be active.



IMPORTANT

Only after your AP is active you will be able to generate your security keys. See Generate your security key [31] for further information.

6 M2M data exchange process

6.1 General concepts and terminology

It is worth mentioning that the concepts listed below will assist you in constructing the XML files that will be used for the M2M data exchange (see Section Technical documentation [56] of the current guide for further details):

- Entity model: Represents the canonical model of business entities (e.g. actor, actor registration, device, certificate, etc.)
- **Service model**: Models how data is shaped in order to be transported, encapsulated and delivered to the right service
- Data exchange communication patterns: Defines how the data is exchanged between participants
- Service definition: Describes how to represent and access the business capability.

Entity model

Most main business entities contain the abstract superclass Entity to express the versioning capability.

Generally, most of the entities exchanged (through the exposed services) are interrelated (have dependencies between them). To model this, a concept of link has been introduced. In this way, it is possible to isolate the information related to a specific sub-domain and only reference to the other related entities.

Service model

The service model describes the EUDAMED data structures used to perform information exchange and consists of the following elements:

- Information about the type of message (from the data exchange messaging patterns pull/push)
- Service destination information (each operation will represent a specific functionality)
- · Means to query / filter (criteria) the request
- · Security rules that may apply depending on the actor that performs it
- Information available as response, number of provided entities, pagination and versioning capabilities.

Supported services operation

The following services operation are supported by EUDAMED:

- 1. **GET**: The GET method requests transfer of a current selected representation for the target resource. GET is the primary mechanism of information retrieval and the focus of almost all performance optimisations. Hence, when people speak of retrieving some identifiable information via HTTP, they are generally referring to making a GET request (PULL message type).
- 2. **POST**: The POST method requests that the target resource process the representation enclosed in the request according to the resource's own specific semantics (PUSH message type).
- 3. PUT: The PUT method requests that the state of the target resource be created or replaced with the state defined by the representation enclosed in the request message payload. A successful PUT of a given representation would suggest that a subsequent GET on that same target resource will result in an equivalent representation being sent in a 200 (OK) response. However, there is no guarantee that such a state change will be observable, since the target resource might be acted upon by other user agents in parallel, or might be subject to dynamic processing by the origin server, before any subsequent GET is received. Thus, a PUT request always contains a full resource. This is necessary because, a necessary quality of PUT requests is idempotence the quality of producing the same result even if the same request is made multiple times (PUSH message type).
- 4. **PATCH**: The PATCH method requests that a set of changes described in the request entity be applied to the resource identified by the Request. With PATCH, however, the enclosed entity contains a set of instructions describing how a resource currently residing on the origin server should be modified to produce a new version. The PATCH method affects the resource identified by the Request-URI, and it also may have side effects on other resources; i.e., new resources may be created, or existing ones modified, by the application of a PATCH. To ensure an idempotent behaviour, clients using this kind of patch application should use a conditional request such that the request will fail if the resource has been updated since the client last accessed the resource (PUSH message type).

Operation	Description	Supported communication patterns	Payload	Return value
Download (GET)	This operation is invoked to request information using a criteria mechanism.	Pull	Search criteria	A PullResponse type message containing a list of the entity(ies) and all related fields based on the criteria specified in the request message
Upload (POST)	This operation is invoked to upload (create) information to EUDAMED.	Push	For a specific entity fields to be filled to create the entity	Acknowledgement
Update (PUT/ PATCH)	This operation is invoked to update information to EUDAMED.	Push	For a specific entity fields to be updated	Acknowledgement

More information for each operation is presented in the table below.

6.2 Message exchange

SOAP messages will be used for data exchange. An example of a SOAP message is presented in the following image:

<pre><soap:envelope <="" th="" xmlns:ns="http://docs.oasis-open.org/ebxml-msg/ebms/v3.0/ns/core/2007/
</pre></th><th>ð4/" xmlns:soap="http://www.w3.org/2003/05/soap-envelope"></soap:envelope></pre>	
<pre>xmlns:_1="http://org.ecodex.backend/1_1/"></pre>	
<soap:header></soap:header>	
<ns:messaging></ns:messaging>	
<ns:usermessage></ns:usermessage>	
<ns:partyinfo></ns:partyinfo>	
<ns:from></ns:from>	
<ns:partyid type="urn:oasis:names:tc:ebcore:partyid-type:unregistered:EUDAMED">domibus-blue</ns:partyid>	
<ns:role>http://docs.oasis-open.org/ebxml-msg/ebms/v3.0/ns/core/200704/initiator</ns:role>	
<ns:to></ns:to>	
<ns:partyid type="urn:oasis:names:tc:ebcore:partyid-type:unregistered:EUDAMED">domibus-blue</ns:partyid> <ns:role>http://docs.oasis-open.org/ebxml-msg/ebms/v3.0/ns/core/200704/responder</ns:role>	
<ns:collaborationinfo></ns:collaborationinfo>	
<ns:service type="e-delivery">http://ec.europa.eu/e-delivery/services/eudamed</ns:service>	
<ns:action ns:action="" submitmessage<=""></ns:action>	
<ns:messageproperties></ns:messageproperties>	
<pre><ns:property name="originalsender">urn:oasis:names:tc:ebcore:partyid-type:unregistered:Cl/ns:Property></ns:property></pre>	
<pre><ns:property name="thnalkecipient">urn:oasis:names:tc:ebcore:partyid-type:unregistered:c4</ns:property></pre>	
<ns:payloadinto></ns:payloadinto>	
<pre><ns:partinfo nref="cla:eudamedxmiAttachment"></ns:partinfo></pre>	
<ns:partproperties></ns:partproperties>	
<pre></pre> //siproperty name= mimerype >text/xmi//siproperty>	
soap : Header	
(soup:bouy)	
<:submitRequest>	
chaluna payloadig= cld:eudamedxmiAttachment contentrype= text/xmi >	
	lau contradam]
	agvezvyumi
<pre></pre>	



IMPORTANT

The entire XML message must be base64 encoded. The payload element contains the encoded message. The highlighted line shows the encoded message.

A basic message structure would consist of the following main elements:



Messaging (MessageType)

Message types and related properties, such as:

- 1. **Message type (Push, PullRequest, PullResponse, Acknowledge)**: Identification, description of the root of the messages
- 2. **Payload (Criteria Payload)**: Canonical entities data models and related attached resources (e.g. attachments, etc.), or querying criteria
- 3. **Capabilities requested/fulfilled metadata**: How the information should be provided to the requester (e.g., max. delay for the request, query type, max number of entities to be provided, pagination, etc.)
- 4. **Reports (ElementReportsType)**: How the reports should be submitted with the processing / request status in case of an initial Push or PullRequest messages.

Service definition (ServiceType)

Description of the services provided by EUDAMED:

- 1. serviceID: A unique identifier of a service in EUDAMED
- 2. serviceOperation: Supported by the service (e.g. download, upload, update, etc.)
- 3. **serviceAccessToken**: Bearer security authentication token (security key) to gain access permission to the requested data by the requester as EUDAMED actor or third party (acting on behalf of the actor mentioned in nodeCode)
- 4. **serviceVersion**: In case of multi-versioned compatible service, it allows to specify what version of the current service is invoked.

Addressing (NodeType)

Logical networking information related to the actors and AP used in DTX process:

- nodeCode: Contains the EUDAMED code (e.g. SRN, CA identifier, NB code etc.) of the party that performs the call of service. In case of multi-profile endpoint (e.g. third-party companies), it contains the actor code on behalf of the request that is performed.
- 2. **nodelD**: Identify the requester (actor/third-party integrators) of the message eDelivery endpoint, it contains the partyID of the requester.



IMPORTANT

In all your XML files you must include the version of the XSD schema that was used. You can visit EUDAMED Information Centre to check the latest version of the XSD schema in use. The version number included in your XML files must match the latest version number of the XSD schema in use, otherwise your XML files will be rejected.

The following figure displays the place that the version number must be included in the XML file.



6.3 Service definition

The service definition contains information about types of messages (from the data exchange messaging patterns) compatible, available operations at service level (each

operation will represent a specific functionality), means to query / filter (criteria) the request, security rules that may apply depending on the actor that perform it and finally the information available as response, eventually number of provided entities, pagination and versioning capabilities. For further details see the Service definitions documents in the Technical Documentation page of the Information Centre.

7 Example of the process

7.1 PULL

Scenario

In this example, a user of a public/private organisation with a CA profile requests from EUDAMED a list with all registered devices for the Manufacture with SRN BE-MF-000001201.

Process

The following image illustrates the message exchange between EUDAMED and the public/private organisation which performs the request.



More specifically, the following steps take place in the above-mentioned scenario:

- 1. A *PullRequest* message (*request0*) is created by the organisation containing the attributes listed below:
 - a. messageID: A unique identifier, issued by the requester
 - b. correlationID: An identifier that will correlate the request to the response or to the acknowledgements, issued by the requester
 - c. sender/service/ServiceID: An identifier of the callback service (for responses and acknowledgements)
 - d. sender/node/nodeCode: An identifier of the EUDAMED unique number of the requester (e.g. SRN, CA number, etc.)
 - e. sender/node/nodeID: An identifier of the eDelivery partyID
 - f. recipient/service/serviceID: An identifier of the EUDAMED service
 - g. recipient/service/serviceOperation: An identifier of the EUDAMED service operation to uniquely define the service scope
 - h. recipient/service/serviceAccessToken: The EUDAMED bearer security token attached to the requester service
 - i. pageNumber: In case of paginated response, the requester can orchestrate multiple page response and request for a specific page to be provided in the response



The first page is page number '0'.

- j. pageSize: The required maximum number of entities on a specific response page
- k. payload/Entities: It may contain the main service entity in case of a query by example criteria
- 2. The *PullRequest* message (*request1*), is sent by the organisation's backend to the organisation's eDelivery AP. As mentioned in Message exchange [40] Section of the current guide, the *request0* is encoded and embedded into the payload of a SOAP envelope. The following attributes are included in the message:
 - a. envelope/header/messaging/usermessage/partyinfo/from/partyID: A unique identifier of the requester's eDelivery AP
 - b. envelope/header/messaging/usermessage/partyinfo/to/partyID: A unique identifier of the EUDAMED eDelivery AP
 - c. envelope/body/submitRequest/payload: It holds the base64 format of the *request0* message

- 3. The *PullRequest* message (*request2*), is sent from the organisation's eDelivery AP to EUDAMED's eDelivery AP. The status of the message is now SENDING.
- 4. The EUDAMED eDelivery AP sends an *Acknowledge* message (*ack1*) to the organisation's eDelivery AP which implies that *request2* was successfully received by the EUDAMED eDelivery AP. The status of the message is now DELIVERED.
- 5. The *PullRequest* message (*request3*), is sent from EUDAMED'S eDelivery AP to EUDAMED's backend. The status of the message is now SENDING.
- 6. The EUDAMED eDelivery AP sends again an *Acknowledge* message (*ack2*) to the organisation's eDelivery AP which implies that *request3* was successfully received by the EUDAMED eDelivery AP. The status of the message is now DELETED.
- 7. A *PullResponse* message (*response0*) is created by EUDAMED containing the following attributes:
 - a. messageID: A unique identifier, issued by submitter
 - b. correlationID: The same as correlationID from the request message
 - c. responseCode: Status code of the service call (success or matching error code)
 - d. sender/service/ServiceID: An identifier of the EUDMAED initiator service
 - e. sender/node/nodeCode: An identifier of the EUDAMED eDelivery party identifier
 - f. sender/node/nodeID: An identifier of the eDelivery partyID
 - g. recipient/service/serviceID: The requester's generic callback service
 - h. recipient/service/serviceOperation: The requester's callback service operation (as specified in the request message)
 - i. payload/entities: It contains the list of entities of the same type that were collected through the service invocation
- 8. The *PullResponse* message (*response1*), is sent by EUDAMED's backend to EUDAMED's eDelivery AP. As mentioned in Message exchange [40] Section of the current guide, the *response0* is encoded and embedded into the payload of a SOAP envelope. The following attributes are included in the message:
 - a. envelope/header/messaging/usermessage/partyinfo/from/partyID: A unique identifier of the requester's eDelivery AP
 - b. envelope/header/messaging/usermessage/partyinfo/to/partyID: A unique identifier of the EUDAMED eDelivery AP
 - c. envelope/body/submitRequest/payload: It holds the base64 format of the *response0* message
- 9. The *PullResponse* message (*response2*), is sent by EUDAMED's eDelivery AP to the organisation's eDelivery AP.

- 10. The organisation's eDelivery AP sends an *Acknowledge* message (*ack3*) to the EUDAMED eDelivery AP which implies that *response2* was successfully received by the organisation's eDelivery AP. The status of the message is now DELIVERED.
- 11. The *PullResponse* message (*response3*), is sent from the organisation's eDelivery AP to organisation's backend. The status of the message is now SENDING.
- 12. The organisation's eDelivery AP sends again an *Acknowledge* message (*ack3*) to the EUDAMED eDelivery AP which implies that *response3* was successfully received by the organisation's eDelivery AP. The status of the message is now DELETED.

Messages

Given the above-mentioned scenario, the following messages will be created:

Request0

```
<message:PullRequest
xmlns:device="https://ec.europa.eu/tools/eudamed/dtx
    /datamodel/Entity/Device/v1"
xmlns:party="https://ec.europa.eu/tools/eudamed/dtx
    /datamodel/Party/v1">
    <message:correlationID>a754cdd7-3602-45b4-a993-c25adb18a60e
    </message:correlationID>
    <message:creationDateTime>2019-05-22T06:58:45.223+02:00
    </message:creationDateTime>
    <message:messageID>a64a5a1f-da86-4810-a0de-27d0338811a9
    </message:messageID>
    <message:recipient>
        <message:node>
            <service:nodeActorCode>EUDAMED
            </service:nodeActorCode>
            <service:nodeID>eDelivery:EUDAMED
            </service:nodeID>
        </message:node>
        <message:service>
          <service:serviceAccessToken>3434524234225234234234
          </service:serviceAccessToken>
          <service:serviceID>DEVICE</service:serviceID>
          <service:serviceOperation>GET
          </service:serviceOperation>
        </message:service>
    </message:recipient>
    <message:payload/>
    <message:sender>
        <message:node>
            <service:nodeActorCode>CA-BE-000000555
            </service:nodeActorCode>
            <service:nodeID>eDelivery:CA-BE-000000555
            </service:nodeID>
```

```
</message:node>
<message:service>
<service:serviceID>REPLY_SERVICE</service:serviceID>
<service:serviceOperation>GET</service:serviceOperation>
</message:sender>
<message:pageNumber>1</message:pageNumber>
<message:pageSize>10</message:pageSize>
<message:criteriaPayload>
<message:diDownloadCriteria>
</message:diDownloadCriteria>
</message:criteriaPayload>
</message:PullRequest>
</message:PullRequest>
```

Response0

```
<message:PullResponse
xmlns:device="https://ec.europa.eu/tools/eudamed/dtx
    /datamodel/Entity/Device/v1">
    <message:correlationID>a754cdd7-3602-45b4-a993-c25adb18a60e
    </message:correlationID>
    <message:creationDateTime>2019-05-22T06:43:12.459+02:00
    </message:creationDateTime>
    <message:messageID>a64a5a1f-da86-4810-a0de-27d0338811a9
    </message:messageID>
    <message:recipient>
        <message:node>
            <service:nodeActorCode>AC-BE-000000555
            </service:nodeActorCode>
            <service:nodeID>eDelivery:AC-BE-000000555
            </service:nodeID>
        </message:node>
        <message:service>
            <service:serviceID>REPLY SERVICE</service:serviceID>
            <service:serviceOperation>GET</service:serviceOperation>
        </message:service>
    </message:recipient>
    <message:payload>
        <device:Device xsi:type="device:IVDRDeviceType"</pre>
            xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
            <device:IVDRBasicUDI>
                . . . . . . .
                <budi:modelName>
                    <budi:model>1001/202</budi:model>
                    <budi:name>Clear-View Sub-Q</budi:name>
                </budi:modelName>
                <budi:MFActorCode>BE-MF-000001201</budi:MFActorCode>
            </device:IVDRBasicUDI>
```

```
<device:IVDRUDIDIData>
                 <udidi:identifier>
                     <udidi:DICode>UDICODE1</udidi:DICode>
                     <udidi:issuingEntityCode>GS1
                     </udidi:issuingEntityCode>
                 </udidi:identifier>
             </device:IVDRUDIDIData>
        </device:Device>
        <device:Device xsi:type="device:MDRDeviceType"</pre>
             xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
             <device:MDRBasicUDI>
                 . . . . . . . . . . . . . . . .
                 <budi:riskClass>IIb</budi:riskClass>
                 <budi:model>SCE8-03-05</budi:model>
                 <budi:identifier>
                     <udidi:DICode>M991CVS1277777</udidi:DICode>
                     <udidi:issuingEntityCode>GS1
                     </udidi:issuingEntityCode>
                 </budi:identifier>
                 <budi:MFActorCode>BE-MF-000001201
                 </budi:MFActorCode>
                 <budi:applicableLegislation>MDR
                 </budi:applicableLegislation>
                 . . . . . . . . . . . . . .
             </device:MDRBasicUDI>
             <device:MDRUDIDIData>
                 . . . . . . . . . . . . . . . .
             </device:MDRUDIDIData>
        </device:Device>
    </message:payload>
    . . . . . .
    <message:maxPageNumber>1</message:maxPageNumber>
    <message:pageNumber>1</message:pageNumber>
    <message:pageSize>10</message:pageSize>
    <message:responseCode>SUCCESS</message:responseCode>
</message:PullResponse>
```

7.2 PUSH

Scenario

In this scenario a user of a public/private organisation with a non-EU Manufacturer profile uploads the organisation's devices in EUDAMED.

Process

The following image displays the message exchange between EUDAMED and the public/ private organisation which performs the upload.



More specifically, the following steps take place in the above-mentioned scenario:

- 1. A *Push* message (*push0*) is created by the organisation containing the following attributes:
 - a. messageID: A unique identifier, issued by the requester
 - b. correlationID: An identifier that will correlate the request to the response or to the acknowledgements, issued by the requester
 - c. sender/service/ServiceID: An identifier of the callback service (for responses and acknowledgements)
 - d. sender/node/nodeCode: An identifier of the EUDAMED unique number of the requester (e.g.SRN, CA number, etc.)
 - e. sender/node/nodeID: An identifier of the eDelivery partyID

- f. sender/node/nodeProfileToken: The EUDAMED bearer security token attached to the requester
- g. recipient/service/serviceID: An identifier of the EUDAMED service
- h. recipient/service/serviceOperation: An identifier of the EUDAMED service operation to uniquely define the service scope
- i. payload/Entities: It contains the main service accepted entity
- The *Push* message (*push1*) is sent from the organisation's backend to the organisation's eDelivery AP. As mentioned in Message exchange [40] Section of the current guide, the *push0* message is encoded and embedded into the payload of a SOAP envelope. The following attributes are included in the message:
 - a. envelope/header/messaging/usermessage/partyinfo/from/partyID: A unique identifier of the organisation's eDelivery AP
 - b. envelope/header/messaging/usermessage/partyinfo/to/partyID: A unique identifier of the EUDAMED eDelivery AP
 - c. envelope/body/submitRequest/payload: It holds the base64 format of the *push0* message
- 3. The *Push* message (*push2*) is sent from the organisation's eDelivery AP to the EUDAMED eDelivery AP. The status of the message is now SENDING.
- 4. An *Acknowledge* message (*ack1*) is sent from the EUDAMED eDelivery AP to the organisation's eDelivery AP which implies that *push2* was successfully received by the EUDAMED eDelivery AP. The status of the message is now DELIVERED.
- 5. The *Push* message (*push3*) is sent from the EUDAMED eDelivery AP to EUDAMED's backend.
- 6. An *Acknowledge* message (*ack2*) is sent from the EUDAMED eDelivery AP to the organisation's eDelivery AP which implies that *push2* was successfully received by the EUDAMED eDelivery AP. The status of the message is now DELETED.
- 7. An *Acknowledge* message (*ack3*) is created by EUDAMED containing the following attributes:
 - a. messageID: A unique identifier, issued by the requester
 - b. correlationID: The same as correlationID from the request message
 - c. sender/service/ServiceID: An identifier of the EUDMAED initiator service
 - d. sender/node/nodeCode: An identifier of the EUDAMED eDelivery party identifier
 - e. sender/node/nodeID: An identifier of the eDelivery partyID
 - f. recipient/service/serviceID: The requester's generic callback service

- g. recipient/service/serviceOperation: The requester's callback service operation (as specified in the request message)
- h. ackCode: The status code of the service call (success or matching error code)
- i. payload/report: It contains a report of processing statuses and details for each entity that have been sent through the Push message.
- 8. An *Acknowledge* message (*ack4*) is sent from the EUDAMED backend to the EUDAMED eDelivery AP with the attributes listed below:
 - a. envelope/header/messaging/usermessage/partyinfo/to/partyID: A unique identifier of the requester's eDelivery AP
 - b. envelope/header/messaging/usermessage/partyinfo/from/partyID: A unique identifier of the EUDAMED eDelivery AP
 - c. envelope/body/submitRequest/payload: It holds the base64 format of the *ack0* message.
- 9. An *Acknowledge* message (*ack5*) is sent from the EUDAMED eDelivery AP to the organisation's eDelivery.
- 10. An *Acknowledge* message (*ack6*) is sent from the organisation's eDelivery AP to the EUDAMED eDelivery AP. The status of the message is now DELIVERED.
- 11. An Acknowledge message (ack7) is sent from the organisation's eDelivery AP to the organisation's backend. As mentioned in Message exchange [40] Section of the current guide, the ack7 message is encoded and embedded into the payload of a SOAP envelope. The following attributes are included in the message:
 - a. envelope/header/messaging/usermessage/partyinfo/from/partyID: A unique identifier of the organisation's eDelivery AP
 - b. envelope/header/messaging/usermessage/partyinfo/to/partyID: A unique identifier of the EUDAMED eDelivery AP
 - c. envelope/body/submitRequest/payload:It holds the base64 format of the *push0* message
- 12. An *Acknowledgment* message (*ack8*) is sent from the organisation's eDelivery AP to the organisation's backend. The status of the message is now DELETED.

Messages

Given the above-mentioned scenario, the following messages will be created:

Push0

```
<message:Push>
<message:correlationID>a754cdd7-3602-45b4-a993-c25adb18a60e
</message:correlationID>
<message:creationDateTime>2019-05-22T07:00:28.066+02:00
```

```
</message:creationDateTime>
<message:messageID>a64a5a1f-da86-4810-a0de-27d0338811a9
</message:messageID>
<message:recipient>
   <message:node>
       <service:nodeActorCode>EUDAMED</service:nodeActorCode>
       <service:nodeID>eDelivery:EUDAMED</service:nodeID>
   </message:node>
   <message:service>
       <service:serviceAccessToken>9434524234225234234239
       </service:serviceAccessToken>
       <service:serviceID>DEVICE</service:serviceID>
       <service:serviceOperation>POST</service:serviceOperation>
   </message:service>
</message:recipient>
<message:payload>
   <device:Device xsi:type="device:IVDRDeviceType"</pre>
       xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
       <device: IVDRBasicUDT>
           <budi:ARActorCode>BE-AR-000033010
           </budi:ARActorCode>
           <budi:MFActorCode>JP-MF-000033020
           </budi:MFActorCode>
           <budi:specialDevice>ORTHOPAEDIC</budi:specialDevice>
           <budi:applicableLegislation>IVDD
           </budi:applicableLegislation>
           </device:IVDRBasicUDI>
       <device:IVDRUDIDIData>
           <udidi:identifier>
               <udidi:DICode>UDICODE1</udidi:DICode>
               <udidi:issuingEntityCode>GS1
               </udidi:issuingEntityCode>
           </udidi:identifier>
           </device:IVDRUDIDIData>
   </device:Device>
   <device:Device xsi:type="device:MDRDeviceType"</pre>
   xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
       <device:MDRBasicUDI>
           <budi:riskClass>IIb</budi:riskClass>
           <budi:model>SCE8-03-05</budi:model>
           <budi:identifier>
               <udidi:DICode>M991CVS1277777</udidi:DICode>
               <udidi:issuingEntityCode>GS1
               </udidi:issuingEntityCode>
           </budi:identifier>
```

```
<budi:ARActorCode>BE-AR-000000077</budi:ARActorCode>
               <budi:MFActorCode>JP-MF-000033020</budi:MFActorCode>
               <budi:applicableLegislation>MDR
               </budi:applicableLegislation>
               </device:MDRBasicUDI>
           <device:MDRUDIDIData>
               </device:MDRUDIDIData>
       </device:Device>
    </message:payload>
    <message:sender>
       <message:node>
           <service:nodeActorCode>JP-MF-000033020
           </service:nodeActorCode>
           <service:nodeID>eDelivery:JP-MF-000033020
           </service:nodeID>
       </message:node>
       <message:service>
           <service:serviceID>REPLY_SERVICE</service:serviceID>
           <service:serviceOperation>GET</service:serviceOperation>
       </message:service>
    </message:sender>
</message:Push>
Ack3
<message:Acknowledgement>
    <message:conversationID>0c4e479e-32a8-4439-9eea-4cd6c25c5745
    </message:conversationID>
    <message:correlationID>a754cdd7-3602-45b4-a993-c25adb18a60e
    </message:correlationID>
    <message:creationDateTime>2019-05-29T00:53:47.165+02:00
    </message:creationDateTime>
    <message:messageID>a64a5a1f-da86-4810-a0de-27d0338811a9
    </message:messageID>
    <message:recipient>
       <message:node>
           <service:nodeActorCode>JP-MF-000033020
           </service:nodeActorCode>
           <service:nodeID>eDelivery:JP-MF-000033020
           </service:nodeID>
       </message:node>
       <message:service>
           <service:serviceID>REPLY SERVICE</service:serviceID>
           <service:serviceOperation>GET</service:serviceOperation>
       </message:service>
    </message:recipient>
    <message:payload/>
```

<message:sender>

<message:node>

<service:nodeActorCode>EUDAMED</service:nodeActorCode>
<service:nodeID>eDelivery:EUDAMED</service:nodeID>

</message:node>

<message:service>

<service:serviceID>DEVICE</service:serviceID>

<service:serviceOperation>GET</service:serviceOperation>

</message:service>

</message:sender>

<message:responseCode>SUCCESS</message:responseCode>

</message:Acknowledgement>

8 Support

8.1 EUDAMED team

You can contact the EUDAMED support team by sending an email message to SANTE-EUDAMED-SUPPORT@ec.europa.eu for the services listed below:

- 1. M2M onboarding
- 2. Generating/regenerating the security key
- 3. XSD/XML validation and error responses
- 4. Data dictionary queries
- 5. Bug reporting and feature suggestions.

8.2 DIGIT AP team

You can contact the DIGIT AP support team by sending an email message to EC-EDELIVERY-SUPPORT@ec.europa.eu for the services listed below:

- 1. Access point connection (once approved by EUDAMED)
- 2. Public Key Infrastructure (PKI) queries
- 3. Pmode configuration
- 4. Advice on AS4 conformant solutions
- 5. Configurations for getting the message to EUDAMED.

8.3 Technical documentation

The following table summarises the content of the supporting documents that can be found in the EUDAMED Information Centre:

Document	Content
DTX XSD	The XML Schema Definition for the available services and entities
DTX XML samples	Bulk upload/download samples covering the most used scenarios per service. These are general samples, not containing personalised data
DTX Service Definition	A business level view of the available service
DTX business rules	All constraints related to the services
Enumerations	Value lists for multiple choice fields
Data dictionaries	Explains the Entity structure and meta data about their attributes
Third-party agreement	Confirms the agreement between an Actor requesting an AP and a 3rd party service provider
Technical onboarding	Contains data that need to be filled in by the Actor requesting an AP for the onboarding procedure

8.4 Useful links

- 1. Domibus
- 2. Connecting Europe Facility (CEF) Digital eDelivery access point documentation
- 3. EUDAMED Information Centre
- 4. EUDAMED European Medical Database on Medical Devices
- 5. DIGIT Access Point Support

9 Annexes

9.1 Annex 1 (Error codes)

GENERIC_INTERNAL_50000("50000"),
UNSUPPORTED_MESSAGE_TYPE_50001("50001"),
EDELIVERY_BRIDGE_READ_NULL_ID_50001("E-B-50001"),
INBOUND_VALIDATION_GENERIC_NULL_OBJECT_I_50001("I-50001"),
INBOUND_VALIDATION_DOWNLOAD_ACTOR_NULL_IMESSAGE_I_50002("I-50002"),
INBOUND_VALIDATION_ACTOR_DOWNLOAD_UNSUPPORTED_SRN_I_50003("I-50003"),
INBOUND_VALIDATION_DOWNLOAD_ACTOR_NULL_IMESSAGE_I_50004("I-50004"),
INBOUND_VALIDATION_CREATE_DEVICE_NULL_IMESSAGE_PAYLOAD_I_50005("I-50005"),
INBOUND_VALIDATION_WRONG_DOWNLOAD_ACTOR_PAYLOAD_TYPE_I_50006("I-50006"),
INBOUND_TRANSFORM_PULL_REQUEST_NULL_MESSAGE_I_50007("I-50007"),
INBOUND_TRANSFORM_PULL_REQUEST_ACTOR_DOWNLOAD_CRITERIA_WRONG_TYPE_MESSAGE_I_50008("I-50008"),
INBOUND_VALIDATION_DOWNLOAD_DEVICE_NULL_IMESSAGE_I_50009("I-50009"),
INBOUND_VALIDATION_DOWNLOAD_DEVICE_NULL_IMESSAGE_PAYLOAD_I_50010("I-50010"),
INBOUND_TRANSFORM_PULL_REQUEST_DEVICE_DOWNLOAD_CRITERIA_NULL_MESSAGE_I_50011("I-50011"),
INBOUND_TRANSFORM_PULL_REQUEST_ACTOR_DOWNLOAD_CRITERIA_WRONG_TYPE_MESSAGE_I_50012("I-50012"),
INBOUND_TRANSFORM_PULL_REQUEST_ACTOR_REGISTRATIONNULL_MESSAGE("I-50013"),
INBOUND_VALIDATION_INVALID_XML_PAYLOAD_I_40000("I-40000"),
INBOUND_VALIDATION_NULL_XML_PAYLOAD_I_40001("I-40001"),
INBOUND_VALIDATION_NULL_OBJECT_PAYLOAD_I_40002("I-40002"),
INBOUND_VALIDATION_SERVICE_ID_I_40003("I-40003"),
INBOUND_VALIDATION_NULL_ACTOR_DOWNLOAD_CRITERIA_PAYLOAD_I_40004("I-40004"),
INBOUND_VALIDATION_NULL_CRITERIA_PAYLOAD_I_40005("I-40005"),
INBOUND_VALIDATION_NULL_DEVICE_DOWNLOAD_CRITERIA_PAYLOAD_I_40006("I-40006"),
INBOUND_VALIDATION_NULL_INBOUND_PAYLOAD_I_40007("I-40007"),
OUTBOUND_TRANSFORM_OBJ_TO_XML_NULL_MESSAGE_O_50001("O-50001"),
OUTBOUND_TRANSFORM_OBJ_TO_XML_NULL_RESPONSE_MESSAGE_O_50002("O-50002"),
OUTBOUND_TRANSFORM_PULL_RESPONSE_ACTOR_DOWNLOAD_NULL_MESSAGE_O_50003("O-50003"),
OUTBOUND_TRANSFORM_PULL_RESPONSE_ACTOR_DOWNLOAD_WRONG_PAYLOAD_TYPE_O_50005("O-50005"),
OUTBOUND_TRANSFORM_PULL_RESPONSE_DEVICE_DOWNLOAD_NULL_MESSAGE_O_50006("O-50006"),
OUTBOUND_TRANSFORM_PULL_RESPONSE_DEVICE_DOWNLOAD_WRONG_PAYLOAD_TYPE_O_50007("O-50007"),
OUTBOUND_TRANSFORM_DOWNLOAD_DEVICE_IDENTIFIER_O_50002("E-O-50002"),
OUTBOUND_TRANSFORM_DOWNLOAD_ACTOR_ACTOR_TYPE_O_50010("O-50010"),
OUTBOUND_TRANSFORM_DOWNLOAD_ACTOR_ACTOR_TYPE_O_50011("O-50011"),
OUTBOUND_TRANSFORM_DOWNLOAD_ACTOR_ACTOR_TYPE_O_50012("O-50012"),
OUTBOUND_VALIDATION_NULL_MESSAGE_O_40000("O-40000"),

9.2 Annex 2 (XML files index)

Use case	Actors	XML file	Description		
Download registered actors	CA,	SAMPLE_DTX_ACT_001.01.xml	Search for an individual manufacturer SRN (EU and non- EU)	Positive	

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Use case	Actors	XML file	Description				
	EO,	SAMPLE_DTX_ACT_001.03.xml	Search for an individual importer				
	NB	SAMPLE_DTX_ACT_001.04.xml	Search for an individual authorised representative				
		SAMPLE_DTX_ACT_001.05.xml	Search for an individual producer				
		SAMPLE_DTX_ACT_001.07.xml	Request to download a registered economic operator using the wrong attribute type in the pull request				
Download actor registration CA		SAMPLE_DTX_ACT_002.01.xml	Download a specific application ID (includes Zip attachment)				
requests		SAMPLE_DTX_ACT_002.02.xml	Request containing incorrect end tag – XSD invalid				
		SAMPLE_DTX_ACT_002.03.xml	Request a specific initial submission date with a mix of EU and non-EU Producers (includes Zip attachments)				
Upload actor registration	CA	SAMPLE_DTX_ACT_003.01.xml	Approve EU manufacturer				
request assessments		SAMPLE_DTX_ACT_003.02.xml	Unknown APPLICATION-ID Provided	Negative			
		SAMPLE_DTX_ACT_003.03.xml	One upload containing an approve and a correct assessment	Positive			
		SAMPLE_DTX_ACT_003.04.xml	Negative assessment with reason: Duplicate				
Download of Basic UDI-DI, UDI-DI and device data	CA, EO,	SAMPLE_DTX_UDI_004.01.xml	Request Download Device (BUDI and UDI-DI) information using a combination of the following criteria: Basic UDIDI Code, UDIDI code, MF actor code, AR actor code				
	NB	SAMPLE_DTX_UDI_004.06.xml	xml Request Download Device (BUDI and UDI-DI) information using a combination of the following criteria: Basic UDIDI Code, UDIDI code, MF actor code, AR actor code Criteria: Manufacturer (State is automatic Registered), Country				
Upload Basic UDI-DI and	EO	SAMPLE_DTX_UDI_001.01.xml	Register New MDR Device BUDI and Device (UDI-DI) information	Positive			
UDI-DI information			Class I Device (Special Device Type (Orthopedic), Substances, Direct Marking DI, Storage and Handling Conditions, Critical Warnings, Market Information, Clinical Sizes, Product Designer SRN)				
		SAMPLE_DTX_UDI_001.02.xml	Register New MDR Device BUDI and 2 or more UDI-DI.	Positive			
			(Special Device Type (Software), Clinical Investigations- EU and NonEU, Substances, Direct Marking DI, Storage and Handling Conditions, Critical Warnings, Market Information, Clinical Sizes, Product Designer SRN)				
		SAMPLE_DTX_UDI_001.03.xml	Register New MDR Device BUDI and UDI-DI for a Risk Class III device to validate BUDI and UDI-DI will be stored in EUDAMED in "Submitted" status Class III (DeviceCertificateLinks, UnitofUseDI, Substances, Direct marking DI, Storage and Handling Conditions, Critical Warnings, Market Information, Clinical Size, Broduct Designer SPN)	Positive			
		SAMPLE_DTX_UDI_001.04.xml	Register New MDR Device BUDI and UDI-DI for a Risk Class II A containing false data (e.g. containing IIb implantable exceptions – sutures) (IIb Implantable exception, Clinical Investigations- EU and NonEU, DeviceCertificatel inks. Substances, Storage and Handling Conditions	Negative			
			Critical Warnings, Market Information, Clinical Sizes, Product Designer SRN)	D			
		SAMPLE_DTX_UDI_001.05.xml	Register New MDR Device BUDI and UDI-DI for a Risk Class II B containing certificate data and implantable and having IIb implantable exceptions – false	Positive			
			Class IIB (IIB Implantable exceptions- false, DeviceCertificateLinks, Direct marking DI, Substances, Direct marking DI, Storage and Handling Conditions, Critical Warnings, Market Information, Clinical Sizes, Product				
		SAMPLE_DTX_UDI_001.12.xml	Register New MDR Device BUDI and UDI-DI with multiple brand/trade names; ensure the "primary" attribute				
		SAMPLE_DTX_UDI_001.13.xml	Register New MDR Device BUDI and UDI-DI with multiple packaging hierarchies (1st, 2nd, 3rd) and different packaging items on each level				
		SAMPLE_DTX_UDI_002.01.xml	Register New IVDR Device BUDI and UDI-DI information	Positive			
			Market Information, Product Designer Organisation)				
		SAMPLE_DTX_UDI_002.03.xml	Register New IVDR Device BUDI and UDI-DI for a Risk Class C device to see how the BUDI and UDI-DI will start in "Submitted" status and then transition to "Registered" status upon NB linking				
			Risk Class C (DeviceCertificateLinks, Storage and Handling Conditions, Critical Warnings, Market Information, Product Designer Organisation)				
		SAMPLE_DTX_UDI_003.01.xml	Register New System or Procedure Pack with only one Basic UDI	Positive			
		SAMPLE_DTX_UDI_005.01.xml	I Upload Legacy Device – Class I MDD Legacy Device				
		SAMPLE_DTX_UDI_005.02.xml	Upload Legacy Device – AIMDD Legacy Device				
		SAMPLE_DTX_UDI_005.03.xml	Upload Legacy Device – IVD_ANNEX_II_LIST_A Risk Class	Positive			

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Use case	Actors	XML file	Description				
Upload a new UDI under an existing Basic UDI-DI	EO	SAMPLE_DTX_UDI_008.02.xml	Register multiple New Device UDI-DI (MDR/IVDR) information related to an already existing (MDR/IVDR) Device B-UDI				
Update Basic UDI-DI	EO	SAMPLE_DTX_UDI_009.01.xml	Update an existing MDR/IVDR Device BUDI				
		SAMPLE_DTX_UDI_009.01.xml	Update an existing MDD Device BUDI				
Update UDI-DI	EO	SAMPLE_DTX_UDI_010.01.xml	Update an existing MDR/IVDR Device UDI-DI				
		SAMPLE_DTX_UDI_010.02.xml	Update an existing MDD Device UDI-DI				
		SAMPLE_DTX_UDI_010.03.xml	Update the first EU country where the device has been put on the market				
		SAMPLE_DTX_UDI_010.04.xml Set the first EU country where the device has been placed on the market for a device that was not on the EU market at the time of its registration in EUDAMED		Positive			
Update product original manufacturer	EO	SAMPLE_DTX_UDI_015.01.xml	Update information about the product original manufacturer registered as an organisation during the initial device registration				
		SAMPLE_DTX_UDI_015.02.xml Update information about the product original manufacturer with an Actor ID/SRN of a manufacturer registered in EUDAMED		Positive			
Update of Market Information	EO	SAMPLE_DTX_UDI_007.01.xml	Submit a list of market info for a specific UDI-DI				
		SAMPLE_DTX_UDI_007.02.xml	Submit a list of market info for a specific list of UDI-Dis				
		SAMPLE_DTX_UDI_007.03.xml	Submit a list of market info for a non-existing UDI-DI				
Update of Container	EO	SAMPLE_DTX_UDI_012.01.xml	Submit a list of container packages to a registered UDI	Positive			
Package Information		SAMPLE_DTX_UDI_012.02.xml	Update the status of a container package	Positive			
Download issued certificate	CA,	SAMPLE_DTX_CRF_02.01.xml	Downloading explicitly a known certificate by its certificate number	Positive			
(last current version)	NB	SAMPLE_DTX_CRF_02.02.xml	Downloading certificates that reference a specific manufacturer by specifying its SRN				
		SAMPLE_DTX_CRF_02.03.xml	_02.03.xml Downloading certificates issued by other Notified Body than the Notified Body requestor				
Download refused certificate	CA,	SAMPLE_DTX_CRF_03.01.xml	Download refused certificates by its number				
	NB	SAMPLE_DTX_CRF_03.02.xml	Download refused certificates by type				
Download SSCP	NB	SAMPLE_DTX_UDI_009.01.xml	Download SS(C)P by Basic UDI-DI				
		SAMPLE_DTX_UDI_009.02.xml	Download SS(C)P by certificate ID	Positive			
Download SSCP	CA,	SAMPLE_DTX_UDI_011.01.xml	Download SS(C)P by Basic UDI-D	Positive			
	EO	SAMPLE_DTX_UDI_011.02.xml Download SS(C)P by certificate number / revision number					

9.3 Annex 3 (AP statuses)

Status	Description
Draft	The request has not yet been submitted.
Submitted	The request is submitted. The AP is not yet active and approval is needed.
Connectivity under validation	The request has been approved but the AP is not yet configured and active.
Rejected	The request is rejected.
Active	The AP is active and ready for M2M data exchange.
Maintenance	This status is only used for migration of APs from one format to another. Contact EUDAMED support [56] if the AP is under maintenance status.
Terminated	The AP is deactivated and cannot be used for M2M data exchange.

You can see the status of your AP in the Access point management page:

Home	Tasks 🗸	Search & view 🗸	Data Transfer 🗸	News	Help 🗸			1 L	est DTHREE-THF	REE Logout
				CURREN	TACTOR:	Manufacturer, D	E-MF-000002295, Tes	t Maker of Things in C	Germany (German	y] #Notifications
Acce Request a	SS POIN	t managem	ent							
Fil Active filter	ter ▼ s:									
Status: A	Clear se	arch						S	show 20 🗸	entries per page
Access P	oint		Party ID			Status	Access Poin	t Type	Ac	tions
TW Demo	3rd Party AP 1		EUDAMED_0000	081		Active	THIRD_PART	Y		•••)

