

# Data Exchange for EOs – User guide

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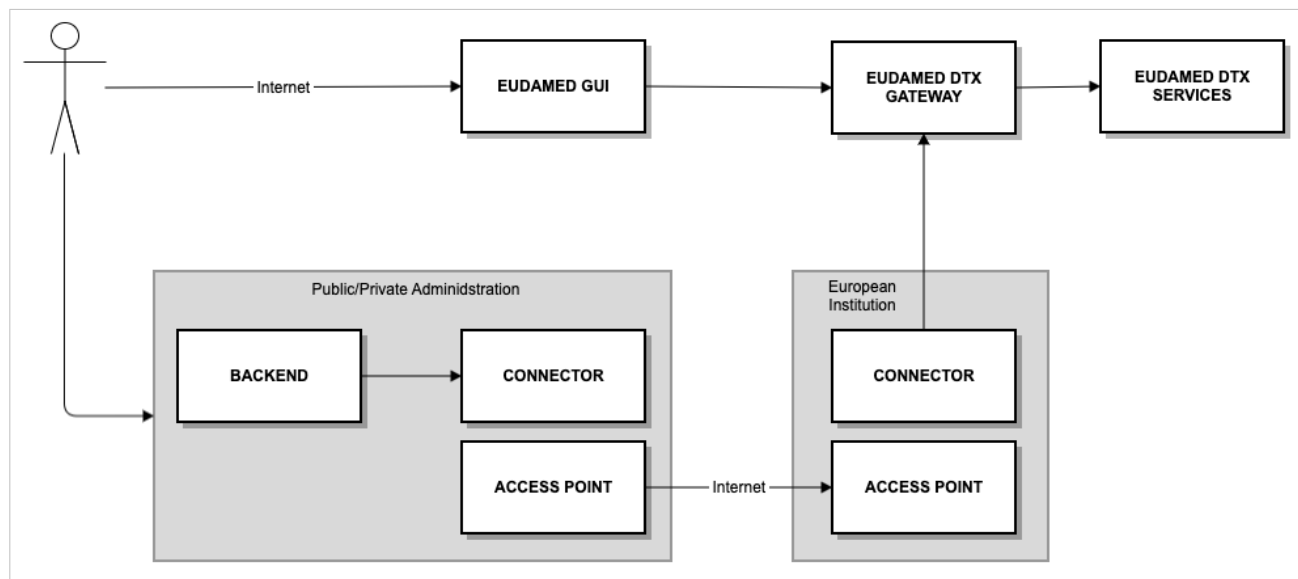
EUDAMED v2.8  
July 2022

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# 1. Machine-to-machine description



For each use case, sample XML files will be circulated in order to help users test functionality. For the Playground environment, any reference to XSD files refer to that which has been circulated to Playground users. Please note that in future the playground XSD may differ to the XSD files available via the production EUDAMED or via the [Europa Medical Device website](#).

This document will explain the details of how to access the security token which is required for M2M connection with EUDAMED. It will NOT cover technical aspects of onboarding connections via eDelivery, which will occur *after* the steps in this document. Nonetheless, we encourage you to review the [CEF eDelivery access point documentation](#) as they may have been updated, and in particular their Access Point Test Guide available [here](#).

## 1.1. Contents of sent messages

Please note: the payload of messages is base64 encrypted, and a sent message for M2M will look something like that outlined in [Section 1.4 \[6\]](#).

Samples of XML files and responses for bulk upload and download are available alongside this document. You will notice that when compared with M2M, there is a key difference: The serviceAccessToken. This token is specific for each module of EUDAMED, and the combination of this token and the SRN of the sender is used as security to ensure that the message is received from the correct actor.

**IMPORTANT**

Without this token, your message will not pass our security checks. An incorrect token will give the following error response:

```
<message:elementReport>
  <message:operationErrorCode>M-50000</message:operationErrorCode>
  <message:operationErrorDetail>The access point code is not valid: please contact the support</message:operationErrorDetail>
</message:elementReport>
</message:report>
<message:responseCode>SERVER_ERROR</message:responseCode>
</message:FullResponse>
```

## 1.2. How to generate your access token in EUDAMED

1. After you log into EUDAMED as a Local Actor Administrator, you will see the link “Machine to machine data delivery preferences” under the “My Actor data” section of your dashboard:

The screenshot shows the EUDAMED dashboard interface. At the top, there is a navigation bar with 'Home', 'Tasks', 'Search & view', 'Transmission', 'News', and 'Help'. The user is logged in as 'Peter Pan'. Below the navigation bar, the current actor is identified as 'Competent Authority LI-CA-014, Playground test CA [Liechtenstein]'. The main content area is titled 'Welcome to EUDAMED' and includes a brief description of the system. A 'Tasks' section is visible, with a sub-section 'My Actor data' containing a red-bordered box around the link 'Machine to machine data delivery preferences'. Other tasks include 'Actor management' and 'User management'.

The preferences are defaulted to “No” as a security measure:

European Commission > EUDAMED

Home Tasks Search & view Transmission News Help

CURRENT ACTOR: Competent Authority, BE-CA-001, [Agence Fédérale des Médicaments et des Produits de Santé](#)

## Machine to machine data delivery preferences

**Note:** The default data upload mechanism is via the EUDAMED Application. Only **one** access point should be used per organisation.

\* Will you be using machine-to-machine services?  
 Yes  No

[Disclaimer relating to access point and machine-to-machine](#)

I have read and agree to the above disclaimer

### Data exchange services

Please select the services you wish to use for data exchange

\* Actor

Actor registration requests download  
 Actor download  
 Device download

How many devices do you intend to exchange data on?

- Select “Yes”, read and agree to the disclaimer. You will be presented with a list of services available to you. This list is specific to your actor type. Select the services you wish to activate and whether you require a new access point configuration:

### Data exchange services

Please select the services you wish to use for data exchange

\* Services list

Actor download  
 Device download  
 Device upload

How many devices do you intend to exchange data on?

### Access point request information

\* Access point request

[CEF eDelivery access point documentation](#)

Do you want to apply for a new access point configuration?  
 Yes  No

Do you already have your own eDelivery access point?:  
 Yes  No

Is this access point already configured for EUDAMED?:  
 Yes  No

- If you require a new access point configuration, you will be asked to enter technical and legal contact details. Economic operators (i.e. non-supervisory bodies) who choose to use a third party must enter this information for the third party company when prompted. When you submit this information, you will be informed that this information will automatically be transmitted to the EUDAMED support team.

\* Your eDelivery access point

The information entered below will be submitted to the EUDAMED support team. **You do not need to do anything else after submitting your details.** The EUDAMED support team will be in contact via email to assist in configuration of your access point.

**Technical Contact**

\* Contact name:  
John Smith

\* Telephone:  
123456789

Telephone format example: +32 x xxx xx xx

\* Email:  
john@smith.com

**Legal Contact**

\* Contact name:  
Joe Bloggs

\* Telephone:  
012345678

Telephone format example: +32 x xxx xx xx

\* Email:  
joe@bloggs.com

**Submission** ✕Close

Are you sure you want to submit your request?

The details entered will be submitted to the EUDAMED support team. **You do not need to do anything else after submitting your details.** The EUDAMED support team will be in contact via email to assist in configuration of your access point.



### IMPORTANT

Email notifications are disabled for the playground, so at this stage you should email EUDAMED Support (<SANTE-EUDAMED-SUPPORT@ec.europa.eu>) to inform us you have submitted an access point request. Please ensure to include:

- Your SRN, Party ID and EU Login username
- The software you are using and your endpoint address
- If you will be using PKI service

Once approved, the support team will contact you regarding technical details of onboarding)

4. Once you confirm submission, your Party ID and access token will be displayed. Below is the M2M data delivery preferences overview, with Party ID and access tokens for Actor and Device module highlighted:

### Machine to machine data delivery preferences

Will you be using machine-to-machine services?:	Yes
---	-----

#### Data exchange services

Party ID:	EUDAMED_000041
Services - Actor:	Actor download
Services - Udi-device:	Device download, Device upload

#### Access point request

Do you want to apply for a new access point configuration?:	Yes
Do you already have your own eDelivery access point?:	Yes
Is this access point already configured for EUDAMED?:	No

#### Technical Contact

Contact name:	ContactMF
Telephone:	+3212311231
Email:	contact@mf.com

#### Legal Contact

Contact name:	LegalMF
Telephone:	+3212311231
Email:	contact@mf.com

Your secure encrypted production codes

These codes must be included in your XML upload or download requests. Note: Codes differ per module.

**Actor**

```
0EFB8D1CA7077F3529BAAB83B0CD325B3A6B970BD1F6B2EFA947F96F14D97BB965F5428D7349D931458A9011C9658AFF70B11E88A0885D7C1C3D80E489DFCA0EB9D91A2E67267655EA5E591D5E81ADF6D0ACF6419AC4F5D747DFCF021DCD99776C3A4792EB3653D9D22673F04BFF5474986CF41DDCB88567FA36F912272A1EDE85C0E4E0F62A457FE143AE7EE53C655699EBA867906C15D0DBA181B9F19B8640737851130C991A718CB91CC15AE86F44A276B1E723741932D02D690C6A0270869419B9BEA76BFFC76C14C4E7AF26687207D5C6E29751F45D4B35761E73E3BDE3627A3E870B2BFC4E8CACA9E3B69679C040A4228E33AC47D0F9F94A277A6B1DB98655D9EB25DE1F57B987471E0E2853C2
```

**Udi/Device**

```
9ED1962BC8A7F016200E723FB16F1C9561C68724D3E3776B84F6F1C447E4AAD5F4259BA1A618195E0C2440E47A4B7BE0A963FFD1511B2E619EF8938C5D270ECB53DDAF98AF56B879D6F14C14A8321C041B1DD1E2497E1100AC186CE660D58B5E42AED4D4839A49E63CBA81911895E791821C494598844673A3E9B53089368F2B582F08BF3797137CCE2E8E2952D6B91617C827E284CFB678C610FA15645844001156A432B296FF76C5B95B43892818B959F69F1DFC3A4DC02DD18E4D9BD6ABC2CA3676235A8F2F5E452BA7C52AC981CF6585D9CE469CE95BBA7957BD206E7818E0BDA38F2AAA46902D442EA65E7E13B727FE92234C35A97FE2620559272A9BCC8D8716F170A24367F230AE71A02AE0E
```

Edit

### Specific notes for testing on the Playground environment:

- Your Actor ID/SRN, access tokens and Party ID will be DIFFERENT between Playground and Production.
- You can continue to use access points from the previous Playground.
- Email notifications are DISABLED for the Playground.
- You **must** successfully connect to the Playground before you can request a Production access point.
- Once successfully connected, the onboarding process as above must be repeated for Production.

Machine-to-machine description

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## 1.3. How to update/disable your machine-to-machine settings

If you no longer need to use machine-to-machine communication, you can edit this page by clicking the Edit button, and:

- Answering “No” to “Will you be using machine to machine services?”, or
- Deselecting the specific services you do not require


### Activation of the new services:

- When a new release of EUDAMED includes new machine-to-machine services, they will NOT be active by default
- You will not be able to use newly added services until you activate them on this page

### Regenerating your access token:

If you have reason to believe your token is no longer secure, you can regenerate the code by clicking the Edit button, selecting the module for which you want to regenerate the code, and clicking submit.

**Your secure encrypted production codes**

 These codes must be included in your XML upload or download requests. Note: Codes differ per module.

Please select the module for which you want regenerate the code (the new code will be displayed after clicking submit)

Actor

80DF55C97F46AAD511154662F3CF23B245BD034BD1772A71FBA13C4E6CC42A59E26A6A1AFE5A4C75F569623AB96AF9F6BDFD06B360D4269F20B66960407AA3675D31F5CF8739927D10A68591E73423D96DB36C870413AA6FDD210EA963E9A521F03451FB1B0BDDCE02D91A649D2D0230A4E208EE56BA0D10C47D87588CC8F2A7BD12AF016A54038E5C0C3FA8649726B44187884C3B0BF03384C32D7D2A4FE6C26E1CBA3907D9EFBBE7F150EFB930166C83617DFC5A67B19180DCBA6770153F30FA7092C4146754432A7AB8A54E7E6A064FC0227B235ADB0F3B408B9B88E25B8E8689F2FDD0DDDB2CEB0CB94650B80298A1B742DEA28915818E2A49FBC5E91295F5D7477FF7C4BA6140C571C56526C71CCE



### IMPORTANT

When a token is regenerated, all new files submitted from this point onwards must include the new token for that module or they will be rejected.

## 1.4. Example of a SOAP sendMessage

```
<soap:Envelope xmlns:soap="http://www.w3.org/2003/05/soap-envelope"
xmlns:ns="http://docs.oasis-open.org/ebxml-msg/ebms/v3.0/ns/core/200704/"
xmlns:_1="http://org.ecodex.backend/1_1/">
```

```
<soap:Header>
<ns:Messaging>
<ns:UserMessage>
<ns:PartyInfo>
<ns:From>
<ns:PartyId type="urn:oasis:names:tc:ebcore:partyid-
type:unregistered">eudamed_mdr_acc</ns:PartyId>
<ns:Role>http://docs.oasis-open.org/ebxml-msg/ebms/v3.0/ns/core/200704/initiator</
ns:Role>
</ns:From>
<ns:To>
<ns:PartyId type="urn:oasis:names:tc:ebcore:partyid-
type:unregistered">eudamed_mdr_demo</ns:PartyId>
<ns:Role>http://docs.oasis-open.org/ebxml-msg/ebms/v3.0/ns/core/200704/responder</
ns:Role>
</ns:To>
</ns:PartyInfo>
<ns:CollaborationInfo>
<ns:Service type="tc1">bdx:noprocess</ns:Service>
<ns:Action>TC1Leg1</ns:Action>
</ns:CollaborationInfo>
<ns:MessageProperties>
<ns:Property name="originalSender">urn:oasis:names:tc:ebcore:partyid-
type:unregistered:C1</ns:Property>
<ns:Property name="finalRecipient">urn:oasis:names:tc:ebcore:partyid-
type:unregistered:C4</ns:Property>
</ns:MessageProperties>
<ns:PayloadInfo>
<ns:PartInfo href="cid:message">
<ns:PartProperties>
```

```
<ns:Property name="MimeType">text/xml</ns:Property>
</ns:PartProperties>
</ns:PartInfo>
</ns:PayloadInfo>
</ns:UserMessage>
</ns:Messaging>
</soap:Header>
<soap:Body>
  <_1:submitRequest>
    <payload payloadId="cid:eudamedxmlAttachment" contentType="text/xml">
      <value>PD94bWwgdmVyc2lvbj0iMS4wliBlbmNvZGluZz0iVVRGLTgiPz4KPGhIbGxvPndv
      cmxkPC9oZWxsby4=</value>
    </payload>
  </_1:submitRequest>
</soap:Body>
</soap:Envelope>
```

## 2. Bulk upload and download

Bulk requests may be sent via the EUDAMED interface in two ways:

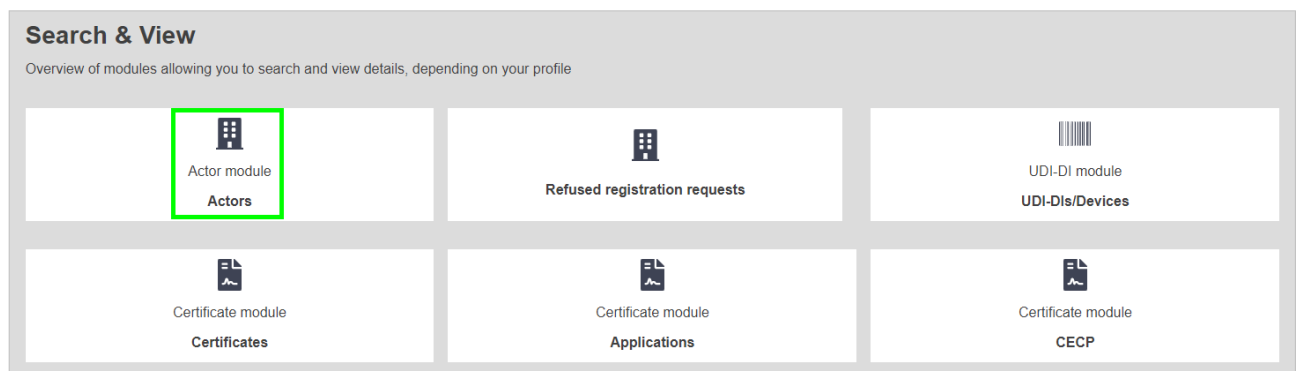
- Click “Generate XML” to generate bulk files for download based on the results list on screen for
  - Search for actors
  - Search for your UDI-DIs/Devices
- Upload files
  - Upload search criteria XML files
  - Bulk upload device XML files (new devices, updates, new UDI for an existing Basic UDI-DI)
  - Upload SS(C)P download criteria

### 2.1. Bulk download requests via the EUDAMED interface

#### 2.1.1. Bulk download of actors via EUDAMED interface

In this Playground release, **all actors** will be able to download registered economic operators via the EUDAMED interface.

1. After successfully logging in, you will be able to access the actors registered in EUDAMED by using the Search and View functionalities for Actors:



2. Enable the filter for bulk download of economic operators that will restrict your search criteria to those that are applicable according to the DTX service definition for actor download. You will notice that those that are not available will become shaded:

**Search & view**

**Actors**

Only enable search filters available for bulk XML download of economic operators

Name  Actor ID/SRN  VAT number  Role

Country  Competent Authority

[Search](#) [Generate XML file](#) [Clear search](#)

- After applying the desired search criteria, use the Search button in order to retrieve the list of actors. If you have provided search criteria that are not compatible with the DTX services definition, you will receive a warning prompt to amend your search. Before using the Generate XML file button, it is important to retrieve the economic operators by using the Search button, otherwise, the list returned in the XML file will not correspond with the scope of the search.

[Search](#) [Generate XML file](#) [Clear search](#)

**Search results for actors**

Active search fields:

Only enable search filters available for bulk XML download of economic operators:  Actor ID/SRN: BE-MF-000000001  [Clear search](#)

Showing 1 to 1 of 1 entries Show  entries per page

Actor ID/SRN <input type="text"/>	Role <input type="text"/>	Name <input type="text"/>	Country <input type="text"/>	Date of registration <input type="text"/>
BE-MF-000000001	Manufacturer	Belgium MF A V4_test [HR]	Belgium	2021-04-02

A confirmation message will be triggered.

- After confirming, you can click “Go to download management” to see the status of your request and download the response XML files. When the file is processing it will receive the state “Pending”:

**Download management**

[Filter](#)

Active filters: No selection

Showing 1 to 4 of 4 entries Show  entries per page

ID	Name	Module <input type="text"/>	Service <input type="text"/>	State <input type="text"/>	Request date <input type="text"/>	Download
APP-DTX-000000934	MedicalDev Fortytwo	Actor	Actor download	<span style="color: green;">●</span> Successful	2021-08-03 [15:25]	<a href="#">XML [7 KB]</a> <span style="color: orange;">⌚</span> Expires in 15 days

## 2.1.2. Bulk download of your devices via EUDAMED interface

After you log in as a user for an economic operator, you will be able to access the list of **your** Devices registered in EUDAMED by using the Search & View functionalities for Devices:

The screenshot shows the EUDAMED user interface. At the top, it says 'CURRENT ACTOR: Manufacturer' and 'Switch actor Notifications'. Below this is a 'Welcome to EUDAMED' section with a 'See all the news' button. The 'Tasks' section is divided into three columns: 'My Actor data', 'UDI-DIs/Device', and 'User management'. The 'UDI-DIs/Device' column contains links for 'Register a new Basic UDI-DI', 'Register a legacy device', 'Manage your Basic UDI-DIs / EUDAMED DIs', and 'Manage your Devices details'. Below the tasks is the 'Search & View' section, which has three main modules: 'Actors', 'UDI-DIs/Devices' (highlighted with a green box), and 'Certificates'.

1. Apply the correct filters from the list presented in order to identify your devices that you want to download.

The screenshot shows the 'Search for UDI-DIs' form. The form is divided into several sections. The top section contains 'UDI-DI code', 'Basic UDI-DI code', 'Status', and 'Model'. The middle section contains 'Name', 'Trade name', 'Applicable regulation' (set to 'MDR (REGULATION (EU) 2017/745 on medical devices)'), 'Risk class', 'Nomenclature code', 'Reference/Catalogue number', and 'Country'. The bottom section contains 'State' (set to 'Registered'), 'Scopes', 'MF / PR SRN' (set to 'BE-MF-000000002'), 'MF / PR Name', 'AR SRN', and 'AR name'. At the bottom of the form are three buttons: 'Search', 'Generate XML file', and 'Clear search'.



**NOTE**

Use only the filters applicable in the Download Device service for Data Exchange: MFACTORCode/ PRACTORCode, ARACTORCode, BasicUDIDCode, UDIDCode, RiskClass, Country, Applicable Legislation, State.

(Please see [Chapter 5](#) for the rules and applicability of these filters in the context of Download Devices)

- After applying any desired search criteria (your SRN/Actor ID will automatically complete in the search criteria), use the Search button in order to retrieve the Devices.



**NOTE**

Before using the Generate XML file button it is important to retrieve the devices by using the Search button, otherwise, the list of Devices returned in the XML file will not correspond with the scope of the search.

Search for UDI-DIs

<input type="text" value="UDI-DI code"/>	<input type="text" value="Basic UDI-DI code"/>	<input type="text" value="Status: --"/>	<input type="text" value="Model"/>
<input type="text" value="Name"/>	<input type="text" value="Trade name"/>	<input type="text" value="Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices)"/>	
<input type="text" value="Risk class: --"/>	<input type="text" value="Nomenclature code"/>	<input type="text" value="Reference/Catalogue number"/>	<input type="text" value="Country: --"/>
<input type="text" value="State: Registered"/>	<input type="text" value="Scopes: You can select more than one value"/>		
<input type="text" value="MF / PR SRN: BE-MF-000000002"/>	<input type="text" value="MF / PR Name"/>	<input type="text" value="AR SRN"/>	<input type="text" value="AR name"/>

**Search results for devices**

Active search fields:

State: Registered  MF / PR SRN: BE-MF-000000002  Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices)


Showing 1 to 20 of 25 entries Show  entries per page

UDI-DI code <input type="text"/>	Basic UDI-DI code <input type="text"/>	MF / PR SRN	Trade name <input type="text"/>	Risk class	Date <input type="text"/>	UDI-DI status
DD121	1211421211211EW	BE-MF-000000002	Trade Name	Class IIa	2021-03-23	On the EU market
1234 1235 3	2131211122348115KF	BE-MF-000000002	Generic Device Name_DEV_3	Class I	2021-03-22	On the EU market

A confirmation message will be triggered.

- After confirming, you can click “Go to download management” to see the status of your request and download the file. When the file is processing it will receive the state “Pending”:

Download management

Filter 

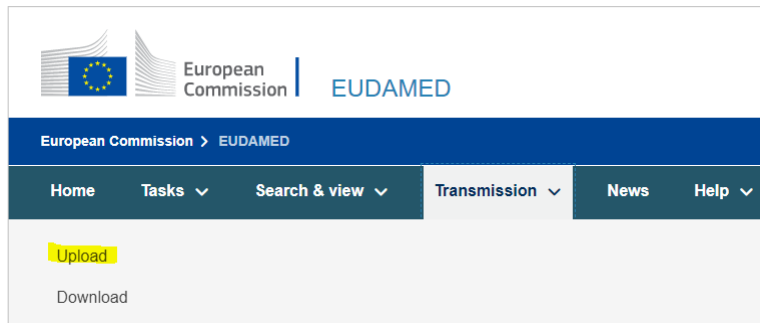
Active filters: No selection

Showing 1 to 10 of 10 entries Show  entries per page

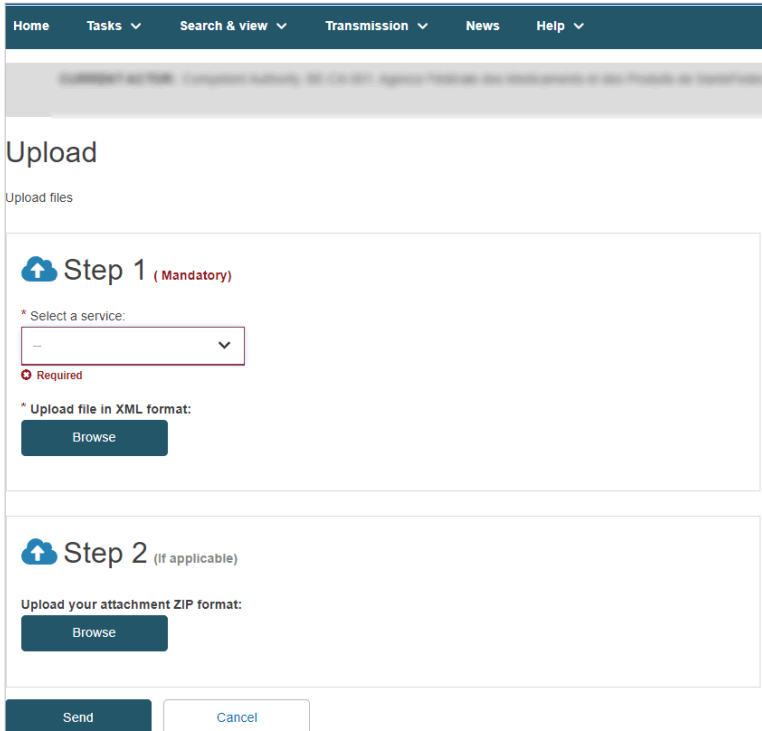
ID	Name	Module ID	Service ID	State ID	Request date ID	Download
		UDI/Device	Device download	<span style="color: orange;">●</span> Pending	2021-03-23 [19:16]	

## 2.2. How to upload a file in EUDAMED

- The file upload screen can be found for **all users** under Transmission > Upload menu when you are logged in with the relevant profile:



- Click on “New upload” to see the file upload screen:



In this screen, you may select the desired service and attach an XML file for upload. Available services depend on which actor you are logged in as.



- Once uploaded, click on “Go to upload management” to see your pending upload. When the file has completed processing, you will see the XML response download link under the “Response” column:

Upload management

[Filter](#)

Active filters: No selection

Showing 1 to 12 of 12 entries

Show  entries per page

ID	Name	Service	State	Request date	Uploaded	Response date	Response
		Actor registration assessments upload	Pending	2020-09-24 [20:49]	XML	-	

## 2.3. Uploading Devices and System or Procedure Packs

Operations described in [Chapter 2.2 \[13\]](#) are applicable also for processing Bulk upload of Devices. Users with the **Confimer profile for actor types Manufacturers or Producers** can access this service via the Transmission menu option for Upload.

Browse the list of services for ‘Upload Device’, and you will be able to upload an XML file containing a set of Devices or System or Procedure Packs according to the XSD schema.

As described in 2.2, you will be able to see the state of your request and download the response file in the Upload Management screen.

# 3. XML Samples descriptions

## 3.1. Actor Sample Description

The sample XML files outline the expected structure for upload, but **must** be adapted in order to match the details required for **your actor's circumstances**.

For example, a registration request assessment file must identify the correct actor and application IDs for a successful outcome.

Use case	XML file name	Description	Result
UC_BLK_ACT_001: Download registered actors	SAMPLE_DTX_ACT_REQ_V1.5_001.01.xml	Search for an individual manufacturer SRN (EU)	Positive
	SAMPLE_DTX_ACT_REQ_V1.5_001.02.xml	Search for an individual manufacturer SRN (non-EU)	Positive
	SAMPLE_DTX_ACT_REQ_V1.5_001.03.xml	Search for an individual importer	Positive
	SAMPLE_DTX_ACT_REQ_V1.5_001.04.xml	Search for an individual authorised representative	Positive
	SAMPLE_DTX_ACT_REQ_V1.5_001.05.xml	Search for an individual producer	Positive
	SAMPLE_DTX_ACT_REQ_V1.5_001.07.xml	Request to download a registered economic operator using the wrong attribute type in the pull request	Negative

## 3.2. UDI/Device Sample Description

Use case	XML file name	Description	Result
UC_BLK_UDI_002 : Upload Basic UDI-DI and UDI-DI information	UDI_POST_V1.5_001.01 (POST_STANDARD_Single Device).xml	Register New MDR Device BUDI and Device (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)	Positive
	UDI_POST_V1.5_001.02 (POST_STANDARD_Several Devices).xml	Register New MDR Device BUDI and 2 or more UDI-DI.  (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)	Positive
	UDI_POST_V1.5_001.03 (POST_STANDARD_CIII).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 Sizes, Product Designer SRN)	Positive
	UDI_POST_V1.5_001.04 (POST_STANDARD_CIIA - Error).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, DeviceCertificateLinks, Substances, Storage and Handling Conditions, Critical Warnings, Market Information, Clinical Sizes, Product Designer SRN)	Negative
	UDI_POST_V1.5_001.05 (POST_STANDARD_CIIIB).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.  Class II B (IIb Implantable exceptions- false, DeviceCertificateLinks, Direct marking DI, Substances, Direct marking DI, Storage and Handling Conditions, Critical Warnings, Market Information, Clinical Sizes, Product Designer SRN)	Positive
	UDI_POST_V1.5_001.12 (POST_STANDARD_Several Trade_names).xml	Register New MDR Device BUDI and UDI-DI with multiple brand/trade names; ensure the "primary" attribute.	Positive
	UDI_POST_V1.5_001.13 (POST_STANDARD_Several ContainersPacks).xml	Register New MDR Device BUDI and UDI-DI with multiple packaging hierarchies (1st , 2nd , 3rd) and different packaging items on each level	Positive

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	UDI_POST_V1.5_002.01 (POST_STANDARD_IVDR).xml	Register New IVDR Device BUDI and UDI-DI information  Risk Class A (Storage and Handling Conditions, Critical Warnings, Market Information, Product Designer Organisation)	Positive
	UDI_POST_V1.5_002.03 (POST_STANDARD_IVDR_Class C).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)	Positive
	UDI_POST_V1.5_003.01 (POST_SPP).xml	Register New System or Procedure Pack with only one Basic UDI	Positive
	UDI_POST_V1.5_005.01 (POST_MDD_LEGACY).xml	Upload Legacy Device - Class I MDD Legacy Device	Positive
	UDI_POST_V1.5_005.02 (POST_AIMDD_LEGACY).xml	Upload Legacy Device - AIMDD Legacy Device	Positive
	UDI_POST_V1.5_005.03 (POST_IVDD_LEGACY).xml	Upload Legacy Device - IVD_ANNEX_II_LIST_A Risk Class	Positive
UC_BLK_UDI_001 : Download of Basic UDI-DI, UDI-DI and device data	UDI_REQ_V1.5_004.01 (MF).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  MF and State Filtering Criteria	Positive
	UDI_REQ_V1.5_004.06 (MF, Country).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	Positive
UC_BLK_UDI_005 : Upload a new UDI under an existing B-UDI	UDI_DI_POST_V1.5_008.02 (Post UDI-DI existing BUDI).xml	Register multiple New Device UDI-DI (MDR/IVDR) information related to an already existing (MDR/IVDR) Device B-UDI	Positive
UC_BLK_UDI_003 : Update BasicUDI	BUDI_PATCH_V1.5_009.01 (Patch BUDI).xml	Update an existing MDR/IVDR Device BUDI	Positive
	UDI_DI_POST_V1.5_009.02 (Patch EUDI).xml	Update an existing MDD Device BUDI	Positive
UC_BLK_UDI_004 : Update UDI-DI	UDI_PATCH_V1.5_010.01 (Patch UDI).xml	Update an existing MDR/IVDR Device UDI-DI	Positive
	UDI_PATCH_V1.5_010.02 (Patch UDI_MDD).xml	Update an existing MDD Device UDI-DI	Positive
	UDI_PATCH_V2.0.2_010.03 (Patch DI-MDD).xml	Update the first EU country where the device has been put on the market	Positive
	UDI_PATCH_V2.0.2_010.04 (Patch UDI).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
UC_BLK_UDI_007 : Update of Market Information	UDI_PATCH_V2.0.2_007.01.xml	Submit a list of market info for a specific UDI-DI.	Positive
	UDI_PATCH_V2.0.2_007.02.xml	Submit a list of market info for a specific list of UDI-Dis.	Positive
	UDI_PATCH_V2.0.2_007.03.xml	Submit list of market info for a non-existing UDI-DI.	Negative

### 3.3. SS(C)P Sample Description

Use case	XML file name	Description	Result
UC_M2M_UDI_009 : Download SSCP	SAMPLE_DTX_UDI_REQ_V2.0_009.01.xml	Download SS(C)P by Basic UDI-DI	Positive
	SAMPLE_DTX_UDI_REQ_V2.0_009.02.xml	Download SS(C)P by certificate ID	Positive

# 4. DTX Exceptions

EUDAMED data exchange involves some layers of validation before successful delivery and response. These occur via several layers of validation:

## 4.1. XSD validation

The XSD schema is the first layer of validation and further information can be found within the XSD files. These ensure that the following correctly match what is expected:

- Datatype
- Field length
- Occurrence
- Enumeration match
- XML file structure

Below you will find an example of an XSD validation error:

```
<message:report>
<message:elementReport>
<message:operationErrorCode>E-I-40000</message:operationErrorCode>
<message:operationErrorDetail>[ValidationProblem { line=32, column=44, type=ERROR, message='cvo
</message:elementReport>
</message:report>
```

## 4.2. Error codes

### **SERVER\_ERROR:**

This is a general error and most frequent error code returned. It is also returned if there is any outbound validation error or something goes wrong while processing.

### **INVALID\_REQUEST\_OBJECTS:**

This error code is returned when the request XML contains any element that could not be mapped to known objects by the EUDAMED data exchange.

### **SERVICE\_NOT\_FOUND:**

This error code is returned when the service requested is not available (yet) in EUDAMED data exchange.

In addition to the above codes, sub-codes are returned which are generated dynamically and accompany further details as part of an error report (see above XML sample in

Section 1.5.1 **??CHECK FOR CROSSREF??** for example). These codes are listed in [Annex 1 \[22\]](#) of this document.

# 5. M2M Environments

Name	Purpose	Test Data Purge Timing	Version Management	Notifications
Playground	External test & Demo	May be purged based on new releases	New version or current version	No
Production	Real data	Never	Current version	Yes

# 6. Support

Domain	Contact	Service
EUDAMED Support	<SANTE-EUDAMED-SUPPORT@ec.europa.eu>	<p>The <b>FIRST</b> point of contact for starting onboarding</p> <p>Generating/regenerating the access token</p> <p>XSD/XML validation and error responses</p> <p>Data dictionary queries</p> <p>Bug reporting and feature suggestions</p>
DIGIT Access Point Support	Multiple sources may contact user, but all replies should go through <SANTE-EUDAMED-SUPPORT@ec.europa.eu>	<p>Access point connection (once approved by EUDAMED support)</p> <p>Public Key Infrastructure (PKI) queries</p> <p>Pmode configuration</p> <p>Advice on AS4 conformant solutions</p> <p>Configurations for getting the message to EUDAMED</p>

# 7. Supporting Documents

<b>Documentation</b>	<b>Content</b>
DTX XSD	The XML Schema Definition for the available services and entities
DTX Samples	Bulk upload samples covering the most used scenario's per service These are general samples, not containing personalized data.
DTX Service Definition	A business level view of the available services
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



# 8. Annexes

## 8.1. Annex - 1: Error sub-codes

<b>GENERIC_INTERNAL_50000("50000"),</b>
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_REGISTRATION_NULL_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"),
OUTBOUND_VALIDATION_NULL_MESSAGEID("O-40001"),
OUTBOUND_VALIDATION_NULL_RESPONSE_O_40002("O-40002"),
OUTBOUND_VALIDATION_NULL_RESPONSE_MESSAGEID("O-40003"),
IO_VALIDATION_NULL_IMESSAGE_50000("E-IO-50000"),
IO_VALIDATION_NULL_IMESSAGE_50001("E-IO-50001"),
E_I_VALIDATION_NULL_IMESSAGE_50000("E-I-50000"),
E_I_VALIDATION_NULL_IMESSAGE_PAYLOAD_XML_50001("E-I-50001"),
E_I_VALIDATION_INVALID_XML_PAYLOAD_40000("E-I-40000"),
E_O_VALIDATION_NULL_IMESSAGE_50000("E-O-50000"),
E_O_VALIDATION_NULL_IMESSAGE_PAYLOAD_XML_50001("E-O-50001"),
E_O_VALIDATION_INVALID_XML_PAYLOAD_O_50002("E-O-50002"),
M_VALIDATION_GENERIC_M_50000("M-50000"),
INBOUND_TRANSFORM_PUSH_REQUEST_DEVICE_UPLOAD_NULL_MESSAGE("RESERVED_X_60001"),

<b>GENERIC_INTERNAL_50000("50000"),</b>
INBOUND_TRANSFORM_PUSH_REQUEST_UDI_ADD_NULL_MESSAGE("RESERVED_X_60002"),
INBOUND_TRANSFORM_PUSH_REQUEST_UDI_UPDATE_NULL_MESSAGE("RESERVED_X_60003"),
INBOUND_TRANSFORM_PUSH_REQUEST_BUD_UPDATE_NULL_MESSAGE("RESERVED_X_60004"),
INBOUND_TRANSFORM_PUSH_REQUEST_MARKET_UPSERT_NULL_MESSAGE("RESERVED_X_60005"),
INBOUND_TRANSFORM_PUSH_REQUEST_DEVICE_UPLOAD_WRONG_TYPE_MESSAGE("RESERVED_X_60101"),
INBOUND_TRANSFORM_PUSH_REQUEST_UDI_ADD_WRONG_TYPE_MESSAGE("RESERVED_X_60102"),
INBOUND_TRANSFORM_PUSH_REQUEST_UDI_UPDATE_WRONG_TYPE_MESSAGE("RESERVED_X_60103"),
INBOUND_TRANSFORM_PUSH_REQUEST_BUD_UPDATE_WRONG_TYPE_MESSAGE("RESERVED_X_60104"),
INBOUND_TRANSFORM_PUSH_REQUEST_MARKET_UPSERT_WRONG_TYPE_MESSAGE("RESERVED_X_601005"),
OUTBOUND_TRANSFORM_ACKNOWLEDGEMENT_UPLOAD_NULL_MESSAGE("RESERVED_X_60501"),
OUTBOUND_TRANSFORM_ACKNOWLEDGEMENT_UDI_ADD_NULL_MESSAGE("RESERVED_X_60502"),
OUTBOUND_TRANSFORM_ACKNOWLEDGEMENT_UDI_UPDATE_NULL_MESSAGE("RESERVED_X_60503"),
OUTBOUND_TRANSFORM_ACKNOWLEDGEMENT_BUD_UPDATE_NULL_MESSAGE("RESERVED_X_60504"),
OUTBOUND_TRANSFORM_ACKNOWLEDGEMENT_DEVICE_UPLOAD_WRONG_MESSAGE_TYPE("RESERVED_X_60601"),
OUTBOUND_TRANSFORM_ACKNOWLEDGEMENT_UDI_ADD_WRONG_MESSAGE_TYPE("RESERVED_X_60602"),
OUTBOUND_TRANSFORM_ACKNOWLEDGEMENT_UDI_UPDATE_WRONG_MESSAGE_TYPE("RESERVED_X_60603"),
OUTBOUND_TRANSFORM_ACKNOWLEDGEMENT_BUD_UPDATE_WRONG_MESSAGE_TYPE("RESERVED_X_60604"),
VALIDATION_MALFORMED_URI("RESERVED_X_61001"),
SERVICE_VALIDATION_INVALID_ENTITY_40000("SERVICE_VALIDATION_40000"),
INBOUND_TRANSFORM_PULL_REQUEST_ACTOR_REGISTRATION_PAYLOAD(("I-50014")),
OUTBOUND_TRANSFORM_DOWNLOAD_ACTOR_ACTOR_TYPE_O_50013("O-50013");

