



DG Health and Food Safety
Unit Information Systems (SANTE.A4)

Data Exchange for NBs – User Guide

EUDAMED: v2.8
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1 MACHINE TO MACHINE DESCRIPTION

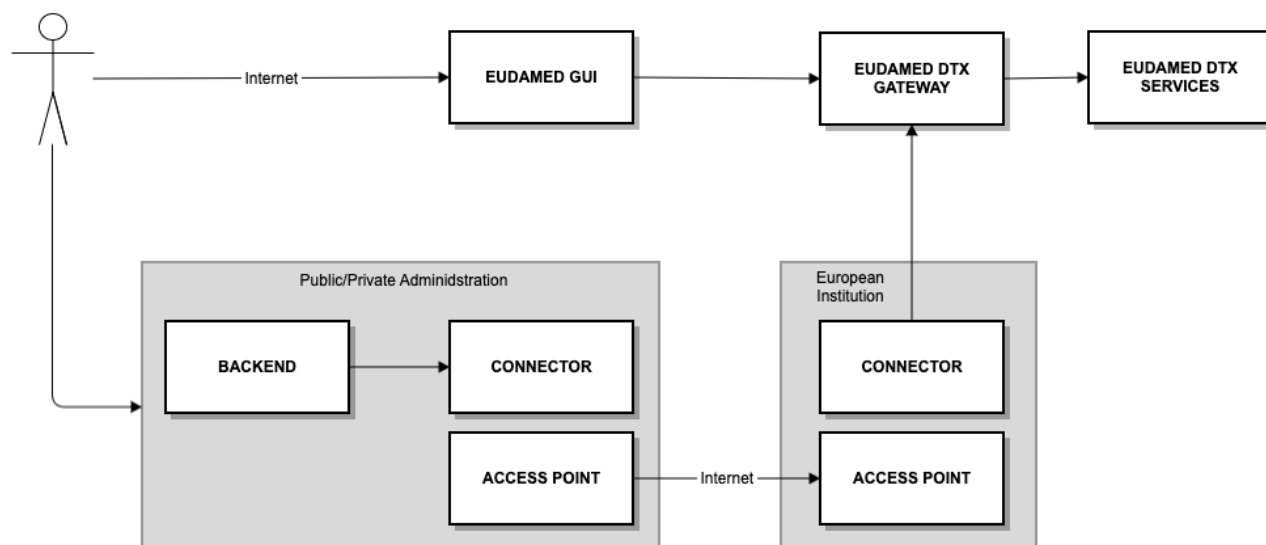


Figure 1: EUDAMED DTX; M2M and Bulk Upload/Download

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 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.

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:PullResponse>
```

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:

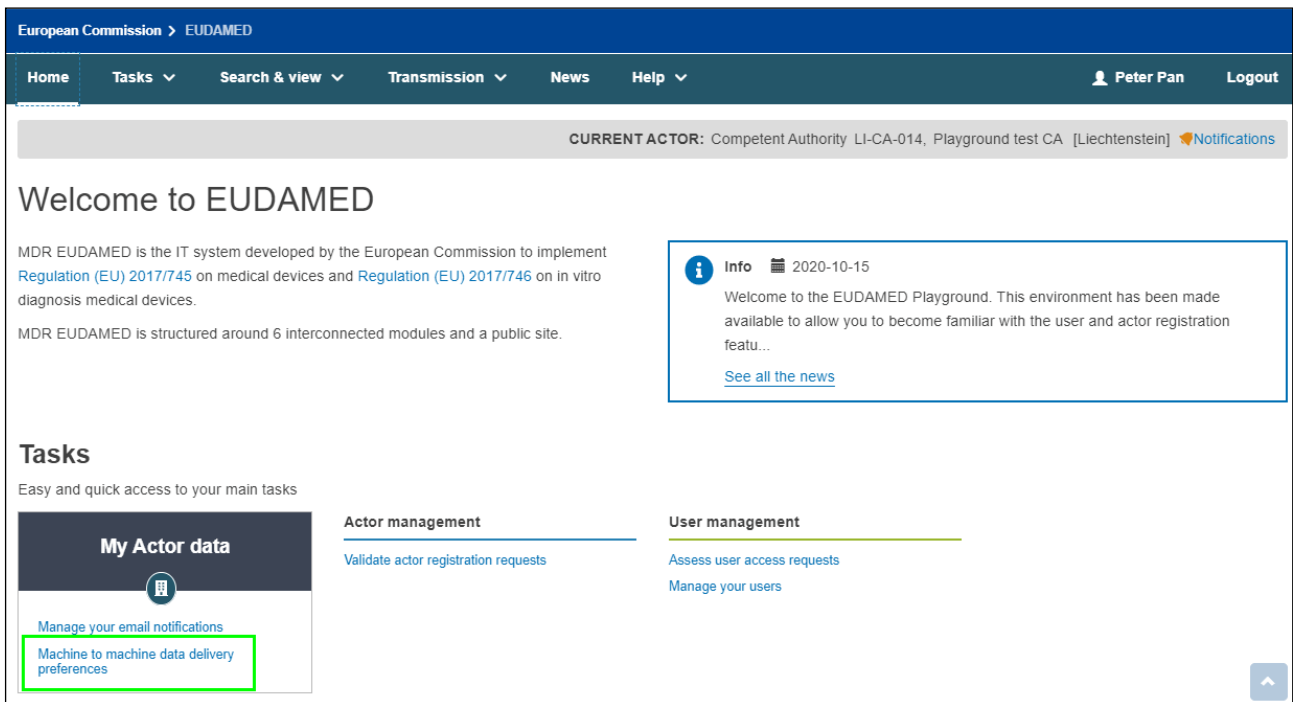


Figure 2: EUDAMED Restricted Dashboard for Competent Authority

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

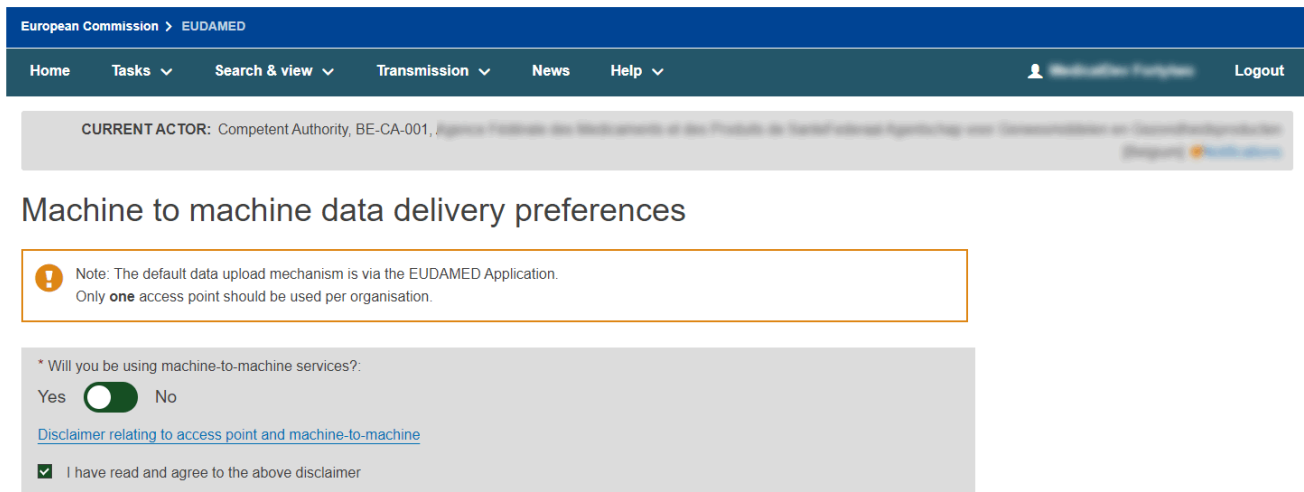


Figure 3: Machine to machine preferences

2. 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

Figure 4: Machine to machine services and request information for a manufacturer

3. 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.

Technical Contact

* Contact name:

* Telephone:

Telephone format example: +32 x xxx xx xx

* Email:

Legal Contact

* Contact name:

* Telephone:

Telephone format example: +32 x xxx xx xx

* Email:

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.

Figure 5: Submission of access point request information

(IMPORTANT: email notifications are disabled for the playground, so at this stage you should email [EUDAMED Support](#) 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:

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

0EFB8D1CA7077F3529BAAB83B0CD325B3A6B970BD1F6B2EFA947F96F14D97BB965F5428D7349D931458A9011C8658AFF70B11E88A0885D7C1C3D80E489DFCA0EB9D91A2E67267655EA5E591D5E81ADF6D0ACF6419AC4F5D747DCFO21DCD99776C3A47792EB3653D9D22673F04BFF5474986CF41DDCB88567FA36F912272A1EDE85C0E4E0F62A457FE143AE7EE53C655699EBA867906C15D0DBA181B9F19B8640737851130C991A718CB91CC15AE86F4A276B1E723741932D02D690C6A0270869419B9BEA76BFFC76C14C4E7AF26687207D5C6E29751F45D4B35761E73E38DE3627A3E870B2BFC4E8CACA9E3B69679C040A4228E33AC47D0F9F94A277A6B1DB98655D9EB25DE1F57B987471E0E2853C2

UDI/Device

9ED1962BC8A7F016200E723FB16F1C9561C68724D3E3776B84F6F1C447E4AADCSF4259BA1A618195E0C2440E47A4B7BE0A963FFD1511B2E619EF8938C5D270ECB53DDAF98AF56B879D6F14C14A8321C041B1DD1E2497E1100AC186CE660D58B5E42AED4D4839A49E63CBA81911895E791821C494598844673A3E9B53089368F2B582F08BF3797137CCE2E8E2952D6B91617C827E284CFB678C610FA15645844001156A432B296FF76C5B95B43892818B959F69F1DFC3A4DC02DD18E4D9BD6ABC2CA3676235A8F2F5E452BA7C52AC981CF6585D9CE469CE95BBA7957BD206E7818E0BDA38F2AAA46902D442EA65E7E13B727FE92234C35A97FE2620559272A9BCC6D8716F170A24367F230AE71A02AE0E

Edit

Figure 6: M2M data delivery preferences overview, with Party ID and access tokens for Actor and Device module highlighted.

Specific notes for testing on the Playground environment.

- Your 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

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 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

80DF55C97F46AAD511154662F3CF23B245BD034BD1772A71FBA13C4E6CC42A59E26A6A1AFE5A4C75F569623AB96AF9F6BDFD06B360D4269F20B66960407AA3675D31F5CF8739927D10A68591E73423D96DB36C870413AA6FDD210EA963E9A521F03451FB1B0BDDCE02D91A649D2D0230A4E208EE56BA0D10C47D87588CC8F2A7BD12AF016A54038E5C0C3FA8649726B44187884C3B0BF03384C32D7D2A4FE6C26E1CBA3907D9EFBBE7F150EFB930166C83617DFC5A67B19180DCBA6770153F30FA7092C4146754432A7AB8A54E7E6A064FC0227B235ADB0F3B408B9B88E25B8E8689F2FDD0DDDB2CEB0CB94650B80298A1B742DEA28915818E2A49FBC5E91295F5D747FF7C4BA6140C571C56526C71CCE

Submit >

Cancel

Figure 7: Machine to machine data delivery preferences edit page with regenerate selected for Actor module token.

Remember: 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>PD94bWwgdmVyc2lvbj0iMS4wliBlbmNvZGluc2Z0iVVVRGLTgiPz4KPGRhGxvPndvcmxkPC9oZWxsbsz4=</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
 - Validation of actor registration requests (as a CA Validator)
 - Search for actors
 - Search for UDI-Dis/Devices
 - Search for issued/refused certificates
- 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. After successfully logging in, you will be able to access the actors registered in EUDAMED by using the Search and View functionalities for Actors:

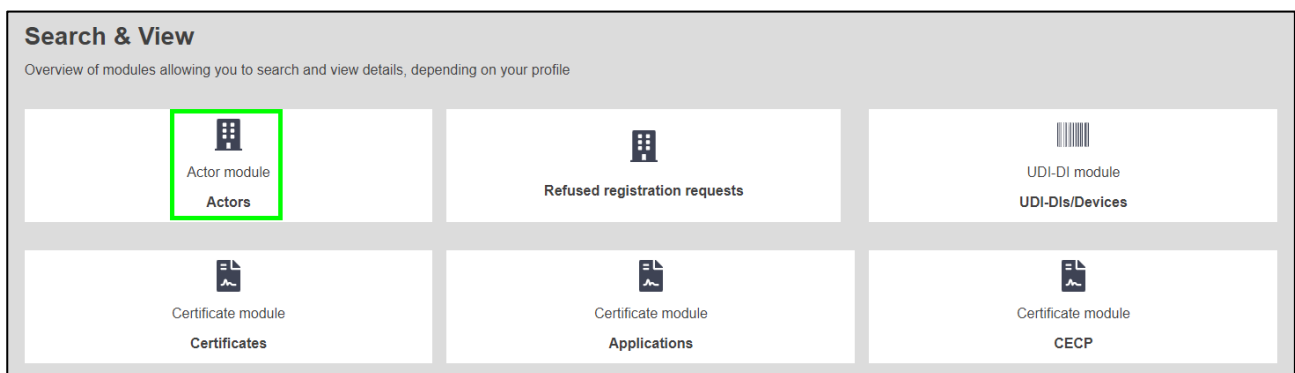


Figure 8: Search and view actors in dashboard screens

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:

Figure 9: Filters for searching actors

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.

Attention: 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 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 20 entries per page

Actor ID/SRN I†	Role I†	Name I†	Country I†	Date of registration I†
BE-MF-000000001	Manufacturer	Belgium MF A V4_test [HR]	Belgium	2021-04-02

Figure 10: Generating the XML with the actor search results in the list

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 20 entries per page

ID	Name	Module I†	Service I†	State I†	Request date I†	Download
APP-DTX-000000934	MedicalDev Fortytwo	Actor	Actor download	● Successful	2021-08-03 [15:25]	XML [7 KB] Expires in 15 days

Figure 11: Download management list

2.1.2 Bulk download of devices via EUDAMED interface

After you log in as a user for **any actor**, you will be able to access the list of Devices registered in EUDAMED by using the Search and View functionalities for Devices:

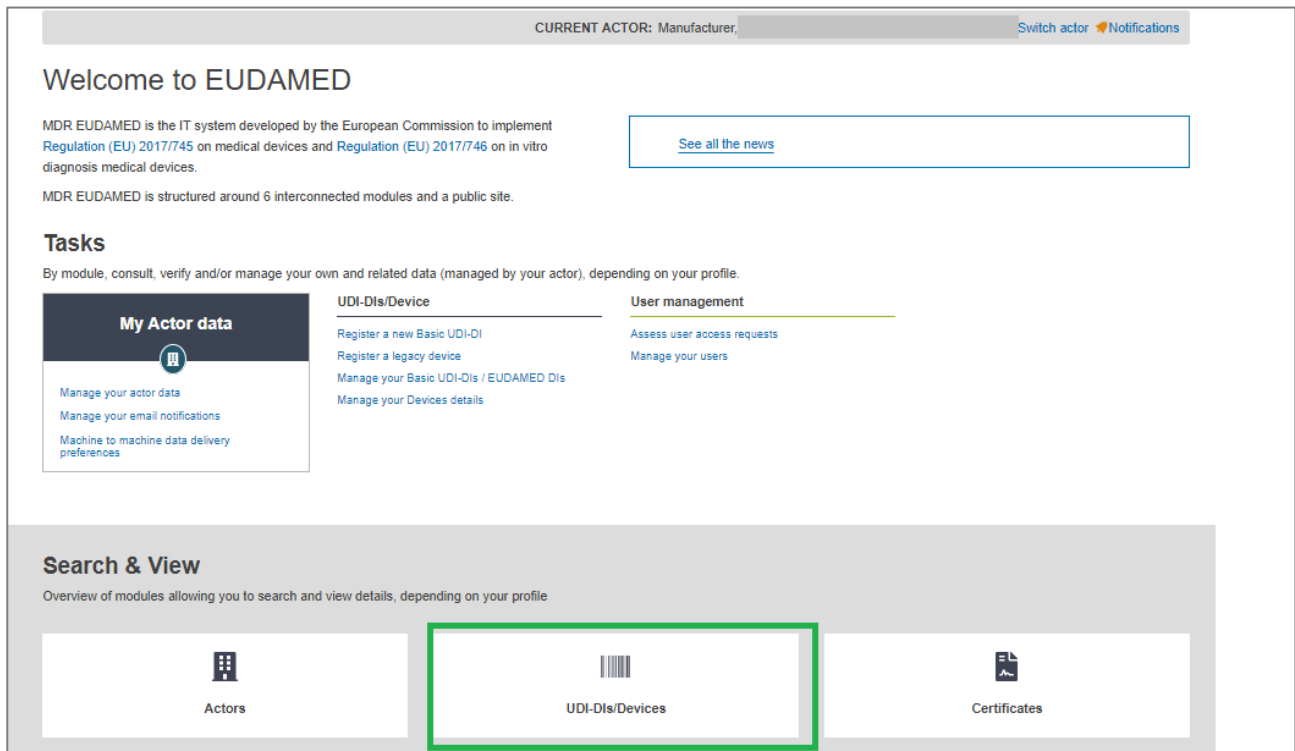


Figure 12: Search and View Devices in Dashboard screens

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

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

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

The screenshot displays a web interface titled "Search for UDI-DIs". At the top, it indicates the "CURRENT ACTOR: Manufacturer," with links for "Switch actor" and "Notifications". The search filters are organized into several sections:

- Top Row:** UDI-DI code, Basic UDI-DI code, Status (dropdown), and Model.
- Second Row:** Name, Trade name, and Applicable regulation (dropdown showing "MDR (REGULATION (EU) 2017/745 on medical devices)").
- Third Row:** Risk class (dropdown), Nomenclature code, Reference/Catalogue number, and Country (dropdown).
- Fourth Row:** State (dropdown showing "Registered"), Scopes (text input with "You can select more than one value"), and a button to "Add new scope".
- Fifth Row:** MF / PR SRN (text input with "BE-MF-000000002"), MF / PR Name, AR SRN, and AR name.

At the bottom, there are three buttons: "Search", "Generate XML file", and "Clear search".

Figure 13: Filters for Searching Devices

After applying the desired search criteria, use the Search button in order to retrieve the Devices.

Attention: 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

UDI-DI code

Basic UDI-DI code

Status

--

Model

Name

Trade name

Applicable regulation

MDR (REGULATION (EU) 2017/745 on medical devices) X

Risk class

--

Nomenclature code

Reference/Catalogue number

Country

--

State

Registered X

Scopes

You can select more than one value

MF / PR SRN

BE-MF-000000002

MF / PR Name

AR SRN

AR name

Search

Generate XML file

Clear search

State: Registered X

MF / PR SRN: BE-MF-000000002 X

Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices) X

Clear search

Show

20

entries per page

Figure 14: Generating the XML with the Devices in the list

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

20

entries per page

ID	Name	Module IT	Service IT	State IT	Request date IT	Download
		UDI/Device	Device download	Pending	2021-03-23 [19:16]	

Figure 15: Download management list

2.1.3 Bulk download of certificates via EUDAMED interface

For this Playground release and testing purposes, **competent authorities** and **notified bodies** will be able to download issued/refused certificates via the EUDAMED interface.

After successfully logging in, you will be able to access the list of certificates registered in EUDAMED by using the Search and View functionalities for Certificates:

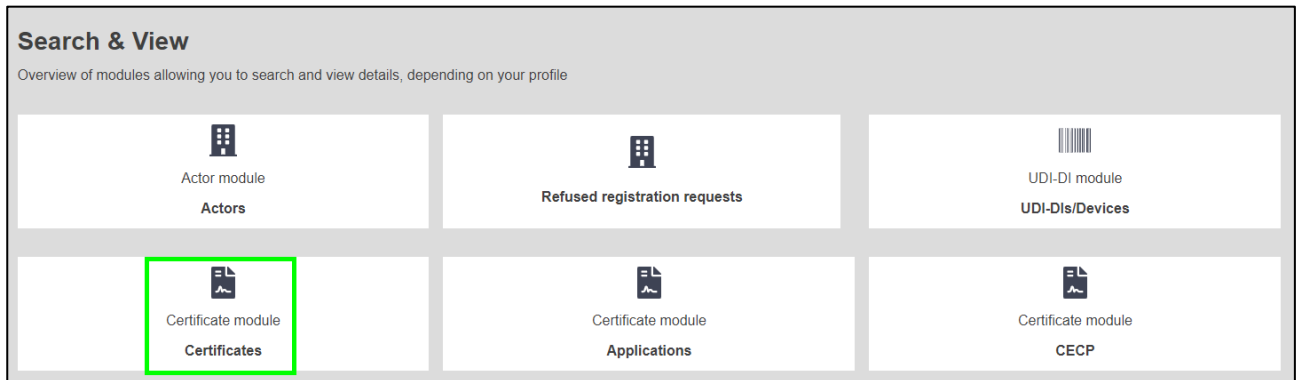


Figure 16: Search and view certificates in Dashboard screens

Enable the filter for bulk download of certificates that will restrict your search criteria to those that are applicable to the issued/refused certificate download service for Data Exchange.

The screenshot shows the 'Certificates' search filter interface. At the top, there is a toggle switch labeled 'Enable filters for certificates bulk download' which is currently turned on and highlighted with a green box. Below this, there are search options for 'Certificates' (selected) and 'Refused certificates'. The 'Certificate data' section includes various filters:

- NB identification: A dropdown menu.
- * Certificate Type: A dropdown menu.
- Certificate number: A text input field.
- Status: A dropdown menu.
- Economic operator Actor ID/SRN: A text input field.
- * Date of issue: A section with 'Between' and 'and' date range selectors (YYYY-MM-DD).
- Date of submission: A section with 'Between' and 'and' date range selectors (YYYY-MM-DD).
- Date of expiry: A section with 'Between' and 'and' date range selectors (YYYY-MM-DD).

At the bottom, there are three buttons: 'Search', 'Generate XML file', and 'Clear search'.

Figure 17: Filters for Searching Devices

After applying the desired search criteria, use the Search button in order to retrieve the certificates. 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.

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

Search results for certificates

Active search fields:

Searching for: Certificates Enable filters for certificates bulk download: ✕ Status: Issued ✕ Between: 2021-07-01 ✕ and: 2021-07-31 ✕

Certificate Type: (MDR) EU type-examination certificate (Annex X) ✕ [Clear search](#)

Showing 1 to 2 of 2 entries Show 20 entries per page

NB number	MF/PR Actor ID/SRN	Actor ID/SRN AR	Certificate number	Certificate type	Date of issue	Date of expiry	Status
NB-1039	BE-MF-000000121		5317_45	(MDR) EU type-examination certificate (Annex X)	2021-07-22	2021-07-31	Issued
NB-1039	BE-MF-000000001		2222222	(MDR) EU type-examination certificate (Annex X)	2021-07-05	2022-01-07	Issued

Figure 18: Generating the XML with the certificates in the list

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 and ZIP files. When the file is processing it will receive the state “Pending”:

Download management

Filter

Active filters: No selection

Showing 1 to 3 of 3 entries Show 20 entries per page

ID	Name	Module	Service	State	Request date	Download
APP-DTX-000000930	MedicalDev Fortytwo	Certificates/Notified Body	Certificate download	Pending	2021-08-03 [15:00]	
APP-DTX-000000836	MedicalDev Fortytwo	Certificates/Notified Body	Refused Certificate download	Successful	2021-07-26 [12:35]	ZIP [165 KB] , XML [11 KB] Expires in 7 days
APP-DTX-000000826	MedicalDev Fortytwo	Certificates/Notified Body	Refused Certificate download	Successful	2021-07-26 [10:18]	ZIP [165 KB] , XML [11 KB] Expires in 7 days

Figure 19: Download management list

2.2 How to upload a file

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

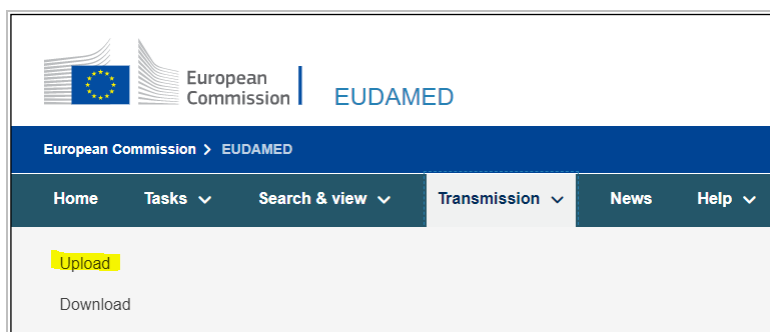


Figure 20: “Upload” menu item in top navigation menu

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

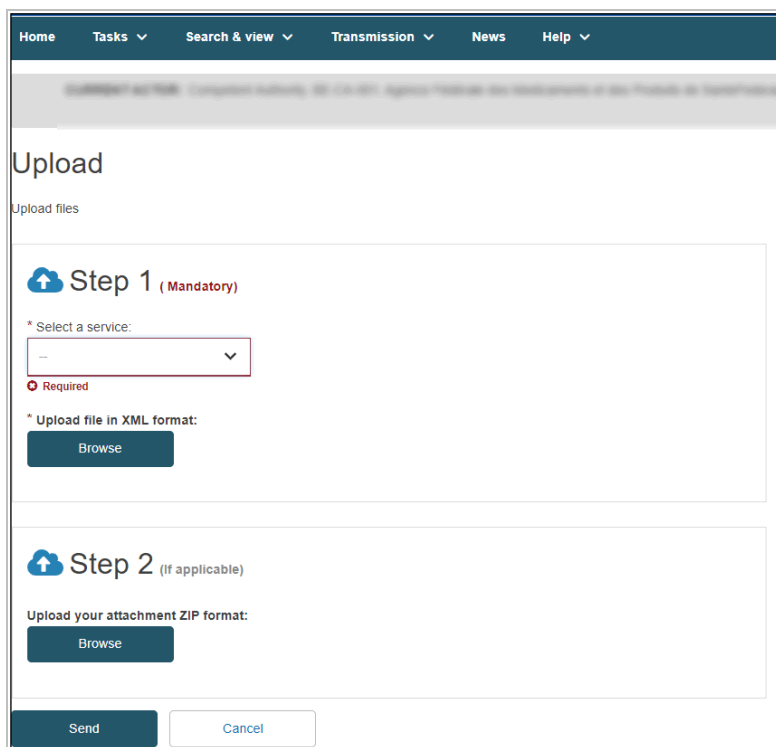
The image shows the 'Upload' page in the EUDAMED portal. The page has a header with the same navigation bar as Figure 20. Below the header, the title 'Upload' is displayed. Underneath, it says 'Upload files'. The main content area is divided into two steps. Step 1 is titled 'Step 1 (Mandatory)' and includes a dropdown menu for 'Select a service:' and a 'Browse' button for 'Upload file in XML format:'. Step 2 is titled 'Step 2 (If applicable)' and includes a 'Browse' button for 'Upload your attachment ZIP format:'. At the bottom of the form, there are 'Send' and 'Cancel' buttons.

Figure 21: “Upload” page – Mandatory XML file

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 under.

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 20 ▼ entries per page

New upload

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

Figure 22: “Upload Management” page – Pending requests

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_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

Use case	XML file name	Description	Result
	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

3.1 Certificate Sample Description

Use case	XML file name	Description	Result
UC_M2M_CRF_02 : Download issued certificate (last current version)	SAMPLE_DTX_CRF_REQ_V1.5_02.01.xml	Downloading explicitly a known certificate by its certificate number.	Positive
	SAMPLE_DTX_CRF_REQ_V1.5_02.02.xml	Downloading certificates that reference a specific manufacturer by specifying its SRN	Positive
	SAMPLE_DTX_CRF_REQ_V1.5_02.03.xml	Downloading certificates issued by other Notified Body than the Notified Body requestor.	Negative
UC_M2M_CRF_03 : Download refused certificate	SAMPLE_DTX_CRF_REQ_V1.5_03.01.xml	Download refused certificates by its number	Positive
	SAMPLE_DTX_CRF_REQ_V1.5_03.02.xml	Download refused certificates by type	Positive

3.2 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='cvc-enumeration-valid: Value 'XX' is not
facet-valid with respect to enumeration '[AR, IM, MF, PR]'. It must be a value from the enumeration.' }, ValidationProblem { line=32,
column=44, type=ERROR, message='cvc-type.3.1.3: The value 'XX' of element 'service:type' is not valid.' }]: please fix the message validation
issues and resend it</message:operationErrorDetail>
</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 for example). These codes are listed in the Annex - 1 to 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	The FIRST point of contact for starting onboarding Generating/regenerating the access token XSD/XML validation and error responses Data dictionary queries Bug reporting and feature suggestions
DIGIT Access Point Support	Multiple sources may contact user, but all replies should go through SANTE-EUDAMED-SUPPORT@ec.europa.eu	Access point connection (once approved by EUDAMED support) Public Key Infrastructure (PKI) queries Pmode configuration Advice on AS4 conformant solutions Configurations for getting the message to EUDAMED

7 SUPPORTING DOCUMENTS

Documentation	Content
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

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_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"),
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");