

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

Data Exchange Guide and Release Notes

EUDAMED v2.0

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	5.2 5.3 5.4	5.1.1 XSD element changes	.22 22 .22 .22 .22 .23 .23 .23 .23 .23 current .24
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6 7	5.2 5.3 5.4 5.5	5.1.1 XSD element changes	.22 22 .22 .22 .23 .23 .23 .23 .23 .23
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1 MACHINE TO MACHINE DESCRIPTION

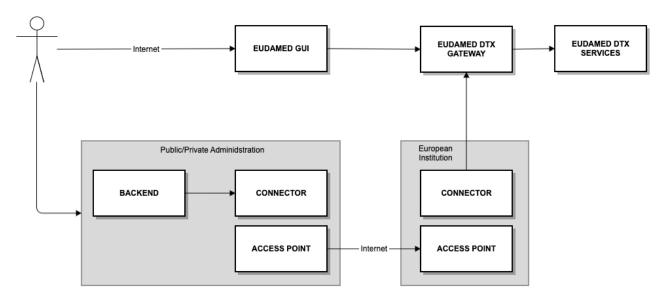


Figure 1: EUDAMED DTX; M2M and Bulk Upload/Download

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 in future the playground XSD may differ to the XSD files available via the production EUDAMED or via the <u>Europa</u> <u>Medical Device website</u>.

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 <u>CEF eDelivery access point documentation</u> as they may have been updated, and in particular their Access Point Test Guide available <u>here</u>.

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.

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

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:

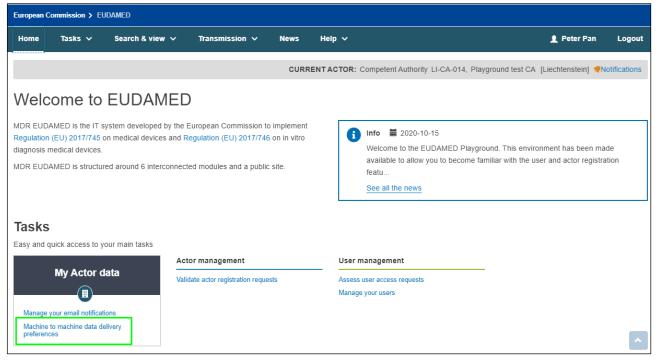


Figure 2: EUDAMED Restricted Dashboard for Competent Authority

The preferences are defaulted to "No" as a security measure:

European Commission > EUDAMED	
Home Tasks v Search & view v Transmission v News Help v	Logout
CURRENT ACTOR: Competent Authority, BE-CA-001, /	eer Terensrettive er Terensbudgestacke Biegerij # rettraten
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	

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:

ata exchange services		
ease select the services you wish to use for da	ata exchange	
* Services list		
 Actor download 		
 Device download 		
 Device upload 		
How many devices do you intend to exchange	ge data on?	
	rmation	
Access point request info	rmation	
Access point request info	rmation	
	rmation	
* Access point request		
* Access point request CEF eDelivery access point documentation		
* Access point request CEF eDelivery access point documentation Do you want to apply for a new access point of	configuration?	
Access point request CEF eDelivery access point documentation Do you want to apply for a new access point c Yes O No	configuration?	
Access point request CEF eDelivery access point documentation Do you want to apply for a new access point c Yes O No Do you already have your own eDelivery acce	:onfiguration?: iss point?:	

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 poir The information entered below will access point details.	Submission			× <u>Close</u>
Technical Contact	Are you sure you want to subn	nit your request?		
* Contact name:	The details entered will be sub	mitted to the EUDAME	D support team. You do not need to	do anything else after
John Smith	submitting your details. The EUDAMED support team will be in contact via email to assist in configuration of your access point.			
* Telephone:				
123456789	Submit my request	Cancel		
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				

Figure 5: Submission of access point request information

(**IMPORTANT**: <u>email notifications are disabled for the playground</u>, so at this stage you should email <u>EUDAMED Support</u> 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:	LegaIMF				
Telephone:	+3212311231				
Email:	contact@mf.com				
Your secure encrypted production codes These codes must be included in your XML upload or de	wnload requests. Note: Codes differ per module.				
5EA5E591D5E81ADF6D0ACF6419AC4F5D747DCF021DCD99 55699EBA867906C15D0DBA181B9F19B8640737851130C991/	FA947F96F14D97BB985F5428D7349D931458A9011C8658AFF70B11E88A0885D7C1C3D80E489DFCA0EB9D91A2E6726785 776C3A47782EB3653D9D22673F04BFF5474986CF41DDC888587FA36F912272A1EDE85C0E4E0F62A457FE143AE7EE53C8 718CB91CC15AE86F44A276B1E723741932D02D690C6A0270869419B9BEA76BFFC76C14C4E7AF26687207D5C6E29751F 79C040A4228E33AC47D0F9F94A277A6B1DB98655D9EB25DE1F57B987471E0E2853C2				
UDI/Device 9ED1962BC8A7F016200E723FB16F1C9561C68724D3E3776B84F6F1C447E4AADC5F4259BA1A618195E0C2440E47A4B7BE0A963FFD1511B2E619EF8938C5D270ECB53DDAF98AF56B8 79D6F14C14A8321C041B1DD1E2497E1100AC186CE660D58B5E42AED4D4839A49E63CBA81911895E791821C494598844673A3E9B53089368F2B582F08BF3797137CCE2E8E2952D6B9 1617C827E284CFB678C610FA15645844001156A432B296FF76C5B95B43892818B959F69F1DFC3A4DC02DD18E4D9BD6ABC2CA3676235A8F2F5E452BA7C52AC981CF6585D9CE469CE 95BBA7957BD206E7818E0BDA38F2AAA46902D442EA65E7E13B727FE92234C35A97FE2620559272A9BCC608716F170A24367F230AE71A02AE0E					
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 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

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) Image: Code of the code (the new code will be displayed after clicking submit) 80DF55C97F46AAD511154662F3CF23B245BD034BD1772A71FBA13C4E6CC42A59E26A6A1AFE5A4C75F569623AB96AF9F6BDFD06B360D4269F20B66960407AA3675D31F5CF8 739927D10A68591E73423D96DB36C870413AA6FDD210EA963E9A521F03451FB1B0BDDCE02D91A649D2D0230A4E208EE56BA0D10C47D87588CC8F2A7BD12AF016A54038E5 C0C3FA8649726B44187884C3B0BF03384C32D7D2A4FE6C26E1CBA3907D9EFBBE7F150EFB930166C83617DFC5A67B191800CBA6770153F30FA7092C4146754432A7AB8A54E 7E6A064FC0227B235ADB0F3B408B9B88E25B8E8689F2FDD0DDB2CEB0CB94650B80298A1B742DEA28915818E2A49FBC5E91295F5D747FF7C4BA6140C571C56526C71CCE					
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.oasisopen.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:Partyld type="urn:oasis:names:tc:ebcore:partyid-type:unregistered">eudamed mdr acc</ns:Partyld> <ns:Role>http://docs.oasis-open.org/ebxml-msg/ebms/v3.0/ns/core/200704/initiator</ns:Role> </ns:From> <ns:To> <ns:Partyld type="urn:oasis:names:tc:ebcore:partyidtype: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>PD94bWwgdmVyc2lvbj0iMS4wliBlbmNvZGluZz0iVVRGLTgiPz4KPGhlbGxvPndvcmxkPC9oZWxsbz4=</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

•

- o 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:

Search & View Overview of modules allowing you to search and view details, depending on your profile						
Actor module Actors						
Certificate module Certificates	Certificate module Applications	Certificate module CECP				

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 searc	ch filters available for bulk XML	download of economi	c operators		
Name	Acto	r ID/SRN	VAT number	Role	~
Country 	Com	petent Authority	~		
Search Gen	erate XML file Clear sear	ch			

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	Generate XML file	Clear search		
Search results for	actors			
Active search fields:				
Only enable search filters availa	ble for bulk XML download c	f economic operators: X Actor ID/SRN:	BE-MF-000000001 X Clear search	
Showing 1 to 1 of 1 entries				Show 20 V entries per page
Actor ID/SRN 11	Role 11	Name If	Country I†	Date of registration I†
BE-MF-00000001	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 managemen	t				
Filter T					
Active filters: No selection					
Showing 1 to 4 of 4 entries				Sł	now 20 🗸 entries per page
ID Name	Module 11	Service If	State Iî	Request date 11	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 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 and View functionalities for Devices:

CURRENT ACTOR: Manufacturer, Switch actor #Notifications						
Welcome to EUDAM	ED					
MDR EUDAMED is the IT system developed by the European Commission to implement Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices. See all the news						
IDR EUDAMED is structured around 6 interce	onnected modules an	d a public site.				
Tasks						
ly module, consult, verify and/or manage you	r own and related dat	a (managed by your actor), depe	nding on your profile.			
	UDI-DIs/Device		User management			
My Actor data	Register a new Basic UDI-DI		Assess user access requests			
	Register a legacy of		Manage your users			
Manage your actor data	Manage your Basi Manage your Devi	o UDI-DIs / EUDAMED DIs				
Manage your email notifications						
Machine to machine data delivery preferences						
Search & View						
Overview of modules allowing you to search a	nd view details, depe	nding on your profile				
<u></u>						
Actors		UDI-DIs/Devices				
Actors		UDI-DIS/I	Devices	Certificates		

Figure 12: Search and View Devices in Dashboard screens

Apply the correct filters from the list presented in order to identify your 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)

CURRENT ACTOR: Manufacturer, Switch actor 📌 Notificati					
Search for UDI-DIs					
UDI-DI code	Basic UDI-DI code	Status	Model		
Name	Trade name	Applicable regulation MDR (REGULATION (EU) 2017/745 on me	dical devices) 🗙 🗸		
Risk class	Nomenclature code	Reference/Catalogue number	Country -		
State Registered X Y	Scopes You can select more than one value				
MF / PR SRN BE-MF-00000002	MF / PR Name	AR SRN	AR name		
Search Generate XMI	L file Clear search				

Figure 13: Filters for Searching 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.

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.

UDI-DI code		Basic UDI-DI code	Status		Model	
			-	~		
Name		Trade name	Applicable regulation	ion		
			MDR (REGULA	TION (EU) 2017/745 on med	ical devices) 🗙 🗸	
Risk class		Nomenclature code	Reference/Catalog	jue number	Country	
	~				-	~
State		Scopes				
Registered	× ×	You can select more than	n one value			
MF / PR SRN		MF / PR Name	AR SRN		AR name	
BE-MF-00000	0002					
<u>Search</u> Search res	Generate XML file	Clear search				
ctive search fields: State: Registered	MF / PR SRN: BE-MF-	0000000 😒 🗛 🗤	e regulation: MDR (REGULATION (EU)	2017/74E on modical device	clear search	
State. Registereu	MIF / PR SRN. DE-MIF-	Applicable	regulation. More (REGULATION (E0)	20 mm 43 on medical device	Glear Search	
					Show 20 V	entries per
howing 1 to 20 of 2	5 entries					
howing 1 to 20 of 2 UDI-DI code 1†	5 entries Basic UDI-DI code 11	MF / PR SRN	Trade name 11	Risk class Date	1; UDI-DI status	
-		MF / PR SRN BE-MF-000000002	Trade name 1† Trade Name		t∓ UDI-DI status -03-23 On the EU market	

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 sele	ction					
Showing 1 to 10 of 10	entries					Show 20 v entries per page
ID	Name	Module ‡î	Service 11	State 11	Request date 11	Download
		UDI/Device	Device download	Pending	2021-03-23 [19:16]	

Figure 15: Download management list

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:

European Commission EUDAMED						
European C	ommission > El	JDAMED				
Home	Tasks 🗸	Search & view 🗸	Transmission 🗸	News	Help 🗸	
Upload Downloa	d					

Figure 16: "Upload" menu item in top navigation menu

Click on "New upload" to see the file upload screen:

Home	Tasks 🗸	Search & view 🗸	Transmission 🗸	News	Help 🗸
	1999 A. 199	Competent Authority 1	0 (3-10 Agence ¹ 08		itarioti e an frank a tamfrain
Uploa	ad				
Upload file:	S				
•	Step 1 🕠	landatory)			
* Select	a service:	~			
* Upload	d file in XML forr Browse	nat:			
	Step 2 (If	applicable)			
Upload	your attachment Browse	ZIP format:			
s	Send	Cancel			

Figure 17: "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 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 ma	nagement						
						±	New upload
Filter 🔻							
Active filters: No select	on						
Showing 1 to 12 of 12 er	tries					Show 20 🗸	entries per page
ID	Name	Service 11	State Iî	Request date ↓î	Uploaded	Response date ↓î	Response
67 C 1 1000	Reductive Testates	Actor registration assessments upload	Pending	2020-09-24 [20:49]	XML	-	

Figure 18: "Upload Management" page – Pending requests

2.3 Uploading Devices and System or Procedure Packs

Operations described in chapter 2.2 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:	SAMPLE_DTX_ACT_REQ_V1.5_001.01.xml	Search for an individual manufacturer SRN (EU)	Positive
Download registered actors	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

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Use case	XML file name	Description	Result
	UDI_POST_V1.5_001.02 (POST_STANDARD_Several Devices).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)	
	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.	Positive
		Class III (DeviceCertificateLinks, UnitofUseDI, Substances, Direct marking DI, Storage and Handling Conditions, Critical Warnings, Market Information, Clinical Sizes, Product Designer SRN)	
	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).	Negative
		(IIb Implantable exception, Clinical Investigations- EU and NonEU, DeviceCertificateLinks, Substances, Storage and Handling Conditions, Critical Warnings, Market Information, Clinical Sizes, Product Designer SRN)	

Use case	XML file name	Description	Result	
	UDI_POST_V1.5_001.05 (POST_STANDARD_CIIB).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		
	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	
	UDI_POST_V1.5_002.01 (POST_STANDARD_IVDR).xml	Register New IVDR Device BUDI and UDI-DI information	Positive	
		Risk Class A (Storage and Handling Conditions, Critical Warnings, Market Information, Product Designer Organisation)		
	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.	Positive	
		Risk Class C (DeviceCertificateLinks, Storage and Handling Conditions, Critical Warnings, Market Information, Product Designer Organisation)		
	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	

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Use case	XML file name	Description	Result
	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	Positive
		MF and State Filtering Criteria	
	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	Positive
		Criteria : Manufacturer (State is automatic Registered), Country	
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
Update BasicUDI			

Use case	XML file name	Description	Result
	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

3.3 SS(C)P Sample Description

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

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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: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 XSD RELEASE NOTES

Note: Some of the descriptions below may not apply to your actor type and may not be accessible to you.

5.1 Version 2.0 (September 2021)

5.1.1 XSD element changes

- Multi-language property type (optional) added for StorageHandlingConditionType, CriticalWarningType, SubstanceType, ProductDesignerOrganisationType
- SSCPDownloadServiceCriteriaType:
 - Naming: Updated naming to NBActorCode, MFActorCode, SSCPReferenceNumber, SSCPRevisionNumber
 - Deleted certificateID item
 - o Added optional Certificate field containing CertificateNumber and RevisionNumber
 - $\circ \quad \mbox{Added optional SSCPReferenceNumber, SSCPRevisionNumber}$
- Special Device Type enumeration updated (MDRSpecialDeviceTypeEnum)
- Updates on Enumerations for Certificate types selectable in the Device Certificate link:
 - Certificate type enumeration (XSD) contains only the Enumeration values for Regulation Devices
 - New enumeration created: Legacy Certificate Type which will contain the Certificate types applicable for Legacy Devices (when the registration of Device is realized in EUDAMED) - details in BR- UDI-824 (replacing BR-UDI-810)
 - Enumeration for Certificate types that can be selected when providing Device Certificate information (https://webgate.ec.europa.eu/tools/eudamed/dtx/data/Entity/Links/LinkType.xsd#DeviceCertificateLinkType): GenericCertificateTypeEnum
- Fixed typo in special device type: EQUIPEMNT_FOR_ADDIPOSE_TISSUE updated to EQUIPMENT_FOR_ADIPOSE_TISSUE
- Country TR added to EUCountryWithSpecialEnum

5.2 Version 1.5.1 (August 2021)

5.2.1 UDI/Device services updates

- Update Basic UDIs / EUDAMED DI
- Update UDI-DIs / EUDAMED ID

5.2.2 Certificates DTX updates

- Updated XSD schema on multiple sterilisers
- added otherChangeReason as LanguageSpecificTextsType
- Updated the cardinality to be zero-to-many for statusChangeReason field
- Enumeration update for certificate status change reason when providing a decision or updating a certificate

5.3 Version 1.5 (July 2021)

- Introduced services for Device and Certificates:
 - Add UDI-DI for existing Basic UDI (UDI_DI.POST)
 - Update Basic UDI-DI (Basic_UDI.PATCH)
 - SS(C)P download (SSCP.GET)
 - Certificate download
 - Refused certificate download

- Updated internal documentation, the elements point now to the updated data dictionary
- Updated XSD to version 1.5

5.3.1 UDI/Device XSD element changes

- Introducing a new attribute type : LanguageOptionalTextsType
- Allows for MultiLanguage fields to provide optional the Language field;
- Applicable for attributes such as Substances (CMR or Endocrine), Critical Warnings and Contra-indications, Storage and Handling Conditions;
- Updates for submitting Language information for Critical Warnings and Contra-indications, Storage and Handling Conditions Description. Language must not be provided for the Description when the selected option of Critical Warnings and Contra-indications or Storage and Handling Conditions Description is different than OTHER. When the option OTHER is selected, providing the Language is required;
- Updates for submitting Language information for Substances being CMR or Endocrine substances. If EC or CAS code is provided, then the Language must not be provided. In case no EC or CAS Code is provided, then the Name of the substance together with its Language is required to be provided;
- Updates of the Enumerations for Clinical Sizes and for Measure Units;
- Description attribute added for Clinical Size and Measure Units. Description of the Clinical Size or of the Measure Unit is a multi-language attribute(requires the Language in which it is given) and is required to be provided when the option selected for Clinical Size or Measure Unit is OTHER;

5.3.2 Certificates XSD element changes

- Updated attribute type for deviceType within the CECP entity. This field takes values from the RiskClassEnum enumeration;
- Updated enumeration for SterilisationMethodsEnum;
- Criterion Status become optional when searching for issued certificates;
- Updated CertificateStatusEnum enumeration

5.3.3 Known issues

- Download certificates service / download refused certificates service fails when bulk downloading (MDR) QMS/QA certificates that contain System or Procedure Pack.
- Adding new UDI-DIs for existing Basic UDIs and Updating Basic UDIs cause errors for Legacy Devices and System or Procedure Packs (entities: IVDEUDeviceType, MDEUDeviceType, PRDeviceType).
- Update UDI-DI (UDI_DI.PATCH) appears as an available service via bulk upload but this service will only be completed in the next Playground release, so will generate an error if selected.

5.4 Version 1.4 (March 2021)

- Introduced services for Device and Certificates:
 - UC_M2M_UDI_001: Download of Basic UDI-DI, UDI-DI and device data (last current version)
 - UC_M2M_UDI_002: Upload information for Basic UDI-DI and UDI-DI
 - UC_M2M_CRF_02: Download issued certificate (last current version)
- Updated internal documentation, the elements point now to the updated data dictionary
- Upgraded the version to V1.4.

5.4.1 Download Device Service - Download of Basic UDI-DI, UDI-DI and device data (last current version)

- Service for Download Devices: UC_M2M_UDI_001: Download of Basic UDI-DI, UDI-DI and device data (last current version) allows the download of Regulation Devices, Legacy Devices and System or Procedure Packs;
- Service returns the list of Devices (Basic UDI-DI/EUDAMED DI and corresponding UDI-DI/EUDAMED ID) and/or System or Procedure Packs corresponding to the applied download criteria;
 - Note : The latest version of the Device (Basic UDI-DI/EUDAMED DI , UDI-DI / EUDAMED ID and associated elements) will be returned for the returned Devices;
- Download criteria:
 - MFActorCode/PRActorCode (When the Actor calling the service is a MF or PR the filter is required to be provided and to have the SRN of the Actor initiating the request. A MF/PR can only download their own Devices)
 - (Only full SRN is taken in consideration, no wildcards);
 - ARActorCode (When the Actor calling the service is an AR the filter is required to be provided and to have the SRN of the Actor initiating the request. An AR can only download the Devices to which they are associated)
 - (Only full SRN is taken in consideration, no wildcards)
 - BasicUDIDICode
 - Basic UDI-DI Version (returns all Basic UDI-DIs which have been updated after the mentioned date together with the UDI-DIs linked to them (latest version)).
 - UDIDICode
 - UDI-DI Version Date (returns all UDI-DIs which have been updated after the mentioned date together with the last version of Basic UDI-DI version linked to them.)
 - RiskClass (Only in combination with MFActorCode or ARActorCode)
 - Country (returns all UDI-DIs which are placed on the market in the selected Country)
 - Applicable Legislation (Device Applicable Legislation);
 - State (Only CAs and NBs can download Submitted Devices can apply the state filter to SUBMITTED);
- Particularities in Download service for entity DeviceCertificateLinks (DeviceBasicUDIType > deviceCertificateLinks)

Entity DeviceCertificateLinks returns the Certificate Identification information provided by the Manufacturer when registering a Device.

When Downloading Regulation Devices entity will be returned only for Devices being in Submitted State. For Legacy Devices entity will returned only for Devices being in Submitted State. Entity will not be provided in case of Regulation Devices, being Registered (certificateLinks entity is provided in this case – the actual Certificates linked to the Device itself);

In the Download of Legacy Devices - entity is always returned with the information provided by the Manufacturer;

• Particularities of the certificateLinks entity

Entity returns the identification details of the Certificates linked to the Device (Basic UDI) from the Certificate module. Entity is only returned in Download (cannot be uploaded with the Device – the link between the Device and the Certificate is made by EUDAMED when the Certificate is provided in EUDAMED).

5.4.2 Upload Device Service - Upload information for Basic UDI-DI and UDI-DI

• Service for Upload Devices: UC_M2M_UDI_002: Upload information for Basic UDI-DI and UDI-DI allows the download of Regulation Devices, Legacy Devices and System or Procedure Packs;

Note: Depending on the type of Actor the upload is restricted : Devices (Regulation and Legacy)can be uploaded by Manufacturer Actors and System or Procedure Packs by Producers;

- Validations on several entities/attributes submissions:
 - MDRBasicUDIType > specialDevice cannot be provided if the attribute MDRBasicUDIType > type has a value different of DEVICE;
 - IVDRBasicUDIType > specialDevice cannot be provided if the attribute IVDApplicablePropertiesGroup > kit is set to true;
 - DeviceBasicUDIType > ARActorCode required for Devices submitted by a NonEU Manufacturer;
 - MDRBasicUDIType > IIb_implantable_exceptions property can be only provided for MDR Devices having Risk Class IIb;
 - Substances being HUMAN_PRODUCT (MedicalHumanProductSubstanceType > type HUMAN_PRODUCT) can be only submitted if MDRBasicUDIType > humanProductCheck has value True;
 - Substances being MEDICINAL_PRODUCT (MedicalHumanProductSubstanceType > type MEDICINAL_PRODUCT) can be only submitted if MDRBasicUDIType > medicinalProductCheck has value True;
 - DeviceUDIDIDataType > baseQuantity attribute cannot be provided for Legacy Devices;
 - DeviceMarkingType entity cannot be provided for Legacy Devices;
 - EndocrineSubstanceType entity cannot be provided for Legacy Devices;
 - CMRSubstanceType entity cannot be provided for Legacy Devices;
 - UDIDIDataType > productionIdentifier attribute cannot be provided for Legacy Devices;
 - MDRUDIDIDataType > annexXVINonMedicalDeviceTypes attribute cannot be provided for Legacy Devices;
 - UDIDIDataType> packages entity cannot be provided for Legacy Devices;
 - MDApplicablePropertiesGroup > implantable and MDApplicablePropertiesGroup > active properties are required to have value True when the Device has the Applicable Legislation AIMDD (MDEUDIType > applicableLegislation has value AIMDD);
 - Languages used for Multi-language properties from Device services :

The following properties in DEVICE /SPP model are multi-language properties (requiring a Language and a name when provided):

- Trade-Name;
- Comments for Storage and Handling Conditions;
- Comments for Critical Warnings and Contra-indications;
- CMR Substance;
- Endocrine Substance;
- Medicinal Substance;
- Human Product Substance;
- Additional product description;
- Intended medicinal purpose of the System or Procedure pack;

Only in case of the following properties language "ANY" can be used when uploading the Device:

- Trade-Name;
- Comments for Storage and Handling Conditions when the selected option for Storage and Handling Conditions is any option outside option OTHER. In this case only language ANY is accepted;

Note: In case option "Other" is selected for the type of Storage and Handling Conditions, Comments need to be provided in a language from the ones available – except language ANY;

 Comments for Critical Warnings and Contra-indications – when the selected option for Critical Warnings and Contra-indications is any option outside option OTHER. In this case – only language ANY is accepted;

Note : In case option "Other" is selected for the type of Critical Warnings and Contra-indications, Comments need to be provided in a language from the ones available – except language ANY;

- CMR Substance (SubstanceType.names) when EC or CAS Code is provided. In this case only language ANY is accepted;
- Endocrine Substance (SubstanceType.names) when EC or CAS Code is provided. In this case only language ANY is accepted;

Properties/ context that do not allow the use of Language ANY

- CMR Substance (SubstanceType.names) when EC or CAS is not provided;
- Endocrine Substance (SubstanceType.names) when EC or CAS is not provided;
- Medicinal Substance (SubstanceType.names);
- Human Product Substance (SubstanceType.names);
- Additional product description (UDIDIDataType.additionalDescription);
- Intended medicinal purpose of the System or Procedure pack (PRBasicUDIType.medicinalPurpose);
- Comments for Storage and Handling Conditions when option Other is selected (StorageHandlingConditionType.comments)
- Comments for Critical Warnings and Contra-indications when option Other is selected (CriticalWarningType.comments)
- Particularities in Upload service for entity entity DeviceCertificateLinks (DeviceBasicUDIType > deviceCertificateLinks)

Entity DeviceCertificateLinks will store (collect) the Certificate Identification information provided by the Manufacturer when registering a Device.

When uploading a Regulation Device, the entity is required to be provided only in case of high-risk devices (Devices for which NB validation is required).

In case of Legacy Devices DeviceCertificateLinks is always required to be provided.

5.5 Version 1.3 (December 2020)

Documentation

- Updated internal documentation, the elements point now to the updated data dictionary
- Updated the references to the common data dictionary
- Upgraded the version to V1.3

Issues Fixed

- UC M2M ACT 001 : Download the registered actors
 - o "LORUM IPSUM" in street and streetNum as default value if street not applicable
 - No GPS Data exported
 - No Mandate exported for a NON EU Manufacturer
 - No link with Importers exported
 - PRRC Person's firstname and lastname is not exported
 - No PRRC exported for an Authorised Representative
- UC M2M ACT 002 : Download actor registration
 - Organisation address mixed up with subcontractor address

Known Issues

• Get all versions service does not exist in the back-end of EUDAMED

XSD Element Changes

- Empty optional field tags should be removed
- Typos in elements fixed
 - ActorRegistrationPreviousAssesmentType
 - ActorRegistrationAssesmentType
 - ApprouvalDecisionEnum
- Became optional
 - DecisionType > DecisionType > comments
 - <u>GeographicAddressType</u> > Address > street
 - <u>GeographicAddressType</u> > Address > streetNum
 - MandateType > MandateARConfirmationDecisionType
- Became mandatory
 - RelationshipType > MandateType > startDate
- Elements removed
 - AddressType > ContactTypeEnum
 - LanguageSpecificNameType > LanguageSpecificTextType > master
- Elements added
 - <u>RegistrationType > ActorRegistrationAssesmentType</u> > LAA
 - <u>RegistrationType > ActorRegistrationAssesmentType</u> > LAASubcontractor
 - <u>RegistrationType > ActorRegistrationAssesmentType</u> > duplicatJustification
 - <u>RegistrationType > ActorRegistrationAssesmentType > Role</u>
- Elements modified
 - ActorRegistrationAssesmentType > validationChkActorOrgName
 - CountryEnum > EUCountryEnum

Service Changes

- UC_M2M_ACT_001 : Download the registered actors
 - REQ : Remove CA from search criteria, no default filter
 - o RESP : Remove CA Version
- UC_M2M_ACT_002 : Download actor registration
 - o RESP : LAA & LAA-Subcontractor not in XSD for Actor Registration Request with fields

- RESP : Add duplicate Justification
- <u>UC_BLK_ACT_003</u> : Upload actor registration assessments

REQ : Actor role added

6 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

7 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 <u>SANTE-EUDAMED-</u> <u>SUPPORT@ec.europa.eu</u>	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

8 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

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 | 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 | 50005("I-50005"), INBOUND VALIDATION WRONG DOWNLOAD ACTOR PAYLOAD TYPE I 50006("I-50006"), INBOUND TRANSFORM PULL REQUEST NULL MESSAGE | 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 | 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");