



EUDAMED Services Definition **DTX for Economic Operators**

Production v 2.14.1
2024



DTX for Economic Operators - Services Definitions

M2M Data Exchange available services for accessing MDR EUDAMED data

1. Introduction

1.1 Supported services operation

The services exposed by EUDAMED DTX are built around well known http standard commands:

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

1.2 Data exchange generic service overview

The service definition must contain the information about types of messages (from the data exchange messaging patterns) compatible, available operations at service level (each operation will represent a specific functionality), means to query / filter (criteria) the request, security rules that may apply depending on the actor that perform it and finally the information available as response, eventually number of provided entities, pagination and versioning capabilities.

In EUDAMED DTX, most of the entities exchanged (through the exposed services) are related (i.e. have dependencies between them). To model this, a concept of link has been introduced. In this way, a service is able to isolate the information related to the main entity and only to reference the other related entities (if those entities are covered by additional services).

Table 1 briefly describes a template to define the service and available operations.

Table 1. Service definition and main operations.

Data Entity Exchanged	Service Type	Operation	Description	Communication Patterns Supported
Main: [Entity] Related: [Entities directly related to the main one]	[Entity] Service	Download (GET)	This operation is invoked to request information using a criteria mechanism.	Pull
		Upload (Create) (POST) Update (PUT / PATCH)	This operation is invoked to upload / update / patch information to EUDAMED.	Push

The parameters and the return values for each operation are described in Table 2.

Table 2. Parameters and return values of the service operations.

Operation	Payload	Return Value
Download	[Criteria] template (empty / query criteria)	A PullResponse type message containing a list of [Entity] + [Entities directly related (linked) to the main one] (optional)
Upload	A list of [Entity] + [Entities directly related (linked) to the main one] (optional)	Acknowledgement

2. Device service

2.1 Service definition

Info	Parameters	Payload
<p>Service Name</p> <ul style="list-style-type: none"> DeviceService <p>Service ID</p> <ul style="list-style-type: none"> DEVICE <p>Message Type</p> <ul style="list-style-type: none"> Pull <p>Operation</p> <ul style="list-style-type: none"> Download <p>Operation Type</p> <ul style="list-style-type: none"> GET <p>Functional requirement</p> <ul style="list-style-type: none"> FS-UDID-008.03 <p>Actors</p> <ul style="list-style-type: none"> NB (M2M NB Profile) CA (M2M CA Profile) MF, Non EU MF (M2M MF Profile) PR (M2M PR Profile) AR (M2M AR Profile) 	<p>Query Entity:</p> <p>[DIDownloadServiceCriteriaType::*]</p> <p>Criteria details:</p> <p>MFACTORCODE/PRACTORCODE Device.BasicUDI::MFCode/PRCode (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)</p> <p>(Only full SRN is taken in consideration, no wildcards)</p> <p>ARACTORCODE Device.BasicUDI::ARCode (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)</p> <p>(Only full SRN is taken in consideration, no wildcards)</p> <p>BASICUDIDICCODE Device.BasicUDI::identifier.DICode</p> <p>BASIC UDI-DI VERSION DATE Device.BasicUDI::entity.versionDate (returns all Basic UDI-DIs which have been updated after the mentioned date - together with the UDI-DIs linked to them (latest version)).</p> <p>UDIDICCODE UDIDIDData::identifier.DICode</p> <p>UDI-DI VERSION DATE Device.UDIDIDData::entity.versionDate (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.)</p> <p>RISKCLASS Device.BasicUDI::riskClass (Only in combination with <i>MFACTORCODE</i> or <i>ARACTORCODE</i>)</p> <p>COUNTRY Device.UDIDIDData.MarketInfos::MarketInfo.Country (returns all UDI-DIs which are placed on the market in the selected Country)</p> <p>APPLICABLE LEGISLATION Device Applicable Legislation;</p> <p>STATE Device {BasicUDIDType UDIDType}.state (Only CAs and NBs can download Submitted Devices - can apply the state filter to SUBMITTED);</p> <p>Applied Default Criteria:</p> <p>Device {BasicUDIDType UDIDType}.state ="REGISTRED / SUBMITTED"</p> <p>General Criteria rules:</p> <p>At least one search criteria provided</p> <p>"AND" condition between provided criteria</p> <p>only one value for a given criteria (exact match)</p>	<p>Entity:</p> <ul style="list-style-type: none"> [IVDRDevice:: *] [MDRDevice:: *] [IVDEUDevice:: *] [MDEUDevice:: *] [PRDevice:: *] <p>Entity Related:</p> <p>[Certificate::CertificateIdentifier] -> BasicUDI.certificateLinks.certificate</p> <p>[ClinicalInvestigation::clinicalInvestigationId] -> BasicUDI.clinicalInvestigationLinks.clinicalInvestigationId</p> <p>Versioning:</p> <p>default latest version will be returned for the Basic UDI-DI, UDI-DI and associated entities</p> <p>Pagination:</p> <p>max 300 items per response</p>

<p>Service Name</p> <ul style="list-style-type: none"> • DeviceService <p>Service ID</p> <ul style="list-style-type: none"> • DEVICE <p>Message Type</p> <ul style="list-style-type: none"> • Push <p>Operation</p> <ul style="list-style-type: none"> • Upload New B-UDIs and UDIDs <p>Operation Type</p> <ul style="list-style-type: none"> • POST <p>Functional requirement</p> <ul style="list-style-type: none"> • FS-UDID-008.01 (System or Procedure Pack) • FS-UDID-008.02 (Device) <p>Actors</p> <ul style="list-style-type: none"> • MF (M2M MF Profile) • PR (M2M PR Profile) 	<p>Criteria:</p> <p>N/A</p> <p>Default Security Validation:</p> <p>DeviceBasicUDIType.MFACTORCode == Push::NodeType.nodeActorCode</p> <p>PRBasicUDIType.PRACTORCode == Push::NodeType.nodeActorCode</p>	<p>Entity:</p> <ul style="list-style-type: none"> • [IVDRDevice:: *] • [MDRDevice:: *] • [IVDEUDevice:: *] • [MDEUDevice:: *] • [PRDevice:: *] <p>Entity Related:</p> <p>[Certificate::CertificateIdentifier] -> BasicUDIType.certificateLinks.certificateLink</p> <p>[ClinicalInvestigation::clinicalInvestigationId] -> DeviceBasicUDIType.deviceData.clinicalInvestigationLinks.clinicalInvestigLink</p> <p>Versioning:</p> <p>Implicit a new incremented version will be created</p> <p>Pagination:</p> <p>N/A</p>
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3. BasicUDI service

3.1 Service definition

Info	Parameters	Payload
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<p>Service Name</p> <ul style="list-style-type: none"> BasicUDIService <p>Service ID</p> <ul style="list-style-type: none"> Basic_UDI <p>Message Type</p> <ul style="list-style-type: none"> Push <p>Operation</p> <ul style="list-style-type: none"> Update <p>Operation Type</p> <ul style="list-style-type: none"> PATCH <p>Functional requirement</p> <ul style="list-style-type: none"> FS-UDID-008.01 (System or Procedure Pack) FS-UDID-008.02 (Device) <p>Actors</p> <ul style="list-style-type: none"> MF, NonEU MF (M2M MF Profile) PR (M2M PR Profile) 	<p>Criteria: N/A</p> <p>Default Validation:</p> <p>DeviceBasicUDI.MFActorCode == Push::NodeType.nodeActorCode</p> <p>PRBasicUDI.PRActorCode == Push::NodeType.nodeActorCode</p> <p>DeviceBasicUDI.identifier must be already registered in EUDAMED</p> <p>Version validation will be performed by the following pseudo code:</p> <p><i>If the BasicUDIType.version == 0 then</i></p> <p><i>EUDAMED will increment with 1 the Basic UDI-DI version without validation against the current version in EUDAMED.</i></p> <p><i>else if the BasicUDIType.version > 1 then</i></p> <p><i>Eudamed will verify if the version provided in the payload is the next incremented version stored currently in Eudamed, otherwise an error will be returned</i></p> <p><i>BasicUDIType.version == Current Eudamed Version +1</i></p> <p>Updatable fields for Basic UDI/ EUDAMED DI are mentioned in the Data Dictionary;</p> <p>Consistency validations between values of the property stored in EUDAMED and the ones supplied in the new version are performed for the following fields:</p> <ul style="list-style-type: none"> Is it a System which is a Device in itself, Procedure pack which is a Device in itself (MDRBasicUDIType.type) Is it a Kit (IVDApplicablePropertiesGroup. KIT) Special Device Type (MDRBasicUDIType/IVDRBasicUDIType.specialDevice) Risk Class (BasicUDIType.riskClass) Active Device (MDRApplicablePropertiesGroup.active) Device Intended to administer and/or Remove medicinal product (MDApplicablePropertiesGroup.administeringMedicine) Implantable (MDApplicablePropertiesGroup.implantable) Is it Device a suture, staple, dental filling, dental brace (...)?(MDRBasicUDIType.Ilb_implantable_exceptions) Measuring Function (MDApplicablePropertiesGroup.measuringFunction) Reusable Surgical Instruments (MDApplicablePropertiesGroup.reusable) Companion Diagnostic (IVDApplicablePropertiesGroup.companionDiagnostics) Near Patient Testing (IVDApplicablePropertiesGroup.nearPatientTesting) Patient Self Testing (IVDApplicablePropertiesGroup.selfTesting) Reagent (IVDApplicablePropertiesGroup.reagent) Professional Testing (IVDApplicablePropertiesGroup.professionalTesting) Instrument (IVDApplicablePropertiesGroup.instrument) Tissues and cells - presence of human tissues or cells, or their derivatives (DeviceBasicUDIType.humanTissuesCells) Tissues and cells - Presence of animal tissues or Cells, or their derivatives (DeviceBasicUDIType.animalTissuesCells) Tissues and cells - Presence of cells or substances of microbial origin (IVDRBasicUDIType.microbialSubstances) Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or plasma (MedicalHumanProductSubstanceType.type) Presence of substance which, if used separately, may be considered to be a medicinal product (MedicalHumanProductSubstanceType.type) 	<p>Entity:</p> <p>[IVDRBasicUDI:: *]</p> <p>[MDRBasicUDI:: *]</p> <p>[IVDEUDI:: *]</p> <p>[MDEUDI:: *]</p> <p>[PRBasicUDI:: *]</p> <p>Entity Related: N/A</p> <p>Versioning: new incremented version will be created</p> <p>Pagination: N/A</p>
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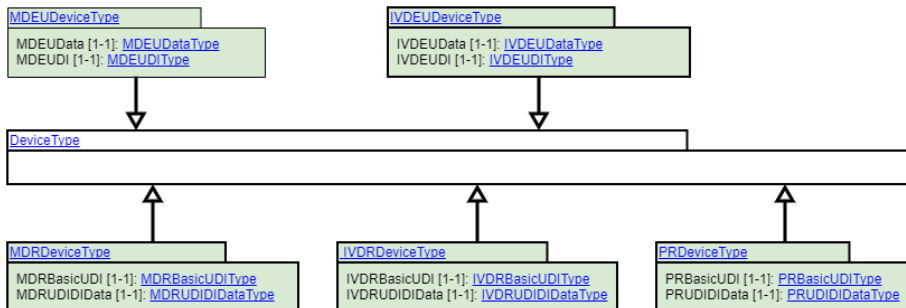
4. UDI-DI service

4.1 Service definition

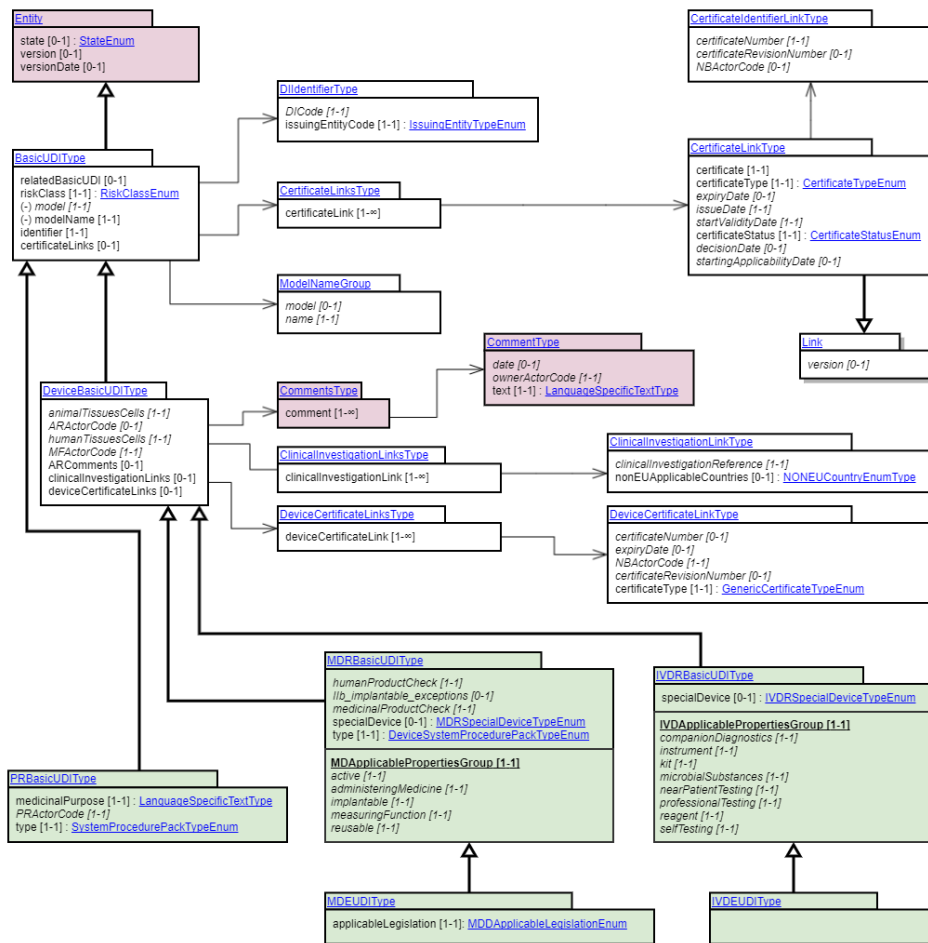
Info	Parameters	Payload
<p>Service Name</p> <ul style="list-style-type: none">• UDIDIService <p>Service ID</p> <ul style="list-style-type: none">• UDI_DI <p>Message Type</p> <ul style="list-style-type: none">• Push <p>Operation</p> <ul style="list-style-type: none">• Upload <p>Operation Type</p> <ul style="list-style-type: none">• POST <p>Functional requirement</p> <ul style="list-style-type: none">• FS-UDID-008.01 (System or Procedure Pack)• FS-UDID-008.02 (Device) <p>Actors</p> <ul style="list-style-type: none">• MF, NonEU MF (M2M MF Profile)• PR (M2M PR Profile)	<p>Criteria: N/A</p> <p>Default Validation Criteria:</p> <p>DeviceBasicUDIType.MFActorCode == Push::NodeType.nodeActorCode</p> <p>PRBasicUDIType.PRActorCode == Push::NodeType.nodeActorCode</p>	<p>Entity:</p> <p>[IVDRUDIDData::*]</p> <p>[MDRUDIDData::*]</p> <p>[PRUDIDData::*]</p> <p>Entity Related: N/A</p> <p>Versioning: Implicit a new incremented version will be created</p> <p>Pagination: N/A</p>

<p>Service Name</p> <ul style="list-style-type: none"> UDIDIService <p>Service ID</p> <ul style="list-style-type: none"> UDI_DI <p>Message Type</p> <ul style="list-style-type: none"> Push <p>Operation</p> <ul style="list-style-type: none"> Upload <p>Operation Type</p> <ul style="list-style-type: none"> PATCH <p>Functional requirement</p> <ul style="list-style-type: none"> FS-UDID-008.01 (System or Procedure Pack) FS-UDID-008.02 (Device) <p>Actors</p> <ul style="list-style-type: none"> MF, NonEU MF (M2M MF Profile) PR (M2M PR Profile) 	<p>Criteria: N/A</p> <p>Default Validation Criteria:</p> <p>UDIDIDataType.basicUDIIdentifier (DeviceBasicUDI).MFActorCode == Push::NodeActorCode</p> <p>UDIDIDataType.basicUDIIdentifier (PRBasicUDI).PRActorCode == Push::NodeActorCode</p> <p>UDIDIDataType.identifier and BasicUDIType.identifier must be already registered in EUDAMED</p> <p>Version validation will be performed by the following pseudo code:</p> <p><i>If the UDIDIDataType.version == 0 then</i></p> <p><i>EUDAMED will increment with 1 the UDI-DI version without validation against the current version in EUDAMED.</i></p> <p><i>else if the UDIDIDataType.version > 1 then</i></p> <p><i>Eudamed will verify if the version provided in the payload is the next incremented version stored currently in Eudamed, otherwise an error will be returned</i></p> <p><i>UDIDIDataType.version == Current Eudamed Version +1</i></p> <p>Updatable fields for UDI-DI/ EUDAMED ID are mentioned in the Data Dictionary;</p> <p>Consistency validations between values of the property stored in EUDAMED and the ones supplied in the new version are performed for the following fields:</p> <ul style="list-style-type: none"> Quantity of Device Type of UDI-PI Containing latex Labelled as single use Maximum number of reuses Device labelled sterile Need for sterilisation before use Reprocessed single use device Intended purpose other than medical (Annex XVI) New Device 	<p>Entity:</p> <p>[IVDRUDIDData:: *] [MDRUDIDData:: *] [IVDEUData:: *] [MDEUData:: *] [PRUDIDData:: *]</p> <p>Entity Related: N/A</p> <p>Versioning: new incremented version will be created</p> <p>Pagination: N/A</p>
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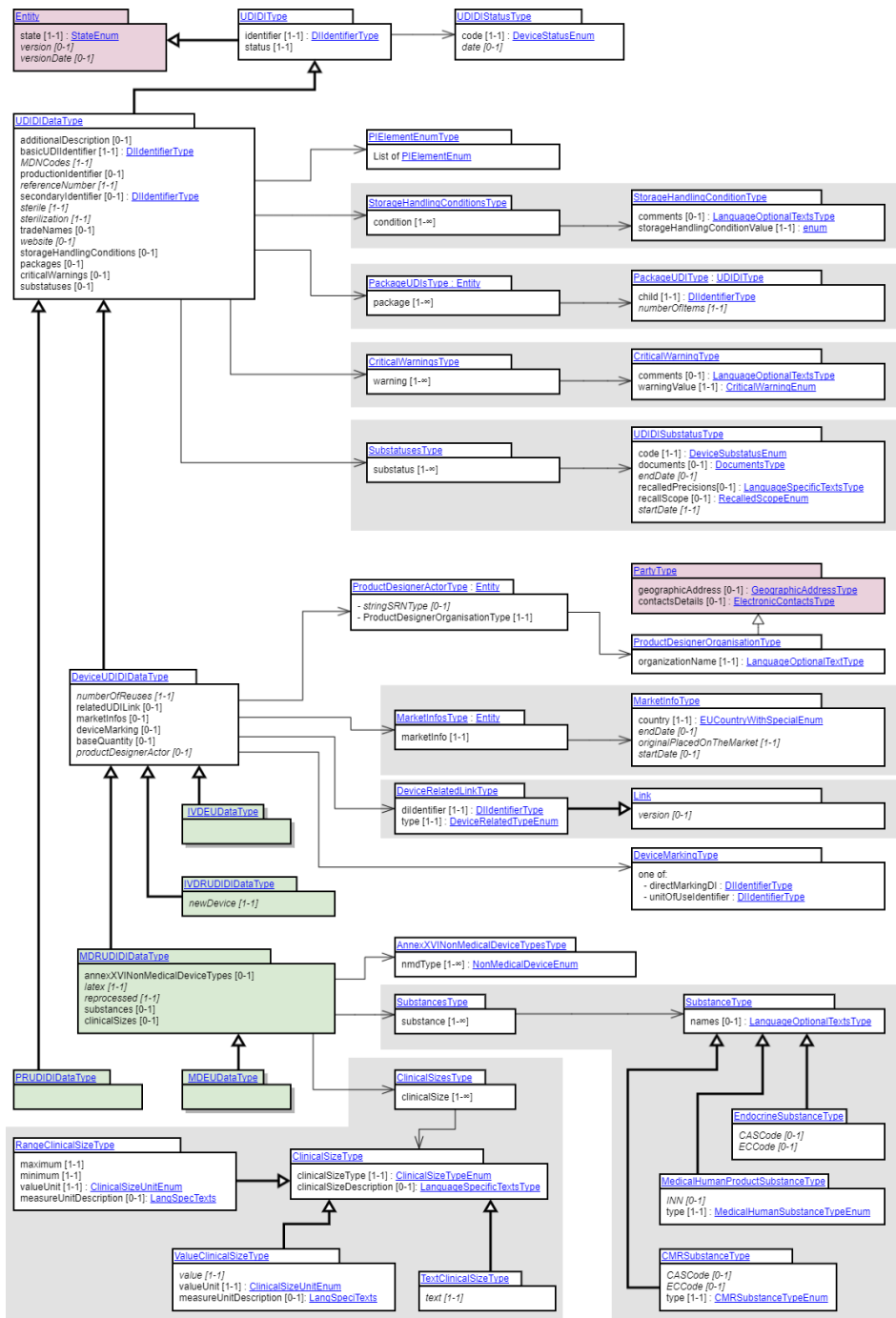
4.1.1 Entity structure overview



4.1.2 Basic UDI-DI/ EUDAMED DI entity structure overview



4.1.3 UDI-DI/ EUDAMED ID entity structure overview

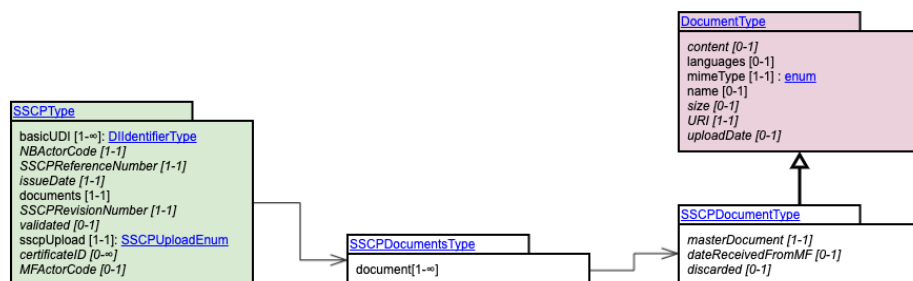


5. SSCP service

5.1 SSCP Service definition

Info	Parameters	Payload
<p>Service Name</p> <ul style="list-style-type: none"> SSCPDownloadService <p>Service ID</p> <ul style="list-style-type: none"> SSCP <p>Message Type</p> <ul style="list-style-type: none"> Pull <p>Operations</p> <ul style="list-style-type: none"> Download <p>Operation Type</p> <ul style="list-style-type: none"> GET <p>Actors</p> <ul style="list-style-type: none"> M2M CA Profile M2M NB Profile M2M MF Profile M2M AR Profile 	<p>Criteria Entity:</p> <p>[SSCPDownloadServiceCriteriaType::*]</p> <p>Criteria details:</p> <p>IssueDate (Start)</p> <p>SSCPType.issueDate</p> <p>IssueDate (End) SSCPType.issueDate</p> <p>SSCPReferenceNumber</p> <p>SSCPType.SSCPReferenceNumber</p> <p>SSCPRevisionNumber SSCPType.SSCPRevisionNumber</p> <p>Basic UDI-DI SSCPType.basicUDI</p> <p>Certificate ID SSCPType.certificateID</p> <p>MFACTORCode SSCPType.MFACTORCode</p> <p>NBACTORCode SSCPType.NBACTORCode</p> <p>Default Applied Security Criteria:</p> <p>MFACTORCode is not available for the MF.</p> <p>General Criteria rules:</p> <p>At least one search criteria provided (except SSCPRevisionNumber, in this case SSCPReferenceNumber must be provided)</p> <p>"AND" condition between provided criteria</p> <p>only one value for a given criteria (exact match)</p>	<p>Entity:</p> <p>[SSCPType::*]</p> <p>Entity Related:</p> <p>[SSCPDocumentType::*]</p> <p>[DocumentType::*]</p> <p>Versioning:</p> <p>Latest SSCP version will be returned if no SSCPRevisionNumber is provided.</p> <p>Pagination:</p> <p>max 300 items per page, multiple pull request / response correlated messages / size of message</p>

5.1.1 SSCP service structure overview

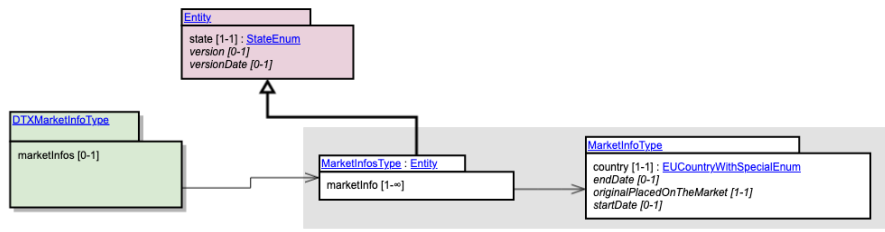


6. MarketInfo service

6.1 MarketInfo Service definition

Info	Parameters	Payload
<p>Service Name</p> <ul style="list-style-type: none"> Update of Market information <p>Service ID</p> <ul style="list-style-type: none"> MARKET_INFO <p>Message Type</p> <ul style="list-style-type: none"> Push <p>Operations</p> <ul style="list-style-type: none"> Upload <p>Operation Type</p> <ul style="list-style-type: none"> PUT <p>Actors</p> <ul style="list-style-type: none"> M2M MF Profile 	<p>Criteria: N/A</p> <p>Default Validation Criteria:</p> <p>UDIDIDDataType.basicUDIIdentifier (DeviceBasicUDI).MFActorCode == Push::NodeType. nodeActorCode</p> <p>UDIDDDIDataType.identifier must be already registered in EUDAMED</p> <p>Version validation will be performed by the following pseudo code:</p> <p><i>If the UDIDIDDataType.version == 0 then</i></p> <p><i>EUDAMED will increment with 1 the market information version</i></p> <p><i>without validation against the current version in EUDAMED.</i></p> <p><i>else if the UDIDIDDataType.version > 1 then</i></p> <p><i>Eudamed will verify if the version provided in the payload is</i></p> <p><i>the next incremented version stored currently in Eudamed, otherwise an error will be returned</i></p> <p><i>UDIDIDDataType.version == Current Eudamed Version +1</i></p> <p><i>else if the UDIDIDDataType.version == 1 then UDIDIDDataType.version will be assigned to Eudamed version</i></p> <p>Updatable fields for the MarketInfo are mentioned in the Data Dictionary;</p> <p>Consistency validations between values of the property stored in EUDAMED and the ones supplied in the new version are performed for the following fields:</p> <ul style="list-style-type: none"> Country <ul style="list-style-type: none"> validated against ENUM_MDR_COUNTRY There cannot be two (2) identical countries provided (ERR-BR-DTX-UDID-098.01-01: A Country can be specified only once in a Market information for a UDI-DI) When country value is not within the ENUM the system will throw: ERR-BR-DTX-UDI-100 : Not a EU country - The country code provided is not an EU country. originalPlacedOnTheMarket <ul style="list-style-type: none"> There must be no 2 siblings that have their value set to True. Only one marketInfo entity shall have originalPlacedOnTheMarket set to True. Otherwise the system will throw the following error: <p>ERR-BR-DTX-UDID-096.01-01: Only one country can be set as a member state where the device is to or has been first placed on the EU market</p> <ul style="list-style-type: none"> The country for which the flag originalPlacedOnTheMarket == true must be the same country as the current stored value of the device in EUDAMED. Otherwise the system will throw: BR-DTX-UDI-101 : The country where the device has been first placed on the EU market cannot be changed during MarketInfo updates. Please use the UDI-DI update service in order to update the first country where the device has been placed on the EU market. StartDate and EndDate <ul style="list-style-type: none"> Date format will be validated against the XSD Schema. 	<p>Entity:</p> <p>[DTXMarketInfo::*]</p> <p>Entity Related:</p> <p>[MarketInfotype::*] [Entity::*]</p> <p>Versioning:</p> <p>New incremented version will be created</p> <p>Pagination:</p> <p>N/A</p>

6.1.1 Market Information service structure overview

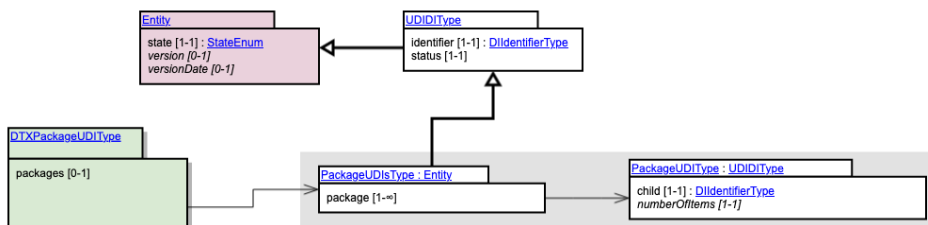


7. Container Package service

7.1 Container Package Service definition

Info	Parameters	Payload
Service Name <ul style="list-style-type: none"> Update of Container Package 	Criteria: N/A Default Validation Criteria: UDIDIDDataType.basicUDIDIdentifier (DeviceBasicUDI).MFACTORCode == Push::NodeType.nodeActorCode UDIDIDDataType.basicUDIDIdentifier (PRBasicUDI).PRACTORCode == Push::NodeType.nodeActorCode	Entity: [DTXPackageUDI::*] Entity Related: [PackageUDI::*] [UDIDIDType::*] [Entity::*]
Service ID <ul style="list-style-type: none"> PACKAGE_UDI 	UDIDIDDataType.basicUDIDIdentifier (DeviceBasicUDI).MFACTORCode == Push::NodeType.nodeActorCode UDIDIDDataType.basicUDIDIdentifier (PRBasicUDI).PRACTORCode == Push::NodeType.nodeActorCode	Versioning: New incremented version will be created
Message Type <ul style="list-style-type: none"> Push 	UDIDIDDataType.identifier must be already registered in EUDAMED	Pagination: N/A
Operations <ul style="list-style-type: none"> Upload 	Version validation will be performed by the following pseudo code: <i>If the UDIDIDDataType.version == 0 then</i>	
Operation Type <ul style="list-style-type: none"> PUT 	<i>EUDAMED will increment with 1 the container package version without validation against the current version in EUDAMED.</i> <i>else if the UDIDIDDataType.version > 1 then</i> <i>Eudamed will verify if the version provided in the payload is the next incremented version stored currently in Eudamed, otherwise an error will be returned</i>	
Actors <ul style="list-style-type: none"> M2M MF Profile 	<i>UDIDIDDataType.version == Current Eudamed Version + 1</i> <i>else if the UDIDIDDataType.version == 1 then UDIDIDDataType.version will be assigned to Eudamed version</i> Updatable fields for the Container Package are mentioned in the Data Dictionary; Consistency validations between values of the property stored in EUDAMED and the ones supplied in the new version are performed for the following fields: <ul style="list-style-type: none"> The last child element in the XML payload (top/down order) will be the root UDI-DI of the container package structure. It will indicate the link between a container package to another and thus creates the hierarchy of the packages. status is validated against ENUM_UDID_ContainedItemStatus numberOfItems is a positive integer and is validated against the XSD Schema 	

7.1.1 Container Package service structure overview



7. Product original manufacturer service

7.1 Product original manufacturer service definition

Info	Parameters	Payload
<p>Service Name</p> <ul style="list-style-type: none"> Update of Product original manufacturer <p>Service ID</p> <p>Message Type</p> <ul style="list-style-type: none"> Push <p>Operations</p> <ul style="list-style-type: none"> Upload <p>Operation Type</p> <ul style="list-style-type: none"> PUT <p>Actors</p> <ul style="list-style-type: none"> M2M MF Profile 	<p>Criteria: N/A</p> <p>Default Validation Criteria:</p> <p>UDIDIDDataType.basicUDIIdentifier (DeviceBasicUDI).MFACTORCode == Push::NodeType.nodeActorCode</p> <p>UDIDIDDataType.identifier must be already registered in EUDAMED</p> <p>Version validation will be performed by the following pseudo code:</p> <p><i>If the UDIDIDDataType.version == 0 then</i></p> <p><i>EUDAMED will increment with 1 the container package version without validation against the current version in EUDAMED.</i></p> <p><i>else if the UDIDIDDataType.version > 1 then</i></p> <p><i>Eudamed will verify if the version provided in the payload is the next incremented version stored currently in Eudamed, otherwise an error will be returned</i></p> <p><i>UDIDIDDataType.version == Current Eudamed Version +1</i></p> <p><i>else if the UDIDIDDataType.version == 1 then UDIDIDDataType.version will be assigned to Eudamed version</i></p> <p>Updatable fields for the product original manufacturer are mentioned in the Data Dictionary;</p> <ul style="list-style-type: none"> <i>UDIDIDDateType.identifier</i> must be registered in Eudamed otherwise the system will respond with BR-DTX-UDI-099 : No device found - No UDI-DI/EUDAMED ID has been found for the given issuing agency. <i>UDIDIDDateType.state</i> must be in Registered state otherwise the system will respond with ERR-BR-DTX-UDI-106.05-01: Product original manufacturer information can be updated for an existing UDI-DI /EUDAMED ID being in state Registered only. <i>ProductDesignerOrganisationType</i> must be registered in Eudamed otherwise the system will respond with ERR-BR-DTX-UDID-629.05-01: No product original manufacturer entity found linked to this device. <i>ProductDesignerorganisationType.organizationName</i> must be unique. otherwise the system will respond with ERR-BR-DTX-UDID-629.05-04: Cannot uniquely identify the entity to update. 	<p>Entity:</p> <p>[DTXProductDesigner::*]</p> <p>Entity Related:</p> <p>[DIIdentifierType::*]</p> <p>[ProductDesignerActorType::*]</p> <p>[ProductDesignerOrganisationType::*]</p> <p>[PartyType::*]</p> <p>[UDIDIDType::*]</p> <p>[Entity::*]</p> <p>Versioning:</p> <p>New incremented version will be created</p> <p>Pagination:</p> <p>N/A</p>

10.1.1 Product original manufacturer service structure overview

