DTX for Notified Bodies - Services Definition - 2.8

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. 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.

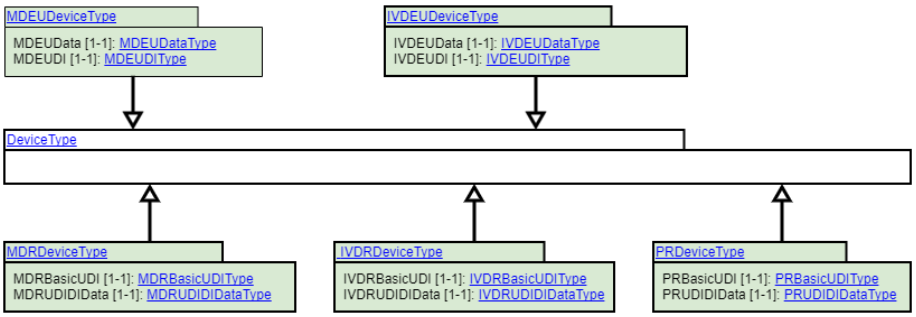
Operation	Payload	Return Value
Download	[Criteria] template (empty / query criteria)	A PullResponse type message containing a list of [Entity] + [Entities directly related (linked) to the main one] (optional)
Upload	A list of [Entity] + [Entities directly related (linked) to the main one] (optional)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

2. Device service

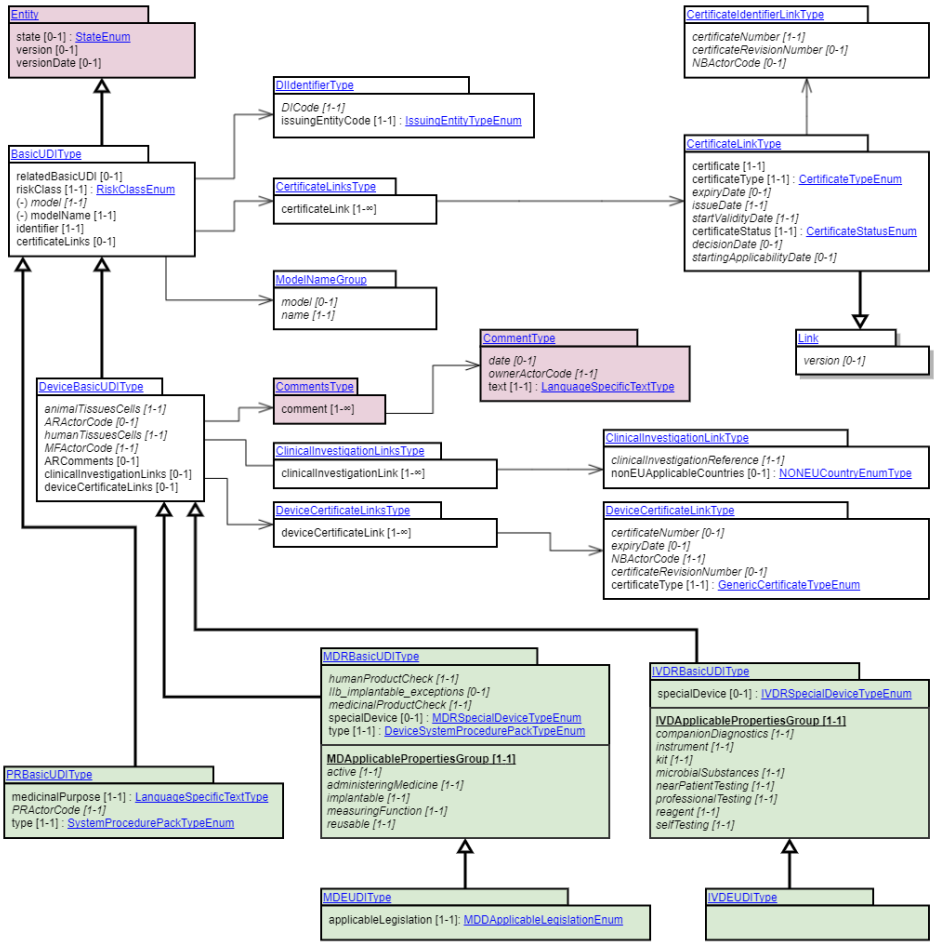
2.1 Service definition

Info	Parameters	Payload
Service Name • DeviceService **Service ID** • DEVICE **Message Type** • Pull **Operation** • Download **Operation Type** • GET **Functional requirement** • FS-UDID-008.03 **Actors** • NB (M2M NB Profile) • CA (M2M CA Profile) • MF, Non EU MF (M2M MF Profile) • PR (M2M PR Profile) • AR (M2M AR Profile)	**Query Entity:** [DIDownloadServiceCriteriaType::*] **Criteria details:** ***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) (Only full SRN is taken in consideration, no wildcards) ***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) (Only full SRN is taken in consideration, no wildcards) ***BasicUDIDICode*** Device.BasicUDI::identifier.DICode **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)). ***UDIDICode*** UDIDIData::identifier.DICode **UDI-DI Version Date** Device.UDIDIData::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.) **RiskClass**Device.BasicUDI::riskClass (Only in combination with *MFActorCode or ARActorCode*) **Country** Device.UDIDIData.MarketInfos::MarketInfo.Country (returns all UDI-DIs which are placed on the market in the selected Country) **Applicable Legislation** Device Applicable Legislation; **State** Device {BasicUDIDIType UDIDIType}.state (Only CAs and NBs can download Submitted Devices - can apply the state filter to SUBMITTED); **Applied Default Criteria:** Device {BasicUDIDIType UDIDIType}.state =”REGISTRED / SUBMITTED” **General Criteria rules:** At least one search criteria provided "AND" condition between provided criteria only one value for a given criteria (exact match)	**Entity:** • [IVDRDevice:: *] • [MDRDevice:: *] • [IVDEUDevice:: *] • [MDEUDevice:: *] • [PRDevice:: *] **Entity Related:** [Certificate::CertificateIdentifier] -> BasicUDI.certificateLinks.certificate [ClinicalInvestigation:: clinicalInvestigationId] -> BasicUDI. clinicalInvestigationLinks. clinicalInvestigationId **Versioning:** **default** latest version will be returned for the Basic UDI-DI, UDI-DI and associated entities **Pagination:** max 300 items per response

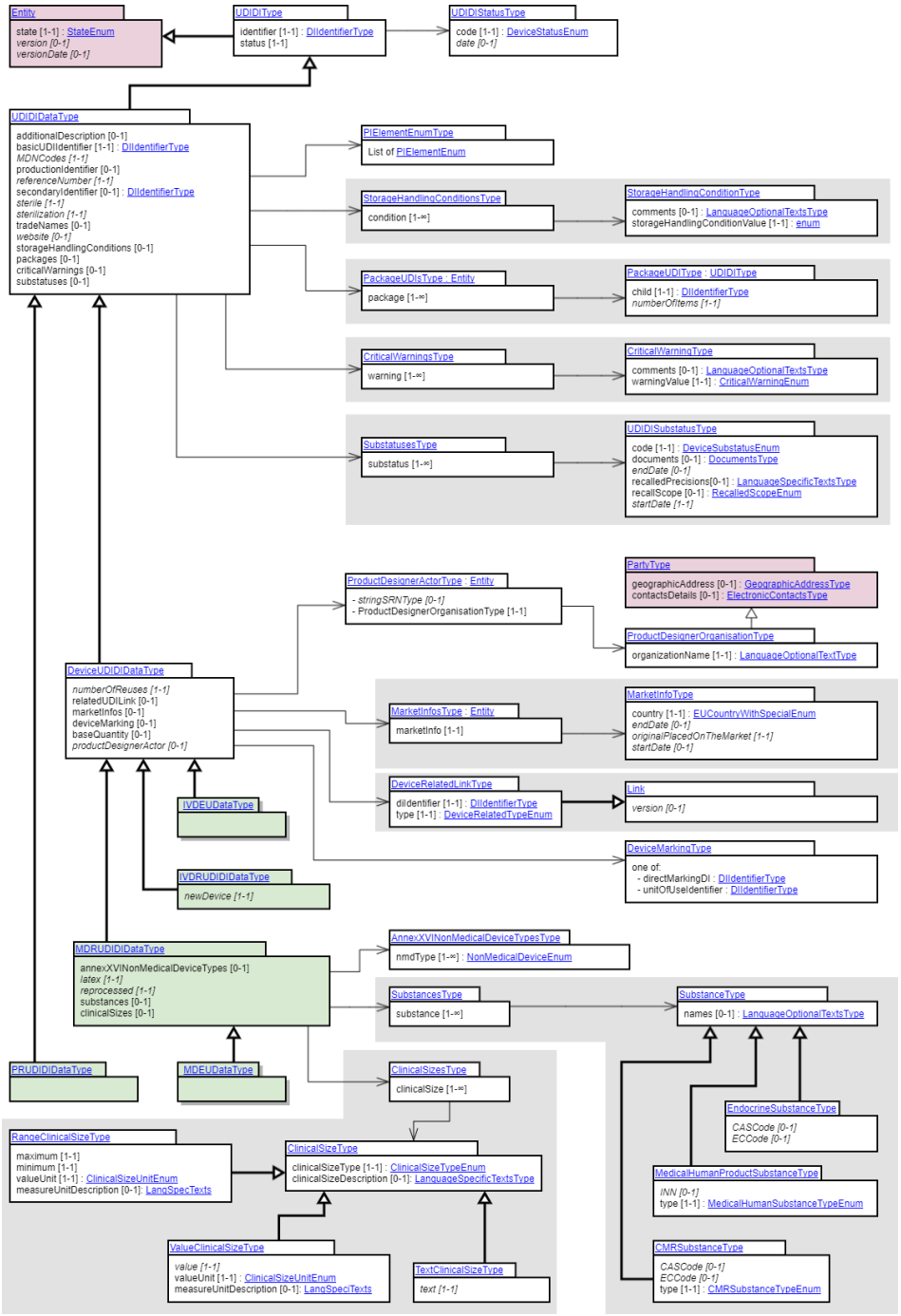
2.2 Entity structure overview



2.2.1 Basic UDI-DI/ EUDAMED DI entity structure overview



2.2.2 UDI-DI/ EUDAMED ID entity structure overview

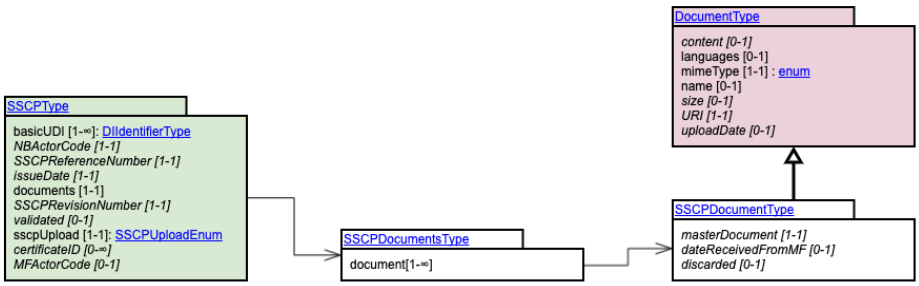


3. SSCP service

3.1 SSCP Service definition

Info	Parameters	Payload
Service Name • SSCPDownloadService **Service ID** • SSCP **Message Type** • Pull **Operations** • Download **Operation Type** • GET **Actors** • M2M CA Profile • M2M NB Profile • M2M MF Profile • M2M AR Profile	**Criteria Entity:** [SSCPDownloadServiceCriteriaType::*] **Criteria details:** **IssueDate (Start)** SSCPType.issueDate **IssueDate (End)** SSCPType.issueDate **SSCPReferenceNumber** SSCPType.SSCPReferenceNumber **SSCPRevisionNumber** SSCPType.SSCPRevisionNumber **Basic UDI-DI** SSCPType.basicUDI **Certificate ID** SSCPType.certificateID **MFActorCode** SSCPType.MFActorCode **NBActorCode** SSCPType.NBActorCode **Default Applied Security Criteria:** **MFActorCode** is not available for the MF. **General Criteria rules:** At least one search criteria provided (except SSCPRevisionNumber, in this case SSCPReferenceNumber must be provided) "AND" condition between provided criteria only one value for a given criteria (exact match)	**Entity:** [SSCPType::*] **Entity Related:** [SSCPDocumentType::*] **Versioning:** Latest SSCP version will be returned if no SSCPRevisionNumber is provided. **Pagination:** max 300 items per page, multiple pull request / response correlated messages / size of message

3.1.1 SSCP service structure overview

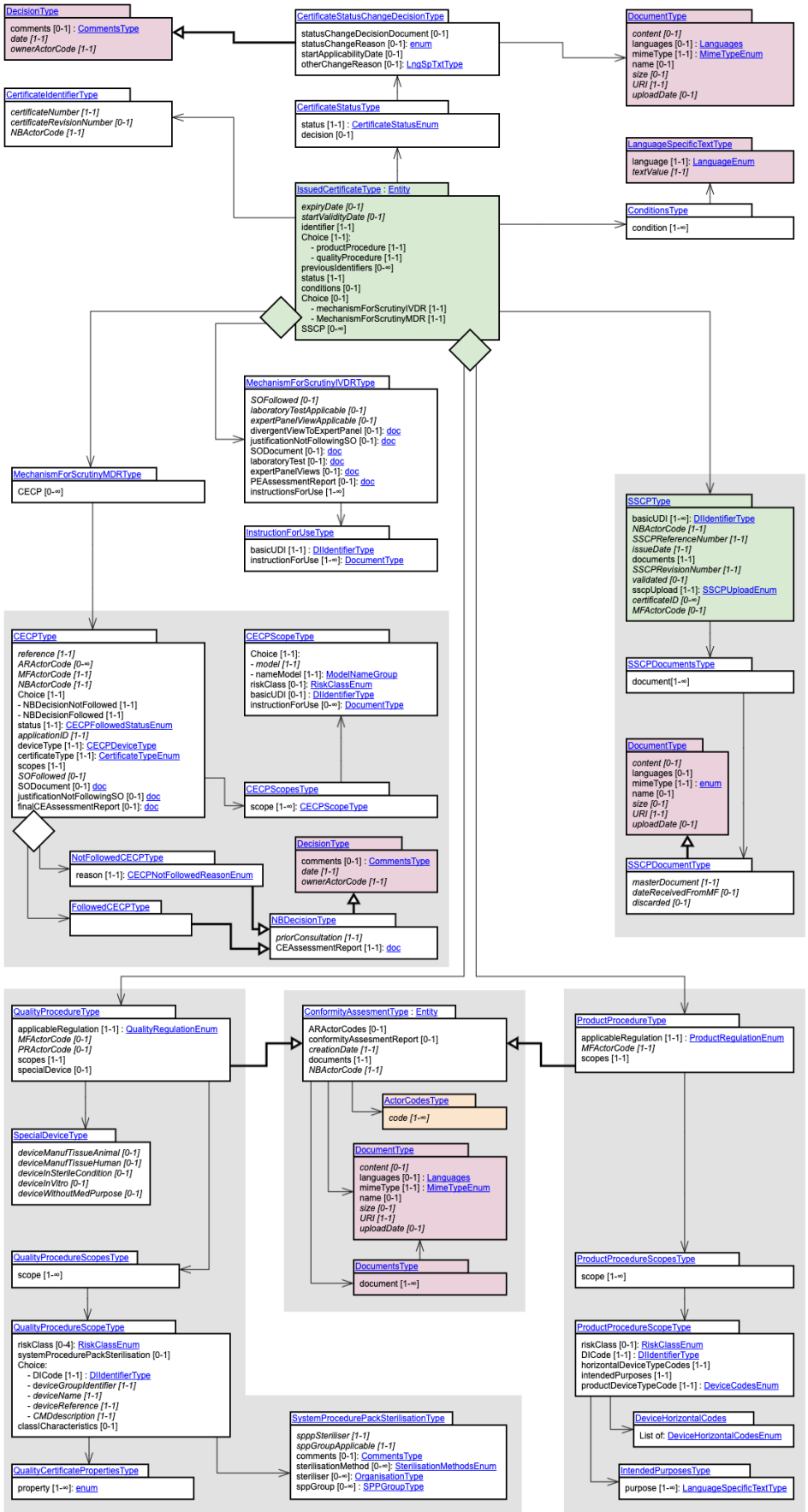


4. CERTIFICATE service

4.1 Issued Certificate Service

Info	Parameters	Payload
Service Name • IssuedCertificateService **Message Type** • Pull **Operations** • Download **Operation Type** • GET **Actors** • M2M CA Profile • M2M NB (OWNER) Profile	**Criteria Entity:** [IssuedCertificateDownloadServiceCriteriaType::*] **Criteria details:** **IssueDate (Start)** CertificateIdentifierType.issueDate **IssueDate (End)** CertificateIdentifierType.issueDate **SubmissionDate (Start)** ConformityAssesmentType.creationDate **SubmissionDate (End)** ConformityAssesmentType.creationDate **ExpiryDate (Start)** IssuedCertificateType.expiryDate **ExpiryDate (End)** IssuedCertificateType.expiryDate **CertificateType** ProductProcedureType.applicableRegulation and QualityProcedureType.applicableRegulation **CertificateNumber** CertificateIdentifierType.certificateNumber **NBActorCode** ConformityAssessmentType.NBActorCode **ActorCode** Actor.actorCode (Only full SRN is taken in consideration, no wildcards) **Status** CertificateStatusType.status **Default Applied Security Criteria:** Only CAs are allowed to search for **NBActorCode** **Mandatory Criteria:** [CertificateIdentifierType.issueDate] [ProductProcedureType.applicableRegulation or QualityProcedureType.applicableRegulation] **General Criteria rules:** At least two search criteria provided "AND" condition between provided criteria only one value for a given criteria (exact match)	**Entity:** [IssuedCertificateType::*] **Entity Related:** (ConformityAssesment) [ProductProcedureType::*] (ConformityAssesment) [QualityProcedureType::*] [SSCPType::*] [CECPType::*] [MechanismForScrutinyType::*] [InstructionForUseType::*] **Versioning:** N/A as no versioning **Pagination:** max 300 items per page, multiple pull request / response correlated messages / size of message

4.1.1 Issued certificate structure overview


DecisionType
comments [0-1] : CommentsType
date [1-1]
ownerActorCode [1-1]
CertificateStatusChangeDecisionType
statusChangeDecisionDocument [0-1]
statusChangeReason [0-1]: enum
startApplicabilityDate [0-1]
otherChangeReason [0-1]: LngSpTxtType
DocumentType
content [0-1]
languages [0-1] : Languages
mimeType [1-1] : MimeTypeEnum
name [0-1]
size [0-1]
URI [1-1]
uploadDate [0-1]
CertificateIdentifierType
certificateNumber [1-1]
certificateRevisionNumber [0-1]
NBActorCode [1-1]
CertificateStatusType
status [1-1] : CertificateStatusEnum
decision [0-1]
LanguageSpecificTextType
language [1-1]: LanguageEnum
textValue [1-1]
IssuedCertificateType : Entity
expiryDate [0-1]
startValidityDate [0-1]
identifier [1-1]
Choice [1-1]:
- productProcedure [1-1]
- qualityProcedure [1-1]
previousIdentifiers [0-∞]
status [1-1]
conditions [0-1]
Choice [0-1]
- mechanismForScrutinyIVDR [1-1]
- MechanismForScrutinyMDR [1-1]
SSCP [0-∞]
ConditionsType
condition [1-∞]
MechanismForScrutinyIVDRType
SOFollowed [0-1]
laboratoryTestApplicable [0-1]
expertPanelViewApplicable [0-1]
divergentViewToExpertPanel [0-1]: doc
justificationNotFollowingSO [0-1]: doc
SODocument [0-1]: doc
laboratoryTest [0-1]: doc
expertPanelViews [0-1]: doc
PEAssessmentReport [0-1]: doc
instructionsForUse [1-∞]
MechanismForScrutinyMDRType
CECP [0-∞]
InstructionForUseType
basicUDI [1-1] : DIIdentifierType
instructionForUse [1-∞]: DocumentType
SSCPType
basicUDI [1-∞]: DIIdentifierType
NBActorCode [1-1]
SSCPReferenceNumber [1-1]
issueDate [1-1]
documents [1-1]
SSCPRevisionNumber [1-1]
validated [0-1]
sscpUpload [1-1]: SSCPUploadEnum
certificateID [0-∞]
MFActorCode [0-1]
SSCPDocumentsType
document[1-∞]
DocumentType
content [0-1]
languages [0-1]
mimeType [1-1] : enum
name [0-1]
size [0-1]
URI [1-1]
uploadDate [0-1]
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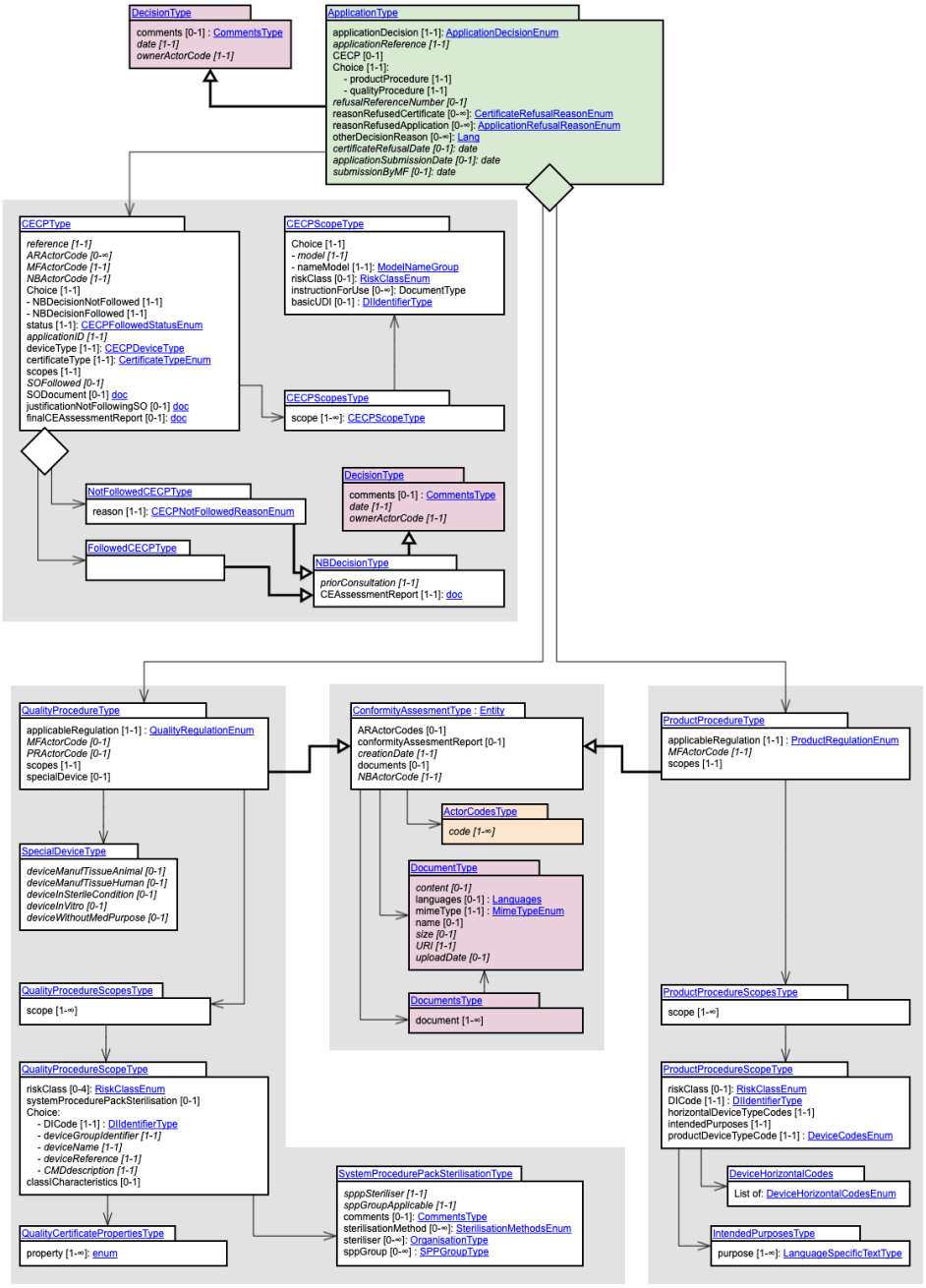
masterDocument [1-1]
dateReceivedFromMF [0-1]
discarded [0-1]
CECPType
reference [1-1]
ARActorCode [0-∞]
MFActorCode [1-1]
NBActorCode [1-1]
Choice [1-1]
- NBDecisionNotFollowed [1-1]
- NBDecisionFollowed [1-1]
status [1-1]: CECPFollowedStatusEnum
applicationID [1-1]
deviceType [1-1]: CECPDeviceType
certificateType [1-1]: CertificateTypeEnum
scopes [1-1]
SOFollowed [0-1]
SODocument [0-1] doc
justificationNotFollowingSO [0-1] doc
finalCEAssessmentReport [0-1]: doc
CECPScopeType
Choice [1-1]:
- model [1-1]
- nameModel [1-1]: ModelNameGroup
riskClass [0-1]: RiskClassEnum
basicUDI [0-1] : DIIdentifierType
instructionForUse [0-∞]: DocumentType
CECPScopesType
scope [1-∞]: CECPScopeType
NotFollowedCECPType
reason [1-1]: CECPNotFollowedReasonEnum
FollowedCECPType
DecisionType
comments [0-1] : CommentsType
date [1-1]
ownerActorCode [1-1]
NBDecisionType
priorConsultation [1-1]
CEAssessmentReport [1-1]: doc
QualityProcedureType
applicableRegulation [1-1] : QualityRegulationEnum
MFActorCode [0-1]
PRActorCode [0-1]
scopes [1-1]
specialDevice [0-1]
SpecialDeviceType
deviceManufTissueAnimal [0-1]
deviceManufTissueHuman [0-1]
deviceInSterileCondition [0-1]
deviceInVitro [0-1]
deviceWithoutMedPurpose [0-1]
QualityProcedureScopesType
scope [1-∞]
QualityProcedureScopeType
riskClass [0-4]: RiskClassEnum
systemProcedurePackSterilisation [0-1]
Choice:
- DICode [1-1] : DIIdentifierType
- deviceGroupIdentifier [1-1]
- deviceName [1-1]
- deviceReference [1-1]
- CMDdescription [1-1]
classICharacteristics [0-1]
QualityCertificatePropertiesType
property [1-∞]: enum
SystemProcedurePackSterilisationType
spppSteriliser [1-1]
sppGroupApplicable [1-1]
comments [0-1]: CommentsType
sterilisationMethod [0-∞]: SterilisationMethodsEnum
steriliser [0-∞]: OrganisationType
sppGroup [0-∞] : SPPGroupType
ConformityAssesmentType : Entity
ARActorCodes [0-1]
conformityAssesmentReport [0-1]
creationDate [1-1]
documents [1-1]
NBActorCode [1-1]
ActorCodesType
code [1-∞]
DocumentType
content [0-1]
languages [0-1] : Languages
mimeType [1-1] : MimeTypeEnum
name [0-1]
size [0-1]
URI [1-1]
uploadDate [0-1]
DocumentsType
document [1-∞]
ProductProcedureType
applicableRegulation [1-1] : ProductRegulationEnum
MFActorCode [1-1]
scopes [1-1]
ProductProcedureScopesType
scope [1-∞]
ProductProcedureScopeType
riskClass [0-1]: RiskClassEnum
DICode [1-1] : DIIdentifierType
horizontalDeviceTypeCodes [1-1]
intendedPurposes [1-1]
productDeviceTypeCode [1-1] : DeviceCodesEnum
DeviceHorizontalCodes
List of: DeviceHorizontalCodesEnum
IntendedPurposesType
purpose [1-∞]: LanguageSpecificTextType

4.2 Refused Certificate Service

Info	Parameters	Payload
Service Name • ApplicationCertificateService **Message Type** • Pull **Operations** • Download **Operation Type** • GET **Actors** • M2M CA Profile • M2M NB (OWNER) Profile	**Criteria Entity:** [RefusedCertificateDownloadServiceCriteriaType::*] **Criteria details:** **RefusalDate (Start)** ApplicationType.certificateRefusalDate **RefusalDate (End)** ApplicationType.certificateRefusalDate **SubmissionDate (Start)** ApplicationType.applicationSubmissionDate **SubmissionDate (End)** ApplicationType.applicationSubmissionDate **CertificateType** ProductProcedureType.applicableRegulation and QualityProcedureType.applicableRegulation **ApplicationNumber** ApplicationType.applicationReference **NBActorCode** ConformityAssessmentType.NBActorCode **ActorCode** Actor.actorCode (Only full SRN is taken in consideration, no wildcards) **Default Applied Security Criteria:** Only CAs are allowed to search for **NBActorCode** **Mandatory Criteria:** [ApplicationType.certificateRefusalDate] [ProductProcedureType.applicableRegulation or QualityProcedureType.applicableRegulation] **Default Applied Criterion:** [ApplicationType.applicationDecision = REFUSED_CERTIFICATE] **General Criteria rules:** At least two search criteria provided "AND" condition between provided criteria only one value for a given criteria (exact match)	**Entity:** [ApplicationType::*] **Entity Related:** (ConformityAssesment) [ProductProcedureType::*] (ConformityAssesment) [QualityProcedureType::*] [CECPType::*] **Versioning:** N/A as no versioning **Pagination:** max 300 items per page, multiple pull request / response correlated messages / size of message

4.2.1 Application structure overview