



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies
Health Technology and Cosmetics

29/05/2019

Machine-to-Machine (M2M) Data Exchange Services Definition

*M2M Data Exchange available services for accessing MDR EUDAMED data available
for Economic Operator (EO) organisations*

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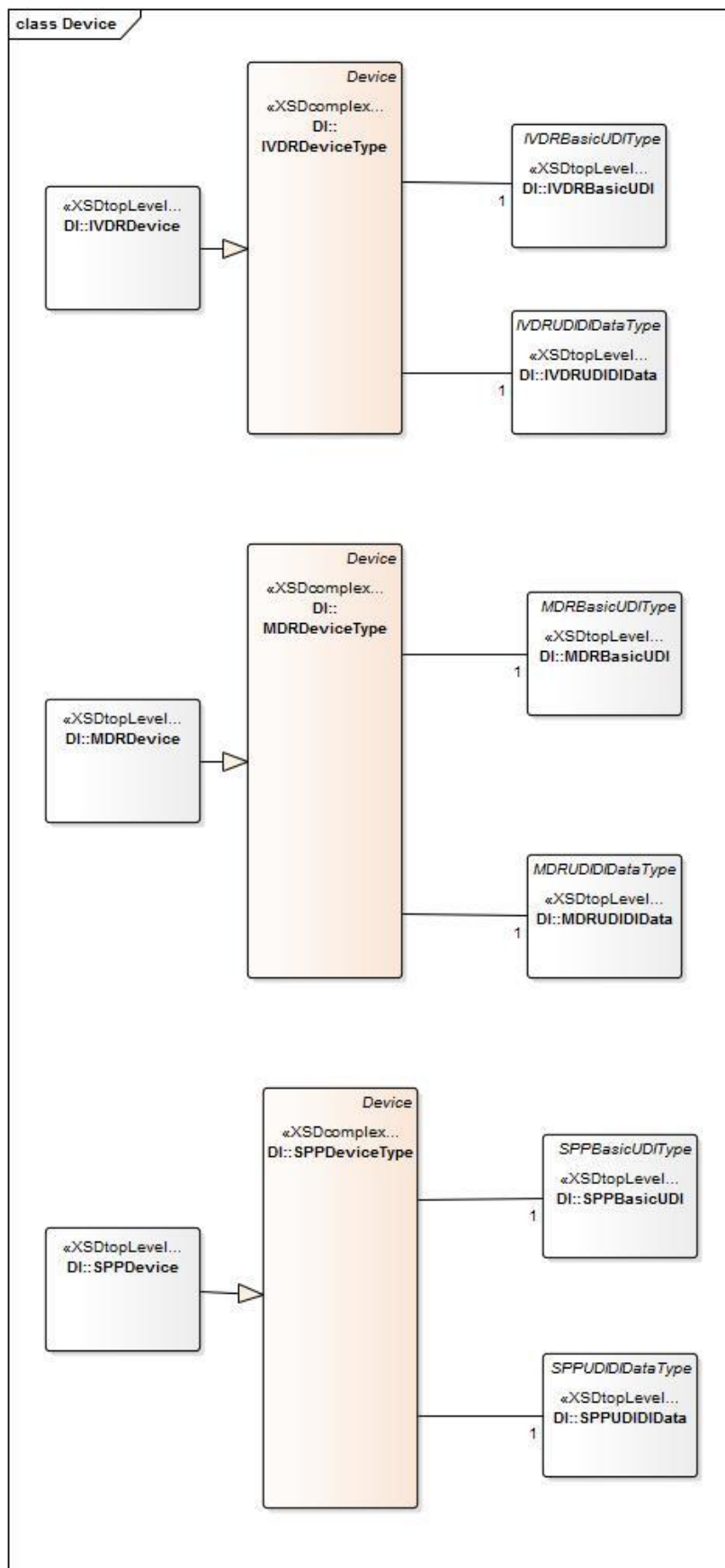
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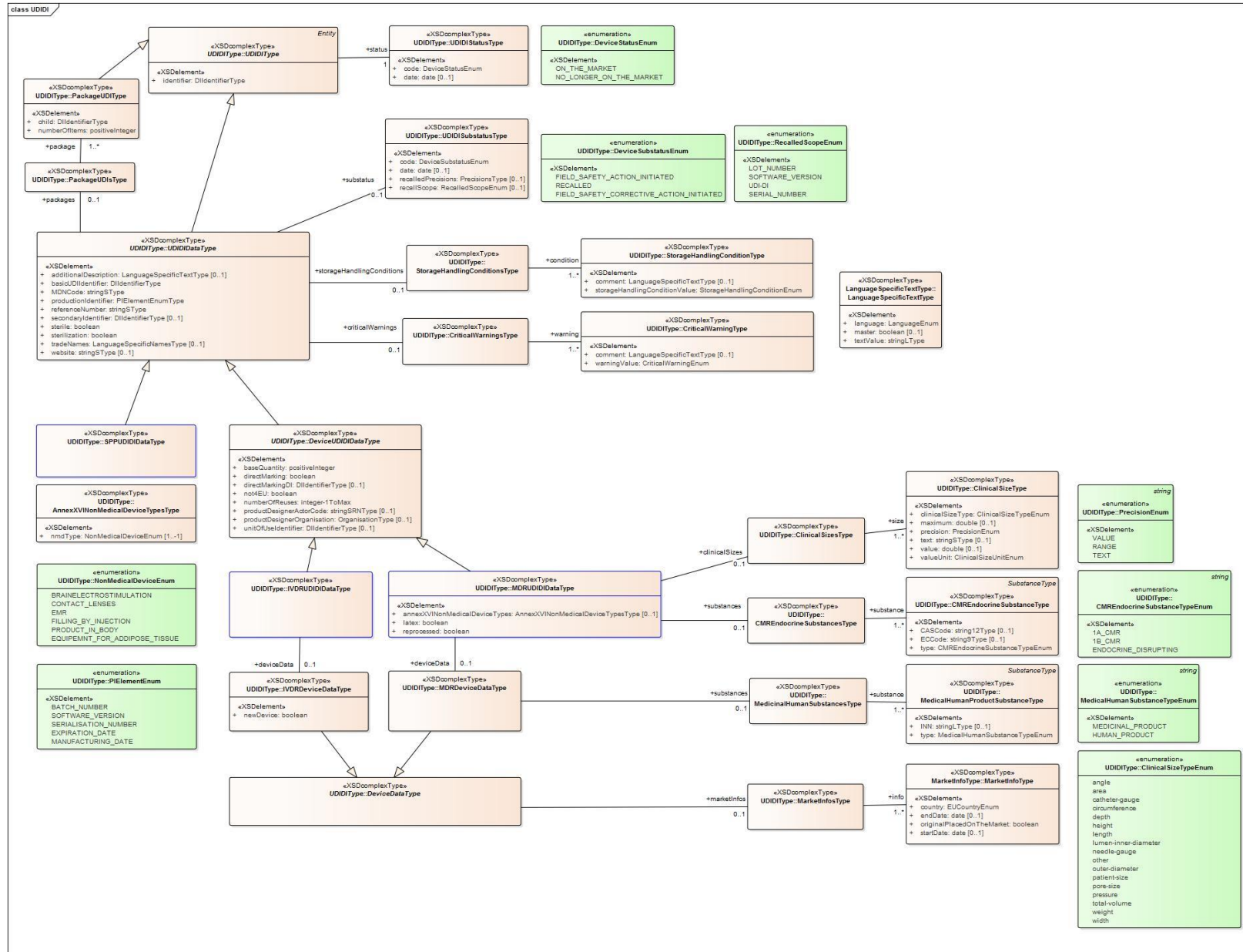
1 Device service

1.1 Service definition

Service Name /Service ID	Message Type	Operation /Operation Type	Actors	Criteria	Payload
DeviceService (DEVICE)	Push	Upload (POST)	EU MF, Non-EU MF, {MF CONFIRMER} PR {PR CONFIRMER}	Criteria: N/A Validation: DeviceBasicUDIType.MFACTORCode == {MF}.code SPPBasicUDIType.PRActorCode == {PR}.code	Entity: [IVDRDevice:: *] {[IVDRBasicUDI::*] [IVDRUDIDData::*]} [MDRDevice:: *] {[MDRBasicUDI::*] [MDRUDIDData::*]} [SPPDevice:: *]{[SPPBasicUDI::*] [SPPUDIDData::*]} Entity Related: [Certificate::CertificateIdentifier] -> BasicUDIType.certificateLinks.certificateLink [ClinicalInvestigation::clinicalInvestigationId] -> DeviceBasicUDIType.deviceData.clinicalInvestigationLinks.clinicalInvestigLink Versioning: Implicit a new incremented version will be created Pagination: N/A

1.2 Entity structure overview





1.3 Expected payload entity example



Device_MDR_DEVICE_entity_sample_1_implantable_suture.xml



Device_MDR_DEVICE_entity_sample_2_implantable_nonsutures_system.xml



Device_MDR_DEVICE_entity_sample_1_implantable_sutures.xml

2 BasicUDI service

2.1 Service definition

Service Name /Service ID	Message Type	Operation /Operation Type	Actors	Criteria	Payload
BasicUDIService (BASIC_UDI)	Push	Update (PATCH)	EU MF, Non-EU MF PR {MF CONFIRMER, PR CONFIRMER}	Criteria: N/A Default Criteria Validation: DeviceBasicUDI.MFACTORCode == {MF}.code SPPBasicUDI.PRACTORCode == {PR}.code BasicUDI.identifier must be already registered in EUDAMED	Entity: [IVDRBasicUDITYPE:: *] [MDRBasicUDITYPE:: *] [SPPBasicUDITYPE:: *] <i>(only the updatable fields BR-UDID-49 will be considered)</i> Entity Related: N/A Versioning: new incremented version will be created Pagination: N/A

3 UDI-DI service

3.1 Service definition

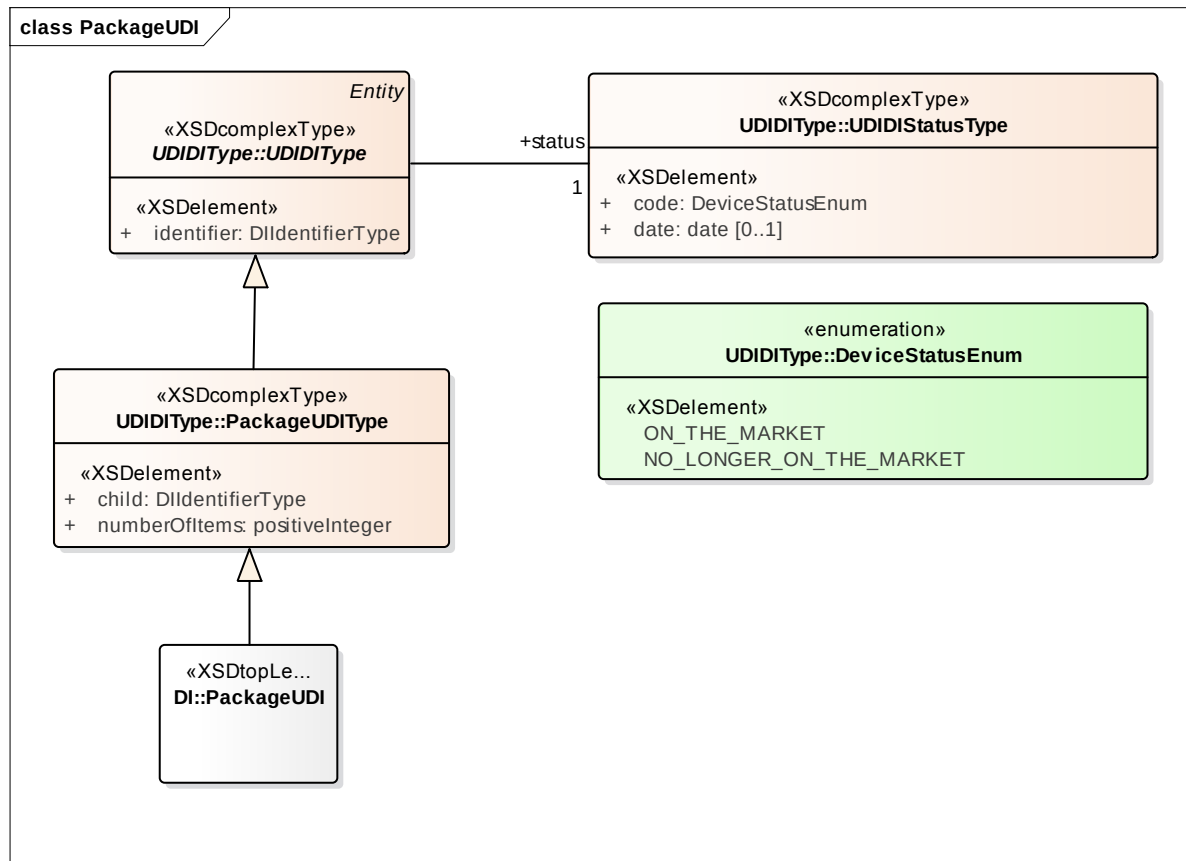
Service Name /Service ID	Message Type	Operation /Operation Type	Actors	Criteria	Payload
UDIDIService (UDI_DI)	Push	Update (PATCH)	EU MF, Non-EU MF PR {MF CONFIRMER, PR CONFIRMER}	Criteria: N/A Default Criteria Validation: UDIDIDDataType.basicUDIIdentifier (DeviceBasicUDI).MFACTORCode == {MF}.code UDIDIDDataType.basicUDIIdentifier (SPPBasicUDI).PRACTORCode == {PR}.code UDIDDIDDataType.identifier and BasicUDIDType.identifier must be already registered in EUDAMED	Entity: [IVDRUDIDIDDataType:: *] [MDRUDIDIDDataType:: *] [SPPUDIDIDDataType:: *] <i>(only the updatable fields BR-UDID-49 will be considered)</i> Entity Related: N/A Versioning: new incremented version will be created Pagination: N/A

4 UDI Package service

4.1 Service definition

Service Name /Service ID	Message Type	Operation /Operation Type	Actors	Parameters	Payload
UDIDIPackageService (PACKAGE_UDI)	Push	Upload (POST)	EU MF, Non-EU MF {MF CONFIRMER, PR CONFIRMER}	Criteria: N/A Validation: Package UDIDI reference -> MDRUDIDIData.basicUDIIdentifier{BasicUDIDIData}.MFACTORCode == {MF}.code Or IVDRUDIDIData.basicUDIIdentifier{BasicUDIDIData}.MFACTORCode == {MF}.code Or SPPUDIDIData.basicUDIIdentifier{BasicUDIDIData}.PRACTORCode == {PR}.code	Entity: [PackageUDI::*] Entity Related: [UDIDI::DIIdentifier] -> PackageUDI.child.UDIIdentifier Versioning: implicit a new incremented UDIDIPackage version will be created Pagination: N/A

4.2 Entity structure overview



5 Market info service

5.1 Service definition

Service Name /Service ID	Message Type	Operation /Operation Type	Actors	Parameters	Payload
MarketInfoService	Push	Upload (POST)	EU MF, Non-EU MF {MF CONFIRMER}	Criteria: N/A Default Security Check: DTXMarketInfo.UDIDIdentifier.basicUDIIdentifier -> {basicUDI}.MFCode == {MF}.code or DTXMarketInfo.UDIDIdentifier.basicUDIIdentifier -> {basicUDI}.ARCode == {MF}.code	Entity: [DTXMarketInfo::*] Entity Related: NA Versioning: A new version of the MarketInfo will be created Pagination: N/A

5.2 Entity structure overview

