EUDAMED Business Rules

UDI/Devices

Production v 2.18.1
2025

UDI/Device - Business Rules - 2.18.1 (PROD), 3.18 (PG)

1 - Introduction

This "Business Rules" document contains the constraints, limitations and business rules that drive the implementation of EUDAMED.

2 - Purpose

This purpose of this document is to provide an overview of the scope and conditions data needs to be provided to be valid information for EUDAMED.

Business rules are describing a required set of conditions who will be validated when submitting information.

3 - Scope

We opted to provide business rules and their detailed descriptions by module. This document refers to UDI/Device module business rules only.

4 - Changelog

Summary	Status	Description

RULE-00014: OCM riskClass

RESOLVED

Instructions: Remove the Label Template_RULE
Link {satisfies} to FS/NFS/CR, {is modified by} Story/Bug

Apart from the values to be set in the table below, you also need to set the fields
- Component/s = module where rule is implemented.
- Category = {Restricted, Public, Restricted and Public}

- Fix Version/s (initial and updates)

tagKey	Value/Content	End tagKey
<BusId>	RULE-00014	</BusId>
<Title>	OCM riskClass	</Title>
<Baseline version>	1.0	</Baseline version>
<Type>	Data constraint	</Type>
<Details>	All the following constraints apply: 1. Is mandatory for all *Applicable legislations* except 'None', or 'Unknown'. (IVDR is not applicable). 2. Only one value from the enumeration is allowed; no other values are allowed. Enumeration: ~~**EU DAMEDMDR 2308**~~ **BR-UDID-817 : Device Risk Class - ENUM_UDID_RiskClass** 3. Value must be permitted for the *Applicable legislation* of the given OCM. Permitted values provided below. *(Error message: A value is not permitted for the Applicable legislation of the OCM.)* 4. Values that correspond to legislation 'IVDR' are not permitted for old/custom-made devices. *(Error message: Values corresponding to legislation 'IVDR' are not permitted for old/custom-made devices.)* 5. If the legislation is 'None' or 'Unknown', no value is permitted. *(Error message: A value is not permitted when legislation is 'None' or 'Unknown'.)* 6. May not be updated in the new version of the old/custom-made device.	</Details>
<Related entities>	OCM	</Related entities>
<Enum>	RiskClassEnum	</Enum>
<Error Message>		</Error Message>
Rule ref <BRref>	BR-OCM-017	</BRref>

Note: derived table, depends on Risk Class Enumeration BR-UDID-817.
OCM riskClass values permitted by the Applicable legislation:

riskClass value	Applicable Legislations permitting each riskClass value
CLASS_I	MDR, MDD
CLASS_IIA	MDR, MDD
CLASS_IIB	MDR, MDD
CLASS_III	MDR, MDD
IVD_ANNEX_II_LIST_A	IVDD
IVD_ANNEX_II_LIST_B	IVDD
IVD_DEVICES_SELF_TESTING	IVDD
IVD_GENERAL	IVDD
AIMDD	AIMDD

1 issue

5 - Business Rules

Registration of (Basic) UDI-DI

Identifier	Status	Description	Previously used
BR-UDID-001 : Registration of new Devices	RESOLVED	Users associated to Manufacturer Actors will be able to enter (to register) new Devices in MDR EUDAMED for all Applicable legislation`s - Regulation Devices having applicable legislation : MDR, IVDR and Legacy devices having Applicable legislation: MDD,AIMDD or IVDD.	
BR-UDID-003: Uniqueness of DI Codes and format structure	RESOLVED	A Device Identifier Code (DI Code) consists of the couple formed by the *Issuing Entity* who is issuing that code and the *Code* itself (uniqueness checks for DI Codes take into account both Issuing Entity and the Code). BASIC UDI- DI, Master UDI-DI, Secondary DI, Package level DI, EUDAMED DI codes must be unique in the system. The codes can be referenced only once inside the system. UDI-DI Codes must be unique in the system but the same code can be referenced by one Regulation Device and by one Legacy Device at the same time as a UDI-DI (both a Regulation and a Legacy Device can have the same UDI-DI code at a time), and several times as a Direct Marking DI code. Direct Marking DI code must be unique in the system but can be referenced by several Devices. A Direct Marking code can be referenced by several devices as a Direct Marking DI and can be also referenced as UDI-DI. Unit of Use DI code must be unique in the system but can be referenced by several Devices as a Unit of Use DI(same Unit of Use DI can be referenced by several UDI-DIs) The format of the Basic UDI-DI structure will be checked against the format structure provided by the Issuing Entities The format of the (Master) UDI-DI code, Secondary DI Code, Unit of Use Code, Direct marking DI Code, Container Package DI Code structure will be checked against the format structure provided by the Issuing Entity when the selected issuing Entity is GS1. Notes: • When mentioning that a Code must be unique in the system, means that it can be provided only once inside the system; (they can be afterwards reused several times as mentioned per each type of Device identifier apart); • The reusability of the Device identifier (referencing the same Device identifier for several Devices) is applicable only for Devices / System or procedure Packs of the same Manufacturer/ Producer (System or Procedure Pack Producer);	
BR-UDID-004 : UDI DI is required when submitting a BASIC UDI DI	RESOLVED	The submission of a new Basic UDI-DI requires always to provide with it a UDI-DI together with all its attributes	
BR-UDID-011 : Providing an Authorised representative for the Device is required when the Manufacturer is NonEU Manufacturer	RESOLVED	When registering a new Basic UDI DI(/EUDAMED DI), if the Manufacturer is NonEU, must specify the Authorised Representative for the Basic UDI-DI/ EUDAMED DI. The Authorised Representative provided for the Basic UDI-DI/ EUDAMED DI has to be registered in EUDAMED and to have an active Mandate registered in EUDAMED with the Manufacturer	
BR-UDID-020: Providing Secondary DI for a UDI DI	RESOLVED	The Secondary DI must be provided for a UDI-DI when another DI exists for that UDI-DI which is issued by a different Issuing Entity.	
BR-UDID-023: Unit of Use applicable	RESOLVED	Unit of Use DI property can be provided (optionally) when the UDI-DI is not Directly marked (Direct marking = no) and the Quantity of Device (base quantity of Device) is greater than 1. Unit of use DI is conditionally updateable. Can be provided later on if initially not provided. Unit of use DI and Direct marking are not applicable for Master UDI-DI.	

BR-UDID-024: Maximum Number of reuses applicable for a Device	RESOLVED	Maximum number of reuses property can be provided (if applicable) when the device is not flagged as Single Use Device. When required to be provided the Maximum number of reuses can be either a specific value (specifying the specific number of reuses for the Device) or can be infinite	
BR-UDID-025: Adding CMR substances	RESOLVED	When registering CMR Substances, the Type of CMR Substance, the Substance Name and the Language in which it is provided are required. Optionally the user can specify the EC# or CAS # of the substance. The Substance Name for a Substance can be provided only once in a Language. In case either the EC# or CAs# is provided, the Language will not be required, otherwise, translations must be provided in all languages used for the labels	
BR-UDID-027: Adding Endocrine-Disrupting substances	RESOLVED	When registering Endocrine Disrupting Substances, the Substance Name and the Language in which it is provided are required. Optionally the user can specify the EC# or CAS #. The Substance Name for a Substance can be provided only once in a Language. In case either the EC# or CAs# is provided , the Language will not be required, otherwise, translations must be provided in all languages used for the labels	
BR-UDID-028: Adding Storage and handling Conditions	RESOLVED	Storage and Handling Conditions can be added by providing a value from the predefined list (list of values for Storage and handling of medical devices) and (if required) adding a description of the value provided. If the value provided by the Manufacturer in the Storage and Handling Conditions requires a Description, the user will be required to provide the appropriate value. If the value provided by the Manufacturer in the Storage and Handling Conditions is 'Other', the user will be required to provide the 'Description' and the Language in which this Description is given. Description associated with the 'Other ' option can be given in several languages. Several Storage and handling conditions can be added for a Device or System or Procedure Pack.	
BR-UDID-030: Adding Critical Warnings and Contra-indications	RESOLVED	Critical Warnings and Contra-indications can be added by providing a value from the predefined list (list of values for Critical Warnings and Contra-indications) and (if required) adding a description of the value provided. If the value provided by the Manufacturer in the Critical warnings or Contraindication requires a Description, the user will be required to provide the appropriate value. If the value provided by the Manufacturer in the Critical warnings or Contraindication is 'Other', the user will be required to provide the 'Description' and the Language in which this Description is given. Description associated with the 'Other ' option can be given in several languages. Several Critical Warnings and Contra-indications can be added for a Device or System or Procedure Pack.	
BR-UDID-041: Registering Substances(Substance that can be considered to be a Medicinal product or medicinal product derived from human blood or plasma)	RESOLVED	When providing INN value for a Substance being medicinal product or substance that can be a medicinal product derived from human blood or plasma, the Name and Language of the substance are not required. Value provided as INN value is not cross-checked with any external database.	
BR-UDID-043: Member States were the Device is made available in the Country Mandatory	RESOLVED	When the Device has as Applicable Legislation MDR or MDD and the Device Risk Class is Class IIa, IIb or Class III the Manufacturer will be required to complete EU countries were the Device is made available when entering Device Data When the Device has as Applicable Legislation IVDR and the Risk Class is Class B, Class C or Class D, the Manufacturer will be required to complete EU countries were the Device is made available when entering Device Data.	
BR-UDID-045: Member States were the Device is placed on the market	RESOLVED	The country selected as the Member State of placing on the Market is considered automatically as a country were the Device is made available. Only one Country can be set as Country where the Device is (initially) placed on the market Member State of placing on the Market can be updated to a country from the list of the countries where the device is made available.	
BR-UDID-046: Countries where placed on the market and made available not applicable for Device not intended for EU market or no longer placed on the EU market	RESOLVED	If the Manufacturer set the Status of the Device as "Not intended for EU market" or "No longer placed on the EU market" then the details about Member State of placing on the Market and Member States were the Device is made available in the Country are not applicable (cannot be provided).	
BR-UDID-047 : No market information for systems and/or procedue packs	RESOLVED	Market information is not required for the registration of systems and/or procedure packs.	

BR-UDID-061: Information completed for a BASIC UDI-DI having Applicable Legislation MDR	CLOSED	For the submission of a BASIC UDI DI for a Device having as Applicable Legislation MDR, the following information`s / attributes are mandatory to be completed: • Applicable Legislation (defines the Legislation applicable for the Devices from that Device Group), • Basic UDI- DI code, • Issuing Entity of the BASIC UDI- DI code, • Is the Device a System or Procedure Pack which is a Device in itself, • Is the Device a Special Device Type • Device Risk Class, • Device Implantable , • Device is Suture , Staple ,Dental filling, etc. • Device Measuring Function, • Device Reusable Surgical Instruments, • Active Device, • Device Intended to Administer/Remove Medicinal Substances, • Name or, if applicable, a Device Model that identifies the Basic UDI- DI Device Group in the Technical Documentation and / or Certificate or Declaration of Conformity Basic UDI details required to be completed as Device information: • Tissues and Cells information`s (Presence of human tissues or cells, or their derivatives/ Presence of animal tissues or cells, or their derivatives), Details that are required to be submitted as Device information, if applicable for the current Device: • Clinical Investigations details.	
BR-UDID-062: Information completed for a BASIC UDI-DI having Applicable Legislation IVDR	CLOSED	For the submission of a BASIC UDI DI for a Device having as Applicable Legislation IVDR , the following information`s / attributes are mandatory to be completed: • Applicable Legislation (defines the Legislation applicable for the Devices from that Device Group); • Basic UDI- DI code, • Issuing Entity of the BASIC UDI- DI code, • Is it a Kit(Is the Device a Kit), • Is the Device a Special Device Type, • Device Risk Class, • Device Intended for Self-Testing, • Device Intended for Near Patient-Testing, • Companion Diagnostics, • Reagent, • Instrument, • Professional Testing, • Name or, if applicable, a Device Model that identifies the Basic UDI- DI Device Group in the Technical Documentation and / or Certificate or Declaration of Conformity, Basic UDI details required to be completed as Device information: • Tissues and Cells information`s (Presence of human tissues or cells, or their derivatives/ Presence of animal tissues or cells, or their derivatives/ Presence of cells or substance of microbial origin); Details that are required to be submitted as Device information, if applicable for the current Device: • Clinical Investigations details.	
BR-UDID-066: Device Model or Device Name mandatory	RESOLVED	Either the Device Model or the Device Name are required when registering a new Basic UDI-DI. (both of them can be provided)	
BR-UDID-069: UDI DI relationship to the BASIC UDI DI	RESOLVED	There must be one and only one Basic UDI-DI for a UDI-DI. Several UDI-DIs can be associated to the same Basic UDI-DI	
BR-UDID-070: Trade Name(s) require the Language in which they are given	RESOLVED	Device Trade Name(s) will require the completion of the Language in which the Trade Name is given. Trade Name can be given in language "Any"- being a generic Trade-Name used as default Trade-Name. Several Trade- Name(s) can be given in the same Language. The order in which the Trade Name(s) are provided is important - the first Trade Name provided will be considered the default Trade-Name.	

BR-UDID-073: Initial Status when registering a Device , System or Procedure Pack or Container Package	RESOLVED	When registering a Regulation Device or System or Procedure Pack, the Status can be set to either
		
		• 'On the Market' or
		• 'Not intended for EU market' or
		• 'No longer placed on the EU market'
		
		No Sub-Status is marked by default.
		
		"Not intended for EU Market" cannot be set as the Status of a Device when performing an update of the Device. Can be set only as an initial status.
		
		When registering a Container Package its status will be:
		
		• if the status of the registered device is 'Not intended for the EU market' then its container packages status will be set to 'Not intended for the EU market' including all the children of the root element.
		• if the status of the registered device is 'No longer placed on the EU market' then its container packages status will be set to 'No longer placed on the EU market' including all the children of the root element.
		
		• if the status of the registered device/system or procedure pack is 'On the EU market' then its container packages status can be any of the three (3) statuses including all the children of the root element:
		  ◦ Not intended for the EU Market
		  ◦ On the EU market
		  ◦ No longer placed on the EU market
		
		When a new device/system or procedure pack version is updated with the status 'No longer placed on the EU market' the system will automatically create a new version of the linked container package(s) and will set their status to 'No longer placed on the EU market'.	

BR-UDID-075: Providing the Clinical Size for a Device	RESOLVED	When providing the Clinical Size information for a Device , the following information will be mandatory : • Type of the Size (Length, Depth, etc.), • Precision (Value, Text, Range), • Value (the value of the Clinical Size). A value of Clinical Size can be provided only once for a specific Type of the Size (Lengh, Depth, Area, etc.) - for a UDI-DI	
BR-UDID-076: Measure Unit in which the Clinical Size is given	RESOLVED	Providing the Measure Unit for the Clinical Size of a Device is mandatory when the Precision in which the Size is provided is either Value (numeric value) or a Range of values.	
BR-UDID-077: Registration of a range of Values for the Size of the Device	RESOLVED	When the Precision in which the size of the Device is entered is 'Range', the Manufacturer will be required to provide a Minimal value and a Maximum value of that Clinical Size	
BR-UDID-090: Several Endocrine Disrupting Substances can be added	CLOSED	Several Endocrine Disrupting Substances can be added for a Device	
BR-UDID-091: Only one value per Language	RESOLVED	For the Language specific properties - only one description can be given per language for each property unless mentioned otherwise.	
BR-UDID-094 : Mentioning several intended purposes (other than medical) for the device	RESOLVED	Several device purposes (other than medical) can be selected at the same time. Exception: Intended purpose other than medical (Annex XVI) for a Master UDI-DI can have only one value (yes/no).	
BR-UDID-095: Legal or Natural person who manufactured / designed the device (Product original manufacturer)	RESOLVED	For the registration of the Legal or Natural person who manufactured/designed the device (Product original manufacturer), either the SRN of the Manufacturer should be provided or all the identification details of the Manufacturer. When the SRN is provided as identification of the Legal or Natural person who Manufactured/ Designed the Device, it must exist in EUDAMED and should not correspond to the SRN of the Manufacturer registering the Device. Information about Product original manufacturer can be updated in case it has been initially provided by specifying details of an Organisation that is not registered as Actor with an Actor ID/SRN . It cannot be updated if initially has been mentioned as 'Not applicable', or specified with an Actor ID/SRN.	
BR-UDID-098: Providing CI/PS details when registering a Device	RESOLVED	When providing Clinical Investigation (CI/PS) details, providing the CI/PS identifier is required (both for EU or NonEU CI/PS). In case of EU Clinical Investigations, the CI/PS identifier refers to the **EU SIN** of the Clinical Investigation List of Countries were the Clinical Investigation has been performed can be provided (optionally) for CI/PS performed outside EU.	
BR-UDID-101 : Adding several Substances (Substance that can be considered to be a medicinal product or medicinal product derived from human blood or plasma)	RESOLVED	Several substances considered to be a medicinal product or medicinal product derived from human blood or plasma, can be added for a Device, but only one containing a specific INN value	

BR-UDID-131: Device additional product description	RESOLVED	Additional product description is mandatory for System or Procedure Packs and Devices which are Systems or Procedure Packs in themselves or KITs. Additional product description is optional for regulation and legacy devices. Additional product description will be provided in a specific language from the list of languages indicated in BR-EUD-005 : EU Languages - ENUM_MDR_LANGUAGE.	
BR-UDID-268: Adding a new UDI DI for an existing Basic UDI DI	RESOLVED	A new UDI DI can be added to an existing Basic UDI DI , only if the Basic UDI DI is in state [Submitted] or [Registered]	
BR-UDID-458: Status of Device or System or Procedure Pack	RESOLVED	The UDI-DI for a Regulation Device or System or Procedure Pack can have the following Statuses : • On the EU Market • Not intended for EU Market or • No Longer placed on the EU Market The UDI-DI for a Legacy Device can have the following Statuses : • On the EU Market • No Longer placed on the Market The UDI-DIs (for Regulation and Legacy Devices and System or Procedure Packs) can have also the following Sub-Statuses : • Recall • FSCA Initiated Note : Sub-status are additional statuses which a Device or SPP can have. They are treated as sub-statuses (and not statuses) as the Device/SPP can have the status 'On the EU Market' or 'No longer placed on the EU Market' having also incidents reported through Vigilance module. In this case the sub-status 'Recall' or 'FSCA initiated' is added. The status is mandatory for the UDI-DI, but the sub-statuses are mandatory, only if applicable. An UDI-DI can have none, only one or both sub-statuses.	
BR-UDID-635 : 'Devices is being marked as Sutures, Staples, etc.,' is a conditional mandatory property	RESOLVED	Property 'Devices is being marked as Sutures, Staples, etc.' is mandatory only for devices having risk Class IIb and being implantable.	
BR-UDID-636: Selecting the appropriate Device Nomenclature codes	RESOLVED	Device Nomenclature codes associated with a UDI-DI will be selected from the list provided in the EMDN Device Nomenclature. Only a 'leaf' code (the lowest level from within the nomenclature`s branch) can be selected as nomenclature code and associated with a UDI-DI. Several Nomenclature Codes can be associated to a UDI-DI CI/PS Field name in Clinical Investigation: "EMDN nomenclature code"	
BR-UDID-639: Direct marking DI applicable	RESOLVED	Direct marking DI is applicable if the Device is Direct marked (Direct Marking is true). Value of Direct marking DI can be the same as the one of the UDI-DI or can be a different one. A value for the direct marking DI can be added at a later time, but once added it cannot be modified or removed. Direct marking DI is not applicable for Master UDI-DI.	
BR-UDID-645 : Automatic linking of a Legacy Device to a Regulation Device	RESOLVED	When registering a Regulation Device if the UDI-DI provided is already assigned to another Device, but having a Legacy Legislation assigned, the registration of the Regulation Device with the same UDI-DI will be permitted and a link will be automatically created between the Legacy and Regulation Device. In a similar way - registering a Legacy Device having a UDI-DI already assigned to another Device, but having a Regulation assigned, will be permitted and a link will be automatically created between the Legacy and Regulation Device. Note : In order to make the link a "consistency check" (validation of different properties) between the Regulation and Legacy Devices is performed. The link is performed if the "consistency check" passes	
BR-UDID-661: Several Container Package Structure elements registered per Container Package level	RESOLVED	Several Container Package Structure elements can be registered at the same level of Packaging Structure.	
BR-UDID-676 : Device Implantable property has value False for Devices having Risk Class I	RESOLVED	Devices having Risk Class I will have automatically the property Implantable set to False(no).	

BR-UDID-677 : Device Reusable surgical instrument property has value False for Devices being Implantable	RESOLVED	Devices having the property Implantable set to True (Yes), will have automatically the property Reusable surgical instrument set to False(no).	
BR-UDID-680 : Duplicate check for Basic UDI-DI /EUDAMED DI	RESOLVED	Duplicate check for Basic UDI-DI/ EUDAMED DI is applied in case of Regulation Devices, Legacy Devices and System and Procedure Packs. The duplicate check of Basic UDI-DI/ EUDAMED DI is performed over the fields: Device Name or Device Model for the Devices/ SPP registered by the same Manufacturer/PR (Producer) . Note : When identifying a similar Device / System or Procedure Pack having the same values for mentioned attributes, the system will notify the users	
BR-UDID-681: Duplicate check for UDI-DI /EUDAMED ID	RESOLVED	Duplicate check for UDI-DI/ EUDAMED ID is applied in case of Regulation Devices, Legacy Devices and System and Procedure Packs. The duplicate check of UDI-DI/ EUDAMED ID is performed over the field: Reference Number for the Devices/ SPP registered by the same Manufacturer/PR (Producer). Note : When identifying a similar Device / System or Procedure Pack having the same values for mentioned attributes, the system will notify the users.	
BR-UDID-705 : Special Device type	RESOLVED	A Device cannot have an attribute of Special Device type marked if initially it has been marked as KIT or as a System or Procedure Pack which is a Device in itself	
BR-UDID-720: When registering a Device for which the Basic UDI has been initially referenced inside a CECP, properties of the Device need to correspond to the ones in CECP	RESOLVED	When registering a Device for which the Basic UDI has been initially referenced inside a CECP, properties of the Device need to correspond to the ones in CECP. CECP can be provided in advance for Devices being : • MDR, Class III and Implantable or • MDR ,Class IIb non-implantable active device intended to administer and/or remove a medicinal product	
BR-UDID-721: When registering new Devices (UDI-DIs) or updating existing UDI-DIs, only references to active items from the existing Enumerations can be used	RESOLVED	Following Enumerations can contain Active or Inactive items : • Critical Warnings • Storage and Handling Conditions • Measure Unit • Clinical Sizes When registering a new Device or when updating a new Device only the Active items from the Enumerations can be referenced. Inactive items from the enumerations will still be reflected in the system - for the already registered versions of Devices	
BR-UDID-722: When registering a Device having Clinical Sizes provided and having option OTHER provided for the Clinical Size type or the Measure Unit Type, the Description needs to be provided	RESOLVED	When providing Clinical Sizes having either the Clinical SIze Type or the Measure Unit Type with option Other, then the Description needs to be provided for the Clinical Size Type or for the Measure Unit type. The Description provided will be Multi-Language. Several descriptions can be provided in several languages- only once in a language. Description in Language ANY (generic language) cannot be provided. In case for both the Clinical Size type and Measure Unit type, option OTHER is selected, Languages in which the Description is provided for both elements should be similar	
BR-UDID-723: Matching device properties referenced in a CECP, refused certificate, refused /withdrawn application	RESOLVED	When registering a device for which the Basic UDI has been initially referenced inside a CECP record, refused certificate or refused/withdrawn application then the following device properties must match: • Risk class • Implantable (applicable only for MDR)	
BR-UDID-724: A manufacturer of a device cannot be its product original manufacturer	RESOLVED	A manufacturer of a device cannot be its product original manufacturer.	

BR-UDID-725: Product original manufacturer registration	RESOLVED	A product original manufacturer registered as an organisation must contain the following data: • Name • Street (if applicable) • Address line 2 (if applicable) • PO box (optional) • City name • Postal code • Country • Telephone (optional) • Email	
BR-UDID-727: The entity where a Basic UDI-DI code was initially referenced must be in state Registered	RESOLVED	The system will not allow the registration of the Basic UDI-DI in the UDI/Devices module when this Basic UDI-DI code has been referenced inside the following entities being in state Draft: • CECP • Refused certificate • Refused/withdrawn application	
BR-UDID-728: Linking a Basic UDI-DI to the same Basic UDI-DI code registered in another entity	RESOLVED	Only the manufacturer that was referenced inside the: • CECP • Refused certificate • Refused/withdrawn application that referenced a Basic UDI-DI not yet registered is allowed to register that Basic UDI-DI in the UDI/Devices module.	
BR-UDID-729: Properties that are not applicable for Master UDI-DI	RESOLVED	When registering a Master UDI-DI the following properties will not be provided: • Unit of Use DI • Direct Marking UDI-DI • Related Device (Legacy- Regulation) • New Device	
BR-UDID-731: Master UDI-DI	RESOLVED	Master UDI-DI is an identifier of a group of highly individualised products/devices presenting specific similarities with respect to defined clinically relevant parameters. It is applicable with REGULATION (EU) 2017/745 on medical devices only. The following special device types require the registration of Master UDI-DI: • Standard soft contact lenses • Standard Rigid Gas Permeable (RGP) contact lenses • Made to order soft contact lenses • Made to order Rigid Gas Permeable (RGP) contact lenses A Master UDI-DI is an alphanumeric code. The system will ensure: • There are no duplicates of a Master UDI-DI code. At the registration of a Master UDI-DI for the GS1 issuing entity, the system will also: • Validate the format of the Master UDI-DI code when registering Master UDI-DI for the following special device types: ◦ Standard soft contact lenses ◦ Standard Rigid Gas Permeable (RGP) contact lenses • for the following special device types the format of the UDI-DI for the GS1 issung entity will be applied ◦ Made to order soft contact lenses ◦ Made to order Rigid Gas Permeable (RGP) contact lenses	
BR-UDID-737: Special device type orthopedic cannot be registered	RESOLVED	Special device type orthopedic cannot be registered anymore.	
BR-UDID-760 : Reference a Product original manufacturer registered as an Organisation	RESOLVED	A manufacturer registering their device and referencing a product original manufacturer (POM) as an organization can only reference their own registered POM(s).	

Registration of Legacy Devices

Identifier	Status	Description	Previously used

BR-UDID-640 : Device Identification elements for a Legacy Device	RESOLVED	Legacy Device has the following identifiers: EUDAMED DI (equivalent of Basic UDI-DI) and either UDI-DI (in case the Legacy Device had a previously assigned UDI-DI) or EUDAMED ID (equivalent of UDI-DI, in case there is no previously assigned UDI-DI)	
BR-UDID-641 : Assigning EUDAMED DI and EUDAMED ID for a Legacy Device	RESOLVED	*EUDAMED DI* If the Device has a previous assigned UDI-DI, then the EUDAMED DI is generated based on the value of the UDI-DI assigned. If it does not have a previously assigned UDI-DI, EUDAMED DI will be required to be provided by the Manufacturer using a specific format. *EUDAMED ID* EUDAMED ID is only applicable when the Device does not have a previously assigned UDI-DI and is generated based on the EUDAMED DI using a specific format.	
BR-UDID-642: Format for generating the EUDAMED DI	RESOLVED	Format of EUDAMED DI when generated based on the UDI-DI is : B- (UDI-DI value). Format of EUDAMED DI when provided (and not generated based on the EUDAMED ID): B-DD(1-21)X1X2 where • DD is the Device identification provided by the Manufacturer and should have a maximum of 21 characters, • X1X2 are the check-digit values, calculated based on the values previously provided. As a best practice the Device identification provided by the Manufacturer should contain also the Manufacturer SRN Note : Algorithm for the calculation of X1 and X2 check digits is available in a separate documentation	
BR-UDID-643: Format for generating the EUDAMED ID	RESOLVED	Format of EUDAMED ID (generated based on the EUDAMED DI) is : D-(EUDAMED DI).	
BR-UDID-644 : Issuing Entity for EUDAMED DI and EUDAMED ID	RESOLVED	Issuing Entity for a EUDAMED DI or EUDAMED ID will be by automatically 'EUDAMED'	
BR-UDID-648 : Only one EUDAMED DI and EUDAMED ID/UDI-DI	RESOLVED	For a Legacy Device there can be only one EUDAMED DI and one EUDAMED DI /UDI-DI	

BR-UDID-669: Information completed for a UDI DI/EUDAMED ID associated to a EUDAMED DI having MDD or AIMDD as Applicable Legislation	CLOSED	For the submission of a UDI DI/EUDAMED ID when the Applicable legislation is MDD or AIMDD, the following information`s / attributes can be completed. Mandatory information needed to be submitted : • UDI DI / EUDAMED ID code and Issuing Entity, • Reference / Catalogue Number, • Label as single use, • Device Labeled as Sterile, • Need for Sterilization, • Containing Latex, • Medical Device Nomenclature Code, • Device Status, Information needed to submitted in case details are applicable for the current device: • Trade Name(s) of the Device, • Clinical Size, • Storage/handling conditions, • Critical Warnings or Contraindications, • Maximum number or reuses. Optional information submitted for a UDI-DI: • Additional product description, URL for additional information When Submitting Device characteristics for a Legacy Device having as Applicable legislation: MDD or AIMDD , the following information is required to be submitted together with the UDI-DI/EUDAMED ID : • Member state on the Placing on EU Market of the Device, • Member state were the Device is made available, • Information`s on substances (Substances that can be considered to be a Medicinal product and Substances that can be a medicinal product derived from human blood or human plasma), Reprocessed single-use; Information that is required to be submitted as Device characteristics, if applicable for the current Device : • Legal or Natural person who manufactured / designed the device,	
BR-UDID-673 : Member States were the Device is made available in the Country (AIMDD Legislation) Mandatory	RESOLVED	When the Device has Applicable Legislation AIMDD and device status is "On the EU market" the Manufacturer will be required to provide EU countries were the Device is made available when entering Device Data.	
BR-UDID-674 : Member States were the Device is made available in the Country (IVDD Legislation) Mandatory	RESOLVED	When the Device Risk Class is IVD Annex II List A, IVD Annex II List B and IVD devices for self-testing and device status is "On the EU market" then the Manufacturer will be required to provide EU countries were the Device is made available when entering Device Data.	

Manage Devices and System or Procedure Packs

Identifier	Status	Description	Previously used
BR-UDID-048 : Update version 1 of the Basic UDI DI (EUDAMED DI) or (Master) UDI-DI (EUDAMED ID) in Draft State	RESOLVED	When updating version 1 of a Basic UDI-DI (EUDAMED DI) in state [Draft], or a (Master) UDI-DI (EUDAMED ID) in state [Draft] (Basic UDI-DI/ EUDAMED DI being also in Draft state) all the fields associated to the Basic UDI (EUDAMED DI), (Master) UDI-DI (EUDAMED ID) and associated elements can be updated, with the following exceptions : • Basic UDI-DI value; • Applicable Legislation; • Is it a System which is a Device in itself, Procedure pack which is a Device in itself ; • Is it a Kit ; • Special Device type ;	
BR-UDID-107 : Deleting a version	RESOLVED	Delete operation can be performed only for Basic UDI-DI (/ EUDAMED DI) and/or (Master) UDI-DI (/EUDAMED ID) versions which are in the state [DRAFT] or [SUBMITTED] . If the UDI-DI (EUDAMED ID) deleted is the last (Master) UDI-DI (EUDAMED ID) associated to a Basic UDI (EUDAMED DI) not in state [Registered], also the Basic UDI-DI (EUDAMED DI) will be deleted	
BR-UDID-114: Comments entered when the Status of the Device is changed	RESOLVED	When the Status of the Device is changed, the Manufacturer will have the possibility (optional) to provide a comment regarding that Status change	

BR-UDID-430 : Updating the Container Package Information	RESOLVED	Details regarding Container Package Information can be updated without creating a new version of the UDI-DI (EUDAMED ID).	
BR-UDID-617 : Update version 1 of the UDI DI (EUDAMED ID) in state [Draft] when Basic UDI (EUDAMED DI) is in state [Submitted] or [Registered]	RESOLVED	When updating version 1 of the (Master) UDI-DI (EUDAMED ID) in state [Draft] , changes can be performed to all fields from (Master) UDI-DI and associated data : Product original manufacturer, Market Information or Package Structure.	
BR-UDID-622 : Restriction on Discarding a Basic UDI-DI and UDI-DI	RESOLVED	A Basic UDI-DI cannot be discarded if it is referenced in other places of the system , such as Certificates (including SS(C)P).	
BR-UDID-623 : Restriction on device discard	RESOLVED	A device referenced in a Vigilance report cannot be discarded or deleted.	
BR-UDID-624 : Discarding Registered (Master) UDI-DI / EUDAMED ID	RESOLVED	Discarding (Master) UDI-DI / EUDAMED ID can be performed for (Master) UDI-DI / EUDAMED ID in state Registered (for Devices or System or Procedure Packs). When discarding a (Master) UDI-DI / EUDAMED ID the states of all the versions of the (Master) UDI-DI / EUDAMED ID will be 'Discarded' (state of the version set to Discarded). If the (Master) UDI-DI is the last (Master) UDI-DI Registered for a Basic UDI, the last Basic UDI will be also Discarded (state of the version set to Discarded). Note : Disacard operation acts as a logical Delete. A Basic UDI-DI (/EUDDAMED DI) and /or a (Master) UDI-DI / EUDAMED ID which is set to the state Discarded, are not seen on the Public site (are no longer active devices). The Codes provided as Basic UDI-DI and/or (Master) UDI-DI can be reused in EUDAMED for registering another Device	
BR-UDID-627 : Adding new Clinical Investigations for a Basic UDI-DI (EUDAMED DI) in status Registered	RESOLVED	Adding new Clinical Investigation details for a Basic UDI-DI (EUDAMED DI) in status Registered will be performed without creating a new version of the Basic UDI-DI (EUDAMED DI) (Clinical Investigation entity is versioned independently of the Basic UDI/ EUDAMED DI). Adding a new Clinical Investigation will create a new entity (version 1) of Clinical Investigation linked to Basic UDI-DI (EUDAMED DI)	
BR-UDID-628 : Applying corrections for Clinical Investigation details	RESOLVED	Clinical Investigation Details can be Deleted (soft Delete) without creating a new version of the Basic UDI-DI (EUDAMED DI). Deleting the Clinical Investigation will set up the State of the Clinical Investigation to Discarded Note: Soft Delete means that the State of the Clinical Investigation is set to 'Discarded', Clinical Investigation will no longer be displayed in the UI, but the information still resides in EUDAMED for auditing purposes.	
BR-UDID-629 : Update Product original manufacturer	RESOLVED	Product original manufacturer information can be updated only if it has been defined as an Organisation. Details regarding Product original manufacturer (Natural or Legal person who designed and manufactured the device) can be updated without creating a new version of the UDI-DI (EUDAMED ID). Each update of the Product original manufacturer will create a new version.	
BR-UDID-630 : Update Market Information	RESOLVED	Details regarding Market Information (Countries were the device is made available on the market) can be updated without creating a new version of the UDI-DI (EUDAMED ID). Each update of the Market Information will create a new version	

BR-UDID-632 : Update Container Package	RESOLVED	Updating the Container Package can be performed for a (Master) UDI-DI in status Registered without creating a new version of the (Master) UDI-DI. When updating the Container Package structure, new elements can be added to the Container Package structure or an update of the Status for an element for the Container Package can be performed. The quantity of a container package cannot be changed during the update of a container package. *Changing the status of a Container Package element* Changing the Status of a Container Package element from 'On the market' to 'No longer on the market' can be performed for any element in the hierarchy (having status 'On the market'), all the children of that element (all lower elements in the hierarchy) having automatically the status 'No longer on the market'. Changing the Status of a Container Package element from 'No longer on the market' to 'On the market' can be performed for the highest element in the hierarchy having the status 'No longer on the market'. No update of the statuses for the lower elements in the hierarchy is performed	
BR-UDID-684: Creating a new version	RESOLVED	Creating a new version operation can be performed only for Basic UDI-DI (/ EUDAMED DI) or UDI-DI (/EUDAMED ID) which have the state of the last version [Registered].	
BR-UDID-685: Editing a version of the Basic UDI-DI (/EUDAMED DI) or (Master) UDI-DI(/EUDAMED ID)	RESOLVED	Edit operation can be performed for Basic UDI-DI (/ EUDAMED DI) and/or (Master) UDI-DI (/EUDAMED ID) versions which have the state in [DRAFT]. Note : Creating a new version for the Basic UDI-DI/ EUDAMED DI or (Master) UDI-DI/EUDAMED ID being in Registered state will not be possible if a higher version in state Draft is available (if the last version of the Basic UDI-DI/ EUDAMED DI or (Master) UDI-DI /EUDAMED ID is in state Draft).	
BR-UDID-686 : Version history	RESOLVED	In the version history for an element all the versions in [Registered] state will be displayed , with the exception of the last (current) one.	
BR-UDID-687 : Container packages for Master UDI-DI	RESOLVED	Only Master UDI-DI identifier can be provided when registering or updating container packages linked to a Master UDI-DI device. The format of Container Package DI Code structure for a Master UDI-DI will be checked against the format structure provided by the Issuing Entity when the issuing Entity is GS1.	
BR-UDID-824 : Product Original Manufacturer update requirements	RESOLVED	Product original manufacturer information can be updated only if • manufacturer was added during device registration process • manufacturer was added manually during the device registration process Product original manufacturer cannot be updated if: • existing manufacturer was added using SRN during the registration process	

Certificate Rules

Identifier	Status	Description	Previously used
BR-UDID-056 : Creating the link between Device (Basic UDI-DI) and Certificate	RESOLVED	The link between the Basic UDI-DI and the Certificate will be created automatically when the Notified Body registers a Certificate referencing the Basic UDI-DI in its scope (inside the Certificate Scope). Note : If inside the Certificate Scope , the Basic UDI-DI is not directly referenced, no link is created between the Certificate and the Device (Basic UDI-DI)	

BR-UDID-109 : Register Certificate Information when Submitting the BASIC UDI-DI/UDI-DI and device information for Devices subject to Article 29.3 (MDR)	RESOLVED	When submitting **BASIC UDI-DI / UDI-DI data** for a device subject to **MDR Article 29.3**, the user must specify: • **Type of product certificate** associated with the device. • **Notified Body** that issued the certificate. • **Certificate ID** *(optional).* • **Revision Number** *(optional).* **Requirements Based on Device Risk Class** 1. **For MDR Devices classified as Risk Class III or Class IIb (implantable = yes, sutures and staples = no):** • The user must manually provide: ▪ The Type of Certificate (**Technical Documentation Certificate** or **Type Examination Certificate**). ▪ The **Notified Body ID** of the Notified Body that issued the certificate. ▪ (Optional) The **Certificate ID** and **Revision Number**. 1. **For MDR Devices classified as:** • **Risk Class IIb (implantable = no),** or • **Risk Class IIb (implantable = yes, sutures and staples = yes):** ▪ The user must specify whether a **Type Examination Certificate** covers the device. ▪ If applicable, the user must provide: • The **Notified Body ID** of the Notified Body that issued the certificate. • (Optional) The **Certificate ID** and **Revision Number**. ▪ If the Type Examination Certificate **does not apply**, no certificate information is required. **Status Updates After Submission** Once the information is submitted, the **BASIC UDI-DI and UDI-DI status** will be set to **Submitted** until the Notified Body **confirms the device data** (when registering the certificate). After confirmation, the status of the **BASIC UDI-DI and all linked UDI-DIs** will be updated to **Registered**.	
BR-UDID-113 :Directive Certificates applicable	RESOLVED	In case of Devices having the Applicable Legislation MDD, AIMDD or IVDD, the Manufacturer must/shall specify the Directive Certificate that covers the Device by entering: • Certificate Type; • Notified Body Identification of the Notified Body that issued the Certificate; • Certificate ID of the Directive Certificate; • Certificate Expiry Date ; Providing Certificate information is optionally for MDD Class I Legacy Devices (with the exception of Measuring function ones) and for IVDD Devices having the risk class General. Note : Directive Certificate details will not be provided by the Notified Bodies. Information provided by the Manufacturer will not be validated by the Notified Body.	
RULE-00015: Register Certificate Information when Submitting the BASIC UDI and UDI DI information for Devices subject to Article 26.2 (IVDR)	RESOLVED	When submitting BASIC UDI DI or UDI DI data for a device under Article 26.2 of the IVDR legislation, the user must provide the following details: **General Requirements:** Type of product certificate associated with the device. Notified Body that issued the certificate. Certificate ID (optional). Revision Number (optional). **Specific Requirements by Risk Class:** **Sc 1:** For **Class D or Class C devices (self-testing or near-patient testing)**: Provide the Type of Certificate (Technical Documentation or Type Examination Certificate), Notified Body ID, and optional Certificate ID and Revision Number. **Sc 2:** For **Class C devices (not for self-testing or near-patient testing)**: If applicable, provide details of the Type Examination Certificate, including Notified Body ID, optional Certificate ID, and Revision Number. If not applicable, no certificate information is required. **Sc 3:** For **Class B devices (self-testing or near-patient testing)**: Provide details of the Technical Documentation Certificate, including Notified Body ID, and optional Certificate ID and Revision Number. **Status Update Process:** Once the required information is submitted, the BASIC UDI DI and UDI DI status will be marked as Submitted. After the Notified Body confirms the device data and registers the certificate, the status will be updated to Registered for the BASIC UDI DI and all linked UDI DIs.	BR-UDID-110

Search and View

Identifier	Status	Description	Previously used

BR-UDID-690 : Device /SPP Search Criteria`s on the Private site	CLOSED	Search Criteria`s based on which a Device can be searched on the Private site can be : • UDI-DI/Eudamed ID code; • BASIC UDI-DI/EUDAMED DI code; • Device/SPP Nomenclature Code; • Model (Device/ SPP Model) , • Name (Device/ SPP Name); • Reference/Catalogue Number • Trade Name - Trade name from the UDI-DI; • Manufacturer/PR SRN; • Manufacturer/PR Name; • Authorised Representative SRN; • Authorized Representative Name; • Country ; • Device Risk Class; • Scope (Device/ System/Procedure Pack) • Status (On the market/ No longer on the market, etc.); • State (Submitted/Registered)- Registered state is set as default;	
BR-UDID-691 : State filter	RESOLVED	State filter is visible only for Authorised Representatives, Notified Bodies, Competent Authority and EC users. The filter will allow the users to filter also (to view) the Devices in Submitted State. Note: When filtering criteria 'State' is not displayed in the list of filters, EUDAMED will bring all items having the state [Registered]; In the case of Authorised Representative, the State filter in 'Submitted' will bring all Devices being in Submitted State to which the AR is linked which correspond to the additional filters placed. In the case of Competent Authority, Notified Body and EC, the State filter in 'Submitted' will bring all Devices being in Submitted State existing in EUDAMED which correspond to the additional filters placed.	
BR-UDID-692 : List of Devices and Systems and Procedure Packs returned	RESOLVED	The Search and View list of Devices will return the latest versions in [Registered] state for Devices and Systems and Procedure Packs, filtered accordingly to the filtering criteria`s introduced by the users, except the situation in which the State filter is applied with the value 'Submitted' (for Competent Authorities, Notified Bodies and EC users), case in which Devices having the latest version in [Submitted] state are returned	
BR-UDID-693 : Device/ SPP details presented in the Search and View screen	RESOLVED	The details displayed for a Device/ SPP will be the details of the latest version in [Registered] state of the UDI-DI/EUDAMED ID and the latest versions in [Registered] state for all the associated elements: Basic UDI-DI, Market Information, Product Designer, Clinical Investigation, Container Package Information, Device Certificate Information and SSCP, linked to that version of UDI-DI/ EUDAMED ID. If the Device (UDI-DI) is in Submitted state, details presented will be the details of the version in [Submitted] state and the versions of Basic UDI-DI, Market Information, Product Designer, Clinical Investigation, Container Package Information, Device Certificate Information, linked to that version of UDI-DI.	
BR-UDID-694 : Search and View Devices - Version history	RESOLVED	The Search and View list of Devices when searching also in historical versions , will return all versions in [Registered] state for Devices and Systems and Procedure Packs, filtered accordingly to the filtering criteria`s introduced by the users, except the situation in which the State filter is applied with the value 'Submitted' (for Competent Authorities, Notified Bodies and EC users), case in which Devices having the latest version in [Submitted] state are returned	
BR-UDID-695 : Device/ SPP details presented for a specific version selected from the version history	RESOLVED	The details displayed for a historical version of the Device/ SPP selected from the list of historical versions of that Device/SPP, will be the details of the selected version for the UDI-DI/EUDAMED ID and the latest versions in [Registered] state for all the associated elements: Basic UDI-DI, Market Information, Product Designer, Clinical Investigation, Container Package Information, Device Certificate Information and SSCP, associated to that UDI-DI/EUDAMED ID.	

Upload SS(C)P

Identifier	Status	Description	Previously used
BR-UDID-710 : One Basic UDI-DI can only be linked to one and only one SS(C)P	RESOLVED	One Basic UDI-DI can be linked to one and only one SS(C)P record.	

BR-UDID-711: Adding translations for a version of the Master Document of an SS(C)P	RESOLVED	Adding translations in different languages for an SS(C)P can be performed for validated and not-validated Master Document versions. Several translations can be added to a version of the Master Document. There can be only one Translation document in a specific language linked to a version of the Master Document. A Translation document cannot be in the language of the Master Document. Adding at least the translation in EN is required if the Master Document is not EN. Note : Performing corrections over the translations uploaded will be possible by Discarding the initial document in a specific language and uploading again the correct document in that language	
BR-UDID-712: A new version of the SS(C)P requires a new Master Document	RESOLVED	A new version of the SS(C)P requires a new version of the Master Document (a new Master Document). Only one Master Document can be attached to a version of the SS(C)P. Several Translation (of the Master Document) can be added to the version of the SS(C)P	
BR-UDID-713: Received Date (from MF) cannot be in future	RESOLVED	Received Date (from MF) given for a SS(C)P translation document cannot be set in future	
BR-UDID-715: SS(C)P Reference Number	RESOLVED	Providing the SS(C)P Reference Number will be required when the SS(C)P is first Registered and cannot be updated. The SS(C)P Reference Number is unique for a Manufacturer (for the Devices (Basic UDI-DIs) of a Manufacturer).	
BR-UDID-716: SS(C)P Revision Number	RESOLVED	Providing the SS(C)P Revision Number will be required each time a new version of the Master Document is created. The SS(C)P Revision number cannot be the same as previous versions for the same SS(C)P Reference Number.	
BR-UDID-719: Date when the version of the Master Document has been issued cannot be in future	RESOLVED	The Date when the version Master Document has been issued (Date issued), cannot be set in future	

Link Regulation Device to a Legacy Device

Identifier	Status	Description	Previously used
BR-UDID-700 The link between a Regulation and a Legacy Device can be created only for Devices of the same Manufacturer (same SRN)	CLOSED	The link between a Regulation and a Legacy Device can be created only for Devices of the same Manufacturer (same SRN)	

BR-UDID-702: Consistency checks performed when linking Devices	RESOLVED	When creating a link between a Legacy and a Regulation Device, EUDAMED will perform a series of checks between the properties of the Regulation and Legacy Device. Performing the link is possible in case no issues are identified after performing these checks. 1. The link between a Regulation and a Legacy Device can be created only for Devices of the same Manufacturer (same SRN); 2. The link between a Regulation and a Legacy Device can be created only for Devices having similar (compatible) Applicable Legislation : • MDD,AIMDD (Legacy Device) <-> MDR (Regulation) • IVDD (Legacy Device) <-> IVDR (Regulation) 3. Properties for which the values need to be consistent between the Regulation and Legacy Device Basic UDI : • Is it a System which is a Device in itself, Procedure pack which is a Device in itself (MDR/MDD,AIMDD); • Is it a Kit (IVDR/IVDD); • Special Device Type (MDR/MDD,AIMDD IVDR/IVDD); • Active Device (MDR/MDD,AIMDD) ; • Device Intended to administer and/or Remove medicinal product (MDR/MDD, AIMDD) ; • Implantable (MDR/MDD,AIMDD); • Measuring Function (MDR/MDD,AIMDD); • Reusable Surgical Instruments (MDR/MDD,AIMDD) ; • Companion Diagnostic (IVDR/IVDD); • Near Patient Testing (IVDR/IVDD); • Patient Self Testing (IVDR/IVDD); • Reagent (IVDR/IVDD); • Professional Testing (IVDR/IVDD); • Instrument (IVDR/IVDD); • Tissues and cells - Presence of human tissues or cells, or their derivates (MDR /MDD,AIMDD IVDR/IVDD); • Tissues and cells - Presence of animal tissues or Cells, or their derivates (MDR /MDD,AIMDD IVDR/IVDD); • Tissues and cells - Presence of cells or substances of microbial origin (IVDR /IVDD); • Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or plasma (MDR/MDD,AIMDD) ; • Presence of substance which, if used separately, may be considered to be a medicinal product (MDR/MDD,AIMDD) ; UDI-DI : • Containing latex (MDR/MDD,AIMDD); • Labelled as single use (MDR/MDD,AIMDD IVDR/IVDD) ; • Device labelled sterile (MDR/MDD,AIMDD IVDR/IVDD) ; • Need for sterilisation before use (MDR/MDD,AIMDD IVDR/IVDD); • Reprocessesed single use device (MDR/MDD,AIMDD) ;	
BR-UDID-704: Linking a legacy device to a regulation device	RESOLVED	When linking a regulation device to its counterpart legacy device and vice-versa then the system will validate: • a regulation device (UDI-DI) can be linked to one and only one legacy device (and vice-versa) • both devices belongs to the same manufacturer • the device being linked or to be linked is not already linked to any other device • both devices must be in state Registered	

BR-UDID-706 Linking AIMDD to MDR risk class III devices	RESOLVED	When performing the link between a (MDR) Risk class III to a legacy (AIMDD) device the system will ensure the values of the following attributes match: Basic UDI-DI / EUDAMED DI level: • Risc class III for MDR / AIMDD for legacy; • Manufacturer SRN; • Is it a System which is a Device in itself, Procedure pack which is a Device in itself; • Special Device Type • Device Intended to administer and/or Remove medicinal product • Measuring Function • Reusable Surgical Instruments • Tissues and cells - presence of human tissues or cells, or their derivates • Tissues and cells - Presence of animal tissues or Cells, or their derivates • Presence of a substance which , if used separately, may be considered to be a medicinal product derived from human blood or plasma • Presence of substance which, if used separately, may be considered to be a medicinal product UDI-DI level: • Containing latex • Labelled as single use • Device labelled sterile • Need for sterilisation before use • Reprocessesed single use device The following attributes will be ignored when performing the link between (MDR) Risk class III and AIMDD: • Implantable • Active device	
BR-UDID-707 Display rule for action 'Link to a legacy device'	RESOLVED	The action-link 'Link to a legacy device' is available to the user when the following conditions are met: • user has CONFIRMER profile for the UDI/Devices module • view device details page belongs to a regulation device (MDR/IVDR) that was registered by the MF actor for which the user is acting on behalf • the regulation device is the latest registered version • the regulation device is in state Registered • the regulation device is not linked to any other legacy device	
BR-UDID-709 Display rule for action delete a manually created link	RESOLVED	The delete a manually created link is available to the user when the following conditions are met: • user acting on behalf of the actor that is the owner of the device • user has CONFIRMER profile • the regulation device is linked to a legacy device. The link was manually created.	
BR-UDID-714 Display legacy devices that can be linked	RESOLVED	The system displays a list of legacy devices (UDI-DI and/or EUDAMED ID) that satisfies the following conditions: • Are registered by the same Manufacturer • Are registered under MDD or AIMDD when linking to MDR or registered under IVDD when linking to IVDR regulations • Are in state Registered • Are not linked to any other devices	
BR-UDID-717 Metadata about device linking	RESOLVED	When creating/deleting a manually created link between a regulation device and its corresponding legacy device the system will store the following data: • UDI-DI of the regulation device • UDI-DI or EUDAMED ID of the legacy device • Operation type (created, deleted) • Datetime of the operation • User ID (EU Login)	

UDI Device - Data Exchange Business Rules

Upload Devices and System or Procedure Packs

<table>
<tr><th>Identifier</th><th>Status</th><th>Description</th><th>Previously used</th></tr>
<tr><td>BR-DTX-UDI-009 : Upload registered Basic UDI /EUDAMED DI information</td><td>RESOLVED</td><td>As a Manufacturer EU MF, Non-EU MF (MF Confirmer/DTX) a user must be able to upload a list of registered Basic UDIs/ EUDAMED DIs information for a Device.

As a Producer PR (PR Confirmer/DTX), a user must be able to upload a list of registered Basic UDIs for a System or Procedure Pack.</td><td></td></tr>
<tr><td>BR-DTX-UDI-010 : Upload Device object structure (main entity and related entities)</td><td>RESOLVED</td><td>A Device upload object should contain the following:

• Basic UDI/EUDAMED DI information
  ○ DeviceCertificateLink (optional)
  ○ Clinical investigation link (optional)
• UDI-DI/EUDAMED ID information (at least one UDI-DI is required to be submitted with the Basic UDI)
  ○ Market Information (optional)
  ○ Product original manufacturer (optional)
  ○ Container Package information (optional - not applicable for Legacy Devices)

All the UDI-DIs referenced inside a Device object must reference the Basic UDI from the Device</td><td></td></tr>
<tr><td>BR-DTX-UDI-025 : Bulk upload of a Basic UDI /EUDAMED DI and UDI-DI/EUDAMED ID list of entities</td><td>RESOLVED</td><td>As a Manufacturer EU MF, Non-EU MF or Proposer (MF CONFIRMER, PR CONFIRMER), an authenticate EUDAMED user must be able to upload a list of registered Basic UDI/EUDAMED DI and UDI-DI/EUDAMED ID information using the dedicated EUDAMED web interface.</td><td></td></tr>
<tr><td>BR-DTX-UDI-026 : Updatable properties of a Basic UDI-DI / EUDAMED DI</td><td>RESOLVED</td><td>For a Basic UDI-DI / EUDAMED DI the following properties can be updated:

<table>
<tr><th>FLD ID</th><th>Attribute</th><th>MDR</th><th>IVDR</th><th>MDD</th><th>AIMDD</th><th>IVDD</th><th>System and Procedure Pack MDR</th><th>Add</th><th>Update</th><th>Delete</th></tr>
<tr><td>FLD-UDID-15</td><td>Authorised Representative</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td></td><td></td><td>x</td><td></td></tr>
<tr><td>FLD-UDID-260</td><td>Medical Purpose of the System or Procedure Pack</td><td></td><td></td><td></td><td></td><td></td><td>x</td><td></td><td>x</td><td></td></tr>
<tr><td>FLD-UDID-20</td><td>Device Model</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td></tr>
<tr><td>FLD-UDID-22</td><td>Device Name</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td></tr>
<tr><td>FLD-UDID-50</td><td>Clinical Investigations associated to the Basic UDI</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td></td><td>x</td><td>x</td><td>x</td></tr>
</table></td><td></td></tr>
<tr><td>BR-DTX-UDI-031 : Non-updatable fields of a UDI-DI / EUDAMED-ID</td><td>RESOLVED</td><td>For an UDI-DI / EUDAMED-ID the following fields are not updatable / conditionally updatable:

<table>
<tr><th>FLD ID</th><th>Attribute</th><th>MDR</th><th>IVDR</th><th>MDD</th><th>AIMDD</th><th>IVDD</th><th>System and Procedure Pack MDR</th><th>Note</th></tr>
<tr><td>FLD-UDID-145</td><td>Basic UDI-DI Identifier</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td></td></tr>
<tr><td>FLD-UDID-292, FLD-UDID-135</td><td>Unit of Use DI</td><td>x</td><td>x</td><td></td><td></td><td></td><td></td><td>Conditionally updatable: Value for this field can be provided during device update. Once added this field cannot be further updated.</td></tr>
<tr><td>FLD-UDID-293, FLD-UDID-136</td><td>Secondary UDI - DI code</td><td>x</td><td>x</td><td></td><td></td><td></td><td>x</td><td>Conditionally updatable: Value for this field can be provided during device update. Once added this field cannot be further updated.</td></tr>
<tr><td>FLD-UDID-294, FLD-UDID-138</td><td>Direct Marking UDI-DI</td><td>x</td><td>x</td><td></td><td></td><td></td><td></td><td>Conditionally updatable: Value for this field can be provided during device update. Once added this field cannot be further updated.</td></tr>
<tr><td>FLD-UDID-163</td><td>Reference / Catalogue Number</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td></td></tr>
<tr><td>FLD-UDID-151</td><td>Quantity of Device</td><td>x</td><td>x</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>FLD-UDID-146</td><td>Clinical Sizes</td><td>x</td><td></td><td>x</td><td>x</td><td></td><td></td><td></td></tr>
<tr><td>FLD-UDID-156</td><td>Containing latex</td><td>x</td><td></td><td>x</td><td>x</td><td></td><td></td><td></td></tr>
<tr><td>FLD-UDID-167</td><td>Labelled as single use</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td></td><td></td></tr>
<tr><td>FLD-UDID-157</td><td>Maximum number of reuses</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td></td><td></td></tr>
<tr><td>FLD-UDID-169</td><td>Device labelled sterile</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td></td></tr>
<tr><td>FLD-UDID-170</td><td>Need for sterilisation before use</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td></td></tr>
<tr><td>FLD-UDID-164</td><td>Reprocessesed single use device</td><td>x</td><td></td><td>x</td><td>x</td><td></td><td></td><td></td></tr>
<tr><td>FLD-UDID-147</td><td>Intended purpose other than medical (Annex XVI)</td><td>x</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
</table></td><td></td></tr>
<tr><td>BR-DTX-UDI-032 : A Device/SPP can be submitted by a Manufacturer/ Producer only in his name</td><td>RESOLVED</td><td>The Manufacturer or Producer for which the Device/ System or Procedure Pack will be registered is the same as the one submitting the message.

(DeviceBasicUDI.MFActorCode == Push::NodeType.nodeActorCode in case of Devices or PRBasicUDI.PRActorCode == Push::NodeType.nodeActorCode in case of System or Procedure Packs)</td><td></td></tr>
</table>

<table>
<tr>
<td>BR-DTX-UDI-033 : Non-updatable fields of a Basic UDI-DI / EUDAMED-DI</td>
<td>RESOLVED</td>
<td>For a Basic UDI-DI / EUDAMED-DI the following fields are <u>not updatable:</u>
<table>
<tr><th>FLD ID</th><th>Attribute</th><th>MDR</th><th>IVDR</th><th>MDD</th><th>AIMDD</th><th>IVDD</th><th>System and Procedure Pack MDR</th></tr>
<tr><td>FLD-UDID-261</td><td>Type of System or Procedure Pack</td><td></td><td></td><td></td><td></td><td></td><td>x</td></tr>
<tr><td>FLD-UDID-12</td><td>Is it a System which is a Device in itself, Procedure pack which is a Device in itself</td><td>x</td><td></td><td>x</td><td>x</td><td></td><td></td></tr>
<tr><td>FLD-UDID-356</td><td>Is it a Kit</td><td></td><td>x</td><td></td><td></td><td>x</td><td></td></tr>
<tr><td>FLD-UDID-13</td><td>Special Device Type</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td></td></tr>
<tr><td>FLD-UDID-16</td><td>Risk Class</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td></tr>
<tr><td>FLD-UDID-28</td><td>Active Device</td><td>x</td><td></td><td>x</td><td>x</td><td></td><td></td></tr>
<tr><td>FLD-UDID-29</td><td>Device Intended to administer and/or Remove medicinal product</td><td>x</td><td></td><td>x</td><td>x</td><td></td><td></td></tr>
<tr><td>FLD-UDID-30</td><td>Implantable</td><td>x</td><td></td><td>x</td><td>x</td><td></td><td></td></tr>
<tr><td>FLD-UDID-265</td><td>Is it Device a suture, staple, dental filling, dental brace (...)?</td><td>x</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>FLD-UDID-31</td><td>Measuring Function</td><td>x</td><td></td><td>x</td><td>x</td><td></td><td></td></tr>
<tr><td>FLD-UDID-32</td><td>Reusable Surgical Instruments</td><td>x</td><td></td><td>x</td><td>x</td><td></td><td></td></tr>
<tr><td>FLD-UDID-33</td><td>Companion Diagnostic</td><td></td><td>x</td><td></td><td></td><td>x</td><td></td></tr>
<tr><td>FLD-UDID-35</td><td>Near Patient Testing</td><td></td><td>x</td><td></td><td></td><td>x</td><td></td></tr>
<tr><td>FLD-UDID-36</td><td>Patient Self Testing</td><td></td><td>x</td><td></td><td></td><td>x</td><td></td></tr>
<tr><td>FLD-UDID-262</td><td>Reagent</td><td></td><td>x</td><td></td><td></td><td>x</td><td></td></tr>
<tr><td>FLD-UDID-263</td><td>Professional Testing</td><td></td><td>x</td><td></td><td></td><td>x</td><td></td></tr>
<tr><td>FLD-UDID-264</td><td>Instrument</td><td></td><td>x</td><td></td><td></td><td>x</td><td></td></tr>
<tr><td>FLD-UDID-23</td><td>Tissues and cells - presence of human tissues or cells, or their derivates</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td></td></tr>
<tr><td>FLD-UDID-18</td><td>Tissues and cells - Presence of animal tissues or Cells, or their derivates</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td></td></tr>
<tr><td>FLD-UDID-34</td><td>Tissues and cells - Presence of cells or substances of microbial origin</td><td></td><td>x</td><td></td><td></td><td>x</td><td></td></tr>
<tr><td>FLD-UDID-155</td><td>Presence of a substance which , if used separately, may be considered to be a medicinal product derived from human blood or plasma</td><td>x</td><td></td><td>x</td><td>x</td><td></td><td></td></tr>
<tr><td>FLD-UDID-158</td><td>Presence of substance which, if used separately, may be considered to be a medicinal product</td><td>x</td><td></td><td>x</td><td>x</td><td></td><td></td></tr>
<tr><td>FLD-UDID-39</td><td>Device Certificate Information associated to the Device</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td></td></tr>
<tr><td>FLD-UDID-37</td><td>AR Comments</td><td>x</td><td>x</td><td>x</td><td>x</td><td>x</td><td></td></tr>
</table>
</td>
<td></td>
</tr>
<tr>
<td>BR-DTX-UDI-034 : New version is created when a new Basic UDI/ EUDAMED DI or UDI-DI/EUDAMED ID entity is submitted</td>
<td>RESOLVED</td>
<td>When a new (or an update of) Basic UDI/EUDAMED DI or UDI-DI/EUDAMED ID entity is submitted in EUDAMED, a new version of the Basic UDI-DI/EUDAMED DI or UDI-DI/ EUDAMED ID will be created (and of the associated items).</td>
<td></td>
</tr>
<tr>
<td>BR-DTX-UDI-035 : Version state for the Basic UDI / EUDAMED DI and UDI-DI/ EUDAMED ID submitted through Data Exchange</td>
<td>RESOLVED</td>
<td>When a new entity (Basic UDI or UDI-DI) is submitted in EUDAMED for a Regulation Device, the version state will be :

• SUBMITTED :
  ◦ (when a Basic UDI-DI is provided) if the Basic UDI-DI provided requires a validation from NB
  ◦ (when an (Master) UDI-DI is provided) if the (Master) UDI-DI provided is attached to a Basic UDI-DI being in the SUBMITTED state
• REGISTERED:
  ◦ (when a Basic UDI-DI is provided) if the Basic UDI-DI provided does not require a validation from NB;
  ◦ (when an (Master) UDI-DI is provided) if the (Master) UDI-DI provided is attached to a Basic UDI-DI being in REGISTERED state

Basic UDI-DI and UDI-DI for System or Procedure Packs will have the state REGISTERED when being submitted in EUDAMED .

EUDAMED DI and UDI-DI/ EUDAMED ID for Legacy Devices will have the state REGISTERED when being submitted in EUDAMED .

When a new version of an entity (Basic UDI-DI/ EUDAMED DI or (Master) UDI-DI/EUDAMED ID) is submitted in EUDAMED, as a result of an update of that entity, the version State will be always REGISTERED;</td>
<td></td>
</tr>
<tr>
<td>BR-DTX-UDI-036 : When performing an update of the Basic UDI or UDI-DI, the version provided in the message is the latest version of the entity registered in EUDAMED</td>
<td>RESOLVED</td>
<td>The version provided in the message (BasicUDIType.version or UDIDIDataType.version) of the entity being updated (Basic UDI, UDI-DI , Market Info , Container Package) will be processed according to the following algorithm:

If version == 0 then

EUDAMED will increment with 1 the entity version without validation against the current version in EUDAMED.

else if payload.entity.version == 1 then An error will be returned

else if version > 1 then

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

UDIDIDataType.version == Current Eudamed Version +1</td>
<td></td>
</tr>
<tr>
<td>BR-DTX-UDI-037 : An update of the UDI-DI can be performed only for a UDI-DI being registered in EUDAMED</td>
<td>RESOLVED</td>
<td>UDI-DI (UDIDDIDataType.identifier) and the Basic UDI (DeviceBasicUDI.identifier) must be already registered in EUDAMED.

UDI-DI must have the version state of the latest version as [REGISTERED]</td>
<td></td>
</tr>
<tr>
<td>BR-DTX-UDI-077: Providing Comments in several languages for Storage and Handling Conditions when uploading a Device or System or Procedure Pack</td>
<td>RESOLVED</td>
<td>If Storage/handling conditions type has value Other, comments can be provided in several Languages.

For all other options (any other option selected in the Storage/handling conditions type field), comments can be provided only in one language, having the value "ANY"</td>
<td></td>
</tr>
</table>

BR-DTX-UDI-078: Providing Comments in several languages for Critical Warnings when uploading a Device or System or Procedure Pack	RESOLVED	If Critical Warnings type (warningValue) has value Other, comments can be provided in several Languages. For all other options (any other option selected in the Critical Warnings type (warningValue) field), comments can be provided only in one language, having the value "ANY"	
BR-DTX-UDI-079: Registeration of Devices (Regulation or Legacy) can be performed only by the Manufacturer	RESOLVED	Only users associated with an Actor being of type Manufacturer can register Devices (Regulation or Legacy)	
BR-DTX-UDI-080: Registeration of System or Procedure Packs can be performed only by the Producer	RESOLVED	Only users associated with an Actor being of type Producer (System or Procedure Pack Producers) can register System or Procedure Packs	
BR-DTX-UDI-084: Submitting Substances being of type Medicinal product when uploading a Device	RESOLVED	Substances being Medicinal Products (Presence of a substance which, if used separately, may be considered to be a medicinal product) can be submitted only if the flag medicinalProductCheck from the Basic UDI (MDRBasicUDI) has value True (medicinalProductCheck==TRUE). When medicinalProductCheck==TRUE then it is mandatory to provide at least one substance being medicinal product.	
BR-DTX-UDI-085: Submitting Substances being of type Human product when uploading a Device	RESOLVED	Substances being Human Products (Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma) can be submitted only if the flag humanProductCheck from the Basic UDI (MDRBasicUDI) has value True (humanProductCheck ==TRUE) When humanProductCheck==TRUE then it is mandatory to provide at least one substance being human products.	

BR-DTX-UDI-096 : Market Information can be added /updated for an existing (Master) UDI-DI being in state Registered	RESOLVED	Followings validations shall be performed:
		
		• UDI-DI is in state Registered and the following data is provided
		  ◦ DICode
		  ◦ Issuing entity
		• Entity version (mandatory)
		• country a value from the ENUM (https://webgate.ec.europa.eu/tools/eudamed/dtx/data/Entity/Common/CountryEnum.xsd#EUCountryWithSpecialEnum)
		• originalPlacedOnTheMarket (True/False)
		• startDate (optional)
		• endDate (optional)	

BR-DTX-UDI-097 : Only one version of Market information can be added for a UDI-DI in a payload	RESOLVED	A Market information version can be submitted only once for a Device (UDI-DI/EUDAMED-ID) in a payload	
BR-DTX-UDI-098 : A Country can be specified only once in a Market information	RESOLVED	A Market information version can be submitted only once for a Device (UDI-DI/EUDAMED-ID) in a payload	
BR-DTX-UDI-099 : No device found	RESOLVED	BR-DTX-UDI-099 : No device found - No (Master) UDI-DI has been found for the given issuing agency.	
BR-DTX-UDI-100 : Not a EU country	RESOLVED	BR-DTX-UDI-100 : Not a EU country - The country code provided is not an EU country.	
BR-DTX-UDI-101 : The country where the device has been first placed on the EU market cannot be changed during MarketInfo updates.	RESOLVED	BR-DTX-UDI-101 : The country where the device has been first placed on the EU market cannot be changed during MarketInfo updates. Please utilise the UDI-DI update service in order to update the first country where the device has been placed on the EU market.	

BR-DTX-UDI-102 : Container package information can be added/updated for an existing (Master) UDI-DI being in state Registered	RESOLVED	Followings validations shall be performed:
		
		• (Master) UDI-DI is in state Registered and the following data is provided:
		• packages
		  ◦ package
		  ◦ version - container package entity version
		  ◦ identifier - container package identifier
		
		• ◦ ▪ DICode
		  ▪ issuingEntityCode
		  ◦ status
		  ▪ code - BR-UDID-804 : Contained Item Status - ENUM_UDID_ContainedItemStatus
		  ◦ child
		  ▪ DICode
		  ▪ issuingEntityCode
		  ◦ numberOfItems	

BR-DTX-UDI-103 : Update of the country where the device has been first placed on the EU market	RESOLVED	During the update of the country where the device has been placed on the EU market the system must ensure that the country provided in the payload is within the list of existing countries in the last version of the Market information.	
BR-DTX-UDI-104 : Validate Type of UDI-PI for Special Device (MDR, IVDR)	RESOLVED	When the value of FLD-UDID-148 productionIdentifier is SOFTWARE_IDENTIFICATION then the system shall validate that the FLD-UDID-13 specialDevice is • MDR_SOFTWARE or • IVDR_SOFTWARE	
BR-DTX-UDI-105 : Update of Market Information will be perfomed only via Update Market Information service	RESOLVED	BR-DTX-UDI-105 : Update of Market Information is allowed only via Update Market Information service. Please use the update of market information service in order to update market information of an UDI-DI or EUDAMED-ID.	
BR-DTX-UDID-086 : When submitting a Device containing Product Designer provided as an Organisation, information about the GPS Coordinates, National Trade Registry and Organisation Short Name must not be provided	RESOLVED	When the Product Designer is provided as an Organisation, information about the GPS Coordinates, National Trade Registry and Organisation Short Name must not be provided	
BR-DTX-UDID-087 : When submitting a Device having a Product Designer either the SRN or the Organisation details can be provided	RESOLVED	Product Designer can be given either as a reference to an existing Manufacturer (SRN) or as Organisation details. (Either PDSRN or the productDesignerOrganisation must be provided)	
BR-DTX-UDID-088 : When submitting a Device, CertificateLinks information cannot be provided	RESOLVED	CertificateLinks entities cannot be provided when registering the Device. They contain the details of Certificates referencing the Device. Note: DeviceCertificateInformation entity contains the initial Certificate Information provided by the Manufacturer with the Device	

BR-DTX-UDID-089 : Properties that must not be provided (are not applicable) when submitting a Legacy Device	RESOLVED	When submitting a Legacy Device having the Applicable Legislation MDD or AIMDD the following entities and properties cannot be submitted : • DeviceUDIDIDataType.deviceMarking (Direct Marking DI or Unit of Use DI information); • DeviceUDIDIDataType.baseQuantity (base quantity of Device); • CMRSubstanceType or EndocrineSubstanceType (CMR and Endocrine substances); • UDIDIDataType.productionIdentifier (Type of UDI-PI); • MDRUDIDIData.annexXVINonMedicalDeviceTypes (attribute Annex XVI); • UDIDIDataType.packages (Container Packages); When submitting a Legacy Device having the Applicable Legislation IVDD the following entities and properties cannot be submitted : • DeviceUDIDIDataType.deviceMarking (Direct Marking DI or Unit of Use DI information); • DeviceUDIDIDataType.baseQuantity (base quantity of Device); • UDIDIDataType.productionIdentifier (Type of UDI-PI); • UDIDIDataType.packages (Container Packages); Mentioned properties are only applicable in case of Regulation Devices. When submitting a Regulation Device having the Applicable Legislation MDR or IVDR the following entities are required to be provided : • DeviceUDIDIDataType.baseQuantity (Base quantity of Device); • UDIDIDataType.productionIdentifier (Type of UDI-PI);	
BR-DTX-UDID-090 : Providing Language ANY for Language specific fields in UDI Device Module	RESOLVED	When submitting a Device (Regulation or Legacy) or a System or Procedure Pack in EUDAMED, language ANY can be used when submitting the following property: Trade-Names.	
BR-DTX-UDID-091 : Providing Several entries in the same Language	RESOLVED	When submitting a Device (Regulation or Legacy) or a System or Procedure Pack in EUDAMED, several Language-specific properties can be submitted. For several of these properties, only one entry per language is acceptable. Properties that accept only one entry per language : • Additional product description • Storage and Handling Condition Description - when option Other is selected; • Critical Warnings - when option Other is selected; • CMR substances - when EC or CAS Code is not provided • Endocrine -discruption substances - when EC or CAS Code is not provided • Presence of substances that may be considered to be a medicinal product- when INN is not provided • Presence of substances that may be considered to be a medicinal product derived from human blood or plasma - when INN is not provided Device Trade-Name can be provided several times in same language (no constraints imposed)	
BR-DTX-UDID-093 : When submitting a (Master) UDI-DI/ EUDAMED ID update, EUDAMED will perform a consistency check of several attributes	RESOLVED	When submitting an update of a (Master) UDI-DI/ EUDAMED ID EUDAMED will perform a consistency check for the following fields (value must be the same between the newly submitted version and the last version existing in EUDAMED) • Quantity of Device • 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)	
BR-DTX-UDID-093.1 : Update of product original manufacturer information	RESOLVED	Update of product original manufacturer information will be performed only via the 'Update of product original manufacturer' service	
BR-DTX-UDID-094 : Providing Language is optional in case of some Language Specific fields from UDI-DI	RESOLVED	Providing the Language is optional for the following attributes : Storage and Handling Conditions, Critical Warnings comments and Substances (CMR or Endocrine substances). In case of Storage and Handling Conditions and Critical Warnings, not providing the language for the Comments is applicable only when the Storage and Handling Conditions or Critical Warning value (type) is different than the value OTHER. In these cases, no language needs to be provided. In case of CMR and Endocrine Substances, if EC or CAS Code are provided for the Substance - the Substance name must be provided without any Language. If no CAS or EC Code is provided then the Name of the Substance must have the Language other than ANY.	
BR-DTX-UDID-095 : A (Master) UDI-DI can be added only for an existing Basic UDI-DI being in state Submitted or Registered	RESOLVED	Additional (Master) UDI-DIs can be added for Regulation Devices or additional UDI-DIs can be added for System or Procedure Packs, when the Basic UDI is in state Submitted or Registered	
BR-DTX-UDID-096 : Market information can be submitted with the Update UDI-DI service only in case the Country where the Device is initially placed on the market is updated	RESOLVED	Market information can be submitted with the Update UDI-DI service only in case the ***Country where the Device is initially placed on the market*** is updated When submitting the Market information together with the UDI-DI, the Market information version will be updated	
BR-DTX-UDID-102.1 : Registration/update of container packages will be perfomed only via 'Update container package' service	RESOLVED	Registration/update of container packages will be perfomed only via Update container package service.	
BR-DTX-UDID-106 : Product original manufacturer information can be updated for an existing (Master) UDI-DI/EUDAMED ID being in state Registered	RESOLVED	Product original manufacturer information can be updated only if the (Master) UDI-DI / EUDAMED ID is in state Registered.	
BR-DTX-UDID-730: Master UDI-DI properties applicability	RESOLVED	When registering or updating a Master UDI-DI the following properties are not applicable or will have a pre-set value: • unitOfUseIdentifier - will not be provided in the payload. • directMarkingDI - will not be provided in the payload. • annexXVINonMedicalDeviceTypes for a Master UDI-DI can have only one value (True or False).	

BR-UDID-718 : When the Product Designer is provided as an Organisation, only one Organisation Name can be provided	RESOLVED	When the Product Designer is provided as an Organisation, only one Organisation Name can be provided and the Language in which is given must be "ANY"	

Download Devices and System or Procedure Packs

Identifier	Status	Description	Previously used
BR-DTX-UDI-001 : Download Basic UDI/ EUDAMED DI information	RESOLVED	As a NB (NB DTX Actor), CA (CA DTX Actor) I must be able to download a paginated list of Registered or Submitted Basic UDIs / EUDAMED DIs information (Basic UDIs/ EUDAMED DIs in REGISTERED and SUBMITTED state) together with the associated UDI-DIs/ EUDAMED IDs. The Authorised Representative(AR DTX Actor) can download only Registered Basic UDIs / EUDAMED DIs information to which they are linked, together with the associated UDI-DIs/ EUDAMED IDs. The Manufacturer (MF DTX Actor), Producer (PR DTX Actor), can download only their own Registered Basic UDIs / EUDAMED DIs information together with the associated UDI-DIs/ EUDAMED IDs	
BR-DTX-UDI-002 : Download registered Basic UDI-DI object structure (main entity and related entities)	RESOLVED	A Basic UDI-DI object shall contain the following details : • Basic UDI-DI information (EUDAMED DI information in case of Legacy Devices) {BasicUDI.State="REGISTERED/SUBMITTED "} • Device Certificate Information (if existing) • Certificate link (if existing) • Clinical investigation link (if existing)	
BR-DTX-UDI-004 : DTX message request to download a criteria queried list of registered Basic UDI/EUDAMED DI information	RESOLVED	In the context of a Basic UDI/ EUDAMED DI download request, a user must be able to submit a queried request to download a paginated list of registered /submitted Basic UDI/EUDAMED DI information. The supported query criteria: • Manufacturer / Producer Actor Code (BasicUDI.MFCode) • Authorized Representative Code (BasicUDI.ARCode) • Basic UDI Code (EUDAMED DI in case of Legacy Devices) (BasicUDI. identifier.DICode) • Basic UDI version date (EUDAMED DI version date in case of Legacy Devices)(BasicUDI.BasicUDIVersionDate) • Risk Class (BasicUDI.RiskClass) • Applicable Legislation (BasicUDI.ApplicableLegislation) • Notified Body (DeviceCertificateInformation.NBActorCode / CertificateLink. CertificateIdentifierLinkType.NBActorCode) • Competent Authority (responsible for the Manufacturer / Producer Actor) • State (BasicUDI.state)	
BR-DTX-UDI-005 : Download registered Basic UDIs/ EUDAMED DIs object versions	RESOLVED	Registered Basic UDI/ EUDAMED DI download object list will contain the latest versions being in status Registered of the Basic UDI-DIs/ EUDAMED DIs corresponding to the applied criteria	
BR-DTX-UDI-007 : Download Basic UDIs /EUDAMED DIs object list pagination	RESOLVED	Registered Basic UDI/EUDAMED DI download object list should be paginated with max of 300 items per response. Also a limitation on accepted maximum size of message is applicable.	
BR-DTX-UDI-008 : Registered Basic UDI / EUDAMED DI download list - unique identifier	RESOLVED	Registered Basic UDI / EUDAMED DI download XML should contain entities having a unique identifier object of type DIIdentifier, except the case when multiple version of the same object are requested.	
BR-DTX-UDI-011 : Download UDI-DI / EUDAMED ID information	RESOLVED	As an NB (NB DTX Actor), CA (CA DTX Actor),I must be able to download a paginated list of Registered or Submitted UDI-DI/EUDAMED ID information together with the Basic UDIs / EUDAMED DIs details associated with the UDI-DIs/ EUDAMED ID. The Authorised Representative (AR DTX Actor), can download only Registered UDI-DIs or EUDAMED IDs to which they are linked, together with the Basic UDIs /EUDAMED DIs details associated with the UDI-DIs/EUDAMED IDs . The Manufacturer (MF DTX Actor), Producer (PR DTX Actor), can download only their own Registered UDI-DIs or EUDAMED IDs together with the Basic UDIs /EUDAMED DIs details associated with the UDI-DIs/EUDAMED IDs .	

BR-DTX-UDI-012 : Download registered UDI-DI/ EUDAMED ID object structure (main entity and related entities)	RESOLVED	A UDI-DI/EUDAMED DI download object shall contain the details : • UDI -DI (or EUDAMED ID in case of Legacy Devices) data information {UDI-DI.State = "REGISTERED/SUBMITTED "} • Market info (if existing) • Product original manufacturer (if existing) • Package information (if existing)	
BR-DTX-UDI-014 : DTX message request to download a criteria queried list of UDI-DIs /EUDAMED IDs information	RESOLVED	In the context of a UDI-DI download request, a user may be able to submit a queried request to download a paginated list of of registered / submitted UDI-DIs information. The supported query criteria : • UDI-DI Code (or EUDAMED ID in case of Legacy Devices) (UDIDIData:: identifier.DICode) • UDI-DI version Date (or EUDAMED ID version Date in case of Legacy Devices) (UDIDI.versionDate) • Country (UDIDI.country) • State (UDIDI.state) In addition to the mentioned criteria`s the criteria`s, the criteria applicable for Basic UDI/ EUDAMED DI can be also used.	
BR-DTX-UDI-015 : Download UDI-DIs object version	RESOLVED	Registered UDI-DI/ EUDAMED ID download object list will contain the latest versions being in status Registered of the UDI-DIs/ EUDAMED IDs corresponding to the applied criteria	
BR-DTX-UDI-017 : Download UDI-DIs/EUDAMED IDs object list pagination	RESOLVED	UDI-DIs/EUDAMED IDs download object list should be paginated with max of 300 items per response. Also a limitation on accepted maximum size of message is applicable.	
BR-DTX-UDI-018 : Download UDI-DI/ EUDAMED ID list - unique identifier	RESOLVED	UDI-DI/ EUDAMED ID download XML should contain entities having a unique identifier object of type DIIdentifier, except the case when multiple versions of the same object are requested.	
BR-DTX-UDI-024 : Bulk dowload of a Basic UDI /EUDAMED DI and UDI-DI/EUDAMED ID list of entities	RESOLVED	As a Manufacturer (MF VIEWER), Producer (PR VIEWER), AR (AR VIEWER), NB (NB VIEWER), CA (CA VIEWER), a EUDAMED authenticated user must be able to download a list of Basic UDI/EUDAMED DI and UDI-DI/EUDAMED ID information using the dedicated EUDAMED web interface. As a NB (NB VIEWER), CA (CA VIEWER) I must be able to download a paginated list of Registered or Submitted Basic UDIs / EUDAMED DIs information (Basic UDIs/ EUDAMED DIs in REGISTERED and SUBMITTED state) together with the associated UDI-DIs/ EUDAMED IDs. The Authorised Representative(AR VIEWER Actor) can download only Registered Basic UDIs / EUDAMED DIs information to which they are linked, together with the associated UDI-DIs/ EUDAMED IDs. The Manufacturer (MF VIEWER), Producer (PR VIEWER), can download only their own Registered Basic UDIs / EUDAMED DIs information together with the associated UDI-DIs/ EUDAMED IDs	
BR-DTX-UDI-027 : State Criteria allowed values	RESOLVED	State Search Criteria can have values :"SUBMITTED" or "REGISTERED" Value "Submitted" can only be applied by CAs and NBs. If no value is provided for the State Search Criteria, by default REGISTERED Devices will be returned	
BR-DTX-UDI-029 : Version Date Search Criteria	RESOLVED	Version Date search Criteria returns all Basic UDI-DIs/EUDAMED DIs or UDI-DIs /EUDAMED IDs versions having the Last Update Date, with a date higher (greater) than the date provided in the search criteria.	
BR-DTX-UDI-050 : "AND" condition applied between the Search Criteria`s	RESOLVED	"AND" condition applied between the Search Criteria`s	
BR-DTX-UDI-053 : Entire value required to be provided - no wildcards	RESOLVED	SRN , Basic UDI-DI Code, UDI-DI Code, NRD Code filters require the entire value of the Code to be provided. No wildcards are applicable.	
BR-DTX-UDI-054 : Basic UDI-DI (EUDAMED DI) and UDI-DI(EUDAMED ID) values provided as filters must exist in EUDAMED	RESOLVED	Basic UDI-DI (/EUDAMED DI) and UDI-DI (/EUDAMED ID) value filters must exist in EUDAMED	
BR-DTX-UDI-064 : Only one value can be provided per filter	RESOLVED	Only one value can be provided per filter	
BR-DTX-UDI-065 : Manufacturer/ Producer Actors can download only own Devices/ System or Procedure Packs	RESOLVED	Manufacturer and Producer Actor will only be able to download their own Devices (Regulation or Legacy)/SPPs. Manufacturer/Producer filter will be required to be provided for requests coming from Manufacturer and Producer Actor and will be required to have the same value as the one of the Actor submitting the request.	

BR-DTX-UDI-068 : Filtering criteria`s UDI-DI Version - From Date requires additional criteria`s to be applied	RESOLVED	Search criteria UDI-DI Version - From Date requires at least one of the following additional filters to be applied: Manufacturer or Producer Actor Code or Authorised Representative Code	
BR-DTX-UDI-069 : At least one search criteria	RESOLVED	At least one search criteria needs to be provided in for downloading registered Devices or System or Procedure Packs.	
BR-DTX-UDI-070: Authorised Representative Actors can download only Devices to which they are linked	RESOLVED	Authorised Representative Actor will only be able to download Devices to which they are linked. Authorised Representative filter will be required to be provided for requests coming from Authorised Representatives and will be required to have the same value as the one of the Actor submitting the request.	
BR-DTX-UDI-076: Provided download criteria Manufacturer, Producer (System or Procedure Pack Producer) or Authorised Representative Code must exist in EUDAMED	RESOLVED	Provided download criteria Manufacturer, Producer (System or Procedure Pack Producer) or Authorised Representative Code must exist in EUDAMED	

Download SS(C)P

Identifier	Status	Description	Previously used
BR-DTX-UDI-200: M2M/bulk download - at least one criterion to be provided	RESOLVED	When requesting M2M or bulk download of SS(C)P records the system will ensure that at least one criterion is provided. Note: SS(C)P revision number as a stand-alone criterion will not be accepted.	
BR-DTX-UDI-202: Only one value per criterion will be accepted	RESOLVED	Only one value per criterion will be accepted. No wildcards.	
BR-DTX-UDI-203: Limited results for MF/AR when downloading SS(C)P records through M2M/Bulk	RESOLVED	Manufacturer and Authorised Representatives will be able to download only those SS(C)P records which contain Basic UDI-DI(s) linked to the Manufacturer and respectively to the Authorised representatives.	

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Identifier	Status	Description	Previously used
BR-DTX-UDI-020 : Update Basic UDI entity fields	RESOLVED	In the context of an update of a basic UDI entity, a user must be able to update only specific Basic UDI fields (as described in the Data Dictionary for UDI Device). There are no other related entities subject to update.	
BR-DTX-UDI-022 : Update UDI-DI entity fields	RESOLVED	In the context of a update of a UDI-DI entity, a user must be able to update only the UDI-DI fields as stated in the Data Dictionary. There are no other related entites subject to update.	
BR-DTX-UDI-023 : An update of the Market Information can be performed only by owner (MF)	RESOLVED	Owner of the Device for which the update (PUT/PATCH) of the Market Information is performed needs to be the same as the one submitting the request for update (DTXMarketInfo.UDIDIdentifier.basicUDIIdentifier (BasicUDIType).MFActorCode == Push::NodeType.nodeActorCode).	
BR-DTX-UDI-026 : Device Download Search Request default State criteria	RESOLVED	State is a Default criteria applied for downloading Devices.	
BR-DTX-UDI-031 : An update for a Basic UDI or a (Master) UDI-DI can be performed only by owner (Manufacturer/PR)	RESOLVED	Owner of the Device for which the update (PATCH) of the Basic UDI or UDI-DI is performed needs to be the same as the one submitting the request for update. **Basic UDI/EUDAMED DI** DeviceBasicUDI.MFActorCode == Push::NodeType.nodeActorCode *in case of Devices or* PRBasicUDI.PRActorCode == Push::NodeType.nodeActorCode *in case of System or Procedure Packs* **(Master) UDI-DI / EUDAMED ID** UDIDIDataType.basicUDIIdentifier (DeviceBasicUDI).MFActorCode == Push::NodeType.nodeActorCode *in case of Devices or* UDIDIDataType.basicUDIIdentifier (PRBasicUDI).PRActorCode == Push::NodeType.nodeActorCode _in case of System or Procedure Pack_s	

BR-DTX-UDI-033 : An update of the Basic UDI can be performed only for a Basic UDI being registered in EUDAMED	RESOLVED	Basic UDI (DeviceBasicUDI.identifier) must be already registered in EUDAMED and must have the version state of the latest version as [REGISTERED]	
BR-DTX-UDI-038 : An update of the Container Package can be performed only by owner (Manufacturer/PR)	RESOLVED	Owner of the Device for which the update (Put) of the Container Package is performed needs to be the same as the one submitting the request for update (DTXPackageUDIType.udiIdentifier::(UDIDIData).basicUDIIdentifier.MFActorCode == Push::NodeType.nodeActorCode).	
BR-DTX-UDI-039 : When submitting Market Information or Container Package information the referenced UDI-DI must be already exist in EUDAMED	RESOLVED	When submitting Market Information or Container Package information, the (Master) UDI-DI/EUDAMED ID (DTXMarketInfo.udiIdentifier or DTXPackageUDIType. udiIdentifier) for which it is submitted must already exist in EUDAMED.	
BR-DTX-UDI-040 : New version is created when a new Container Package or Market information entity is submitted	RESOLVED	When a new (or an update of) Container Package or Market Info entity is submitted in EUDAMED, a new version of that entity will be created.	
BR-DTX-UDI-060 : An update of the EUDAMED DI can be performed only for a EDUAMED DI being registered in EUDAMED	RESOLVED	EUDAMED DI (EUDI.identifier) must be already registered in EUDAMED and must have the version state of the latest version as [REGISTERED]	
BR-DTX-UDID-092 : When submitting a Basic UDI/ EUDAMED DI update, EUDAMED will perform a consistency check of several attributes	RESOLVED	When submitting an update of a Basic UDI-DI, EUDAMED will perform a consistency check for the following fields (value must be the same between the newly submitted version and the last version existing in EUDAMED) • Is it a System which is a Device in itself, Procedure pack which is a Device in itself • Is it a Kit • Special Device Type (Flag Yes/No and the type of special Device selected) • Risk Class • Active Device • Device Intended to administer and/or Remove medicinal product • Implantable • Is it Device a suture, staple, dental filling, dental brace (...)? • Measuring Function • Reusable Surgical Instruments • Companion Diagnostic • Near Patient Testing • Patient Self Testing • Reagent • Professional Testing • Instrument • Tissues and cells - presence of human tissues or cells, or their derivate • Tissues and cells - Presence of animal tissues or Cells, or their derivate • Tissues and cells - Presence of cells or substances of microbial origin • Presence of a substance which , if used separately, may be considered to be a medicinal product derived from human blood or plasma • Presence of substance which, if used separately, may be considered to be a medicinal product	
BR-DTX-UDID-107 : Download NRD service access rules	RESOLVED	All the following rules apply: 1. Only Competent Authorities, Manufacturers and Authorized Representatives are authorized to access the NRD download service. 2. Manufacturers are authorized to download only their own NRDs. 3. Authorized Representatives are authorized to download their own NRDs and the NRDs owned by the Manufacturers that have authorized the given Authorized Representative to act on their behalf (AR has an active mandate with MF and is authorised to manage Vigilance data). 4. Competent Authorities are authorized to download all NRDs.	

BR-DTX-UDID-108 : Download NRD search criteria and search rules	RESOLVED	Search is performed to find NRDs that match search criteria. 1. General rules for search: 1. Only the latest version of the NRD that matches search criteria must be returned. 2. Only NRDs in 'Submitted' or 'Discarded' state must be returned. 2. Specific rules for search criteria: 1. The exact match search must be performed for provided search criteria *NRD code*, *UDI-DI code* and *Basic UDI-DI code*, see ~~EUDAMEDMDR-5184~~ **BR-DTX-UDI-053 : Entire value required to be provided - no wildcards** 2. Only a single value of those listed in ~~EUDAMEDMDR-2128~~ **BR-EUD-003 : Applicable Legislation - ENUM_MDR_LEG** may be provided as *Applicable legislation* search criterion. 3. Only a single value of those listed in ~~EUDAMEDMDR-2308~~ **BR-UDID-817 : Device Risk Class - ENUM_UDID_RiskClass** may be provided as *Risk class* search criterion. 4. Only a single value of those listed in ~~EUDAMEDMDR-2297~~ **BR-UDID-807 : Device Status** - **ENUM_UDID_DeviceStatus** may be provided as *Device status* search criterion. 5. Only a single value of those listed in ~~EUDAMEDMDR-27381~~ **BR-UDID-827: NRD Version States - ENUM_UDID_NRDVersionStates** may be provided as *S tate* search criterion. 6. Value 'DRAFT' is not permitted to use as *State* search criterion. 7. Search criterion *State* is mandatory (must be provided for every search).	
BR-UDID-052 : Displaying device sub-status	CLOSED	Device sub-status is to be displayed when the Manufacturer owner of the device registers the respective FSN report in the Vigilance module. Similarly, device sub-status will be removed when the respective FSCA report is finalised by the Manufacturer.	
BR-UDID-729: Corrective actions within device sub-status	RESOLVED	Only one corrective action will be displayed within a device sub-status. When the corrective actions per respective FSCA defines two (2) sub-statuses as per BR-VGL-DEV-004 and BR-VGL-DEV-005 then the system will display only the actions that trigger the "Recall" sub-status. The "Product Removal - Full Recall" action precedes "Product Removal - Partial Recall (Lot/Batch/Model)". When both actions are present in the related FSCA the system will display only the "Product Removal - Full Recall".	
BR-VGL-UDID-001 : Device Sub-status	RESOLVED	In EUDAMED will exist two sub-statuses which can be attached to a Device : • Field safety corrective action initiated; • Recalled; Device sub-statuses will be triggered (computed) based on the Vigilance data stored for that device. A device can be referenced in many FSCA(s) reports and in one or many linked FSN(s) but no more then the number of FSCA(s).	
BR-VGL-UDID-002 : Several Sub-Statuses can exist for a Device	RESOLVED	Several Device Sub-Statuses can exist at the same time for a Device in EUDAMED. Each Sub- status will be referencing the respective FSN.	
BR-VGL-UDID-003 : Triggering a new Sub-status for a Device	RESOLVED	A subs-status will be triggered (visible) for a Device when a Final FSN Report referencing that Device is registered and there is at least one FSCA report refereincing the Device that is not in the status "Action completed".	
BR-VGL-UDID-004 : Triggering an FSCA initiated Sub-status for a Device	RESOLVED	An FSCA initiated Sub-status is triggered (visible) for a Device, when the Corrective Actions (Manufacturer Action required) referenced in the FSN report (from the FSCA) for that Device are having one of the values : • IFU or labeling change • Software Upgrade • On-site modification/inspection by • Customer information only • Other	
BR-VGL-UDID-005 : Triggering an Recall Sub-status for a Device	RESOLVED	A Recall Sub-status is triggered (visible) for a Device, when the Corrective Actions (Manufacturer Action required) referenced in the FSN report (from the FSCA) for that Device are having one of the values : • Product Removal - Partial Recall (Lot/Batch/Model) • Product Removal - Full Recall	

BR-VGL-UDID-006 : Closing a Sub-status for a Device	RESOLVED	A subs-status will no longer be visible for a device when the corresponding FSCA report will be in status 'Action completed'. When there are multiple FSCAs opened for the same device then device sub-status will no longer be displayed when all the FSCAs will be in status 'Action completed'.	
RULE-00014: OCM riskClass	RESOLVED	All the following constraints apply: 1. Is mandatory for all *Applicable legislations* except 'None', or 'Unknown'. (IVDR is not applicable). 2. Only one value from the enumeration is allowed; no other values are allowed. Enumeration: ~~**EUDAMEDMDR-2308**~~ **BR-UDID-817 : Device Risk Class - ENUM_UDID_RiskClass** 3. Value must be permitted for the *Applicable legislation* of the given OCM. Permitted values provided below. *(Error message: A value is not permitted for the Applicable legislation of the OCM.)* 4. Values that correspond to legislation 'IVDR' are not permitted for old /custom-made devices. *(Error message: Values corresponding to legislation 'IVDR' are not permitted for old/custom-made devices.)* 5. If the legislation is 'None' or 'Unknown', no value is permitted. *(Error message: A value is not permitted when legislation is 'None' or 'Unknown'.)* 6. May not be updated in the new version of the old/custom-made device.	BR-OCM-017


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