UDI/Device - Business Rules - 2.7

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

Changed

- BR-UDID-113 - BR Update - Added the mention for "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.

5 - Business Rules

Registration of (Basic) UDI-DI

Summary	Status	Description
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, 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 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.
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 Placed on the market country always in list of made available countries if the Member States were the Device is made available in the Country are provided for the current Device
BR-UDID-046 : Countries where placed on the market and made available not applicable for Device not intended for EU market	RESOLVED	If the Manufacturer set the Status of the Device as Not intended for EU market, 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-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'. No Sub-Status is marked by default. When registering a Legacy Device - initial status can be only 'On the Market' When registering a Container Package for the first time initial status can be only 'On the Market'. "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
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-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.
BR-UDID-095 : Mandatory information for the registration of the Legal or Natural person who manufactured / designed the device	RESOLVED	For the registration of the Legal or Natural person who manufactured/designed the device, 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.
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 is mandatory for System or Procedure Packs and Devices which are Systems or Procedure Packs in themselves or KITs	RESOLVED	Providing the Additional Product Description is required for System or Procedure Packs or for Device when the Device is marked as System or Procedure Pack which is a Device in itself (Device is a System or) or when the Device is marked as a KIT
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 in which a Device or SPP can reside. They are treated as sub-statuses (and not statuses) as the Device/SPP ca be at the same time in the status 'On the EU Market' or 'No longer placed on the EU Market' having also incidents reported through VIgilance module, case in which the sub-status 'Recall' or 'FSCA initiated' is applied as well for that Device/SPP. The Status is mandatory for the UDI-DI, but the sub-statuses are mandatory, if applicable. None, only one or both sub - statuses can be marked for a UDI-DI
BR-UDID-635 : 'Devices is being marked as Sutures, Staples, etc.,' property applicable	RESOLVED	Property 'Devices is being marked as Sutures, Staples, etc.' is applicable 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.
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-646 : List of Applicable Legislations for Devices and System or Procedure Pack

RESOLVED

Applicable Legislation valid for a Regulation Device are :

Label	Value	Notes
REGULATION (EU) 2017/745 on medical devices	MDR	
REGULATION (EU) 2017/746 on in vitro diagnostic medical devices	IVDR	

Applicable Legislation valid for a Legacy Device are:

Label	Value	Notes
Council Directive 93/42/EEC on Medical devices	MDD	
Council Directive 90/385/EEC - Approximation of the laws of the Member States relating to active implantable medical devices	AIMDD	
Directive 98/79/EC on in vitro diagnostic medical devices	IVDD	

Applicable Legislation valid for a System or Procedure Pack :

Label	Value	Notes
REGULATION (EU) 2017/745 on medical devices	MDR	

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 and Device intended to administer and/or remove the 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

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Registration of Legacy Devices

Summary	Status	Description
BR-UDID-007 : Devices having the Applicable legislation AIMDD, are by default Implantable and Active Devices	RESOLVED	Devices having AIMDD as Applicable legislation will have implicit the properties Implantable and Active device
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-673 : Member States were the Device is made available in the Country (AIMDD Legislation) Mandatory	RESOLVED	When the Device has Applicable Legislation AIMDD, 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 the Manufacturer will be required to provide EU countries were the Device is made available when entering Device Data

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Manage Devices and System or Procedure Packs

Summary	Status	Description
BR-UDID-048 : Update version 1 of the Basic UDI DI (EUDAMED DI) or UDI-DI (EUDAMED ID) in Draft State	RESOLVED	When updating version 1 of a Basic UDI-DI (EUDAMED DI) in state [Draft], or a 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), 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-052 : Information completed for Sub-statuses Recall and FSCA initiated	RESOLVED	When setting manually the Sub-status of Device to Recall the following elements will be required to be completed by the Manufacturer: • Start Date when the Sub status is registered; • End Date (optional to be completed - is provided at a later moment) • Description/Comments (optional); • Precision; • Scope; When setting manually the Sub-status of Device to FSCA (Field Safety Corrective action) Initiated, the following elements will be required to be completed by the Manufacturer: • Start Date when the Substatus is registered; • End Date (optional to be completed - is provided at a later moment) • Description/Comments (required in case of FSCA) When the Substatus will be set up automatically for the Device from the Vigilance module, the link with the FSN will be stored together with the Sub-status .

BR-UDID-107 : Deleting a version	RESOLVED	Delete operation can be performed only for Basic UDI-DI (/ EUDAMED DI) and/or UDI-DI (/EUDAMED ID) versions which are in the state [DRAFT] or [SUBMITTED] . If the UDI-DI (EUDAMED ID) deleted is the last 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 UDI- DI (EUDAMED ID) in state [Draft] , changes can be performed to all fields from UDI-DI and associated data : Product Designer, Market Information or Package Structure.
BR-UDID-622 : Restriction on Discarding a Basic UDI-DI	RESOLVED	A Basic UDI-DI cannot be discarded if it is referenced in other places of the system , such as Certificates or Vigilance reports.
BR-UDID-624 : Discarding Registered UDI-DI (EUDAMED ID)	RESOLVED	Discarding UDI-DI (EUDAMED ID) can be performed for UDI-DI (EUDAMED ID) in state Registered (for Devices or System or Procedure Packs). When discarding a UDI-DI (EUDAMED ID) the states of all the versions of the UDI-DI (EUDAMED ID) will be 'Discarded' (state of the version set to Discarded). If the UDI-DI is the last 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 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 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 Designer	RESOLVED	Product Designer information can be updated only if it has been defined as an Organisation. Details regarding Product Designer (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 Designer 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 UDI-DI in status Registered without creating a new version of the 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. *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-685: Editing a version of the Basic UDI-DI (/EUDAMED DI) or UDI-DI(/EUDAMED ID)	RESOLVED	Edit operation can be performed for Basic UDI-DI (/ EUDAMED DI) and/or UDI-DI (/EUDAMED ID) versions which have the state in [DRAFT]. Note : Creating a new version for the Basic UDI-DI/ EUDAMED DI or 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 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.

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Certificate Rules

Summary	Status	Description
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 the BASIC UDI DI / UDI DI data, for a device that is subject to Article 29.3 (MDR Legislation), user will be required to specify : • Type of product certificate associated with the device ; • Notified Body that issued the Certificate; • Certificate ID of the Certificate (optional); • Revision Number (optional); For MDR Devices having device Risk Class III or IIb implantable and non sutures (implantable = true and Sutures, Staples=false) - user will be required to manually provide the Type of Certificate (Technical Documentation Examination Certificate or Type Examination Certificate) the Notified Body Id of the Notified Body that issued the Certificate and optional the Certificate ID of the Certificate and the Revision Number. For MDR Devices having device Risk Class IIb non implantable (implantable = false) or Risk Class IIb implantable which are sutures (implantable = true and Staples, Sutures= true) - user will be required to specify if a Technical Documentation Examination Certificate is covering the Device and if yes provide the Notified Body Id of the Notified Body that issued the Certificate and optional the Certificate ID of the Certificate and the Revision Number. If the Technical Documentation Examination certificate is not applicable, certificate information will not be provided. After the Submission of information, the BASIC UDI DI and UDI DI status will be set to Submitted until the Device Data is Confirmed by the Notified Body (when registering the Certificate). After the confirmation is given by the Notified Body, the state of Basic UDI-DI and UDI-DIs linked to it is set to Registered.

BR-UDID-110 : Register Certificate Information when Submitting the BASIC UDI and UDI DI information for Devices subject to Article 26.2 (IVDR)	RESOLVED	When submitting the BASIC UDI DI / UDI DI data, for a device that is subject to Article 26.2 (IVDR Legislation), user will be required to specify : • Type of product certificate associated with the device ; • Notified Body that issued the Certificate; • Certificate ID of the Certificate (optional); • Revision Number (optional); For IVDR Devices having device Risk Class D or C being for self or near patient testing (self testing = Yes or near patient testing=Yes) - user will be required to manually provide the Type of Certificate (Technical Documentation or Type Examination Certificate) the Notified Body Id of the Notified Body that issued the Certificate and optional the Certificate ID of the Certificate and the Revision Number. For IVDR Devices having device Risk Class C not being for self or near patient testing (self testing = No and near patient testing = No) - user will be required to manually provide the details of the Type Examination certificate (if applicable) - the Notified Body Id of the Notified Body that issued the Certificate and optional the Certificate ID of the Certificate and the Revision Number. If the Type Examination certificate is not applicable, , certificate information will not be provided. For IVDR Devices having device Risk Class B being for self or near patient testing (self testing = Yes or near patient testing = Yes) - user will be required to manually provide the details of the Technical Documentation certificate (if applicable) - the Notified Body Id of the Notified Body that issued the Certificate and optional the Certificate ID of the Certificate and the Revision Number. If the Technical Documentation certificate is not applicable, certificate information will not be provided. After the Submission of information, the BASIC UDI DI and UDI DI status will be set to Submitted until the Device Data is Confirmed by the Notified Body (when registering the Certificate). After the confirmation is given by the Notified Body, the state of Basic UDI-DI and UDI-DIs linked to it is set 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 Issue Date ; • 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.

4 issues

Search and View

Summary	Status	Description
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] stat e 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

4 issues

Upload SS(C)P

Summary	Status	Description
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

7 issues

Link Regulation Device to a Legacy Device

Summary	Status	Description
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 Only one Legacy Device can be linked to a Regulation Device (and vice versa)	RESOLVED	A Regulation device (UDI-DI) can be linked to only one Legacy device (and vice-versa)

2 issues

UDI Device - Data Exchange Business Rules

Upload Devices and System or Procedure Packs

Summary	Status	Description
BR-DTX-UDI-009 : Upload registered Basic UDI/EUDAMED DI information	RESOLVED	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.

BR-DTX-UDI-010 : Upload Device object structure (main entity and related entities)	RESOLVED	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 Designer (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

BR-DTX-UDI-025 : Bulk upload of a Basic UDI/EUDAMED DI and UDI-DI/EUDAMED ID list of entities	RESOLVED	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.
BR-DTX-UDI-032 : A Device/SPP can be submitted by a Manufacturer/ Producer only in his name	RESOLVED	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)
BR-DTX-UDI-034 : New version is created when a new Basic UDI/ EUDAMED DI or UDI-DI/EUDAMED ID entity is submitted	RESOLVED	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).

BR-DTX-UDI-035 : Version state for the Basic UDI / EUDAMED DI and UDI-DI/ EUDAMED ID submitted through Data Exchange	RESOLVED	When a new entity (Basic UDI or UDI-DI) is submitted in EUDAMED for s Regulation Device, the version state will be :
		
		• SUBMITTED :
		  ◦ (when Basic UDI is provided) if the Basic UDI-DI provided requires a validation from NB
		  ◦ (when UDI-DI is provided) if the UDI-DI provided is attached to a Basic UDI being in the SUBMITTED state
		• REGISTERED:
		  ◦ (when Basic UDI is provided) if the Basic UDI-DI provided does not require a validation from NB;
		  ◦ (when UDI-DI is provided) if the UDI-DI provided is attached to a Basic UDI 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/ EUDMAED ID or UDI-DI /EUDAMED DI) is submitted in EUDAMED, as a result of an update of that entity, the version State will be always REGISTERED;

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"

BR-DTX-UDI-077: Providing Comments in several languages for Storage and Handling Conditions when uploading a Device or System or Procedure Pack	RESOLVED	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"
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)
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)
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-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 UDI-DI can be added only for an existing Basic UDI-DI being in state Submitted or Registered	RESOLVED	Additional UDI-DIs can be added for Regulation Devices or for System or Procedure Packs, when the Basic UDI is in state Submitted or Registered

BR-DTX-UDI-096 : Market Information can be added/updated for an existing 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)

22 issues

Download Devices and System or Procedure Packs

Summary	Status	Description

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 object structure (main entity and related entities)	RESOLVED	A Basic UDI download object shall contain the details : • Basic UDI 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) • 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-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 Designer (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-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-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-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
BR-DTX-UDI-050 : "AND" condition applied between the Search Criteria`s	RESOLVED	"AND" condition applied between the Search Criteria`s
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-053 : Entire value required to be provided - no wildcards	RESOLVED	SRN , Basic UDI-DI Code, UDI-DI 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-068 : Filtering criteria`s UDI-DI Version - From Date and Risk Class require additional criteria`s to be applied	RESOLVED	Search criteria UDI-DI Version - From Date and Risk Class require at least one of the following additional filters to be applied: Manufacturer or Producer Actor Code or Authorised Representative Code
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.

22 issues

Download SS(C)P

Summary	Status	Description
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-201: "AND" condition applied between the search criterion	RESOLVED	"AND" condition applied between search criterion
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.

4 issues