swissmedic

Technical document
swissdamed Business Rules

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1 Terms, definitions, abbreviations

1.1 Definition

This document contains the business rules for swissdamed.

1.2 Abbreviations

MF manufacturer
PR person who assembles system and procedure packs

2 Introduction

The purpose of this document is to provide the business rules for swissdamed. These are conditions that need to be fulfilled to provide correct data to swissdamed.
The corresponding EUDAMED business rules are indicated in brackets after the swissdamed business rules in the “Summary” column, in order to establish a link between the rules from EUDAMED and swissdamed.
Not all business rules from EUDAMED are used in the same way in swissdamed and some business rules only apply to swissdamed and have no equivalent in EUDAMED. Some rules from EUDAMED may be merged into one swissdamed rule.

3 Scope

The business rules are provided in a chapter structure similar to the corresponding business rules in EUDAMED. Current business rules may already cover/include future functionality, whereas additional rules may be added to fully cover the respective functionality.

4 Business rules

4.1 swissdamed business rules

Summary	Description
UDI-1159: Private address details	Address details marked as private will be ignored by swissdamed.
UDI-1163: Type of UDI-PI is mandatory when submitting a UDI-DI	For the submission of a UDI-DI under the applicable legislations MDR, IVDR (devices and system or procedure packs), the following attribute is mandatory to be completed: - Type of UDI-PI (one or more UDI-PI types can be selected).
UDI-1165: Base quantity of device is mandatory when submitting a UDI-DI	For the submission of a UDI-DI under the applicable legislations MDR and IVDR, the following attribute is mandatory to be submitted: - Quantity of device (Base quantity of device) The attribute is not applicable for system or procedure packs.
UDI-1181: Reprocessing of single used devices in CH and Liechtenstein not allowed	Reprocessing of single use devices is prohibited in Switzerland and Liechtenstein. Therefore, no such devices are allowed to be uploaded on swissdamed.
UDI-1182: AIMDD can only have software or orthopedic as special device type	Devices under legislation AIMDD can only have software or orthopedic as special device type.
UDI-1183: Legacy devices with special device types cannot be uploaded to swissdamed.	Legacy devices that would have a Master UDI-DI according to the MDR and therefore require a special device type cannot be uploaded to swissdamed.
UDI-1194: Issuing entities for Master UDI-DI	Issuing entities for Master UDI-DIs are: - GS1 - HIBCC - IFA
UDI-1095: EDMN codes for specific devices	EDMN codes for specific devices: - for devices which have an intended purpose other than medical (Annex XVI) the EMDN code has to start with a X - for IVDR and IVDD devices the EMDN code has to start with a W

4.2 Registration of (Basic) UDI-DI

Summary	Description
UDI-1062 (BR-UDID-001): Register new medical devices	UDI Editors of MF or of MF mandates will be able to register Basic UDI-DIs / EUDAMED DIs and (Master) UDI-DIs / EUDAMED IDs for the applicable legislations MDR, IVDR, MDD, AIMDD and IVDD for a device. UDI Editors of PR or of PR mandates will be able to register Basic UDI-DIs and UDI-DIs for the applicable legislation MDR for a system or procedure pack.
UDI-1063 (BR-UDID-003): Uniqueness of DI codes	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 UDI-DI, Package UDI-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.

Summary	Description
	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 UDI-DI code, Unit of Use DI code, Direct marking DI code, Package UDI-DI code structure will be checked against the format structure provided by the issuing entities. Notes: When mentioning that a code must be unique in the system, this 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/ person who assembles systems or procedure packs.
UDI-1064 (BR-UDID-004): UDI-DI is required when submitting a new Basic UDI-DI	The submission of a new Basic UDI-DI always requires providing an associated UDI-DI along with all its attributes.
UDI-1067 (BR-UDID-020): Providing Secondary UDI-DI for a UDI-DI	The Secondary UDI-DI must be provided for a UDI-DI when a second UDI-DI exists which is issued by a different issuing entity.
UDI-1068 (BR-UDID-023): Unit of Use DI applicable	A Unit of Use DI can (optionally) be provided when no Direct marking DI is provided and the base quantity of device is greater than 1. The Unit of Use DI is conditionally updatable. It can be provided later on if initially not provided. Unit of Use DI and Direct marking DI are not applicable for Master UDI-DI.
UDI-1069 (BR-UDID-024): Maximum number of reuses	When property single use = false, the maximum number of reuses must be provided and can either be a specific value or infinite.
UDI-1070 (BR-UDID-025): Mandatory information for CMR substance registration	When registering CMR substances, the type of CMR substance, the substance name, and the language in which it is provided, are required. Optionally, the EC# or CAS# of the substance can be specified. The substance name for a substance can be provided only once per language. If either the EC# or CAS# is provided, substance name can be provided without language or in the language “ANY”. Otherwise, translations must be provided in all languages used for the labels (at least one out of German, French, Italian or English).
UDI-1071 (BR-UDID-027): Mandatory information for endocrine disrupting substance registration	When registering endocrine disrupting substances, the substance name and the language in which it is provided, are required. Optionally, the EC# or CAS# can be specified. The substance name for a substance can be provided only once per language. If either the EC# or CAS# is provided, substance name can be provided without language or in the language “ANY”. Otherwise, translations must be provided in all languages used for the labels (at least one out of German, French, Italian or English).
UDI-1072 (BR-UDID-028): Submitting storage and handling conditions	Storage and handling conditions can be submitted by providing a value from the predefined list (list of values for storage and handling) and, if required, including a description for the specified value.

Summary	Description
	If the value provided in the storage and handling conditions requires a description, the appropriate value must be provided. If the value provided in the storage and handling conditions is “Other”, a description and the language of the description must be provided. The description associated with the “Other” option can be given 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". Several storage and handling conditions can be submitted for a device or system or procedure pack.
UDI-1073 (BR-UDID-030): Submitting critical warnings and contra-indications	Critical warnings and contra-indications can be submitted by providing a value from the predefined list (list of values for critical warnings and contra-indications) and, if required, including a description for the specified value. If the value provided in the critical warnings or contra-indications requires a description, the appropriate value must be provided. If the value provided in the critical warnings or contra-indications is "Other", a description and the language of the description must be provided. The description associated with the “Other” option can be given in several languages. For all other options (any other option selected in the critical warnings or contra-indications, comments can be provided only in one language, having the value "ANY" Several critical warnings and contra-indications can be submitted for a device or system or procedure pack.
UDI-1074 (BR-UDID-041): Mandatory information for substance registration (substance that can be considered to be a medicinal product or medicinal product derived from human blood or plasma)	When registering a substance that can be considered to be a medicinal product or medicinal product derived from human blood or plasma, the name and language of the substance are mandatory. If the INN is provided, the substance name can be provided without language or in the language “ANY”. The value provided as the INN is not cross-checked with any external database.
UDI-1081 (BR-UDID-066): Device model or device name mandatory	Either the device model or the device name are required when registering a new Basic UDI-DI. Both of them can be provided.
UDI-1082 (BR-UDID-069): UDI-DI relationship to the Basic UDI-DI	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.
UDI-1084 (BR-UDID-073): Market status	(Master) UDI-DIs / EUDAMED IDs uploaded for the first time will be set to the draft status by default. Initially, draft (Master) UDI-DIs / EUDAMED IDs can be set to 'On the market' or can be deleted from swissdamed. The status 'No longer placed on the market' can be set subsequently. If no market status is assigned to a draft (Master) UDI-DI / EUDAMED ID within 30 days of uploading, the (Master) UDI-DI / EUDAMED ID is automatically deleted from swissdamed. If the deleted (Master) UDI-DI / EUDAMED ID is the last associated with a Basic UDI-DI / EUDAMED DI, also the Basic UDI-DI / EUDAMED DI is deleted. Draft Package UDI-DIs that are linked to a UDI-DI with status “No longer placed on the market” can only be deleted. Draft Package UDI-DIs that are linked to a UDI-DI with status “On the market”, can either be set to the same status or be deleted.
UDI-1085 (BR-UDID-075): Providing the clinical size	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). The value of clinical size can be provided only once for a specific type of the size (length, depth, area, etc.) - for a UDI-DI

<table>
<tr><th>Summary</th><th>Description</th></tr>
<tr><td>UDI-1086 (BR-UDID-076): Measure unit in which the clinical size is given</td><td>Providing the measure unit for the clinical size of a device is mandatory when the precision in which the size is provided is either a value (numeric value) or a range of values.</td></tr>
<tr><td>UDI-1087 (BR-UDID-077): Range of values for the clinical size</td><td>When the precision in which the size of the device is entered is 'Range', it is mandatory to provide a minimal value and a maximum value of that clinical size.</td></tr>
<tr><td>UDI-1089 (BR-UDID-094): Several intended purposes other than medical for the device</td><td>Several intended purposes other than medical can be provided.
Exception: Intended purpose other than medical (Annex XVI) for a Master UDI-DI can have only one value (annexXVINonMedicalDeviceTypes for a Master UDI-DI can have only one value (true or false)).</td></tr>
<tr><td>UDI-1090 (BR-UDID-095): Mandatory information for the registration of the legal or natural person who manufactured / designed the device (product original manufacturer)</td><td>For the registration of the legal or natural person who manufactured/designed the device (product original manufacturer), either their SRN or all the identification details should be provided. When the SRN is provided, it should not correspond to the SRN of the manufacturer registering the device.</td></tr>
<tr><td>UDI-1098 (BR-UDID-131): Additional product description is mandatory for system or procedure packs and for system or procedure packs which are devices in themselves and kits.</td><td>The additional product description is mandatory for system or procedure packs or for devices that are marked as system or procedure packs which are devices in themselves or when devices are marked as a kit.</td></tr>
<tr><td>UDI-1110 (BR-UDID-635): Device is a suture, staple, etc.</td><td>The property 'device is a suture, staple, etc.' is only mandatory for devices with risk class IIb and being implantable.</td></tr>
<tr><td>UDI-1111 (BR-UDID-636): Nomenclature codes</td><td>Nomenclature codes for a UDI-DI must be selected from the EMDN nomenclature list published by the European Commission (currently https://webgate.ec.europa.eu/dyna2/emdn/). Only a 'leaf' code, which is the lowest level within the nomenclature branch, can be submitted as nomenclature code.
Several nomenclature codes can be associated to a UDI-DI.
At least one valid nomenclature code is mandatory for a UDI-DI.</td></tr>
<tr><td>UDI-1112 (BR-UDID-639): Direct marking DI applicable</td><td>The Direct marking DI can be the same as the one of the UDI-DI or can be different. A 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.</td></tr>
<tr><td>UDI-1119 (BR-UDID-646): Applicable legislation and risk class for devices</td><td>A device can have only one applicable legislation:
For regulation devices:
<table>
<tr><th>Legislation</th><th>Value</th></tr>
<tr><td>REGULATION (EU) 2017/745 on medical devices</td><td>MDR</td></tr>
<tr><td>REGULATION (EU) 2007/746 on in vitro diagnostic medical devices</td><td>IVDR</td></tr>
</table>
For legacy devices:
<table>
<tr><th>Legislation</th><th>Value</th></tr>
<tr><td>Council Directive 93/42 on Medical Devices</td><td>MDD</td></tr>
<tr><td>Council Directive 90/385/EEC – Approximation of the laws of the member States relating to active implantable medical devices</td><td>AIMDD</td></tr>
<tr><td>Directive 98/78/EC on in vitro diagnostic devices</td><td>IVDD</td></tr>
</table>
A system or procedure pack can only have the applicable legislation MDR
<table>
<tr><th>Legislation</th><th>Value</th></tr>
<tr><td>REGULATION (EU) 2017/745 on medical devices</td><td>MDR</td></tr>
</table>
Devices must be assigned a risk class corresponding to the legislation under which they fall.
MDD, MDR: I, IIa, IIb, III
IVDR: A, B, C, D
IVDD: IVD annex II list A, IVD annex II list B, IVD devices for self-testing, IVD general
AIMDD: AIMDD</td></tr>
</table>

Summary	Description
UDI-1121 (BR-UDID-661): Several Package UDI-DIs can be registered per packaging level	Several Package UDI-DIs can be registered at the same level of a packaging structure and can be added to an already registered UDI-DI.
UDI-1124 (BR-UDID-676): Devices of risk class I must have the implantable property set to false	Devices of risk class I must have the property implantable = false.
UDI-1125 (BR-UDID-677): Implantable devices can not be reusable surgical instruments	Devices with the property implantable = true must have the property reusable surgical instrument = false.
UDI-1136 (BR-UDID-705): Special device type	A device cannot have an attribute of special device type marked if it was initially marked as a kit or as a system or procedure pack, which is a device in itself.
UDI-1148 (BR-UDID-718): When the product original manufacturer is provided as an organisation, only one organisation name can be provided	When the product original manufacturer is provided as an organisation, only one organisation name can be provided.
UDI-1151 (BR-UDID-721): When registering new devices (UDI-DIs) or updating existing UDI-DIs, only references to active items from the existing enumerations should be used	The 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 device only the active items from the enumerations should be referenced. Inactive items from the enumerations will still be reflected in the system
UDI-1152 (BR-UDID-722): Clinical sizes: clinical size or measure unit type option 'Other': description required	When providing clinical sizes having either the clinical size type or the measure unit type 'Other', then the description needs to be provided. Several descriptions can be provided in several languages, but only once in a language. The languages considered for these fields are German, French, Italian or English, other languages will be ignored. If both the clinical size type and measure unit type option 'Other' is selected, the languages of both descriptions should be the same. If clinical size precision is ‘’TEXT’’ text can be provided without language or in the language “ANY”.
UDI-1154 (BR-UDID-724): A manufacturer of a device cannot be its product original manufacturer	A manufacturer of a device cannot be its product original manufacturer.
UDI-1155 (BR-UDID-725): Organisation details for the registration of the product original manufacturer	When the organisation details are provided for the registration of the product original manufacturer, the following data must be included: - Name - Street (if applicable) - Address line 2 (if applicable) - PO box (optional) - City name - Postal code - Country - Telephone (optional) - Email
UDI-1167 (BR-UDID-731): For Master UDI-DI a special device type is mandatory	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 a Master UDI-DI: - Standard soft contact lenses

Summary	Description
	- Standard rigid gas permeable (RGP) contact lenses - Made to order soft contact lenses - Made to order rigid gas permeable (RGP) contact lenses - Spectacle frames - Spectacle lenses - Ready-made reading spectacles Master UDI-DIs for spectacles cannot be registered in swissdamed before the format has been defined by the issuing entities.
UDI-1173 (BR-UDID-729): Upload Master UDI-DI	When registering a Master UDI-DI the following properties cannot be provided: - Unit of Use DI - Direct marking DI - Related device (legacy - regulation) - New device
UDI-1186 (BR-UDID-090): Several endocrine disrupting substances can be added	Several endocrine disrupting substances can be added.

4.3 Registration of legacy devices

Summary	Description
UDI-1113 (BR-UDID-640): Device identification elements for a legacy device	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)
UDI-1114 (BR-UDID-641): Assigning EUDAMED DI and EUDAMED ID for a legacy device	If the device has a previously 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 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.
UDI-1115 (BR-UDID-642): Format of the EUDAMED DI	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 with 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 EUDAMED documentation
UDI-1116 (BR-UDID-643): Format of the EUDAMED ID	Format of EUDAMED ID (generated based on the EUDAMED DI) is: D-(EUDAMED DI).
UDI-1117 (BR-UDID-644): Issuing entity for a EUDAMED DI or EUDAMED ID	Issuing entity for a EUDAMED DI or EUDAMED ID is 'EUDAMED'. The issuing entity EUDAMED is not allowed for regulation devices.
UDI-1120 (BR-UDID-648): Only one EUDAMED DI and one EUDAMED DI / UDI-DI	For a legacy device there can be only one EUDAMED DI and one EUDAMED DI / UDI-DI.

4.4 Manage devices and system or procedure packs

Summary	Description
UDI-1093 (BR-UDID-107): Deleting an uploaded device	Uploaded (Master) UDI-DIs / EUDAMED IDs without assigned market status can be manually deleted, or will be deleted automatically if no market status is assigned, within 30 days of the upload. If the deleted (Master) UDI-DI / EUDAMED ID is the last associated with a Basic UDI-DI / EUDAMED DI, also the Basic UDI-DI / EUDAMED DI is deleted.
UDI-1104 (BR-UDID-624): Discard registered (Master) UDI-DI / EUDAMED ID	A registered (Master) UDI-DI / EUDAMED ID can be manually discarded to allow error correction of all fields. Business rules regarding uniqueness are inactivated for the discarded devices. When all (Master) UDI-DI assigned to a Basic UDI-DI are discarded, then the Basic UDI-DI will also be discarded. A Basic UDI-DI / EUDAMED DI and/or a (Master) UDI-DI / EUDAMED ID which is discarded, is not visible to the public. The codes provided as Basic UDI-DI / EUDAMED DI and/or (Master) UDI-DI / EUDAMED ID can be reused in swissdamed for registering another device.
UDI-1107 (BR-UDID-629): Update product original manufacturer information	Product original manufacturer information can be updated only if it has been registered as an organisation and it can be updated to SRN.
UDI-1129 (BR-UDID-686): Version history	The version history shows the state of the (Master) UDI-DI / EUDAMED ID or Basic UDI-DI / EUDAMED DI at a selected date.
UDI-1166 (BR-UDID-687): Master UDI-DI devices can have only Package UDI-DIs linked to a Master UDI-DI	Only Master UDI-DI identifier can be provided when registering or updating Package UDI-DIs linked to a Master UDI-DI device.

4.5 Certificate rules

Summary	Description
UDI-1080 (BR-UDID-056): Regulation certificates	For regulation devices, certificate information and certificate links are not considered by swissdamed. Certificates are referred to EUDAMED through the SRN of the manufacturer and/or the Basic UDI-DI of the device.
UDI-1096 (BR-UDID-113): Directive certificates	In case of devices having the applicable legislation MDD, AIMDD or IVDD, the manufacturer must specify the directive certificate that covers the device by providing: certificate type; ID of the notified body that issued the certificate; certificate ID of the directive certificate; certificate expiry date. Providing certificate information is optional for MDD class I devices (unless with measuring function) and for IVDD devices having the risk class general.

4.6 Link regulation device to a legacy device

Summary	Description
UDI-1135 (BR-UDID-704): Linking a legacy device to a regulation device	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) - the device being linked or to be linked is not already linked to any other device.

4.7 UDI Devices – Data exchange business rules

<table>
<tr><th>Summary</th><th>Description</th></tr>
<tr><td>UDI-1007 (BR-DTX-UDI-010): Upload device object structure (main entity and related entities)</td><td>A device upload object should contain the following:

Basic UDI-DI / EUDAMED DI information

- DeviceCertificateInformation (optional for regulation devices)

UDI-DI / EUDAMED ID information (at least one UDI-DI is required to be submitted with the Basic UDI-DI)

- 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-DI from the device.</td></tr>
<tr><td>UDI-1017 (BR-DTX-UDI-031): Non-updatable fields of a UDI-DI</td><td>For a 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</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>
</table>
</td></tr>
</table>

Summary	Description

FLD-UDID-156	Containing latex	X		X	X			
FLD-UDID-167	Labelled as single use	X	X	X	X	X		
FLD-UDID-157	Maximum number of reuses	X	X	X	X	X		
FLD-UDID-169	Device labelled sterile	X	X	X	X	X	X	
FLD-UDID-170	Need for sterilization before use	X	X	X	X	X	X	
FLD-UDID-147	Intended purpose other than medical (Annex XVI)	X						
FLD-UDID-309	Container packages related to UDI-DI	X	X				X	FLD-UDID-130 Package UDI-DIs can be added, but not updated (except market status) FLD-UDID-121 is editable for Master UDI-DIs

UDI-1019 (BR-DTX-UDI-033): Non-updatable fields of a Basic UDI-DI

For a Basic UDI-DI / EUDAMED DI the following fields are not updatable:

FLD ID	Attribute	MDR	IVDR	MDD	AIMDD	IVDD	System and procedure pack MDR
FLD-UDID-261	Type of system or procedure pack						X
FLD-UDID-12	Is it a system which is a device in itself, procedure pack which is a device in itself	X		X	X		
FLD-UDID-356	Is it a kit		X			X	
FLD-UDID-13	Special device type	X	X	X	X	X	
FLD-UDID-16	Risk class	X	X	X	X	X	X
FLD-UDID-28	Active device	X		X	X		
FLD-UDID-29	Device intended to administer and/or remove medicinal product	X		X	X		
FLD-UDID-30	Implantable	X		X	X		
FLD-UDID-265	Is it device a suture, staple, dental filling, dental brace (...)?	X					
FLD-UDID-31	Measuring function	X		X	X		
FLD-UDID-32	Reusable surgical instruments	X		X	X		
FLD-UDID-33	Companion diagnostic		X			X	
FLD-UDID-35	Near patient testing		X			X	
FLD-UDID-36	Patient self testing		X			X	
FLD-UDID-262	Reagent		X			X	
FLD-UDID-263	Professional testing		X			X	
FLD-UDID-264	Instrument		X			X	
FLD-UDID-23	Tissues and cells - presence of human tissues or cells, or their derivates	X	X	X	X	X	
FLD-UDID-18	Tissues and cells - presence of animal tissues or cells, or their derivates	X	X	X	X	X	
FLD-UDID-34	Tissues and cells - presence of cells or substances of microbial origin		X			X	
FLD-UDID-155	Presence of a substance which, if used separately, may be considered to be a	X		X	X		

Summary	Description
	<table><tr><td></td><td>medicinal product derived from human blood or plasma</td><td></td><td></td><td></td><td></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></td><td></td><td>X</td><td>X</td><td>X</td><td></td></tr><tr><td>FLD-UDD-10</td><td>Legal manufacturer SRN</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr></table>
UDI-1035 (BR-DTX-UDI-084): Submitting substances being medicinal product	Substances being medicinal products (presence of a substance which, if used separately, may be considered to be a medicinal product) can only be submitted if the medicinalProductCheck flag from the Basic UDI-DI (MDRBasicUDI) is set to true (medicinalProductCheck = true). When medicinalProductCheck = true, it is mandatory to provide at least one substance being medicinal product.
UDI-1036 (BR-DTX-UDI-085): Submitting substances being human product	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 only be submitted if the humanProductCheck flag from the Basic UDI-DI (MDRBasicUDI) is set to true (humanProductCheck = true). When humanProductCheck = true, it is mandatory to provide at least one substance being human product.
UDI-1044 (BR-DTX-UDI-104): Software special device type for UDI-PI software identification.	When the UDI-PI is SOFTWARE_IDENTIFICATION then the special device type needs to be MDR_SOFTWARE or IVDR_SOFTWARE.
UDI-1053 (BR-DTX-UDI-089): Data not applicable when submitting a legacy device.	When submitting a legacy device having the applicable legislation MDD or AIMDD the following data cannot be submitted: - Direct marking DI or Unit of Use DI; - Quantity of device; - CMR and endocrine substances; - Type of UDI-PI; - Intended purpose other than medical (Annex XVI); - Package UDI-DI; - Secondary UDI-DI When submitting a legacy device having the applicable legislation IVDD the following data cannot be submitted: - Direct marking DI or Unit of Use DI; - Quantity of device; - Type of UDI-PI; - Package UDI-DI - Secondary UDI-DI
UDI-1055 (BR-DTX-UDI-091): Language	When submitting a device (regulation or legacy) or a system or procedure pack, several language-specific properties can be submitted. For these properties, only one entry per language is accepted: - Additional product description - Storage and handling conditions description - when option 'Other' is selected - Critical warnings - when option 'Other' is selected - CMR substances - when EC# or CAS# is not provided - Endocrine disrupting substances - when EC# or CAS# 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. - Medical purpose of the system or procedure pack The languages considered for these fields are German, French, Italian or English, other languages will be ignored.

Summary	Description
	Trade name can be provided several times in the same language. The languages permitted for trade name are German, French, Italian, English, or the value “ANY”, other languages will be ignored.

4.8 Miscellaneous

Summary	Description
UDI-1158 (BR-ACT-017): SRN format	The format of the SRN is CC-TT-NNN where CC is the country code, TT is the actor role code, and NNN is a 9 digit numerical value. The legal manufacturer SRN is a non-updatable field. For companies that are not registered in EUDAMED, and therefore don't have a legal manufacturer SRN, NA can be entered. The SRN in the mandate and the legal manufacturer SRN supplied with the device must be identical.

Change history

Version	Change	sig
5.0	▪ Adaptation of: o UDI-1107, UDI-1111 ▪ Addition of: o UDI-1195 ▪ Deletion of: o UDI-1065	enb
4.0	▪ Adaptation of: o Chapter 3 and UDI-1017, UDI-1019, UDI-1053, UDI-1063, UDI-1070, UDI-1071 o UDI-1074, UDI-1089, UDI-1096, UDI-1152, UDI-1158 ▪ Addition of: o UDI-1148, UDI-1166, UDI-1167, UDI-1173, UDI-1194	enb
3.0	▪ Adaptation of: UDI-1158, UDI-1112, UDI-1055	enb
2.0	▪ Correction of typos ▪ Addition of: UDI-1053, UDI-1065, UDI-1093, UDI-1096, UDI-1113, UDI-1114, UDI-1115, UDI-1116, UI-1117, UDI-1120, UDI-1135, UDI-1182, UDI-1183, UDI-1186 ▪ Adaptation of: UDI-1017: FLD-UDID-309 added ▪ Deletion of: ▪ UDI-1193	enb
1.0	Initial document for swissdamed V2.0	enb