

# UDI Add-On for EUDAMED manual - Version V2024/12

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# 1 Change history

Version	Date	User	Description
1.0	05.12.2019	ID	Initial creation
1.1	13.07.2020	PM	Description area menu added
2.0	12.08.2020	PM	Adaptation to the German version
2.0	23.09.2020	PM	UDI DI Type (field disabled)
2.1-2.3	07.05.2020	CF	Adjustments selection fields / New functions
V2021/06	27.05.2021	leDz	Updates regarding SRN, various adjustments selection fields
V2021/11	01.12.2021	leDz	New transaction: <ul style="list-style-type: none"><li>- "/UDI/PDADDRESS" Product Designer Address</li><li>- "/UDI/VERSION" Version Maintenance</li></ul> Various enhancements and bug fixes
V2022/02	13.02.2022	TL	Application parameter added
V2022/12	15.12.2022	SC	Udi record submission status added Application parameter added
V2023/12	20.11.2023	UM	Minor changes, optimizations, and bug fixes. Manual modus to change submission status for xml upload.
V2024/12	17.11.2024	ID	Minor changes, optimizations, and bug fixes. Application versioning changed, parameter added to switch between "old" and "new" logic.
V2025/05	29.07.2025	ID	GTIN based Udi records supported, Custom Screen extension added, XSLT has been extended, automatic Version numbering from EUDAMED added

## 2 Support und contact information

A support request is usually made by e-mail. In urgent cases you can call us.

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**Phone:** +41 61 508 73 34

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Steinentorstrasse 35  
4051 Basel  
Switzerland

## 3 Introduction

The UDI SAP Add-On (EU) enables the maintenance of UDI attributes in SAP. The UDI attributes and their characteristics have been defined by the **European Database for Medical Devices (EUDAMED)**.

According to the regulatory requirements of the European Union the UDI/Device information of all medical devices placed on the EU market has to be submitted in EUDAMED data base.

The UDI SAP Add-On (EU) enables companies the administration of UDI master data in SAP.

The functionality UDI Add-On (EU) has been divided into three sections.

### 1) **Maintenance of the code lists**

In these SAP transactions, default values are defined for the dropdown lists in UDI master data maintenance. For this purpose, unit value ranges as well as approval data acquired by the respective company are defined.

In addition, these values serve as an input check and are used for the data validation during data upload.

### 2) **Application settings**

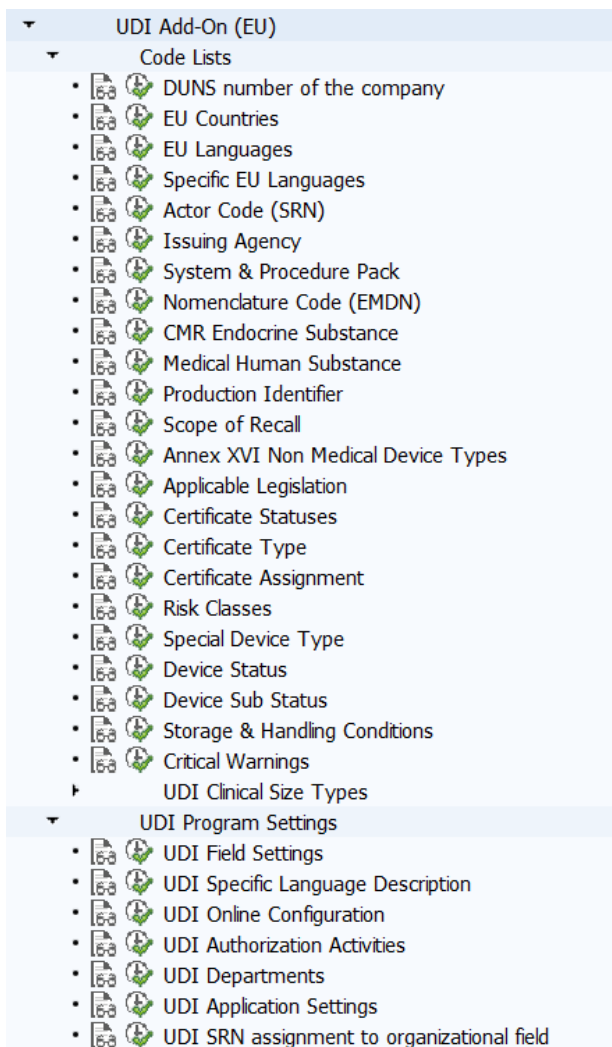
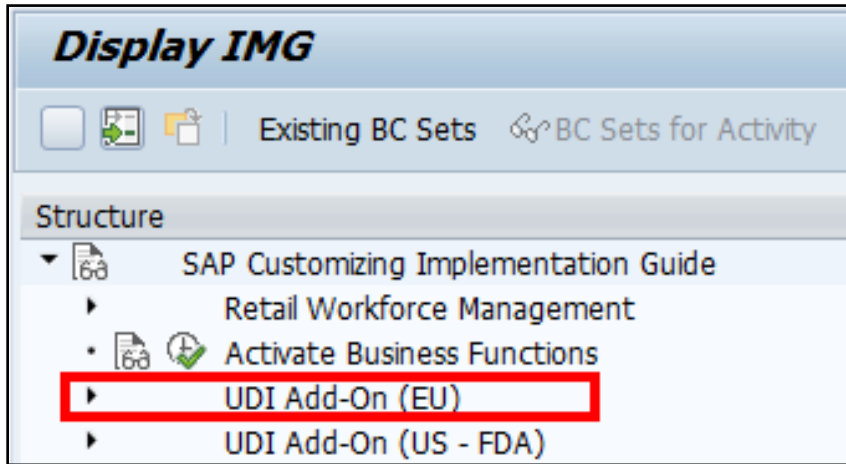
Basic settings of the application are made in this area. Application settings affect the UDI maintenance transaction and the permissions. They also have an impact on the layout.

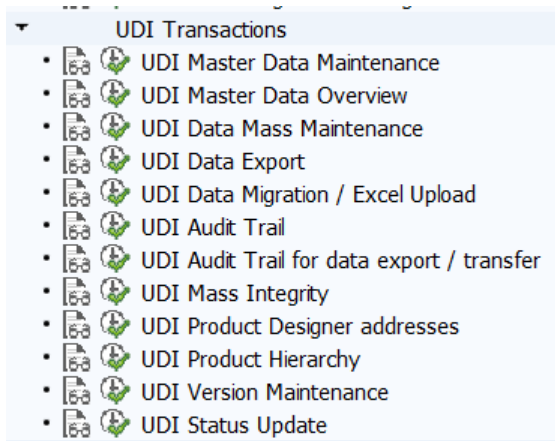
### 3) **UDI transactions**

This category includes all applications where you can maintain, evaluate, release and export the UDI attributes.

## 4 UDI transactions in SAP

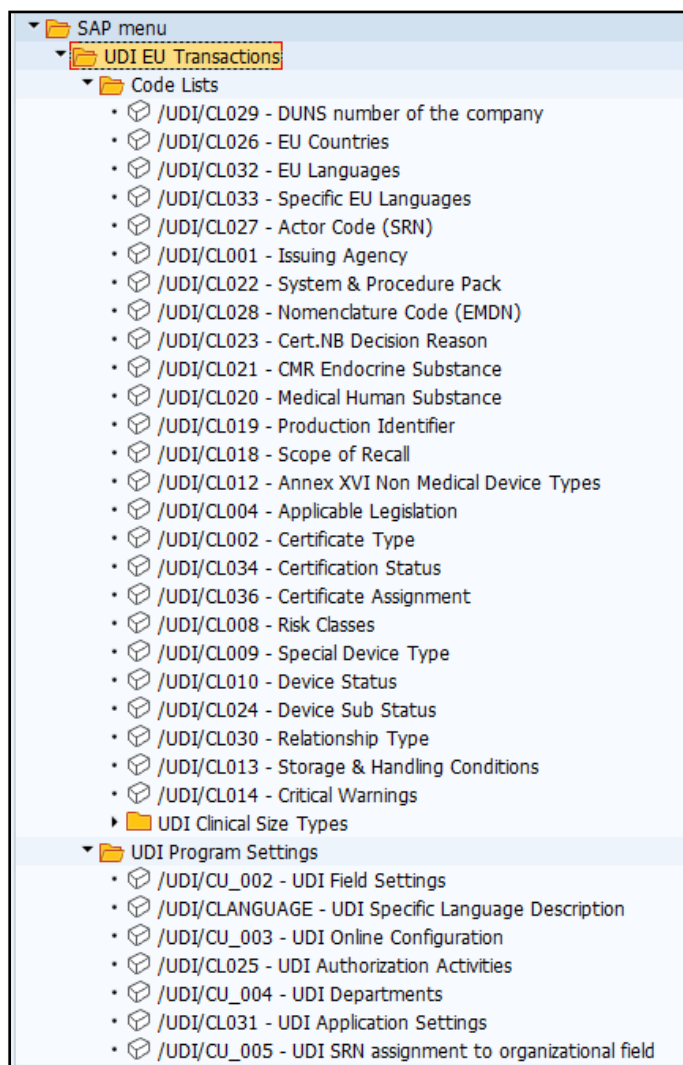
All available transactions are listed in transaction SPRO => SAP Reference IMG under the entry "UDI Add-On (EU)".





To make your daily work easier, you can save the transaction names you need as favorites in the SAP user menu.

It is also possible to display an area menu with an overview of all transactions. This can be activated with the transaction /n/UDI/EU, which must be entered in the SAP user menu.



- ▼ UDI Transactions
  - /UDI/MAINTAIN - UDI Master Data Maintenance
  - /UDI/ATTRIBUTES - UDI Master Data Overview
  - /UDI/MASS - UDI Data Mass Maintenance
  - /UDI/EXPORT - UDI Data Export
  - /UDI/UPLOAD - UDI Data Migration
  - /UDI/AUDITTRAIL - UDI Audit Trail
  - /UDI/EXPAUDIT - UDI Audit Trail for Data Export
  - /UDI/INTEGRITY\_MASS - UDI Mass Integrity
  - /UDI/PHT\_MAT\_ASSIGN - UDI Product Hierarchy
  - /UDI/PDADDRESS - UDI Product Designer Addresses
  - /UDI/VERSION - UDI Version Maintenance
  - /UDI/STATUS - UDI Status Update

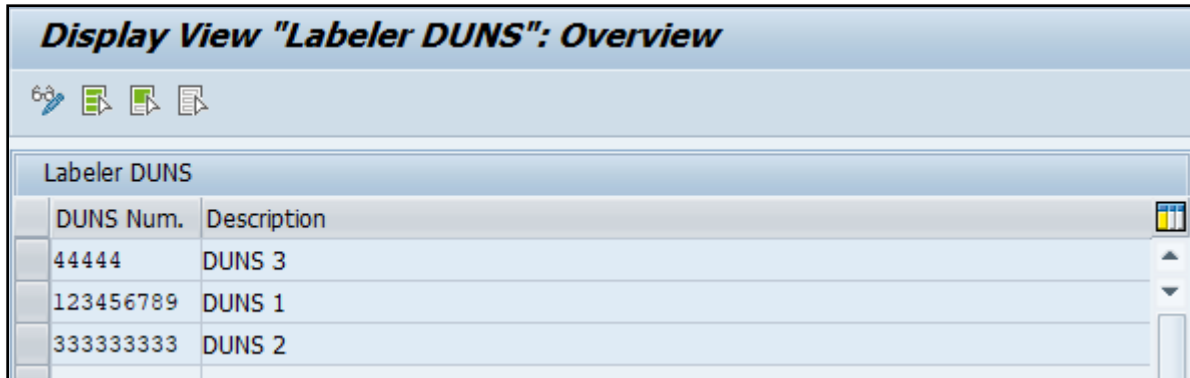
## 5 Code Lists

The code lists support you in your daily work. All available entries in the code lists will be displayed in the maintenance transactions as dropdown lists. Additionally, these values also have an influence on data export and data upload.

- ▼ UDI EU Transactions
  - ▼ Code Lists
    - /UDI/CL029 - DUNS number of the company
    - /UDI/CL026 - EU Countries
    - /UDI/CL032 - EU Languages
    - /UDI/CL033 - Specific EU Languages
    - /UDI/CL027 - Actor Code (SRN)
    - /UDI/CL001 - Issuing Agency
    - /UDI/CL022 - System & Procedure Pack
    - /UDI/CL028 - Nomenclature Code (EMDN)
    - /UDI/CL023 - Cert.NB Decision Reason
    - /UDI/CL021 - CMR Endocrine Substance
    - /UDI/CL020 - Medical Human Substance
    - /UDI/CL019 - Production Identifier
    - /UDI/CL018 - Scope of Recall
    - /UDI/CL012 - Annex XVI Non Medical Device Types
    - /UDI/CL004 - Applicable Legislation
    - /UDI/CL002 - Certificate Type
    - /UDI/CL034 - Certification Status
    - /UDI/CL036 - Certificate Assignment
    - /UDI/CL008 - Risk Classes
    - /UDI/CL009 - Special Device Type
    - /UDI/CL010 - Device Status
    - /UDI/CL024 - Device Sub Status
    - /UDI/CL030 - Relationship Type
    - /UDI/CL013 - Storage & Handling Conditions
    - /UDI/CL014 - Critical Warnings
  - ▶ UDI Clinical Size Types
  - ▼ UDI Program Settings
    - /UDI/CU\_002 - UDI Field Settings
    - /UDI/CLANGUAGE - UDI Specific Language Description
    - /UDI/CU\_003 - UDI Online Configuration
    - /UDI/CL025 - UDI Authorization Activities
    - /UDI/CU\_004 - UDI Departments
    - /UDI/CL031 - UDI Application Settings
    - /UDI/CU\_005 - UDI SRN assignment to organizational field
  - ▼ UDI Transactions
    - /UDI/MAINTAIN - UDI Master Data Maintenance
    - /UDI/ATTRIBUTES - UDI Master Data Overview
    - /UDI/MASS - UDI Data Mass Maintenance
    - /UDI/EXPORT - UDI Data Export

## 5.1 DUNS number of the company

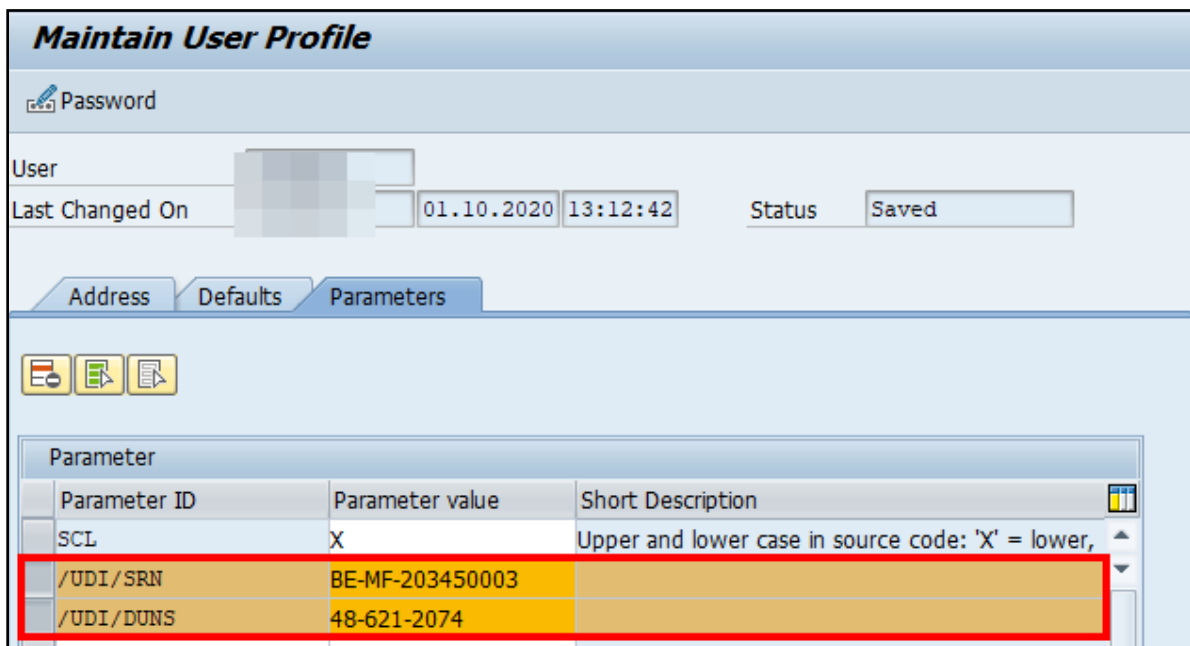
One or more DUNS numbers of the company can be entered here. This information is not required by the EU and is used for internal purposes with a view on the development of a global UDI solution.



**Display View "Labeler DUNS": Overview**

DUNS Num.	Description
44444	DUNS 3
123456789	DUNS 1
333333333	DUNS 2

With the transaction "SU3" the parameter "/UDI/DUNS" can be added to the user profile to filter all UDI information according to the parameter value DUNS number. Multiple DUNS numbers can be entered using a comma.



**Maintain User Profile**

Password

User: [blurred]

Last Changed On: 01.10.2020 13:12:42 Status: Saved


Address Defaults Parameters

Parameter ID	Parameter value	Short Description
SCL	X	Upper and lower case in source code: 'X' = lower,
/UDI/SRN	BE-MF-203450003	
/UDI/DUNS	48-621-2074	

## 5.2 EU Countries

The EU countries are defined by the European Union and are delivered as standard in the UDI-Add-On (EU). These are used as selection aids for various fields in the Add-On.

**Display View "EU Countries": Overview**



EU Countries	
EU Country	Description
AT	Austria
BE	Belgium
BG	Bulgaria
CY	Cyprus
CZ	Czech Republic
DE	Germany
DK	Denmark
EE	Estonia
ES	Spain
FI	Finland
FR	France
GR	Greece
HR	Croatia
HU	Hungary
IE	Ireland
IS	Iceland
IT	Italy
LI	Liechtenstein
LT	Lithuania
LU	Luxembourg
LV	Latvia
MT	Malta
NL	Netherlands
NO	Norway
PL	Poland
PT	Portugal
RO	Romania
SE	Sweden
SI	Slovenia
SK	Slovakia
TR	Turkey
UK	United Kingdom (Northern Ireland only)

### 5.3 EU Languages

**Display View "European languages": Overview**



European languages	
EU Lang.	Description
BG	Bulgarian
CS	Czech
DA	Danish
DE	German
EL	Greek
EN	English
ES	Spanish
ET	Estonian

### 5.4 Specific EU Languages

Specific EU languages contain all EU languages and also the value "ANY" which includes all languages.

**Display View "Specific EU Languages": Overview**

Language	Description
ANY	All languages
BG	Bulgarian
CS	Czech
DA	Danish
DE	German

## 5.5 Actor Code (SRN)

Actor Code (SRN - Single Registration Number) is a unique code that is assigned to manufacturers, authorized representatives or importers after they have registered in the EUDAMED Actor registration module.

**Display View "Actor Code (SRN)": Overview**

Actor SRN	Description
BE-MF-203450003	BE-MF-203450003 (Plant 1000,2000)
BE-MF-203450004	BE-MF-203450004 (Plant 1000,4000)
BE-MF-203450033	BE-MF-203450033 (Plant 3000)
BE-MF-203450663	BE-MF-203450663 (Plant 3300)
BE-MF-203450773	BE-MF-203450773
CH-PR-000004021	
DE-AR-000006585	

With the transaction "SU3" the parameter "/UDI/SRN" can be added to the user profile to filter all UDI information according to the parameter value SRN. Multiple SRN's can be entered using a comma.

**Maintain User Profile**

Password   
 User   
 Last Changed On   Status

Address Defaults **Parameters**

Parameter ID	Parameter value	Short Description
SCL	X	Upper and lower case in source code: 'X' = lower,
/UDI/SRN	BE-MF-203450003	
/UDI/DUNS	48-621-2074	

## 5.6 Issuing Agency

The issuing agency code list is delivered in the UDI Add-On (EU). The number (GTIN) given by the selected agency is a worldwide unique number which is used to identify your product.

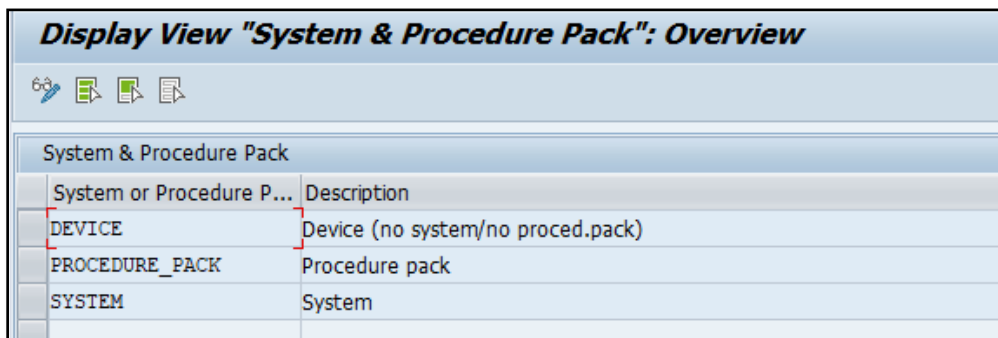
You should only enter the issuing agencies that are used by your company or by your partner company.

Existing issuing agencies allowed by EUDAMED are:

- EUDAMED
- GS1
- HIBCC
- ICCBBA
- IFA

## 5.7 System & Procedure Pack

The European legislation defines systems and procedure packs and distinguishes between different configurations. The regulatory requirements placed on the manufacturer are heavily dependent on these configurations.



System & Procedure Pack	
System or Procedure P...	Description
DEVICE	Device (no system/no proced.pack)
PROCEDURE_PACK	Procedure pack
SYSTEM	System

## 5.8 Nomenclature Code (EMDN)

The EMDN nomenclature of medical devices is a coding system based on the CND (the Italian nomenclature) used to generically identify medical devices and related health products.

The EMDN has a tree-like hierarchy, and users must always assign the most granular and terminal term available (lowest level in the tree) to their device. In UDI Add-On (EU), the bottom level of the tree of EMDN is marked in the column "Bottom".

**Display View "Nomenclature Code (EMDN)": Overview**

Nomenclature Code (EMDN)		
Nomenclature C...	Bottom	Description
A	<input type="checkbox"/>	DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTIO
A01	<input type="checkbox"/>	NEEDLES
A0101	<input type="checkbox"/>	NEEDLES FOR INFUSION AND SAMPLING
A010101	<input type="checkbox"/>	HYPODERMIC NEEDLES
A01010101	<input type="checkbox"/>	HYPODERMIC SYRINGE NEEDLES
A0101010101	<input checked="" type="checkbox"/>	HYPODERMIC SYRINGE NEEDLES, WITH SAFETY SYSTEMS
A0101010102	<input checked="" type="checkbox"/>	HYPODERMIC SYRINGE NEEDLES, W/O SAFETY SYSTEMS
A01010102	<input type="checkbox"/>	HYPODERMIC PEN NEEDLES
A0101010201	<input checked="" type="checkbox"/>	HYPODERMIC PEN NEEDLES, WITH SAFETY SYSTEMS
A0101010202	<input checked="" type="checkbox"/>	HYPODERMIC PEN NEEDLES, W/O SAFETY SYSTEMS
A01010199	<input checked="" type="checkbox"/>	HYPODERMIC NEEDLES - OTHER
A010102	<input type="checkbox"/>	BUTTERFLY NEEDLES
A01010201	<input checked="" type="checkbox"/>	BUTTERFLY NEEDLES, WITH SAFETY SYSTEMS
A01010202	<input checked="" type="checkbox"/>	BUTTERFLY NEEDLES, W/O SAFETY SYSTEMS

### 5.9 Cert. NB Decision Reason

Currently not used.

### 5.10 CMR Endocrine Substance

When registering a new device containing in its composition substances (substances being CMR of category 1A or 1B / substances having endocrine-disrupting properties), Manufacturer will have to submit the details of those substances.

**Display View "CMR Endocrine Substance": Overview**

CMR Endocrine Substance	
CMR Endocrine Substance	Description
CMR_1A	1A
CMR_1B	1B
ENDOCRINE_DISRUPTING	ENDOCRINE DISRUPTING

### 5.11 Medical Human Substance

When registering a new device containing in its composition substances (substances which may be considered to be a medicinal product / substances which may be considered to be a medicinal product derived from human blood or human plasma), Manufacturer will have to submit the details of those substances.

<b>Display View "Medical Human Substance": Overview</b>	
Medical Human Substance	
Medical Human Substa...	Beschreibung
HUMAN_PRODUCT	Human Product
MEDICINAL_PRODUCT	Medicinal Product

## 5.12 Production Identifier

Production identifier (PI) is a conditional, variable portion of an UDI. The existing types of identifiers are specified in this code list.

<b>Display View "PI Element": Overview</b>	
PI Element	
PI Element	Description
BATCH_NUMBER	Batch Number
EXPIRATION_DATE	Expiration Date
MANUFACTURING_DATE	Manufacturing Date
SERIALISATION_NUMBER	Serial Number
SOFTWARE_IDENTIFICATION	Software identification

## 5.13 Scope of Recall

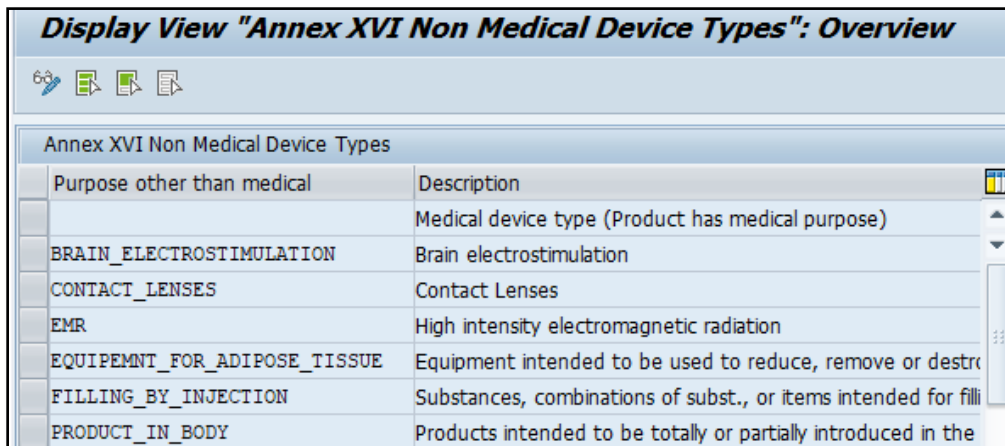
When the status of a device is set to Field Safety Corrective Action Initiated or Recalled, details about the scope of the Recall/ FSCA are required.

The field "Scope of Recall" is not available in the current version of EUDAMED.

<b>Display View "Scope of Recall": Overview</b>	
Scope of Recall	
Scope of Recall	Description
LOT_NUMBER	Lot Number
SERIAL_NUMBER	Serial Number
SOFTWARE_VERSION	Software Version
UDI-DI	UDI-DI

## 5.14 Annex XVI Non-Medical Device Types

MDR Annex XVI covers devices without an intended medical purpose. These are similar to medical devices in functioning and risk-profile.

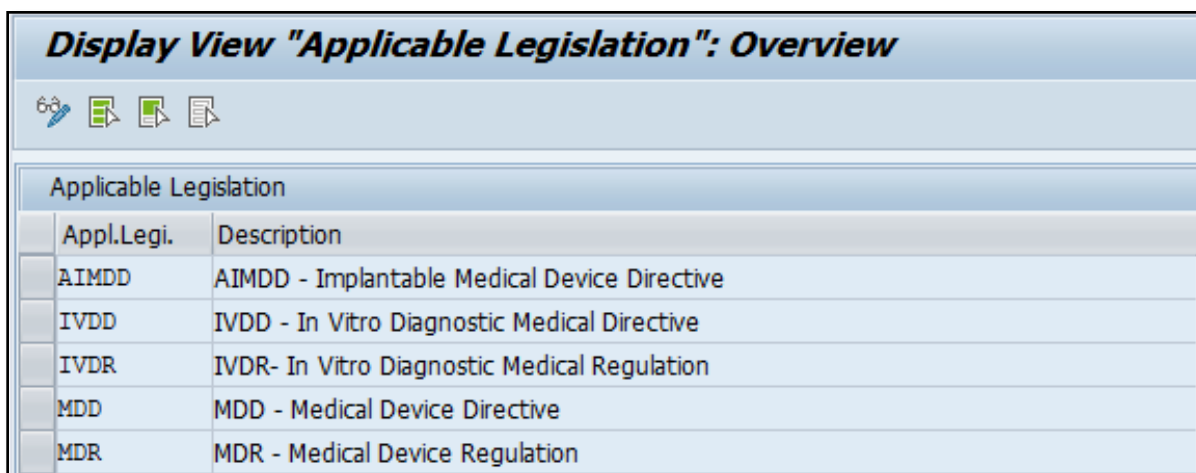


**Display View "Annex XVI Non Medical Device Types": Overview**

Purpose other than medical	Description
	Medical device type (Product has medical purpose)
BRAIN_ELECTROSTIMULATION	Brain electrostimulation
CONTACT_LENSES	Contact Lenses
EMR	High intensity electromagnetic radiation
EQUIPEMNT_FOR_ADIPOSE_TISSUE	Equipment intended to be used to reduce, remove or destr
FILLING_BY_INJECTION	Substances, combinations of subst., or items intended for filli
PRODUCT_IN_BODY	Products intended to be totally or partially introduced in the

## 5.15 Applicable Legislation

Applicable legislations are listed below.



**Display View "Applicable Legislation": Overview**

Appl.Legi.	Description
AIMDD	AIMDD - Implantable Medical Device Directive
IVDD	IVDD - In Vitro Diagnostic Medical Directive
IVDR	IVDR- In Vitro Diagnostic Medical Regulation
MDD	MDD - Medical Device Directive
MDR	MDR - Medical Device Regulation


## 5.16 Certificate statuses

Currently not used.

## 5.17 Certificate Type

Certificate types are listed below and can be selected in the table "Certificate Links" in BASIC UDI-DI data.

**Display View "Certificate Type": Overview**



Certificate Type	
Certificate type	Description
AIMDD_III	Directive 90/385/EEC Annex 3 (Applicable for AIMDD)
AIMDD_II_4	Directive 90/385/EEC Annex 2 section 4 (Applicable for AIMDD)
AIMDD_II_EX_4	Directive 90/385/EEC Annex 2 excluding section 4 (Applicable for AIMDD)
AIMDD_IV	Directive 90/385/EEC Annex 4 (Applicable for AIMDD)
AIMDD_V	Directive 90/385/EEC Annex 5 (Applicable for AIMDD)
IVDD_III_6	Directive 98/79/EC Annex III section 6 (Applicable for IVDD)
IVDD_IV_4	Directive 98/79/EC Annex IV section 4 (Applicable for IVDD)
IVDD_IV_6	Directive 98/79/EC Annex IV section 6 (Applicable for IVDD)
IVDD_IV_EX_4-6	Directive 98/79/EC Annex IV excl. section 4 and 6 (Applicable for IVDD)
IVDD_V	Directive 98/79/EC Annex V (Applicable for IVDD)
IVDD_VI	Directive 98/79/EC Annex VI (Applicable for IVDD)
IVDD_VII_5	Directive 98/79/EC Annex VII section 5 (Applicable for IVDD)
IVDD_VII_EX_5	Directive 98/79/EC Annex VII excluding section 5 (Applicable for IVDD)
IVDR_PRODUCTION_QUALITY_ASSURANCE	(IVDR) EU Production Quality Assurance certificate (Annex D)
IVDR_QUALITY_MANAGEMENT_SYSTEM	(IVDR) EU Quality Management System certificate (Annex D)
IVDR_TECHNICAL_DOCUMENTATION	(IVDR) EU Technical Documentation certificate (Annex D)
IVDR_TYPE_EXAMINATION	(IVDR) EU Type Examination certificate (Annex X)
MDD_III	Directive 93/42/EEC Annex III (Applicable for MDD)
MDD_II_4	Directive 93/42/EEC Annex II section 4 (Applicable for MDD)
MDD_II_EX_4	Directive 93/42/EEC Annex II excluding section 4 (Applicable for MDD)
MDD_IV	Directive 93/42/EEC Annex IV (Applicable for MDD)
MDD_V	Directive 93/42/EEC Annex V (Applicable for MDD)
MDD_VI	Directive 93/42/EEC Annex VI (Applicable for MDD)
MDR_PRODUCT_VERIFICATION	(MDR) EU Product verification certificate (Annex XI Part B)
MDR_QUALITY_ASSURANCE	(MDR) EU Quality Assurance certificate (Annex XI Part A)
MDR_QUALITY_MANAGEMENT_SYSTEM	(MDR) EU Quality Management System certificate (Annex XI Part A)
MDR_TECHNICAL_DOCUMENTATION	(MDR) EU Technical Documentation certificate (Annex IX)
MDR_TYPE_EXAMINATION	(MDR) EU Type Examination certificate (Annex X)

## 5.18 Certificate Assignment

Depending on Applicable Legislation, Risk Class and some additional criteria (for example, implantable device or not), different data regarding certification is required by EUDAMED. This matrix helps the user to enter the correct data.

**Display View "Certificate Assignemnt": Overview**

Certificate Assignemnt

Appl.Legisl.	Risk Class	Certificate type	Cert. No.?	Cert. Rev. No?	Exp. Date?
AIMDD	AIMDD	AIMDD_III	2	0	2
AIMDD	AIMDD	AIMDD_II_4	2	0	2
AIMDD	AIMDD	AIMDD_II_EX_4	2	0	2
AIMDD	AIMDD	AIMDD_IV	2	0	2
AIMDD	AIMDD	AIMDD_V	2	0	2
IVDD	IVD_ANNEX_II_LIST_A	IVDD_III_6	0	0	1
IVDD	IVD_ANNEX_II_LIST_A	IVDD_IV_4	0	0	1
IVDD	IVD_ANNEX_II_LIST_A	IVDD_IV_6	0	0	1
IVDD	IVD_ANNEX_II_LIST_A	IVDD_IV_EX_4-6	2	0	2
IVDD	IVD_ANNEX_II_LIST_A	IVDD_V	2	0	2
IVDD	IVD_ANNEX_II_LIST_A	IVDD_VI	2	0	2
IVDD	IVD_ANNEX_II_LIST_A	IVDD_VII_5	2	0	2
IVDD	IVD_ANNEX_II_LIST_A	IVDD_VII_EX_5	2	0	2
IVDD	IVD_ANNEX_II_LIST_B	IVDD_III_6	2	0	2
IVDD	IVD_ANNEX_II_LIST_B	IVDD_IV_4	2	0	2
IVDD	IVD_ANNEX_II_LIST_B	IVDD_IV_6	2	0	2
IVDD	IVD_ANNEX_II_LIST_B	IVDD_IV_EX_4-6	2	0	2
IVDD	IVD_ANNEX_II_LIST_B	IVDD_V	2	0	2
IVDD	IVD_ANNEX_II_LIST_B	IVDD_VI	2	0	2
IVDD	IVD_ANNEX_II_LIST_B	IVDD_VII_5	2	0	2
IVDD	IVD_ANNEX_II_LIST_B	IVDD_VII_EX_5	2	0	2
IVDD	IVD_DEVICES_SELF_TESTING	IVDD_III_6	2	0	2
IVDD	IVD_DEVICES_SELF_TESTING	IVDD_IV_4	2	0	2
IVDD	IVD_DEVICES_SELF_TESTING	IVDD_IV_6	2	0	2
IVDD	IVD_DEVICES_SELF_TESTING	IVDD_IV_EX_4-6	2	0	2
IVDD	IVD_DEVICES_SELF_TESTING	IVDD_V	2	0	2
IVDD	IVD_DEVICES_SELF_TESTING	IVDD_VI	2	0	1

## 5.19 Risk Classes

Device risk classes which are defined in the applicable legislations are listed in this code list.

**Display View "Risk Class": Overview**

Risk Class

Risk Class	Description
AIMDD	AIMDD
CLASS_A	Class A (IVDR)
CLASS_B	Class B (IVDR)
CLASS_C	Class C (IVDR)
CLASS_D	Class D (IVDR)
CLASS_I	Class I (MDR, MDD)
CLASS_IIA	Class IIa (MDR, MDD)
CLASS_IIB	Class IIb (MDR, MDD)
CLASS_III	Class III (MDR, MDD)
IVD_ANNEX_II_LIST_A	IVD Annex II List A (IVDD)
IVD_ANNEX_II_LIST_B	IVD Annex II List B (IVDD)
IVD_DEVICES_SELF_TESTING	IVD devices for self-testing (IVDD)
IVD_GENERAL	IVD General (IVDD)

## 5.20 Special Device Type

Special device type defines if the device is a special device type and if so, the type of the special device type.

<b>Display View "Special Device Type": Overview</b>	
Special Device Type	
Special Device Type	Description
	No special device type
MDR_MADE_TO_ORDER	Made to order soft contact lenses (MDR, MDD)
MDR_ORTHOPEDIC	Orthopedic (MDR, MDD, AIMDD)
MDR_READY_MADE_SPECTACLES	Ready-made reading spectacles (MDR, MDD)
MDR_RIGID_GAS_PERMEABLE	Rigid Gas Permeable (RGP) Contact Lenses (MDR, MDD)
MDR_SOFTWARE	Software (MDR, MDD, AIMDD, IVDR, IVDD)
MDR_SPECTACLES_FRAMES	Spectacle frames (MDR, MDD)
MDR_SPECTACLES_LENSSES	Spectacle lenses (MDR, MDD)
MDR_STANDARD_SOFT_CONTACT_LENSSES	Standard soft contact lenses (MDR, MDD)

## 5.21 Device Status

Device status codes are listed below:

<b>Display View "Device status": Overview</b>	
Device status	
Device status	Description
NOT_INTENDED_FOR_EU_MARKET	Not Intended for EU market
NO_LONGER_PLACED_ON_THE_MARKET	No longer placed on the EU market
ON_THE_MARKET	On the EU market

## 5.22 Device Sub Status

Device sub status codes are listed below:

<b>Display View "Device Sub Status": Overview</b>	
Device Sub Status	
Device Sub Status	Description
FIELD_SAFETY_CORRECTIVE_ACTION_INITIATED	Field Safety Corrective Action Initiated
RECALLED	Recalled

## 5.23 Relationship Type

Only to be considered for Legacy Devices. These entries will probably be used internally in the future. Currently it's not used.

## 5.24 Storage & Handling Conditions

The storage and handling table describes how the device should be stored and how to handle it during the transport. Entries with "\*" will require additional data while maintaining storage and handling in the maintenance program.

Storage & Handling Conditions	
Storage & Handling Condit. Type	Description
SHC001	Fragile, handle with care
SHC002	Keep away from sunlight
SHC003	Protect from heat and radioactive sources
SHC004	Protect from radioactive sources
SHC005	Keep dry
SHC006	Lower limit of temperature *
SHC007	Upper limit of temperature *
SHC008	Temperature limit *
SHC009	Humidity limitation *
SHC010	Atmospheric pressure limitation *
SHC012	Dangerous voltage
SHC013	P401 – Store at... *
SHC014	P402 – Store in a dry place.
SHC015	P403 – Store in a well-ventilated place.
SHC016	P404 – Store in a closed container.
SHC017	P405 – Store locked up.
SHC018	P406 – Store in corrosive resistant/... container with a resistant inl
SHC019	P407 – Maintain air gap between stacks/pallets.
SHC021	P411 – Store at temperatures not exceeding ... °C/ ... °F *

## 5.25 Critical Warnings

Critical warnings or contra-indications specified on the label of the device or in the instruction of use must be registered in EUDAMED, if applicable.

<b>Display View "Critical warnings": Overview</b>	
Critical warnings	
Critical warning typ	Description
CW001	Do not resterilize
CW006	Defibrillation-proof type B applied part
CW007	Do not use if package is damaged
CW008	Biological risks
CW009	Do not re-use
CW010	Consult instructions for use
CW011	Caution
CW012	Caution: Electrostatic sensitive, do not touch directly.

## 5.26 UDI Clinical Size Types

The clinical size describes the size dimensions of the medical device. In case clinical parameters are printed on the label of the device, these should also be included in the data collection.

### 5.26.1 UDI Clinical Size Types

The Clinical Size Types represent the category of the clinical size.

<b>Display View "Clinical Size Types": Overview</b>	
Clinical Size Types	
Size type	Description
CST1	Acidity
CST10	Diameter (inner)
CST11	Diameter (outer)
CST12	Pole distance
CST13	Flow rate
CST14	Gauge
CST15	Guide wire type
CST16	Inflation volume
CST17	Body side
CST18	Balloon length (nominal)
CST19	Length

### 5.26.2 Clinical Units of measure

The Clinical Unit of measure describes in which unit the clinical size is measured.

<b>Display View "Units of Measure": Overview</b>		
Units of Measure		
Size unit	Description	
MU01	%	
MU02	/litre (/L)	
MU03	/millilitre (/mL)	
MU04	/millimole (/mmol)	
MU05	international unit [IU]	
MU06	international unit per day [IU]/day ([IU]/d)	
MU07	international unit per litre [IU]/litre [IU]/L	
MU08	international unit per millilitre [IU]/millilitre [IU]/mL	

### 5.26.3 Assignment of Clinical Size Types/ UoM

The Assignment of Clinical Size Types/ UoM serves to match the Clinical Size Types to the adequate Clinical Units of measure (UoM).

<b>Display View "Clinical Size Types": Overview</b>		
Dialog Structure	Clinical Size Types	
<ul style="list-style-type: none"> <li>▼ Clinical Size Types               <ul style="list-style-type: none"> <li>• Units of measure</li> </ul> </li> </ul>	Size type	Description
	CST1	Acidity
	CST10	Diameter (inner)
	CST11	Diameter (outer)
	CST12	Pole distance
	CST13	Flow rate
	CST14	Gauge
	CST15	Guide wire type
	CST16	Inflation volume
	CST17	Body side
	CST18	Balloon length (nominal)
	CST19	Length
	CST2	Amount of fingers

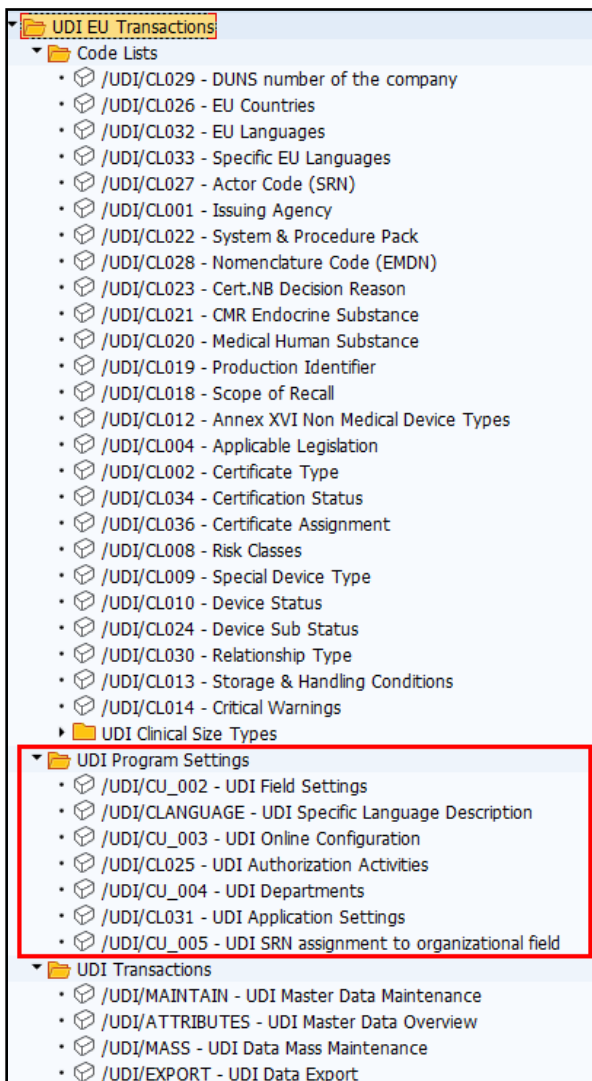
### 5.26.4 Precision

The Precision allows to determine how the clinical size value is expressed. It can either be a range, a text or a (numeric) value. If you have to enter numeric values with decimal places in Excel template or using /UDI/MAINTAIN, please note that the digits after comma have to be separated using dot (for example "0.123").

Precision	
Precision	Description
RANGE	
TEXT	
VALUE	

## 6 UDI Program Settings

The UDI program settings are the main settings for the appearance and behavior of the maintenance transaction. The layout settings of the status log and the authorizations for the applications can also be adjusted here.



### 6.1 UDI Field Settings

The field name refers to the technical database structure " /UDI/FLD\_CTRL ". All fields can be changed specifically in that table during the presentation in the application. The following properties can be modified:

### 6.1.1 Trigger field

If a field is marked as a trigger field, this is prevented later with the lock function "lock trigger fields" against accidental modification of the data. Trigger fields have a key icon before the input fields.

### 6.1.2 Obligatory

If a field is marked as obligatory, the name of the field is displayed in blue color in the application. These fields must be filled out before you transfer data to EUDAMED.

### 6.1.3 Editable

If a field is not marked as editable, this field is not changeable by the user. The user cannot change or enter wrong data.

In addition, this property in combination with the "Default value" field makes it possible to define default values which cannot be changed by the user.

### 6.1.4 Visible

If a field is not marked as visible, this field is hidden in the input mask. Thus, UDI attributes that are not applicable to the company's devices can be hidden.

### 6.1.5 Default value

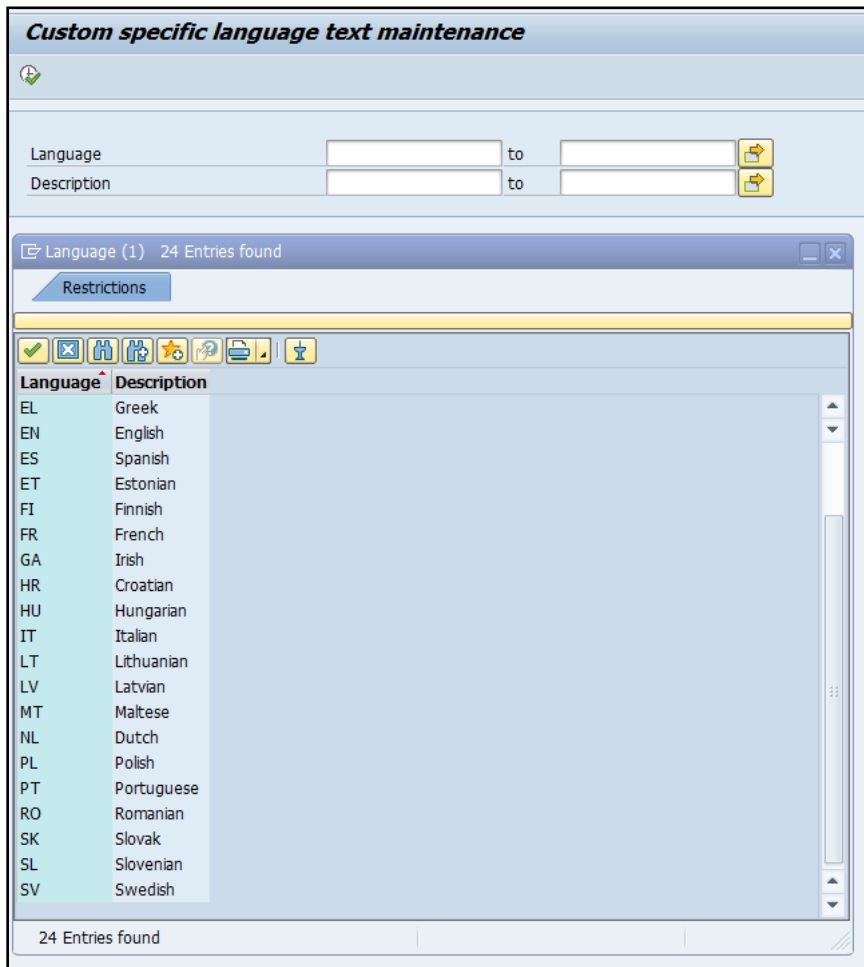
The default value is a value that is already pre-assigned when a new UDI master data record is created. This means that certain attributes, such as the issuing agency, can be preassigned with a default value.

**Attention: This function is not active during data upload with the Excel data upload template. The data from the Excel template is copied one to one.**

Display View "UDI field settings": Overview						
UDI field settings						
Area	Field Name	Trigger	Obligatory	Editable	Visible	Default value
Basic UDI data	ACTIVEDEVICE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Basic UDI data	ADMINMEDICINE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Basic UDI data	ARCODE	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Basic UDI data	CDIAGNOSTIV	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Basic UDI data	CERTIFICATION_LINKS	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Basic UDI data	CLINICAL_INVESTIGATION	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Basic UDI data	DELKZ	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Basic UDI data	DEVICEMODEL	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Basic UDI data	DEVICENAME	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Basic UDI data	DIAGENCY	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Basic UDI data	DICODE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Basic UDI data	HUMPRODCHECK	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

## 6.2 UDI Specific Language Description

Customer-specific language texts can be maintained and adapted with /UDI/CLANGUAGE. Additional languages can be added or languages that are not required can be removed.



### 6.3 UDI Online Configuration

Detailed information regarding “UDI Online Configuration” can be found in the following document:

“TD01 UDI EUDAMED Rest API Service EN V01.docx”.

### 6.4 UDI Authorization Activities

The authorization activities are stored in this table. The following settings are delivered with the UDI module. The associated authorization object "/UDI/EU" can be assigned to the corresponding user roles.

**Display View "UDI Authorization": Overview**

Activity	Description
1	UDI master data show (BUDI and UDI-DI)
2	GTIN Trigger field lock/unlock
3	UDI master data insert/update/delete (BUDI only)
5	UDI Audittrail
6	UDI maintain specific language descriptions
10	Mass integrity check
30	Mass change
40	Product hierarchy template assignment
50	Data migration / excel upload
80	UDI master data release
81	Release Regulatory Affairs
82	Release Marketing
83	Release Development
90	UDI master data excel(xlsx) file export
91	UDI master data XML file export
92	UDI master data XML file transfer to web service

## 6.5 UDI Departments

These departments are necessary to carry out the release process for UDI master data. Each department can release UDI master data separately. The activities listed in the table "Departments" must be assigned to the user roles in related departments.

**Display View "Departments": Overview**

Department	Object	Activity
Labeling	/UDI/EUUDI	82
Marketing	/UDI/EUUDI	83
Quality	/UDI/EUUDI	81

## 6.6 UDI Application settings

The transaction “UDI Application Settings” is another tool for controlling the program logic. The configuration can be extended in the future.

Group	Parameter name	Default Parameter value	Possible entries	Description
APPLICATION_BASIC	LOCK_AFTER_RELEASE	X	X or space	When the UDI records are released, the Trigger fields will be locked at the same time. This prevents the user from changing these fields after the UDI data has been published in the EUDAMED database.
APPLICATION_BASIC	PROD_HIER_ACTIVE	space	X or space	This option activates the product hierarchy function.
APPLICATION_BASIC	RANGE_SELECT_SIZE	2000	numbers	This configuration is used to restrict the maximum number of entries for the selection range which is used in the data collection. Performance test result gave us this number for optimum performance. This can be different for different SAP versions and the used database type.
APPLICATION_BASIC	RECENT_EXCEL_VERSION	5 - check recent Excel version	numbers like 1,2,3..	This entry will be checked against the recent Excel upload/download template version. It should prevent the user from using an old Excel template with a newer SAP Add-On version.
APPLICATION_BASIC	DEACT_INTEGRITY_FUNC	space	X or space	This function deactivates the data integrity check in the /UDI/MAINTAIN program
APPLICATION_BASIC	AUTH_SRN_FIELD	space	WERKS	This setting activates SRN authorization check for all T-Codes
APPLICATION_BASIC	AUTH_SRN_OBJECT	space	M_MATE_WRK	This setting activates SRN authorization check for all T-Codes
APPLICATION_BASIC	EXPORT_XML_SENT_FLAG	space	space, X	In /UDI/EXPORT T-Code the default value for “Mark records as sent” is controlled
(SRN Number)	ACCESSTOKEN_NO	space	alphanumeric	<p>The AccessToken has a length of up to 545 Characters and is system dependent. Therefore multiple entries for the access token are needed. All selected values will be concatenated. Example:</p> <p>The SAP System ID is: <b>DEV</b> and the client is: <b>100</b> . The Final number behind the Parameter name (<b>NO</b>) is only used for the sort order.</p> <p>Entries like:</p> <p>DE-MF-123456789   ACCESSTOKEN_01   A12345..</p> <p>DE-MF-123456789   ACCESSTOKEN_02   B12345..</p> <p>until.....   ACCESSTOKEN_05  </p> <p>Will be concatenated into one value like: A12345B12345..</p>
APPLICATION_BASIC	XML_VERSION	2.0.1	string	XML Version which is valid for EUDAMED XML Upload. Reflects the XSD Version of EUDAMED

CPROG_SETTINGS	[REPORT Name]	space	alphanumeric	<p>This setting allows you to change the default values and behavior in the selections screen of any program.</p> <p>The Syntax: [TYPE];[Techn. Fieldname]=[VALUE];[Techn. Fieldname]=[VALUE];</p> <p>Possible values for TYPE: DEFAULT, DISABLED, ENABLED, HIDDEN</p> <p>Example: DEFAULT:P_ONE_FB=X,P_NEWFO=X;</p> <p>Explanation: For the SAP Program in "Parameter Name" the default value "X" will be set for the field "P_ONE_FB" and "P_NEWFO"</p>
APPLICATION_BASIC	XML_SPLIT_SIZE	1000,300	comma separated numbers	<p>Number of UDI-DI's in one XML. The maximum number of UDI-DI's within one XML is limited to 1000.</p> <p>In the application the value should be less or equal than 1000. But greater than 1.</p> <p>First number limits the number of UDI-DI's in the process "INSERT BUDI &amp; UDI-DI" and the second number limits the number of UDI-DI's in other cases.</p>
APPLICATION_BASIC	EXEC_VALIDATE	/UDI/UPLOAD,/UDI/ATTRIBUTES,/UDI/PHT_MAT_ASSIGN	Comma separated Tcodes	<p>If the one of the Tcodes: /UDI/UPLOAD,/UDI/ATTRIBUTES,/UDI/PHT_MAT_ASSIGN is entered, the validation check is executed immediately after the data are displayed. This may cause a longer time until the data are displayed.</p>
APPLICATION_BASIC	EXPORT_ONLY_RELEASED	X	X, SPACE	<p>This parameter forces the user only to export released UDI data in /UDI/EXPORT TCode. The checkbox "Only released UDI Data" is set to read-only for XML and Webservice option</p>
APPLICATION_BASIC	DEACT_DI_CONVERT		X, SPACE	<p>This parameter deactivates the conversion of DI Codes to external format. Generally it add's leading zeros to GS1 UDI-DI Codes (effected are all GS1 Codes like: Di Code, Direct Marking Code, Secondary Code e.g</p> <p>Basic UDI-DI Code is not effected from this setting</p>
(SRN Number)	NODE_ID	space	Alphanumeric	<p>This settings is only to use if EUDAMED M2M changes it's checking rules for data submission using AS4.</p> <p>If the NODE_ID is needed for Data submission please enter the Party ID in the M2M settings from the EUDAMED Account.</p>
APPLICATION_BASIC	SHOW_ATT_SUCCESS_BTN	space	X, SPACE	<p>This setting activates/displays the button " Set Submission status &gt;&gt;Success&lt;&lt;" button in</p>
APPLICATION_BASIC	VERSION_DECREMENT	space	X, SPACE	<p>This activates the old versioning in EUDAMED. That means, when value is set to "X" the version of the UDI-record in the XML is decreased by 1 if the version is higher than 2. If value is space, the version is not decreased in the XML file.</p>

APPLICATION_BASIC	GTIN_BASED_DI	space	X,space	Active Parameter enables the maintenance of UDI-DI data based on primary DI Code (GTIN) additionally to only material number. After activating and maintenance of UDI-DI data which are not anymore unique by material number - you can't deactivate the function anymore ,since the material number is not anymore unique
APPLICATION_BASIC	VERSION_ZERO_INACTIV	space	X,space	In this Version the UI records version will be submitted to EUDAMED with version 0 in order to uye the EUDAMED autoincrement feature. To deactivate it you can set this parameter to X.

## 6.7 UDI SRN assignment to organizational field

With “UDI SRN assignment to organizational field” it is possible to assign Actor SRN to plants. One plant can be assigned to one or more SRNs and one SRN can be assigned to one or more plants.

All UDI programs will check if the materials (UDI-DIs) are assigned to the correct Basic UDI-DI which contains the SRN number as an UDI attribute. Data access will be restricted based on the plant authorization of the user.

Display View "SRN assignment to organizational field": Overview	
SRN assignment to organizational field	
Actor SRN	Description
BE-MF-203450003	<input type="checkbox"/> BE-MF-203450003 (Plant 1000,2000)
BE-MF-203450003	BE-MF-203450003 (Plant 1000,2000)
BE-MF-203450004	BE-MF-203450004 (Plant 1000,4000)
BE-MF-203450004	BE-MF-203450004 (Plant 1000,4000)
BE-MF-203450033	BE-MF-203450033 (Plant 3000)
BE-MF-203450663	BE-MF-203450663 (Plant 3300)

## 7 UDI Transactions

The UDI application transactions are the actual applications that have been developed for the maintenance and evaluation of the UDI master data. Within these transactions, the UDI data can be recorded and evaluated.

- /UDI/CL014 - Critical Warnings
- ▶ UDI Clinical Size Types
- ▼ UDI Program Settings
  - /UDI/CU\_002 - UDI Field Settings
  - /UDI/CLANGUAGE - UDI Specific Language Description
  - /UDI/CU\_003 - UDI Online Configuration
  - /UDI/CL025 - UDI Authorization Activities
  - /UDI/CU\_004 - UDI Departments
  - /UDI/CL031 - UDI Application Settings
  - /UDI/CU\_005 - UDI SRN assignment to organizational field
- ▼ UDI Transactions
  - /UDI/MAINTAIN - UDI Master Data Maintenance
  - /UDI/ATTRIBUTES - UDI Master Data Overview
  - /UDI/MASS - UDI Data Mass Maintenance
  - /UDI/EXPORT - UDI Data Export
  - /UDI/UPLOAD - UDI Data Migration
  - /UDI/AUDITTRAIL - UDI Audit Trail
  - /UDI/EXPAUDIT - UDI Audit Trail for Data Export
  - /UDI/INTEGRITY\_MASS - UDI Mass Integrity
  - /UDI/PHT\_MAT\_ASSIGN - UDI Product Hierarchy
  - /UDI/PDADDRESS - UDI Product Designer Addresses
  - /UDI/VERSION - UDI Version Maintenance

## **Integration of the UDI relevant marking in the material master:**

The UDI data is basically an additional master data for each material. For this reason, an additional sub screen area is displayed in the material master (transactions MM01 / MM02 / MM03) by customizing.

The area in the lower screen labeled "EU UDI Information" makes it possible to mark this material as relevant to EU UDI when creating materials or during maintenance.

The "EU UDI relevant" indicator is represented by a MARA appendix of the field **"ZZEUDAMED"**.

As soon as the setting is set to "Yes" or "Preparation", the function to jump to the UDI master data maintenance is enabled.

This setting only has to be made once, so that the material is taken into account later in all evaluations.

The UDI master data maintenance itself can also be called up with its own transaction. This has the advantage that even users who are not authorized to change the material master record can still maintain the UDI data.

Meaning of the selection list:

- 1 (Yes): The material is flagged as UDI relevant and is considered in all other UDI transactions.
- 2 (Preparation): The material is fundamentally UDI relevant, but it can be distinguished whether this material is considered during the data export or not. Use cases would be if this material becomes relevant later for an export to the EU or if you have newly created a material and want to maintain the data in preparation.
- 3 (No): The material was explicitly marked as not UDI relevant. Thus, it is not considered in the UDI transactions.
- Not defined: This status represents the initial status of the material. All materials that existed before the implementation of the UDI module have this status.

**Change Material 2511-7 (Finished product)**

Additional Data   Org. Levels   Check Screen Data

Basic data 1   Basic data 2   WM Execution   WM Packaging

Material: 2511-7   2511-7 Test

**General data**

Base Unit of Measure: EA   Each   Material Group: 015

Old material number:   Ext. Matl Group:

Division: 00   Lab/Office:

Product allocation:   Prod.hierarchy:

X-plant matl status:   Valid from:

Assign effect. vals   GenItemCatGroup: NORM   Standard item

**Dimensions/EANs**

Gross Weight: 5   Weight unit: LB

Net Weight: 4

Volume: 2   Volume unit: FT3

Size/dimensions:

EAN/UPC:   EAN Category:

**Packaging material data**

Matl Grp Pack.Matls:

Ref. mat. for pckg:

**Basic Data Texts**

Languages Maintained: 0   Basic Data Text   Language:

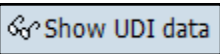
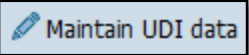
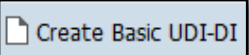
**FDA UDI Information**

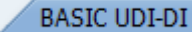
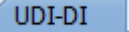
FDA UDI relevant: N No   FDA UDI Master data

**EU UDI Information**

EU UDI relevant: 1 Yes (dropdown menu open showing: 1 Yes, Not defined, 1 Yes, 2 Preparation, 3 No)   EU UDI Master data

## 7.1 UDI master data maintenance transaction

Button	Description
	Shows existing UDI data as read only
	Edits existing UDI data
	Creates a new UDI data

We have left the naming of the fields as they were defined by the EUDAMED. UDI master data consists of two parts which are **Basic UDI**  and **UDI-DI** .

## Basic UDI-DI Tab

**UDI data maintenance for GMN 261121MedDevTestJ2**

Audit trail Check UDI data

BASIC UDI-DI  
 Authority EU Description MedDevice Type1 BUUDI 261121MedDevTestJ2 Data Transfer Protocol

Release status  
 BASIC UDI-DI released  All UDI-DIs released

**BASIC UDI-DI** UDI-DI

Status  
 Released   Trigger fields locked  To be submitted Version: 1

DUNS number  
 Applicable Legislation MDR - Medical Device Regulatio...  
 Issuing Agency GS1 Basic UDI-DI Code 261121MedDevTestJ2  
 Risk Class Class III (MDR, MDD) Actor SRN BE-MF-203450003 (Plant 1000,20...)

System or Procedure Pack Device (no system/no proced... Special Device Type No special device type

Measuring function  Active device  Administer device  Reusable surgical instrument  Suture, Staple, Dental filling (Iib)  
 Implantable device

Device Model MedDevice-Model1 Presence of animal tissues or cells   
 Device Name Presence of human tissues or cells   
 Authorised Represent. SRN

Additional Information  
 Certificate Links Clinical Investigation Links Indication of Medical Purpose

Certificate Links

Cert. type	Certification No.	Cert. rev. ...	NB Code	Expiry Date
MDR_TECHNICAL_DOCUMENTATION	2611	1	0123	

## UDI-DI Tab

**UDI data maintenance for GMN 261121MedDevTestJ2**

Audit trail Check UDI data

BASIC UDI-DI  
 Authority EU Description MedDevice Type1 BUUDI 261121MedDevTestJ2 Data Transfer Protocol

Release status  
 BASIC UDI-DI released  All UDI-DIs released

**BASIC UDI-DI** UDI-DI

Add UDI-DI Unlink UDI-DI

Material	Material Description
2611-1	MatTest 2611
2611-2	MatTest 2611-2

UDI-DI data

Release status  
 Released   Trigger fields locked  To be submitted Version: 1

Material master data  
 Material 2611-1 Short text MatTest 2611

Product information  
 Issuing Agency GS1  
 UDI-DI Code 0404936333772  
 Purp. other than medical  
 Quantity of device 1  
 Max. number of reuses 0  
 Reference number 2611-123  
 Second. DI Agency  
 Second. UDI-DI Code  
 Direct Marking



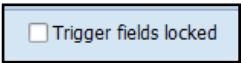
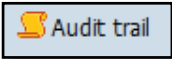
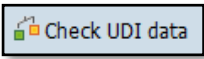
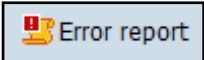
Product status  
 Device Status On the EU market  
 Device SubStatus  
 Substatus Start date Subst. End date  
 Scope of Recall  
 Recall Precision Prec. Language  
 URL for Additional Information (eIFU)  
 Website

Is the device designed or manufactured by another legal or natural person?  
 Yes (If yes, please enter SRN or Product Designer ID)

UDI-DI Attributes  
 Device labelled as sterile  Containing latex  Labeled as single use  
 Device needs sterilisation before use  New Device  
 Reprocessed single use device

Production identifier  
 Lot or Batch no.  Expiration date  Manufacturing date  Serial number  Software identification

The following functions are available within this transaction:

Symbol	Function	Description
	Save	Save data
	Leave transaction	Leaving the transaction. If unsaved changes exist, you will be asked if you want to save before leaving the transaction.
	Lock/unlock trigger fields	This function locks and unlocks the UDI trigger fields. The trigger fields have to be previously defined in UDI Field Settings.
	Displaying the audit trail	In the UDI audit trail, you can view all changes to the UDI data. The transaction code, time, old value and new value can be displayed. You can also use the SAP standard transaction AUT10 to view the changes.
	Check entries	Checks entered data according to defined business rules and whether the data is synchronous with the comparison data. A customer-specific implementation defines which data is compared.
	Error report	Shows errors which are not passed by business rules (validation check).

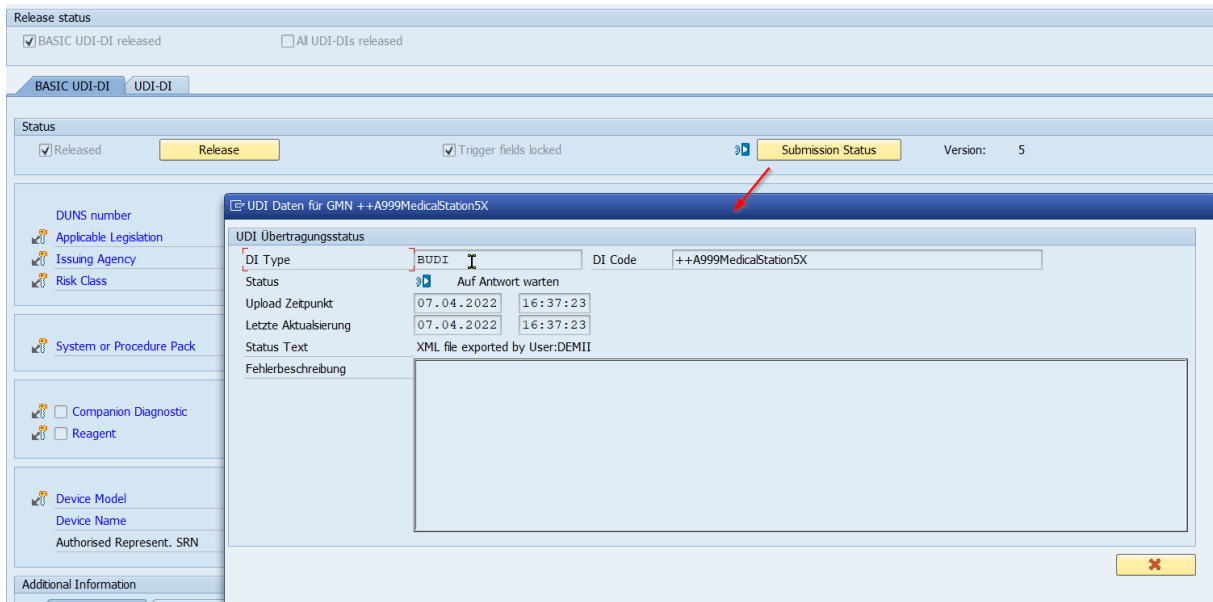
### 7.1.1 UDI record submission status

The UDI record submission status can be displayed in the UDI maintain T-Code and in the UDI Attributes T-Code. Submission and error details are shown in the popup.

The icon shows the recent status for Basic UDI-Data (visible in the Basic UDI-DI tab) and the status for the UDI-DI record (in UDI-DI tab).

Depending on the previous release and recent status of the Udi record, there are different icons for the same status. The reason is that the status handling changed comparing to the previous Udi Add-On version.

The status will change depending when you change, submit and import/update the submission status.

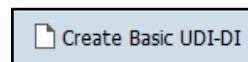


The following status are available:

Status Icon (new)	Status Icon (old)	Description	Executed actions
		UDI record has been submitted and up-to-date in EUDAMED	You have submitted the Udi data to EUDAMED and updated the status importing XML response or (when you use M2M) executed /UDI/STATUS T-Code
		UDI is not up-to-date in EUDAMED. Record should be released and sent to EUDAMED.	UDI record was changed or created and is not yet submitted to EUDAMED
	N/A	Waiting for UDI record status response	UDI record has been submitted to EUDAMED but the response is not being updated yet. Execute /UDI/STATUS T-Code

### 7.1.2 UDI record creation

A new UDI master data can be created by using this button:



**UDI data maintenance for GMN**

Audit trail   Check UDI data

**BASIC UDI-DI**

Authority: EU   Description: [ ]   BUDI: [ ]

**Release status**

BASIC UDI-DI released    All UDI-DIs released

**BASIC UDI-DI**   **UDI-DI**

**Status**

Released   **Release**    Trigger fields locked   To be submitted   Version: 0

DUNS number: [ ]

Applicable Legislation: [ ]

Issuing Agency: [ ]   Basic UDI-DI Code: [ ]

Risk Class: [ ]   Actor SRN: [ ]

System or Procedure Pack: Device (no system/no proced...   Special Device Type: No special device type

### 7.1.3 UDI data integrity check

The data integrity function checks whether there are any differences between the UDI data and the existing UDI attributes in the SAP system in the standard fields. For example, you have already created an UDI attributes in the material classification in your system.

With an custom ABAP coding it is possible to check the values in the SAP classification or any other existing UDI data in your system against the entered value in the UDI Add-On application.

Even if these UDI attributes exists in two places in Sap, it can be checked if the values are the same.

If a change of such "mirrored" fields is detected, you can copy all values to the UDI master record checking the fields as shown in the figure below. Only the source data is transferred to the UDI master record. The original value of the data source remains unaffected by the change since it has been set as the leading field.

**UDI data maintenance for GMN 12345HearingAid2021C8**

Result of the data integrity check

Take over	Trig.lock	Basic UDI-DI Code	Material	Area	Field name	UDI value	Direction	Orig.value	Source	Note
<input type="checkbox"/>	<input type="checkbox"/>	12345HearingAid2021C8	1743	UDI-DI	Second UDI DI Code		←		International Article Number (EAN/UPC)	

To accept the selected field contents, press the Save Button. Only the values are transferred which are checked before. Click Save button to take over the values into the UDI Master Data Maintenance.

### 7.1.4 UDI data release status

After the data maintenance is completed, the data has to be released by the responsible departments. The departments responsible for data release can be defined in UDI Program Settings / UDI Departments. Each department has it's own authorization values. Ideally 2 or 3 different people are releasing the data.

Basic UDI and UDI-DI data have separate release statuses

Sample departments: (Test screenshot with only one user, in your system it should be different users)

Released	Department	User	Change date	Change time
<input checked="" type="checkbox"/>	Labeling	DZENEI	26.11.2021	17:39:24
<input checked="" type="checkbox"/>	Marketing	DZENEI	26.11.2021	17:39:26
<input checked="" type="checkbox"/>	Quality	DZENEI	26.11.2021	17:39:29

Attention: Each department that is defined in UDI Program Settings must release UDI data to complete the release process. Don't forget to save the change in the release status.

Symbol	Function	Description
	Release status indicator of Basic UDI-DI data	This checkbox is set to "checked" automatically after Basic UDI-DI data has been released by all departments.
	Release status indicator of all UDI-DI data records	This checkbox is set to "checked" automatically after all UDI-DI records have been released by all departments.
	Release status indicator of Basic UDI-DI data	This checkbox is set to "checked" automatically after Basic UDI-DI data has been released by all departments.
	Release status indicator of each UDI-DI data record	This checkbox is set to "checked" automatically after related UDI-DI record has been released by all departments.

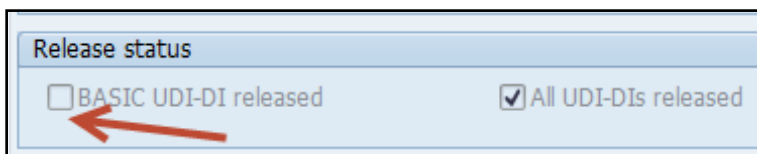
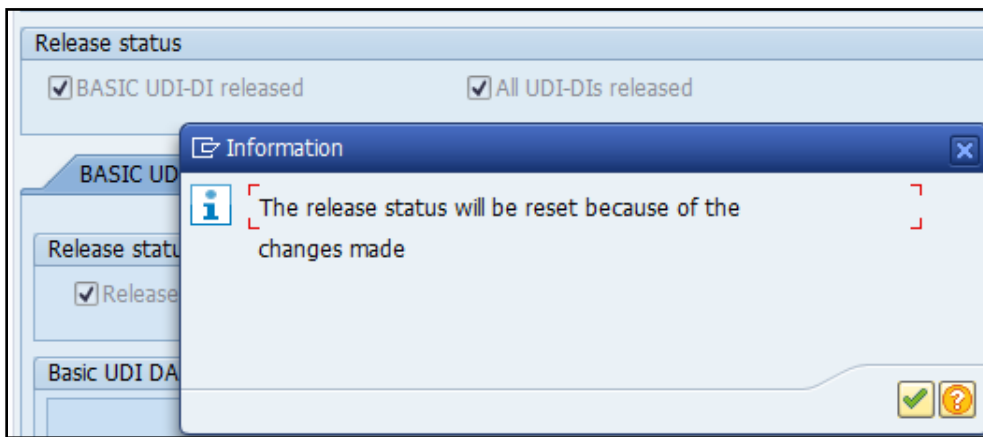
After releasing Basic UDI-DI data and all UDI-DI data, release status indicators are as shown in the image below:

Release status

BASIC UDI-DI released       All UDI-DIs released

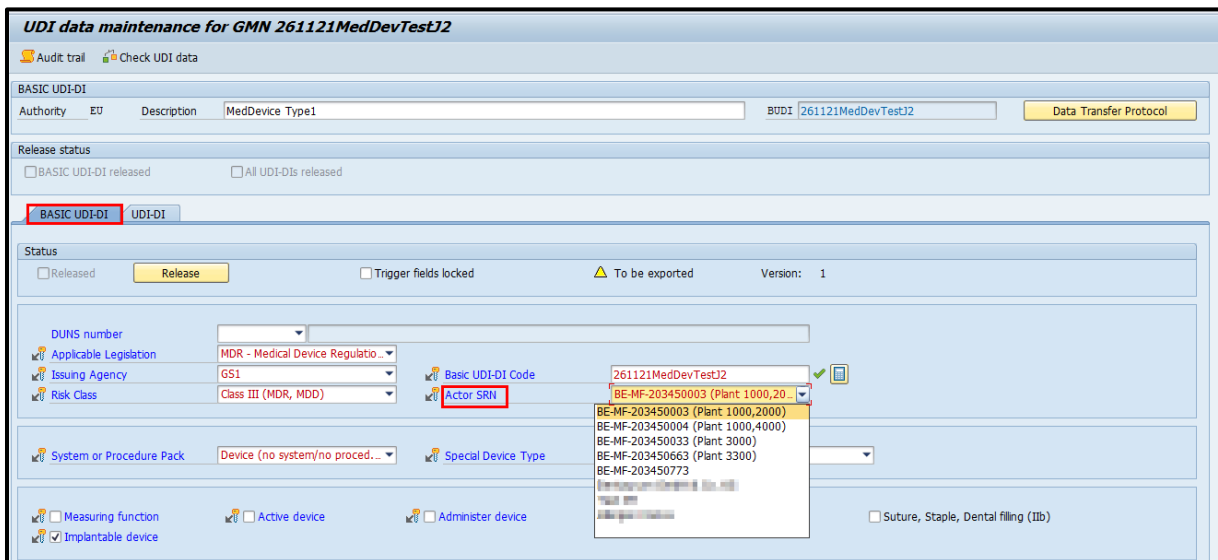
Attention: If any changes are made in Basic UDI-DI or UDI-DI attributes, after all release statuses have been checked, the system will reset release status of the related Basic UDI-DI or UDI-DI data.

Message screen after changing released Basic UDI-DI data:



### 7.1.5 SRN Authorization

Basic UDI-DI data: In the field "Actor SRN" users must select a value for the SRN from the dropdown list. The user can see only the SRN-s he/she is authorized for.



UDI-DI data: The user can only add materials from the plants assigned to SRN which the user is authorized for:

The user is able to see and unlink UDI-DI data which was assigned to a BASIC UDI-DI with a different SRN for which the user is not authorized. The following error message is displayed for such data: "SRN xxx: wrong assignment of material xxx":

**UDI data maintenance for GMN 201910001770WH**

DI Type	Material	Status	Message
BUDI		●	Technical: (This UDI - Add-On) is not valid
BUDI		●	Termination of the UDI "Packaging Information" and "UDI data" is mandatory and should be done before the UDI is entered into the system
DI	900-003	●	
DI	T-F723	●	SRN BE-MF-203450003: wrong assignment of material T-F723
DI	T-F723	●	Technical: (This UDI - Add-On) is not valid
DI	T-F723	●	SRN BE-MF-203450003: wrong assignment of material T-F724
DI	T-F724	●	SRN BE-MF-203450003: wrong assignment of material T-F724
DI	T-F724	●	Please enter the value for the first three fields

SAP | EU\_TEST01 | SAP01 | INS

## 7.1.6 Maintaining data in “Packaging”

The data in the table “Packaging” should be maintained as shown in the example below, in order to be uploaded to the EUDAMED section “Container Package Information” correctly:

Additional data

Packaging | Storage&Handling | Market Info | Critical Warning | Clinical Size | Substance | Add'l Description | Trade Name | EMDN

Packaging

Issuing Agency	Package UDI-DI code	Device status	Child DI agency	Child UDI-DI Code	Quantity per package
HIBCC	+A999RETIN000PACK2	ON_THE_MARKET	HIBCC	+A999RETINOGRAPH2	10
HIBCC	+A999RETIN000PACK3	ON_THE_MARKET	HIBCC	+A999RETIN000PACK2	5

**Container Package Information** Create new version

Version 1 | Last update date: 2021-10-14

- [Root] UDI-DI: +A999RETINOGRAPH2 (HIBCC)
  - UDI-DI: +A999RETIN000PACK2 (HIBCC) | Quantity per package: 10 (10)
    - o UDI-DI: +A999RETIN000PACK3 (HIBCC) | Quantity per package: 5 (50)

## 7.2 UDI data overview display transaction

### 7.2.1 UDI data overview

It is possible to display an overview of the data for all Basic UDI-DIs and also the UDI-DIs. You can also enter additional parameters to obtain an overview of the desired materials.

### Display EUDAMED UDI Attributes

Data area

Show Basic UDI-DI Data     Show UDI-DI Data

Basic UDI-DI Fields

Basic UDI-DI Code	<input type="text"/>	to	<input type="text"/>	
Actor SRN	<input type="text"/>	to	<input type="text"/>	
Applicable Legislation	<input type="text"/>	to	<input type="text"/>	
Device Model	<input type="text"/>	to	<input type="text"/>	
Device Name	<input type="text"/>	to	<input type="text"/>	
Risk Class	<input type="text"/>	to	<input type="text"/>	
Basic UDI Description	<input type="text"/>	to	<input type="text"/>	
BUDI Guid	<input type="text"/>	to	<input type="text"/>	
DUNS	<input type="text"/>	to	<input type="text"/>	

UDI-DI Fields

EU UDI relevant	<input type="text" value="1"/>	to	<input type="text"/>	
Material	<input type="text"/>	to	<input type="text"/>	
UDI-DI Code	<input type="text"/>	to	<input type="text"/>	

Data transfer status

Data transfer pending  
 Show only released records

Basic UDI Overview in ALV table:

**BASIC-UDI Attribute - Selected Records: 282**

Validate data    Export messages    Release    Un-Release    Save only valid data    Save All Data (Ignore Errors)

Messages	Labeling	Marketing	Quality	Exported	Version	Descri..	DUNS	Basic U Ag	Basic UDI-DI Code	Basic UDI Description	Trig.Lock.	Released	All DI rel	Appl.Le..
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1			HIBCC	++A99913082021NW	Test 13082021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	MDR
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1			HIBCC	++A999MDRTest2610X8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	MDR
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		6	Duns 2	123456789	HIBCC	++A999MedicalStation5X	Medical Station TEST	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	MDR
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		3	Duns 3	333333333	HIBCC	++A999RetinographMP	Retinograph	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	MDR
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1			HIBCC	++A999SPPtestBY		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	MDR
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1			HIBCC	++A999Upload2FF		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	MDR
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		13	Duns 2	123456789	HIBCC	++EFOR1100000075	Blood glucose meter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	MDR
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		2			HIBCC	++EFOR122225SEN	Test Send	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	MDR

UDI-DI Overview in ALV table:

**UDI-DI Attribute - Selected Records: 1.218**



Validate data    Export messages    Release    Un-Release    Save only valid data    Save All Data (Ignore Errors)

Messages	Labeling	Marketing	Quality	Exported	Version	Basic UDI-DI Code	Material	Trig.lock.	Released	Iss.Agency	UDI-DI Code	Device status
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1	++A99913082021NW	1308TEST	<input type="checkbox"/>	<input type="checkbox"/>	HIBCC	1308	ON_THE_MARKET
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1	++A999MDRTest2610X8	2501-5	<input type="checkbox"/>	<input type="checkbox"/>	HIBCC	+A999MDRTEST2610X8	ON_THE_MARKET
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4	++A999MedicalStation5X	1734	<input type="checkbox"/>	<input type="checkbox"/>	HIBCC	+A999IVDD-TEST1	NO_LONGER_PLACED_ON_THE_MARKET
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1	++A999MedicalStation5X	1011-5	<input type="checkbox"/>	<input type="checkbox"/>	GS1	04049368551188	ON_THE_MARKET
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1	++A999MedicalStation5X	2411-5	<input type="checkbox"/>	<input type="checkbox"/>	HIBCC	++A999MedicalSt1	ON_THE_MARKET
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		3	++A999RetinographMP	1739	<input type="checkbox"/>	<input type="checkbox"/>	GS1	4049368137719	NO_LONGER_PLACED_ON_THE_MARKET
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		3	++A999RetinographMP	1740	<input type="checkbox"/>	<input type="checkbox"/>	GS1	98798798798111	ON_THE_MARKET
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1	++A999SPPtestBY	2710-2	<input type="checkbox"/>	<input type="checkbox"/>	HIBCC	+A999SPPPTTESTBY1	NOT_INTENDED_FOR_EU_MARKET
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1	++A999SPPtestBY	2710-3	<input type="checkbox"/>	<input type="checkbox"/>	HIBCC	+A999SPPPTTESTBY2	NOT_INTENDED_FOR_EU_MARKET
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1	++A999Upload2FF	1011-2	<input type="checkbox"/>	<input type="checkbox"/>	HIBCC	++A999UPLOAD2FFUDIWS	ON_THE_MARKET

The color of the icon in the column “messages” indicates whether data validation errors has been detected.

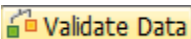
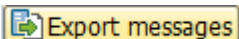
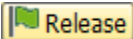
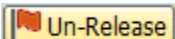
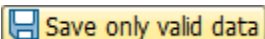
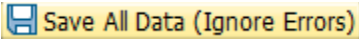
**Meaning of the colors in the column Messages:**

Symbol	Description
	No errors were detected. The data is valid.

	Errors were detected and must be fixed before you upload the data to EUDAMED.
	Serious error were detected. Data record cannot be saved, changed or uploaded.

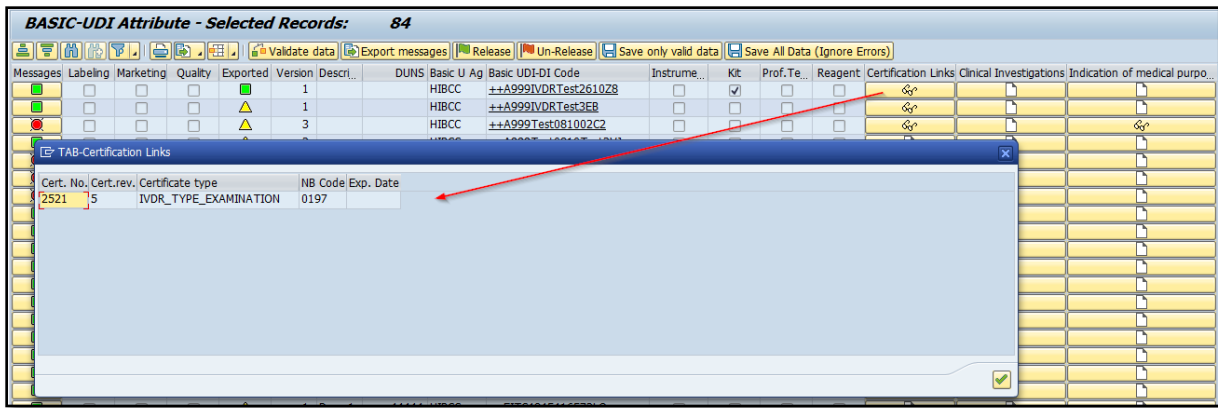
## 7.2.2 UDI master data release

This transaction offers the possibility of mass release of all selected UDI data records. In addition, all displayed data can be checked.

Symbol	Function	Description
	Data check according business rules for UDI data	This function starts the validation of the data. After starting the transaction, the check is initially triggered. Warnings and errors are displayed in the first column labeled "Messages". Detailed error messages can be viewed by clicking on the message icon.
	Export error messages to an Excel file	This function exports all error messages in an Excel file.
	Release	This function sets all release tags for the displayed records.
	Un-Release	This function sets all un-release tags for the displayed records.
	Save only valid records	Only those data records are saved that have no errors according to the Business Rules.
	Save all records	All data records are saved, even those with incorrect data.

## 7.2.3 Displaying Multi-Value data

At the end of the ALV table, the details of the tabular data are displayed as buttons. The eyeglasses icon indicates that there exists data for this line. The recorded data is displayed in a pop-up window after clicking the button with the eyeglasses icon.

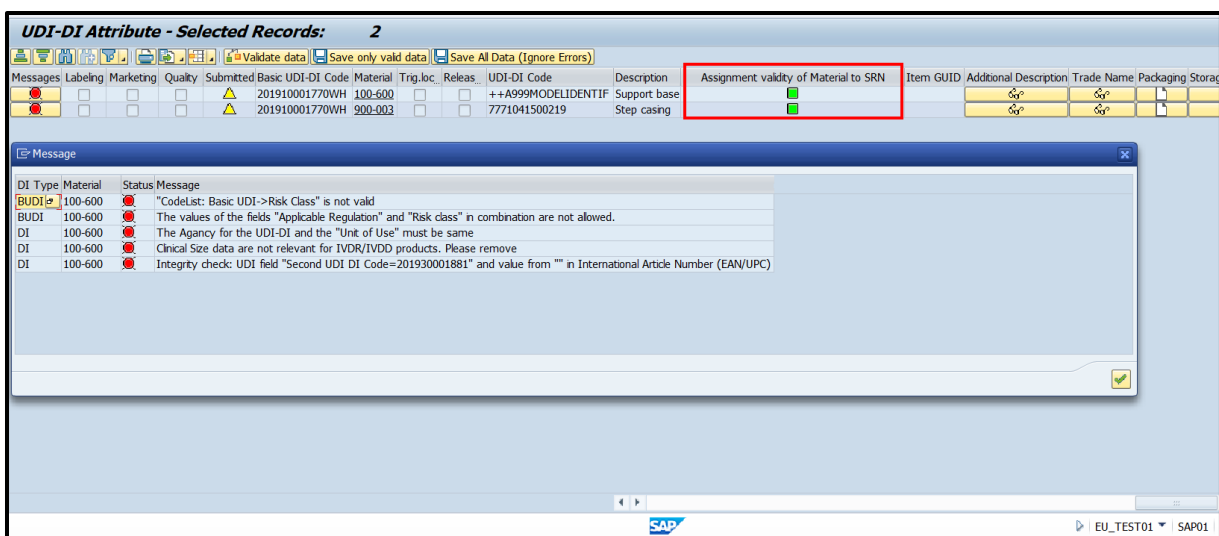


### 7.2.4 SRN Authorization

By clicking “Show Basic UDI-DI Data” users can see only the Actor SRNs for which they are authorized for.

BASIC-UDI Attribute - Selected Records: 29													
Messages	Labeling	Marketing	Quality	Exported	Version	Descri..	DUNS	Basic U Ag	Basic UDI-DI Code	Actor SRN	Risk Class	Syst.or Proc.Pack	
				▲	1			HIBCC	++A99913082021NW	BE-MF-203450003	CLASS_III	DEVICE	
				▲	1			HIBCC	++A999MDRTest2610X8	DE-MF-000001044	CLASS_III	DEVICE	
				▲	1			HIBCC	++A999NEUTest33011ZE	CH-PR-000004021	CLASS_III	SYSTEM	
				▲	1			HIBCC	++A999SPPPtestBY	CH-PR-000004021	CLASS_III	PROCEDURE_PACK	
				▲	1	Duns 1	44444	HIBCC	++A999Test33011S9	CH-PR-000004021	CLASS_III	SYSTEM	
				▲	1	Duns 2	123456789	HIBCC	++EITC5001225179	DE-MF-000001044	CLASS_III	DEVICE	
				▲	1	Duns 2	123456789	GS1	0013444443343JABX6	FR-MF-000000541	CLASS_III	DEVICE	
				▲	1	Duns 1	44444	GS1	040821PHTEST2F	BE-MF-203450003	CLASS_III	DEVICE	
	✓			▲	3			GS1	074521Test1MDRYUV	DE-MF-000001044	CLASS_III	DEVICE	
	✓			▲	1			GS1	1234507.JuniTesG8	BE-MF-203450003	CLASS_III	DEVICE	
				▲	1	Duns 1	44444	GS1	12345678901234567892123P9	FR-MF-000000541	CLASS_III	DEVICE	
	✓			▲	1	Duns 1	44444	GS1	12345AGTESTPHCF	BE-MF-203450003	CLASS_III	DEVICE	

Also by clicking “Show UDI-DI Data” users can see only the Actor SRNs for which they are authorized for. There is an extra field “Assignment validity of Material to SRN” which shows if the assignment to the SRN is correct. This column is only visible, when SRN assignment function is activated.



### 7.3 UDI data mass maintenance

In UDI mass maintenance, several data records can be changed at the same time.

### 7.3.1 Selection screen

Different selection criteria can be entered in the selection screen. In the field "Data Area" either the "Basic UDI Data" or the "UDI-DI Data" has to be selected. After selecting the data area, the single fields of the respective area are displayed.

**UDI data mass maintenance**

Basic UDI-DI Fields

Basic UDI-DI Code	<input type="text"/>	to	<input type="text"/>	<input type="button" value="↕"/>
Actor SRN	<input type="text"/>	to	<input type="text"/>	<input type="button" value="↕"/>
Applicable Legislation	<input type="text"/>	to	<input type="text"/>	<input type="button" value="↕"/>
Device Model	<input type="text"/>	to	<input type="text"/>	<input type="button" value="↕"/>
Device Name	<input type="text"/>	to	<input type="text"/>	<input type="button" value="↕"/>
Risk Class	<input type="text"/>	to	<input type="text"/>	<input type="button" value="↕"/>
Basic UDI Description	<input type="text"/>	to	<input type="text"/>	<input type="button" value="↕"/>
BUDI Guid	<input type="text"/>	to	<input type="text"/>	<input type="button" value="↕"/>
DUNS	<input type="text"/>	to	<input type="text"/>	<input type="button" value="↕"/>

UDI-DI Fields

Material	<input type="text"/>	to	<input type="text"/>	<input type="button" value="↕"/>
UDI-DI Code	<input type="text"/>	to	<input type="text"/>	<input type="button" value="↕"/>

Scope

Data Area

### 7.3.2 Field selection

All data fields for the selected area are displayed and the fields which have to be changed can be selected:

**UDI data mass maintenance**

Field selection

Field Name	Long Field Label
ACTIVEDEVICE	Active Device
MFCODE	Actor SRN
ADMINMEDICINE	Administer Device
LEGISLATION	Applicable Legislation
ARCODE	Authorised Representative SRN
BUDI_DESCR	Basic UDI Description
DIAGENCY	Basic UDI Issuing Agency
DICODE	Basic UDI-DI Code
CDIAGNOSTIV	Companion Diagnostic
DUNS	DUNS
DEVICEMODEL	Device Model
DEVICENAME	Device Name
IMPLANTABLE	Implantable Device
INSTRUMENT	Instrument
KIT	Kit
MEASUREFUNC	Measuring function
NEARPATIENT	Near-patient testing
MICSUBSTANCE	Pres. of cells/subst. of microb. orig.
TISSUE_ANIMALS	Presence of animal tissues or cells
TISSUE_HUMAN	Presence of human tissues or cells
PROFTESTING	Professional Testing
REAGENT	Reagent
REUSABLE	Reusable Surgical Instrument
RISKCLASS	Risk Class
SELFTESTING	Self-patient testing
SPECIALDEVICE	Special Device Type
IMPLEXCEPT	Suture,Staple,Dental filling (Iib)
SPPTYPE	System or Procedure Pack
LOCKED	Trigger fields locked

After that, the field with the possible entries appears on the right side.

In the lower part of the screen you will see all the products that you have narrowed down at the beginning.

**Field selection**

Field Name	Long Field Label
ACTIVEDEVICE	Active Device
ADMINMEDICINE	Administer Device
ARCODE	Authorised Representative SRN
BUDI_DESCR	Basic UDI Description

**New field value**

Field Name	Long Field Label	Condition	Appl.regulation	Action	NEW:Applic
LEGISLATION	Applicable reg...				

**Selected records:55**

Basic UDI-DI Code	Basic UDI Description	Field Name	Long Field Label	Appl.regu.	Message
++EFOR1100000075	OTHERBlood glucose meter	LEGISLATION	Applicable regulation	IVDR	
++EITC-SCHEERE-V1XM	Scheere V1	LEGISLATION	Applicable regulation	IVDR	
++EITC4444455555JG	Reagenzgläser klein	LEGISLATION	Applicable regulation	IVDD	Trigger fields are locked. Changes cannot be done
++EITC4845412002JE	HEXAGON HEAD SCREW	LEGISLATION	Applicable regulation	MDR	
++EITC4845412003JG	FLY WHEEL W-102	LEGISLATION	Applicable regulation	IVDR	

You can now enter the new value in the right-hand area of the screen. You also have the option of linking the change to a condition.

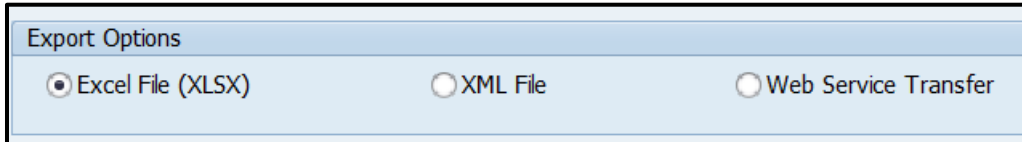
With the function "Start in test mode" you can display all affected data fields. These are marked in green. With "Activate change" the changes are carried out.

## 7.4 UDI master data export

### 7.4.1 General settings

In the “Export Options” you can decide what kind of export file should be created. It is possible that not all options are available in your system because of restrictions or not existing authority.

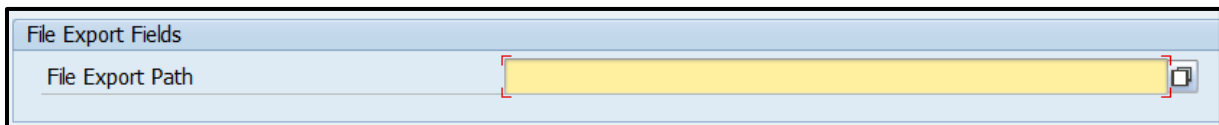
Possible export types are Excel file, XML file or XML file which will be submitted to a third party service.



Export Options

Excel File (XLSX)       XML File       Web Service Transfer

File Export field is available only for Excel export and XML File option. In this folder the exported file(s) will be saved.



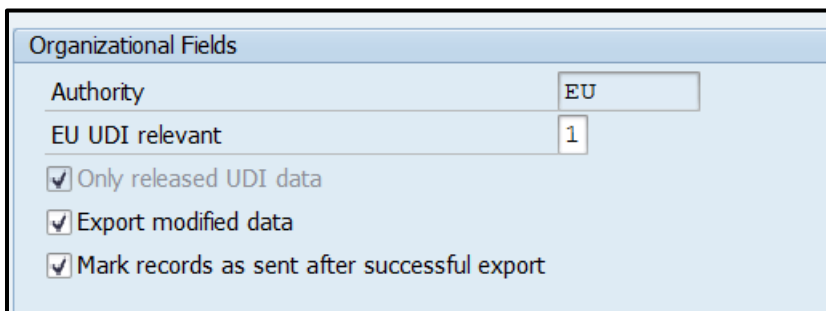
File Export Fields

File Export Path

In this section you can select which records should be exported. Depending on the Export Options selection some settings can't be changed, are not visible or have default values.

“Export modified data” are such records which were changed since the last export and are marked as exported.

“Mark records as sent after successful export” will set the internal indicator that this record was exported.



Organizational Fields

Authority: EU

EU UDI relevant: 1

Only released UDI data

Export modified data

Mark records as sent after successful export

### 7.4.2 UDI master data export (Excel)

The UDI master data export generates an Excel file with all UDI data. You can use the Excel file for various purposes. Various selection criteria are available to obtain the result that is adjusted to your needs.

It is possible to export only the BUDI and UDI-DI data for the materials assigned to the SRN's the user is authorized for.

**UDI Master Data Export**

Export Options

Excel File (XLSX)     XML File     Web Service Transfer

File Export Fields

File Export Path

Organizational Fields

Authority

EU UDI relevant

Only released UDI data

Export modified data

Mark records as sent after successful export

Basic UDI-DI Fields

Basic UDI-DI Code	<input type="text"/>	to	<input type="text"/>	
Actor SRN	<input type="text"/>	to	<input type="text"/>	
Applicable Legislation	<input type="text"/>	to	<input type="text"/>	
Device Model	<input type="text"/>	to	<input type="text"/>	
Device Name	<input type="text"/>	to	<input type="text"/>	
Risk Class	<input type="text"/>	to	<input type="text"/>	
Basic UDI Description	<input type="text"/>	to	<input type="text"/>	
BUDI Guid	<input type="text"/>	to	<input type="text"/>	
DUNS	<input type="text"/>	to	<input type="text"/>	

UDI-DI Fields

Material	<input type="text"/>	to	<input type="text"/>	
UDI-DI Code	<input type="text"/>	to	<input type="text"/>	

### 7.4.3 UDI master data export (XML)

The UDI master data export generates XML files for uploading the UDI data into EUDAMED database. You can also use the exported XML data for other purposes.

You can enter your selection criteria in the selection screen. In most cases, it makes sense to export only released UDI data.

It is possible to export only the BUDI and UDI-DI data for the materials assigned to the SRN's the user is authorized for.

**UDI Master Data Export**

Export Options  
 Excel File (XLSX)  XML File  Web Service Transfer

File Export Fields  
 Attention: All XML files in the target folder will be deleted  
 File Export Path   
 Create new sub folder

Organizational Fields  
 Authority   
 EU UDI relevant   
 Only released UDI data  
 Export modified data  
 Mark records as sent after successful export

XML Settings  
 Merge multiple UDI records into a single XML file  


---

 System controlled  
 Create "INSERT BUDI & UDI-DI"  
 Create "UPDATE BUDI"  
 Create "ADD UDI-DI to BUDI"  
 Create "UPDATE UDI-DI"

Basic UDI-DI Fields

Basic UDI-DI Code	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>
Actor SRN	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>
Applicable Legislation	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>
Device Model	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>
Device Name	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>
Risk Class	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>
Basic UDI Description	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>
BUDI Guid	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>
DUNS	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>

UDI-DI Fields

Material	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>
UDI-DI Code	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>

Defined by EUDAMED, there exist 4 different XML file structures. These file structures are:

1. Insert action with 1 x Basic UDI-DI and 1-n UDI-DI (to EUDAMED database)
2. Update 1 x Basic UDI-DI (in EUDAMED database)
3. Add 1-n UDI-DI to existing Basic UDI-DI (in EUDAMED database)
4. Update 1-n UDI-DI (in EUDAMED database)

The option "Merge multiple XML files into a single XML file" will create only one file for all same action types. This allows you to have less manual upload effort.

The option "System controlled" will determine if a UDI record was already exported and which version this record has. Depending on these parameters the program will create one of above XML file types. All other options are forcing the program to create the selected file type.

**XML Settings**

Merge multiple UDI records into a single XML file

---

System controlled

Create "INSERT BUDI & UDI-DI"

Create "UPDATE BUDI"

Create "ADD UDI-DI to BUDI"

Create "UPDATE UDI-DI"

## 7.4.4 UDI data upload via Webservice

This Web Service Transfer is still not released and functional.

**UDI Master Data Export**

Excel File (XLSX)     XML File     Web Service Transfer

**Organizational Fields**

Authority:

EU UDI relevant:

Only released UDI data

Export modified data

Mark records as sent after successful export

**Basic UDI-DI Fields**

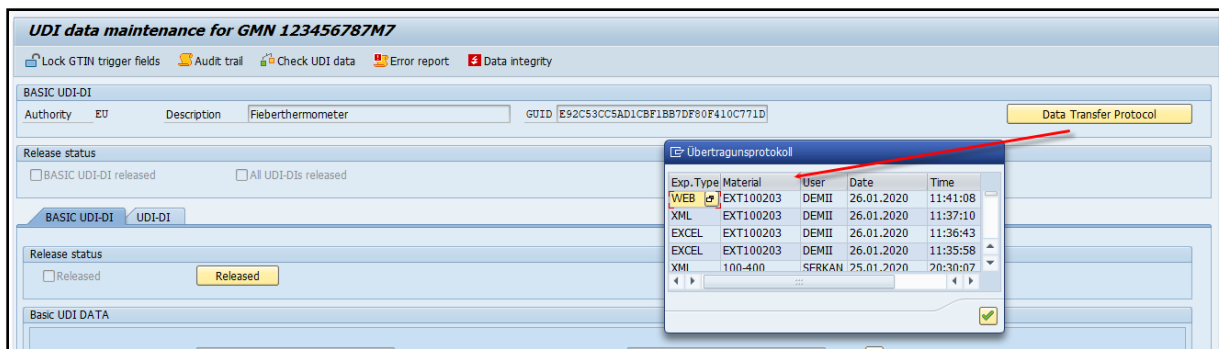
Basic UDI-DI Code	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>
Actor SRN	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>
Applicable Legislation	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>
Device Model	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>
Device Name	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>
Risk Class	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>
Basic UDI Description	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>
BUDI Guid	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>
DUNS	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>

**UDI-DI Fields**

Material	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>
UDI-DI Code	<input type="text"/>	to	<input type="text"/>	<input type="button" value="→"/>

This transaction is identical to the UDI data export to hard disk with the only difference that the data is transferred directly to the web server of Europe IT. For the user, the transfer process is completed after choosing the criteria and clicking “Web Service Transfer”.

You can see the “data transfer protocol” in UDI maintenance screen.



## 7.5 UDI data upload via MS Excel (xlsx) template

This function is used to upload data into the UDI module from an Excel file. Following process types are available:

Process Type	Description
Insert Process – Full upload	Initial data upload/creation (Basic UDI-DI Code and Material number are required)
Insert Process – BUDI only	Data upload/creation related Basic UDI fields only (Basic UDI-DI Code is required)
Insert Process – UDI DI only	Data upload/creation related UDI-DI fields only (Basic UDI-DI Code and Material number are required)
Update Process – BUDI and UDI DI	Update existing Basic UDI and UDI DI data (Basic UDI-DI Code and Material number are required)
Update Process – BUDI only	Update existing Basic UDI fields only (Basic UDI-DI Code is required)
Update Process – UDI DI only	Update existing UDI DI fields only (Basic UDI-DI Code and Material number are required)

Planned action	Data status in Add-On before carrying out the planned action				Process type
	BUDI exists		UDI-DI exists		
	Yes	No	Yes	No	
Create new BUDI and new UDI-DI data		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	Insert Process - Full upload
Create new BUDI data		<input checked="" type="checkbox"/>	N/A	N/A	Insert Process - BUDI only
Create new UDI-DI data	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	Insert Process - UDI DI only
Update existing BUDI and existing UDI-DI data	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>		Update Porcess - BUDI and UDI DI
Update existing BUDI data	<input checked="" type="checkbox"/>		N/A	N/A	Update Process - BUDI only
Update existing UDI-DI data	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>		Update Process - UDI DI only

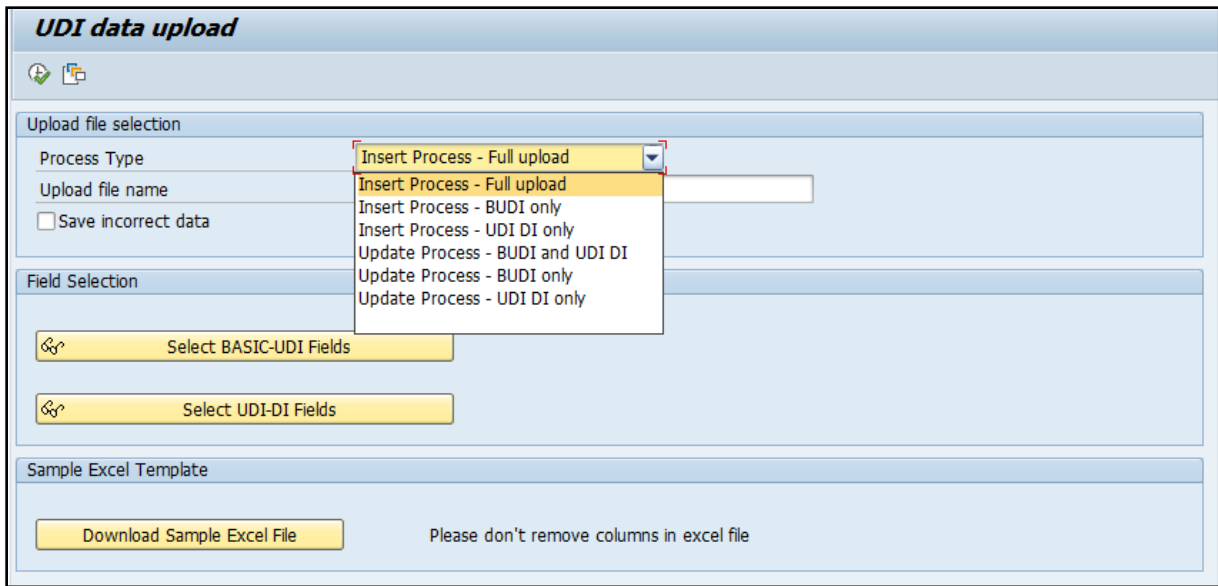
**Creation of a new record and updating of an existing record in the same process (with the same excel file) is not supported**

The data upload should only be done with the provided Excel template. The template is delivered with the UDI module and supports the upload of all UDI attributes.

Sample Excel (xlsx) template file can be downloaded using button “Download Sample Excel File”. During the upload, the fields are checked against their technical names, whether they exist in the SAP system.

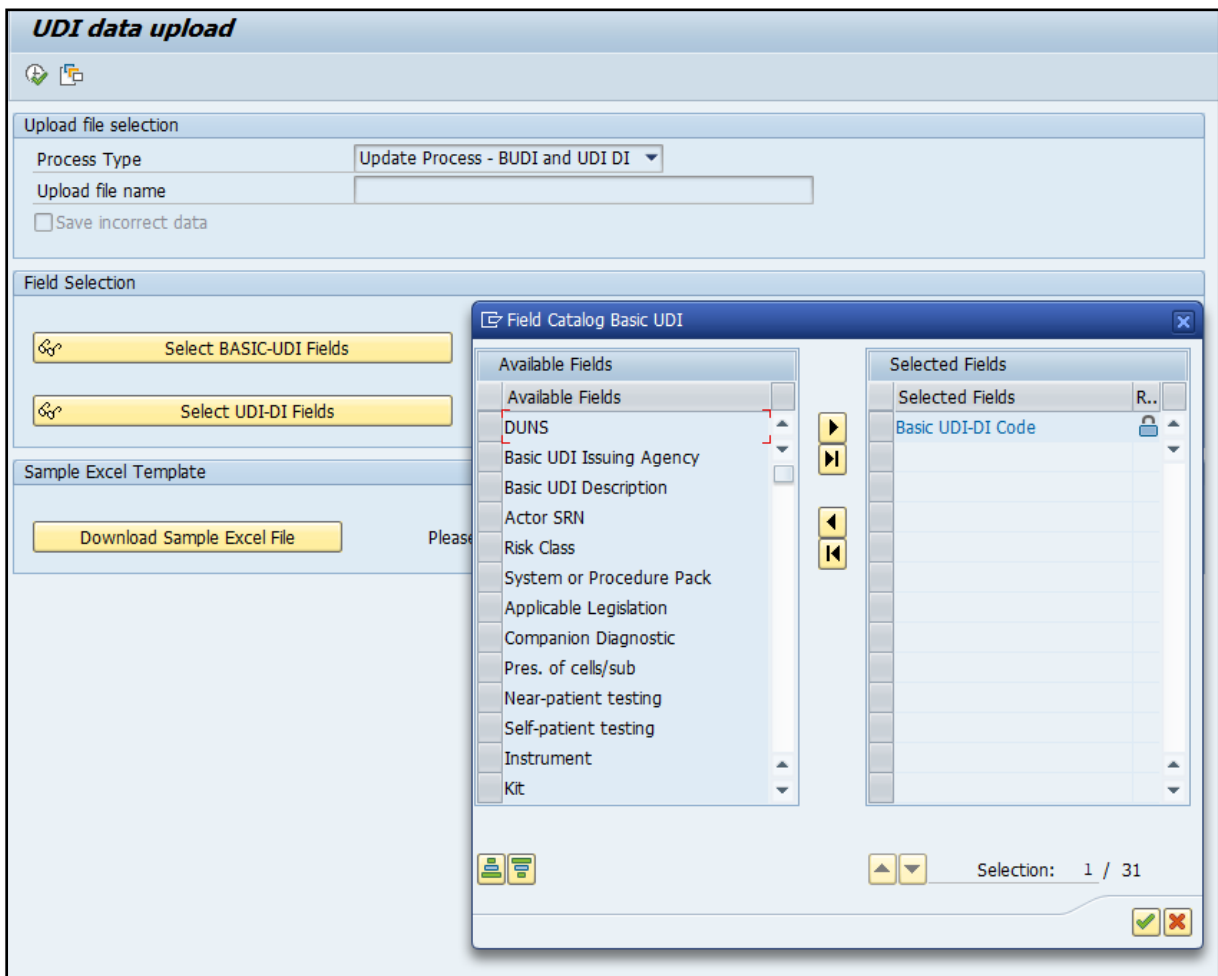
**Attention: The function “Insert Processes” is only designed for the initial data upload. If data for the Basic UDI-DI Code / material already exists in the SAP system the application will abort.**

It is also not possible to combine in one Excel file data which should be initially uploaded and others should be updated. Only one process can be executed with one excel file.

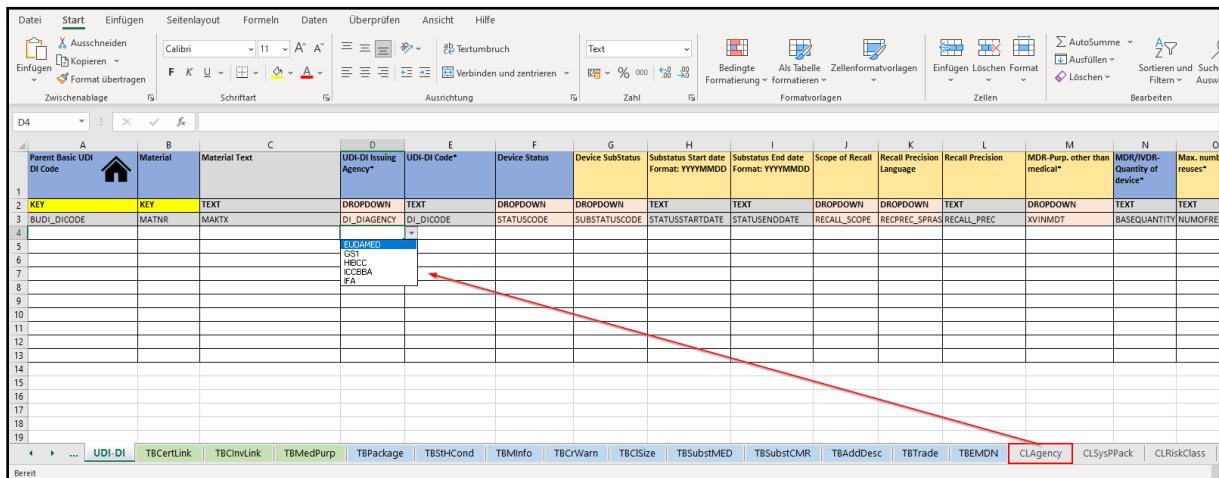


**For “Update” process it is possible to select the fields which should be considered by an update:**

All UDI data fields can be selected dynamically for insert and update processes.



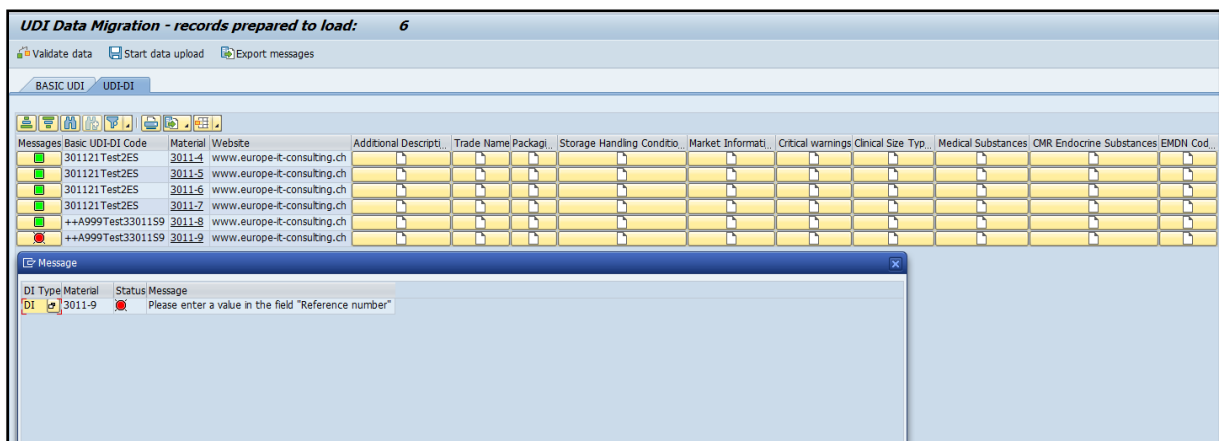
The Excel template contains code lists, which can be found in separate sheets. The code lists are the source of the dropdown values in the sheets “BASIC UDI-DI”; “UDI-DI” and sheets for additional information (name starting with “TB”):



During data upload, the filled target file is specified and displayed in a tabular view. This gives you another opportunity to check the data for accuracy.

By checking “Save incorrect data” in the selection screen it is possible to save data which contains errors.

In the ALV display you can check the data records prepared to load in SAP. It is possible to validate the data and see warnings and error messages by clicking on the pop-up window. If you want to correct the data before saving, you must do this in the Excel template and start the upload again.



With the function "Start data upload", the data is now stored in SAP. The lines marked green have been saved. Red lines are not, unless you have checked “Save incorrect data” in the selection screen.

In the example below the user tried to update the website information for 6 UDI-DI records. There are two Basic UDI-DI-s: “301121Test2ES” with 4 UDI-DI records and “++A999Test33011S9” with 2 UDI-DI records. One of the UDI-DI records which belongs to the Basic UDI-DI “++A999Test33011S9” contains errors. For that reason also the other UDI-DI was not updated and the update for 4 UDI-DIs was saved.

**UDI Data Migration - Loaded records: 6**

Validate data Start data upload Export messages

BASIC UDI UDI-DI

Messages	Basic UDI-DI Code	Material	Website	Additional Descripti...	Trade Name Packagi...	Storage Handling Conditio...	Market Informati...	Critical warnings Clinical Size Typ...	Medical Substances	CMR Endocrine Substances	EMDN Cod
✓	301121 Test2ES	3011-4	www.europe-f-consulting.ch								
✓	301121 Test2ES	3011-5	www.europe-f-consulting.ch								
✓	301121 Test2ES	3011-6	www.europe-f-consulting.ch								
✓	301121 Test2ES	3011-7	www.europe-f-consulting.ch								
++	A999 Test3301159	3011-8	www.europe-f-consulting.ch								
+	A999 Test3301159	3011-9	www.europe-f-consulting.ch								

0 Basic UDI-DI data and 4 UDI-DI data has been saved

SAP DZENEI SAP01

## 7.6 UDI data audit trail

The audit trail can be called either through the UDI maintenance transaction /UDI/MAINTAIN or through the audit trail transaction /UDI/AUDITTRAIL. In the selection screen, you can narrow down your search using the available selection criteria.

**UDI audit trail**

Object type

GUID  to

Basic UDI-DI Code  to

Material  to

Table Name  to

User Name  to

Transaction Code  to

Field Name  to

Date selection  to

Available Change Pointer Objects:

Change Pointer Objects	Meaning
UDI_DATA	Changes in UDI master data
UDI_REL	Changes in the data release
UDI_VERSIO	Changes in UDI data versions
UDI_PDADDR	Changes in Product Designer address

Evaluation of the UDI audit trail as ALV output

**UDI audit trail**

Object type	Doc. no.	GUID	Basic UDI-DI Code	Material	Key fields	Key values	TCode	Action	Current Date	Time	User	Table Name	Field Name	New value	Old value
UDI_DATA	786411	EC51EE...		3011-7			/UDI/UPLOAD	U	02.12.2021	13:11:51	DZENEI	/UDI/UIDATA	RELEASED_DI	X	
UDI_DATA	786410	EC51EE...		3011-6			/UDI/UPLOAD	U	02.12.2021	13:11:51	DZENEI	/UDI/UIDATA	RELEASED_DI	X	
UDI_DATA	786409	EC51EE...		3011-5			/UDI/UPLOAD	U	02.12.2021	13:11:51	DZENEI	/UDI/UIDATA	RELEASED_DI	X	
UDI_DATA	786408	EC51EE...		3011-4			/UDI/UPLOAD	U	02.12.2021	13:11:51	DZENEI	/UDI/UIDATA	RELEASED_DI	X	
UDI_REL	786407	EC51EE...	301121 Test2ES	3011-7	DEPARTMENT	Quality	/UDI/UPLOAD	U	02.12.2021	13:11:51	DZENEI	/UDI/RELEASE	RELEASETIME	085341	131143
UDI_REL	786406	EC51EE...	301121 Test2ES	3011-7	DEPARTMENT	Quality	/UDI/UPLOAD	U	02.12.2021	13:11:51	DZENEI	/UDI/RELEASE	RELEASED	X	
UDI_REL	786405	EC51EE...	301121 Test2ES	3011-7	DEPARTMENT	Marketing	/UDI/UPLOAD	U	02.12.2021	13:11:51	DZENEI	/UDI/RELEASE	RELEASETIME	085340	131143

## 7.7 UDI Audit Trail for data export / transfer

The audit trail of data exports and data transfers can be carried out in a separate transaction. In the selection area, you can narrow down your search using the available selection criteria.

**UDI Audit Trail for data export / transfer**

General

Export Type  to

User Name  to

Date  to

Time  to

Basic UDI-DI Fields

Basic UDI-DI Code  to

Actor SRN  to

Basic UDI Description  to

BUDI Guid  to

DUNS  to

UDI-DI Fields

Material  to

UDI-DI Code  to

DI Guid  to

Available Export Types:

Export Type	Short description
EXCEL	Export to an Excel file
XML	Export as XML file
WEB	UDI data transfer using Web Transfer

Evaluation of the UDI audit trail as ALV output

**UDI Audit Trail for data export / transfer**

Exp. Type	Transformation	User	Date	Time	Actor SRN	GUID	Basic UDI-DI Code	Basic UDI Description	DI GUID	UDI-DI Code	Material
EXCEL		DZENEI	01.12.2021	16:02:39	BE-MF-203450003	ECS1EE18A6AFA7F19A53F80F410C77	301121Test1EQ	3011 Test1	ECS2807F9118F3F19A53F80F410C771D	04049363422247	3011-14
EXCEL		DZENEI	01.12.2021	16:02:39	BE-MF-203450003	ECS1EE18A6AFA7F19A53F80F410C77	301121Test1EQ	3011 Test1	ECS2807F9118F2F19A53F80F410C771D	04049363456785	3011-13
EXCEL		DZENEI	01.12.2021	16:02:39	BE-MF-203450003	ECS1EE18A6AFA7F19A53F80F410C77	301121Test1EQ	3011 Test1	ECS1EE18A6AFA7F19A53F80F410C771D	04049363430143	3011-3
EXCEL		DZENEI	01.12.2021	16:02:39	BE-MF-203450003	ECS1EE18A6AFA7F19A53F80F410C77	301121Test1EQ	3011 Test1	ECS1EE18A6AFA7F19A53F80F410C771D	04049363430136	3011-2
EXCEL		DZENEI	01.12.2021	16:02:39	BE-MF-203450003	ECS1EE18A6AFA7F19A53F80F410C77	301121Test1EQ	3011 Test1	ECS1EE18A6AFA7F19A53F80F410C771D	04049363430112	3011-1
XML	/UDI/XSLT_EU_V3_S	DEMII	30.11.2021	14:30:16	DE-MF-000001044	ECS1DFE7FC0DE1F19A53F80F410C771D	21000T700CHECK	UPLOAD 30.11.2021	ECS1DFE7FC0DE3F19A53F80F410C771D	07822200000122	T800-02
XML	/UDI/XSLT_EU_V3_S	DEMII	30.11.2021	14:30:16	DE-MF-000001044	ECS1DFE7FC0DE1F19A53F80F410C771D	21000T700CHECK	UPLOAD 30.11.2021	ECS1DFE7FC0DE3F19A53F80F410C771D	07822200000115	T800-01
XML	/UDI/XSLT_EU_V3_S	DEMII	30.11.2021	14:27:46	DE-MF-000001044	ECS1DFE7FC0DE1F19A53F80F410C771D	21000T700CHECK	UPLOAD 30.11.2021	ECS1DFE7FC0DE3F19A53F80F410C771D	07822200000122	T800-02
XML	/UDI/XSLT_EU_V3_S	DEMII	30.11.2021	14:27:46	DE-MF-000001044	ECS1DFE7FC0DE1F19A53F80F410C771D	21000T700CHECK	UPLOAD 30.11.2021	ECS1DFE7FC0DE3F19A53F80F410C771D	07822200000115	T800-01
XML	/UDI/XSLT_EU_V3_S	DEMII	30.11.2021	14:23:17	DE-MF-000001044	ECS1DFE7FC0DE1F19A53F80F410C771D	21000T700CHECK	UPLOAD 30.11.2021	ECS1DFE7FC0DE3F19A53F80F410C771D	07822200000122	T800-02
XML	/UDI/XSLT_EU_V3_S	DEMII	30.11.2021	14:23:17	DE-MF-000001044	ECS1DFE7FC0DE1F19A53F80F410C771D	21000T700CHECK	UPLOAD 30.11.2021	ECS1DFE7FC0DE3F19A53F80F410C771D	07822200000115	T800-01

## 7.8 UDI data mass integrity check

UDI data integrity check can be done in bulk in this transaction. This function is only available, if a custom coding has been done before.

### UDI Data Mass Integrity

Organisational Fields

Authority:

Basic UDI-DI Fields

Basic UDI-DI Code	<input type="text"/>	to	<input type="text"/>	
Actor SRN	<input type="text"/>	to	<input type="text"/>	
Applicable Legislation	<input type="text"/>	to	<input type="text"/>	
Device Model	<input type="text"/>	to	<input type="text"/>	
Device Name	<input type="text"/>	to	<input type="text"/>	
Risk Class	<input type="text"/>	to	<input type="text"/>	
Basic UDI Description	<input type="text"/>	to	<input type="text"/>	
BUDI Guid	<input type="text"/>	to	<input type="text"/>	
DUNS	<input type="text"/>	to	<input type="text"/>	

UDI-DI Fields

EU UDI relevant	<input type="text" value="1"/>	to	<input type="text"/>	
Material	<input type="text"/>	to	<input type="text"/>	
UDI-DI Code	<input type="text"/>	to	<input type="text"/>	

Selection parameters

Show only different values

Execute data correction:

UDI Data Mass Integrity - Selected Records: 2.075

Data area: All

Messages Status: Uncheck All, Validate data, From UDI, Save

Messages	Status	Field name	Area	UDI value	Dir...	Original value	Source	Message
		Material	UDI-DI				International Article Numb...	
		Second UDI DI Code	UDI-DI				International Article Numb...	
		Second UDI DI Code	UDI-DI				International Article Numb...	
		Second UDI DI Code	UDI-DI				International Article Numb...	Entry in "Certification Links table" Line "1" not allowed.
		Second UDI DI Code	UDI-DI				International Article Numb...	Entry in "Certification Links table" Line "1" not allowed.
		Second UDI DI Code	UDI-DI				International Article Numb...	Entry in "Certification Links table" Line "1" not allowed.
		Second UDI DI Code	UDI-DI				International Article Numb...	The value in "Certification Links table", line "1", row "E...
		Second UDI DI Code	UDI-DI				International Article Numb...	
		Second UDI DI Code	UDI-DI	04049364523653			International Article Numb...	Entry in "Certification Links table" Line "1" not allowed.
		Second UDI DI Code	UDI-DI				International Article Numb...	Entry in "Certification Links table" Line "1" not allowed.
		Second UDI DI Code	UDI-DI				International Article Numb...	Entry in "Certification Links table" Line "1" not allowed.
		Second UDI DI Code	UDI-DI				International Article Numb...	Entry in "Certification Links table" Line "1" not allowed.
		Device Count	FDA Add-On	2		1	Device Count	For IVDR products only "SOFTWARE" is allowed as "Sp...
		Device packaged as sterile	FDA Add-On				Device packaged as sterile	For IVDR products only "SOFTWARE" is allowed as "Sp...
		Direct marking DI differs fro...	FDA Add-On	X			Direct marking DI differs fr...	For IVDR products only "SOFTWARE" is allowed as "Sp...
		Direct marking DI number	FDA Add-On	19191919191922			Direct marking DI number	For IVDR products only "SOFTWARE" is allowed as "Sp...

Validation Check:

UDI Data Mass Integrity - Selected Records: 2.075

Data area: All

Messages Status: Check All, Uncheck All, Validate data, From UDI, Save

Messages	Status	Take over	Field name	Area	UDI value	Dir...	Original value	Source	Message
			Second UDI DI Code	UDI-DI				International Article Numb...	
			Second UDI DI Code	UDI-DI				International Article Numb...	
			Second UDI DI Code	UDI-DI				International Article Numb...	Entry in "Certification Links table" Line "1" not allowed.
			Second UDI DI Code	UDI-DI				International Article Numb...	Entry in "Certification Links table" Line "1" not allowed.
			Second UDI DI Code	UDI-DI				International Article Numb...	Entry in "Certification Links table" Line "1" not allowed.
			Second UDI DI Code	UDI-DI				International Article Numb...	The value in "Certification Links table", line "1", row "E...
			Second UDI DI Code	UDI-DI				International Article Numb...	
			Second UDI DI Code	UDI-DI	04049364523653			International Article Numb...	Entry in "Certification Links table" Line "1" not allowed.
			Second UDI DI Code	UDI-DI				International Article Numb...	Entry in "Certification Links table" Line "1" not allowed.
			Second UDI DI Code	UDI-DI				International Article Numb...	Entry in "Certification Links table" Line "1" not allowed.
			Device Count	FDA Add-On	2		1	Device Count	For IVDR products only "SOFTWARE" is allowed as "Sp...
			Device packaged as sterile	FDA Add-On				Device packaged as sterile	For IVDR products only "SOFTWARE" is allowed as "Sp...
			Direct marking DI differs fro...	FDA Add-On	X			Direct marking DI differs fr...	For IVDR products only "SOFTWARE" is allowed as "Sp...
			Direct marking DI number	FDA Add-On	19191919191922			Direct marking DI number	For IVDR products only "SOFTWARE" is allowed as "Sp...
			Expiration date	FDA Add-On				Expiration date	For IVDR products only "SOFTWARE" is allowed as "Sp...
			Issuing Agency	FDA Add-On	GS1		HBCC	Issuing Agency	For IVDR products only "SOFTWARE" is allowed as "Sp...

### 7.8.1.1 UDI Product Designer addresses

If a medical device is designed or manufactured by another legal or natural person (a “Product Designer”), the information regarding the Product Designer has to be maintained at UDI-DI level in the transaction /UDI/MAINTAIN.

After activating the corresponding checkbox the user is asked to enter SRN or, if the SRN is not available, a Product Designer ID.

**UDI data maintenance for GMN 301121Test2ES**

Audit trail | Check UDI data

Authority: EU | Description: 3011Test2 | BUDI: 301121Test2ES | Data Transfer Protocol

Release status:  BASIC UDI-DI released |  All UDI-DIs released

**UDI-DI**

Material list:

Material	Material Description
3011-4	MatTest 2611
3011-5	MatTest 2611
3011-6	MatTest 2611
3011-7	MatTest 2611

UDI-DI data:

Release status:  Released |  |  Trigger fields locked |  To be exported | Version: 1

Material master data: Material: 3011-5 | Short text: MatTest 2611

Product information:

- Issuing Agency: GS1
- UDI-DI Code: 04049363430167
- Purp. other than medical: [empty]
- Quantity of device: 1
- Max. number of reuses: [empty]
- Reference number: 01125
- Second. DI Agency: [empty]
- Second. UDI-DI Code: [empty]
- Direct Marking

Product status:

- Device Status: On the EU market
- Device SubStatus: [empty]
- Substatus Start date: [empty] | Subst. End date: [empty]
- Scope of Recall: [empty]
- Recall Precision: [empty] | Prec. Language: [empty]
- URL for Additional Information (eIFU): [empty]
- Website: www.europe-it-consulting.ch

Is the device designed or manufactured by another legal or natural person?

Yes (If yes, please enter SRN or Product Designer ID)

Product Designer SRN: [empty]

Product Designer ID: PD1 | Product Designer 1

The information regarding Product Designer is stored using the transaction /UDI/PDADDRESS.

**Product Designers addresses**

Product Designer ID: [input] to [input] [button]

Product Designer name: [input] to [input] [button]

Country: [input] to [input] [button]

City: [input] to [input] [button]

**Display View "Product Designer address data": Overview**

Product Designer ID	Product Designer Name	Street	Number	PO Box	City	Post code	C...	Name	Email	Telephone number
PD1	Product Designer 1	Teststreet	1		Prague	100 00	CZ	Tschechien	ne@europe-it-consult	
PD2	Product Designer 2				Geneve	12345	CH	Switzerland	euit@email.ch	

In this transaction, you can add new entries with Product Designer related information and maintain the information for existing Product Designer entries.

The following data is required:

- Product Designer ID (used in Add-On internally, mandatory field)
- Product Designer Name (mandatory field)
- Street
- Street number
- PO Box
- City (mandatory field)
- Postal code (mandatory field)
- Country (mandatory field)
- Email (mandatory field)
- Telephone

**New Entries: Details of Added Entries**

Product Designer ID

**Product Designer address data**

Product Design. Name

Street

Street number

Address line 2

PO Box

City

Postal code

Country

Email

Telephone

## 7.9 UDI Version Maintenance

### What can I do in the UDI Version maintenance application?

The version maintenance application allows you to change/maintain the internal version number of the following data areas:

#### Basic UDI-DI

- BUDI - Clinical Investigation Links
- BUDI – Certification Links

#### UDI-DI

- DI – Market Information
- DI – Packaging Hierarchy

### Why do I need this application?

Each data area has a version number, which exists because the EUDAMED database expects this information in the XML file. The idea of the EUDAMED is to keep the UDI record in your UDI data management system and the UDI data in the EUDAMED synchronous.

Usually the version number is managed by the UDI Add-On, but if the version in the UDI Add-On differs from the version in the EUDAMED, you need to correct the version number in UDI Add-On.

This can happen when:

- Somebody changes the UDI data directly in EUDAMED and creates a new version there.
- UDI XML upload fails and you have to maintain and release the UDI data again in the UDI add-On.

### **Which version number EUDAMED is expecting?**

In the XML file you must have the last version number which exists in EUDAMED.

Example:

When a UDI record has the version “2” in EUDAMED and you want to upload a XML file with a newer version number “3”, then the XML file should contain the last version in EUDAMED, which is “2”.

As soon as the XML file is uploaded successfully in EUDAMED, the version number will be incremented by “1” to version number “3” in EUDAMED.

Exception: For the initial XML file Upload the version number “1” is always used.

### **How does the UDI application handle this?**

Each UDI data change, release and XML export is incrementing the version number for each changed area by 1, starting with version number 1.

The XML Export program is decrementing the existing version number in the XML file by 1 only if the version number greater than 1.

Example:

- Exporting UDI record version 1 → XML file will contain version 1 (no version number decrementing, because this is the initial version)
- Exporting UDI record version 2 → XML file will contain version 1 (version number decrementing by 1)
- Exporting UDI record version 3 → XML file will contain version 2 (version number decrementing by 1)
- Exporting UDI record version 4 → XML file will contain version 3 (version number decrementing by 1)

and so on.

### **When is the version number changed/incremented in the UDI Add-On?**

When you did a change in the BASIC UDI data area in the transaction /UDI/MAINTAIN or any other data changing transaction:

- The versions of BASIC UDI-DI, Clinical Investigation Links and Certification Links are incremented at the same time

When you did a change in the UDI-DI data area in the transaction /UDI/MAINTAIN or any other data changing transaction:

- The versions of UDI-DI, Market Information and Packaging Hierarchy are incremented at the same time

### Which UDI areas belong together?

- Basic UDI-DI  
BUDI - Clinical Investigation Links  
BUDI – Certification Links
- UDI-DI  
DI – Market Information  
DI – Packaging Hierarchy

### When is the UDI data shown as “Exported”?

Always when you export the UDI data as XML with the option “Mark records as sent after successful export”

In the transaction /UDI/VERSION, version numbers for the following data areas can be maintained separately:

- 01 All
- 02 Basic UDI-DI
- 03 UDI-DI
- 04 BUDI - Clinical Investigation Links
- 05 BUDI – Certification Links
- 06 DI – Market Information
- 07 DI – Packaging Hierarchy

Status	Basic U Ag	Basic UDI	Material	Data Ar...	Data Area Description	Old Vers.	NewVersion	Data Changed	
GS1	11111Ver			BUDI	Basic UDI-DI	4	0	<input type="checkbox"/>	
GS1	11111Versions-TESTSP			CERT	BUDI - Certification Links	2	0	<input type="checkbox"/>	
GS1	11111Versions-TESTSP			CLIN	BUDI - Clinical Investigation Links	2	0	<input type="checkbox"/>	
GS1	11111Versions-TESTSP	GS1	04049368551140	0811-1	DI	UDI-DI	2	0	<input type="checkbox"/>
GS1	11111Versions-TESTSP	GS1	04049368551140	0811-1	PACK	DI - Packaging Hierarchy	2	0	<input type="checkbox"/>
GS1	11111Versions-TESTSP	GS1	04049368551140	0811-1	MARK	DI - Market Information	2	0	<input type="checkbox"/>

## 7.10 UDI Master Data Export


The UDI Master Data Export is an SAP application designed to streamline the process of exporting master data records related to Unique Device Identifiers (UDI) for medical devices. This application is essential for organizations in the medical device industry to manage, analyze, and report UDI data efficiently.

This documentation covers the functionalities and usage of the /UDI/EXPORT T-Code in SAP for exporting UDI master data.

**T-Code:** /UDI/EXPORT

**Application Name:** UDI Master Data Export

### UDI Master Data Export



**Export Options**

Excel File (XLSX)       XML File       Web Service Transfer

**File Export Fields**

File Export Path

**Organizational Fields**

Authority










EU UDI relevant

Only released UDI data


Export modified data


Mark records as sent after successful export

**Basic UDI-DI Fields**

Basic UDI-DI Code	<input type="text"/>	to	<input type="text"/>	
Actor SRN	<input type="text"/>	to	<input type="text"/>	
Applicable Legislation	<input type="text"/>	to	<input type="text"/>	
Device Model	<input type="text"/>	to	<input type="text"/>	
Device Name	<input type="text"/>	to	<input type="text"/>	
Risk Class	<input type="text"/>	to	<input type="text"/>	
Basic UDI Description	<input type="text"/>	to	<input type="text"/>	
BUDI Guid	<input type="text"/>	to	<input type="text"/>	
DUNS	<input type="text"/>	to	<input type="text"/>	

**UDI-DI Fields**

Material  to  

UDI-DI Code  to  

## 7.11 Options for Export

The UDI Master Data Export application offers three export options:

### Option 1: Excel File (xlsx)

This option allows users to export UDI master data into an Excel file format (.xlsx). This is useful for internal analysis and reporting.

- Go to T-Code: /UDI/EXPORT in SAP.
- Select "Excel File (xlsx)" from the options provided.
- If no selection criteria are provided, the program will export the records changed after the last export.
- Click on the "Export" button.
- Choose a location to save the file and click "Save".

### Option 2: XML File

This option enables users to export the UDI master data in XML file format. This format is generally used manual upload to EUDAMED.

Steps:

- Go to T-Code: /UDI/EXPORT in SAP.
- Select "XML File" from the options provided.
- If no selection criteria are provided, the program will export the records changed after the last export.
- Click on the "Export" button.
- Choose a location to save the files and click "Save".

### Naming Convention:

The XML files generated have a naming convention that indicates the order in which the files should be uploaded to EUDAMED. Files starting with ACTION-1 should be uploaded first, followed by ACTION-2, and so on.

Process ID	Service Name in EUDAMED	SAP File name	Description
1	Upload of Legacy or Regulation Device (Basic UDI + UDI-DI)	ACTION-1_*.xml	Initial Process for the first upload
2	UPLOAD UDI-DI for existing BASIC UDI	ACTION-2_*.xml	Adding new UDI-DI to existing
3	UPDATE BASIC UDI	ACTION-3_*.xml	Update of the Basic UDI data
4	UPDATE UDI-DI	ACTION-4_*.xml	Update of the UDI-DI data
5	UPDATE container package	ACTION-5_*.xml	is using Process 3, increases the version of UDI-DI as well
6	UPDATE market Information	ACTION-6_*.xml	Update of the market information

### Option 3: Web Service Transfer

This option enables direct submission of UDI master data to the European IT submission service through web service transfer. This method is particularly relevant for businesses operating in the European market, as it streamlines the compliance process.

Steps:

- Go to T-Code: /UDI/EXPORT in SAP.
- Select "Web Service Transfer" from the options provided.
- If no selection criteria are provided, the program will export the records changed after the last export.
- Click on the "Transfer" button.
- You may be prompted to enter your credentials for the European IT submission service.
- Review your submission and click "Confirm".

### Permissions

To use the UDI Master Data Export application, users must have the necessary permissions assigned to their profile. If you do not have access, please contact your SAP administrator.

## 7.12 UDI Status Update

Use this application to update the status of your UDI records which have been uploaded to EUDAMED.

When you have uploaded the XML files to EUDAMED. You will see after a couple of minutes response XML files on the right of the screen in EUDAMED web interface for XML file Upload. These xml files has to be downloaded to a local folder on your computer.

ID	Name	Service IT	State IT	Request date IT	Uploaded	Response date IT	Response
APP-DTX-000008888	Ieva Dzene	Update UDI-DI	● Failed	2022-03-08 [14:14]	XML [10 KB]	2022-03-08 [14:15]	XML [5 KB]
APP-DTX-000008887	Ieva Dzene	Upload UDI-DI for existing Basic UDI	● Successful	2022-03-08 [14:03]	XML [5 KB]	2022-03-08 [14:03]	XML [4 KB]
APP-DTX-000008886	Ieva Dzene	Update Basic UDI	● Successful	2022-03-08 [13:56]	XML [5 KB]	2022-03-08 [13:56]	XML [4 KB]
APP-DTX-000008885	Ieva Dzene	Upload of Legacy / Regulation Device/ SPP (Basic UDI and UDI-DI)	● Successful	2022-03-08 [13:42]	XML [9 KB]	2022-03-08 [13:43]	XML [4 KB]
APP-DTX-000008869	Ieva Dzene	Update UDI-DI	● Successful	2022-03-07 [12:29]	XML [5 KB]	2022-03-07 [12:30]	XML [4 KB]
APP-DTX-000008868	Ieva Dzene	Upload of Legacy / Regulation Device/ SPP (Basic UDI and UDI-DI)	● Successful	2022-03-07 [12:11]	XML [6 KB]	2022-03-07 [12:11]	XML [4 KB]
APP-DTX-000008867	Ieva Dzene	Update UDI-DI	● Failed	2022-03-07 [12:03]	XML [11 KB]	2022-03-07 [12:03]	XML [5 KB]

Example of downloaded XML response files:

### T-Code: /UDI/STATUS

There are two options how you can upload UDI records to EUDAMED:

1. Manual XML upload
2. M2M Submission using the Data Submission service of Europe IT.

**Status Update**

UDI Status Update

Update Options

Web Interface  XML Response Files

Auto Update

Auto Update  
Auto. Selection of not updated status

Selection criteria Basic UDI-DI

Basic UDI-DI Code [ ] to [ ]

Actor SRN [ ] to [ ]

Selection criteria UDI-DI

Material [ ] to [ ]

UDI-DI Code [ ] to [ ]

Start the /UDI/STATUS application in SAP and select the “XML Response Files” option.

Execute the application. Alle files will read from the application and processed.

### Status Update

XML Response Files       Web Interface

Selection criteria Basic UDI-DI

XML Reponse Directory:

In the /UDI/MAINTAIN and in /UDI/ATTRIBUTES you can see the status of the UDI record.

Audit trail    Check UDI data    Data integrity

BASIC UDI-DI

Authority: EU    Description: Test Data    BUDI: ++A999MDRTest2699YJ

Release status

BASIC UDI-DI released     All UDI-DIs released

BASIC UDI-DI    UDI-DI


Status

Released         Trigger fields locked     Submission Status    Version: 2

UDI data maintenance for GMN ++A999MDRTest2699YJ

UDI Submission Status

DI Type: BUDI    DI Code: ++A999MDRTest2699YJ

Status:  Rejected by EUDAMED





Upload Time: 17.03.2022 08:28:35

Last Update: 25.03.2022 13:44:32

Status Text: UDI data was processed by the EUDAMED

Error Description: EntityCode: ++A999MDRTest2699YJ  
 ErrorCode: basicUd  
 ErrorDetail: There is no existing latest and Registered version for device identifier code: ++A999MDRTest2699YJ  
 EntityCode: ++A999MDRTest2699YJ  
 ErrorCode: versionState  
 ErrorDetail: The version state is invalid. It should be REGISTERED

### 7.13 UDI Status Icon's

Icon	Status	Possible action's
	UDI record is not send after a change or new creation	Release Udi record and upload/send it to EUDAMED
	Waiting for response.	Execute /UDI/Status to update the status
	UDI record successfully processed by EUDAMED	Everything is ok
	UDI record rejected by EUDAMED	Please check error description and correct the error in the udi record. Repeat your upload/send.