



UDI Add-On (EU) Release Notes

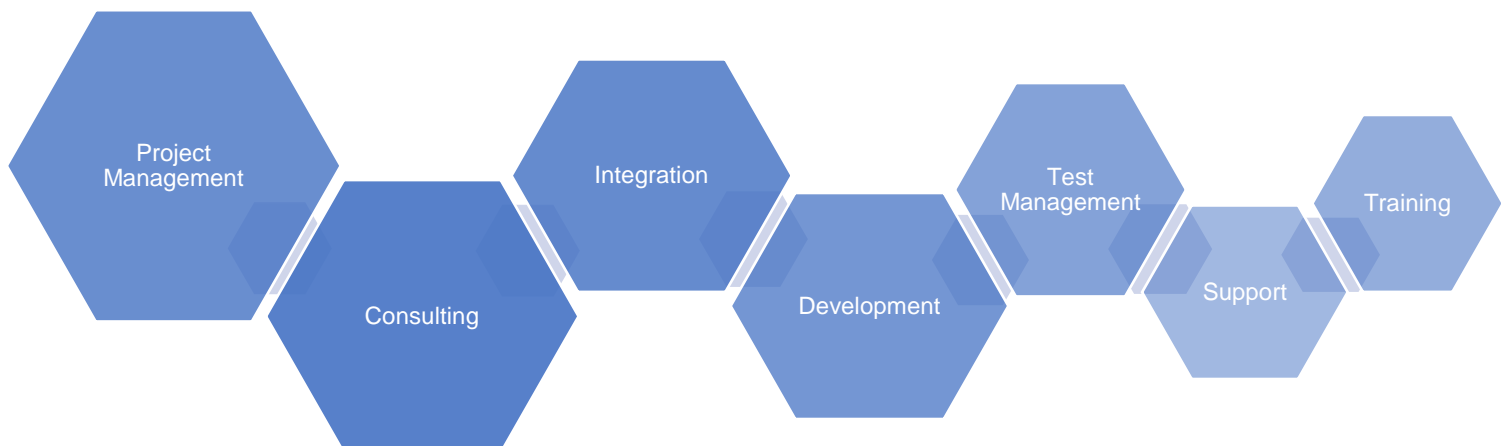




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1. Updates in V2021/06

1.1 Transports

Transport	Description	Released
ECCK900638	EITC: UDI EUDAMED Add-On V2021/06	11.06.2021
ECCK900646		
ECCK900652		

1.2 Change Log

1.2.1 SRN authorization function

A new authorization check based on the SRN was implemented. Users should have restricted rights to create/change BASIC UDI-DI records for specific SRN and plants. That means a new authorization object is needed to restrict the access on SRN level. The restriction on plant level can be realized using SAP standard authorization for plants. In a customizing table should be entered the combination between SRN and plants. An additional field is needed, which indicates if the SRN/ plant combination is active.

The affected SAP applications are:

- /UDI/MAINTAIN
 - Basic UDI-DI: Check user authorization if he used the right SRN number for which he is authorized while saving
 - UDI-DI: Check user authorization if he is assigning the right plant/SRN combination and if he has plant authorization for that specific material
- /UDI/ATTRIBUTES
 - User should be able to show only SRN and plant for which he is authorized
- /UDI/UPLOAD
 - User should be able to upload only data (BASIC and UDI-DI) for which he is authorized
 - Combination of BASIC SRN and Material Plant should correspond to SRN/PLANT customizing table
- /UDI/EXPORT
 - Export should be able only for which is the user authorized

JIRA	Type	Involved transactions
UEA-326	Feature	Various transactions

1.2.2 New selection criteria for Basic UDI-DI

For all UDI transactions the entry mask was improved with the following feature:

- A new selection criteria "Applicable Legislation" on Basic UDI-DI level was implemented

JIRA	Type	Involved transactions
UEA-365	Feature	Various transactions



1.2.3 UDI EU data upload template V6

The UDI EU data upload template was adjusted in line with the EUDAMED updates. The detailed changes can be seen in the “Change log” of the document.

JIRA	Type	Involved transactions
UEA-294	Feature	/UDI/UPLOAD

1.2.4 UDI attributes function

The UDI attributes function was improved with the following features:

- A new selection screen was implemented that allows to display only released and only changed data

JIRA	Type	Involved transactions
UEA-273	Feature	/UDI/ATTRIBUTES

1.2.5 Subtable “Certificate Links”

The Basic UDI-DI subtable “Certificate Links” was adjusted in line with the EUDAMED updates. The following columns were adjusted:

- Remove column “NB Reason”
- Remove column “NB Decision Reason”
- Remove column “Decision Date”
- Remove column “Decision Applicability Date”
- Remove column “Issue Date”
- Remove column “Status”

Accordingly, the EUDAMED upload template was adjusted for the correct import and export of the certificate link data in excel into SAP.

JIRA	Type	Involved transactions
UEA-315 UEA-306 UEA-310	Feature	/UDI/MAINTAIN

1.2.6 Subtable “Substance”

The UDI-DI subtable “Substance” was adjusted in line with the EUDAMED updates. For the “Medical Human” and “CMR Endocrine” substances the following columns were adjusted:

- Add column “Group” with fieldname SUBSTANCE_INDEX
- Add column “Custom language” with fieldname SPRAS
- Add column “Substance Name” with fieldname LONG_TEXT

These additional columns allow to “Group” the substances together, in case that the substance is described in “Substance Name” in different “Languages”, i.e. multiple entries for the same substance with translations in other languages are made and assembled in one group.

Further the editability of the subtable was determined according to the “INN” for medical & human substances and the “CAS/ EC” for CMR endocrine substances:

- If the “INN” or “CAS/ EC” code is entered – not further editable
- If the “INN” or “CAS/ EC” code is not entered – language dependent value for substance name, one language can only be used once

JIRA	Type	Involved transactions
UEA-317	Feature	/UDI/MAINTAIN



UEA-285		
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1.2.7 Subtable “Storage & Handling Conditions”

The UDI-DI subtable “Storage & Handling Conditions” was adjusted in line with the EUDAMED updates. The following columns were adjusted:

- Add column “Group” with fieldname CONDITION_NUMBER
- Add column “Custom language” with fieldname SPRAS
- Add column “Description” with fieldname COMMENTS
- Add code lists for column “Storage & Handling conditions” with fieldname STHACO

Further the editability of the subtable was determined according to the “Storage & Handling type” selection:

- Codes without * - not editable
- Codes with * – language independent value for description
- Code with ** (OTHER**) – language dependent value for description, one language can only be used once

JIRA	Type	Involved transactions
UEA-316	Feature	/UDI/MAINTAIN
UEA-292		

1.2.8 Subtable “Critical Warnings”

The UDI-DI subtable “Critical Warnings” was adjusted in line with the EUDAMED updates. The editability of the subtable was determined according to the “Critical warning type” selection:

- Codes without * - not editable
- Codes with * – language independent value for description
- Code with ** (OTHER**) – language dependent value for description, one language can only be used once

JIRA	Type	Involved transactions
UEA-289	Feature	/UDI/MAINTAIN

1.2.9 Subtable “Clinical Size”

The UDI-DI subtable “Clinical Size” was adjusted in line with the EUDAMED updates. Based on the “Precision” the clinical sizes are now editable. When the “Precision” is:

- “Range” – “Size unit”, “Value/ Min. value”, “Max value” can be edited
- “Value” – “Size unit”, “Value/ Min. value” can be edited
- “Text” – “Text” can be edited

JIRA	Type	Involved transactions
UEA-284	Feature	/UDI/MAINTAIN

1.2.10 Subtable “EMDN”

The UDI-DI subtable “EMDN” was created in line with the EUDAMED updates. The following columns were adjusted:

- Add column “Nomenclature Code (EMDN)” with fieldname EMDN and the respective code list
- Add column “Description” with fieldname DESCR
- Remove the UDI attribute “EMDN Code” on the UDI-DI level

JIRA	Type	Involved transactions
UEA-304	Feature	/UDI/MAINTAIN



1.2.11 Triggerfields adjustment

The UDI trigger fields were adjusted in line with the EUDAMED updates. The following UDI fields were adjusted:

- New triggerfield "Trade name"
- New triggerfield "Device model"
- New triggerfield "Quantity of device"
- New triggerfield "Critical warning"
- New triggerfield "CRM Endocrine substance"
- New triggerfield "Direct Marking"

JIRA	Type	Involved transactions
UEA-277	Feature	/UDI/MAINTAIN

1.2.12 Release of UDI-DI

Bugfix of release checkbox on Basic UDI-DI and UDI-DI level. Display of the checkbox is always provided as well as the possibility to check and uncheck the release. If all UDI-DI's are released the flag "ALL_DI_RELEASED" shown on Basic UDI-DI level is set automatically.

JIRA	Type	Involved transactions
UEA-325	Bug	Various transactions

1.2.13 Lock of triggerfields

Bugfix of triggerfields lock and unlock, when maintaining the UDI subtables. Automatic adaption of the editability of the UDI subtables when locking and unlocking the triggerfield box.

JIRA	Type	Involved transactions
UEA-278	Bug	/UDI/MAINTAIN

1.2.14 Number of hits

Bugfix of the number of hits, displaying the real number of records as hits and not the entered value. Therefore, if the entered value exceeds the number of records, the maximum number of records will be displayed in hits.

JIRA	Type	Involved transactions
UEA-356	Bug	/UDI/MAINTAIN

1.2.15 Language independent entry

A language independent value "ANY" was added to the "Specific EU Languages" selection to indicate entries that are applicable in all languages.

JIRA	Type	Involved transactions
UEA-399	Feature	/UDI/CL033

1.2.16 Extend table for certificate links

The subtable "Certificate Links" were adjusted in line with the EUDAMED updates. The following adjustments were made:



- New field "Issue Date"
- New field in audit log
- Extension of the table /UDI/CERTLINK
- Display fields in ALV – Basic UDI-DI
- Resize of ALV

JIRA	Type	Involved transactions
UEA-283	Bug	/UDI/MAINTAIN