



UDI Add-On (EU) Release Notes

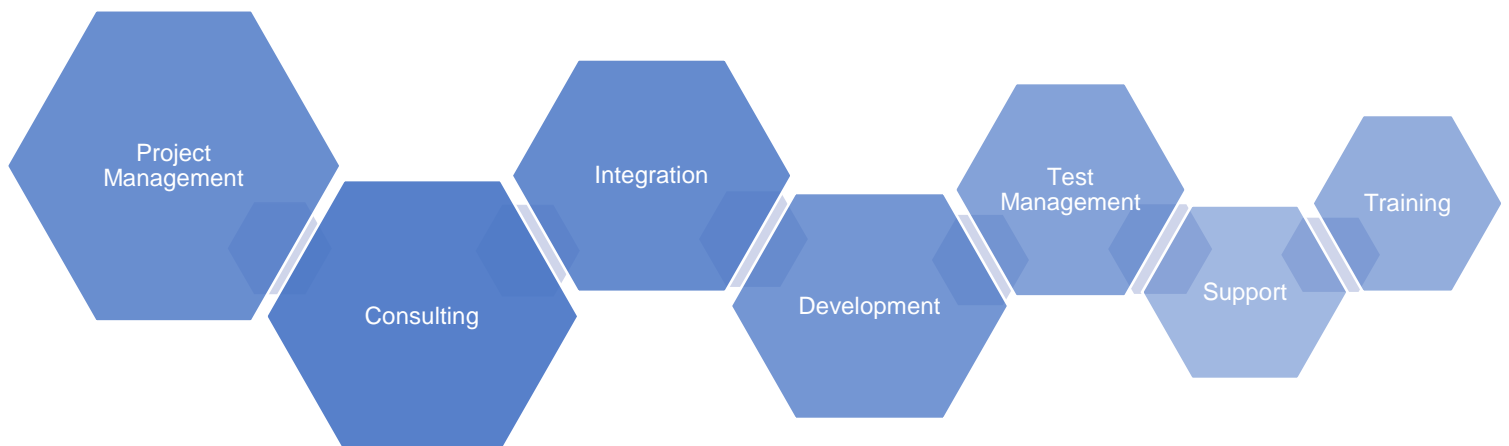




Table of contents

1.	Updates in V2021/11.....	4
1.1	Transports.....	4
1.2	Change Log.....	4
1.2.1	Product Designer – separated maintenance.....	4
	A new transaction for maintaining Product Designer information.....	4
1.2.2	Improvement of the user experience in the transaction /UDI/MASS.....	5
1.2.3	UDI-DI assignment to another Basic UDI-DI.....	5
1.2.4	Typo in the titles of tab & column headers in the area “Additional data”.....	5
1.2.5	GMN check digit calculation.....	5
1.2.6	Time zones display.....	6
1.2.7	Improvements in the /UDI/MAINTAIN Basic UDI-DI data screen.....	6
1.2.8	Adjustment of the default column width in the sheet “EMDN”.....	6
1.2.9	Renaming UDI-DI unlinking button and updating the popup message.....	6
1.2.10	Separate Basic UDI-DI and UDI-DI export is now possible.....	6
1.2.11	GUID as an active link in /UDI/AUDITTRAIL and /UDI/EXPAUDIT.....	7
1.2.12	Business Rules implementation.....	7
1.2.13	Text correction in EU UDI Information section header.....	7
1.2.14	Validation check in the tab “Certificate links”.....	7
1.2.15	Changes to /UDI/EXPAUDIT regarding historical values.....	8
1.2.16	Layout saves.....	8
1.2.17	Exporting only valid data without errors to XML.....	8
1.2.18	The text “Originally placed on the market” in “Market Info” corrected.....	8
1.2.19	Text correction in the tab “Critical Warnings”.....	8
1.2.20	Corrections in the tab “Substances”.....	8
1.2.21	Messages after uploading data.....	9
1.2.22	Showing UDI-DI data after reassigning UDI-DI.....	9
1.2.23	Material template adding possibility for Product Hierarchy.....	9
1.2.24	Changes in the tab “Packaging”.....	9
1.2.25	Excel Upload for sub tables.....	9
1.2.26	Changes in the texts of the help fields in the section Product Identifier.....	10
1.2.27	Information message during data export corrected.....	10
1.2.28	Adjustments in the selection screen of /UDI/AUDITTRAIL.....	10
1.2.29	Field selection list in case of wrong upload attempt.....	10
1.2.30	Deleted Flag in Basic UDI-DI removed.....	10
1.2.31	Double horizontal scrollbars in /UDI/ATTRIBUTES.....	10
1.2.32	Typo correction in /UDI/UPLOAD.....	11



1.2.33	Applying various changes to the Excel Template.....	11
1.2.34	Entries in the EMDN are now mandatory	11
1.2.35	The tab “Comments” in Basic UDI-DI data removed.....	11
1.2.36	Business Rules Implementation	11
1.2.37	Excel Template V7 changed.....	11
1.2.38	XML Creation / Data export updated	12



1. Updates in V2021/11

1.1 Transports

Transport	Description	Released
ECCK900691	EITC: UDI EUDAMED Add-On V2021/11	03.11.2021
ECCK900752		
ECCK900773		

1.2 Change Log

1.2.1 Product Designer – separated maintenance

A new transaction for maintaining Product Designer information

Previously, there were the following fields regarding Product Designer details in the transaction /UDI/MAINTAIN, which were visible after clicking the checkbox “Yes (Enter SRN or Name)”:

- Prod. Designer Actor Code
- National trade registry
- Product Designer Organisation
- Language
- Short Name
- Language

These fields were removed from /UDI/MAINTAIN.

A new transaction Product Designers addresses /UDI/PDADDRESS was created, where the following data can be maintained:

- Product Designer ID (mandatory field)
- Product Design. Name (mandatory field)
- Street
- Street number
- Address line 2
- PO Box
- City (mandatory field)
- Postal code (mandatory field)
- Country (mandatory field)
- Email (mandatory field)
- Telephone

The transaction /UDI/PDADDRESS contains the following search fields in the selection screen:

- Product Designer ID
- Product Designer Name
- Country
- City

The fields “Product Designer SRN” and “Product Designer ID” were created in /UDI/MAINTAIN.



These fields are visible after checking the checkbox “Yes (If yes, please enter SRN or Product Designer ID)” in the area “Is the device designed or manufactured by another legal or natural person?”.

The search mask of the field “Product Designer ID” contains the entries which have been maintained using /UDI/PDADDRESS.

The transactions /UDI/ATTRIBUTES and /UDI/MASS were updated accordingly and now contain the fields “Product Designer SRN” and “Product Designer ID”.

JIRA	Type	Involved transactions
UEA-378	Feature	/UDI/MAINTAIN /UDI/PDADDRESS /UDI/ATTRIBUTES /UDI/MASS

1.2.2 Improvement of the user experience in the transaction /UDI/MASS

Previously, in order to select a new field in the transaction /UDI/MASS, the user had to leave the transaction and re-enter it again. Now it is possible to select a different field without leaving the transaction.

JIRA	Type	Involved transactions
UEA-418	Feature	/UDI/MASS

1.2.3 UDI-DI assignment to another Basic UDI-DI

There was the following bug regarding the reassignment of a UDI-DI to a different Basic UDI-DI: after a UDI-DI had been reassigned to a different Basic UDI-DI, the UDI-DI data was not loaded. This bug was fixed.

JIRA	Type	Involved transactions
UEA-428	Bug	/UDI/MAINTAIN

1.2.4 Typo in the titles of tab & column headers in the area “Additional data”

First letters of the titles in tab and column headers were capitalized in the “Additional Data” section in the transaction /UDI/MAINTAIN (for example: “Trade name” was changed to “Trade Name”).

JIRA	Type	Involved transactions
UEA-495	Bug	/UDI/MAINTAIN

1.2.5 GMN check digit calculation

A bug regarding the GMN getting calculated with a wrong check digit was fixed.

JIRA	Type	Involved transactions
UEA-501	Bug	/UDI/MAINTAIN



1.2.6 Time zones display

UTC time was being displayed in the transactions /UDI/EXPAUDIT and /UDI/AUDITTRAIL. This bug was fixed and now the correct user's local date and time in the fields "Date" and "Time" of the transaction /UDI/EXPAUDIT and in the fields "Current Date" and "Time" of the transaction /UDI/AUDITTRAIL is displayed.

JIRA	Type	Involved transactions
UEA-502	Bug	/UDI/AUDITTRAIL /UDI/EXPAUDIT

1.2.7 Improvements in the /UDI/MAINTAIN Basic UDI-DI data screen

The following improvements have been made in the Basic UDI-DI data screen in the transaction /UDI/MAINTAIN:

- Trigger lock icons brought closer to their associated data label
- Space added after the comma's in "Suture, Staple, Dental filling (Iib)"
- Column titles added to the 2nd and 4th columns of the "Certificate Links" section
- Column title added to the 1st column of the "Clinical Investigation Links" section

JIRA	Type	Involved transactions
UEA-508	Feature / Bug	/UDI/MAINTAIN

1.2.8 Adjustment of the default column width in the sheet "EMDN"

The default column width in the sheet "EMDN" in the transaction /UDI/MAINTAIN has been adjusted and now it is possible to see the descriptions of the EMDN codes in full length.

JIRA	Type	Involved transactions
UEA-518	Feature	/UDI/MAINTAIN

1.2.9 Renaming UDI-DI unlinking button and updating the popup message

The button «Delete UDI-DI» (EN) / «UDI-DI löschen» (DE) in the transaction /UDI/MAINTAIN is renamed as follows: «Unlink UDI-DI» (EN) / «UDI-DI entfernen» (DE)».

The message which appears in the popup window when unlinking the UDI-DI from a Basic UDI-DI was updated and reads as follows: "Are you sure you want to unlink the UDI-DI record from this BUDI?" (EN) / "Wollen Sie wirklich die Zuordnung des UDI-DI Datensatzes von dem aktuellen BUDI aufheben?" (DE).

JIRA	Type	Involved transactions
UEA-523	Feature	/UDI/MAINTAIN

1.2.10 Separate Basic UDI-DI and UDI-DI export is now possible

For the XML Export the following functions are possible:

- Export of BUDI if BUDI changed only (MDR/IVDR) - mark record as "sent"
- Export of DI if DI changed (MDR/IVDR) - mark record as "sent"
- Export of BUDI and DI's when both changed (MDR/IVDR) - mark record UDI + DI as "sent"



- For MDD/IVDD/AIMDD always both parts (BUDI and DI) have to be exported - mark record BUDI + DI as "sent"

JIRA	Type	Involved transactions
UEA-543	Bug	/UDI/EXPORT

1.2.11 GUID as an active link in /UDI/AUDITTRAIL and /UDI/EXPAUDIT

The GUID in /UDI/AUDITTRAIL and /UDI/EXPAUDIT is now made as an active link. It is possible to enter /UDI/MAINTAIN in display-only mode by clicking on this link to view the data.

JIRA	Type	Involved transactions
UEA-572	Feature	/UDI/AUDITTRAIL /UDI/EXPAUDIT

1.2.12 Business Rules implementation

Various business rules were implemented. For example, the following:

- For "Procedure pack" or "Kit", "Additional Description" has to be entered
- The UDI-DI code, Secondary DI Code, Unit of Use Code, Direct marking DI Code, Container Package DI Code structure is checked against the format structure
- Various business rules regarding Risk Class and Applicable Legislation were implemented
- The device status "Not intended for the EU market" is not allowed for legacy devices (when "Applicable Legislation" is "MDD/AIMDD/IVDD")

JIRA	Type	Involved transactions
UEA-319 UEA-432	Feature	Various transactions

1.2.13 Text correction in EU UDI Information section header

EU UDI Information section header in MM01/MM02/MM03 was renamed and reads as follows: "EU UDI Information".

JIRA	Type	Involved transactions
UEA-461	Bug	MM01/MM02/MM03

1.2.14 Validation check in the tab "Certificate links"

The following business rule was implemented: If in the Basic UDI-DI data the Applicable Legislation was set to MDD; AIMDD, IVDD, then all entries in the tab "Certificate Links" should contain values in all columns, except "Cert. rev. no." (it can be entered or can be empty). Otherwise, the following error message is displayed: "Bitte pflegen Sie alle Felder in der Tabelle "Certificate Links" (DE) or "Please maintain all fields in the table "Certificate Links"" (EN).

JIRA	Type	Involved transactions
UEA-486	Feature	/UDI/MAINTAIN



1.2.15 Changes to /UDI/EXPAUDIT regarding historical values

When an export is made and afterwards the Basic UDI-DI Code, SRN Nr, or UDI-DI code is changed, the previous values are displayed in the Export Audit. Now, these values will be shown with their new content.

JIRA	Type	Involved transactions
UEA-504	Bug	/UDI/EXPAUDIT

1.2.16 Layout saves

It is now possible to save layout variants for all tables.

JIRA	Type	Involved transactions
UEA-533	Feature	/UDI/MAINTAIN

1.2.17 Exporting only valid data without errors to XML

Only valid data (without errors) can be exported to XML. If there is at least one error, the export will be cancelled and an error message regarding validation error will be displayed.

JIRA	Type	Involved transactions
UEA-557	Feature	/UDI/EXPORT

1.2.18 The text “Originally placed on the market” in “Market Info” corrected

A column title in the tab “Market Info” was corrected and reads as follows: “Originally placed on the market”. The error message texts regarding “Originally placed on the market” were also corrected.

JIRA	Type	Involved transactions
UEA-513	Bug	/UDI/MAINTAIN

1.2.19 Text correction in the tab “Critical Warnings”

The tab and column header titles in the tab “Critical Warnings” were adjusted.

JIRA	Type	Involved transactions
UEA-514	Bug	/UDI/MAINTAIN

1.2.20 Corrections in the tab “Substances”

In the tab “Substances”, the code values were displayed instead of descriptions. It was changed and now descriptions are displayed.

JIRA	Type	Involved transactions
UEA-516	Bug	/UDI/MAINTAIN



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1.2.21 Messages after uploading data

Status messages after uploading data in /UDI/UPLOAD were adjusted to report the result in a better way.

JIRA	Type	Involved transactions
UEA-524	Feature	/UDI/UPLOAD

1.2.22 Showing UDI-DI data after reassigning UDI-DI

Previously, the UDI-DI data was not displayed after unlinking a UDI-DI from a Basic UDI-DI and linking it to a Basic UDI-DI again. Now, the UDI-DI data is displayed and can be maintained after the UDI-DI has been unlinked from a Basic UDI-DI and linked to the same Basic UDI-DI or to any other Basic UDI-DI.

JIRA	Type	Involved transactions
UEA-531	Bug	/UDI/MAINTAIN

1.2.23 Material template adding possibility for Product Hierarchy

A new functionality has been implemented to add a template material which handles the data for a Product Hierarchy in MM02.

JIRA	Type	Involved transactions
UEA-553	Feature	MM02

1.2.24 Changes in the tab “Packaging”

The field “Date” has been removed from the tab “Packaging” in /UDI/MAINTAIN. Slight changes in the column titles have been carried out.

JIRA	Type	Involved transactions
UEA-558 UEA-559 UEA-512	Feature	/UDI/MAINTAIN

1.2.25 Excel Upload for sub tables

Bugfix of the Excel insert upload function for sub tables in the UDI-DI area when the SRN authorization is activated.

JIRA	Type	Involved transactions
UEA-560	Bug	/UDI/UPLOAD



1.2.26 Changes in the texts of the help fields in the section Product Identifier

In the section “Production Identifier”, the texts in the help fields (which can be accessed by clicking F1) were corrected.

JIRA	Type	Involved transactions
UEA-565	Bug	/UDI/MAINTAIN

1.2.27 Information message during data export corrected

During the data export, an information message is displayed. A grammar mistake in this message was corrected and the message reads now as follows: “Data are being exported”.

JIRA	Type	Involved transactions
UEA-568	Bug	/UDI/EXPORT

1.2.28 Adjustments in the selection screen of /UDI/AUDITTRAIL

Previously, in the field “Date selection” in the selection screen the beginning date was defaulted to today’s date. Now, the beginning date is defaulted to today’s date minus 7 days and the end date is defaulted to today’s date.

JIRA	Type	Involved transactions
UEA-569	Feature	/UDI/AUDITTRAIL

1.2.29 Field selection list in case of wrong upload attempt

A bug in the field selection list when setting up the upload was fixed. Now it works as follows: when the process type is changed or when the transaction is closed, the data field selection is cleared. In case of failed attempt (upload cannot be executed because the file name is missing), the field list selection remains as it was.

JIRA	Type	Involved transactions
UEA-575	Bug	/UDI/UPLOAD

1.2.30 Deleted Flag in Basic UDI-DI removed

The deleted Flag in BASIC UDI-DI data was removed.

JIRA	Type	Involved transactions
UEA-591	Bug	/UDI/MAINTAIN

1.2.31 Double horizontal scrollbars in /UDI/ATTRIBUTES

Previously, double horizontal scrollbars were displayed. This bug has been solved.

JIRA	Type	Involved transactions
UEA-592	Bug	/UDI/ATTRIBUTES



1.2.32 Typo correction in /UDI/UPLOAD

Some grammar mistakes were corrected: The word “UDI-DI” as well in the warning text next to the “Download Sample Excel File” button.

JIRA	Type	Involved transactions
UEA-593	Bug	/UDI/UPLOAD

1.2.33 Applying various changes to the Excel Template

Various changes were applied to the UDI EU Excel Template according to the EU Eudamed Business Rules, enumerations lists and data dictionary. The detailed list of changes please see the change log in UDI EU Excel Template.

JIRA	Type	Involved transactions
UEA-465	Feature	Various transactions

1.2.34 Entries in the EMDN are now mandatory

It is now mandatory to enter at least one Nomenclature Code (EMDN) in the tab “EMDN” if the Applicable Legislation is MDR, IVDR.

JIRA	Type	Involved transactions
UEA-464	Bug	/UDI/MAINTAIN

1.2.35 The tab “Comments” in Basic UDI-DI data removed

The tab “Comments” was removed from the Basic UDI-DI data.

JIRA	Type	Involved transactions
UEA-509	Feature	/UDI/MAINTAIN

1.2.36 Business Rules Implementation

Additional 41 Business rules are implemented, which checks the data quality.

JIRA	Type	Involved transactions
UEA-319	Feature	/UDI/MAINTAIN

1.2.37 Excel Template V7 changed

The Excel Template for UDI data download and Upload has been changed.

- Code lists are updated
- Additional Tab for SPPP (medicinal purpose) data is added
- Changed descriptions



JIRA	Type	Involved transactions
UEA-465	Feature	/UDI/UPLOAD

1.2.38 XML Creation / Data export updated

The XSLT file which creates the XML files is updated and the Export Program is adjusted to create valid XML files.

JIRA	Type	Involved transactions
UEA-600	Feature	/UDI/EXPORT