



UDI Add-On (EU) Release Notes

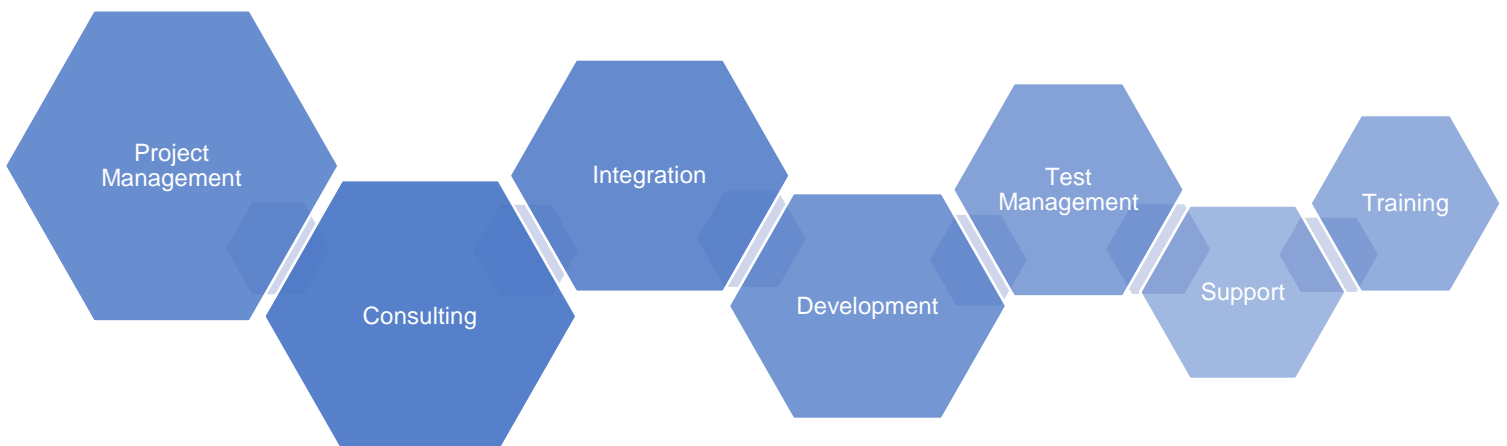




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1. Updates in V2022/02

1.1 Transports

Transport	Description	Released
ECCK900764	EITC: UDI EUDAMED Add-On V2022/02	18.02.2022
ECCK900769		

1.2 Change Log

1.2.1 SRN Code was not available in the dropdown

SRN Code was not available in the dropdown list if the description of SRN was not translated for the logon language. This bug was fixed.

JIRA	Type	Involved transactions
UEA-658	Bug	/UDI/MAINTAIN

1.2.2 Custom language functionality for System or Procedure Pack texts

Indication of Medical Purpose was not handled by a multi-language feature while XML export (/UDI/CLANGUAGE). This bug was fixed.

JIRA	Type	Involved transactions
UEA-659	Feature	/UDI/EXPORT

1.2.3 UDI MASS is changing the preview data for UDI-DI data

In the transaction UDI/MASS, the data was changed after clicking "Apply changes (Test – no update)". After clicking "Apply changes" the condition was not working, because the data had already been changed during the test mode. This bug was fixed.

JIRA	Type	Involved transactions
UEA-660	Bug	/UDI/MASS

1.2.4 Business Rules regarding Direct Marking and Quantity of Device



Previously there was an error message if the Quantity of device was greater than 1 and the fields regarding Direct Marking were maintained. This error message was removed.

Previously there was an error message that the Unit of Use fields are mandatory. This error message was removed and the following business rule was implemented: Unit of Use DI can be entered optionally when the UDI-DI is not Directly marked and the Quantity of Device is greater than 1.

The error message regarding the Unit of Use Issuing Agency being different than the Issuing Agency was removed and now Unit of Use Issuing Agency can be different from the Issuing Agency.

JIRA	Type	Involved transactions
UEA-662	Feature	/UDI/MAINTAIN

1.2.5 Empty Cells in Excel Upload template are disrupting the upload

The following bug was fixed: If the Excel template contained formatted cells or cells with an empty value in the columns on the right side from the data columns, the upload did not add the values correctly into SAP.

JIRA	Type	Involved transactions
UEA-664	Bug	/UDI/UPLOAD

1.2.6 Adjusting the code EQUIPMENT_FOR_ADIPOSE_TISSUE according to EUDAMED requirements

After EUDAMED changed their own typo for the code list “ANNEX XVI”, the EUDAMED Add-On code list were adjusted to EUDAMED change.

The code was corrected from EQUIPMNT_FOR_ADIPOSE_TISSUE to EQUIPMENT_FOR_ADIPOSE_TISSUE according to the requirements during XML upload.

JIRA	Type	Involved transactions
UEA-671	Bug	Various

1.2.7 XML Label

For XML export additional information are displayed in the EXPORT program which are maintained in the application setting:

- Free text label (XML_LABEL)
- XML Split Size (XML_SPLIT_SIZE)
- XML Version number (XML_VERSION)
- XSLT File name (XSLT_VERSION)



Settings in application setting table.

APPLICATION_BASIC	XML_LABEL	EUDAMED Production
APPLICATION_BASIC	XML_SPLIT_SIZE	1000,300
APPLICATION_BASIC	XML_VERSION	2.0.2
APPLICATION_BASIC	XSLT_VERSION	/UDI/XSLT_EU_V3_S

JIRA	Type	Involved transactions
UEA-675	Feature	/UDI/EXPORT

1.2.8 Solving performance issues while uploading Excel template

Due to additional checks the performance of the Excel upload was effected. After code optimization the performance has been increased.

JIRA	Type	Involved transactions
UEA-676	Feature	/UDI/UPLOAD

1.2.9 Fixing issues with the field “Suture, Staple, Dental filling (Iib)”

The XML upload for Class Iib implantable device in EUDAMED Playground failed, because the field “Suture, Staple, Dental filling (Ii)” did not have a value. Even if no data are entered, EUDAMED requests the value “false” in the xml file. This bug was fixed.

JIRA	Type	Involved transactions
UEA-678	Bug	/UDI/EXPORT

1.2.10 Customizing tables for SRN and Applications settings changed to master data

Customizing tables for SRN and Application settings changed to master data and do not need a transport request anymore.

Changes can be made in every SAP system.

JIRA	Type	Involved transactions
UEA-680	Feature	/UDI/CL031 /UDI/CU_005 /UDI/CLDUNS

1.2.11 XML Split Size implemented

The number of UDI-DI's in the process “INSERT BUDI&UDI-DI” within one XML file is limited to max. 1000 records by EUDAMED XML Upload function.



The number of UDI-DI's in the process "Add UDI-DI to BUDI" and "UPDATE UDI-DI" within one XML file is limited to 300 records by EUDAMED.

Therefore an automatic splitting of the XML file is needed.

A new entry in the Application Settings can be entered which controls the split size for the "INSERT BUDI&UDI-DI" and all other processes.

Default value is 1000 for process "INSERT BUDI&UDI-DI" and 300 for all other cases in one XML file.

Custom number can be set by the application parameter: XML_SPLIT_SIZE.

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. In the application the value should be less than or equal to 1000, but greater than 1.</p> <p>First number limits the number of UDI-DI's in the process "INSERT BUDI & UDI-DI" and the second number limits the number of UDI-DI's in other cases.</p>
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JIRA	Type	Involved transactions
UEA-682	Feature	/UDI/EXPORT