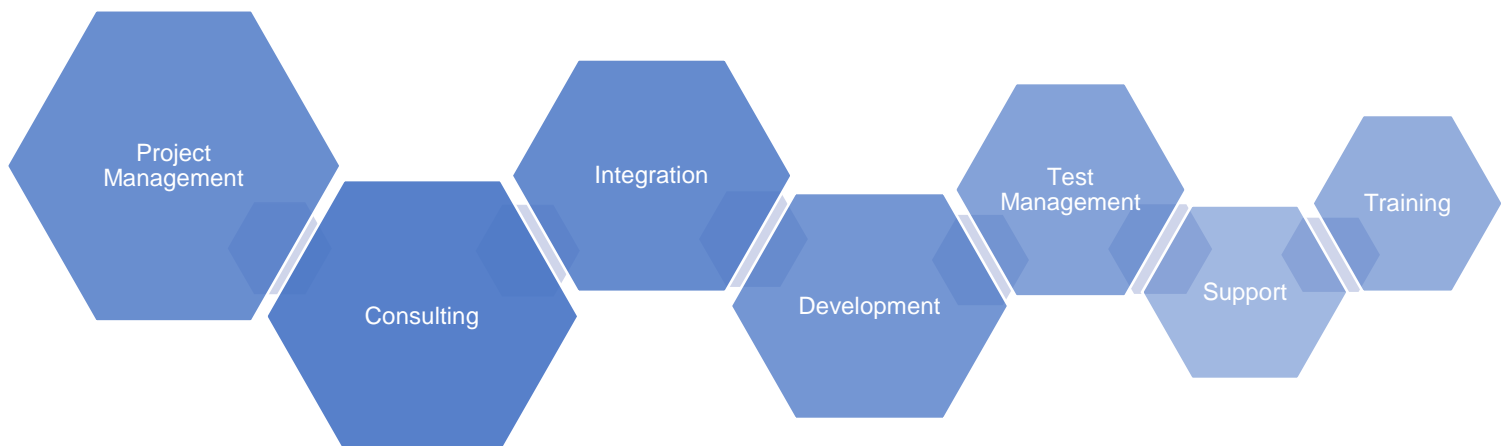




## UDI Add-On (EU) Release Notes





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## 1. Initial Version V2020/10

The UDI EUDAMED Add-On was developed for master data management and data transfer of UDI relevant attributes. It supports you in compiling and managing all data required by the European Commission and helps you to transfer them to the European Commission database (EUDAMED).

### 1.1 Transports

Transport	Description	Type	Date	System
ECCK900132	EITC: UDI EUDAMED Add-On V2020/09	Workbench	27.09.2020	SAP01 - ECC6.0 NW 7.01
ECCK900321	EITC: Customizing UDI EUDAMED Add-On V2020/09	Customizing	27.09.2020	SAP01 - ECC6.0 NW 7.01
ECCK900362	EITC: UDI EUDAMED Add-On V2020/10	Workbench	05.10.2020	SAP01 - ECC6.0 NW 7.01
ECCK900366	EITC: Customizing UDI EUDAMED Add-On V2020/10	Customizing	05.10.2020	SAP01 - ECC6.0 NW 7.01
ECCK900370	EITC: UDI EUDAMED Add-On V2020/10 V2	Workbench	20.10.2020	SAP01 - ECC6.0 NW 7.01

### 1.2 Code lists

Within these SAP transactions, default values are created for the dropdown lists in the UDI master data maintenance. For this purpose, unit value ranges recorded by the company and approval data are determined. In addition, these values are used as input checks and when uploading data for data verification.

#### 1.2.1 Available lists

The code lists support you in your daily work. All available entries in the code lists are displayed as a drop-down list in the maintenance transactions. Furthermore, these values also influence the data export and upload of data.

JIRA	Type	Transaction involved	Description
n.a.	Initial	/UDI/CL029	DUNS number of the company
n.a.	Initial	/UDI/CL026	EU Countries
n.a.	Initial	/UDI/CL027	Manufacturer Code (SRN)
n.a.	Initial	/UDI/CL001	Issuing Agency
n.a.	Initial	/UDI/CL011	UDI DI Type
n.a.	Initial	/UDI/CL022	System & Procedure Pack
n.a.	Initial	/UDI/CL028	Nomenclature Code (EMDN)
n.a.	Initial	/UDI/CL023	Cert.NB Decision Reason
n.a.	Initial	/UDI/CL021	CMR Endocrine Substance
n.a.	Initial	/UDI/CL020	Medical Human Substance
n.a.	Initial	/UDI/CL019	Production Identifier
n.a.	Initial	/UDI/CL018	Recalled Scope
n.a.	Initial	/UDI/CL012	Annex XVI Non Medical Device TypES
n.a.	Initial	/UDI/CL004	Applicable Legislation



n.a.	Initial	/UDI/CL002	MODUL CERT: Certification Type
n.a.	Initial	/UDI/CL008	Risk Classes
n.a.	Initial	/UDI/CL009	Special Device Type
n.a.	Initial	/UDI/CL010	Device Status
n.a.	Initial	/UDI/CL024	Device Sub Status
n.a.	Initial	/UDI/CL030	Relationship Type
n.a.	Initial	/UDI/CL013	Storage Handling Conditions
n.a.	Initial	/UDI/CL014	Critical warnings
n.a.	Initial	/UDI/CL015	Clinical Size Types
n.a.	Initial	/UDI/CL016	Clinical Size Types Unit
n.a.	Initial	/UDI/CL017	Precision

### 1.3 UDI program settings

This section is used to configure the basic settings of the application. The settings affect the UDI maintenance transaction and authorizations. They also have an impact on the layout.

#### 1.3.1 Available setting parameters

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

JIRA	Type	Transaction involved	Description
n.a.	Initial	/UDI/CU_002	UDI Field Settings
n.a.	Initial	/UDI/CU_003	UDI Online Configuration
n.a.	Initial	/UDI/CL025	UDI Authority Activities
n.a.	Initial	/UDI/CU_004	UDI Departments
n.a.	Initial	/UDI/CL031	UDI Application settings

### 1.4 UDI transactions

This category includes all applications in which you can manage, evaluate, release and export UDI attributes.

#### 1.4.1 Available transactions

The UDI application transactions are the current applications developed for the management and evaluation of UDI master data. Within these transactions the UDI data can be recorded and evaluated.

JIRA	Typ	Transaction involved	Description
n.a.	Initial	/UDI/MAINTAIN	UDI Master Data Maintenance
n.a.	Initial	/UDI/ATTRIBUTES	UDI Master Data Overview
n.a.	Initial	/UDI/EXPORT	UDI Data Export
n.a.	Initial	/UDI/UPLOAD	UDI Data Migration / Excel Upload
n.a.	Initial	/UDI/AUDITTRAIL	UDI Audit Trail
n.a.	Initial	/UDI/EXPAUDIT	UDI Audit Trail for data export / transfer
n.a.	Initial	/UDI/INTEGRITY_MASS	UDI Mass Integrity