

Release notes - UDI EUDAMED Add-On - EU V2022/12

Bug

[UEA-703](#) Existence check for SRN number raises an error

Description

The existence for SRN number raises an error, when the maintained SRN's in the codelist's are not alphabetic sorted.

Effected T-Code: All T-Codes where Validation check is executed.

Environment

Effected T-Code: /UDI/MAINTAIN

[UEA-704](#) GS1 Number Check doesn't raise error for specific numbers

Description

The Checkdigit validation for GS1 number which contains only zeros (e.g. 000000000000) doesn't raise an error.

This issue has been corrected.

Environment

Effected T-Code: /UDI/MAINTAIN - Validation check function

[UEA-712](#) In Product Hierarchy the "Assign" column was not editable

Description

In the Product Hierarchy Application the "Assigned" Column was not editable in higher SAP Netweaver 7.50 versions. This issue is corrected.

Environment

Effected T-Code: /UDI/PHT_MAT_ASSIGN

Story

[UEA-708](#) "Select all" and "Unselect all" button in data integrity for single added

Description

In the integrity check function "Select all" and "Unselect all" button has been added.

This makes it easier to select many rows at once.

Environment

Effected T-Code: /UDI/MAINTAIN

Task

[UEA-698](#) "Relationship type" from customizing removed

Description

These entries are not anymore needed. EUDAMED is handling this internally.

Environment

Effected T-Code: SPRO entry for EUDAMED Add-On

[UEA-699](#) Material Text - Replacement Text

Description

If material description is not found for the logon language the application will look

1. for Material text in english
2. if not found the material text for german will be displayed
3. if no language is found the text "[Descr. not maintained]" will be displayed

Environment

Effected T-Code: /UDI/MAINTAIN - Tab UDI-DI

[UEA-710](#) Codelist changes for several entries

Description

Clinical Size UOM

- Entry "MU155" removed
- Entry "MU176" Standard - added

Medical Substances:

Code	Description
HUMAN_PRODUCT_SUBSTANCE	Human Product
MEDICINAL_PRODUCT_SUBSTANCE	Medicinal Product

Special Device Types

- Multiple entries added (multiplied by regulations)

The following entries added:

- AIMDD_ORTHOPEDIC
- AIMDD_SOFTWARE
- IVDD_SOFTWARE
- IVDR_SOFTWARE
- MDD_MADE_TO_ORDER
- MDD_ORTHOPEDIC
- MDD_READY_MADE_SPECTACLES
- MDD_RIGID_GAS_PERMEABLE
- MDD_SOFTWARE
- MDD_SPECTACLES_FRAMES
- MDD_SPECTACLES_LENSES
- MDD_STANDARD_SOFT_CONTACT_LENSES
- MDR_MADE_TO_ORDER
- MDR_ORTHOPEDIC
- MDR_READY_MADE_SPECTACLES
- MDR_RIGID_GAS_PERMEABLE
- MDR_SOFTWARE
- MDR_SPECTACLES_FRAMES
- MDR_SPECTACLES_LENSES
- MDR_STANDARD_SOFT_CONTACT_LENSES

XSD Issues - Europe IT request to EUDAMED - solved by EUDAMED

- Device upload: "links:certificateType is not valid" error corrected;
- Unexpected error "sutures from the submitted version of Basic UDI-DI/EUDAMED DI have different values than the ones existing in EUDAMED" fixed;
- Fixed typo in special device type: EQUIPEMNT_FOR_ADDIPOSE_TISSUE updated to EQUIPMENT_FOR_ADIPOSE_TISSUE - fixed b EUDAMED

Environment

Effected T-Code: Various codelist entries in SPRO

[UEA-713 UDI Status Update T-Code /UDI/STATUS Added](#)

Description

Application Status Update for EUDAMED has been added to the UDI Add-On.

Using this application, the user can update the UDI status of the submitted record (M2M). Alternatively the manual uploaded UDI record's responses can be imported from local drive.

Environment

Effected T-Code:

UEA-714 Market Info - Versioning and separate XML file generation

Description

Market Info data update (not initial upload) will be splitted into separated XML files.

This is requested by EUDAMED.

Environment

Effected T-Code : /UDI/EXPORT

UEA-717 MDR 2b Certification are set from mandatory to optional

Description

MDR 2b certifications are set from mandatory to optional in the certification assignment.

Default customizing changed

Customer has to take care to change this settings itself.

MDR CLASS_IIB MDR_TECHNICAL_DOCUMENTATION Optional Optional No

MDR CLASS_IIB MDR_TYPE_EXAMINATION Optional Optional No

UEA-719 New Application Parameter "EXEC_VALIDATION"

Description

With the new application parameter it is possible to execute the validation check function automatically after start of the Program.

Parameter name: APPLICATION_BASIC | EXEC_VALIDATE

Supported programs and T-Codes: /UDI/UPLOAD, /UDI/ATTRIBUTES, /UDI/PHT_MAT_ASSIGN

Group Parameter Possible parameter values

APPLICATION_BASIC EXEC_VALIDATE /UDI/UPLOAD,/UDI/ATTRIBUTES,/UDI/PHT_MAT_ASSIGN

Environment

Effected T-Code: /UDI/CL031 (Customizing)

Impact to: /UDI/UPLOAD, /UDI/ATTRIBUTES, /UDI/PHT_MAT_ASSIGN

UEA-720 Customizing adjustment: Hiding not needed fields

Description

The following fields will be hidden by configuration, because it's not expected from EUDAMED to be submitted:

- Device SubStatus
- Device Substatus Start
- Device Substatus End date
- Scope of Recall
- Recall Precision
- Precision Language

Customer should take care itself to hide these fields via customizing.

UEA-722 Changing EMDN Table to type master data (before customizing)

Description

The EMDN table type is changed from Customizing table to Master data type.

This enables the user to maintain the content without transport request in the relevant system.

Environment

Effected T-Code:

UEA-723 Refresh Button added for /UDI/ATTRIBUTES

Description

Refresh button added to T-Code /UDI/ATTRIBUTES. This enables the user to reload the displayed data without leaving the recent screen.

Environment

Effected T-Code: /UDI/ATTRIBUTES

UEA-726 Special Device Type validation rule check

Description

Due to the code list change from the EUDAMED, the special device type validation didn't work correctly. Application is now change in the way that depending on the legislation the validation is checking according to the legislation.

All T-Code are effected which is using the validation check.

Environment

Effected T-Codes: /UDI/ATTRIBUTES, /UDI/MAINTAIN

UEA-731 Request: Force Upload Button instead of Option in SelScreen

Description

The option in /UDI/UPLOAD to upload records with errors is moved to the upload screen. You have now two buttons to save record without error and records with errors.

Records with serious errors, which are highlighted with an red arrow icon, can't saved.

UEA-733 Unlinked UDI-DI can now be found in /UDI/ATTRIBUTES

Description

UDI-DI's which are not assigned to an existing BUDI can now displayed in the /UDI/ATTRIBUTES T-Code.

An additional checkbox "Show unlinked UDI-DI entries" activates the listing of those entries.

Environment

Effected T-Code:

UEA-734 New feature: Data Submission Status Change

Description

In /UDI/ATTRIBUTES it's now possible to overwrite the Data Submission status.

This is necessary, when you need to change the status independent from the EUDAMED feedback

The new button Name is called "Set submission status >>Success<<".

This button is only visible when the user has **ACTVT 91 or 92**

and the following application parameter is set:

Group: APPLICATION_BASIC

Parametername: SHOW_ATT_SUCCESS_BTN

UEA-736 Adding DI Converstion for GS1 number to external format for XML creation

Description

DI number will be converted to external GS1 format. That means missing leading zeros will be added only for XML file.

Environment

Effected T-Code: /UDI/EXPORT

UEA-739 UDI Excel Upload Template updated to Version 8

Description

UDI Excel template updated to Version 8.

Changes in the codelist has been updated in the excel file.

Updated sheets:

- CLSDeviceType
- CLUOM
- CLSubstMed

Environment

Effected T-Code: /UDI/UPLOAD