



UDI Add-On (EU) Release Notes

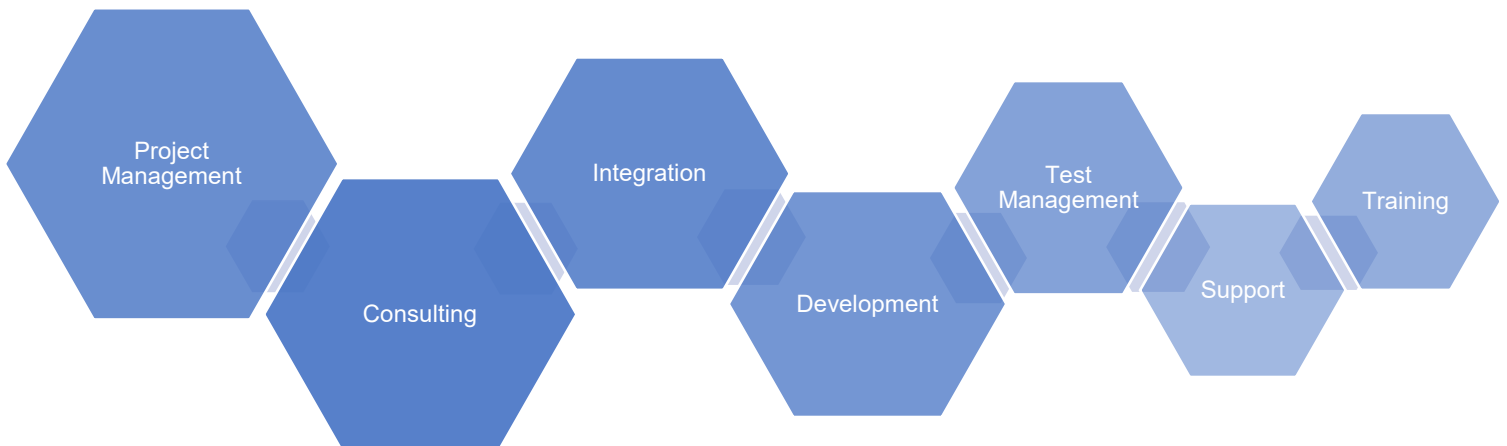




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V2024/11 – Release Notes EU V2025/05

Summary

Release **EU V2025/05** introduces an extensible customer screen for BASIC UDI-DI maintenance and improves the handling of EUDAMED versioning. In addition, several issues in the XML generation and validation logic have been fixed to increase data quality and reduce manual corrections.

New Features

UEA-764 – Customer screen extension for BASIC UDI-DI

An extensible customer screen framework has been added to the EUDAMED Add-On.

When activated via configuration parameter, customers can plug in their own Z-screens in the BASIC UDI-DI area (/UDI/MAINTAIN) to maintain additional UDI-related attributes (e.g. MDA/MDN, MDS/MDT codes, internal change number, conformity assessment route). This allows customers to store project- or authority-specific data without modifying the standard Add-On screens.

Improvements to existing features

UEA-767 – New parameter for EUDAMED version handling

A new application parameter **MC_PAR_VERSION_ZERO_INACTIVE** has been introduced to control how version numbers are submitted to EUDAMED.

By default, all objects are submitted with version “0”, and EUDAMED automatically increments the version in its own database, effectively skipping version number validation on the Add-On side.

If customers want to enforce version validation in the Add-On, they can activate this behaviour by setting the parameter to “X”.

Bug fixes

- **UEA-765 – Incorrect XML generation for legacy devices**

Fixed several issues in the XML generation for legacy devices:

- The tag “**Unit of use DI**” has been removed from the legacy XML.
- The order of XML tags has been adjusted to comply with the expected EUDAMED structure.

- **UEA-766 – Tradename validation for language ANY**

Corrected the validation logic for tradenames when language “**ANY**” is used.

Previously, an empty line with language “ANY” did not raise an error. The validation now correctly throws an error message in this case, ensuring that incomplete entries are detected before export.



UEA-767: Version Number to 0

New application parameter has been applied. This comes with the new feature to use the autoincrement of EUDAMED versioning.

By default the versions for all objects will be submitted with "0". EUDAMED is upcounting the version in their database automatically and will skip the Version number validation.

To activate this version validation you can activate it by using this parameter with "X".

MC_PAR_VERSION_ZERO_INACTIVE

UEA-766: Validation for Tradename is not covering language ANY

The validation for Tradename is not covering language ANY.

If somebody entered an empty line with language "ANY", the validation didn't throw an error message.

UEA-765: XSLT modified

Incorrect generation of the XML file for legacy devices.

The following changes were made:

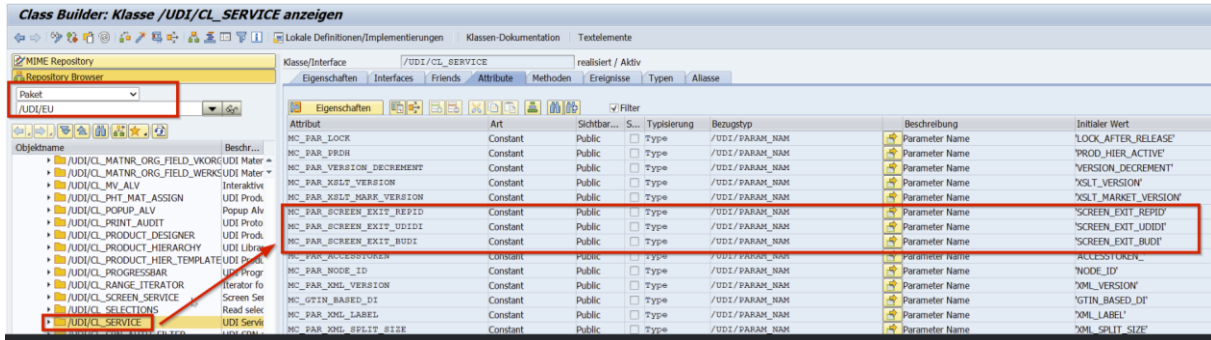
- "Unit of use DI" removed
- Order of XML tags changed

UEA-764: Customer Screen

In the EUDAMED Add-On we have to add a extension, which can be activated via parameter, so that customer can display a own customer screen with data. Similar how SAP is doing it for MM02 for example.

1. Customer screen should be , if activated, available in BUDI screen and a if activated for UDI-DI screen.
2. The Parameters are already created in the cl_service class.
3. Create your own developer key in SAP
4. To add the functionality of screen extensions , please add the development into the TR ECCK901005
5. For the Customer screens in Z- Namespace use the package ZMM1 and TR ECCK901002
EITC: LR Screen extension - 2025

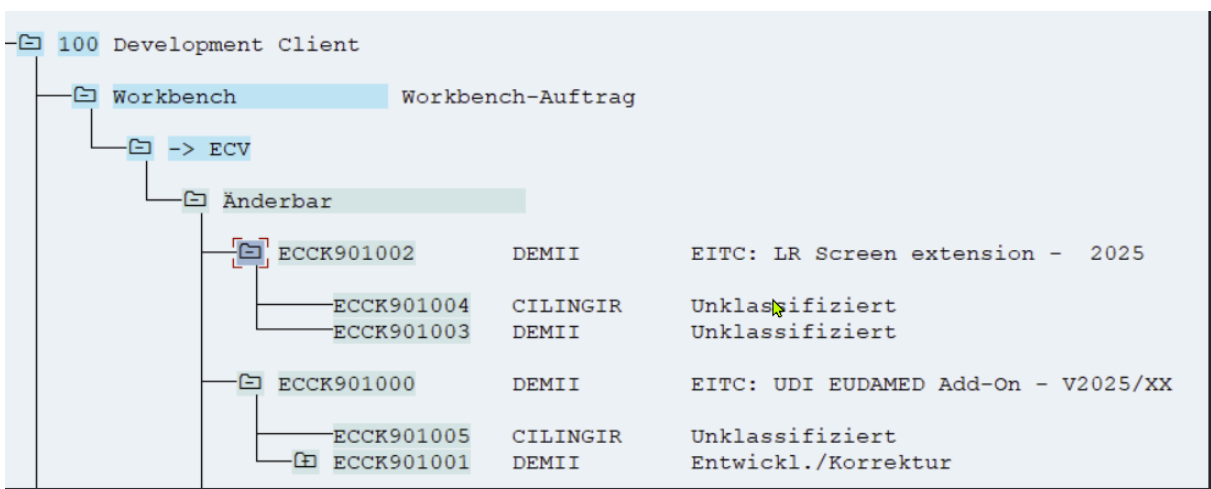
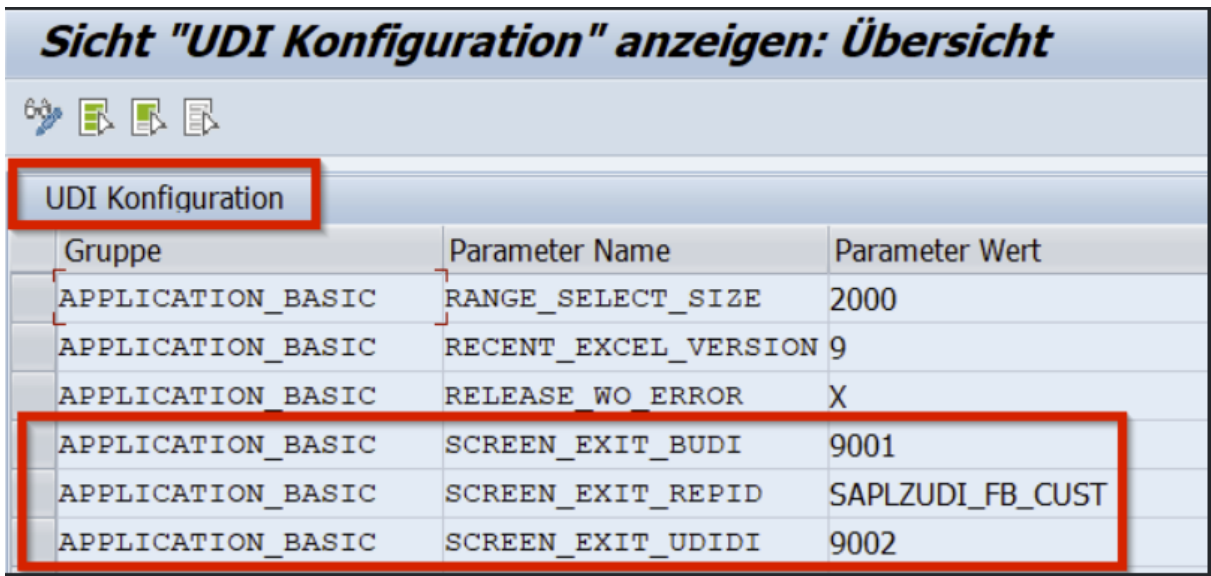
Parameters in CL_SERVICE



Configuration is done. Here I have added 2 screen numbers and the function module main program.

The screen numbers or the FM name could be different in customer system.

Check if its possible to add custom title using the parameter: SCREEN_EXIT_B_TITLE and SCREEN_EXIT_U_TITLE



Customer Screen obnly needed in BASIC UDI-DI area



Tablename start with: ZMM_UDI_*

ZMM_UDI_MDA / ZMM_UDI_MDAT

Fields:

- Name: MDA / MDN Codes (alphanumerisch 10-char)
 - Dropdown or single select
 - Catalog table as selection with : Code (10char), SPRAS , Description (80 Text)
(Multilanguage possible - text table)
- MDS Codes
 - Multiselect Table (like ion Add-On “Indication of Medical Purpose”)
 - Catalog table as selection with : Code (10char), SPRAS , Description (80 Text)
(Multilanguage possible - text table)
- MDT Codes
 - Multiselect Table (like ion Add-On “Indication of Medical Purpose”)
 - Catalog table as selection with : Code (10char), SPRAS , Description (80 Text)
(Multilanguage possible - text table)
- Internal Change Number (Text field length 30)
- Conformity Assesment Route (alphanumerisch 150 text)
 - Multiselect Table (like ion Add-On “Indication of Medical Purpose”)
 - Catalog table as selection with : Code (10char), SPRAS , Description (80 Text)
(Multilanguage possible - text table)
 - If key field is needed, than add just a number field (numc 3)



Where to add the fields in ADD-ON

The screenshot displays the SAP UDI Data Maintenance interface. At the top, the title is "UDI Daten für GMN ++EITC4845416563LP". Below the title, there are several checkboxes for diagnostic and testing methods, such as "Companion Diagnostic", "Reagent", "KIT", "Professional testing", "Near-patient testing", "Presence of cells or subst. of microbial origin", "Self-patient testing", and "Instrument".

The "Additional Information" section is active, showing tabs for "Certificate Links", "Clinical Investigation Links", "Indication of Medical Purpose", "Additional Data 1", and "Additional Data 2". The "Additional Data 2" tab is highlighted with a red X. Below this, several fields are highlighted with red boxes:

- Internal Change no.
- MDA/MDN Codes
- MDS Codes
- Description
- MDT Codes
- Conformity Assessment Route

- SAP Menue section Tcode : /n/UDI/EU
- EUDAMED Add-On T-Code : /UDI/MAINTAIN
- Test BUDI Code : ++EITC4845416563LP