

Release notes - UDI EUDAMED Add-On - EU V2024/11

Bug

[UEA-758](#) XSLT Transformation changed for UPDATE BASIC UDI-DI

Description

The XSLT has been updated to support the modification of MDR and IVDR Basic UDI-DI entries.

The Upload XML to update Basic UDI-DI data for MDR and IVDR can now be updated.

Task

[UEA-755](#) Missing Display of Release Date/Time in UDI-DI Release Popup

Description

- Under specific circumstances, the release date/time was not displayed when re-entering the UDI-DI Release popup, despite being saved correctly.
- This issue has been addressed in the latest update, ensuring the release date/time is now always visible.

[UEA-757](#) Update: NodeID Configuration for EUDAMED M2M Submission Interface

Description

- The NodeID, used to identify the AS4 submitting partner, has been updated in the EUDAMED M2M submission interface.
- To accommodate this change, an additional parameter has been introduced to ensure the correct AS4 partner is targeted for each SRN number.

Note:

This setting applies only to users utilizing Europe IT's AS4 submission services. It does not affect users who upload files directly to their EUDAMED account.

Parameter 1	Parameter 2	Description
(SRN Number)	NODE_ID	This settings is only to use if EUDAMED M2M changes it's

		checking rules for data submission using AS4. If the NODE_ID is needed for Data submission please enter the Party ID in the M2M settings from the EUDAMED Account.
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UEA-761 Validation Update: EMDN Code Entry in EUDAMED Add-On

Description

- Previously, it was possible to enter EMDN codes listed in the EMDN codelist but not marked as leaf nodes.
- The application now validates EMDN codes to ensure only leaf nodes can be entered. Non-leaf codes will trigger an error message

UEA-762 Improvement: Codelist Tables Converted to Master Data Type

Description

- To enhance flexibility, certain codelist table types have been converted to master data types.
- This change allows you to maintain these tables without requiring a customizing transport request.
- The authorization check remains active to ensure controlled access.

Changed tables:

- Applicable legislation
- Risk class
- Annex XVI
- Certification Type
- Certificate Assignemnt
- Special Device Type