



UDI Add-On (EU) Release Notes

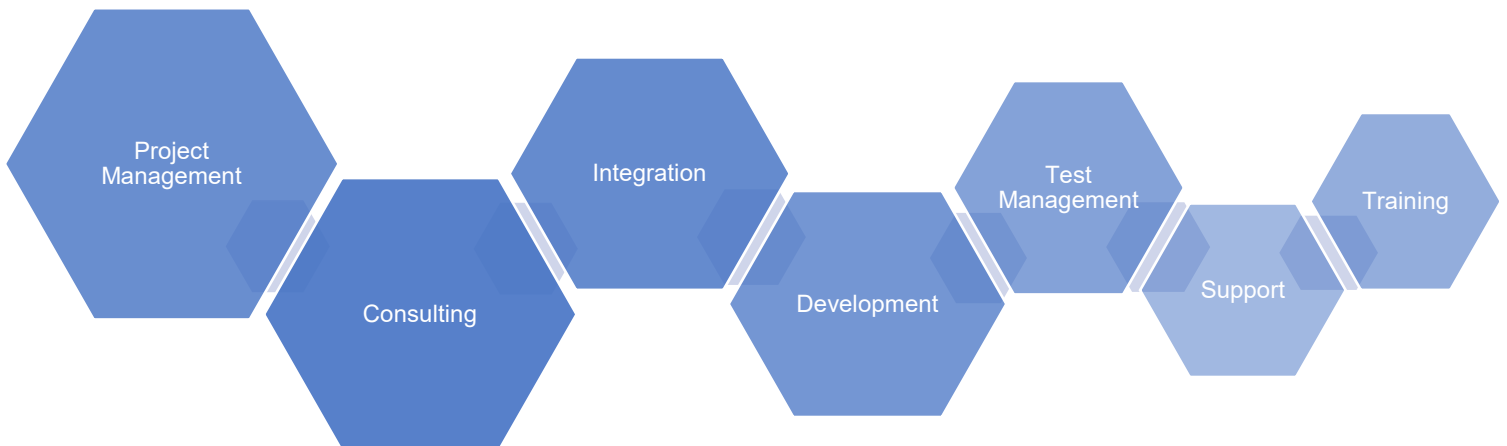




Table of contents

V2024/11 – Release Notes EU V2025/11	3
Summary	3
New Features	3
Improvements to existing features	3
Bug fixes	3
UEA-775: Special Device Type "Orthopädic" cannot registered anymore	4
UEA-773: Critical Warning Text creates an error when longer than 2000 characters	4
UEA-768: Market Info Parameter added	4



V2024/11 – Release Notes EU V2025/11

Summary

Release **EU V2025/11** provides an updated device type list according to the latest EUDAMED changes, introduces a new “Market Info” parameter in the application settings, and fixes an error that occurred when very long text fields were uploaded. The update improves regulatory alignment and system stability for EUDAMED submissions.

New Features

UEA-768 – Market Info parameter added

A new Market Info parameter has been added to the application settings.

This parameter can be used to control market-related behaviour in the EUDAMED Add-On configuration and allows a more flexible handling of market-specific requirements.

Improvements to existing features

UEA-775 – Update of Special Device Type list

The dropdown list for **Special Device Type** has been updated according to the current EUDAMED specification:

- The option “**Orthopädic**” has been removed, as it is no longer available in EUDAMED for any legislation.
- The option “**Made to order Rigid Gas Permeable (RGP) contact lenses**” has been added for MDR.
Users can now select only valid options that are accepted by EUDAMED.

Bug fixes

UEA-773 – Error when critical warning text exceeds 2000 characters

Fixed an issue where text fields (e.g. **Critical warnings, Substances**) longer than 2000 characters caused a SQL error during upload.

- The maximum field length is now enforced in the save class to prevent such errors.
- UDI data entries that were not fully uploaded previously can now be corrected and updated:
 - Use transaction **/UDI/UPLOAD**
 - Choose process type “**Update BUDI and UDI-DI**”
 - Select all fields for both areas.



UEA-775: Special Device Type "Orthopädic" cannot registered anymore

Special Device Type "Orthopädic" cannot registered anymore. This option has been removed from EUDAMED for all legislations.

Option: "Made to order Rigid Gas Permeable (RGP) contact lenses" has been added to MDR. This dropdown list will be updated.

UEA-773: Critical Warning Text creates an error when longer than 2000 characters

When the the text fields of any section like ciritical warnings or substance is longer than 2000 characters, it creates a sql error while uploading.

The field length is now ristricted in the save class. UDI data entries which wasnt fully uploaded can be updated now.

Choose in T-Code /UDI/UPLOAD the Process type "Update BUDI and UDI-DI" and select all fields for both areas

UEA-768: Market Info Parameter added

Market Info parameter added in application settings.