EUDAMED

Release notes

Production 2.15.0
2025

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1 Introduction

1.1 Release content

This document outlines the main new features in EUDAMED Production v 2.15 compared to the previous release.

For all modules: The following languages have been added to all country-related fields throughout the application:

- Icelandic

- Norwegian

- Turkish

2 Actors module

2.1 New

1. The requester and the LAA/LUA of the actor can now view the refused user access requests.

2.2 Changed

No changes.

2.3 Fixed

No fixes.

2.4 Known issues

3 UDI/Devices module

3.1 New

1. When registering a Basic UDI-DI, if one of the following special device types is selected, the Master UDI-DI applies:
    *   Standard soft contact lenses

    *   Standard Rigid Gas Permeable (RGP) contact lenses

    *   Made to order soft contact lenses

    *   Made to order Rigid Gas Permeable (RGP) contact lenses.

3.2 Changed

1. The type 'Orthopaedic' has been removed from the list of special device types.

3.3 Fixed

No fixes.

3.4 Known issues

1. "Resource Not Found" Error for Linked Regulation Devices:
    Users may encounter a "Resource Not Found" error on the public Eudamed portal when trying to view a "Related Regulation Device" from a legacy device page. This error occurs when a user, while viewing a public legacy device, clicks the link for its associated regulation device. The issue happens specifically because the linked regulation device is in a "Submitted" status. As this status means the device is not yet public, the system cannot display the resource, resulting in an error page.
    The issue will be fixed with the next release.

4 NB & Certificates module

4.1 New

1. It is now possible to discard a refused/withdrawn application, a refused certificate and a certificate version.

4.2 Changed

1. When a Notified Body registers a refused certificate or a refused/withdrawn application, the application submission date cannot be in the future.

4.3 Fixed

4.4 Known issues

5 DTX

5.1 New

No new developments.

5.2 Changed

No changes.

5.3 Fixed

No fixes.

5.4 Known issues

1. System or Procedure Pack Producer Actors may experience issues while trying to register a System or a Procedure Pack. The system may reject the request throwing an error "Only users associated with an Actor being of type Manufacturer can register Devices (Regulation or Legacy)". The correction will be provided in a future release.

6 Public site

6.1 New

6.2 Changed

1. When searching for devices using multiple criteria, the field options are displayed based on the selected value for each criterion.

6.3 Fixed

6.4 Known issues

7 List of bugs fixed

The full list of bugs reported by the users and fixed in this release is presented in the table below.

Ticket number	Summary
EUDAMEDMDR-28461	"SLEEP" keyword blocked in EUDAMED
EUDAMEDMDR-34113	[DTX] - Unable to register legacy MDD class I due to unexpected certificate error
EUDAMEDMDR-18835	[DTX] - Basic UDI-DI POST - System throws a timeout
EUDAMEDMDR-22080	[DTX] - Bulk - Download of Legacy/ Regulation Device/SPP - The number of pages is not correct
EUDAMEDMDR-31195	[DTX] - Bulk downloading devices in PROD contains duplicated results
EUDAMEDMDR-27139	[DTX] - Database Exception Error for bulk upload
EUDAMEDMDR-23001	[DTX] - Devices - Bulk XML download - System does not include all devices in the XML response
EUDAMEDMDR-25020	[DTX] - Download devices - System responds with Database Exception : Please contact the support
EUDAMEDMDR-25021	[DTX] - Download devices - System responds with generic M-50000 error code
EUDAMEDMDR-25299	[DTX] - Download devices service - Number of pages is reset to 0
EUDAMEDMDR-25300	[DTX] - Download devices service - System responds with 'An invalid XML character (Unicode: 0x1e) was found in the element content of the document.' when validating the output
EUDAMEDMDR-25301	[DTX] - Download devices service - System responds with E-O-50002 'message='cvc-maxLength-valid: Value 'Tip Diameter(d±0.1mm)' when validating the output
EUDAMEDMDR-26753	[DTX] - Download of Legacy/ Regulation Device/SPP - Download own devices via M2M - Error ERR-BR-DTX-UDI-065.05-01 in response
EUDAMEDMDR-31166	[DTX] - ERR-BR-DTX-UDID-036.05-02: error received when adding a new UDI under an existing PR Basic UDI
EUDAMEDMDR-34117	[DTX] - UDI_DI PATCH for legacy fails due to clinical size error
EUDAMEDMDR-26009	[DTX] - Update UDI-DI - System incorrectly validates the version number of the provided UDI-DI
EUDAMEDMDR-19964	[DTX] - Upload of Basic UDI-DI / UDI-DI - System throws generic M-50000 when information about the certificate is provided
EUDAMEDMDR-31175	[DTX] - Uploading a PR device with packages using DEVICE POST throws generic error
EUDAMEDMDR-35064	[DTX] PROD-BULK Download result with duplicate UDI DIs
EUDAMEDMDR-21990	Abort an Actor registration request - Actor registration requests page of an existing User (with one actor already registered) cannot be accessed at first loading (after account login)
EUDAMEDMDR-30513	Access Point - Rejection reason link is not functioning
EUDAMEDMDR-32041	Actor - User cannot finalise their registration process in EUDAMED
EUDAMEDMDR-22282	Actor registration management filter does not display the searched value and sort function throws a system error.
EUDAMEDMDR-23641	AP management - 'Reason for rejection' is not displayed in AP request details
EUDAMEDMDR-25192	Authorized Representative unable to access 'Manage your actor data' and no current version of actor is displayed on public website
EUDAMEDMDR-33996	BUDI duplicate error message
EUDAMEDMDR-25877	CA cannot see details for actors in "Correction requested"
EUDAMEDMDR-24823	Cannot create a new version or delete the draft version of a registered UDI
EUDAMEDMDR-27878	Cannot view actor - the system throws an error
EUDAMEDMDR-32026	Certificate - 500 Internal Server Error on certificate submission
EUDAMEDMDR-24894	Changes made on EU Login details do not get updated on EUDAMED
EUDAMEDMDR-32341	Create new UDI version - Fast double click creates two (2) Draft instances
EUDAMEDMDR-25315	Create new version for an EUDAMED DI - System displays the old AR when creating a new version of a legacy device by a non-EU MF
EUDAMEDMDR-29412	DA Validator cannot validate user access requests for first NB LAA
EUDAMEDMDR-25784	Device registration - System displays the old AR when for non-EU MF when it expires
EUDAMEDMDR-33656	Discarded devices are not being relinked to a new AR version causing the non-EU MF to not see devices in mgmt page
EUDAMEDMDR-34129	Error message when viewing UDI-DI details
EUDAMEDMDR-33994	Eu Login Id: User cannot see the Actor
EUDAMEDMDR-30639	LAA to assess the request for change
EUDAMEDMDR-30177	Legacy device view details page, incorrect label is displayed
EUDAMEDMDR-27800	NB historical versions appear on search and an error is thrown if a historical version is selected
EUDAMEDMDR-33995	None of the existing LAA users have access to its own Actor
EUDAMEDMDR-29940	Orphan EUDAMED DI after its device has been discarded
EUDAMEDMDR-24946	Product certificate registration - System does not show the Add SS(C)P button

Ticket number	Summary
EUDAMEDMDR-27638	PUBLIC - View Manufacturers on AR side take a long time to load and eventually gives an internal error
EUDAMEDMDR-31435	Public site - Basic UDI-DI details - Certificate information is not displayed
EUDAMEDMDR-27879	Public site - cannot search for actor - the system displays "No records found."
EUDAMEDMDR-31979	Public site - EU MFs linked to an AR not shown
EUDAMEDMDR-31979	Public site - EU MFs linked to an AR not shown
EUDAMEDMDR-32216	Searching function on UI working improperly for the EC ADMIN users
EUDAMEDMDR-25489	System/Procedure Pack Producer cannot create a new version of PP
EUDAMEDMDR-25489	System/Procedure Pack Producer cannot create a new version of PP
EUDAMEDMDR-32138	Terminate mandate by AR - When an AR TERMINATES a mandate an error appears and the mandate IS NOT terminated - 500 internal server error
EUDAMEDMDR-31453	UDI - Draft device is not visible in MF mgmt page
EUDAMEDMDR-31565	UDI/Device - Manufacturer cannot delete their device in Draft
EUDAMEDMDR-29206	UDI-DI in draft cannot be deleted
EUDAMEDMDR-28521	Unable to EDIT or DELETE DRAFT UDI
EUDAMEDMDR-30275	Unable to request for a new actor registration in EUDAMED - Role and Country drop down menus not populated
EUDAMEDMDR-25270	Unable to view device details for some devices
EUDAMEDMDR-29916	Unable to view own devices in Draft state under a Basic UDI-DI in Registered state
EUDAMEDMDR-25190	User Eudamed Email Address is set to Approver's Eudamed Email Address on approval of User Profile Change
EUDAMEDMDR-30259	User unable to submit or delete draft UDI
EUDAMEDMDR-26077	Wrong number of pending actor requests entries shown

8 List of implemented changes

The full list of implemented changes in this released based on users' feedback is presented in the table below.

No changes.