



EUDAMED

Release notes

Production 2.27.0
2026



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1 Actor Module

New

Mergers and Acquisitions (M&A) functionality - Actor Flow

1. The system now supports the initiation of the Mergers and Acquisitions (for Manufacturer (MF) or Producer (PR) LAA Users) flow directly in the “My Actor data” section. The key features of the new functionality are:
 - a. Create acquisition/merger requests by selecting the actor and defining acquisition parameters;
 - b. Centralised management screen to view, track, and withdraw requests if needed;
 - c. Approval workflow where the receiving actor can review and approve or refuse the request, with confirmation steps to avoid accidental actions;
 - d. Notifications and alerts, including a bell indicator, to inform users when requests are submitted, approved, refused, or withdrawn;
 - e. Visibility of acquisition relationships in actor details within search results, helping users understand organisational links.

Changed

Fixed

Known Issues

1. Mergers and Acquisitions (M&A) functionality: please note that this functionality currently covers the Actor flow. This means that the relationships between actors are reflected in the system. However, the workflow for Devices ownership (and consequently Certificates) is yet to be developed and will be introduced in a future release.
2. The system currently permits users to proceed with data entry even when the acquiree manufacturer has not been selected, provided an Actor ID/SRN is entered. While the system correctly halts submission upon clicking the Submit button, it does not yet prevent data entry at earlier stages if the acquiree manufacturer is missing. A fix to enforce upfront validation (blocking further input until an acquiree manufacturer is selected) will be implemented in an upcoming release.

2 UDI/Devices Module

New

Changed

Fixed

Known Issues

3 Certificates

New

1. The Clinical Evaluation Consultation Procedure (CECP) feature, as well as Mechanism for Scrutiny (MfS) feature are now available in the EUDAMED.
2. When searching for the Certificates (not applicable for Refused Certificates), the system displays the expiry date in red and an exclamation mark next to it. This allows to visually differentiate between expired and not expired Certificates in the list.

Changed

Fixed

Known Issues

4 Market Surveillance

Please note that with this Release, the Market Surveillance module is available in EUDAMED.

New

1. To complement the development on the EMDN Versioning introduced in previous releases, the system now enables auto-update of the EMDN code changes and provides relevant information for MSU Procedures. This feature is now available for Draft as well as Registered MSU Procedures.

Changed

Fixed

Known Issues

1. Once the EMDN code is chosen from the list, the version details are not available. They are only visible when browsing EMDN code.

5 DTX

New

1. Certificate Upload functionality is available for Notified Bodies. For this particular release, Product type certificates are allowed to be uploaded without SS(C)P or Mechanism for Scrutiny enabled. Users can now upload certificates using XML format, either via M2M or Bulk Upload in the user interface. More functionality to be added in the coming releases (Quality type certificates, SS(C)P, Mechanism for Scrutiny).
2. New service CECP.GET - for CAs
3. Market Surveillance services:
 - a. ANNUAL_SUMMARY_REPORT.GET,
 - b. FINAL_INSPECTION_REPORT.GET,
 - c. FOUR_YEAR_REPORT.GET
 - d. MSU_PROCEDURE.GET

The above are described in the services definition documents.

Changed

1. For the Service DEVICE GET functionality when requesting the device update starting with specific date, the system now provides full list of devices including the updates on the non-versioning attributes of the Device (Basic UDI-DI - Clinical Investigations; UDI-DI - Market Info, Container Package, Product Designer).
2. Update on the BR for Master UDI - update on BR-UDID-731.

Fixed

Known Issues

1. Certificates User Interface - Attachment link of a certificate generated by DTX points to an incorrect URL page.
2. Conditions and limitations are not shown in the UI even if they have been added in the XML request for a certificate creation.

- 3. Bulk download MSU Procedure (Search & View/Market Surveillance/Search for procedures) - when enabling filters for bulk download, the field 'Item type' is wrongfully not marked as Mandatory. If "Item Type" is left empty, after clicking on 'Generate XML file' an error is thrown "This operation is not possible, please reload the page". A fix will be provided in a later release. For the time being, please select a value inside the "Item Type" and " Last update date from" fields before performing the search.

Procedures

Enable filters for procedures bulk download

Item type

Procedure type

Item ID

Item status

Local CA reference

EO Actor ID/SRN

State

* Last update date from

YYYY-MM-DD

6 Public Site

New

1. In the 'Certificate details' section in 'Preceding certificate(s) identifier', when the certificate's first version is in a status other than 'Issued' (Supplemented, Amended, Restricted) there will be just partial information of preceding certificate - only the value of preceding certificate identifier will be displayed. The link with preceding certificate information is only applicable for the Certificate with the first version Issued.
2. When searching for the Certificates, the system displays the expiry date in red and an exclamation mark next to it (not applicable for Refused Certificates). This allows visually to differentiate between expired and not expired Certificates in the list.

Changed

Fixed

Known Issues

7 List of Bugs Fixed

Ticket number	Summary
EUDAMEDMDR-41683	DTX - directMarkingDI not saved in the DB if the same device was previously discarded
EUDAMEDMDR-40889	DTX - unable to retrieve devices due to XSD validation error
EUDAMEDMDR-40017	DTX - Unable to perform UDI_DI.PATCH and declare direct marking
EUDAMEDMDR-42408	Certificates - Amend / Restrict / Supplement Certificate - Under 'Status change reason' section (Certificates identification tab), system does NOT save any info filled in mandatory 'Other reason' text field
EUDAMEDMDR-42191	Certificates - Option to add System and Procedure Pack group(s) is missing when registering Restricted, Issued, Supplemented and Amended Quality Certificate with both SPP and Device (MF) and submission is getting blocked
EUDAMEDMDR-41191	Devices - Search & View UDI Devices not displaying results (timeout error)
EUDAMEDMDR-39507	Public - System fails to display actor details page for certain actors

8 List of Implemented Changes

Ticket number	Summary
EUDAMEDMDR-39001	DTX Devices - MUDI format not accepted through M2M channel
EUDAMEDMDR-40656	Certificates (Public & Private View) - Expired Certificates are now clearly marked in EUDAMED to avoid any confusion

