EUDAMED

Release Notes

Production v 2.25.2
2026

Table of Contents

1 Actor Module

New

1. The system introduces new notification for the non-EU manufacturers. When the Authorised Representative of a non EU manufacturer (with an active mandate between them) changes their responsible Competent Authority, the non-EU Manufacturer will be notified by the system.

2. In order to ensure compliance with GDPR and to ensure data integrity, EUDAMED will not be displaying the Person Responsible for Regulatory Compliance (PRRC) data for inactive or historical versions of MF/AR on Public website. The same behaviour will be applicable for the restricted website (only supervising entities will have the option to view historical data on PRRC).

Changed

Fixed

Known Issues

2 UDI/Devices Module

New

Changed

Fixed

Known Issues

3 Certificates

New

1. This release complements already introduced functionality for EU Manufacturers - 'EUDAMED now allows Notified Bodies to reference unregistered Manufacturers or Producers when creating Refused Certificates or Refused/Withdrawn Applications' with the flow for the non-EU Manufacturer.

2. EUDAMED will now display the registration date (Last Update Date). It shall be displayed by EUDAMED for Refused/withdrawn applications and refused certificates (for public site, it concerns only refused certificates).

Changed

1. The system introduces limitation in the IVDR Certificate registration. This constraint will be applied only for certificate and refused certificate registration (not for applications refusal/withdrawal). For (IVDR) TDA certificate registration, the system will now allow only risk class D, C, B, where:
   a. Risk class C - Self testing and/or near patient testing devices and/or companion diagnostics

   b. Risk class B - Self testing and/or near patient testing devices

   c. Business Rule BR-CRF-029 will be updated to RULE-00020 with new restrictions according to the certificates matrix

2. The system introduces limitations on possible combinations of certificates for a device's conformity assessment based on it's risk class and attributes. If an incorrect combination of certificates is selected for a device, then certificate registration should be halted. When searching for Basic UDI-DIs, the system will display Basic UDI-DIs applicable to that certificate type. However, if the user selects a Basic UDI-DI that belongs to a different path for conformity assessment, the system will prevent the submission of the form and display an error to the user (Back end validation)

3. The system now validates that when a device holds both a Quality Management System and a Technical Documentation Assessment certificate, both must be issued by the same Notified Body. Additionally, a certificate is only considered active when it is not withdrawn or cancelled, not in draft or discarded state, and the current date falls within its validity period.

4. System will now enable initial registration of a certificate with statuses other than “Issued,” without requiring prior versions to be present. It will enable the user to reference previous certificate IDs, even if those versions are not in EUDAMED. In addition, it will allow statuses like:
    a. Amended
    b. Supplemented
    c. Restricted
    d. Re-issued for initial registration

Fixed

Known Issues

1. For the functionality enabling initial registration of a certificate with statuses other than "Issued", following functions will be delivered in the next releases:
    a. Private website - preview of my certificate registration information in wizard before I submit certification request
    b. Private website - the system will display the reason and associated comments regarding the preceding certificate version
    c. Public website - information on the preceding certificate identifier

4 DTX

New

1. Competent Authority is now able to download discarded devices utilizing DEVICE.GET Service as well as via Bulk Download option from Search & View screen.

2. Manufacturer and System or procedure pack producer are now able to download their own registered/submitted and discarded Devices utilizing DEVICE.GET Service. The Bulk download functionality will be provided in the upcoming releases.

Changed

Fixed

1. For Competent Authority actor DEVICE GET: missing CASCode and ECCode is now fixed

2. For Competent Authority actor DEVICE GET: Clinical Investigations missing clinical investigation links is now fixed

3. For Competent Authority actor DEVICE GET: Clinical Size missing description is now fixed

4. For Competent Authority actor DEVICE GET: PRODUCT DESIGNER missing info is now fixed

5. For Competent Authority actor DEVICE GET: time zone issues are now fixed

Known Issues

5 Public site

New

1. EUDAMED now provides the functionality of dedicated Public API that allows the download of publicly available data in Actor and Devices modules in machine readable format - JSON. The API is accessible via link in the EUDAMED Public website directly under the header of the individual search sections. Please consult dedicated User guide and swagger file in the Information center for further details.

Changed

Fixed

Known Issues

6 List of bugs fixed

Ticket number	Summary
EUDAMEDMDR-41580	DTX - Pagination incorrect for DEVICE.GET not in line with pagination on ACTOR.GET
EUDAMEDMDR-41396	DTX-ACTOR.GET and DEVICE.GET XML response not valid against the XSD schema
EUDAMEDMDR-40428	DTX - Exporting device with Clinical Size Type/ Measure Unit Type with "Other" Option does not contain information
EUDAMEDMDR-40191	UDI - General error when clicking "Save & Next" during UDI-DI registration
EUDAMEDMDR-40131	Actor - Non EU Manufacturer cannot complete registration as no CA entry is displayed in final step
EUDAMEDMDR-40130	Actor - Authorised Representative cannot complete Non EU MF registration assessment. Generic error displayed to user
EUDAMEDMDR-40107	UDI - System/Procedure Pack Producer - Wrong actor's role is displayed for SPP actor on registered UDI details and on Refused Certificates
EUDAMEDMDR-39191	DTX - XML responses not sent due to edelivery connection error
EUDAMEDMDR-37969	Certificates - SS(C)Ps page - After initiating the registration of an SS(C)P, "Add SS(C)P" button (in order to add more than one SS(C)P) is missing
EUDAMEDMDR-37295	UDI - Registered UDI DI without current version

7 List of implemented changes

Ticket Number	Summary
EUDAMEDMDR-28252	PRRC data should not be displayed for inactive or historical versions of MF/AR on Public website. For Restricted, same behavior for all actors except CA, DA and EC


European
Commission