EUDAMED

Release Notes

Production v 2.22.0
2026

Table of Contents

1 Actor Module

1.1 New

1. To help tracking data confirmation dates by version, EUDAMED is now able to display accurate "Last data confirmation" dates for each Actor version and attribute dates confirmed during previous versions with version number. The version number is displayed along with the date on which the Actor confirmed the accuracy of their data.

1.1.1 Changed

1. As part of the update for MS Summary Report, Designating Authority can request "Slim viewer" user profile for modules: Market Surveillance, Vigilance and post-market surveillance and Clinical Investigations & Post-Market Performance Studies

1.1.2 Fixed

1.1.3 Known Issues

2 UDI/Devices Module

2.1 New

1. The system now enables versioning of the European Medical Devices Nomenclature (EMDN) Codes. This functionality enables the traceability and transparency in terms of EMDN code evolution as well as its linkage to the devices registered in EUDAMED. The system shows the evolution of the EMDN codes via Information pop-up during the registration of a device. Different versions are displayed in the table with relevant status and dates of change. In addition, obsolete codes (for example discarded ones) are not available for selection anymore.
   Users are able to version the device with updated EMDN codes – this action is linked to Discarded, Split and Scope reduced of EMDN codes where system will notify the user on the need to update the EMDN codes. Once the update is done, the device is versioned with correct EMDN code associated to it. This change is linked to the Restricted as well as the Public Website.

2.1.1 Changed

2.1.2 Fixed

2.1.3 Known Issues

1. The functionality linked to the Market Surveillance and Vigilance modules in regards to the versioning of EMDN codes is to be developed in the coming releases.

3 Certificates

3.1 New

1. In order to improve the user experience in the Certificates module for Legacy devices, during the registration/update of the Legacy Device, the status of Notified Body (expired, withdrawn or suspended) is displayed in brackets next to the Notified Body's name in Certificates Section.

2. EUDAMED now allows Notified Bodies to reference unregistered Manufacturers or Producers when creating Refused Certificates or Refused/Withdrawn Applications. For the Release 2.22.0, this functionality is available for EU Manufacturer or Producer.

3.2 Changed

1. The following updates were executed for MS Summary report (the changes aim to improve the user experience and usability of the reports):
   a. In the section "Register new Summary Report":
      i. "From date" and "To date" cannot be in the future;

      ii. "To date" can be on current system date the latest;

      iii. "From date" must be at least 1 day less than "To date" (n-1).

   b. In Restricted "manage" page:
      i. Added column named "Report file" - report file contains hyperlink to MS report which will enable the user to automatically download it upon clicking on the link;

      ii. Added column named "Submission date" - this represents the last action performed on the report;

      iii. Last column "Action" does not contain "Download" function as this appears in the "Report File" column now. The only action in the column is "Discard".

   c. In Restricted "Search and View" page:
      i. Renamed the column "Member state" into "Country;

      ii. Renamed the column "Summary report" into "Report file";

      iii. Added the column "Submission date".

   d. In Restricted "Search and View" Page - filter/search criteria box:
      i. Renamed the current field "Member state" into "Country";

      ii. In the "Country" field, an option to cancel selection of country by clicking on "X" was enabled;

   e. In Public Page - NB Monitoring Summaries - filter/search criteria box:
      i. Renamed the current field "Member state" into "Country";

      ii. In "Country" and "Designating authority" fields an option to choose "All" value was enabled;

      iii. A selection of 5 additional states was enabled: Iceland, Norway, Liechtenstein, Northern Ireland and Türkiye.

3.3 Fixed

3.4 Known Issues

1. The functionality allowing Notified Bodies to reference unregistered Manufacturers or Producers when creating Refused Certificates or Refused/Withdrawn Applications applies to EU Manufacturer or Producers. Non-EU Manufacturer or Producer workflow will be deployed in the next Production Release.

2. When registering or referencing a SS(C)P during certificate registration, the button allowing to add more than one SS(C)P when there are multiple Basic UDI-Dis in the scope of the certificate that require SS(C)P, is missing. This will be fixed in the upcoming Production Release.

4 DTX

4.1 New

1. Intended purpose other than medical (Annex XVI) for Master UDI is implemented as a Boolean (true/false) field.

4.2 Changed

1. Enhancement of the DEVICE.GET service:
   a. When sending any request to EUDAMED, the XML Payload should contain a few message identifiers. These are: messageID, conversationID, correlationID;

   b. The correlationID from your initial request will be used to "store" the results of the initial search and provide the next page of results from this "snapshot";

   c. Example:
      i. In case of sending a request for DEVICE.GET using certain search criteria, EUDAMED will respond with the first page of results (page 0) and will state how many pages of results exist (numberOfPages);

      ii. If a new request for the next page of results was sent and the same correlation ID as the one in the initial request was kept, EUDAMED will investigate the "snapshot" of results and provide the next page of results;

      iii. Sending the same correlationID in all subsequent page requests will ensure the following:
         A. Shorter response time;

         B. No data drift. Even if changes occur in the database (for example, new device was created in the meantime), once the user finishes retrieving all pages, they will get all results from the initial query.

2. Additional important changes:
   a. Limit of the number of UDI DIs for a BASIC UDI-DI in the DEVICE.POST service. Only one UDI DI can be added. Subsequent UDI DIs will be added via the UDI_DI.POST service;

   b. Change of the file path inside the XML payload request when providing attachments. The FileURI in your XML Payload will have the following path: Parent Folder inside the ZIP/Child folder/Child folder[…]/FileName.extension;

   c. New structure of XML response. EUDAMED will process each object inside a request individually and the related response will contain a line for each object;

   d. New statuses for bulk upload. Partially Successful status is introduced for the cases when at least one object inside the XML request was processed successfully.

4.3 Fixed

4.4 Known Issues

5 Public site

5.1 New

1. EUDAMED now allows versioning of European Medical Devices Nomenclature (EMDN) Codes. This functionality enables the traceability and transparency in terms of EMDN code evolution as well as its linkage to the Devices registered in EUDAMED. This change is linked to the Restricted as well as Public Website.

5.2 Changed

1. Changes to the Public page in regards to the MS Summary Report:
   a. Renamed the current column "Member state" into "Country";

   b. Added the column "Submission date" - this represents the last action performed on the report;

   c. In NB Monitoring Summaries - filter/search criteria box:
      i. Renamed the field "Member state" into "Country";

      ii. In "Country" and "Designating authority" fields, an option to choose "All" value was enabled;

      iii. A selection of 5 additional states was enabled: Iceland, Norway, Liechtenstein, Northern Ireland and Türkiye.

5.3 Fixed

5.4 Known Issues

6 List of bugs fixed

Ticket Number	Summary
EUDAMEDMDR-40428	DTX - exporting device with Clinical Size Type/Measure Unit Type with "Other" Option does not contain information
EUDAMEDMDR-39694	DTX - unsanitised data sent via DTX - characters that are not allowed by XML 1.
EUDAMEDMDR-39626	DTX - when downloading an IVDD device, storage conditions, critical warnings and market info are missing from the response
EUDAMEDMDR-39601	DTX - ACTOR.GET unexpected validation error when searching for type = MF
EUDAMEDMDR-38839	DTX - UDI Bulk Download issue with pagination and response sent
EUDAMEDMDR-38488	DTX - bulk upload with directMarkingDI - Same as UDI-DI is not saved in DB
EUDAMEDMDR-37063	DTX - BULK DOWNLOAD when searching for Basic UDI not working
EUDAMEDMDR-36328	DTX - DEVICE.GET - when using country as search criteria, this criteria is ignored and the system responds with all devices
EUDAMEDMDR-34329	DTX - Bulk Download - 3 Missing blocks of information in System and Procedure Pack downloaded XML that is present in the application for this device
EUDAMEDMDR-34223	DTX - DEVICE GET where country search criteria is used cannot be retrieved due to random responses returned with error
EUDAMEDMDR-30072	DTX - exporting device with Clinical Size Type/ Measure Unit Type with "Other" Option does not contain information
EUDAMEDMDR-39596	Private Website - UDI/Devices - User unable to discard a (Master-) UDI from a Basic UDI due to error: "Internal connectivity issues to Vigilance module prevent you completing this operation currently, please try again later"
EUDAMEDMDR-39099	Incorrect label (Expired) shown for NB 0068
EUDAMEDMDR-39040	Search & View devices - container package details show "Undefined text" instead of "Quantity per package"
EUDAMEDMDR-35585	User unable to update Market Info due to server error

7 List of implemented changes

Ticket Number	Summary


European
Commission