EUDAMED

Release notes

Production v 2.10
January 2023

Table of Contents

1 Introduction

Landing page and Help

The EUDAMED landing page has been improved.

You can now easily access the *EUDAMED Information Centre* directly from the landing page. Moreover, once logged in to EUDAMED, you can access the *EUDAMED Information Centre* from the dashboard and from the *Help* menu at the top.

2 Release content

This document outlines a brief overview of the main new features in EUDAMED Production **v 2.10** compared to the previous release:

2.1 Actors module

New

- New feature to set an Economic Operator as inactive (*status inactive*). This leads to:
  - A new version of the Economic Operator with the new status.
  - *Inactive* status will be displayed in various selected screens, next to the Actor ID/ SRN, in both Restricted and Public sites.
  - Persons Responsible for Regulatory Compliance are not displayed when viewing an inactive Actor's details.
- Added a separate section and label to highlight the Termination date of a Mandate.

Fixed

- When creating a new version for a Non-EU Manufacturer (MF) actor, the system was improperly updating the Mandate's End date as well. This has been fixed.

2.2 UDI/Device module

New

- Possibility to search for devices by indicating the Competent Authority (CA) responsible for the MF. The system will display the devices manufactured by the MFs for which the indicated CA is responsible.
- Possibility to search for devices by indicating a Notified Body referenced in the certificate section of that device.
- The system now prohibits the registration process when the provided UDI for a regulation device is matched against an already registered legacy device (and vice versa) but the regulations of both devices do not match (MDR→MDD/AIMDD, IVDR→IVDD).

Changed

- Several User experience/User Interface improvements related to the *Search & view* page.

- Enforced the rule on inability to discard a Basic UDI-DI that is linked to an SS(C)P.

Fixed

- Notification to the respective Notified Body when a device awaits their confirmation (Device is in state *submitted*).
- The status of a container package for a device or system or procedure pack is now displayed.
- Removed the unexpected {clinicalItemNumber} placeholder within the *Clinical Sizes* section of a device registration.
- It is now possible to remove an item from the *Certificate information* section of a legacy device registration.
- Various fixes for linking legacy to regulation devices.
- Enforced the business rule on having the secondary UDI-DI's issuing agency be different from the issuing entity of the primary UDI-DI.
- Fixed a bug related to re-use of a discarded UDI.
- All the UDI-DIs are now displayed under a Basic UDI-DI in the *Management* page.
- *Search & View* of devices: When going back from the view details page to the result list the filter values were lost – this is now fixed.
- The missing Notified Body (2934) when registering legacy devices is now visible again.
- The measuring unit (MU 139) value was displayed as 'S' – this is now displayed as 'Straight'.

2.3 NB & Certificates module

New

- Possibility to register refused certificates, refused applications and withdrawn applications of type product (MDR/IVDR) having in their scope devices without a known Basic UDI-DI but only known by name or reference/catalogue number.

Changed

- The system now allows the selection of a preceding expired certificate when registering a reissued certificate. The Issue date of the reissued certificate must not be later/greater than three months after the preceding certificate's expiry date.

2.4 DTX

The XSD version of the services is updated from **2.0.6** to **2.0.7** – this needs to be manually adapted in your service requests. The following changes have been implemented:

- Actor download service:
  - New data added to the service: Status, StatusChangeDate, StatusChangeReason.
  - Regulatory persons data for Inactive Actors removed from the service (the removal is not applicable for the CAs).
- Download devices: NB/CA/DA actors can specify the NBActorCode criterion to filter devices for which the NB issued a certificate.
- Fixed the error when the value for the nodeActorCode field is missing for the EC actor when downloading devices via bulk XML download.
- Added the possibility to provide information more than once for the type *OTHER* in the same language when registering Storage and Handling Conditions, Critical warnings and Clinical sizes for a device.
- Fixed the discrepancy of the registration date of a Basic UDI-DI and its respective UDI-DIs when submitting device registration. The registration dates are now the same.
- Fixed the issue when registering an IVDR device having risk class C (attributes near patient and self-testing having value false) with the IVDR_TYPE_EXAMINATION certificate type. The system accepts the EU Type-Examination certificate (Annex X) in case it is provided.
- Fixed the validation of a Basic UDI-DI version provided in the payload. System throws an error when the version does not meet the version incremental scheme.
- The validation process for updating market information for a device that was originally placed on the market in a country within the European Union (EU) has been fixed. If an attempt is made to update the first EU country where the device was initially placed, the system will generate an error stating that the EU country where the device was originally placed on the market can only be updated through the Update of UDI-DI service.
- Fixed the automatic link creation between a legacy and regulation devices that share the same UDI-DI.
- Fixed a generic error message thrown when the payload contains certificateLinks data for a device that does not require a certificate to be provided.
- Fixed the bug when downloading bulk XML of certificates of type *Quality* result. System threwunrelated error.
- Fixed the issue of responses not being provided in some cases.


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