



EUDAMED

Release notes

Production v 2.12
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1 Introduction

1.1 Release content

This document outlines a brief overview of the main new features in EUDAMED Production v2.12 compared to the previous release:

2 Actors module

2.1 New

View historical actor versions (Chapter 2.1.4.1 in the Economic Operators user guide)

Search and View Actor information: It is now possible to access every historical version of the actor data separately and to select the search option *Include historical version*.

Confirm actor data accuracy (Chapter 2.1.7 in the Economic Operators user guide)

Economic Operators must confirm the accuracy of their data no later than one year after submission of the information and every other year thereafter. An Actor's LAA can now manage this information from the menu *Manage your actor data*.

2.2 Fixed

1. Refuse user access request: when an access request was refused by the LUA/LAA with the reason *Refused request*, an error previously prevented the user from proceeding.
2. The message *An error has occurred - Undefined text* no longer displays when the LAA approves or rejects an access request or a change request from a user.
3. When viewing an Importer's details, the list of linked non-EU manufacturers is now displayed.
4. The issue of the registration for a new version of an Authorised Representative has been fixed. The system prevented the registration of a new version when the applicability of VAT information was toggled in the UI.

3 UDI/Device module

3.1 New

1. A confirmation pop-up is now available when submitting a new version of a registered UDI-DI and also for a new version of a registered legacy device (with a EUDAMED ID).
2. When registering a device in the UDI/Devices module with a Basic UDI-DI code that was previously referenced in a refused certificate and/or refused/withdrawn application, the system now validates the characteristics of the Basic UDI-DI to match the characteristics of the non-registered Basic UDI-DI referenced in a refused certificate and/or refused/withdrawn application.

3.2 Changed

1. The country list of the *Country* filter in the *Search Devices and System or Procedure Packs* page to EU Member States, Special and Extended countries has been updated.
2. The displayed values for the following enumerations have been updated:
 - Storage and handling conditions
 - Clinical size measure units
 - Critical warning: all the values are being displayed in alphabetical order.

3.3 Fixed

1. Display of clinical sizes: All numerical precision types are now being displayed in decimal format.
2. Accessibility: It is now possible to select the Member States where the device is or is to be made available on the market when using a screen reader.
3. Automatic linking of devices having the same UDI-DI: The issue of incorrect linking UDI-DI(s) and the regulation device that has multiple UDI-DI(s) has been fixed. This caused the generic error to be displayed when viewing device details page.
4. New version of Basic UDI-DI: When registering a new version of a Basic UDI-DI, the system will not display the *Device model* field if its applicability in the previous version was set to *No*.

4 NB & Certificates module

4.1 New

1. When registering a refused certificate or a refused/withdrawn application (MDR/IVDR), there is now the possibility to reference a Basic UDI-DI that is not registered in the UDI/Devices module (**Chapter 5 in the Notified Bodies & Certificates user guide**).
2. It is now possible to reference the same non-registered Basic UDI-DI in a refused certificate or a refused/withdrawn application record when registering another refused/withdrawn application or refused certificate.
3. The BR-CRF-270 is now enforced when registering a (MDR) EU Technical Documentation certificate type (Annex IX Chapter II) for an issued certificate, for a refused certificate or for a refused/withdrawn application. This certificate type accepts only Basic UDI-DI(s) of risk class III or risk class IIb (implantable and not sutures/staples/dental fillings).
4. SS(C)P registration is now possible within the certificate type *(MDR) EU Quality Management System certificate certificate (Annex IX Chapter I)* for Basic UDI-DI(s) of risk class IIb (that are implantable and sutures/staples/dental fillings) for which the *(MDR) EU Type Examination certificate (Annex X)* is not applicable and is not being referenced in another SS(C)P.

4.2 Changed

1. Search & View for refused certificates and refused/withdrawn applications: It is possible to search for Basic UDI-DI(s) that are not registered in the UDI/Devices module and were referenced in a refused certificate or in a refused/withdrawn application.
2. It is now possible to enter more than 2,000 characters in the *Intended purpose* field.
3. *View refused certificate details* page: The *Reason for refusal* comment and *Decision on refusal document* are being displayed only for NB (OWNER), CA/DA and EC actors.
4. *View refused/withdrawn application details* page: The *Reason for refusal* comment and *Decision on refusal document* are being displayed only for NB (OWNER), CA/DA and EC actors.
5. *View certificate details* page: *Decision* comments and *Decision document* are being displayed only for NB (OWNER), CA/DA and EC actors.

6. Re-issued certificate registration: Preceding certificate information in the left panel is displayed as a hyperlink consisting of Certificate number and Revision number (if applicable). Only the certificate ID was displayed before the change.

4.3 Fixed

1. The system displays the *Inactive* status of an Authorised Representative actor when applicable within certificate registration workflow.
2. We fixed the reset issue in the *Reason for refusal* comment when continuing a registration of a draft saved refused certificate.
3. Search for applications: The impossibility to enter data into the *Enter the device identification value/text* box has been fixed.
4. Registration of a new Notified Bodies monitoring summary report: We fixed the issue with the duplication of a report. The unique report ID is no longer duplicated during the registration of a new report after a previous report has been discarded.
5. *View certificate details* page: See version history displays the historical versions for a certificate with multiple versions that has also a *Draft* version linked to it.
6. Supplement or Restrict a certificate: The system correctly displays the languages of the *Conditions or limitations* and matches the language display in the accordion and text entry when opening a saved draft.
7. Manage SS(C)P: We fixed the result list of SS(C)P after the previous search filter was removed from the current search.
8. Request for suspension/withdrawal of certificates, management page: Certificate duplication in the result list has been fixed.
9. MS summary report management: The system displays only the reports in state *Registered* when the respective value is selected.
10. Withdraw a certificate: We fixed the error messages displayed when two validations happen at the same time: i) Starting decision applicability date cannot exceed certificate expiry date, and ii) Decision date may be up to three months before starting decision applicability date occurs.

5 DTX

5.1 New

No new developments.

5.2 Changed

The XSD version of the services is updated from 2.0.8 to 2.0.10 – this needs to be manually adapted in your service requests. The following changes have been implemented:

1. Update of UDI-DI service: The system provides the possibility to skip the version synchronisation between external systems and EUDAMED. The updated version validation algorithm is described in the *DTX for EOs – services definition.pdf* document. Version validation was aligned across the following services:
 - Update of Basic UDI-DI
 - Update of Market Information
 - Update of Container Package.
2. Updated the XML structure of device download response payload. Each device entity represents a single UDI/EUDAMED ID device along its Basic UDI-DI or EUDAMED DI. This change allows the alignment of the number of devices available in the UI and the number of devices fetched via DTX.
3. Updated the download of refused certificates service in relation to Basic UDI-DI(s) not registered in the UDI/Devices module. The payload contains a new field called 'isRegisteredInUDIModule' that differentiates between registered and un-registered Basic UDI-DI(s) in a refused certificate payload response.

5.3 Fixed

1. Access Point (AP) access/link request and management - several fixes were applied to improve the functionality:
 - In a new AP request:
 - a. The *Access point* field is now correctly auto-populated with the Organisation name of the given actor. If necessary, the user can still edit this field, which indicates the name of the AP.
 - b. The user needed to click the **Next** and the **Save & Next** buttons twice before the system reacted.
 - While in draft state of an AP request or when clicking the *Edit* button of an existing AP in *Active* status, the user was unable to edit and submit the data for Step 4.
 - In the Edit mode of an AP request, the *Manage security keys* link was not presented.
 - In the AP management screen:
 - a. The user was sometimes incorrectly presented with the message *You do not have any access point links set up, when you do, they will appear here*. This was even when there were items applicable to the given user that should have been displayed. The error message was not displayed for actors that did not have any APs drafted or submitted.
 - b. The system displayed the error message *Error Code: 400* when the user attempted to view the APs in *Terminated* status.
 - In the *Organisation* frame, the label for *Name (Manufacturer Name)* has been corrected to *Name (3rd Party Service Provider Name)*.
2. Validation of updatable fields performed via the Update of Basic UDI-DI service: System responds with the error ERR-DTX-UDI-031-033.02: \$field_name is not updatable when the provided field(s) are not updatable.
3. Non-existent EMDN codes in the payload are being correctly validated: System responds with ERR-BR-UDID-636.05-01: Provided Device Nomenclature item cannot be found or is not the lowest element from the structure (leaf element) when the provided code is invalid or is not the lowest element from the structure.
4. Fixed the payload validator for the Actor download service in relation to the changes in the schema version 2.0.7.1.
5. Update the status of an UDI-DI from *Not intended for the EU market* to *On the EU market*: Fixed the wrong validation error to utilise the *Update of Market Information* service. The update of device status can be performed via the Update of UDI-DI service having provided in the payload the mandatory Market Information data.

6. Upload a device: System responds with the error ERR-BR-DTX-UDI-085.03: *At least one medicinal and/or human product substances must be provided when humanProductCheck and/or medicinalProductCheck properties are true.* when humanProductCheck and/or medicinalProductCheck flags are true but the payload does not contain respective data.
7. Update of UDI-DI: The system does not respond with an error when the *Clinical Size* entities are provided in the payload without any change in respect to the data saved in EUDAMED.

