EUDAMED

Release notes

Production v 2.11
June 2023

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1 Introduction

1.1 Release content

This document outlines a brief overview of the main new features in **EUDAMED Production v2.11.0** compared to the previous release.[1]

[1]For a wider understanding of how to use the platform (in the Production environment), visit the EUDAMED Information Centre.

2 Actors module

2.1 Changed

1. **Updated tooltips** on the *User access request* / *Change user access request* screen.

2. **Change of CA feature**:
   - Link displayed in notification messages was adapted.
   - An *Assessment outcome* field is now displayed to the LAA of the EO requesting the change and change of label: *CA SRN* on this screen is changed to *Assessor CA Actor ID*.

2.2 Fixed

1. It was possible to initiate a Change of CA request while the current Economic Operator has no other CA to choose from. This has been resolved.

2. The *Organisation identification* document can be accessed again.

3 UDI/Device Module

3.1 Changed

1. Automatic linking rules in case of MDR risk class III and AIMDD. The validation ignores the attributes *Implantable* and *Active* when linking a regulation device to its respective legacy device.

3.2 Fixed

1. When navigating within the versions of an UDI-DI in the view device details page, the option **Go back to previous UDI-DI** navigation link was missing. It is now possible to go back to a previous version of a UDI-DI when the number of devices list span across multiple pages.

2. The label for regulation device registration is now correctly displayed as *Basic UDI-DI information*.

3. The length of the field *FLD-UDID-176 – Trade name* has been increased to up to 255 characters.

4. When searching devices by UDI-DI criterion, the system provides the response within a reasonable timeframe.

5. Several criteria were not being cleared from the previous search when switching to *Bulk XML download* within the search for devices page. Now the system clears criteria that are not part of the bulk XML download.

6. System allowed to remove the country where the device has been placed on the EU market from the list of countries where device is or is to be made available. Issue appeared when returning to the respective step in the registration wizard of a device from the preview page. Now the system does not allow to remove the country where the device has been placed on the EU market.

4 NB & Certificates module

4.1 New

1. Possibility to reference a device by name or reference/catalogue number when registering a refused certificate or refused/withdrawn applications of type product.

4.2 Changed

1. Updated the view details of a refused certificate or refused/withdrawn applications (MDR/IVDR) that have in their scope devices referenced by name or reference/ catalogue number within the Notified Bodies' management page.

2. Updated the view details of a refused certificate or refused/withdrawn applications (MDR/IVDR) that have in their scope devices referenced by name or reference/ catalogue number within the *Search & View* for refused certificates (all actors), and search & view for refused/withdrawn applications for NB, CA/DA and EC actors.

4.3 Fixed

1. When searching for refused certificates by the Economic Operator name criterion, the system responded with a generic error. Now the system provides the respective search result.

2. When using *Include historical version* slider and when viewing a historical version of a certificate, the **Go back to list** action-button was causing a generic error.

3. When reinstating a QMS certificate (MDR/IVDR) that was linked to an SS(C)P, the system linked the old version of the SS(C)P. Now the system provides the latest SS(C)P version.

5 Public site

5.1 Changed

1. Homepage:
   a. Current *News* items are displayed on the top-right corner. To view older data published for this section, the *News list* option is now available.

   b. In the case where there is important information for EUDAMED's public site visitors that needs to be displayed for a long period, it will appear on the homepage in a new section called *Important information*.

2. When searching for devices within the *Search & View* of devices/system or procedure packs, the system filters the list of device types according to the selected applicable regulation.

3. Updated to reflect the changes of the view details page of a refused certificate or refused/withdrawn applications (MDR/IVDR) that references in their scope a device by name or reference/catalogue number.

5.2 Fixed

1. The hyperlinks of a Basic UDI-DI, in the scope of a certificate of type *Quality*, are now fixed.

2. The list criteria issue, when going back to the result list from the *View details* page of a certificate, has been fixed.

3. The system now correctly displays the size of the uploaded document.

4. The search results when providing the manufacturer's SRN are now fixed. The system now fetches and displays the correct result list of devices registered by the given manufacturer.

5. Various misspelled labels and messages within the public site of NB & Certificates module, UDI/Devices module and Actor module have been fixed.

6. The non-display of the inactive status of an Authorised Representative or Producer actor within the certificate details page has been fixed. Same fix for the inactive status of a Manufacturer in the SS(C)P section – certificate details page.

7. The list of non-EU manufacturers linked to a given importer is now correctly displayed when viewing the importer's details.

8. The system was changing the initially provided EMDN code when searching for devices. This has been fixed.

9. Improved system time response when searching for devices using the UDI-DI/ EUDAMED ID criterion.

10. Navigating to the correct certificate version of type *Product* and *Quality* from a device details page has been fixed.

11. The issue with the initial criteria being cleared when going back to the result list from a certificate view details page has been fixed.

12. The issue with no results being displayed when searching for devices using the manufacturer's SRN has been fixed. The system returns the devices registered by the given manufacturer's SRN.

13. The *Inactive* label displaying within various search & view pages for actors that have been inactivated has been fixed.

14. The issue with displaying a hyperlink for certificates issued for legacy devices has been fixed.

15. The *Issued date* instead of the *Starting certificate validity date* being displayed within the result grid of the search for certificates and refused certificates page has been fixed.

16. The display of a certificate's status field within a legacy device details page has been fixed. The certificate status field is not applicable for certificates provided during legacy devices registration.

6 Horizontal

1. A new section for *Important information* has been added to the dashboard – here users can find data that needs to be taken into consideration for a longer period of time.

2. **The list of countries has been updated**:
   - Removed countries: French Guiana, Guadeloupe, South Georgia & the South Sandwich Islands, British Indian Ocean Territory, Martinique, Montserrat, Pitcairn and Turks & Caicos Islands.
   - Added countries: Jersey, Guernsey and South Sudan.

3. **Active hyperlinks within the notifications are now available**. The system will redirect you accordingly.

4. The issue with **paginating notification messages** within the *Notifications inbox* page has been fixed.

7 DTX

7.1 New

1. **New feature for M2M onboarding**:[2]
   There is a new request process for machine-to-machine (M2M) Access Points (AP). It is now possible to request either a new AP, which will need to be configured, or to request to link to an AP that has already been configured to work with EUDAMED.

   Any EUDAMED actor can own 1 AP and can have up to 2 active AP links (including the one owned by the actor already, if any). If the AP is owned by a EUDAMED actor and it may also be used by another EUDAMED actor, this must be specified in the original AP request. If the AP does not exist yet and its owner is an organisation that is not a EUDAMED actor (i.o.w. it is owned by a 3rd party), the AP needs to be requested by the first EUDAMED actor who will use it, which will trigger a request for a 3rd party AP.

   A 3rd party provider can use the same AP for multiple EOs, and an EO can use its own AP and a second AP either from a 3rd party provider or from another EO, if the AP is set up to be used outside of the given EO's organization.

7.2 Changed & fixed

The **XSD version of the services is updated** from **2.0.7** to **2.0.8** – this needs to be manually adapted in your service requests. The following changes have been implemented:

1. The system enforces BR-UDID-020 when the issuing entity of the secondary DI must differ from the issuing entity of the primary DI of a device.

2. We updated the *Refused certificate download* service to reflect the changes on refused certificates of type product having in their scope a device referenced by name or reference/catalogue number.

3. We fixed the validation issue with the secondary UDI-DI that is not an updateable field, but must be provided in the payload. The system verifies if the device has already been assigned a secondary UDI-DI before responding with *Cannot update Secondary UDI-DI (Secondary UDI-DI is already provided)*.

4. The issue with updating an existing container package structure has been fixed. When updating container packages, the system no longer allows the removal of existing container packages.

[2]See Chapter 5 in the M2M User guide.

5. We fixed the validation of the quantity for container packages. The system does not allow a change in the quantity of container packages for a device during its update.

6. The issue with false success message when updating an UDI-DI via the *Update of UDI-DI* service is now fixed. The system returns an exception message for the fields that are not updateable.

7. Fixed is the validation of the startDate and/or endDate for the country where the device has been originally placed on the market, when provided during the *Update of UDI-DI* service. When startDate and/or endDate provided in the market info entity in the payload differ from the information persisted in EUDAMED, the system returns an error.

8. We fixed the issue with the type of Notified Body actor within the DeviceCertificateLinkType. The NBActorCode is of string type.

9. The wrong exception response *Cannot update Secondary UDI-DI (Secondary UDI-DI is already provided)* when the payload contains data about the Secondary UDI-DI that is already registered for this UDI-DI has been fixed. The correct logic is now being applied.

10. Updating FLD-UDID-138 Direct Marking UDI-DI code has been addressed. The system now responds with the respective error message.

11. In some cases the downloaded data of a device does not contain information about *Storage and handling conditions*, *Critical warnings* and *Container packages*. This has been fixed.

12. Fixed is the issue when providing an incorrect NB number within the deviceCertificateLink entity.

13. Fixed is the issue on divergence between UI and downloaded data via DTX on container package status.


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