EUDAMED

Release notes

Production v 2.9
December 2022

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1 Introduction

This document gives a brief overview of the main new features in EUDAMED production v2.9 compared to the previous release.

2 Restricted site

Changed

1. Actor module:
   a. User registration: The telephone number for a sub-contractor is no longer mandatory.

   b. View mandates: the mandates information display has been improved and it now clearly identifies mandates that are *Expired* or *Terminated*.

   c. Change of Competent Authority - a new request-based functionality has been implemented:
      - Given certain criteria, some EOs will be able to request the change of their Competent Authority (CA) when necessary.

      - As long as the request is pending assessment, the EO will be unable to make other changes to their actor data.

      - The new CA will then be able to assess the request for change and accept or reject the change.

2. UDI/Device module:
   a. Possibility to indicate up to 255 chars for the Device name/Device model fields (FLD-UDID-20 and FLD-UDID-22).

   b. Removed the constraint for the provision of a Manufacturer identification when indicating the Country criterion within the Search & View of devices and procedure packs having bulk XML download option enabled.

Fixed

1. Actor module:
   a. EOs are now able to update their mandate document again, some users were blocked due to an issue.

2. UDI/Device module:
    a. View UDI details no longer displays *Container Packages* in the title of a legacy device.

    b. Fixed duplicate error bug when registering a second UDI using the UDI registered for a legacy device.

    c. Fixed the persistence of a wrong *From date* when updating *Market Information* entity.

    d. Fixed the registration of a legacy device after being discarded.

    e. Fixed the slowness reaction of the system when registering previously discarded devices.

3. NB & Certificates module:
    a. Fixed the removal of the previously added device when adding a new device at the registration of an SS(C)P.

    b. Fixed the navigation among preceding certificates version of a reissued certificate.

    c. Fixed the uniqueness check of a revision number for an SS(C)P during its new version registration.

    d. Fixed the possibility to add new devices to an SS(C)P that is attached to a certificate of type quality.

3 Public site

1. Terminated and Expired labels were added to highlight the Terminated or Expired mandates:
   - Termination date will now be displayed for the Terminated mandates.
2. Displaying the correct label (UDI-DI or EUDAMED ID) of a legacy device based on the issuing entity.
3. Possibility to search and view historical version of certificates.
4. Fixed the search for devices when providing the criterion *System which is a device in itself*. The system fetches the corresponding devices.
5. Fixed the search for *Devices/SPP* when clicking on **New search** and **Clear search** the system did not clear the previous criteria.
6. Fixed the search for EOs when using the AR name or AR ID/SRN search criteria, in combination with Manufacturer data when relevant.

4 DTX

The XSD version of the services is updated from 2.0.4 to 2.0.6 - this needs to be manually adapted in your service requests. The following changes have been implemented:

1. Reference/Catalogue number is not an updateable field (Enforced business rule when registering a device via M2M).
2. Respond with error message when trying to remove medicinal and/or human product substances associated to the device.
3. Respond with error message when trying to update Product Designer entity for which the SRN was provided at previous updates or registration.
4. Enforcing the business rule when specialDevice field is MDR_SOFTWARE or IVDR_SOFTWARE then productionIdentifier (UDI-PI) can have the value SOFTWARE_IDENTIFICATION.
5. Respond with an error when trying to update *Intended purpose other than medical (Annex XVI)* field.
6. Fixed the ENUM value (IVDD_IV_EX_4_6) for the Directive 98/79/EC Annex IV excl. Section 4 and 6.
7. Responding with an enhanced error message for the provided UDI-DI code validation for GS1 issuing entity.
8. Enforcing the business rule when trying to update an UDI with human product substances and medicinal substances when the previous value was *No applicable*. System throws the respective error.
9. Fixed the issue when MarketInfo entity containing the country where the device was initially placed on the market was not provided in the response.
10. Enforcing the business rule when updating the *Device Certificate Information* that is associated with the device.
11. Fixed the discrepancy of the data presented in the GUI and the data downloaded for devices having information about human product substance.
12. Enforcing the rule on updating clinical sizes of a device. System throw a corresponding error.
13. Enforcing the rule for *Secondary UDI-DI code* that cannot be updated when not initially provided. System throws a corresponding error.
14. Fixed the issue when the value for FLD-UDID-135 (Unit of Use DI code) is not saved despite responding with a SUCCESS message.


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