EUDAMED

Release Notes

Production v 2.8
July 2022

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1 Introduction

This document outlines a brief overview of the main new features in EUDAMED production v2.8 compared to the previous release.

2 Restricted site

Changed

1. Actor module:
   - The Former Yugoslav Republic of Macedonia (the country code remains unchanged MK) - renamed to Republic of North Macedonia.
   - Added an info text explaining the CA validation and AR verification activities during the actor registration process.
   - Added the possibility to delete a draft version of an actor.
2. UDI/Device module:
   - When registering a legacy device, fields *Implantable*, *Active or Reusable surgical instrument* will have no default value and are editable.
   - The search on UDI-DI code field on the Private and Public sites also comprises the UDI-DI (Primary DI), Unit of Use DI, Direct Marking DI, Container Package DI, Secondary DI.
   - It is possible to update the property *New device* (if initially was set) when creating a new version for a regulation device, having the applicable legislation IVDR.
   - Field UDI-PI type can be updated when registering a new version of the UDI-DI for a Device (MDR/IVDR) or System or Procedure Pack (MDR).
3. NB & Certificates module:
   - Registering an SS(C)P via the SS(C)P management page now searches for Quality certificates type that have in their scope a device group/device by name or reference catalogue number of the respective risk class.
   - Added the possibility to filter devices registered by the Manufacturer in the scope of the quality certificate registration within the SS(C)P registration dialogue.
   - Added a warning icon along the expiry date of a certificate that is expired.
   - Search by Notified Bodies includes only Notified Bodies designated for MDR/IVDR.

Fixed

1. Actor module:
   - Fixed assessing user access request issue.
   - Fixed approval of other LAA requests of a NB by the respective DA.

2. UDI/Device module:
   - Fixed the *Network error* popup.
   - System no longer requires the provision of certificate information when registering legacy (IVDD) with Risk Class IVD General.
   - Search for devices within a specific country now returns devices that were initially placed on the EU market of that country and/or made available on the EU market of that country.
   - Updating UDI-PI values for a System or Procedure packs when registering a new version for a UDI-DI.
3. NB & Certificates module:
   - Providing at least three (3) characters search for devices within the SS(C)P registration dialogue.
   - The preview button works as expected when registering a new SS(C)P version.
   - Fixed cancelling/withdrawing/suspending a certificate that is linked to one or more SS(C)Ps.
   - Fixed supplementing a certificate with a new device that requires SS(C)P.
   - Fixed the issue with draft SS(C)P removal on various operations over a certificate. Now the system reverts back the preceding SS(C)P version.

3 Public site

1. Search for device types behaves dynamically based on the selected applicable legislation.
2. Removed duplicates from the list of Notified Bodies.
3. Search by Notified Bodies includes only Notified Bodies designated for MDR/IVDR.
4. Fixed the search combination *All applicable regulation* and *All risk classes* when searching for devices.
5. Fixed the search for *Trade name* of a device.
6. Fixed the view device details page on several fields not being displayed.
7. Added the last update date when viewing an actor.

4 DTX

The XSD version of the services is updated from 2.0.2 to 2.0.4 - this needs to be manually adapted in your service requests. The following changes have been implemented:

1. Search for devices within a specific country now returns devices that were initially placed on the EU market of that country and/or made available on the EU market of that country.
2. Fixed the creation of the *marketInfo* entity for the countries where the device is made available via the Update of UDI-DI service.
3. Fixed the issue with the response not being sent to the corresponding requests.
4. Aligned values of MedicalHumanSubstanceTypeEnum with ENUM_UDID_SubstType.
5. Aligned values of MDDSpecialDeviceTypeEnum and IVDDSpecialDeviceTypeEnum with ENUM_UDID_SpecialDevice.
6. Corrected the ENUM value from IVDD_IV_ ex_4-6 to IVDD_IV_EX_4_6 for Directive 98/79/EC Annex IV excl. Section 4 and 6.


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