Release Production 2.8 - July 2022

Release note

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

Restricted site:

Changed

- 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.
- 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);

- 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

- Actor module:
  - Fixed assessing user access request issue;

    - Fixed approval of other LAA requests of a NB by the respective DA.
- 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;

- 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;

Public site:

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

DTX:

- 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;
- Fixed the creation of the 'marketInfo' entity for the countries where the device is made available via the Update of UDI-DI service;
- Fixed the issue with the response not being sent to the corresponding requests;
- Aligned values of MedicalHumanSubstanceTypeEnum with ENUM_UDID_SubstType;
- Aligned values of MDDSpecialDeviceTypeEnum and IVDDSpecialDeviceTypeEnum with ENUM_UDID_SpecialDevice;
- 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.