

# Production Release 2.0 - September 2021 - Release highlights since 1.0

This document outlines a brief overview of the main new features in EUDAMED v2.0 compared to the previous production release:

## **Actor/User Module**

- Non-EU manufacturers can now indicate if their AR has the right to manage their vigilance data
- Bulk download feature integrated into search screen
- PRRC definition is now included on-screen during actor registration
- A user may now act on behalf of >1 competent authority within their country.
- M2M: Actor download criteria can now include versionDate.
- M2M: Actor download criteria: Country filter is now optional

## **UDI/Device Module**

- Registration of Regulation and Legacy Devices by Manufacturers;
- Management of Basic UDI-DIs /EUDAMED DIs and UDI-DIs /EUDAMED IDs for Devices by Manufacturers;
- Registration of System or Procedure Packs by System and Procedure Pack Producers (Producers);
- Management of Basic UDI-DIs and UDI-DIs for System or Procedure Packs by Producers;
- Search and View Devices and System or Producer Packs (all users of the Private website);
- Search and View Historical versions of the Basic UDIs / UDI-DIs and associated elements (all users of the Private website);
- Automatic linking of Regulation and Legacy Devices (when providing the same UDI-DI for the Regulation and Legacy Device);

## New DTX Services:

- Registration of a Basic UDI-DI and UDI-DI (covers Regulation and Legacy Devices and System or Procedure Packs);
- Download Devices;
- Update Basic UDIs / EUDAMED DI (covers Regulation and Legacy Devices and System or Procedure Packs);
- Update UDI-DIs / EUDAMED ID (covers Regulation and Legacy Devices and System or Procedure Packs);
- Add new UDI-DIs for existing Basic UDIs (covers Regulation Devices and System or Procedure Packs);

## **Certificates Module**

- Registration of issued certificates
- Management of registered certificates
  - Suspend, reinstate, withdraw, cancel by MF
  - Amend, supplement, Restrict
  - Reissue certificates
- SS(C)P registration and management
- Registration and management of refused certificate
- Registration and management of refused/withdrawn applications for conformity assessment
- Search and View of certificates, refused certificates and refused/withdrawn applications
- Bulk XML download of certificates and refused certificates

## New DTX Services:

- Download of certificates
- Download of refused certificates
- Download of SS(C)P

## Playground-only features:

- CECP registration and management
- Registration of certificates requiring mechanism for scrutiny step