EUDAMED

Release notes

Playground v 3.11.0
2025

Table of Contents

1 Introduction

Notifications

Email notifications are disabled in the Playground environment. Users can view the notifications via the top right CURRENT ACTOR notifications hyperlink (bell symbol) in the EUDAMED dashboard.

Multi-lingual feature

The Playground environment allows the user to switch the language of the EUDAMED user interface. However, for the time being, the labels are only partially available in a language other than English and only for the Actors module and the UDI/Devices module.

1.1 Release content

This document outlines the main new features in EUDAMED Playground v 3.11.0 compared to the previous release.

2 Actors module

2.1 New

No new developments.

2.2 Changed

No changes.

2.3 Fixed

1. Importers and non-EU Manufacturers can now view all updates in their relationship link.

3 UDI/Devices module

3.1 New

No new developments.

3.2 Changed

1. Master UDI-DI:
   - For MDR, the following *Special device type* trigger Master UDI-DI registration:
     a. Standard soft contact lenses
     b. Standard Rigid Gas Permeable (RGP) contact lenses
     c. Made to order soft contact lenses
     d. Made to order Rigid Gas Permeable (RGP) contact lenses.
   - A tooltip has been added to the *Reference/Catalogue number* and *Quantity of Device* fields.
   - It is now possible to provide information about *CMR/Endocrine disruptor*, *Tissues and cells* and *Information on substances*.
   - The label of the link *Update container package status* has been changed to *Update container package*.
   - It is now possible to update the *Quantity per package* for a Master UDI-DI.
   - The field *Quantity per package* has been renamed to *Maximum Quantity* per package.
   - It is now possible to update the information provided for the *CMR/Endocrine disruptor* and *Information on substances* sections and the value for the *Quantity of device* field when creating a new version of a Master UDI-DI.

3.3 Fixed

No fixes.

3.4 Known issues

1. When registering a Master UDI-DI, the issue of how to address multiple Trade names remains unresolved.

4 NB & Certificates module

4.1 New

No new developments.

4.2 Changed

No changes.

4.3 Fixed

No fixes.

5 Vigilance module

5.1 New

No new developments.

5.2 Changed

1. Field Safety Notice (FSN): When registering a Final FSN report, in the Country Specific Details section, any uploaded PDF documents will automatically become publicly available.

2. Old/custom-made devices:
   - The *Registration* and *Register* terms are now used instead of the terms *Create* and *Creation*
   - After the old/custom-made device is successfully registered, the state *Registered* is now used instead of the previous state *Submitted*
   - The term *Device Identifier* is now used instead of the terms *NRD code* and *NRD identifier*
   - The *Unknown* option was added for the following mandatory fields:
     a. Measuring function
     b. Reusable surgical instruments
     c. Device intended to administer and/or remove medicinal product
     d. Near-patient testing
     e. Self-patient testing
     f. Companion diagnostic
     g. Reagent
     h. Instrument
     i. Professional testing
     j. Device labelled as sterile
     k. Presence of human tissues or cells, or their derivatives
     l. Intended purpose other than medical (Annex XVI)
     m. Presence of a substance which, if used separately, may be considered to be a medicinal product
     n. Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma.

5.3 Fixed

1. All reports: Common functionalities across the Vigilance reports have been harmonised to ensure a smoother user experience for Manufacturer and Authorised Representatives. This includes enhancements to various tooltips, smart filtering and other related features.
2. Old/custom-made devices:
   - The *IVDR* option was removed from the *Applicable legislation* field.

5.4 Known issues

1. Manufacturer Serious Incident Report (MIR):
   - The user cannot submit a MIR report after adding a device which is registered and linked to a certificate.
   - When creating a new version with status *Final non reportable*, an error message incorrectly asks for 'expected date of the next report' even though it is not mandatory in this case. A fix for this issue is already included in the next release.
2. National Competent Authority Report (NCAR): When creating a new version, the AR data is not saved.
3. Manufacturer's Trend Report (MTR): The system displays the Applicable legislation field twice for both MD and IVD legislations.
4. PSR Periodic Analysis Update (PSRP): The notification about a PSRP is sent before the actual end of period.
5. Old/custom-made devices: After successfully registering an Old/custom-made device, the link on the congratulations page labelled 'View submitted old/custom-made device' should instead be 'View registered old/custom-made device'.
6. Manufacturer Serious Incident Report (MIR): Under the *Device information* section, the term *NDR ID* is displayed instead of the *Device identifier* term.
7. When a Manufacturer registers an new FSCA, the drop-down list for the *Reference to actual incident (MIR)* field displays all available MIR reports, instead of only the MIRs registered by that Manufacturer. The system filters the relevant MIR entries as the user starts typing.

6 CIPS module

6.1 New

No new developments.

6.2 Changed

No changes.

6.3 Fixed

No fixes.

6.4 Known issues

1. When a user registers a new *CI/PS single application - coordinated assessment* form and selects more than two countries in the *Country for this single application for coordinated assessment* field that do not share a common language, the dropdown list of the field *Select the language(s) in which you will provide the national information* will randomly display one of the languages spoken in the selected countries.

7 Market Surveillance module

7.1 New

No new developments.

7.2 Changed

No changes.

7.3 Fixed

1. When manually adding a Manufacturer or a System Pack Producer during the registration of either a *Procedure* or a *Final Inspection Report (FIR)*, it is now possible to select any available country for the *Country* field.

7.4 Known issues

1. The *Procedure trigger CA link* for Procedure trigger type *SAE* is not yet implemented; it requires the *Serious Adverse Event* implementation in the CI/PS module.

8 DTX

8.1 New

1. New download service for retrieving existing dossiers applicable for:
   - Manufacturer Serious Incident Report (MIR)
   - Field Safety Corrective Action (FSCA)
   - Field Safety Notice (FSN)
   - National Competent Authority Report (NCAR)
   - Manufacturer’s Trend Report (MTR)
   - Periodic Safety Update Report (PSUR)
2. New upload service for registering new dossiers applicable for:
   - Manufacturer Serious Incident Report (MIR)
   - Field Safety Corrective Action (FSCA)
   - Field Safety Notice (FSN)
   - National Competent Authority Report (NCAR)
   - Manufacturer’s Trend Report (MTR)
   - Periodic Safety Update Report (PSUR)
3. New upload service for updating existing dossiers applicable for:
   - Manufacturer Serious Incident Report (MIR)
   - Field Safety Corrective Action (FSCA)
   - Field Safety Notice (FSN)
   - National Competent Authority Report (NCAR)
   - Manufacturer’s Trend Report (MTR)
   - Periodic Safety Update Report (PSUR).

8.2 Changed

1. It is now possible to provide details on the *Tissues and Cells* and *Substances* associated to a Device and the value for the *Quantity of device* when registering a Master UDI-DI via DTX.

2. It is now possible to update the details on the *Tissues and Cells* and *Substances* associated to a Device and the *Container Package Information* when updating a Master UDI-DI via DTX.

8.3 Fixed

No fixes.

8.4 Known issues

1. The system may return a false positive response when the provided entities to be registered/updated within the XML request payload do not match the entities expected by the indicated service ID. No updates are performed in EUDAMED. The validation and the provision of dedicated error messages will be improved in a future release.

2. In general, the validation messages and dedicated error messages are under development for particular specific cases and will be provided in a future releases.

9 Public site

9.1 New

1. Public API: The general public can now download publicly available information related to *Actor*, *Devices* and *Certificates* modules in a machine-readable format (Please refer to the new *Public API* user guide and the following link: Public API).

2. It is now possible to view details for the following sections of a Master UDI-DI:
   - Tissues and cells
   - CMR/Endocrine disruptor
   - Information on substances
   - Maximum quantity per package.

3. It is now possible to view details for the following sections of a Master UDI-DI's historical versions:
   - Tissues and cells
   - CMR/Endocrine disruptor
   - Information on substances.

9.2 Changed

No changes.

9.3 Fixed

No fixes.

9.4 Known issues

1. When the FSCA report referencing a device (for which a sub-status has been added) switches to status *Action completed*, the sub-status of the corresponding device is not removed. The issue will be fixed in a future release.

2. When a device sub-status is displayed, the link to view the related FSN leads to a *Page not found* screen. The feature to view the FSN information will be delivered in a future release.

10 List of bugs fixed

The full list of bugs reported by the users and fixed in this release is presented in the table below.

Ticket number	Summary
EUDAMEDMDR-30639	LAA to assess the request for change
EUDAMEDMDR-31006	Eudamed private | View pending requests | requests are not loaded and the page needs refresh
EUDAMEDMDR-33994	Production user is having issues accessing the Actor
EUDAMEDMDR-33995	EUDAMED PROD PRIVATE: Non-EU MF none of the existing LAA users have access to this Actor
EUDAMEDMDR-32429	User access request cannot be assessed when no SIN(s) exist for the Sponsor actor
EUDAMEDMDR-29412	DA Validator cannot validate user access requests for first NB LAA
EUDAMEDMDR-32041	Prod - Actor - User cannot finalise their registration process in EUDAMED
EUDAMEDMDR-31133	DTX - Generic validation error received when trying to register a device with a PR actor
EUDAMEDMDR-31195	DTX - Bulk downloading devices in PROD contains duplicated results
EUDAMEDMDR-34113	DTX PRODUCTION-unable to register legacy MDD class I due to unexpected certificate error
EUDAMEDMDR-34200	DTX Playground -false success for a UDI_DI PATCH
EUDAMEDMDR-32026	Prod - Certificate - 500 Internal Server Error on certificate submission
EUDAMEDMDR-32715	Eudamed private | Download CECP | XML fails for not supported operation
EUDAMEDMDR-18439	DTX - Download of Basic UDI-DI - Duplicate UDIs returned
EUDAMEDMDR-33777	DTX - Download device - IVDR - Some data is missing in the response
EUDAMEDMDR-31635	Clinical Investigations should be included in "No update performed" validation
EUDAMEDMDR-34073	DTX Playground - unexpected UNAUTHORISED_ERROR for UDI_DI PATCH for SPPs
EUDAMEDMDR-31138	Validation error code passed incorrectly to the error report
EUDAMEDMDR-31560	PG-M2M download SSCP- no SSCP master document in PDF format is available
EUDAMEDMDR-34117	DTX PROD- UDI_DI PATCH for legacy fails due to clinical size error
EUDAMEDMDR-32213	Vigilance - Orthopedics still appearing the Special Device type for NRD
EUDAMEDMDR-33996	EUDAMED PROD PRIVATE: BUDI duplicate error message
EUDAMEDMDR-33656	Production - UDI - Discarded devices are not being relinked to a new AR version causing the non-EU MF to not see devices in mgmt page
EUDAMEDMDR-31453	Private - UDI - Draft device is not visible in MF mgmt page
EUDAMEDMDR-34129	Error message when viewing UDI-DI details
EUDAMEDMDR-31565	Production - UDI/Device - EU-MF cannot delete their device in Draft
EUDAMEDMDR-32040	UDI - Submit new UDI-DI version - Exception is thrown when the UDI-DI has an active sub-status
EUDAMEDMDR-32341	UDI - Create new UDI version - Fast double click creates two (2) Draft instances
EUDAMEDMDR-32241	Duplicity of data related to the specific UDIs in PG
EUDAMEDMDR-28461	Backend - PROD- Private website - "SLEEP" keyword blocked in EUDAMED
EUDAMEDMDR-29940	Orfan EUDAMED DI after its device has been discarded
EUDAMEDMDR-28041	Private website : Market Surveillance : Discarded FIR throws error when viewing version history
EUDAMEDMDR-31979	PROD - Public site - EU MFs linked to an AR not shown
EUDAMEDMDR-31856	v3.9 testing feedback- Public site: Search for Vigilance reports does not work properly.
EUDAMEDMDR-29876	Public - Final (reportable) MIR is not visible on public website
EUDAMEDMDR-32192	VIG-MIR-Admin Info section - inconsistent behavior in mandatory fields marking in Date of Incident part
EUDAMEDMDR-32233	Vigilance report- MIR - smart filter not working as expected
EUDAMEDMDR-32055	MIR: submissions of NRD device shows error messages for Device Nomenclature codes
EUDAMEDMDR-32344	Vigilance - MIR - Device information - incorrect retrieval of labels
EUDAMEDMDR-32057	Missing IMDRF codes in the UI for the MIR
EUDAMEDMDR-32197	VIG-MIR-Incident Information section - error with patient Age (not allowing to submit double-digit age)
EUDAMEDMDR-32801	MIR report - uploaded documents are not visible after the submission
EUDAMEDMDR-32232	Vigilance - MIR - Temporary device - not able to update the device data in the submission
EUDAMEDMDR-32322	Private - Vigilane - FSCA More than one device, the certificate shown is always the one of the first device
EUDAMEDMDR-32306	Private website - Vigilance FSCA - As a Manufacturer/AR (Confirmer) I must provide the country specific subaction details for the FSCA -& "Progress (%)" is not accepting only positive values from 0 to 100

11 List of implemented changes

The full list of implemented changes in this released based on users' feedback is presented in the table below.

Ticket number	Summary
EUDAMEDMDR-23489	Manually added EOs, role Manufacturer, System pack producer - all countries in Country field of address


European
Commission