EUDAMED

Release notes

Playground v 3.6
2023

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 field labels are partially available in a language other than English only for the Actors module and the UDI/Devices module.

1.1 Release content

This document outlines a brief overview of the main new features in EUDAMED Playground v3.6.0 compared to the previous release:

2 Actors module

2.1 Fixed

1. Actor registration: The first time that a user clicked on **Save & next** the system did not proceed to the *Step 2* page.

2. New actor version: The list of Authorised Representatives did not load correctly when a new actor version was submitted for a non-EU MF.

3. The link to view the historical versions of an actor was not always displayed when it should be.

4. Access Point management: The *Reason for rejection* was not visible to the user when the access point request was rejected by the Commission.

5. Change of CA: The old CA did not receive the notification they were supposed to receive (ACT-038).

3 UDI/Device module

3.1 New

1. Manufacturers can now manually create the link between their regulation device (MDR/IVDR) and its corresponding legacy device (MDD/AIMDD/IVDD) (*Chapter 6.2.7* in the *UDI Devices user guide*).

2. The *View device details* page is enhanced with information about the Actors version in EUDAMED private. The respective version of the MF/AR/PR Actors is being displayed in relation to the device version.

3. The respective certificate version in relation to Basic UDI-DI version is now being displayed in the *Device details* page.

3.2 Changed

1. It is now possible to register a device with its initial status being *No longer placed on the EU market*.

2. Container packages status inherit the status of their device or system or procedure pack except when the device status is *On the EU market*. For the latter status the manufacturers and producers can indicate other than *On the EU market* status for the related container packages in line with the updated BR-UDID-073.

3. Container packages can now be registered for a device or system or procedure pack having the status *No longer placed on the EU market*.

4. When the status of a device or system or procedure pack is changed from *On the EU market* to *No longer placed on the EU market* then the linked container packages' status will automatically be set to *No longer placed on the EU market* by the system. The user is informed during the action confirmation.

5. There is the possibility to provide container packages information when the device status is *Not intended for the EU market*.

6. The functionality for the provision of Product original manufacturer's information has been enhanced. The system provides the possibility to find and reference an already registered Product original manufacturer as an organisation by the same MF Actor.

> **NOTE**
> Please ensure to check the box *I know the Actor ID/SRN* in order to search for an existing registered Manufacturer Actor either by SRN or by name.

7. The dialog for manually providing the Product original manufacturer data is now accessible within the dialog for selecting an already registered Product original manufacturer as an organisation. Therefore, the risk of duplicating data about the Product original manufacturer has been mitigated.

8. A Product original manufacturer registered as an organisation can now be referenced in other devices registered by the same MF. Once a new version of the Product original manufacturer is created, all devices that reference the same Product original manufacturer will display the latest version of the Product original manufacturer.

9. The dialog for selecting a Product original manufacturer that is registered as an Actor in EUDAMED, when searching by Actor ID/SRN or Name, has been updated.

10. A constraint has been added on new version creation for a Product original manufacturer when the current version of the Product original manufacturer is referenced within a device registration having the *draft* state.

3.3 Fixed

1. *Last update* date is correctly being displayed within the *View details* page of a Basic UDI-DI.

2. The date when two devices were manually linked is shown within the *Linked devices* section.

3. The duplicated display of the *Active* property when informing the user about properties that do not match in the manual linking devices is now resolved.

4. The system accurately verifies the property *Is a system or procedure pack which is a device in itself* when manually linking regulation and legacy devices.

5. When registering an (MDR) EU Product verification certificate (Annex XI Part B), having in its scope devices of type risk class IIb implantable, i.e. sutures, staples, dental fillings etc. (WET), the certificate information was not displayed within the *Device details* page. The issue is now fixed.

4 NB & Certificates module

4.1 Changed

1. The User Interface on associating Basic UDI-DI(s) to an SS(C)P during issued/ supplemented/reissued certificate registration has been enhanced.

4.2 Fixed

1. The issue when a user who can act on behalf of several Actors opens a direct link to a certificate *Details* page has been fixed. The system correctly pre-loads the user profile for the session and displays the respective certificate *View details* page.

2. When there was a more recent version of the linked SS(C)P that the user could either update to the latest current version or create a new version during a certificate update, the system used to display the action *Create a new version* of an SS(C)P twice.

3. A fix for the non-existent page within the notification being sent at the submission of a Member State summary report has been implemented. The system correctly directs the user to the respective page.

4. The list of Notified Bodies within the *Search & view certificates* page is now being correctly displayed with the corresponding statuses (*expired*, *suspended*, *withdrawn*) based on the Notified Body's MDR and/or IVDR legislation designation.

5. The issue of multiple displays of the Basic UDI-DI and the linked certificate within the *SS(C)P View details* page when suspending and then reinstating the certificate has been resolved.

6. The system responded with an error during the submission of a refused certificate or of a withdrawn application of *Quality* class when the corresponding CECP record has been identified and its applicability for the CECP was set to No. Now the system does not respond with an error and the respective refused certificate or withdrawn application is correctly registered.

7. Devices associated with an SS(C)P were duplicated within the *SS(C)P View details* page when the linked certificates were suspended and then reinstated multiple times. The system now correctly displays the devices that are associated to an SS(C)P.

8. The issue of not displaying the *device model* and *device name* (if one exists) for a Basic UDI-DI referenced in a refused certificate registration and when the same Basic UDI-DI was provided within a CECP record without being registered in the UDI/Device module has been resolved.

9. The system correctly displays the *Historical view details* page of a certificate when accessing the historical certificate details page from the related *SS(C)P View details* page.

10. When updating the non-EU MF actor version within a certificate, the system used to remove the related AR record. Now the respective AR is no longer being removed.

11. The issue where the status of a CECP dossier was set incorrectly to *Issued-Certificate*, having in its scope two devices of risk class IIb active devices intended to administer and/or remove a medicinal product and registering an (MDR) EU Quality Management System certificate (Annex IX Chapter I), has been resolved.

5 Vigilance module

5.1 New

FSN (Field Safety Notice, see Chapter 5 in the *Vigilance for EOs* user guide).

The FSN has six sections:

1. *Report Primary Details*: General information about MF or AR registering the FSN.

2. *Administrative information*: Information regarding the FSN type and the FSN registering date.

3. *FSCA(s) & device(s)*: In this section the user will be able to select the FSCA(s) which will be linked to a specific FSN, and also to the devices automatically retrieved from the selected FSCA(s); the affected countries and corrective action(s) will also be retrieved and displayed by EUDAMED.

4. *Country-specific details*: The section is automatically created by EUDAMED for each selected affected country; here the user will be able to select the FSN document(s) to be uploaded, and the language(s) of the document.

5. *CA Comments*: This section is visible after at least one of the CAs has provided comments for the registered FSN; the concerned actors will be able to see the outcome of the comments here.

6. *Report history overview*: Information about the FSN historical versions and *Comments* together with the identity of the CA(s) that provided the comments will also be visible in this section.

An FSN can be updated by creating a new version. At submission of the FSN, the new device sub-status (when applicable) is not visible in the UDI module. This will be implemented in the next release.

5.2 Changed

1. MIR and FSCA: *Initial* / *Initiated* status is now available for selection only for the first version of the report.

2. MIR: Additional functionalities for *Number of incidents/devices* section:
   • The system will validate the information entered for *Number of incidents on the market in EEA+TR+XI* and *Number of incidents in the world* fields, based on the existing relationship between those fields.

   • *0* value is allowed to be entered in all fields inside the section.

3. FSCA: The system now checks if all the affected countries are among the countries selected for Market Distribution.

4. MIR: *Contact information of the report* sub-section has been modified (the user can directly specify if the submitter contact details are the same as the manufacturer's, the AR's or other (e.g. subcontractor).

5. MTR: For *Device nomenclature code* field, the entire code hierarchy is now visible and selectable.

6. FSCA: A reference regarding PMCF/PMPF has been added for *What is the FSCA based on?* section.

7. MIR: The field entitled *Has a scientific opinion been requested for the device or, in the case of a companion diagnostic, have the CA or EMA been consulted?* is now marked as mandatory and displayed only for MDR/IVDR legislations (the field will not be displayed for other legislations).

8. FSCA and MTR: Device identifiers (UDI-DI/EUDAMED ID) are filtered from selected applicable legislation.

9. FSCA: For EMDN terminology selected, the user will be able to input multiple nomenclature codes for a device, if applicable.

5.3 Fixed

1. MIR: The issue regarding the *Device type* field which was not being displayed when the risk class I was selected for MDD legislation, has been fixed.

2. MIR: Notification inbox – for a new MIR version registered, the system now displays the notification in the notification inbox of the CA dashboard.

3. FSCA: The issue regarding the missing fields when selected legislation was set to *None* has been fixed.

4. FSCA: When the applicable legislation is IVDD, the system now displays the field: *Did this device continue to be placed on the EU market after MDR / IVDR date of application?*.

5. MIR: The issue regarding the Authorised Representative contact details has been fixed (now mandatory).

6. FSCA: *Progress (%)* field now accepts only integer values.

7. FSCA: The issue related to the *nomenclature code* and *text* previously not displayed by the system for a selected device has now been fixed.

8. FSCA: The issue of not displaying the *UDI-DI/EUDAMED ID* component, for IVDR, has been fixed.

5.4 Known issues

1. Applicable to all reports:
   - Some screens are showing the loading icon and do not seem to be responding. Refreshing the screen does not solve the problem; the user needs to close the browser and try again.

   - Some of the error messages issued by the system are not applicable (following the submission phase).

   - Some fields accept inappropriate values (e.g. integer instead of text).

2. FSCA: The system allows the user to enter devices for both MD (MDD, AIMDD, MDR) and IVD (IVDD, IVDR) legislations.

3. FSN – new version: The system does not display the **Create new version** button in a registered *Preliminary* FSN after two working days of its first submission. Due to an error, the button is only displayed after four working days instead. This will be fixed in the next release.

4. NCAR: when submitting an NCAR for an EU Manufacturer, the system blocks the process because of missing data about an Authorised Representative (which is not needed for an EU Manufacturer).

5. NCAR: when creating a new version of an NCAR, the previously filled-in information about an Authorised Representative is not saved and the user must select an Authorised Representative once again.

6. The mandatory documents are not marked with an asterisk (*) symbol. However, the user is correctly blocked at submission of the given form when the mandatory documents are not uploaded.

6 Clinical investigations and Performance study (CI/PS) module

6.1 Changed

1. The pop-up screen that allows either the Sponsor or the Competent Authority to submit the application/notification version or status update to the relevant party now always includes at least the option to provide comments and to upload a file. In certain cases, the comments were already mandatory, and this has not been changed.

6.2 Fixed

1. Form content:
   - Coordinated assessment information: The system allowed the user to submit a form with incompatible values between Proposed coordinating CA and Country for this single application.

   - Contact person tab: In the case of a non-EU Sponsor, it was possible to define that the contact person is the same as the contact person of Sponsor's legal representative while specifying that there is no legal representative. This inconsistency is fixed.

   - Coordinating investigator: Possible values for *Country* are no longer restricted to EU countries.

   - Common documents and statements: When mandatory documents were missing at submission of the form, the error message did not include the name of the document that was missing. It stated *At least one file should be provided in section [X]*. The system now does include the name of the missing document in the error message.

   - Investigational/Study device(s) tab and Comparator tab:
     - The value selected for the field *Is an Authorised Representative applicable?* no longer disappears.

     - In read-only mode, the field EMDN nomenclature code appeared twice in certain cases.

   - Comparator tab: The field *Risk class* was not always displayed in edit mode when it should be.

   - National information tab: *Greek* was not offered as a value for the language(s).

2. Notification: The notification to inform CAs that a *Start date* was defined by the sponsor is now correctly triggered by the system.

6.3 Known issues

1. For both CI/PS and PMCF/PMPF forms: *Description – part 2*: you cannot enter the *0* value and the *Total number of subjects* is not automatically calculated.

2. The mandatory documents are not marked with an asterisk (*) symbol. However, the user is correctly blocked at submission of the given form when the mandatory documents are not uploaded.

7 Market Surveillance module

7.1 New

1. MSU Procedure machine-to-machine download is now available for CA and NB users.

2. Search by *Procedure type* in the *Search & View procedures* page (see *Chapter 10.1* in the *Market Surveillance* user guide)*.

7.2 Changed

1. *Four-Years Report* identifier creation – the year part of the identifier is the year provided in the *Date to* field (see *Chapter 9.1.2.4* in the *Market Surveillance* user guide).

2. *Information of the Economic Operators* is now displayed in the search results table of the *Search & View procedures* page.

7.3 Fixed

1. Procedure:
   • Linked Economic Operators did not remain linked after a non-registered device was replaced by a registered one (for the *Production identifier* device scope type). This issue has been resolved.

   • It was possible to refer a registered MDR device to an IVDR-related procedure and vice versa, when this should not be possible. This issue has been resolved.

   • *Additional information* of the procedure and *Contact information of the Economic Operators* were visible to Notified Bodies referenced in the procedure, when they should not be. This issue has been resolved.

7.4 Known issues

1. Procedure:

   • When the role selected is *Distributor*, the user needs to enter the name of the Economic Operator and still has to click the **Find** button, even though distributors are never registered in EUDAMED. In the pop-up, the user needs to select the option *Enter data manually*. Direct registration of the *Distributor* is not possible yet.

   • The procedure trigger type *SAE* is not yet implemented.

8 DTX

8.1 Changed

1. When registering or updating the container package details on a device with status other than *On the EU market* , the system verifies that the provided container package status is in line with the BR-UDID-073. This ensures the container package status is the same as the device status.

2. The validation of the initial registration status of a container package has been updated. The system allows the registration of a container package having the status *NO_LONGER_PLACED_ON_THE_MARKET*.

8.2 Fixed

1. It is now possible to select the value *Other* multiple times with the same language for critical warnings, storage and handling conditions.

2. The issue with the unauthorised exception when an MF Actor was using the linked Access Point during data transmission via M2M has been fixed.

3. The system incorrectly provided the Importer Actor type and failed validation when the requester asked for the MF Actor type within the download registered Actors in EUDAMED.

4. There was a validation issue when downloading registered Actors in EUDAMED and the *Actor ID/SRN* containing a recently updated country code that has now been fixed.

5. The system allowed the registration of container packages for a device with state *submitted*. The issue is now fixed and the system will respond with a relevant error message.

6. The issue of registering container packages for a legacy device has been fixed. The system responds with the relevant error when the payload contains data about container packages for a legacy device.

8.3 Known issues

1. When utilising the *Update of UDI-DI* service, you may encounter the following error ERR-BR-DTX-UDID-093.05-01: Please utilise *Update of product designer information* service to update the information about the product designer when the provided payload contains information about Product original manufacturer. The fix will be delivered in the next release version. Please update the information on the Product original manufacturer via user interface if needed.