



EUDAMED

Release notes

Production v 2.13
2023



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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 Production v 2.13.0 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. 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.
7. 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.
8. 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.

5 DTX

5.1 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*.

5.2 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.

5.3 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.

