EUDAMED

Release notes

Production v 2.14
2024

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1 Introduction

1.1 Release content

This document outlines a brief overview of the main new features in EUDAMED Production v 2.14.0 compared to the previous release.

2 Actors module

2.1 New

1.   No new development.

2.2 Changed

1.   No changes.

2.3 Fixed

1.   When displaying the actor search results after having set the option *Include historical version* to *Yes*, the system now correctly displays the most recent version of the actor at the top of the list.

2.   When viewing the NB details, CA users can now correctly view the information under the section *Legislations (Notifications)*.

3.   The system now correctly saves the action date for *Confirm actor data accuracy*. The error shown to CAs when trying to filter a given *Application ID* in order to assess the actor registration request has been resolved.

4.   Several accessibility issues were resolved for users accessing the system with keyboard and screen reader: the menu is now accessible, the combo box information is no longer repeated, some labels were adjusted for screen readers.

3 UDI/Devices module

3.1 New

1. No new development.

3.2 Changed

1. Certificate information and related SS(C)Ps information (if applicable) are being displayed within the *Basic UDI-DI/EUDAMED DI* section. Before the change, the information was presented within the *UDI-DI/EUDAMED ID* section of a device details page.

3.3 Fixed

1. When creating a new device version, it is possible to update the Authorised Representative with whom a new mandate has been created.

2. Information about substances is now correctly displayed within the *EUDAMED DI* section in the *View device details* page.

3. It is now possible to delete a draft version of a device that was previously transitioned to *Registered* state via confirmation by an issued certificate.

4. The system now correctly filters devices by the nomenclature code in the *Device details management* page.

4 NB & Certificates module

4.1 New

1. It is possible to add or remove Basic UDI-DI(s) to/from a registered SS(C)P linked to quality certificate(s) (Chapter *Create new SS(C)P version* in the Notified Bodies & Certificates user guide).

2. NBs can now inactivate registered SS(C)P(s) (Chapter *Inactivate an SS(C)P* in the Notified Bodies & Certificates user guide).

3. When a Basic UDI-DI has been registered as a non-registered device type within a refused/withdrawn application or a refused certificate, and meanwhile the Manufacturer of the device registers the Basic UDI-DI in the UDI/Devices module, the system will now automatically update the related refused/withdrawn applications or refused certificates with a hyperlink pointing towards the *Basic UDI-DI details* page.

4.2 Changed

1. Certificates, refused certificates and refused/withdrawn applications that reference a Basic UDI-DI that is registered in the UDI/Devices module display the referenced Basic UDI-DI as a hyperlink pointing towards the *Basic UDI-DI details* page.

2. Each new version creation of a registered SS(C)P linked to quality certificates type within the *SS(C)P management* page requires indication if the SS(C)P master document is validated or not.

3. When amending, re-instating, supplementing or restricting a quality certificate type and creating a new SS(C)P version, the NBs must indicate if the new SS(C)P master document is validated or not.

4.3 Fixed

1. The issue with the auto un-checking Basic UDI-DI(s) within the scope of the certificate has been fixed. This was occurring during the filtering of the *Basic UDI-DI code* in the selection dialogue for *Basic UDI-DIs to be associated to an SS(C)P linked to a quality certificate type*.

2. Registering new SS(C)Ps within the registration of product certificate types has been fixed. The system now correctly displays the button to register a new SS(C)P within the product certificate type registration.

3. When re-using a registered SS(C)P that had its new version created, an error appeared during certificate submission for the registration. The issue is now fixed.

4. During the registration of product type refused certificate, refused/withdrawn application for a Basic UDI-DI where the code is known but not registered in the UDI/Devices module, the user was unable to provide the mandatory code for the device type. This is fixed now.

5. NB details are correctly displayed within the respective drop-down list in the search & view pages for certificates, refused certificates or refused/withdrawn applications. When a NB has its designation status changed to any other status than *Active for MDR and/or IVDR regulations*, the information about designated status is displayed. If the NB's status for the designated regulation is *Active*, then no additional information is displayed.

5 DTX

5.1 New

1. No new development.

5.2 Changed

1. The Download SS(C)P service has been updated to include in the payload the information of whether the SS(C)P is inactivated, and if yes, since when was it inactivated.

2. The Download SS(C)P service includes the information of the related certificate linked to the respective Basic UDI-DI within the SS(C)P payload.

3. The Update of UDI-DI service – the status of the linked container packages gets automatically updated to *No longer placed on the EU market* when the status of the device/system or procedure pack is being changed into *No longer placed on the EU market*. The UDIs for which the status of the linked container packages were automatically changed are displayed in the response message.

4. The Download issued certificates service has been updated to include in the payload the information of whether the SS(C)P is inactivated, and if yes, since when was it inactivated.

5.3 Fixed

1. Download registered actors service
   • Pagination issue: the system provided data duplicated from other pages of the XML result. This has now been fixed.

   • The error *invalid XML characters (Unicode: 0x2) was found in the element content of the document* has now been fixed.

2. Update of UDI-DI service
   - No validation for the *Unit of use DI* was in place – Now the system applies the correct validation for the *Unit of use DI* that can be added after initial registration of the device but once added, it can no longer be updated.

   - The validation of the payload if the device is linked to a product original manufacturer entity has been fixed. The system will not require the information about the product original manufacturer when updating device data. Information about the product original manufacturer will be updated by utilising the dedicated *Update of product original manufacturer* service.

   - The system is now correctly validating the version number when updating device data. When the payload.version > 1 the system will ensure that the payload.version provided == EUDAMED.version incremented by 1.

3. Download of Legacy/ Regulation Device/SPP service
   - The FLD-UDID-151 Quantity of Device is not being populated now in the payload response for a legacy device.

   - Information about container packages status NOT_INTENDED_FOR_EU_MARKET is now correctly displayed within the response payload.

4. Upload of Legacy / Regulation Device/ SPP (Basic UDI and UDI-DI) service
   - The validation of certificate information provision for legacy devices has been fixed. The system correctly validates the exceptions for devices of Class I or IVD General.

5.4 Known issues

1. You may experience an issue being unable to perform the update of your Basic UDI-DI or EUDAMED DI by providing the next incremented version when utilising the 'Update Basic UDI' service. To overcome this limitation please indicate version number = 0 (<e:version>0</e:version>) within the payload. The correction of the version number validation will be fixed in a future release.