EUDAMED

Release Notes

Production v 2.18.0
2025

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1 Actor Module

1.1 New

1. System now allows to change the VAT/ EORI and or NTR by relevant EUDAMED actors. The actor will have an option to change the required information via a new workflow; once this request is submitted, it will be evaluated by relevant Competent Authority. Once the assessment is completed, the data is changed appropriately.
   a. If the actor doesn't have a pre-existing value for these fields, they can provide them via a new actor version.

1.2 Changed

1. There is a new constrain in the system, when terminating the mandate with an authorised representative, the 'Termination End date' cannot be in the future. This is applicable to the Terminate action only when this is an 'abnormal' situation (not planned in advance).

1.3 Fixed

1. The system prevents e-mail notifications from being sent to the users past the End Date in EUDAMED.
2. Vietnam was incorrectly named as Viet Nam in dropdown lists
3. The system no longer allows the update of the e-mail address for the Notified Bodies set in EUDAMED to be changed during the nightly synchronization with NANDO.
4. Only the first LAA is now requested to verify the actor notification email address when they first log in.

1.4 Known Issues

1. Change of the VAT/EORI and NTR functionality - upon approval from the relevant Competent Authority, the manufacturer is not clearly notified. The notification appears once you click on the Notifications button and then another click is required to view the notification of the approval.

2 UDI/Devices Module

2.1 New

1. New notification introduction for Authorised Representative linked to the Basic UDI-DI
   a. Authorised Representative will receive notification when Basic UDI-DI is submitted and it is linked to the respective Authorised Representative

   b. Authorised Representative will receive notification when Basic UDI-DI is registered in EUDAMED and it is linked to the respective Authorised Representative

2.2 Changed

1. Harmonization of all labels related to the Clinical Investigations/ Performance Study(ies) across the whole module to ensure the consistency in terminology.

2.3 Fixed

1. Public Website - Related legacy device was not shown in device details

2. Related device was not shown in device details from Search & View

2.4 Known Issues

3 Certificates

3.1 New

1. The System now enables Notified bodies when registering application (refused/ withdrawn) to reference any Basic UDI-DI regardless of any risk class or other characteristic. There is no active system filter applied on Basic UDI-DI. The only constraint is that the Basic UDI-DI must be among the ones of the manufacturer (and Authorised Representatives if applicable) that is (are) specified for the refused/ withdrawn application. The same conditions also apply for manually entered Device Groups, Device Names or Device Reference/Catalogue numbers.

2. The System now introduces important limitation for the registration of the High Risk Devices. The confirmation of High Risk Devices for issuing, supplementing or re-issuing certificate can only happen with Product Type Certificate - this is a change as previously you would be able to confirm it with any Certificate type. In addition, High Risk Device in state "Submitted" will not be displayed during SS(C)P creation unless it is linked to the Product Type Certificate. State "Registered" devices will be displayed normally as long as they meet the eligibility criteria.

3. System now enables the Designating Authority to specify the Certificate type and the certificate's expiry date when registering a new request for suspension/withdrawal of a certificate that is not yet registered in EUDAMED.

3.2 Changed

1. The Certificates module dashboard/ main page introduces the following updates:
   a. Rename the link from 'Manage your refused certificates/applications' to 'Manage applications/refused certificates' (Dashboard)

   b. Rename the page title from 'Refused certificates/applications management' to 'Manage withdrawn/refused applications and refused certificates' (Management Page)

   c. Add two buttons, 'Register a refused certificate' and 'Register a withdrawn/ refused application' that redirect the user to 'Register a refused certificate' and 'Register a refused/withdrawn application for conformity assessment', respectively. (Management Page)

3.3 Fixed

3.4 Known Issues

4 DTX

4.1 New

4.2 Changed

4.3 Fixed

1. During the download of SS(C)P the revision number as a stand alone number is not to be accepted
2. SS(C)P having at least 2 revisions (one current and one historical) the system now responds with the details and attachments for the historical version.
3. Unable to download certificate of type MDR_TECHNICAL_DOCUMENTATION
4. MARKET_INFO/PUT how to differentiate if the request is for regulation or legacy when the same UDI DI is registered as both
5. Update Unit of Use DI fails with unexpected error
6. Unable to register a regulation device with container package when device status is other than ON THE MARKET
7. BULK Download result with duplicate UDI DIs
8. PR cannot create device through M2M
9. ACTOR/GET using versionDate as criteria returns results for BULK but empty results for M2M
10. MDR ClassIII devices are directly registered and certificate info is not persisted in GUI
11. Unable to add container package for a regulation device that has a link with legacy
12. Initial status No Longer Placed on the EU Market-incorrect behaviour for POST and PATCH
13. FINAL_INSPECTION_REPORT.GET responds with no zip attachment
14. Product Designer PUT for another Actor- unexpected generic error
15. UDI DI PATCH unable to update the status from No longer on the market to On the Market due to generic error

16. Issue sending Items via 3rd Party DTX
17. Problems updating UDI-DI references on EUDAMED for Procedure Pack Producer
18. Unclear error codes and error details for Device POST in PG
19. Bulk upload with directMarkingDI - Same as UDI-DI is not saved in DB which prevents subsequent versioning of the device

4.4 Known Issues

5 Public Site

5.1 New

5.2 Changed

5.3 Fixed

5.4 Known Issues

1. EUDAMED Public - NB - Monitoring Summaries Search is currently not available in EUDAMED Production Public website. This section of the Public search will be made publicly available in the next Releases.

6 List of bugs fixed

Ticket number	Summary
EUDAMEDMDR-36514	DTX-SSCP GET- rule "SS(C)P revision number as a stand-alone criterion will not be accepted" not enforced
EUDAMEDMDR-36513	DTX-SSCP GET-empty response for historical revision numbers
EUDAMEDMDR-35800	DTX - Unable to download certificate of type MDR_TECHNICAL_DOCUMENTATION
EUDAMEDMDR-35110	DTX - MARKET_INFO/PUT how to differentiate if the request is for regulation or legacy when the same UDI DI is registered as both
EUDAMEDMDR-35083	DTX - update Unit of Use DI fails with unexpected error
EUDAMEDMDR-35077	DTX - Unable to register a regulation device with container package when device status is other than ON THE MARKET
EUDAMEDMDR-35064	DTX -BULK Download result with duplicate UDI DIs
EUDAMEDMDR-34907	DTX - PR cannot create device through M2M
EUDAMEDMDR-34629	DTX - ACTOR/GET using versionDate as criteria returns results for BULK but empty results for M2M
EUDAMEDMDR-34532	DTX - MDR ClassIII devices are directly registered and certificate info is not persisted in GUI
EUDAMEDMDR-34512	DTX - Unable to add container package for a regulation device that has a link with legacy
EUDAMEDMDR-34472	DTX - initial status No Longer Placed on the EU Market-incorrect behaviour for POST and PATCH
EUDAMEDMDR-34462	DTX- FINAL_INSPECTION_REPORT.GET responds with no zip attachment
EUDAMEDMDR-34286	DTX - Product Designer PUT for another Actor- unexpected generic error
EUDAMEDMDR-34173	DTX - UDI DI PATCH unable to update the status from No longer on the market to On the Market due to generic error
EUDAMEDMDR-31234	DTX - Issue Sending Items via 3rd Party DTX
EUDAMEDMDR-30509	DTX - Problems updating UDI-DI references on EUDAMED for Procedure Pack Producer
EUDAMEDMDR-29690	DTX - Unclear error codes and error details for Device POST in PG
EUDAMEDMDR-36332	DTX - DEVICE.GET country as search criteria - unexpected BR validation error
EUDAMEDMDR-38184	DTX - Submission Error – (DE-PR-000001002)
EUDAMEDMDR-38183	DTX - (ERR-BR-DTX-UDI-079) - Unable to Post with System and Procedure Pack Producer SRN
EUDAMEDMDR-30514	DTX - Adding UDI to BUDI with wrong serviceID response is a false positive
EUDAMEDMDR-37063	DTX- BULK DOWNLOAD when searching for Basic UDI not working
EUDAMEDMDR-32868	DTX - M2M and Bulk Upload DTX - Various IVDR Class B SUBMITTED devices are incorrectly rejected by the DTX processor
EUDAMEDMDR-35916	DTX - Responses not being sent for both M2M and BULK
EUDAMEDMDR-38488	DTX - DTX - bulk upload with directMarkingDI - Same as UDI-DI is not saved in DB
EUDAMEDMDR-39601	DTX- ACTOR.GET validation error when searching for type= MF (The CW iso country code is missing)
EUDAMEDMDR-38344	Actor - Mandate Summary Document isn't shown when AR assesses Non-EU MF Actor Registration Request
EUDAMEDMDR-34713	Vietnam incorrectly named as Viet Nam in dropdown lists
EUDAMEDMDR-34710	Public - Related legacy device not shown in device details
EUDAMEDMDR-34706	Related device not shown in device details from Search & View
EUDAMEDMDR-37034	Actor not able to upload documents during registration process
EUDAMEDMDR-36554	Investigation needed on potential duplicate UDI DI
EUDAMEDMDR-34946	Error when viewing UDI details
EUDAMEDMDR-34595	User cannot finalize their registration process in EUDAMED
EUDAMEDMDR-37034	Actor not able to upload documents during registration process
EUDAMEDMDR-36554	Investigation needed on potential duplicate UDI DI
EUDAMEDMDR-25279	Vigilance logout issue
EUDAMEDMDR-37263	Correction needed - PR Actor was able to register regular devices in EUDAMED
EUDAMEDMDR-36925	Cannot create new Access Point
EUDAMEDMDR-35106	Cannot register new UDI version due to Direct Marking Di cannot be null when direct marking is true
EUDAMEDMDR-33901	Unable to terminate a mandate

7 List of implemented changes

Ticket number	Summary
EUDAMEDMDR-28205	Labels to update within the clinical investigation entity
EUDAMEDMDR-23647	EUDAMED dashboard - menu 'CI/PS' to be renamed to 'Clinical investigation/Performance study'
EUDAMEDMDR-22722	When terminating the mandate, the system should not allow to put a date 'End date' in the future.
EUDAMEDMDR-22717	Prevent Notifications from being sent to users after end date expiration


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