



EUDAMED

Release notes

Production v 2.7
April 2022



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1 Introduction

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

2 Restricted site

Added

1. NB & Certificates module:
 - Designating authorities can register requests for suspension or withdrawal of registered certificates (and not yet registered certificates in EUDAMED).
 - EC, CA and DA can search and view requests for suspension/withdrawal of certificates.
 - When amending or supplementing a certificate that is linked to an SS(C)P the system warns if there is a newer version of that SS(C)P created. User is able to update to the newer version or create a new SS(C)P version.
 - Possibility to create new SS(C)P version when issuing a certificate.
 - Possibility to create new SS(C)P version of an SS(C)P from the preceding certificate when supplementing or reissuing that certificate.
 - Search & View of historical certificate versions.
 - EC can share with CA/DA the list of nominated experts.
 - SS(C)P translation documents are being displayed within certificate view page.
 - System ensures that *Devices in sterile condition* is checked for devices of risk class I - (Placed on the market in sterile condition) (MDR) or risk class A (sterile) (IVDR) when registering a certificate.
2. Actor module:
 - EC can search on SRN/Actor ID in all actor management page.
 - Searching for CA based on their scope/responsibilities.
 - Possibility to search for designating authorities.
 - Warning an already registered user when requesting new access.

Changed

1. NB & Certificates module:
 - It is possible to reference more than one steriliser when issuing a certificate.
 - Reference additional sterilisers even if the SPP Producer is a steriliser.
 - When cancelling by MF a certificate, the provision of a decision document is optional.
 - A certificate in status Suspended cannot be cancelled.
 - It is possible to change the scope of certificates from devices + SPP sterilisation to either devices only or SPP sterilisation only when reissuing or restricting a certificate.
 - Translations can be added to a not-validated SS(C)P.
2. UDI module:
 - When registering a legacy device MDD Class I or IVDD General, certificate information is not required to be provided.
 - Translation documents can be added to a not validated SS(C)P master document.
 - Minimum 3 characters needed when searching for Basic UDI-DI or UDI-DI.
3. Actor module:
 - VAT, EORI and national trade register may now be entered if previously empty when creating new version of your actor.
 - Designating authorities now appear as separate actors during actor search and new access requests.
 - Responsibilities and scope are now included in details when viewing a CA/DA.

Fixed

1. NB & Certificates module:
 - Removed date restriction when inactivating a link with a non-EU manufacturer.
 - When searching for an existing SS(C)P record within certificate registration process then the system will not allow referencing twice the same SS(C)P record.
 - When previewing/viewing a certificate that does not reference a custom made device then the field *Custom made class III implantable: No* is not displayed (Private site).
 - Various scenarios for unlinking SS(C)Ps when removing the corresponding device group and/or device (MDR/IVDR).
 - Re-issue certificate: Updating with new manufacturer version no longer removes the authorised representative.

2. UDI module:
 - UDI/Device: GS1 UDI-DI validation included for *Is the device directly marked = Yes*.
3. Actor module:
 - Search/View actor: *Last update date* is now included.
 - Manage your actor data: When a second LAA attempted to create a new version, they no longer receive an error.

3 Public site

1. Designating authorities considered as a separate list of actors to competent authorities.
2. Possibility to search for designating authorities.
3. Responsibilities and scope added to search criteria and details for competent authorities.
4. Authorised representative's details can now be used as search criteria for non-EU manufacturers.
5. Update: Not-validated SS(C)P master documents are now visible.
6. Fixed: Current BUDI version was missing from *See all versions* pop-up.
7. Fixed: Non-EU manufacturer details: no data showing for certain authorised representatives.
8. Fixed: UDI-DIs attached to a Basic UDI-DI were not displaying correctly on the list screen.
9. Fixed: Importer heading was missing from non-EU manufacturer detail view.

4 DTX

1. CorrelationID and ConversationID now behave consistently as described.
2. Field name update: previousIdentifiers to precedingCertificates.
3. The payload of a certificate now contains link(s) to the preceding certificate(s).

**NOTE**

There can be multiple preceding certificates in case when merging two or more certificates during the reissue operation.

4. The payload of a certificate that had a decision or update now contains information about the statusChangeReason, decision document and comments where applicable.
5. Device upload: *links:certificateType is not valid* error corrected.
6. Unexpected error *sutures from the submitted version of Basic UDI-DI/EUDAMED DI have different values than the ones existing in EUDAMED* fixed.
7. Possibility to set/update the first country where the device has been put on the EU market via Update of UDI-DI service.
8. Registering a Market Information entity via the *Update of market Information* service.
9. For security reason a new master password was used for generation of DTX Services tokens. This implies that all Services tokens must be regenerated.

**NOTE**

Please see *Action required* section.

Action required

Please follow the steps depicted in the following pictures to regenerate services token:

Figure 2: Module selection dialogue

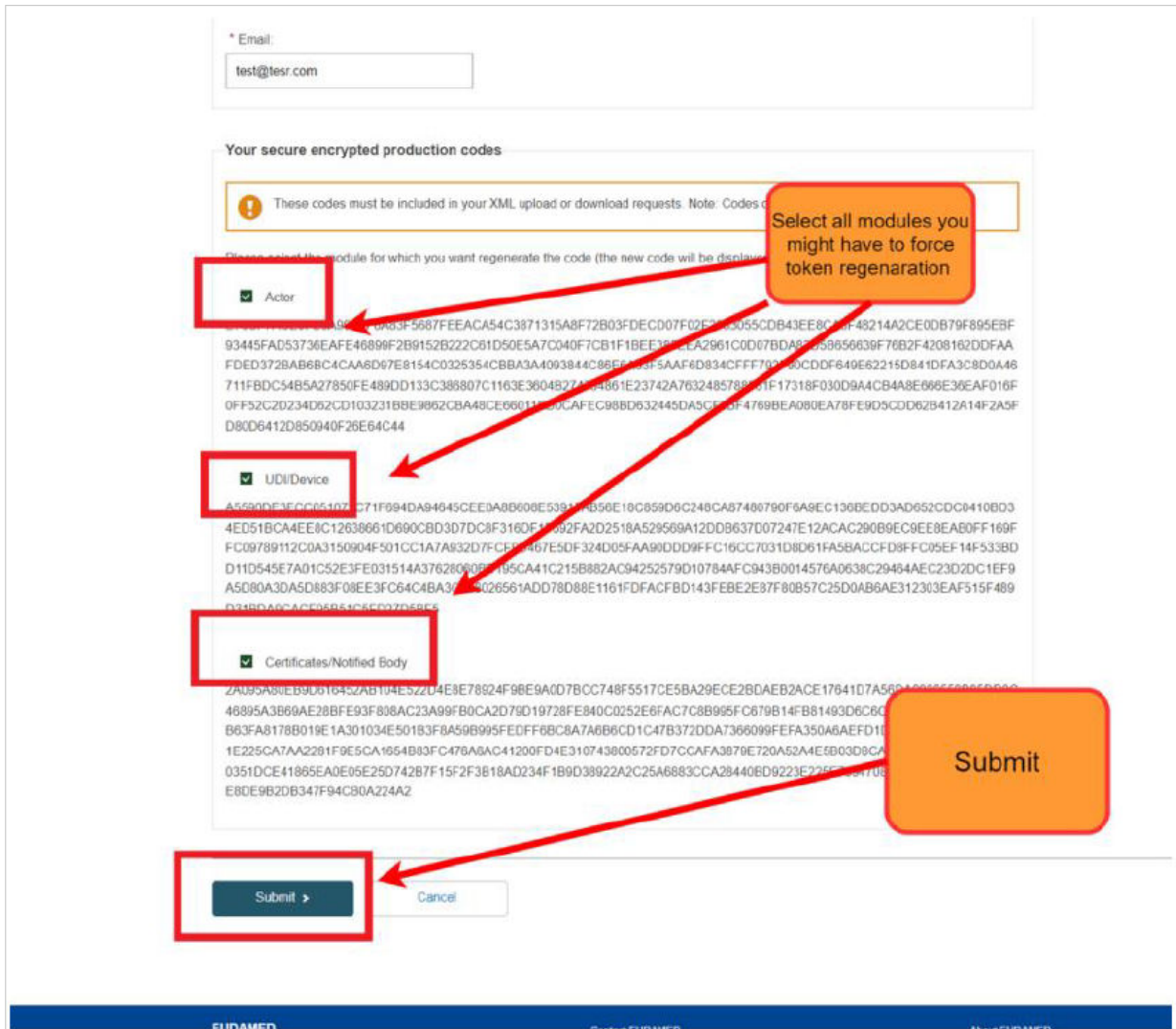


Figure 3: Regenerated tokens page

Machine to machine data delivery preferences

Will you be using machine-to-machine services?: Yes

Data exchange services

Party ID: EUDAMED_000001

Services - Actor: Actor registration requests download, Actor download

Services - Udi-device: Download of Legacy/ Regulation Device/SPP


Services - Certificate: Refused Certificate download, SS(C)P Download, Certificate download

Access point request

Do you want to apply for a new access point configuration?: No

Do you plan on using an access point from a third party company?: No

Your secure encrypted production codes

 These codes must be included in your XML upload or download requests. Note: Codes differ per module.

Actor
E0397ABD530300A9F8777BCEA8F3EDB3013E07F98DF2616779F9428BA0B55E23557D063114C08CA6D67E548AD067DC026C1E31FF5F190EF844DD3C77A69CB1A0C3D17EBF06EB03
F1C2D203E9E19F1C03DAE6BDC5B0FABDE8D7EB345E2F5C7983B61E4A3E33EBC1589B32DBED37886665711950A2A4F92D8F1F2F0C8E37AFA89FCF17443D380C2100C4202393A7
8C132F783290B1F61C9E0EEEDAE480038C583C4C7D779CB34BA01929AD902F8F9963107303E97296AD95B2647A34CDDDB6606CE5FE0B70778C78037C15AFC46091A9258F798631
DD8E8E4758903509F15636804A794DDCC965239586DAF769AD02211232F59202B53CAD6A7AD530342FD59A963E4602C4F03BFAF744097C8162A5E

UDI/Device
6927AFFC4FD58CB99F77EA2EA67111E949F259995D2ACAFF98AEFBC1FFF198E9AB3C581EE2789A857FDC3E37EE5DE5D36FD842D8E7B81A16633CABECC8E5A8056F94BA8AB6F
3EB174CCF017C8A744F0EB48BFC70609F02BAF54C99E86106688501062379A9377507912157C85C3E8EE80507ADF5A6DE4AF2E67695A9B61EBAD827EA1476884531F72504192724
D8A0B9EAE7F2B6DE19BA74B964068FCB64288C40E4515506A264FBE977AB2FD0B82BA93E367CB88310736122AA68A7274D8D02BDF3565AD590BA2E79C6651D4AEADB391BA4C35A
0EC3AED78684E3FB7232C5C5A8771D845D146073A1FBAA71BB8958F54064AAE2D5AB8589C89686F8C2E2E930183CE0D35A2B7EE6756654F7442

Certificates/Notified Body
86C8731F84D47AC0F48CB091AE7B710D3750C21335EE5646C80002099272E7F58F7992E7AA2FE36319CF04D7CC7BE903188EC7D3C6185295DF8F4BE8EC1A1C8501D12FB3CCF4
521BC12A9378690F5F13D72ACF24A1091FF89AD05E979AC6A3C62BAA5627ABA8102919C5AAC750CB4B3DFEF0EA4C267839A179069F6AFFDCF727E3DBE938ED041C762C7F11DFC
BA8369184E9C2931D4AC0A181DAA2B341BA919E01BB12005CA831768E177F4FEEB990A1B05C960A53AB0E7B27053F21EADDE86508E9628543F0E53C24A0B15B754A8D7D881BB
8233426FEA25C9F992DD231B721989FA670024C5CEC5F3AC73F3FCE17E1625BC2878DEBC498DF27548D9E6AF0A0D7B7A4B35AFB7B6A03FD1A5092C

