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 1: Machine to machine data delivery preferences page

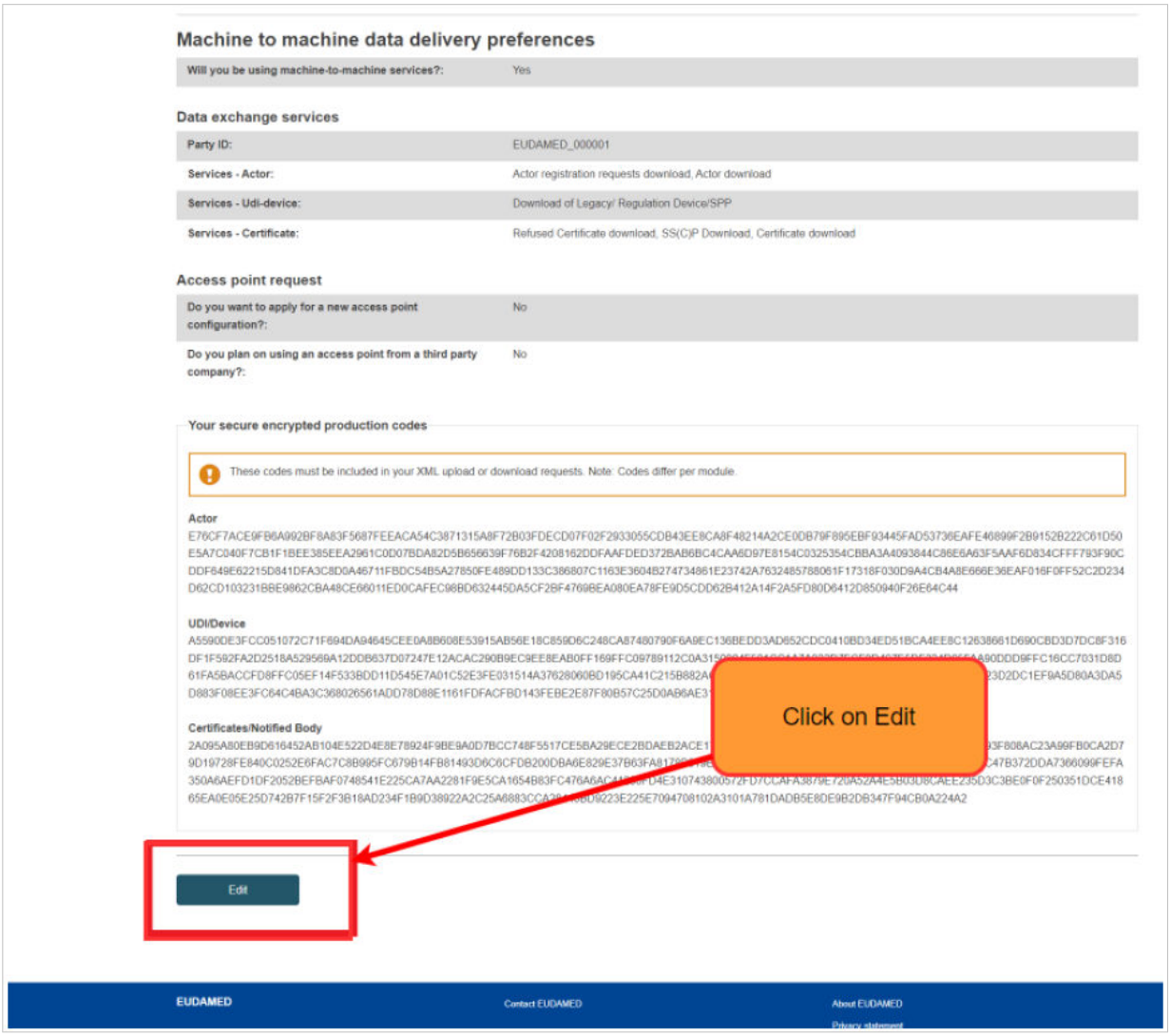


Figure 2: Module selection dialogue

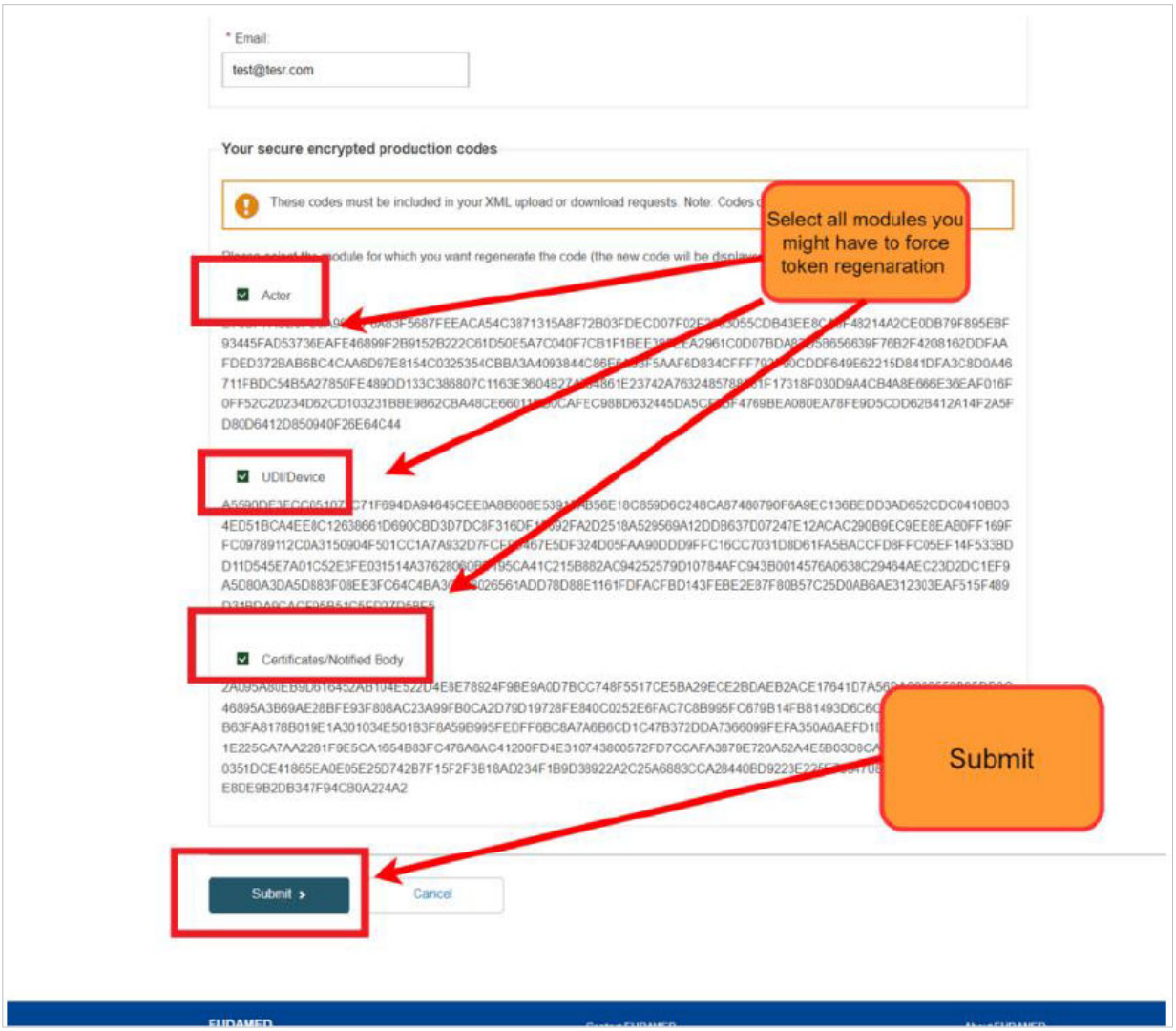
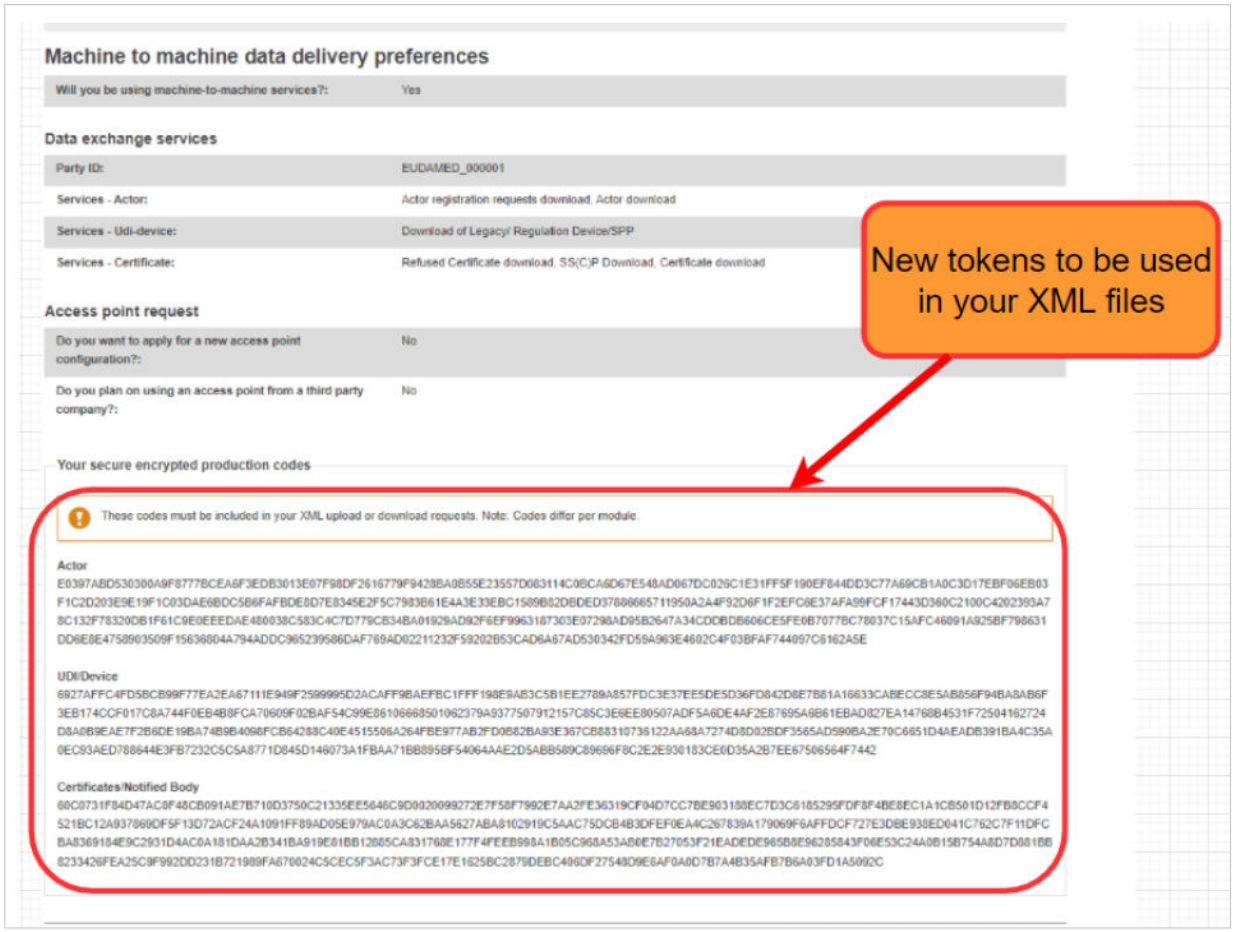


Figure 3: Regenerated tokens page



European
Commission