European Commission

EUDAMED

European database on medical devices

ACTOR MODULE FAQs

December 2020 v1.1

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1. Countries available in EUDAMED from December 2020

1.1 Which national competent authorities will be registered in EUDAMED Actor module from December 2020?

As of December 2020, the national competent authorities from EU 27, Iceland, Liechtenstein and Norway will be registered in EUDAMED. Concerning other third countries national competent authorities, the Commission may in principle be able to register them in the actor module from a later date under the condition that an international legal agreement including the MDR (and in due course the IVDR) has been concluded or fully updated.

1.2 Which economic operators (including manufacturers, system/procedure pack producers, authorised representatives (AR) and importers) will be able to submit an actor registration request in EUDAMED actor module from December 2020?

Economic operators (including manufacturers, system/procedure pack producers, AR and importers) established within the EU 27, Iceland, Liechtenstein and Norway will be able to submit actor registration requests in EUDAMED.

Non-EU manufacturers will be able to register only if their authorised representative is established within the EU 27, Island, Lichtenstein and Norway. Economic operators from the UK, Switzerland and Turkey will only be able to submit actor registration requests in EUDAMED at a later stage, not from December 2020.

1.3 Will UK national competent authorities be registered in EUDAMED Actor module from December 2020?

No, UK national competent authorities will not be registered in EUDAMED and therefore will not have access to the actor module from December 2020.

1.4 Will economic operators (including manufacturers, system/procedure pack producers, AR and importers) established in UK be able to submit actor registration requests in EUDAMED actor module from December 2020?

As the UK country will not exist in EUDAMED yet and the UK national competent authorities will not be registered in EUDAMED, Economic operators (including manufacturers, SPP producers, AR and importers) established in the UK will not be able to submit actor registration requests in EUDAMED actor module for the time being. The situation will be updated according to future relation arrangements with the UK/Northern Ireland, but not before January 2021.

1.5 Will Swiss national competent authorities be registered in EUDAMED Actor module from December 2020?

No, Swiss national competent authorities will not be registered in EUDAMED until the mutual recognition agreement with Switzerland is fully updated to MDR (and in due course IVDR/IVDR Eudamed provisions) therefore they will not have access to the actor module from December 2020.

1.6 Will economic operators (including manufacturers, system/procedure pack producers, AR and importers) established in Switzerland be able to submit actor registration requests in EUDAMED and have their details verified by the Swiss NCA?

As the Switzerland country will not exist in EUDAMED yet and that the Swiss national competent authorities will not be registered in EUDAMED, economic operators (including manufacturers, SPP producers, AR and importers) established in Switzerland will not be able to submit actor registration requests in EUDAMED in the absence of a fully updated mutual recognition agreement.

1.7 Will the Turkish national competent authorities be registered in EUDAMED actor module from December 2020?

No, Turkish national competent authorities will not be registered in EUDAMED as long as the Customs Union Agreement with Turkey has not been upgraded to MDR (and in due course the IVDR/IVDR EUDAMED provisions), therefore they will not have access to the actor module from December 2020.

1.8 Will economic operators (including manufacturers, SPP producers, AR and importers) established in Turkey be able to submit actor registration requests in EUDAMED and have their details verified by the Turkish NCA?

As the Turkey country will not exist in EUDAMED yet and that the Turkish national competent authorities will not be registered in EUDAMED, Economic operators (including manufacturers, SPP producers, AR and importers) established in Turkey will not be able to submit actor registration requests in EUDAMED in the absence of an updated Customs Union Agreement.

2. Actor registration process

2.1 Will actor information registered in EUDAMED be publicly available already from 1st December 2020?

Yes, the EUDAMED public website will be made available on 1st December 2020 together with the restricted EUDAMED site. The public website will follow the same roadmap as the restricted website for the gradual availability of the modules.

2.2 If an EU Legal Manufacturer completing Actor registration whose legal office is based in Amsterdam but whose Medical Device is only distributed in another country such as Germany, who will act as the Competent Authority (CA) for such organisation?

The CA that has to validate an EU Actor registration request is a CA where the economic operator is located. When entering an Actor registration request, the name of the manufacturer must match with the name placed on the device label and in official documents like the certificates and the technical documentation.

2.3 Does an Actor has to provide Competent Authority details?

The actor must indicate the CA to which the Actor registration request is sent. The choice will be limited to the CA(s) responsible for the Actor registration validation in the country where the Actor is located or in case of a non-EU manufacturer, it will be the CA responsible of the AR selected for the non-EU manufacturer registration request.

2.4 If an actor (legal entity name + address) may only be registered once in EUDAMED, will a second registration of an actor under the same name and entity address be regarded as a duplicate and thus potentially rejected?

EUDAMED performs a duplicate check on the same Actor role. So, an Actor registering a second time with the same name and address but for another actor role will not be marked as duplicate. On the other hand, in case it would be for the same actor role, it will be indicated as a possible duplicate but it will be up to the CA assessing the request to decide if rejected for this reason or not.

I.e.: If “Company A” has activities as manufacturer, System/Procedure Pack producer and Importer, it will have to be registered 3 times, for each actor role and it will obtain 3 different SRNs, one for each actor role.

2.5 Does an Economic Operator having different actor roles need to enter a separate registration for each actor role in EUDAMED?

Yes, if the economic operator has multiple roles, separate registration requests are required in order to obtain a different and specific SRN for each actor role. The economic operator will obtain a unique SRN for each actor role.

2.6 Can the same legal entity with the same contact details (name, address, etc.) apply for different actor roles (if acting as both the Authorised Representative and Importer or Legal Manufacturer as well as a System and Procedure Pack Producer)?

Yes, a same organisation (same legal entity name + address) can apply for more than one actor role. However, an actor will have only one registration per actor role, not per organisation. I.e.: if an organisation is manufacturer and importer, it will mean two registrations (and two SRNs), one (and only one) for each actor role.

2.7 Can the same legal entity register several actors within the same role (i.e. manufacturer, with different brands, addresses, etc.)?

A same legal entity may use several Trade Names (e.g. Company Medical Systems, Company Ultra-Sound, etc.) in this case they will enter separate registrations under their different Trade Names.

This registration scenario will most likely trigger the duplicate check warning, requiring a justification. In the end it is up to the CA to assess your requests, EUDAMED provides only warnings, it does not define what the assessment criteria are.

2.8 EORI / national trade registry ID are non-mandatory data to be provided in EUDAMED for actor registration. Is there any expectation from any of the national competent authorities to request any of these?

Depending on the country, the actor role and its location, CAs could require the EORI number, the national trade registry ID and/or the VAT. These fields are optional, however the good practice is to provide such fields when available.

These fields are part of the duplicate check as they uniquely identify an Economic operator in its country.

Providing those fields might speed up the actor registration request assessment by the CA.

2.9 Are the documents to be provided with the actor registration request harmonised documents or unique ones per country or organisation?

These documents in some cases are based on a PDF template available in EUDAMED and Europa Medical device sector website as a download during

registration. In the case where no template is provided, the requestor is free to choose the content, at least containing the required information in a PDF file.

2.10 Which are the administrative documents required to register in EUDAMED in order to obtain an SRN?

All economic operators must upload a signed Declaration on information security responsibilities

The non-EU manufacturers must have an active mandate with an already registered authorised representative (having an SRN) and upload with the registration a Mandate Summary document

2.11 Who must sign the declaration on information security responsibility?

The declaration on information security responsibility must be signed by a person entitled to represent the Economic Operator

2.12 If there are two identical entries in a submitted state, will this duplication be captured by the Competent Authority or spotted by EUDAMED?

EUDAMED will normally trigger a duplicate warning for first the requester and next for the potential AR verifier and CA assessor. The CA will have to look into these requests as they might contain differences on different fields not shown in the list. EUDAMED does not perform any assessment, The CA is responsible.

2.13 Is there an agreed timeline between Member States / Competent Authorities to complete the validation of the submitted Actor registration applications?

No, there is no agreed timeline for validation, except that it should be done within the best delay.

3. SRN

3.1 What's an SRN?

The SRN is the Single Registration Number that uniquely identifies every economic operator in EUDAMED and in the relevant official documents and related reports.

The SRN is generated by EUDAMED and issued through EUDAMED by the competent authority that has validated the Actor registration request in EUDAMED.

3.2 Does the SRN include a reference to the actor role?

Yes the SRN includes the actor role abbreviation: infographic Actor roles

3.3 How will the SRN be notified to the requester economic operator, via EUDAMED only or also by email?

An email will notify the economic operator that the SRN has been issued. The SRN itself will not be in the notification email but available via a link to a EUDAMED page with the SRN value.

3.4 EUDAMED playgrounds use dummy SRNs. Will dummy SRNs need to be used for the Playground (instead of SRNs assigned in the production/in EUDAMED Actor registration module after its launch)?

EUDAMED has a Playground environment for training and testing with dummy data only. Dummy SRNs from playground are only for playground, never to be referenced in any official documents. Any SRN issued in the Playground environment is dummy and it is just for the purpose of EUDAMED testing.

4. Actor roles

What are the different Actor roles for Economic Operators in EUDAMED?

The different EO Actor roles are listed in the infographic Actor Roles

4.1 Manufacturers

4.1.1. Which name the manufacturer has to indicate in the Actor registration request?

When entering an Actor registration request, the name of the manufacturer must match with the name put on the device label and in official documents like the certificates and the technical documentation.

4.2 Authorised Representatives

4.2.1. Can a non-EU Manufacturer indicate whether the Authorised Representative (AR) may or may not submit vigilance data for registered devices associated to the AR?

The non-EU manufacturer can indicate whether it authorises an Authorised representative to enter vigilance data for devices associated with this AR. However, this option to delegate Vigilance reports to an AR will be only activated when the Vigilance module will be available.

4.2.2 In case a non-EU manufacturer has several authorised representatives (AR), which AR(s) may be selected for the non-EU manufacturer Actor registration request in EUDAMED?

For registration of a non-EU manufacturer, only one authorised representative of their choice has to be selected from those already registered (with an SRN) in EUDAMED.

4.3 Sponsors

4.3.1 Can a Sponsor register in the EUDAMED actor module from December 2020?

No, Sponsors are only related to the Clinical investigation/Performance study (CI/PS) module. Sponsors will register in EUDAMED only when this module will be made available.

4.4 Importers

4.4.1 Is there any limitation on how many importers can be linked to a manufacturer?

There is no limitation of the number of importers that can be linked to a manufacturer. However, the links are made by the importers and there is no limitation on the number of manufacturers an importer can link to itself.

4.4.2 Is the linking for importer is foreseen only at the actor level, not device level?

Linking Importers to Manufacturers is only at the actor level for the time being.

4.4.3 Will the Manufacturer be able to see in the system the importers linked to him?

Yes, the Manufacturer can see the linked Importers on the actor detail page on the Restricted website. Also everyone will be able to see them on the public website.

4.4.4 Is there a notification to the Manufacturer of the linkage by an Importer?

Yes, notification to the manufacturer will be sent for all linking done by an importer to a manufacturer. However, this particular notification is not foreseen in the December 2020 release 0.1 of EUDAMED. After completion of the minimal viable product of EUDAMED (which fulfils legal obligations only and only notifies users when a direct action is necessary), informational notifications will be added in the raft of improvements to be rolled out after release.

4.4.5 Will there be a confirmation required from the Manufacturer when an Importer links to them?

No.

4.5 Distributor

4.5.1 Does Distributors need to register on EUDAMED?

The Distributors do not need to register and cannot register in EUDAMED. There is no actor role for distributor/wholesaler in EUDAMED and therefore no SRN for them.

4.6 Person Responsible for Regulatory Compliance (PRRC)

4.6.1 When does an Economic operator have to declare the PRRC?

Only Manufacturers and Authorised Representatives need to declare at least one PRRC during their actor registration in EUDAMED. Additional PRRCs can be added afterwards.

4.6.2 Can PRRC be appointed in the UK for EU Legal Manufacturer?

Please refer to MDCG 2019-7 Guidance on article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a 'person responsible for regulatory compliance' (PRRC).

4.6.3 Can a PRRC be Local Actor Administrator (LAA) for EU Manufacturer?

There are no limitations in EUDAMED on who can be the LAA, except that the LAA will need an EU Login account as any other type of users, it is the Actor's decision to choose the person who will be LAA.

4.6.4 Are the PRRC details public?

The Medical Devices Regulations have provisions (MDR Art 31(7)/IVDR Art 28(7)) requiring to have the PRRC data accessible to the public.

There are 3 different contacts information to provide for an actor registration:
1. the actor public contact details,
2. the actor contact details only for the Competent Authorities and the Commission
3. the PRRC details.

It is well displayed in the actor registration form which contact is not public, all the other ones are public.

For avoiding to expose the PRRC personal email address and telephone, the PRRC details entered in EUDAMED should not be personal but a non-personal professional email and telephone that may be used to contact the PRRC as well in this context.

In case the PRRC is also the actor contact person for the Competent Authorities and the Commission, their personal contact details can be provided then for this contact information

5. EUDAMED Users

5.1 How can a user request access to EUDAMED?

The process to request access is described in the Infographic user access requests

5.2 Can a same user belong to multiple economic operators?

Yes, a user can belong to multiple economic operators at the same time.

5.3 It is possible to grant access for the same user in EUDAMED to multiple Actors E.g. for an organisation with multiple actor roles (Manufacturer, Authorised Representative, Importer and System and Procedure Pack Producer). Could the same user (through delegation) act under several actors in the actor module on their behalf for the purpose of registering and maintaining the data in the Actor Module?

It is only possible if related to economic operators and sponsors. Users will then need several EUDAMED account registrations, one for each actor. Each actor registration or user account must be requested independently and accepted by the responsible CA (for actor registration request) or by a Local Actor/User Administrator (LAA/LUA) (for user access request) of each actor.

5.4 What are the user profiles that are available and the associated privileges within EUDAMED?

The user guide for Economic Operators contains a description of these in section 1.2.3 (User rights & profiles) on p6 as well as the Infographic on User access requests

5.5 Is it possible to delegate both the Local User Administrator (LUA) profile and the Local Actor Administrator (LAA) profile?

It is possible to delegate a profile of choice to any user, It is up to the already existing LAA/LUA to assess who is allowed to be part of the actor inside EUDAMED.

However, a good practice is to have at least one LAA who is not a sub-contractor but working directly for the actor (or being part of the organisation structure) to avoid any loss of access control in case of loss of contract or a conflict with the sub-contractor.

5.6 Can an actor have several LAAs and LUAs, and can those individuals differ?

There are no limitations on the LAAs and LUAs and other user profiles. It is possible to have multiple users with the same profile for the same Actor (no limit). However, it is either LAA or LUA, considering that LAA includes the rights of the LUA profile.

5.7 If the Local User Administrator (LUA) profile and the Local Actor Administrator (LAA) profile needed to be revoked from a person, is it possible to do an update to that record without impacting the Actor set-up or the other LUA's/LAA's?

Yes. A user can request a change in their profile, i.e. a viewer can request LUA access which can be granted by a LUA (or LAA). Conversely, the LUA can terminate a user's access under the "Manage your users" page. In a later release, we will add the ability to suspend/reactivate a user. These actions do not have an impact on the actor but only on the selected user. There will be a constraint to block the termination

of the last remaining LAA of the actor (at least one LAA must remain active at all time as long as the Actor has not ceased activity).

5.8 Within the role profiles there is a profile called 'Linker'. What does this profile enable a user to do within EUDAMED?

This profile is only part of the Importer actor role, which can be used inside the Actor module. It allows an Importer user to manage Importer-Manufacturer relationships (LAA and LUA profiles for Importer users also allow management of this link).

6. Support

6.1 Which training material will the Commission be providing to support the rollout of the Actor Registration module?

The Commission provides a user guide for Economic Operators and the CA quick guide as well as infographics.

6.2 Will the Commission provide technical support as from 1 December 2020 for the Actors module?

Yes, as from 1st December 2020 the application support will be available on SANTE-EUDAMED-SUPPORT@ec.europa.eu

7. Data Exchange

7.1 For the Token process, how is this linked to Actor Registration? Can an actor get the SRN first and then the token for submitting data to other modules later?

Security tokens are used when communicating with EUDAMED through M2M. Security tokens are generated for each module. First, the Actor needs to be registered in EUDAMED and for economic operators, an SRN needs to be obtained in order to configure the Transmission settings for M2M (available only for CAs in the Actor module for the time being). Tokens for future modules will become available/configurable (depending on actor role) when each module is available.