European Commission

EUDAMED

European database on medical devices

# ACTOR MODULE FAQs

**March 2022 v1.8**

Table of Contents



## 1. Countries available in EUDAMED

### 1.1 Which national competent authorities (NCA) are registered in EUDAMED Actor module?

The national competent authorities from EU 27, Iceland, Liechtenstein, Norway and Turkey are registered in EUDAMED as well as the UK competent authorities in respect of Northern Ireland. 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 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 (SPPP), authorised representatives (AR) and importers) are able to submit an actor registration request in EUDAMED actor module ?

Economic operators (including manufacturers, SPPP, AR and importers) established within the EU 27, Iceland, Liechtenstein, Norway, Turkey or Northern Ireland are able to submit actor registration requests in EUDAMED.

Manufacturers established outside the EU 27, Iceland, Liechtenstein, Norway, Turkey or Northern Ireland will be able to register only if their authorised representative is established within the EU 27, Island, Lichtenstein, Norway, Turkey or Northern Ireland.

### 1.3 Are Swiss national competent authorities registered in the EUDAMED Actor module?

No, the Swiss national competent authorities are not registered in EUDAMED as there is no longer a mutual recognition agreement between the EU and Switzerland for medical devices as of 26 May 2021. Switzerland is therefore considered as a non-EU country.

### 1.4 Are economic operators established in Switzerland able to submit actor registration requests in EUDAMED

Only Swiss manufacturers having an Authorised Representative already registered in EUDAMED and System/Procedure pack producers established in Switzerland can submit actor registration requests in EUDAMED. Switzerland is available in the non-EU countries list.

### 1.5 Are the Turkish national competent authorities registered in the EUDAMED actor module?

Turkish national competent authorities are registered in EUDAMED.

### 1.6 Are economic operators (including manufacturers, SPPP, AR and importers) established in Turkey able to submit actor registration requests in EUDAMED and have their details verified by the Turkish NCA?

Yes, Turkish economic operators (including manufacturers, SPPP, AR and importers) established in Turkey can submit actor registration requests in EUDAMED..

## 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 is available since 1st December 2020 together with the restricted EUDAMED site. The public website 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 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

**2.10 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

**2.11 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.

**2.12 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.

### 2.13 Does manufacturers that only produce custom-made devices have to register in EUDAMED?

No, manufacturers that only produce custom-made devices are not required to register in EUDAMED, see Article 31(1) MDR'. Only when a serious incident has occurred involving their custom-made device or if they have taken a field safety corrective action related to their custom-made device, which they have to report via EUDAMED (see Article 87 MDR), the manufacturer of that custom-made device will have to register in EUDAMED in order to report the serious incident.

## 3. Actor ID/SRN

### 3.1 What's an Actor ID/SRN?

The Actor ID (Actor identifier)/SRN (Single Registration Number) uniquely identifies every economic operator registered in EUDAMED and in the relevant official documents and related reports. Further information is available in MDCG 2021-13 rev.1.

The ActorID/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 Actor ID/SRN include a reference to the actor role?

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

### 3.3 How will the Actor ID/SRN be notified to the requester economic operator?

An email will notify the concerned economic operator that the Actor ID/SRN has been issued. The Actor ID/SRN itself will not be in the notification email but available via a link to an EUDAMED page.

### 3.4 EUDAMED playgrounds use dummy Actor IDs/SRNs. Will dummy Actor IDs/SRNs need to be used for the Playground (instead of Actor ID/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 Actor IDs/SRNs from playground are only for playground, never to be referenced in any official documents. Any Actor ID/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 Person Responsible for Regulatory Compliance (PRRC) details public? - *Updated*

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 contact details.

The actor registration form display which contact details are not public, all the other ones are public.

The PRRC contact details entered in EUDAMED should not be personal, but professional/business contact details. (use of functional mailboxes is allowed).

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.