

# EUDAMED

European Database  
on Medical Devices

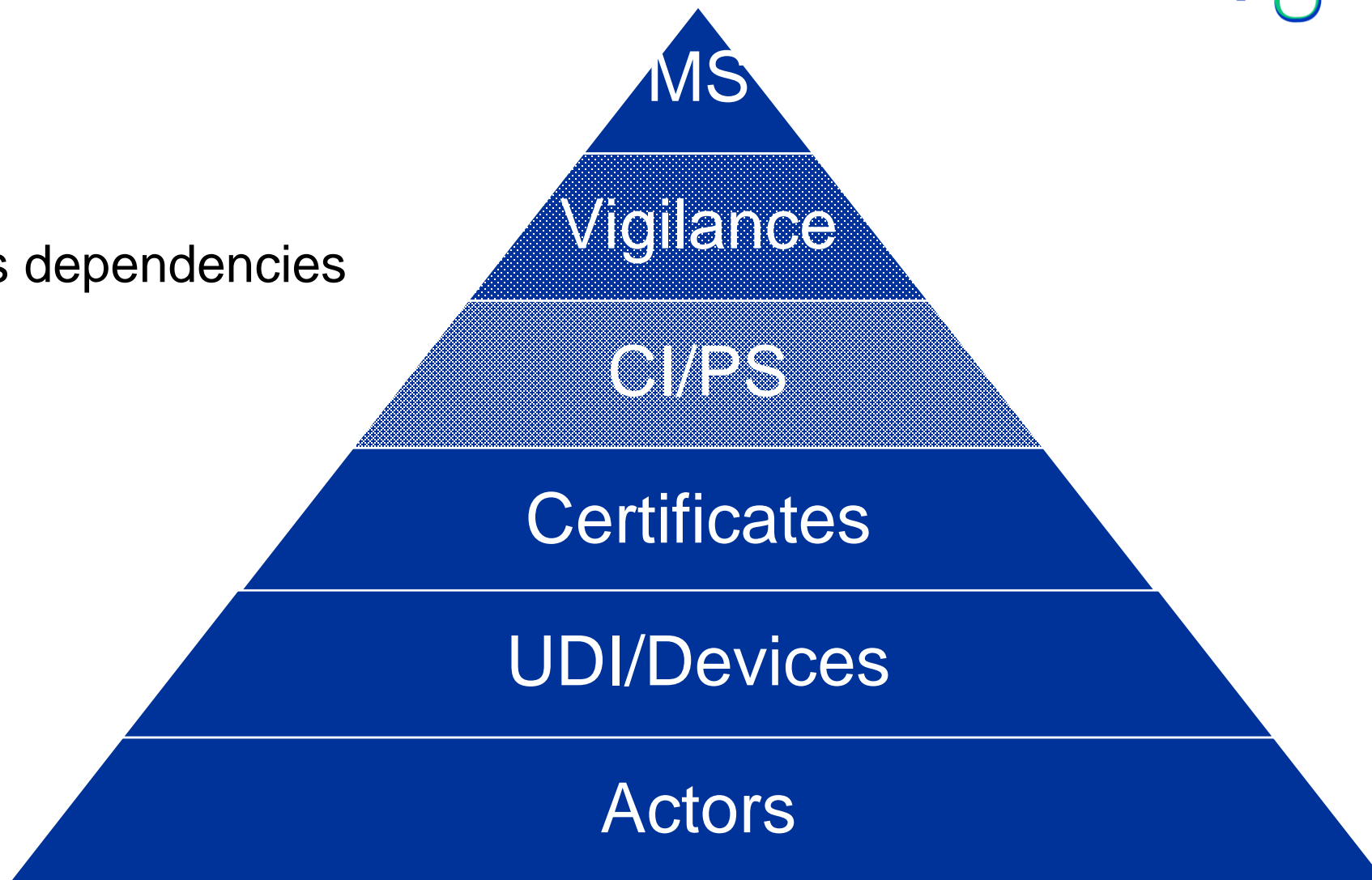
# Overview and Actors module

Stuttgart Workshop – 21 May 2025

# Table of content

1	EUDAMED overview concepts
2	Actor concept and roles
3	The Actor identifier (Actor ID/SRN)
4	Actor registration for economic operators
5	User profiles and access

Modules dependencies



## Versioning

Updates through create new version:

All history of changes will be in EUDAMED to guarantee traceability on changes

A registered version will be always kept (cannot be changed or deleted), only version in draft can be directly updated and deleted

Discard option for logical delete in case of mistakes (data are kept but with a new state: Discarded)

## States in EUDAMED for a version

Version has a state assigned by EUDAMED to determine the step in the registration workflow

Mainly you have the state Draft and Registered, but also Submitted, Discarded ... depending on the item and module.

Depending on the state, actions are possible or not

State and Status are not the same thing

## Notification

At Actor level and at user level (optional)

On user interface and by email (not in Playground)

For action and for information

## Data exchange

Machine to machine XML  
upload/download (M2M) requires Access  
point link (max 2/per Actor) with  
justification (PLG), proof of testing (Prod)  
and 3rd party agreement when applicable  
to be approved by EC

Bulk XML upload/download

Public download API Json format

Availability depends on Actor role and  
data

**Actor:**

an organisation/legal entity that is or must be registered in EUDAMED due to legal obligations to provide data and/or to access EUDAMED content

**Supervising roles**

- Commission (EC)
- Competent authorities (CA)
- Designating authorities (DA)
- Notified bodies (NB)

**Economic operators' roles**

- Manufacturers (EU and non-EU)
- Importers (EU)
- Authorised representatives (EU)
- System/procedure pack producers (EU and non-EU)

**Sponsors**

- Sponsors of clinical investigations / performance studies

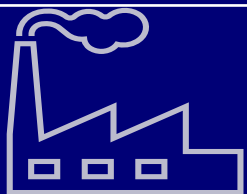
*Distributors not in EUDAMED!*

**Actor:**

an organisation/legal entity that is or must be registered in EUDAMED due to legal obligations to provide data and/or to access EUDAMED content

**Note!**

- Competent authorities and designating authorities are registered by the Commission
- Notified bodies are registered from data in NANDO
- An actor can have only one role



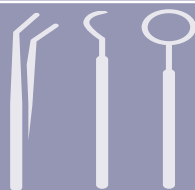
**Manufacturers (MF):** register themselves, manage mandates with their authorised representative(s) when applicable, register their devices (and SS(C)Ps' translations) and related post-market surveillance and vigilance reports



**Importers (IM):** register themselves, associate themselves to the non-EU manufacturers for which they place devices on the market and can check those non-EU manufacturers and devices data entered into EUDAMED



**Authorised representatives (AR):** register themselves, participate to the registration of the non-EU manufacturer, participate to the management of the mandates, register vigilance reports when applicable and check the information provided by the non-EU manufacturers



**System/procedure pack producers (PR):** register themselves and their systems/procedure packs.

**Single Registration Number  
(SRN)**

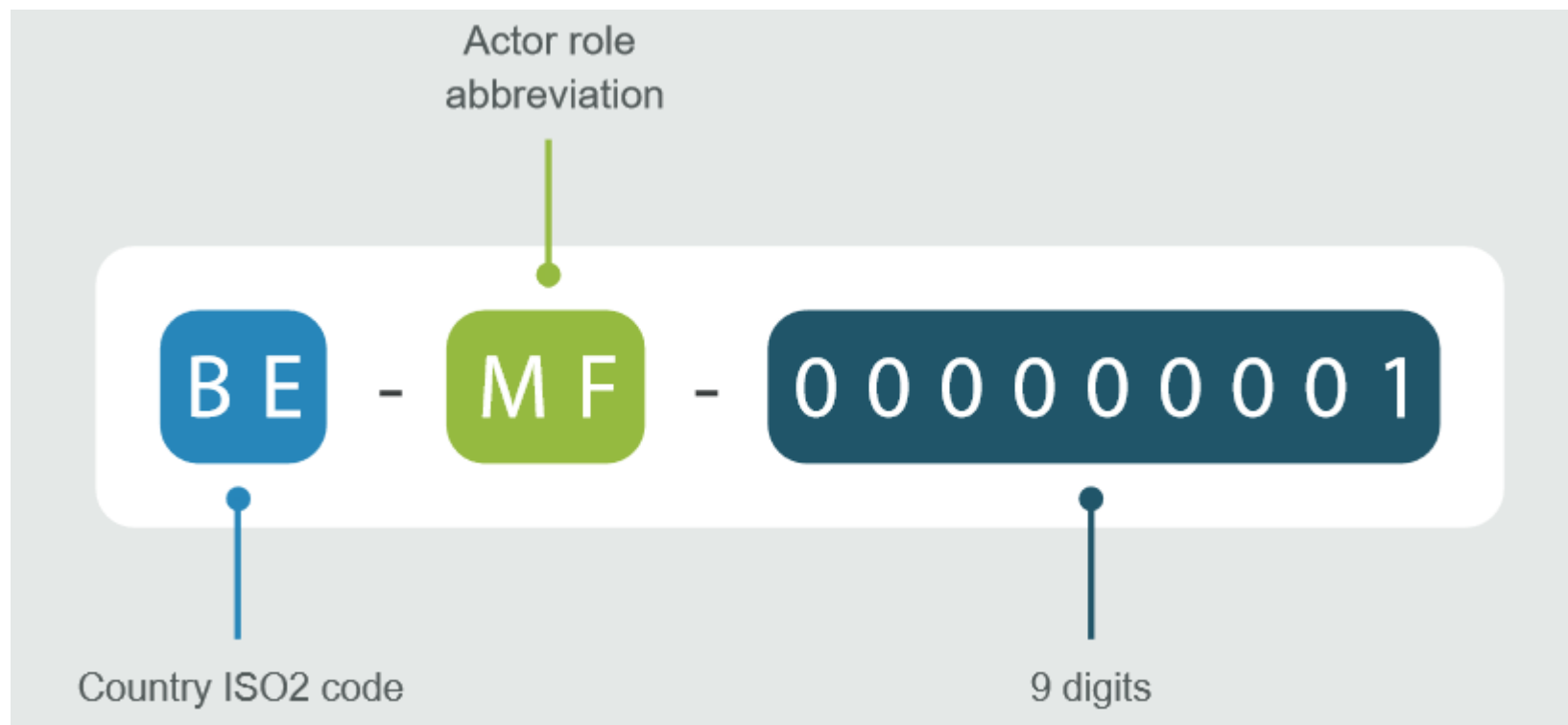
Manufacturers, importers and  
authorised representatives placing  
Regulation devices on the market

**Actor ID**

All other actors

Format of the Actor ID/SRN for **economic operators**

**Note:** Competent  
authorities,  
Designating  
authorities and  
notified bodies  
have a different  
format for their  
Actor ID.



Non-EU MF must  
have an Authorised  
Representative  
(this does not apply to  
non-EU SPPPs)

Economic  
operators must be  
validated by a  
responsible CA



The responsible CA  
can be changed in  
case of change of  
address

For NB, the  
responsible DA is  
determined from the  
data in NANDO

- To be considered as  
'registered', economic  
operators must:
- have a **validated actor registration request**
  - have an Actor ID/SRN

Have an EU Login  
account



Go to EUDAMED  
restricted website  
and create an Actor  
registration request



Select your AR (only  
for non-EU MF) and  
responsible CA

Note: Only registered  
AR can be selected



Your request will  
need to be verified  
by the AR (only for  
non-EU MF) and  
approved by the CA



The responsible CA is the one of your Actor location or the one of your AR (for non-EU MF).  
For non-EU SPP producers, CA is determined by where the first SPP will be placed on the market.  
There is a duplicate check with warning message for both requester and CA validator

- Actor role
- Organisation name (and optionally abbreviated name)
- Organisation identifiers (VAT, EORI, National trade register, if applicable)
- Organisation address
- Authorised representative (for non-EU MF)
- Responsible CA (depending on address)
- Public contact details
- Contact details for CAs (non-public)
- Person Responsible for regulatory compliance (only for MF and AR)
- Signed agreement annex (non-public)
- Organisation identification document (optional, non-public)
- Sub-contractor information (if applicable, non-public)

## User profiles - Local Actor Administrator (LAA) and Local User Administrator (LUA)

### LAA:

Advisable to have two per Actor

They manage actor's data

User who submitted the actor registration request is the first LAA

First NB LAA to be approved by DA

### LUA:

Manages users for the Actor

**Note:** users (LAA, LUA included) may not manage their own access rights/profile, any change of profile requires a change request to be approved by another LAA or LUA

## Profiles available for all Actor roles

- **Local Actor administrator (LAA):** Manage Actor data and Access point for M2M data exchange and has the rights of LUA
- **Local user administrator (LUA):** Manage user access requests for the Actor and has the rights of Viewer/Validator/Mandate manager/Verifier/Linker
- **Viewer:** May view all his/her Actor data and all public data from other Actors

## Specific profiles for Actor roles

- **Validator:** For CA users for validating Actor registration request and has the rights of a Viewer
- **Mandate manager:** For non-EU MF users for managing mandates with ARs and has the rights of a Viewer
- **Verifier:** For AR users to verify Actor registration requests and has the rights of a Viewer
- **Linker:** For importer users to link their Actor to non-EU MF and has the rights of a Viewer

Have an EU Login  
account



Go to EUDAMED  
restricted website  
and request access  
to act on behalf of  
an Actor



Select your profile for  
each relevant module

Note: By default user  
profile is 'Viewer' for  
the first three  
modules.



Your request will  
need to be  
validated by a LAA  
or LUA



Profiles are modules related, which means you don't have necessarily the same profiles for the different modules. Profiles are hierarchical, it means a higher profile will always contain the rights of the profile(s) below it.



# Thank you!



#EUDAMED

