

# Single Registration Number (SRN) and EUDAMED



**The new version of EUDAMED is a multipurpose system, which contains information about medical devices, supervising entities and economic operators (“Actors”)**

The new version of EUDAMED will consist of a public site and these 6 interconnected modules:

- Actor and user registration and management (01 Dec 2020)**
- UDI database and registration of devices (May 2021)
- Certificates and Notified Bodies (May 2021)
- Clinical Investigation and performance studies
- Vigilance and post-market surveillance
- Market surveillance

## Module 1 – Actors Registration

- The Actor Registration Module is an electronic system for the registration of the economic operators (EOs), i.e. all companies that act as
  - ✓ **MF=Manufacturer**
  - ✓ **AR +Authorized Representative**
  - ✓ **PR=System and Procedure Pack Producer (PR)**
  - ✓ **IM=Importer**
- It allows the creation of the unique single registration number (SRN) (see Art. 31(2)) and enables EOs to submit the necessary information such as Name, Address, Country, Contact Data.
- The SRN guarantees a EU-wide unique identification for EOs

### EU-based EOs

- The SRN request is being assessed and approved by the National Competent Authority in the first place and after that the SRN is issued and provided to the requesting economic operator by an EUDAMED e-mail.

### Documents to provide with the Actor Registration Request

- Declaration on information security responsibilities
- Mandate Summary document for non-EU manufacturers

## Definitions

- A **Single Registration Number (SRN)** is a unique code that is assigned to Manufacturers, Authorised Representatives or Importers after they have registered in the European Database on Medical Devices (EUDAMED).
- An **Actor** is a natural or legal person (organisation) with a specific role that has to be registered in EUDAMED.
- A **Local Actor Administrator (LAA)** is a person appointed by every Actor to manage “Actor data” and “Actor notification email addresses” that has the power to accept request from others within Actor’s organization to get access to EUDAMED. The European Commission strongly recommends having at least two LAAs.

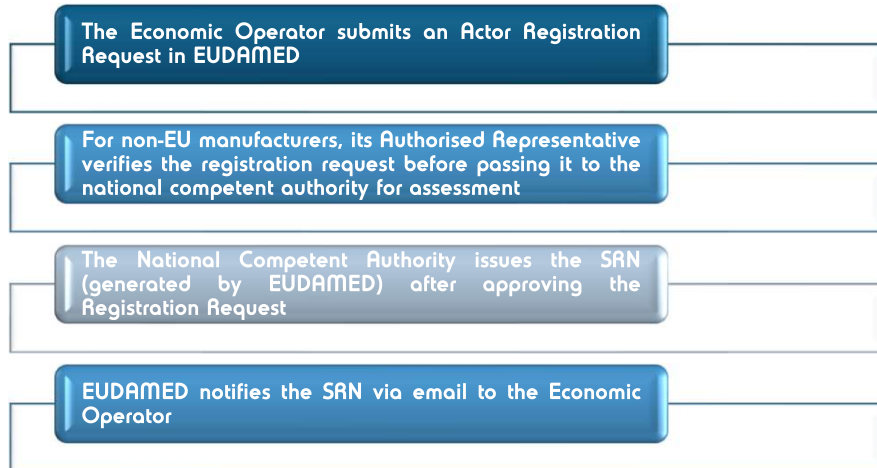
### Non-EU manufacturers

- The Authorised Representative has to verify the registration request made by the manufacturer upon submitting an Actor Registration Request, before it is passed on to the National Competent Authority. After approving the Registration Request, the responsible National Competent Authority issues the SRN and the non-EU Manufacturer is notified via an EUDAMED email as well.

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## Validation Process



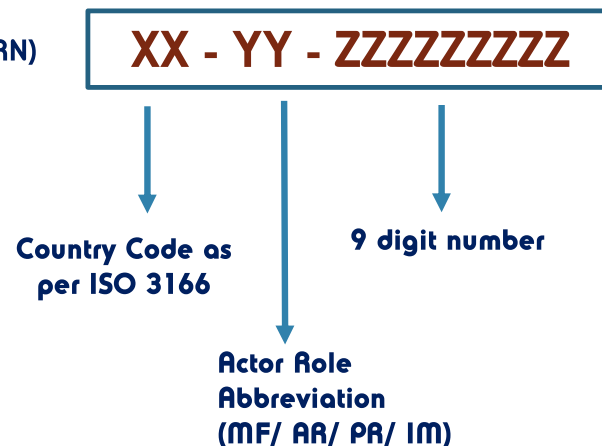
The Single Registration Number (SRN) identifies every Economic Operator in EUDAMED in a **unique** way.



The Economic Operator will receive a unique SRN for **EACH** Actor Role

**1 ACTOR ROLE = 1 SRN**

Format of Single Registration Number (SRN)



## Advantages of Early Registration

- ❑ Inclusion in relevant regulatory documentation (e.g. DoC, Technical Documentation, Certificates issued by NBs) without the need to update all later.
- ❑ The SRN guarantees an EU-wide unique identification of Economic Operators
- ❑ Registration as an Economic Operator is a **precondition** to start using the next modules of EUDAMED