



European Commission

EUDAMED

European database on medical devices

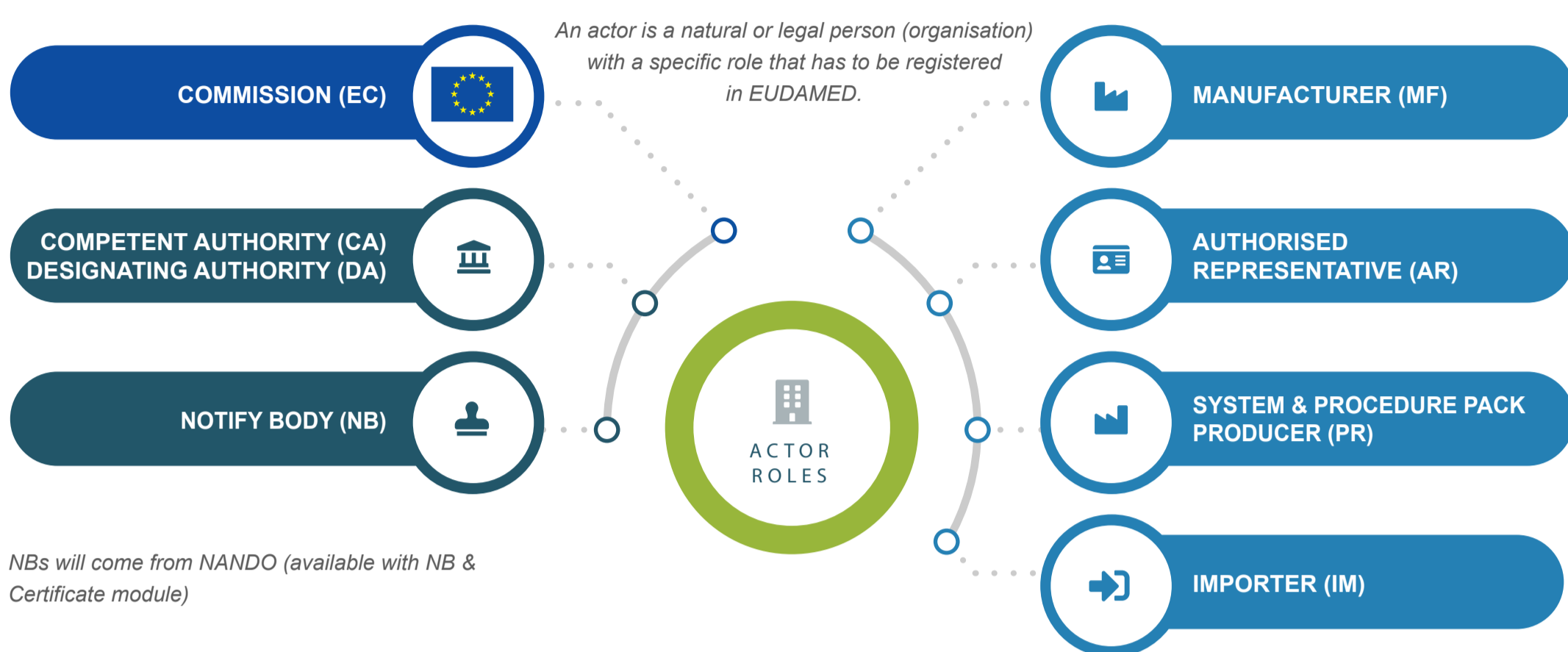
EUDAMED is the IT system that will be made of 6 modules, among which the first one is the Actor registration module, developed by the European Commission to implement **Regulation (EU) 2017/745 on medical devices** and **Regulation (EU) 2017/746 on in vitro diagnosis medical devices**.

ACTOR ROLES

What are the different Actor roles in EUDAMED?

SUPERVISING ENTITIES

ECONOMIC OPERATORS



NBs will come from NANDO (available with NB & Certificate module)

Distributors are not registered in EUDAMED

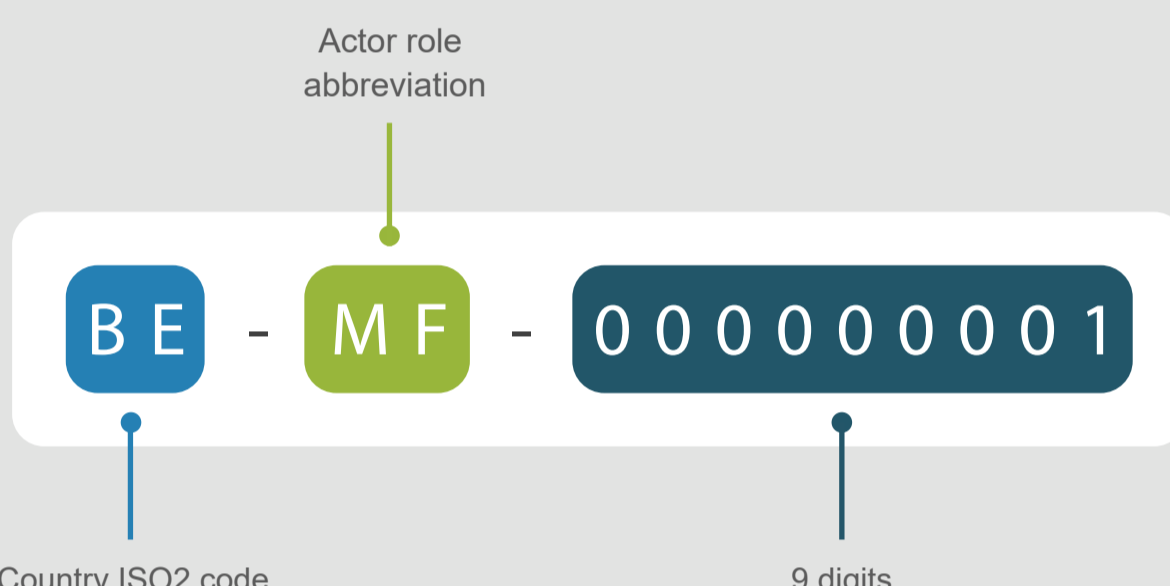


WHAT'S AN SRN?

The Single Registration Number (SRN) uniquely identifies every economic operator in EUDAMED. The SRN is issued once the relevant competent authority has validated the Actor registration request.

SRN

Single Registration Number



ECONOMIC OPERATORS

Manufacturer, Authorised representative, System & Procedure pack producer and Importer

Example for Organisation A



Organisation A is located in Belgium and acting as a:

- Manufacturer

This organisation will have to register via EUDAMED its actor for its single role. Following approval of the competent authority, its actor will be assigned as example the following SRN:

BE-MF-000000001

Example for Organisation B



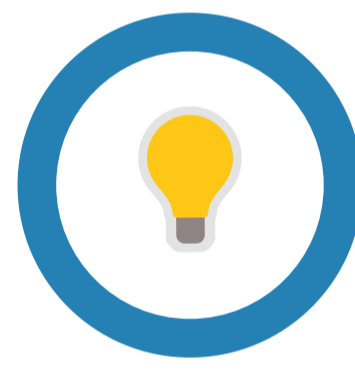
Organisation B is located in Belgium, and is acting as a:

- Manufacturer
- Importer

This organisation will have to register via EUDAMED an actor for each role of the organisation. Following approval of the competent authority, each actor will be assigned as example the following SRNs:

BE-MF-000000002
(for manufacturer actor)

BE-IM-000000003
(for importer actor)



1 ACTOR ROLE
=
1 SRN

The economic operator will obtain a unique SRN for each actor role.

If the economic operator has multiple roles, separated registration requests are required in order to obtain a different and specific SRN for each actor role.

GENERAL VALIDATION PROCESS

What's the validation process to receive an SRN



VALIDATION PROCESS

1 The economic operator submits an actor registration request in EUDAMED.

2 For non-EU manufacturers, its authorised representative verifies the registration request before passing it to the national competent authority for assessment.

3 The national competent authority issues the SRN (generated by EUDAMED) after approving the registration request.

EUDAMED notifies the SRN via email to the economic operator.

