



European
Commission

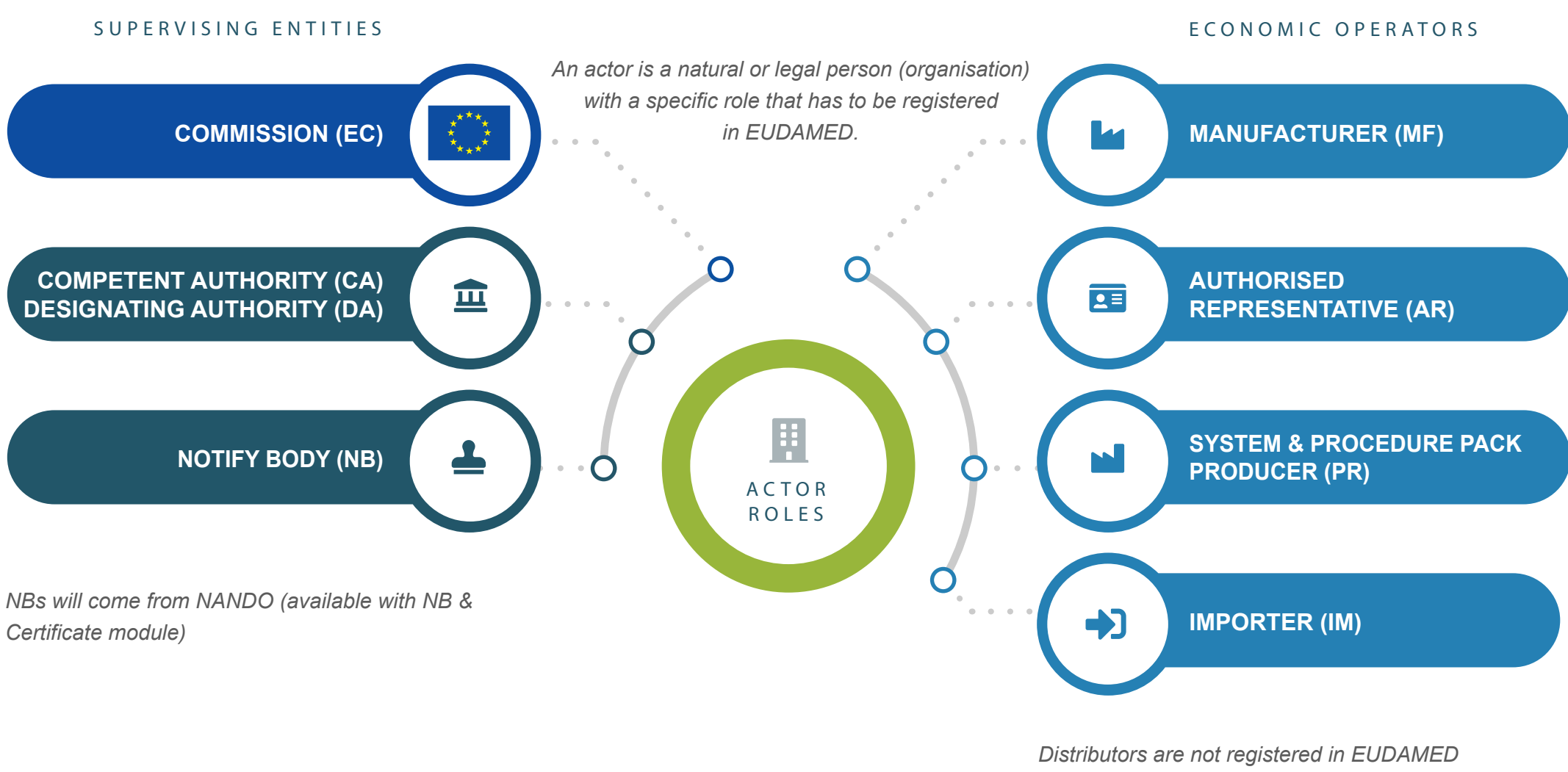
EUDAMED

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?



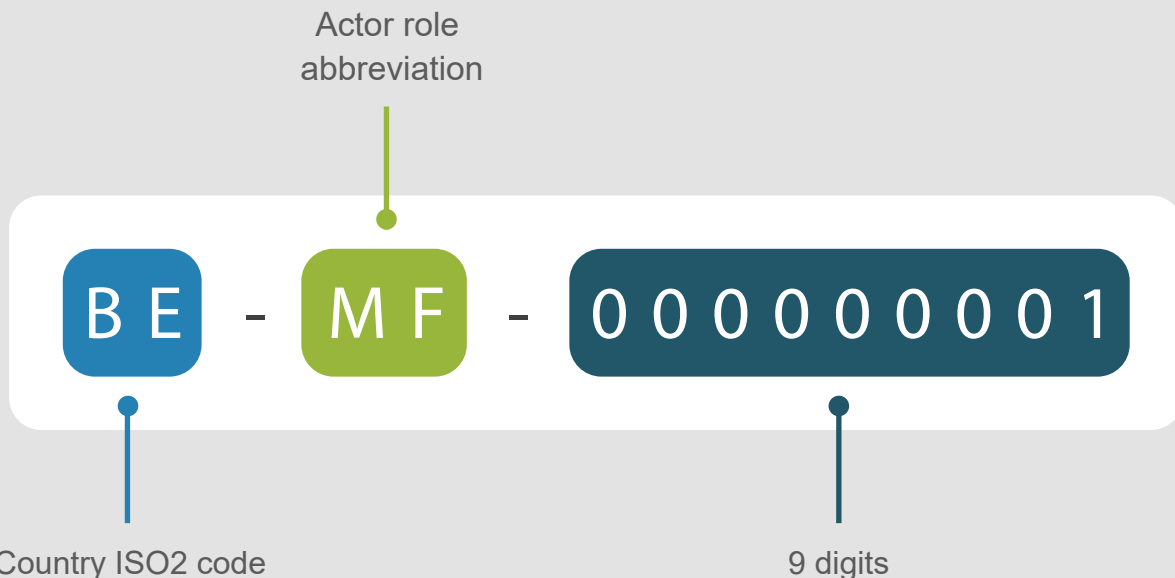
SRN

Single Registration Number

WHAT'S AN SRN?

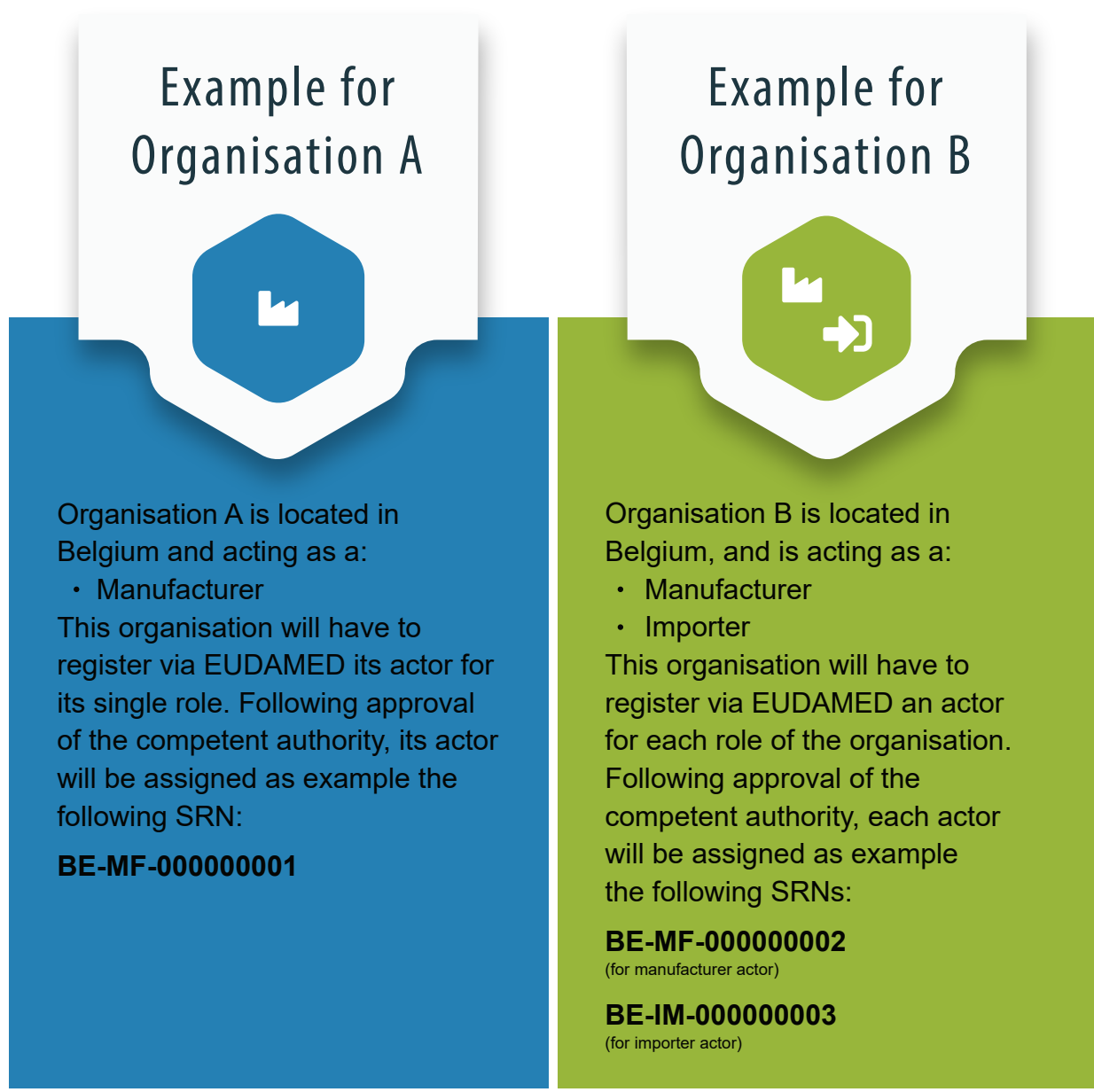
The Single Registration Number (SRN) uniquely identifies every economic operator in EUDAMED.

The SRN is issued once the relevant competent authority has validated the Actor registration request.



ECONOMIC OPERATORS

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



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



医课汇
公众号
专业医疗器械资讯平台
WECHAT OF
HLONGMED



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CONSULTING
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