



European Database on Medical Devices

## ACTOR REGISTRATION REQUEST PROCESS

FOR ECONOMIC OPERATORS EXCEPT NON-EU MANUFACTURERS

To obtain an **Actor ID/SRN**, **economic operators that are not non-EU manufacturers** (i.e. EU manufacturers, authorised representatives, system/procedure pack producers and importers) must submit an actor registration request in **EUDAMED**.





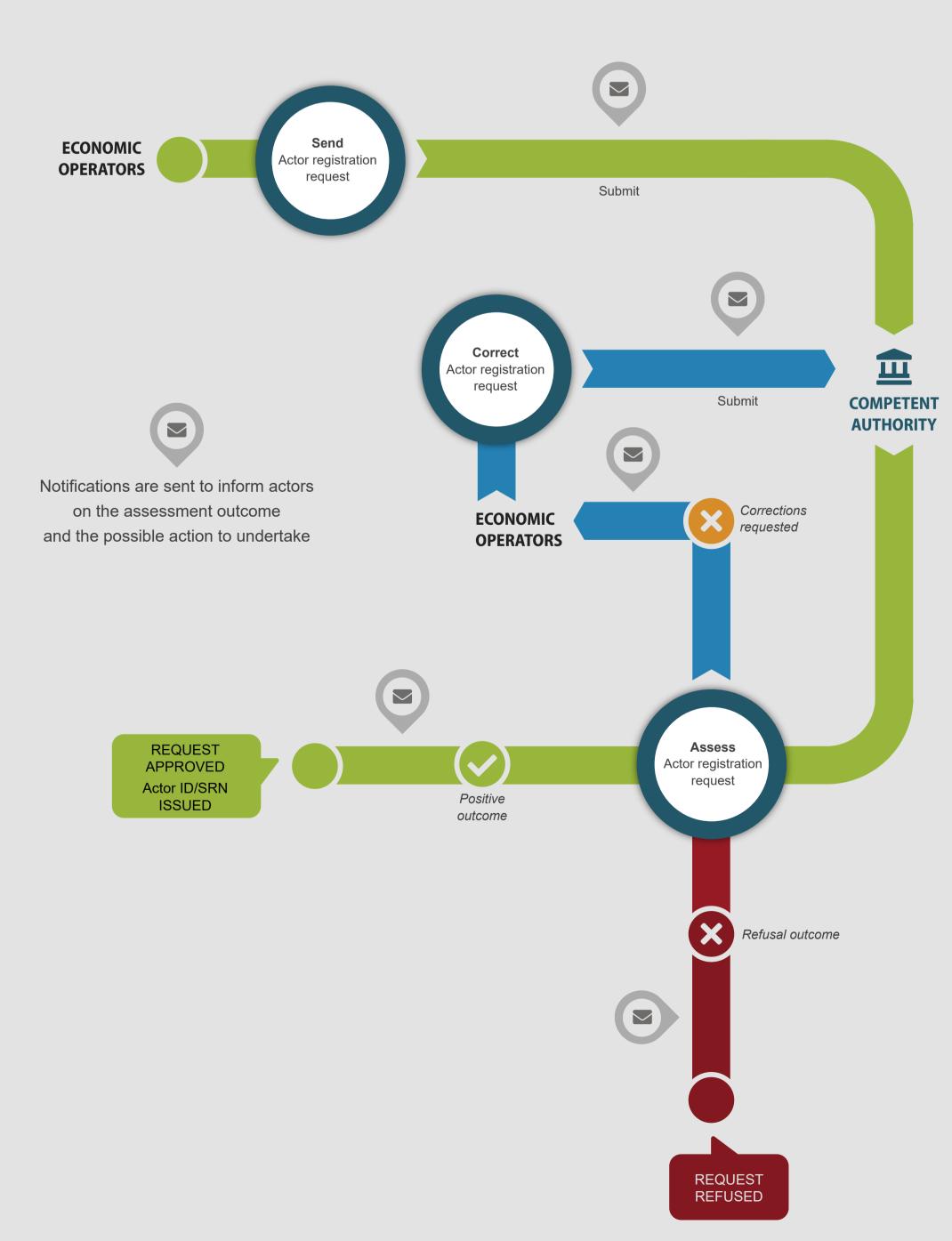
When an economic operator has submitted its actor registration request, the selected relevant competent authority issues the Actor ID/SRN (generated by EUDAMED) after approving the registration request.

EUDAMED notifies the economic operator of the Actor ID/SRN via email.

EU manufacturer, authorised representative, importer and system/procedure pack producer

## VALIDATION PROCESS AND NOTIFICATIONS

What's the validation process for an economic operator to obtain an Actor ID/SRN





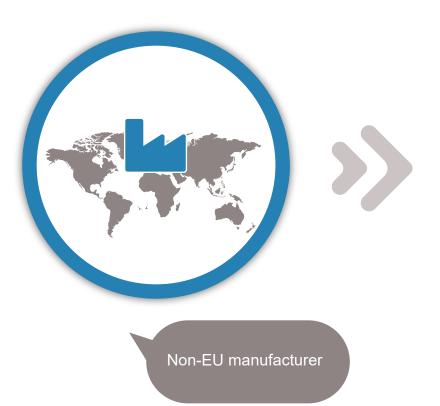


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## **ACTOR REGISTRATION REQUEST PROCESS**

FOR NON-EU MANUFACTURER

To obtain an Actor ID/SRN, non-EU manufacturers must submit an actor registration request through EUDAMED.



When a non-EU manufacturer (non-EU MF) has submitted its actor registration request, its selected authorised representative verifies the registration request before passing it to the national competent authority for assessment.

The competent authority (CA) responsible for the authorised representative issues the Actor ID/SRN (generated by EUDAMED) after approving the registration request.

EUDAMED notifies the non-EU manufacturer of the Actor ID/SRN via email.

## **VALIDATION PROCESS AND NOTIFICATIONS**

What's the validation for a non-EU manufacturer process to obtain an Actor ID/SRN

