



European Commission

EUDAMED

European database on medical devices

ACTOR REGISTRATION REQUEST PROCESS FOR ECONOMIC OPERATORS EXCEPT NON-EU MANUFACTURER

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



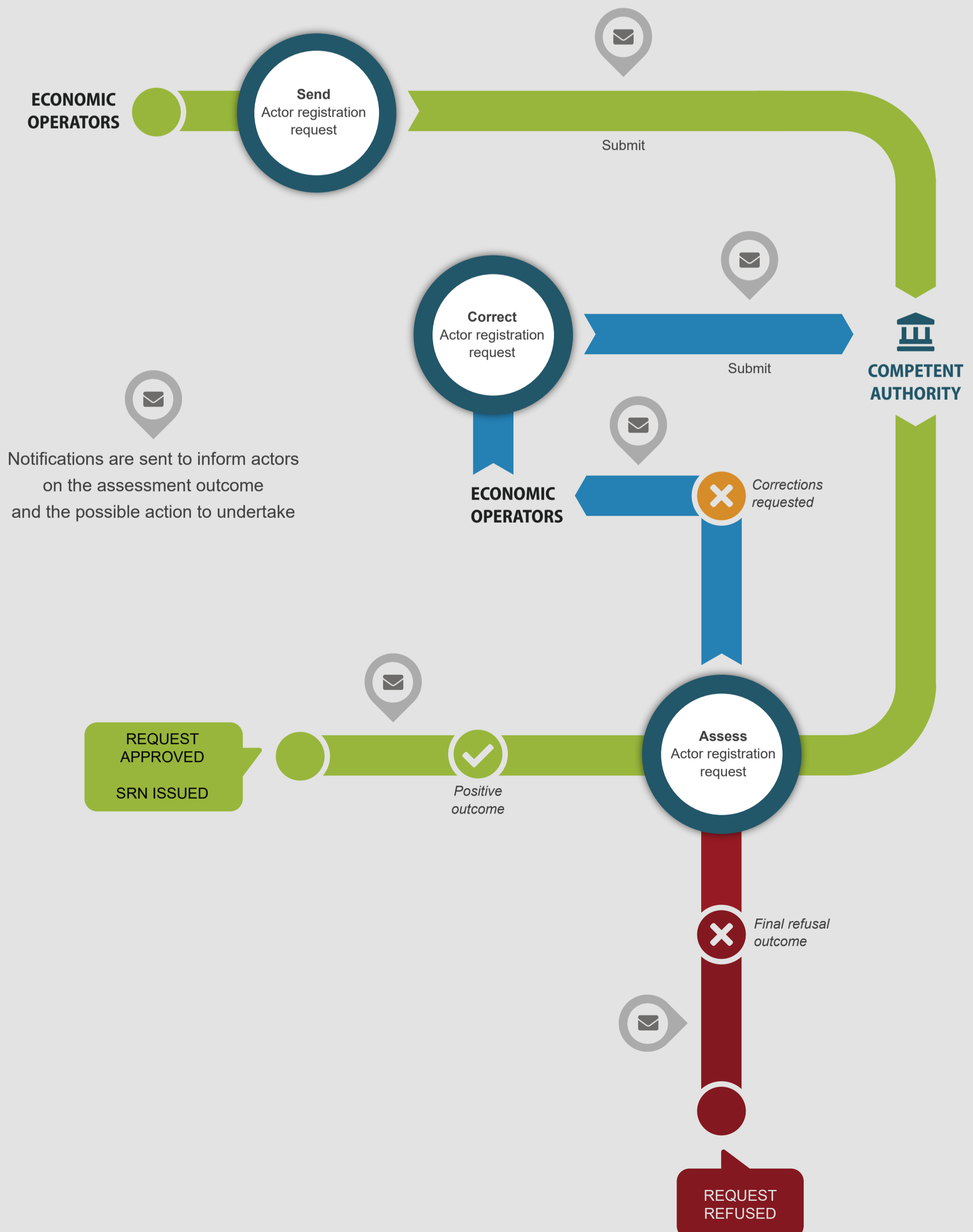
When an economic operator has submitted its actor registration request, the selected relevant national competent authority issues the SRN (generated by EUDAMED) after approving the registration request.

EUDAMED notifies the SRN via email to the economic operator.

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

VALIDATION PROCESS AND NOTIFICATIONS

What's the validation process for an Economic operator that is not a non-EU manufacturer to obtain an SRN





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ACTOR REGISTRATION REQUEST PROCESS FOR NON-EU MANUFACTURER

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



Non-EU manufacturer

When a non-EU manufacturer 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 national competent authority responsible for the authorised representative issues the SRN (generated by EUDAMED) after approving the registration request.

EUDAMED notifies the SRN via email to the non-EU manufacturer

VALIDATION PROCESS AND NOTIFICATIONS

What's the validation for a non-EU Manufacturer process to obtain an SRN

