EUDAMED

European database on medical devices

MANDATES

Each **non-EU manufacturer** must have at least **one active mandate** with an **authorised representative** established within the European Union in order to place devices on the EU market.

Moreover, the non-EU manufacturer must register itself in EUDAMED indicating an authorised representative already with a SRN and to provide some information on the mandate including a mandate summary document (A mandate in EUDAMED means a link between a non-EU manufacturer and an authorised representative).

1 As a non-EU manufacturer, enter your organisation identification data to start the Actor registration process.

2 EUDAMED will ask you to select your authorised representative already registered with an SRN in EUDAMED and upload the mandate summary document.

3 EUDAMED will then invite you to enter details about your organisation and submit the Actor registration request.

4 Your Actor registration request will be first verified by the authorised representative you have selected during the process, and assessed by the competent authority of the authorised representative.

5 The SRN is issued for your non-EU manufacturer by the competent authority through EUDAMED and the link with the authorised representative (mandate) is registered.

WHAT'S THE MANDATE SUMMARY DOCUMENT?

A PDF document containing essential and public information on the mandate including the list of generic device group(s) covered by the mandate.

The Commission makes available on its Europa website a a downloadable mandate summary template.

Afterwards, the non-EU manufacturer can add more mandates and/or update existing ones from the Mandate management page in EUDAMED and each concerned authorised representative (AR) must accept the submitted mandate information for being registered.
The AR may reject the submitted mandate.

NON-EU MANUFACTURER

How to manage my mandates as a manufacturer?

An overview of the mandates is available for the **non-EU manufacturer** in the "**Mandates management**" page which is accessible from the dashboard.

The **non-EU manufacturer** can consult the state, manage its current mandates (update or terminate) or create new mandates from this page.
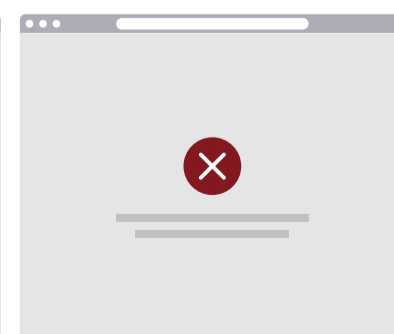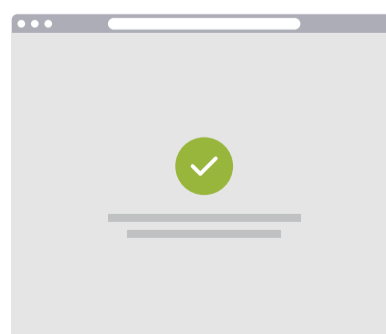
AUTHORISED REPRESENTATIVE

How to manage my mandates as an authorised representative?

An overview of the mandates is available for the **authorised representative** in the "**Mandates management**" page which is accessible from the dashboard.

On this page, the **authorised representative** can consult the list of pending mandates related to its AR and accept/reject them.

The **authorised representative** can also view the details of its related registered mandates, and terminate them, from this Mandate management page.