Instructions for economic operators on registration to the Eudamed actor module

This guideline pertains to manufacturers of medical devices established in Finland, system/procedure pack manufacturers or sterilisers thereof, authorised representatives and importers who, under Fimea Administrative Regulation 2/2021, are actors liable to submit a notification to Eudamed.

Filling out the notification

First, familiarise yourself with the Eudamed user guide for economic operators, "Actor registration module", provided by the European Commission. The user guide describes the basics of the system and how to use the Eudamed actor module. The purpose of this guideline is to provide additional clarifications on how the notification is to be filed.

Clarification to the information to be entered in Eudamed:

1. Actor identification

    a. Actor / organisation name: In the form used in the Finnish Business Information System

    - Auxiliary trade names are registered to Eudamed with a separate actor registration, and Eudamed creates a separate SRN for each auxiliary trade name

    b. VAT number: In the format FIxxxxxxxx

    c. National trade register: Business ID in the format used in the Finnish Business Information System (xxxxxxx-x)

2. Actor address

    a. Street information: As entered in the Finnish Business Information System

3. Actor contact details

    a. Non-public contact details: Enter the contact details intended for competent authorities

b. Telephone number in the format +358 xxxx

4. Regulatory persons

a. If there are several persons responsible for regulatory compliance, specify the areas they are responsible for

b. Telephone number in the format +358 xxxx

5. Registering Local Actor Administrator

a. The details of the person who was entered as the local actor administrator in the signed declaration

b. The 'Declaration on Information Security Responsibilities' attachment must be duly completed and signed

- Company name and address information in the format used in the Finnish Business Information System, role to be underlined or circled
- Details of the Local Actor Administrator, details of the same person whose details were entered in registration request step 5, Registering Local Actor Administrator

6. Competent Authority

a. Finnish Medicines Agency, Supervision and licences, Medical Device Unit

Non-EU registration to Eudamed – Guidelines for an authorised representative

1. The authorised representative first registers with Eudamed using the role authorised representative

2. The authorised representation verifies the non-EU manufacturer's registration request before the registration request is submitted to the competent authority for validation

3. The mandate summary document (Mandate Summary document) is uploaded with the registration request

If you need further information, send e-mail to laiterekisteri@fimea.fi.