EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Medical devices

Expression of interest form for the coordinated assessment pilot procedure

CLINICAL INVESTIGATIONS UNDER MDR

To be filled out by the sponsor or the legal representative.

Application title

Please provide a title and short description of the clinical investigation.

1. Sponsor information

- **Name of sponsor/legal representative**: [name]
- **Address**: [sponsor's address]
- **Name of the main contact point for the coordinated assessment pilot procedure**: [name of contact person]
- **Email**: [contact person's email]
- **Phone number**: [contact person's phone number]
- **Name of the manufacturer**: [name]

2. Study details:

- **Objective**: [objective of the Investigation]
- **Study design**: [brief description of study design]
- **Population**: [target population]
- **Duration**: [estimated number of months from start date to end of trial)

3. Device description

- ❑ **Main investigational device risk-class III**
- ❑ **Main investigational device risk-class IIb invasive**
- ❑ **Main investigational device risk-class IIa invasive**

- **Name of the device**: [device name]
- **Intended use**: [intended use of the device]
- **Description**: [brief description of the device]
- **Combined study with a medicinal product**: [yes/no]

4. Member States involved

- **Proposed coordinating Member State**: [name of the proposed coordinating Member State]
- **Other Member States involved**:
  - [Member State 1]
  - [Member State 2]
  - [Member State 3]
  - [Add as necessary]

❖ Please consult the list of available Member States for the pilot coordinated assessment.

5. Desired timing for submission to Competent Authorities for the coordinated assessment pilot procedure: [week (if known), month, year]

The secretariat can be contacted at SANTE-CA-CIPS@ec.europa.eu.

By submitting this document, the information provided will be collected, processed, and stored in compliance with the Regulation 2018/1725 ("EUDPR"). You can consult the privacy statement below.

MDR
Eudamed_PrivacyStat

Date: