Action grant to support increased capacity of notified bodies for medical devices

INFORMATION SESSION

FIRST WAVE OF OPEN CALLS FOR ACTION GRANTS

10 March 2022

Main Objectives

With reference to implementation of the medical devices Regulations (MDR/IVDR),

1. Increase capacity of notified bodies, and
2. Increase preparedness of market operators, in particular SMEs

With the overall purpose to ensure availability of medical devices in the EU market in the medium to long term

Activities (1/4)

Supporting **training, coaching and internship activities** addressed to medical devices' **notified bodies** as well as third-party entities (**conformity assessment bodies**) on the process to become a notified body for medical devices

Mandatory deliverables:

- At least two training sessions/year
- Updated list of existing/potential new notified bodies
- Internship activities to be performed at within a manufacturer (in the design, manufacture or testing of devices)

Activities (2/4)

Capacity building activities such as **webinars, workshops, targeted feedback and informative sessions** addressed to **market operators** (especially SMEs manufacturers of medical devices, including *in-vitro* diagnostics medical devices)

Mandatory deliverables:

- At least two training sessions/year with a minimum of 50 participants each

Activities (3/4)

Appraisal of the **certification demand**, with the objective to identify the **types of devices** for which availability of notified bodies is particularly low or lacking

Mandatory deliverables:

- Manufacturers' surveys as soon as the action starts, updates depending on needs
- Inclusion of both EU and non-EU manufacturers as well as SMEs
- Coverage of manufacturers of all different types of medical devices (codes listed in Regulation 2017/2185)

Activities (4/4)

Proposing solutions to facilitate **matching the demand of market operators with the availability of notified bodies**, in particular in the area of IVDs where SMEs are prominent

Mandatory deliverables:

- Including a proposal for a mechanism to gather information from notified bodies on their availability to certify medical devices.

Action-level indicators for reporting purposes

- List of manufacturers involved
- List of existing and potential new notified bodies
- Number of training, coaching and internship sessions developed
- Number of people and entities attending capacity building activities
- Number of new potential MDR and IVDR notified bodies (i.e. applicant notified bodies)
- Number of certifications requests received by the notified bodies
- Additional action-level indicators to be agreed with the Commission during the grant agreement preparation

Thank you

European Commission