COCIR WEBINAR

COUNTDOWN TO THE MEDICAL DEVICE REGULATION

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SAVE THE DATE

Wednesday 17 February 2021

14:00 - 16:00 BRUSSELS TIME (CET)

The last year has been tumultuous for the Medical Device Regulation. Implementation was severely impacted by COVID-19, resulting in the postponement of the Date of Application. With little more than three months to go until 26 May 2021, the aim of this virtual session is to build awareness on the latest progress made towards the implementation of the Regulation and discuss the last steps necessary to ensure continued supply of safe medical devices to the European market.

The event is open to anybody involved and interested to learn more about the latest developments in the implementation of the Medical Device Regulation. It is a great opportunity to openly discuss any last questions or unsolved issues with experts in the field, including representatives of the European Commission, Competent Authorities, Notified Bodies, and manufacturers.

WHO SHOULD ATTEND?

This event is intended for all interested actors in the regulatory system for medical devices: manufacturers of medical devices and medical software, including SMEs, who are in the process of compliant to the forthcoming Medical Device Regulation, Notified Bodies, representatives of healthcare delivery organisations and Competent Authorities.

WHY SHOULD YOU ATTEND?

- Gain insight into the latest developments in the MDR implementation process
- Discuss specific questions with industry experts, regulators, Notified Bodies and other stakeholders
- Understand what companies still need to do to prepare and get ready

DRAFT AGENDA

14:00 - 14:05 **Welcome and Introduction** (Nicole DENJOY, COCIR Secretary General)

14:05 - 15:00 **PART 1** STATE-OF-PLAY OF MDR IMPLEMENTATION

- **Overview of the MDR implementation status** (Erik HANSSON, Deputy Head of Unit, DG SANTE, European Commission)
- **View of hospitals on MDR implementation** (Paul GARASSUS, UEHP President)
- **MDR Readiness – The industry perspective** (Philippe LARTIGUE, COCIR EU RA Focus Group Chair & GE Healthcare)
- **Interactive discussion with participants**

15:00 - 15:50 **PART 2** EXPERIENCES WITH MDR AUDITS

- **MDR Implementation - An EU member state view** (Thomas WEJS MØLLER, CAMD Chair)
- **MDR audits from the Notified Body perspective** (Suzanne HALLIDAY, NBCG-MED Co-Chair)
- **Industry experiences in MDR audits** (Philippe SOLY, COCIR EU RA Focus Group Co-Chair & Philips)
- **Interactive discussion with participants**

15:55 - 16:00 **Concluding remarks** (Nicole DENJOY, COCIR Secretary General)

COCIR, the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry