MDR is now

Program:

08:30 – 09:00 Registration

09:00 - 10:00 MDD versus MDR

- Manufacturers and Notified Bodies, what can we all expect?
- Technical overview MDR
- Emphasizing the need for different views of clinical aspects – the theory
- Overview over guidance documents

10:00 – 10:30 Break

10:30 - 12:00 Workshop and presentation: Corona virus versus regulation

This part will require active contributions of all participants.

- Don't wait, strive for the MDR full power
- Clinical safety and performance aspects -- the practical approach
- UDI and EUDAMED – a status report
- Practical tips -- audits during lock down, software for archiving and electronical signature, lifetime versus stability and much more

12:00 – 12:30 Break

12:30 - 13:15 Panel discussion Q&A

13:15 - 14:00 Devices which undergo up classification under MDR

- Definition
- Regulatory timelines
- Clinical and safety aspects
- Which certification strategy to choose?

14:00 – 14:30 Break

14:30 - 15:30 Economic operators in the EU

- Strategy questions
- Manufacturer or distributor
- How do I build my supply chain in times of corona?
- Content of contracts and quality agreements

15:30 Networking

EVROPSKÁ UNIE
Evropské strukturální a investiční fondy
Operační program Výzkum, vývoj a vzdělávání

MINISTERSTVO ŠKOLSTVÍ, MLÁDEŽE A TĚLOVÝCHOVY

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