

Meet with ZWIERS!

# DeviceDay 7DEC2023

- **Full day** course
- Basics and **more**
- Examples and **interaction**
- **Certificate** included



## MORNING PROGRAM

### Meet with Zwiers!

Introduction to Zwiers, and each other...

### The MDR routes and requirements

Overview of conformity assessment routes and technical documentation

### Biological safety evaluation: characterise, categorise and test for compatibility

Explanation of ISO 10993, material characterisation, tests, plan and reports  
+ hands-on examples and DYI

## AFTERNOON PROGRAM

### Showing (sufficient) clinical evidence for safety and performance

Explanation of strategic clinical data generation incl. literature, benefit-risk analysis for clinical evaluation

### Risk management: the challenge of controlling hazards and harms

Explanation of ISO 14971, risk assessment methods, risk reduction and control  
+ hands-on examples and DYI

### Informative & informal interaction

Summarizing remarks, Q&As followed by drinks

**Oss offices  
Certificate  
€595,- fee  
Including lunch & drinks**