

# Implementation of the MDR for CE Marking

## Day 1

08.30 – 09.00 **Registration and breakfast**

09.00 – 09.10 **Welcome by Medicoindustrien**

09.10 – 16.30 **General obligations**

- Who is responsible?
- Items for technical documentation
- Conformity assessment

### **Scope of the MDR**

- Relation of the MDR to other Union legislations
- Definition: Medical device and accessories

### **Determine risk class and applicable 'NBOG' codes**

- Applying the rules
- Different codes for medical devices

### **Select conformity assessment procedure**

- Quality system assessment

### **Amend and maintain QMS**

- ISO 13485: A stairway to MDR

**Identify applicable safety and performance requirements**

**Day 1 review and questions**

**Day 2**

08.30 – 09.00 **Breakfast**

09.00 – 17.00 **Identify applicable safety and performance requirements ... continued**

- How long must devices stay safe and effective?
- Risk management process
- Demonstration of conformity
- Labelling

**Assemble Technical Documentation**

- Use of symbols for information
- Pillars of the technical documentation
- Content of a technical documentation under MDR
- Good Laboratory Practice (GLP)
- Clinical evidence and development plan
- Clinical investigation report

**Apply conformity assessment procedure**

**Day 2 review and questions**

**Day 3**

08.30 – 09.00 **Breakfast**

09.00 – 16.30 **Apply conformity assessment procedure ... continued**

- Submission of technical documentation
- Surveillance of technical documentation
- Evaluation of changes
- Strategy for regulatory compliance (concept)

**Assign Unique Identifications**

- European database on medical devices
- Difference in meaning
- Dealing with EUDAMED

**Complete DoC (Declaration of Conformity) and affix CE mark**

- Statements for devices
- CE mark

**Post Market Surveillance (PMS)**

- Plans needed for the MDR
- Periodic Safety Update Report (PSUR)
- Summary of Safety and Performance (SSCP)
- Alarming issues
- Lines of communication
- Vigilance reporting

**Recap and transition arrangements & review of course and final questions**

**Breaks**

Lunch from 12-13

Coffee breaks