MEDICO INDUSTRIEN
MEDTECH DENMARK

Technical Documentation for Medical Devices According to the MDR

08.30 – 09.00	**Registration and breakfast**
09.00 – 09.10	**Welcome by Medicoindustrien**
09.10 – 10.30	**Technical documentation: Conformity assessment, overview and contents MDR Annex II:** • Section 1: Device description and specifications, including variants and accessories • Section 2: Information to be supplied by the manufacturer • Section 3: Design and manufacturing information
10.30 – 10.45	**Coffee break**
10.45 – 12.00	**Technical documentation: Conformity assessment, overview and contents MDR Annex II:** • Section 4: General safety and performance requirements • Section 5: Benefit-risk analysis and risk management • Section 6: Product verification and validation
12.00 – 13.00	**Lunch**
13.00 – 14.00	**Technical documentation: Conformity assessment, overview and contents MDR Annex III:** • Section 1: Technical documentation on post-market surveillance
14.00 – 15.00	**Technical documentation: Conformity assessment, overview and contents MDR Annex XIV:** • Part A: Clinical evaluation • Part B: Post-market clinical follow-up
15.00 – 15.15	**Coffee break**
15.15 – 16.00	**Technical documentation: Conformity assessment, overview and contents MDR Annex IV: Declaration of conformity**

16.00 – 16.30	**Technical documentation summary**
16.30 – 16.50	**Guidance documents: Technical documentation structures**
16.50 – 17.00	**Wrap up and conclusions**