Implementation of the IVDR for CE Marking

08.30 – 09.00 **Registration and breakfast**

09.00 – 09.10 **Welcome by Medicoindustrien**

12.00 – 13.00 **Lunch**

The course will end at 17:00 on day 1,2 and 3.

Day 1:

Topic
Benefits to you, welcome and introductions
Boundaries: Conflicts of interest and expertise
Course aims, objectives and structure
What is an IVD?
Background to EU and CE marking • Journey to IVD Regulation
Responsibilities • Economic operators • Person responsible for regulatory compliance • Notified bodies • Competent authorities • Others in supply chain
Placing on the market • Putting into service
Harmonized standards and common specifications
CE mark
Risk based classification
Conformity assessment

• Routes of Conformity • Certificate scopes • Certificates issued under Annexes • EU reference laboratories • Companion diagnostics
Notified bodies and scrutiny • Unannounced audits
Reflection and feedback
Close of day

Day 2

Topic
Welcome to day 2
Case study business case
GSPRs • GSPR Trace Matrix • Risk Management • EN ISO 14971:2012
Performance evaluation, clinical evidence and post market performance follow up • General requirements for performance studies • Clinical evidence, performance evaluation, scientific validity and analytical performance • Performance evaluation plans and reports • Summary of safety and performance • Interventional and special clinical studies
Post-market surveillance and vigilance reporting • Post market activities and post market surveillance • Vigilance reporting
End of day 2

MEDICO INDUSTRIEN
MEDTECH DENMARK

Day 3

Topic
Welcome to day 3
Case study regulatory strategy
Technical documentation • Demonstration of conformity • Technical file review
Product claims and labelling • Claims • Labelling • Symbols • Safety data sheets
EUDAMED and registration • Annex VI Registration • Unique Device Identifier (UDI)
Process validation and supplier control • Validation versus verification • Process validation in the IVDR • Validation planning • What the notified bodies will be looking for • Control of suppliers • Significant changes
Other Directives and Regulations
Case study: Product strategy
End of course