

SOFTWARE training by



AIM

This training is aimed to help notified bodies deal with new software requirements in their assessments.

This will be supported by focused discussions during the cases study sessions.

The following topics will be covered:
Basic requirements of the MDR at the light of the guidances including classification, cybersecurity, artificial intelligence.

WHEN ?

First 2 sessions:
Thursday, February 4th
and
Tuesday, February 23rd
09.00—17.00 CET

3rd & 4th sessions :
Thursday, March 3rd
and
Tuesday, March 15th
09.00—17.00 CET

HOW / WHERE ?

Remotely

LANGUAGE

English

The training is organized in groups of maximum 20 persons to ensure a good level of exchange.



PROGRAM

9.00 to 09.30

Welcome of participants and tour de table

9.30 to 10.45

Basic requirements of the MDR

An introduction including software qualification and classification in the light of guidance

by Fiona Dunn(BSI)

10.45 to 11.00 — Morning break

11.00 to 12.15

Cybersecurity

Basic overview, General safety and performance requirements, Risk evaluation

by Christoph Sturm (TÜV Rheinland)

≈ Lunch ≈

13.30 to 14.45

Artificial intelligence (AI)

More and more medical devices use AI and machine learning (ML) to perform or support medical applications. Despite the risks associated with the use of AI, common standards and regulations do not yet include specific requirements addressing these innovative technologies in medical field. In this talk common risks, pitfalls and major issues with AI are discussed including a short outlook to the upcoming regulations

by Abtin Rad (TÜV Süd)

14.45 to 15.00 — Afternoon break

15.00 to 16.30

Case studies

in 3 rotating sub-groups (exchanges - presentation - adjustments and harmonisation)

16.30 to 17.00

Closing session

- Summary of main elements
- Feedback and suggestions

REGISTRATION FEE

- 1500 Euros / person for non members
- 250 Euros / person, for Team-NB members **only**

The fee includes the participation to an on-line MCQ to prove Continuing Professional Development. Depending on results a certificate or an attestation will be delivered.

REGISTRATION

Send an email to assistant@team-nb.org with participant information (name & email)

PAIEMENT

The receipt of the paiement will confirm the registration of the participant.

Team-NB Account - IBAN n°: BE09 340 1 5174 8757
SWIFT code : BBRUBEBB

INVOICE

The sent of an invoice will be done (please mention your VAT number).