MDR Technical Documentation Training for Manufacturers

AIM

The MDCG Position Paper Transition to the MDR and IVDR (MDCG 2022-14) encourages notified bodies to strengthen the communication with manufacturers by means of webinars, workshops, targeted feedback and informative sessions.

The aim of this training is to review the MDR requirements related to Technical Documentation and share notified bodies insights; it is also planned to review the Team-NB Technical Documentation Best Practice document for MDR (version 2—published on April 24th, 2023).

The topics are presented by MDR experts of designated notified bodies.

The content was elaborated by MDR experts of 9 notified bodies, namely **BSI, CeCertiso, Dekra, DNV, ECM, GMED, SGS, TÜV Rheinland**, **TÜV SÜD.**

WHEN ?

Wednesday
2024, March 27th
9:00-17:00 CET

WHERE ?

Remotely

LANGUAGE

English

PARTICIPANTS

limited to 50 organisations with up to 2 connections of staff member

Priority for SMEs registration (25 places reserved) until February 26th

In case we reach the limit, an additional session will be programmed in the coming months.

PROGRAM

9.00 to 9.30 Welcome and logistic information

9.30 to 10.15

1. Structure of Technical Documentation

Introduction to Team-NB BPG for MDR Technical Documentation with focus on documents or information commonly missing or unclear in the technical documentation.

Q&A session

≈ Morning break ≈

10.30 to 12.00

2. MDR Annex II Sections 1-3

Common nonconformities found with the device description and specification, information to be supplied by the manufacturer and design and manufacturing information.

Q&A session

≈ Lunch ≈

13.15 to 14.45

3. MDR Annex II Sections 4-6 (excluding clinical data)

Common nonconformities found with demonstration of conformity with the GSPRs, benefit-risk and risk management, and pre-clinical data.

Q&A session

≈ Afternoon break ≈

15.00 to 16.30

4: MDR Annex II Section 6 (clinical data) and Annex III (post-market surveillance)

Common nonconformities found with clinical data and post market surveillance.

Q&A session

16.30 to 17.00 Closing session

With last questions, feedback and suggestions.

REGISTRATION FEES

900 Euros / organisation
for up to 2 persons max.

Reduction for EU-SMEs
(SME EU assessment report to be sent)

450 Euros / organisation
for up to 2 persons max.

The fee includes

- the release of a Certificate of attendance (delivered on request) and
- the presentations in pdf format which will be sent to the participants after the training

REGISTRATION

Fulfill the form accessible at the address :

www.team-nb.org/ManufacturerTraining

PAYMENT

The receipt of the payment will confirm the registration of the participant.
Team-NB Account - IBAN n°:
BE09 340 1 5174 8757
SWIFT code : BBRUBEBB

INVOICE

An invoice will be provided (please mention your VAT number)