

TECHNICAL DOCUMENTATION training by



AIM

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

Another purpose is to achieve a better harmonisation among notified bodies thanks to the exchanges that will be favored especially during the cases studies sessions.

The trainings are organized in groups of maximum 20 persons to ensure a good level of exchange.

WHEN ?

- ◇ September 29th & 30 2020
- ◇ January 13th 2022
- ◇ January 25th 2022
09.00—17.00 CET

WHERE ?

Remotely

LANGUAGE

English



PROGRAM

9.30 to 11.00

Annex II - 3 first sections, namely
by Martin Witte (TÜV SÜD)

- Device description and specification, including variants and accessories
- Information to be supplied by the manufacturer
- Design and manufacturing information

11.10 to 12.40

Annex II - 3 last sections, namely
by Tatiana Vignudelli (Entecerma)

- General safety and performance requirements
- Benefit –risk analysis and risk management
- Product verification and validation

≈ Lunch ≈

13.20 to 14.35

Sampling

Depth of review,

Ask good questions &

Issuing non-conformities

by Sharmila Gardner (BSI)

14.45 to 17.15

Case studies

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

17.15 to 17.30

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).