

# Technical Documentation for IVDR (including Performance Evaluation) training by



## AIM

**This training is aimed to help notified bodies deal with new requirements for Technical Documentation and performance evaluation for IVDs when conducting conformity assessment and to develop alignment between notified bodies in our approach to Technical Documentation and performance evaluation assessment. This will be supported by focused discussions during the cases study sessions.**

## **The following topics will be covered:**

Comparison IVDD – IVDR including expert panel consultation. Guidance, templates, ISO 20916 related to performance. How to assess performance evaluation documentation?

## WHEN ?

2 sessions:  
October 28th;2021  
09.00—17.00 CET

December 1st;2021  
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**

***Comparison IVDD – IVDR including expert panel consultation.***

This section will give an overview of the main differences between the IVDD and IVDR regarding Technical Documentation including performance evaluation and will cover the additional requirements that manufacturers must meet under the IVDR.

***by Nick Baker (DNV)***

**10.45 to 11.00 Morning break**

**11.00 to 12.15**

***Guidance, templates, ISO 20916 related to performance.***

This part will include a review of existing and/or future guidance documents that can be used by manufacturers to fulfil IVDR requirements with regard to Technical Documentation including Performance Evaluation.

***by Marta Carnielli (TÜV SÜD)***

**≈ Lunch ≈**

**13.30 to 14.45**

**How to assess IVD Technical Documentation?**

This session will address how to approach Technical Documentation reviews in general in the frame of conformity assessments, with special focus on the respective performance parts and underlying competencies required by the assessor(s).

***by Sven Hoffmann (TÜV Rheinland)***

**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](mailto: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).