



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 IVDR 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 IVDR (currently in preparation, expected completion Q1 2023).

The topics are presented by IVD experts of IVDR designated notified bodies.

The content was elaborated by IVD experts of 7 notified bodies, namely BSI, Dekra B.V., Dekra GmbH, GMED, NSAI, TÜV Rheinland LGA and TÜV SÜD.

WHEN ?

Wednesday,

June 14th

9:00-17:00 CET

WHERE ?

Remotely

LANGUAGE

English

PARTICIPANTS

limited to

40 organisations with up to 2 connections of staff member

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



PROGRAM

9.00 to 9.30 Welcome

9.30 to 10.45 The (pre) application phase :

Structure of a TD file, NB code assignment, classification, creation of sampling groups.

Q&A moderated IVD expert

≈ **Morning break** ≈

11.00 to 12.15 Directive to Regulation data :

Completion of a gap assessment, tips & tricks, state of the art concept.

Q&A moderated IVD expert

≈ **Lunch** ≈

13.30 to 14.45 Performance Evaluation :

How to demonstrate Performance Evaluation

Q&A moderated IVD expert

≈ **Afternoon break** ≈

15.00 to 16.15 Clinical Evidence and Post Market Surveillance :

IVDR requirements & NB insights

Q&A moderated IVD expert

16.15-17.00 Closing session

- Summary of main elements
- 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

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

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)