



# IVDR 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 V.2 (published on September 3<sup>rd</sup> 2025).

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 ?

July 2<sup>nd</sup> 2026

09.00 — 17.00 CET

## HOW / WHERE ?

Remotely

## LANGUAGE

English

## PARTICIPANTS

limited to 50

organisations with up to 2 connections of staff member

*Prerequisite : Expert*

*members of a*

*Manufacturer's clinical team*

*Priority for*

*SMEs registration (25 places reserved) until April 24<sup>th</sup>*

*In case we reach the limit, an additional session will be organised*



## PROGRAM

**09.00 to 09.20** Welcome of participants

**09.20 to 10.30**

### The (pre) application phase

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

***Q&A moderated IVD expert***

*≈ Morning break ≈*

**10.45 to 11.45**

### Directive to Regulation data

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

***Q&A moderated IVD expert***

*Lunch break ≈*

**12.45 to 14.10**

### Performance Evaluation

How to demonstrate Performance Evaluation.

***Q&A moderated IVD expert***

*≈ Afternoon break ≈*

**14.25 to 15.30**

### Post market surveillance and PMPF

IVDR requirements & NB insights.

***Q&A moderated IVD expert***

**15.30 to 16.20 IVD Medical Device Software**

The specificities of the Technical Documentation of IVD Medical Device Software and AI.

**16.20 to 17.00 Closing session**

- Summary of main elements
- Last questions
- Feedback and suggestions

## REGISTRATION FEE

1200 Euros / organisation for up to 2 persons max.

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

600 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](http://www.team-nb.org/ManufacturerTraining)

## INVOICE

An invoice will be sent to companies registered on the website after the deadline for priority registration of SMEs.

## PAYMENT

The receipt of the payment on the basis of the invoice sent will confirm the registration of the participant.