

LIST OF BEST-PRACTICE GUIDANCE DOCUMENTS FOR IVDR NOTIFIED BODY SUBMISSIONS

This document provides a list of best-practice guidance and standards relevant to preparing for conformity assessment under the EU IVDR. Adopting the templates and approaches described in the state of the art guidance below is strongly recommended, as they help assure the highest standards of device safety while supporting a more efficient and predictable certification process.

GUIDANCE BY TOPIC

- Common specifications and harmonised standards
- Device qualification and classification
- Conformity assessment processes under the IVDR
- Transitional provisions for legacy devices
- Device categorization and traceability
 - Notified body competence codes
 - European Medical Device Nomenclature (EMDN)
 - Unique Device Identification (UDI)
- Quality management and related processes
 - Quality Management Systems
 - Risk Management
- Technical documentation
 - Structure and contents of technical documentation
 - Labeling
- Performance evaluation
 - Clinical Evidence
 - Conduct and administration of IVDR performance studies
 - Scientific Validity
 - Analytical Performance
- Post-Market Surveillance (PMS) and vigilance
- IVD medical device software

DISCLAIMER

Links are provided to all publicly available documents. For licensed materials, such as standards published by ISO or CLSI, please obtain official copies through authorized vendors or distributors. The references provided are intended solely as informational resources. Their inclusion does not imply a legal obligation to adopt the approaches described, nor should they be interpreted as conferring a presumption of conformity with the In Vitro Diagnostic Medical Devices Regulation (IVDR), unless explicitly stated. Manufacturers remain fully responsible for evaluating the relevance, applicability, and regulatory alignment of any referenced materials for their specific products and obligations under the IVDR.

COMMON SPECIFICATIONS AND HARMONISED STANDARDS

Where common specifications relevant to a device are present, they must be followed. Application of harmonised standards is not compulsory but strongly recommended, as they carry a presumption of conformity with the relevant IVDR requirements.

EU Regulation setting out Common Specifications for certain high-risk in vitro diagnostic medical devices under the IVDR

[Commission Implementing Regulation \(EU\) 2022/1107 of 4 July 2022 laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation \(EU\) 2017/746 of the European Parliament and of the Council](#)

List of international standards harmonised under the IVDR

[Regulation \(EU\) 2017/746 on In vitro diagnostic medical devices \(xlsx file\)](#)

DEVICE QUALIFICATION AND CLASSIFICATION

MDCG guidance on qualification of in vitro diagnostic medical devices

[MDCG 2024-11 Guidance on qualification of in vitro diagnostic medical devices](#)

MDCG guidance on classification of in vitro diagnostic medical devices

[MDCG 2020-16 rev.4 Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation \(EU\) 2017/746](#)

MDCG manual of Competent Authority consensus opinions on device qualification and classification under the MDR and IVDR

[Manual on borderline and classification for medical devices under Regulation \(EU\) 2017/745 on medical devices and Regulation \(EU\) 2017/746 on in vitro diagnostic medical devices](#)

CONFORMITY ASSESSMENT PROCESSES UNDER THE IVDR

Team-NB consensus paper on the IVDR certification process

[IVDR Certification Process \(including Pre-application, Application and Post Application phases\) – Consensus document](#)

Summary of the SGS NB1639 certification process under the IVDR

[SGS EU IVDR Information Center](#)

TRANSITIONAL PROVISIONS FOR LEGACY DEVICES

European Commission Q&A on the extended IVDR transitional period

[Q&A on practical aspects related to the implementation of the extended transitional period provided for in the IVDR, as amended by Regulation \(EU\) 2024/1860 of 13 June 2024 \[...\]](#)

Guidance on significant changes for legacy devices during the IVDR transitional period

[MDCG 2022-6 Guidance on significant changes regarding the transitional provision under Article 110\(3\) of the IVDR](#)

DEVICE CATEGORIZATION AND TRACEABILITY

NOTIFIED BODY COMPETENCE CODES

EU regulation listing competence codes describing the scope of designation of notified bodies under MDR and IVDR, and which are to be assigned to devices undergoing conformity assessment

[Commission Implementing Regulation \(EU\) 2017/2185 of 23 November 2017](#)

MDCG guidance on IVDR competence codes

[MDCG 2021-14: Explanatory note on IVDR codes](#)

EUROPEAN MEDICAL DEVICE NOMENCLATURE (EMDN)

European Commission EMDN browser, submission platform and FAQ page

[European Medical Device Nomenclature \(EMDN\)](#)

List of MDCG guidance on the EMDN

[Guidance - MDCG endorsed documents and other guidance - European Commission](#)

UNIQUE DEVICE IDENTIFICATION (UDI)

European Commission EU UDI Helpdesk

[EU UDI Helpdesk](#)

List of MDCG guidance on the UDI

[MDCG endorsed documents and other guidance \(Section on UDI\)](#)

QUALITY MANAGEMENT AND RELATED PROCESSES

QUALITY MANAGEMENT SYSTEMS

Harmonised ISO standard on quality management systems

EN ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes

RISK MANAGEMENT

Harmonised ISO standard on risk management

EN ISO 14971:2019/A11:2021- Medical devices – Application of risk management to medical devices (ISO 14971:2019)

Guidance on application of ISO 14971

ISO/TR 24971:2020 Medical devices — Guidance on the application of ISO 14971
(*In particular: Annex H 'Guidance for in vitro diagnostic medical devices'*)

TECHNICAL DOCUMENTATION

STRUCTURE AND CONTENTS OF TECHNICAL DOCUMENTATION

Consensus guidance on best practices for submission of technical documentation from the trade association of notified bodies

[Team-NB Best Practice Guidance for the Submission of Technical Documentation Under Annex II and III of In Vitro Diagnostic Regulation \(EU\) 2017/746](#)

IVDR Technical Documentation submission checklist from SGS NB1639

[SGS IVDR Technical Documentation Submission Checklist](#)

MDCG template for the Summary of Safety and Performance (SSP)

[MDCG 2022-9 Rev.1 - Summary of safety and performance Template](#)

LABELING

Harmonised, compulsory standard on symbols to be used on medical device labeling and IFU

EN ISO 15223-1:2021 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements

State of the art standard for in vitro medical device labeling

ISO 18113-1:2022: In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements.

PERFORMANCE EVALUATION

CLINICAL EVIDENCE

MDCG guidance on principles of clinical evidence for in vitro diagnostic medical devices

[MDCG 2022-2 Guidance on general principles of clinical evidence for In Vitro Diagnostic medical devices \(IVDs\)](#)

MedTech Europe e-book on clinical evidence for in vitro diagnostic medical devices under the IVDR

[MedTech Europe Clinical Evidence Requirements under the EU Diagnostics Regulation \(IVDR\)](#)

CONDUCT AND ADMINISTRATION OF IVDR PERFORMANCE STUDIES

MDCG Q&A on IVDR performance studies

[MDCG 2025-5 Questions & Answers regarding performance studies of in vitro diagnostic medical devices under regulation \(EU\) 2017/746](#)

MDCG guidance on IVDR performance study applications

[MDCG 2022-19 Performance study application/notification documents under Regulation \(EU\) 2017/746](#)

MDCG guidance on changes to performance studies

[MDCG 2022-20 Substantial modification of performance study under Regulation \(EU\) 2017/746](#)

MDCG guidance on safety reporting for performance studies

[MDCG 2024-4 Safety reporting in performance studies of in vitro diagnostic medical devices under Regulation \(EU\) 2017/746](#)

Harmonised standard on the conduct of clinical performance studies

EN ISO 20916:2024 In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice

SCIENTIFIC VALIDITY

Section 6.4 of [MDCG 2022-2](#) as well as Chapter 2 of the [MedTech Europe e-book on clinical evidence for IVDRs](#) provide explanations of the concept of Scientific Validity.

Manufacturers are expected to document and implement a suitable systematic literature review methodology, considering all relevant sources of data listed in IVDR Annex XIII 1.2.1. It is recommended to adopt one of the existing state of the art systematic review frameworks. No methodology is harmonised with the IVDR - it is the manufacturer's responsibility to ensure that the chosen approach is fit-for-purpose and aligned with the requirements of the Regulation.

ANALYTICAL PERFORMANCE

At present, only a limited number of standards have been harmonised under the IVDR.

Where relevant non-harmonised technical standards exist, we highly recommend considering and applying them as appropriate. Use of such standards is not compulsory, but notified bodies will consider these consensus documents as representative of the generally acknowledged state of the art when carrying out conformity assessments. This includes standards published by the International Organization for Standardization (ISO) as well as those from the Clinical and Laboratory Standards Institute (CLSI), International Electrotechnical Commission (IEC) and other recognised standards bodies.

It should be noted that non-harmonised standards are not formally aligned with the IVDR – their use does not yield a presumption of conformity with the Regulation. They may also diverge from IVDR terminology and requirements – it is the manufacturer's responsibility to identify and address any gaps or misalignments between the applied standards and the regulatory requirements.

Harmonised ISO standard on metrological traceability of calibrators, control materials and human samples

EN ISO 17511:2021 *In vitro* diagnostic medical devices – Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples.

ISO standard on reference measurement procedures

ISO 15193: 2009 - *In vitro* diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for content and presentation of reference measurement procedures.

ISO standard on metrological traceability of calibrators and controls intended for measurement of enzyme activity

ISO 18153: 2003 - *In vitro* diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials.

ISO standard series on measurement accuracy (trueness and precision)

ISO 5725-1:2023 – Accuracy (trueness and precision) of measurement methods and results – Part 1: General principles and definitions.

ISO 5725-2:2019 – Accuracy (trueness and precision) of measurement methods and results –

Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method.

ISO 5725-3:2023 – Accuracy (trueness and precision) of measurement methods and results – Part 3: Intermediate precision and alternative designs for collaborative studies.

ISO 5725-4:2020 – Accuracy (trueness and precision) of measurement methods and results – Part 4: Basic methods for the determination of the trueness of a standard measurement method

ISO 5725-5:1998/Cor 1:2005 – Accuracy (trueness and precision) of measurement methods and results – Part 5: Alternative methods for the determination of the precision of a standard measurement method.

ISO 5725-6:1994 – Accuracy (trueness and precision) of measurement methods and results – Part 6: Use in practice of accuracy values.

ISO standard specific to self-testing IVDs for monitoring of oral anticoagulant therapy

ISO 17593:2022 - Clinical laboratory testing and in vitro medical devices – Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy

ISO standard specific to self-testing IVDs for the monitoring of blood glucose

ISO 15197:2013: In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

POST-MARKET SURVEILLANCE (PMS) AND VIGILANCE

Section 7.1 of [MDCG 2022-2](#) provides an introduction of the requirements for Post-Market Surveillance and Post-Market Performance Follow up.

MDCG guidance on application of IVDR requirements to legacy devices

[MDCG 2022-8 Regulation \(EU\) 2017/746 - application of IVDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC](#)

MDCG guidance on vigilance reporting for medical devices

[MDCG 2024-1 Guidance on the vigilance system for CE-marked devices](#)

IVD MEDICAL DEVICE SOFTWARE

MDCG guidance on qualification and classification of IVD software

[MDCG 2019-11 Rev.1: Guidance on Qualification and Classification of Software in Regulation \(EU\) 2017/745 – MDR and Regulation \(EU\) 2017/746 – IVDR](#)

MDCG guidance on clinical evidence of medical device software – including performance evaluation of IVD software

[MDCG 2020-1 Guidance on Clinical Evaluation \(MDR\) / Performance Evaluation \(IVDR\) of Medical Device Software](#)

Joint guidance of MDCG and Artificial Intelligence Board (AIB) on the interplay between the MDR/IVDR and the EU AI Act for AI-enabled medical device software

[MDCG 2025-6 Interplay between the Medical Devices Regulation \(MDR\) & In vitro Diagnostic Medical Devices Regulation \(IVDR\) and the Artificial Intelligence Act \(AIA\)](#)

MDCG guidance on the application of cybersecurity to medical devices

[MDCG 2019-16 Rev.1 Guidance on Cybersecurity for medical devices](#)

MDCG guidance on the regulatory status of app stores and other online software platforms in relation to software medical devices

[MDCG 2025-4 Guidance on the safe making available of medical device software \(MDSW\) apps on online platform](#)