

Regulatory Landscape in EU, Updates and Important Timelines – Notified Body Perspective on IVDR

16.9.2026 — Mikko Soikkeli, CEO

Content



- Sertio introduction
- IVDR basics, key definitions, manufacturer obligations
- Classification, conformity assessment and the role of notified bodies
- IVDR transition deadlines under Regulation (EU) 2024/1860 and the conditions attached to them
- Regulatory updates
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 - KIWA India
- Key takeaway and closing statement

Sertio introduction

Sertio Oy — designated as IVDR notified body 31.10.2023



Notification of a Body in the framework of a technical harmonization directive

From: Finnish Medicines Agency
P.O. Box 55
FI-00034 FIMEA
Finland

To: European Commission
GROWTH Directorate-General
200 Rue de la Loi,
B-1049 Brussels.

Other Member States

Reference:

Legislation: Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Body name, address, telephone, fax, email, website :

Sertio Oy
Biokatu 10
Tampere
Finland

info@sertio.fi

Body info:

NB 3018

- 12th IVDR notified body
- CE 3018
- Business ID 3243786-4
- Address: Biokatu 10, 33520 Tampere, Finland
- www.sertio.fi
- [Sertio a Kiwa company](#)
- sertio@kiwa.com

Sertio value statement



- Sertio provides customer-oriented, high-level conformity assessment services to enable access to the regulated medical device market globally.
- 1. Strategic partner in market access
- 2. One desk, multiple services
- 3. Capacity and competence. Local teams supporting sales and conformity assessment
- 4. Fast final review and decision making

Sertio Oy personnel



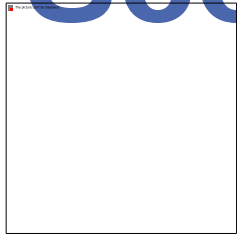
- Experienced personnel: cumulatively 60+ years of notified body work experience
 - Previous head of NB of IVD of Eurofins Finland (0537), deputy head of medical devices Eurofins Finland (0537)
- Sertio personnel locations: Finland, Estonia, Belgium, Spain.
 - Build up of local teams globally.
 - KIWA India team
- Strong clinical team, cumulatively 50+ years of clinical experience
 - MD specialized in clinical chemistry, multiple authorized clinical chemists, authorized clinical microbiologists, clinical genetician, adjunct professor in cancer genetics
 - Personnel with work experience from IVD legal manufacturers
 - Software specialists
- IVDR, IVDD, MDR, MDD, MDSAP, ISO 13485, ISO 9001, ISO 14001 auditing experience

Sertio became part of Kiwa 1.5.2026



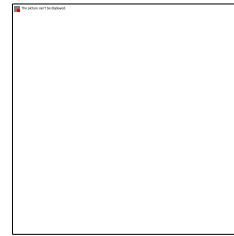
- Sertio, now part of Kiwa, is a conformity assessment body based in Finland.
- Sertio specializes in in vitro diagnostic medical devices and quality management systems, serving customers globally.
- Sertio provides notified body conformity assessment services under Regulation (EU) 2017/746 on in vitro diagnostic medical devices, known as the IVDR.
- Sertio is also a FINAS-accredited certification body providing ISO 13485 quality management system certification.

Scope



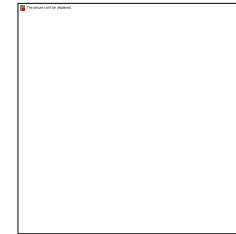
Conformity assessment routes

Liite IX chapter (I) QMS,
Liite IX chapter (II) TDA
Liite XI Prod QA



Competence codes in scope:

IVR0300 cancer markers and non-malignant tumours
IVR0400 human genetic testing
IVR0500 markers of infections / immune status
IVR0600 non-infectious pathologies, physiological markers, disorders / impairments (except human genetic testing), and therapeutic measures (clinical chemistry)
IVR0700 controls without assigned value
IVR0800 sterile devices



Codes not covered:

IVR010X blood grouping,
IVR020X tissue typing ,
IVP3009 assay utilizing radioactivity

Horizontal codes covered in FULL

Services and capabilities



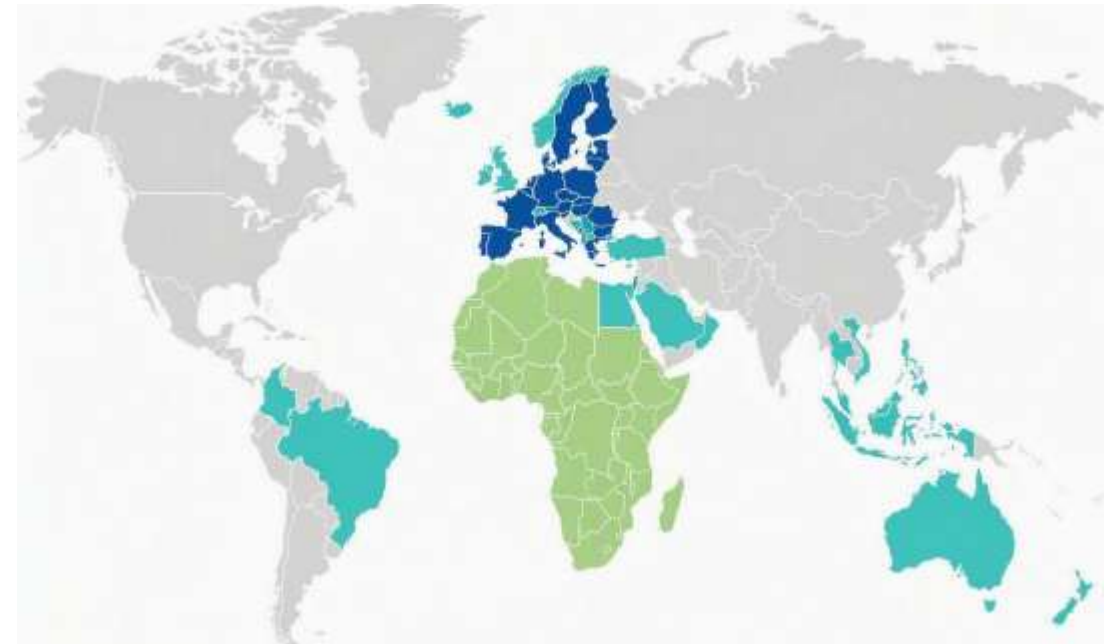
- 1. IVDR conformity assessment
 - Specialized in IVD products, large scope
 - Clinical laboratory for testing and verification purposes
 - EU reference laboratories
- 2. ISO 13485 certification — IVD and sterilization
- 3. MDSAP in cooperation with Kiwa UK
- 4. UK Approved Body in cooperation with Kiwa UK

IVDR intro, definitions

Introduction



- The EU IVDR has fundamentally transformed the regulatory framework for in vitro diagnostic medical devices: higher requirements for clinical evidence, performance evaluation, post-market surveillance and notified body oversight.
- The CE mark opens the 27 EU member states and is recognised in 25 further countries.
 - 27 EU member states — one single set of rules
 - 25 other countries — CE mark recognised or accepted



What is an in vitro diagnostic device?



- An IVD medical device is any medical device that is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, used alone or in combination, intended to be used in vitro for the examination of specimens derived from the human body.
- Examples: devices for blood grouping, tissue typing, cancer, genetic testing, infectious diseases, clinical chemistry.
- Special groups:
 - Self-tests such as SARS-CoV-2, pregnancy, ovulation, fertility and coeliac disease tests, and blood glucose monitoring systems
 - Near-patient and point-of-care testing devices, such as haematology and blood gas analysers
 - Companion diagnostic tests (CDx),
 - sterile devices,
 - software and AI devices

Definitions for medical devices (MDR/IVDR)



- 'In vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, used alone or in combination, intended to be used in vitro for the examination of specimens derived from the human body, solely or principally for the purpose of providing information:
 - concerning a physiological or pathological process or state; congenital physical or mental impairments; predisposition to a medical condition or a disease
 - to determine safety and compatibility with potential recipients; to predict treatment response or reactions; to define or monitor therapeutic measures
- Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices.
- 'Medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended to be used for human beings for a specific medical purpose — diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease or injury, investigation or modification of the anatomy or of a physiological process, or providing information by in vitro examination of specimens — and which does not achieve its principal intended action by pharmacological, immunological or metabolic means.

The structure of the IVDR



- Regulation (EU) 2017/746 is built from three parts:
 - Recitals 1–101 — the reasoning behind the rules, useful when interpreting intent
 - Articles 1–113 — the binding obligations, including definitions, manufacturer duties, classification and conformity assessment
 - Annexes I–XV — the detailed requirements, including the general safety and performance requirements, technical documentation and conformity assessment routes
- The most significant changes compared with the Directive: reclassification of many devices into higher classes, far greater notified body involvement, stronger clinical evidence and performance evaluation requirements, and lifecycle obligations such as post-market surveillance and EUDAMED registration.

Key definitions to get right



- Intended purpose — the use for which the device is intended according to the label, instructions for use, promotional material or the performance evaluation. It drives classification and everything downstream.
 - what is detected and/or measured;
 - its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);
 - the specific information that is intended to be provided in the context of:
 - a physiological or pathological state; — congenital physical or mental impairments; — the predisposition to a medical condition or a disease; — the determination of the safety and compatibility with potential recipients; — the prediction of treatment response or reactions; — the definition or monitoring of therapeutic measures;
 - (iv) whether it is automated or not;
 - (v) whether it is qualitative, semi-quantitative or quantitative;
 - (vi) the type of specimen(s) required;
 - (vii) where applicable, the testing population; and
 - (viii) for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for which it is a companion test.

Key definitions to get right



- User and lay person — a user is any healthcare professional or lay person using the device; a lay person has no formal education in the relevant healthcare field.
- Economic operators — manufacturer, authorised representative, importer and distributor, each with defined obligations.
 - The notified body operates with the manufacturer.
- Performance — the ability of a device to achieve its intended purpose, consisting of analytical and, where applicable, clinical performance.

Key definitions to get right — performance



- 'Analytical performance' means the ability of a device to correctly detect or measure a particular analyte.
- 'Clinical performance' means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended user.
- 'Scientific validity of an analyte' means the association of an analyte with a clinical condition or a physiological state.

Key definitions to get right — risk and benefit



- 'It should be recognised that the concept of clinical benefit for in vitro diagnostic medical devices is fundamentally different from that which applies in the case of pharmaceuticals or of therapeutic medical devices, since the benefit of in vitro diagnostic medical devices lies in providing accurate medical information on patients, where appropriate, assessed against medical information obtained through the use of other diagnostic options and technologies, whereas the final clinical outcome for the patient is dependent on further diagnostic and/or therapeutic options which could be available.'

Classification and conformity assessment route

IVDR risk classes A–D



Classification follows the seven rules of Annex VIII — risk to the individual and to public health increases from A to D

Increasing risk →



Lowest risk to the individual and to public health
Specimen receptacles, instruments, buffers, general laboratory use
Self-certification — notified body only if sterile

Moderate individual risk, low public health risk
Prof use tests.
Self-tests such as pregnancy, cholesterol and fertility tests
Notified body assesses QMS and a sample of technical documentation

High individual risk, moderate public health risk
Cancer markers, genetic testing, companion diagnostics, majority of self-tests
Notified body assesses QMS and technical documentation

High individual risk and high public health risk
HIV, hepatitis, blood grouping and other transmissible agent markers
Notified body + EU reference laboratory + batch verification

Key definitions to get right — risk and benefit



- Application of the classification rules shall be governed by the intended purpose of the devices.
- Highest risk class applies
- If a device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.
- Accessories for an in vitro diagnostic medical device shall be classified in their own right separately from the device with which they are used.

Conformity assessment routes



- All classes except non-sterile class A require a notified body in conformity assessment
- Device class and intended use drive the conformity assessment route

→ Different certificates

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Manufacturer: Company name
address
country

Single registration number:

Authorized representative: Company name
address
country

Single registration number:

Notified Body Sertio Oy declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the

**REGULATION (EU) 2017/746
on In Vitro Diagnostic Devices**

EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE

Manufacturer: Company name
address
country

Single registration number:

Authorized representative: Company name
address
country

Single registration number:

Notified Body Sertio Oy declares that the requirements of Annex IX, Chapter II of the

**REGULATION (EU) 2017/746
on In Vitro Diagnostic Devices**

EU PRODUCTION QUALITY ASSURANCE CERTIFICATE

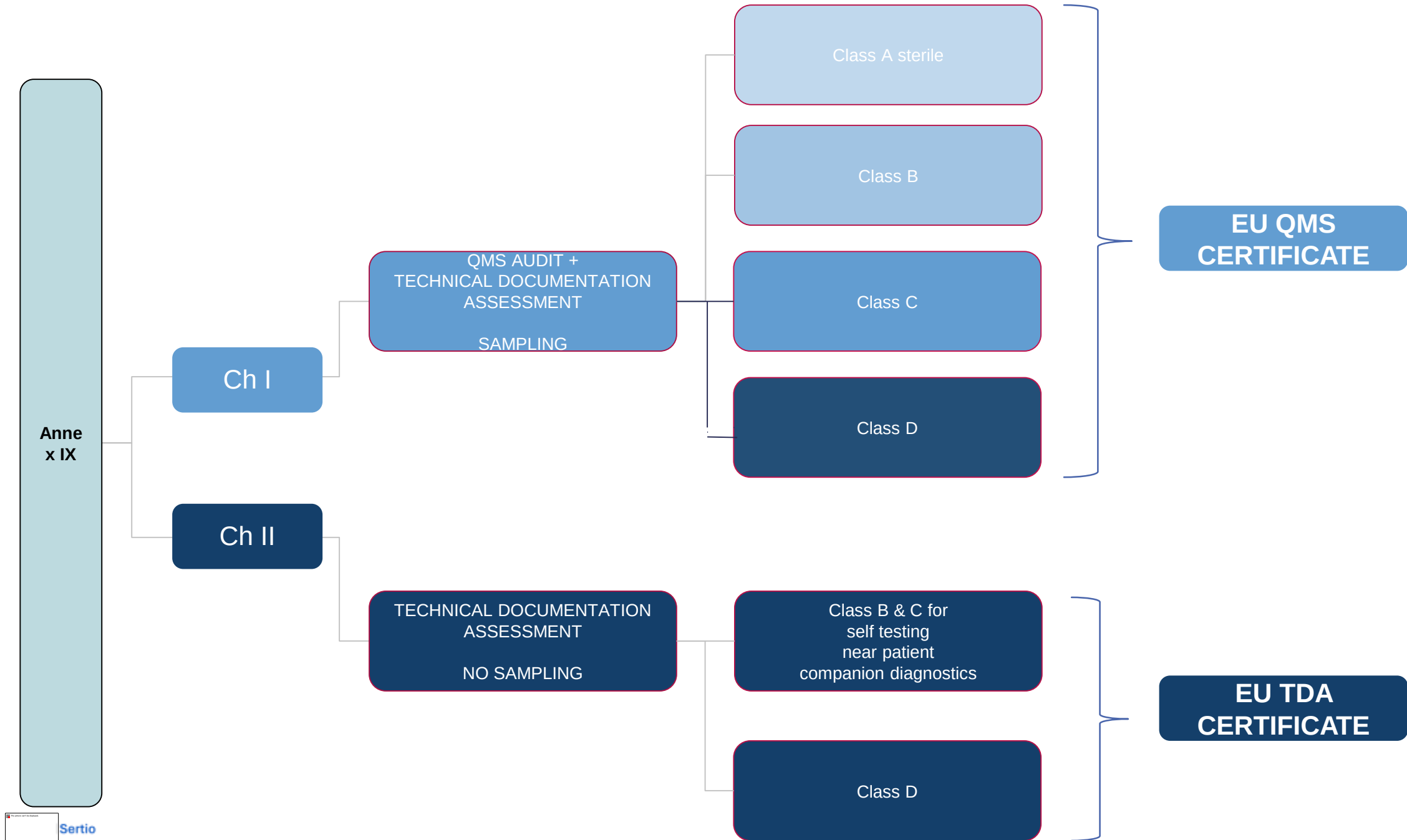
Manufacturer: Company name
address
country

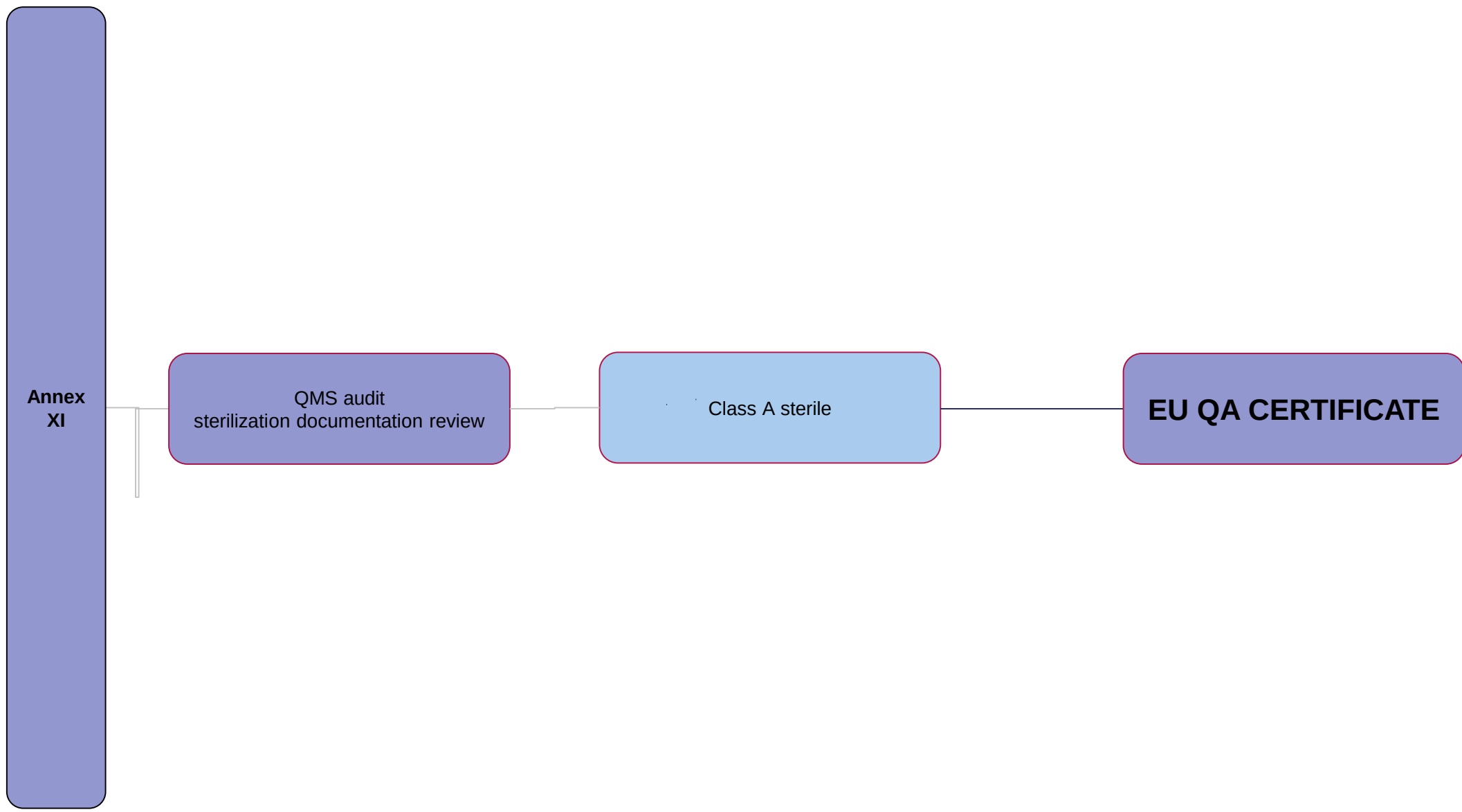
Single registration number:

Notified Body Sertio Oy declares that the requirements of Annex XI of the

**REGULATION (EU) 2017/746
on In Vitro Diagnostic Devices**

- Harmonised standards, common specifications and MDCG guidance support compliance





Common specifications & standards



- **Commission Implementing Regulation (EU) 2022/1107**, the EU Common Specifications (CS) apply to specific **Class D IVD analytes/markers**. The covered analytes are:
 - Plan as part of performance verification

- Harmonised standards, and MDCG guidance support compliance

Category

Analyte

ABO blood groups

Blood grouping

Blood grouping

Blood grouping

Blood grouping

Infectious disease

Infectious disease

Infectious disease

Infectious disease

Infectious disease

Infectious disease

Infectious disease

Infectious disease

Infectious disease

Infectious disease

Infectious disease

Rh (Rhesus) blood groups

Kell blood groups

Kidd blood groups

Duffy blood groups

HIV (Human Immunodeficiency Virus)

HTLV (Human T-cell Lymphotropic Virus)

HBV (Hepatitis B Virus)

HCV (Hepatitis C Virus)

HDV (Hepatitis D Virus)

vCJD markers (variant Creutzfeldt-Jakob Disease)

CMV (Cytomegalovirus)

EBV (Epstein-Barr Virus)

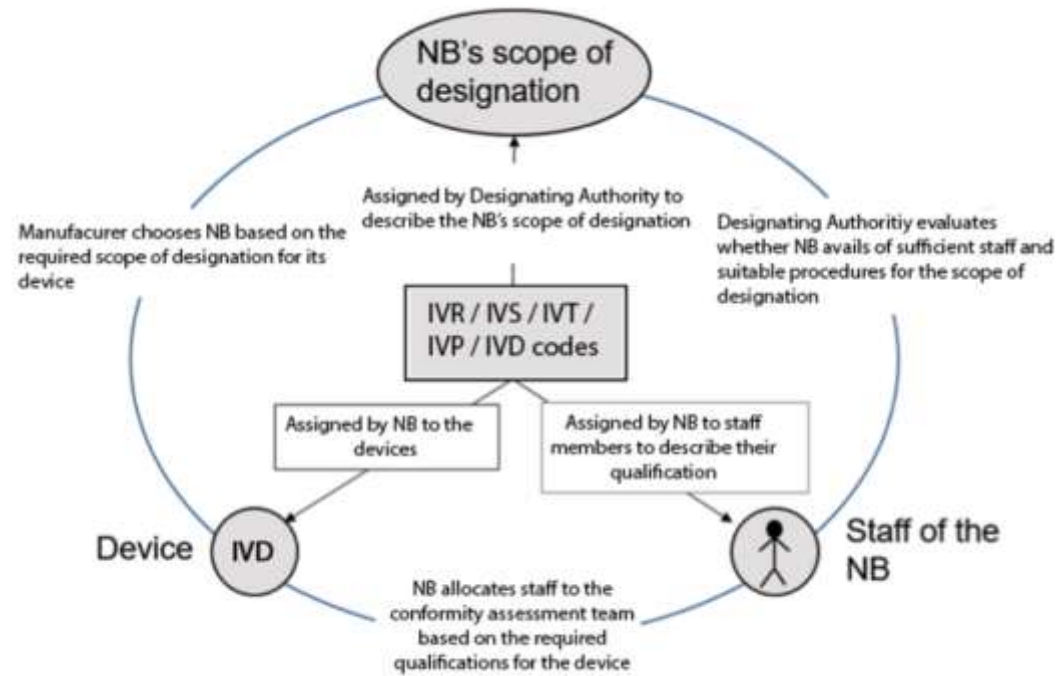
Treponema pallidum (Syphilis)

Trypanosoma cruzi (Chagas disease)

SARS-CoV-2

Coding of devices

IVDR codes required for conformity assessment



Implementing regulation lays down the codes.

MDCG 2021-14 provides explanation to the codes.

Manufacturer responsibility to define the codes for every device.

NB checks the codes.

Guidance for selecting the requested codes: Regulation 2017/2185 and MDCG 2021-14 Explanatory note on IVDR codes

IVR codes reflect the design and intended purpose of the device

I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE

- IVR codes, [select exactly 1 code per device, in rare cases more than one](#)
 - IVR 0300: Devices intended to be used for markers of cancer and non-malignant tumours except devices for human genetic testing
 - IVR 0400: Devices intended to be used for human genetic testing
 - IVR 0500: Devices intended to be used for the screening, confirmation, identification of infectious agents or determination of immune status
 - IVR 0601-0604: Devices intended to be used for a specific disease
 - IVR 0605-0609: Devices intended to be used to define or monitor physiological status and therapeutic measures
 - IVR 0700: Controls without a quantitative or qualitative assigned value
 - IVR 0800: Class A devices in sterile condition

IVR codes reflect the design and intended purpose of the device

II. HORIZONTAL CODES, [select all applicable](#)

- IVS codes: *In vitro* diagnostic devices with specific characteristics
- IVT codes: *In vitro* diagnostic devices for which specific technologies are used
- IVP codes: *In vitro* diagnostic devices which require specific knowledge in examination procedures for the purpose of product verification
- IVD codes: *In vitro* diagnostic devices which require specific knowledge in laboratory and clinical disciplines for the purpose of product verification

European Medical Device Nomenclature (EMDN)

- Aims at supporting the functioning of the European database on medical devices (EUDAMED)
- Utilised by manufacturers for the registration of medical devices in EUDAMED, where it will be associated to each Unique Device Identifier – Device Identifier (UDI-DI)
- Plays a key role in MDR/IVDR device documentation and technical documentation, sampling of technical documentation conducted by notified bodies, post-market surveillance, vigilance and post-market data analysis, etc.
 - Sampling of Class B: category of devices based on IVD codes
 - Sampling of Class C: Generic device group 3rd level of the EMDN (i.e. combination of one letter plus 4 digits respectively) in combination with the most appropriate IVP code

MDCG 2021-12 FAQ on the European Medical Device Nomenclature (EMDN)

MDCG 2019-13 Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class E

Class C devices for the assessment of the technical documentation



Manufacturer obligations

Article 10 — general obligations of manufacturers



- Establish a quality management system and technical documentation — and keep them up to date
- Carry out performance evaluation and draw up the declaration of conformity and CE marking
- Meet UDI and registration requirements and keep the device identification current
- Operate post-market surveillance, including incident reporting and field safety corrective actions
- Take corrective action on non-conforming devices and cooperate with competent authorities

The person responsible for regulatory compliance



- Article 15 requires at least one person responsible for regulatory compliance (PRRC) available within the organisation.
- Qualification: a university degree in law, medicine, pharmacy, engineering or another relevant science plus one year of professional experience in regulatory affairs or quality management for IVDs — or four years of such experience.
- The PRRC ensures conformity is checked before release, that technical documentation and the declaration of conformity are drawn up and kept up to date, that post-market surveillance obligations are met, and that reporting obligations are fulfilled.
- Other duties include keeping the EUDAMED registration current and specifying and justifying the level of clinical evidence needed to demonstrate conformity.

Annex I: safety and performance



- Annex I sets the general safety and performance requirements every IVD must meet
 - Chapter I: general requirements — safety, risk management and acceptable benefit/risk
 - Chapter II: performance, design and manufacture, including analytical and clinical performance
 - Chapter III: information supplied with the device — labelling and instructions for use
- Each requirement must be addressed and justified in the technical documentation.

Annex II: technical documentation



- Device description and specification: variants, accessories and previous generations
- Information supplied by the manufacturer: labels, IFU and language versions
- Design and manufacturing information, including manufacturing sites
- General safety and performance requirements: the Annex I checklist with evidence
- Benefit-risk analysis, risk management, verification and validation data
- Annex III adds the PMS file: PMS plan, PMPF plan and PSUR

Timelines

IVDR transition deadlines



- Regulation (EU) 2024/1860 extended the transition periods first set by (EU) 2022/112:
- FULL COMPLIANCE WITH IVDR LATEST:
 - Class D legacy devices: 31 December 2027
 - Class C legacy devices: 31 December 2028
 - Class B and class A sterile legacy devices: 31 December 2029
 - In-house devices under Article 5(5)(d): 31 December 2030
- The original date of application of the IVDR remains 26 May 2022 — the extensions apply only to legacy devices already on the market.
- Any new IVD device placed on the EU market needs to be IVDR compliant.

Transition periods are conditional



- The extended deadlines are not automatic. They apply only if:
 - The device is not a new device — new devices must comply with the IVDR from the outset
 - The device continues to comply with the IVD Directive
 - No significant changes are made to design or intended purpose
 - The device does not present an unacceptable risk to patient safety
 - An IVDR-compliant quality management system has been in place since 26 May 2025
 - The manufacturer applies to a notified body and signs a conformity assessment agreement within the class-specific deadlines

Transition time deadlines



- **Class C device – agreement with notified body by 26.9.2026**
 - Time to act
- **Class B and class A sterile — application by 26 May 2027,**
 - agreement signed by 26 September 2027
- Missing a date ends the benefit of the extension, whatever the 2028 or 2029 end date
- IVDD-certified devices stay under notified body surveillance without interruption

Regulatory updates

EUDAMED mandatory from 28 May 2026



- Available EUDAMED modules became mandatory to use on 28 May 2026.
- Register the SRN
- Prepare UDI-DI data
- Assign internal ownership of EUDAMED data quality

The screenshot shows the EUDAMED website interface. At the top, there is a header with the European Commission logo, a language selector set to 'English', and a search bar. Below the header, the main title 'EUDAMED - European Database on Medical Devices' is displayed. A navigation menu includes links for Home, Actors, Devices/SPPs, Certificates, and News. The 'Home' link is active. The main content area is titled 'EUDAMED database' and contains a paragraph explaining the purpose of the database, followed by a paragraph detailing its composition. Below this, there is a 'Search for' section with three search options: 'Economic Operators', 'Devices, Systems, Procedure packs', and 'Certificates (issued or Refused)'. Each option has a corresponding icon and a brief description of the search criteria. At the bottom, there is an 'Important information' section with a date of 2021-06-24 and a link to 'See all important information'.

European Commission

English

Search

EUDAMED - European Database on Medical Devices

Home Actors Devices/SPPs Certificates News

Home >

EUDAMED database

The creation of a European database on medical devices (EUDAMED) is one of the key aspects of the new rules on medical devices ([Regulation \(EU\) 2017/745](#)) and in vitro diagnostic medical devices ([Regulation \(EU\) 2017/746](#)).

EUDAMED will provide a living picture of the lifecycle of medical devices that are made available in the European Union (EU). It will integrate different electronic systems to collate and process information about medical devices and related companies (e.g. manufacturers). In doing so, EUDAMED aims to enhance overall transparency, including through better access to information for the public and healthcare professionals, and to enhance coordination between the different Member States in the EU.

EUDAMED will be composed of six modules related to: actor registration, unique device identification (UDI) and device registration, notified bodies and certificates, clinical investigations and performance studies, vigilance and market surveillance.

Search for

Economic Operators

Search for economic operators (manufacturers, system/procedure pack producers, authorised representatives, importers).

Devices, Systems, Procedure packs

Search for UDI-DI and device data including SS(C)P.

Certificates (issued or Refused)

Search for certificates and refused certificates.

Important information

INFO 2021-06-24

If not in EUDAMED, the SSCP shall be made available to the public upon request without undue delay or the manufacturer shall specify where it is made available to the public. See MDCG 2021-1 Rev. 1 https://ec.europa.eu/health/sites/default/files/mdcg_sectiondocs/2021-1_guidance-administrative-practices_en.pdf

[See all important information](#)

EUDAMED: Four Mandatory Modules

Mandatory use from 28 May 2026

Actor

Manufacturers, authorised
representatives, importers and
other economic operators

UDI / Device

Device registration and unique
device identifiers

Certificate

Notified bodies and the certificates
they issue

Market surveillance

Post-market surveillance reporting

Secure the SRN, prepare UDI-DI data and assign internal ownership of EUDAMED data quality well before the date.

MDCG 2020-16 rev.5 IVDR classification rules

- Published in September 2026.
- What are the main changes?
- Clarification of the rationale for Rule 7.
- Revision of the examples under Rule 7.

The revised text now provides much more detailed guidance on:

- Standalone quality control (QC) materials
- Controls without assigned quantitative/qualitative values
- Distinction between:
 - QC materials classified under Rule 7 (Class B)
 - Controls with assigned values that take the classification of the associated assay under Implementing Rule 1.6

This clarification is particularly relevant for manufacturers of QC materials

MDCG 2026-4 SSP mgt in EUDAMED

- Published June 2026.
- What are the main changes?
- Under the current process, SSPs are uploaded to EUDAMED by Notified Bodies as part of the certificate registration process. However, this is expected to change with the revision of MDCG 2019-9. In the future, manufacturers will be responsible for uploading the master SSP validated by the Notified Body, together with the relevant translations.
- Until the new EUDAMED functionalities are available, Notified Bodies will continue to upload SSPs. During this period, only the master version will be uploaded; translations will not be included.

MDCG 2026-4 SSP mgt in EUDAMED

- The new functionalities are to become available in the EUDAMED in **October 2026**. Once these functionalities are available, manufacturers will be expected to upload SSP documents directly to EUDAMED.
- An important point concerns devices placed on the market before the mandatory use date of the EUDAMED UDI/Device module.
 - For these devices, manufacturers are advised to complete the SSP uploads as soon as possible, with 27 February 2027 indicated as the deadline.
 - This means that manufacturers should start reviewing their internal responsibilities for SSP management and plan the transition together with their Notified Bodies.
- The process is not changing overnight, but the direction is clear: manufacturers will have a more active role in managing SSPs in EUDAMED.

MDCG 2021-24 rev.1 Classification

- Updated April 2026
- MDR classification rule updates

Borderline manual

- Updated April 2026
- No new classifications decisions regarding IVD
- Nasal spray with antibodies for COVID-19
- Product for professional removal of dental biofilm
- Smartphone application for STI prevention strategies
- Medical calculators

MDCG 2021-12 EMDN FAQ

- Updated April 2026
- Use of EMDN, link to training material

Q&A on obligation to inform interruption or discontinuation

- Updated April 2026
- Editorial update upon decision tree

MDCG 2025-10 PMS

- Published December 2025
- Worthy guidance for PMS

MDCG 2021-5 rev 1 Appendix

- Updated June 2026
- Transition to term "EU REP" in EN ISO 15223-1

EU Reference Laboratories

- EU reference laboratories (EURLs) have been operational for class D devices since October 2024.
- EURLs verify performance against common specifications, carry out batch testing, advise the Commission, MDCG, member states and notified bodies, and work as a coordinated network.
- EURL involvement adds lead time to class D conformity assessment and must be built into project plans.

EU Reference Laboratories by Category

Category	Designated	Reference laboratories
Hepatitis and retrovirus markers	Dec 2023	Paul-Ehrlich-Institut, DE; Instituto de Salud Carlos III, ES
Respiratory virus markers	Dec 2023	Paul-Ehrlich-Institut, DE; RISE Research Institutes of Sweden, SE
Herpesvirus markers	Dec 2023	Consortium coordinated by SERMAS, ES
Bacterial agent markers	Dec 2023	Consortium coordinated by SERMAS, ES
Parasite infection markers	Dec 2025	Instituto de Salud Carlos III, ES; Consulting Quimico Sanitario, ES
Blood grouping markers	Dec 2025	Paul-Ehrlich-Institut, DE; Consulting Quimico Sanitario, ES; RISE, SE
Arboviruses	Not yet	Second call for applications expected

Targeted Revision of the EU Device Rules

- In December 2025 the European Commission published a proposal to simplify the rules for medical devices and in vitro diagnostics, with the legislative process starting in early 2026.
- A public feedback period is open; language versions in all official EU languages are expected during 2026
- Until the revision is adopted, current IVDR obligations and deadlines remain fully in force.
- No change to the current transition deadlines
 - plan by the rules in force today

Market surveillance

Market surveillance in the device sector



- Market surveillance ensures that devices on the market meet legal requirements and do not pose safety risks.
- Surveillance is risk-based and retrospective, using inspections, sampling, marketing monitoring and operator guidance
- Manufacturers and authorised representatives carry primary responsibility; importers and distributors carry their own obligations
- Legal basis: IVDR Article 88

Overview of conformity assessment process

Conformity assessment services at Sertio



- The service covers the full certification process.
- Sertio will appoint a project leader as point of contact and as a role which pushes the assessment forward and communicates effectively with parties.
- IVDR conformity assessment can be easily combined with ISO 13485 certification with minor additional cost and additional audit time.
- Possibility for structured dialogue with experts (available for customers)
- Transfer process available, ensuring smooth transitioning.

Conformity assessment process — quotation to contract



- 1. Manufacturer fills in the **quotation request form**
- 2. Sertio reviews the quotation request, compiles a preliminary technical documentation assessment plan and performs resource planning
- 3. Sertio issues **quotation** for manufacturer
- 4. Manufacturer submits the **application**, signed by an authorised person,
 - Attachment to the application: product list, QMS documents and necessary TD documents
 - For all devices: technical documentation summary or index, instructions for use, draft declaration of conformity
 - Full technical documentation for class D devices, companion diagnostics, self-testing and near-patient testing devices
- 5. **Contract** between the manufacturer and the notified body is signed

Conformity assessment process — assessment to certificate



- Sertio performs the technical documentation review, including performance evaluation assessment
 - Technical documentation must be in English or Finnish
- Quality management system assessment (audit) according to the selected Annex IX or Annex XI route
- Where applicable,
 - EU reference laboratory involvement for class D devices
 - EMA consultation for companion diagnostics
- Final review
- Certification decision and issuing of the EU certificates,
- Surveillance of the certified QMS and devices
- A typical certification process takes 12 months. Ranging from 6–18 months
 - contact a notified body early enough

kiwa

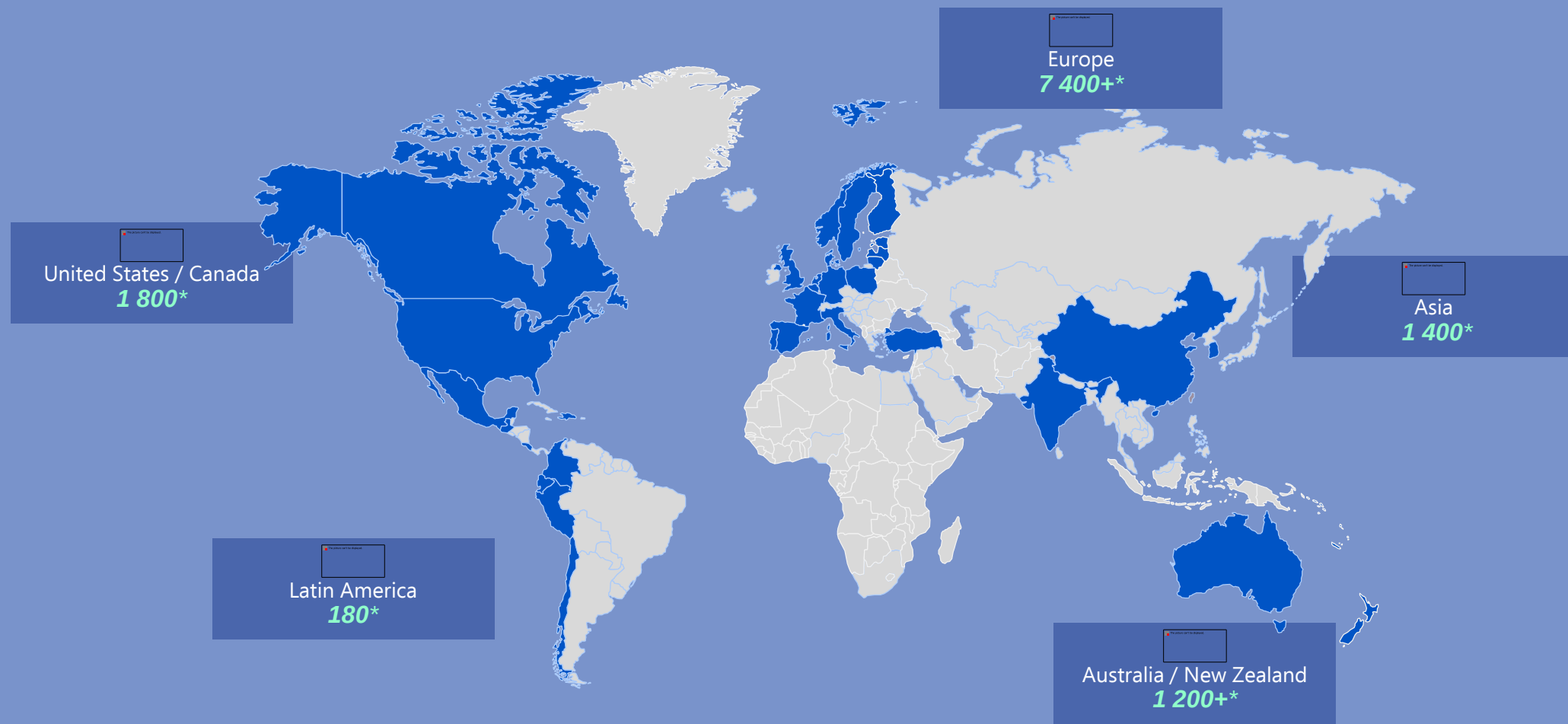


We are Kiwa one of the world's leading
Testing, Inspection and **Certification** companies.



Geographical presence

~12,300 experts in 42 countries



*Kiwa experts, 2025

Kiwa: Global Presence

- Kiwa is an independent global Testing, Inspection and Certification (TIC) company, part of SHV
- Around 12,300 employees working in 42 countries, with head office locations across Europe, Asia and the Americas
- Local presence combined with an international outlook — the same requirements assessed the same way in every market
- [kiwa.com](https://www.kiwa.com)

Four notified bodies: a broader Kiwa portfolio

Three medical device notified bodies plus newly acquired IVDR capability through Sertio Oy

Notified bodies

NB 0476 — Kiwa Cermet Italia

NB 0476

Italy
Medical devices / MDR
Established Italian notified body in the Kiwa network.

NB 1984 — Kiwa Belgelendirme Hizmetleri

NB 1984

Türkiye
Medical devices / MDR
Türkiye-based notified body supporting medical device conformity assessment.

NB 1912 — Kiwa Assurance BV

NB 1912

Netherlands
Medical devices / MDR
Netherlands-based notified body in the Kiwa portfolio.

NB 3018 — Sertio Oy

NB 3018

Finland
IVD / IVDR
Finland based notified body focused on IVDR.

Kiwa offers a multi-notified-body portfolio, enabling discussion of the most appropriate conformity assessment route based on product type, regulatory classification, capacity and scope.

Source basis: European Commission NANDO for notified body identification numbers; user-provided list of Kiwa notified bodies.



Testing and Laboratory Services

- Kiwa laboratories cover electrical safety, electromagnetic compatibility and functional testing against the harmonised standards
- Group laboratories such as Kiwa Primara and Kiwa Creiven support medical device manufacturers across product types
- Accredited testing, measurement and calibration alongside notified body certification
- One group for testing, inspection and certification shortens the route from development to CE marking
- [kiwa.com](https://www.kiwa.com) → Laboratory Services for Medical Devices



Kiwa India Medical

Kiwa India Medical operates through KGI Certification Pvt. Ltd., a Kiwa Group company.

kiwa

Kiwa India: Your Trusted Partner for IVDR Certification and Regulatory Success

Why Partner with Kiwa India?

- **Manufacturers can move forward with confidence and complete contracting activities ahead of the 26 September 2026 IVDR deadline.**
- **India is a key strategic growth market for Kiwa, reinforcing our long-term commitment to the region.**
- **Established in April 2026, Kiwa India is already supporting manufacturers with MDR certification projects locally.**
- **Dedicated team for local delivery.**
- **Efficient, transparent, and customer-focused processes designed to deliver predictable timelines.**
- **Long-term partnership approach focused on enabling innovation and supporting the growth of the Indian medical device industry.**

Meet the team – Your Key Contacts

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Creating Trust, Driving Progress.

Key takeaway and closing statement

Takeaway

- The IVDR transition is not merely a compliance exercise but a strategic transformation. Manufacturers who invest in robust evidence generation, technical documentation, and regulatory planning will be best positioned to maintain uninterrupted access to the European market and to markets in which CE marking is recognized and leveraged.
- Seek and select NB

Closing Statement

- “From a Notified Body perspective, the most successful IVDR projects are those that begin early, identify regulatory gaps proactively, and treat compliance as a continuous lifecycle activity. The remaining transition period should be viewed as an opportunity to strengthen product evidence, quality systems, and long-term market sustainability rather than simply meeting a regulatory deadline.”

creating
trust
*driving
progress*

Thank you!

Mikko Soikkeli, CEO —sertio@kiwa.com