THE

European Union In Vitro Diagnostic Medical Device Regulation (IVDR)

About the European Union (EU)

The EU population numbers more than 447 million people*.

The total medical device sales in the EU is close to EUR 150 billion.*

The European medical device industry employs approx. 800,000.*

The European medical device sector is comprised of 34,000 companies.

Source: https://www.medtecheurope.org/wp-content/uploads/2022/09/the-european-medical-technology-industry-in-figures-2022.pdf

What is the IVDR?

The IVDR is the regulatory basis for placing on the market, making available and putting into service in vitro diagnostic medical devices on the European market. It replaced the EU's Directive on in vitro diagnostic medical devices (98/79/EC). As a European regulation, it will be effective in all EU member states and EEA states immediately without need to be transferred into the law of respective states, however national laws may be adapted to back up some requirements in more detail.

Following the publication of regulation (EU) 2022/112, the IVDR will be rolled out gradually. Find out more in the timeline section below.

Timeline of the IVDR

2017 – IVDR enters into force on 26 May 2017.

2022 – New IVDs and self-declared (class A non-sterile) devices must be placed on the market under the IVDR from 26 May 2022.

2025 – Devices placed on the EU market with a IVDD certificate and IVDR (article 110 (3)) class D devices can be placed on the market until 26 May 2025. IVDD certificates will be invalid from 27 May 2025.

2026 – End of placing on the market under the IVDD of IVDR class C (article 110 (3)).

2027 – From 26 May 2027: End of placing on the market under the IVDD of class B, class As*.

*With the removal of sell-off date, devices can continue to be made available on the market until the stocks are sold or device expires, whichever comes first

From the 26 May 2022, the requirements of the IVDR related to post-market surveillance, vigilance, registration of economic operators and of devices applies to all IVDs.

Regardless of the device risk class, if a significant change to design and intended purpose is done, the IVD will need to comply with the IVDR as soon as the change(s) are implemented.

*As: Class A devices placed on the market in sterile conditions

Risk classes

IVDD 4*

IVDR 4

*Risk not consequently considered except for high risk products.

Notified Body involvement

Under IVDD about **8 percent** of IVDs

Under IVDR **80 percent or more** of IVDs

Key changes

- Product scope expansion
- Re-classification according to risk
- More stringent clinical evidence
- Identification of person responsible for regulatory compliance
- More stringent documentation
- Implementation of unique device identification
- Rigorous post-market oversight
- Increased Notified Body involvement

Step-by-step guide to IVDR certification

1. Step 1: Conduct an independent gap assessment for IVD medical devices

2. Step 2: Contact TÜV SÜD to start conformity assessment procedures

3. Step 3: Complete the conformity assessment for IVDR and applicable standards

4. Step 4: Your IVD medical device is ready for certification

TÜV SÜD

IVD medical device testing services

Our testing labs, supported by a global team of over 750 healthcare and medical device testing experts, offer a comprehensive range of services to test and assess your in-vitro diagnostic (IVD) medical devices.

TÜV SÜD Medical Device Testing Services is a unit of TÜV SÜD, completely independent from the Notified Body. In support of IVDR requirements, TÜV SÜD can conduct testing to ensure conformity against various standards.

Cybersecurity testing

Our comprehensive service portfolio supports the entire product life cycle:

- IEC 81001-5-1 - Health software and health IT systems safety, effectiveness, and security
- ISO 14971 - Application of risk management to medical devices
- Several frameworks exist for conducting penetration testing. TÜV SÜD performs the best practice from all methods (OSSTM, PTES, NIST 800-115, ISSAF and OWSAP).

Software life cycle testing

IVD software lifecycle testing services:

- IEC 62304 - Medical device software - Software life cycle processes
- IEC 82304-1 - Health software: General requirements for product safety

Electromagnetic compatibility (EMC) testing

Testing services conducted at our labs, your premises or the product's location:

- IEC 61326-1 - General EMC requirements for electrical equipment for measurement, control and laboratory use
- IEC 61326-2-6 - Particular EMC requirements for IVD medical equipment
- IEC 60601-1-2 – US FDA requirements for IVD EMC

Electrical safety and functional safety testing

Our full suite of testing services:

- IEC 61010-1 - Safety requirements for electrical equipment for measurement, control, and laboratory use: General requirements
- IEC 61010-2-101 - Particular requirements for IVD medical equipment
- IEC 61010-2-081 - Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
- Additional particular standards from the IEC 61010 series on request

Certification and global market access

Our comprehensive certification services include:

- IECEE CB certification - IEC 61010-1 (general requirements) and IEC 61010-2-XX (product specific standards)
- NRTL certification for USA and Canada
- INMETRO certification for Brazil
- Further national certifications on request

Environmental & packaging testing

Testing services for all medical devices:

- IEC 60721-3-2 - Classification of environmental conditions - Transportation and Handling
- IEC 60721-3-3 - Classification of environmental conditions - Stationary use at weather-protected locations
- IEC 60529 - Degrees of protection provided by enclosures (IP Code)
- IEC 60068 series - Environmental testing
- ISTA - Packaging testing
- ASTM - Series testing

Radio equipment testing

Our testing services support market access for 180 countries and include:

- Radio Equipment Directive (RED) 2014/53/EU
- ANSI C63.10 series / FCC Part 15 B / FCC Part 15 C
- FDA wireless co-existence standard
- RSS-Gen / RSS-210 / RSS-247
- Japan - ARIB standards / MIC ordinances

Battery testing

Our comprehensive battery testing services include:

- IEC 62133-1 - Safety requirements for nickel systems
- IEC 62133-2 - Safety requirements for lithium systems
- CB-Certification - according to IEC 62133-1 or IEC 62133-2
- UN 38.3 - Transportation testing for lithium batteries and cells

Usability testing

- IEC 62366-1 - Medical devices: Application of usability engineering to medical devices
  - Usability engineering process and files with the focus on safety
  - Assessment of risk management process associated with correct use, use errors and abnormal use according to ISO 14971

Get ready for the In Vitro Diagnostic Device Regulation now

www.tuvsud.com/ivdr