The European In Vitro Diagnostic Medical Device Regulation (IVDR)

Add value.
Inspire trust.

The In Vitro Diagnostic Regulation (EU) 2017/746 (IVDR) is the EU's regulatory basis for placing in vitro diagnostic medical devices on the European market. It is mandatory for access to all EU member states.

About the European Union

The European population numbers more than 448 million people.

Total medical device sales in the EU are close to € 160 billion

The European medical device industry employs approximately 850,000 people.

The European medical device sector comprises 35,000 companies.[1]

What is the IVDR?

The In Vitro Diagnostic Regulation (IVDR) is the current European Union (EU) regulatory legislation for placing in-vitro diagnostic devices on the EU market, making them available and putting them into service.

The IVD Regulation was published in the Official Journal of the EU on 5 May 2017, and entered into force on 26 May 2017, gradually replacing the EU's former Directive on in vitro diagnostic medical devices (IVDD 98/79/EC).

As a European regulation, it is effective in all EU member states and EFTA states immediately without needing to be transposed into the law of respective states. However, national laws may be adapted to back up some requirements in more detail.

[1] Source https://www.medtecheurope.org/wp-content/uploads/2023/10/the-european-medical-technology-industry-in-figures_2023.pdf

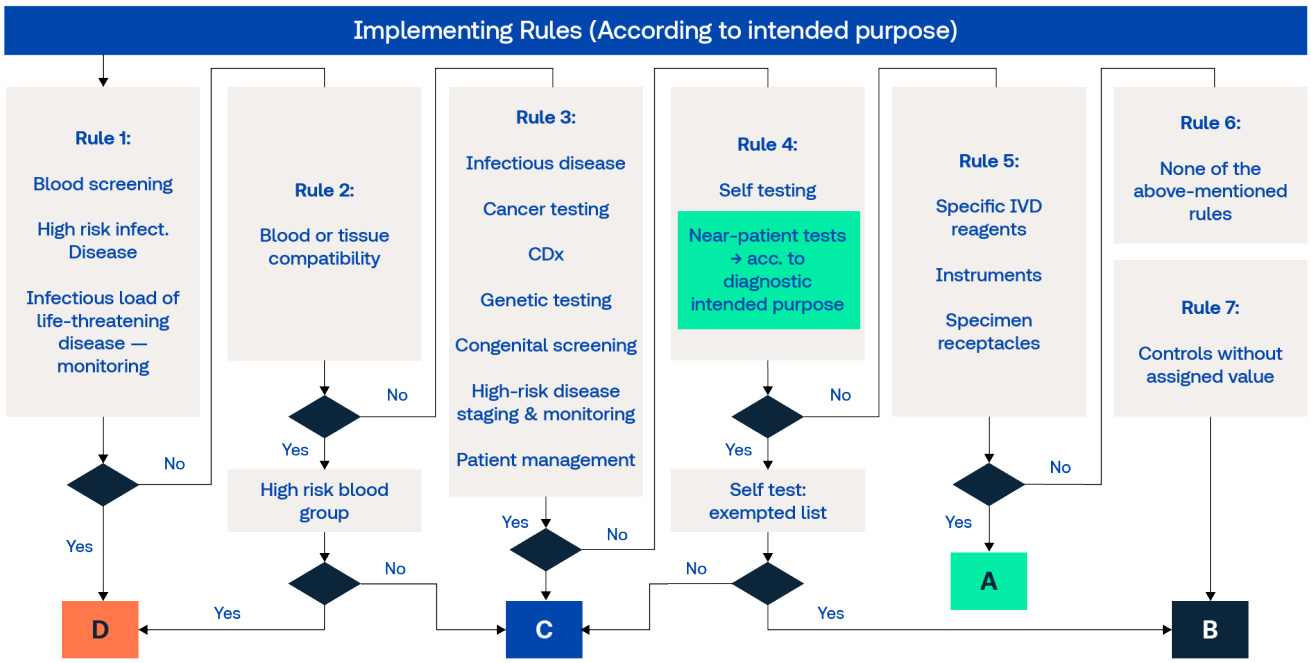
Key IVDR Amendments

Four additional regulations have been enacted with the primary purpose of providing adequate time and resources to ensure continued availability of devices on the EU market.

Regulation	Key Provisions
(EU) 2022/112	• First extension of transitional provisions for legacy devices • Introduction of staggered transition periods based on device classification
(EU) 2023/503	• Extension of the frequency of reassessment of notified bodies
(EU) 2023/607	• Removal of the sell-off period for devices placed on the market during the transition period
(EU) 2024/1860	• Second extension of transitional provisions • Addition of timelines for implementation of an IVDR-compliant quality system • Addition of timelines for application to and completion of a signed agreement with a notified body • Phased roll-out of the European Database on Medical Devices (EUDAMED) • Introduction of an obligation to notify an anticipated discontinuation of supply of devices

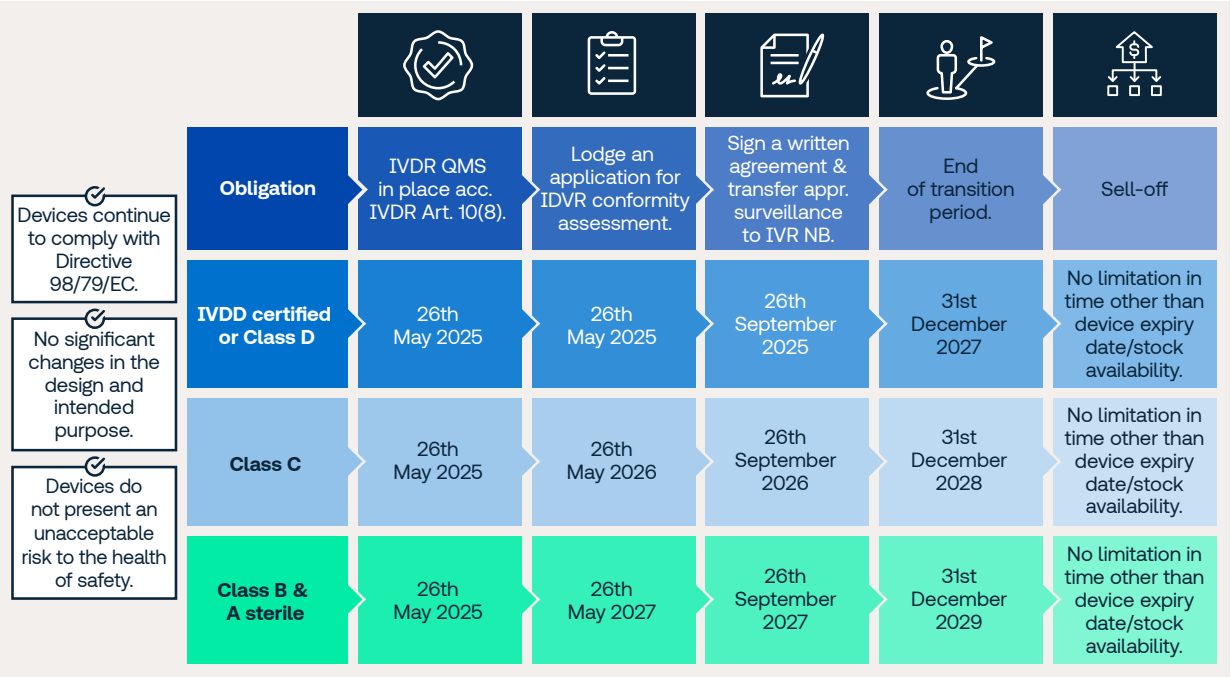
Risk-based Classification

Under the IVDR, IVD devices are classified using a risk-based approach, with Class D presenting the highest risk, and Class A the lowest. See our infosheet on classification for details.



IVDR Timelines

Devices that were placed on the market prior to 26 May 2022 can benefit from extended timelines as described below, providing that they continue to comply with the requirements of IVDD 98/79/EC, they have not undergone any significant changes to their design and intended purpose, and they do not present an unacceptable risk to health and safety.



Note: Class A (non-sterile) devices do not benefit from the extended timelines. These devices must be compliant with the IVDR as of 26 May 2022.

Step by step guide to IVDR certification

Step 1	Step 2	Step 3	Step 4
Implement an IVDR-compliant Quality Management System **Prepare IVDR-compliant technical documentation**	**Contact TÜV SÜD to start conformity assessment procedures**	**Complete the conformity assessment for IVDR and applicable standards**	**Your IVD medical device is ready for certification**

Why choose TÜV SÜD?
TÜV SÜD is designated as a full scope notified body under the IVDR. We are also, one of the world's largest notified bodies for all types of medical devices covered by EU directives and regulations. We were the first notified body to issue an IVDR certificate worldwide. Our global network of more than 750 dedicated experts include noted scientists, engineers, and physicians, all recognised as professionals in their fields. These capabilities make TÜV SÜD the preferred single source partner for worldwide compliance with medical device regulations.

Add value. Inspire trust.
TÜV SÜD is your trusted partner of choice for safety, security and sustainability solutions. We specialise in testing, certification, auditing and advisory services. Through more than 28,000 employees across over 1,000 locations, the company adds value to its customers by enabling market access and managing risks. By anticipating technological developments and facilitating change, TÜV SÜD inspires trust in a physical and digital world to create a safer and more sustainable future.

Related services[2]

TÜV SÜD provides the following related services

- EN ISO 13485 certification
- Medical Device Single Audit Program (MDSAP)
- Certification of devices under Japanese PAL
- IEC 60601 – Medical electrical equipment
- IEC 61010 – Laboratory electrical equipment safety
- IEC 62443 – Cybersecurity Management
- Testing services including EMC and NRTL testing

[2] TÜV SÜD's certification and testing services are independent of each other and do not impact one another. Our certification services are delivered by TÜV SÜD's recognised Certification Bodies, while our testing services are conducted through TÜV SÜD Testing Labs.

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