THE European Union In Vitro Diagnostic Medical Device Regulation (IVDR)

About the European Union (EU)

The EU population numbers more than **445 million people.**

The total medical device sales in the EU is close to **EUR 140 billion.***

Source: https://www.medtecheurope.org/wp-content/uploads/2021/06/medtech-europe-facts-and-figures-2021.pdf

The European medical device industry employs approx. **760,000.***

The European medical device sector is comprised of **33,000 companies.**

Source: https://www.emergobyul.com/resources/market-europe

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 will replace the EU's current Directive on in vitro diagnostic medical devices (98/79/EC). As a European regulation, it will be effective in all EU member states and EFTA 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 must meet the requirements of 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 under the Directive 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)); end of sell off period for IVDD with certificate and of IVDR class D (article 110 (3)) placed on the market from 26 May 2022.

2027 – From 26 May 2027: End of placing on the market under the IVDD of class B, class As* and of sell-off period for IVDR (article 110 (3)) class C devices.

2028 – From 26 May 2028: End of sell of period for IVDR (article 110 (3)) Class B and As* devices.

From the 26 May 2022, the requirements of the IVDR related to post-market surveillance, vigilance, registration of economic operators and of devices will apply 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***

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*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

Get ready for the new In Vitro Diagnostic Device Regulation now

www.tuv-sud.com/ivdr