THE NEW 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 110 billion.***

Source: https://ec.europa.eu/growth/sectors/medical-devices_en

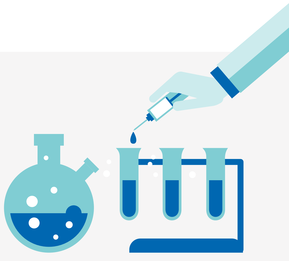
The European medical device industry employs approx. **500,000.***

The European medical device sector is comprised of **22,000 companies**.

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

What is the IVDR?

The EU Regulation 2017/746 on in vitro diagnostic medical devices (IVDR) is a new regulation that will replace the EU's current Directive on In Vitro Diagnostic Medical Devices (IVDD) (98/79/EC). The regulation applies to all IVD manufacturers who intend to place their IVDs in the EU.



Timeline of the IVDR

- **2010** – EU Commission launches public consultation
- **2012** – EU Commission publishes proposal for IVDR
- **2014** – EU Parliament reviews draft and proposes changes
- **2015** – EU Council reviews draft and proposes additional changes
- **2017** – IVDR enters into force on 26 May 2017
- **2022** – New IVDs and IVDs without a valid IVDD certificate will have to meet IVDR requirements from 26 May 2022
- **2024** – Extended transition period ends on 26 May 2024 for IVDs with valid IVDD certification

Risk classes

IVDD **4***

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*Risk not consequently considered except for high risk products.

Notified Body involvement

Under IVDD about **15 percent** of IVDs

Under IVDR **90 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.tuvsud.com/ivdr