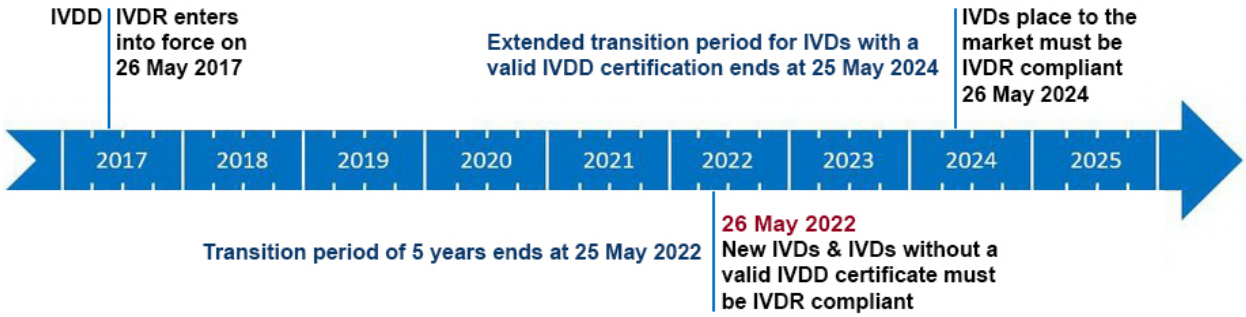
European Union (EU) 2017/746 In Vitro Diagnostic Medical Device Regulation (IVDR)

What is the IVDR?

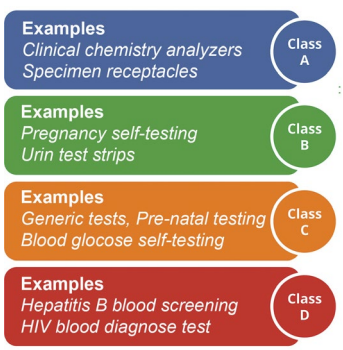
The In Vitro Diagnostic Medical Device Regulation (IVDR) (EU) 2017/746 is the new EU legislation applicable to In Vitro Diagnostic (IVD) Medical Devices and the IVDR replaces the EU In Vitro Diagnostics Directive (IVDD) 98/79/EC.
The regulation applies to IVD manufacturers who are intended to place IVDs to the EU market.
The involvement of a Notified Body (NB) is necessary for different risk classes.

For Non-EU manufacturers is an EU Registered Authorised Representative (AR) mandatory.

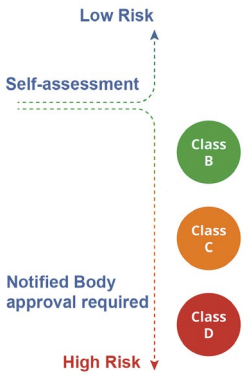
Timeline of the IVDR



Risk Classes



Notified Body



EU Registered AR

- Mandate NON-EU manufacturer
- Provide EU registered address
- Inspections of CE documents
- Represent manufacturer in EU
- Keep documents for inspection
- EUDAMED registration
- Take care incident reporting
- Consulting for EU Directives
- Safeguard regulation updates
- Support NB applications

Key changes

- Product scope expansion
- New classification according to risks
- Stricter requirements for clinical evidence
- EU Registered Authorised Representative
- More stringent documentations
- Unique device identification
- EUDAMED registration increase transparency
- Notified Bodies increased involvement

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