EU MDR/IVDR - European Medical Device Regulations

The EU has strengthened medical device regulations with **MDR (Medical Device Regulation)** and **IVDR (In Vitro Diagnostic Regulation)**

🗓️ MDR (EU 2017/745)

Fully implemented May 2021, general medical device regulation

💉 IVDR (EU 2017/746)

Fully implemented May 2022, in vitro diagnostic medical device regulation

Key Changes

- **Enhanced risk classification:** Increase in Class IIb/III devices
- **Increased clinical evidence requirements:** More stringent clinical evaluations
- **Expanded Notified Body role:** Strengthened independent body reviews
- **UDI (Unique Device Identification):** Improved device traceability
- **EUDAMED database:** Centralized information system
- **Enhanced post-market surveillance:** Mandatory PSUR, PMS

Class I

Low risk, self-declaration

Class IIa/IIb

Medium risk, NB review

Class III

High risk, NB review

💡 **Key Point:** MDR/IVDR prioritizes patient safety, and AI/ML devices must also be appropriately classified and evaluated within this framework