

Comparing Medical Device Regulations in the EU and US



- **EU:**
 - **European Medicines Agency (EMA)**
 - **Notified Bodies:** Independent organizations designated by EU countries to assess product conformity.

- **US:**
 - **Food and Drug Administration (FDA)**
 - **Center for Devices and Radiological Health (CDRH)**



- Class I: Low risk (e.g., bandages)
- Class IIa: Medium risk (e.g., dental fillings)
- Class IIb: Higher risk (e.g., ventilators)
 - Class III: High risk (e.g., pacemakers)

- **US:**
 - Class I: Low risk and subject to general controls (e.g., tongue depressors)
 - Class II: Moderate risk with special controls (e.g., pregnancy test kits)
 - Class III: High risk requiring premarket approval (e.g., heart valves)



● UE Regulatory Processes

Conformity Assessment:

Conducted by Notified Bodies.

CE Marking:

Required for market access.

Post-Market Surveillance:

Ongoing responsibility for manufacturers.

Premarket Notification

(510(k)): For Class I and II devices, demonstrating substantial equivalence.

Premarket Approval

(PMA): Required for Class III devices, demonstrating safety and effectiveness.

Post-Market Surveillance:

Includes medical device reporting and quality system regulations.

● US Regulatory Processes

- **EU:** Typically faster for low-to-medium risk devices due to reliance on Notified Bodies.
- **US:** More rigorous for high-risk devices due to PMA requirements.