Regulatory Resources

Regulatory Directives

- European Commission Medical Devices Sector
  - MDR (EU 2017/745) and IVDR (EU 2017/746)
  - Implementation timelines
  - Factsheets and updates
  - FAQs on regulatory transition
- Official Journal of the European Union (OJEU):
  - Search for official legal texts, delegated acts, implementing regulations, etc.
  - Use the consolidated versions to include amendments and corrigenda.

Ethics Committees:

- EUREC - European Network of Research Ethics Committees
- EC Ethics Self-Assessment & Templates
- Ethics and Research Integrity in the European Research Area (ERA)

Notified Bodies:

- List of Notified bodies by country: https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies/by-country

Registration systems:

- Medical Devices: EUDAMED (European Database on Medical Devices)
- Clinical Trials: EU Clinical Trials Register

Harmonised Standards and Interoperability

- Medical devices Harmonised Standards (HAS) Database: Access harmonised standards under MDR/IVDR (these standards help prove conformity with general safety and performance requirements)
- The New European Interoperability Framework | ISA^2
- European Institute for Innovation through Health Data (i~HD): Support on health data governance, GDPR, and real-world data validation

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GDPR and Data Protection Compliance

- European Commission central resource on European Data Protection rules and legislation: Data protection - European Commission
- European Data Protection Board (EDPB) Guidelines
- European Commission GDPR Portal

Other Support Tools and Portals

- CE Tool explains the application of the new regulations for medical devices, the MDR and IVDR and allows to identify the classification.
- EU Regulatory Navigator for Medical Devices (Cencenelec & EU Joint Initiative): https://www.cencenelec.eu (search for "Regulatory Navigator"). Provides flowcharts and tools to understand steps for CE marking and compliance under MDR/IVDR.
- European Medicines Agency (EMA) – if product is a combination with medicinal substances (relevant for drug-device combinations, nanomedicine, or ATMPs)

Examples

Examples of resources related to national registration requirements in Spain, Belgium, France and Germany:

Country	Authority	Main Portal	Device Registration Info
Spain	AEMPS	Agencia Española de Medicamentos y Productos Sanitarios	Comercialización de productos sanitarios en España | AEMPS
Belgium	FAMHP	FAMHP | Your medicine and health products	Health Products | FAMHP
France	ANSM	Accueil - ANSM	Agence nationale de sécurité du médicament et des produits de santé - ANSM
Germany	BfArM	BfArM - Medical devices	BfArM - Homepage - Page not found (error 404)

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