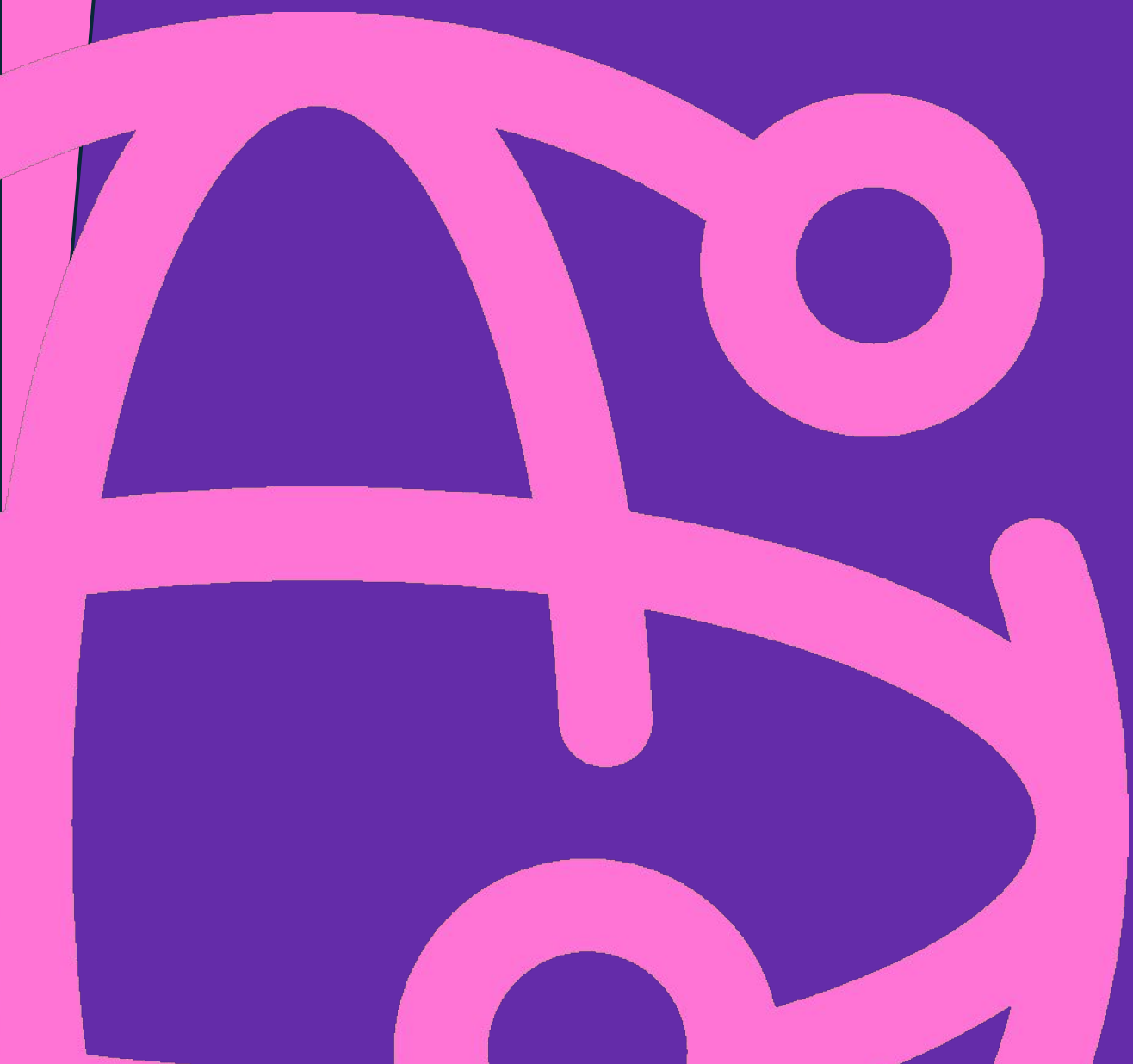
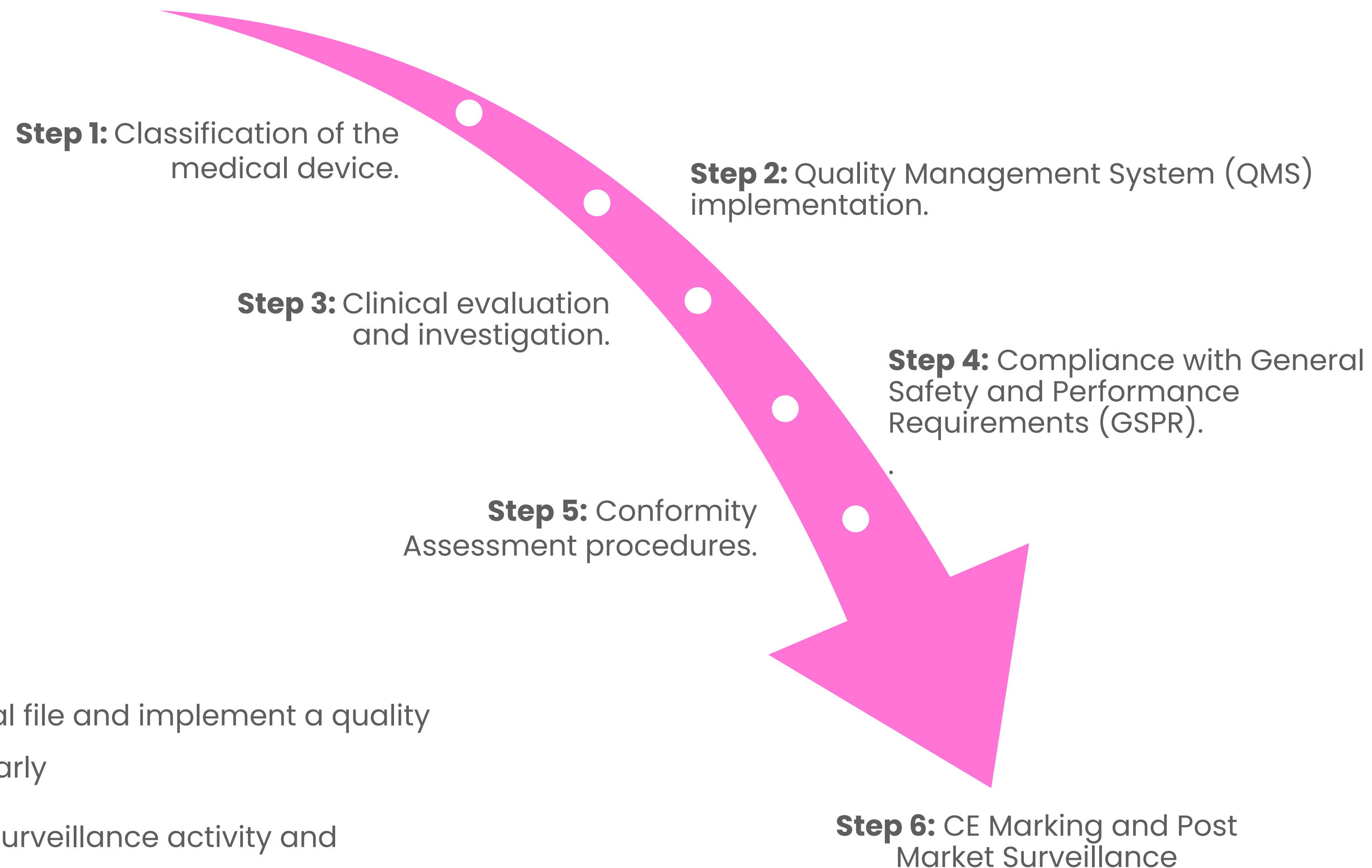


How to bring a medical device to market in the EU



Six Steps to EU Market Entry

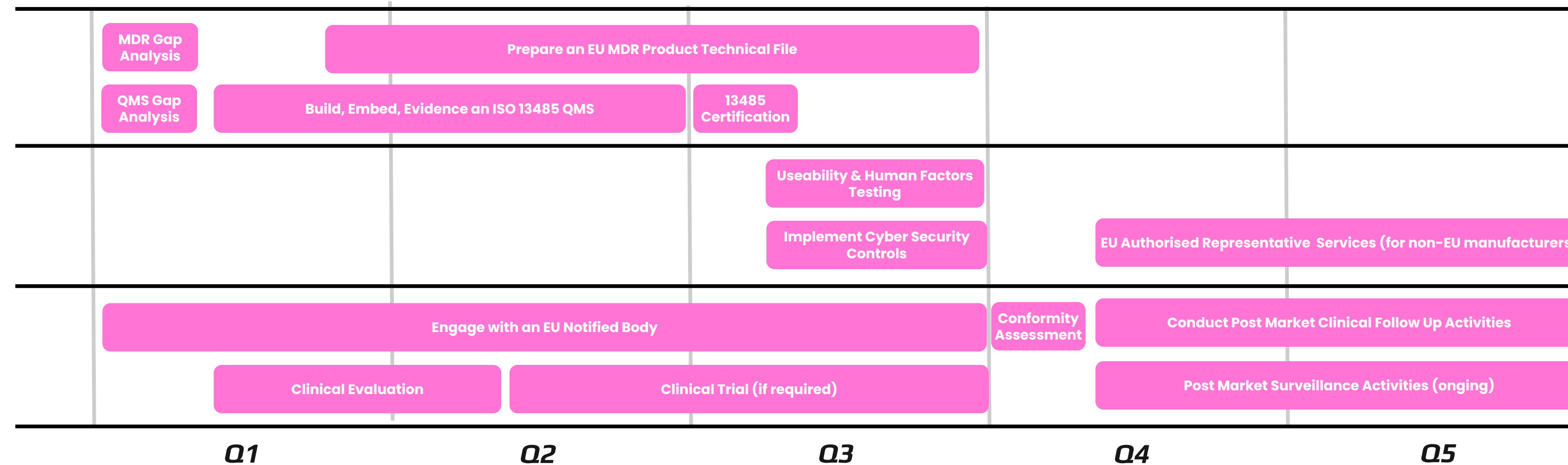


Tips for success

Build a product technical file and implement a quality management system early

Plan your post-market surveillance activity and document them appropriately.

Example Class IIa EU MDR Timeline



The timeline for completing an EU MDR conformity assessment will vary depending upon the specifics of the medical device under assessment. Planning for a best case 9-to-15-month programme of work would be a sensible approach.

Often the key constraint is availability of Notified Body audit dates, so engaging early to secure your dates is advisable.

The level of clinical evidence required will vary from device to device, influenced significantly by the medical claims you are making in your Intended Use statement. Plan these activities into your certification cycle from the start.

Appointing an EU Authorised Representative (EU AR) is only required for non-EU manufacturers.

Post-market surveillance activities are required for the lifetime of the medical device.

Common Challenges and Solutions

Challenge 1: Understanding EU MDR Requirements

- **Solution:** use EU MDCG guidance documents and specialist resources.

Challenge 2: Implementing Quality Management System

- **Solution:** Adopt ISO 13485, implement continuous improvement, conduct regular audits.

Challenge 3: Clinical Evaluation and Post-Market Surveillance

- **Solution:** Develop clinical evaluation plans, conduct post-market clinical followup studies, establish PMS procedures.

Challenge 4: Technical Documentation

- **Solution:** Use standardised templates, ensure team collaboration, employ document management systems.

Challenge 5: Transition Timelines

- **Solution:** Create a transition plan, allocate resources, prioritise high-risk areas.

Challenge 6: Engaging Notified Bodies

- **Solution:** Engage early, prepare thoroughly, maintain open communication.

Challenge 7: Supply Chain Management

- **Solution:** Evaluate and audit suppliers, implement vendor qualification, establish quality agreements.

What are the EU Medical Device Regulations?

The EU Medical Device Regulation (**MDR**) **2017/745** sets out the **standards of quality, safety, and performance** for medical devices made available within the EU market.

This regulation mandates **comprehensive oversight and accountability throughout the entire supply chain**. It applies to manufacturers, authorised representatives, importers, and distributors of medical devices. **Each stakeholder has defined responsibilities to ensure compliance with the regulation**, contributing to a unified approach to patient safety and product efficacy.

Under the MDR, medical devices are classified into **four risk-based categories: Class I, IIa, IIb, and III**. This classification ensures that regulatory scrutiny is proportional to the potential risks posed by the devices. The higher the risk associated with the device, the more rigorous the requirements for evidence of safety and performance.

What are the four risk-based categories?

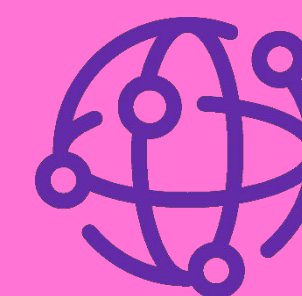
- Class I** **Low-risk** devices such as health and wellness apps, mobile apps for general health tracking, and software for simple clinical decision support. These devices typically do not require extensive clinical testing and can be self-certified by the manufacturer.
- Class IIa** **Moderate-risk** devices such as medical imaging analysis software, diabetes management apps, and software for remote patient monitoring. These devices require some clinical evaluation and must undergo a conformity assessment by a notified body.
- Class IIb** **Higher-risk** devices including software for diagnostic support in oncology, advanced imaging software for detecting conditions like heart disease, and clinical decision support systems for critical care. These devices undergo rigorous testing and require a more detailed conformity assessment to ensure safety and effectiveness.
- Class III** **High-risk** devices such as software for controlling active implantable medical devices, software for advanced surgical planning, and applications for predicting severe medical conditions. These devices are subject to the highest level of scrutiny, requiring extensive clinical trials and a comprehensive conformity assessment to ensure their safety and performance.

About us

Deviceology aims to make medical device compliance easier. We provide regulatory and compliance guidance and support for medical device manufacturers, and health organisations.

We aim to solve your AI governance, certification, compliance, digital clinical safety and market access challenges, so you can focus on delivering innovation, bringing and safely maintaining products in your chosen markets.

We're passionate about doing things the right way and delivering pragmatic, value-adding insight and assurance. Our services include regulatory strategies, market access, reimbursement models, product registration and post market surveillance for major markets including Europe, UK and the U.S.,



www.deviceology.net

info@deviceology.net

www.linkedin.com/company/deviceology/