Medical device services

Market entry for medical devices and IVDs

Dr. Guido Middeler
Partner

Further information:
Phone +49 (0)251-60935-0
info@diapharm.com

Diapharm its there to advise and support you on all topics relating to medical devices and in vitro diagnostics, from borderline issues and feasibility to conformity assessment and responsibility as manufacturer. Our EN ISO 13485-certified QM system allows us to offer our clients comprehensive service in line with all guidelines and standards.

Our medical device services include:

- Feasibility assessment
- Compilation of technical documentation
- Preparation of clinical assessments and performance evaluations
- Implementation of quality management systems (ISO 13485)
- Risk management in accordance with EN ISO 14971
- Auditing of manufacturing operations and self-inspection
- Performance of conformity assessment procedures
- Assumption of product responsibility for marketing activities
- Post-marketing surveillance

Diapharm develops medical devices and IVDs on behalf of clients and helps get them market ready. If necessary, the company can also take over regulatory responsibility as the manufacturer, EU authorised representative or as Trustee Service for OEM / PLM manufacturers.

The products are always marketed in the name and corporate identity of the client or its appointed licensee or marketing partner.

As a result, Diapharm makes it fast and easy for clients to gain market entry.

Get in touch with us!

Your benefits:

- **Safe and secure market entry**
- **Access to certified quality management for medical devices**
- **Outsourcing of responsibility as manufacturer or EU authorised representative**
- **Trustee-Service for OEM / PLM manufacturers**

Diapharm