



Quality Consulting Medical GmbH

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qcmed is the No. 1 full service provider for medical device QM & Regulatory Affairs in the Euregio! qcmed guides manufacturers, operators and users of medical devices safely through the medical device law and regulatory requirements. As consulting engineers we accompany our clients on their way to international market approval for their products.

20 years of experience, class I-III medical devices of all types: Electrical, software, mechanical, implantable, biological, IVD. Partner for manufacturers and Notified Bodies. Network to operate as one-stop-shop.

Installation and maintenance of QM-Systems: ISO 9001, 13485, GMP

- Technical documentation
- Risk management ISO 14971, ISO 22442, IEC 80001-1
- Validation for product & process: Software, Product, Biology, Sterilization
- Approval: CE, USA, Canada, other markets
- Post Market Surveillance
- Audits: Internal, Suppliers; international
- Seminars, Trainings: Your team, your event, your location

Management, consulting and training. Quality for success.