LINK MEDICAL

MD

Medical Device. Regulatory and Clinical Guidance. From Concept to Commercialization.

Get it right the first time. With the optimal regulatory and clinical strategy, we help you navigate medical device development efficiently — from concept to approval, all from a single source.

Our international, multidisciplinary experts with proven experience in medical device development will lead you through every step. We provide tailored packages that include an efficient CE-mark (EU)/FDA (USA) strategy, compliance readiness, and clinical investigations — streamlining the entire journey from development to commercialization and ensuring patient benefit as early as possible.

Let us simplify the process — tell us about your needs today.

info@linkmedical.eu

Your LINK to // innovation & health

LINKMEDICAL.EU

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Meet One of Our Team Members

Lauren Willgeroth
Medical Device Manager

Lauren holds a Master of Science in Physics and has more than 10 years of experience with medical devices. She is an expert in all aspects of technical documentation, with a special focus on hardware and software products, and is currently expanding the regulatory toolbox to include AI.

She has worked on active devices, non-active implantables, software, reprocessables, and devices with a measuring function. Lauren understands the requirements from the authorities and will pragmatically guide you through the development of your product. She is based in LINK Medical's Berlin office in Germany.

Numbers That Count

+30 Full-Service Clinical Investigations

Including wound care, anesthesia, dental devices, active implants, diagnostic devices, single-use devices, reusable instruments, and technical aids.

+150 Regulatory Projects

In the last 5 years, we have worked with more than 100 clients, from small startups to major international companies.

Why Partner with LINK Medical Device Experts?

- **Regulatory Strategy & Gap Analysis** – Identify requirements, close gaps, and speed up development.
- **Intended Use and Risk Classification** – Define use and risk class to guide your regulatory pathway.
- **Technical Documentation** – Aligned with ISO and MDR/FDA requirements to support regulatory submissions.
- **Clinical Evaluation and Investigation** – Guidance on designing, conducting, and documenting clinical activities aligned with regulatory expectations.
- **Quality Management System** – QMS in accordance with ISO 13485 and other relevant standards.
- **CE-mark/FDA Approval and Commercialization** – End-to-end support to enable market access in Europe and the US.
- **Provide interim PRRC assignments.**
- **MDD to MDR Transition** – Smooth migration planning to meet MDR deadlines and avoid non-compliance issues.