Medical Device

Breaking barriers to market entry? Let us guide you.

Do you require CE mark certification of your medical device in Europe? Would guidance for US FDA 510(k) clearance be of interest? Is a clinical study required?

We are the link between your medical device idea and market ensuring you overcome regulatory barriers on your way to success.

Our experienced team can direct the creation of your quality management system, providing device classification guidance, undertaking health economic evaluations, developing required documentation as well as conducting your clinical studies.

people and plans

LINKMEDICAL.NO

Medical Device

LINK Medical offers a unique portfolio of medical device services for small start-up companies to large established organisations. We can provide you with recommendations on your regulatory strategy as well as guide you within your national and international requirements in an ever-changing regulatory climate. Our extensive experience and expertise enable us to guide your product and will increase its chances to launch to the designated market.

We can assist you irrespective of which phase your product is in including setting up your initial Quality Management System (QMS). Our medical device team is knowledgeable and experienced in handling all classes of medical device or medical device-drug combination products. Our project management system ensures systematic undertaking of your project from inception to completion.

Post-marketing follow-up surveillance is now being reinforced by the authorities. LINK Medical provides services related to regular updates of your clinical evaluation report including running literature searches or conducting an additional clinical study if necessary.

Health economic evaluation

Performing a health economic evaluation is vital to understand your products market potential and is best started at an early stage of the products life cycle. Our health economics team can assist you in demonstrating the value of your product to payers.

Our services

Medical device requirements

- European and national regulatory requirements
- Product/Risk Classification
- Guidance for regulatory processes
- Risk management

Quality Management System (QMS)

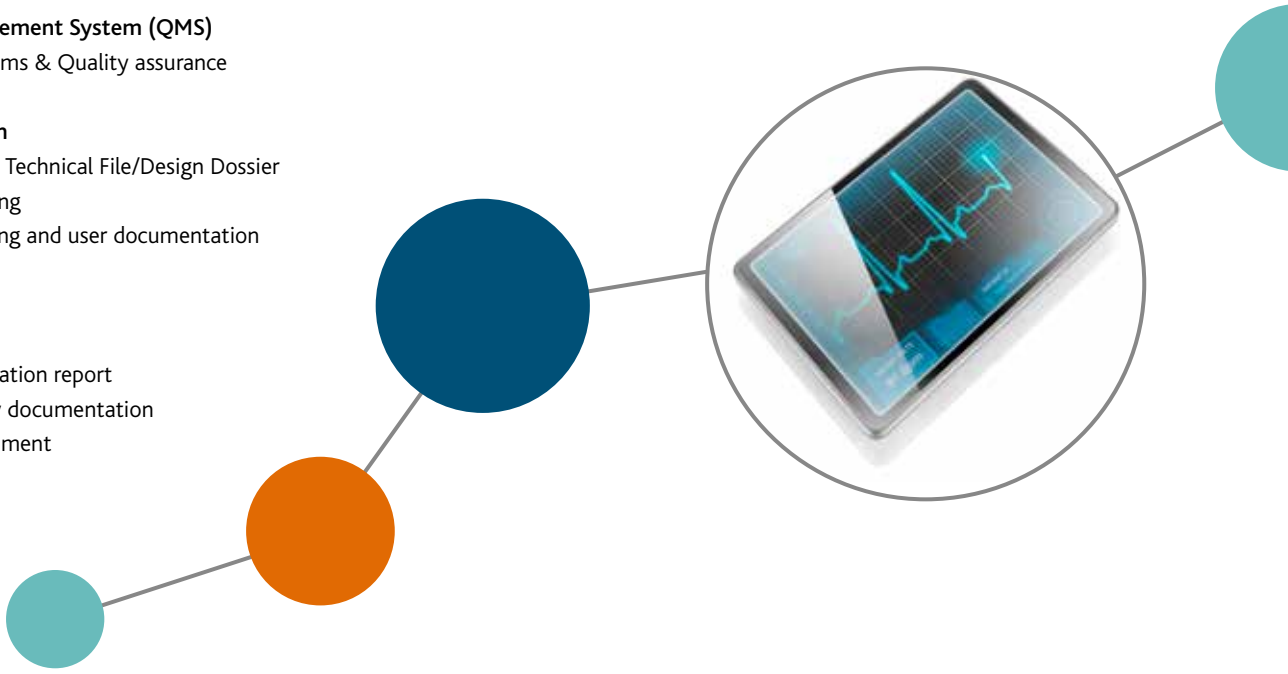
- Quality systems & Quality assurance

Documentation

- Create CE EU Technical File/Design Dossier
- Medical writing
- Review labeling and user documentation
- User testing

Clinical

- Clinical evaluation report
- Clinical study documentation
- Data management
- Statistics



LINK MEDICAL RESEARCH

NORWAY
link@linkmedical.no
+47 22 58 90 00
www.linkmedical.no

SWEDEN
link@linkmedical.se
+46 706 041 163
www.linkmedical.se

DENMARK
link@linkmedical.dk
+45 22 15 85 56
www.linkmedical.dk

GERMANY
link@linkmedical.de
+ 49 30 2461 2025
www.linkmedical.de