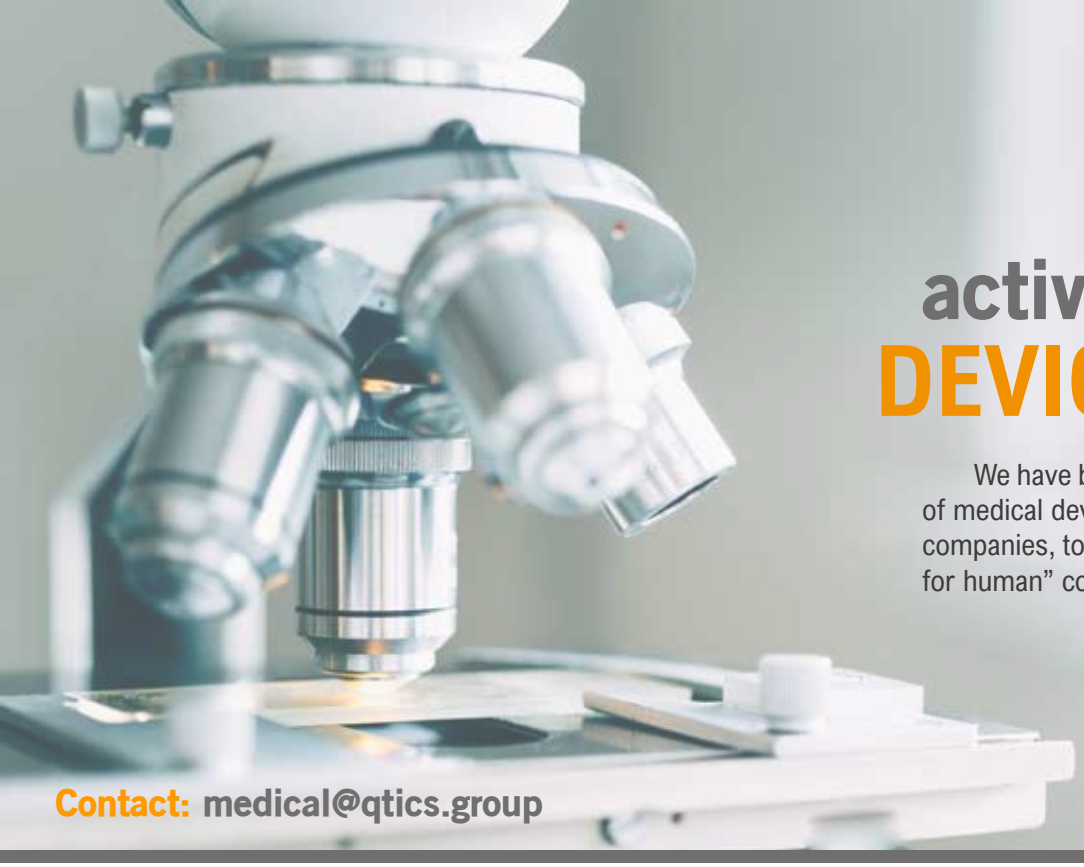

active MEDICAL DEVICES services

We have been building a global, trusted network of medical device Testing, Inspection & Certification companies, to prove the power of intelligent “human for human” cooperation and service.

Contact: medical@qtics.group

www.qtics.group

OUR SERVICE PORTFOLIO BY MEDICAL SEGMENTS

Consulting

Compliance with the regulation of medical devices poses an increasingly difficult task for economic operators. In order to reduce the burden on economic operators, we provide full support for the CE marking of medical devices, from regulatory strategy to post-market surveillance.

consulting

Education

Fulfilling the requirements of the CE marking is inconceivable without acquiring the appropriate knowledge. We provide training in all relevant areas related to the CE marking of medical devices in the form that best suits your needs: open and outsourced or customized training.

education

Certification

The entrance ticket to the international medical device market is ISO 13485 certification. With our accredited ISO 13485 and ISO 27001 certification service, we provide internationally recognized certificates. In addition, we provide effective support for the selection of a notified body.

certification

Cybersecurity evaluation

Active and IVD devices which are connected, store any data, include any computing, control analogue or digital functionality are subject of mandatory assessment and validation of cyber security risk. We execute cybersecurity evaluations based on strictest accreditations and standards.

cybersecurity evaluation

Clinical investigation

The key to CE marking of medical devices is validation of clinical safety and performance. With our team of doctors and biologists, we provide a full range of services from the design of clinical investigations, through licensing, to the preparation of a clinical investigation report.

clinical investigation

Preclinical testing

Verification of medical devices safety is mandatory for all manufacturers. We provide biocompatibility, safety and usability testing services to verify the safety of active and IVD devices.

preclinical testing