QTICS GROUP

PROFESSIONAL.INTELLIGENT.HUMAN

„Possibilities and challenges 2021”

Online conference 27.01.2021.

Zoltán Karászi

QTICS GROUP
PROFESSIONAL.INTELLIGENT.HUMAN

ALLIANCE
for compliance

We have combined assets, competences and creative efforts of People and Companies into a networked, connected, intelligent, thinking structure. The networked group provides our Customers & Partners valuable services, utilizes and shares assets, qualifications globally. Reaching so a higher efficiency enables investing in new technologies and service innovation. QTICS seek to create a community, whithin our Clients, Colleagues and Stakeholders prevail with their undivided trust in our services.

Contact: info@qtics.group

www.qtics.group

QTICS GROUP

medical

segments:

Energy & Infrastructure & Industry

QTICS ENERGY with its IEC/ISO accreditations and notified body (NoBo) activity areas focuses on serving the ever digitalizing industrial products, systems and experts.

Medical device & Health

QTICS MEDICAL provides a consistent and complete chain of services for producers of active medical devices, enabling the mandatory compliance with requirements of certification.

Mobility & Drones

QTICS MOBILITY has been building a relevant product testing, evaluation and certification capability for the automotive and drone industry, including NoBo services.

Consumer & IoT

QTICS CONSUMER assesses & certifies electric devices and network-connected devices, which must comply with mandatory cybersecurity regulations (e.g. CSA, (EU))

OUR SERVICE PORTFOLIO BY MEDICAL SEGMENTS

QTICS medical

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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.

Education

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

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.Further we provide effective support for the selection of a NoBo.

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.

Clinical investigation

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

Preclinical testing

The verification of medical devices safety is mandatory for all manufacturers. We provide biocompatibility, toxicology, safety and usability testing services to verify the safety of active and IVD devices based on ISO/IEC accreditations and an extensive range of technical standards.

medical@qtics.group

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