

FISBA receives ISO13485 certificate for medical devices

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St.Gallen, Switzerland February 7, 2023. FISBA AG, one of the world's leading suppliers in the optical industry, has further expanded its expertise in high-precision optical manufacturing, coating and assembly/system mounting for use in medical devices with the successful implementation of a quality management system according to ISO 13485:2016. The scope of ISO13485:2016 certification includes engineering, manufacturing and distribution of customized optical components, optomechanical/optoelectronic systems and microsystems. FISBA AG meets internationally recognized Medical Devices standards and applies these as an integrated quality management system also in the areas of Industrial Applications as well as Aerospace & Defense.

"With this additional certification, FISBA AG in St.Gallen confirms a sustainable service level based on the highest international quality standards in medical devices. The entire organization has worked together to achieve this," said Bernd Reiss, Director of Quality & EHS at FISBA AG. "For our current and future customers in the medical device industry, we see ourselves as an important strategic and qualified partner and therefore proactively fulfill the corresponding internationally recognized requirements and regulatory frameworks. These are required from our customers for the marketing of their final medical devices, which must ensure a high level of patient safety/functional reliability during use."



As an internationally recognized standard in the medical device industry, ISO13485:2016 defines guidelines for management responsibility, resource management, overall product realization, and continuous measurement, analysis, and improvement. In particular, the certification places high demands on the capabilities as well as compliance of all processes, to the qualification of employees, to the constant consideration of quality risks in the event of changes, and finally to a consistent assurance and complete traceability of the product quality based on its documentation throughout the entire value chain.

About FISBA

FISBA is a global company dedicated to shaping light through excellence in optical design, system engineering, high precision volume production and advanced optical coating. Specialties include aspherical/spherical microlenses, complex flat optics, precise/complex optical assemblies, sophisticated optical systems and compact laser modules. In the broad field of photonics, FISBA focuses on solutions for Life Sciences, Industrial Applications and Aerospace and Defense – always with the mission of empowering customers to exceed their goals. FISBA operates from its headquarters in Switzerland with subsidiaries in Germany, the US and China. The company is privately owned and employs over 360 people from 30 nations worldwide.

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