Standards-compliant software development for medical devices

„For us, infoteam Software AG is a valuable and versatile partner for regulated software development. Thanks to their many years of expertise and routine handling of the normative requirements for medical products, infoteam provides a crucial component that allows us to offer our clients and their patients products of the highest standard."

Project manager, Technolas Perfect Vision GmbH

For our client:

BAUSCH+LOMB | TECHNOLAS

Initial situation

- Technolas Perfect Vision GmbH develops and distributes medical devices for ophthalmology (e.g., eye lasers for surgical procedures).

- The company designs the firmware and application software for the devices in-house and builds the software together with external development partners.

- Development partners must have many years of experience in building standards-compliant software for medical devices.

- Other key requirements are a very high level of quality consciousness and a true wealth of expertise in the latest state of technology.

Solution

- **since 2017:** provision of several teams for MDR-compliant development of device and application software for an eye laser (highest software safety class)

- coordination of the teams by infoteam project managers, with simultaneous close and agile consultation with the client

- experienced application of the customer's own development process according to IEC 62304

- seamless cooperation with other external service providers (e.g., software testing)

- development according to state-of-the-art design and architecture principles to achieve optimum quality, stability and maintainability

- cybersecurity analysis and consulting

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