

Protembis Achieves ISO 13485:2016 Quality Management System Certification

Aachen, Germany, January 9, 2018

Protembis GmbH announced today its successful certification in compliance with ISO 13485:2016. ISO 13485:2016 indicates that the Protembis Quality Management System complies with the stringent, international ISO standards for the design and development of medical devices. The certification was provided by BSI Group.



“This is an important milestone towards CE certification for our novel cerebral protection device. Achieving this certification reflects the high quality of standards to which we adhere and that we apply to our products and our company” stated Karl von Mangoldt, Co-CEO and Co-Founder of Protembis.

Protembis is developing a novel technological approach to minimize the risk of embolic cerebral lesions during minimally invasive cardiovascular interventions; embolic events are a significant potential side-effect of these procedures, and preventing these embolic events using the ProtEmbo[®] System is a significant benefit to patients. Protembis' ProtEmbo[®] System consists of a filter device that is introduced into the aortic arch during a minimally invasive procedure and, when positioned in the aorta, prevents the migration of embolic particles into the brain by deflecting the debris away from the three major vessels branching from the aorta to supply blood to the brain.

The first generation of the ProtEmbo[®] System is currently being investigated in a safety and feasibility study in patients undergoing transcatheter aortic valve implantations (TAVI/ TAVR). Enrollment in the study was initiated in Q3 2017. “The first results are promising and have demonstrated that our device can be a simple, quick and effective solution to improve patient care” said Conrad Rasmus, Co-CEO and Co-Founder of Protembis.



About Protembis

Founded in 2013, Protembis is a medical device start-up company with its headquarters in the city of Aachen, Germany. The company's vision is to bring the ProtEmbo[®] System into every interventional procedure which bears a risk of neurologic injury, thereby radically improving patient safety.

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