Press Release
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EMOSIS announces ISO 9001:2015 and ISO 13485:2016 certifications

The company is getting one step closer to market its first Emo-test

Strasbourg, France – November 14th 2017

Emosis, a medical device company specializing in cell-based hemostasis and thrombosis diagnostics, is glad to announce that the company has recently obtained its ISO 9001:2015 and ISO 13485:2016 certificates.

These two certifications imply that the quality management processes established by Emosis are compliant with the requirements of the standards of the ISO – International Organization for Standardization - regarding the design, manufacturing and sale of In Vitro diagnostic tests.

Emosis is growing, and along with this growth comes a continuous drive to improve its processes and methods, to provide the clinical lab specialists and the medical community with the best products possible, and thus contribute positively to patient disease management.

ISO 9001:2015 is the most recent standard of its kind and it focuses on quality management systems and performance. Its requirements lead companies to develop a management system that aligns quality with their wider business strategy.

As for ISO 13485:2016, it specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and IVD that consistently meet customer and applicable regulatory requirements.

Dr. Frederic Allemand, CEO of Emosis, declared: “We are proud to have achieved this crucial milestone. These certifications are the acknowledgement of processes we have built to aim for excellence in In Vitro diagnostics. They show how strongly Emosis is dedicated to continuously improve and sharpen its quality processes, to deliver the best hemostasis diagnostics solutions, in the best conditions”.

About Emosis

Since its inception in 2015, EMOSIS, a young innovative company, is dedicated to the development and marketing of a first-in-class, high-performance and user-friendly system combining various cell- and microparticle-based assay kits to be performed on user-friendly, benchtop flow cytometers. Routinely diagnosing and differentiating various bleeding and thrombotic disorders will allow faster and better therapeutic decisions. The system will support a broad range of clinical applications such as: confirming the diagnosis of heparin–induced thrombocytopenia (first test, launch in 2017), assessing platelet function and personalizing antiplatelet therapies, testing hypercoagulable states, and others.

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