

BIO SERENITY OBTAINS CERTIFICATION EN ISO 13485 AND CE MARKING FOR THE NEURONAUTE®

Paris, Monday May 16th

The French start-up company, BioSerenity, specializing in smart clothing for medical diagnostics has been certified EN ISO 13485:2003 & ISO 13485:2012 and has received CE Marking for its device, the NEURONAUTE®.



After a successful year, BioSerenity will move past the trial stage with this market approval and commercialize its first medical device for Epilepsy.

The NEURONAUTE® is the first diagnostic solution for Epilepsy using smart clothing, a smartphone application and a Cloud platform. The system will allow for a mobile and continuous electroencephalogram (EEG) recording with the objective of giving neurologists a tool for reducing the time for an accurate Epilepsy diagnosis.

Pierre-Yves Frouin, the president of BioSerenity states: "We are happy to obtain these two certifications. It is the fruit of two years of Quality and Regulatory work by the company team and the recognition of our Quality Standards by a leading organization in the domain." The CE Marking for the NEURONAUTE® will allow BioSerenity to commercialize its remote diagnostic solution with several expert centers for Epilepsy in the upcoming months before preparing a large-scale launch.

BioSerenity will also continue its work in Big Data and the development of artificial intelligence help for diagnostics in a shared laboratory setting with the ICM (icm-institute.org). The company was recently awarded a co-recipient trophy for Big Data.

About ISO standards

The EN ISO norm 13485 outlines the requirements for Quality Management Systems (QMS) in the industry of medical devices. To obtain EN ISO 13485 certification, a company must use all means necessary to guarantee the quality and safety of commercial products and services. The certification is used to determine the manufacturer's capacity to meet the regulatory requirements in the domain of medical devices. This certification is given by a certification agency.

About the CE marking

The CE label is the means of proof of product conformity to EU legislation and allows for free circulation of the product within the European market. For certain medical devices, among which are active systems, a third-party organization's evaluation, called notified body, designated by member states is necessary before awarding the CE Marking.

About BioSerenity

BioSerenity, a company founded in 2014, is located within the ICM (icm-institute.org), with whom the company shares a common laboratory. With over 30 employees, BioSerenity has rapidly become a leader in smart clothing innovation for Medical Devices and in Electrophysiology detection patterns with the help of Deep Learning.

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