

Press release

SmartCardia SA Receives CE Medical Device Certification for its Wearable Medical Multi Sensor System

Today [On March 9th], Lausanne, Switzerland

SmartCardia SA announced today that it has received CE Class IIa certification for its cordless wearable medical multi-sensor monitoring system, SmartWearable. The device measures a complete set of physiological and vital parameters continuously, including the Electrocardiogram (ECG), heart rate, heart rate variability, pulse rate, oxygen saturation (SpO2), blood pressure variations and trends, skin temperature, activity and posture from a single miniaturized unit at clinical accuracy.

A major challenge with today's wearables is to measure and provide clinically meaningful information to doctors and patients that could help diagnose a disease or prevent a deterioration of health condition. SmartCardia's wearable device uniquely allows for the continuous monitoring and analysis of important vital signs to provide early warning of a health risk.



"Most wearables today measure a limited set of parameters. For clinicians to make informed decisions, several important vitals are needed, and continuously measured in the hospital Intensive Care Units, such as the ECG, SpO2 and blood pressure data. We have developed a system to measure all the important vitals continuously from a single easy-to-wear unit, and have rigorously validated them in several clinical trials in leading hospitals globally. There is a tremendous response and demand for the system from the different clinics and patients we have been working with", said Dr. Srinivasan Murali, CEO and co-founder of SmartCardia.

SmartCardia's core technology is based on several years of R&D from top researchers and clinicians across the world. It is working with key opinion leaders across a variety of clinical fields, from cardiovascular surgery, intensive care medicine, anesthesiology, vascular medicine, sleep and COPD to validate the unique insights provided by the system.

“We have developed SmartNeuralNet, a world-leading machine learning technology that powers our medical wearables. Our mission is to empower the millions of patients with chronic conditions with actionable insights to improve their health and provide a better quality of life for them and their carers. We have designed the wearable system from ground up to meet the rigorous clinical standards for continuous and efficient patient monitoring.”, said Dr. Francisco Rincon, co-founder and CTO of SmartCardia.

About SmartCardia:

SmartCardia SA is a Swiss medical device company with focus on clinical quality data and scientific validation. It is an ISO 13485 and ISO 9001 certified medical device manufacturer and meets the strict quality control standards for the solutions. The company is also ISO 27001 certified for data security and privacy.

For more information:

SmartCardia SA.
EPFL Innovation Park
Batiment C
CH1015 Lausanne
Contact: contact@smartcardia.com

<http://www.smartcardia.com>
<http://www.facebook.com/smartcardia>
<http://www.twitter.com/smartcardia>