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ASIA EDITION

CardiacSense Atrial Fibrillation detection watch receives CE Mark

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The watch will begin shipping in EU as a medical device for continuous measurement of heart rate and arrhythmias at ECG-level accuracy



CardiacSense - a digital health company that developed and clinically verified a medical grade watch capable of detecting and remotely monitoring Atrial Fibrillation (A-Fib) and Heart Rate Variability (HRV) announced that it received the CE Mark for marketing & sales of the device in the European Union. The indications certified include "detection of Atrial Fibrillation (A-Fib)" and "monitoring of Heart Rate Variability (HRV)" with continuous Photoplethysmography (PPG) and spot Electrocardiogram (ECG).

CardiacSense's medical watch CE Mark enables continuous, long-term, accurate and comfortable patient monitoring without the need to implant invasive cardiac monitors - a prevalent practice for patients experiencing arrhythmias. Data from 2 clinical trials reviewed for the CE Mark demonstrated accurate detection of A-Fib by continuous PPG of over 99%.

The certification will enable commercialize of the medical watch in the EU and other CE Mark approved countries. In parallel, the company has launched clinical trials to receive regulatory certification for additional vital signs including continuous respiratory rate, core temperature, oxygen saturation, blood pressure, and other arrhythmias.

"Following an extensive development process and clinical trials, CardiacSense is the first and only company to receive CE Mark certification for continuous PPG wrist based monitoring at the individual heart beat level and arrhythmias detection, a milestone that will enable us to implement the distribution agreements we have signed in 15 countries," announcedEldad Shemesh, Co-founder and CEO of CardiacSense. "We anticipate additional commercial agreements and partnerships over the coming months and our watch has been submitted for FDA Clearance. Our watch was developed by integrating sophisticated proprietary electro-mechano-optical sensors and advanced software algorithms, providing physicians with precise, long-term, remote monitoring of medical parameters wherever their patients may be situated."

The Arrhythmia detection market opportunity represents a multi-billion-dollar business opportunity. CardiacSense has signed $70 million distribution agreements in 15 countries and is developing its commercial strategy in theUSA, China, Japan, and major countries in Europe for both the arrhythmia detection market and for continuous, comfortable, wrist based, accurate vital signs monitoring in acute care setting and home monitoring of chronic disease patients both of which represent additional

multi-billion-dollar business opportunities for the company.