



First AI-based continuous ambulatory cough monitoring system approved as medical device

Zurich, July 16th, 2024 – SIVA Health AG, a Swiss MedTech company, has received certification according to the European Medical Device Regulation (EU) 2017/745 for its continuous cough monitoring system. This is the first fully automated AI-based continuous ambulatory cough monitoring system that has been approved as a medical device facilitating objective monitoring of treatment for patients with chronic cough in clinics and clinical trials.

Having the CE mark as a Class IIa medical device signifies that the product complies with rigorous EU health, safety and security protection legislation for medical devices, granting the Swiss medical device company the right to market its system in Europe. The company is now planning to launch the system in EU countries while pursuing marketing authorization for the USA.

Millions of people in the world suffer from chronic cough, a highly burdensome disease. SIVA Health's novel cough monitoring system significantly enhances the care of chronic cough patients by enabling objective measurement of treatment response. In current patient journeys, patient reports are recorded using questionnaires, which leads to long treatment times.

This innovation in the respiratory field is comparable to continuous blood glucose monitoring in diabetes.

Dr. Alexander Duschau-Wicke, CEO: "This important milestone allows us to support clinicians caring for patients with chronic cough. For the first time, they can measure the disease burden of their patients and objectively assess how they respond to treatment options. We expect our system to be crucial in shortening long diagnostic journeys and helping patients to receive proper treatment faster."

Additionally, the certification is crucial for pharmaceutical companies to obtain high-resolution real-world data in global drug development studies. In addition to serving study sites in the Americas and APAC countries, the CE mark now unlocks the collection of long-term 24/7 cough data in European study centres as well.

Dr. Laura Kütt, Director of Clinical Affairs: "Drug developers are facing increasing pressure from regulators to provide meaningful data on the real-life benefits of their molecules. The single-day measurements of cough frequency, which are currently being used, have turned out to be insufficient due to huge day-to-day variability. Long-term cough monitoring will increase statistical power and reduce required sample sizes, leading to faster time to market for new medications."





About the company: SIVA Health AG is a Swiss MedTech company in the field of AI-based sound biomarkers and collaborates with global healthcare companies, researchers and clinics. Based on close collaboration with clinical drug development, SIVA Health has developed an AI-based continuous ambulatory cough detection system, that provides seamless data sets over several weeks or months. The SIVA system is now used in global drug development studies as well as scientific studies around the world.

About the product: The SIVA system combines a novel patient-centric, light weight wearable with a medical device software operating in a secure cloud. It provides longitudinal real-life cough profiles and contextual data.

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