

PMcardio Secures EU MDR Certification, Transforming ECG Interpretation and Patient Management

Bratislava, Slovakia/Aalst, Belgium – June 9th 2022: **Powerful Medical, a deep-tech medical research company, has successfully obtained certification under the EU Medical Device Regulation (MDR) for its flagship product PMcardio, the world's first AI-powered platform for ECG digitization, interpretation, and patient management. Thanks to the obtained certification, the cutting-edge technology can be officially deployed in emergency services, hospitals and outpatient systems, where it will utilise its potential to save lives.**

The Class IIb medical device empowers healthcare professionals to **diagnose and treat 38 cardiovascular diseases**. Thanks to AI algorithms that use data from millions of previous patient records, clinical studies have shown that the diagnostic precision of **PMcardio can be compared to a seasoned cardiologist**.

The platform is directly implemented into existing hospital systems and is also available as a smartphone application, making it accessible to physicians and medical professionals – helping to optimise hospital resources.

*"We are a European company and Europe is our key market. Having successfully obtained the CE-marking certification under the new MDR regulations, we can now launch the **world's first artificial intelligence-based ECG digitization, interpretation and diagnostics platform across Europe**", said **Martin Herman**, CEO and Co-Founder of Powerful Medical. „This makes it a valuable tool in the pocket of healthcare professionals, which is confirmed by PMcardio being in use **by more than 10,000 healthcare professionals in 122 countries around the world**"*

According to Dr. Robert Herman, Chief Medical Officer and Co-Founder of Powerful Medical, being certified as a class II(b) medical device allows PMcardio to **not only assist decision-making but actually drive it**.

The Powerful Medical team is currently working on further research to enable doctors to predict the risk of death and assess the **most effective treatment for heart failure patients**, which is on the rise with our aging population.

*"Based on the ECG of cardiovascular patients, we will be able to evaluate not only whether the patient is currently having a heart attack, but also which heart artery is causing it and what the patient's prognosis is. We are also working on algorithms that will be able to **prematurely predict the risk of acute heart attack** from the ECG. This way, our application will contribute to a much more effective management of this common disease," said Dr. Robert Herman.*

Cooperating with the German-based certification body TÜV SÜD, Powerful Medical has a strong international partner for the whole of Europe, including the United Kingdom, which, after Brexit, requires the UKCA mark, starting from summer of 2023.

After obtaining the European certification, the med-tech company aims at the US market, where they are a candidate for the FDA clearance.

Powerful Medical currently has offices in Bratislava, Slovakia and Aalst, Belgium, where they cooperate with one of the most prominent cardiology centres in Europe – Cardiovascular Center Aalst.