PRESS RELEASE
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Coala Life's unique system receives CE-mark according to MDR

Coala Life today proudly announces that its portable ECG solution, Coala Heart Monitor, has been certified as a Class IIa medical device in conformity with the new European Medical Device Regulation 2017/745 (MDR). This is an important milestone for the company and a prerequisite to be able to expand the company's offer in Europe and other markets.

This certificate further strengthens Coala Life's position and shows that the company offers a solution that meets the new increased regulatory requirements and stands out from the competition. It lets the company continue to develop and offer clinics worldwide a patient-centric medical device system for remote monitoring with market-leading accuracy that may help to improve the clinical outcomes for millions of patients affected by cardiovascular disease.

"To achieve this certification is of high importance to our business and shows once again that our product meets new stricter standards and regulations. We are proud to be approved early on in this process as we know there are still a great majority of companies struggling with regulation conformity and application processes.
Even though our focus is on the US market this certificate is important to let us develop our business and continue to offer healthcare providers our products within Europe and other markets requiring a CE-mark", says Dan Pitulia, CEO, Coala Life AB.

MDR certification essential to the future of medical devices

The new regulations, compared to previous directives (MDD), are stricter and emphasize a life-cycle approach to safety, backed up by clinical data. The purpose of the MDR is to better ensure that medical devices are safe and effective and aim to limit interpretation discrepancies across the EU market. Compliance with the new regulations will be mandatory to continue to sell and distribute medical devices in the European Union.

The MDR represents a major challenge for medtech companies as there are more than 500,000 medical devices on the market and certification is a time-consuming process with timelines that usually range from 13 to 18 months, or even longer. Also, there are only a limited number notified bodies designated under the MDR to handle applications which makes the processes for approval even more complicated.
Numbers from July 2023 showed that out of 23,000 certifications according to former directives (MDD and AIMDD), only less than 3,000 have renewed their certification according to MDR.

The new European law, EU Medical Device Regulation (EU MDR), was published in May 2017 and became mandatory as of May 2021, with a transition period that allows devices to register for certification and to continue to be available on the market for a certain prolonged period. As of 2027/2028 devices that do not comply with the new regulations are no longer allowed on the EU market.

About us

Coala-Life Group AB ("Coala Life" or the "Company") founded in 2015, is a Cloud Based Software as a Service provider, and medical device developer and reseller, listed on Nasdaq First North Growth Market. The Company focuses on B2B solutions for managed Remote Patient Monitoring ("RPM"), offering medical care providers, primarily in the US, with a highly scalable, cost-efficient platform to remotely and virtually manage large volumes of patients suffering from chronic diseases. The company offers care providers a comprehensive solution and lifts the administrative work from the care providers regarding, amongst other things, follow-up, 24/7 monitoring, as well as the reimbursement process from state and private health insurance companies. Patients are monitored long-term in everyday life and typically have diabetes, obesity, and /or cardiovascular disease.
For more information see **www.coalalife.com**

For more information, please contact:

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Certified Adviser
The company's Certified Adviser is Erik Penser Bank AB.

Attachments

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