



Acarix receives Regulatory Approval in Saudi Arabia.

Malmö, Sweden – Acarix AB (publ), a leader in acoustic and AI-based cardiac diagnostics, today announces that its CADScor® System has received regulatory approval in the Kingdom of Saudi Arabia (KSA), marking an important milestone in the Company's expansion into the Middle East.

The approval, confirmed through the Medical Devices Marketing Authorization (MDMA) certificate, represents a significant step toward introducing the CADScor System to the substantial Saudi Arabian healthcare market.

Following receipt of the MDMA certificate, the next step is getting registered with the Saudi Arabian Ministry of Health. Acarix is currently working with its local partners to establish the timeline for this process.

"We are very pleased to have achieved this important regulatory milestone in Saudi Arabia. The approval represents another important step in our strategy to expand access to the CADScor System in international markets. We look forward to progressing the remaining registration activities and preparing for commercial launch," said Aamir Mahmood, President and CEO of Acarix.

The Company will provide further updates as the registration and commercialization process progresses.

About the CADScor®System

The CADScor System is a point-of-care diagnostic aid that uses highly sensitive acoustics and advanced computational analysis and AI to assess a patient's coronary blood flow. It calculates a patient-specific CAD-score and combines it with clinical risk factors to rapidly indicate the risk of significant coronary stenosis, prior to potential secondary evaluation. The system produces a result in under 10 minutes and is designed to rule out significant CAD with at least 96% negative predictive value at point of care. The CADScor System has been used in over 60,000 patient assessments, is built on 15+ years of R&D covered by 45 patents, is CE-marked in accordance with EU MDR 2017/745, and has received FDA De Novo clearance as a diagnostic aid for symptomatic patients with suspected CAD.

About Acarix

Acarix is a Swedish medical device company that develops solutions for rapid, AI-based rule-out of coronary artery disease at the point of care. The CE-marked and FDA De Novo-cleared CADScor System is intended for patients experiencing chest pain with suspected CAD and is designed to support clinical decisions by helping reduce unnecessary, invasive, and costly diagnostic procedures. Acarix is listed on the Nasdaq First North Premier Growth Market in Stockholm (ticker: ACARIX) and cross-traded on the OTCQB market in the US (ticker: ACIXF). The Company's Certified Adviser is Tapper Partners AB. For more information, please visit www.acarix.com



For more information, contact

Macie May, phone +1 405 517 5161, email mmay@saxum.com

This information is information that Acarix is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2026-10-19 08:53 CEST.

Attachments

[Acarix receives Regulatory Approval in Saudi Arabia.](#)