



Acarix Receives EU MDR Certification for the CADScor®System

Malmö, Sweden – Acarix, a global leader in AI- and acoustics-based cardiac diagnostics, today announced that its CADScor System has successfully achieved certification under the European Union Medical Device Regulation (EU MDR 2017/745).

The MDR certification confirms that the CADScor System meets the European Union's most stringent regulatory requirements for safety, quality, and clinical performance. This milestone ensures continued and expanded access to the CADScor System across European markets and supports Acarix's long-term growth strategy in the region.

The CADScor System is a non-invasive, point-of-care diagnostic aid designed to help rule out significant coronary artery disease in patients presenting with chest pain, enabling faster clinical decision-making while reducing unnecessary downstream testing.

"This certification is an important regulatory and strategic milestone for Acarix," said Aamir Mahmood, President and CEO of Acarix. "EU MDR approval reinforces the strength of our clinical evidence, the robustness of our quality systems, and our commitment to delivering high-value diagnostic solutions to healthcare systems across Europe."

With MDR certification in place, Acarix is well positioned to support existing customers, expand commercial partnerships, and continue advancing the adoption of the CADScor System throughout the European Union.

About Acarix

Acarix is a Swedish medical device company that innovates solutions for rapid rule out of coronary artery disease (CAD) at point of care. The CE-approved and FDA DeNovo-cleared Acarix CADScor System is intended for patients experiencing chest pain with suspected CAD and designed to help reduce millions of unnecessary, invasive, and costly diagnostic procedures. The CADScor System has been used on more than 40,000 patients. Acarix recommends CADScor System as a first-line diagnostic aid that uses highly sensitive acoustics and advanced computational processing to analyze coronary blood flow to rule out significant coronary artery disease (CAD), with at least 96% certainty at point of care. 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

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Attachments

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