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ASIA EDITION

South Korea-based Vuno's AI-powered cardiac arrest risk management system earns CE MDR and UKCA certifications

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Early regulatory approval accelerates expansion plans in Europe and the Middle East



Vuno, a leading South Korean medical artificial intelligence (AI) startup, has announced that its flagship AI-powered cardiac arrest risk management system Vuno Med-DeepCARS (DeepCARS) has received CE MDR (Medical Device Regulation) certification in the European Union, as well as the UKCA (UK Conformity Assessed) mark in the United Kingdom. Achieving these regulatory milestones more than a year ahead of schedule significantly accelerates the company's global market entry.

The CE MDR certification affirms the clinical safety and effectiveness of Vuno's solution across the 27 EU member states, enabling the company to actively pursue expansion in European markets. Vuno plans to collaborate with experienced local AI healthcare partners who have successfully introduced similar solutions in the region to streamline hospital adoption and reimbursement processes.

Simultaneously, Vuno is preparing to enter the Middle Eastern market, where CE MDR and US FDA certifications are commonly recognised as key references in the regulatory process, supporting a smoother pathway to market entry. With CE MDR in hand, the company aims to complete regulatory registrations in key Middle Eastern countries within the year and initiate full-scale operations across the region by 2026.

As of April 2025, DeepCARS has been implemented across more than 48,000 hospital beds in South Korea, including over 20 tertiary general hospitals, establishing itself as an essential part of care.