AI Reads the Heart: Coronary CT Software Earns CE Certification under EU MDR

Class IIa medical device certification enables clinical use of AI-powered cardiac CT decision support for radiologists and cardiologists across Europe.

WROCŁAW, POLAND, June 26, 2026 /EINPresswire.com/ -- Hemolens Diagnostics achieves CE certification under MDR for Cardiolens Viewer®, enabling clinical use of AI-based coronary CT analysis in Europe.

> MDR evaluates a product across every dimension: technical, clinical, and regulatory. For partners and investors, it is a clear signal that they are working with a company ready for a demanding market."
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> *Bernard Gołko, CEO, Hemolens Diagnostics Sp. z o.o.*

Hemolens Diagnostics announced that its AI-based non-invasive clinical decision support software, Cardiolens Viewer®, has received CE certification under the European Medical Device Regulation (EU) 2017/745 (MDR) as a Class IIa medical device. This certification marks a crucial milestone in bringing AI-based analysis of cardiac CT data into routine clinical practice, enabling radiologists and cardiologists across the European Economic Area to use Cardiolens Viewer within their everyday workflows.

Supporting the evaluation of coronary artery disease using CT data

Cardiolens Viewer is designed to visualize, process and analyze cardiac computed tomography (CT) data acquired in DICOM format. It supports radiologists and cardiologists in the evaluation of coronary arteries by enabling detailed assessment of the vessel lumen, as well as the detection and measurement of potential lesions. The software is intended for use as an adjunctive tool in the assessment of clinically stable patients with suspected or known coronary artery disease and does not replace clinical decision-making.

Integration into existing diagnostic pathways

By building on routinely acquired CT imaging data, Cardiolens Viewer can be integrated into existing diagnostic pathways, offering clinicians an additional layer of insight without requiring changes to how data is acquired. This supports the use of non-invasive imaging in the clinical evaluation of coronary artery disease in everyday practice.

From development to regulated clinical use under MDR

Bringing AI-based medical software into clinical use under MDR requires compliance with stringent requirements for clinical evaluation, risk management, and software lifecycle processes. The MDR certification of Cardiolens Viewer confirms that these requirements are met.

Hemolens Diagnostics team receives CE certification under EU MDR 2017/745 for Cardiolens Viewer®

Data governance and secure European deployment
A key element in the design of Cardiolens Viewer is its approach to data governance. The solution has been developed with a strong focus on responsible handling of medical data, risk management and cybersecurity. Patient data is processed and stored via a secure cloud-based infrastructure in Europe.

Availability and next steps
With MDR certification now in place, Cardiolens Viewer may be placed on the market in hospitals, cardiology clinics and imaging centers across the Union. Research institutions and clinical partners are invited to collaborate in implementation, further evaluation and validation studies.

Cardiolens Viewer is the first in a planned family of Hemolens Diagnostics products designed to support non-invasive diagnosis of coronary artery disease. In parallel, the company is developing additional solutions intended to assist clinicians at different stages of the patient pathway. Interested parties are encouraged to contact Hemolens Diagnostics for further information.

Interested in a demo? Contact Bernard Gołko, CEO, Hemolens Diagnostics:
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