SYGNAL by MYCOR receives CE marking: ECG-based pre-screening for cardiac amyloidosis

The software supports healthcare professionals in identifying possible indications of cardiac amyloidosis.

Düsseldorf/Darmstadt, Nov. 12, 2026: SYGNAL by MYCOR has received CE marking as a Class IIa medical device under the European Medical Device Regulation (MDR, EU 2017/745). The legal manufacturer of the medical device is BAYOOCARE GmbH, based in Darmstadt. myCor GmbH of Düsseldorf handles distribution.

SYGNAL by MYCOR is software that supports pre-screening for cardiac amyloidosis. ECG data is recorded with an approved ECG device connected to a compatible Android smartphone, using a defined electrode placement.

A cloud-based algorithm analyzes the recorded data. The result gives healthcare professionals an indication of possible abnormalities, which can be clarified in a further medical examination. The result is available in under one minute.

SYGNAL does not provide a diagnosis and does not replace further diagnostic examinations.

Cardiac amyloidosis is a condition in which misfolded proteins deposit as amyloid fibrils in heart tissue and can impair cardiac function. Diagnostic clarification is carried out using established medical examination methods.

The algorithm underlying SYGNAL by MYCOR was published in the scientific journal ESC Heart Failure in 2025 and examined in an independent validation cohort. The West German Centre for Cardiology and Vascular Medicine (Westdeutsche Herz- und Gefäßzentrum) was among those involved in the scientific work.

In the validation cohort examined, a sensitivity of 79.3 percent and a specificity of 82.4 percent were determined. The negative predictive value was 92 percent at a disease prevalence of 33 percent. These results relate to the study population examined.

> **“With CE marking, SYGNAL by MYCOR moves from research result to patient care. Physicians receive a tool that helps them identify affected patients earlier, without additional hardware and without waiting time.”**
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> **Prof. Dr. Dr. h.c. Tienush Rassaf** (Director, Department of Cardiology & Angiology, University Hospital Essen · Vice Dean for Knowledge and Technology Transfer)

The underlying technical method is patent pending.

REGULATORY INFORMATION

Legal manufacturer	BAYOOCARE GmbH, Darmstadt
Product	SYGNAL by MYCOR
Risk class	IIa according to MDR (EU) 2017/745
Notified body	TÜV SÜD Product Service GmbH
Distribution	myCor GmbH, Düsseldorf

ABOUT MYCOR GMBH

myCor GmbH, based in Düsseldorf, develops software and hardware solutions for analyzing ECG data, with a focus on structural heart disease. The company distributes SYGNAL by MYCOR, an ECG-based software supporting pre-screening for cardiac amyloidosis. More information: www.mycor.ai

ABOUT BAYOOCARE GMBH

BAYOOCARE GmbH, based in Darmstadt, is part of the BAYOONET Group and, as legal manufacturer, assumes regulatory responsibility for medical devices and software as a medical device. The company supports medical devices throughout their entire lifecycle and is responsible for quality management, regulatory compliance, post-market surveillance, and vigilance, among other areas.

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