

QUALITY SYSTEM

CERTIFICATE

ISO 13485:2016

Precordior OyAurakatu 6, FI-20100 Turku
Finland

Eurofins Expert Services has assessed the company's quality system and found that it meets the requirements of ISO 13485:2016.

This certificate covers the following functions/services:

Design, development, manufacture and distribution of software for detection of atrial fibrillation in the area of cardiology.

Issued:

30th April 2021

Valid until:

19th February 2022

First issued:

19th February 2019

Satu Rajala
Certifier
Eurofins Expert Services



Aliina Nieminen
Lead Auditor
Eurofins Expert Services



Certificate nr.
EUFI29-21002157-S



Certification body:
Eurofins Expert Services
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

QUALITY SYSTEM

EC-CERTIFICATE

Directive 93/42/EEC

Manufacturer: Precordior Oy
Aurakatu 6
FI-20100 Turku
FINLAND

Coverage of Certificate: Design, manufacture and final inspection

Product category: Software for detection of atrial
fibrillation in the area of cardiology

Valid until: 19th February 2024

The manufacturer's quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 93/42/EEC as set out in Annex II Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex II in Directive 93/42/EEC. Products covered by the certificate are specified in the attachment(s).

Valid from: 30th April 2021



Satu Rajala




Certificate no.
C-01-1202-767-21



Aliina Nieminen

Notified Body no. 0537:
Eurofins Expert Services
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

Attachment 1 to the Certificate number: C-01-1202-767-21

Manufacturer:	Precordior Oy Aurakatu 6, FI-20100 Turku FINLAND			
Activity and product category:	Design, manufacture and final inspection of software for detection of atrial fibrillation in the area of cardiology. GMDN-code: 59086			
Products:	The certificate covers the following products:			
	<i>Name</i>	<i>Brand name</i>	<i>Model</i>	<i>Class</i>
	Application for detection of atrial fibrillation	Precordior	CardioSignal	IIa
	Cloud service for detection of atrial fibrillation	Precordior	CardioSignal Cloud service	IIa
Date:	Valid from: 30 th April 2021			
	  			
	Satu Rajala		Aliina Nieminen	

This attachment 1 supersedes the previous attachment 1 signed 24th August 2020.

Eurofins Expert Services is Notified Body no. 0537 under Council Directive 93/42/EEC.