eurofins | Expert Services

FINAS
Finnish Accreditation Service
S021 (EN ISO/IEC 17021-1)

QUALITY SYSTEM

EC-CERTIFICATE

Directive 93/42/EEC

Manufacturer:	Eko Devices, Inc. 1212 Broadway, Suite 100 Oakland, CA 94612 U.S.A.
Coverage of Certificate:	Design, manufacture and final inspection
Product category:	Electronic stethoscope and ECG systems and mobile device software for the area of cardiovascular devices
Valid until:	27th May 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: 14th April 2020

EUROFINS EXPERT SERVICES OY

Anniina Mäkelä

Satu Rajala

Certificate no.

C-01-1189-729-20

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

Regulation (EU) 2017/745 (MDR)

NOTIFIED BODY COMMUNICATION LETTER

Resolution on the manufacturer's notification of change to the quality system or the product-range

Manufacturer	Eko Devices, Inc.
Date of notification	5 May 2023
Annex of MDD	Annex II
Product and product class	QMS change, relates to the following products: - Eko CORE (Eko CORE Digital Stethosscope); class IIa - Eko CORE Digital Attachment; class IIa - Eko DUO; class IIa - Eko Analysis Software; class IIa
Description of the changes	Eko Devices, Inc. will undergo the following changes effective on June 1, 2023: 1) Company name change from Eko Devices, Inc. to Eko Health, Inc. 2) Eko headquarter address change from 1212 Broadway, Suite 100, Oakland, CA 94612, USA to 2100 Powell St, Suite 300, Emeryville, CA 94608, USA. 3) Emergo Europe address change from Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands to Emergo Europe, Westervoortsedijk 60, 6827 AT, Arnhem, The Netherlands. Regarding the company name and address changes, the approval of the change affects both the valid certificate C-01-1189-729-20 and Attachments 1, 2 and 3 related to it. The manufacturer information will be as follows: Eko Health, Inc. 2100 Powell St, Suite 300 Emeryville, CA 94608 U.S.A.
Material dispatched by manufacturer	See Change assessment report: NB-1189-MR12.

Change assessed by	Satu Rajala
Significance of the change	The manufacturer has provided sufficient justification for the resolution of the notified change being considered as non-significant in the intended use or design of the product: The change is not considered as a change concerning the design or intended purpose of the product according to the principles of the MDR Article 120 and MDCG 2020-3 guidance document.
The resolution	☒ The change is approved and is considered non-significant in the intended purpose or design of the device. ☐ The approval of the change affects the attachment related to the valid certificate. The manufacturer shall attach this "*NOTIFIED BODY COMMUNICATION LETTER*" as part of its valid EC-Certificate (MDD 93/42/EEC). ☒ The approval of the change affects both the valid certificate and attachment related to it. The manufacturer shall attach this "*NOTIFIED BODY COMMUNICATION LETTER*" as part of its valid EC-Certificate (MDD 93/42/EEC). ☐ The approval of the change will require a separate audit of the manufacturer, its subcontractor or supplier. ☐ The change is rejected; it is considered significant in the intended purpose of the device. ☐ The change is rejected; it is considered significant in the design of the device.
Date and signatures	Digitally signed by Satu Rajala Date: 2023.05.22 14:35:53 +03'00' Satu Rajala Lead Auditor
	Digitally signed by Liisa-Ida Sorsa Date: 2023.05.22 15:05:59 +03'00' Liisa-Ida Sorsa Decision Maker

Eurofins Electric & Electronics Finland Oy has operated as a notified body (NB-0537) for Directive 93/42/EEC Medical devices (MDD). As from 26 May 2021, the notified body is no longer able to issue new certificates under MDD but only allowed to carry out surveillance activities for certificates validity issued under that Directive in the transitional period, as established in Article 120 of Regulation (EU) 2017/745 (MDR).

According to Article 120 of MDR, certificates issued by notified bodies in accordance with MDD from 25 May 2017 shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its issuance. They shall however become void at the latest on 27 May 2024.

Guidance document MDCG 2020-3 (Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD) highlights that no issuing of new MDD certificates, including amended or supplemented certificates, is allowed under MDR Article 120(3). In particular, if the manufacturer wishes to make a "significant change in design or intended purpose" under MDR Article 120(3), the implementation of such a change would prevent the manufacturer from continuing to place that device on the market under the MDD.

It is also important that the MDD certificates remain valid following changes that are not significant with regard to design or intended purpose, provided that the required surveillance is carried out by the notified body that issued the certificate.

For instance, administrative changes of organisations are considered in principle as nonsignificant. This includes changes of the manufacturer's name, address or legal form (legal entity remains) or changes of the authorised representative.

Furthermore, all changes not having an impact on the design or the intended purpose of the device can be regarded as not significant in the meaning of MDR Article 120(3). This is the case for example of relocation or addition of new manufacturing sites, including when it affects subcontractors or suppliers, or of certain changes of the quality management system, provided that the conditions for which the conformity assessment certification was granted are maintained.

For more information, please refer to MDCG 2020-3 guidance.

Notified body confirmation letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **Eurofins Electric & Electronics Finland Oy**, a notified body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the **number 0537** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Eko Health, Inc.
2100 Powell St, Suite 300
Emeryville, CA 94608
USA
SRN Number: US-MF-000034386

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. **Table 1** identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. **Table 2** identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as reusable surgical instruments)

On behalf of the Notified Body,

Aliisa Siljander
Head of Notified Body; NB-0537
Eurofins Electric & Electronics Finland Oy

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Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:			
Device name under MDR application)	*MDR device classification (as proposed by the manufacturer and verified at the pre-application stage)*	*If the MDR device is a substitute device, identification of the corresponding MDD device*	*MDD certificate reference of the devices under MDR application, and the NB identification*
Eko CORE	Class IIa	N/A, same device. Corresponding MDD device: Eko CORE (Eko Electronic Stethoscope System) - Eko CORE (Eko CORE Digital Stethoscope) & Eko CORE Digital Attachment	C-01-1189-729-20 Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
Eko Analysis Software	Class IIa	N/A, same device.	C-01-1189-729-20 Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive			
Device name under MDR application	*MDR device classification (as proposed by the manufacturer and verified at the pre-application stage)*	*If the MDR device is a substitute device, identification of the corresponding MDD device*	*MDD certificate reference of the devices under MDR application, and the NB identification* ***Or*** *N/A – MDD class I device*
N/A	N/A	-	-

Confirmation Letter Revision History			
Revision	**Date**	**NB internal reference traceable to each version of the letter**	**Description of changes**
1.0	30.04.2024	THTR-02-L08 (NB-1189; 29.04.2024)	Initial version.