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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

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Anniina Mäkelä

Satu Rajala

Certificate no.

C-01-1189-729-20

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

Attachment 1 to the Certificate number: C-01-1189-729-20

Manufacturer:	Eko Devices, Inc. 1212 Broadway, Suite 100 Oakland, CA 94612 U.S.A.
Activity and product category:	Design, manufacture and final inspection of electronic stethoscope and ECG systems and mobile device software for the area of cardiovascular devices GMDN-code(s): 13754
Products:	The certificate covers the following products: **Eko CORE (Eko Electronic Stethoscope System)**

Brand name	*Model*	*Class*
Eko Devices	Eko CORE (Eko CORE Digital Stethoscope)	IIa
Eko Devices	Eko CORE Digital Attachment	IIa

Date:	Valid from: 21st May 2021

Aliina Nieminen

Satu Rajala

This Attachment 1 supersedes the previous Attachment 1 signed 14th April 2020.

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

Attachment 2 to the Certificate number: C-01-1189-729-20

Manufacturer:	Eko Devices, Inc. 1212 Broadway, Suite 100 Oakland, CA 94612 U.S.A.
Activity and product category:	Design, manufacture and final inspection of electronic stethoscope and ECG systems and mobile device software for the area of cardiovascular devices GMDN-code(s): 13754
Products:	The certificate covers the following products: *Brand name* — *Model* — *Class* Eko Devices — Eko DUO — IIa
Date:	Valid from: 8th October 2020 Aliina Nieminen Satu Rajala

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This attachment 2 supersedes the previous attachment 2 signed 21st August 2020.

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Attachment 3 to the Certificate number: C-01-1189-729-20

Manufacturer:	Eko Devices, Inc. 1212 Broadway, Suite 100 Oakland, CA 94612 U.S.A.
Activity and product category:	Design, manufacture and final inspection of electronic stethoscope and ECG systems and mobile device software for the area of cardiovascular devices GMDN-code(s): 47699
Products:	The certificate covers the following products: *Brand name* — *Model* — *Class* Eko Devices — Eko Analysis Software — IIa
Date:	Valid from: 8th October 2020 Aliina Nieminen Satu Rajala

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