DECLARATION OF CONFORMITY

We hereby declare that the products identified below are in conformity with all relevant provisions of Council Directive 93/42/EEC, (2007/47/EC as amended September 21, 2007 (M5)), concerning Medical Devices. Conformity to Directive 93/42/EEC is assessed by the notified body, Eurofins Electric & Electronics Finland Oy. This Declaration of Conformity is made under Annex II, section 3 of this directive.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIa, meet the provisions of the EC-Directive, which apply to them, including an EC Authorized Representative. The Authorized Representative is Emergo Europe, located at Westervoortsedijk 60, 6827 AT, Arnhem, The Netherlands.

We ensure and declare that the distributed products, as mentioned and falling within Class IIa, Rule 10, meet the provisions of ISO 13485 under CMDR (Health Canada). Eko will serve as the Canadian regulatory correspondent.

This declaration is based on the application of the Quality System approved for the design, manufacture, and distribution of the products concerned, in accordance with Annex II (section 3, Full Quality Assurance System) of Directive 93/42/EEC. This declaration is supported by the Quality System certification based on the harmonized standards ISO 13485:2016, certificate number EUFI29-230020909-S (expiration date: 18th December 2024), EC Certificate No. C-01-1189-729-20 (expiration date: 27th May 2024) and MDSAP certificate number 528011 MDSAP16 (Certificate Unique ID: 170782190; expiration date: 17th December 2024).

Notified Body:
Eurofins Electric & Electronics Finland Oy
Notified Body No. 0537
Kivimiehentie 4
02150 Espoo
Finland

This Declaration of Conformity covers and concerns the following products:

Product name	Version/Model	Catalogue number/REF
Eko CORE Digital Stethoscope	E6	COR201*
Eko CORE Digital Attachment	E6	COR200
		COR200-3M

*Note: The Eko CORE Digital Stethoscope consists of the Eko CORE Digital Attachment and the commercially available manual stethoscope.

Eko declares that the above mentioned product:

- meets the provision of EU Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS), as amended per 2015/863/EU, and compliance to the requirements of EN IEC 63000:2018.
- meets the provision of EU Radio Equipment Directive 2014/53/EU (RED), and compliance to the requirements of EN 300 328 V2.2.2, EN 301 489-1 V2.2.3 and EN 301 488-17 V3.2.4.

This Declaration of Conformity is valid for all products described here above, bearing the CE marking and manufactured at the following site(s):

Eko Health, Inc.
2100 Powell St, Suite 300
Emeryville, CA 94608
USA

Authorized Signatory: _____ Date: 13 June 2023
Nicholas Metrakos
Senior Director of Technical Operations and Quality