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 Expert Services 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 (Rule 10 of Directive 93/42/EEC), 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, meet the provisions of ISO 13485 under CMDR (Health Canada). Eko Devices 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 EUFI29-23002099-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 Expert Services 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 DUO	E5	DUO100
	E7	DUO200 DUO201 DAC200

Eko declares that the above-mentioned products meet the provision of EU Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast), and is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.

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: 08 June 2023
Nicholas Metrakos
Senior Director of Technical Operations and Quality