Eko

DECLARATION OF CONFORMITY
MEDICAL DEVICES

We hereby declare that the products identified above 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, meet the provisions of the EC-Directive, which apply to them, including an EC Authorized Representative. The Authorized Representative is Emergo Europe, located at Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.

We ensure and declare that the distributed products, as mentioned and falling within Class II, 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 EN ISO 13485:2016, certificate number EUFI29-19005428-S and MDSAP, certificate number 528011 MDSAP16.

Notified Body:
Eurofins Expert Services Oy
Notified Body No. 0537

The following standards are used:

Standard Number	Standard Title
Directive 2007/47/EC	EU Consolidated Medical Devices Directive 93/42/EEC (2007/47/EC)
ISO 13485:2016	Medical Devices – Quality management systems
EN ISO 14971: 2012	Medical Devices – Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
BS EN 1041:2008	Information supplied by the manufacturer with medical devices
BS EN ISO 15223-1:2016	Medical devices- Symbol to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements

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Standard Number	Standard Title
IEC 60601-1	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2: 2014	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance – Collateral standard: electromagnetic compatibility - Requirements and test
IEC 60601-2-47 (2012)	Medical Electrical Equipment – Part 2-47: Particular Requirements for the Basic Safety and Essential Performance of Ambulatory Electrocardiographic Systems
EN ISO 10993-1:2009	Biological Evaluation of Medical Devices
ISO 14155:2011	Clinical investigation of medical devices for human subjects -- Good clinical practice
IEC 62304:2006	Medical Design Software – Software Life Cycle
ISO 62366:2008	Medical Devices -Application of Usability Engineering to Medical Devices

This declaration covers the and concerns the following products:

Eko Model E5 System (EME5)
- Eko DUO

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

1212 Broadway, Suite #100
Oakland, CA 94612
United States of America

Phu Trinh
VP of Regulatory & Quality Affairs
Eko Devices Inc.

2020-04-08
Date