

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


Anniina Mäkelä


Satu Rajala



Certificate no.
C-01-1189-729-20

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