

EC DECLARATION OF CONFORMITY

File No.: QR-HC03-C-C20 Version: A/4

Annex II excluding (4) of Directive 93/42/EEC according to EC-certificate No.: HD 60135250 0001 issued by Notified Body TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg, Germany

> Product: Vital Signs Monitor Model: HC-03

> > GMDN-Code: 33586

Class IIa (according to Annex IX, Rule 10 of the Directive 93/42/EEC)

We

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manufacturer of the above products, hereby declare under our sole responsibility for this Declaration of Conformity that the referenced products comply with all relevant provisions of Directive 93/42/EEC, as amended by 2007/47/EC, Regulation(EU) 2017/745 Article 120(3), and its transposition into national laws. The products comply with the essential requirements of Annex I, further applicable standards and/or other normative documents as listed in the applicable technical documentation. All supporting documentation is kept under the premises of the manufacturer.

The above referenced products will bear the CE mark as below.

C€₀₁₉₇

Authorized EU Representative:

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Xiamen, 20 Mar. 2023

Signature, Position

Place and date of issue

Valid starting with the original date of the document until product change. Expiry date of EC certificate: 2028-12-31

Xiamen Linktop Technology Co., Ltd

Page: 1 of 1