Declaration

Hereby, **livetec Ingenieurbüro GmbH, Marie-Curie-Str. 8, 79539 Lörrach**, Germany as legal Manufacturer of the **Kardiobeat.ai** ECG Holter-/ Longterm recorder declare, that the **Kardiobeat.ai** is a White Labelled Device of the livetec **kECG-3** Device and identical to this device.

The **kECG-3** device is registered under Directive 93/42/EEC, Annex II for europe, **Certificate registration no. Z-19-124-S-R II-N2-E.**

See attached certificate.

Lörrach, Germany, 2024-01-12

livetec Ingenieurbüro GmbH, Klaus Reichenbach (CEO)

living technology for life

livetec
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Amtsgericht Freiburg
HRB 413392
USt.IdNr. DE225419183
Steuer-Nr. 11091/04761
WEEE-Reg.Nr. DE 98689867

Certificate registration no.: Z-19-124-S-R II-N2-E

EC-Certificate

Directive 93/42/EEC, Annex II excluding (4)

Full Quality Assurance System

Benannt durch Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-207 15.04

Berlin Cert
Prüf- und Zertifizierstelle für Medizinprodukte GmbH

hereby certifies that

livetec Ingenieurbüro GmbH
Marie-Curie-Str. 8, 79539 Lörrach, Germany

has implemented and uses a quality assurance system for the following scope of application:

Development, production and final inspection of devices for monitoring and recording ECG signals (see appendix)

The audit in accordance with Annex II of MDD 93/42/EEC (report no. B-19-124-S-EZ) provided confirmation that the requirements of Annex II of MDD 93/42/EEC have been fulfilled. The Manufacturer has to be inspected periodically by the notified body according the requirements of Annex II, Article 5 of MDD 93/42/EEC. The manufacturer is allowed to use this certification in his process for the declaration of conformity.

The manufacturer is allowed to place the CE-mark on the above-mentioned products in combination with the identification No. **0633**.

issued on:	**14.04.2021**
valid from:	**14.04.2021**
valid to:	**26.05.2024**

Prüf- und Zertifizierstelle BERLIN CERT AFNOR Group Medizinprodukte GmbH

Dr. N. Eschweiler
Signature of authorized representative

livetec

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Appendix to certificate Z-19-124-S-R II-N2-E

from 14.04.2021

product/product category	UMDNS	Classification
Wireless ECG Holter Recorder – kECG-3	18-361	IIa

Prüf- und Zertifizierstelle BERLIN CERT für Medizinprodukte GmbH

Dr. N. Eschweiler

Signature of authorized representative