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 Medizinprodukte
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) 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:	**2020-05-06**
valid from:	**2020-05-06**
valid to:	**2024-05-26**

Dipl.-Ing. Martin Tettke
Signature of authorized representative

Appendix to certificate Z-19-124-S-R II-N1-E

from 2020-05-06

product/product category	UMDNS	Classification I s/m	II a	II b
Wireless ECG Holter Recorder - dpv-ritmo III	18-361	☐	☒	☐
[redacted]				

Dipl.-Ing. Martin Tettke
Signature of authorized representative