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
www.zlg.de
ZLG-BS-207.15.04

Berlin Cert
Prüf- und Zertifizierstelle für Medizinprodukte GmbH

hereby certifies that

miha bodytec GmbH
Siemensstr.1, 86368 Gersthofen, Germany

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

Development, production and final inspection of devices for electrical stimulation of muscles (see appendix)

The audit in accordance with Annex II of MDD 93/42/EEC (report no. B-18-140-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: **12.04.2021**

valid from: **12.04.2021**

valid to: **20.02.2024**

Prüf- und Zertifizierstelle BERLIN CERT AFNOR Group für Medizinprodukte GmbH

Dipl.-Ing. Martin Tettke
Signature of authorized representative

Appendix to certificate Z-18-140-S-R II-N1-E

from 12.04.2021

product/product category	UMDNS	Classification
miha bodytec II medical	11-454	IIa
miha bodytec m.ove	11-454	IIa
i-body connect wireless	11-454	IIa

Dipl.-Ing. Martin Tettke
Signature of authorized representative