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, Deutschland

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. A-18-140-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:	**2019-02-21**
valid from:	**2019-02-21**
valid to:	**2024-02-20**

Dr. N. Eschweiler
Signature of authorized representative

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

from 2019-02-21

product/product category	UMDNS	Classification		
		I s/m	II a	II b
miha bodytec II medical electrostimulation devices	11-454	☐	☒	☐

und Zertifizierstelle

Medizinprodukte GmbH

Dr. N. Eschweiler
Signature of authorized representative