

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



MediTECH Electronic GmbH

Langer Acker 7, 30900 Wedemark, Germany

with the additional sites

- Ölweide 12, 39114 Magdeburg, Germany

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

**Engineering, production and quality assurance of medical
 devices related to acoustic, visual and/or motor skill related
 analysis and training (see annex)**

The audit in accordance with Annex II of MDD 93/42/EEC (report no. A-19-003-SZ) 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 to 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: 2019-03-22

valid from: 2019-04-01

valid to: 2024-03-31

Dipl.-Ing. Martin Tettke
 Signature of authorized representative



**Appendix to certificate Z-19-003-S-R II-E
from 2019-03-22**

product/product category	UMDNS	Classification		
		I s/m	II a	II b
Audio-Trainer AT 3000	13-764	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BrainBoy	13-764	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>



Dipl.-Ing. Martin Tettke
Signature of authorized representative

