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

dantschke Medizintechnik GmbH & Co. KG

Apelsteinallee 3, 04416 Markkleeberg, Germany

dantschke
intelligent medical systems

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

Development, production and final inspection of medical devices for ENT-diagnostics and therapy (see appendix)

The audit in accordance with Annex II of MDD 93/42/EEC (report no. A-16-169-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 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:	**2019-04-02**
valid from:	**2019-04-02**
valid to:	**2022-07-31**

Dipl.-Ing. Martin Tettke
Signature of authorized representative

Appendix to certificate Z-16-169-SZ-R II-E

from 2019-04-02

product/product category	UMDNS	Classification		
		I s/m	II a	II b
ENT-treatment unit type MEDICENTER	11-585	☐	☒	☐

Dipl.-Ing. Martin Tettke
Signature of authorized representative