

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

Dolosys GmbH
 Wöhlertstr. 8, 10115 Berlin



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

**Development, production and final checking of
 neurophysiological devices for medical applications (see
 Appendix)**

The audit in accordance with Annex II of MDD 93/42/EEC (report no. A-17-077-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: 2017-10-25
valid from: 2017-11-03
valid to: 2022-11-02



Appendix to certificate Z-17-077-S-R II-E
from 2017-10-25

product/product category	UMDNS	Classification		
		I s/m	II a	II b
Painttracker model V1	11-614	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>



Dipl.-Ing. Martin Tettke
 Signature of authorized representative