

**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**  
 Wöhlerstr. 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