

BERLIN CERT CERTIFICATION

www.berlincert.de

Certificate registration no.: Z-14-085-SZ-R II-E-N1

EC Certificate Directive 93/42/EEC, Annex II excluding (4) Full Quality Assurance System

Berlin Cert

Prüf- und Zertifizierstelle für Medizinprodukte GmbH
an der Technischen Universität Berlin

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-14-085-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: 2016-01-21
valid from: 2015-09-29
valid to: 2017-11-02



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-207.15.04

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**Appendix to certificate Z-14-085-SZ-R II-E-N1
from 2016-01-21**

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



Dipl.-Ing. Martin Tettke
Signature of authorized representative

Management

Dipl.-Kfm. Uwe Ahnert

Commercial register

HRB 78 249
Registergericht Berlin

Bank details

Postbank Berlin
BLZ 100 100 10 Konto 6472 43-107
IBAN DE18100100100647243107
BIC: PBNKDEFF

Deutsche Bank PGK AG
BLZ 100 700 24 Konto 605808500
IBAN DE91100700240605808500
BIC: DEUT DE DBBER