ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 11 53268 076

Manufacturer:

RAUMEDIC AG
Hermann-Staudinger-Strasse 2
95233 Helmbrechts
GERMANY

Facility(ies):

RAUMEDIC AG
Am Mühlgraben 10, 08297 Zwönitz, GERMANY

Product Category(ies):

Precision pressure- and multi-parameter catheters for use in neurosurgery and compartment pressure measurement including accessories as specified in the attachment

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713117430

Valid from: 2018-03-06
Valid until: 2023-03-05

Date, 2018-02-20

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV SÜD Product Service

Attachment for Certificate no G1 17 11 53268 076
valid from 2018-03-06

Non-Active Accessories:	**Model:**	**Class**
	Catheterisation-Kits for use in Neurosurgery	III
	BOLT KIT	
	DRILL KIT	
	BOLT-DRILL KIT	

Active Accessories:	**Model:**	**Class**
	NPS3	IIb
	MPR 1 DATALOGGER	IIb
	MPR2 logO DATALOGGER	IIb
	EASY logO	IIb

Munich, MHS-CRT, 2018-02-20

I. Preiß

Stefan Preiß

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TÜV®