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

Product Service

EC Certificate

Full Quality Assurance System

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 excluding (4)
(Other devices than custom made or intended for clinical investigation)

No. I1 14 09 53268 066

Manufacturer: **RAUMEDIC AG**
Hermann-Staudinger-Strasse 2
95233 Helmbrechts
GERMANY

Product: **Implantable pressure sensor systems**

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 AIMDD Annex 2. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of the devices / device categories an additional Annex 2 (4) certificate is mandatory. See also notes overleaf.

Report No.: 713045233

Valid from: 2014-11-12
Valid until: 2019-11-11

639257

Date, 2014-11-04

Hans-Heiner Junker

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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Facility(ies):

RAUMEDIC AG
Am Mühlgraben 10, 08297 Zwönitz, GERMANY

Design Facility(ies):

RAUMEDIC AG
Hermann-Staudinger-Strasse 2, 95233 Helmbrechts, GERMANY

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