



Benannt durch/Designated by  
 Zentralstelle der Länder  
 für Gesundheitsschutz  
 bei Arzneimitteln und  
 Medizinprodukten  
 www.zlg.de  
 ZLG-BS-200.14.03



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 053268 0085 Rev. 00**

**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.:**

713171002

**Valid from:**

2019-11-12

**Valid until:**

2024-05-26

**Date,**

2019-11-07

Christoph Dicks

Head of Certification/Notified Body

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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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