ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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 033623 0017 Rev. 00

Manufacturer:

mahe medical gmbh
Friedrich-Wöhler-Straße 10
78576 Emmingen-Liptingen
GERMANY

Facility(ies):

mahe medical gmbh
Friedrich-Wöhler-Straße 10, 78576 Emmingen-Liptingen, GERMANY

Product Category(ies):

- **HF-Instruments and Electrodes**
- **Optics (Endoscopes/Laparoscopes/Arthroscopes)**
- **Suction Irrigators / Surgical Lavage Unit**
- **Micromotor-Drivers (Surgical Power Tool System)**
- **Orthopaedic and Laparoscopic Trocars**
- **Orthopaedic Drills and Taps**
- **Orthopaedic Reamers**
- **Saw Blades**
- **Orthopaedic Internal Fixation Systems, Spinal (Pedicular-Screw System/Cervical Plates/Spinal Fusion Cages)**
- **Orthopaedic Implants**
  - **Bone Nails**
  - **Bone Plates**
  - **Bone Screws**
  - **Staples**
  - **Bone Wires**
  - **Screws for Cranioplasty Plates**
  - **Craniofacial Fixation Plates**

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.: 713155506

Valid from: 2019-08-01
Valid until: 2024-05-26

Date, 2019-07-17

Stefan Preiß
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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