Medicon – Implants have a valid CE approval according to medical directive 93/42/EEC

The CE certificate confirms the design, manufacturing process and final inspection of Medicon implants for oral and maxillofacial surgery, and thus grants the approval to place them on the market in the European union.

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

ZLG-BS-244 10.08

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 020808 0036 Rev. 02

Manufacturer: **MEDICON eG**
Gänsäcker 15
78532 Tuttlingen
GERMANY

Product Category(ies): **Active medical devices,
non-active medical devices,
implants and sterile medical devices
(for detailed information: see page 2)**

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 020808 0036 Rev. 02

Report No.: 713201059/713201073

Valid from: 2021-04-16

Valid until: 2024-05-26

Date, 2021-04-16

Christoph Dicks
Head of Certification/Notified Body

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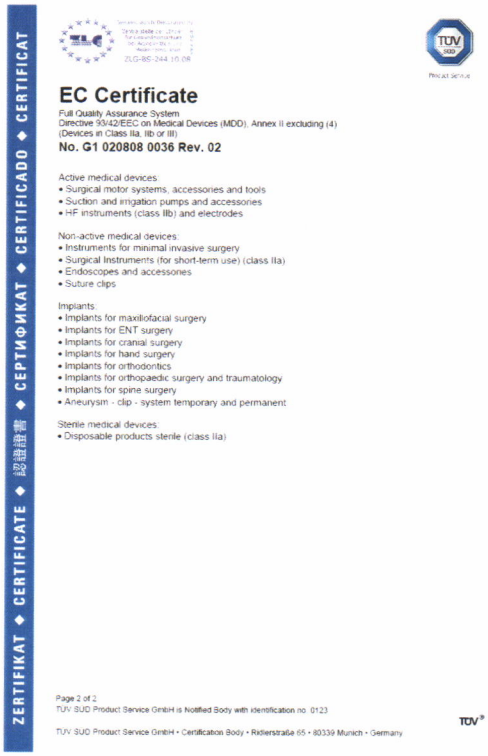

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

ZLG-BS-244 10.08

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 020808 0036 Rev. 02

Active medical devices:
- Surgical motor systems, accessories and tools
- Suction and irrigation pumps and accessories
- HF instruments (class IIb) and electrodes

Non-active medical devices:
- Instruments for minimal invasive surgery
- Surgical instruments (for short-term use) (class IIa)
- Endoscopes and accessories
- Suture clips

Implants:
- Implants for maxillofacial surgery
- Implants for ENT surgery
- Implants for cranial surgery
- Implants for hand surgery
- Implants for orthodontics
- Implants for orthopaedic surgery and traumatology
- Implants for spine surgery
- Aneurysm - clip - system temporary and permanent

Sterile medical devices:
- Disposable products sterile (class IIa)

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Our **instructions for use G687004 for the Titanium Mini and Micro Plate Systems**, refers to the complete traceability through the „LOT" number (batch number) noted on the packaging of the implant.

The same information can also be found in our **instructions for use** for all other Medicon plating systems and implants.

The instructions for use can be requested at the Medicon customer service.

In addition to traceability via the „LOT" number (batch number), Medicon Titanium plating systems offer sophisticated tools for organizational support in clinics and practices.

medicon®

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