ZERTIFIKAT ■ CERTIFICATE ■ 認證書 ■ СЕРТИФИКАТ ■ CERTIFICADO ■ CERTIFICAT

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Aesculap AG

Am Aesculap-Platz, 78532 Tuttlingen, Germany
Carl-Braun-Straße 1, 34212 Melsungen, Germany

has established and applies
a Quality Management System for

Design and Development, Technical Service, Production and Distribution of Implants, Instruments, Containers, Devices, Suture Material, Tissue Adhesive and Procedure Kits

Aesculap AG Tuttlingen

- Surgical, diagnostic and dental instruments
- Joint Implants (hip, knee)
- Spinal Implants
- Implants for Osteosynthesis
- Neurosurgical Vascular Implants
- Motor systems
- Sterilization containers and accessories
- High frequency surgery devices
- Endoscopie systems
- Navigation systems
- Surgical suction pumps
- Veterinary instrumentation
- Special suture-sets
- Other surgical accessories
- Instrument Management System

Aesculap AG Melsungen

- Implants for replacement of connective tissue
- Tissue adhesive
- Vascular prostheses and accessories
- Local haemostatic

An audit was performed, Report No. **70062209**.
Proof has been furnished that the requirements according to

ISO 9001:2015

are fulfilled. The certificate is valid from **2017-06-01** until **2020-05-31**.
Certificate Registration No.: **12 100 21724 TMS**.

Product Compliance Management
Munich, 2017-04-11

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

"TEHNOMEDICA" S.R.L. 1002600005866

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

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 14 05 10066 366

Manufacturer:

AESCULAP AG
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Facility(ies):

AESCULAP AG
Am Aesculap-Platz, 78532 Tuttlingen, GERMANY

AESCULAP AG
Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

Product Category(ies):

Implants, Instruments, Devices, Tissue Adhesive and Procedure Kits (for detailed information see 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.: 713043279

Valid from: 2014-07-27
Valid until: 2019-07-26

Date, 2014-07-11

Hans-Heiner Junker

604705

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

TÜV®

A1 / 04.11

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

Attachment for Certificate no G1 14 05 10066 366
dated 2014-07-27

TÜV SÜD Product Service

Surgical, diagnostic and dental instruments
Joint implants (hip, knee)
Spinal implants
Implants for osteosynthesis
Neurosurgical vascular implants
Products for ligature
Motor systems
High frequency surgery devices
Endoscopic systems
Navigation system
Surgical suction pumps
Special suture sets
Implants for replacement of connective tissue
Tissue adhesive
Vascular prostheses and accessories
and other surgical accessories

Munich, CRT 2, 2014-07-11

Hans-Heiner Junker

"TEHNOMEDICA" S.R.L. IDNO 1002600053256

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

TÜV®

A1 / 04.11

B|BRAUN

Declaration

The certification body of TÜV Management Service GmbH and the TÜV Product Service GmbH confirm that we,

AESCULAP AG
AM AESCULAP-PLATZ
78532 TUTTLINGEN / GERMANY

have established and are maintaining a quality management system according to

ISO 9001:2008
(Certificate Registration No.: 12 100 21724 TMS)
EN ISO 13485:2012 / AC:2012
(Certificate No.: Q1N 14 05 10066 365)

for the following area

Development, Production and Distribution of Implants, Instruments, Containers, Devices, Suture Material, Tissue Adhesives and Procedure Kits.

Furthermore we have implemented the conformity assessment procedure as per annex II, clause 3 of the Medical Device Directive 93/42/EEC of June 14th, 1993 for medical products. (EC certificate No.: G1 14 05 10066 366)

By labeling the products

Aesculap Product Groups as per attached list

with the CE mark

we, **AESCULAP AG** confirm, that we follow the essential requirements according to MDD 93/42/EEC Annex I.

TUTTLINGEN, 2014-11-26

AESCULAP AG

i. V.

Thomas Marquard
Director Regulatory Affairs

i. A.

S. Maier
Sandra Maier
Regulatory Affairs

"TEHNOMEDICA" S.R.L. IDNO 1002600053256

B|BRAUN

Attachment to Declaration of 2014-11-26

Aesculap Product Groups
Surgical, diagnostic and dental instruments
Joint implants (hip, knee)
Spinal implants
Implants for osteosynthesis
Neurosurgical vascular implants
Products for ligature
Motor systems
Sterilization containers and accessories
High frequency surgery devices
Endoscopic systems
Navigation systems
Surgical suction pumps
Special suture-sets
Implants for replacement of connective tissue
Tissue adhesives
Vascular prostheses and accessories
Local haemostatics
Other surgical accessories

"TEHNOMEDICA" S.R.L. IDNO 1002600053256

2014-11-26