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

TÜV SÜD Product Service

CERTIFICATE

No. Q5 17 03 10066 408

Holder of Certificate: **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

Certification Mark:

TÜV SÜD DIN EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate: **Design and development, production, technical service and distribution of implants, instruments, instrument management systems, containers, devices, tissue adhesives and procedure kits (for detailed information see attachment)**

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713098053

Valid from: 2017-06-01
Valid until: 2020-05-31

Date, 2017-05-30

Stefan Preiß

0405276881603

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

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

TÜV®

DAkkS CRT2 / 10.13

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

TÜV SÜD Product Service

Attachment for certificate no Q5 17 03 10066 408
dated 2017-06-01

- 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
- Endoscopie 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

Munich, CRT2 2017-05-30

I. Preiß

Stefan Preiß

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

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

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

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A1 / 04.11

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

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

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.

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

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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.

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.

2014-11-26

ZERTIFIKAT ■ CERTIFICATE ■ 認證證書 ■ 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**

"TEHNOMEDICA" S.R.L. IDNO 1002600052266

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

Product Compliance Management
Munich, 2017-04-11

B|BRAUN

Quality Management
Aesculap AG
Postfach 40
D-78501 Tuttlingen
e-mail: konrad.kobel@aesculap.de
http://www.aesculap.de

Quality Inspection Certificate

Cert.-No.: 1- 010212

Aesculap AG certifies, that

our products and raw materials

Instrument-type	Steel-type	Hardness-HRC
Retractors	X20Cr13	40-48
Scissors	X50CrMoV15; X38CrMoV15	50-58
Chisel, Gouges, Curettes	X46Cr13; X20Cr13	50-58; 40-48
(Bone) Rongeure	X46Cr13	50-58
Dissecting Forceps	X15Cr13; X20Cr13	40-48
Forceps with shaft handle	X15Cr13; X20Cr13	40-48
Forceps with ring handle	X20Cr13	40-48

are designed, manufactured and tested according defined and documented specifications and procedures.

The following national and international standards and requirements were met:

☒ EN ISO 13485:2003 (AC 2009)
☒ Council Directive 93/42 EEC of 14. June 1993 concerning Medical Devices
☒ ISO 7153-1 (Surgical Instruments-Metallic materials; Part 1: Stainless steel)
☒ Others: The defined requirements and performed tests cover also corrosion analisis, cutting ability, elasticity and mechanical resistance were applicable.
Technical / physical test according to the quality specification – passes test
Chemical test according to the quality specification – passes test

AESCULAP AG

i. V.
Georg Erhard
Director Quality Management Organization

i. V.
Wolfgang Fuchs
Project Manager QM-Instruments

"TEHNOMEDICA" S.R.L. IDNO 1002600053256