



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:



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

Stefan Preiß

Date, 2017-05-30

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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
- Endoscopy 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

S. Preiß

Stefan Preiß

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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: **AESULAP AG**

Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Facility(ies):

AESULAP AG
Am Aesculap-Platz, 78532 Tuttlingen, GERMANY

AESULAP 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



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

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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



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.


Sandra Maier
Regulatory Affairs



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 |



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
- Endoscopic 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



CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT

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) Rongeur | X46Cr13 | 50-58 |
| Dissecting Forceps | X15Cr13; X20Cr13 | 40-48 |
| Forceps with shaft handle | X15Cr13; X20Cr13 | 40-48 |
| Forceps with ring handle | X20Cr13 | 40-48 |

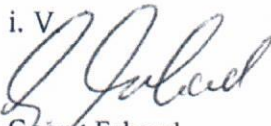
are designed, manufactured and tested according defined and documented specifications and procedures.

The following national and international standards and requirements were met:

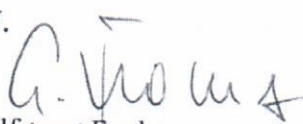
- EN ISO 13485:2003 (AC 2009)
- Council Directive 93/42 EEC of 14. June 1993 concerning Medical Devices
- ISO 7153-1 (Surgical Instruments-Metallic materials; Part 1: Stainless steel)
- Others: The defined requirements and performed tests cover also corrosion analysis, cutting ability, elasticity and 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

Vorsitzender des Aufsichtsrates:
 Prof. Dr. h.c. Ludwig Georg Braun

Vorstand:
 Prof. Dr. Hanns-Peter Knaebel
 (Vorsitzender)
 Dr. Harald Stallforth
 (stellv. Vorsitzender)
 Dr. Joachim Schulz

Sitz der Gesellschaft: Tuttlingen
 Reg. Gericht: Stuttgart HRB 726261
 Steuernummer: 21060/00036
 WEEE-Reg.-Nr. DE 65109852

Bankverbindungen:
 Deutsche Bank AG Tuttlingen
 BLZ 653 700 75, Konto 21 22 000
 IBAN DE44 6537 0075 0212 2000 00
 SWIFT CODE: DEUT DESS 603
 Baden-Württembergische Bank
 BLZ 600 501 01, Konto 487 1905
 IBAN DE31 6005 0101 0004 8719 05
 SWIFT CODE: SOLA DE ST

