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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



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 010066 0426 Rev. 00

Manufacturer: **AESFULAP AG**
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Product Category(ies): **Implants, Instruments and Devices**
(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.: 713159626

Valid from: 2019-07-27

Valid until: 2024-05-26

Date, 2019-07-16

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



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Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 010066 0426 Rev. 00

Facility(ies): AESCULAP AG
Am Aesculap-Platz, 78532 Tuttlingen, GERMANY

Surgical 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
Implants for replacement of connective tissue
Vascular prostheses and accessories
and other surgical accessories
Collagen implants

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

CERTIFICATE

No. Q5 17 03 10066 408



Product Service

Holder of Certificate: **AESFULAP AG**

Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Facility(ies):

AESFULAP AG
Am Aesculap-Platz, 78532 Tuttlingen,
GERMANY

AESFULAP 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.

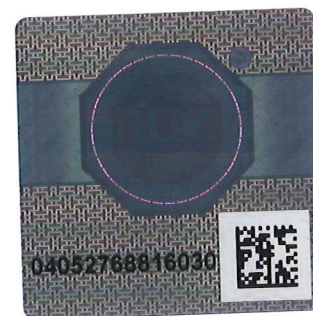
Report No.: 713098053

Valid from: 2017-06-01

Valid until: 2020-05-31

Date, 2017-05-30

Stefan Preiß



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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

Stefan Preiß

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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



ZERTIFIKAT ■ CERTIFICATE ■ CERTIFICADO ■ CERTIFICAT ■ 認證證書 ■

B | BRAUN

Declaration

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

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

TUTTLINGEN, 2014-11-26

AESFULAP 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