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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 010066 0426 Rev. 00

Manufacturer: **AESCULAP 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 Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 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

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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

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:

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

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

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

TÜV®

DAkkS CRT2 / 10.13

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

TÜV SÜD 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

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

"TEHNOMEDICA" S.R.L.

B|BRAUN

Declaration

The certification body of TÜV Süd Management Service GmbH and the TÜV Süd 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 9001:2015
(Certificate Registration No.: 12 100 21724 TMS)
EN ISO 13485:2016
(Certificate No.: Q5 17 03 10066 408)

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.

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, 2018-03-13

AESCULAP AG

i. V.

Thomas Marquard
Regulatory Affairs

i. A.

Denise Hermle
Regulatory Affairs

B|BRAUN

Attachment to Declaration of 2018-03-13

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 Accessoires
Hifh Frequency Surgery Devices
Endoscopic Systems
Navigation Systems
Surgical Suction Pumps
Special Suture-Sets
Implants for Replacement of Connective Tissue
Tissue Adhesives
Vascular Prosthesis and Accessories
Local Haemostatics
Other Surgical Accessories

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TEHNOMEDICA"
ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de indentificare de stat - codul fiscal

1002600053256

Data înregistrării **17.04.2002**

Data eliberării **16.02.2005**

Bolboceanu Adela, registrator de stat
Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

CAMERA ÎNREGISTRĂRII DE STAT L.Ș.

"TEHNOMEDICA" S.R.L. IDNO 1002600053256

MD 0027040

INFORMAȚII GENERALE DESPRE OFERTANT

1.	**Numele juridic al ofertantului:**	**Tehnomedica SRL**
2.	**Adresa juridică a ofertantului:**	Republica Moldova, mun.Chişinău, str. Ciuflea 38/1
3.	**Director:**	Tatiana Roibu
4.	**Telefon / Fax:**	022 601 102, 022 601 087
5.	**E-mail:**	tehnomedica_md@yahoo.com tehnomedicamd@gmail.com
6.	**Cont de decontare IBAN:**	MD65MO2224ASV98310887100
7.	**Banca:**	BC „Mobiasbanca – OTP Group" S.A., fil nr. 26 Negruzzi
8.	**Adresa poştală a băncii:**	Chişinău, str.Negruzzi 1
9.	**Codul băncii:**	MOBBMD22
10.	**Cod fiscal:**	1002600053256
11.	**Cod TVA:**	0207719

Director Tehnomedica SRL Tatiana Roibu

Semnătura: