TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com>

Către IMSP Institutul de Cardiologie

În atenția Grupului de lucru
al procedurii: COP nr: ocds-b3wdp1-MD-1570599343335;
ID: 21013054 din 18.10.2019
Instrumente Cardiochirurgicale

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că, în decurs de 3 zile de la solicitarea autorității contractante, vom prezenta mostre a produselor oferite în cadrul procedurii prenotate.

Cu respect,

Director Tatiana Roibu

18.10.19

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

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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

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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

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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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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

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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

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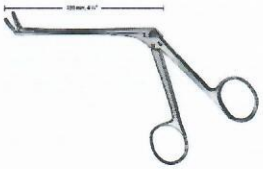
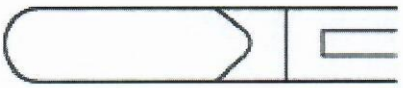
SHARING EXPERTISE

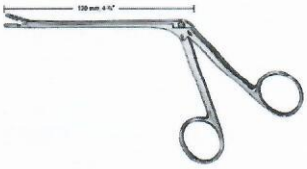
Item No.	Material	Product Description	Quantity Unit	Item Price EUR	Price Unit	Total Price EUR
10	OM488	SEIFFERT SILVER PROBE 1.0MM	1 PC			

20	OK526R	TAKAHASHI RONGEUR UP-BITE 3MM 120MM	1 PC			





30	OK525R	TAKAHASHI RONGEUR STR 3MM120MM	1 PC			



40	LX159R	REILL CUTTERF/WIRE CLOSE BONE2/1.5/175MM	2 PC			

50	FM583R	DIADUST MICRO FORCEPS PLATEAU CVD.185MM	1 PC			

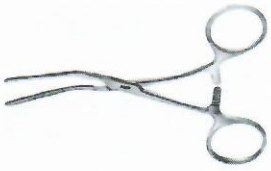
B|BRAUN
SHARING EXPERTISE

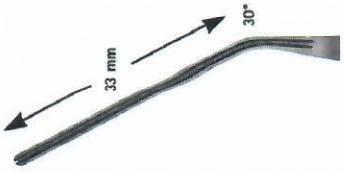
Item No.	Material	Product Description	Quantity Unit	Item Price EUR	Price Unit	Total Price EUR
60	FM581R	DIADUST MICRO FORCEPS PLATEAU CVD.150MM	1 PC			

70	FM481R	MICRO SCISSORS CVD.165MM	1 PC			

80	FD247R	MICRO-NEEDLE HLDR W/CATCH CVD185MM	1 PC			

90	FB581R	CASTANEDA NEONATAL CLAMP 30DG48/120MM	1 PC			





100	FB494R	DE'BAKEY ATR.AORTA CRSS-CLMP240MM	1 PC			

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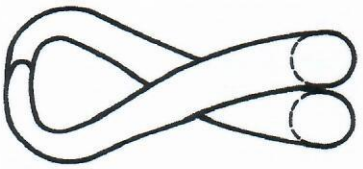
SHARING EXPERTISE

Item No.	Material	Product Description	Quantity Unit	Item Price EUR	Price Unit	Total Price EUR
110	FB423R	DE'BAKEY ATR.BULLDOGCLAMP CVD.30/90MM	1 PC			

120	BV075R	WEITLANER RETRACTOR 3X4T.BL.165MM	1 PC			



130	BN172R	KILLIAN PROBE CVD 1.5MM 165MM	1 PC			

140	BN101R	PROBE 2.0MM 300MM	1 PC			

150	BM078R	TC HEGAR NEEDLE HOLDER HVY- SERR240MM	2 PC			

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SHARING EXPERTISE

Item No.	Material	Product Description	Quantity Unit	Item Price EUR	Price Unit	Total Price EUR
160	BM077R	TC HEGAR NEEDLE HOLDER HVY-SERR 205MM	2 PC			

170	BM067R	TC MAYO-HEGAR NDL HOLDERHVYSERR205MM	1 PC			

180	BM037R	TC DE'BAKEY NDL HOLDER DEL SERR 260MM	1 PC			

190	BD257R	DELICATE FORCEPS SERR ANG 200MM	2 PC			

200	BC265R	TC METZENBAUM SCISSORS CVD 200MM	1 PC			

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SHARING EXPERTISE

Item No.	Material	Product Description	Quantity Unit	Item Price EUR	Price Unit	Total Price EUR
210	JK346	BOTTOM FOR 1/2 CONTAINER HEIGHT:247MM	2 PC			
						
220	JK389	1/2-SIZE LID W/RETENTION PLATE SILVER	2 PC			
						
230	JF113R	1/2 SIZE PERF BASKET 243X253X76MM	2 PC			
						
240	JK090	REUSABLE FILTER FOR CONTAINER	1 PAC			
						
250	JG785U	IDENTIFICATION LABEL RED	4 PC			

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Aesculap AG
Global Sales & Market Management

Postfach 40
78501 Tuttlingen
Germany

Contact: Selina Riester

Fon: +49 7461 95-31578
Fax: +49 746178980
Email: selina.riester@aesculap.de
Internet: http://www.bbraun.com

Date: March 01, 2017

To whom it may concern

German DIN Standard DIN 58953-8
Logistics of sterile medical devices

The requested information regarding the storage time of sterile containers is part of the DIN 58953 part 8- Logistics of sterile medical devices. Unfortunately this German standard is not available in English language.
The European standard for packaging materials EN 868 and the ISO standard for sterile packaging materials do not include any information regarding the storage time of packaging materials.

The above mentioned DIN standard 58953-8 gives the following recommendations with regards to the storage time of containers:

It is pointed out that the loss of sterility is more event related than time related. The storage time is not such an important factor, more important are different influences during storage, transport and handling of sterile goods. Therefore the storage time cannot be fixed in a general matter. The DIN standard gives only recommendations for storage time of containers. The final decision has to be made by the hygienic commission of the respective hospital considering the detailed storage conditions in this hospital. The recommendation for the storage time for sterile containers is generally 6 months, no matter if the container is single packed or double packed or stored in open or closed shelves.

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The following notes are made in DIN58953-8:

1. The recommendation of storage time of 6 months for container is only a recommendation which would diminish the risk of contamination during transport and opening of the container. Longer storage time would increase the risk of contamination on the surface of the container depending on the storage conditions. However this would not necessarily lead to a recontamination of the packed instruments during storage time.

Tabelle 1 – Empfohlene Lagerdauer für sterile Medizinprodukte

Art der Verpackung	Lagerung ungeschützt[3]	Lagerung geschützt (nach 7.1.2)
Sterilbarrieresystem	Dient zur Bereitstellung zum alsbaldigen Gebrauch[6] Ist als Lagerungsart zu vermeiden	6 Monate jedoch nicht länger als das Verfallsdatum
Verpackungssystem (Kombination aus Sterilbarrieresystem und Schutzverpackung)	5 Jahre sofern keine andere Verfallsfrist vom Hersteller festgelegt ist	
ANMERKUNG siehe auch [4] und [5]		

[3] In Regalen in Räumen, die nicht der Raumklasse II nach DIN 19464:2008-12 entsprechen.
[6] Unter alsbaldigem Gebrauch wird die Anwendung bzw. der Gebrauch des Produktes innerhalb von maximal 2 Tagen / 48 h verstanden

With kind regards,

Aesculap AG

i.V. AESCULAP AG
Lena Burghardt

i.A.
Selina Riester

"TEHNOMEDICA" S.R.L. IDNO 1002600053256 CHISINAU 3 SOCIETATEA CU RĂSPUNDERE LIMITATĂ REPUBLICA MOLDOVA