INFORMAȚII GENERALE DESPRE OFERTANT

1.	**Numele juridic al ofertantului:**	**Tehnomedica SRL**
2.	**Adresa juridică a ofertantului:**	Republica Moldova, mun.Chișinău, 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:**	Chișinău, str.Negruzzi 1
9.	**Codul băncii:**	MOBBMD22
10.	**Cod fiscal:**	1002600053256
11.	**Cod TVA:**	0207719

Director Tehnomedica SRL Tatiana Roibu

Semnătura:

TEHNOMEDICA

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

Către IMSP Institutul de Cardiologie

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că instrumentele chirurgicale oferite în cadrul achiziției de valoare mică ***nr. ocds-b3wdp1-MD-1614761021304, ID: 21036835 din 07.03.2021*** sunt bine cunoscute de către specialiștii IMSP Institutul de Cardiologie şi au fost utilizate pe parcursul ultimilor ani în cadrul instituției. Totodată, corespunderea parametrilor tehnici poate fi regăsită în catalogul producătorului Aesculap AG, Germania.

Cu respect,

Director Tatiana Roibu

Benannt durch/Designated by
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: **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

Benannt durch/Designated by
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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

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TÜV®

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

Product Service

Certificate

No. Q5 010066 0435 Rev. 00

Holder of Certificate: **AESCULAP AG**
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Certification Mark:

Scope of Certificate: **Design and development, production, technical service and distribution of implants, instruments, instrument management systems, containers, devices, tissue adhesives**

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.: 713175266

Valid from: 2020-06-01
Valid until: 2023-05-31

Date, 2020-05-27

Christoph Dicks
Head of Certification/Notified Body

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

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

TÜV SÜD
Product Service

Certificate

No. Q5 010066 0435 Rev. 00

Applied Standard(s):

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

Facility(ies):

AESCULAP AG
Am Aesculap-Platz, 78532 Tuttlingen, GERMANY

AESCULAP AG
Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

- Surgical 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
- Implants for replacement of connective tissue
- Tissue adhesives
- Vascular prostheses and accessories
- Local haemostatics
- Other surgical accessories
- Collagen implants

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TÜV®

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 and Tissue Adhesive

Aesculap AG Tuttlingen

- Surgical 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
- Other surgical accessories
- Instrument Management System
- Collagen implants

Aesculap AG Melsungen

- Implants for replacement of connective tissue
- Tissue adhesive
- Local haemostatic

An audit was performed, Order No. **70062209**.

Proof has been furnished that the requirements according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2020-06-01** until **2023-05-31**.

Certificate Registration No.: **12 100 21724 TMS**.

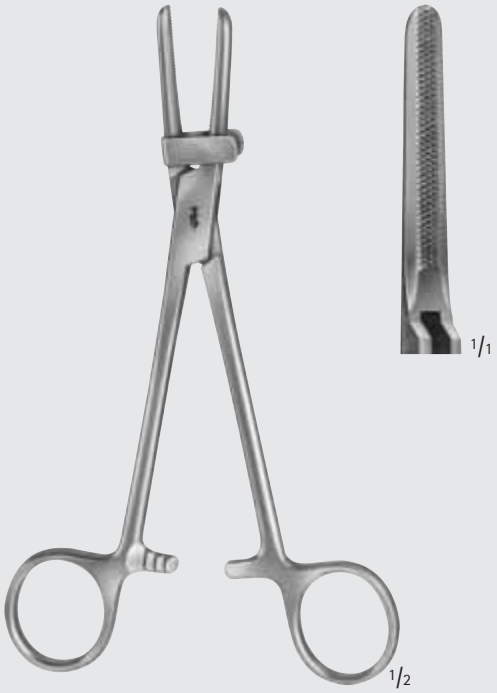
Product Compliance Management
Munich, 2020-05-20

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

MS/01-01/2019

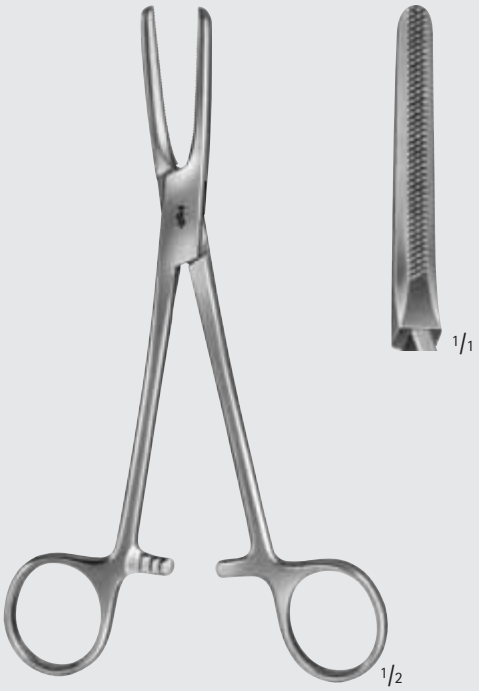
Untersuchung – Diagnostik – Examination – Diagnostic

Vorbereitung
Preparation



AN911R

Schlauchklemme
Tubing clamp
180 mm, 7"



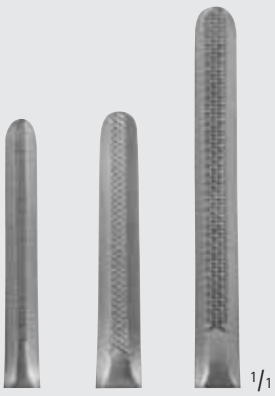
AN912R

Schlauchklemme
Tubing clamp
180 mm, 7"

kräftig gerieftes Maul
heavy wedge jaw

AN913R

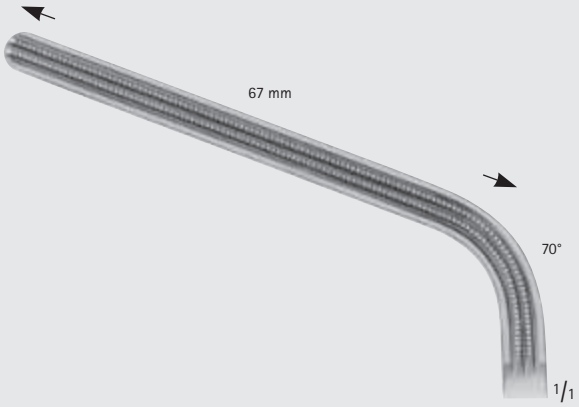
Schlauchklemme
Tubing clamp
200 mm, 8"



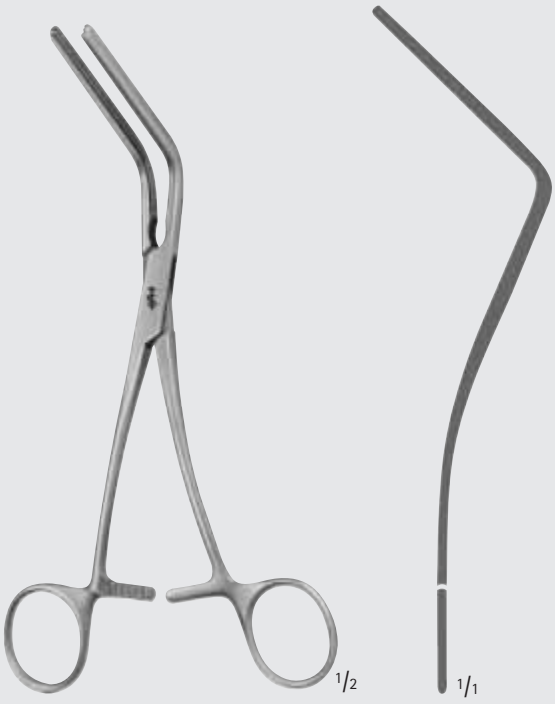
MD452R	MD453R	MD454R
155 mm	185 mm	200 mm
6"	7 1/4"	8"

MD452R–MD454R

Schlauchklemmen
Tubing clamps



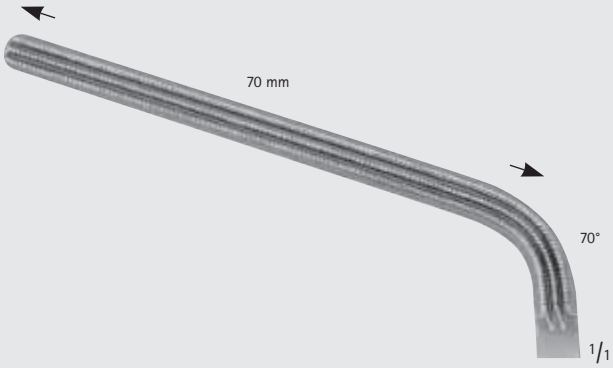
93 mm



MORRIS

FB493R

175 mm, 7″



93 mm

DE BAKEY
(MORRIS MODIF.)

FB494R

240 mm, 9″

Ø 0,8 mm
Diam. 0.8 mm

1/2

STACKE

BN160

Silber
silver
100 mm, 4"

1/2

CAWTHORNE

BN161

flaches Ende
Silber
flattened end
silver
140 mm, 5 1/2"

Ø 1,5 mm
Diam. 1.5 mm

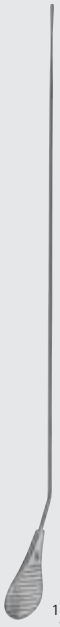
1/2

KILLIAN

BN172R

165 mm, 6 1/2"

Ø 1,4 mm
Diam. 1.4 mm

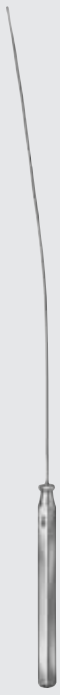


1/2

BN170R

160 mm, 6 1/4"

Ø 1,0 mm
Diam. 1.0 mm



1/2

SEIFFERT

OM488

Silber
silver
195 mm, 7 3/4"

1/2

BOWMAN

OB510–OB514

Neusilber
German silver
130 mm, 5 1/8"

	Ø Diam.	
OB510	0,7 + 0,8 mm	Fig. 00/0
OB511	0,9 + 1,1 mm	Fig. 1/2
OB512	1,3 + 1,4 mm	Fig. 3/4
OB513	1,5 + 1,6 mm	Fig. 5/6
OB514	1,8 + 1,9 mm	Fig. 7/8