TEHNOMEDICA

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

Anexa nr. 7
la Documentația standard nr.115
din 15.09.2021

CERERE DE PARTICIPARE

Către **IMSP Spitalul Clinic Republican „Timofei Moșneaga”**

Stimaţi domni,

Ca urmare a anunțului/invitației de participare/de preselecție apărut în Buletinul achizițiilor publice și/sau Jurnalul Oficial al Uniunii Europene, nr.16 din 15.04.2022, publicat BAP nr. 30 din 19.04.2022; JOUE nr. 2022/S 077-210793 din 20.04.2022, LD nr.*ocds-b3wdp1-MD-1651130054540,ID:21055740din 31.05.2022* privind aplicarea procedurii pentru atribuirea contractului privind *achiziționarea necesarului de piese de schimb pentru dispozitive medicale pentru anul 2022*, noi, *Tehnomedica SRL,* am luat cunoștință de condițiile și de cerințele expuse în documentația de atribuire și exprimăm prin prezenta interesul de a participa, în calitate de ofertant/candidat, neavînd obiecții la documentația de atribuire.

Data completării: 30.05.2022

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)

Digitally signed by Roibu Tatiana
Date: 2022.05.30 12:48:20 EEST
Reason: MoldSign Signature
Location: Moldova

TEHNOMEDICA

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

Anexa nr. 8
la Documentația standard nr.115
din 15.09.2021

DECLARAŢIE
privind valabilitatea ofertei

Către **IMSP Spitalul Clinic Republican „Timofei Moșneaga”**

Stimaţi domni,

Ne angajăm să menținem oferta valabilă, privind *achiziționarea necesarului de piese de schimb pentru dispozitive medicale pentru anul 2022* prin procedura de achiziție licitație deschisă, pentru o durată de 120 zile, începând cu data de 31.05.2022, respectiv până la data de 30.09.2022 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 30.05.2022

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)

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 109 L.Ș.

MD 0027040

TEHNOMEDICA

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

Către IMSP Spitalul Clinic Republican
„Timofei Moșneaga”

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1651130054540,
ID:21055740 din 31.05.2022

Declarație privind termenul de garanție

Prin prezenta, declarăm că termenul de garanție la momentul livrării a produselor oferite în cadrul licitației prenonate privind ***achiziționarea necesarului de piese de schimb pentru dispozitive medicale pentru anul 2022,*** va constitui cel puțin 12 luni.

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
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®

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

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®

Aesculap Sterile Technology

Sterilit®

B BRAUN
SHARING EXPERTISE

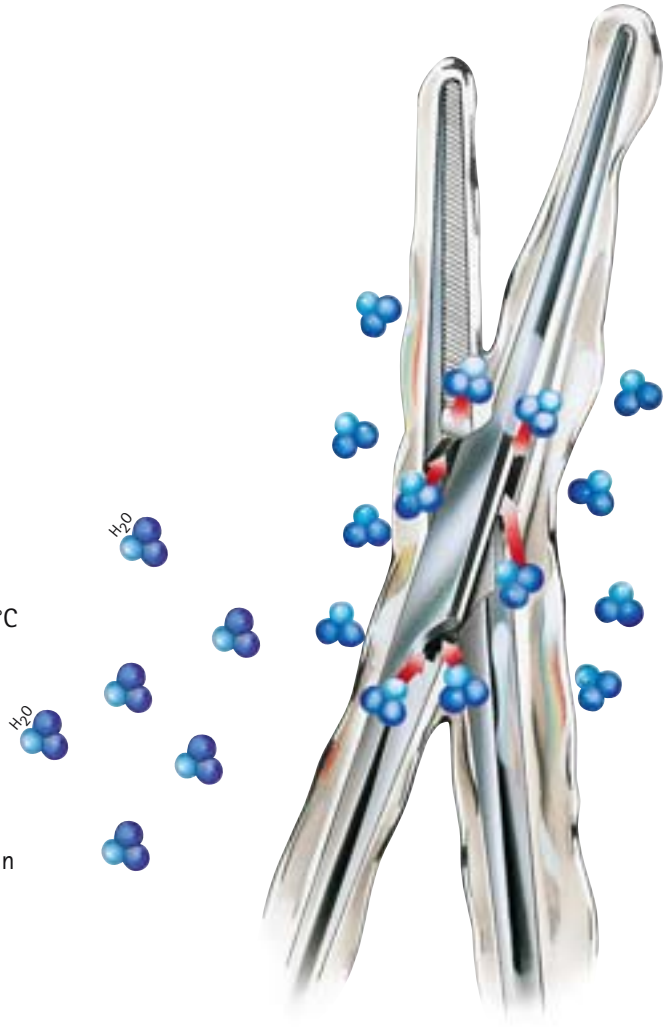
Sterilit® our Know-how in instrument care

Sterilit® – Oil spray

- reduces friction and protects against friction corrosion
- ensures good gliding and lubrication characteristics
- proven physiologically safe in accordance with ISO 10993
- environmentally friendly (CFC-free)
- suitable for steam sterilisation procedures in accordance with ISO 13683 and for hot air sterilisation up to max. 180°C

Sterilisability

Sterilit®s special composition guarantees penetration of the oil film by the water vapour during the sterilisation process, even in more inaccessible places.



Aesculap maintenance oils Sterilit® I, Sterilit® Hi, Sterilit® mini, Sterilit® M

Applications
All Sterilit® maintenance oils are validated for steam sterilization methods according to EN 554/ISO 13683, as well as for dry heat (heated air) sterilization up to 180 °C. They are applied prior to sterilization.

Microbiological efficiency controls for steam sterilization (fractioned vaccuum and gravity procedure) have been carried out according AAMI TIR 12-1994, RKI-Directive, E DIN EN ISO 17664, DIN EN 554 (half cycle method); ANSI/AAMI/ISO 11134, DIN EN 556-1, AAMI/CDV-3 ST 67.

Sterilit®	Art.-No.
Sterilit® I, spray	JG600
Sterilit® I, drip oiler	JG598
Sterilit® Hi, spray	GA536
Sterilit® mini, spray	GB372
Sterilit® M, spray	GB149
Sterilit® M, drip oiler	GA059

Registration
Sterilit® oils are registered as medical accessory class 1 in conformity with Annex 1 MDD 93/42/EEC CE marking according to directive 93/42/EEC.

Properties
- Steam-permeable oil film
- No adverse effect on the sterilization performance due to the oil film
- Lubricating effect and corrosion protection
- Silicon-free, no staining and incrustation on the instrument surfaces

Biological safety – toxycology
There is no evidence that hazards to the patient will arise during surgical application of Sterilit®-treated devices. This is only valid that the Sterilit® oil is properly and carefully used as described in the instructions for use. According EN ISO 10993-1.

Safe handling
- Only apply prior to sterilization.
- Store in a cool and dry place protected from light.
- Take note of the use-by date.
- Before using Sterilit, reprocess the object to be lubricated according to the relevant instructions for use.

Warning
Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- Avoid release to the environment.
- Refer to special instructions/safety data sheets.

What products are available for instrument care?




STERILIT$^{®}i$

JG600
including
2 spray nozzles

Aesculap Oil Spray
in spray cans (CFC-free),
for **instrument care** prior to sterilization

STERILIT$^{®}M$

GB149

Aesculap Oil Spray
in spray cans (CFC-free),
especially for the care of
handpieces with intra-coupling
prior to sterilization

STERILIT$^{®}Hi$

GA536

Aesculap Oil Spray
in spray cans (CFC-free),
especially for the care of
Hilan motors and handpieces
prior to sterilization

STERILIT$^{®}mini$

GB372

Aesculap Oil Spray
in spray cans (CFC-free),
especially for the care of
miniMotors and handpieces prior to sterilization

STERILIT$^{®}i$

JG598

Aesculap Instrument Oil
for lubricating **joints and locks**
prior to sterilization

STERILIT$^{®}M$

GA059

Aesculap Motor-Handpiece Oil,
for lubricating **friction bearings on motors** prior to sterilization

AESCULAP®

B BRAUN
SHARING EXPERTISE

Aesculap AG & Co. KG

Am Aesculap-Platz
78532 Tuttlingen
Germany

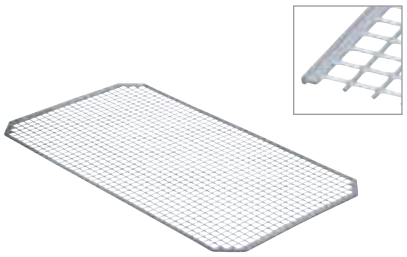
Phone +49 7461 95-0
Fax +49 7461 95-2600

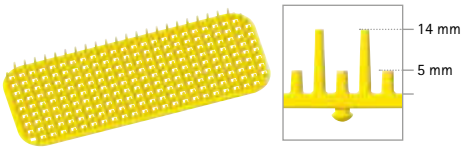
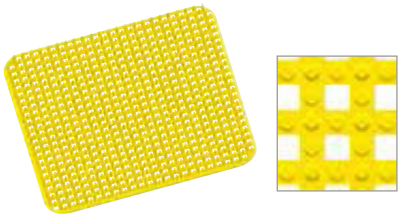
www.aesculap.de

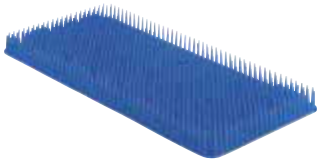
Brochure No. C06402

0907/2/6

Aesculap InOS® – INSTRUMENT ORGANISATION SYSTEM

SILICONE MATS (MESH)		Outside dim.	Art. no.
	fitting to 1/2 basket	240 x 250 mm	JF938
	fitting to 3/4 basket	402 x 250 mm	JF940
	fitting to 1/1, short basket	480 x 250 mm	JF939
	fitting to 1/1, long basket	536 x 250 mm	JF941

SILICONE MATS WITH PERFORATION (NUBS)		Outside dim.	Art. no.
	fitting to JF159R	248 x 102 mm	JF944
	fitting to 1/2 basket	248 x 237 mm	JF945
	fitting to 3/4 basket	394 x 242 mm	JF947
	fitting to 1/1, short basket	472 x 242 mm	JF948
	fitting to 1/1, long basket	517 x 242 mm	JF949

POSITIONING MAT		Outside dim.	Art. no.
		470 x 230 x 30 mm	JF932
		276 x 125 x 17 mm	JF934