

TEHNOMEDICA

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

CERERE DE PARTICIPARE

Către IMSP Spitalul Clinic Republican „Timofei Moșneaga”

Stimați domni,

Ca urmare a anunțului/invitației de participare/de preselecție apărut în Buletinul achizițiilor publice și/sau Jurnalul Oficial al Uniunii Europene, BAP nr. 53 din 07.07.2023, LD nr. ocds-b3wdp1-MD-1689084056659, ID: 21084566 din 02.08.2023 privind aplicarea procedurii pentru atribuirea contractului privind achiziționarea pieselor de schimb pentru dispozitive medicale pentru anul 2023 etapa II, 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: 01.08.2023

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)

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

DECLARAȚIE privind valabilitatea ofertei

Către IMSP Spitalul Clinic Republican „Timofei Moșneaga”

Stimați domni,

Ne angajăm să menținem oferta valabilă, privind achiziționarea pieselor de schimb pentru dispozitive medicale pentru anul 2023 etapa II prin procedura de achiziție licitație deschisă, pentru o durată de 90 zile, începând cu data de 02.08.2023, respectiv până la data de 01.11.2023 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 01.08.2023

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

MD 0027040



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

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1689084056659,
ID: 21084566

Declarație privind termenul de garanție

Prin prezenta, declarăm că termenul de garanție la momentul livrării a produselor oferite în cadrul licitației preonate privind *achiziționarea pieselor de schimb pentru dispozitive medicale pentru anul 2023 etapa II*, 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
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

Declaration

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

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

TUTTLINGEN, 2018-03-13

AESULAP AG

i. V.



Thomas Marquard
Regulatory Affairs

i. A.



Denise Hermle
Regulatory Affairs

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
High 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

Aesculap Sterile Technology Sterilit®



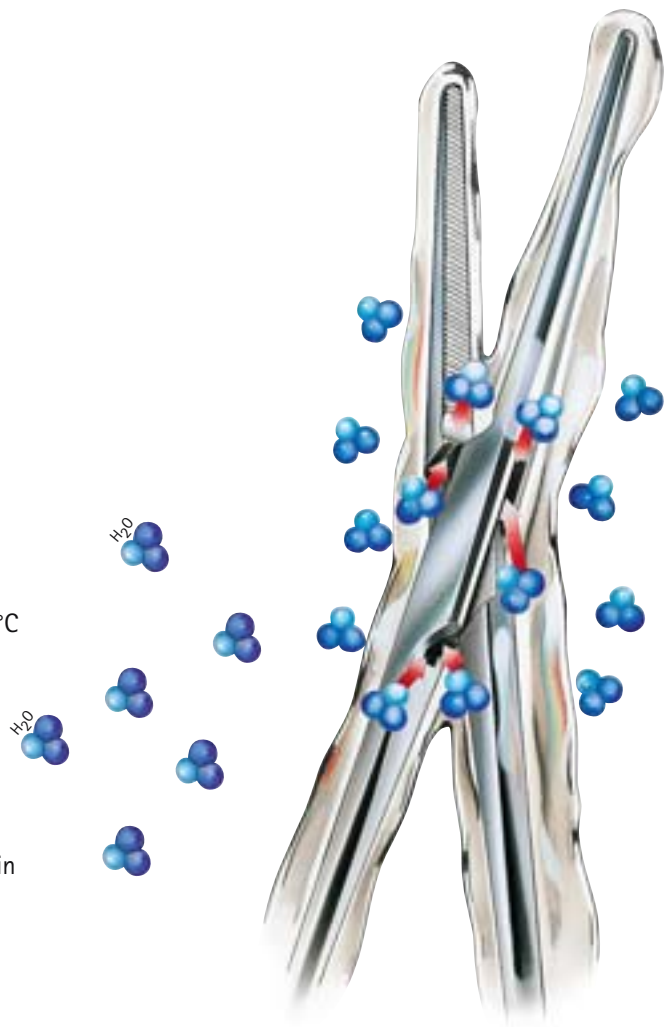
Sterilit® our Know-how in instrument care

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 (fractionated vacuum and gravity procedure) have been carried out according to 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 – toxicology

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 to 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[®]

JG600
including
2 spray nozzles



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

STERILIT[®]

GB149



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

STERILIT[®]

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[®]

JG598



Aesculap Instrument Oil
for lubricating joints and locks
prior to sterilization

STERILIT[®]

GA059



Aesculap Motor-Handpiece Oil,
for lubricating friction
bearings on motors prior to steri-
lization



AESCULAP®

B | BRAUN
SHARING EXPERTISE

Aesculap AG & Co. KG

Am Aesculap-Platz
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Germany

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Fax +49 7461 95-2600

www.aesculap.de

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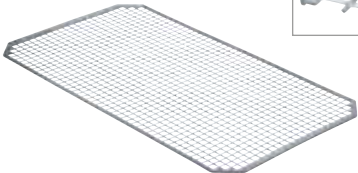

PRODUCT DATA SHEET

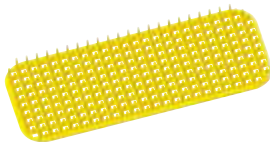
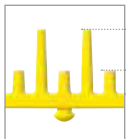
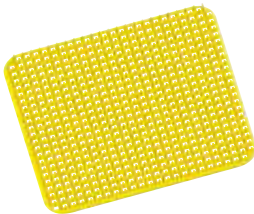
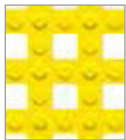
Oil, volume: 50 ml (JG598)

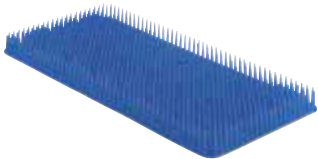




Attribute Name	Attribute Value
Product search type	Oil
Aesculap Product Groups	Sterile Technology, General Surgical Instruments, Dental, Endoscopic Technology
Volume	50.0 ml
Surgical Step	Others
Product contains Latex	No
Sterility	non-sterile
Disposable / Reusable	reusable

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
 	Mini	276 x 125 x 17 mm	JF934