



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:

AESCLAP 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



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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):

AESCLAP 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



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:

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.

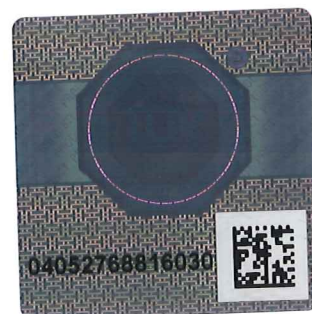
Report No.: 713098053

Valid from: 2017-06-01

Valid until: 2020-05-31

Date, 2017-05-30

Stefan Preiß



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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
- Endoscopy 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

Stefan Preiß

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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
- Endoscopy 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



ZERTIFIKAT ■ CERTIFICATE ■ CERTIFICADO ■ CERTIFIKAT ■ 認證證書 ■ CERTIFICATE ■ CERTIFIKAT

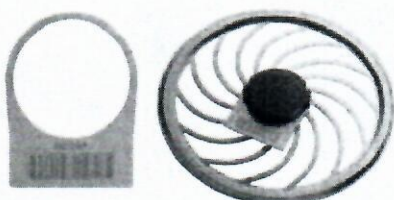
ACCESSORIES

FILTER ACCESSORIES



JK100

Universal filter retention plate for reusable filters and paper filters, fitting for all lid and body components of standard sterile containers.



JG731R

Bar code identification ring for filter retention plate. For recording the cycle count of reusable filter JK090. Lettering acc. to specification, up to 6 digits with bar code BC128A.



JK098

Outside dim.

245 x 100 x 6

Universal filter retention plate for reusable and paper filters, fitting for all lid and base components of mini, dental and scope sterile containers.



JK096

Outside dim.

197 x 197 x 40

Filter dispenser for round filters.



JP050

Filter insert for PRIMELINE® and PRIMELINE® PRO lids validated for 5,000 sterilization cycles.



JP055

Mounting handle for filter insert, PRIMELINE® and PRIMELINE® PRO lids.

Angled Hi-Line XS handpieces for the Hi-Line XS burr range



GB756R

GB614R

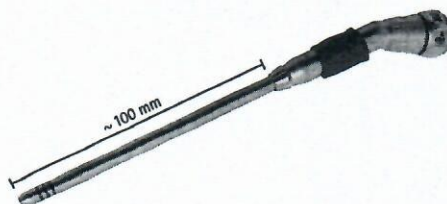
Hi-Line XS handpiece, angled
1 ring code;
spray nozzle GB761SU (not
included)



GB757R

GB614R

Hi-Line XS handpiece, angled
2 ring code;
spray nozzle GB762SU (not
included)



GB758R

GB614R

Hi-Line XS handpiece, angled
3 ring code;
spray nozzle GB763SU (not
included)

Hi-Line XS

Craniotome and multipurpose handpiece



GB740R

GB614R

Hi-Line XS craniotome and multi purpose handpiece

to be used with dura guards, drill depth guard and holding sleeve
GB741R - GB748R,
spray nozzle GB767SU (not included)



GB741R

GB615R

Hi-Line XS dura guard

fixed;
1 ring code;
to be used with craniotome burr
GE420R, GE420SU, GE429SU



GB742R

GB615R

Hi-Line XS dura guard

fixed;
2 ring code;
to be used with craniotome burr
GE520R, GE520SU, GE529SU



GB743R

GB615R

Hi-Line XS dura guard

fixed;
3 ring code;
to be used with craniotome burr
GE620R, GE620SU, GE629SU



GB746R

GB615R

Hi-Line XS dura guard

steerable;
1 ring code;
to be used with craniotome burr
GE420R, GE420SU, GE429SU



GB747R

GB615R

Hi-Line XS dura guard

steerable;
2 ring code;
to be used with craniotome burr
GE520R, GE520SU, GE529SU

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 Spitalul Clinic Republican
"Timofei Moșneaga"**

În atenția Grupului de lucru
al LP nr. ocds-b3wdp1-MD-1582201504217;
ID: 21020127 din 23.03.2020

Declarație privind termenul de garanție a bunurilor

Prin prezenta, declarăm că pentru produsele oferite în cadrul Licităției Publice nr. ocds-b3wdp1-MD-1582201504217; ID:21020127 din 23.03.2020 privind **achiziționarea de piese de schimb, accesorii și consumabile pentru mentenanța dispozitivelor medicale pentru anul 2020, termenul de garanție va constitui 12 luni la momentul livrării fiecărui produs.**

Cu respect,

Director

Tatiana Roibu

23.03.2020

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 Spitalul Clinic Republican
"Timofei Moșneaga"**

În atenția Grupului de lucru
al LP nr. ocds-b3wdp1-MD-1582201504217;
ID: 21020127 din 23.03.2020

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că vom prezenta mostre în decurs de 5 zile de la solicitarea autorității contractante pentru produsele oferite în cadrul Licitației Publice nr. ocds-b3wdp1-MD-1582201504217; ID:21020127 din 23.03.2020 privind **achiziționarea de piese de schimb, accesorii și consumabile pentru mentenanța dispozitivelor medicale pentru anul 2020.**

Cu respect,

Director

Tatiana Roibu

23.03.2020