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

"TEHNOMEDICA" S.R.L. IDNO 1002600053256

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® 0034

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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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"TEHNOMEDICA" S.R.L. IAȘI

TÜV® 0035

A4 / 07.17

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:

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**

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

"TEHNOMEDICA" S.R.L.

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

TÜV® 0036

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

"TEHNOMEDICA" S.R.L. IDNO 1002600053256

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TÜV® 0038

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD 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

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

"TEHNOMEDICA" S.R.L. IDNO 1002600056256

TÜV SÜD Management Service GmbH • Zertifizierungsstelle • Ridlerstrasse 57 • 80339 München • Germany
www.tuev-sued.de/certificate-validity-check

TÜV®

0037

MS/01-01/2019

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

"TEHNOMEDICA" S.R.L. IDNO 1002600025258

B|BRAUN

Attachment to Declaration of 2018-03-13

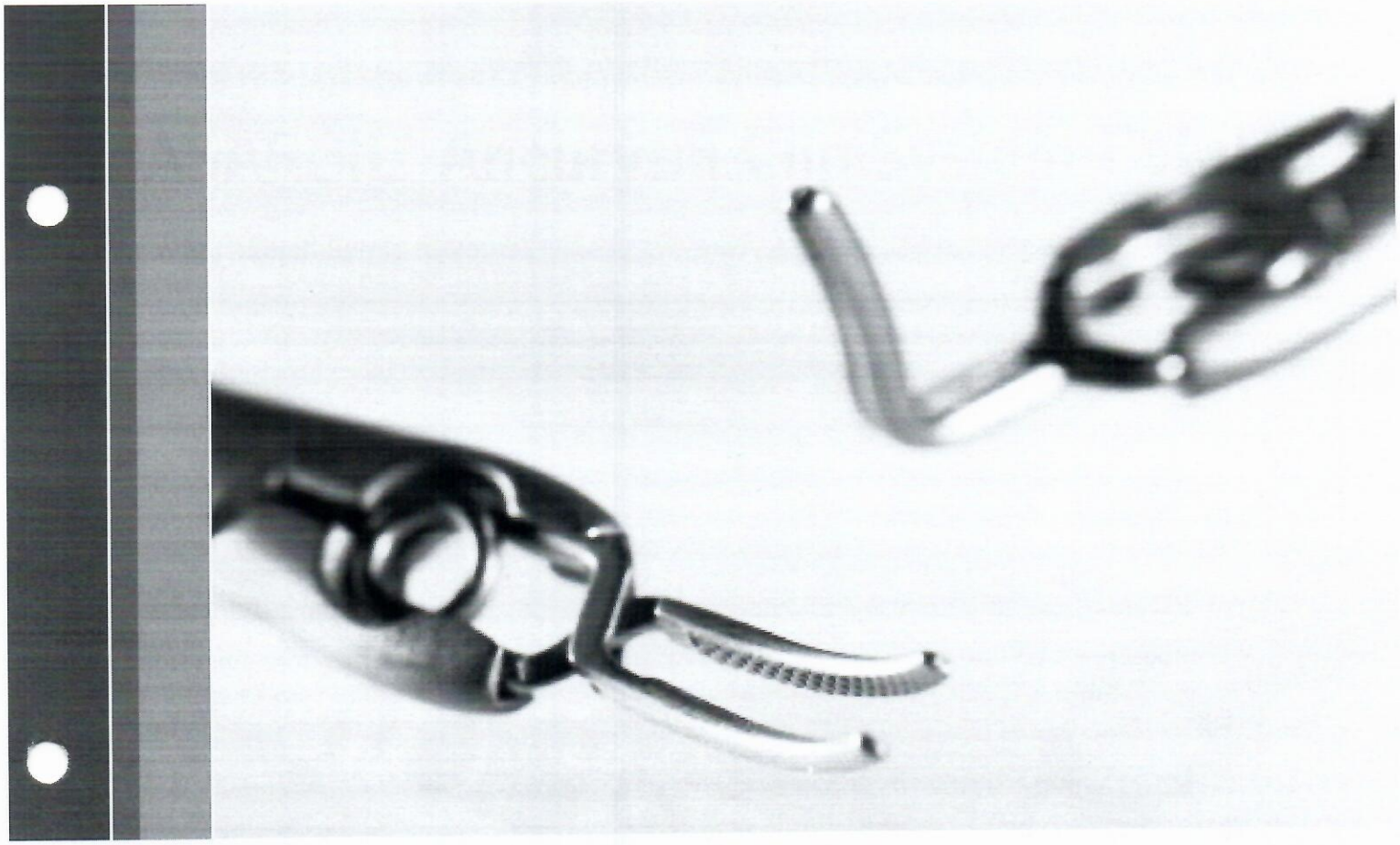
Aesculap Product Groups
Surgical, diagnostic and dental instruments
Joint Implants (Hip, Knee)
Spinal Implants
Implants for osteosynthesis
Neurosurgical Vascular Implants
Products for Ligature
Motor Systems
Sterilization Containers and Accessoires
Hifh Frequency Surgery Devices
Endoscopic Systems
Navigation Systems
Surgical Suction Pumps
Special Suture-Sets
Implants for Replacement of Connective Tissue
Tissue Adhesives
Vascular Prosthesis and Accessories
Local Haemostatics
Other Surgical Accessories

0040

Lotul nr. 1

YASARGIL® Aneurysm Clip System Catalog

From our skilled hands to yours.



Aesculap Neurosurgery

AESCULAP®

0028

TEMPORARY

Item No.		Blade length mm	Maximum opening mm	Closing force N (+/- 7.5%)	g (+/- 7.5%)
FT214T		3.9	3.5	0.78	80
FT224T		5.0	4.0	0.69	70
FT216T		5.0	3.5	0.69	70
FT307T		4.7	4.0	0.69	70
FT217T		6.3	6.0	0.69	70
FT227T		4.0	7.0	0.69	70
FT228T		7.0	5.7	0.69	70
FT306T		7.0	4.5	0.69	70

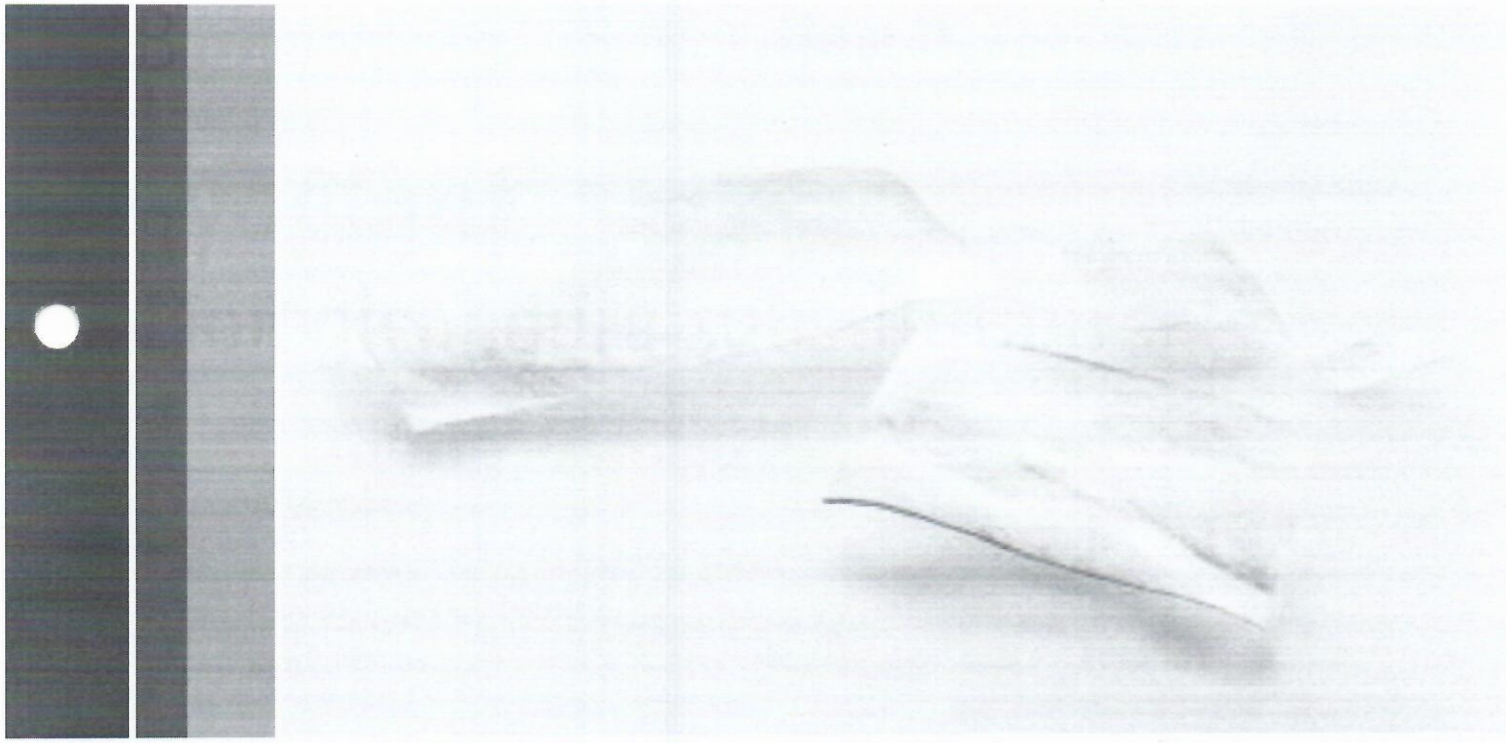
PERMANENT

Item No.		Blade length mm	Maximum opening mm	Closing force N (+/- 7.5%)	g (+/- 7.5%)
FT714T		3.9	3.5	1.08	110
FT724T		5.0	4.0	1.08	110
FT716T		5.0	3.5	1.08	110
FT807T		4.7	4.0	1.08	110
FT717T		6.3	6.0	1.08	110
FT727T		4.0	7.0	1.08	110
FT728D		7.0	5.7	1.08	110
FT806T		7.0	4.5	1.08	110

Lotul nr. 2

Lyoplant®

Biological dura substitution



Aesculap Neurosurgery

B|BRAUN

SHARING EXPERTISE

0030

Lyoplant®

INDICATIONS

Dura substitute in intracranial and intraspinal procedures

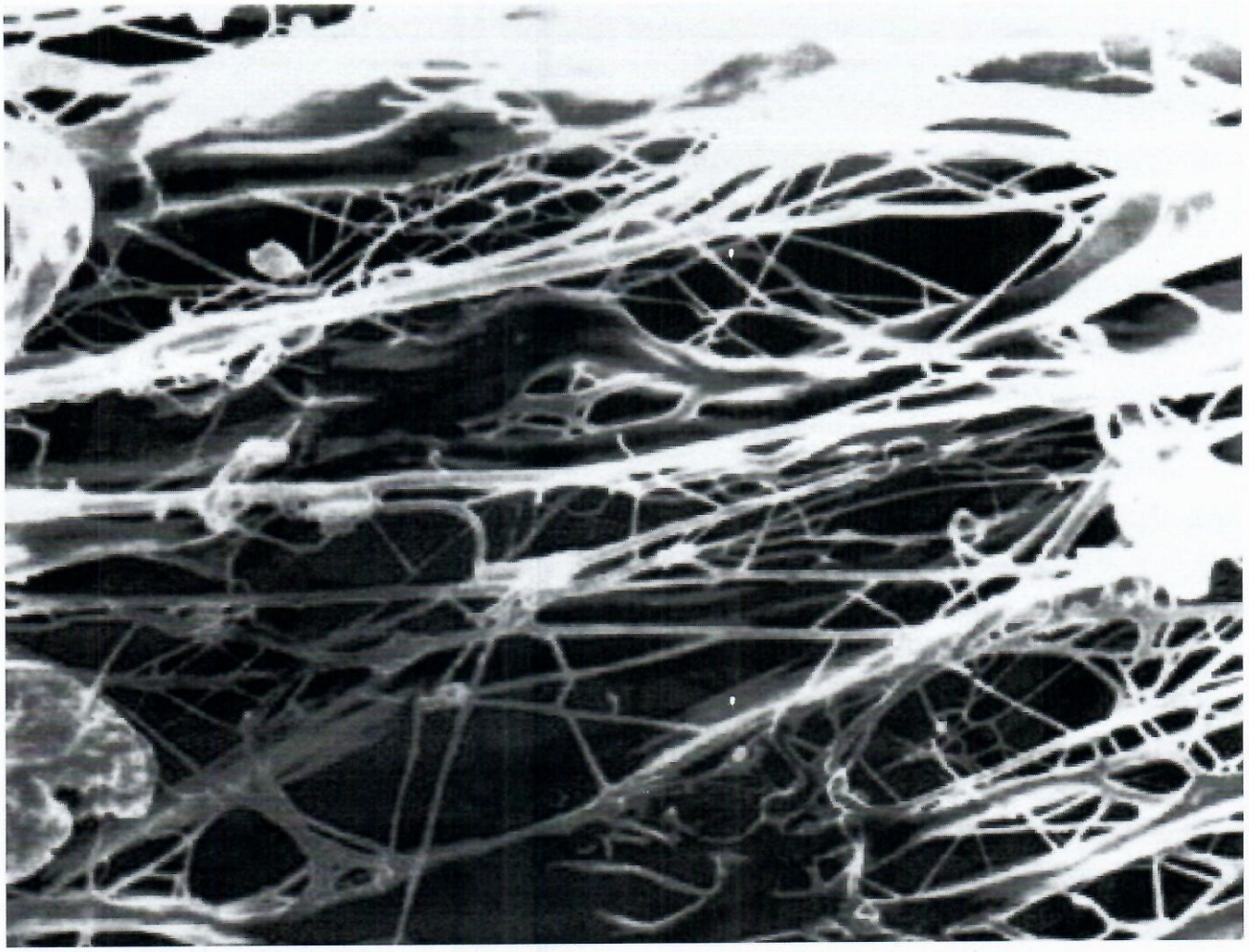
CONTRAINDICATIONS

Lyoplant® should not be used:

- In infected areas
- For substitution of mechanically strained connective tissue (tendons / sinews)
- For substitution of parts of the arterial system or the heart walls
- In case of known hypersensitivity against proteins of bovine origin

ADVANTAGES

- Fluid-tight to prevent CSF leakage
- Absorbable
- Well tolerated by tissue
- Good modelling qualities and elasticity
- No suture pull-out



DESCRIPTION

Lyoplant® is a pure collagen implant that is produced from bovine pericardium. This highly purified collagen is known for its low propensity to cause immunological reactions.

A controlled lyophilisation (freeze drying) process supports that the loose fibre structure of Lyoplant® is preserved to offer appropriate conditions for integration after implantation.

Sizes	Content	Art. No.
6 x 14 cm	1 piece	106 6021
8 x 9 cm	1 piece	NEW 106 6030
6 x 8 cm	1 piece	106 6242
5 x 6 cm	1 piece	NEW 106 6050
4 x 10 cm	1 piece	106 6048
4 x 5 cm	2 pieces	106 6064
2 x 10 cm	2 pieces	106 6080
1.5 x 3 cm	2 pieces	106 6102

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Phone +1 650 624-5005 | Fax +1 610 231-3713 | www.aesculap.com

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Phone +49 74 61 95-0 | Fax +49 74 61 95-26 00 | www.aesculap.de

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