



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 14 05 10066 366

Manufacturer: **AESCLAP AG**
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Facility(ies): AESCLAP AG
Am Aesculap-Platz, 78532 Tuttlingen, GERMANY

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

Product Category(ies): **Implants, Instruments, Devices,
Tissue Adhesive and Procedure Kits
(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.: 713043279

Valid from: 2014-07-27
Valid until: 2019-07-26

Date, 2014-07-11

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2



Attachment for Certificate no G1 14 05 10066 366
dated 2014-07-27



Product Service

Surgical, diagnostic 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
Special suture sets
Implants for replacement of connective tissue
Tissue adhesive
Vascular prostheses and accessories
and other surgical accessories

Munich, CRT 2, 2014-07-11

Hans-Heiner Junker





Product Service

CERTIFICATE

No. Q5 17 03 10066 408

Holder of Certificate: **AESULAP AG**

Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Facility(ies):

AESULAP AG
Am Aesculap-Platz, 78532 Tuttlingen,
GERMANY

AESULAP 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

Stefan Preiß

Page 1 of 2



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



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
- Endoscopic 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

Page 2 of 2



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

B | BRAUN

Declaration

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

**AESCLAP AG
AM AESCLAP-PLATZ
78532 TUTTLINGEN / GERMANY**

have established and are maintaining a quality management system according to

ISO 9001:2008
(Certificate Registration No.: 12 100 21724 TMS)
EN ISO 13485:2012 / AC:2012
(Certificate No.: Q1N 14 05 10066 365)

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. (EC certificate No.: G1 14 05 10066 366)

By labeling the products

**Aesculap Product Groups
as per attached list**

with the CE mark

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


TUTTLINGEN, 2014-11-26

AESCLAP AG

i. V.


Thomas Marquard
Director Regulatory Affairs

i. A.


Sandra Maier
Regulatory Affairs



Attachment to Declaration of 2014-11-26

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 accessories
High frequency surgery devices
Endoscopic 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



Quality Inspection Certificate

Cert.-No.: 1- 010212

Aesculap AG certifies, that
our products and raw materials

Instrument-type	Steel-type	Hardness-HRC
Retractors	X20Cr13	40-48
Scissors	X50CrMoV15; X38CrMoV15	50-58
Chisel, Gouges, Curettes	X46Cr13; X20Cr13	50-58; 40-48
(Bone) Rongeur	X46Cr13	50-58
Dissecting Forceps	X15Cr13; X20Cr13	40-48
Forceps with shaft handle	X15Cr13; X20Cr13	40-48
Forceps with ring handle	X20Cr13	40-48

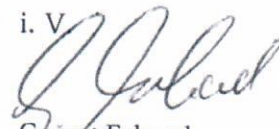
are designed, manufactured and tested according defined and documented specifications and procedures.

The following national and international standards and requirements were met:

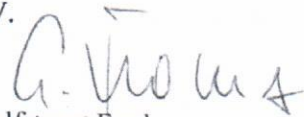
- EN ISO 13485:2003 (AC 2009)
- Council Directive 93/42 EEC of 14. June 1993 concerning Medical Devices
- ISO 7153-1 (Surgical Instruments-Metallic materials; Part 1: Stainless steel)
- Others: The defined requirements and performed tests cover also corrosion analysis, cutting ability, elasticity and mechanical resistance were applicable.
 Technical / physical test according to the quality specification – passes test
 Chemical test according to the quality specification – passes test

AESCULAP AG

i. V.


 Georg Erhard
 Director Quality Management Organization

i. V.


 Wolfgang Fuchs
 Project Manager QM-Instruments

Vorsitzender des Aufsichtsrates:
 Prof. Dr. h.c. Ludwig Georg Braun

Vorstand:
 Prof. Dr. Hanns-Peter Knaebel
 (Vorsitzender)
 Dr. Harald Stallforth
 (stellv. Vorsitzender)
 Dr. Joachim Schulz

Sitz der Gesellschaft: Tuttlingen
 Reg. Gericht: Stuttgart HRB 726261
 Steuernummer: 21060/00036

WEEE-Reg.-Nr. DE 65109852

Bankverbindungen:

Deutsche Bank AG Tuttlingen
 BLZ 653 700 75, Konto 21 22 000
 IBAN DE44 6537 0075 0212 2000 0000
 SWIFT CODE: DEUTDE33

Baden-Württembergische Bank
 BLZ 600 501 01, Konto 487 1905
 IBAN DE31 6005 0101 0004 8719 0000
 SWIFT CODE: SOLA DE 33



Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
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000010	HEATH Mallet, 240 mm (9 1/2"), diam. 40 mm, peek handle, stainless steel, 850 g, 500 g	FL068R	4 PC				
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000020	HEATH Mallet, 240 mm (9 1/2"), diam. 45 mm, peek handle, stainless steel, 1160 g, 810 g	FL069R	2 PC				
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000030	STILLE Chisel, straight, 10 mm, 205 mm, 8"	FL503R	2 PC				
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000040	STILLE Chisel, straight, 12 mm, 205 mm, 8"	FL504R	2 PC				
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000050	STILLE Chisel, straight, 15 mm, 205 mm, 8"	FL505R	2 PC				
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Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
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000060	STILLE Chisel, straight, 20 mm, 205 mm, 8"	FL506R	2 PC				
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000070	STILLE Chisel, straight, 25 mm, 205 mm, 8"	FL507R	2 PC				
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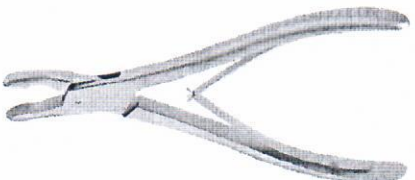
000080	LANGE-HOHMANN Bone Lever, curved, 250 mm (10"), width: 24 mm	FK160R	2 PC				
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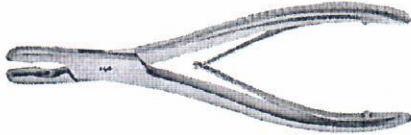
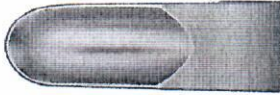
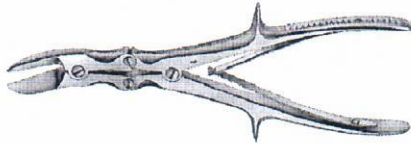
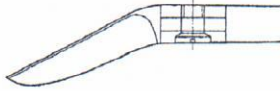
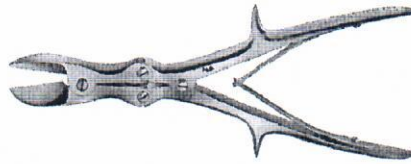

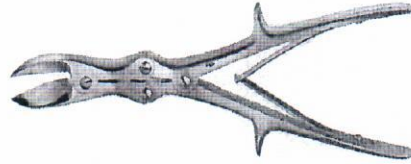
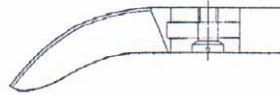

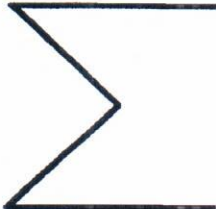
000090	HOHMANN Bone Lever, curved, 240 mm (9 1/2"), width: 17 mm	FK171R	6 PC				
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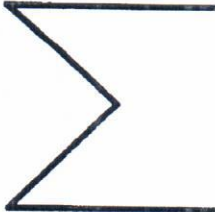
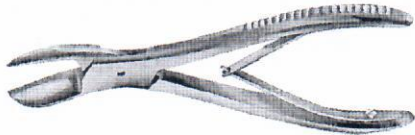

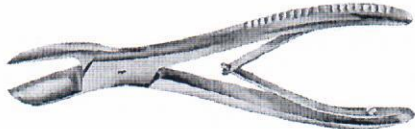




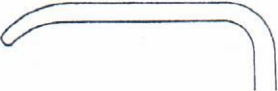
000100	LUER Bone Rongeur, curved, 175 mm (7")	FO461R	1 PC				
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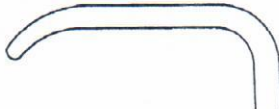


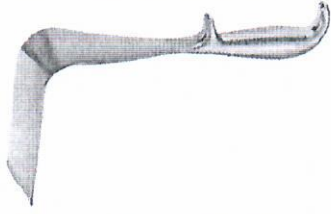
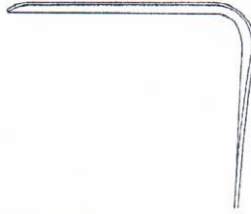


Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
000110	LUER Bone Rongeur, straight, 180 mm (7"), oval	F0462R	2 PC				
							
000120	LISTON Bone Cutting Forceps, angled, 240 mm (9 1/2"), double action, non-sterile, reusable	F0645R	1 PC				
							
000130	LISTON Bone Cutting Forceps, straight, 280 mm (11"), double action, non-sterile, reusable	F0646R	1 PC				
							
000140	LISTON Bone Cutting Forceps, curved, 280 mm (11"), double action, non-sterile, reusable	F0647R	1 PC				
							
000150	FARABEUF Bone Holding Forceps, 230 mm (9"), small, adjustable jaw, width: 9 mm, non-sterile, reusable	F0140R	2 PC				
							


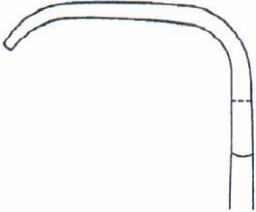

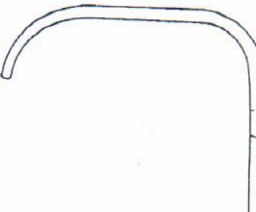
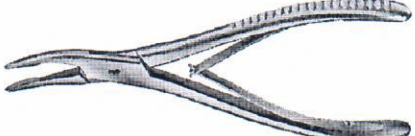

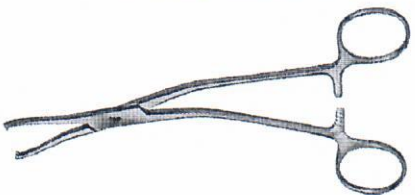
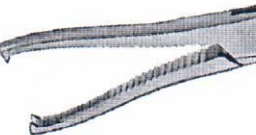

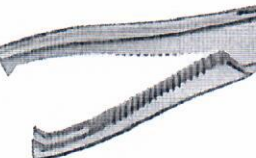
Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
000160	FARABEUF Bone Holding Forceps, 255 mm (10"), large, adjustable jaw, width: 11 mm, non-sterile, reusable	F0141R	2 PC				
							
000170	LISTON Bone Cutting Forceps, angled, 200 mm (7 7/8"), non-sterile, reusable	F0634R	4 PC				
							
000180	LISTON Bone Cutting Forceps, curved, 220 mm (8 3/4"), non-sterile, reusable	F0636R	2 PC				
							
000190	LANGENBECK Retractor, 215 mm (8 1/2"), handle vertical to the blade, depth: 83 mm, width: 15 mm, non-sterile, reusable	BT332R	4 PC				
							
000200	LANGENBECK Retractor, 210 mm (8 1/4"), depth: 40 mm, width: 10 mm, non-sterile, reusable	BT325R	2 PC				
							

Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
000210	LANGENBECK Retractor, 210 mm (8 1/4"), depth: 40 mm, width: 13 mm, non-sterile, reusable	BT326R	2 PC				
							
000220	LANGENBECK Retractor, 210 mm (8 1/4"), depth: 33 mm, width: 14 mm, non-sterile, reusable	BT322R	2 PC				
							
000230	LANGENBECK Retractor, 230 mm (9"), solid, depth: 43 mm, width: 13 mm, non-sterile, reusable	BT316R	2 PC				
							
000240	DOYEN Vaginal Specula, 240 mm (9 1/2"), depth: 120 mm, width: 60 mm, non-sterile, reusable	EL639R	2 PC				
							
000250	HOHMANN Bone Lever, curved, 240 mm (9 1/2"), sharp, width: 17 mm	FK166R	4 PC				
							

Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
000260	OLLIER Retractor, 230 mm (9"), 4 prongs, blunt, depth: 35 mm, width: 55 mm, non-sterile, reusable	BT288R	4 PC				
							
000270	KOERTE Retractor, 230 mm (9"), deep form, 4 prongs, blunt, handle vertical to the blade, depth: 45 mm, width: 55 mm, non-sterile, reusable	BT280R	2 PC				
							
000280	BEYER Bone Rongeur, curved, 180 mm (7")	FO453R	4 PC				
							
000290	DINGMANN Bone Holding Forceps, curved to side, 185 mm (7 1/4"), non-sterile, reusable	FO110R	5 PC				
							
000300	DINGMANN (MODIF.) Bone Holding Forceps, curved to side, 185 mm (7 1/4"), non-sterile, reusable	FO111R	10 PC				
							

Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
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000310 Dressing Forceps (Tweezers), standard, straight, 200 mm (7 7/8"), standard, serrated, non-sterile, reusable

BD051R

10 PC



000320 KOCHER-OCHSNER Hemostatic Forceps, straight, 260 mm (10 1/4"), toothed (1x2), non-sterile, reusable

BH652R

4 PC



000330 KOCHER-OCHSNER Hemostatic Forceps, straight, 200 mm (7 7/8"), toothed (1x2), non-sterile, reusable

BH646R

8 PC



000340 KOCHER-OCHSNER Hemostatic Forceps, curved, 200 mm (7 7/8"), toothed (1x2), non-sterile, reusable

BH647R

8 PC



Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
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000400 ESMARCH Plaster Shears, angled to side, 200 mm (7 7/8"), serrated (inside), 1 blade probe pointed, non-sterile, reusable

LX550R

1 PC



000410 LISTER Bandage- And Cloth Scissors, angled to side, 180 mm (7"), 1 blade probe pointed, non-sterile, reusable

BC862R

3 PC



000420 Bottom, without base perforation, Standard 1/1, outer length: 592 mm, outer width: 274 mm, outer height: 247 mm, inner length: 544 mm, inner width: 258 mm, inner height: 232 mm

JK446

3 PC



000430 Inner Lid, basis, Standard 1/1 silver, outer length: 592 mm, outer width: 295 mm, outer height: 90 mm

JK489

3 PC



Chairman of Supervisory Board:
Prof. Dr. Heinz-Walter Große
Management Board:
Dr. Joachim Schulz (Chairman)
Dr. Jens von Lackum (Deputy Chairman)
Dr. Katrin Sternberg

Corporate Office: Tuttlingen
Register Court: Stuttgart HRB 726261
VAT reg. no. DE 812 160 059
WEEE-Reg.-No. DE 65109852

Bank Details:
Deutsche Bank AG Tuttlingen
Bank code 653 700 75 Acc. 21 22 000 00
IBAN DE44 6537 0075 0212 2000 00
SWIFT / BIC DEUTDE33
Baden-Württembergische Bank
Bank code 600 501 01 Acc. 487 1905
IBAN DE31 6005 0101 0004 8719 05
SWIFT / BIC SOLADEST

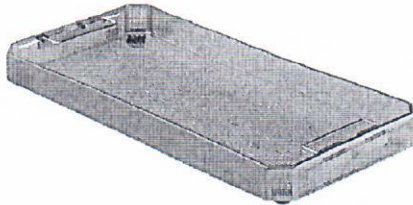
Office Address:
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78532 Tuttlingen
Germany

Tel. no. (+49) 7461 95-0
Telefax (+49) 7461 95-26 00
Internet www.aesculap.com

Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
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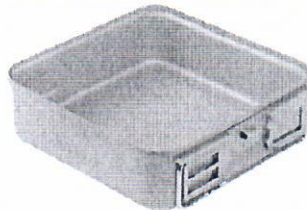
000440	Perforated basket, Standard 1/1, 540 x253 x 56 mm, with feet	JF222R	3 PC				
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000450	Reusable Filter, package of 10 pieces, diam. 190 mm 1 PAC = 10 PC	JK090	1 PAC				
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000460	Bottom, without base perforation, Standard 1/2, outer length: 300 mm, outer width: 274 mm, outer height: 247 mm, inner length: 254 mm, inner width: 258 mm, inner height: 232 mm	JK346	2 PC				
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000470	Inner Lid, basis, Standard 1/2, silver, outer length: 298 mm, outer width: 285 mm, outer height: 46 mm	JK389	2 PC				
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Aesculap AG
Global Sales & Market Management

Postfach 40
78501 Tuttlingen
Germany

To whom it may concern

Contact: Selina Riester

Fon: +49 7461 95-31578
Fax: +49 746178980
Email: selina.riester@aesculap.de
Internet: <http://www.bbraun.com>

Date: March 01, 2017

German DIN Standard DIN 58953-8 Logistics of sterile medical devices

The requested information regarding the storage time of sterile containers is part of the DIN 58953 part 8- Logistics of sterile medical devices. Unfortunately this German standard is not available in English language.

The European standard for packaging materials EN 868 and the ISO standard for sterile packaging materials do not include any information regarding the storage time of packaging materials.

The above mentioned DIN standard 58953-8 gives the following recommendations with regards to the storage time of containers:

It is pointed out that the loss of sterility is more event related than time related. The storage time is not such an important factor, more important are different influences during storage, transport and handling of sterile goods. Therefore the storage time cannot be fixed in a general matter. The DIN standard gives only recommendations for storage time of containers. The final decision has to be made by the hygienic commission of the respective hospital considering the detailed storage conditions in this hospital. The recommendation for the storage time for sterile containers is generally 6 months, no matter if the container is single packed or double packed or stored in open or closed shelves.

Chairman of Supervisory Board:
Prof. Dr. h.c. Ludwig Georg Braun

Executive Board:
Prof. Dr. Hanns-Peter Knaebel
(Chairman)
Dr. Jens von Lackum
Dr. Joachim Schulz

Corporate Office: Tuttlingen
Register Court: Stuttgart HRB 726261
VA1 reg. no. DE812160059
WEEE-Reg.-No. DE 65109852

Bank Account:
Deutsche Bank AG Tuttlingen
BLZ 653 700 75 Konto 21 22 000490
IBAN DE44 6537 0075 0212 2004 90
SWIFT / BIC DEUTDE33
Baden-Württembergische Bank
BLZ 600 501 01 Konto 487 1905
IBAN DE31 6005 0101 0004 8719 05
SWIFT / BIC SOLADEST



The following notes are made in DIN58953-8:

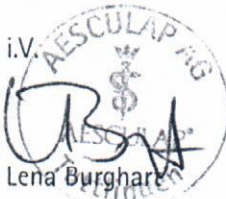
1. The recommendation of storage time of 6 months for container is only a recommendation which would diminish the risk of contamination during transport and opening of the container. Longer storage time would increase the risk of contamination on the surface of the container depending on the storage conditions. However this would not necessarily lead to a recontamination of the packed instruments during storage time.

Tabelle 1 – Empfohlene Lagerdauer für sterile Medizinprodukte

Art der Verpackung	Lagerung ungeschützt ³	Lagerung geschützt (nach 7.1.2)
Sterilbarriersystem	Dient zur Bereitstellung zum alsbaldigen Gebrauch ⁶ Ist als Lagerungsart zu vermeiden	6 Monate jedoch nicht länger als das Verfallsdatum
Verpackungssystem (Kombination aus Sterilbarriersystem und Schutzverpackung)	5 Jahre sofern keine andere Verfallsfrist vom Hersteller festgelegt ist	
ANMERKUNG siehe auch [4] und [5]		
³ In Regalen in Räumen, die nicht der Raumklasse II nach DIN 19464:2008-12 entsprechen.		
⁶ Unter alsbaldigem Gebrauch wird die Anwendung bzw. der Gebrauch des Produktes innerhalb von maximal 2 Tagen / 48 h verstanden		

With kind regards,

Aesculap AG

i.V.

Lena Burghard

i.A.


Selina Riester

