



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



Page 1 of 2





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

S. Preiß

Stefan Preiß

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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



Declaration

The certification body of TÜV Management Service GmbH and the TÜV 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 9001:2008
(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**

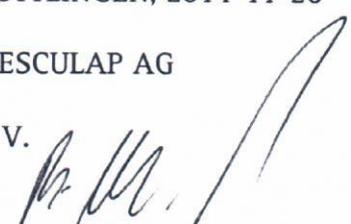
with the CE mark

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

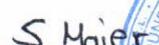
TUTTLINGEN, 2014-11-26

AESULAP 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

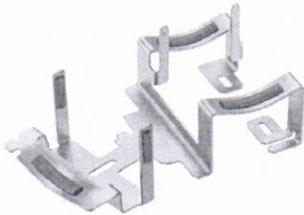
Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
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000010	Acculan 3Ti oscillating saw	GA673	1 PC				
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000020	Eccos Fixation	GB495R	1 PC				
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000030	Eccos Fixation	GB481R	1 PC				
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000040	Eccos Fixation	GB486R	1 PC				
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000050	Eccos Fixation	GB487R	1 PC				
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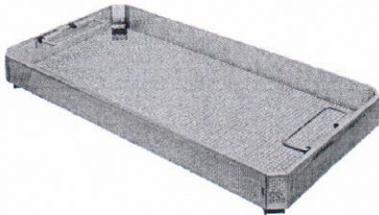
Iehnomedica SRL, 2001 Crisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
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000060	Eccos Fixation	GB488R	1 PC				
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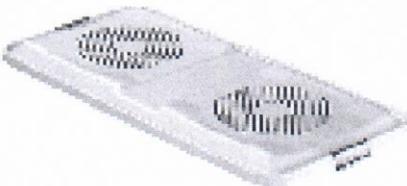
000070	Perforated basket, Standard DIN, 485 x253 x 56 mm, with feet	JF212R	1 PC				
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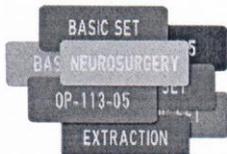
000080	Bottom, with base perforation, Standard 1/1, outer length: 592 mm, outer width: 274 mm, outer height: 120 mm, inner length: 544 mm, inner width: 258 mm, inner height: 105 mm	JN441	1 PC				
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000090	Inner Lid, basis, Standard 1/1, silver, outer length: 582 mm, outer width: 291 mm, outer height: 36 mm	JK489	1 PC				
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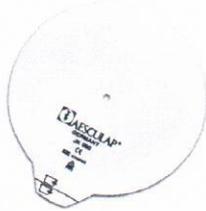
000100	Accessories Container, identification label, standard, aluminium, red, outer length: 56 mm, outer width: 18 mm	JG785B	2 PC				
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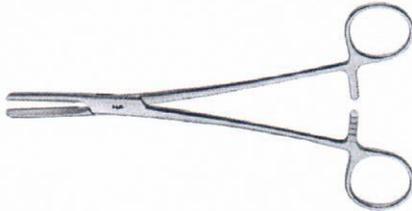
Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
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000110	Reusable Filter, package of 10 pieces, diam. 190 mm 1 PAC = 10 PC	JK090	1 PAC				
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000120	Tubing Clamp, straight, 200 mm (8"), heavy wedge jaw, fluted, serrated, non-sterile, reusable	AN913R	2 PC				
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000130	CASPAR Scalpel Handle, 180 mm (7"), round handle, non-sterile, reusable	BB052R	1 PC				
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000140	Scalpel Handle, 125 mm (5"), No. 3, non-sterile, reusable	BB073R	2 PC				
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000150	Scalpel Handle, 210 mm (8 1/4"), long pattern, No. 3 L, non-sterile, reusable	BB075R	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
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000160 Scalpel Handle, 160 mm (6 1/4"), No. 7, non-sterile, reusable

BB077R

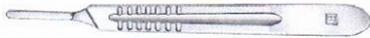
1 PC



000170 Scalpel Handle, 135 mm (5 1/4"), No. 4, non-sterile, reusable

BB084R

1 PC



000180 JOSEPH Dissecting Scissors, straight, 150 mm (6\"), delicate pattern, sharp/sharp, large rings, non-sterile, reusable

BC006R

2 PC



000190 JOSEPH Dissecting Scissors, curved, 150 mm (6\"), delicate pattern, sharp/sharp, large rings, non-sterile, reusable

BC007R

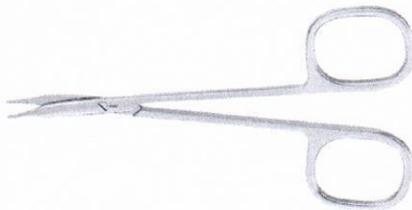
2 PC



000200 STEVENS Tenotomy Scissors, curved, 115 mm (4 1/2\"), delicate pattern, sharp/sharp, large rings, non-sterile, reusable

BC009R

2 PC



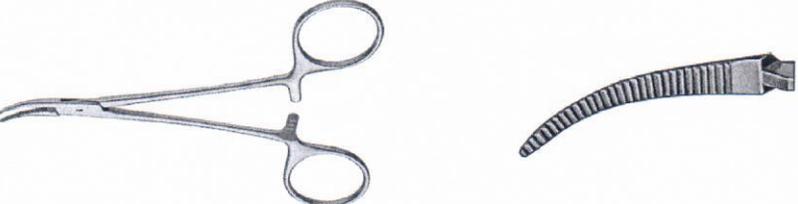
Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
000210	METZENBAUM DUROTIP TC Dissecting Scissors, curved, 180 mm (7"), wave cut, blunt/blunt, non-sterile, reusable	BC263W	2 PC				
							
000220	METZENBAUM DUROTIP TC Dissecting Scissors, curved, 200 mm (7 7/8"), wave cut, blunt/blunt, non-sterile, reusable	BC265W	2 PC				
							
000230	METZENBAUM DUROTIP TC Dissecting Scissors, curved, 200 mm (7 7/8"), delicate pattern, blunt/blunt, non-sterile, reusable	BC275R	2 PC				
							
000240	METZENBAUM DUROTIP TC Dissecting Scissors, curved, 230 mm (9"), wide pattern, blunt/blunt, non-sterile, reusable	BC287R	2 PC				
							
000250	COOPER Surgical Scissors, curved, 145 mm (5 3/4"), standard, blunt/blunt, non-sterile, reusable	BC414R	1 PC				
							

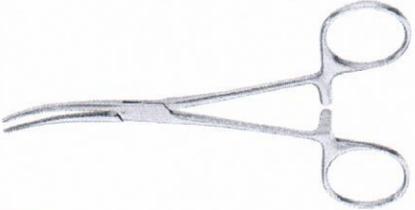
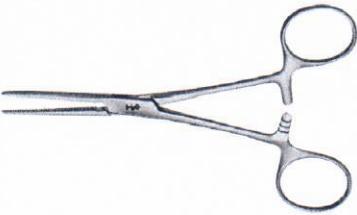
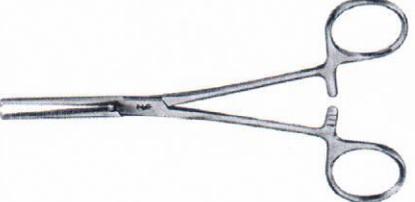
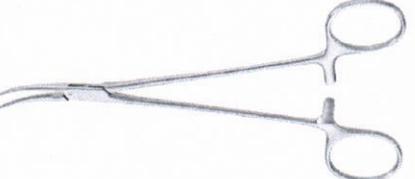
Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
000260	MAYO Dissecting Scissors, curved, 170 mm (6 3/4"), chamfered blades, blunt/blunt, non-sterile, reusable	BC557R	1 PC				
							
000270	METZENBAUM Dissecting Scissors, curved, 200 mm (7 7/8"), blunt/blunt, non-sterile, reusable	BC607R	1 PC				
							
000280	NELSON-METZENBAUM Dissecting Scissors, curved, 250 mm (9 3/4"), blunt/blunt, non-sterile, reusable	BC616R	1 PC				
							
000290	TOENNIS-ADSON Dissecting Scissors, curved, 175 mm (6 7/8"), delicate pattern, blunt/blunt, non-sterile, reusable	BC631R	1 PC				
							
000300	Surgical Scissors, straight, 180 mm (7"), heavy pattern, blunt/blunt, non-sterile, reusable	BC774R	1 PC				
							

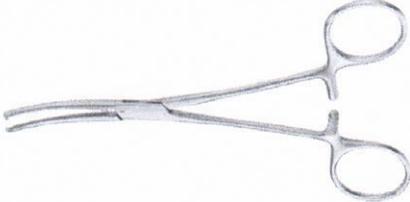
Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
000310	GERALD Dressing Forceps (Tweezers), straight, 230 mm (9"), delicate, serrated, non-sterile, reusable	BD230R	1 PC				
							
000320	Tissue Forceps, straight, 145 mm (5 3/4"), medium, toothed (1x2), non-sterile, reusable	BD537R	1 PC				
							
000330	FOERSTER-BALLENGER Sponge Forceps, straight, 245 mm (9 5/8"), oval, serrated, fenestrated, box lock, with ratchet, non-sterile, reusable	BF122R	2 PC				
							
000340	DE BAKEY-HESS Bulldog Clamp, angled, jaw length: 30 mm (1 3/16"), non-sterile, reusable	BH031R	2 PC				
							
000350	HALSTED (MOSQUITO) Hemostatic Forceps, curved, 125 mm (5"), delicate, non-sterile, reusable	BH111R	20 PC				
							

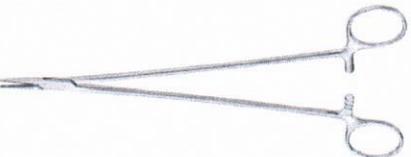
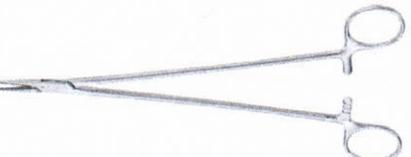
Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
000360	HEISS Hemostatic Forceps, straight, 200 mm (7 7/8"), delicate, blunt, non-sterile, reusable	BH206R	1 PC				
							
000370	PEAN Hemostatic Forceps, curved, 130 mm (5 1/8"), delicate, slender pattern, blunt, non-sterile, reusable	BH413R	14 PC				
							
000380	PEAN Hemostatic Forceps, straight, 130 mm (5 1/8"), blunt, non-sterile, reusable	BH422R	30 PC				
							
000390	KOCHER-OCHSNER Hemostatic Forceps, straight, 160 mm (6 1/4"), toothed (1x2), non-sterile, reusable	BH642R	8 PC				
							
000400	MOSQUITO ATRAUMATA Hemostatic Forceps, curved, 165 mm (6 1/2"), toothing DE BAKEY, jaw length: 27 mm, non-sterile, reusable	FB443R	2 PC				
							

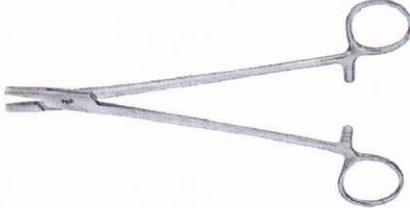
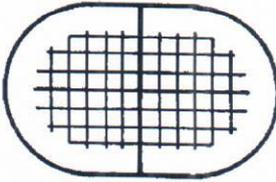
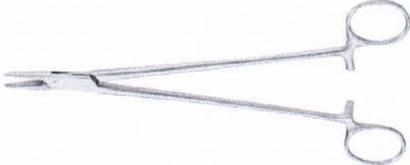
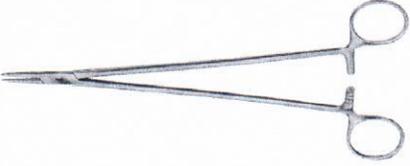
Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
000410	KOCHER-OCHSNER Hemostatic Forceps, curved, 160 mm (6 1/4"), toothed (1x2), non-sterile, reusable	BH643R	10 PC				
							
000420	RUMEL Dissecting Forceps, angled right, 240 mm (9 1/2"), Fig. 5, non-sterile, reusable	BJ045R	1 PC				
							
000430	WIKSTROEM Dissecting a. Ligature Forceps, angled right, 205 mm (8"), non-sterile, reusable	BJ051R	1 PC				
							
000440	MIXTER Dissecting a. Ligature Forceps, angled right, 230 mm (9"), non-sterile, reusable	BJ055R	1 PC				
							
000450	MIXTER Dissecting Forceps, curved, 220 mm (8 3/4"), serrated, non-sterile, reusable	BJ061R	1 PC				
							

Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
000460	MIXTER Dissecting Forceps, curved, 250 mm (9 3/4"), serrated, non-sterile, reusable	BJ062R	1 PC				
							
000470	GEMINI Dissecting Forceps, angled right, 200 mm (7 7/8"), non-sterile, reusable	BJ103R	1 PC				
							
000480	MIKULICZ Peritoneum Forceps, curved, 200 mm (7 7/8"), toothed (1x2), non-sterile, reusable	BJ314R	1 PC				
							
000490	DE BAKEY DUROGRIP TC Needleholder, straight, 230 mm (9"), with 0.4 mm pitch of serration, suture 4/0 - 6/0, non-sterile, reusable	BM036R	2 PC				
							
000500	DE BAKEY DUROGRIP TC Needleholder, straight, 260 mm (10 1/4"), with 0.4 mm pitch of serration, suture 4/0 - 6/0, non-sterile, reusable	BM037R	2 PC				
							

Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
000510	BAUMGARTNER DUROGRIP TC Wire Twister, straight, 205 mm (8"), with 0.5 mm pitch of serration, box lock, with ratchet, non-sterile, reusable	BM112R	1 PC				
							
000520	MAYO-HEGAR Needleholder, straight, 200 mm (7 7/8"), medium fine pattern, jaw with longitudinal groove, non-sterile, reusable	BM237R	3 PC				
							
000530	JAMESON Needleholder, straight, 230 mm (9"), delicate, non-sterile, reusable	BM270R	3 PC				
							
000540	MASSON Needleholder, straight, 265 mm (10 1/2"), jaw with longitudinal groove, non-sterile, reusable	BM275R	1 PC				
							

Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
000550	PATTERN US-ARMY Wound Retractor, 220 mm (8 3/4"), double ended, 22 x 15 mm, 26 x 15 mm, 39 x 15 mm, 43 x 15 mm, non-sterile, reusable, Set of 2	BT041R	3 SET				
							
000560	CUSHING Vein Retractor, 205 mm (8"), depth: 10 mm, width: 13 mm, non-sterile, reusable	BT184R	1 PC				
							
000570	VOLKMANN Wound Retractor (With Prong), 220 mm (8 3/4"), 6 prongs, semi-sharp, depth: 8,5 mm, width: 29 mm, non-sterile, reusable	BT261R	1 PC				
							
000580	KOCHER Retractor, 230 mm (9"), depth: 36 mm, width: 20 mm, non-sterile, reusable	BT459R	1 PC				
							
000590	ZENKER Retractor, 255 mm (10"), depth: 60 mm, width: 12 mm, non-sterile, reusable	BT595R	1 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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000600 ZENKER Retractor, 270 mm (10 5/8"), depth: 75 mm, width: 12 mm, non-sterile, reusable

BT596R

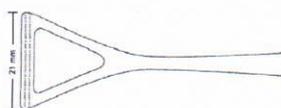
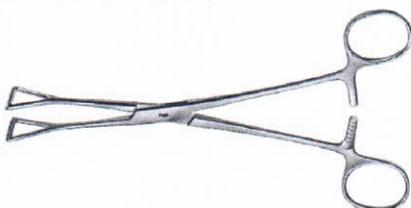
1 PC



000610 COLLIN ATRAUMATA Grasping Forceps, straight, 195 mm (7 3/4"), toothing DE BAKEY, width: 21 mm, non-sterile, reusable

EA061R

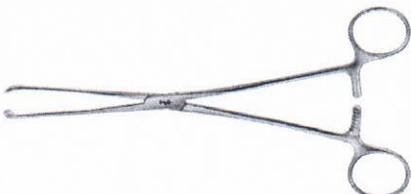
2 PC



000620 ALLIS ATRAUMATA Grasping Forceps, straight, 200 mm (7 7/8"), very delicate, toothing DE BAKEY, width: 7 mm, non-sterile, reusable

EA095R

1 PC



000630 Clip Applier Forceps, single-fire, 25 °, angled, 203 mm (8"), Size S, yellow, non-sterile, reusable, to be used with: PL565T, PL566T

FB223R

1 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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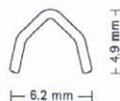
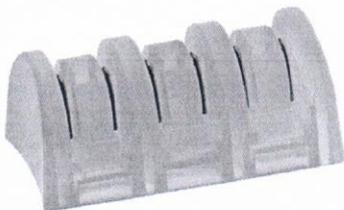
000640 Single fire clips, titanium, small, yellow, 4 mm, 3.1 mm, sterile, package of 8 cartridges a 24 clips, to be used with FB222R; FB223 R; FB226R; FB224R; FB227R
1 PAC = 8 PC



000650 Clip Applier Forceps, single-fire, 25 °, angled, 203 mm (8"), Size M, blue, non-sterile, reusable, to be used with: PL567T



000660 Single fire clips, titanium, medium, blue, 6.2 mm, 4.9 mm, sterile, package of 30 cartridges, to be used with FB234R; FB235R; FB238R ; FB236R; FB239R; PL504R
1 PAC = 30 PC



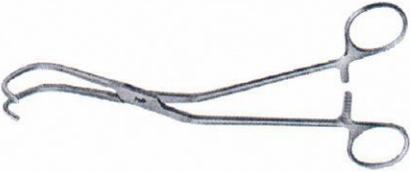
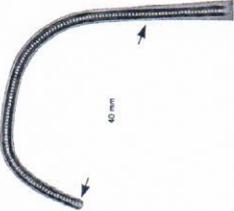
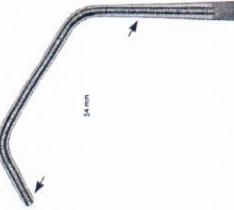
000670 DE BAKEY ATRAUMATA Atraumatic Forceps, straight, 200 mm (7 7/8"), toothing DE BAKEY, width: 2 mm, non-sterile, reusable



Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
000680	DE BAKEY ATRAUMATA Atraumatic Forceps, straight, 240 mm (9 1/2"), toothing DE BAKEY, width: 2 mm, non-sterile, reusable	FB404R	2 PC				
000690	DE BAKEY ATRAUMATA Atraumatic Forceps, straight, 240 mm (9 1/2"), toothing DE BAKEY, width: 3,50 mm, non-sterile, reusable	FB407R	1 PC				
000700	DE BAKEY ATRAUMATA Atraumatic Forceps, straight, 200 mm (7 7/8"), toothing DE BAKEY, width: 2,80 mm, non-sterile, reusable	FB415R	3 PC				
000710	DE BAKEY ATRAUMATA Atraumatic Forceps, straight, 240 mm (9 1/2"), toothing DE BAKEY, width: 2,80 mm, non-sterile, reusable	FB416R	1 PC				

Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
000720	DE BAKEY ATRAUMATA Coarctation Clamp, angled, 15°, 225 mm (8 7/8"), tooting DE BAKEY, jaw length: 65 mm, non-sterile, reusable	FB455R	1 PC				
							
000730	LAMBERT-KAY ATRAUMATA Aorta Clamp, angled, 215 mm (8 1/2"), tooting DE BAKEY, jaw length: 93 mm, width: 40 mm, non-sterile, reusable	FB490R	1 PC				
							
000740	DE BAKEY (MODIF. LAMBERT) ATRAUMATA Aorta Clamp, angled, 255 mm (10"), tooting DE BAKEY, jaw length: 97 mm, width: 40 mm, non-sterile, reusable	FB491R	1 PC				
							
000750	DE BAKEY ATRAUMATA Tangential Occlusion Clamp, curved, 270 mm (10 5/8"), satinsky-shaped, tooting DE BAKEY, jaw length: 99 mm, width: 54 mm, non-sterile, reusable	FB502R	1 PC				
							
000760	FB651R IS NO MORE AVAILABLE						

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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000770 Tourniquet, small, 220 mm, 8 3/4", guide only, to be used with FB651R

FB653R 1 PC



000780 BOROWSKI Aortic Valve Retractor, 270 mm (10 3/4"), malleable shaft, depth: 16 mm, width: 23 mm, non-sterile, reusable

FB972R 1 PC



000790 COLLEY-STRUCK Atrium Retractor, 265 mm (10 1/2"), serrated (slightly), depth: 45 mm, width: 35 mm, non-sterile, reusable

FB866R 1 PC



000800 Micro scissors, angled, 25 °, 165 mm (6 1/2"), very delicate blade, sharp/sharp, flat handle, non-sterile, reusable

FM437R 1 PC

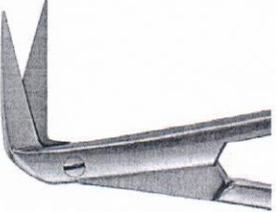
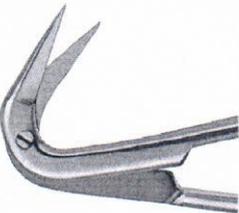


000810 Micro scissors, angled, 45 °, 165 mm (6 1/2"), very delicate blade, sharp/sharp, flat handle, non-sterile, reusable

FM438R 1 PC



Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
000820	Micro scissors, angled, 60 °, 165 mm (6 1/2"), very delicate blade, sharp/sharp, flat handle, non-sterile, reusable	FM439R	1 PC				
							
000830	Micro scissors, angled, 90 °, 165 mm (6 1/2"), very delicate blade, sharp/sharp, flat handle, non-sterile, reusable	FM440R	1 PC				
							
000840	Micro scissors, angled, 125 °, 165 mm (6 1/2"), very delicate blade, sharp/sharp, flat handle, non-sterile, reusable	FM441R	1 PC				
							
000850	DE BAKEY Micro Forceps, straight, 210 mm (8 1/4"), toothing DE BAKEY, round handle, width: 1 mm, non-sterile, reusable	FM600R	1 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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000860 DE BAKEY Micro Forceps, straight, 185 mm (7 1/4"), toothing DE BAKEY, round handle, width: 1 mm, non-sterile, reusable

FM592R

1 PC



000870 DIADUST Micro Forceps, straight, 185 mm (7 1/4"), platform tip, round handle, diamond dust coated, non-sterile, reusable

FM580R

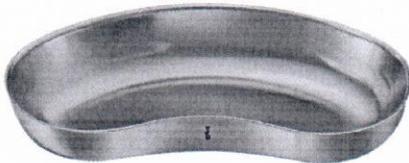
1 PC



000880 Kidney Tray, 250 mm (10"), stainless steel

JG506R

4 PC



000890 Round Bowl, 83 mm, height: 41 mm, width: 54 mm, 160 ml

JG522R

4 PC



000900 KRAYENBUEHL Nerve Retractor, 90 °, angled, 185 mm (7 1/4"), probe-ended, round handle, non-sterile, reusable

FD396R

1 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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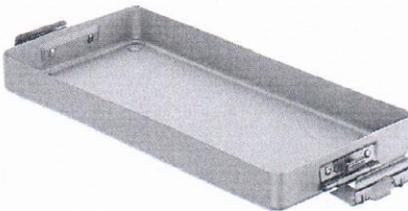
000910	KRAYENBUEHL Nerve Retractor, 90 °, angled, 185 mm (7 1/4"), probe-ended, round handle, non-sterile, reusable	FD397R	1 PC				
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000920	Dressing Forceps (Tweezers), angled, 200 mm (7 7/8"), serrated, non-sterile, reusable	BD257R	2 PC				
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000930	Bottom, without base perforation, mini, outer length: 310 mm, outer width: 132 mm, outer height: 30 mm, inner length: 274 mm, inner width: 126 mm, inner height: 25 mm	JK187	2 PC				
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000940	Lid (Outer), mini, silver, outer length: 305 mm, outer width: 140 mm, outer height: 25 mm	JK174	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
000950	Reusable Filter, package of 2 pieces, outer length: 95 mm 1 PAC = 2 PC	JK091	5 PAC				



000960	Positioning mat, Mini, 276 x 125 x 17 mm, trimmed and perforated, slip-free storage of instruments, good drying characteristics, gen	JF934	2 PC				
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000970	Bottom, without base perforation, Standard 3/4, outer length: 470 mm, outer width: 274 mm, outer height: 135 mm, inner length: 421 mm, inner width: 258 mm, inner height: 157 mm	JK742	5 PC				
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000980	Inner Lid, basis, Standard 3/4, red, outer length: 465 mm, outer width: 285 mm, outer height: 36 mm	JK785	5 PC				
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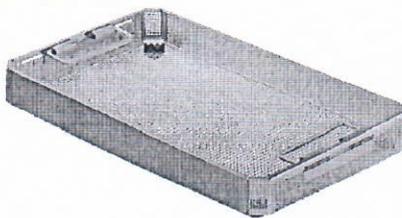
Tehnomedica SRL, 2001 Chisinau, Moldavia

Position	Product description	Material	Quantity Unit	List Price EUR	Discount %	Item Price EUR	Total Price EUR
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000990	Accessories Container, identification label, standard, aluminium, red, outer length: 56 mm, outer width: 18 mm	JG785U	5 PC				
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001000	Perforated basket, Standard 3/4, 406 x253 x 76 mm, with feet	JF253R	5 PC				
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001010	Reusable Filter, package of 10 pieces, diam. 190 mm 1 PAC = 10 PC	JK090	1 PAC				
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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

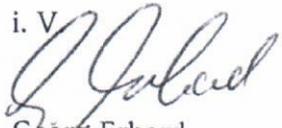
are designed, manufactured and tested according defined and documented specifications and procedures.

The following national and international standards and requirements were met:

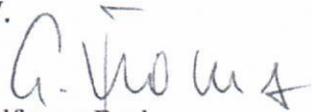
- EN ISO 13485:2003 (AC 2009)
- Council Directive 93/42 EEC of 14. June 1993 concerning Medical Devices
- ISO 7153-1 (Surgical Instruments-Metallic materials; Part 1: Stainless steel)
- Others: The defined requirements and performed tests cover also corrosion analysis, cutting ability, elasticity and 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

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 Baden-Württembergische Bank
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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

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Aesculap AG
Am Aesculap Platz
78532 Tuttlingen
Germany



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)
Sterilbarrieresystem	Dient zur Bereitstellung zum alsbaldigen Gebrauch ⁶ Ist als Lagerungsart zu vermeiden	6 Monate jedoch nicht länger als das Verfallsdatum
Verpackungssystem (Kombination aus Sterilbarrieresystem 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		

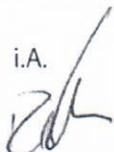
With kind regards,

Aesculap AG

i.V.

Lena Burghart

i.A.


Selina Riester

