

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



INFORMAȚII GENERALE DESPRE PARTICIPANT

1.	Numele juridic al ofertantului:	Tehnomedica SRL
2.	Adresa juridică a ofertantului:	Republica Moldova, mun.Chișinău, str. Ciuflea 38/1
3.	Director:	Tatiana Roibu
4.	Telefon / Fax:	022 601 102, 022 601 087
5.	E-mail:	tehnomedica_md@yahoo.com tehnomedicamd@gmail.com
6.	Cont de decontare IBAN:	MD65MO2224ASV98310887100
7.	Banca:	BC „Mobiasbanca – OTP Group” S.A., fil nr. 26 Negruzzi
8.	Adresa poștală a băncii:	Chișinău, str.Negruzzi 1
9.	Codul băncii:	MOBBMD22
10.	Cod fiscal:	1002600053256
11.	Cod TVA:	0207719

Director Tehnomedica SRL

Tatiana Roibu

Semnătura:

Nr. CIF26-842.2020
Data: 13 Februarie 2020

**CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE**

Prin prezentul, **Mobiasbanca - OTP Group S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **TEHNOMEDICA S.R.L.** cod fiscal (IDNO) **1002600053256**, detine următoarele conturi curente la Mobiasbanca - OTP Group S.A., Sucursala. 26 Negruzzi:

1. **MDL - MD65MO2224ASV98310887100**
2. **EUR - MD06MO2224ASV98311097100**


L.S.
Numele, Prenumele si Semnatura
Director sucursalei „Gheorghe Mocanu”



Executor :Eduard Cilcic
Tel: 022-812-150

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 Institutul Mamei și Copilului

În atenția Grupului de lucru
al procedurii nr. ocds-b3wdp1-MD-1625568228164;

ID: 21041557 din 13.07.2021

Piese pentru utilaj medical

Declarație privind termenul de garanție

Prin prezenta, în conformitate cu Formularul 4.1, specificațiile tehnice solicitate pentru **lotul nr.3 - Piesă de mână multifuncțională compatibil cu craniotom Aesculap Elan 4** declarăm că, termenul de garanție oferit de producător constituie 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:

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



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

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 010066 0435 Rev. 00

Holder of Certificate: **AESCLAP AG**
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Certification Mark:



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

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
- Endoscopic 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



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
- Endoscopic 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



CERTIFICAT



CERTIFICADO



СЕРТИФИКАТ



認證證書



CERTIFICATE



ZERTIFIKAT

ELAN 4 electro

CRANIOTOME & ATTACHMENTS

GA849

GB085R

ELAN 4 electro CRANIOTOME AND MULTIFUNCTION HANDPIECE

2-ring coding; for use with dura guards and holding sleeves GB941R – GB947R; spray nozzle GA259SU (not included)

140 W;   0 – 80,000 rpm; 2.2 Ncm; 156 x 17 mm;  121 g



GB941R

GB719R

ELAN 4 DURA GUARD PEDIATRIC

fixed; 1 dot coding; for craniotome and multifunction handpieces GA749, GA849



GB942R

GB719R

ELAN 4 DURA GUARD STANDARD

fixed; 2 dot coding; for craniotome and multifunction handpieces GA749, GA849



GB943R

GB719R

ELAN 4 DURA GUARD LONG

fixed; 3 dot coding; for craniotome and multifunction handpieces GA749, GA849

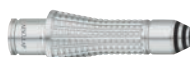


GB945R

GB719R

ELAN 4 HOLDING SLEEVE

for craniotome and multifunction handpieces GA749, GA849



GB947R

GB719R

ELAN 4 DURA GUARD STANDARD

turnable; 2 dot coding; for craniotome and multifunction handpieces GA749, GA849



PRODUCT DATA SHEET

ELAN 4 electro craniotome and multifunction handpiece (GA849)



Attribute Name	Attribute Value
Product search type	Craniotome
Brand name	ELAN 4
Aesculap Product Groups	Power Systems
Product family	Motors
Outer length (mm)	156 mm
Outer width (mm)	17 mm
Type of motor	electric
Power output	140 W
Rotational direction	clockwise/counter clockwise
Speed	0 1/min
Tool hub	ELAN 4 II
Torque	2.2 N cm
Weight	121.00 g
consisting parts	GB600860
Article code ECCOS fixation	GB085R
Dangerous good	No
Data Matrix	Yes
Product contains Latex	No
Sterility	non-sterile

Attribute Name	Attribute Value
Disposable / Reusable	reusable