„Tehnomedica” S.R.L. **Director Tatiana Roibu**
Adresa poştală: str. Ciuflea 38/1, MD 2001, mun.Chișinău, R.Moldova
Telefon: 022 601 087 Telefon/Fax: 022 601 102 Email: tehnomedica_md@yahoo.com; tehnomedicamd@gmail.com
Cont de decontare: MD65MO2224ASV98310887100
Banca: BC „ OTP Bank” S.A., fil nr. 26 Negruzzi
Adresa poştală a băncii: Chisinau, str.Negruzzi 1
Cod: MOBBMD22
Cod fiscal: 1002600053256
Cod TVA: 0207719

Digitally signed by Roibu Tatiana
Date: 2024.08.23 18:25:58 EEST
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Location: Moldova
MOLDOVA EUROPEANĂ

I.P. "AGENŢIA SERVICII PUBLICE"

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. **1968** din **01.02.2019**

Denumirea completă: **SOCIETATEA CU RĂSPUNDERE LIMITATĂ «TEHNOMEDICA» .**
Denumirea prescurtată: **«TEHNOMEDICA» S.R.L. .**
Forma juridică de organizare: **Societate cu Răspundere Limitată.**
Numărul de identificare de stat şi codul fiscal: **1002600053256.**
Data înregistrării de stat: **17.04.2002.**
Sediul: **MD-2001, str. Ciuflea, 38/1, mun.Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1 Fabricarea utilajului medical şi chirurgical şi a dispozitivelor ortopedice;
2 Comerţul cu ridicata al produselor farmaceutice;
3 Comerţul cu amănuntul al produselor farmaceutice;
4 Practica medicală;
5 Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii;
6 Activităţi de consultare pentru afaceri şi management.
Capitalul social: **5400** lei.
Administrator: ROIBU TATIANA,
Asociaţi:
1. ROIBU TATIANA 100 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: 01.02.2019.

Specialist coordonator
tel. 022-20-7838

Clichici Elena

INSTITUŢIA PUBLICĂ AGENŢIA SERVICII PUBLICE IDNO 1002600024700 REPUBLICA MOLDOVA CHIŞINĂU 003

EB 0257484

Anexa nr. 2
la Regulamentul cu privire la achiziţiile
publice de valoare mică

DECLARAŢIE DE ELIGIBILITATE

Către IMSP SCR „Timofei Moșneaga”

Stimaţi domni,

Subsemnatul, reprezentant împuternicit al Tehnomedica SRL, în calitate de ofertant, declar pe propria răspundere, sub sancţiunea excluderii din procedură şi sub sancţiunile aplicate faptei de fals în acte publice, că nu mă aflu în una dintre situaţiile prevăzute la art. 19 din Legea nr. 131/2015 privind achizițiile publice.

Mă oblig, la solicitarea autorității/entității contractante, în scopul verificării şi confirmării declaraţiei, să prezint orice document doveditor de care dispun.

Data completării 23.08.2024

Ofertant/candidat

_____
(semnătura autorizată)

B|BRAUN

Quality Management
Aesculap AG
Postfach 40
D-78501 Tuttlingen
e-mail: konrad.kobel@aesculap.de
http://www.aesculap.de

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) Rongeure	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 analisis, 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

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Către IMSP SCR „Timofei Moșneaga”

Declarație

În contextul participării la achiziția de valoare mică nr. ocds-b3wdp1-MD-1724248694581, ID:21271021 privind achiziționarea *instrumentarului pentru intervenții chirurgicale vasculare de urgență majoră*, declarăm că termenul de garanție al produselor la momentul livrării va constitui 12 luni și vom prezenta mostre la sediul autorității contractante în decurs de 7 zile de la solicitare.

Cu respect,

Director Tatiana Roibu

EU Quality Management System Certificate

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
7400GB448230921	7400AU08F	2023-09-21	2025-11-15

This is to certify that the quality system of

Aesculap AG

Am Aesculap-Platz, 78532 Tuttlingen, Germany
SRN: DE-MF-000005504

For design, production, and final product inspection/testing of
Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to
The conformity assessment procedure described in Annex IX Chapter I of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2023-09-21

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-096

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany

Lorenz Runge
Director Certification Body

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact info@medcert.de

Certificate no.: 7400GB448230921
Place and date: Hamburg, 2023-09-21

Preceding certificate

Certificate no.	Issue date	Identification of changes
7400GB448220414	2022-04-14	Exension by class IIa + Intended purpose class IIb, WO-009751, WO-010862

Sites covered by this certificate

Aesculap AG, Am Aesculap-Platz, 78532 Tuttlingen, Germany

Products covered by this certificate

Class I medical devices

For class I medical devices that are reusable surgical instruments (class Ir), the audit of the quality management system was limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilisation, maintenance and functional testing, and the related instructions for use.

Category	Class	Medical devices/groups of medical devices
MDN 1208	Ir	Non-active non-implantable instruments

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0202	Z120111	Instruments for operative microscopy
MDN 1208	K010201	Minimally invasive surgery surgical instruments, single-use
MDN 1208	L031205	Orthopaedic surgery trocar, reusable
MDN 1208	L070702	Cardiac dilators and retractors, reusable
MDN 1208	L091099	Osteosynthesis instruments, reusable - other
MDN 1208	L091102	Orthopaedic prostheses reamers and burs, reusable
MDN 1208	L091199	Orthopaedic prosthetics instruments, reusable - other
MDN 1208	L110501	Vertebral surgery spreaders and retractors, reusable
MDN 1208	P091203	Bone fixation wires
MDN 1208	P091303	Orthopaedic implant drill bits, single-use
MDN 1208	P091399	Orthopaedic implant instruments, single-use - other
MDN 1208	V0199	Cutting devices, single-use - other
MDN 1208	Z120114	Surgical navigation instruments
MDN 1208	Z120190	Various instruments for general and multidisciplinary surgery
MDN 1208	Z120207	Genitourinary endoscopy instruments
MDN 1208	Z120209	Neuroendoscopy instruments
MDN 1208	Z120211	Orthopaedic endoscopy instruments
MDN 1208	Z120290	Various instruments for endoscopy and mini-invasive surgery
MDN 1208	Z121305	Motorised orthopaedic surgery system instruments

Certificate no.: 7400GB448230921
Place and date: Hamburg, 2023-09-21

Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090701	Spinal fusion systems

Intended purpose

TA012095: PEEK Cages are used as follows:

- CeSPACE® PEEK: stabilization of the cervical spine C2-T1 through anterior approach, monosegmental and multisegmental
- PROSPACE® PEEK: stabilization of the lumbar and thoracic spine through posterior approach, monosegmental and multisegmental
- TSPACE® PEEK: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental.

TA012353: Titanium cages are used as follows:

- CeSPACE® Ti: stabilization of the cervical spine C2-T1 through anterior approach, monosegmental and multisegmental
- PROSPACE® Ti PLIF: stabilization of the lumbar and thoracic spine through posterior approach, monosegmental and multisegmental
- PROSPACE® Ti TLIF: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental
- TSPACE® Ti: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental.

TA013625: PLASMAPORE XP® Cages are used as follows:

- CeSPACE® XP: stabilization of the cervical spine C2-T1 through anterior approach, monosegmental and multisegmental
- PROSPACE® XP: stabilization of the lumbar and thoracic spine through posterior approach, monosegmental and multisegmental
- TSPACE® XP: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental.

TA015914: 3D Cages are used as follows:

- CeSPACE® 3D: stabilization of the cervical spine C2-T1 through anterior approach, monosegmental and multisegmental
- PROSPACE® 3D: stabilization of the lumbar and thoracic spine through posterior approach, monosegmental and multisegmental
- PROSPACE® 3D Oblique: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental
- TSPACE® 3D: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090703	Implantable vertebral stabilisation or fixation systems

Intended purpose

TA009693: The ABC implants are used exclusively for anterior monosegmental and multisegmental stabilization of the cervical spine in the region from C2 to Th1.

TA011187: The S4 Spinal System Implants are used for dorsal monosegmental and multisegmental stabilization of the lumbar and thoracic spine. They comprise: ■ Mono/polyaxial screws ■ Rods ■ Hook ■ Cross connector ■ Rod connectors – parallel, axial and lateral offset ■ appropriate fixation elements. Special instruments must be used for implanting these components, as well as for the distraction, compression and reduction of the lumbar and thoracic spine.

TA011700: The ABC implants are used exclusively for anterior monosegmental and multisegmental stabilization of the cervical spine in the region from C2 to Th1.

TA012865: The S4 Spinal System implants are used for dorsal monosegmental and multisegmental stabilization of the lumbar and thoracic spine. The S4 Spinal System – augmentation screw can be fixed with bone cement to increase anchoring stability. In this case, the injection cannula is inserted in the S4 Spinal System – augmentation screw for application of the bone cement. The S4 Spinal System - augmentation screw comprises: ■ S4 Monoaxial/polyaxial screws (augmentation screw), supplied in sterile condition ■ S4 Element monoaxial/polyaxial screws (augmentation screw), supplied in sterile condition ■ Cement injection cannula (sterile), see TA013132 ■ for percutaneous application with S4 Element monoaxial/polyaxial screws (augmentation screws): S4 Element Augmentation instruments, see TA014315.
Note: There are special S4 instruments provided for the implantation of these system components and for the augmentation, distraction, compression, and reduction of the lumbar and thoracic spine.

TA013366: The Quintex cervical plating system is used for the anterior monosegmental and multisegmental stabilization of the cervical spine.

TA013579: Note: The S4 Spinal System – in sterile condition is addressed in general in the operating instructions for the S4 Spinal System – Lumbar/Deformity TA011187. This information on the sterile-packaged S4 implants supplements the respective information in the instructions for use of the S4 Spinal System – Lumbar/Deformity. The S4 Spinal System implants are used for dorsal monosegmental and multisegmental stabilization of the lumbar and thoracic spine. The parallel (closed and open) and axial rod connectors are connected to S4 Spinal System rods in order to connect a rod parallel or in a line with another rod. The lateral offset connectors are connected to the S4 Spinal System rods in order to place a screw offset. The rod connectors thus extend the rod to the adjacent spinal column segments. The S4 Spinal System – sterile-packaged comprises: ■ Rod connector – parallel (closed and open), axial and lateral offset connectors.

Note: Special S4 instruments must be used for implanting these components, as well as for the distraction, compression and reduction of the lumbar and thoracic spine.

TA014887: The Ennovate Spinal System implants are used for dorsal monosegmental and multisegmental stabilization of the lumbar, thoracic and sacral spine.

TA015555: The ArcadiusXP L Interbody Fusion System is a stand alone device intended to be used with four bone screws if no supplement fixation is used to stabilize the lumbar spine through an anterior approach. The system contains: ■ Cages in different heights, angles and footprints ■ Bone screws in different lengths.

TA015777: The Ennovate Cervical Spinal System implants are used for the posterior monosegmental and multisegmental stabilization of the occipitocervical junction and of the cervical and upper thoracic spine. The system consists of: Occiput plates and screws, Rods, Polyaxial screws, Bone screws, Set screws, Hook, Cross connectors (head-to-head cross connectors, rod-to-rod cross connectors), Other connectors, Laminoplasty plate. The Ennovate Cervical laminoplasty plate is intended for use in the cervical spine (C3-C6) after a unilateral laminoplasty has been performed. It is fixated to the lamina with the SecureSpan screws. Surgically installed implants serve to support the normal healing process. They are not supposed to replace normal body structures or to support permanent loads that occur in cases where healing does not occur. The laminoplasty plate should be used with a stabilization block (by e.g. a bone graft). Appropriate implant components from Ennovate Spinal System (e.g. rods) can also be used. Special instruments must be used for implanting these components, as well as for the distraction, compression and reduction of the thoracolumbar spine.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090703	Implantable vertebral stabilisation or fixation systems

Intended purpose

TA018000: The ArcadiusXP C spinal system is intended to be used as an intervertebral body fusion cage as a standalone system used with two bone screws. It is inserted between the vertebral bodies into the disc space from C2 to T1 in skeletally mature patients.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090803	Hip prostheses acetabular components

Intended purpose

TA013800: The implant is used: ■ As a component of a human hip endoprosthesis: Hip endoprosthesis cup, consisting of outer cup Plasmafit® Poly or Plasmafit® Plus, possibly central screw plug, possibly anchoring screws and modular Plasmafit® inserts (standard, asymmetrical or with shoulder) ■ In combination with Aesculap hip endoprosthesis components ■ In combination with implant components explicitly approved by Aesculap ■ For implantation without bone cement.
Note: The options of patient-specific care depend on the available implant components. Implant dimensions and any possible combinations in individual cases can be found in the operating technique instructions for the individual systems.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090880	Hip prostheses - accessories

Intended purpose

TA008056: The Centralizer is used as an additional guide when using cemented Aesculap endoprosthesis stems. It acts as a guide for the distal tip of the prosthesis when inserting the stem into the bone cement. If the correct size has been selected, the Centralizer guarantees a closed and uniform cement socket.
Different outer diameters are available for centralizers; they are marked on the packaging. The selection of the correct centralizer depends on the Aesculap hip implant stem used or the Aesculap knee implant component used, and the operative preparation and size of the medullary cavity. Observe the instructions for use for the Aesculap endoprosthesis components used.
The Centralizer is used with Aesculap Endoprosthesis Centrament, Bicontact, Excia, SLA, Vega and Columbus.

TA009897: The anchoring screws are used in combination with Aesculap acetabular implants. They are used to increase stability in the event of insufficient primary stability in Plasmacup® and Plasmafit® press fit cups and to secure the Aesculap reconstruction cup and the acetabular Structan® Augment in the bone. The 6.5 mm anchoring screws may only be used as explained below: ■ in combination with Aesculap hip endoprosthesis components ■ in combination with implant components explicitly approved by Aesculap ■ in compliance with the instructions for use of the individual implant components ■ in the listed implant systems according to their color coding. Color coding of anchoring screws / Permissible use - Yellow oxide layer Plasmacup® and Aesculap recon ring - Blue oxide layer Plasmafit® and acetabular Structan® Augment. Anchoring screws are available in different lengths. Note: The options of patient-specific care depend on the available implant components. Implant dimensions and any possible combinations in individual cases can be found in the operating technique instructions for the individual systems.

TA012315: For use with a cemented Trilliance or CoreHip hip endoprosthesis stem.
See instructions for use of Trilliance-/CoreHip hip endoprosthesis stems.

TA012526: The implant is used: ■ as a component part of a human hip endoprosthesis: Locking screw ■ in combination with Aesculap hip endoprosthesis stems with locking holes ■ in combination with implant components explicitly approved by Aesculap ■ in compliance with the instructions for use of the individual implant components.
The locking screws are intended for the fixation of above-mentioned implant components that allow distal locking. The operating surgeon decides, depending on the indication, if and to what degree implant locking is necessary. Note: The options of patient-specific care depend on the available implant components. Implant dimensions and any possible combinations in individual cases can be found in the operating technique instructions for the individual systems.

TA013723: The implant is used: ■ as a component of a human hip endoprosthesis: augmentation implant for filling of acetabular bone defects ■ in combination with Aesculap hip endoprosthesis components: Plasmafit, Plasmafit Revison, Plasmacup, cemented PE cups ■ in combination with implant components explicitly approved by Aesculap ■ in combination with hip endoprosthesis cups with the same nominal diameter, or one that is a maximum of 4 mm smaller/larger ■ in combination with bone cement at the interface to the hip cup.
The anchoring screws must only ever be used as follows: ■ In compliance with the instructions for use of the individual implant components ■ In the stated implant systems according to their color coding.
Yellow oxide layer - Plasmacup; Blue oxide layer - Plasmafit Plus, Plasmafit Revision, Structan acetabulum augmentation implant; Pink oxide layer - Structan acetabulum augmentation implant.
Note: The options for patient-specific care depend on the available implant components. Implant dimensions and any possible combinations in individual cases can be found in the operating technique instructions for the individual systems.

TA015599: The 4.5 mm anchoring screws are used in conjunction with Aesculap acetabulum implants. It serves to secure the Structan® acetabulum augmentation in the bone. The 4.5 mm anchoring screws may only be used as follows: ■ In compliance with the instructions for use of the individual implant components ■ In the stated implant systems according to their color coding.
Pink oxide layer - Structan® acetabulum augmentation.
The anchoring screws are available in various lengths.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090908	Knee prostheses spacers

Intended purpose

TA016100: The implant is used:

■ as a component of a human knee endoprosthesis that consists of a femoral, tibial and meniscal implant component and possibly patella, extension stems and augment implants

■ in combination with implant components explicitly approved by Aesculap

– univation® X

– Columbus®

– e.motion®

– VEGA System®

– EnduRo

■ for implantation without bone cement with PLASMAPORE® or PLASMAPORE® µ-CaP coated implants and cementless extension stems

■ for implantation with bone cement for other knee implants including All-poly tibia implants except meniscal components.

Note: The options for patient-specific care depend on the available implant components. Implant dimensions and any possible combinations in individual cases can be found in the operating technique instructions for the individual systems.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090980	Knee prostheses - accessories

Intended purpose

TA016100: The implant is used:

■ as a component of a human knee endoprosthesis that consists of a femoral, tibial and meniscal implant component and possibly patella, extension stems and augment implants

■ in combination with implant components explicitly approved by Aesculap

– univation® X

– Columbus®

– e.motion®

– VEGA System®

– EnduRo

■ for implantation without bone cement with PLASMAPORE® or PLASMAPORE® µ-CaP coated implants and cementless extension stems

■ for implantation with bone cement for other knee implants including All-poly tibia implants except meniscal components.

Note: The options for patient-specific care depend on the available implant components. Implant dimensions and any possible combinations in individual cases can be found in the operating technique instructions for the individual systems

Category	EMDN code	Medical devices/groups of medical devices
MDN 1104	H030102	Singular clips for open surgery

Intended purpose

TA013486: The DS titanium ligation-clips are used for the ligation of vessels and hollow organs and for marking anatomical structures

Class III custom-made implantable medical devices

Category	Medical devices/groups of medical devices
MDN 1102	Non-active osteo- and orthopaedic implants

Certificate no.: 7400GB448230921
Place and date: Hamburg, 2023-09-21

Class III medical devices

For placing on the market of class III medical devices covered by this certificate, an additional EU Technical Documentation Assessment Certificate according to Annex IX Chapter II of Regulation (EU) 2017/745 is required, which also contains the exact determination of medical devices covered by certification.

Category	Medical devices/groups of medical devices
MDA 0312	Other active non-implantable surgical devices
MDN 1101	Non-active cardiovascular, vascular and neurovascular implants
MDN 1102	Non-active osteo- and orthopaedic implants
MDN 1202	Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
MDN 1208	Non-active non-implantable instruments

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 010066 0438 Rev. 01

Manufacturer:

AESCULAP AG
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

SRN Manufacturer: DE-MF-000005504

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 010066 0438 Rev. 01

Report No.: 713203407 / 713203404 / 713203403 / 713203400 / 713203397 / 713203393 / 713203388 / 713205439 / 713229575

Preceding Certificate No.: G10 010066 0438 Rev. 00

Valid from: 2021-12-09
Valid until: 2025-09-07

Date of Initial Issuance: 2020-07-10

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-12-09

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD
Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 010066 0438 Rev. 01

Classification:	IIa
Device Group:	H030201 - MULTIPLE CLIP APPLIERS FOR VIDEOSURGERY
Intended Purpose:	-
Classification:	IIa
Device Group:	Z120114 - SURGICAL NAVIGATION INSTRUMENTS
Intended Purpose:	-
Classification:	IIa
Device Group:	Z121009 - INSTRUMENTS FOR MOTORISED NEUROSURGERY SYSTEMS
Intended Purpose:	-
Classification:	IIa
Device Group:	Z121305 - MOTORISED ORTHOPAEDIC SURGERY SYSTEM INSTRUMENTS
Intended Purpose:	-
Classification:	IIa
Device Group:	Z12011482 - SURGICAL NAVIGATION INSTRUMENTS - SOFTWARE ACCESSORIES
Intended Purpose:	-
Classification:	IIb
Device Group:	K020101 - MONO- AND BIPOLAR SURGICAL INSTRUMENTS, SINGLE-USE
Intended Purpose:	All professional disciplines that use endoscopy: Cutting, dissection, mobilization and coagulation of tissue. The endoscopic bipolar multifunctional instruments are used for the cutting, dissection, grasping, and coagulation of tissue in minimally invasive surgery. The instruments are used for the cutting, dissection, grasping, and coagulation of tissue in minimally invasive surgery. The monopolar single-use shafts are used in all endoscopic disciplines, for cutting, dissection, mobilization and coagulation of tissue. The monopolar single-use shafts are supplied in sterile condition. They are used in combination with the reusable handles of the Adtec monopolar product line. The SINGLE USE / Bipolar - Coagulation Tweezers from AESCULAP are used for the same purpose as the comparative models already on the market for several years. It is intended for grasping, coagulating tissues, organs and other medical supplies.

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 010066 0438 Rev. 01

It differs slightly in shape due to the materials used and can only be used once (SINGLE USE) by the user.

The single-use electrode handle with fingertip keys (monopolar) is fitted with a fixed cable and a disposable knife electrode and is used in open surgical procedures. The single-use electrode handle with fingertip keys (monopolar) is used to conduct the HF current from the HF device to the operating site, to hold the required working electrode and to activate the cutting or coagulating current supplied by the HF device.

Classification:	IIb
Device Group:	L180202 - ENDOSCOPIC ELECTROSURGERY SCISSORS, REUSABLE
Intended Purpose:	All professional disciplines that use endoscopy: Cutting, preparation, and grasping of tissues, Biopsies, Suturing.

Classification:	IIb
Device Group:	L180302 - ENDOSCOPIC ELECTROSURGERY HANDPIECES, REUSABLE
Intended Purpose:	All professional disciplines that use endoscopy: Cutting, preparation, and grasping of tissues, Biopsies, Suturing.

Classification:	IIb
Device Group:	L180402 - ENDOSCOPIC ELECTROSURGERY FORCEPS, REUSABLE
Intended Purpose:	The instruments are used for preparing and grasping and for removal of biopsies, with different working tips for each intended use. Bipolar, detachable tubular shaft instruments are used for the cutting, dissection, grasping, and coagulation of tissue in minimally invasive surgery. All professional disciplines that use endoscopy: Cutting, preparation, and grasping of tissues, Biopsies, Suturing. The MIC tubular shaft instruments, with different working tips for each intended use, are used for cutting, dissection, grasping, removal of biopsies and/or for coagulation.

Classification:	IIb
Device Group:	L180201 - OPEN ELECTROSURGERY SCISSORS, REUSABLE
Intended Purpose:	Surgical scissors: The instruments are used to cut tissue and/or medical materials and supplies. Dissecting scissors: The instruments are used to cut and/or dissect tissue. Nail scissors:

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Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

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The instruments are used to cut or split finger nails and toe nails and/or cuticles. Bandage scissors and material scissors: The instruments are used to cut medical materials and supplies and/or clothing. Micro scissors: The instruments are used to cut and/or dissect tissue during micro surgical procedures.

Classification:	IIb
Device Group:	L180401 - OPEN ELECTROSURGERY FORCEPS, REUSABLE
Intended Purpose:	Bipolar forceps are used for hemostatic coagulation as well as grasping and dissecting of tissue in surgical procedures. These Aesculap instruments are used in general surgery. Depending on the design of the working ends, they are used for cutting, preparing, holding and/or monopolar coagulation.

Classification:	IIb
Device Group:	Z120109 - ELECTROSURGICAL INSTRUMENTS
Intended Purpose:	The generator GN160 is a bipolar high frequency surgical device. It is used to convert electrical current into bipolar energy for coagulation with bipolar instruments in all fields of surgery. The single foot switches GN161 and GK226 are used for activating compatible Aesculap devices for HF surgery. The single foot switch GN092 is used for activating the JET function of the JET irrigation unit (GN090). The foot controls are Class AP devices. The foot control circuit is ignition-safe and approved for operation in medical environments according to IEC/DIN EN 60601-1. The housing is constructed according to Protection Type IPX8. The Lektrafuse HF generator GN200 is used for vessel sealing and vessel division in open and minimally invasive surgery. The instruments can seal vessels of up to and including 7 mm. The Lektrafuse HF generator is not suitable for use in tube sterilization/ tube coagulation for sterilization. With respect to the electric shock hazard, the Lektrafuse HF generator meets the classification and safety requirements of a type CF device. The Lektrafuse HF generator is intended for operation and storage in closed spaces.

Classification:	IIa
Device Group:	Z120103 - DERMOTOMY EQUIPMENT
Intended Purpose:	-

Classification:	IIa
Device Group:	Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY
Intended Purpose:	-

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Classification:	IIa
Device Group:	L090901 - BONE CUTTERS, REUSABLE
Intended Purpose:	-
Classification:	IIa
Device Group:	Q019001 - SALIVA ASPIRATORS AND SALIVA ABSORBENTS
Intended Purpose:	-
Classification:	IIa
Device Group:	A0701 - ADAPTERS AND CONNECTORS
Intended Purpose:	-
Classification:	IIa
Device Group:	L030101 - SUCTION AND IRRIGATION SURGICAL CANNULAS AND HANDPIECES, REUSABLE
Intended Purpose:	-
Classification:	IIa
Device Group:	A019001 - BLUNT NEEDLES
Intended Purpose:	-
Classification:	IIa
Device Group:	Z120204 - INSTRUMENTS FOR THE ACQUISITION AND MANAGEMENT OF ENDOSCOPIC AND MINIMALLY INVASIVE SURGERY IMAGES
Intended Purpose:	-
The validity of this certificate depends on conditions and/or is limited to the following:	./.

Revision History:

Rev.	Dated	Report
00	2020-07-10	713175266

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