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>

Anexa nr. 7
la Documentația standard nr.115
din 15.09.2021

CERERE DE PARTICIPARE

Către **IMSP Institutul Mamei și Copilului**

Stimaţi domni,

Ca urmare a anunțului/invitației de participare/de preselecție apărut în Buletinul achizițiilor publice și/sau Jurnalul Oficial al Uniunii Europene, *LD nr. ocds-b3wdp1-MD-1707227963054, ID: 21166991 din 06.02.2024* privind aplicarea procedurii pentru atribuirea contractului privind *achiziționarea pieselor pentru dispozitive medicale*, noi, *Tehnomedica SRL,* am luat cunoștință de condițiile și de cerințele expuse în documentația de atribuire și exprimăm prin prezenta interesul de a participa, în calitate de ofertant/candidat, neavînd obiecții la documentația de atribuire.

Data completării: 23.02.2024

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)

Digitally signed by Roibu Tatiana
Date: 2024.02.22 11:34:11 EET
Reason: MoldSign Signature
Location: Moldova

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>

Anexa nr. 8
la Documentația standard nr.115
din 15.09.2021

DECLARAŢIE
privind valabilitatea ofertei

Către **IMSP Institutul Mamei și Copilului**

Stimaţi domni,

Ne angajăm să menținem oferta valabilă, privind achiziționarea pieselor pentru dispozitive medicale, prin procedura de achiziție LD nr. ocds-b3wdp1-MD-1707227963054, ID: 21166991 din 26.02.2024, pentru o durată de 60 zile (șaizeci zile), respectiv până la data de 29.04.2024 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 23.02.2024

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)

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

F/COM/CC/23/02

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.Ş.

Numele, Prenumele si Semnătura
Director sucursalei „Gheorghe Mocanu"

Executor :Eduard Cilcic
Tel: 022-812-150

Mobiasbanca - OTP Group S.A. • Capital Social: 100 000 000 MDL • Număr de înregistrare de stat – 1002600006089
bd. Ştefan cel Mare şi Sfînt 81A • MD-2012 Chişinău, Moldova • telefon: +373 22 256 456 • e-mail: info@mobiasbanca.md • www.mobiasbanca.md

GUVERNUL REPUBLICII MOLDOVA

SERVICIUL FISCAL DE STAT

MCabinet
PORTALUL GUVERNAMENTAL AL CETĂȚEANULUI ȘI AL UNITĂȚILOR DE DREPT

CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr. № **1330256**

Din От **21.02.2024 13:30**

DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare
Фискальный код / Идентификационный номер

1002600053256

Denumirea
Наименование

SOCIETATEA CU RĂSPUNDERE LIMITATĂ TEHNOMEDICA

ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСВИЯ ИЛИ НАЛИЧИЯ ЗАДОЛЖНОСТЕЙ СОГЛАСНО ДАННЫМ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie
На дату выдачи данной справки задолжность перед национальном публичным бюджетом составляет

0 MDL

VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО **07.03.2024 13:30**

Prezentul document este eliberat în temeiul Art. 29, alin. (3) din Legea cu privire la registre nr. 71/2007 și în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Cetățeanului și al Unităților de Drept / Справка выдана в соответсвие со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предостоставленных Государственной налоговой службой на Портале Правительства Гражданина и Юридических Лиц.

Generat și semnat de Portalul Guvernamental al Cetățeanului și al Unităților de Drept la **21.02.2024 13:30**

Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022
Сертификат подписан электронной попдписью в соответсвие с Законом № 124 от 19.05.2022

Certificatul este descărcat din Portalul Guvernamental al Cetățeanului și al Unităților de Drept (mcabinet.gov.md) și este semnat electronic de către posesorul acestui portal și are aceiași valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală. Verificarea autenticității semnăturii electronice poate fi realizată cu ajutorul Serviciului Guvernamental de Semnătură Electronică (msign.gov.md)

Сертификат скачен с Правительственного Портала Гражданина и Юридических Лиц (mcabinet.gov.md) и подписан электронной подписью владельца портала и имеет такаю же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлиности электронной подписи можно осуществить с помощью Государсвенной Службой Электронной Подписью (msign.gov.md)

TEHNOMEDICA

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e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Către IMSP Institutul Mamei și Copilului

În atenția Grupului de lucru
al procedurii nr. ocds-b3wdp1-MD-1707227963054,
ID: 21166991

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că vom prezenta mostre în decurs de 5 zile de la solicitarea autorității contractante pentru produsele oferite în cadrul procedurii prenonate privind *achiziționarea pieselor pentru dispozitive medicale.*

Cu respect,

Director Tatiana Roibu

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 Institutul Mamei și Copilului

În atenția Grupului de lucru
al procedurii nr. ocds-b3wdp1-MD-1707227963054,
ID: 21166991

DECLARAŢIE

privind înregistrarea în Registrul de Stat al Dispozitivelor Medicale al Agenției Medicamentului și Dispozitivelor Medicale

Prin prezenta, declarăm că produsele oferite în cadrul procedurii prenotate sunt înregistrate în Registrul de Stat al Dispozitivelor Medicale a Agenției Medicamentului și Dispozitivelor Medicale.

Dovada înregistrării dispozitivelor medicale se regăsește pe pagina web a Agenției Medicamentului și Dispozitivelor Medicale www.amdm.gov.md.

DM000411424	ELAN 4 ELECTRO CRANIOTOME 2-RING	GA849	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000013

Cu respect,

Director Tatiana Roibu

APROBAT
prin Ordinul
Ministrului Finanțelor
nr. 145 din 24 noiembrie 2020

DECLARAŢIE
privind confirmarea identității beneficiarilor efectivi și neîncadrarea acestora în situația condamnării pentru participarea la activităţi ale unei organizaţii sau grupări criminale, pentru corupţie, fraudă şi/sau spălare de bani.

Subsemnatul(a), Tatiana Roibu, reprezentant împuternicit al „Tehnomedica” SRL în calitate de ofertant/ofertant asociat desemnat câștigător în cadrul procedurii de achiziție publică *nr. ocds-b3wdp1-MD-1707227963054, ID: 21166991 din 20.02.2024* declar pe propria răspundere, sub sancţiunile aplicabile faptei de fals în acte publice, că beneficiarul/beneficiarii efectivi ai operatorului economic în ultimii 5 ani nu au fost condamnați prin hotărâre judecătorească definitivă pentru participarea la activităţi ale unei organizaţii sau grupări criminale, pentru corupţie, fraudă și/sau spălare de bani.

Numele și prenumele beneficiarului efectiv	IDNP al beneficiarului efectiv
Tatiana Roibu	0992606484592

Data completării: 23.02.2024
Semnat: electronic
Nume/prenume: Tatiana Roibu
Funcţia: Director
Denumirea operatorului economic: Tehnomedica SRL
IDNO al operatorului economic: 1002600053256

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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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. 03

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. 03

Report No.: 713203406 / 713205438 / 713218837 / 713218822

Preceding Certificate No.: G10 010066 0438 Rev. 02

Valid from: 2022-11-17
Valid until: 2025-07-09

Date of Initial Issuance: 2020-07-10

Digitally signed by Roibu Tatiana
Date: 2023.01.20 10:48:29 EET
Reason: MoldSign Signature
Location: Moldova

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-11-17

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

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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. 03

Classification:	IIa
Device Group:	L030101 - SUCTION AND IRRIGATION SURGICAL CANNULAS AND HANDPIECES, REUSABLE
Intended Purpose:	-

Classification:	IIa
Device Group:	L031309 - SUTURE NEEDLE PASSERS, REUSABLE
Intended Purpose:	-

Classification:	IIa
Device Group:	L031401 - GENERAL SURGERY SPREADERS AND RETRACTORS, REUSABLE
Intended Purpose:	-

Classification:	IIa
Device Group:	L040901 - ABDOMINAL SPREADERS, REUSABLE
Intended Purpose:	-

Classification:	IIa
Device Group:	L050902 - GYNECOLOGICAL USE DILATORS AND SPREADERS, REUSABLE
Intended Purpose:	-

Classification:	IIa
Device Group:	L060502 - NON-ENDOSCOPIC UROLOGY SPREADERS, REUSABLE
Intended Purpose:	-

Classification:	IIa
Device Group:	L070702 - CARDIAC DILATORS AND RETRACTORS, REUSABLE
Intended Purpose:	-

Classification:	IIa
Device Group:	L080602 - THORACIC SURGERY SPREADERS, REUSABLE
Intended Purpose:	-

Classification:	IIa
Device Group:	L090901 - BONE CUTTERS, REUSABLE
Intended Purpose:	-

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(Class IIa and Class IIb Devices)

No. G10 010066 0438 Rev. 03

Classification:	IIa
Device Group:	L090901 - BONE CUTTERS, REUSABLE
Intended Purpose:	-

Classification:	IIa
Device Group:	L110501 - VERTEBRAL SURGERY SPREADERS AND RETRACTORS, REUSABLE
Intended Purpose:	-

Classification:	IIa
Device Group:	L110503 - CRANIAL SURGERY SPREADERS AND RETRACTORS, REUSABLE
Intended Purpose:	-

Classification:	IIa
Device Group:	L149003 - ENT RETRACTORS, REUSABLE
Intended Purpose:	-

Classification:	IIa
Device Group:	L031201 - THORACIC TROCAR, REUSABLE
Intended Purpose:	-

Classification:	IIa
Device Group:	L031202 - ABDOMINAL TROCAR, REUSABLE
Intended Purpose:	-

Classification:	IIa
Device Group:	L031280 - SURGICAL TROCAR, REUSABLE - ACCESSORIES
Intended Purpose:	-

Classification:	IIa
Device Group:	A019001 - BLUNT NEEDLES
Intended Purpose:	-

Classification:	IIa
Device Group:	A070199 - ADAPTERS AND CONNECTORS - OTHER
Intended Purpose:	-

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No. G10 010066 0438 Rev. 03

Classification:	IIa
Device Group:	C019019 - VESSEL STRIPPER SYSTEMS
Intended Purpose:	-

Classification:	IIa
Device Group:	G020401 - HAEMORRHOID LIGATURE SETS
Intended Purpose:	-

Classification:	IIa
Device Group:	H030102 - SINGULAR CLIPS FOR OPEN SURGERY
Intended Purpose:	-

Classification:	IIa
Device Group:	H030201 - MULTIPLE CLIP APPLIERS FOR VIDEOSURGERY
Intended Purpose:	-

Classification:	IIa
Device Group:	K010101 - TROCAR, SINGLE-USE
Intended Purpose:	-

Classification:	IIa
Device Group:	K010201 - MINIMALLY INVASIVE SURGERY SURGICAL INSTRUMENTS, SINGLE-USE
Intended Purpose:	-

Classification:	IIa
Device Group:	K0104 - VERESS NEEDLES
Intended Purpose:	-

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(Class IIa and Class IIb Devices)

No. G10 010066 0438 Rev. 03

Classification:	IIb
Device Group:	K020101 - MONO- AND BIPOLAR SURGICAL INSTRUMENTS, SINGLE-USE
Intended Purpose:	Depending on the design of the working end, the instruments are used for cutting, dissecting, grasping and suturing tissues, as well as for biopsies and/ or for thermal tissue treatment during minimal-invasive procedures. Bipolar forceps are used for hemostatic coagulation as well as grasping and dissecting of tissue in surgical procedures. The monopolar HF electrodes are combined with appropriate handles and generators, for coagulation and/ or dissecting (cutting) of tissue in endoscopic surgery. 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:	K020301 - RADIOFREQUENCY SURGERY INSTRUMENTS, SINGLE-USE
Intended Purpose:	Caiman Seal & Cut is a bipolar RF sealing system, which consists of the LEKTRAFUSE RF Generator and Caiman instruments. This system can be used for grasping, preparation, sealing and cutting of tissue during open and minimally invasive surgical procedures. Caiman Seal & Cut can be used on vessels and vessel bundles with diameters up to and including 7 mm as well as soft tissue in general surgery and also surgical specialties such as gynecology, urology and bariatric, colorectal and thoracic surgery.

Classification:	IIb
Device Group:	L180201 - OPEN ELECTROSURGERY SCISSORS, REUSABLE
Intended Purpose:	Bipolar scissors are used for cutting, dissecting and coagulating tissues in surgical operations.

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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. 03

Classification:	IIb
Device Group:	L180202 - ENDOSCOPIC ELECTROSURGERY SCISSORS, REUSABLE
Intended Purpose:	Depending on the design of the working end, the instruments are used for cutting, dissecting, grasping and suturing tissues, as well as for biopsies and/ or for thermal tissue treatment during minimal-invasive procedures.

Classification:	IIb
Device Group:	L180302 - ENDOSCOPIC ELECTROSURGERY HANDPIECES, REUSABLE
Intended Purpose:	Depending on the design of the working end, the instruments are used for cutting, dissecting, grasping and suturing tissues, as well as for biopsies and/ or for thermal tissue treatment during minimal-invasive procedures. The monopolar electrodes are high-quality products used for monopolar cutting, coagulating and dissecting in HF surgery.

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:	L180402 - ENDOSCOPIC ELECTROSURGERY FORCEPS, REUSABLE
Intended Purpose:	Depending on the design of the working end, the instruments are used for cutting, dissecting, grasping and suturing tissues, as well as for biopsies and/ or for thermal tissue treatment during minimal-invasive procedures.

Classification:	IIa
Device Group:	Q019001 - SALIVA ASPIRATORS AND SALIVA ABSORBENTS
Intended Purpose:	-

Classification:	IIa
Device Group:	Q0299 - OPHTHALMIC DEVICES - OTHER
Intended Purpose:	-

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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. 03

Classification:	IIb
Device Group:	Q0299 - OPHTHALMIC DEVICES - OTHER
Intended Purpose:	A single-use medical device designed to be used with a syringe and intended to refill (in situ) the Implant with Roche medicinal product when needed.
Classification:	IIa
Device Group:	T030199 - COVERS, INSTRUMENTS AND EQUIPMENT - OTHER
Intended Purpose:	-
Classification:	IIa
Device Group:	V010101 - SCALPELS WITH SAFETY SYSTEMS, SINGLE-USE
Intended Purpose:	-
Classification:	IIa
Device Group:	V010302 - BLADES WITHOUT SAFETY SYSTEMS, SINGLE-USE - NOT INCLUDED IN OTHER CLASSES
Intended Purpose:	-
Classification:	IIa
Device Group:	V0199 - CUTTING DEVICES, SINGLE-USE - OTHER
Intended Purpose:	-
Classification:	IIa
Device Group:	Z120103 - DERMOTOMY EQUIPMENT
Intended Purpose:	-
Classification:	IIb
Device Group:	Z120109 - ELECTROSURGICAL INSTRUMENTS
Intended Purpose:	The foot switch is used for activating compatible devices for HF surgery. The bipolar HF generator is used for coagulation with bipolar instruments. The HF generator is used for sealing and cutting of vessels with compatible seal and cut instruments.

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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. 03

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

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

Classification:	IIa
Device Group:	Z120114 - SURGICAL NAVIGATION INSTRUMENTS
Intended Purpose:	-

Classification:	IIa
Device Group:	Z12011482 - SURGICAL NAVIGATION INSTRUMENTS - SOFTWARE ACCESSORIES
Intended Purpose:	-

Classification:	IIa
Device Group:	Z120204 - INSTRUMENTS FOR THE ACQUISITION AND MANAGEMENT OF ENDOSCOPIC AND MINIMALLY INVASIVE SURGERY IMAGES
Intended Purpose:	-

Classification:	IIa
Device Group:	Z120590 - VARIOUS INSTRUMENTS FOR CARDIOLOGY AND CARDIAC SURGERY
Intended Purpose:	-

Classification:	IIa
Device Group:	Z121305 - MOTORISED ORTHOPAEDIC SURGERY SYSTEM INSTRUMENTS
Intended Purpose:	-

Classification:	IIa
Device Group:	Z121305 - MOTORISED ORTHOPAEDIC SURGERY SYSTEM INSTRUMENTS
Intended Purpose:	-

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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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. 03

Classification:	IIa
Device Group:	Z121009 - INSTRUMENTS FOR MOTORISED NEUROSURGERY SYSTEMS
Intended Purpose:	-

Classification:	IIa
Device Group:	Z121009 - INSTRUMENTS FOR MOTORISED NEUROSURGERY SYSTEMS
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
01	2021-12-09	713203407 / 713203404 / 713203403 / 713203400 / 713203397 / 713203393 / 713203388 / 713205439 / 713229575
02	2022-11-08	713203406 / 713205438 / 713218837 / 713218822

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B BRAUN

Digitally signed by Roibu Tatiana
Date: 2022.10.24 15:48:59 EEST
Reason: MoldSign Signature
Location: Moldova

Declaration

For the products as specified below we,

AESCULAP AG
AM AESCULAP-PLATZ
78532 TUTTLINGEN / GERMANY
(SRN: DE-MF-000005504)

have carried out a conformity assessment procedure according to the Medical Device Regulation (EU) 2017/745 by involving the Notified Body as indicated on the CE mark and in relation to the Notified Body as applicable for the respective EU risk class.

Involved Notified Body	
CE	Conformity assessment without Notified Body involvement
CE 0123	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München, Germany
CE 0482	MEDCERT GmbH, Pilatuspool 2, 20355 Hamburg, Germany

Risk class	**Sub-cat.**	**Procedure**	**Applicable System Certificate (TÜV SÜD or MEDCERT)**
I	--	Annex II & III	n/a
I	s, m, r	Annex IX	Certificate No.: G11 010066 0437 (Rev. xx) or 7400GB448xxxxxx
IIa	--	Annex IX	Certificate No.: G10 010066 0438 (Rev. xx) or 7400GB448xxxxxx
IIb	--	Annex IX	Certificate No.: G10 010066 0438 (Rev. xx) or 7400GB448xxxxxx
IIb	impl.	Annex IX	Certificate No.: G12 010066 0441 (Rev. xx) or 7400GB448xxxxxx
III	--	Annex IX	Certificate No.: G12 010066 0441 (Rev. xx) or 7400GB448xxxxxx + applicable EU Technical Documentation Assessment Certificate

The validity of this document corresponds to the expiry date of the currently applicable system certificate for the respective product.

By labeling the products with the CE mark (see attached list below)

we, **AESCULAP AG,** under sole responsibility confirm,
that we follow the general safety and performance requirements
according to MDR (EU) 2017/745, Annex I.

TUTTLINGEN, 2022-09-29

AESCULAP AG

i. V.

Mandy Blocher
Global Regulatory Affairs

i. A.

Birgit Körber
Global Regulatory Affairs

GA800	ELAN 4 ELECTRO CONTROL UNIT	40392390000014362F	EU Risk Class IIa
GA804	ELAN 4 ELECTRO MOTOR CABLE W/HAND SWITCH	40392390000004672K	EU Risk Class I
GA805	ELAN 4 ELECTRO MOTOR CABLE W/HAND CTRL.	40392390000004672K	EU Risk Class I
GA806	ELAN 4 ELECTRO MOTOR CABLE F/FOOT CTRL.	40392390000004992Y	EU Risk Class I
GA808	ELAN 4 ELECTRO FOOT CONTROL	40392390000004662H	EU Risk Class I
GA810	ELAN 4 ELECTRO WIRELESS FOOT CONTROL	40392390000004652F	EU Risk Class I
GA822	ELAN 4 ELECTRO PERFORATOR DRIVER	40392390000143329	EU Risk Class IIa
GA824	ELAN 4 ELECTRO LOW SPEED MOTOR INTRA	40392390000014342B	EU Risk Class IIa
GA831	ELAN 4 ELECTRO SAGITTAL SAW	40392390000143227	EU Risk Class IIa
GA832	ELAN 4 ELECTRO RECIPROCATING SAW	40392390000143023	EU Risk Class IIa
GA833	ELAN 4 ELECTRO TRANSVERSAL SAW	40392390000143125	EU Risk Class IIa
GA836	ELAN 4 ELECTRO MICRO SAGITTAL SAW	40392390000014272E	EU Risk Class IIa
GA837	ELAN 4 ELECTRO MICRO RECIPROCATING SAW	40392390000014282G	EU Risk Class IIa
GA844	ELAN 4 ELECTRO DRILL	40392390000014292J	EU Risk Class IIa
GA849	ELAN 4 ELECTRO CRANIOTOME 2-RING	40392390000014352D	EU Risk Class IIa
GA860	ELAN 4 ELECTRO MIS HANDPIECE STRAIGHT	40392390000014372H	EU Risk Class IIa
GA861	ELAN 4 ELECTRO 1-RING HANDPIECE L4	40392390000014382K	EU Risk Class IIa
GA862	ELAN 4 ELECTRO 1-RING HANDPIECE L7	40392390000014382K	EU Risk Class IIa
GA863	ELAN 4 ELECTRO 1-RING HANDPIECE L10	40392390000014382K	EU Risk Class IIa
GA864	ELAN 4 ELECTRO 1-RING HANDPIECE L13	40392390000014382K	EU Risk Class IIa
GA865	ELAN 4 ELECTRO 2-RING HANDPIECE L7	40392390000014382K	EU Risk Class IIa
GA866	ELAN 4 ELECTRO 2-RING HANDPIECE L10	40392390000014382K	EU Risk Class IIa
GA867	ELAN 4 ELECTRO 2-RING HANDPIECE L13	40392390000014382K	EU Risk Class IIa
GA868	ELAN 4 ELECTRO 2-RING HANDPIECE L17	40392390000014382K	EU Risk Class IIa
GA869	ELAN 4 ELECTRO 2-RING HANDPIECE L22	40392390000014382K	EU Risk Class IIa
GA875	ACCULAN 3TI ELECTRO LID	40392390000002962G	EU Risk Class I
GA876	ACCULAN ELECTRO ADAPTER	40392390000002962G	EU Risk Class I
GA877	ACCULAN 3TI ELECTRO CONSOLE	40392390000052528	EU Risk Class IIa
GA878	ACCULAN 3TI ELECTRO CONNECTION CABLE	40392390000002972J	EU Risk Class I
GB053R	ELAN 4 AIR ECCOS MOTOR HOSE	40392390000003912B	EU Risk Class I
GB056R	ELAN 4 AIR ECCOS PERFORATOR DRIVER GA722	40392390000003912B	EU Risk Class I