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 **Centrul pentru Achiziții Publice Centralizate în Sănătate**

Stimaţi domni,

Ca urmare a anunțului/invitației de participare/de preselecție apărut în Buletinul achizițiilor publice și/sau Jurnalul Oficial al Uniunii Europene, nr. ocds-b3wdp1-MD-1712306545326/ 21200380 privind aplicarea procedurii pentru atribuirea contractului privind *Achiziționarea Instrumentarului Cardiochirurgical conform necesităților IMSP Institutul de Cardiologie pentru anul 2024*, 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: 26.04.2024

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)

Digitally signed by Roibu Tatiana
Date: 2024.04.26 09:46:14 EEST
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 **Centrul pentru Achiziții Publice Centralizate în Sănătate**

Stimaţi domni,

Ne angajăm să menținem oferta valabilă, privind Achiziționarea Instrumentarului Cardiochirurgical conform necesităților IMSP Institutul de Cardiologie pentru anul 2024 prin procedura de achiziție licitație deschisă, pentru o durată de 160 zile, (una sută șaizeci zile), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 26.04.2024

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)

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

CAMERA ÎNREGISTRĂRII DE STAT 109 L.Ș.

MD 0027040

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

LISTA FONDATORILOR
SRL TEHNOMEDICA

Fondator unic: Roibu Tatiana

IDNP: date cu caracter personal

Data prezentării 22.03.2023 12:45:54

Anexe la SNC
"Prezentarea situatiilor financiare"
Aprobat de Ministerul Finantelor
al Republicii Moldova

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2022 - 31.12.2022

Entitatea: TEHNOMEDICA S.R.L.
Cod CUIÎO: 37700778
Cod IDNO: 1002600053256

Sediul:
MD:
Raionul(municipiul): 102, DDF CENTRU
Cod CUATM: 0130, SEC.CENTRU
Strada: Ciuflea nr.38 bl.1

Activitatea principală: G4646, Comert cu ridicata al produselor farmaceutice
Forma de proprietate: 16, Proprietate colectivă
Forma organizatorico-juridică: 530, Societăţi cu răspundere limitată

Date de contact:
Telefon: +37369153407
WEB:
E-mail: troibu@yahoo.com
Numele şi coordonatele al contabilului-şef: Dl (dna) Popescu Ecaterina Tel. 069153407

Numărul mediu al salariaților în perioada de gestiune: 4 **persoane.**

Persoanele responsabile de semnarea situațiilor financiare* Roibu Vladimir

Unitatea de măsură: leu

BILANŢUL

Anexa 1

la

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrșitul perioadei de gestiune
1	2	3	4	5
	A C T I V			
A.	**ACTIVE IMOBILIZATE** **I. Imobilizări necorporale**			
	1. Imobilizări necorporale în curs de execuție	010		
	2. Imobilizări necorporale în exploatare, total	020	255	255
	din care: 2.1. concesiuni, licențe și mărci	021		
	2.2. drepturi de autor și titluri de protecție	022		
	2.3. programe informatice	023		
	2.4. alte imobilizări necorporale	024	255	255
	3. Fond comercial	030		
	4. Avansuri acordate pentru imobilizări necorporale	040	3906847	2296440
	Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050	3907102	2296695
	II. Imobilizări corporale			
	1. Imobilizări corporale în curs de execuție	060		

	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130	15068026		2655319	12412707
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X	2603153		2603153
	4. Profit utilizat al perioadei de gestiune	150	X	( )	( )	( )
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160	15068026	2603153	2655319	15015860
V.	**Rezerve din reevaluare**	170				
VI.	**Alte elemente de capital propriu**	180				
	Total capital propriu (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180)	190	15073426	2603153	2655319	15021260

SITUAŢIA FLUXURILOR DE NUMERAR

de la pînă la

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vînzări	010	23444192	25886423
Plăți pentru stocuri și servicii procurate	020	18993827	19645736
Plăți către angajați și organe de asigurare socială și medicală	030	456668	446482
Dobînzi plătite	040		
Plata impozitului pe venit	050	331089	279058
Alte încasări	060	1598942	1619791
Alte plăți	070	3293285	6413686
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080	1968265	721252
Fluxuri de numerar din activitatea de investiții			
Încasări din vînzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobînzi încasate	110		
Dividende încasate	120		
inclusiv: dividende încasate din străinătate	121		
Alte încasări (plăți)	130		
Fluxul net de numerar din activitatea de investiții (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite și împrumuturi	150	800000	739000
Plăți aferente rambursării creditelor și împrumuturilor	160		268530
Dividende plătite	170	2512000	2499064
inclusiv: dividende plătite nerezidenților	171		
Încasări din operațiuni de capital	180		
Alte încasări (plăți)	190		
Fluxul net de numerar din activitatea financiară (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200	-1712000	-2028594
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210	256265	-1307342

Diferențe de curs valutar favorabile (nefavorabile)	220	-305668	-160086
Sold de numerar la începutul perioadei de gestiune	230	6916759	6867356
Sold de numerar la sfîrşitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240	6867356	5399928

Documente atașate - Notă explicativă (fișierul pdf)

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. № **1244256**

Din От **25.04.2024 12:44**

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 **10.05.2024 12:44**

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 **25.04.2024 12:44**

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

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 Centrul pentru Achiziții Publice Centralizate în Sănătate

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1712306545326,
ID: 21200380

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că vom prezenta mostre în decurs de 10 zile de la solicitarea autorității contractante pentru produsele oferite în cadrul licitației prenonate privind *Achiziționarea Instrumentarului Cardiochirurgical conform necesităților IMSP Institutul de Cardiologie pentru anul 2024.*

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 Centrul pentru Achiziții Publice
Centralizate în Sănătate

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1712306545326,
ID: 21200380

Declarație privind termenul de valabilitate

Prin prezenta, declarăm că termenul de valabilitate restant la momentul livrării pentru produsele oferite în cadrul licitației prenonate privind *Achiziționarea Instrumentarului Cardiochirurgical conform necesităților IMSP Institutul de Cardiologie pentru anul 2024* va constitui nu mai puțin de 80% din termenul total al produsului.

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 Centrul pentru Achiziții Publice Centralizate în Sănătate

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1712306545326,
ID: 21200380

Declarație privind înregistrarea dispozitivelor medicale

Prin prezenta, declarăm că, produsele oferite în cadrul licitației deschise prenotate sunt înregistrate în Registrul de Stat al Dispozitivelor Medicale a Agenției Medicamentului și Dispozitivelor Medicale, precum urmează:

DM000 407916	INSTRUMENT CHIRURGICAL	FULL-SIZE LID W/RETENTION PLATE BLUE	JK486	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023
DM000 407463	INSTRUMENT CHIRURGICAL	1/1 SIZE PERF BASKET 540X253X76 MM	JF223R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023
DM000 407504	INSTRUMENT CHIRURGICAL	SILICONE PAD BLUE 470X230X30 MM	JF932	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023
DM000 407759	INSTRUMENT CHIRURGICAL	REUSABLE FILTER FOR CONTAINER	JK090	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023

JG786B – sunt etichete din aluminiu, accesorii la container. Certificatul CE și EU Quality Management System Certificate (MDR) se anexează.

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

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: **AESCULAP 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

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
ZLG-BS-244.10.08

TÜV SÜD 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):

AESCULAP 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

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

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

TÜV®

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

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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. 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

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-11-17

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

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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:	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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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:	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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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:	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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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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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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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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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:	-

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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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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

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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.

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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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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:	./.

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