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 **Serviciul Medical al Ministerului Afacerilor Interne**

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-1722585607745, ID: 21265537 din 02.08.2024* privind aplicarea procedurii pentru atribuirea contractului privind *achiziţionarea dispozitivelor 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: 21.08.2024

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)

Digitally signed by Roibu Tatiana
Date: 2024.08.20 10:09:53 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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 **Serviciul Medical al Ministerului Afacerilor Interne**

Stimaţi domni,

Ne angajăm să menținem oferta valabilă, privind *achiziționarea dispozitivelor medicale,* prin procedura de achiziție licitație deschisă, pentru o durată de 60 zile, (șaizeci zile), din data deschiderii ofertei, respectiv până la data de 24.10.2024 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 21.08.2024

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

LISTA FONDATORILOR
SRL TEHNOMEDICA

Fondator unic: Roibu Tatiana

IDNP: date cu caracter personal

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

Data prezentării 19.03.2024 10:40:02

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

SITUAŢIILE FINANCIARE

pentru perioada 01.01.2023 - 31.12.2023

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, Societăți cu răspundere limitată

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

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

Persoanele responsabile de semnarea situațiilor financiare* Roibu Tatiana

Unitatea de măsură: leu

BILANŢUL

Anexa 1

la

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrşitul 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		

	3. Alte rezerve	100				
	Total rezerve (rd.080 + rd.090 + rd.100)	110				
IV.	**Profit (pierdere)**					
	1. Corecții ale rezultatelor anilor precedenți	120	X	27561		27561
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130	15015860		3625532	11390328
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X	6531847		6531847
	4. Profit utilizat al perioadei de gestiune	150	X	( )	( )	( )
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160	15015860	6559408	3625532	17949736
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	15021260	6559408	3625532	17955136

SITUAŢIA FLUXURILOR DE NUMERAR

de la 01.01.2023 pînă la 31.12.2023

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vînzări	010	25886423	36294157
Plăți pentru stocuri și servicii procurate	020	19645736	29605666
Plăți către angajați și organe de asigurare socială și medicală	030	446482	485617
Dobînzi plătite	040		
Plata impozitului pe venit	050	279058	498688
Alte încasări	060	1619791	2027610
Alte plăți	070	6413686	5293780
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080	721252	2438016
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	739000	1450000
Plăți aferente rambursării creditelor și împrumuturilor	160	268530	900000
Dividende plătite	170	2499064	3408000
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	-2028594	-2858000
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210	-1307342	-419984
Diferențe de curs valutar favorabile (nefavorabile)	220	-160086	-192712
Sold de numerar la începutul perioadei de gestiune	230	6867356	5399928
Sold de numerar la sfîrşitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240	5399928	4787232

Documente atașate - Notă explicativă (fișierul pdf)

Notă explicativă Tehnomedica 2023.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. № **1223256**

Din От **19.08.2024 12:23**

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 **03.09.2024 12:23**

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 **19.08.2024 12:23**

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 Serviciul Medical al Ministerului Afacerilor Interne

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1722585607745,
ID: 21265537

Declarație privind instalarea și instruirea personalului

Prin prezenta, declarăm că vom asigura instalarea dispozitivului oferit și instruirea personalului privind utilizarea utilajului la sediul beneficiarului.

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 Serviciul Medical al Ministerului Afacerilor Interne

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1722585607745,
ID: 21265537

Declarație privind termenul de garanție

Prin prezenta, declarăm că termenul de garanție pentru dispozitivul livrat și instalat va constitui 24 luni. Condițiile de valabilitate a garanției emise de producător sunt descrise în scrisoarea anexată la prezenta declarație.

Cu respect,

Director Tatiana Roibu

Aesculap AG
Global Marketing & Sales

Postfach 40
78501 Tuttlingen

Contact: Alexandra Samara

Fon: +49 7461 95-2450
Fax: +49 7461 95-
Email: alexandra.samara@aesculap.de
Internet: http://www.bbraun.com

To whom it may concern

Date: March 28, 2022

Quality standards and warranty for AESCULAP products

Dear Sirs,

In the following, we would like to explain some of the points that make our AESCULAP products the quality products that they are. Since 1867, our trademark symbol, the AESCULAP crowned serpent staff, represents attributes such as quality, functionality, safety, reliability, durability and economy. All our quality products "Made by Aesculap" carry this symbol. An AESCULAP quality product in your hands is, therefore, a contribution to success and quality for the benefit of the patient – because we do not want any compromises when it comes to our health.

MATERIAL

The material used for our instruments complies with the steel qualities recommended in DIN, ISO and ASTM standards. However, we fulfill even higher requirements, as they are defined in these standards, by our own delimitation of the analysis values and the permissible structural states. By doing this, we improve the characteristics and the corrosion resistance of our instruments.

In our material testing laboratory, equipped with state of the art testing equipment (emission spectrometer for chemical analysis, scanning electron microscope, etc.), we test and monitor the material we receive.

PATTERN CONSISTENCY

The raw parts for our surgical instruments are manufactured in our own forge, by using tools we have designed and produced in accordance with our own special construction guidelines.

During manufacturing, the production stages of our instruments are monitored by using measurement check sheets, factory samples and internal quality guidelines.

These measures and an internal quality standard applying only to our AESCULAP instruments allow us to produce instruments within even tighter tolerances than those defined by the relevant industry standards. As a consequence we can enable an excellent pattern consistency.

MANUFACTURING

In our manufacturing, we only use state of the art machines and equipment. Qualified skilled workers, which are factory-trained, enable a precise and professional production.

The computer controlled thermal treatment in our modern vacuum hardening units and random checks conducted on the hardening results, are leading to enhanced mechanical characteristics and corrosion resistance for our instruments.

CHECKS

For us, the quality control already begins with the decision of the material to be used and is continued in the check of the supplied material, the testing of the unmachined parts, as well as in the various checks during and after important stages of the production process, right up to the extensive final inspection of the finished product.

QUALITY

The quality of all AESCULAP products is enabled by our quality assurance system, which fulfills the requirements of the world wide valid quality management standards DIN EN ISO 9001, DIN EN 46001, DIN EN ISO 13485 and the Medical Devices Directive 93/42/EEC of the Council of 14 June 1993. This quality management system is described in an AESCULAP quality manual and procedures which are certified by an independent certification organisation accredited/notified. This certification allows us to label our products with the CE-Mark.

WARRANTY

We warrant that every AESCULAP product that leaves the factory, is free from any defects in material and workmanship.
This warranty will be valid for the period of 24 months, starting on the day of the original delivery, defined by the date of the invoice.

The prerequisite for this is a professional use, reprocessing, care and sterilisation of the products. Please refer to the recommendations of the working team “Proper Maintenance of Instruments” and the IFU.

...

Excluded from this warranty are:

- Damage due to overstressing or droppage
- Improper usage which is not according to the product´s intended use
- Damage due to corrosion by chemicals. For instance, physiologic saline solution.
- Improper handling, cleaning and care during disposal and reprocessing, such as

  - unsuitable disinfectant and cleaning agents,
  - unsuitable cleaning methods,
  - unsuitable care additives
  - unsuitable storage in the tray
- Normal wear and tear
- Inadequate sterilisation conditions,
  e.g. insufficient quality of the sterilising steam.
- Disassembling, repair or modification by a customer or third party
- Malfunctions due to an exceeding of the recommended maintenance interval (e.g. wear of ball bearings etc.)
- usage with defective accessories or components which are not certified by AESCULAP

With kind regards,

Aesculap AG

i. V.
Reinhard Frombach
Director Global Sales
Mid-Sized Countries Europe

AESCULAP AG
AESCULAP®
Aesculap a B. Braun brand

i. V.
Lena Burghart
Senior Business Development Manager Global Sales
Mid-Sized Countries Europe

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Către Serviciul Medical al Ministerului Afacerilor Interne

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1722585607745,
ID: 21265537

Declarație privind perioada de reacție

Prin prezenta, declarăm că, în cazul apariției defecțiunilor tehnice, perioada de reacție va fi mai puțin de jumătate de oră la telefon și 24 ore sau mai puțin la sediul beneficiarului.

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 Serviciul Medical al Ministerului Afacerilor Interne

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1722585607745,
ID: 21265537

Declarație privind anul de producere, livrarea componentelor noi și prezentarea suplimentară a parametrilor tehnici

Prin prezenta, declarăm că, anul de producere a dispozitivului medical oferit nu este mai vechi de anul 2023, iar toate componentele sunt noi (nefolosite). Documente detaliate privind parametrii tehnici vor fi prezentate la solicitarea grupului de lucru, conform declarațiilor semnate în textul DUAE, dat fiind volumul acestora considerabil, ce nu poate fi plasat pe platforma electronică.

Cu respect,

Director Tatiana Roibu

TEHNOMEDICA

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

Către Serviciul Medical al Ministerului Afacerilor Interne

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1722585607745,
ID: 21265537

Declarație

Prin prezenta, declarăm că, în perioada garanției, vom asigura organizarea inspecțiilor planificate/întreținere profilactică conform unui grafic prestabilit și mentenanța dispozitivului medical. Cu titlu informativ, dispozitivul medical oferit se autocalibrează.

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 Serviciul Medical al Ministerului Afacerilor Interne

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1722585607745,
ID: 21265537

Prin prezenta, Vă informăm că, dispozitivul medical oferit, conform codului vamal atribuit, nu se regășeste în Lista echipamentelor electrice și electronice indicate în Anexa 1B din HG nr. 212/2018 pentru aprobarea Regulamentului privind DEEE. Astfel, înregistrarea în lista producătorilor nu se impune în cazul livrării și plasării pe piață a dispozitivului menționat.

Totodată, menționăm că aspectul dat a fost consultat cu specialiștii din cadrul sistemului colectiv de gestionare a deșeurilor de EEE, asociația patronală „Moldcontrol”, care au confirmat că eventuala livrare a dispozitivului în cauză nu se supune prevederilor regulamentului menționat supra.

Cu respect,

Director Tatiana Roibu

TEHNOMEDICA

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Către Serviciul Medical al Ministerului Afacerilor Interne

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1722585607745,
ID: 21265537

Declarație privind înregistrarea dispozitivelor medicale

Prin prezenta, declarăm că, dispozitivul medical și accesoriile oferite în cadrul licitației deschise prenotate sunt înregistrate în Registrul de Stat al Dispozitivelor Medicale al Agenției Medicamentului și Dispozitivelor Medicale.

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

Anexă: extrase din Registrul de Stat al Dispozitivelor Medicale al Agenției Medicamentului și Dispozitivelor Medicale

Cu respect,

Director Tatiana Roibu

DM000411415	GA800	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000013	24.01.2023
DM000407261	GA808	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023
DM000407260	GA806	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023
DM000407277	GB073R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023
DM000411427	GA862	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000013	24.01.2023
DM000411429	GA864	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000013	24.01.2023
DM000407281	GB083R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023
DM000411424	GA849	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000013	24.01.2023
DM000407283	GB085R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023
DM000514013	GB942R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000407320	GB719R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023
DM000514015	GB945R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000515040	GP342R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000411416	GA822	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000013	24.01.2023
DM000407278	GB076R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023
DM000513924	GB302R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000513925	GB304R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000407304	GB572R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023
DM000514780	GP124R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000514786	GP126R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000514792	GP128R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000514796	GP129R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000514774	GP121R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000514830	GP152R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000514832	GP153R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000514836	GP155R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000514840	GP157R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000514842	GP158R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000514824	GP149R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000514768	GP118R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000514884	GP189R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000514898	GP202R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000514900	GP203R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123	05.06.2023
DM000407319	GB718R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023
DM000407315	GB698R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023
DM000407305	GB600	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023
DM000407882	JK442	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023
DM000391837	JF221R	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000280	28.11.2022
DM000407922	JK489	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023
DM000407759	JK090	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023
DM000407641	JG744	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023

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

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Declaration

The certification body of TÜV Süd Management Service GmbH and the TÜV Süd Product Service GmbH confirm that we,

AESCULAP AG
AM AESCULAP-PLATZ
78532 TUTTLINGEN / GERMANY

have established and are maintaining a quality management system according to

ISO 9001:2015
(Certificate Registration No.: 12 100 21724 TMS)
EN ISO 13485:2016
(Certificate No.: Q5 17 03 10066 408)

for the following area

Development, Production and Distribution of Implants, Instruments, Containers, Devices, Suture Material, Tissue Adhesives and Procedure Kits.

Furthermore we have implemented the conformity assessment procedure as per annex II, clause 3 of the Medical Device Directive 93/42/EEC of June 14th, 1993 for medical products.

By labeling the products

Aesculap Product Groups
as per attached list

with the CE mark

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

TUTTLINGEN, 2018-03-13

AESCULAP AG

i. V.

Thomas Marquard
Regulatory Affairs

i. A.

Denise Hermle
Regulatory Affairs

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Attachment to Declaration of 2018-03-13

Aesculap Product Groups
Surgical, diagnostic and dental instruments
Joint Implants (Hip, Knee)
Spinal Implants
Implants for osteosynthesis
Neurosurgical Vascular Implants
Products for Ligature
Motor Systems
Sterilization Containers and Accessoires
Hifh Frequency Surgery Devices
Endoscopic Systems
Navigation Systems
Surgical Suction Pumps
Special Suture-Sets
Implants for Replacement of Connective Tissue
Tissue Adhesives
Vascular Prosthesis and Accessories
Local Haemostatics
Other Surgical Accessories