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 de Medicină Urgentă**

Stimaţi domni,

Ne angajăm să menținem oferta valabilă, privind achiziționarea consumabilelor angiografice, prin procedura de achiziție COP, pentru o durată de 60 zile (șaizeci zile), respectiv până la data de 20.08.2023 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 14.06.2023

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)

Digitally signed by Roibu Tatiana
Date: 2023.06.14 15:58:16 EEST
Reason: MoldSign Signature
Location: Moldova

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

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

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 de Medicină Urgentă

În atenția Grupului de lucru
al procedurii nr. ocds-b3wdp1-MD-1686042869396,
ID: 21081874

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că vom prezenta mostre în decurs de 3 zile de la solicitarea autorității contractante pentru produsele oferite în cadrul procedurii prenonate privind achiziționarea consumabilelor angiografice.

Cu respect,

Director Tatiana Roibu

Aesculap AG
Global Marketing & Sales

Postfach 40
78501 Tuttlingen

Contact: Sibylle Richter

Fon: +49 7461 95-2760
Fax: +49 7461 95-78980
Email: sibylle.richter@aesculap.de
Internet: http://www.bbraun.com

Date: January 20, 2022

Centrul petru Achizitii Publice Centralizate
in Sanatate (Center for Central Pubic
Procurements in Healthcare System)
Moldova

LETTER OF AUTHORIZATION

Dear Sirs,

Whereas, Aesculap AG, who is an established manufacturer of medical devices since 1867, having factories at Am Aesculap-Platz, 78532 Tuttlingen, Germany, does hereby authorize

Tehnomedica SRL
Str. Ciuflea 38/1
Chisinau / Republic of Moldova

to submit a bid and subsequently negotiate and sign a contract in its own name with you up to a total of 5.000,00 EUR (five thousand) regarding the periodical deliveries for the following tender

- TENDER No. 21047377 dated 04.02.2022 for the supply of
- Hemodynamic Products

based on order from the contractor valid for the period of contract, but in no case longer than 3 years from date of issue of this letter.

Aesculap AG may revoke granted Letter of Authorization in the event that Tehnomedica SRL, Str. Ciuflea 38/1, Chisinau, Repubic of Moldova turns out to be a sham company / letterbox company or that the business is not in accordance with the principles and ethical standards of the B. Braun Group.

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

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 012974 0608 Rev. 00

Manufacturer: **B. Braun Melsungen AG**
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Product Category(ies): **Coronary stent systems, PTCA catheters, PTA catheters, PTCA sets, Probes for stimulation and Electrophysiology, Angiography sets, manifolds, guide wires, tubes and syringes, single use Right heart pulmonary artery catheters, Monitoring sets for invasive physiological pressure measurement, Introducer sheaths and sets, Arterial puncture cannulae, arterial catheter sets**

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.: 713168177

Valid from: 2020-05-06
Valid until: 2024-05-26

Date, 2020-05-14

Christoph Dicks
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 012974 0608 Rev. 00

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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®

B|BRAUN

Declaration

The certification body of TÜV Management Service GmbH and the TÜV 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 9001:2008
(Certificate Registration No.: 12 100 21724 TMS)
EN ISO 13485:2012 / AC:2012
(Certificate No.: Q1N 14 05 10066 365)

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. (EC certificate No.: G1 14 05 10066 366)

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, 2014-11-26

AESCULAP AG

i. V.

Thomas Marquard
Director Regulatory Affairs

i. A.

S. Maier

Sandra Maier
Regulatory Affairs

"TEHNOMEDICA" S.R.L.

B|BRAUN

Attachment to Declaration of 2014-11-26

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 accessories
High frequency surgery devices
Endoscopic systems
Navigation systems
Surgical suction pumps
Special suture-sets
Implants for replacement of connective tissue
Tissue adhesives
Vascular prostheses and accessories
Local haemostatics
Other surgical accessories

"TEHNOMEDICA" S.R.L.

2014-11-26

B|BRAUN

Konformitätserklärung
Declaration of Conformity

Document-No.:	39.05.621
Revision-No.:	02
Effective Date:	2020-05-19
Page:	1 of 2

Wir | We

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany

erklären in eigener Verantwortung,
dass das/die Produkt/e

Torquer

PTCA-Zubehör
(Artikelnummern siehe Anlage)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

Richtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EG

Konformitätsbewertungsverfahren
nach Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinie

Klassifizierung
gemäß Anhang IX der
oben genannten Richtlinie
Klasse Is / Regel 1
Klasse IIa / Regel 2

Benannte Stelle
TÜV SÜD Product Service GmbH (ID-Nr. 0123)
Ridlerstraße 65, 80339 München, Deutschland

Ausgestellte Bescheinigung(en):
G1 012974 0608 Rev. 00
G2S 012974 0609 Rev. 00

Datum der ersten CE-Kennzeichnung
1999-02-17

Gültig bis
2024-05-26

hereby declare in our own responsibility
that the product/s

Torquer

PTCA Accessories
(article numbers see attachment)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June 1993
concerning Medical Devices
amended by Directive 2007/47/EC

Conformity Assessment Procedure
according to annex II (excluding section 4)
of the Council Directive named above

Classification
according to annex IX of the
Council Directive named above
Class Is / Rule 1
Class IIa / Rule 2

Notified Body
TÜV SÜD Product Service GmbH (ID no. 0123)
Ridlerstraße 65, 80339 Munich, Germany

Certificate(s) issued:
G1 012974 0608 Rev. 00
G2S 012974 0609 Rev. 00

Date of first CE-marking
1999-02-17

Valid until
2024-05-26

Berlin, 2020-05-19

B. Braun Melsungen AG

i. A.

Dr. S. Vogelbein
Head of Quality Management CoE VS

Berlin, 2020-05-19

B. Braun Melsungen AG

i. V.

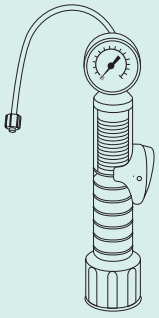
Dr. H. Schlicht
Head of Regulatory Affairs

Anlage I / Attachment I

Art.-Nr. REF No.	Artikelbezeichnung	Article description	Klasse Class
5023687	Torquer, rund	Torquer	Is
5023689	Torquer, zweiteilig	Torquer, 2-ply	Is
5017826	Metall Einführhilfe 20G, 7,5 cm	Metal Insert Tool 20G, 7.5 cm	IIa

Accessories for PTCA

Introducer, Inflation Device etc.



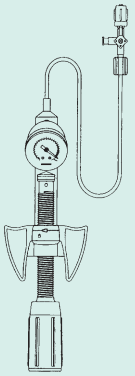
Inflation Device for PTCA

Pressure gauge:
- 90° rotating manometer for "custom" handling
- coded figures from nominal to burst pressures for easy reading

Body and button:
- unique mechanism for rapid pressure increase, i.e. effective and fast procedures
- grip design for better handling
- clear material for easy air bubble detection and removal

Handle:
- ergonomic design for optimal handling
- progressive resistance while inflating for pressure feedback

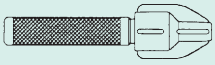
	Code-Number	Sales unit-pcs.
Inflation Device for PTCA, 20 ml / 30 atm	**5028900**	1



Inflation Device for PTCA

- easy handling by winged locking mechanism
- angled, luminous pressure gauge
- precise inflation, quick deflation
- crystal clear barrel for easy debubbling
- 30 cm high pressure tubing with three-way stopcock and rotating adaptor

	Code-Number	Sales unit-pcs.
Inflation Device for PTCA, 25 ml / 30 atm	**622510**	1



Torquer
Torque device for guide wires

- luminescent
- wire grip for all diameters up to 0.022"

	Code-Number	Sales unit-pcs.
Torque device	**5023687**	10