

CERERE DE PARTICIPARE

Către: **IMSP Institutul Oncologic**
(mun. Chișinău, str. Testemitanu, 30)

Stimați domni,

Ca urmare a anunțului de participare apărut în Buletinul achizițiilor publice nr ocds-b3wdp1-MD-1664799119185 din 10 octombrie 2022 privind aplicarea procedurii pentru atribuirea contractului Consumabile medicale (diverse ace și măști pentru radioterapie) Repetat, noi Tetis Internatioenl Co 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, neavînd obiecții la documentația de atribuire.

Data completării 10 octombrie 2022

Cu stimă,

Ofertant
Tetis International Co SRL
(semnătura autorizată)

DECLARAȚIE
privind valabilitatea ofertei

Către **IMSP Institutul Oncologic**
(mun. Chișinău, str. Testemitanu, 30)

Stimați domni,

Ne angajăm să menținem oferta valabilă, privind achiziționarea **Consumabile medicale (diverse ace și măști pentru radioterapie) Repetat**, prin procedura de achiziție – **Licitație deschisă**, pentru o durată de **30 zile**, (treizeci zile), respectiv până la data de 09 noiembrie 2022, și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării 10 octombrie 2022

Cu stimă,

Ofertant/candidat
Tetis International Co SRL
(semnătura autorizată)

Specificații tehnice

[Acest tabel va fi completat de către ofertant în coloanele 2, 3, 4, 6, 7, iar de către autoritatea contractantă – în coloanele 1, 5,]
Numărul procedurii de achiziție ocds-b3wdp1-MD-1664799119185 _din_10 octombrie 2022__
Obiectul achiziției: Consumabile medicale (diverse ace și măști pentru radioterapie) Repetat

Denumirea bunurilor/serviciilor	Denumirea modelului bunului/serviciului	Țara de origine	Producătorul	Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către ofertant	Standarde de referință
1	2	3	4	5	6	7
Bunuri						
Ac ULTRAPLEX 360, 30 ° 20GX100MM-EU	Ultraplex 360 30 22Gx100mm /4892610-01/	Germania	B/Braun	Ac ULTRAPLEX 360, 30 ° 20GX100MM-EU	Ac ULTRAPLEX 360, 30 ° 20GX100MM-EU	CE,ISO

Semnat: _____ Numele, Prenumele: Igor Perepețița În calitate de: Director general
 Ofertantul: Tetis International Co SRL Adresa: mun. Chișinău, str. Calea Orheiului 103/3

Specificații de preț

Numărul procedurii de achiziție ocds-b3wdp1-MD-1664799119185 _din_10 octombrie 2022__
Obiectul achiziției: Consumabile medicale (diverse ace și măști pentru radioterapie) Repetat

Cod CP V	Denumirea bunurilor/serviciilor	Unitatea de măsură	Cantitatea	Preț unitar (fără TVA)	Preț unitar (cu TVA)	Suma fără TVA	Suma cu TVA	Termenul de livrare	Clasificație bugetară (IBAN)
1	2	3	4	5	6	7	8	9	10
	Bunuri								
33140000-3	Ac ULTRAPLEX 360, 30 ° 20GX100MM-EU	fl	75	201,10	217,188	15082,50	16289,10	În condiții Incoterms 2013, DDP, pe parcursul anului 2022, în decurs de 20 zile, conform solicitării IMSP IO	

Semnat: _____ Numele, Prenumele: Igor Perepețița În calitate de: Director general
Ofertantul: Tetis International Co SRL Adresa: mun. Chișinău, str. Calea Orheiului 103/3



Certificate

No. Q5 012974 0590 Rev. 01

Holder of Certificate: **B. Braun Melsungen AG**
 Carl-Braun-Str. 1
 34212 Melsungen
 GERMANY

Certification Mark:



Scope of Certificate: Design and Development, Manufacture, Distribution, Installation and Servicing of:

Non-active Medical Devices (Sterile and Non-Sterile) for:

- Injection, Infusion, Transfusion and Nutrition
 (Hypodermic Needles, Pen Cannulas for Subcutaneous Injection of Fluid Drug Products, Lancets for Blood Sampling, Intravenous Administration Sets, Tube Connectors, Closing Cones, Vascular Access Devices (Sterile Disposables for Infusion, Transfusion and Vein Puncture), Sterile Disposable Infusion Sets for Volume Control, Measuring of Central Venous Pressure, Filters and Stopcocks for Infusion Therapy, Oral Dispenser (sterile and non-sterile), Withdrawal and Injection Spikes and Needles for Drug Admixture, Syringes, Administration Sets for Enteral Nutrition Therapy)

- Wound care
 (Bandages and Retainers for Compression and Fixation, Sterile Products, Disposables and Sets for Wound Care)

- Anesthesia, Emergency, Intensive and Home Care
 (Central Venous Catheter Sets for Catheterization of the Superior Vena Cava, Needles and Catheters and Sets for Spinal and Epidural Anesthesia, Needles and Catheters and Sets for Plexus Anesthesia, Needles and Catheters and Sets for Combined Spinal and Epidural Anesthesia, Sets for Pleura- and Thorax Drainage, Thoracic Aspiration Set, Wound Drainage System, Sets for Fine Needle Biopsy and Percutaneous Liver Biopsy, Sets for Urology, Nephrology and Incontinence)

- Disinfecting, Cleaning and Rinsing

- Irrigation
 (Administration Accessories, Fixation Accessories for Stoma and Rectal Irrigation)

- Cryotherapy

- Configured Customized Sets

Non-active Medical Devices (Sterile and Non-Sterile):

- Medical Gloves
 (Examination and Surgical Gloves for Surgical and Aseptic Medical

Certificate

No. Q5 012974 0590 Rev. 01

Applications)

- Sterile Solutions

Active Medical Devices for:

- Fluid Management

(Infusion Pumps, including Management Units, and Software, and Elastomeric Infusion Pumps)

- Nerve Stimulation

(Nerve Stimulators for Peripheral Regional Anesthesia)

- Wound Drainage System

- Enteral Feeding

- Irrigation

(Irrigation Pump with Power Supply for Stoma and Rectal Irrigation)

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 012974 0590 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_012974_0590_Rev.01)

Report No.: 713218550
Valid from: 2021-10-22
Valid until: 2024-10-21

Date, 2021-10-22



Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 012974 0590 Rev. 01

Applied Standard(s):	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) DIN EN ISO 13485:2016
Facility(ies):	<p>B. Braun Melsungen AG Carl-Braun-Str. 1, 34212 Melsungen, GERMANY</p> <p>Headquarters, of Division Hospital Care Management Quality Management</p> <p>B. Braun Melsungen AG OPM Carl-Braun-Straße 1, 34212 Melsungen, GERMANY</p> <p>Headquarters, of Out Patient Market Management Quality Management</p> <p>B. Braun Melsungen AG Werk A und K Carl-Braun-Str. 1, 34212 Melsungen, GERMANY</p> <p>Design and Development, Manufacture of: Sterile Solutions</p> <p>Manufacture of Non-active Medical Devices for: Anesthesia, Emergency, Intensive and Home Care Injection, Infusion, Transfusion and Nutrition</p> <p>B. Braun Melsungen AG Werk B Dörnbach 10, 34286 Spangenberg, GERMANY</p> <p>Design and Development, Manufacture of: Configured Customized Sets</p> <p>B. Braun Melsungen AG Schwarzenberger Weg 73-79, 34212 Melsungen, GERMANY</p> <p>Service of Active Medical Devices for: Fluid Management</p> <p>B. Braun Melsungen AG Werk E Schwarzenberger Weg 21-27, 34212 Melsungen, GERMANY</p> <p>Design and Development, Manufacture of Active and Non-active Medical Devices for:</p> <p>Injection, Infusion, Transfusion and Nutrition Anesthesia, Emergency, Intensive and Home Care Nerve Stimulation (Nerve Stimulators for Peripheral Regional Anesthesia) Wound Drainage System Enteral Feeding</p>



Certificate

No. Q5 012974 0590 Rev. 01

B. Braun Melsungen AG
Pfieffewiesen, 34212 Melsungen, GERMANY

Manufacture of Non-active Medical Devices for:
Injection, Infusion, Transfusion and Nutrition
Central Laboratories,
Central Warehouse, Supply Chain Management
Central Sterilization (Radiation)

B. Braun Melsungen AG
Am Buschberg 1, 34212 Melsungen, GERMANY

Headquarters, of Center of Excellence Automated Infusion
Systems

Management of Active Medical Devices for

Fluid Management
(Infusion Pumps, including Management Units, and Software)

Irrigation
(Irrigation Pump with Power Supply for Stoma and Rectal
Irrigation)

B. Braun Melsungen AG
Neue Stiftingtalstrasse 2, 8010 Graz, AUSTRIA

Design and Development, Manufacture of:
Non-active Medical Devices for:
Emergency, Intensive and Home Care

B. Braun Melsungen AG OPM
Schwarzenberger Weg 73-79, 34212 Melsungen, GERMANY

Design and development, Control of production, distribution,
installation and servicing
of products for the injection, infusion, transfusion, incontinence
care, stoma care, wound care, diabetes care, urology, disinfecting,
cleaning and rinsing, cryotherapy, irrigation (Administration
Accessories, Fixation Accessories for Stoma and Rectal Irrigation),
medical gloves for single use, protection clothing, medical waste
container, home care of patients.
Individual compounded parenteral nutrition.



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 18 04 12974 455

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



Product Category(ies): Non-active medical devices (sterile and non-sterile) for:
- Injection, Infusion, transfusion and nutrition
- Anaesthesia, emergency, intensive and home care
- Disinfecting, cleaning, rinsing
- Irrigation
- Cryotherapy
- Configured customized sets
- Medical devices for wound care
- Medical Gloves
- Sterile Solutions

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.: 713128918

Valid from: 2018-05-11
Valid until: 2023-05-01

Date, 2018-05-11

S. Preiß
Stefan Preiß





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 18 04 12974 455****Facility(ies):**

B. Braun Melsungen AG
Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

ALMO-Erzeugnisse Erwin Busch GmbH
Große Allee 84, 34454 Bad Arolsen, GERMANY

B. Braun Medical SAS
13 rue Croix Comtesse, 28402 Nogent-le-Rotrou, FRANCE

B. BRAUN Vietnam Co., Ltd.
170 La Thanh Road, Dong Da District, 63000 Hanoi, VIETNAM

B. Braun Medical Kft Production Division
Déli-Külhatár út 2-4, 3200 Gyöngyös, HUNGARY

B. Braun Medical Inc.
901 Marcon Boulevard, Allentown PA 18109-9341, USA

B. Braun Melsungen AG
Neue Stiftingtalstrasse 2, 8010 Graz, AUSTRIA

B. Braun Aesculap Japan Co., Ltd. Tochigi Factory - Hospital Care
285 Ogaki, Tsuga-machi, Tochigi-shi, Tochigi, 328-0101 JAPAN

B. Braun Medical Industries Sdn. Bhd.
Bayan Lepas Free Industrial Zone, 11900 Penang, MALAYSIA

B. Braun Medical AG
Hauptstraße 39, 6182 Escholzmatt, SWITZERLAND

B. BRAUN Vietnam Co., Ltd.
Thanh Oai Industrial Complex, Thanh Oai District, 156800 Hanoi,
VIETNAM

B. Braun Melsungen AG OPM
Carl-Braun-Straße 1, 34212 Melsungen, GERMANY

B. Braun Melsungen AG OPM
Schwarzenberger Weg 73-79, 34212 Melsungen, GERMANY

B. Braun Medical AG
Seesatz 17, 6204 Sempach, SWITZERLAND