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 seturilor jetabile pentru operații neurochirurgicale – 2023, prin procedura de achiziție COP nr. ocds-b3wdp1-MD-1693388144784, ID: 21090583 din 13.09.2023, pentru o durată de 60 zile (șaizeci zile), respectiv până la data de 13.11.2023 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 11.09.2023

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)

I.P. "AGENŢIA SERVICII PUBLICE"

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. **1968** din **01.02.2019**

Denumirea completă: **SOCIETATEA CU RĂSPUNDERE LIMITATĂ «TEHNOMEDICA» .**
Denumirea prescurtată: **«TEHNOMEDICA» S.R.L. .**
Forma juridică de organizare: **Societate cu Răspundere Limitată.**
Numărul de identificare de stat şi codul fiscal: **1002600053256.**
Data înregistrării de stat: **17.04.2002.**
Sediul: **MD-2001, str. Ciuflea, 38/1, mun.Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1 Fabricarea utilajului medical şi chirurgical şi a dispozitivelor ortopedice;
2 Comerţul cu ridicata al produselor farmaceutice;
3 Comerţul cu amănuntul al produselor farmaceutice;
4 Practica medicală;
5 Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii;
6 Activităţi de consultare pentru afaceri şi management.
Capitalul social: **5400** lei.
Administrator: ROIBU TATIANA,
Asociaţi:
1. ROIBU TATIANA 100 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: 01.02.2019.

Specialist coordonator
tel. 022-20-7838

Clichici Elena

INSTITUŢIA PUBLICĂ AGENŢIA SERVICII PUBLICE IDNO 1002600024700 REPUBLICA MOLDOVA CHIŞINĂU 003

EB 0257484

F/COM/CC/23/02

Nr. CIF26-842.2020
Data: 13 Februarie 2020

CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **Mobiasbanca - OTP Group S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **TEHNOMEDICA S.R.L.** cod fiscal (IDNO) **1002600053256**, detine următoarele conturi curente la Mobiasbanca - OTP Group S.A., Sucursala. 26 Negruzzi:

1. **MDL - MD65MO2224ASV98310887100**
2. **EUR - MD06MO2224ASV98311097100**

L.Ş.

Numele, Prenumele si Semnătura
Director sucursalei „Gheorghe Mocanu"

Executor :Eduard Cilcic
Tel: 022-812-150

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

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-1693388144784,
ID: 21090583

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 seturilor jetabile pentru operații neurochirurgicale – 2023.

Cu respect,

Director Tatiana Roibu

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Către IMSP Institutul de Medicină Urgentă

În atenția Grupului de lucru
al procedurii nr. ocds-b3wdp1-MD-1693388144784,
ID: 21090583

DECLARAȚIE

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

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

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

DM000374810	NEUROSURGICAL TRAYS	97094658	Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDICA S.R.L.	Rg04-000229	27-09-2022
DM000374811	NEUROSURGICAL TRAYS	97095457	Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDICA S.R.L.	Rg04-000229	27-09-2022

Cu respect,

Director Tatiana Roibu

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Mölnlycke Health Care AB
Gamlestadsvägen 3C
Box 13080
SE-402 52 Göteborg
Sweden

Holds Certificate Number: **MD 83345**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture, marketing, sales and distribution of sterile wound and scar dressings, open wound products, cavity dressings, polyurethane foam with and without additives for incorporation into medical devices, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and support, sterile wound irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves, self-warming blankets, turning and positioning devices.
The design, development, manufacture, marketing, sales and distribution of single patient use Negative Pressure wound therapy pumps and accessories. Distribution of laparoscopic instruments.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2004-07-21
Latest Revision Date: 2021-11-24

Effective Date: 2021-11-28
Expiry Date: 2024-11-27

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EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 722506 R000

Manufacturer: Mölnlycke Health Care AB

Address:
Gamlestadsvägen 3C
Box 13080
SE-402 52 Göteborg
Sweden

Single Registration Number: SE-PR-000016902

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2020-04-22**

Current Issue Date: **2023-06-05**

Starting Validity Date: **2023-06-05**

Expiry Date: **2025-04-21**

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EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 722506 R000

Device Schedule: Article 22.3 Systems and Procedure Pack

Device(s)	Highest Risk Classification within the System or Procedure Pack
(1) Angiographic Trays	Class III Class IIb Class IIa Class Is
(2) Arthroscopic Trays	Class III Class IIb Class IIa Class Is
(3) Cardiothoracic Trays	Class III Class IIb Class IIa Class Is
(4) ENT Trays	Class III Class IIb Class IIa Class Is
(5) General Purpose Trays	Class III Class IIb Class IIa Class Is
(6) Neurosurgical Trays	Class III Class IIb Class IIa Class Is
(7) Obstetrical/Gynaecological Trays	Class III Class IIb Class IIa Class Is

First Issue Date: **2020-04-22**

Current Issue Date: **2023-06-05**

Starting Validity Date: **2023-06-05**

Expiry Date: **2025-04-21**

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EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 722506 R000

Device(s)	Highest Risk Classification within the System or Procedure Pack
(8) Ophthalmic Trays	Class III Class IIb Class IIa Class Is
(9) Orthopaedic Trays	Class III Class IIb Class IIa Class Is
(10) Urological Trays	Class III Class IIb Class IIa Class Is
(11) Dental Trays	Class III Class IIb Class IIa Class Is
(12) Laparoscopic Trays	Class III Class IIb Class IIa Class Is
(13) Anaesthesia Trays	Class III Class IIb Class IIa Class Is
(14) Haemodialysis Trays	Class III Class IIb Class IIa Class Is
(15) Negative Pressure Wound Therapy Trays	Class IIa Class IIb
For Systems and Procedure Packs under Article 22.3, the Notified Body conformity assessment is limited to the aspects relating to ensuring sterility until the sterile packaging is opened or damaged.	

First Issue Date: **2020-04-22**

Current Issue Date: **2023-06-05**

Starting Validity Date: **2023-06-05**

Expiry Date: **2025-04-21**

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EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 722506 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
2020-04-22	3110440	First Issue.
Current	3732487	Supplemented – addition of Negative Pressure Wound Therapy Trays Amended – addition of certificate revision number R000, addition of SRN, addition of highest risk classifications, addition of subcontractor for packaging

First Issue Date: **2020-04-22**

Current Issue Date: **2023-06-05**

Starting Validity Date: **2023-06-05**

Expiry Date: **2025-04-21**

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Title: Mölnlycke Procedure Trays MDD Article 12 (former Class IIa trays)

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being the assembler of the following declare that the procedure packs listed in the attached schedule are in conformity with the provisions of Article 12 in the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade Name: *Mölnlycke® Procedure Trays*

The mutual compatibility of each device within the Mölnlycke Health Care procedure packs has been verified in accordance with the relevant instructions for use provided by the manufacturer of each device and / or the approved indications for use of each device.

Where appropriate, the relevant instructions for use are provided.

Procedure packs are assembled in accordance with a documented quality management system and therefore, subject to internal controls and inspection prior to release that ensures the safety, quality and performance of the procedure pack.

Sterilisation after assembly:	*EtO, Ethylene Oxide*
CE certificate	*CE 01966*
Certificate issued by	*BSi (0086)*

For sterilised procedure packs, the sterilisation process is performed in accordance with the manufacturer(s)' instructions and follows the procedures of Annex V of 93/42/EEC.

For systems and procedure packs, the intervention of the notified body is limited to the aspects of the procedure relating to the obtaining of sterility.

Signed for and on behalf of Mölnlycke Health Care

Authorised Signatory:

Name of signing person
RA Manager, Medical Devices

Product reference	Product Name	Product Description / included devices	GMDN code
See products linked to this document in the ERP system.			

Product name, article number, manufacturer and notified body number for each device included in the system or procedure pack can be found in the BOM in the ERP system.

Signed for and on behalf of Mölnlycke Health Care

Authorised Signatory:

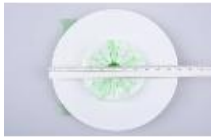
Name of signing person

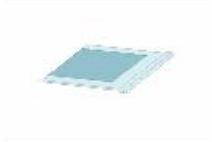
RA Manager, Medical Devices

Mölnlycke®

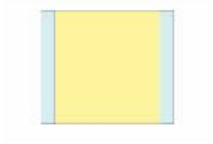
Tray ID	97095457
Tray name	SET CHIRURGICAL ABORD CEREBRAL
Speciality filter	NEUROSURGERY
Intervention filter	Craniotomy
Hospital filter	Tehnomedica SRL

	Description	Qty
	Crepe paper 60x60cm 60g/m2 White	1
	BNS Craniotomy Drape 230x300cm Inc. 30x20	1
	Adh. op towel 50x50cm	4
	Hand towel 18x25cm	2
	Op tape 9x49cm	1
	Suction And Diathermy Bag, 40x35 cm	1
	Neuro swab gauze 12,7x38,1mm	10
	Microscope Drape Zeiss 117 x 267cm	1

	Forceps Bipolar Bayonet	1
	Skin Stapler for Wound Closure	2
	Medicine/Specimen cup 120ml Polyethylene	1
	Scalpel blade CS N°22	1
	Plastic bag 20x30cm Ziplock Transp.	1
	Instrument cleaner 5x5cm	1
	Scalpel blade CS N°15	1
	Syringe 20ml L/L 3parts Conc.	3
	Light handle cover large Light green/white collar	2
	Suction Catheter 12Ch 50cm 2eyes Funnel str PVC Shore 70	1

	Mayo stand cover 79x145cm Abs.65x85cm	2
	Surg.glove latex 8.0 PF 2/1	2
	Surg.glove latex 8.5 PF 2/1	1
	Skin marker taper tip Violet	1
	Reinforced Table Cover 190 x280 wrapping	1
	SA Label 1,6 x 5cm Red TEHNOMEDICA SRL	1

Tray ID	97094658
Tray name	SET CHIRURGICAL ABORD SPINAL
Colour code	
Speciality filter	NEUROSURGERY
Intervention filter	Laminectomy/Spinal
Hospital filter	Tehnomedica SRL (245686)

	Description	Qty
	Adh. op sheet 240x150cm	1
	Op tape 9x49cm	1
	Adh. op sheet 175x175cm	1
	Incise drape 30x26cm Inc.30x20cm	1
	Suction And Diathermy Bag, 40x35 cm	2
	Crepe paper 60x60cm 60g/m2 White	1
	Adhesive op towel 90x75cm Reinf.	2

Hand towel 18x25cm 4

Neuro swab gauze 12,7x38,1mm 10

Medicine/Specimen cup 120ml Polyethylene Transp. Lid 1

Banded bag 140cm Circ. Elast. Transp. 1

Microscope Drape Zeiss 117 x 267cm 1

Scalpel blade CS N°11 1

Forceps Bipolar Straight 200mm 1

Scalpel blade CS N°22 1

Plastic bag 20x30cm Ziplock Transp. 1

Instrument cleaner 5x5cm 1

– 	Syringe 20ml L/L 3parts Conc.	3
– 	Light handle cover large Light green/white collar	2
– 	Suction Catheter 12Ch 50cm 2eyes Funnel str PVC Shore 70	1
– 	Mayo stand cover 79x145cm Abs.65x85cm	3
	Surg.glove latex 8.0 PF 2/1	2
	Surg.glove latex 8.5 PF 2/1	1
	Skin marker taper tip Violet	1
– 	Reinforced Table Cover 190 x280 wrapping	1
– 	SA Label 1,6 x 5cm Red TEHNOMEDICA SRL	1