

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

DECLARAȚIE privind valabilitatea ofertei

Către **IMSP Institutul de Medicină Urgentă**

Stimați domni,

Ne angajăm să menținem oferta valabilă, privind achiziționarea Produselor parafarmaceutice - 2023 (2), prin procedura de achiziție LD nr. ocds-b3wdp1-MD-1699270200588, ID: 21114426 din 27.11.2023, pentru o durată de 60 zile (șaizeci zile), respectiv până la data de 30.01.2024 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 24.11.2023

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)



I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților 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 și codul fiscal: **1002600053256.**

Data înregistrării de stat: **17.04.2002.**

Sediul: **MD-2001, str. Ciuflea, 38/1, mun.Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1 Fabricarea utilajului medical și chirurgical și a dispozitivelor ortopedice;**
- 2 Comerțul cu ridicata al produselor farmaceutice;**
- 3 Comerțul cu amănuntul al produselor farmaceutice;**
- 4 Practica medicală;**
- 5 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 6 Activități de consultare pentru afaceri și management.**

Capitalul social: **5400 lei.**

Administrator: ROIBU TATIANA,

Asociați:

- 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 și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 01.02.2019.

Specialist coordonator
tel. 022-20-7838



Clichici Elena



EB 0257484



GUVERNUL
REPUBLICII
MOLDOVA



SERVICIUL FISCAL DE STAT



CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr.
Nº

Din
От

1

DATE DESPRE CONTRIBUABIL/ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal/Numărul de identificare

Фискальный код/Идентификационный номер

Denumirea

Наименование

2

ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI INFORMAȚIONAL AUTOMATIZAT/ПОДТВЕРЖДЕНИЕ ОТСУТСТВИЯ ИЛИ НАЛИЧИЯ НЕДОИМКИ СОГЛАСНО ДАННЫХ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie/На дату выдачи данной справки, недоимка перед национальным публичным бюджетом составляет

lei/лей

3

VALABIL PÂNĂ LA/ДЕЙСТВИТЕЛЕН ДО



Prezentul certificat este eliberat în temeiul Art. 131, alin. (5³) din Codul fiscal nr. 1163/1997, în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Antreprenorului/Сертификат выдан в соответствии со ст. 131, п. (5³) Налогового кодекса №1163/1997, на основании данных, предоставленных Государственной налоговой службой на Портале Правительства Предпринимателя

Generat și semnat de Portalul Guvernamental al Antreprenorului (<https://mcabinet.gov.md>) la

Prezentul certificat este semnat electronic în conformitate cu Legea nr. 124 din 19.05.2022 /
Сертификат подписан электронной подписью в соответствии с Законом № 124 от 19.05.2022

Certificatul este descărcat de pe Portalul Guvernamental al Antreprenorului (<https://mcabinet.gov.md>) și este semnat electronic de către posesorul acestui portal și are aceeași 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 la adresa: <https://msign.gov.md>.

Сертификат выгружен с Правительственного Портала Предпринимателя (<https://mcabinet.gov.md>) и подписан электронной подписью владельца портала и имеет такую же юридическую силу, как и документы, выдаваемые на бумаге органами налоговой администрации.
Проверку подлинности электронной подписи можно осуществить по адресу: <https://msign.gov.md>.

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.S.
Numele, Prenumele si Semnatura
Director sucursalei „Gheorghe Mocanu”



Executor :Eduard Cilcic
Tel: 022-812-150

TEHNOMEDICA

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Către IMSP Institutul de Medicină Urgentă

În atenția Grupului de lucru
al procedurii nr. ocds-b3wdp1-MD-1699270200588,
ID: 21114426

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 preonate privind achiziționarea produselor parafarmaceutice 2023.

Cu respect,

Director

Tatiana Roibu

TEHNOMEDICA

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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-1699270200588,
ID: 21114426

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.

DM000465401	SET PENTRU PROCEDURI ORTOPEDICE	97128849	Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDICA S.R.L.	Rg04- 000075
DM000375989	SET PENTRU PROCEDURI CHIRURGICALE	669600	Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDICA S.R.L.	Rg04- 000236
DM000465403	SET PENTRU PROCEDURI ORTOPEDICE	97128754	Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDICA S.R.L.	Rg04- 000075

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



Page: 1 of 1

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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:

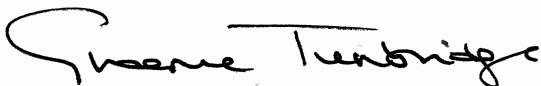
Gamlestadsvägen 3C
Box 13080
SE-402 52 Göteborg
Sweden

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

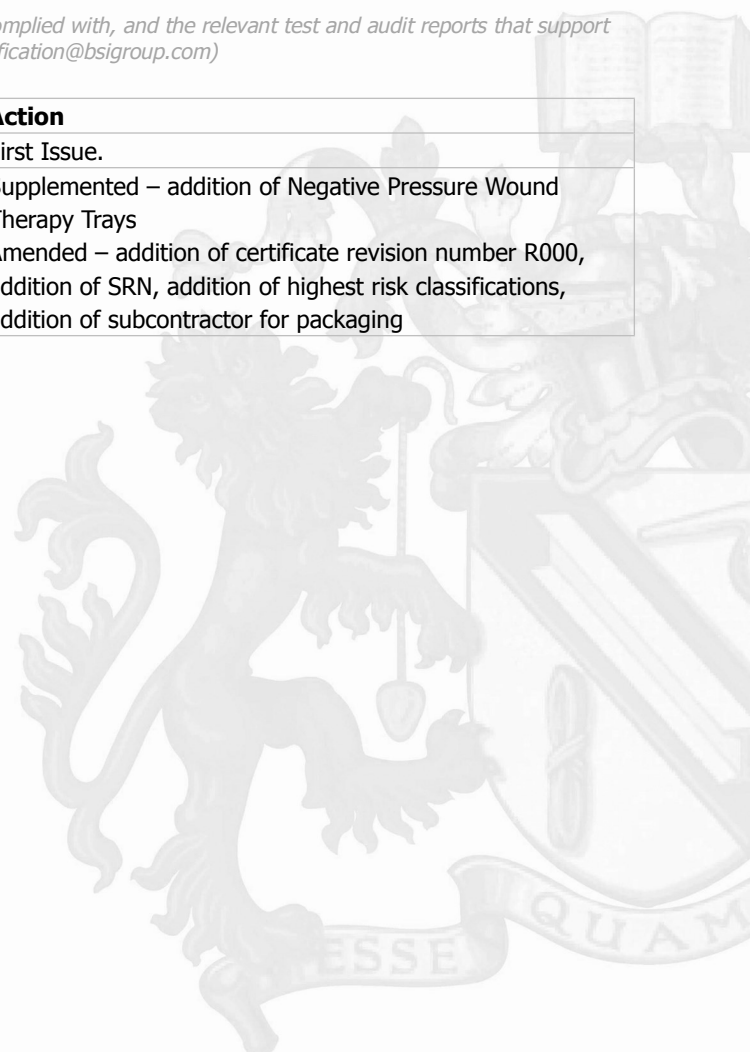
Regulation (EU) 2017/745, Annex XI Part A

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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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.

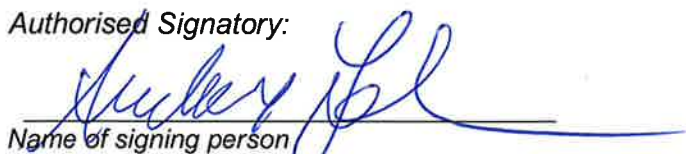
Sterilisation after assembly:	<i>EtO, Ethylene Oxide</i>
CE certificate	<i>CE 01966</i>
Certificate issued by	<i>BSi (0086)</i>

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

This document has been printed by the PRIME system. The validity of this document cannot be guaranteed.

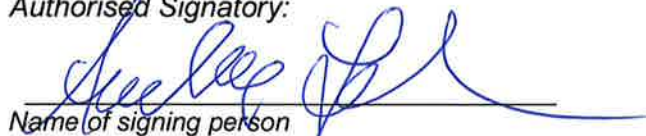
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Product reference	Product Name	Product Description / included devices	GMDN code
See products linked to this document in the ERP system.			

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

Tray ID 97128849
 Tray name Set coxo-femoral, steril
 Speciality filter ORTHOPAEDIC
 Intervention filter Hip replacement
 Hospital filter Tehnomedica SRL

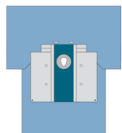
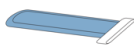
	Description	Qty
	Crepe paper 60x60cm 60g/m2 White	1
	BNS Hip Drape w/dislocation bags 220/300x340cm Ap. 18x22cm elastic	1
	Incise drape 40x40cm Inc.40x34cm	1
	Adh. op towel 75x75cm	2
	Impervious stockinette 32x120cm	1
	Op tape 9x49cm	2
	Tube holder 2,5x30cm Velcro/Adh	1



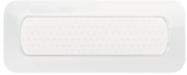
Table cover 150x190cm Abs.75x190cm Folded

1



Sharp container 500ml Aspen Basin

1



MEPILEX BORDER POST OP 10 x 25cm

1



Gauze lap 45x45cm 20Th 4P Loop XRD White Pre-washed

2



Suture Vicryl Plus 1 CT1 1/2c 36mm Taperpoint 90cm Undyed

1



Plastic bag 20x30cm Ziplock Transp.

1



Skin marker taper tip Violet

1



Suture Vicryl Plus 2-0 Violet

1



BNS Mayo Stand Cover 79x145 cm Reinforced

1



BNS Surgical Gown UL HP XXL

2



Reinforced Table Cover 150 x 190 wrapping

1



Crepe paper 60x60cm 60g/m2 White

1



Surgical gown Classic Standard Performance L 121cm

1



Surgeons hood with sweatband one-size (tie-band) green

3



SA Label 1,6 x 5cm Red TEHNOMEDICA SRL

1

669600 Acute Thoracic Set

Product details

Sterile : Sterile

Brand : BARRIER

Images



Products included in set

Product ID	Quantity	Product name	Size	Product description
996109	1	Reinforced Mayo Stand Cover	79cm x 145cm	Absorbent
	1	Perineal Cover	40x17cm	
	6	Cellulose Towel	18cm x 25cm	
824098	2	Tube Holder	2.5cm x 30cm	Adhesive, Velcro
910598	1	Adhesive OP-Towel	75cm x 75cm	3PLY, Adhesive
	1	Defibrillator Bag	38x33cm	
911500	2	OP-Tape	9cm x 49cm	Adhesive
966960	1	Acute Thoracic Drape	200cm / 300cm x 350cm, Incise 37x65cm	Incise film, Patched, Pouch
90240	1	Table Cover	150cm x 240cm	Absorbent

Delivered items

Find out more at www.molnlycke.com

Mölnlycke Health Care AB, Box 13080, Gamlestadsvägen 3 C, SE-402 52 Göteborg, Sweden. Phone +46 31 722 30 00.
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Tray ID 97128754

Tray name Set genunchi, steril

Speciality filter ORTHOPAEDIC

Intervention filter Knee replacement

Hospital filter Tehnomedica SRL

	Description	Qty
	Crepe paper 60x60cm 60g/m2 White	1
	Knee Arthroscopy Drape 220x320cm, ap.7cm	1
	Incise drape 30x26cm Inc.30x20cm	1
	Sharp container 500ml Aspen Basin	1
	BNS Adhesive OP-Towel 90x75 cm ISCC	2
	Suction And Diathermy Bag, 40x35 cm	2
	Skin marker regular tip Violet	1



Impervious stockinette 22x75cm 1



BNS Mayo Stand Cover 79x145 cm Reinforced 1



Reinforced Table Cover 190 x280 wrapping 1



Surgeons hood with sweatband one-size (tie-band) green 3



SA Label 1,6 x 5cm Red TEHNOMEDICA SRL 1

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