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 **IMSP „Spitalul Clinic Bălți"**

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-1674572129267, ID: 21072242 din 24.01.2023 privind aplicarea procedurii pentru atribuirea contractului privind *achiziționarea articolelor parafarmaceutice pentru anul 2023*, 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: 29.03.2023

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)

Digitally signed by Roibu Tatiana
Date: 2023.03.29 17:35:45 EEST
Reason: MoldSign Signature
Location: Moldova

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 „Spitalul Clinic Bălți”**

Stimaţi domni,

Ne angajăm să menținem oferta valabilă, privind achiziționarea articolelor parafarmaceutice pentru anul 2023, prin procedura de achiziție licitație deschisă, pentru o durată de 90 zile (nouăzeci zile), respectiv până la data de 03.07.2023 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 29.03.2023

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

DIRECȚIA GENERALĂ COMERȚ, ALIMENTAȚIE PUBLICĂ ŞI PRESTĂRI SERVICII

NOTIFICARE NR. P-12697/2020 DIN 22.07.2020

Valabila de la: ***22.07.2020*** *Pina la:* ***NELIMITAT***

Eliberat pentru

Denumire companie: **TEHNOMEDICA**, Societate cu răspundere limitată

Detalii suplimentare

CAEM

G.46.46

depozit;

SEC.CENTRU, Ciuflea str., nr. 38/1

suprafața comercială: 31,2 m^2

cu program de lucru: 09:00 – 17:00

zile de odihnă: Sîmbătă, Duminică

https://comert.chisinau.md/autorizatii.php?l=ro

Anexa nr.7.2 la Instrucțiunea
aprobată prin ordinul IFPS
nr. 400 din 14 martie 2014

CC 04 AE

CERTIFICAT
privind lipsa sau existenţa restanţelor faţă de bugetul public naţional

Nr. № A2304879 **din** от 29.03.2023

1. Destinația / Назначение

PENTRU PARTICIPAREA LA PROCEDURI PRIVIND ACHIZIȚIILE PUBLICE

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea Наименование	**Codul fiscal / Numărul de identificare** Фискальный код / Идентификационный номер
TEHNOMEDICA S.R.L.	1002600053256
Adresa sediului de bază (strada, numărul) Адрес основного месторасположения (улица, номер)	**Codul - Denumirea localității** Код - Наименование населенного пункта
Ciuflea nr.38 bl.1	0130-SEC.CENTRU

3. 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: **0,00** lei/лей.

4. Valabil pînă la / Действителен до 13.04.2023

5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы

Digitally signed by Muntean Iuliana
Date: 2023.03.29 16:51:40 EEST
Reason: MoldSign Signature
Location: Moldova

Șef interimar Direcție — **Funcția**/Должность
Semnătura/Подпись
Elena TÎRSÎNA — **Numele și prenumele**/Фамилия и имя

L.Ș/ М.П.

Executor: FODOR V.
Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 29.03.2023 ora 15:22:03 cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (100,54)

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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By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 722028 R000

Manufacturer: Mölnlycke Health Care AB

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

Single Registration Number: SE-MF-000014042

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

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 Issued: **2020-05-08** Date: **2022-07-13** Expiry Date: **2025-05-07**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 722028 R000

Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
Gelling fibre dressing with silver	See MDR 722078
Soft silicone foam dressing with silver	See MDR 722079
Self-adherent soft silicone foam dressing with silver	See MDR 758927
Soft silicone exudate transfer dressing with silver	See MDR 758929
Saline dressing	See MDR 722077

Class IIb	Intended purpose
Self-adherent soft silicone multi-layer foam dressing	Management of exuding wounds Protection of compromised and/or fragile skin May be used as part of a prophylactic therapy to prevent skin damage and to reduce postoperative blistering May be used on dry necrotic wounds in combination with gels
Self-adherent soft silicone flexible foam dressing	Management of exuding wounds Protection of compromised and/or fragile skin May be used as part of a prophylactic therapy to prevent skin damage and to reduce postoperative blistering May be used on dry necrotic wounds in combination with gels
Self-adherent soft silicone foam dressing - lite	Management of non/low exuding wounds Protection of compromised and/or fragile skin
Self-adherent soft silicone flexible foam dressing - lite	Management of non/moderately exuding wounds Protection of compromised and/or fragile skin
Soft silicone foam dressing	Management of exuding wounds Protection of compromised and/or fragile skin May be used as part of a prophylactic therapy to prevent skin damage
Soft silicone foam dressing with channels	Management of exuding wounds
Soft silicone foam dressing - lite	Management of non/low exuding wounds Protection of compromised and/or fragile skin

First Issued: **2020-05-08** Date: **2022-07-13** Expiry Date: **2025-05-07**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 722028 R000

Class IIb	Intended purpose
Soft silicone exudate transfer dressing	Management of exuding wounds Protection of compromised and/or fragile skin
Soft silicone wound contact layer	Non-adherent Allows passage of exudate and provides protection of tissues
Saline topical irrigation solution	Topical irrigation, wound cleansing, irrigation of mucous membranes and rinsing of eyes
Alginate dressing	Moderately to heavily exuding wounds, infected and non-infected such as pressure sores, venous and arterial ulcers, diabetic ulcers, post-operative sounds, dermal lesions and other external wounds inflicted by trauma
Adhesive dressing with absorbent pad	To absorb, protect and maintain a moist wound healing environment in open and closed wounds Intended for low to moderately exuding wounds
Gelling fibre dressing	Intended for exuding wounds: leg and foot ulcers, pressure ulcers, partial thickness burns, surgical wounds, donor sites and malignant wounds
Thermic drape	Intended to help prevent the patient from cooling during the perioperative period
Absorbent / superabsorbent dressing	Moderately to heavily exuding wounds As a primary or secondary dressing where high absorbency is required

First Issued: **2020-05-08** Date: **2022-07-13** Expiry Date: **2025-05-07**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 722028 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Self-adherent soft silicone surgical dressing	Class IIa
Adhesive dressing with absorbent pad	Class IIa
Surgical gloves - natural rubber latex	Class IIa
Surgical gloves - polychloroprene	Class IIa
Surgical gloves - polyisoprene	Class IIa
Film dressing	Class IIa
Film dressing, non-adherent	Class IIa
Transparent adhesive IV film dressings	Class Is
Surgical gowns	Class Is
Swabs and sponges	Class Is
Scar management dressings	Class Is
Surgical and equipment drapes	Class Is
Examination gloves	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile condition	

First Issued: **2020-05-08** Date: **2022-07-13** Expiry Date: **2025-05-07**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 722028 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
08 May 2020	3110440	First Issue.
17 December 2021	3331670	Change to address of Siam Steri Services. Addition of Radiation (Gamma Sterilization) to activities for Siam Steri Services
22 April 2021	3406750	Amended - Addition of critical subcontractor STERIS TOMOE (Thailand) Ltd for Radiation (Gamma Sterilization) Amended - Removal of critical subcontractor Steris Applied Sterilisation Technologies, Swindon Amended - Addition of critical subcontractor Synergy Health Sterilisation UK Ltd, Bradford for Radiation (Gamma Sterilization)
03 May 2021	3426520	Supplemented – addition of device category: Absorbent post-operative wound dressings Amended – addition of Sterigenics Belgium (Petit-Rechain) SA for ETO Sterilization
08 July 2021	3479391	Supplemented – addition of device self-adherent soft silicone multi-layer foam dressing Supplemented – addition of device self-adherent soft silicone flexible foam dressing Supplemented – addition of device self-adherent soft silicone foam dressing - lite Supplemented – addition of device self-adherent flexible foam dressing - lite Supplemented – addition of device soft silicone foam dressing Supplemented – addition of device soft silicone dressing with channels Supplemented – addition of device soft silicone foam dressing - lite Supplemented – addition of device soft silicone exudate transfer dressing Supplemented – addition of device saline topical irrigation solution Amended – addition of Sterigenics North Carolina for ETO sterilization Amended - addition of Molnlycke Manufacturing, Brunswick for Manufacture Amended - addition of Moist Heat Sterilization for services supplied by Mölnlycke Health Care, Oldham Amended - update device schedule description for post-operative dressing to self-adherent soft silicone surgical dressing

First Issued: **2020-05-08** Date: **2022-07-13** Expiry Date: **2025-05-07**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 722028 R000

Date	Reference number	Action
23 September 2021	3496354	Supplemented – addition of gelling fibre dressing with silver Supplemented – addition of surgical gloves, natural rubber latex Supplemented – addition of surgical gloves, polychloroprene Supplemented – addition of surgical gloves, polyisoprene Amended – addition of packaging for services supplied for Mölnlycke Oldham Amended – addition of Freudenberg for manufacturing Amended – addition of Colonial metals as a Crucial Supplier of medicinal substance Amended – addition design for Mölnlycke, Lot 9, Malaysia and Mölnlycke, Lot B5 & B6, Malaysia Amended – addition of design, packaging and final inspection for Mölnlycke, Plot 204 Malaysia
07 December 2021	3551783	Supplemented – addition of alginate dressing Amended – addition of critical subcontractor Foshan United Medical Technologies for manufacture and control of sterilization Amended – addition of critical subcontractor Synergy Health Ede BV for irradiation (x-ray sterilization)
18 January 2022	3598641	Supplemented – addition of adhesive dressing with absorbent pad and soft silicone wound contact layer Amended – minor correction to intended purpose for self-adherent soft silicone flexible foam dressing – lite
18 February 2022	3617621	Supplemented – addition of soft silicone foam dressing with silver Supplemented – addition of self-adherent soft silicone foam dressing with silver Supplemented – addition of soft silicone exudate transfer dressing with silver Supplemented – addition of adhesive dressing with absorbent pad (Class IIa) Amended – subcontractors: change of address for two Mölnlycke Thailand sites and addition of Mölnlycke Manufacturing, Wiscasset
30 March 2022	3638164	Supplemented – addition of saline dressing & gelling fibre dressing. Amended – addition of critical subcontractors Dansk & SteriServices.
09 May 2022	3675862	Supplemented – addition of thermic drape, film dressing & film dressing, non-adherent

First Issued: **2020-05-08** Date: **2022-07-13** Expiry Date: **2025-05-07**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 722028 R000

Date	Reference number	Action
Current	3719023	Supplemented – addition of absorbent / superabsorbent dressing Amended – addition of critical subcontractors Winner Medical (Jiayu) and Winner Medical (Chongyang), 9A

First Issued: **2020-05-08** Date: **2022-07-13** Expiry Date: **2025-05-07**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 01965**

Issued To: **Mölnlycke Health Care AB**
Box 13080
Gamlestadsvägen 3C
SE-402 52 Göteborg
Sweden

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **1998-06-29** Date: **2018-05-30** Expiry Date: **2023-06-28**

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By Royal Charter

Certificate No: CE 01965

Certificate Scope:

The design and manufacture of sterile medicated and non-medicated open wound products:

- **Adhesive bandage and dressing**
- **Exudate-absorbent dressing, hydrophilic-gel (alginate and gel fibre**
- **Exudate-absorbent dressing, non-gel (absorbent,superabsorbent,foam)**
- **Semi-permeable film dressing, wound-nonadherent**
- **Semi-permeable film dressing**
- **Sterile wound irrigation solutions**
- **Wound-nonadherent dressing, absorbent**
- **Wound-nonadherent dressing, permeable**
- **Wound dressing with silver salt**
- **Wound dressing with sodium salt**
- **Wound dressing with porcine collagen**

The design and manufacture of non-sterile emollient creams, self-warming blankets and negative pressure wound therapy (NPWT) system, pumps and accessories.

The design and manufacture of sterile suction irrigation sets, veress needles, trocars, laparoscopic instruments, endo retrieval pouches, XRD swabs and sponges.

The manufacture of sterile surgical gloves.

First Issued: **1998-06-29** Date: **2018-05-30** Expiry Date: **2023-06-28**

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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 „Spitalul Clinic Bălți"

În atenția Grupului de lucru
al LD nr. ocds-b3wdp1-MD-1674572129267,
ID: 21072242 din 31.03.2023

Declarație privind înregistrarea dispozitivelor medicale

Prin prezenta, declarăm că produsele oferite în cadrul licitației deschise 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.

DM000239405	PANSAMENT STERIL ABSORBANT RADIOOPAC	187805	Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDICA S.R.L.	Rg04-000253	2019-08-10
DM000239401	PANSAMENT STERIL ABSORBANT RADIOOPAC	187605	Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDICA S.R.L.	Rg04-000253	2019-08-10
DM000375929	MĂNUȘI CHIRURGICALE STERILE	82270	Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDICA S.R.L.	Rg04-000236	2022-06-10
DM000375930	MĂNUȘI CHIRURGICALE STERILE	82275	Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDICA S.R.L.	Rg04-000236	2022-06-10
DM000375931	MĂNUȘI CHIRURGICALE STERILE	82280	Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDICA S.R.L.	Rg04-000236	2022-06-10
DM000375932	MĂNUȘI CHIRURGICALE STERILE	82285	Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDICA S.R.L.	Rg04-000236	2022-06-10
DM000375933	MĂNUȘI CHIRURGICALE STERILE	82290	Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDICA S.R.L.	Rg04-000236	2022-06-10

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 „Spitalul Clinic Bălți"

În atenția Grupului de lucru
al LD nr. ocds-b3wdp1-MD-1674572129267,
ID: 21072242 din 31.03.2023

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că vom prezenta mostre în decurs de 5 zile lucrătoare de la solicitarea autorității contractante pentru produsele oferite în cadrul procedurii prenonate privind achiziționarea **articolelor parafarmaceutice pentru anul 2023.**

Cu respect,

Director Tatiana Roibu

APROBAT
prin Ordinul
Ministrului Finanțelor
nr. 145 din 24 noiembrie 2020

DECLARAŢIE
privind confirmarea identității beneficiarilor efectivi și neîncadrarea acestora în situația condamnării pentru participarea la activităţi ale unei organizaţii sau grupări criminale, pentru corupţie, fraudă şi/sau spălare de bani.

Subsemnatul(a), Tatiana Roibu, reprezentant împuternicit al „Tehnomedica” SRL în calitate de ofertant/ofertant asociat desemnat câștigător în cadrul procedurii de achiziție publică nr. ocds-b3wdp1-MD-1674572129267, ID: 21072242 din 31.03.2023 declar pe propria răspundere, sub sancţiunile aplicabile faptei de fals în acte publice, că beneficiarul/beneficiarii efectivi ai operatorului economic în ultimii 5 ani nu au fost condamnați prin hotărâre judecătorească definitivă pentru participarea la activităţi ale unei organizaţii sau grupări criminale, pentru corupţie, fraudă şi/sau spălare de bani.

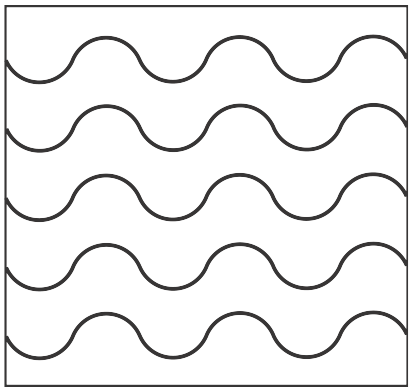
Numele și prenumele beneficiarului efectiv	IDNP al beneficiarului efectiv
Tatiana Roibu	0992606484592

Data completării: 29.03.2023
Semnat: electronic
Nume/prenume: Tatiana Roibu
Funcţia: Director
Denumirea operatorului economic: Tehnomedica SRL
IDNO al operatorului economic: 1002600053256

Tampoane si bureti detectabili la raze X

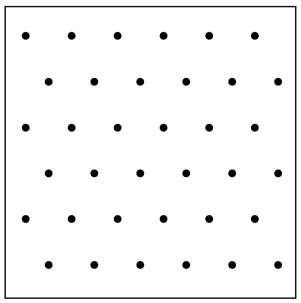
Prosoape ansorbante abdominale din material netesut, 130 g

187605	Prosop abdominal, 10x60cm, 5buc	40 / 240
187802	Prosop abdominal, 40x40cm, 2buc	24 / 144
187805	Prosop abdominal, 40x40cm, 5buc	25 / 150
187901	Prosop abdominal, 40x60cm, 5buc	14 / 84



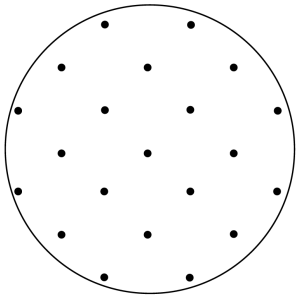
Tampoane abdominale din material netesut – standard, 70 g

185060	Tampon abdominal 10x40cm, 5buc	125 / 750
185460	Tampon abdominal 30x40cm, 5buc	45 / 270
185830	Tampon abdominal 40x65cm, 1buc	30 / 180



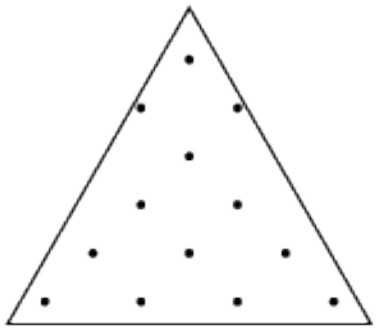
Bureti abdominali din material netesut – standard, 40 g

154160	Burete No1, 5buc	175 / 1050
154360	Burete No3, 5buc	150 / 900
154460	Burete No4, 5buc	75 / 450
154560	Burete No5, 5buc	75 / 450



Comprese abdominale din material netesut – standard, 70 g

185305	impachetat 6 straturi, 10x10cm, 5buc	90 / 540
185405	impachetat 6 straturi, 10x20cm, 5buc	90 / 540



Latex
Biogel® Surgeons

The Biogel® Surgeons is a sterile, latex surgical glove with excellent barrier protection. The unique Biogel® coating provides great fit, feel and comfort and makes the glove easy to don, even with damp hands.

ACTUAL COLOUR REF 822

Biogel® key features and benefits

- 9/10 surgeons prefer Biogel for fit, feel and comfort[1]
- Reduced chance of a hole with an industry-leading AQL* result of 0.65[1]
- Every glove (100%) is air inflation tested and visually inspected for quality and safety[1]
- Improved efficiency as less gloves are wasted[2]
- Non-pyrogenic, potentially reducing the risk of post-operative complications[3]

Recommended use

Recommended for all surgical procedures.

Material information

- Natural rubber latex
- Micro-roughened surface
- Biogel hydrogel polymer coating
- Beaded cuff
- Powder-free
- Non-pyrogenic

Biogel quality

Biogel has an industry leading freedom from holes AQL* of 0.65. The industry standard requirement for AQL* is 1.5. The lower the number, the fewer the holes and the higher the quality of glove. Biogel is proven to have the lowest glove failure rate among major competitors. Non-Biogel gloves are at least 3.5 times as likely to fail than Biogel gloves[2].

Re-order REF 822

REF	Size	Pairs
82255	5½	50/Box
82260	6	50/Box
82265	6½	50/Box
82270	7	50/Box
82275	7½	50/Box
82280	8	50/Box
82285	8½	50/Box
82290	9	40/Box

4 boxes per case

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Product specifications Biogel® Surgeons gloves REF 822

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
82255	5.5	283	71
82260	6.0	285	77
82265	6.5	285	85
82270	7.0	288	91
82275	7.5	298	96
82280	8.0	299	103
82285	8.5	301	109
82290	9.0	301	115

Pairs per box: 50/40 for size 9

Typical thickness profile – single wall		
Cuff	8.1 mils	0.21 mm
Palm	10.0 mils	0.26 mm
Finger	10.6 mils	0.27 mm

Physical glove properties	Standard requirement	Biogel
Force at break (N) (EN455) Initial Aged	 ≥9 ≥9	 19 17
Typical accelerator analysis % w/w Dithiocarbamate (DTC)	n/a	<0.02
Diphenyl thiourea (DPTU)	n/a	none
Diphenyl guanidine (DPG)	n/a	none
Zinc mercaptobenzothiazole (ZMBT)	n/a	none
Thiurams	n/a	none
Typical extractable protein (using Modified Lowry EN455/ ASTM D5712)	<50µg/g	<20µg/g
AQL* freedom from holes (1000 ml water leak test) Post packing and irradiation Process average typically	1.5	0.65 <0.20%
Grip (Measure of the surface grip. Scale of 1-5, the higher the value, the greater the level of drag)	n/a	1.0

General information

Contra-indications: This product contains natural rubber latex which may cause allergic reactions including anaphylactic responses.

Allergenicity: Biogel gloves are produced to have low levels of aqueous extractable protein and have been shown to have a low potential for inducing allergic contact dermatitis or 'Type IV allergy'.

Pyrogenicity: Each batch of Biogel gloves is tested to have a low endotoxin level (<20 EU/pair).

Product standards: Biogel gloves are tested and manufactured to the following standards:

- **Quality/Environmental:** ISO 9001, ISO 13485, ISO 14001
- **Product:** ASTM D3577, EN455-1, EN455-2, EN455-3, EN455-4
- **Sterilisation:** Gamma irradiation
- **Viral Penetration:** Bacteriophage test, ASTM F1671
- **Allergenicity/Pyrogenicity:** ISO 10993 (PART 5 and 10)

Registering authority: In Europe the gloves are CE marked (notified body BSi, number 0086) indicating compliance with Council Directive 93/42/EEC. In US the gloves are FDA registered. Biogel Surgical gloves are a Class IIa Product.

Storage: Store in a cool, dry place away from sources of heat or direct sunlight.

Packaging: One pair per pack, in a high quality inner wrap, packed into a film pack (constructed of a laminate of polyester and low-density polyethylene). 50 pairs per collation case for sizes 5.5–8.5; 40 pairs for size 9.0; 200 pairs per transit case for sizes 5.5–8.5; 160 pairs for size 9.0.

Disposal: Gloves & outer wrap dispose of as clinical waste. Paper inner wrap, collation case & transit case can be recycled as paper or disposed of as clinical waste.

Shelf life: Five (5) years from date of manufacture.

Manufacturer: Made and packed in Malaysia by Mölnlycke Health Care Sdn Bhd.

Country of origin: Malaysia.

E-mail address: biogel@molnlycke.com

Date of issue: May 2012.

References: 1. Why Choose Biogel. MKT004. 2009. Data on file. 2. In Use Surgical Glove Failure Rate Comparison. Study G009-005. 2009. Data on file. 3. Biogel Endotoxin Report, Non-Pyrogenic Surgical Gloves. REPRHJV004. 2010. Data on file.

*AQL=Acceptable Quality Level refers to the maximum number of defective products that could be considered acceptable during the random sampling of an inspection, in this case freedom from holes in gloves.

Find out more at www.molnlycke.com

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