

# **TEHNOMEDICA**

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

Anexa nr. 7  
la Documentația standard nr.115  
din 15.09.2021

## **CERERE DE PARTICIPARE**

Către **Centrul pentru Achiziții Publice Centralizate în Sănătate**

**Stimați 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-1651213449314, ID: 21055803 privind aplicarea procedurii pentru atribuirea contractului privind achiziționarea consumabilelor pentru serviciu aritmologie (electrocardiostimulare), conform necesităților IMSP SCM Sfânta Treime, pentru anul 2022, 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: 10.05.2022

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)

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Anexa nr. 8  
la Documentația standard nr.115  
din 15.09.2021

## **DECLARAȚIE privind valabilitatea ofertei**

Către **Centrul pentru Achiziții Publice Centralizate în Sănătate**

**Stimați domni,**

Ne angajăm să menținem oferta valabilă, privind achiziționarea consumabilelor pentru serviciu aritmologie (electrocardiostimulare), conform necesităților IMSP SCM Sfânta Treime, pentru anul 2022 prin procedura de achiziție COP, pentru o durată de 40 zile, (patruzeci zile), respectiv până la data de 22.06.2022 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 10.05.2022

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)

REPUBLICA



MOLDOVA

# CERTIFICAT DE ÎNREGISTRARE

**SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TEHNOMEDICA"**  
**ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT**

*Numărul de indentificare de stat - codul fiscal*

**1002600053256**

*Data înregistrării*

**17.04.2002**

*Data eliberării*

**16.02.2005**

**Bolboceanu Adela, registrator de stat**

*Funcția, numele, prenumele persoanei  
care a eliberat certificatul*

*semnătura*

**MD 0027040**



# **LISTA FONDATORILOR SRL TEHNOMEDICA**

***Fondator unic: Roibu Tatiana***

***IDNP: date cu caracter personal***

# ***TEHNOMEDICA***

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

**Către Centrul pentru Achiziții Publice  
Centralizate în Sănătate**

În atenția Grupului de lucru  
al COP nr. ocds-b3wdp1-MD-1651213449314,  
ID: 21055803

## **Declarație privind termenul de valabilitate**

Prin prezenta, declarăm că termenul de valabilitate la momentul livrării a produselor oferite în cadrul procedurii preonate privind **achiziționarea consumabilelor pentru serviciu aritmologie (electrocardiostimulare), conform necesităților IMSP SCM Sfânta Treime, pentru anul 2022** va constitui cel puțin 80% din termenul total de valabilitate a acestora, dar nu mai mic de 12 luni.

Cu respect,

Director

Tatiana Roibu

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e-mail <[tehnomedica\\_md@yahoo.com](mailto:tehnomedica_md@yahoo.com)> <[tehnomedicamd@gmail.com](mailto:tehnomedicamd@gmail.com)>

**Către Centrul pentru Achiziții Publice  
Centralizate în Sănătate**

În atenția Grupului de lucru  
al COP nr. ocds-b3wdp1-MD-1651213449314,  
ID: 21055803

## **Declarație privind disponibilitatea prezentării mostrelor**

Prin prezenta, declarăm că vom prezenta mostre în decurs de 5 zile de la solicitarea autorității contractante/beneficiarului pentru produsele oferite în cadrul licitației preonate privind **achiziționarea consumabilelor pentru serviciu aritmologie (electrocardiostimulare), conform necesităților IMSP SCM Sfânta Treime, pentru anul 2022.**

Cu respect,

Director

Tatiana Roibu

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**Către Centrul pentru Achiziții Publice  
Centralizate în Sănătate**

În atenția Grupului de lucru  
al COP nr. ocds-b3wdp1-MD-1651213449314,  
ID: 21055803

## **Declarație privind înregistrarea 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](http://www.amdm.gov.md)

Cu respect,

Director

Tatiana Roibu



**CERTIFICAT**  
**privind lipsa sau existența restanțelor față de bugetul public național**

Nr.  
№ **A2208050**

din  
от **04.05.2022**

**1. Destinația / Назначение**

AGENȚIA ACHIZIȚII PUBLICE

**2. Date despre contribuabil / Информация о налогоплательщике**

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

**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 19.05.2022**

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

Șef DDF CENTRU Funcția/Dолжность	 Semnătura/Подпись	Veronica IASINSCHI Numele și prenumele/Фамилия и имя
L.S./ М.П. Executor: Fodor V. Numele și prenumele/Фамилия и имя		

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 04.05.2022 ora 10:47:56  
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,09)



# 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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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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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Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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.

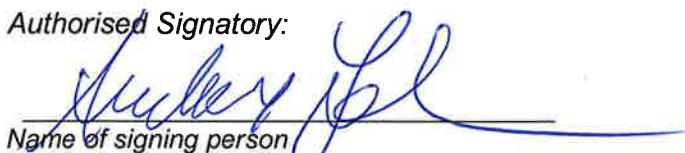
Sterilisation after assembly:	<i>EtO, Ethylene Oxide</i>
CE certificate	<i>CE 01966</i>
Certificate issued by	<i>BSi (0086)</i>

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

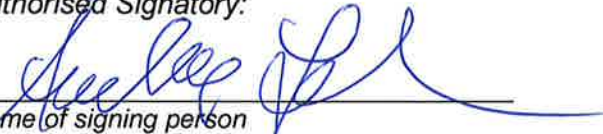
Page 2(2)

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

# 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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# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 9001:2000

*This is to certify that:*

**Mölnlycke Health Care AB**  
**Gamlestadvägen 3 C**  
**S-402 52**  
**Göteborg**  
**Sweden**

*Holds Certificate No:* **FM 39247**

*and operates a Quality Management System which complies with the requirements of ISO 9001:2000 for the following scope:*

The design, development and manufacture of sterile wound and scar dressings, open wound products, wound management gels, cavity dressings, swabs, sponges, sterile alcohol wipes, skin care products, non sterile textile bandages and supports, sterile wound irrigation solutions, abdominal towels, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and other medical staff clothing for use in the patient environment, sterile and non sterile medical gloves and sterile surgical gloves.

The design, development and manufacture of pharmaceuticals and other healthcare products.

*For and on behalf of BSI:*

*Managing Director, BSI Management Systems (CEMEA)*

Originally registered: **31/03/1998**

Latest Issue: **10/01/2007**



Page: 1 of 3

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The British Standards Institution is incorporated by Royal Charter.  
Management Systems (CEMEA) Headquarters: 389 Chiswick High Road, London, W4 4AL, United Kingdom





Certificate No: **FM 39247**

**Location**

**Registered Activities**

Mölnlycke Health Care AB  
Gamlestadsvägen 3 C  
S-402 52 Göteborg  
Sweden

The design, development and manufacture of sterile wound and scar dressings, open wound products, wound management gels, cavity dressings, swabs, sponges, sterile alcohol wipes, skin care products, non sterile textile bandages and supports, sterile wound irrigation solutions, abdominal towels, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and other medical staff clothing for use in the patient environment, sterile and non sterile medical gloves and sterile surgical gloves.

The design, development and manufacture of pharmaceuticals and other healthcare products.

Mölnlycke Health Care Oy  
PO Box 76  
Saimaankatu 6  
Mikkeli  
FIN 50101  
Finland

Manufacture of swabs, sponges, towels, wound dressings, open wound products, scar dressings and procedure packs.

Mölnlycke Health Care AB  
Mölnlycke Health Care (Thailand) Lt  
160 Bangplee Industrial Estate  
Bangna-Trad Rd  
Samutprakarn  
Bansaothong  
10540  
Thailand

Manufacture of surgical drapes and sets, equipment drapes, surgical and protective gowns and other staff clothing.

Mölnlycke Health Care AB  
T/A Mölnlycke Health Care SA  
Parc Industrial  
B-4300 Waremmé  
Belgium

Manufacture of sterile drapes, operating sets and procedure packs.

Mölnlycke Health Care Klinipro s.r.  
Na Novem Poli 382  
Prumyslova zona Karvina  
Karvina - State Mesto  
733 01  
Czech Republic

Manufacture of surgical drapes and procedure packs.

Originally registered: **31/03/1998**

Latest Issue: **10/01/2007**

Page: 2 of 3

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Management Systems (CEMEA) Headquarters: 389 Chiswick High Road, London, W4 4AL, United Kingdom

Certificate No: **FM 39247**

<b>Location</b>	<b>Registered Activities</b>
Mölnlycke Health Care AB Mölnlycke Health Care (Thailand) Lt Amata Nakorn (Bang Pakong) Industrial Estate 700/461 Moo Bangha-Trad Rd. KM.57 Tambol Donhuaroh, Amphur Muang Chonburi 20000 Thailand	Manufacture of surgical drapes and sets, equipment drapes, surgical and protective gowns and other staff clothing.
Mölnlycke Health Care AB Tubiton House Medlock Street Oldham OL1 3HS United Kingdom	The design, development and manufacture of sterile wound dressings, non sterile textile bandages and supports, procedure packs, sterile irrigation solutions, sterile alcohol wipes, skin care products, pharmaceuticals and other healthcare products.
Mölnlycke Health Care AB Lot 9, Lorong Perusahaan 4 Kulim Industrial Estate PO Box 52, 09000 Kulim Kedah Darulaman Malaysia	The design, development and manufacture of sterile and non sterile medical gloves and sterile surgical gloves.
Mölnlycke Health Care AB Plot 204 Kawasan Perindustrian Kula Ketil Phas II 09300 Kula Ketil Malaysia	The design, development and manufacture of sterile and non sterile medical gloves and sterile surgical gloves.
Mölnlycke Health Care AB Lot B5 & B6 Kawasan Perindustrian Miel Batang Kali Phase II 44300 Batang Kali Malaysia	The design, development and manufacture of sterile and non sterile medical gloves and sterile surgical gloves.

Originally registered: **31/03/1998**

Latest Issue: **10/01/2007**

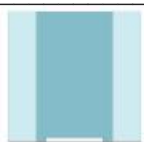







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Tray ID 97039056  
 Tray name SET INTERVENTII CARDIO STIMULATOARE  
 Speciality filter CARDIOVASCULAR  
 Intervention filter Cardiovascular Other  
 Hospital filter Tehnomedica SRL

	Description	Qty
	Adh. op sheet Light 175x175cm	1
	BNS Angiography Drape 240x330 cm	1
	Adh. op towel Light 90x75cm SA edge 5cm	1
	Surgical gown Primary Standard Perfomance XL 127cm	2
	Hand towel 18x25cm	2
	Op tape 9x49cm	1
	Banded bag 140cm Circ. Elast. Transp.	1
	Bowl 500ml Graduated (transparent)	2



Bowl 250ml Graduated red 2



Medicine/Specimen cup 120ml Polyethylene Transp. Lid 1



Forceps tweezer plastic green 1



Scalpel SS N°22 1



Sponge appl. 15cm 3,5x3,5cm Blue 5



Forceps 12cm plastic green 4



Paper bag 25x38x10cm White 1



Light handle cover large Light green/white collar 1



Nonwoven swab 7,5x7,5cm 30g 4P White 200



Paper bag 25x38x10cm White 1



Surg.glove latex 7.0 PF 2/1 Biogel Surgeons 2



Surg.glove latex 8.0 PF 2/1 Biogel Surgeons 2



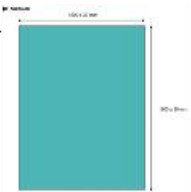
Surgical gown Primary Standard Performance XL 127cm 1



Hand towel 18x25cm 1



Mayo stand cover 79x145cm Abs.65x85cm 1



Reinforced Table Cover 150 x 190 wrapping 1