

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, registruator de stat

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

semnătura

MD 0027040



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 Semnătura
Director sucursalei „Gheorghe Mocanu”



Executor :Eduard Cilcic
Tel: 022-812-150

TEHNOMEDICA

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

Către IMSP Institutul de Medicină Urgentă

În atenția Grupului de lucru
al procedurii LP nr. ocds-b3wdp1-MD-1593426318428;
ID: 21025372 din 20.07.2020

Pansamente atraumatice

Declarație privind termenul de valabilitate

Prin prezenta, declarăm că termenul de valabilitate a produselor oferite în cadrul Licităției Publice ***nr.ocds-b3wdp1-MD-1593426318428; ID: 21025372 din 20.07.2020*** privind achiziționarea ***pansamentelor atraumatice*** va fi nu mai mic de 80% din termenul total de valabilitate a acestora la momentul livrării.

Cu respect,

Director

20.07.2020

Tatiana Roibu

TEHNOMEDICA

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

Către IMSP Institutul de Medicină Urgentă

În atenția Grupului de lucru
al procedurii LP nr. ocds-b3wdp1-MD-1593426318428;
ID: 21025372 din 20.07.2020

Pansamente atraumatice

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, în conformitate cu pct.15.12 al anunțului de participare aferent procedurii **LP nr. ocds-b3wdp1-MD-1593426318428; ID: 21025372 din 20.07.2020**, declarăm că vom prezenta mostre în decurs de 5 zile de la solicitarea autorității contractante pentru produsele licitate.

Cu respect,

Director

20.07.2020

Tatiana Roibu

EC Certificate - Full Quality Assurance System

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

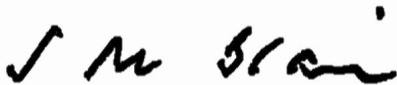
No. CE 01965
Issued To: **Mölnlycke Health Care AB**
Box 13080
Gamlestadsvägen 3C
SE-402 52 Göteborg
Sweden

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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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:

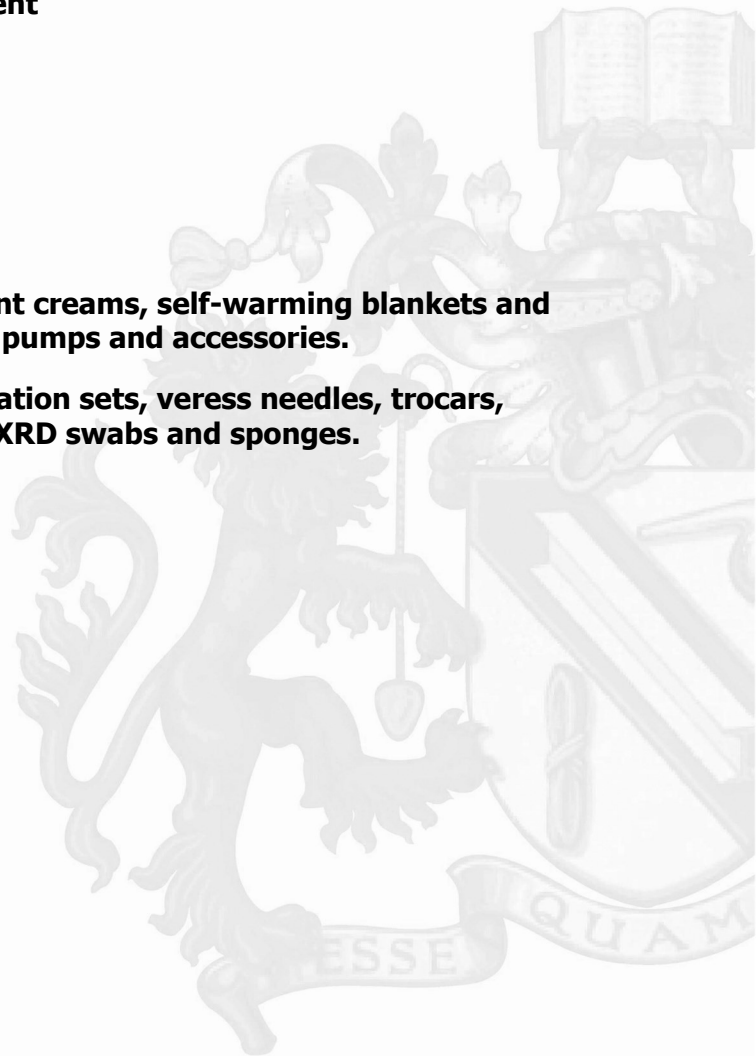
The design and manufacture of sterile medicated and non-medicated open wound products:

- 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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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.

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

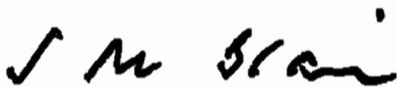
No. **CE 01966**
Issued To: **Mölnlycke Health Care AB**
Box 13080
Gamlestadsvägen 3C
SE-402 52 Göteborg
Sweden

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 V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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 01966

Certificate Scope:

Those aspects of manufacture related to securing and maintaining sterility of absorbent tracheostomy dressing, sterile scar management dressing and transparent adhesive IV film dressing.

Those aspects of manufacture related to securing and maintaining sterility of negative pressure wound therapy (NPWT) accessories, surgical and equipment drapes and surgical gowns.

Those aspects of manufacturing relating to securing and maintaining sterility in the assembly of procedure packs in accordance with article 12 of the MDD.

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

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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 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

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. This certificate does not expire. An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +44 (0)20 8996 7033.

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

Certificate of Registration

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

This is to certify that:

Mölnlycke Health Care AB
Box 13080
Gamlestadsvägen 3C
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, porcine collagen wound 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.
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:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2004-07-21

Effective Date: 2018-11-28

Latest Revision Date: 2018-11-26

Expiry Date: 2021-11-27



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Certificate No: **MD 83345**

| Location | Registered Activities |
|--|---|
| Mölnlycke Health Care AB Box 13080 Gamlestadsvägen 3C SE-402 52 Göteborg Sweden | The design, development, manufacture, marketing, sales and distribution of sterile wound and scar dressings, porcine collagen wound 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. The design, development, manufacture, marketing, sales and distribution of single patient use Negative Pressure wound therapy pumps and accessories. Distribution of laparoscopic instruments. |
| Molnlycke Health Care Pty Ltd Level 4 12 Narabang Way Belrose New South Wales 2085 Australia | The provision of sales, marketing, and distribution of sterile wound and scar dressings, open wound products, cavity dressings, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and supports, sterile irrigation solutions, 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 and laparoscopic instruments. |

Original Registration Date: 2004-07-21

Latest Revision Date: 2018-11-26

Effective Date: 2018-11-28

Expiry Date: 2021-11-27

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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