

## SPECIFICATII TEHNICE (F4.1)

Numărul licitației: nr. **ocds-b3wdp1-MD-1577180329010**, ID:21017065 din 06.02.2020

Denumirea licitației: **Articole parafarmaceutice pentru anul 2020 conform necesităților IMSP SCM 1**

<b>Cod CPV</b>	<b>Nr.lot</b>	<b>Descrierea bunurilor</b>	<b>Modelul articolului</b>	<b>Tara de origine</b>	<b>Producatorul</b>	<b>Specificatia tehnica deplina solicitata de catre autoritatea contractanta</b>	<b>Specificatia tehnica deplina propusa de catre ofertant</b>	<b>Standarde de referinta</b>
33141100-1	52	Pansament ster.adeziv hipoalergic 10x25 cm	<b>671200</b>	Suedia	Molnlycke Health Care	Conform anunțului de participare	Mepore 9x25cm Pansament absorbant, steril, autoadeziv pe bază de apă, fără solvent. -Radioparent; - Stratul de contact cu plaga cu aderență gentilă, minimizând riscul de lipire pe plagă. -Strat exterior impermeabil la fluide, flexibil. -Folia protectoare 2 componente permite aplicarea aseptică. -Permeabil la aer pentru a preveni macerarea. - Dimensiuni: 9x25cm	CE, Declarație de conformitate, ISO 13485, ISO 9001
33141100-1	108	Mănuși anatomice ortopedice mărimea 7,5	<b>82275</b>	Suedia	Molnlycke Health Care	Conform anunțului de participare	Mănuși sterile, nepudrate, mărimea N 7,5 - din cauciuc deproteinizat, non-alergene, rezistente la intervenții chirurgicale îndelungate și cu utilizarea instrumentelor grele, apirogenice, rezistența la rupere – nu mai puțin de 18N, acoperit pe interior cu biogel pentru protecție dublă și rezistența la rupere. Prețul este indicat pentru 1 pereche.	CE, Declarație de conformitate, ISO 13485, ISO 9001



33141100-1	109	Mănuși anatomice ortopedice mărimea 8	82280	Suedia	Molnlycke Health Care	Conform anunțului de participare	Mănuși sterile, nepudrate, mărimea N 8 - din cauciuc deproteinizat, non- alergene, rezistente la intervenții chirurgicale îndelungate și cu utilizarea instrumentelor grele, apirogenice, rezistența la rupere – nu mai puțin de 18N, acoperit pe interior cu biogel pentru protecție dublă și rezistența la rupere. Prețul este indicat pentru 1 pereche.	CE, Declarație de conformitate, ISO 13485, ISO 9001
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Director Tehnomedica SRL



Tatiana Roibu





By Royal Charter

# 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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A member of BSI Group of Companies.



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

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# 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.

*Stewart Brain*

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

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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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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# 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**



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**BSI**  
Management  
Systems



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 Waremmes 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

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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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**Title:** Mepore

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We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being exclusively responsible manufacturer for conformity of the device/s; declare that the devices listed in the attached schedule are in conformity with the provisions of 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/ Product name:	<b>Mepore</b>
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Product classification: **Ila**Sterility Status: **Sterile**Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with

Annex/es: **II**Certificate number: **CE 01965**Issued by: **BSI (0086)**

For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: **2017-03-24**Function: **Manager, Regulatory Affairs  
Medical Devices**Name: **Anders Johansson**

Signature:





**Product(s) covered by this declaration:**

Product Reference:	Product Descriptor:	GMDN Code:
670700	Adhesive surgical dressing	34864
670800	Adhesive surgical dressing	34864
670840	Adhesive surgical dressing	34864
670870	Adhesive surgical dressing	34864
670880	Adhesive surgical dressing	34864
670900	Adhesive surgical dressing	34864
670940	Adhesive surgical dressing	34864
670970	Adhesive surgical dressing	34864
670980	Adhesive surgical dressing	34864
671000	Adhesive surgical dressing	34864
671040	Adhesive surgical dressing	34864
671070	Adhesive surgical dressing	34864
671080	Adhesive surgical dressing	34864
671100	Adhesive surgical dressing	34864
671140	Adhesive surgical dressing	34864
671170	Adhesive surgical dressing	34864
671180	Adhesive surgical dressing	34864
671200	Adhesive surgical dressing	34864
671299	Adhesive surgical dressing	34864
671300	Adhesive surgical dressing	34864
671400	Adhesive surgical dressing	34864
671500	Adhesive surgical dressing	34864



Title: Mepore

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Product Reference:	Product Descriptor:	GMDN Code:
671600	Adhesive surgical dressing	34864



## EC Declaration of Conformity

Page 1 of 2

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, SE-402 52 Göteborg, Box 13080, SE-402 52 Göteborg, Sweden being the manufacturer of the following, declare that the devices listed in the attached schedule is in conformity with the provisions of 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 2009:18.

Trade name/ Product name:	Biogel Sterile latex Powder Free surgical gloves
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Product classification

(choice: Class I, Class IIa, Class IIb, Class III)

Sterility

(choice: sterile, non sterile)

Measuring function

(choice: yes, no)

This declaration is supported by a conformity assessment procedure in accordance with Annex/es

**V + VII**

Certificate number: CE 91450

Issued by BSi


For non sterile, non-measuring class I products, no certificate is issued by a Notified Body.

MHC issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: April 21, 2010 Function: EMEA Director Regulatory AffairsName: Kathleen Harris

Signature:



**Schedule:**

Ref.	LATEX - Single Gloving
S822	BIOGEL SURGEONS
S304	BIOGEL SURGEONS
S961	BIOGEL SURGEONS
S305	BIOGEL M SURGEONS
S962	BIOGEL M SURGEONS
S823	BIOGEL M SURGEONS
S825	BIOGEL SUPER SENSITIVE
S975	BIOGEL SUPER SENSITIVE
S306	BIOGEL SENSOR
S310	BIOGEL OPTIFIT ORTHOPAEDIC
S826	BIOGEL OPTIFIT S/SENSITIVE
S321	Biogel OrthoPro
S326	Biogel OrthoPro Underglove
S329	Biogel OrthoPro Indicator Overglove
	LATEX - Double Gloving
S842	BIOGEL INDICATOR
S312	BIOGEL INDICATOR U/GLOVES
S942	BIOGEL INDICATOR U/GLOVES
S941	BIOGEL REVEAL