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

CAMERA ÎNREGISTRĂRII DE STAT 109 L.Ș.

MD 0027040

By Royal Charter

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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By Royal Charter

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

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:	*EtO, Ethylene Oxide*
CE certificate	*CE 01966*
Certificate issued by	*BSi (0086)*

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

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

By Royal Charter

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

Effective Date: 2018-11-28

Latest Revision Date: 2018-11-26

Expiry Date: 2021-11-27

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**

003

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 Republican
„Timofei Moșneaga”

În atenția Grupului de lucru
al Licitației deschise nr. ocds-b3wdp1-MD-1619597249717,
ID: 21039071

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că vom prezenta mostre în decurs de 7 zile de la solicitarea autorității contractante pentru produsele oferite în cadrul Licitației deschise nr. ocds-b3wdp1-MD-1619597249717, ID: 21039071 privind **achiziționarea necesarului suplimentar de consumabile medicale pentru anul 2021.**

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 Republican
„Timofei Moșneaga”

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1619597249717,
ID: 21039071

Declarație privind termenul de valabilitate

Prin prezenta, declarăm că termenul de valabilitate a produselor oferite în cadrul Licitației Deschise nr. ocds-b3wdp1-MD-1619597249717, ID: 21039071 privind **achiziționarea necesarului suplimentar de consumabile medicale pentru anul 2021** va constitui cel puțin 80% din termenul total de valabilitate a acestora la momentul livrării.

Cu respect,

Director Tatiana Roibu

Číslo setu: 97038757
Revize návodky: 34
Status: REL TO PRODTN
Datum revize: 17.07.20
Platnost BOMu: 01.08.20 do 31.12.9999

97038757 Set Radial Angio absorbant steril

Komponent	Číslo komponentu	Ks/set
Crepe paper 60x60cm 45g/m2 White	2316730-00	1
BNS Radial Angiography Drape 240x330cm 5	958284-07	1
NS. Kidney bowl 800ml Polypropylene Yell	2308944-00	1
BNS Adhesive towel 50x50cm	947064-07	1
NS.bowl gallipot 250ml PP pink graduated	2308024-00	1
BNS Absorbent Towel 34x50cm	830204-07	1
Gallipot 120ml Graduated Clear Plastic	2302055-00	1
Bowl 2500ml Polypropylene Blue Guidewire	2314188-00	1
Medicine/Specimen cup 100ml Polypropylen	2315740-00	1
Forceps Tube Clamp Plastic Green 10cm	2300323-00	1
FORCEPS GREEN DISPOSABLE	2302144-00	1
Banded Bag Circular 75cm	15351-90	1
BNS Banded Bag 140cm	990375-10	2
BNS Surgical Gown PR SP XL	68000624-02	2
Hand towel white 47x38 cm White	2308641-00	4
Table Cover 150x190 Abs. 75x190cm Wrappi	5200460-08	1
Breather Bag 613x504mm	32635-92	1
Syringe 20ml Luer Lock transparent		1
SA Label 1,6 x 5cm TEHNOMEDICA SRL	2322733-00	1

Metoda balení: A
Ks do krabice: 3
Země určení: Moldavia

POZNÁMKA - set:

Text na S/B etiketě: