

Nr 22/26-03/20
Data: 14 martie 2016

CERTIFICAT PRIVIND EXISTENTA CONTURILOR CURENTE

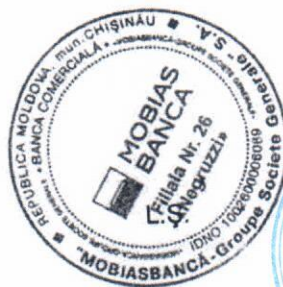
Prin prezentul, BC „Mobiasbancă – Groupe Societe Generale” S.A., codul băncii (BIC): **MOBBMD22**, confirmă că compania **TEHNOMEDICA S.R.L** cod fiscal (IDNO) **1002600053256**, detine următoarele conturi curente la BC Mobiasbanca-Groupe Societe Generale SA, Filiala. Nr. 26 Negruzzi:

1. MDL - MD65MO2224ASV98310887100
2. EUR - MD06MO2224ASV98311097100

Certificatul este emis in baza cererii întreprinderii **TEHNOMEDICA S.R.L.**

Railean Galina

Director filiala „nr 26 Negruzzi”



Ex. Galenau Cristina
tel: 0228121153

MD-2001, Chișinău, Moldova
Cod MOBBMD22
Cont de corespondență 35213892
la Centrul de Decontări al BNM

Tel. +373 22 27 34 79
Fax. +373 22 27 95 01
www.mobiasbanca.md

BC „Mobiasbancă – Groupe Société Générale” SA
Capital Social: 100 000 000 MDL
Număr de înregistrare de stat - 1002600006089
Sediul Central:
bd. Ștefan cel Mare și Sfânt 81a
MD-2012, Chișinău, Moldova

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087

e-mail <tehnomedica_md@yahoo.com>

Către IMSP Institutul Mamei și Copilului

În atenția Grupului de lucru
al Licităției nr. ocds-b3wdp1-MD-1572440046995,
ID: 21013907 din 21.11.2019

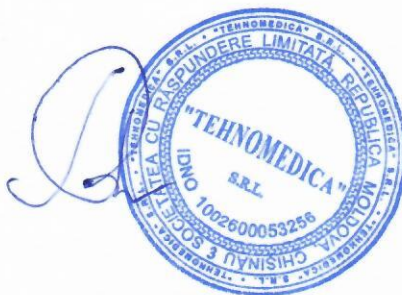
Produse parafarmaceutice

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, în conformitate cu pct.15.9 al anunțului de participare aferent **Licităției nr. ocds-b3wdp1-MD-1572440046995, ID: 21013907 din 21.11.2019**, declarăm că vom prezenta mostre în decurs de 3 zile de la solicitarea autorității contractante pentru produsele oferțate.

Cu respect,

Director
21.11.19



Tatiana Roibu



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**

...making excellence a habit.™

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 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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A member of BSI Group of Companies.





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



BSI
Management
Systems

Location

FM 39247

Location

Registered Activities

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.

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

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

Manufacture of sterile drapes, operating sets and procedure packs.

Manufacture of surgical drapes and procedure packs.

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 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**

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
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Title: Sets Class I sterile

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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:	Set
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Product classification: **IS**
Sterility Status: **Sterile**
Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with	
Annex/es:	V, VII

Certificate number:	CE 01966
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: **2017-02-05** Function: **Manager, Regulatory Affairs
Medical Devices**

Name: **Anders Johansson** Signature:



Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
1218	E.N.T. SET	33961
251	LITHOTOMY SET	33961
282	SET-UP SET	33961
306480	DENTAL SET	33961
565710	GYNAECOLOGY SET	33961
60001	SHOULDER SET	33961
60002	SHOULDER SET W/POUCH	33961
60003	BEACH CHAIR SHOULDER SET	33961
60005	SHOULDER SPLIT SHEETS W/POUCH	47783
60101	KNEE ARTHROSCOPY SET	33961
60102	KNEE ARTHROSCOPY SET	33961
60103	KNEE ARTHROSCOPY SET	33961
60200	EXTREMITY SET	33961
60202	EXTREMITY SET	33961
60203	EXTREMITY SET	33961
60204	EXTREMITY SET	33961
60205	EXTREMITY SET	33961
60206	EXTREMITY SET	33961
60207	EXTREMITY SET	33961
60208	EXTREMITY SET	33961
60209	EXTREMITY SET	33961
60300	EXTREMITY SET, BILATERAL FOOT	33961

Title: Sets Class I sterile

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Product Reference:	Product Descriptor:	GMDN Code:
60301	EXTREMITY SET, BILATERAL LEG	33961
60302	HAND AND FOOT SET	33961
60303	HAND AND FOOT SET	33961
60305	HAND SET	33961
60306	HAND SET	33961
60307	HAND SET	33961
60602	HIP SET W/DISLOCATION BAGS	33961
60603	HIP SET	33961
60604	HIP SET	33961
60606	HIP SET	33961
60607	HIP SET	33961
60608	HIP SET	33961
60609	HIP SET	33961
60610	HIP SET	33961
60611	HIP SET	33961
60612	HIP SET	33961
60613	HIP SET	33961
60614	HIP SET	33961
60615	HIP SET	33961
60616	HIP SET	33961
60617	SPLIT SHEET SET	33961
60618	SPLIT SHEET SET	33961
60619	ORTHOPAEDIC SET	33961
60620	SPLIT SHEET SET	33961
61010	LITHOTOMY SET	33961

Title: Sets Class I sterile

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Product Reference:	Product Descriptor:	GMDN Code:
61020	LITHOTOMY SET	33961
61030	LITHOTOMY SET	33961
61040	LAPAROSCOPY SET	33961
61400	VARICOSE VEIN SET	33961
61450	Laparoscopy Set Bariatric	33961
61800	Hybrid Cardiovascular Set	33961
61920	CARDIOVASCULAR UNIVERSAL SET	33961
65000	E.N.T. SET	33961
65020	E.N.T. Set	33961
65043	C-SECTION SET	33961
65790	OPHTHALMIC SET	33961
65800	TUR SET	33961
66010	UNIVERSAL SET	33961
66100	REINFORCED UNIVERSAL SET	33961
66200	UNIVERSAL SET STANDARD	33961
66300	UNIVERSAL SET STANDARD	33961
669600	ACUTE THORACIC SET	33961
692300	PLASTIC SURGERY SET	33961
694000	DENTAL SET	33961
694110	C-SECTION SET	33961
694135	C-SECTION SET	33961
694140	C-SECTION SET	33961
694145	C-SECTION SET	33961
694240	LAPAROSCOPY SET ABDO-PERINEAL	33961
694241	LAPAROSCOPY SET ABDO-PERINEAL	33961

Product Reference:	Product Descriptor:	GMDN Code:
694242	LAPAROSCOPY SET ABDO-PERINEAL	33961
694245	LAPAROSCOPY SET	33961
694265	LAPAROSCOPY SET	33961
694500	PFANNENSTIEL SET	33961
694640	CARDIOVASCULAR SET	33961
694700	CARDIOVASCULAR SET	33961
695000	DELIVERY SET	33961
695400	OPHTHALMIC SET	33961
696110	GYNAECOLOGY AND CYSTOSCOPY SET	33961
696310	TUR SET	33961
696450	LITHOTOMY SET	33961
696500	GYNAECOLOGY LAPAROSCOPY SET	33961
696600	GYNAECOLOGY LAPAROSCOPY SET	33961
696700	GYNAECOLOGY SET	33961
696810	GYNAECOLOGY SET	33961
696940	HEAD SET	33961
697000	E.N.T. SET	33961
697100	LAPAROTOMY SET	33961
697250	NECK SET	33961
697260	THYROID SET	33961
697600	APERTURE SET BASIC	33961
697640	E.N.T. SET	33961
698220	ANGIOGRAPHY SET	33961
698260	ANGIOGRAPHY RADIALIS SET	33961

Title: Sets Class I sterile

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Product Reference:	Product Descriptor:	GMDN Code:
698740	UNIVERSAL SET BASIC	33961
698780	UNIVERSAL SET STANDARD	33961
698900	UNIVERSAL SET BASIC	33961
699010	PAEDIATRIC SET BASIC	33961
699054	UNIVERSAL SET STANDARD	33961
699110	UNIVERSAL SET	33961
699140	UNIVERSAL SET STANDARD	33961
699145	UNIVERSAL SET BASIC	33961
699175	REINFORCED UNIVERSAL SET	33961
699180	REINFORCED UNIVERSAL SET	33961
699340	UNIVERSAL SET STANDARD	33961
699354	UNIVERSAL SET STANDARD	33961
699540	UNIVERSAL SET STANDARD	33961
699600	UNIVERSAL SET STANDARD	33961
699640	UNIVERSAL SET STANDARD	33961
699700	UNIVERSAL SET STANDARD	33961
790000	UNIVERSAL SET	33961
790500	UNIVERSAL SET	33961
793000	UNIVERSAL SET	33961
793500	SET BASIC	33961
794000	UNIVERSAL SET	33961
795500	SPLIT SHEET SET	33961
796000	SPLIT SHEET SET	33961
798000	EXTREMITY SET	33961
798500	EXTREMITY SET	33961

Product Reference:	Product Descriptor:	GMDN Code:
80005471	SPINAL SET	33961
80011660	HEAD TURBAN SET	33961
80574671	HEAD TURBAN SET	33961
80974401	CYSTOSCOPY SET	33961
84511411	ABDOMINAL LAPAROSCOPY SET	33961
84511451	OPHTHALMIC SET	33961
84511461	OPHTHALMIC SET	33961
888112	GYNAECOLOGY SET	33961
888113	GYNAECOLOGY SET	33961
888142	CRANIOTOMY SET	33961
888212	GYNAECOLOGY SET	33961
888222	TUR SET	33961
888224	TUR SET	33961
888225	TUR SET	33961
888226	TUR SET	33961
888228	TUR SET	33961
888242	CRANIOTOMY SET	33961
902496	GYNAECOLOGY AND CYSTOSCOPY SET	33961
903014	VERTICAL ISOLATION SET	33961
903016	VERTICAL ISOLATION SET	33961
903020	GYNAECOLOGY AND LAPAROSCOPY SET	33961
903026	VERTICAL ISOLATION SET	33961
903163	OPHTHALMIC SET	33961
903165	OPHTHALMIC SET	33961

Title: Sets Class I sterile

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Product Reference:	Product Descriptor:	GMDN Code:
903167	OPHTHALMIC SET	33961
903286	OPHTHALMIC SET	33961
903328	C-SECTION SET	33961
903355	C-SECTION SET	33961
903440	C-SECTION SET	33961
904194	UNIVERSAL SET BASIC	33961
904383	DELIVERY SET	33961
904730	ANGIOGRAPHY SET	33961
905020	URO AND GYNAECOLOGY SET	33961
914341	DELIVERY SET	33961
915322	OPHTHALMIC SET	33961
925982	GYNAECOLOGY SET	33961
925984	GYNAECOLOGY SET	33961