

# CERTIFICATION OF THE SECOND OF DE ÎNRECISTRARE

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

uncția, numele, prenumele per care a eliberat certificatul

MD 0027040





#### I.P. "AGENTIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

#### **EXTRAS**

din Registrul de stat al persoanelor juridice

nr. 1968 din 01.02.2019

Denumirea completă: SOCIETATEA CU RĂSPUNDERE LIMITATĂ

«TEHNOMEDICA».

Denumirea prescurtată: «TEHNOMEDICA» S.R.L..

Forma juridică de organizare: Societate cu Răspundere Limitată. Numărul de identificare de stat și codul fiscal: 1002600053256.

Data înregistrării de stat: 17.04.2002.

Sediul: MD-2001, str. Ciuflea, 38/1, mun. Chişinău, Republica Moldova.

Obiectul principal de activitate:

1 Fabricarea utilajului medical și chirurgical și a dispozitivelor ortopedice;

2 Comertul cu ridicata al produselor farmaceutice;

3 Comerțul cu amănuntul al produselor farmaceutice;

4 Practica medicală;

5 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale si (sau) a opticii;

6 Activități de consultare pentru afaceri și management.

Capitalul social: 5400 lei.

Administrator: ROIBU TATIANA,

Asociati:

1. ROIBU TATIANA 100 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 01.02.2019.

Specialist coordonator tel. 022-20-7838



Clichici Elena



### **TEHNOMEDICA**

Ciuflea 38/1 2001 Chisinau Moldova tel./fax 601 102, 601 087 e-mail <a href="mailto:tehnomedica\_md@yahoo.com">tehnomedica\_md@yahoo.com</a>

Către IMSP "Spitalul Clinic Bălți"

În atenția Grupului de lucru al LP nr. ocds-b3wdp1-MD-1584442018692 din 06.04.2020

Declarație privind liciențierea activității și certificarea igienică

Prin prezenta, vă aducem la cunoștință că, în conformitate cu prevederile Legii Nr. 160 din 22.07.2011 privind reglementarea prin autorizare a activității de întreprinzător, certificatul igienic nu face parte din nomenclatorul actelor permisive eliberate de către autoritățile emitente persoanelor fizice și persoanelor juridice pentru practicarea activității de întreprinzător (anexa nr.1 al legii prenotate).

Totodată, genul de activitate nu se supune licențierii (Legea Nr. 451 din 30.07.2001 privind licențierea unor genuri de activitate).

Cu respect,

Director Tatiana Roibu

Data: 06.04.2020

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

$ \begin{array}{c c} Nr. \\ N_2 \end{array} $ A2008526  din or 27.03.20	020	
1. Destinația / Назначение		
ACHIZIȚII PUBLICE		
2. Date despre contribuabil / Информация о налогоплатель	ьщике	
<b>Denumirea</b> Наименование	Codul fiscal / Numărul de identificare Фискальный код / Идентификационный номер	
TEHNOMEDICA S.R.L.	1002600053256	
	Codul - Denumirea localității Код - Наименование населенного пункта	
Ciuflea nr.38 bl.1	0130-SEC.CENTRU	
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.		
<b>4. Valabil pînă la</b> / Действителен до 11.04.2020		
5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы		
Şef DDF Centru	Viorica CĂUŞ	
Finetia/Должность  Semnătura/Поді	Numele și prenumele/Фамилия и имя	

Este extras din Sistemul Informațional al SFS SIA "Contul curent al contribuabilului"// 27.03.2020 ora 12:06:09 cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,01)



F/COM/CC/23/02

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. <u>EUR MD06MO2224ASV98311097100</u>

Numele, Prenumele si Semnatura Sucursala Nr. 26
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 "Spitalul Clinic Bălți"

În atenția Grupului de lucru al LP nr. ocds-b3wdp1-MD-1584442018692

ID: 21021350 din 06.04.2020

#### Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că vom prezenta mostre în decurs de 5 zile de la solicitarea autorității contractante pentru produsele ofertate în cadrul Licitației Publice nr. ocds-b3wdp1-MD-1584442018692, ID: 21021350 privind achiziționarea articolelor parafarmaceutice pentru anul 2020.

Cu respect,

Director Tatiana Roibu

Data: 06.04.2020

# bsi.



# 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 company 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

First Issued: 1998-06-29

- 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.

Date: 2018-05-30 Expiry Date: 2023-06-28

...making excellence a habit."

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the requirement of the Directive as demonstrated through the Directive

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.



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 Ki

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

Thailand

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

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 Waremme 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

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of control certificate does not expire. An electronic certificate can be authenticated <u>online.</u>

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 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 This certificate does not expire. An electronic certificate can be authenticated <u>online</u>. 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

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# bsi.



# 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 Latest Revision Date: 2018-11-26

Effective Date: 2018-11-28 Expiry Date: 2021-11-27

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, A Member of the BSI Group of Companies.

Certificate No:

MD 83345

#### Location

Mölnlycke Health Care AB Box 13080 Gamlestadsvägen 3C SE-402 52 Göteborg

Sweden

Registered Activities

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

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

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>.

Printed copies can be validated at www.bsigroup.com/ClientDirectory

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 the BSI Group of Companies.





### EC Certificate

#### **Full Quality Assurance System**

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 15 04 12974 422

Manufacturer:

B. Braun Melsungen AG

Carl-Braun-Str. 1 34212 Melsungen GERMANY

Facility(ies):

B. Braun Melsungen AG Vascular Systems Mistelweg 2, 12357 Berlin, GERMANY

AESCULAP CHIFA Sp. z o.o.

ul. Tysiaclecia 14, 64-300 Nowy Tomysl, POLAND

B. Braun Melsungen AG Vascular Systems Sieversufer 8, 12359 Berlin, GERMANY

**Product** 

Category(ies):

Coronary stent systems, PTCA catheters, PTA catheters,

PTCA guide wires and sets,

Probes for stimulation and electrophysiology,

Procedure Kits,

Angiography sets, manifolds, guide wires,

single use Right heart pulmonary artery catheters,

Monitoring sets for invasive physiological

pressure measurement, Introducer sheaths and sets,

Arterial puncture cannulae, arterial catheter sets

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713055006

Valid from:

2015-06-16

Valid until:

2020-06-13

Date, 2015-06-18

Hans-Heiner Junker

642819

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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**DAKKS CRT2 / 10.13** 



## CERTIFICATE

No. Q5 17 03 10066 408

**Holder of Certificate: AESCULAP AG** 

> Am Aesculap-Platz 78532 Tuttlingen **GERMANY**

Facility(ies): **AESCULAP AG** 

Am Aesculap-Platz, 78532 Tuttlingen,

**GERMANY** 

**AESCULAP AG** 

Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

**Certification Mark:** 



**Scope of Certificate:** Design and development, production,

technical service and distribution of

implants, instruments,

instrument management systems,

containers, devices, tissue adhesives and procedure kits (for detailed information see

attachment)

**Applied** 

EN ISO 13485:2016

Medical devices - Quality management systems -Standard(s):

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:

713098053

Valid from:

2017-06-01

Valid until:

2020-05-31

2017-05-30 Date,

Stefan Preiß







**JAKKS CRT2 / 10.13** 



#### Attachment for certificate no Q5 17 03 10066 408 dated 2017-06-01

- Surgical, diagnostic and dental instruments
- Joint implants (hip, knee)
- Spinal implants
- Implants for osteosynthesis
- Neurosurgical vascular implants
- Products for ligature
- Motor systems
- Sterilization containers and accessories
- High frequency surgery devices
- Endoscopie systems
- Navigation systems
- Surgical suction pumps
- Special suture-sets
- Implants for replacement of connective tissue
- Tissue adhesives
- Vascular prostheses and accessories
- Local haemostatics
- Other surgical accessories

Munich, CRT2 2017-05-30

1. Pumil Stefan Preiß

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