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

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. **EUR - MD06MO2224ASV98311097100**

L.Ş.

Numele, Prenumele si Semnătura
Director sucursalei „Gheorghe Mocanu"

Executor :Eduard Cilcic
Tel: 022-812-150

Mobiasbanca - OTP Group S.A. • Capital Social: 100 000 000 MDL • Număr de înregistrare de stat – 1002600006089
bd. Ştefan cel Mare şi Sfînt 81A • MD-2012 Chişinău, Moldova • telefon: +373 22 256 456 • e-mail: info@mobiasbanca.md • www.mobiasbanca.md

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 Institutul de Medicină Urgentă

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1612534465125,
ID: 21035966 din 23.03.2021

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că vom prezenta mostre în decurs de 3 zile de la solicitarea autorității contractante/beneficiarului pentru produsele oferite în cadrul Licitației Deschise nr. ocds-b3wdp1-MD-1612534465125, ID: 21035966, privind **achiziționarea produselor parafarmaceutice – 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 Institutul de Medicină Urgentă

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1612534465125,
ID: 21035966 din 23.03.2021

Declarație privind termenul de valabilitate

Prin prezenta, declarăm că termenul de valabilitate pentru produsele oferite în cadrul Licitației Deschise nr. ocds-b3wdp1-MD-1612534465125, ID: 21035966, privind **achiziționarea produselor parafarmaceutice – 2021,** va constitui cel puțin 80% din termenul total de valabilitate la momentul livrării acestora.

Cu respect,

Director Tatiana Roibu

APROBAT
prin Ordinul
Ministrului Finanţelor
nr. 145 din 24 noiembrie 2020

DECLARAŢIE
privind confirmarea identității beneficiarilor efectivi și neîncadrarea acestora în situaţia condamnării pentru participarea la activităţi ale unei organizaţii sau grupări criminale, pentru corupţie, fraudă şi/sau spălare de bani.

Subsemnatul(a), Tatiana Roibu, reprezentant împuternicit al „TEHNOMEDICA" SRL în calitate de ofertant/ofertant asociat desemnat câștigător în cadrul procedurii de achiziție publică nr. ocds-b3wdp1-MD-1612534465125, ID: 21035966 din data 23.03.2021, declar pe propria răspundere, sub sancţiunile aplicabile faptei de fals în acte publice, că beneficiarul/beneficiarii efectivi ai operatorului economic în ultimii 5 ani nu au fost condamnați prin hotărâre judecătorească definitivă pentru participarea la activităţi ale unei organizaţii sau grupări criminale, pentru corupţie, fraudă şi/sau spălare de bani.

Numele și prenumele beneficiarului efectiv	IDNP al beneficiarului efectiv
Tatiana Roibu	0992606484592

Data completării:23.03.2021
Semnat: electronic
Nume/prenume: Tatiana Roibu
Funcţia: Director
Denumirea operatorului economic: Tehnomedica SRL
IDNO al operatorului economic: 1002600053256

B BRAUN

Konformitätserklärung
Declaration of Conformity

Document-No.:	39.05.641
Revision-No.:	15
Effective Date:	2020-05-19
Page:	1 of 2

Wir | We

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany

erklären in eigener Verantwortung,
dass das/die Produkt/e

Arteriofix

Arterienpunktionskanülen, Arterien-Katheter-Set
(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

Richtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EG

Konformitätsbewertungsverfahren
nach Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinie

Klassifizierung
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa / Regel 7

Benannte Stelle
TÜV SÜD Product Service GmbH (ID-Nr. 0123)
Ridlerstraße 65, 80339 München, Deutschland

Ausgestellte Bescheinigung(en):
G1 012974 0608 Rev. 00

Datum der ersten CE-Kennzeichnung
1996-06-13

Gültig bis
2024-05-26

hereby declare in our own responsibility
that the product/s

Arteriofix

Arterial puncture needle, Arterial Catheter Set
(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June 1993
concerning Medical Devices
amended by Directive 2007/47/EC

Conformity Assessment Procedure
according to annex II (excluding section 4)
of the Council Directive named above

Classification
according to annex IX of the
Council Directive named above
Class IIa / Rule 7

Notified Body
TÜV SÜD Product Service GmbH (ID-No. 0123)
Ridlerstraße 65, 80339 Munich, Germany

Certificate(s) issued:
G1 012974 0608 Rev. 00

Date of first CE-marking
1996-06-13

Valid until
2024-05-26

Berlin, 2020-05-19

B. Braun Melsungen AG

i. A.

Dr. S. Vogelbein
Head of Quality Management CoE VS

Berlin, 2020-05-19

B. Braun Melsungen AG

i. V.

Dr. H. Schlicht
Head of Regulatory Affairs

Anlage I / Attachment I

Art.-Nr. / Art. No.	Artikelbezeichnung	Article description	Klasse / Class
5206316	Arteriofix Art.-Kath.-Set 22G/80 mm	Arteriofix 22G/80 mm	IIa
5206324	Arteriofix Art.-Kath.-Set 20G/80 mm	Arteriofix 20G/80 mm	IIa
5206332	Arteriofix Art.-Kath.-Set 20G/160 mm	Arteriofix 20G/160 mm	IIa
5206359	Arteriofix Art.-Kath.-Set 18G/160 mm	Arteriofix 18G/160 mm	IIa
5206345	Arteriofix Art.-Kath.-Set 18G/80 mm	Arteriofix 18G/80 mm	IIa

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

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 012974 0608 Rev. 00

Manufacturer: **B. Braun Melsungen AG**
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Product Category(ies): **Coronary stent systems, PTCA catheters, PTA catheters, PTCA sets, Probes for stimulation and Electrophysiology, Angiography sets, manifolds, guide wires, tubes and syringes, 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.: 713168177

Valid from: 2020-05-06
Valid until: 2024-05-26

Date, 2020-05-14

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

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 012974 0608 Rev. 00

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

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TÜV®

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

Quality Austria
has issued an IQNet recognized certificate that the organization:

B. Braun Medical s.r.o.
V Parku 2335/20, CZ-14800 Praha

for the following scope:

Distribution of medicinal products for infusion therapy, injectable drugs, parenteral and enteral nutrition and dialysis.
Distribution of active, passive and implantable medical devices.
Distribution of disinfectants, hygiene and sanitary products.
Maintenance, service, repair and inspection of medical devices for infusion therapy, dialysis and parenteral nutrition.
Service and repairs of Aesculap motor systems. Repairs of Aesculap instruments

EAC: 29

has implemented and maintains a

QUALITY MANAGEMENT SYSTEM

which fulfils the requirements of the following standard

ISO 9001:2015

Issued on:	2018-07-16
Validity date:	2021-07-27
Quality Austria certified since:	2015-07-28

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: AT-16699/4

Alex Stoichitoiu
President of IQNet

Mag. Friedrich Khuen-Belasi
Authorised Representative
of Quality Austria

qualityaustria
Succeed with Quality

IQNet Partners*:
AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

Quality Austria
has issued an IQNet recognized certificate that the organization:

B. Braun Medical s.r.o.

V Parku 2335/20, CZ-14800 Praha

for the following scope:

Distribution of active, passive and implantable medical devices.
Maintenance, service, repair and inspection of medical devices for infusion therapy, dialysis and parenteral nutrition.

EAC: 29

has implemented and maintains a

QUALITY MANAGEMENT SYSTEM

which fulfils the requirements of the following standard

ISO 13485:2016

Issued on:	2018-07-16
Validity date:	2021-07-27
Quality Austria certified since:	2015-07-28

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: AT-00200/4

Alex Stoichitoiu
President of IQNet

Mag. Friedrich Khuen-Belasi
Authorised Representative of Quality Austria

qualityaustria
Succeed with Quality

IQNet Partners*:
AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 012974 0606 Rev. 00

Holder of Certificate: **B. Braun Melsungen AG**
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and development, production and distribution of sterile single use products for angiography, surgery, angioplasty, stimulation, coronary stent systems, PTCA catheters, PTA catheters, PTCA guide wires and sets, probes for stimulation and electrophysiology, procedure kits, angiography sets, manifolds, guide wires, tubes, syringes, single use right heart pulmonary artery catheters, monitoring sets for invasive physiological pressure measurement, introducer sheaths and sets, arterial punture cannula, arterial catheter sets**

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.: 713160067

Valid from: 2019-10-08
Valid until: 2022-09-30

Date, 2019-10-08

Stefan Preiß
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 012974 0606 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

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

./.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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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.™

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**

...making excellence a habit.™

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:	**Surgical and Equipment Drapes (Sets)**

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: **2018-11-16** Function: **Regulatory Affairs Manager Compliance**

Name: **Karin Darle Olsson** 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

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

Product Reference:	Product Descriptor:	GMDN Code:
61020	LITHOTOMY SET	33961
61030	LITHOTOMY SET	33961
61040	LAPAROSCOPY SET	33961
61400	VARICOSE VEIN SET	33961
61450	Laparoscpy 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

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

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

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**

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