

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 de Cardiologie

În atenția Grupului de lucru
al procedurii **COP nr. ocds-b3wdp1-MD-1580207760688,**
ID: 21018647 din 06.02.2020

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că vom prezenta mostre în decurs de 3 zile de la solicitarea autorității contractante pentru produsele oferite în cadrul procedurii COP nr.ocds-b3wdp1-MD-1580207760688, ID:21018647 din 06.02.2020 privind achiziționarea **consumabilelor pentru angiografie.**

Cu respect,

Director

05.02.2020



Tatiana Roibu

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 W9 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**

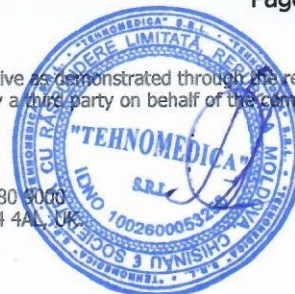
Expiry Date: **2023-06-28**

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Page 2 of 2

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Created by: Anders Johansson
Approved by: Anders Johansson
Approval date: 2017-09-01
Project ID: 006270

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

Page 1(2)

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:	<i>EtO, Ethylene Oxide</i>
CE certificate	<i>CE 01966</i>
Certificate issued by	<i>BSI (0086)</i>

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



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

Page 2(2)

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



Göteborg 2006-08-07

To Whom It may concern:

We hereby declare that,

Following Mölnlycke Health Care surgical drapes comply with the High Performance requirements of EN13795:

- Klinidrape® laminated Patient Drapes
- BARRIER® reinforced and laminated Patient Drapes
- Klinidrape® and BARRIER® Stockinettes and plastic/laminated Leggings
- Klinidrape® and BARRIER® Table Covers and Mayo Stand Covers

Following Mölnlycke Health Care surgical drapes comply with the Standard Performance requirements of EN13795:

- Klinidrape® Utility Drapes
- BARRIER® non-reinforced Patient Drapes (less critical area)
- Klinidrape® and BARRIER® nonwoven OP-tapes (less critical area)
- Klinidrape® and BARRIER® fluid repellent Leggings and Supplementary Products (less critical area)

Mölnlycke Health Care standard Klinidrape® and BARRIER® Surgical Gowns comply with the Standard Performance requirements of EN13795.

Mölnlycke Health Care reinforced Klinidrape® and BARRIER® Surgical Gowns comply with the High Performance requirements of EN13795

Mölnlycke Health Care Clean Air Suits comply with the performance requirements of EN13795



Anders Odmyr
International Technical Support Manager
Drapes and Sets





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**

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 Waremmé
Belgium

Manufacture of sterile drapes, operating sets and procedure packs.

Mölnlycke Health Care Klinipro s.r.
Na Novem Poli 382
Prumysiova 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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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

Latest Revision Date: 2018-11-26

Effective Date: 2018-11-28

Expiry Date: 2021-11-27

Page: 1 of 2



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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.



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.

Mölnlycke 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

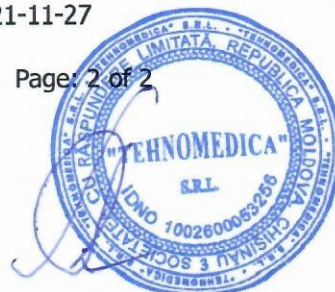
Effective Date: 2018-11-28

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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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Wir

We

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

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

Kundenspezifische Sets
Zubehör Sets für Angiographie
(Artikelnummern siehe Anlage)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

Richtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte

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

Klassifizierung
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa / Regel 2
Klasse IIb / Regel 3
Klasse Is / Regel 2

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

Datum der ersten CE-Kennzeichnung
2003-09-15

Gültig bis
2020-06-13

Berlin, 2017-02-08

B. Braun Melsungen AG

i. A.

Ralf Lorenz
Head of Quality Management

hereby declare in our own responsibility
that the product/s

Customized Kits
Accessory Kits for Angiography
(article numbers see attachment)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June 1993
concerning Medical Devices

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

Classification
according to annex IX of the
Council Directive named above
Class IIa / Rule 2
Class IIb / Rule 3
Class Is / Rule 2

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

Date of first CE-marking
2003-09-15

Valid until
2020-06-13

Berlin, 2017-02-08

B. Braun Melsungen AG

i. V.

Dr. Bernhard Jänicke
Head of Regulatory Affairs Management



Art.-Nr. / Art. No.	Artikelbezeichnung	Article description	Klasse / Class
5010550	Angiodyn Angiographie Set 3-fach, OFF	Angiodyn 5ngiographic kit 3-way, OFF	Ila
5010582	Coroset Marienhospital Herne	Coroset Marienhospital Herne	Ila
5010583	Hahnbank-Set Kard. GMP Göttingen	Hahnbank-Set Kard. GMP Göttingen	Ila
5010584	Abdeck-Set Kard. GMP Göttingen	Abdeck-Set Kard. GMP Göttingen	Ila
5010585	Coro Set Hagen	Coro Set Hagen	Ila
5010592	Kalmar Pacemakerset	Kalmar Pacemakerset	Ila
5010595	Schrittmacher-Set Pirna	Schrittmacher-Set Pirna	Ila
5010602	Schrittmacherset Nordhorn	Schrittmacherset Nordhorn	Ila
5010609	Tab. Cateterismo – Hosp. Santa Marta	Tab. Cateterismo – Hosp. Santa Marta	Ila
5010622	Biopsiasetti Kymenlaakson KS, RTG	Biopsiasetti Kymenlaakson KS, RTG	Ila
5010628	Schrittmacherset HPK Dr. Natour	Schrittmacherset HPK Dr. Natour	Ila
5010635	Angiodyn Angioset EVK Hamm	Angiodyn Angioset EVK Hamm	Ila
5010637	Schrittmacher Set Helios Klinikum München West	Schrittmacher Set Helios Klinikum München West	Ila
5010646	Radialis Set EKO	Radialis Set EKO	Ila
5010647	Coro Set Marktredwitz	Coro Set Marktredwitz	Ila
5010651	Putra Medical Center, Alor Star	Putra Medical Center, Alor Star	Ila
5010660	Angiodyn Hahnbankbaugruppe 3-fach, OFF	Angiodyn manifold assembly 3-way OFF	Ila
5010662	Schrittmacher Set	Schrittmacher Set	Ila
5010687	Hahnbankset Uni Münster	Hahnbankset Uni Münster	Ila
5010690	Feinnadelset KH-Stuttgart	Feinnadelset KH-Stuttgart	Ila
5010691	Angiodyn Coroset Villingen-Schwenningen	Angiodyn Coroset Villingen-Schwenningen	Ila
5010696	Coroset Bad Pyrmont	Coroset Bad Pyrmont	Ila
5010701	Coroset Nagold	Coroset Nagold	Ila
5010709	PTCA Set	PTCA Set	Ila
5010714	Port-Punktionsset	Port-Punktionsset	Ila
5010724	Angiodyn EPU Set Kaufbeuren	Angiodyn EPU Set Kaufbeuren	Ila
5010727	Laser-Set, KSSP Aarau	Laser-Set, KSSP Aarau	Ila
5010744	Toimenpidesetti Seinäjoe ks, röntgen	Toimenpidesetti Seinäjoe ks, röntgen	Ila
5010749	Schrittmacher-Set Medinos Sonneberg	Schrittmacher-Set Medinos Sonneberg	Ila
5010794	Angiosetti PHKS, ELFYS	Angiosetti PHKS, ELFYS	Ila
5010764	Angiodynset 3FRR35 15360	Angiodynset 3FRR35 15360	Ila
5010778	Angio-Neuro-Set Heinrich-Braun-Krankenhaus	Angio-Neuro-Set Heinrich-Braun-Krankenhaus	Ila
5010782	Pädiatrie-Set Uni Homburg	Pädiatrie-Set Uni Homburg	Ila
5010783	Set steril pentru Angiografie	Set steril pentru Angiografie	Ila
5010796	Add On Kit	Add On Kit	Ila





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 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

AESCLAP 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



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

Page 1 of 1





Product Service

CERTIFICATE

No. Q5 17 03 10066 408

Holder of Certificate: **AESULAP AG**

Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Facility(ies):

AESULAP AG
Am Aesculap-Platz, 78532 Tuttlingen,
GERMANY

AESULAP 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 Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - 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

Date, 2017-05-30

Stefan Preiß



Page 1 of 2





Product Service

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
- Endoscopic 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

Stefan Preiß

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