

We, Mölnlycke Health Care AB, Gamlestadvägen 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.

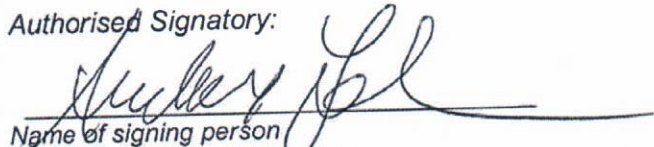
Sterilisation after assembly: *EtO, Ethylene Oxide*
CE certificate *CE 01966*
Certificate issued by *BSi (0086)*

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

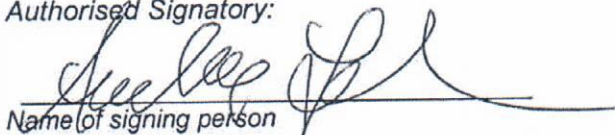


Product reference	Product Name	Product Description / included devices	GMDN code
See products linked to this document in the ERP system.			

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





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.

Lot 45

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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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.



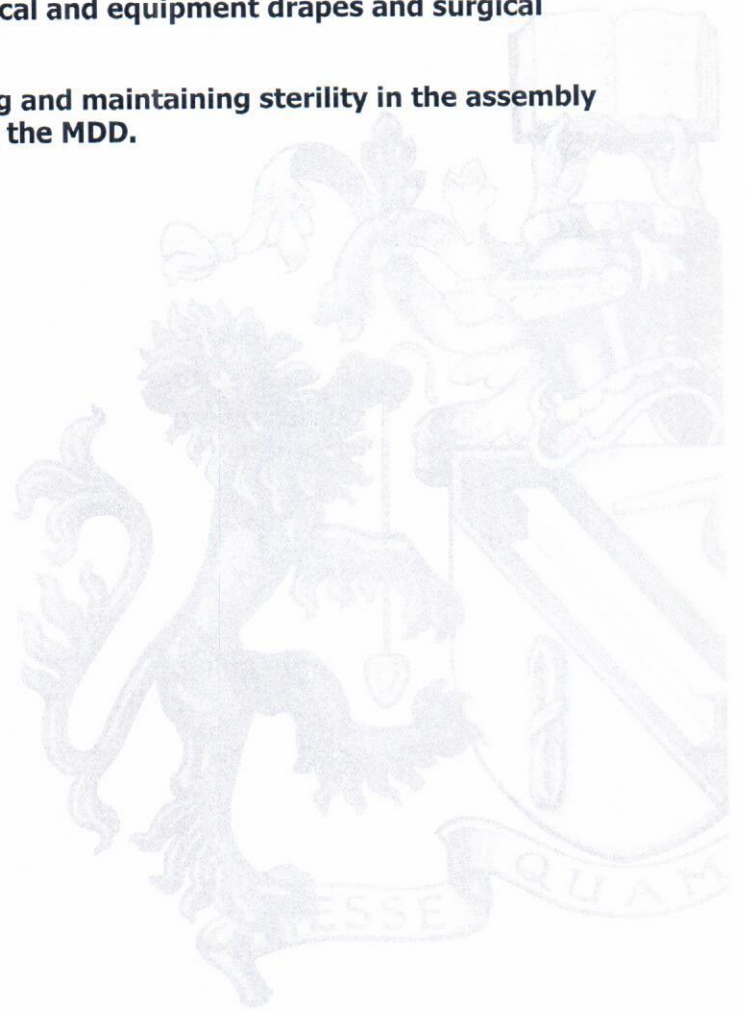
Certificate No: CE 01966

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.



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Page 2 of 2

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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

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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
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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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/übereinstimmenRichtlinie 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 Managementhereby 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	Is

