Mölnlycke®

Declaration According to MDD Article 12

Document ID: PD-533752 Rev: 00

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)

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:	*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

bsi.

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.

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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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.

bsi.

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**

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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**

BSI REGISTERED

UKAS QUALITY MANAGEMENT 003

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 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**

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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Konformitätserklärung
Declaration of Conformity

Document-No.:	39.05.600
Revision-No.:	65
Effective Date:	2017-02-08
Page:	1 of 71

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 Managment

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	IIa
5010582	Coroset Marienhospital Herne	Coroset Marienhospital Herne	IIa
5010583	Hahnbank-Set Kard. GMP Göttingen	Hahnbank-Set Kard. GMP Göttingen	IIa
5010584	Abdeck-Set Kard. GMP Göttingen	Abdeck-Set Kard. GMP Göttingen	IIa
5010585	Coro Set Hagen	Coro Set Hagen	IIa
5010592	Kalmar Pacemakerset	Kalmar Pacemakerset	IIa
5010595	Schrittmacher-Set Pirna	Schrittmacher-Set Pirna	IIa
5010602	Schrittmacherset Nordhorn	Schrittmacherset Nordhorn	IIa
5010609	Tab. Cateterismo – Hosp. Santa Marta	Tab. Cateterismo – Hosp. Santa Marta	IIa
5010622	Biopsiasetti Kymenlaakson KS, RTG	Biopsiasetti Kymenlaakson KS, RTG	IIa
5010628	Schrittmacherset HPK Dr. Natour	Schrittmacherset HPK Dr. Natour	IIa
5010635	Angiodyn Angioset EVK Hamm	Angiodyn Angioset EVK Hamm	IIa
5010637	Schrittmacher Set Helios Klinikum München West	Schrittmacher Set Helios Klinikum München West	IIa
5010646	Radialis Set EKO	Radialis Set EKO	IIa
5010647	Coro Set Marktredwitz	Coro Set Marktredwitz	IIa
5010651	Putra Medical Center, Alor Star	Putra Medical Center, Alor Star	IIa
5010660	Angiodyn Hahnbankbaugruppe 3-fach, OFF	Angiodyn manifold assembly 3-way OFF	IIa
5010662	Schrittmacher Set	Schrittmacher Set	IIa
5010687	Hahnbankset Uni Münster	Hahnbankset Uni Münster	IIa
5010690	Feinnadelset KH-Stuttgart	Feinnadelset KH-Stuttgart	IIa
5010691	Angiodyn Coroset Villingen-Schwenningen	Angiodyn Coroset Villingen-Schwenningen	IIa
5010696	Coroset Bad Pyrmont	Coroset Bad Pyrmont	IIa
5010701	Coroset Nagold	Coroset Nagold	IIa
5010709	PTCA Set	PTCA Set	IIa
5010714	Port-Punktionsset	Port-Punktionsset	IIa
5010724	Angiodyn EPU Set Kaufbeuren	Angiodyn EPU Set Kaufbeuren	IIa
5010727	Laser-Set, KSSP Aarau	Laser-Set, KSSP Aarau	IIa
5010744	Toimenpidesetti Seinäjoe ks, röntgen	Toimenpidesetti Seinäjoe ks, röntgen	IIa
5010749	Schrittmacher-Set Medinos Sonneberg	Schrittmacher-Set Medinos Sonneberg	IIa
5010794	Angiosetti PHKS, ELFYS	Angiosetti PHKS, ELFYS	IIa
5010764	Angiodynset 3FRR35 15360	Angiodynset 3FRR35 15360	IIa
5010778	Angio-Neuro-Set Heinrich-Braun-Krankenhaus	Angio-Neuro-Set Heinrich-Braun-Krankenhaus	IIa
5010782	Pädiatrie-Set Uni Homburg	Pädiatrie-Set Uni Homburg	IIa
5010783	Set steril pentru Angiografie	Set steril pentru Angiografie	IIa
5010796	Add On Kit	Add On Kit	Is