

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**
Gamlestadvägen 3C
Box 13080
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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **1998-06-29**

Date: **2019-05-17**

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.

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
- 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.

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Supplementary Information to CE 01965

Issued To:

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NBOG code(s)	Device description	Intended purpose
Class III		
MD0301 MDS7001 MDS7006	Mepilex Ag Mepilex Border Ag Mepilex Transfer Ag	See CE 514235
MD0301 MDS7001 MDS7006	Mesalt	See CE 610149
MD0301 MDS7002 MDS7006	EZ Derm	See CE 596088
MD0301 MDS7001 MDS7006	Exufiber Ag+	See CE 670599

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NBOG code(s)	Device description	Intended purpose
Class IIb		
MD0106 MDS7006	Laparoscopic instruments - forceps, scissors, instrument cables	Surgery
MD0106 MD1104 MDS7006	Laparoscopic instruments – hook electrodes	Surgery
MD0108 MDS7006	Sterile wound irrigation solutions	Topical irrigation
MD1403	Non-sterile self-warming blankets	Patient warming blankets
MD0301	Adhesive bandage & dressing	Wound dressing
MDS7006	Exudate-absorbent dressing, hydrophilic-gel (alginate and gel fibre)	
	Exudate- absorbent dressing, non-gel (absorbent, superabsorbent, foam)	
	Wound-nonadherent dressing, absorbent Wound-nonadherent dressing permeable	
MD0303 MD1103 MDS7006	Negative pressure wound therapy (NPWT) system, pumps and accessories	Wound care

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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NBOG code(s)	Device description	Intended purpose
Class IIa		
MD0106	Suction irrigation sets	Not applicable for class IIa devices
MDS7006	Veress needles	
	Tocars	
	Endo retrieval pouches	
	XRD swabs and sponges	
MD0101	Surgical gloves	
MDS7006		
MD0301	Semi-permeable film dressing, wound non-adherent	
MDS7006	Semi-permeable film dressing	
MD0303	Non-sterile emollient creams	

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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Subcontractor:	Service(s) supplied
Akzo Nobel Salt A/S Hadsundvej 17 P.O. Box 103 DK-9550 Mariager Denmark	Medicinal Substances
Alfa Aesar 26 Parkridge Road Ward Hill Massachusetts USA	Medicinal Substances
Colonial Metals, Inc. PO Box 726 Triumph Industrial Park Elkton Maryland 21922 USA	Medicinal Substances

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Subcontractor:	Service(s) supplied
Copious International Inc Wei 11 Road, Huada Street New City, Heyuan 517000 Guangdong China	Manufacture
Foshan United Medical Technologies Ltd. Southern Medical Devices Industrial Park 89 Taoyuan East Road Shishan, Nanhai Foshan, Guangdong Province 528225 China	Manufacture
Freudenburg Performance Materials SE & Co. KG Höhnerweg 2-4 69469 Weinheim Germany	Manufacture

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Subcontractor:	Service(s) supplied
Molnlycke Health Care ProcedurePak, s.r.o Sachetni 73564 Havirov - Dolni Sucha Czech Republic	ETO Sterilization Manufacture
Molnlycke Health Care Tubiton House Medlock Street Oldham OL1 3HS United Kingdom	Manufacture
Molnlycke Health Care (Thailand) Ltd Amatanakorn Industrial Estate 700/461 Moo 7 Bangna-Trad RD. KM.57 Tambol Donhuaroh Amphur Muang Chonburi 20000 Thailand	Manufacture

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Subcontractor:	Service(s) supplied
Molnlycke Health Care Oy Saimaankatu 6 PO Box 76 FI-50101 Mikkeli Finland	ETO Sterilization Manufacture
Molnlycke Health Care S.A. 176 Chaussee Romaine Waremme 4300 Belgium	E Beam Sterilization Manufacture Moist Heat Sterilization
Molnlycke Health Care Sdn Bhd Lot 9, Lorong Perusahaan 4, P.O Box 52 Kulim Industrial Estate Kulim, Kedah 09000 Malaysia	Manufacture

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Subcontractor:	Service(s) supplied
Molnlycke Health Care Sdn Bhd Plot 204 Kawasan Perindustrian Kuala Ketil 09300 Kuala Ketil Kuala Ketil Kedah 09300 Malaysia	Manufacture
Molnlycke Health Care Sdn. Bhd. Lot B5 & B6 Kawasan Perindustrian MIEL Batang Kali Phase II 44300 Batang Kali, Selangor Malaysia	Manufacture
Mölnlycke Manufacturing US, LLC 11 Twins Rivers Drive Wiscasset Maine 04578 USA	Manufacture

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Subcontractor:	Service(s) supplied
Molnlycke Manufacturing, US LLC 191 Admiral Fitch Avenue Brunswick Maine 04011 USA	Manufacture
Pharmaset SAS 3 Rue de Luan 31130 Balma France	ETO Sterilization Manufacture
Pine Ridge Farms 1800 SE Maury St. Des Moines Iowa 50317 USA	Animal Tissues / Derivatives

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Subcontractor:	Service(s) supplied
Siam Steri Services Co. Ltd 700/644 Amata Nakorn Industrial Estate Moo 3, Tambol Bankao Amphur Panthong, Chonburi 20160 Thailand	ETO Sterilization
Stellen Medical, LLC 1290 Hammond Road St. Paul Minnesota 55110 USA	Control of Sterilization Manufacture
Sterigenics Belgium (Petit- Rechain) SA Zoning Industriel Avenue Andre Enst 21, Verviers Liège B-4800 Belgium	ETO Sterilization

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Subcontractor:	Service(s) supplied
Sterigenics Germany GmbH Kasteler Strasse 45 Wiesbaden 65203 Germany	ETO Sterilization
Sterigenics US LLC 7695 Formula Place San Diego California 92121 USA	E Beam Sterilization
Sterigenics US, LLC 10821 Withers Cove Park Drive Charlotte North Carolina 28278 USA	ETO Sterilization

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Subcontractor:	Service(s) supplied
STERIS Applied Sterilization Technologies (Formerly Synergy Health Applied Sterilization Technologies) Moray Road, Elgin Industrial Estate Swindon SN2 8XS UK	Gamma Sterilization
Steriservices 20 rue des Canadiens Bernay 27300 France	Moist Heat Sterilization
Synergy Health AST, Ede Morsestraat 3 Ede 6716 AH The Netherlands	Gamma Sterilization

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Subcontractor:	Service(s) supplied
Synergy Health Sterilisation UK Ltd (Synergy Health - AST-Swindon) Moray Road Elgin Industrial Estate Swindon SN2 8XS United Kingdom	Gamma Sterilization
Synergy Sterilisation (M) Sdn Bhd. (Steris) Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	Gamma Sterilization
Unimax Medical Systems Inc. 8F-2, No. 127, Lane 235 Pao Chiao Road, Hsin Tien Taipei Taiwan	Finished Device Supplier

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Subcontractor:

Service(s) supplied

Winner Medical (Jiayu) Co., Ltd.
No. 172, Fenghuang Avenue,
Jiayu
Hubei
437500
China

Manufacture

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Date	Reference Number	Action
29 June 1998		First issue
13 November 1998		Addition of cavity dressings to scope
11 June 1999		Re-structure of certificate
01 October 1999		Addition of new subcontractor
26 October 1999		Addition of Advanced Medical Solutions as a subcontractor
11 December 2000		Removal of Swedish manufacturing site
30 March 2001		Addition of new subcontractor
19 June 2001		Addition of new subcontractor
15 November 2002		Addition of Mölnlycke Health Care Klinipro S.R.O and Mölnlycke Health Care Inc, El Paso. Change of subcontractor name from Gammaster to Isotron
26 February 2004		Reissue in new format and addition of Waremmes Isotron NL and IBA Belgium as subcontractors
04 June 2004		Addition of Sterigenics Holland BV as a subcontractor
21 January 2005		Correction of subcontractor address and activities
23 June 2005		Change to scope to state surgical swabs, addition of Bioster SPA (Italy) as a subcontractor

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Date	Reference Number	Action
18 July 2005		Addition of Sterigenics in Germany as a new sterilisation facility
17 February 2006		Amendment to address to include 'Gamlestadsvägen 3 C' and to remove 'Box 13080'. Addition of Biora AB, Winner Industries (Shenzhen) Co Ltd, Ebster s.r.o. and Orifice Medicals AB as subcontractors. Change of scope to state porcine based wound dressings. Change of activity from Sterilisation to ETO sterilisation for subcontractor Sterigenics in Germany. Correction of typing errors
28 April 2006		Removal of Mölnlycke Health Care Inc (El Paso, Texas) as a subcontractor
27 September 2006		Transfer of certification from SGS, certificate GB 05/63789. Addition of sterile medicated and non-medicated polyurethane foam dressings, sterile hydrogel dressings and sterile saline solutions to the scope. Addition of Mölnlycke Health Care (Oldham) Ltd, Simco/SSL, SSL International (Peterlee), Theo Manufacturing and Unither as subcontractors for manufacture. Addition of Microbiological Validation Services as a subcontractor for testing. Addition of Isotron PLC (Bradford and Swindon sites) as subcontractors for Gamma Irradiation.

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Date	Reference Number	Action
06 June 2008	7005787	Removal of Mölnlycke Health Care AB, Mexico and Microbiological Validation Services Ltd, UK from the list of significant subcontractors. Certificate renewal
18 November 2009	7446394	Removal of sterile saline solutions for topical irrigation (moved to CE 01966). Medicated statement repositioned
14 September 2010	7574343	Addition of significant subcontractor IDT Biologika GmbH
24 February 2011	7649524	Addition of significant subcontractor Statens Serum Institut, Denmark
29 March 2012	7790680	Extension of scope to include self-warming blankets; addition of subcontractor Copious International Inc for the manufacture of self-warming blankets; addition of subcontractor PHARMASET for the manufacture and sterilisation of procedure packs. Subcontractor name update for Synergy Group sites (formerly Isotron)
23 August 2012	7802614	Scope extension to include emollient creams; updates to subcontractor addresses (Mölnlycke Health Care Klinipro s.r.o., Czech Republic, Mölnlycke Health Care Oy, Finland, Pharmaset SAS, France and Advanced Medical Solutions Limited, UK)

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Date	Reference Number	Action
26 April 2013	7961702	Scope extension to include abdominal wound dressings
03 June 2013	7956998	Extension to scope to include beta-glucan based devices and the addition of related subcontractors: Stellen Medical, LLC, Dakota Pack, Pine Ridge Farms, LLC and Sterigenics, San Diego CA
5 June 2013	7997983	Certificate renewal. Registered changes for significant subcontractors Winner Industries (Shenzhen) Co Ltd, Synergy Health - AST – Daventry, Mölnlycke Healthcare (Mikkeli) and Stellen Medical LLC. Addition of significant subcontractor Mölnlycke Healthcare (Oldham). Removal of significant subcontractors Bioster SPA, Sterigenics Germany GmbH (Kalle-Albert), Sterigenics Holland BV (Storkstraat), Simco/SSL, Theo Manufacturing and IDT Biologika GmbH. Scope clarification
24 October 2013	8068475	Extension to scope to include 'sterile wound irrigation systems'
28 May 2014	8149110	Extension to scope to include electro-stimulation devices for wound care; addition of related subcontractors (m.u.t AG Germany and Comepa Industries, France)
10 February 2016	8265950	Extension to scope to include superabsorber and alginate wound care devices. Addition of subcontractors Foshan United Medical Technologies Ltd, China and Steriservices, France.

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Date	Reference Number	Action
11 May 2016	8501420	Extension to scope to add suction irrigation sets, veress needles, trocars, laparoscopic instruments and negative pressure wound therapy system pumps and accessories. Addition of subcontractors Rynel, Inc., Maine, USA; Bioster S.p.A., Seriate, Italy; Sterigenics Germany GmbH, Wiesbaden, Germany; Unimax Medical Systems Inc., Taipei, Taiwan; Medela AG, Baar, Switzerland; Winner Medical (Chongyang) Co. Ltd., No 8 Jincheng Avenue, Tiancheng Town, China; Winner Medical (Chongyang) Co. Ltd., Pailou, China, Winner Medical (Chongyang) Co. Ltd., Qingshan Town, China and Winner Medical (Chongyang) Co. Ltd., No 9A Jincheng Avenue, Tiancheng Town, China.
16 January 2017	8636476	Addition of subcontractors Mölnlycke Manufacturing US, LLC, Brunswick, USA for manufacture and Sterigenics US, LLC, Charlotte, USA for ETO sterilisation. Update of Mölnlycke Oldham address from Tubiton House to Unity House. Update to Gothenburg address format. Update of Waremmes name and address from Mölnlycke Health Care AB, T/A Mölnlycke Health Care SA, Parc Industriel, Waremmes to Mölnlycke Health Care SA, 176 Chaussee Romaine, 4300 Waremmes.

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Date	Reference Number	Action
15 March 2017	8651564	Addition of subcontractor Mölnlycke Health Care ProcedurePak , s.r.o., Czech Republic for ETO sterilization and update of Mölnlycke Oldham from Unity House to Tubiton House.
11 May 2017	8732846	Update to subcontractor Mölnlycke Health Care ProcedurePak, s.r.o., Czech Republic activity to add manufacture. Addition of subcontractors Mölnlycke Health Care (Thailand) Ltd for manufacture and Siam Steri Services Co., Ltd. For ETO sterilisation.
30 May 2018	8901179	Certificate Renewal. Removal of scope expressions electro-stimulation devices for wound care, wound management gels, cavity dressing, wound dressings, abdominal towels, hydrogel dressings, abdominal wound dressings, procedure packs and beta-glucan based wound care devices. Re-wording of scope. Update to subcontractors and suppliers. Transfer of scope expression sterile surgical gloves from CE 01966.
22 November 2018	9656937	Addition of subcontractor Synergy Sterilisation (M) Sdn. Bhd, Kuala Ketil, Kedah, Malaysia for gamma sterilization.
25 February 2019	9684650	Addition of supplier Akzo Nobel Salt A/S, Denmark for medicinal substances.
5 March 2019	7779293	Traceable to NB 0086.

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Date	Reference Number	Action
Current	9675178	Addition of new subcontractor Freudenburg Performance. Materials SE & Co. KG, Höhnerweg 2-4, 69469 Weinheim, Germany. Change of company name for Rynel Inc to Mölnlycke Manufacturing US, LLC. Addition of supplementary product tables. Removal of subcontractor Redwood Farms Meat Processing.