

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
Göteborg
SE-402 52
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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **29 June 1998**

Date: **11 May 2016**

Expiry Date: **28 June 2018**

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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.

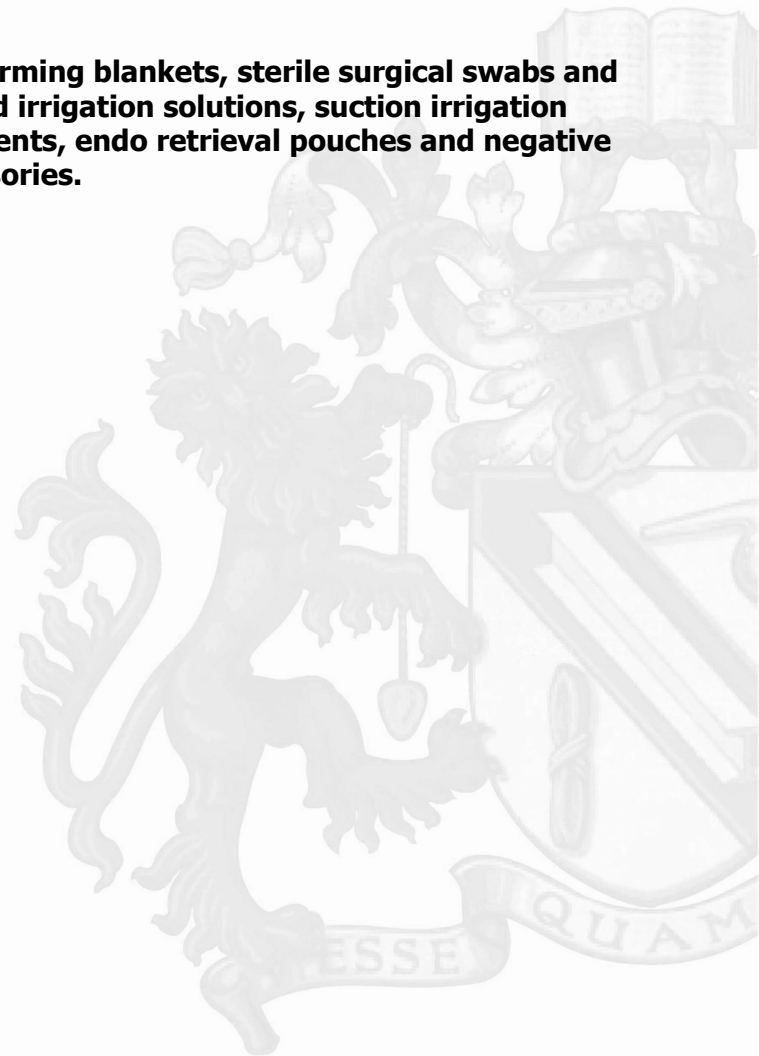
This certificate was issued electronically and is bound by the conditions of the contract.

Certificate No: CE 01965

Certificate Scope:

The design and manufacture of non-sterile emollient creams, electro-stimulation devices for wound care, sterile medicated and non-medicated open wound products: wound management gels, cavity dressings, wound dressings, abdominal towels, porcine based wound dressings, hydrogel dressings, polyurethane foam dressings, alginate dressings, superabsorbent dressings, abdominal wound dressings and beta-glucan based woundcare devices.

The design and manufacture of non-sterile self-warming blankets, sterile surgical swabs and sponges, sterile procedure packs and sterile wound irrigation solutions, suction irrigation sets, veress needles, trocars, laparoscopic instruments, endo retrieval pouches and negative pressure wound therapy system pumps and accessories.

First Issued: **29 June 1998**Date: **11 May 2016**Expiry Date: **28 June 2018**

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	Service(s) supplied
Advanced Medical Solutions Ltd Premier Park 33 Road One Winsford Industrial Estate Winsford, Cheshire CW7 3RT United Kingdom	Control of Sterilization Manufacture Moist Heat Sterilization
Biora AB Medeon Science Park SE-205 12 Malmö Sweden	Aseptic Processing Manufacture
Bioster S.p.A Via Ca' Bertoncina, 29 Seriate (BG) 24068 Italy	ETO Sterilization
Comepa Industries 88, avenue du Général de Gaulle 93541 Bagnolet Cedex France	Control of Sterilization Design Manufacture

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Subcontractor:	Service(s) supplied
Copious International Inc Wei 11 Road, Huada Street New City, Heyuan 517000 Guangdong China	Manufacture
Dakota Pack, Inc. 2421 9th Avenue South Estherville Iowa 51334 USA	Animal substances Supply
Ebster s.r.o. Průmyslová Zóna Kořikov 59501 Velká Bíteš Czech Republic	ETO Sterilization

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Subcontractor:	Service(s) supplied
Foshan United Medical Technologies Ltd. Southern Medical Devices Industrial Park 89 Taoyuan East Road Shishan, Nanhai Foshan Guangdong 528225 China	Manufacture
m.u.t AG Am Marienhof 2 D-22880 Wedel Germany	Design Manufacture
Medela AG Uittichstrasse 4b 6341 Baar Switzerland	Finished Device Supplier

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Subcontractor:	Service(s) supplied
Mölnlycke Health Care (Oldham) Ltd Tubiton House Medlock Street Oldham OL1 3HS United Kingdom	Manufacture
Mölnlycke Health Care AB T/A Mölnlycke Health Care SA Parc Industriel B-4300 Waremmes Belgium	E beam Sterilization Manufacture Moist Heat Sterilization
Mölnlycke Health Care Ltd 2 Omega Drive Irlam Manchester M44 5BJ United Kingdom	Complaints Handling Vigilance

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Subcontractor:	Service(s) supplied
Molnlycke Health Care Oy Saimaankatu 6 PO Box 76 FI-50101 Mikkeli Finland	ETO Sterilization Manufacture
Mölnlycke Health Care Klinipro, s.r.o. Na Novém Poli 382/1 733 01 Karviná - Staré Mesto Czech Republic	Manufacture
Orifice Medicals AB Aktergatan 2 SE-271 53 Ystad Sweden	Packaging
Pharmaset SAS 3 Avenue de Luan 31130 Balma France	ETO Sterilization Manufacture

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Subcontractor:	Service(s) supplied
Pine Ridge Farms 1800 SE Maury St. Des Moines Iowa 50317 USA	Animal substances Supply
Rynel, Inc. 11 Twin Rivers Drive Wiscasset Maine 04578 USA	Manufacture
SSL International PLC Whitehouse Business Park Traynor Way Peterlee County Durham SR8 2RU United Kingdom	Manufacture

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Subcontractor:	Service(s) supplied
Statens Serum Institut (SSI) Artillerivej 5 2300 Copenhagen Denmark	Aseptic Processing Manufacture
Stellen Medical, LLC 1290 Hammond Road St. Paul Minnesota 55110 USA	Control of Sterilization Manufacture
Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit-Rechain Avenue du Parc, 29 B-4800 Verviers Belgium	ETO Sterilization
Sterigenics Germany GmbH Kasteler Strasse 45 65203 Wiesbaden Germany	ETO Sterilization

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Subcontractor:	Service(s) supplied
Sterigenics US, LLC 7695 Formula Place San Diego California 92121 USA	E beam Sterilization
Steriservices 20, rue des Canadiens 27300 Bernay France	Moist Heat Sterilization
Synergy Health AST, Ede Morsestraat 3 6716 AH Ede Netherlands	Sterilization
Synergy Health AST, Etten-Leur Soeverinstraat 2 4879 NN Etten-Leur Netherlands	Gamma Sterilization

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Subcontractor:	Service(s) supplied
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Bradford) Roydsdale Way Euroway Industrial Estate Bradford BD4 6SE United Kingdom	Gamma Sterilization
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Daventry) Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	Gamma Sterilization
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Swindon) Moray Road Elgin Industrial Estate Swindon SN2 8XS United Kingdom	Gamma Sterilization

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Subcontractor:	Service(s) supplied
Unimax Medical Systems Inc. 8F-2, No. 127, Lane 235 Pao Chiao Road, Hsin Tien Taipei Taiwan	Finished Device Supplier
Unither Z.I. Longpre 10, rue Andre Duouchez 80052 Amiens Cedex 2 France	Manufacture
Winner Industries (Shenzhen) Co., Ltd. Winner Industrial Park No 660 Bulong Road Longhua District 518109 Shenzhen China	Control of Sterilization Manufacture

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Subcontractor:	Service(s) supplied
Winner Medical (Chongyang) Co., Ltd No. 8 Jincheng Avenue Tiancheng Town 437500 Chongyang Hubei China	Manufacture
Winner Medical (Chongyang) Co., Ltd No. 9A Jincheng Avenue Zhongjin Village Tiancheng Town 437500 Chongyang Hubei China	Manufacture
Winner Medical (Chongyang) Co., Ltd Te 1, Winner Avenue Qingshan Industrial Zone Qingshan Town 437542 Chongyang Hubei China	Manufacture

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Subcontractor:

Service(s) supplied

Winner Medical (Jingmen) Co., Ltd
Special No.1 Hangkong Avenue
Pailou
448121 Jingmen
Hubei
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 Waremm 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 'Gamlestadvägen 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 polythurethane 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