



BUREAU
VERITAS

Bureau Veritas Certification

Mölnlycke Health Care AB

Gamlestadsvägen 3C, 402 52 Göteborg, Sweden

This is a multi-site certificate, additional site(s) are listed on the next page(s)

Bureau Veritas Certification Holding SAS – UK Branch certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below.

ISO14001:2015

Scope of certification

Design, development, procurement, manufacturing, marketing, sales, and distribution of wound care treatment products, surgical products, and medical devices.

Original cycle start date:	13-February-2002
Expiry date of previous cycle:	NA
Certification / Recertification Audit date:	NA
Certification / Recertification cycle start date:	26-November-2019

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: 08-December-2022

Certificate No. SE007019 **Version: No.3** **Revision date: 16-March-2021**

Certification body address: 5th Floor, 66 Prescot Street, London E1 8HG, United Kingdom
Local office: **Fabriksgatan 13, 412 50 Gothenburg, Sweden**



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Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.
To check this certificate validity please call: **+46-31-606500**



BUREAU
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Bureau Veritas Certification

Mölnlycke Health Care AB

14001:2015

Design, development, procurement, manufacturing, marketing, sales, and distribution of wound care treatment products, surgical products, and medical devices.

<u>Site Name/Location</u>	<u>Site Address</u>	<u>Site Scope</u>
Mölnlycke Health Care AB	Gamlestadvägen 3C, 402 52 Göteborg, Sweden	Design, development, procurement, manufacturing, marketing, sales, and distribution of wound care treatment products and surgical products.
Mölnlycke Health Care Oy	Saimaankatu 6, Mikkeli, FI- 50101 Finland	The manufacture of towels, wound dressings, open wound products and scar dressing.
Mölnlycke Health Care SA	176 Chaussee Romaine, Waremmе, 4300 Belgium	The manufacture of sterile and non sterile drapes and swabs. The manufacture of sterile operating sets. The administrative management of logistics operations for distribution of medical devices.
Mölnlycke Health Care Ltd	Tubiton House Medlock Street Oldham OL1 3HS United Kingdom	The design, development and manufacture of sterile wound and scar dressings, emollients, non sterile textile retention bandages and garments, tubular support bandages and sterile wound irrigation solutions.

Certificate No. SE007019

Version: No. 3 Revision date: 16-March-2021

Certification body address: 5th Floor, 66 Prescott Street, London E1 8HG, United Kingdom

Local office: Fabriksgatan 13, 412 50 Gothenburg, Sweden



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Mölnlycke Health Care AB

14001:2015

Design, development, procurement, manufacturing, marketing, sales, and distribution of wound care treatment products, surgical products, and medical devices.

<u>Site Name/Location</u>	<u>Site Address</u>	<u>Site Scope</u>
Mölnlycke Health Care	Avda. De la Vega, 15, Edificio 3, 3ª Planta. 28108 Alcobendas. Madrid, Spain	The sales and distribution of products and/or dressings for the prevention and treatment of wounds and scars, antiseptics, surgical drapes, customized procedure packs, surgical gowns, surgical gloves and other clothing for personnel within the hospital environment.
Mölnlycke Health Care- Comercialização De Produtos Hospitalares, LDA.	Rua Brito capelo 807 4450-068 Matosinhos, Portugal	The sales and distribution of products and/or dressings for the prevention and treatment of wounds and scars, antiseptics, surgical drapes, customized procedure packs, surgical gowns, surgical gloves and other clothing for personnel within the hospital environment.

Certificate No. SE007019

Version: No. 3 Revision date: 16-March-2021

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Mölnlycke Health Care AB

14001:2015

Design, development, procurement, manufacturing, marketing, sales, and distribution of wound care treatment products, surgical products, and medical devices.

<u>Site Name/Location</u>	<u>Site Address</u>	<u>Site Scope</u>
Mölnlycke Health Care s.r.o.	Na Novem Poli c.p. 382/1 Prumyslova zona Karvina Karvina-Stare Mesto 733 01 Czech Republic	The manufacture of surgical drapes and procedure packs.
Mölnlycke Health Care ProcedurePak s.r.o.	ul. Šachetní 439/1 735 64 Havířov-Dolní Suchá, Czech Republic.	The manufacture of surgical drapes and procedure packs.
Mölnlycke Health Care Sdn. Bhd.	Sdn.Bhd. Lot 9, Lorong Perusahaan 4 P.O. Box 52 Kulim Industrial Estate 09000 Kulim Kedah, Malaysia	The design, development, manufacturing and packaging of sterile and non sterile medical gloves.
Mölnlycke Health Care Sdn. Bhd.	Sdn. Bhd. Plot 204, Kawasan Perindustrian Kuala Ketil 09300 Kuala Ketil Kedah, Malaysia	The design, development, manufacturing and packaging of sterile and non sterile medical gloves.
Mölnlycke Health Care Sdn. Bhd.	Sdn. Bhd. Lot B5 & B6, Kawasan Perindustrian MIEL, Batang Kali Phase II, 44300 Batang Kali, Selangor, Malaysia	The design, development, manufacturing and packaging of sterile and non sterile medical gloves.

Certificate No. SE007019

Version: No. 3 Revision date: 16-March-2021

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Mölnlycke Health Care AB

14001:2015

Design, development, procurement, manufacturing, marketing, sales, and distribution of wound care treatment products, surgical products, and medical devices.

<u>Site Name/Location</u>	<u>Site Address</u>	<u>Site Scope</u>
Mölnlycke Health Care (Thailand) Ltd	160 Moo 17 Bangplee Industrial Estate, Bangna-Trad Rd.KM.23 Tambol Bangsaothong Ampur Bangsaothong Samutprakarn Bangplee 10450, Thailand	The manufacture of surgical drapes and sets, equipment drapes, surgical and protective gowns, other staff clothes and wound dressing.
Mölnlycke Health Care Amata Narkorn (Bang Pakong) Mölnlycke Health Care (Thailand) Ltd	Industrial Estate 700/461 Moo 7 Bangna-Trad Rd.KM.57 Tambol Donhuaroh, Amphur Muang Chonburi 20000, Thailand	The manufacture of surgical drapes and sets, equipment drapes, surgical and protective gowns, other staff clothes and wound dressing.

Certificate No. SE007019

Version: No. 3 Revision date: 16-March-2021

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Mölnlycke Health Care AB

Gamlestadsvägen 3C, 402 52 Göteborg, Sweden

This is a multi-site certificate, additional site(s) are listed on the next page(s)

Bureau Veritas Certification Holding SAS – UK Branch certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below.

ISO45001:2018

Scope of certification

Design, development, procurement, manufacturing, marketing, sales, and distribution of wound care treatment products, surgical products, and medical devices.

Original cycle start date:	18-July-2008
Expiry date of previous cycle:	NA
Certification / Recertification Audit date:	NA
Certification / Recertification cycle start date:	22-December-2020

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: 08-December-2022

Certificate No. SE007379

Version: No.1

Revision date: 22-December-2020

Certification body address: **5th Floor, 66 Prescot Street, London E1 8HG, United Kingdom**
Local office: **Fabriksgatan 13, 412 50 Gothenburg, Sweden**



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To check this certificate validity please call: **+46-31-606500**



BUREAU
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Bureau Veritas Certification

Mölnlycke Health Care AB

ISO45001:2018

Design, development, procurement, manufacturing, marketing, sales, and distribution of wound care treatment products, surgical products, and medical devices.

<u>Site Name/Location</u>	<u>Site Address</u>	<u>Site Scope</u>
Mölnlycke Health Care AB, Head Office	Gamlestadvägen 3C, 402 52 Göteborg, Sweden	Design, development, procurement, manufacturing, marketing, sales, and distribution of wound care treatment products and surgical products.
Mölnlycke Health Care Oy	Saimaankatu 6, Mikkeli, FI-50101 Finland	The manufacture of towels, wound dressings, open wound products and scar dressing.
Mölnlycke Health Care AB	176 Chaussee Romaine, Wareme, 4300 Belgium	The manufacture of sterile and non sterile drapes and swabs. The manufacture of sterile operating sets. The administrative management of logistics operations for distribution of medical devices.
Mölnlycke Health Care Ltd	Tubiton House, Medlock Street Oldham OL1 3HS United Kingdom	The design, development and manufacture of sterile wound and scar dressings, emollients, non sterile textile retention bandages and garments, tubular support bandages and sterile wound irrigation solutions.

Certificate No. SE007379

Version: No. 1 Revision date: 22-December-2020

Certification body address: 5th Floor, 66 Prescott Street, London E1 8HG, United Kingdom

Local office: Fabriksgatan 13, 412 50 Gothenburg, Sweden



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Mölnlycke Health Care AB

ISO45001:2018

Design, development, procurement, manufacturing, marketing, sales, and distribution of wound care treatment products, surgical products, and medical devices.

<u>Site Name/Location</u>	<u>Site Address</u>	<u>Site Scope</u>
Mölnlycke Health Care Klinipro s.r.o.	Na Novem Poli c.p. 382/1 Prumyslova zona Karvina Karvina-Stare Mesto 733 01 Czech Republic	The manufacture of surgical drapes and procedure packs.
Mölnlycke Health Care ProcedurePak s.r.o.	ul. Šachetní 439/1 735 64 Havířov-Dolní Suchá, Czech Republic.	The manufacture, completion and sterilisation of surgical procedure packs.
Mölnlycke Health Care Sdn. Bhd.	Sdn.Bhd. Lot 9, Lorong Perusahaan 4 P.O. Box 52 Kulim Industrial Estate 09000 Kulim Kedah, Malaysia	The design, development, manufacturing and packaging of sterile and non sterile medical gloves.
Mölnlycke Health Care Sdn. Bhd.	Sdn. Bhd. Plot 204, Kawasan Perindustrian Kuala Ketil 09300 Kuala Ketil Kedah, Malaysia	The design, development, manufacturing and packaging of sterile and non sterile medical gloves.
Mölnlycke Health Care Sdn. Bhd.	Sdn. Bhd. Lot B5 & B6, Kawasan Perindustrian MIEL, Batang Kali Phase II, 44300 Batang Kali, Selangor, Malaysia	The design, development, manufacturing and packaging of sterile and non sterile medical gloves.

Certificate No. SE007379

Version: No. 1 Revision date: 22-December-2020

Certification body address: 5th Floor, 66 Prescott Street, London E1 8HG, United Kingdom

Local office: Fabriksgatan 13, 412 50 Gothenburg, Sweden



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ISO45001:2018

Design, development, procurement, manufacturing, marketing, sales, and distribution of wound care treatment products, surgical products, and medical devices.

<u>Site Name/Location</u>	<u>Site Address</u>	<u>Site Scope</u>
Mölnlycke Health Care (Thailand) Ltd	160 Moo 17 Bangplee Industrial Estate, Bangna-Trad Rd.KM.23 Tambol Bangsaothong Ampur Bangsaothong Samutprakarn Bangplee 10450, Thailand	The manufacture of surgical drapes and sets, equipment drapes, surgical and protective gowns, other staff clothes and wound dressing.
Mölnlycke Health Care Amata Narkorn (Bang Pakong) Mölnlycke Health Care (Thailand) Ltd	Industrial Estate 700/461 Moo 7 Bangna-Trad Rd.KM.57 Tambol Donhuaroh, Amphur Muang Chonburi 20000, Thailand	The manufacture of surgical drapes and sets, equipment drapes, surgical and protective gowns, other staff clothes and wound dressing.

Certificate No. SE007379

Version: No. 1 Revision date: 22-December-2020

Certification body address: 5th Floor, 66 Prescott Street, London E1 8HG, United Kingdom

Local office: Fabriksgatan 13, 412 50 Gothenburg, Sweden



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Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.

To check this certificate validity please call: **+46-31-606500**

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Mölnlycke Health Care AB
Gamlestadvägen 3C
Box 13080
Göteborg
SE-402 52
Sweden

Holds Certificate Number:

FM 39247

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The manufacture of sterile and non-sterile drapes, swabs and sterile operating sets. The servicing, decontamination, distribution and repair of negative pressure wound therapy pumps. The control of distribution of medical devices. Distribution of laparoscopic instruments. Previous certificate expired on 15th September 2018 Transition to ISO 9001:2015 completed on 13/09/2018

For and on behalf of BSI:

Andrew Launn, EMEA Systems Certification Director

Original Registration Date: 1998-03-31

Latest Revision Date: 2018-10-10

Effective Date: 2018-11-28

Expiry Date: 2021-11-27



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Page: 1 of 3

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Certificate No: FM 39247

Location	Registered Activities
Mölnlycke Health Care AB Box 13080 Gamlestadsvägen 3C SE-402 52 Göteborg Sweden	The design, development and manufacture of wound and scar dressings, porcine-based wound dressings, glucan-based wound 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, electro stimulation wound healing products and accessories.
MÖLNLYCKE HEALTH CARE S.A. Avda. Vega, 15 - Edificio 3-3. planta Alcobendas Madrid Madrid 28108 Spain	<p>The sales and distribution 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 servicing and repair of Negative Pressure Wound Therapy Pumps.</p> <p>Comercialización y distribución de apósitos para el tratamiento de cicatrices, productos para heridas abiertas, geles para el tratamiento de heridas, apósitos para heridas cavitadas, compresas, torundas, toallitas con alcohol estériles, productos para la protección de la piel, vendajes textiles no estériles, soluciones para la limpieza de heridas, paños abdominales, equipos para operaciones, cobertura quirúrgica y equipos, packs de procedimientos hechos a medida, batas quirúrgicas y otra vestimenta para personal usada dentro del ambiente hospitalario, guantes de uso médico estériles y no estériles, guantes quirúrgicos estériles. Servicio y reparación de máquinas de Presión Negativa.</p>

Original Registration Date: 1998-03-31

Effective Date: 2018-11-28

Latest Revision Date: 2018-10-10

Expiry Date: 2021-11-27

Page: 2 of 3

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

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Certificate No: FM 39247

Location

MOLNLYCKE HEALTH CARE-COMERCIALIZAÇÃO
DE PRODUTOS HOSPITALARES, LDA.
Rua Brito Capelo , 807
Matosinhos
4450-068
Portugal

Registered Activities

The sales and distribution 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 servicing and repair of Negative Pressure Wound Therapy Pumps.

A venda e comercialização de produtos estéreis e pensos para feridas e cicatrizes, produtos para feridas abertas, géis para o tratamento de feridas, pensos cavitários, esponjas, toalhetes com álcool esterilizados, produtos para cuidado da pele, compressas têxteis não estéreis, soluções de irrigação estéreis para feridas, compressas abdominais, trouxas cirúrgicas e coberturas para equipamentos, packs cirúrgicos, batas cirúrgicas e outro vestuário médico para uso em ambiente clínico, luvas médicas estéreis e não estéreis e luvas cirúrgicas. O serviço de reparação e manutenção dos equipamentos para tratamentos de feridas por pressão negativa.

Original Registration Date: 1998-03-31

Latest Revision Date: 2018-10-10

Effective Date: 2018-11-28

Expiry Date: 2021-11-27

Page: 3 of 3

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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 of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

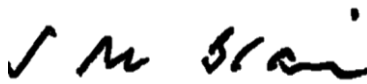
This is to certify that: Mölnlycke Health Care AB
Gamlestadsvägen 3C
Box 13080
Göteborg
SE-402 52
Sweden

DUNS Number: 63-177-0658

Holds certificate No: **MDSAP 692942**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure [if design controls are part of the certification]; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1-SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

Please see scope page.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk – Medical Devices

Original Registration Date: 2019-02-11

Effective Date: 2019-02-11

Expiry date: 2021-11-27

Page: 1 of 2

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BSI Group America Inc. is an MDSAP authorized auditing organization

Certificate No:

MDSAP 692942

Registered Scope:

The design, development, manufacture and distribution of sterile wound and scar dressings, porcine collagen wound dressing, open wound products, wound management gels, 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, abdominal towels, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and other medical staff clothing for use in the patient environment, electro stimulation wound healing products and accessories, sterile and non-sterile medical gloves and sterile surgical gloves.



Original Registration Date: 2019-02-11

Effective Date: 2019-02-11

Expiry date: 2021-11-27

Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request.
To be read in conjunction with the scope above or the attached appendix.

Managed by: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.