



By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 722028 R000

Manufacturer: Mölnlycke Health Care AB

Address:

Gamlestadsvägen 3C
Box 13080
SE-402 52 Göteborg
Sweden

Single Registration Number: SE-MF-000014042

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2020-05-08**

Date: **2022-05-09**

Expiry Date: **2025-05-07**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
Gelling fibre dressing with silver	See MDR 722078
Soft silicone foam dressing with silver	See MDR 722079
Self-adherent soft silicone foam dressing with silver	See MDR 758927
Soft silicone exudate transfer dressing with silver	See MDR 758929
Saline dressing	See MDR 722077
Class IIb	Intended purpose
Self-adherent soft silicone multi-layer foam dressing	Management of exuding wounds Protection of compromised and/or fragile skin May be used as part of a prophylactic therapy to prevent skin damage and to reduce postoperative blistering May be used on dry necrotic wounds in combination with gels
Self-adherent soft silicone flexible foam dressing	Management of exuding wounds Protection of compromised and/or fragile skin May be used as part of a prophylactic therapy to prevent skin damage and to reduce postoperative blistering May be used on dry necrotic wounds in combination with gels
Self-adherent soft silicone foam dressing - lite	Management of non/low exuding wounds Protection of compromised and/or fragile skin
Self-adherent soft silicone flexible foam dressing - lite	Management of non/moderately exuding wounds Protection of compromised and/or fragile skin
Soft silicone foam dressing	Management of exuding wounds Protection of compromised and/or fragile skin May be used as part of a prophylactic therapy to prevent skin damage
Soft silicone foam dressing with channels	Management of exuding wounds
Soft silicone foam dressing - lite	Management of non/low exuding wounds Protection of compromised and/or fragile skin

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Class IIb	Intended purpose
Soft silicone exudate transfer dressing	Management of exuding wounds Protection of compromised and/or fragile skin
Soft silicone wound contact layer	Non-adherent Allows passage of exudate and provides protection of tissues
Saline topical irrigation solution	Topical irrigation, wound cleansing, irrigation of mucous membranes and rinsing of eyes
Alginate dressing	Moderately to heavily exuding wounds, infected and non-infected such as pressure sores, venous and arterial ulcers, diabetic ulcers, post-operative wounds, dermal lesions and other external wounds inflicted by trauma
Adhesive dressing with absorbent pad	To absorb, protect and maintain a moist wound healing environment in open and closed wounds Intended for low to moderately exuding wounds
Gelling fibre dressing	Intended for exuding wounds: leg and foot ulcers, pressure ulcers, partial thickness burns, surgical wounds, donor sites and malignant wounds
Thermic drape	Intended to help prevent the patient from cooling during the perioperative period

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Self-adherent soft silicone surgical dressing	Class IIa
Adhesive dressing with absorbent pad	Class IIa
Surgical gloves - natural rubber latex	Class IIa
Surgical gloves - polychloroprene	Class IIa
Surgical gloves - polyisoprene	Class IIa
Film dressing	Class IIa
Film dressing, non-adherent	Class IIa
Transparent adhesive IV film dressings	Class Is
Surgical gowns	Class Is
Swabs and sponges	Class Is
Scar management dressings	Class Is
Surgical and equipment drapes	Class Is
Examination gloves	Class Is

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile condition

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
08 May 2020	3110440	First Issue.
17 December 2021	3331670	Change to address of Siam Steri Services.
22 April 2021	3406750	Addition of Radiation (Gamma Sterilization) to activities for Siam Steri Services Amended - Addition of critical subcontractor STERIS TOMOE (Thailand) Ltd for Radiation (Gamma Sterilization) Amended - Removal of critical subcontractor Steris Applied Sterilisation Technologies, Swindon Amended - Addition of critical subcontractor Synergy Health Sterilisation UK Ltd, Bradford for Radiation (Gamma Sterilization)
03 May 2021	3426520	Supplemented – addition of device category: Absorbent post-operative wound dressings Amended – addition of Sterigenics Belgium (Petit-Rechain) SA for ETO Sterilization
08 July 2021	3479391	Supplemented – addition of device self-adherent soft silicone multi-layer foam dressing Supplemented – addition of device self-adherent soft silicone flexible foam dressing Supplemented – addition of device self-adherent soft silicone foam dressing - lite Supplemented – addition of device self-adherent flexible foam dressing - lite Supplemented – addition of device soft silicone foam dressing Supplemented – addition of device soft silicone dressing with channels Supplemented – addition of device soft silicone foam dressing - lite Supplemented – addition of device soft silicone exudate transfer dressing Supplemented – addition of device saline topical irrigation solution Amended – addition of Sterigenics North Carolina for ETO sterilization Amended - addition of Molnlycke Manufacturing, Brunswick for Manufacture Amended - addition of Moist Heat Sterilization for services supplied by Mölnlycke Health Care, Oldham Amended - update device schedule description for post-operative dressing to self-adherent soft silicone surgical dressing

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Date	Reference number	Action
23 September 2021	3496354	Supplemented – addition of gelling fibre dressing with silver Supplemented – addition of surgical gloves, natural rubber latex Supplemented – addition of surgical gloves, polychloroprene Supplemented – addition of surgical gloves, polyisoprene Amended – addition of packaging for services supplied for Mölnlycke Oldham Amended – addition of Freudenberg for manufacturing Amended – addition of Colonial metals as a Crucial Supplier of medicinal substance Amended – addition design for Mölnlycke, Lot 9, Malaysia and Mölnlycke, Lot B5 & B6, Malaysia Amended – addition of design, packaging and final inspection for Mölnlycke, Plot 204 Malaysia
07 December 2021	3551783	Supplemented – addition of alginate dressing Amended – addition of critical subcontractor Foshan United Medical Technologies for manufacture and control of sterilization Amended – addition of critical subcontractor Synergy Health Ede BV for irradiation (x-ray sterilization)
18 January 2022	3598641	Supplemented – addition of adhesive dressing with absorbent pad and soft silicone wound contact layer Amended – minor correction to intended purpose for self-adherent soft silicone flexible foam dressing – lite
18 February 2022	3617621	Supplemented – addition of soft silicone foam dressing with silver Supplemented – addition of self-adherent soft silicone foam dressing with silver Supplemented – addition of soft silicone exudate transfer dressing with silver Supplemented – addition of adhesive dressing with absorbent pad (Class IIa) Amended – subcontractors: change of address for two Mölnlycke Thailand sites and addition of Mölnlycke Manufacturing, Wiscasset
30 March 2022	3638164	Supplemented – addition of saline dressing & gelling fibre dressing. Amended – addition of critical subcontractors Dansk & SteriServices.
Current	3675862	Supplemented – addition of thermic drape, film dressing & film dressing, non-adherent

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