EU Quality Management System Certificate

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

MDR 722028 R001

Manufacturer: Mölnlycke Health Care AB

Address:
Entreprenörsstråket 21
SE-431 53 Mölndal
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 devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional 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 Global Regulatory & Quality

First Issue Date: **2020-05-08**

Current Issue Date: **2025-12-17**

Starting Validity Date: **2025-12-17**

Expiry Date: **2030-05-07**

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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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Device Schedule: Class III and Class IIb devices

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 sounds, dermal lesions and other external wounds inflicted by trauma
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
Absorbent / superabsorbent dressing	Moderately to heavily exuding wounds As a primary or secondary dressing where high absorbency is required
Negative pressure wound therapy dressings	For patients that would benefit from NPWT device and with low to moderately exuding wounds

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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
Scar management dressings	Class IIa
Surgical gloves - powder free natural rubber latex	Class IIa
Surgical gloves - powder free polychloroprene	Class IIa
Surgical gloves - powder free polyisoprene	Class IIa
Film dressing	Class IIa
Film dressing, non-adherent	Class IIa
Negative pressure wound therapy pump	Class IIa
Emollient Creams	Class IIa
Transparent adhesive IV film dressings	Class Is
Surgical gowns	Class Is
Swabs and sponges	Class Is
Surgical and equipment drapes	Class Is
Examination gloves - powder free	Class Is
Negative pressure wound therapy canister	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 2020	3331670	Amended – change to address and addition of radiation (gamma sterilization) to sterilization subcontractor.
22 April 2021	3406750	Amended – addition of two subcontractors for radiation (gamma sterilization) and removal of one subcontractor for radiation (gamma sterilization).
03 May 2021	3426520	Supplemented – addition of device category: Absorbent post-operative wound dressings. Amended – addition of subcontractor 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 subcontractor for ETO, addition of subcontractor for manufacturing, addition of subcontractor for moist heat Sterilization. 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 to services supplied for subcontractor, addition of subcontractor for manufacturing, addition of crucial suppler of medical substances, addition of design to services supplied for two subcontractors, addition of design, packaging and final inspection to services supplied for subcontractor.
07 December 2021	3551783	Supplemented – addition of alginate dressing. Amended – addition of subcontractor for manufacture and control of sterilization, addition subcontractor for 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 – change of address for two subcontractors, addition of subcontractor for manufacture.
30 March 2022	3638164	Supplemented – addition of saline dressing & gelling fibre dressing. Amended – addition of crucial supplier for medicinal substance, addition of subcontractor of moist heat sterilization.
09 May 2022	3675862	Supplemented – addition of thermic drape, film dressing & film dressing, non-adherent.

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Date	Reference number	Action
2022-07-13	3719023	Supplemented – addition of absorbent / superabsorbent dressing. Amended – addition two subcontractors for ETO sterilization.
2022-10-26	3785653	Amended – addition of x-ray sterilization to services supplied for subcontractor. Amended – administrative update to previous history entries 3331670, 3406750, 3426520, 3479391, 3496354, 3551783, 3617621, 3638164, 3719023.
2023-06-13	3732486	Supplemented – addition of negative pressure wound therapy dressings, emollient creams, negative pressure wound therapy pump and negative pressure wound therapy canister. Amended – addition of two critical subcontractors for radiation (gamma sterilization); addition of subcontractor for design & manufacture; addition of subcontractor for manufacture; addition of subcontractor for manufacture & packaging. Amended – update device schedule description: addition of 'powder free' for surgical and examination gloves
2023-08-18	30005897	Amended – addition of critical subcontractor for x-ray sterilization
2025-02-25	30252437	Re-issued – certificate renewal Restricted – removal of adhesive dressing with absorbent pad (Class IIb)
2025-04-18	30252114	Amended – change to legal manufacturer address. Change from Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden to Entreprenörsstråket 21, SE-431 53 Mölndal, Sweden Amended – change to parametric release (Class IIa and Class IIb) for sterilisation subcontractor (-001) Amended – change to classification of scar management dressings from Class Is to Class IIa
2025-05-19	30288158	Amended – change to parametric release for sterilisation subcontractor (A) for devices manufactured at subcontractor (-037)
2025-10-27	30453179	Amended – change to parametric release for sterilisation subcontractor (C) for devices manufactured at subcontractor (-037)
2025-11-27	30460050	Amended – addition of subcontractor for ETO sterilisation

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Date	Reference number	Action
Current	30364227	Amended – addition of subcontractor for ETO sterilisation

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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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
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