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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**
Gamlestadsvägen 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: **2020-12-17** 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.

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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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**

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 XRD swabs and sponges.

The design and manufacture of sterile surgical gloves.

Those aspects of Annex II related to securing and maintaining sterility in the manufacturer of examination gloves.

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Supplementary Information to CE 01965

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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 MDS7001 MDS7006	Exufiber Ag+	See CE 670599

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NBOG code(s)	Device description	Intended purpose
Class IIb		
MD0108 MDS7006	Sterile wound irrigation solutions	Topical irrigation
MD1403	Non-sterile self-warming blankets	Patient warming blankets
MD0301 MDS7006	Adhesive bandage & dressing	Wound dressing
	Exudate-absorbent dressing, hydrophilic-gel (alginate and gel fibre)	
	Exudate-absorbent dressing, non-gel (absorbent, superabsorbent, foam)	
	Semi-permeable film dressing, wound non-adherent	
	Semi-permeable film dressing	
	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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NBOG code(s)	Device description	Intended purpose
Class IIa		
MD0106 MDS7006	XRD swabs and sponges	Not applicable for class IIa devices
MD0101 MDS7006	Surgical gloves – Natural Rubber Latex	
	Surgical gloves – Synthetic Latex	
MD0301 MDS7006	Adhesive bandage & dressing	
	Wound-nonadherent dressing, absorbent	
	Semi-permeable film dressing, wound non-adherent	
	Semi-permeable film dressing	
MD0303	Non-sterile emollient creams	
Class Is		
MD0101	Examination gloves	Not applicable for Class Is devices

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