EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 722079 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 assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III 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: **2022-02-18**

Current Issue Date: **2024-06-12**

Starting Validity Date: **2024-06-12**

Expiry Date: **2027-02-17**

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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 389 Chiswick High Road, London, W4 4AL, UK.
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Device Schedule:

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Intended purpose** (as per the IFU)	**Risk Classification**	**Basic UDI-DI**
Mepilex Ag	287021	MDN 1204	Management of low to moderately exuding leg and foot ulcers, pressure ulcers and partial thickness burns May be used on infected wounds as part of a treatment regime under supervision of a healthcare professional May be used under compression bandaging	Class III	733243000000000027JU
	287050				
	287110				
	287121				
	287210				
	287221				
	287310				
	287321				
	287410				
	287510				
	287640				
	287740				
	388100				
	388300				

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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
2022-02-18	3110875	Issued
Current	30033718	Amended – change to raw material shelf life & addition of SRN

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