

EU Technical Documentation Assessment Certificate

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

MDR 758927 R000

Manufacturer: Mölnlycke Health Care AB

Address:

Gamlestadsvägen 3C
Box 13080
SE-402 52 Göteborg
Sweden

Single Registration Number: Not Available

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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2022-02-18**

Date: **2022-02-18**

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

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Page 1 of 3

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 Border Ag	382000	MDN 1204	<p>Management of medium to high exuding wounds leg and foot ulcers, pressure ulcers, malignant wounds, partial thickness burns, traumatic and surgical wounds where a moist environment, exudate handling, gentle fixation and an antimicrobial action is indicated</p> <p>May be used on infected wounds as part of a treatment regimen under supervision of a qualified health care professional</p> <p>Can be used under compression bandaging</p>	Class III	73324300000000028JW
	382200				
	382400				
	395010				
	395200				
	395221				
	395260				
	395300				
	395360				
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	395700				
	395800				
	395900				

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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
Current	3371632	Issued



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