

EU Technical Documentation Assessment Certificate

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

MDR 758929 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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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 Transfer Ag	394000	MDN 1204	Low to high exuding leg and foot ulcers, pressure ulcers, malignant wounds, partial thickness burns and donor sites, where there is a risk of infection May be used on infected wounds as part of a treatment regimen under supervision of a qualified health care professional Can be used under compression bandaging	Class III	73324300000000029JY
	394100				
	394500				
	394700				
	394800				

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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	3371662	Issued



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