By Royal Charter

EU Technical Documentation Assessment Certificate

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

MDR 722078 R000

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 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: **2021-09-23**

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

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

Expiry Date: **2026-09-22**

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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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Device Schedule:

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Risk Classification	Basic UDI-DI
Exufiber Ag+					
Exufiber Ag+ gelling fibre dressing with silver	603400	MDN 1204	Management of the following medium to high exuding wounds: Venous leg ulcers Diabetic foot ulcers Pressure ulcers	Class III	7332430000000000010JB
	603401				
	603402				
	603403				
	603404				
	603405				
	603406				
	603407				
	603412				
	603413				

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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
2021-09-23	3110873	Issued
2024-06-12	30033714	Amended – change to raw material shelf life & addition of SRN
2025-04-18	30252107	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
2025-06-16	30274549	Amended – change to parametric release for sterilisation subcontractor -001
Current	30365406	Amended – expansion of clean room

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