EU Declaration of Conformity according to MDR

Title: Exufiber Ag+

We, Mölnlycke Health Care AB, Entreprenörsstråket 21, SE-431 53, Mölndal, Sweden, SRN SE-MF-000014042, being exclusively responsible manufacturer for conformity of the device/s; declare that the devices listed in the attached schedule are in conformity with the provisions of the Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: Not applicable

Trade name / Product name:	Exufiber Ag+

Product Classification:	MDR Class III
MDR Classification Rule:	4, 14
Sterility:	Sterile
Measuring Function:	No

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: IX
Common Specification: No CS is applicable

Certificate number:	MDR 722028, MDR 722078		
Issued by:	BSi	Id No:	2797
	(Notified Body Name)		

NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

Mölnlycke Health Care AB issues this declaration in recognition of applied harmonized standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Mölndal, Sweden

Date: 2025-05-08 Function: Regulatory Affairs Excellence Director

Name: Karin Darle Olsson Signature:

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Generic product information	
Intended Purpose:	Exufiber Ag+ is intended to be used in the following medium to high exuding wounds by absorbing and retaining exudate, inactivating a variety of wound related pathogens. • Venous leg ulcers • Diabetic foot ulcers • Pressure ulcers
Basic UDI-DI:	733243000000000010JB
GMDN Code:	47474 Exudate - absorbent dressing, hydrophilic-gel, antimicrobial, sterile
EMDN Code:	M04040801, SILVER DRESSINGS, NON-COMBINED

Product References Covered by this Declaration:	Product	Product Descriptor:
603400	Exufiber Ag+ 2x45cm x 5 pcs	Gelling Fibre Dressing with silver
603401	Exufiber Ag+ 5x5cm x 10 pcs	Gelling Fibre Dressing with silver
603402	Exufiber Ag+ 10x10cm x 10 pcs	Gelling Fibre Dressing with silver
603403	Exufiber Ag+ 15x15cm x 10 pcs	Gelling Fibre Dressing with silver
603404	Exufiber Ag+ 4.5x10cm x 10 pcs	Gelling Fibre Dressing with silver
603405	Exufiber Ag+ 4.5x20cm x 10 pcs	Gelling Fibre Dressing with silver
603406	Exufiber Ag+ 4.5x30cm x 10 pcs	Gelling Fibre Dressing with silver
603407	Exufiber Ag+ 20x30cm x 5 pcs	Gelling Fibre Dressing with silver