



**EU Declaration of Conformity
according to MDR**

Document ID: PD-578601 **Rev:**00
Created by: Kristin Ödling
State: Released
Approved by: Christina Lewing
Release date: 2022-05-13 12:24:08

Title: MDR DoC Exufiber Ag+

Dates and times in Greenwich Mean Time, 24 hours format

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, 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+
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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
	<i>(Notified Body Name)</i>	
<i>NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.</i>		

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: Göteborg, Sweden

Date: 2022-05-13 Function: Global Regulatory Affairs Director

Name: Christina Lewing

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

Product References Covered by this Declaration:	Product Descriptor:
603400	Gelling Fibre Dressing with silver
603401	Gelling Fibre Dressing with silver
603402	Gelling Fibre Dressing with silver
603403	Gelling Fibre Dressing with silver
603404	Gelling Fibre Dressing with silver
603405	Gelling Fibre Dressing with silver
603406	Gelling Fibre Dressing with silver
603407	Gelling Fibre Dressing with silver