



**EU Declaration of Conformity
according to MDR**

Document ID: PD-709923 **Rev:** 1
Created by: Anu-Maria Hokkanen
State: Released
Approved by: Christina Lewing
Release date: 2022-05-11 14:28:49

Title: Exufiber

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: Packaging and Packaging Waste Directive

Trade name / Product name:	Exufiber
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Product Classification: MDR Class IIb
MDR Classification Rule: 4
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	
Issued by:	BSi	Id No: 2797
	(Notified Body Name)	
<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: 2022-05-11 Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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Generic product information	
Intended Purpose:	Exufiber wound dressing is intended to be used on a wide range of exuding wounds: • Leg and foot ulcers • Pressure ulcers • Partial thickness burns • Surgical wounds • Donor sites • Malignant wounds
Basic UDI-DI:	733243000000000008JQ
GMDN Code:	43186 Exudate - absorbent dressing, hydrophilic-gel, sterile

Product References Covered by this Declaration:	Product Descriptor:
709900	Gelling fibre dressing
709901	Gelling fibre dressing
709902	Gelling fibre dressing
709903	Gelling fibre dressing
709904	Gelling fibre dressing
709905	Gelling fibre dressing
709906	Gelling fibre dressing
709907	Gelling fibre dressing
709908	Gelling fibre dressing
709909	Gelling fibre dressing
709912	Gelling fibre dressing
709913	Gelling fibre dressing
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709918	Gelling fibre dressing
709919	Gelling fibre dressing