



## EU Declaration of Conformity according to MDR

Title: Exufiber

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
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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)

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: Göteborg, Sweden

Date: 2024-08-16 Function: Regulatory Affairs Excellence Manager

Name: Karin Darle Olsson

Signature:



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Generic product information	
<b>Intended Purpose:</b>	Exufiber wound dressing absorbs and retains a large amount of exudate. It is transformed into a gel that facilitates moist wound healing and ease of removal during dressing change. Exufiber is intended to be used on a wide range of exuding wounds: <ul style="list-style-type: none"> <li>• Leg and foot ulcers</li> <li>• Pressure ulcers</li> <li>• Partial thickness burns</li> <li>• Surgical wounds</li> <li>• Donor sites</li> <li>• Malignant wounds</li> </ul>
<b>Basic UDI-DI:</b>	733243000000000008JQ
<b>GMDN Code:</b>	43186 Exudate - absorbent dressing, hydrophilic-gel, sterile
<b>EMDN Code:</b>	M040204 NON-ADHESIVE ABSORBENT DRESSINGS

Product References Covered by this Declaration:	Product	Product Descriptor:
709900	Exufiber 5x5cm	Gelling fibre dressing
709901	Exufiber 10x10cm	Gelling fibre dressing
709902	Exufiber 10x12cm	Gelling fibre dressing
709903	Exufiber 15x15cm	Gelling fibre dressing
709904	Exufiber 20x30cm	Gelling fibre dressing
709905	Exufiber 4.5x10cm	Gelling fibre dressing
709906	Exufiber 4.5x20cm	Gelling fibre dressing
709907	Exufiber 4.5x30cm	Gelling fibre dressing
709908	Exufiber 1x45cm	Gelling fibre dressing
709909	Exufiber 2x45cm	Gelling fibre dressing
709912	Exufiber FR 5x10cm x 16	Gelling fibre dressing
709913	Exufiber FR 10x10cm x 16	Gelling fibre dressing
709914	Exufiber FR 12x13cm x 16	Gelling fibre dressing
709915	Exufiber FR 10x20cm x 16	Gelling fibre dressing



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709916	Exufiber FR 20x20cm x 10	Gelling fibre dressing
709917	Exufiber FR 20x30cm x 10	Gelling fibre dressing
709918	Exufiber FR 2.5x40cm x 16	Gelling fibre dressing
709919	Exufiber FR 5x40cm x 16	Gelling fibre dressing