



PD-519257 Rev: 05 Kristin Ödling Karin Darle Olsson 2020-03-17



Title: Exufiber Ag Page 1(2)

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden 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 Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade name/
Product name:

Exufiber Ag+

Product classification: III

Sterility Status: Sterile

Measuring function: No

This declaration is supported by a conformity assessment procedure in accordance with

Annex/es:

Certificate number: CE 01965;CE 670599

Issued by: **BSI (2797)**

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

Body.

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: 2020-03-17 Function: Regulatory Affairs Manager

Compliance

Name: Karin Darle Olsson Signature:



Title: Exufiber Ag Page 2(2)

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
603400	Gelling Fibre Dressing with silver	47474 Exudate - absorbent dressing, hydrophilic-gel, antimicrobial, sterile
603401	Gelling Fibre Dressing with silver	47474 Exudate - absorbent dressing, hydrophilic-gel, antimicrobial, sterile
603402	Gelling Fibre Dressing with silver	47474 Exudate - absorbent dressing, hydrophilic-gel, antimicrobial, sterile
603403	Gelling Fibre Dressing with silver	47474 Exudate - absorbent dressing, hydrophilic-gel, antimicrobial, sterile
603404	Gelling Fibre Dressing with silver	47474 Exudate - absorbent dressing, hydrophilic-gel, antimicrobial, sterile
603405	Gelling Fibre Dressing with silver	47474 Exudate - absorbent dressing, hydrophilic-gel, antimicrobial, sterile
603406	Gelling Fibre Dressing with silver	47474 Exudate - absorbent dressing, hydrophilic-gel, antimicrobial, sterile
603407	Gelling Fibre Dressing with silver	47474 Exudate - absorbent dressing, hydrophilic-gel, antimicrobial, sterile