



EU Declaration of Conformity according to MDR

Document ID: PD-608930 **Rev:**00
Created by: Pia Malmberg
State: Released
Approved by: Karin Darle Olsson
Release date: 2022-10-25 11:49:44

Title: Mextra Superabsorbent/Superabsorbant

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:	Mextra Superabsorbent/Mextra Superabsorbant
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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: 2022-10-25

Function:

Regulatory Affairs Excellence
Manager

Name: Karin Darle Olsson

Signature:



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Generic product information	
Intended Purpose:	Mextra Superabsorbent is intended for use on moderately to heavily exuding wounds.
Basic UDI-DI:	733243000000000014JK
GMDN Code:	44970 Exudate - absorbent dressing, non-gel

Product References Covered by this Declaration:	Product Descriptor:
610000	Superabsorbent dressing with fluid-repellent backing
610100	Superabsorbent dressing with fluid-repellent backing
610180	Superabsorbent dressing with fluid-repellent backing
610200	Superabsorbent dressing with fluid-repellent backing
610280	Superabsorbent dressing with fluid-repellent backing
610300	Superabsorbent dressing with fluid-repellent backing
610400	Superabsorbent dressing with fluid-repellent backing
610500	Superabsorbent dressing with fluid-repellent backing
610580	Superabsorbent dressing with fluid-repellent backing
610600	Superabsorbent dressing with fluid-repellent backing
610680	Superabsorbent dressing with fluid-repellent backing
610700	Superabsorbent dressing with fluid-repellent backing
610710	Superabsorbent dressing with fluid-repellent backing
610720	Superabsorbent dressing with fluid-repellent backing
610730	Superabsorbent dressing with fluid-repellent backing
610740	Superabsorbent dressing with fluid-repellent backing
610750	Superabsorbent dressing with fluid-repellent backing



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610760	Superabsorbent dressing with fluid-repellent backing
610780	Superabsorbent dressing with fluid-repellent backing