EU Declaration of Conformity according to MDR

Title: Mextra Superabsorbent/Superabsorbant

We, Mölnlycke Health Care AB, Entreprenörsstråket 21, SE-431 53, Mölndal, 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:	Mextra Superabsorbent/Mextra Superabsorbant

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: Mölndal, Sweden

Date:	2025-05-12	Function:	Regulatory Affairs Excellence Director
Name:	Karin Darle Olsson	Signature:	

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Title: Mextra Superabsorbent/Superabsorbant

Generic product information	
Intended Purpose:	Mextra Superabsorbent is intended for use on moderately to heavily exuding wounds. Mextra Superabsorbent is a superabsorbent dressing with a fluid-repellent nonwoven backing, a core consisting of superabsorbent particles and a nonwoven wound contact layer. Mextra Superabsorbent absorbs wound exudate through the wound contact layer, retains the exudate within the core and reduce the risk for maceration. The fluid-repellent nonwoven backing acts as a barrier and prevents exudate strike-through.
Basic UDI-DI:	733243000000000014JK
GMDN Code:	44970 Exudate - absorbent dressing, non-gel
EMDN Code:	M040204 NON-ADHESIVE ABSORBENT DRESSINGS

Product References Covered by this Declaration:	Product	Product Descriptor:
610000	Mextra Superabsorbent 12,5x12,5 cm	Superabsorbent dressing with fluid-repellent backing
610100	Mextra Superabsorbent 12,5x17,5 cm	Superabsorbent dressing with fluid-repellent backing
610180	Mextra Superabsorbant 12,5x12,5 cm, FR	Superabsorbent dressing with fluid-repellent backing
610200	Mextra Superabsorbent 12,5x22,5 cm	Superabsorbent dressing with fluid-repellent backing
610280	Mextra Superabsorbant 17,5x22,5 cm, FR	Superabsorbent dressing with fluid-repellent backing
610300	Mextra Superabsorbent 17,5x22,5 cm	Superabsorbent dressing with fluid-repellent backing
610400	Mextra Superabsorbent 22,5x27,5 cm	Superabsorbent dressing with fluid-repellent backing
610500	Mextra Superabsorbent 22,5x32,5 cm	Superabsorbent dressing with fluid-repellent backing
610580	Mextra Superabsorbant 22,5x27,5 cm, FR	Superabsorbent dressing with fluid-repellent backing
610600	Mextra Superabsorbent 22,5x42,5cm	Superabsorbent dressing with fluid-repellent backing

610680	Mextra Superabsorbant 12,5x22,5cm, FR	Superabsorbent dressing with fluid-repellent backing
610700	Mextra Superabsorbent 10x10cm	Superabsorbent dressing with fluid-repellent backing
610710	Mextra Superabsorbent 10x15cm	Superabsorbent dressing with fluid-repellent backing
610720	Mextra Superabsorbent 10x20cm	Superabsorbent dressing with fluid-repellent backing
610730	Mextra Superabsorbent 15x20cm	Superabsorbent dressing with fluid-repellent backing
610740	Mextra Superabsorbent 20x25cm	Superabsorbent dressing with fluid-repellent backing
610750	Mextra Superabsorbent 20x30cm	Superabsorbent dressing with fluid-repellent backing
610760	Mextra Superabsorbent 20x40cm	Superabsorbent dressing with fluid-repellent backing
610780	Mextra Superabsorbant 22,5x42,5cm, FR	Superabsorbent dressing with fluid-repellent backing