EU Declaration of Conformity according to MDR

Title: Mesoft non-sterile

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:	Mesoft non-sterile

Product Classification:	MDR Class I ns
MDR Classification Rule:	4
Sterility:	Non-sterile
Measuring Function:	No

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: IV
Common Specification: No CS is applicable

Certificate number:	Not Applicable	
Issued by:	Not Applicable	Id No:
	(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: 2025-05-06 Function: Regulatory Affairs Excellence Director

Name: Karin Darle Olsson Signature:



Title: Mesoft non-sterile

Generic product information	
Intended Purpose:	Mesoft is intended for skin cleaning prior to surgical operation, wound cleaning and protection, and to absorb wound exudates when used as a secondary dressing.
Basic UDI-DI:	733243000000000026JS
GMDN Code:	48131 Non-woven gauze pad
EMDN Code:	M0202030102 NON-WOVEN GAUZE PADS, WITHOUT X-RAY DETECTABLE THREAD, NON-STERILE

Product References Covered by this Declaration:	Product	Product Descriptor:
156000	Mesoft 40 gsm, Non-sterile 5x5 30 pcs	Nonwoven swabs
156015	Mesoft 40 gsm, Non-sterile 5x5 100pcs	Nonwoven swabs
156056	Mesoft 30 gsm, Non-sterile 5x5 150pcs, Aseptic box	Nonwoven swabs
156100	Mesoft 40 gsm, Non-sterile 7,5x7,5 300pcs	Nonwoven swabs
156115	Mesoft 40 gsm, Non-sterile 7,5x7,5 100pcs	Nonwoven swabs
156150	Mesoft 40 gsm, Non-sterile 7,5x7,5 100pcs	Nonwoven swabs
156156	Mesoft 30 gsm, Non-sterile 7,5x7,5 150pcs, Aseptic box	Nonwoven swabs
156300	Mesoft 40 gsm, Non-sterile 10x10 200pcs	Nonwoven swabs
156315	Mesoft 40 gsm, Non-sterile 10x10 100pcs	Nonwoven swabs
156350	Mesoft 40 gsm, Non-sterile 10x10 100pcs	Nonwoven swabs
156356	Mesoft 30 gsm, Non-sterile 10x10 120pcs, Aseptic box	Nonwoven swabs

156400	Mesoft 40 gsm, Non-sterile 10x20 200pcs	Nonwoven swabs
156415	Mesoft 40 gsm, Non-sterile 10x20 100pcs	Nonwoven swabs
156700	Mesoft 30 gsm, Non-sterile round sponge S	Nonwoven round sponges
156800	Mesoft 30 gsm, Non-sterile round sponge M	Nonwoven round sponges
156900	Mesoft 30 gsm, Non-sterile round sponge L	Nonwoven round sponges
157000	Mesoft 30 gsm, Non-sterile 5x5 100 pcs	Nonwoven swabs
157100	Mesoft 30 gsm, Non-sterile 7,5x7,5 100pcs	Nonwoven swabs
157300	Mesoft 30 gsm, Non-sterile 10x10 100pcs	Nonwoven swabs
157400	Mesoft 30 gsm, Non-sterile 10x20 100pcs	Nonwoven swabs