



EU Declaration of Conformity according to MDR

Document ID: PD-595158 **Rev:**02
Created by: Pia Malmberg
State: Released
Approved by: Christina Lewing
Release date: 2021-11-24 09:29:04

Title: Mesoft non-sterile

Dates and times in Greenwich Mean Time, 24 hours format

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 Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: Not applicable

Trade name / Product name:	Mesoft non-sterile
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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:
	<i>(Notified Body Name)</i>	
<i>Note. For non-sterile, non-measuring class I products there is no Notified Body certificate</i>		

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

Signed for and on behalf of Mölnlycke Health Care

Place of Issue: Göteborg, Sweden

Date: 2021-11-24 Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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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

Product References Covered by this Declaration:	Product Descriptor:
156000	Nonwoven swabs
156015	Nonwoven swabs
156056	Nonwoven swabs
156100	Nonwoven swabs
156115	Nonwoven swabs
156150	Nonwoven swabs
156156	Nonwoven swabs
156300	Nonwoven swabs
156315	Nonwoven swabs
156350	Nonwoven swabs
156356	Nonwoven swabs
156400	Nonwoven swabs
156415	Nonwoven swabs
156700	Nonwoven round sponges
156800	Nonwoven round sponges
156900	Nonwoven round sponges
157000	Nonwoven swabs
157100	Nonwoven swabs
157300	Nonwoven swabs



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157310	Nonwoven swabs
157400	Nonwoven swabs