

Title: Mesoft non-sterile

Page 1(3)

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 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: **I**
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

NB. 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: **2020-09-03** Function: **Regulatory Affairs Director**

Name: **Christina Lewing** Signature:





**EU Declaration of Conformity
according to MDR**

Document ID: PD-595158 Rev: 00

Title: Mesoft non-sterile

Page 2(3)

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.

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
156000	Nonwoven swabs	733243000000000026JS	48130 Non-woven gauze pad, non-sterile
156015	Nonwoven swabs	733243000000000026JS	48130 Non-woven gauze pad, non-sterile
156056	Nonwoven swabs	733243000000000026JS	48130 Non-woven gauze pad, non-sterile
156100	Nonwoven swabs	733243000000000026JS	48130 Non-woven gauze pad, non-sterile
156115	Nonwoven swabs	733243000000000026JS	48130 Non-woven gauze pad, non-sterile
156150	Nonwoven swabs	733243000000000026JS	48130 Non-woven gauze pad, non-sterile
156156	Nonwoven swabs	733243000000000026JS	48130 Non-woven gauze pad, non-sterile
156300	Nonwoven swabs	733243000000000026JS	48130 Non-woven gauze pad, non-sterile
156315	Nonwoven swabs	733243000000000026JS	48130 Non-woven gauze pad, non-sterile
156350	Nonwoven swabs	733243000000000026JS	48130 Non-woven gauze pad, non-sterile
156356	Nonwoven swabs	733243000000000026JS	48130 Non-woven gauze pad, non-sterile
156400	Nonwoven swabs	733243000000000026JS	48130 Non-woven gauze pad, non-sterile



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Page 3(3)

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
156415	Nonwoven swabs	73324300000000026JS	48130 Non-woven gauze pad, non-sterile
156700	Nonwoven round sponges	73324300000000026JS	48130 Non-woven gauze pad, non-sterile
156800	Nonwoven round sponges	73324300000000026JS	48130 Non-woven gauze pad, non-sterile
156900	Nonwoven round sponges	73324300000000026JS	48130 Non-woven gauze pad, non-sterile
157000	Nonwoven swabs	73324300000000026JS	48130 Non-woven gauze pad, non-sterile
157100	Nonwoven swabs	73324300000000026JS	48130 Non-woven gauze pad, non-sterile
157300	Nonwoven swabs	73324300000000026JS	48130 Non-woven gauze pad, non-sterile
157310	Nonwoven swabs	73324300000000026JS	48130 Non-woven gauze pad, non-sterile
157400	Nonwoven swabs	73324300000000026JS	48130 Non-woven gauze pad, non-sterile