

Title: Mesoft (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 (sterile) |
|------------------------------|-------------------------|

Product classification: **IS**

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 (2797) |
|------------|-------------------|

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: **2020-06-23**

Function: **Regulatory Affairs Director**

Name: **Christina Lewing**

Signature:





**EU Declaration of Conformity
according to MDR**

Document ID: PD-582214 Rev: 00

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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: |
|--------------------|---------------------|----------------------|------------------------------------|
| 155030 | Split swab | 733243000000000025JQ | 48131 Non-woven gauze pad, sterile |
| 156029 | Nonwoven swabs | 733243000000000025JQ | 48131 Non-woven gauze pad, sterile |
| 156040 | Nonwoven swabs | 733243000000000025JQ | 48131 Non-woven gauze pad, sterile |
| 156065 | Nonwoven swabs | 733243000000000025JQ | 48131 Non-woven gauze pad, sterile |
| 156129 | Nonwoven swabs | 733243000000000025JQ | 48131 Non-woven gauze pad, sterile |
| 156140 | Nonwoven swabs | 733243000000000025JQ | 48131 Non-woven gauze pad, sterile |
| 156149 | Nonwoven swabs | 733243000000000025JQ | 48131 Non-woven gauze pad, sterile |
| 156159 | Nonwoven swabs | 733243000000000025JQ | 48131 Non-woven gauze pad, sterile |
| 156165 | Nonwoven swabs | 733243000000000025JQ | 48131 Non-woven gauze pad, sterile |
| 156329 | Nonwoven swabs | 733243000000000025JQ | 48131 Non-woven gauze pad, sterile |
| 156340 | Nonwoven swabs | 733243000000000025JQ | 48131 Non-woven gauze pad, sterile |
| 156349 | Nonwoven swabs | 733243000000000025JQ | 48131 Non-woven gauze pad, sterile |



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| Product Reference: | Product Descriptor: | Basic UDI-DI: | GMDN Code: |
|---------------------------|----------------------------|----------------------|------------------------------------|
| 156359 | Nonwoven swabs | 73324300000000025JQ | 48131 Non-woven gauze pad, sterile |
| 156365 | Nonwoven swabs | 73324300000000025JQ | 48131 Non-woven gauze pad, sterile |
| 156440 | Nonwoven swabs | 73324300000000025JQ | 48131 Non-woven gauze pad, sterile |
| 156465 | Nonwoven swabs | 73324300000000025JQ | 48131 Non-woven gauze pad, sterile |
| 156760 | Nonwoven round sponges | 73324300000000025JQ | 48131 Non-woven gauze pad, sterile |
| 156860 | Nonwoven round sponges | 73324300000000025JQ | 48131 Non-woven gauze pad, sterile |
| 156960 | Nonwoven round sponges | 73324300000000025JQ | 48131 Non-woven gauze pad, sterile |