

**Title:** Mesoft (sterile)

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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:	<b>Mesoft (sterile)</b>
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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:	<b>IX</b>
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Common Specification:	<b>No CS is applicable</b>
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Certificate number:	<b>MDR 722028</b>
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Issued by:	<b>BSI (2797)</b>
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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**

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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	73324300000000025JQ	48131 Non-woven gauze pad, sterile
156029	Nonwoven swabs	73324300000000025JQ	48131 Non-woven gauze pad, sterile
156040	Nonwoven swabs	73324300000000025JQ	48131 Non-woven gauze pad, sterile
156065	Nonwoven swabs	73324300000000025JQ	48131 Non-woven gauze pad, sterile
156129	Nonwoven swabs	73324300000000025JQ	48131 Non-woven gauze pad, sterile
156140	Nonwoven swabs	73324300000000025JQ	48131 Non-woven gauze pad, sterile
156149	Nonwoven swabs	73324300000000025JQ	48131 Non-woven gauze pad, sterile
156159	Nonwoven swabs	73324300000000025JQ	48131 Non-woven gauze pad, sterile
156165	Nonwoven swabs	73324300000000025JQ	48131 Non-woven gauze pad, sterile
156329	Nonwoven swabs	73324300000000025JQ	48131 Non-woven gauze pad, sterile
156340	Nonwoven swabs	73324300000000025JQ	48131 Non-woven gauze pad, sterile
156349	Nonwoven swabs	73324300000000025JQ	48131 Non-woven gauze pad, sterile



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<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>Basic UDI-DI:</b>	<b>GMDN Code:</b>
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