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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:	**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:

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	7332430000000000025JQ	48131 Non-woven gauze pad, sterile
156029	Nonwoven swabs	7332430000000000025JQ	48131 Non-woven gauze pad, sterile
156040	Nonwoven swabs	7332430000000000025JQ	48131 Non-woven gauze pad, sterile
156065	Nonwoven swabs	7332430000000000025JQ	48131 Non-woven gauze pad, sterile
156129	Nonwoven swabs	7332430000000000025JQ	48131 Non-woven gauze pad, sterile
156140	Nonwoven swabs	7332430000000000025JQ	48131 Non-woven gauze pad, sterile
156149	Nonwoven swabs	7332430000000000025JQ	48131 Non-woven gauze pad, sterile
156159	Nonwoven swabs	7332430000000000025JQ	48131 Non-woven gauze pad, sterile
156165	Nonwoven swabs	7332430000000000025JQ	48131 Non-woven gauze pad, sterile
156329	Nonwoven swabs	7332430000000000025JQ	48131 Non-woven gauze pad, sterile
156340	Nonwoven swabs	7332430000000000025JQ	48131 Non-woven gauze pad, sterile
156349	Nonwoven swabs	7332430000000000025JQ	48131 Non-woven gauze pad, sterile

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
156359	Nonwoven swabs	733243000000000025JQ	48131 Non-woven gauze pad, sterile
156365	Nonwoven swabs	733243000000000025JQ	48131 Non-woven gauze pad, sterile
156440	Nonwoven swabs	733243000000000025JQ	48131 Non-woven gauze pad, sterile
156465	Nonwoven swabs	733243000000000025JQ	48131 Non-woven gauze pad, sterile
156760	Nonwoven round sponges	733243000000000025JQ	48131 Non-woven gauze pad, sterile
156860	Nonwoven round sponges	733243000000000025JQ	48131 Non-woven gauze pad, sterile
156960	Nonwoven round sponges	733243000000000025JQ	48131 Non-woven gauze pad, sterile