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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:	**Gauze (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:	**2020-09-03**	Function:	**Regulatory Affairs Director**
Name:	**Christina Lewing**	Signature:	

Intended Purpose: Gauze is intended for wound cleansing, skin cleansing e.g. before a surgical operation, and absorption of exudates when used as a secondary dressing.

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
150760	Gauze sponges	733243000000000066K6	48134 Woven gauze pad, sterile
150860	Gauze sponges	733243000000000066K6	48134 Woven gauze pad, sterile
151360	Gauze sponges	733243000000000066K6	48134 Woven gauze pad, sterile
151460	Gauze sponges	733243000000000066K6	48134 Woven gauze pad, sterile
151760	Gauze sponges	733243000000000066K6	48134 Woven gauze pad, sterile
152040	Gauze swabs	733243000000000066K6	48134 Woven gauze pad, sterile
152440	Gauze swabs	733243000000000066K6	48134 Woven gauze pad, sterile
152465	Gauze swabs	733243000000000066K6	48134 Woven gauze pad, sterile
153040	Gauze swabs	733243000000000066K6	48134 Woven gauze pad, sterile
153065	Gauze swabs	733243000000000066K6	48134 Woven gauze pad, sterile
153165	Gauze swabs	733243000000000066K6	48134 Woven gauze pad, sterile
153340	Gauze swabs	733243000000000066K6	48134 Woven gauze pad, sterile

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
153349	100% cotton swabs	733243000000000066K6	48134 Woven gauze pad, sterile
153365	Gauze swabs	733243000000000066K6	48134 Woven gauze pad, sterile
153449	100% cotton swabs	733243000000000066K6	48134 Woven gauze pad, sterile
153665	Gauze swabs	733243000000000066K6	48134 Woven gauze pad, sterile
153765	Gauze swabs	733243000000000066K6	48134 Woven gauze pad, sterile
158040	Gauze swabs	733243000000000066K6	48134 Woven gauze pad, sterile
158049	100% cotton swabs	733243000000000066K6	48134 Woven gauze pad, sterile
158149	100% cotton swabs	733243000000000066K6	48134 Woven gauze pad, sterile
158440	Gauze swabs	733243000000000066K6	48134 Woven gauze pad, sterile
158465	Gauze swabs	733243000000000066K6	48134 Woven gauze pad, sterile
158540	Gauze swabs	733243000000000066K6	48134 Woven gauze pad, sterile
158560	Gauze swabs	733243000000000066K6	48134 Woven gauze pad, sterile