



**EU Declaration of Conformity
according to MDR**

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Approval date: 2020-11-04

Title: Bulk non-sterile, bags

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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:	Bulk non-sterile, bags
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Product classification: **I**
MDR Classification Rule: **1**
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: **2020-11-04** Function: **Regulatory Affairs Director**

Name: **Christina Lewing** Signature:

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Intended Purpose: The bags are attached to other draped areas and are used for storing instruments during surgical procedures. The bags are provided non-sterile for final packaging and sterilisation prior to use.

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
815320	INSTRUMENT BAG	73324300000000020JE	58968 Instrument management bag, non-sterile
8183	TUBE POCKET	73324300000000020JE	58968 Instrument management bag, non-sterile
975880	INSTRUMENT BAG	73324300000000020JE	58968 Instrument management bag, non-sterile
977035	SUCTION AND DIATHERMY BAG	73324300000000020JE	58968 Instrument management bag, non-sterile
977050	Instrument Bag	73324300000000020JE	58968 Instrument management bag, non-sterile