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**

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:

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	733243000000000020JE	58968 Instrument management bag, non-sterile
8183	TUBE POCKET	733243000000000020JE	58968 Instrument management bag, non-sterile
975880	INSTRUMENT BAG	733243000000000020JE	58968 Instrument management bag, non-sterile
977035	SUCTION AND DIATHERMY BAG	733243000000000020JE	58968 Instrument management bag, non-sterile
977050	Instrument Bag	733243000000000020JE	58968 Instrument management bag, non-sterile