EU Declaration of Conformity according to MDR

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Title: Sterile bags

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden, SRN SE-MF-000014042, 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 the Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: Not applicable

Trade name / Product name:	Sterile bags

Product Classification:	MDR Class IS
MDR Classification Rule:	1
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	Id No:	2797
	(Notified Body Name)		

NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

Mölnlycke Health Care AB issues this declaration in recognition of applied harmonized standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Göteborg, Sweden

Date:	2022-06-09	Function:	Regulatory Affairs Excellence Manager
Name:	Karin Darle Olsson	Signature:	

Generic product information	
Intended Purpose:	The bags are attached to other draped areas and are used for storing instruments during surgical procedures.
Basic UDI-DI:	7332430000000000037JX
GMDN Code:	58968 Instrument management bag

Product References Covered by this Declaration:	**Product Descriptor:**
705860	INSTRUMENT BAG
707035	SUCTION AND DIATHERMY BAG
80003113	TUBE POCKET