EU Declaration of Conformity according to MDR

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Title: Bulk non-sterile, OP-tape

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 the Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: Not applicable

Trade name / Product name:	Bulk non-sterile, patient drape

Product Classification:	MDR Class I ns
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	Id No:
	(Notified Body Name)	

Note. For non-sterile, non-measuring class I products there is no Notified Body certificate

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Place of Issue: Göteborg, Sweden

Date: 2021-12-13 Function: Global Regulatory Affairs Director

Name: Christina Lewing Signature:

Generic product information	
Intended Purpose:	The OP-tape is intended to be used to attach drapes to the patient or other drapes to enable a sterile field. The OP-tape is provided non-sterile for final packaging and sterilisation prior to use.
Basic UDI-DI:	733243000000000223JW
GMDN Code:	58986 Multi-purpose surgical skin adhesive tape

Product References Covered by this Declaration:	**Product Descriptor:**
911500	OP-TAPE