

EU Declaration of Conformity according to MDR

Document ID: PD-596162 **Rev:**02

Created by: Gayle Wood State: Released

Approved by: Christina Lewing

Release date: 2021-12-21 16:29:23

Dates and times in Greenwich Mean Time, 24 hours format

Title: Bulk non-sterile, equipment drapes

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 Bulk non-sterile, equipment drapes name:

MDR Class I ns Product Classification:

MDR Classification Rule:

Non-sterile Sterility:

Measuring Function: Nο

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

Id No: Issued by: Not Applicable

(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

Clumber 1 2021-12-21 Function: Date:

Signature: Christina Lewing Name:



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GMDN Code:

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Generic product information		
Intended Purpose:	The surgical equipment drapes are intended to be used as protective equipment covering and to create a sterile field for a surgical procedure. The drapes are provided non-sterile for final packaging and sterilisation prior to use.	
Basic UDI-DI:	7332430000000079KF	

Product References Covered by this Declaration:	Product Descriptor:
50009	CAMERA DRAPE
815330	CAMERA DRAPE
815331	CAMERA DRAPE
815332	CAMERA DRAPE
815333	CAMERA DRAPE
815362	EQUIPMENT DRAPE
815425	EQUIPMENT DRAPE
815426	Transparent Table Cover

47783 Patient surgical drape, single-use