	EU Declaration of Conformity	Document ID:	PD-588745 Rev: 01
· · · · · · · · · · · · · · · · · · ·	according to MDR	Created by:	Gayle Wood
Mölnlycke		State:	Released
		Approved by:	Christina Lewing
		Release date:	2021-12-13 17:22:32
Title: Bulk non-sterile, patien	t incise drapes	Dates and times in G	reenwich Mean Time, 24 hours format

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 drapes
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	ld 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

Christina Lewing Name:

Signature:

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Title: Bulk non-sterile, patient incise drapes

Dates and times in Greenwich Mean Time, 24 hours format

Generic product information		
Intended Purpose:	The surgical patient drapes are intended to be used as protective patient covering 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:	7332430000000082K4	
GMDN Code:	47783 Patient surgical drape, single-use	

Product References Covered by this Declaration:	Product Descriptor:
921014	INCISE DRAPE
921526	INCISE DRAPE
923026	INCISE DRAPE
924040	INCISE DRAPE
924555	INCISE DRAPE
925680	INCISE DRAPE