



**EU Declaration of Conformity
according to MDR**

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Approval date: 2020-08-17

Title: Bulk non-sterile, patient incise drapes

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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, patient drapes**

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: **2020-08-17** Function: **Regulatory Affairs Director**

Name: **Christina Lewing** Signature:

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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.

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
921014	INCISE DRAPE	73324300000000082K4	47782 Patient surgical drape, single-use, non-sterile
921526	INCISE DRAPE	73324300000000082K4	47782 Patient surgical drape, single-use, non-sterile
923026	INCISE DRAPE	73324300000000082K4	47782 Patient surgical drape, single-use, non-sterile
924040	INCISE DRAPE	73324300000000082K4	47782 Patient surgical drape, single-use, non-sterile
924555	INCISE DRAPE	73324300000000082K4	47782 Patient surgical drape, single-use, non-sterile
925680	INCISE DRAPE	73324300000000082K4	47782 Patient surgical drape, single-use, non-sterile