



**EU Declaration of Conformity
according to MDR**

Document ID: PD-596162 Rev: 00
Created by: Gayle Wood
Approved by: Christina Lewing
Approval date: 2021-01-11

Title: Bulk non-sterile, equipment 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, equipment 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: **2021-01-11** Function: **Regulatory Affairs Director**

Name: **Christina Lewing** Signature:

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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.

Product(s) covered by this declaration:

| Product Reference: | Product Descriptor: | Basic UDI-DI: | GMDN Code: |
|---------------------------|----------------------------|----------------------|---|
| 815330 | CAMERA DRAPE | 73324300000000079KF | 47782 Patient surgical drape, single-use, non-sterile |
| 815331 | CAMERA DRAPE | 73324300000000079KF | 47782 Patient surgical drape, single-use, non-sterile |
| 815332 | CAMERA DRAPE | 73324300000000079KF | 47782 Patient surgical drape, single-use, non-sterile |
| 815333 | CAMERA DRAPE | 73324300000000079KF | 47782 Patient surgical drape, single-use, non-sterile |
| 815362 | EXTREMITY DRAPE | 73324300000000079KF | 47782 Patient surgical drape, single-use, non-sterile |
| 815425 | EQUIPMENT DRAPE | 73324300000000079KF | 47782 Patient surgical drape, single-use, non-sterile |