



EU Declaration of Conformity according to MDR

Document ID: PD-596211 Rev:01
Created by: Gayle Wood
State: Released
Approved by: Christina Lewing
Release date: 2021-12-13 17:22:38

Title: Bulk non-sterile, patient drapes supplementary

Dates and times in Greenwich 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
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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
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Issued by:	Not Applicable
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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:



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Generic product information	
Intended Purpose:	The absorbent towels are intended to be used as sterile absorbing material during a surgical procedure. The absorbent towels are provided non-sterile for final packaging and sterilisation prior to use.
Basic UDI-DI:	733243000000000089KJ
GMDN Code:	58934 Infant blanket, single-use

Product References Covered by this Declaration:	Product Descriptor:
304998	CELLULOSE TOWEL
830204	ABSORBENT TOWEL
910433	BABY BLANKET
910434	BABY BLANKET
923720	ABSORBENT TOWEL
923721	HAND TOWEL
80057095	BABY BLANKET