



## EU Declaration of Conformity according to MDR

**Title:** Sterile patient utility drapes (non-adhesive)

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden, SRN SE-MF-000014042, 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:	Patient drapes
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Product Classification: MDR Class IS

MDR Classification Rule: 1

Sterility: Sterile

Measuring Function: No

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: IX

Common Specification: No CS is applicable

Certificate number: MDR 722028

Issued by: BSi

Id No: 2797

*(Notified Body Name)*

*NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.*

Mölnlycke Health Care AB issues this declaration in recognition of applied harmonized standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Göteborg, Sweden

Date: 2024-06-17

Function:

Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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**Title:** Sterile patient utility drapes (non-adhesive)

Generic product information	
<b>Intended Purpose:</b>	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.
<b>Basic UDI-DI:</b>	733243000000000177KG
<b>GMDN Code:</b>	47783 Patient surgical drape, single-use
<b>EMDN Code:</b>	T020199 SURGICAL DRAPES - OTHER

Product References Covered by this Declaration:	Product	Product Descriptor:
229	Under Buttocks Drape 85x120 cm	UNDER BUTTOCKS DRAPE
60530	OP-towel 75x90 cm, 2-ply ISCC	OP-TOWEL
706401	OP-Towel 45x75 cm	OP-TOWEL
777900	OP-Sheet 90x150 cm	OP-SHEET
778000	OP-Sheet 150x175 cm	OP-SHEET
778100	OP-Sheet 150x240 cm	OP-SHEET
800330	OP-Towel 37,5x45 cm.	OP-TOWEL
800430	OP-Towel 45x75 cm.	OP-TOWEL
800530	OP-towel 75x90 cm, 2-ply	OP-TOWEL
828900	Under Buttocks Drape 75x100cm	UNDER BUTTOCKS DRAPE
80649015	OP-Sheet 90x150 cm	OP-SHEET
84532081	OP-sheet (plastic) 150x180 cm, wrapped	OP-SHEET (PLASTIC)