



EU Declaration of Conformity according to MDR

Title: Sterile patient utility drapes (adhesive)

We, Mölnlycke Health Care AB, Entreprenörstråket 21, SE-431 53, Mölndal, 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:	Sterile 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: Mölndal, Sweden

Date: 2025-05-08

Function: Regulatory Affairs Excellence Director

Name: Karin Darle Olsson

Signature:



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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.
Basic UDI-DI:	733243000000000177KG
GMDN Code:	47783 Patient surgical drape, single-use
EMDN Code:	T020199 SURGICAL DRAPES - OTHER

Product References Covered by this Declaration:	Product	Product Descriptor:
60500	Adhesive OP-Towel 75X75 cm, ISCC certified	ADHESIVE OP-TOWEL
60677	Adhesive OP-Towel 90x75 cm ISCC certified	ADHESIVE OP-TOWEL
60750	Adhesive OP-Sheet 175x175 cm, ISCC certified	ADHESIVE OP-SHEET
60761	Adhesive OP-Sheet 240x150cm, ISCC certified	ADHESIVE OP-SHEET
60800	Adhesive OP-Towel Standard, 90x75 cm ISCC	ADHESIVE OP-TOWEL
66001	Adhesive OP-Towel 90x75 cm, BARRIER Flex	ADHESIVE OP-TOWEL
66002	Adhesive OP-Sheet 175x175 cm, BARRIER Flex	ADHESIVE OP-SHEET
66003	Adhesive OP-Sheet 300x175 cm, BARRIER Flex	ADHESIVE OP-SHEET
66520	Adhesive OP-Towel 120x100 cm	ADHESIVE OP-TOWEL
66540	Adhesive OP-Sheet 260x175 cm, full adh	ADHESIVE OP-SHEET
66550	Adhesive OP-Sheet 200x200 cm	ADHESIVE OP-SHEET
706100	Adhesive absorbent pad 55x70cm	ADHESIVE ABSORBENT PAD



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706300	Adhesive OP-Towel 75X50 cm	ADHESIVE OP-TOWEL
706400	Adhesive OP-Towel 50X50 cm	ADHESIVE OP-TOWEL
706500	Adhesive OP-Towel 75X75 cm	ADHESIVE OP-TOWEL
706700	Adhesive OP-Towel 75X100 cm	ADHESIVE OP-TOWEL
706800	Adhesive OP-Towel Standard, 90x75 cm	ADHESIVE OP-TOWEL
706900	Adhesive Towel 100x100 cm	ADHESIVE OP-TOWEL
707500	Adhesive OP-Towel 75x75 cm, 2 pcs	ADHESIVE OP-TOWEL
777025	Adhesive OP-Sheet 140x100 cm, narrow adh.	ADHESIVE OP-SHEET
777400	Adhesive OP-Sheet 175x150 cm	ADHESIVE OP-SHEET
777525	Adhesive OP-Sheet 175x173 cm, narrow adh	ADHESIVE OP-SHEET
777600	Adhesive OP-Sheet 240x150 cm	ADHESIVE OP-SHEET
778200	Adhesive OP-Sheet 300x175 cm	ADHESIVE OP-SHEET
906677	Adhesive OP-Towel 90x75 cm	ADHESIVE OP-TOWEL
920496	Adhesive OP-Sheet 175x175 cm	ADHESIVE OP-SHEET