

We, Mölnlycke Health Care AB, Gamlestadvägen 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 Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade name/ Product name:	Patient drapes
------------------------------	-----------------------

Product classification: **IS**
Sterility Status: **Sterile**
Measuring function: **No**

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

Certificate number:	CE 01966
Issued by:	BSI (2797)
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 AB Care

Date: **2021-04-27** Function: **Regulatory Affairs Manager
Compliance**

Name: **Karin Darle Olsson**

Signature:



Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
229	UNDER BUTTOCKS DRAPE	47783 Patient surgical drape, single-use, sterile
255	LITHOTOMY LEGGINGS	47783 Patient surgical drape, single-use, sterile
269	STOCKINET	47783 Patient surgical drape, single-use, sterile
610930	LITHOTOMY LEGGINGS	47783 Patient surgical drape, single-use, sterile
611105	STOCKINET	47783 Patient surgical drape, single-use, sterile
611205	STOCKINET	47783 Patient surgical drape, single-use, sterile
61340	ADHESIVE APERTURE DRAPE	47783 Patient surgical drape, single-use, sterile
65210	ANGIOGRAPHY DRAPE	47783 Patient surgical drape, single-use, sterile
65211	ANGIOGRAPHY DRAPE	47783 Patient surgical drape, single-use, sterile

Product Reference:	Product Descriptor:	GMDN Code:
65212	Brachial Angiography Drape	47783 Patient surgical drape, single-use, sterile
66001	ADHESIVE OP-TOWEL	47783 Patient surgical drape, single-use, sterile
66002	ADHESIVE OP-SHEET	47783 Patient surgical drape, single-use, sterile
66003	ADHESIVE OP-SHEET	47783 Patient surgical drape, single-use, sterile
66520	ADHESIVE OP-TOWEL	47783 Patient surgical drape, single-use, sterile
66540	ADHESIVE OP-SHEET	47783 Patient surgical drape, single-use, sterile
66550	ADHESIVE OP-SHEET	47783 Patient surgical drape, single-use, sterile
691005	FOOT COVER	47783 Patient surgical drape, single-use, sterile
706100	ADHESIVE ABSORBENT PAD	47783 Patient surgical drape, single-use, sterile
706300	ADHESIVE OP-TOWEL	47783 Patient surgical drape, single-use, sterile

Product Reference:	Product Descriptor:	GMDN Code:
706400	ADHESIVE OP-TOWEL	47783 Patient surgical drape, single-use, sterile
706500	ADHESIVE OP-TOWEL	47783 Patient surgical drape, single-use, sterile
706610	ADHESIVE APERTURE DRAPE	47783 Patient surgical drape, single-use, sterile
706620	ADHESIVE APERTURE DRAPE, VARIABLE	47783 Patient surgical drape, single-use, sterile
706630	ADHESIVE APERTURE DRAPE, VARIABLE	47783 Patient surgical drape, single-use, sterile
706700	ADHESIVE OP-TOWEL	47783 Patient surgical drape, single-use, sterile
706800	ADHESIVE OP-TOWEL	47783 Patient surgical drape, single-use, sterile
706900	ADHESIVE OP-TOWEL	47783 Patient surgical drape, single-use, sterile
707500	ADHESIVE OP-TOWEL	47783 Patient surgical drape, single-use, sterile
708840	ADHESIVE APERTURE DRAPE	47783 Patient surgical drape, single-use, sterile

Product Reference:	Product Descriptor:	GMDN Code:
708850	ADHESIVE APERTURE DRAPE	47783 Patient surgical drape, single-use, sterile
708860	ADHESIVE APERTURE DRAPE	47783 Patient surgical drape, single-use, sterile
708870	ADHESIVE APERTURE DRAPE	47783 Patient surgical drape, single-use, sterile
708880	ADHESIVE APERTURE DRAPE	47783 Patient surgical drape, single-use, sterile
777025	ADHESIVE OP-SHEET	47783 Patient surgical drape, single-use, sterile
777400	ADHESIVE OP-SHEET	47783 Patient surgical drape, single-use, sterile
777525	ADHESIVE OP-SHEET	47783 Patient surgical drape, single-use, sterile
777600	ADHESIVE OP-SHEET	47783 Patient surgical drape, single-use, sterile
777900	OP-SHEET	47783 Patient surgical drape, single-use, sterile
778000	OP-SHEET	47783 Patient surgical drape, single-use, sterile

Product Reference:	Product Descriptor:	GMDN Code:
778100	OP-SHEET	47783 Patient surgical drape, single-use, sterile
778200	ADHESIVE OP-SHEET	47783 Patient surgical drape, single-use, sterile
800530	OP-TOWEL	47783 Patient surgical drape, single-use, sterile
801526	INCISE DRAPE	47783 Patient surgical drape, single-use, sterile
803026	INCISE DRAPE	47783 Patient surgical drape, single-use, sterile
804040	INCISE DRAPE	47783 Patient surgical drape, single-use, sterile
804555	INCISE DRAPE	47783 Patient surgical drape, single-use, sterile
805680	INCISE DRAPE	47783 Patient surgical drape, single-use, sterile
80649015	OP-SHEET	47783 Patient surgical drape, single-use, sterile
828900	UNDER BUTTOCKS DRAPE	47783 Patient surgical drape, single-use, sterile

Product Reference:	Product Descriptor:	GMDN Code:
84521200	ADHESIVE APERTURE DRAPE	47783 Patient surgical drape, single-use, sterile
888521	GYNAECOLOGY DRAPE	47782 Patient surgical drape, single-use, non-sterile
906540	ADHESIVE APERTURE DRAPE	47783 Patient surgical drape, single-use, sterile
906677	ADHESIVE OP-TOWEL	47783 Patient surgical drape, single-use, sterile
915447	ADHESIVE APERTURE DRAPE	47783 Patient surgical drape, single-use, sterile
920496	ADHESIVE OP-SHEET	47783 Patient surgical drape, single-use, sterile
935569	ADHESIVE APERTURE DRAPE	47783 Patient surgical drape, single-use, sterile