

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

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

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 Care

Date: **2020-07-23** Function: **Regulatory Affairs Manager
Compliance**

Name: **Karin Darle Olsson**

Signature:



Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
1213	OPHTHALMIC DRAPE	47783 Patient surgical drape, single-use, sterile
1272	ADHESIVE APERTURE DRAPE	47783 Patient surgical drape, single-use, sterile
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
272	STOCKINET	47783 Patient surgical drape, single-use, sterile
273	STOCKINET	47783 Patient surgical drape, single-use, sterile
274	STOCKINET	47783 Patient surgical drape, single-use, sterile
2750	SPLIT SHEET (PLASTIC)	47783 Patient surgical drape, single-use, sterile

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Product Reference:	Product Descriptor:	GMDN Code:
2751	SPLIT SHEET (PLASTIC)	47783 Patient surgical drape, single-use, sterile
381035	OP-TAPE	58484 Multi-purpose surgical adhesive tape, sterile
381045	OP-TAPE	58484 Multi-purpose surgical adhesive tape, sterile
60004	BEACH CHAIR SHOULDER DRAPE	47783 Patient surgical drape, single-use, sterile
60104	KNEE ARTHROSCOPY DRAPE	47783 Patient surgical drape, single-use, sterile
60105	KNEE ARTHROSCOPY DRAPE	47783 Patient surgical drape, single-use, sterile
60210	EXTREMITY DRAPE	47783 Patient surgical drape, single-use, sterile
60211	EXTREMITY DRAPE	47783 Patient surgical drape, single-use, sterile
60212	EXTREMITY DRAPE	47783 Patient surgical drape, single-use, sterile
60213	EXTREMITY DRAPE	47783 Patient surgical drape, single-use, sterile

Product Reference:	Product Descriptor:	GMDN Code:
60214	EXTREMITY DRAPE	47783 Patient surgical drape, single-use, sterile
60308	HAND AND FOOT DRAPE	47783 Patient surgical drape, single-use, sterile
60309	HAND AND FOOT DRAPE	47783 Patient surgical drape, single-use, sterile
60310	HAND DRAPE	47783 Patient surgical drape, single-use, sterile
60502	SPLIT SHEET	47783 Patient surgical drape, single-use, sterile
60503	SPLIT SHEET	47783 Patient surgical drape, single-use, sterile
60504	SPLIT SHEET	47783 Patient surgical drape, single-use, sterile
60506	SPLIT SHEET	47783 Patient surgical drape, single-use, sterile
60600	HIP DRAPE	47783 Patient surgical drape, single-use, sterile
60601	HIP DRAPE W/DISLOCATION BAGS	47783 Patient surgical drape, single-use, sterile

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Product Reference:	Product Descriptor:	GMDN Code:
61000	LITHOTOMY DRAPE	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
61310	PAEDIATRIC DRAPE	47783 Patient surgical drape, single-use, sterile
61320	Laparotomy Drape	47783 Patient surgical drape, single-use, sterile
61330	Laparotomy Drape	47783 Patient surgical drape, single-use, sterile
61340	Adhesive Aperture Drape	47783 Patient surgical drape, single-use, sterile
61350	LAPAROTOMY DRAPE W/POUCHES	47783 Patient surgical drape, single-use, sterile
61900	CARDIOVASCULAR DRAPE	47783 Patient surgical drape, single-use, sterile

Product Reference:	Product Descriptor:	GMDN Code:
65011	NECK AND THYROID DRAPE	47783 Patient surgical drape, single-use, sterile
65022	Angiography Drape	47783 Patient surgical drape, single-use, sterile
65031	C-Section Drape	47783 Patient surgical drape, single-use, sterile
65040	C-Section 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
65212	Brachial Angiography Drape	47783 Patient surgical drape, single-use, sterile
65213	Angiography Set	47783 Patient surgical drape, single-use, sterile
65218	Angiography Drape	47783 Patient surgical drape, single-use, sterile
65810	NEPHROSCOPY DRAPE	47783 Patient surgical drape, single-use, sterile

Product Reference:	Product Descriptor:	GMDN Code:
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
66530	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
69200	ADHESIVE OP-SHEET	47783 Patient surgical drape, single-use, sterile
706100	ADHESIVE ABSORBENT PAD	47783 Patient surgical drape, single-use, sterile

Product Reference:	Product Descriptor:	GMDN Code:
706200	PERINEAL DRAPE+OP-TOWEL	47783 Patient surgical drape, single-use, sterile
706300	ADHESIVE OP-TOWEL	47783 Patient surgical drape, single-use, sterile
706400	ADHESIVE OP-TOWEL	47783 Patient surgical drape, single-use, sterile
706401	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

Product Reference:	Product Descriptor:	GMDN Code:
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
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

Product Reference:	Product Descriptor:	GMDN Code:
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
778100	OP-SHEET	47783 Patient surgical drape, single-use, sterile
778200	ADHESIVE OP-SHEET	47783 Patient surgical drape, single-use, sterile
778900	SPLIT SHEET	47783 Patient surgical drape, single-use, sterile
779300	SPLIT SHEET	47783 Patient surgical drape, single-use, sterile
791000	SPLIT SHEET	47783 Patient surgical drape, single-use, sterile
792100	ADHESIVE OP-TOWEL	47783 Patient surgical drape, single-use, sterile
792200	ADHESIVE OP-SHEET	47783 Patient surgical drape, single-use, sterile

Product Reference:	Product Descriptor:	GMDN Code:
792300	ADHESIVE OP-SHEET	47783 Patient surgical drape, single-use, sterile
792400	ADHESIVE OP-SHEET	47783 Patient surgical drape, single-use, sterile
792600	ADHESIVE OP-TOWEL	47783 Patient surgical drape, single-use, sterile
792700	ADHESIVE OP-SHEET	47783 Patient surgical drape, single-use, sterile
80000527	VERTICAL ISOLATION DRAPE	47783 Patient surgical drape, single-use, sterile
80005361	OPHTHALMIC DRAPE W/POUCHES	47783 Patient surgical drape, single-use, sterile
80006214	PREPARATION PAD	47783 Patient surgical drape, single-use, sterile
800330	OP-Towel	47783 Patient surgical drape, single-use, sterile
800430	OP-Towel	47783 Patient surgical drape, single-use, sterile
80051411	OPHTHALMIC DRAPE W/POUCH+WICK	47783 Patient surgical drape, single-use, sterile

Product Reference:	Product Descriptor:	GMDN Code:
800530	OP-TOWEL	47783 Patient surgical drape, single-use, sterile
8005390	OPHTHALMIC DRAPE W/POUCHES +WICK	47783 Patient surgical drape, single-use, sterile
801014	INCISE DRAPE	47783 Patient surgical drape, single-use, sterile
804526	INCISE DRAPE	47783 Patient surgical drape, single-use, sterile
80649015	OP-SHEET	47783 Patient surgical drape, single-use, sterile
824400	OPHTHALMIC DRAPE W/POUCHES +INCISE	47783 Patient surgical drape, single-use, sterile
824600	THORACIC DRAPE	47783 Patient surgical drape, single-use, sterile
824700	SPLIT SHEET W/PERINEAL COVER	47783 Patient surgical drape, single-use, sterile
825000	LAPAROTOMY DRAPE	47783 Patient surgical drape, single-use, sterile
826010	VERTICAL ISOLATION DRAPE	47783 Patient surgical drape, single-use, sterile



Product Reference:	Product Descriptor:	GMDN Code:
826020	VERTICAL ISOLATION DRAPE	47783 Patient surgical drape, single-use, sterile
826900	HEAD DRAPE+OP-TAPE	47783 Patient surgical drape, single-use, sterile
828300	ANGIOGRAPHY DRAPE	47783 Patient surgical drape, single-use, sterile
828900	UNDER BUTTOCKS DRAPE	47783 Patient surgical drape, single-use, sterile
831600	OPHTHALMIC DRAPE W/POUCH	47783 Patient surgical drape, single-use, sterile
832000	FLUID COLLECTION POUCH W/INCISE	47783 Patient surgical drape, single-use, sterile
84521200	ADHESIVE APERTURE DRAPE	47783 Patient surgical drape, single-use, sterile
84521220	RECTAL DRAPE	47783 Patient surgical drape, single-use, sterile
84551230	ADHESIVE APERTURE DRAPE	47783 Patient surgical drape, single-use, sterile
888342	CRANIOTOMY DRAPE	47783 Patient surgical drape, single-use, sterile

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Product Reference:	Product Descriptor:	GMDN Code:
888442	CRANIOTOMY DRAPE	47783 Patient surgical drape, single-use, sterile
888521	Gynaecology Drape	47782 Patient surgical drape, single-use, non-sterile
901680	LITHOTOMY LEGGINGS	47783 Patient surgical drape, single-use, sterile
903005	Laparoscopy Drape	47783 Patient surgical drape, single-use, sterile
903153	PERINEAL COVER	47783 Patient surgical drape, single-use, sterile
904622	Adhesive Aperture Drape	47783 Patient surgical drape, single-use, sterile
904624	Adhesive Aperture Drape	47783 Patient surgical drape, single-use, sterile
906540	ADHESIVE APERTURE DRAPE	47783 Patient surgical drape, single-use, sterile
906542	ADHESIVE APERTURE DRAPE	47783 Patient surgical drape, single-use, sterile
906544	APERTURE DRAPE	47783 Patient surgical drape, single-use, sterile

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Product Reference:	Product Descriptor:	GMDN Code:
906677	ADHESIVE OP-TOWEL	47783 Patient surgical drape, single-use, sterile
906693	ADHESIVE APERTURE DRAPE	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