

Title: Class I Sterile, patient drapes

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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 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	
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Certificate number:	CE 01966
Issued by:	BSI (0086)
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: **2017-12-15** 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
1272	ADHESIVE APERTURE DRAPE	47783
229	UNDER BUTTOCKS DRAPE	47783
255	LITHOTOMY LEGGINGS	47783
269	STOCKINET	47783
272	STOCKINET	47783
273	STOCKINET	47783
274	STOCKINET	47783
2750	SPLIT SHEET (PLASTIC)	47783
2751	SPLIT SHEET (PLASTIC)	47783
381035	OP-TAPE	58484
381045	OP-TAPE	58484
60004	BEACH CHAIR SHOULDER DRAPE	47783
60104	KNEE ARTHROSCOPY DRAPE	47783
60105	KNEE ARTHROSCOPY DRAPE	47783
60210	EXTREMITY DRAPE	47783
60211	EXTREMITY DRAPE	47783
60212	EXTREMITY DRAPE	47783
60213	EXTREMITY DRAPE	47783
60214	EXTREMITY DRAPE	47783
60308	HAND AND FOOT DRAPE	47783
60309	HAND AND FOOT DRAPE	47783

Product Reference:	Product Descriptor:	GMDN Code:
60310	HAND DRAPE	47783
60501	SPLIT SHEET	47783
60502	SPLIT SHEET	47783
60503	SPLIT SHEET	47783
60504	SPLIT SHEET	47783
60506	SPLIT SHEET	47783
60600	HIP DRAPE	47783
60601	HIP DRAPE W/DISLOCATION BAGS	47783
61000	LITHOTOMY DRAPE	47783
610930	LITHOTOMY LEGGINGS	47783
611105	STOCKINET	47783
611205	STOCKINET	47783
61310	PAEDIATRIC DRAPE	47783
61320	Laparotomy Drape	47783
61330	Laparotomy Drape	47783
61340	Adhesive Aperture Drape	47783
61350	LAPAROTOMY DRAPE W/POUCHES	47783
61360	Laparoscopy Drape	47783
61900	CARDIOVASCULAR DRAPE	47783
65011	NECK AND THYROID DRAPE	47783
65022	Angiography Drape	47783
65023	Angiography Drape	47783
65031	C-Section Drape	47783
65040	C-Section Drape	47783
65210	Angiography Drape	47783

Product Reference:	Product Descriptor:	GMDN Code:
65211	Angiography Drape	47783
65212	Brachial Angiography Drape	47783
65213	Angiography Set	47783
65218	Angiography Drape	47783
65810	NEPHROSCOPY DRAPE	47783
66001	ADHESIVE OP-TOWEL	47783
66002	ADHESIVE OP-SHEET	47783
66003	ADHESIVE OP-SHEET	47783
66520	ADHESIVE OP-TOWEL	47783
66530	ADHESIVE OP-TOWEL	47783
66540	ADHESIVE OP-SHEET	47783
66550	ADHESIVE OP-SHEET	47783
691005	FOOT COVER	47783
69200	KNEE ARTHROSCOPY POUCH	47783
706100	ADHESIVE ABSORBENT PAD	47783
706200	PERINEAL DRAPE+OP-TOWEL	47783
706300	ADHESIVE OP-TOWEL	47783
706400	ADHESIVE OP-TOWEL	47783
706401	OP-TOWEL	47783
706500	ADHESIVE OP-TOWEL	47783
706610	ADHESIVE APERTURE DRAPE	47783
706620	ADHESIVE APERTURE DRAPE, VARIABLE	47783
706630	ADHESIVE APERTURE DRAPE, VARIABLE	47783
706700	ADHESIVE OP-TOWEL	47783

Product Reference:	Product Descriptor:	GMDN Code:
706800	ADHESIVE OP-TOWEL	47783
706900	ADHESIVE OP-TOWEL	47783
707500	ADHESIVE OP-TOWEL	47783
708840	ADHESIVE APERTURE DRAPE	47783
708850	ADHESIVE APERTURE DRAPE	47783
708860	ADHESIVE APERTURE DRAPE	47783
708870	ADHESIVE APERTURE DRAPE	47783
708880	ADHESIVE APERTURE DRAPE	47783
777025	ADHESIVE OP-SHEET	47783
777400	ADHESIVE OP-SHEET	47783
777525	ADHESIVE OP-SHEET	47783
777600	ADHESIVE OP-SHEET	47783
777900	OP-SHEET	47783
778000	OP-SHEET	47783
778100	OP-SHEET	47783
778200	ADHESIVE OP-SHEET	47783
778900	SPLIT SHEET	47783
779300	SPLIT SHEET	47783
791000	SPLIT SHEET	47783
792100	ADHESIVE OP-TOWEL	47783
792200	ADHESIVE OP-SHEET	47783
792300	ADHESIVE OP-SHEET	47783
792400	ADHESIVE OP-SHEET	47783
792600	ADHESIVE OP-TOWEL	47783
792700	ADHESIVE OP-SHEET	47783

Product Reference:	Product Descriptor:	GMDN Code:
80000527	VERTICAL ISOLATION DRAPE	47783
80005361	OPHTHALMIC DRAPE W/POUCHES	47783
80006214	PREPARATION PAD	47783
800330	OP-Towel	47783
800430	OP-Towel	47783
80051411	OPHTHALMIC DRAPE W/POUCH+WICK	47783
800530	OP-TOWEL	47783
8005390	OPHTHALMIC DRAPE W/POUCHES +WICK	47783
80057565	OPHTHALMIC DRAPE	47783
801014	INCISE DRAPE	47783
801526	INCISE DRAPE	47783
803026	INCISE DRAPE	47783
804040	INCISE DRAPE	47783
804526	INCISE DRAPE	47783
804555	INCISE DRAPE	47783
805680	INCISE DRAPE	47783
80649015	OP-SHEET	47783
824400	OPHTHALMIC DRAPE W/POUCHES +INCISE	47783
824600	THORACIC DRAPE	47783
824700	SPLIT SHEET W/PERINEAL COVER	47783
825000	LAPAROTOMY DRAPE	47783
826010	VERTICAL ISOLATION DRAPE	47783
826020	VERTICAL ISOLATION DRAPE	47783
826900	HEAD DRAPE+OP-TAPE	47783

Product Reference:	Product Descriptor:	GMDN Code:
828300	ANGIOGRAPHY DRAPE	47783
828900	UNDER BUTTOCKS DRAPE	47783
831600	OPHTHALMIC DRAPE W/POUCH	47783
832000	FLUID COLLECTION POUCH W/INCISE	47783
84521200	ADHESIVE APERTURE DRAPE	47783
84521220	RECTAL DRAPE	47783
84551230	ADHESIVE APERTURE DRAPE	47783
888227	TUR DRAPE	47783
888342	CRANIOTOMY DRAPE	47783
888442	CRANIOTOMY DRAPE	47783
888521	Gynaecology Drape	47782
901680	LITHOTOMY LEGGINGS	47783
903005	LAPAROSCOPY DRAPE	47783
903153	PERINEAL COVER	47783
904622	Adhesive Aperture Drape	47783
904624	Adhesive Aperture Drape	47783
904664	ADHESIVE OP-TOWEL	47783
906540	ADHESIVE APERTURE DRAPE	47783
906542	ADHESIVE APERTURE DRAPE	47783
906544	APERTURE DRAPE	47783
906677	ADHESIVE OP-TOWEL	47783
906693	ADHESIVE APERTURE DRAPE	47783
915447	ADHESIVE APERTURE DRAPE	47783
920496	ADHESIVE OP-SHEET	47783
921249	SPLIT SHEET	47783



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Product Reference:	Product Descriptor:	GMDN Code:
935569	ADHESIVE APERTURE DRAPE	47783