

**Title:** Surgical and Equipment Drapes (Sets) Class I sterile

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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.

<b>Trade name/ Product name:</b>	<b>Surgical and Equipment Drapes (Sets)</b>
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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	
<b>Annex/es:</b>	<b>V, VII</b>

<b>Certificate number:</b>	<b>CE 01966</b>
<b>Issued by:</b>	<b>BSI (2797)</b>
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:**

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
1218	E.N.T. SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
251	LITHOTOMY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
282	SET-UP SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
306480	DENTAL SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
565710	GYNAECOLOGY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60001	SHOULDER SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60002	SHOULDER SET W/POUCH	33961 General/plastic surgical procedure kit, non-medicated, single-use
60003	BEACH CHAIR SHOULDER SET	33961 General/plastic surgical procedure

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
		kit, non-medicated, single-use
60005	SHOULDER SPLIT SHEETS W/POUCH	47783 Patient surgical drape, single-use, sterile
60101	KNEE ARTHROSCOPY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60102	KNEE ARTHROSCOPY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60103	KNEE ARTHROSCOPY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60202	EXTREMITY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60203	EXTREMITY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60204	EXTREMITY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60206	EXTREMITY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use

Product Reference:	Product Descriptor:	GMDN Code:
60207	EXTREMITY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60208	EXTREMITY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60209	EXTREMITY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60300	EXTREMITY SET, BILATERAL FOOT	33961 General/plastic surgical procedure kit, non-medicated, single-use
60301	EXTREMITY SET, BILATERAL LEG	33961 General/plastic surgical procedure kit, non-medicated, single-use
60303	HAND AND FOOT SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60305	HAND SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60306	HAND SET	33961 General/plastic surgical procedure kit, non-medicated, single-use

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
60307	HAND SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60602	HIP SET W/DISLOCATION BAGS	33961 General/plastic surgical procedure kit, non-medicated, single-use
60603	HIP SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60604	HIP SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60606	HIP SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60607	HIP SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60608	HIP SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60609	HIP SET	33961 General/plastic surgical procedure kit, non-medicated, single-use

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
60610	HIP SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60613	HIP SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60616	HIP SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60617	SPLIT SHEET SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60618	SPLIT SHEET SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60619	ORTHOPAEDIC SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
60620	SPLIT SHEET SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
61010	LITHOTOMY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use

Product Reference:	Product Descriptor:	GMDN Code:
61020	LITHOTOMY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
61030	LITHOTOMY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
61040	LAPAROSCOPY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
61400	VARICOSE VEIN SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
61450	Laparoscopy Set Bariatric	33961 General/plastic surgical procedure kit, non-medicated, single-use
61800	Hybrid Cardiovascular Set	33961 General/plastic surgical procedure kit, non-medicated, single-use
61920	CARDIOVASCULAR UNIVERSAL SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
65000	E.N.T. SET	33961 General/plastic surgical procedure kit, non-medicated, single-use

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
65020	E.N.T. Set	33961 General/plastic surgical procedure kit, non-medicated, single-use
65043	C-SECTION SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
65800	TUR SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
66010	UNIVERSAL SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
66100	REINFORCED UNIVERSAL SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
66200	UNIVERSAL SET STANDARD	33961 General/plastic surgical procedure kit, non-medicated, single-use
66300	UNIVERSAL SET STANDARD	33961 General/plastic surgical procedure kit, non-medicated, single-use
669600	ACUTE THORACIC SET	33961 General/plastic surgical procedure kit, non-medicated, single-use



Product Reference:	Product Descriptor:	GMDN Code:
692300	PLASTIC SURGERY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
694000	DENTAL SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
694110	C-SECTION SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
694135	C-SECTION SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
694140	C-SECTION SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
694145	C-SECTION SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
694240	LAPAROSCOPY SET ABDO-PERINEAL	33961 General/plastic surgical procedure kit, non-medicated, single-use
694241	LAPAROSCOPY SET ABDO-PERINEAL	33961 General/plastic surgical procedure kit, non-medicated, single-use

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
694242	LAPAROSCOPY SET ABDO-PERINEAL	33961 General/plastic surgical procedure kit, non-medicated, single-use
694245	LAPAROSCOPY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
694265	LAPAROSCOPY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
694500	PFANNENSTIEL SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
694640	CARDIOVASCULAR SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
694700	CARDIOVASCULAR SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
695000	DELIVERY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
695400	OPHTHALMIC SET	33961 General/plastic surgical procedure kit, non-medicated, single-use

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
696110	GYNAECOLOGY AND CYSTOSCOPY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
696310	TUR SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
696450	LITHOTOMY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
696500	GYNAECOLOGY LAPAROSCOPY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
696600	GYNAECOLOGY LAPAROSCOPY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
696700	GYNAECOLOGY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
696810	GYNAECOLOGY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
696940	HEAD SET	33961 General/plastic surgical procedure kit, non-medicated, single-use

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
697000	E.N.T. SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
697100	LAPAROTOMY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
697250	NECK SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
697260	THYROID SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
697600	APERTURE SET BASIC	33961 General/plastic surgical procedure kit, non-medicated, single-use
697640	E.N.T. SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
698220	ANGIOGRAPHY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
698260	ANGIOGRAPHY RADIALIS SET	33961 General/plastic surgical procedure kit, non-medicated, single-use

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
698740	UNIVERSAL SET BASIC	33961 General/plastic surgical procedure kit, non-medicated, single-use
698900	UNIVERSAL SET BASIC	33961 General/plastic surgical procedure kit, non-medicated, single-use
699010	PAEDIATRIC SET BASIC	33961 General/plastic surgical procedure kit, non-medicated, single-use
699054	UNIVERSAL SET STANDARD	33961 General/plastic surgical procedure kit, non-medicated, single-use
699110	UNIVERSAL SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
699140	UNIVERSAL SET STANDARD	33961 General/plastic surgical procedure kit, non-medicated, single-use
699340	UNIVERSAL SET STANDARD	33961 General/plastic surgical procedure kit, non-medicated, single-use
699354	UNIVERSAL SET STANDARD	33961 General/plastic surgical procedure kit, non-medicated, single-use

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
699540	UNIVERSAL SET STANDARD	33961 General/plastic surgical procedure kit, non-medicated, single-use
699600	UNIVERSAL SET STANDARD	33961 General/plastic surgical procedure kit, non-medicated, single-use
699640	UNIVERSAL SET STANDARD	33961 General/plastic surgical procedure kit, non-medicated, single-use
790000	UNIVERSAL SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
790500	UNIVERSAL SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
793000	UNIVERSAL SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
793500	SET BASIC	33961 General/plastic surgical procedure kit, non-medicated, single-use
<b>Document template:</b> Declaration of Conformity EU Rev: 05		
794000	UNIVERSAL SET	33961 General/plastic surgical procedure kit, non-medicated, single-use

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
795500	SPLIT SHEET SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
796000	SPLIT SHEET SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
798000	EXTREMITY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
798500	EXTREMITY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
80005471	SPINAL SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
80011660	HEAD TURBAN SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
80574671	HEAD TURBAN SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
80974401	CYSTOSCOPY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
84511411	ABDOMINAL LAPAROSCOPY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
84511451	OPHTHALMIC SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
84511461	OPHTHALMIC SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
888112	GYNAECOLOGY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
888113	GYNAECOLOGY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
888142	CRANIOTOMY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
888212	GYNAECOLOGY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
888222	TUR SET	33961 General/plastic surgical procedure kit, non-medicated, single-use



<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
888224	TUR SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
888225	TUR SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
888226	TUR SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
888228	TUR SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
888242	CRANIOTOMY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
902496	GYNAECOLOGY AND CYSTOSCOPY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
903014	VERTICAL ISOLATION SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
903016	VERTICAL ISOLATION SET	33961 General/plastic surgical procedure kit, non-medicated, single-use

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
903020	Laparoscopy Set Abdo-Perineal	33961 General/plastic surgical procedure kit, non-medicated, single-use
903026	VERTICAL ISOLATION SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
903163	OPHTHALMIC SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
903165	OPHTHALMIC SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
903167	OPHTHALMIC SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
903286	OPHTHALMIC SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
903355	C-SECTION SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
904194	UNIVERSAL SET BASIC	33961 General/plastic surgical procedure kit, non-medicated, single-use

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
904383	DELIVERY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
904730	ANGIOGRAPHY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
905020	URO AND GYNAECOLOGY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
914341	DELIVERY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
915322	OPHTHALMIC SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
925982	GYNAECOLOGY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
925984	GYNAECOLOGY SET	33961 General/plastic surgical procedure kit, non-medicated, single-use
<b>Document template:</b> Declaration of Conformity EU Rev: 05		