



**EU Declaration of Conformity
according to MDR**

Document ID: PD-705669 **Rev:**10
Created by: Gayle Wood
State: Released
Approved by: Christina Lewing
Approval date: 2023-07-24 16:44:16
Release date: 2023-07-24 16:44:26

Title: Sterile drapes - speciality sets

Dates and times in Greenwich Mean Time, 24 hours format

We, Mölnlycke Health Care AB, Gamlestadvägen 3C, Box 13080, SE-402 52 Göteborg, 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 drape sets
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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 <i>(Notified Body Name)</i>
	Id No: 2797
<i>NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.</i>	

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: Göteborg, Sweden

Date: 2023-07-24 Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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Generic product information	
Intended Purpose:	The surgical drape sets consists of both surgical drapes and supplementary products intended be used to create a sterile field for a surgical procedure.
Basic UDI-DI:	733243000000000182K9
GMDN Code:	33961 General/plastic surgical procedure kit, non-medicated, single-use

Product References Covered by this Declaration:	Product Descriptor:
251	LITHOTOMY SET
1218	E.N.T. SET
60001	SHOULDER SET
60002	SHOULDER SET W/POUCH
60003	BEACH CHAIR SHOULDER SET
60005	SHOULDER SPLIT SHEETS W/POUCH
60101	KNEE ARTHROSCOPY SET
60102	KNEE ARTHROSCOPY SET
60103	KNEE ARTHROSCOPY SET
60200	EXTREMITY SET
60202	EXTREMITY SET
60203	EXTREMITY SET
60204	EXTREMITY SET
60206	EXTREMITY SET
60207	EXTREMITY SET
60208	EXTREMITY SET
60209	EXTREMITY SET
60300	EXTREMITY SET, BILATERAL FOOT
60301	EXTREMITY SET, BILATERAL LEG
60303	HAND AND FOOT SET



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60305	HAND SET
60306	HAND SET
60307	HAND SET
60602	HIP SET W/DISLOCATION BAGS
60603	HIP SET
60604	HIP SET
60606	HIP SET
60607	HIP SET
60608	HIP SET
60609	HIP SET
60610	HIP SET
60613	HIP SET
60616	HIP SET
60617	SPLIT SHEET SET
60618	SPLIT SHEET SET
60619	ORTHOPAEDIC SET
60620	SPLIT SHEET SET
61010	LITHOTOMY SET
61030	REINFORCED ADHESIVE OP-SHEET
61040	LAPAROSCOPY SET ABDO-PERINEAL
61400	VARICOSE VEIN SET
61450	LAPAROSCOPY SET BARIATRIC
61800	Hybrid Cardiovascular Set
61920	CARDIOVASCULAR UNIVERSAL SET
65000	E.N.T. SET
65020	E.N.T. SET
65043	C-SECTION SET, WRAPPED



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65213	ANGIOGRAPHY SET
65800	TUR SET
306480	DENTAL SET
565710	GYNAECOLOGY SET
669600	ACUTE THORACIC SET
692300	PLASTIC SURGERY SET
694000	DENTAL SET
694110	C-SECTION SET
694135	C-SECTION SET
694140	C-SECTION SET
694145	C-SECTION SET
694240	LAPAROSCOPY SET ABDO-PERINEAL
694241	LAPAROSCOPY SET ABDO-PERINEAL
694245	LAPAROSCOPY SET
694265	LAPAROSCOPY SET ABDO-PERINEAL
694500	PFANNENSTIEL SET
694640	CARDIOVASCULAR SET
694700	CARDIOVASCULAR SET
695000	DELIVERY SET
696110	GYNAECOLOGY AND CYSTOSCOPY SET
696450	LITHOTOMY SET
696600	LAPAROSCOPY SET ABDO-PERINEAL
696700	GYNAECOLOGY SET
696810	GYNAECOLOGY SET
696940	HEAD SET
697000	E.N.T. SET
697100	LAPAROTOMY SET



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697250	NECK SET
697260	THYROID SET
697600	APERTURE SET BASIC
697640	ENT SET
698220	ANGIOGRAPHY SET
698260	ANGIOGRAPHY RADIALIS SET
706200	PERINEAL DRAPE+OP-TOWEL
826900	HEAD DRAPE W/TURBAN
888112	GYNAECOLOGY SET
888113	GYNAECOLOGY SET
888142	CRANIOTOMY SET
888212	GYNAECOLOGY SET
888226	TUR SET
888242	CRANIOTOMY SET
902496	GYNAECOLOGY AND CYSTOSCOPY SET
903014	VERTICAL ISOLATION SET
903016	VERTICAL ISOLATION SET
903020	LAPAROSCOPY SET ABDO-PERINEAL
903026	VERTICAL ISOLATION DRAPE
903355	C-SECTION SET
904730	ANGIOGRAPHY SET
905020	URO AND GYNAECOLOGY SET
914341	DELIVERY SET
925982	GYNAECOLOGY SET
925984	GYNAECOLOGY SET
80005471	SPINAL SET
80011660	HEAD TURBAN SET



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80574671	HEAD TURBAN SET
80974401	CYSTOSCOPY SET
84511411	LAPAROSCOPY SET