

Title: Sterile drapes - surgical sets

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We, Mölnlycke Health Care, 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 Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: **Not applicable**

Trade name/ Product name:	Sterile drapes - surgical sets
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Product classification: **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 (2797)

NB. 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 applied harmonised standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Göteborg, Sweden

Date: 2021-01-29 **Function:** Regulatory Affairs Director

Name: Christina Lewing

Signature:



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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.

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
565710	GYNAECOLOGY SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
60054	UNIVERSAL SET STANDARD	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
60200	EXTREMITY SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
60202	EXTREMITY SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
60203	EXTREMITY SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
60204	EXTREMITY SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
60207	EXTREMITY SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
60208	EXTREMITY SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
60209	EXTREMITY SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
60303	HAND AND FOOT SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
60603	HIP SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
60604	HIP SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
60606	HIP SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
60607	HIP SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
60608	HIP SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
60609	HIP SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
60613	HIP SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
60616	HIP SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
60617	SPLIT SHEET SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
60618	SPLIT SHEET SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
60619	ORTHOPAEDIC SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
60620	SPLIT SHEET SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
61400	VARICOSE VEIN SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
65000	E.N.T. SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
66200	UNIVERSAL SET STANDARD	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
696940	HEAD SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
697000	E.N.T. SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
697100	LAPAROTOMY SET	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
697600	APERTURE SET BASIC	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
698740	UNIVERSAL SET BASIC	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
698900	UNIVERSAL SET BASIC	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
699010	PAEDIATRIC SET BASIC	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
699054	UNIVERSAL SET STANDARD	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
699110	PAEDIATRIC SET BASIC	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
699140	UNIVERSAL SET STANDARD	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
699340	UNIVERSAL SET STANDARD	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
699354	UNIVERSAL SET STANDARD	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
699540	UNIVERSAL SET STANDARD	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
699600	UNIVERSAL SET STANDARD	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
699640	UNIVERSAL SET STANDARD	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use
904194	UNIVERSAL SET BASIC	733243000000000182K9	33961 General/plastic surgical procedure kit, non-medicated, single-use