



EU Declaration of Conformity according to MDR

Title: Sterile drapes - universal sets

We, Mölnlycke Health Care AB, Entreprenörstråket 21, SE-431 53, Mölndal, 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 drapes - surgical 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
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Common Specification: No CS is applicable

Certificate number:	MDR 722028
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Issued by:	BSi	Id No: 2797
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(Notified Body Name)

NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

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: Mölndal, Sweden

Date:	2025-05-08	Function:	Regulatory Affairs Excellence Director
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Name: Karin Darle Olsson

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
EMDN Code:	T0202 SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS)

Product References Covered by this Declaration:	Product	Product Descriptor:
282	Set-Up Set	SET-UP SET
60054	Universal Set Standard ISCC	UNIVERSAL SET STANDARD
60340	Universal Set Standard, ISCC	UNIVERSAL SET STANDARD
60900	Universal Set Basic, ISCC	UNIVERSAL SET BASIC
66010	Universal set w. MSC BARRIER Flex	UNIVERSAL SET
66100	Universal set special	REINFORCED UNIVERSAL SET
66200	Universal Set Standard	UNIVERSAL SET STANDARD
66530	Universal Set Basic	UNIVERSAL SET BASIC
698740	Universal Set Basic	UNIVERSAL SET BASIC
698900	Universal Set Basic	UNIVERSAL SET BASIC
699010	Paediatric set Basic	PAEDIATRIC SET BASIC
699054	Universal set Standard	UNIVERSAL SET STANDARD
699110	Universal Set w/ narrow adhesive	PAEDIATRIC SET BASIC
699140	Universal set Standard	UNIVERSAL SET STANDARD
699340	Universal Set Standard	UNIVERSAL SET STANDARD
699354	Universal Set Standard	UNIVERSAL SET STANDARD



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699540	Universal Set Standard	UNIVERSAL SET STANDARD
699600	Universal set with gowns LL and XLL	UNIVERSAL SET STANDARD
699640	Universal Set Standard	UNIVERSAL SET STANDARD
904194	Universal Set Basic	UNIVERSAL SET BASIC