



**EU Declaration of Conformity
according to MDR**

Document ID: PD-602960 Rev:05
Created by: Gayle Wood
State: Released
Approved by: Karin Darle Olsson
Release date: 2022-06-09 13:16:59

Title: Sterile drapes - specialty sets

Dates and times in Greenwich Mean Time, 24 hours format

We, Mölnlycke Health Care AB, Gamlestadsvägen 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 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
Common Specification: No CS is applicable

Certificate number:	MDR 722028	
Issued by:	BSi	Id No: 2797
	(Notified Body Name)	
<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: 2022-06-09 Function: Regulatory Affairs Excellence Manager

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

Product References Covered by this Declaration:	Product Descriptor:
282	SET-UP SET
60054	UNIVERSAL SET STANDARD
60340	UNIVERSAL SET STANDARD
60900	UNIVERSAL SET BASIC
66200	UNIVERSAL SET STANDARD
66530	UNIVERSAL SET BASIC
698740	UNIVERSAL SET BASIC
698900	UNIVERSAL SET BASIC
699010	PAEDIATRIC SET BASIC
699054	UNIVERSAL SET STANDARD
699110	PAEDIATRIC SET BASIC
699140	UNIVERSAL SET STANDARD
699340	UNIVERSAL SET STANDARD
699354	UNIVERSAL SET STANDARD
699540	UNIVERSAL SET STANDARD
699600	SURGICAL GOWN
699640	UNIVERSAL SET STANDARD
904194	UNIVERSAL SET BASIC