



**EU Declaration of Conformity
according to MDR**

Document ID: PD-705214 Rev:5
Created by: Gayle Wood
State: Released
Approved by: Karin Darle Olsson
Release date: 2022-06-09 13:17:00

Title: Sterile aperture drapes

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 patient drapes
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Product Classification: MDR Class IS
MDR Classification Rule: 1
Sterility: Sterile
Measuring Function: Yes

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 patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.
Basic UDI-DI:	733243000000000160JX
GMDN Code:	47783 Patient surgical drape, single-use

Product References Covered by this Declaration:	Product Descriptor:
61340	ADHESIVE APERTURE DRAPE
706610	ADHESIVE APERTURE DRAPE
706620	ADHESIVE APERTURE DRAPE, VARIABLE
706630	ADHESIVE APERTURE DRAPE, VARIABLE
708840	ADHESIVE APERTURE DRAPE
708850	ADHESIVE APERTURE DRAPE
708860	ADHESIVE APERTURE DRAPE
708870	ADHESIVE APERTURE DRAPE
708880	ADHESIVE APERTURE DRAPE
904622	ADHESIVE APERTURE DRAPE
904624	ADHESIVE APERTURE DRAPE
906540	ADHESIVE APERTURE DRAPE
906542	ADHESIVE APERTURE DRAPE
906544	APERTURE DRAPE
906693	ADHESIVE APERTURE DRAPE
915447	ADHESIVE APERTURE DRAPE
935569	ADHESIVE APERTURE DRAPE
84521200	ADHESIVE APERTURE DRAPE
84551230	ADHESIVE APERTURE DRAPE