EU Declaration of Conformity according to MDR

Title: FPP Surgical Gowns, sterile

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:	Surgical gowns Fluid Protection Plus (FPP), sterile

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)		

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: Göteborg, Sweden

Date:	2024-02-27	Function:	Regulatory Affairs Excellence Manager
Name:	Karin Darle Olsson	Signature:	

EU Declaration of Conformity according to MDR

Title: FPP Surgical Gowns, sterile

Generic product information	
Intended Purpose:	The Surgical Gowns are single use, disposable, fluid repellent garments intended to be used as sterile by operating room personnel during surgical procedures to protect both the patient and the operating room personnel (users) from the transfer of microorganisms, body fluids and particulate material.
Basic UDI-DI:	733243000000000187KK
GMDN Code:	35091 Operating room gown, single-use
EMDN Code:	T020402 REINFORCED SURGICAL GOWNS

Product References Covered by this Declaration:	Product	Product Descriptor:
670101	Surgical Gown FPP M 2 towels wrap	FLUID PROTECTION PLUS SURGICAL GOWN
670102	Surgical Gown FPP L 2 towels wrap	FLUID PROTECTION PLUS SURGICAL GOWN
670103	Surgical Gown FPP LL 2 towels wrap	FLUID PROTECTION PLUS SURGICAL GOWN
670104	Surgical Gown FPP XL 2 towels wrap	FLUID PROTECTION PLUS SURGICAL GOWN
670105	Surgical Gown FPP XLL 2 towels wrap	FLUID PROTECTION PLUS SURGICAL GOWN
670106	Surgical Gown FPP XXLXL 2 towels wrap	FLUID PROTECTION PLUS SURGICAL GOWN
670107	Surgical Gown FPP XXLL 2 towels wrap	FLUID PROTECTION PLUS SURGICAL GOWN
6701021	Surgical Gown FPP L 2 towels wrap	FLUID PROTECTION PLUS SURGICAL GOWN
6701031	Surgical Gown FPP LL 2 towels wrap	FLUID PROTECTION PLUS SURGICAL GOWN
6701041	Surgical Gown FPP XL 2 towels wrap	FLUID PROTECTION PLUS SURGICAL GOWN
6701051	Surgical Gown FPP XLL 2 towels wrap	FLUID PROTECTION PLUS SURGICAL GOWN

Title: FPP Surgical Gowns, sterile

6701061	Surgical Gown FPP XXLXL 2 towels wrap	FLUID PROTECTION PLUS SURGICAL GOWN
6701071	Surgical Gown FPP XXLL 2 towels wrap	FLUID PROTECTION PLUS SURGICAL GOWN