



EU Declaration of Conformity according to MDR

Title: HP Classic Surgical Gowns FSC, 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:	HP Classic Surgical Gowns FSC, Sterile
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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)

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: 2023-10-18

Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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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:	73324300000000334K8
GMDN Code:	35091 Operating room gown, single-use
EMDN Code:	T020402 REINFORCED SURGICAL GOWNS

Product References Covered by this Declaration:	Product	Product Descriptor:
860101	CL HP FSC Surg gown L 2 towels wrap	SURGICAL GOWN
860102	CL HP FSC Surg gown LL	SURGICAL GOWN
860103	CL HP FSC Surg gown LL 2 towels wrap	SURGICAL GOWN
860104	CL HP FSC Surg gown LL mask loop 2 towels wrap	SURGICAL GOWN
860105	CL HP FSC Surg gown XL	SURGICAL GOWN
860106	CL HP FSC Surg gown XL 2 towels wrap	SURGICAL GOWN
860107	CL HP FSC Surg gown XLL	SURGICAL GOWN
860108	CL HP FSC Surg gown XLL 2 towels wrap	SURGICAL GOWN
860109	CL HP FSC Surg gown XLL mask loop 2 towels wrap	SURGICAL GOWN
860110	CL HP FSC Surg gown XXLL 2 towels wrap	SURGICAL GOWN
860111	CL HP FSC Surg gown XXLXL 2 towels wrap	SURGICAL GOWN