



EU Declaration of Conformity according to MDR

Title: Protective Gown, 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:	Protective Gown
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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: 2024-02-27

Function:

Regulatory Affairs Excellence
Manager

Name: Karin Darle Olsson

Signature:



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Generic product information	
Intended Purpose:	The intended use is to reduce contamination in a non-sterile environment when there is a need for additional cleanliness for procedures with, for example, smaller open wounds etc. within health care.
Basic UDI-DI:	733243000000000095KD
GMDN Code:	35492 Isolation gown, single-use
EMDN Code:	T0205 NON-SURGICAL GOWNS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE)

Product References Covered by this Declaration:	Product	Product Descriptor:
616641	Protective Gown, Cuffs, L, Towel 1pc. Sterile	PROTECTIVE GOWN
616650	Protective Gown L with cuff. sterile	PROTECTIVE GOWN