

EU Declaration of Conformity according to MDR

Document ID: PD-608127 Rev:01 Created by: Zahrah Chaudhary

State: Released

Approved by: Christina Lewing

Release date: 2021-11-24 09:10:31

Title: Non-sterile Protective gowns and Isolation Gowns, Impervious

Dates and times in Greenwich Mean Time, 24 hours format

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden 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 Protective Gowns and Isolation Gowns, Impervious name:

MDR Class I ns Product Classification:

MDR Classification Rule:

Non-sterile Sterility:

Measuring Function: Nο

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: IV

Common Specification: No CS is applicable

Certificate number: Not Applicable

Id No: Issued by: Not Applicable

(Notified Body Name)

Note. For non-sterile, non-measuring class I products there is no Notified Body certificate

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Place of Issue: Göteborg, Sweden

Clumberry 2021-11-24 Function: Date:

Signature: Christina Lewing Name:



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Generic product information		
Intended Purpose:	The intended use is to reduce contamination in a non-sterile environment within health care.	
Basic UDI-DI:	73324300000000096KF	
GMDN Code:	35492 Isolation gown, single-use	

Product References Covered by this Declaration:	Product Descriptor:
1901	PROTECTIVE GOWN
1902	PROTECTIVE GOWN
1903	PROTECTIVE GOWN
1904	PROTECTIVE GOWN
1905	PROTECTIVE GOWN
1921	PROTECTIVE GOWN
1922	PROTECTIVE GOWN
1923	PROTECTIVE GOWN
1924	PROTECTIVE GOWN
1925	PROTECTIVE GOWN
1931	ISOLATION GOWN, IMPERVIOUS
1932	ISOLATION GOWN, IMPERVIOUS
1933	ISOLATION GOWN, IMPERVIOUS
1934	ISOLATION GOWN, IMPERVIOUS
1935	ISOLATION GOWN, IMPERVIOUS
19055	PROTECTIVE GOWN WITH SLEEVE CUFFS
19255	PROTECTIVE GOWN WITH SLEEVE CUFFS