



# EU Declaration of Conformity according to MDR

**Title:** Protective and Isolation Gowns, Impervious, BNS

We, Mölnlycke Health Care AB, Gamlestadvägen 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 Gowns and Isolation Gowns, Impervious
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Product Classification: MDR Class I ns

MDR Classification Rule: 1

Sterility: Non-sterile

Measuring Function: No

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	
Issued by:	Not Applicable	Id No:
	<i>(Notified Body Name)</i>	
<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:	2024-02-12	Function:	Regulatory Affairs Excellence Manager
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Name:	Karin Darle Olsson	Signature:	
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Generic product information	
<b>Intended Purpose:</b>	The intended use is to reduce contamination in a non-sterile environment within health care.
<b>Basic UDI-DI:</b>	733243000000000096KF
<b>GMDN Code:</b>	35492 Isolation gown, single-use
<b>EMDN Code:</b>	T0205 NON-SURGICAL GOWNS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE)

Product References Covered by this Declaration:	Product	Product Descriptor:
1901	Protective Gown L, yellow	PROTECTIVE GOWN
1902	Protective Gown L, blue	PROTECTIVE GOWN
1903	Protective Gown L, green	PROTECTIVE GOWN
1904	Protective Gown L, white	PROTECTIVE GOWN
1905	Protective Gown L, Dark blue	PROTECTIVE GOWN
1921	Protective Gown XL, yellow	PROTECTIVE GOWN
1922	Protective Gown XL, blue	PROTECTIVE GOWN
1923	Protective Gown XL, green	PROTECTIVE GOWN
1924	Protective Gown XL, white	PROTECTIVE GOWN
1925	Protective Gown XL, Dark blue	PROTECTIVE GOWN
1931	Isolation Gown, Impervious, L, yellow	ISOLATION GOWN, IMPERVIOUS
1932	Isolation Gown, Impervious, L, blue	ISOLATION GOWN, IMPERVIOUS
1933	Isolation Gown, Impervious, XL, yellow	ISOLATION GOWN, IMPERVIOUS
1934	Isolation Gown, Impervious, XL, blue	ISOLATION GOWN, IMPERVIOUS
1935	Isolation Gown, Impervious, L, green	ISOLATION GOWN, IMPERVIOUS



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19055	Protective Gown with sleeve cuffs, L (dark blue)	PROTECTIVE GOWN WITH SLEEVE CUFFS
19255	Protective Gown with sleeve cuffs, XL (dark blue)	PROTECTIVE GOWN WITH SLEEVE CUFFS