



**EU Declaration of Conformity
according to MDR**

Document ID: PD-608127 Rev: 00
Created by: Zahrah Chaudhary
Approved by: Christina Lewing
Approval date: 2021-03-23

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

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We, Mölnlycke Health Care, Gamlestadvägen 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 Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: **Not applicable**

Trade name/ Product name:	Non-sterile Isolation gowns and Isolation Gowns, Impervious
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Product classification: **I**
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
NB. For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.	

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

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Göteborg, Sweden

Date: **2021-03-23** Function: **Regulatory Affairs Director**

Name: **Christina Lewing**

Signature:

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Intended Purpose: The intended use is to reduce contamination in a non-sterile environment within health care.

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
1901	ISOLATION GOWN	73324300000000096KF	35492 Isolation gown, single-use
1902	ISOLATION GOWN	73324300000000096KF	35492 Isolation gown, single-use
1903	ISOLATION GOWN	73324300000000096KF	35492 Isolation gown, single-use
1904	ISOLATION GOWN	73324300000000096KF	35492 Isolation gown, single-use
19055	ISOLATION GOWN WITH SLEEVE CUFFS	73324300000000096KF	35492 Isolation gown, single-use
1905	ISOLATION GOWN	73324300000000096KF	35492 Isolation gown, single-use
1921	ISOLATION GOWN	73324300000000096KF	35492 Isolation gown, single-use
1922	ISOLATION GOWN	73324300000000096KF	35492 Isolation gown, single-use
1923	ISOLATION GOWN	73324300000000096KF	35492 Isolation gown, single-use
1924	ISOLATION GOWN	73324300000000096KF	35492 Isolation gown, single-use
19255	ISOLATION GOWN WITH SLEEVE CUFFS	73324300000000096KF	35492 Isolation gown, single-use
1925	ISOLATION GOWN	73324300000000096KF	35492 Isolation gown, single-use



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Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
1931	ISOLATION GOWN, IMPERVIOUS	73324300000000096KF	35492 Isolation gown, single-use
1932	ISOLATION GOWN, IMPERVIOUS	73324300000000096KF	35492 Isolation gown, single-use
1933	ISOLATION GOWN, IMPERVIOUS	73324300000000096KF	35492 Isolation gown, single-use
1934	ISOLATION GOWN, IMPERVIOUS	73324300000000096KF	35492 Isolation gown, single-use
1935	ISOLATION GOWN, IMPERVIOUS	73324300000000096KF	35492 Isolation gown, single-use