

We, Mölnlycke Health Care AB, 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 the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade name/ Product name:	Non-sterile Isolation gowns and Isolation Gowns, Impervious
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Product classification: **I**Sterility Status: **Non-sterile**Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with	
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Annex/es:	VII
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Certificate number:	Not Applicable
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Issued by:	Not Applicable
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For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.	
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Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: **2020-05-15**Function: **Regulatory Affairs Manager
Compliance**Name: **Karin Darle Olsson**

Signature:



Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
1901	ISOLATION GOWN	35492 Isolation gown, single-use
1902	ISOLATION GOWN	35492 Isolation gown, single-use
1903	ISOLATION GOWN	35492 Isolation gown, single-use
1904	ISOLATION GOWN	35492 Isolation gown, single-use
19055	ISOLATION GOWN WITH SLEEVE CUFFS	35492 Isolation gown, single-use
1905	ISOLATION GOWN	35492 Isolation gown, single-use
1921	ISOLATION GOWN	35492 Isolation gown, single-use
1922	ISOLATION GOWN	35492 Isolation gown, single-use
1923	ISOLATION GOWN	35492 Isolation gown, single-use
1924	ISOLATION GOWN	35492 Isolation gown, single-use
19255	ISOLATION GOWN WITH SLEEVE CUFFS	35492 Isolation gown, single-use
1925	ISOLATION GOWN	35492 Isolation gown, single-use
1931	ISOLATION GOWN, IMPERVIOUS	35492 Isolation gown, single-use
1932	ISOLATION GOWN, IMPERVIOUS	35492 Isolation gown, single-use

Product Reference:	Product Descriptor:	GMDN Code:
1933	ISOLATION GOWN, IMPERVIOUS	35492 Isolation gown, single-use
1934	ISOLATION GOWN, IMPERVIOUS	35492 Isolation gown, single-use
1935	Isolation Gown, Impervious	35492 Isolation gown, single-use