

Title: Isolation gowns, sterile

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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:	Isolation gowns
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Product classification: **IS**
Sterility Status: **Sterile**
Measuring function: **No**

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

Certificate number:	CE 01966
Issued by:	BSI (2797)
For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.	

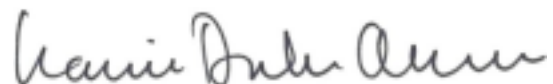
Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: **2020-11-30** Function: **Regulatory Affairs Manager
Compliance**

Name: **Karin Darle Olsson**

Signature:





Declaration of Conformity EU

Document ID: PD-393193 Rev: 02
Created by: Zahrah Chaudhary
Approved by: Karin Darle Olsson
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Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
616641	ISOLATION GOWN	35492 Isolation gown, single-use
616650	ISOLATION GOWN	35492 Isolation gown, single-use