

Declaration of Conformity EU

Document ID: Created by: Approved by: Approval date: PD-439856 Rev: 01 Technia Support Karin Darle Olsson 2021-03-03

Title: Class I sterile, Surgical gowns (2)

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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 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:

BARRIER Surgical Gowns

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 AB Care

Date: 2021-03-03 Function: Regulatory Affairs Manager

Compliance

Name: Karin Darle Olsson Signature:

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Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
97000518	SURGICAL GOWN BLUE LINE	35091 Operating room gown, single-use
97000519	SURGICAL GOWN BLUE LINE	35091 Operating room gown, single-use
97000520	SURGICAL GOWN BLUE LINE	35091 Operating room gown, single-use
99000511	SURGICAL GOWN BLUE LINE	35091 Operating room gown, single-use
99000512	SURGICAL GOWN BLUE LINE	35091 Operating room gown, single-use
99000513	SURGICAL GOWN BLUE LINE	35091 Operating room gown, single-use
99000514	SURGICAL GOWN BLUE LINE	35091 Operating room gown, single-use
99000515	SURGICAL GOWN BLUE LINE	35091 Operating room gown, single-use
99000516	SURGICAL GOWN BLUE LINE	35091 Operating room gown, single-use

Document template: Declaration of Conformity EU Rev: 05