

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:	BARRIER Surgical 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 (0086)
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: **2019-01-31** Function: **Regulatory Affairs Manager
Compliance**

Name: **Karin Darle Olsson**

Signature:



Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
93000620	SURGICAL GOWN	35091
93000621	SURGICAL GOWN	35091
93000622	SURGICAL GOWN	35091
93000623	SURGICAL GOWN	35091
93000624	SURGICAL GOWN	35091
93000625	SURGICAL GOWN	35091
93000720	SURGICAL GOWN	35091
93000721	SURGICAL GOWN	35091
93000722	SURGICAL GOWN	35091
93000723	SURGICAL GOWN	35091
93000724	SURGICAL GOWN	35091
93000725	SURGICAL GOWN	35091