

Title: Classic Surgical 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:	Classic 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 (2797)
For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.	

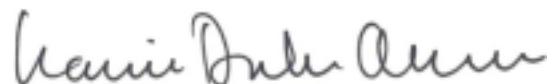
Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of M ö Inlycke Health Care

Date: **2020-10-20** Function: **Regulatory Affairs Manager
Compliance**

Name: **Karin Darle Olsson**

Signature:





Declaration of Conformity EU

Document ID: PD-533384 Rev: 03
Created by: Gayle Wood
Approved by: Karin Darle Olsson
Approval date: 2020-10-20

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Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
640101	TIE-BACK SURGICAL GOWN	35091 Operating room gown, single-use
640102	TIE-BACK SURGICAL GOWN	35091 Operating room gown, single-use
640103	TIE-BACK SURGICAL GOWN	35091 Operating room gown, single-use
650101	SURGICAL GOWN	35091 Operating room gown, single-use
650102	SURGICAL GOWN	35091 Operating room gown, single-use
650104	SURGICAL GOWN	35091 Operating room gown, single-use
650105	SURGICAL GOWN	35091 Operating room gown, single-use
650106	SURGICAL GOWN	35091 Operating room gown, single-use
650107	SURGICAL GOWN	35091 Operating room gown, single-use

Document template: Declaration of Conformity EU Rev 03

Product Reference:	Product Descriptor:	GMDN Code:
650108	SURGICAL GOWN	35091 Operating room gown, single-use
650110	SURGICAL GOWN	35091 Operating room gown, single-use
650111	SURGICAL GOWN	35091 Operating room gown, single-use
650113	SURGICAL GOWN	35091 Operating room gown, single-use
650114	SURGICAL GOWN	35091 Operating room gown, single-use
650115	SURGICAL GOWN	35091 Operating room gown, single-use
650116	SURGICAL GOWN	35091 Operating room gown, single-use
660101	REINFORCED SURGICAL GOWN	35091 Operating room gown, single-use
660102	REINFORCED SURGICAL GOWN	35091 Operating room gown, single-use
660103	REINFORCED SURGICAL GOWN	35091 Operating room gown, single-use

Product Reference:	Product Descriptor:	GMDN Code:
660104	REINFORCED SURGICAL GOWN	35091 Operating room gown, single-use
660105	REINFORCED SURGICAL GOWN	35091 Operating room gown, single-use
660106	REINFORCED SURGICAL GOWN	35091 Operating room gown, single-use
660107	REINFORCED SURGICAL GOWN	35091 Operating room gown, single-use
660108	REINFORCED SURGICAL GOWN	35091 Operating room gown, single-use
660110	REINFORCED SURGICAL GOWN	35091 Operating room gown, single-use
660111	REINFORCED SURGICAL GOWN	35091 Operating room gown, single-use
660113	REINFORCED SURGICAL GOWN	35091 Operating room gown, single-use
670301	UROLOGY SURGICAL GOWN	35091 Operating room gown, single-use
670302	UROLOGY SURGICAL GOWN	35091 Operating room gown, single-use