

Manufacturer's **Declaration of Conformity**

Document Id: PD-701708 Rev:1

State: Released

Created by: Zahrah Chaudhary Title: Classic SP Surgical

Gowns, BNS

Page 1(2)

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 Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: Not applicable

Trade name / Product Classic SP Surgical Gowns, BNS name:

Product Classification: MDR Class I ns

MDR Classification Rule:

Non-sterile Sterility:

Measuring Function: Nο

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

Common Specification: No CS is applicable

Certificate number: Not Applicable

Id No: Issued by: Not Applicable

(Notified Body Name)

Note. For non-sterile, non-measuring class I products there is no Notified Body certificate

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

Signed for and on behalf of Mölnlycke Health Care

Place of Issue: Göteborg, Sweden

2021-05-24 Function: Global Regulatory Affairs Director Clumberry Date:

Signature: Christina Lewing Name:



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Page 2(2)

Generic product information		
Intended Purpose:	Surgical Gowns are single use, disposable, fluid repellent garments intended to be used as sterile by operating room personnel during surgical procedures to protect both the patient and the operating room personnel (users) from the transfer of microorganisms, body fluids and particulate material.	
Basic UDI-DI:	73324300000000196KL	
GMDN Code:	35091 Operating room gown, single-use	

Product References Covered by this Declaration:	Product Descriptor:
740101	TIE-BACK SURGICAL GOWN
740103	TIE-BACK SURGICAL GOWN
750101	SURGICAL GOWN
750102	SURGICAL GOWN
750103	SURGICAL GOWN
750105	SURGICAL GOWN
750106	SURGICAL GOWN
750108	SURGICAL GOWN
750111	SURGICAL GOWN
750113	SURGICAL GOWN
750114	SURGICAL GOWN
770301	UROLOGY SURGICAL GOWN
770302	UROLOGY SURGICAL GOWN