



**Manufacturer's
Declaration of Conformity**

Document Id: PD-701692 Rev:1
State: Released
Created by: Zahrah Chaudhary
Title: Ultimate SP Surgical Gowns, BNS

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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 Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: Not applicable

Trade name / Product name:	Ultimate SP Surgical Gowns, BNS
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Product Classification: MDR Class I ns
MDR Classification Rule: 1
Sterility: Non-sterile
Measuring Function: No

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	
Issued by:	Not Applicable	Id No:
	<i>(Notified Body Name)</i>	
<i>Note. For non-sterile, non-measuring class I products there is no Notified Body certificate</i>		

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

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

Name: Christina Lewing

Signature:



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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:	73324300000000201JL
GMDN Code:	35091 Operating room gown, single-use

Product References Covered by this Declaration:	Product Descriptor:
780102	SURGICAL GOWN
780103	SURGICAL GOWN
780104	SURGICAL GOWN
780105	SURGICAL GOWN
780106	SURGICAL GOWN