



**Manufacturer's
Declaration of Conformity**

Document Id: PD-701707 Rev:1
State: Released
Created by: Zahrah Chaudhary
Title: Classic HP 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:	Classic HP 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:	The 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:	733243000000000195KJ
GMDN Code:	35091 Operating room gown, single-use

Product References Covered by this Declaration:	Product Descriptor:
760101	REINFORCED SURGICAL GOWN
760103	REINFORCED SURGICAL GOWN
760104	REINFORCED SURGICAL GOWN
760105	REINFORCED SURGICAL GOWN
760107	REINFORCED SURGICAL GOWN
760108	REINFORCED SURGICAL GOWN
760110	REINFORCED SURGICAL GOWN
760111	REINFORCED SURGICAL GOWN