



**EU Declaration of Conformity  
according to MDR**

Document ID: PD-608126 Rev: 00  
Created by: Zahrah Chaudhary  
Approved by: Christina Lewing  
Approval date: 2021-03-23

**Title:** Universal Surgical Gowns, non-sterile

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We, Mölnlycke Health Care, 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 Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: **Not applicable**

Trade name/ Product name:	<b>Universal Surgical Gowns, non-sterile</b>
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Product classification: **I**  
MDR Classification Rule: **1**  
Sterility: **Non-sterile**  
Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with	
Annex/es:	<b>IV</b>
Common Specification:	<b>No CS is applicable</b>

Certificate number:	<b>Not Applicable</b>
Issued by:	<b>Not Applicable</b>
NB. 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 applied harmonised standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Göteborg, Sweden

Date: **2021-03-23** Function: **Regulatory Affairs Director**

Name: **Christina Lewing**

Signature:

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**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.

**Product(s) covered by this declaration:**

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>Basic UDI-DI:</b>	<b>GMDN Code:</b>
63000620	SURGICAL GOWN	73324300000000203JQ	35091 Operating room gown, single-use
63000621	SURGICAL GOWN	73324300000000203JQ	35091 Operating room gown, single-use
63000622	SURGICAL GOWN	73324300000000203JQ	35091 Operating room gown, single-use
63000623	SURGICAL GOWN	73324300000000203JQ	35091 Operating room gown, single-use
63000624	SURGICAL GOWN	73324300000000203JQ	35091 Operating room gown, single-use
63000625	SURGICAL GOWN	73324300000000203JQ	35091 Operating room gown, single-use
63000720	SURGICAL GOWN	73324300000000202JN	35091 Operating room gown, single-use
63000721	SURGICAL GOWN	73324300000000202JN	35091 Operating room gown, single-use
63000722	SURGICAL GOWN	73324300000000202JN	35091 Operating room gown, single-use
63000723	SURGICAL GOWN	73324300000000202JN	35091 Operating room gown, single-use
63000724	SURGICAL GOWN	73324300000000202JN	35091 Operating room gown, single-use



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<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>Basic UDI-DI:</b>	<b>GMDN Code:</b>
63000725	SURGICAL GOWN	733243000000000202JN	35091 Operating room gown, single-use