



**EU Declaration of Conformity
according to MDR**

Document ID: PD-602997 Rev: 00
Created by: Zahrah Chaudhary
Approved by: Christina Lewing
Approval date: 2021-02-05

Title: Medical Face Masks

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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:	Medical Face Masks
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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:	IV
Common Specification:	No CS is applicable

Certificate number:	Not Applicable
Issued by:	Not Applicable

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: **2021-02-05** Function: **Regulatory Affairs Director**

Name: **Christina Lewing** Signature:

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Intended Purpose: The device is intended to be worn to protect both the patient and the healthcare personnel from the transfer of microorganisms, body fluids and particulate matter.

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
106332	MEDICAL FACE MASK	733243000000000205JU	35177 Surgical face mask, single-use
4224	MEDICAL FACE MASK	733243000000000206JW	35177 Surgical face mask, single-use
42270	MEDICAL FACE MASK	733243000000000205JU	35177 Surgical face mask, single-use
42280	MEDICAL FACE MASK	733243000000000205JU	35177 Surgical face mask, single-use
4228	MEDICAL FACE MASK	733243000000000205JU	35177 Surgical face mask, single-use
42290	MEDICAL FACE MASK	733243000000000205JU	35177 Surgical face mask, single-use
4230	MEDICAL FACE MASK	733243000000000205JU	35177 Surgical face mask, single-use
4231	MEDICAL FACE MASK	733243000000000205JU	35177 Surgical face mask, single-use
4232	MEDICAL FACE MASK	733243000000000206JW	35177 Surgical face mask, single-use
4234	MEDICAL FACE MASK	733243000000000206JW	35177 Surgical face mask, single-use
4236	MEDICAL FACE MASK	733243000000000206JW	35177 Surgical face mask, single-use
4237	MEDICAL FACE MASK	733243000000000205JU	35177 Surgical face mask, single-use



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Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
4238	MEDICAL FACE MASK	73324300000000205JU	35177 Surgical face mask, single-use
4239	MEDICAL FACE MASK	73324300000000205JU	35177 Surgical face mask, single-use
4267	MEDICAL FACE MASK	73324300000000206JW	35177 Surgical face mask, single-use
428801	MEDICAL FACE MASK	73324300000000205JU	35177 Surgical face mask, single-use
428901	MEDICAL FACE MASK	73324300000000205JU	35177 Surgical face mask, single-use
4291	MEDICAL FACE MASK	73324300000000206JW	35177 Surgical face mask, single-use
4301	MEDICAL FACE MASK	73324300000000205JU	35177 Surgical face mask, single-use
4302	MEDICAL FACE MASK	73324300000000205JU	35177 Surgical face mask, single-use
4311	MEDICAL FACE MASK	73324300000000205JU	35177 Surgical face mask, single-use
4312	MEDICAL FACE MASK	73324300000000205JU	35177 Surgical face mask, single-use
4313	MEDICAL FACE MASK	73324300000000206JW	35177 Surgical face mask, single-use
4315	MEDICAL FACE MASK	73324300000000206JW	35177 Surgical face mask, single-use
4330	MEDICAL FACE MASK	73324300000000205JU	35177 Surgical face mask, single-use
4334	MEDICAL FACE MASK	73324300000000205JU	35177 Surgical face mask, single-use
657000	MEDICAL FACE MASK	73324300000000205JU	35177 Surgical face mask, single-use
657100	MEDICAL FACE MASK	73324300000000205JU	35177 Surgical face mask, single-use



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Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
657200	MEDICAL FACE MASK	733243000000000205JU	35177 Surgical face mask, single-use
658000	MEDICAL FACE MASK	733243000000000205JU	35177 Surgical face mask, single-use
658010	MEDICAL FACE MASK	733243000000000205JU	35177 Surgical face mask, single-use
658200	MEDICAL FACE MASK	733243000000000205JU	35177 Surgical face mask, single-use
658300	MEDICAL FACE MASK	733243000000000205JU	35177 Surgical face mask, single-use
658391	MEDICAL FACE MASK	733243000000000206JW	35177 Surgical face mask, single-use