



EU Declaration of Conformity according to MDR

Title: Medical Face Masks Type II

We, Mölnlycke Health Care AB, Entreprenörstråket 21, SE-431 53, Mölndal, Sweden, SRN SE-MF-000014042, 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:	Medical Face Mask
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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:

(Notified Body Name)

NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

Mölnlycke Health Care AB issues this declaration in recognition of applied harmonized standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Mölndal, Sweden

Date: 2025-05-06

Function:

Regulatory Affairs Excellence
Director

Name: Karin Darle Olsson

Signature:

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Generic product information	
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.
Basic UDI-DI:	733243000000000205JU
GMDN Code:	66199 Surgical/medical face mask, non-antimicrobial, single-use
EMDN Code:	T020604 MEDICAL USE FACE MASKS, TYPE II AND IIR

Product References Covered by this Declaration:	Product	Product Descriptor:
4228	MEDICAL FACE MASK	MEDICAL FACE MASK
4230	MEDICAL FACE MASK	MEDICAL FACE MASK
4231	MEDICAL FACE MASK	MEDICAL FACE MASK
4237	MEDICAL FACE MASK	MEDICAL FACE MASK
4238	MEDICAL FACE MASK	MEDICAL FACE MASK
4239	MEDICAL FACE MASK	MEDICAL FACE MASK
4301	MEDICAL FACE MASK	MEDICAL FACE MASK
4302	MEDICAL FACE MASK	MEDICAL FACE MASK
4311	MEDICAL FACE MASK	MEDICAL FACE MASK
4312	MEDICAL FACE MASK	MEDICAL FACE MASK
4330	MEDICAL FACE MASK	MEDICAL FACE MASK
4334	MEDICAL FACE MASK	MEDICAL FACE MASK
42270	MEDICAL FACE MASK	MEDICAL FACE MASK
42280	MEDICAL FACE MASK	MEDICAL FACE MASK
42290	MEDICAL FACE MASK	MEDICAL FACE MASK
106332	MEDICAL FACE MASK	MEDICAL FACE MASK
428801	MEDICAL FACE MASK	MEDICAL FACE MASK
428901	MEDICAL FACE MASK	MEDICAL FACE MASK



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657000	MEDICAL FACE MASK	MEDICAL FACE MASK
657100	MEDICAL FACE MASK	MEDICAL FACE MASK
657200	MEDICAL FACE MASK	MEDICAL FACE MASK
658000	MEDICAL FACE MASK	MEDICAL FACE MASK
658010	MEDICAL FACE MASK	MEDICAL FACE MASK
658200	MEDICAL FACE MASK	MEDICAL FACE MASK
658300	MEDICAL FACE MASK	MEDICAL FACE MASK