



## EU Declaration of Conformity according to MDR

**Title:** Medical Face Masks Type IIR

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 |
|----------------------------|-------------------|

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:

**Title:** Medical Face Masks Type IIR

| Generic product information |                                                                                                                                                                 |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Intended Purpose:</b>    | The device is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate matter. |
| <b>Basic UDI-DI:</b>        | 733243000000000206JW                                                                                                                                            |
| <b>GMDN Code:</b>           | 66199 Surgical/medical face mask, non-antimicrobial, single-use                                                                                                 |
| <b>EMDN Code:</b>           | T020604 MEDICAL USE FACE MASKS, TYPE II AND IIR                                                                                                                 |

| Product References Covered by this Declaration: | Product           | Product Descriptor: |
|-------------------------------------------------|-------------------|---------------------|
| 4224                                            | MEDICAL FACE MASK | MEDICAL FACE MASK   |
| 4232                                            | MEDICAL FACE MASK | MEDICAL FACE MASK   |
| 4234                                            | MEDICAL FACE MASK | MEDICAL FACE MASK   |
| 4236                                            | MEDICAL FACE MASK | MEDICAL FACE MASK   |
| 4267                                            | MEDICAL FACE MASK | MEDICAL FACE MASK   |
| 4291                                            | MEDICAL FACE MASK | MEDICAL FACE MASK   |
| 4313                                            | MEDICAL FACE MASK | MEDICAL FACE MASK   |
| 4315                                            | MEDICAL FACE MASK | MEDICAL FACE MASK   |
| 658391                                          | MEDICAL FACE MASK | MEDICAL FACE MASK   |