

Declaration of Conformity EU

Document ID: Created by: Approved by: Approval date:

Clumsery

PD-452450 Rev: 01 Zahrah Chaudhary Christina Lewing 2020-07-10

Title: Filtering Half Mask

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We, Mölnlycke Health Care AB, Gamlestadsvägen 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 Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade name/ Product name:

Filtering Half Mask

Product classification:

Sterility Status: Non-sterile

Measuring function: No

This declaration is supported by a conformity assessment procedure in accordance with

Annex/es: VII

Certificate number: Not Applicable

Issued by: Not Applicable

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 all applicable harmonised standards.

Signed for and on behalf of M ö Inlycke Health Care

Date: 2020-07-10 Function: Regulatory Affairs Director

Name: **Christina Lewing** Signature:

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Title: Filtering Half Mask Page 2(2)

Product(s) covered by this declaration:

| Product Reference: | Product Descriptor: | GMDN Code: |
|--------------------|---------------------|---|
| 42902 | FILTERING HALF MASK | 57794 Surgical/ medical respirator, non-antimicrobia I, single-use |
| 42904 | FILTERING HALF MASK | 57794 Surgical/ medical respirator, non-antimicrobia I, single-use |

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