Mölnlycke®

Declaration of Conformity EU PPE Regulation

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Title: Filtering Half Masks

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being exclusively the responsible manufacturer for conformity of the following, declare that the Personal Protective Equipment (PPE) listed in the attached schedule are in conformity with the provisions of the REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC

Trade name / Product name:	Filtering Half Masks

Product classification: Category III

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: V & VII

Certificate number: CE 579219

Issued by: BSi (Notified Body Name) Id No: 2797 (Notified Body)

Notified Body Address: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands

Mölnlycke Health Care AB issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care AB

Date: 16 Feb. 2022 Function: Regulatory Affairs Director

Name: Christina Lewing Signature:

Title: Filtering Half Masks

Product Reference:	Product Descriptor:
42902	Filtering Half Mask
42904	Filtering Half Mask

List of Harmonised Standards

- ISO 9001:2015 Quality Management Systems. Requirements
- ISO 13485:2016 and EN ISO 13485:2016.Medical Devices, Quality Management Systems. Requirements for Regulatory Purposes
- ISO 14001:2015 Environmental Management Systems – Requirements with guidance for use
- EN ISO 14971: 2012 Medical Devices – Application of risk management to medical devices (and with reference to ISO 10993 – Biological evaluation of Medical Devices)
- EN ISO 15223-1: 2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied.
- EN ISO 10993-1:2020 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-10:2013 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- EN 149 + A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking
- EN 14683:2019+AC:2019 - Medical face masks - Requirements and test methods