We, Mölnlycke Health Care, 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 Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: **Personal Protective Equipment Directive 89/686/EEC**

Trade name/ Product name:	**Filtering Half Masks**

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: **2021-04-21** Function: **Regulatory Affairs Director**

Name: **Christina Lewing** Signature:

Intended Purpose: The device is intended to be worn to protect the patient and/or user 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:
42902	FILTERING HALF MASK	733243000000000204JS	57794 Surgical/medical respirator, non-antimicrobial, single-use
42904	FILTERING HALF MASK	733243000000000204JS	57794 Surgical/medical respirator, non-antimicrobial, single-use