

Filtration Efficiency of Particle Filtering Half Masks and Medical Face Mask

Confidentiality: Confidential

Report's title Filtration Efficiency of Particle Filtering Half Masks and Medical Face Mask	
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Summary <p>The purpose of the commission was to determine the filtration efficiency of particle filtering half masks and medical face mask.</p> <p>The filtration efficiency was determined using measurement methods defined in SFS-EN ISO 29463-3:2018 (High-efficiency filters and filter media for removing particles in air. Part 3: Testing flat sheet filter media). The filtration efficiency was measured with DEHS (di-ethyl-hexyl-sebacate) test aerosol. The efficiency was determined by measuring particle concentrations alternately from the air downstream of the filter material and from the unfiltered air from the reference line. The air flow rate drawn through the respiratory protective device was 95 l/min in accordance with SFS-EN 149:2009 (Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking). The air flow rate through the medical face mask was 28,3 l/min in accordance with SFS-EN 14683:2019 + AC:2019 (Medical face masks. Requirements and test methods).</p> <p>According to the filtration efficiency measurement results, the penetration of the respiratory protective device:</p> <ul style="list-style-type: none"> • "Baner CE2163 BT-005, FFP2, KN95, without exhalation valve" was 0,3% • "Baner CE2163 BT-005, FFP2, KN95, with exhalation valve" was 0,5% • "Laiianzhi 9180A, FFP2, with valve, Model K9211, CE0370" was 0,2% • "Laiianzhi 9103A, FFP3, NR, Model KP39211, CE0370" was 0,2% <p>According to the defined process method description they match the requirement of the standard SFS-EN 149:2009 for class FFP3.</p> <p>The filtration efficiency of the medical face "Intco 3-ply IIR CE0197" was 99,4% and according to the defined process method description it matches the requirement of the standard EN 14683 for class Type II.</p> <p>These results do not however replace official tests required for a product acceptance process like declaration of conformity or type approval.</p>	
Espoo 8.10.2020	
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1. Description and objectives

The objective of the commission was the determination of the filtration efficiency of particle filtering half masks and medical face mask against particulate impurities. The inspected protective devices are presented in Table 1. The commission was performed to the samples delivered to VTT Technical Research Centre of Finland by the customer on September 23th, 2020.

Table 1. The inspected protective devices.

Protective device	
1.	Particle filtering half mask Baner CE2163 BT-005, FFP2, KN95, without exhalation valve , Shandong Sanitary Products Co., Ltd, Meditammer Oy, samples delivered 23.9.2020
2.	Particle filtering half mask Baner CE2163 BT-005, FFP2, KN95, with exhalation valve , Shandong Jiangpo Sanitary Products Co., Ltd, Meditammer Oy, samples delivered 23.9.2020
3.	Particle filtering half mask Laianzhi 9180A, FFP2, with valve, Model K9211, CE0370 , Zhongshan Saifure Labor Protective Articles Co., Ltd, Meditammer Oy, samples delivered 23.9.2020
4.	Particle filtering half mask Laianzhi 9108A, FFP3, NR, Model KP39211, CE0370 , Zhongshan Saifure Labor Protective Articles Co., Ltd, Meditammer Oy, samples delivered 23.9.2020
5.	Medical face mask Intco 3-ply IIR CE0197 , 0 Meditammer Oy, samples delivered N.5.2020

2. Methods /realisation

The filtration efficiency measurements were made in accordance with the standard SFS-EN ISO 29463-3:2018 (High-efficiency filters and filter media for removing particles in air. Part 3 Testing flat sheet filter media). The surface area of the sample was the whole particle filter that was attached to the adapter as shown in Figure 1.

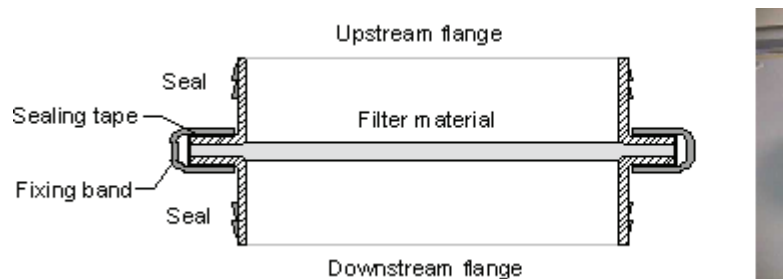


Figure 1. Principle of the sample adapter.

The airflow through the material was adjusted with an orifice plate ASME 17/34 mm complying with standard ASME MFC-14M-2001, and the pressure drop was measured with a FPM TT570SV micromanometer. The flow rate through the protective device according to standard SFS-EN 149:2009 (Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking) is 95 l/min. The flow rate through the medical face mask according to standard SFS-EN 14683:2019 + AC:2019 (Medical face masks Requirements and test methods) is 28 l/min.

The filtration efficiency was determined by utilizing the flow-through method (Figure 2). It was measured with DFHS (diethyl-hexyl-sebacate) test aerosol generated with a pneumatic aerosol nebulizer. The test aerosol was evenly mixed into HEPA filtered supply air. The efficiency was determined by measuring particle concentrations and size distribution immediately before (unfiltered air) and after the sample (filtered air). The particle concentrations were determined with an optical particle size analyser PMS LAS-X2 in the size range of 0,1...3,0 μm . The result is presented as the filtration efficiency of particle size range 0,6 μm as given for the particle size (NaCl) in the method presented in standard SFS-EN 149.

The filtration efficiency the medical face mask was measured an optical particle size analyser PMS LAS-X2 in the size range of 0,1...3,0 μm and an aerodynamic particle sizer APS Mode 3321 in the size range of 3,0...7,0 μm . The result is presented as the average of the filtration efficiencies of six different particle size ranges (0,65 μm , 1,1 μm , 2,1 μm , 3,3 μm , 4,7 μm , 7,0 μm) according to the method presented in standard SFS-EN 14683. Departing from the standard SFS-EN 14683, the samples were not conditioned at 85 % relative humidity before the measurements.

Three parallel samples were measured and the average value together with the standard deviation was calculated.

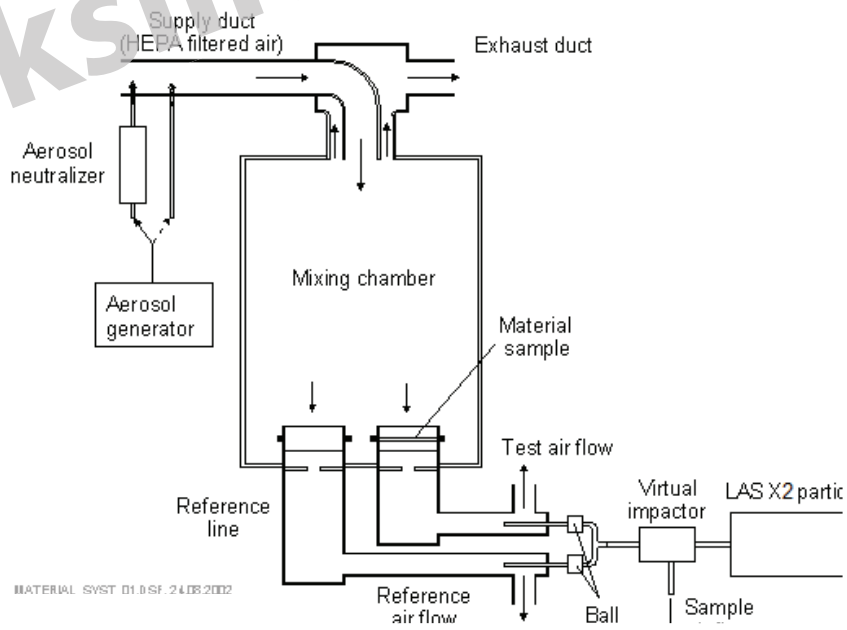


Figure 2. Principle of the test system.

3. Results

The measurements were made in the laboratory of the VTT Technical Research Centre of Finland on September 25th, 2020. The filtration efficiencies of the protective devices are presented in Table 2 and Table 3.

Table 2. Filtration efficiency of the particle filtering half mask.

Protective devices		PENETRATION [%]	FILTRATION EFFICIENCY [%]
		Dp 0.58 µm	Dp 0.58 µm
Particle filtering half mask Baner CE2163 BT-005 FFP2 KN95 without exhalation valve, Shandong Sanitary Products Co., Ltd, Meditammer Oy, samples delivered 23.9.2020	1	0,6	99,4
	2	0,2	99,8
	3	0,0	100,0
	Average	0,3	99,7
	Standard deviation	0,3	0,3
Particle filtering half mask Baner CE2163 BT-005 FFP2 KN95 with exhalation valve, Shandong Jiangpo Sanitary Products Co., Ltd, Meditammer Oy, samples delivered 23.9.2020	1	0,8	99,2
	2	0,5	99,5
	3	0,3	99,7
	Average	0,5	99,5
	Standard deviation	0,2	0,2
Particle filtering half mask Laianzhi 9180A FFP2 with valve, Model K9211, CE0370, Zhongshan Saifure Labor Protective Articles Co., Ltd, Meditammer Oy, samples delivered 23.9.2020	1	0,3	99,7
	2	0,1	99,9
	3	0,1	99,9
	Average	0,2	99,8
	Standard deviation	0,1	0,1
Particle filtering half mask Laianzhi 9108A FFP3, NR, Model KP39211, CE0370, Zhongshan Saifure Labor Protective Articles Co., Ltd, Meditammer Oy, samples delivered 23.9.2020	1	0,1	99,9
	2	0,3	99,7
	3	0,2	99,8
	Average	0,2	99,8
	Standard deviation	0,1	0,1

Table 3. Filtration efficiency of the medical face masks.

Protective devices		AVERAGE FILTRATION EFFICIENCY [%] (0.65 μm - 7 μm)
Medical face mask Intco 3-ply IIR CE0197, Meditammer Oy, samples delivered 23.9.2020	1	99,3
	2	99,5
	3	99,2
	Average	99,4
	Standard deviation	0,1

4. Conclusions and summary

The results of the inspected protective devices are summarised in Table 4.

Table 4. Summary of the test results.

Protective devices	PENETRATION [%] Air flow 95 l/min (EN 149)		FILTRATION EFFICIENCY [%] Air flow 95 l/min (EN 149)		AVERAGE FILTRATION EFFICIENCY [%] Air flow 28.3 l/min (EN 14683)	
	Dp 0.58 µm		Dp 0.58 µm		0.65 µm - 7 µm	
	Average	Standard deviation	Average	Standard deviation	Average	Standard deviation
Particle filtering half mask Baner CE2163 BT-005 FFP2 KN95 without exhalation valve, Shandong Sanitary Products Co., Ltd, Meditammer Oy, samples delivered 23.9.2020	0,3	0,3	99,7	0,3	-	-
Particle filtering half mask Baner CE2163 BT-005 FFP2 KN95 with exhalation valve, Shandong Jiangpo Sanitary Products Co., Ltd, Meditammer Oy, samples delivered 23.9.2020	0,5	0,2	99,5	0,2	-	-
Particle filtering half mask Laianzhi 9180A FFP2 with valve, Model K9211, CE0370, Zhongshan Saifure Labor Protective Articles Co., Ltd, Meditammer Oy, samples delivered 23.9.2020	0,2	0,1	99,8	0,1	-	-
Particle filtering half mask Laianzhi 9108A FFP3, NR, Model KP39211, CE0370, Zhongshan Saifure Labor Protective Articles Co., Ltd, Meditammer Oy, samples delivered 23.9.2020	0,2	0,1	99,8	0,1	-	-
Medical face mask Intco 3-ply IIR CE0197, Meditammer Oy, näytteet saapuneet 23.9.2020	-	-	-	-	99,4	0,1

According to the standard EN 149 the penetration requirements of the filter material of respiratory protective devices of different classes are:

- FFP1: max 20 %
- FFP2: max 6 %
- FFP3: max 1 %.

According to the filtration efficiency measurement results, the penetration of the respiratory protective device "Baner CE2163 BT-005 FFP2 KN95 without exhalation valve" was 0,3% and according to the defined process method description it matches the requirement of the standard SFS-EN 149:2009 for class FFP3. The penetration of the respiratory protective device "Baner CE2163 BT-005 FFP2 KN95 with exhalation valve" was 0,5% and according to the defined process method description it matches the requirement of the standard SFS-EN 149:2009 for class FFP3. The penetration of the respiratory protective device "Laianzhi 9180A, FFP2 with valve, Model K9211, CE0370" was 0,2% and according to the defined process method description it matches the requirement of the standard SFS-EN 149:2009 for class FFP3. The penetration of the respiratory protective device "Laianzhi 9108A, FFP3, NR, Model KP39211, CE0370" was 0,2% and according to the defined process method description it matches the requirement of the standard SFS-EN 149:2009 for class FFP3.

According to the standard EN 14683 the performance requirements (BFE) of the medical face masks of different classes are:

- Type I: ≥ 95 %
- Type II: ≥ 98 %.

According to the measurement results, the filtration efficiency of the medical face "Intco 3-ply IIR CE0197" was 99,4%, and according to the defined process method description it matches the requirement of the standard EN 14683 for class Type II.

These results do not however replace official tests required for a product acceptance process like declaration of conformity or type approval.