PURE Environments by Shatkin F.I.R.S.T.

Dear Valued Customer: October 2020

Pure Environments by Shatkin F.I.R.S.T., Inc. is manufacturing USA made N95 disposable face masks in Amherst, NY USA! The quality and manufacturing practices are second to none, and we have built a clean room environment for the manufacturing of these masks and received our approvals for use of the facility here in Amherst, NY. In the spirit of full transparency, here is the current standing on our face masks, which we have opted to make available prior to NIOSH and FDA certification/registration, due to the desperate need for these masks in our current worldwide situation and the shortages of N95 masks. We are pleased to inform you that our masks have passed all precertification testing, have been submitted to NIOSH for approval and assigned a task number of TN-24343.

These face masks are available immediately and orders will be shipped on a first come, first served basis.

These masks are currently listed as FDA Class I device listing number 401288. The masks we are manufacturing have been laboratory tested by ICS Inc. Laboratories in Brunswick, OH and have exceeded the NIOSH N95 precertification requirements, which include both N95 filtration efficiency and exhalation and inhalation resistance qualifications. We additionally have had the masks tested by Vance Lab at the University of Colorado Boulder, and SGS IBR Laboratories (the worlds leading inspection, verification, testing and certification company) under European standard EN 149, where they also passed and exceeded the N95 filtration and exhalation and inhalation efficiency requirements (see attached testing documents and technical data sheet). The masks will be sold as laboratory tested Pre-Certified NIOSH N95 filtration masks, conforming to NIOSH N95 standards prior to NIOSH approval. After NIOSH approval, the masks will then be listed with the FDA and CDC as USA made N95 NIOSH respirator masks. The precertification testing was a necessary step in the NIOSH certification process. Due to the urgency of the situation, we are making these masks available prior to final NIOSH approval. Any masks purchased prior to NIOSH approval will have a retroactive NIOSH certification once we receive the NIOSH approval.

These masks comply with the requirements of EU regulation (EU) 2016/425 (see testing results below) for Personal Protective Equipment and meet the requirements of European standard EN 149:2001 + AI:2009.

- Masks are model PESF-N95H: designed to protect the wearer against inhalation of both droplets and particles suspended in the air.
- FFP2 masks that meet the EN-149 standard are the closest to N95 masks in the ability to filter particles.
- See attached 3M technical bulletin describing similarities between N95 NIOSH regulated and EN 149:2001 FFP2 "during pandemic or emergency situations, health authorities often reference these standards when making respirator recommendations, stating, for example, that certain populations should use an N95, FFP2 or equivalent respirator"

Thank you for your interest in our face masks from Pure Environments by Shatkin F.I.R.S.T., Inc.

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PURE Environments

by Shatkin Ey.R.S.T.

Technical Data Sheet

	N95 PROTECTIVE MASK			
ITEM	TDs	Standard	Remark	
BRAND	Pure Environments by Shatkin F.I.R.S.T., Inc.			
MODEL	SFN95H	Regular Size		
WEIGHT	4.85g/pcs	ISO9073-1-1989		
CLASSIFICATION	N95	PARTICLE FILTERING HALF MASK	FILTER RATING	>95%
			INSPIRATORY RESISTANCE	<.0.?mbar
			EXPIRATORY RESISTANCE	<3.0mbar
	FFP2/P2/P3	EN149:2001+A1:2009	>95%	
COMPOSITION	Outer Layer	Non-wovens	50g/m2	
	1st Filter Layer	PP melt blown	50g/m2	
	2nd Filter Layer	Hot AirCotton	30g/m2	
	3rd Filter Layer	PP meltblown	25g/m2	
	Inner Layer	Non-wovens	25g/m2	
	Headbands	PP& PE	5mm x 0.5 mm	
	Nose Bridge	PP & Wire	5mm x 0.5 mm	
CERTIFICATE	FDA LISTED	D401288	DISPOSABLE FACE MASK	
	CE		PENDING	
	Niosh		PENDING	
SHELF LIFE	5 Years	Storage Temp: -22 F - 104 F Humidity < 80%		
APPLICATION	Personal Protective Filtration Mask			
FEATURE	High efficiency and comfortable			
COLOR	WHITE			

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Test Report No. T15003-01-1 Issue 1
N95 Pre-Certification: NIOSH TEB-APR-STP -0003,
NIOSH TEB-APR-STP-0007, and NIOSH TEB-APR-STP-0059
Pure Environments by Shatkin First, Inc.
Shatkin First N95 Respirator
15 September 2020

DD
Crrtifira1r: 1122:01

Authorized by:

Tyler Jenkins
Manager
Respiratory and Chemical Protective Equipment

Performed by:

Jessica Corvin
Laboratory Technician
Respiratory and Chemical Protective Equipment

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c) Unless othenvise indicated, the test results contained in this report apply only to the samples tested and not to lots or batches from which they were taken.

d) Where applicable, test data provided by subcontractor is uniquely identified in the test report.

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ICS Laboratories, Inc. e1072 Industrial Parkway North • Brunswick, Ohio 44212 USA
Phone: 330.220.0515 Fax: 330.220.0516

JCS

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ACCREDITED Test Laboratory Certificate: 1722.01

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Summary:

23 Shatkin First N95 respirators were tested for exhalation resistance, inhalation resistance, and filtration efficiency to NIOSH standards TEB-APR-STP-0003, TEB-APR-STP-0007, and TEB-APR-STP-0059. The samples were submitted by Pure Environments by Shatkin First, Inc. All samples met exhalation and inhalation resistance requirements as well as N95 filtration efficiency requirements, having exhalation resistances < 25 mmH2O, inhalation resistances < 35 mmH2O, and maximum penetrations < 5%.

Objectives:

Testing to: *NIOSH Procedure TEB-APR-STP-0003* "Determination of Exhalation Resistance Test, Air-Purifying Respirators Standard Testing Procedure (STP)" Revision: 2.4, 15 March 2019
NIOSH Procedure TEB-APR-STP-0007 'Determination of Inhalation Resistance Test, Air-Purifying Respirators Standard Testing Procedure (STP)" Revision: 2.3, 8 March 2019
NIOSH Procedure TEB-APR-STP-0059 "Determination of Particulate Filter Efficiency Level for N95 Series Filters against Solid Particulates for Non-Powered, Air-Purifying Respirators Standard Testing Procedure (STP)" Revision 3.2, 13 December 2019

Materials:

Model No.	*Description*	*Qty*
SFN95	White respirator with head straps and N95 markings	40

Date provided by the Client: 08 July 2020
Date Testing Authorized: 08 July 2020
Dates of tests: 08-09 September 2020
Manufacturer/Supplier Pure Environments by Shatkin First, Inc.

Equipment:

TSI 8130A Filter Tester, test bench configured for sodium chloride aerosol (EQ1279)
TSI 8130 Filter Tester, configured for sodium chloride aerosol (EQ0087)
Flow Meters, Fisher & Porter Co., (EQ0098-03 & EQ0098-04) Calibrated
Digital Manometer; Dwyer Instruments, (EQ0501) Calibrated
Humidity chamber, Envirotronics (EQ0327)
Vacuum Pumps; Marathon Electric (EQ0088-04-02 &-03)
ISI Headform (EQ0477)
Mask Fixture, Custom design ICS Labs
Sodium Chloride, 99+%, Fisher Chemical, (C0015-03)

Procedure:

All tests were conducted in a standard laboratory atmosphere unless otherwise specified. The equipment and instrument calibrations were verified current and within specification prior to use. The materials for assessment were inventoried, numbered, and logged upon receipt.

The exhalation resistance test was performed in general accordance with NIOSH Procedure TEB-APR- STP-0003. A positive 85 LPM airflow through the respirator was established and the pressure difference across the respirator was determined with the digital manometer. The pressure was corrected for systemic resistance and recorded in mmH2O column height.

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Procedure (cont.):

The inhalation resistance test was performed in general accordance with NIOSH Procedure TEB-APR-STP-0007. A negative 85 LPM airflow through the respirator was established and the pressure difference across the respirator was determined with the digital manometer. The pressure was corrected for systemic resistance and recorded in mmH20 column height.

The filter efficiency test was performed in general accordance with NIOSH Procedure TEB-APR-STP-0059. The respirators were challenged to a sodium chloride aerosol neutralized to a Boltzmann equilibrium state at 25 +/-5°C and a relative humidity of30 +/- 10%. Particle size distribution was verified to be a count median diameter of0.075 +/- 0.020 microns, with a geometric standard deviation not exceeding 1.86.

The respirators were conditioned at 85 % +/- 5 % relative humidity and 38°C +/- 2.5°C for 25 hours prior to the filter efficiency test. Three respirators were selected at random from the quantity provided. Each respirator was then assembled into a fixture and subjected to aerosol loading. The filter loading was performed by depositing 200 mg of sodium chloride aerosol at airflow rate of 85 LPM. Flow rate was monitored every 5-10 minutes on average and adjusted to maintain a flow rate of85 LPM +/- 4 LPM. The initial flow rate, initial resistance, initial penetration, and maximum penetration data were recorded.

An aerosol loading graph for each respirator was created to determine the filter type. The respirator was identified as a Type II filter based on the performance graph. As such, the following 17 samples, selected at random, were subjected to instantaneous aerosol loading. The loading was performed by depositing sodium chloride aerosol at an airflow rate of 85 LPM for one minute. Flow rate was maintained at 85 LPM +/- 4 LPM. The flow rate, resistance, and penetration data were recorded for each respirator.

Results:

The results for the exhalation and inhalation resistance of the respirators are provided in Table I.

Table I
Breathing Resistance- Shatkin First N95 Respirator

Sample ID	*Exhalation Resistance * (mmH20)*	*Inhalation Resistance * (mmH20)*	*Results*
PE-21	17.3	19.3	Pass
PE-22	18.6	21.9	Pass
PE-23	18.5	21.0	Pass
Specification:**	:S 25	:S 35	

*Resistance corrected for systemic response **Specification based on non-powered air purifying respirator

Table II outlines the results of the full loading tests. All respirators followed the Type II filter profile defined by *NIOSHTEB-APR-STP-0059.*

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Results (cont.):

Table II

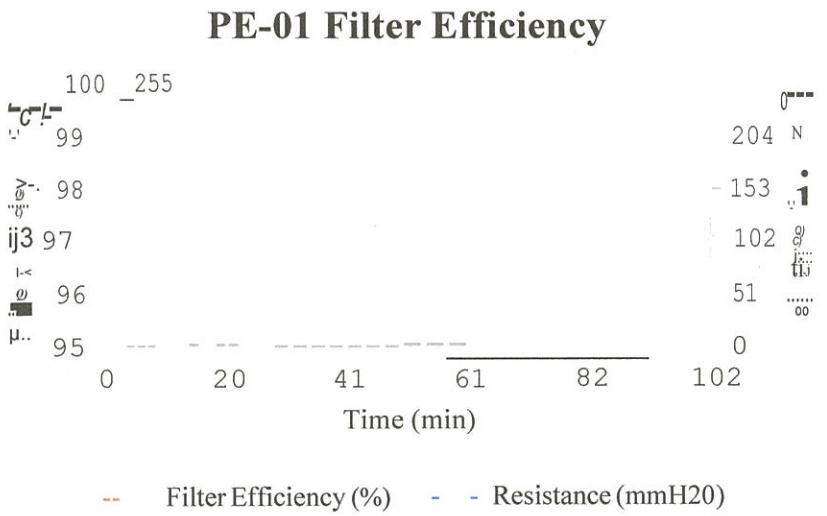
Full Loading Efficiencies - Shatkin First N95 Respirator

Sample ID	*Initial Flow Rate (LPM)*	*Initial Resistance (mmH20)*	*Initial Penetration (%)*	*Maximum Penetration (%)*	*Filter Efficiency* (%)*	*Result*
PE-01	85	19.3	0.42	0.42	99.58	Pass
PE-02	85	18.5	0.85	0.85	99.15	Pass
PE-03	85	19.8	0.50	0.50	99.50	Pass
Specification:	**81- 89**			**$ 5.0**	**95.0**	

**Filter efficiency percent is based on maximum penetration value.*

Below are the filter efficiency and resistance graphs over the loading time for each test. Raw data tables are located in the appendix of this report.

Filter performance graph, Sample PE-01



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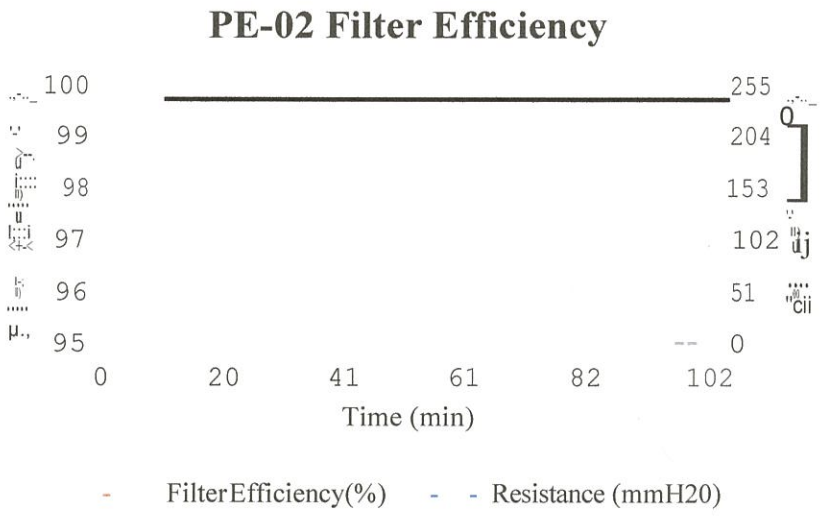
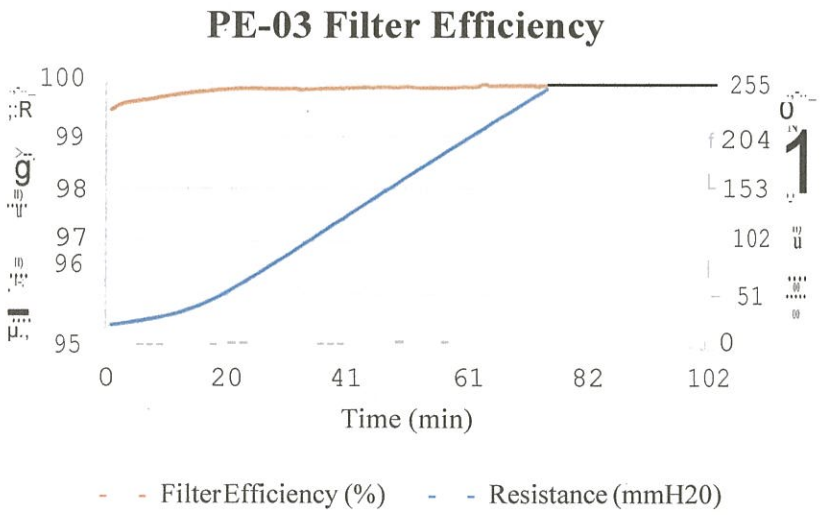
Results (cont.):

Filter performance graph, Sample PE-02



Filter performance graph, Sample PE-03



As outlined in TEB-APR-STP-0059, the respirator was identified as Type II filter by its loading profile. Table Ill outlines the 17 instantaneous aerosol loading test results for each respirator.

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Results (cont.):

Table ID
Ints antaneous Load"mg Eff.ic1enc1es - ShatkinF"rrstN95 Res.p!Tator

Sample ID	*Flow Rate (LPM)*	*Resistance (mmH20)*	*Penetration (%)*	*Filter Efficiency(%)*	*Result*
PE-04	85	19.3	0.78	99.22	Pass
PE-05	85	17.6	0.84	99.16	Pass
PE-06	85	18.0	0.26	99.74	Pass
PE-07	85	20.5	0.27	99.73	Pass
PE-08	85	18.7	0.25	99.75	Pass
PE-09	85	19.4	0.66	99.34	Pass
PE-10	85	18.0	0.30	99.70	Pass
PE-11	85	18.7	1.13	98.87	Pass
PE-12	85	19.5	0.45	99.55	Pass
PE-13	85	19.2	0.27	99.73	Pass
PE-14	85	18.0	0.32	99.68	Pass
PE-15	85	19.7	0.50	99.50	Pass
PE-16	85	19.0	0.33	99.67	Pass
PE-17	85	21.4	1.35	98.65	Pass
PE-18	85	19.0	1.28	98.72	Pass
PE-19	85	19.3	0.84	99.16	Pass
PE-20	85	21.9	0.37	99.63	Pass
Specification :	**81- 89**		**5.0**	2::95.0	

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Photo ra hs:

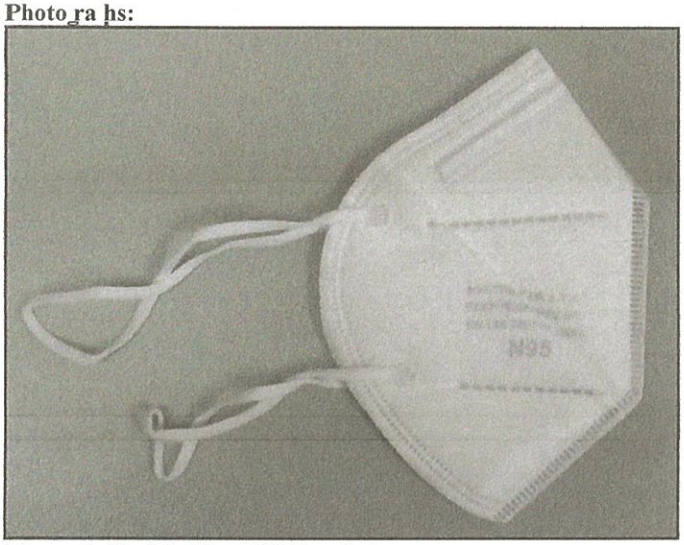
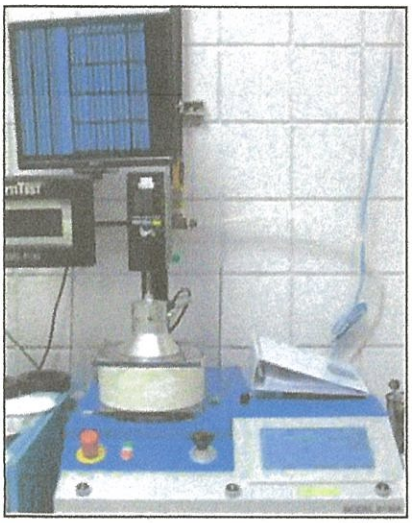


Figure 1: Shatkin First N95 Respirator



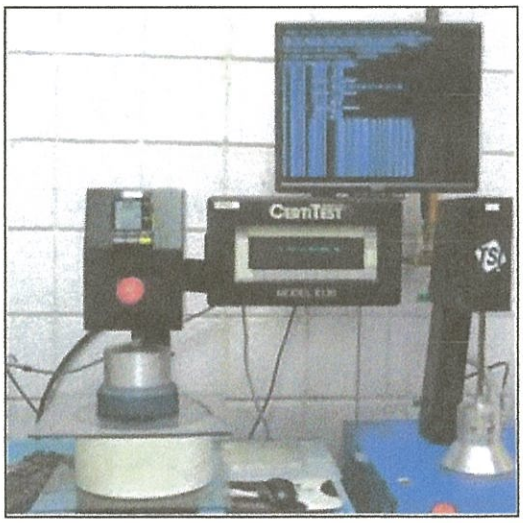


Figure 2 & **3.** Respirator under test using both 8130A and 8130 instruments

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Photographs (cont.):

Figure 4. Resistance measurement

Appendix:

L oad"ml! data tior Sample PE-01

1	84.84	19.31	0.42	35	84.33	99.98	0.06	69	83.38	224.30	0.0Z
2	84.80	19.80	0.40	36	84.31	103.82	0.08	70	83.38	228.04	0.0Z
3	84.79	20.52	0.37	37	84.29	107.57	0.08	71	83.36	231.52	0.02
4	84.80	21.20	0.34	38	84.27	111.34	0.o7	72	83.32	234.99	0.02
5	84.77	21.94	0.32	39	84.25	115.04	0.o7	73	83.31	238.53	0.02
6	84.78	22.73	0.31	40	84.21	118.81	0.o7	74	83.31	242.00	0.02
7	84.76	23.51	0.29	41	84.17	122.54	0.06	75	83.25	245.44	0.01
8	84.76	24.40	0.27	42	84.14	126.26	0.06	76	83.21	248.85	0.01
9	84.77	25.34	0.26	43	84.09	130.02	0.06	77	83.20	252.28	0.01
10	84.77	26.47	0.24	44	84.06	133.70	0.05	78	83.18	254.98	0.01
11	84.77	27.61	0.22	45	84.05	137.54	0.05	79	83.11	254.98	0.01
12	84.78	28.88	0.21	46	83.99	141.22	0.04	80	83.07	254.98	0.01
13	84.75	30.36	0.19	47	83.98	144.98	0.04	81	83.06	254.98	0.01
14	84.74	32.03	0.18	48	83.94	148.67	0.04	82	82.98	254.98	0.01
15	84.74	33.80	0.16	49	83.92	152.38	0.04	83	82.%	254.98	0.01
16	84.71	35.77	0.15	50	83.88	156.08	0.03	84	82.94	254.98	0.01
17	84.70	38.07	0.14	51	83.84	159.76	0.03	85	82.89	254.98	0.01
18	84.69	40.48	0.13	52	83.81	163.35	0.03	86	82.85	254.98	0.01
19	84.67	43.13	0.12	53	83.77	167.01	0.03	87	82.85	254.98	0.01
20	84.64	46.01	0.11	54	83.75	170.71	0.03	88	82.81	254.98	0.01
21	84.64	49.06	0.11	55	83.72	174.35	0.03	89	82.76	254.98	0.02
22	84.61	52.27	0.11	56	83.70	178.00	0.03	90	82.75	254.98	0.02
23	84.58	55.72	0.10	57	83.67	181.66	0.03	91	82.73	254.98	0.02
24	84.56	59.21	0.09	58	83.64	185.41	0.03	92	82.69	254.98	0.02
25	84.56	62.77	0.10	59	83.60	188.83	0.03	93	82.67	254.98	0.0Z
26	84.53	66.32	0.09	60	83.61	192.51	0.03	94	82.66	254.98	0.02
27	84.50	70.08	0.09	61	83.60	196. 04	0.03	95	82.63	254.98	0.02
28	84.48	73.75	0.09	62	83.55	199.59	0.03	96	82.60	254.98	0.02
29	84.46	77.48	0.09	63	83.53	203.27	0.03	97	82.58	254.98	0.02
30	84.41	81.21	0.09	64	83.50	206.71	0.03	98	82.56	254.98	0.02
31	84.44	84.94	0.08	65	83.50	210.32	0.03	99	82.52	254.98	0.02
32	84.39	88.70	0.07	66	83.44	213.72	0.03	100	82.50	254.98	0.0Z
33	84.35	92.50	0.08	67	83.47	217.28	0.03	101	82.48	254.98	0.02
34	84.35	%.22	0.08	68	83.43	220.81	0.02	102	82.45	254.98	0.02

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Appendix (cont.):

Load"m2 data ior Sample PE-02

1	85.30	18.49	0.85	35	84.60	97.68	0.32	69	83.57	220.93	0.25
2	85.32	18.96	0.82	36	84.59	101.45	0.31	70	83.54	224.52	0.25
3	85.27	19.55	0.77	37	84.53	105.13	0.31	71	83.49	228.06	0.23
4	85.23	20.27	0.74	38	84.50	108.90	0.30	72	83.49	231.55	0.25
5	85.22	20.95	0.71	39	84.48	112.56	0.31	73	83.43	235.21	0.24
6	85.22	21.66	0.69	40	84.44	116.26	0.36	74	83.42	238.68	0.25
7	85.23	22.49	0.66	41	84.37	119.88	0.36	75	83.41	242.19	0.24
8	85.22	23.37	0.64	42	84.36	123.53	0.35	76	83.36	245.77	0.22
9	85.19	24.26	0.61	43	84.35	127.23	0.36	77	83.32	249.27	0.21
10	85.19	25.32	0.59	44	84.29	130.96	0.35	78	83.32	252.85	0.19
11	85.15	26.48	0.57	4S	84.27	134.67	0.35	79	83.27	254.98	0.21
12	85.18	27.72	0.55	46	84.25	138.28	0.34	80	83.24	254.98	0.19
13	85.15	29.12	0.51	47	84.20	141.95	0.34	81	83.19	254.98	0.17
14	85.14	30.72	0.49	48	84.17	145.60	0.33	82	83.14	254.98	0.17
15	85.10	32.42	0.46	49	84.13	149.13	0.33	83	83.IO	254.98	0.20
16	85.11	34.40	0.44	50	84.11	152.76	0.34	84	83.06	254.98	0.23
17	85.07	36.48	0.43	51	84.08	156.36	0.35	85	83.04	254.98	0.22
18	85.05	38.86	0.40	52	84.05	159.98	0.34	86	83.01	254.98	0.21
19	85.04	41.42	0.39	53	84.02	163.48	0.34	87	82.98	254.98	0.20
20	85.01	44.20	0.37	54	83.99	167.09	0.35	88	82.94	254.98	0.19
21	84.99	47.20	0.35	55	83.97	170.66	0.34	89	82.91	254.98	0.19
22	85.00	50.39	0.35	56	83.94	174.24	0.33	90	82.89	254.98	0.18
23	84.95	53.65	0.35	57	83.90	177.90	0.32	91	82.86	254.98	0.20
24	84.92	57.17	0.34	58	83.84	181.56	0.30	92	82.83	254.98	0.19
25	84.91	60.68	0.33	59	83.86	185.18	0.31	93	82.79	254.98	0.18
26	84.87	64.24	0.32	60	83.80	188.82	0.29	94	82.76	254.98	0.20
27	84.82	67.86	0.30	61	83.78	192.47	0.29	95	82.76	254.98	0.19
28	84.82	71.61	0.31	62	83.75	196.05	0.29	96	82.74	254.98	0.18
29	84.80	75.26	0.30	63	83.72	199.64	0.28	97	82.70	254.98	0.18
30	84.72	78.95	0.30	64	83.69	203.23	0.28	98	82.67	254.98	0.15
31	84.72	82.76	0.29	65	83.69	206.78	0.26	99	82.65	254.98	0.13
32	84.71	86.40	0.30	66	83.64	210.34	0.28	100	82.62	254.98	0.17
33	84.68	90.10	0.32	67	83.61	213.90	0.27	IOI	82.60	254.98	0.16
34	84.65	93.91	0.32	68	83.60	217.42	0.26	102	82.58	254.98	0.15

Load"m2 data ior Sample PE-03

1	85.37	19.83	0.50	35	84.56	104.85	0.10	69	83.49	229.60	0.03
2	85.34	20.50	0.43	36	84.54	108.48	0.09	70	83.47	233.17	0.04
3	85.29	21.37	0.38	37	84.49	112.32	0.09	71	83.44	236.73	0.03
4	85.31	22.18	0.36	38	84.43	116.11	0.08	72	83.39	240.32	0.04
5	85.24	23.11	0.35	39	84.41	119.92	0.09	73	83.37	243.82	0.05
6	85.22	23.98	0.33	40	84.38	123.61	0.09	74	83.31	247.39	0.04
7	85.22	24.89	0.31	41	84.34	127.43	0.D7	75	83.32	250.89	0.03
8	85.21	25.99	0.29	42	84.30	131.17	0.D7	76	83.26	254.41	0.03
9	85.17	27.14	0.27	43	84.27	134.87	0.07	77	83.20	254.98	0.03
10	85.17	28.37	0.25	44	84.22	138.55	0.06	78	83.17	254.98	0.02
11	85.16	29.74	0.22	45	84.21	142.27	0.07	79	83.14	254.98	0.02
12	85.13	31.38	0.21	46	84.17	146.02	0.06	80	83.11	254.98	0.02
13	85.13	33.10	0.20	47	84.14	149.71	0.06	81	83.07	254.98	0.02
14	85.12	35.04	0.18	48	84.09	153.44	0.06	82	83.04	254.98	0.02
15	85.07	37.14	0.17	49	84.08	157.24	0.D7	83	83.00	254.98	0.02
16	85.08	39.34	0.15	50	84.06	160.93	0.06	84	82.98	254.98	0.02
17	85.06	41.85	0.14	51	84.01	164.69	0.06	85	82.94	254.98	0.02
18	85.03	44.55	0.13	52	83.98	168.35	0.06	86	82.91	254.98	0.02
19	85.02	47.44	0.12	53	83.98	172.03	0.D7	87	82.89	254.98	0.ot
20	85.02	50.50	0.11	54	83.92	175.77	0.D7	88	82.88	254.98	0.ot
21	84.97	53.74	0.10	55	83.92	179.38	0.D7	89	82.84	254.98	0.01
22	84.96	57.16	0.10	56	83.89	182.98	0.D7	90	82.82	254.98	0.01
23	84.92	60.56	0.09	57	83.85	186.67	0.07	91	82.78	254.98	0.01
24	84.89	64.04	0.09	58	83.82	190.29	0.07	92	82.76	254.98	0.01
25	84.85	67.67	0.08	59	83.80	193.85	0.D7	93	82.71	254.98	0.01
26	84.86	71.30	0.09	60	83.77	197.47	0.06	94	82.70	254.98	0.01
27	84.81	74.89	0.10	61	83.74	201.08	0.06	95	82.69	254.98	0.00
28	84.78	78.60	0.10	62	83.71	204.55	0.06	96	82.63	254.98	0.00
29	84.77	82.30	0.09	63	83.67	208.11	0.06	97	82.62	254.98	0.00
30	84.75	85.98	0.10	64	83.63	211.71	0.00	98	82.62	254.98	0.00
31	84.71	89.72	0.09	65	83.62	215.32	0.04	99	82.60	254.98	0.00
32	84.68	93.50	0.09	66	83.58	218.82	0.04	100	82.57	254.98	0.01
33	84.63	97.18	0.11	67	83.56	222.43	0.04	101	82.54	254.98	0.01
34	84.58	101.03	0.10	68	83.54	226.03	0.04	102	82.50	254.98	o.oi

ICS LABORATORIES

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Technical Report #2020-002
Vance Lab - University of Colorado Boulder
www.colorado.edu/lab/vance

Laboratory Testing for Respirators, Masks, and Filter Media

Prepared by:
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Submitted on: 30-June-2020

Supplier: Shatkin F.I.R.S.T.

Executive Summary

As with multiple aerosol science and engineering laboratories around the world, our laboratory aims to aid in the COVID-19 healthcare crisis by providing particle filtration testing for new mask and respirator designs. Our goal is to help researchers and manufacturers by testing their filters and mask designs to aid in product development before they are ready for official testing and distribution. As such, our goal is to relieve pressure from official certifying labs and to provide more feedback to manufacturers to aid in their product design. This report documents the results for one respirator sample as to its filtration efficiency and inhalation resistance, according to the methods detailed in the methods section of this report. Results are summarized below:

Sample ID	Average Filtration Efficiency (± standard deviation)		Average Inhalation Resistance (± standard deviation)
	In terms of total particle mass	In terms of total particle number	
2020-002-002	95%± 1%l	96% + 1o/d	18.6 ± 0.2 mm H2d

1. Introduction

Due to the Coronavirus Disease (COVID-19) global pandemic and healthcare crisis, there is an urgent need to manufacture, test, and supply respirators and masks to healthcare providers, essential workers, and to the general population. As with multiple aerosol science and engineering laboratories around the world, our laboratory aims to aid in the COVID-19 health care crisis by providing particle filtration testing for new mask and respirator designs. Our goal is to help researchers and manufacturers by testing their filters and mask designs to aid in product development before they are ready for official testing and distribution. As such, our goal is to relieve pressure from official certifying labs and to provide more feedback to manufacturers to aid in their product design.

2. Testing Methods

Our laboratory has adapted from the NIOSH testing procedures for filtration efficiency (TEB-APR-STP-0059-508) and inhalation resistance (TEB-APR-STP-0007-508),[2] to the extent possible using our research-grade particle sizing instrumentation. Similar tests to what we are performing are also reported in the scientific literature.[3] A detailed list of testing procedures follows:

Sample pre-conditioning

Respirators, masks, and filter material are pre-conditioned at 85 ± 5% relative humidity and 38 ± 2.5 °C for 25 ± 1 hours. After conditioning, filters are either tested immediately or sealed in a gas-tight container and tested within 10 hours.

Aerosol generation

A solution of 10% by weight of ammonium sulfate [$(NH_4)zSO_4$] in deionized water is prepared and placed in a Collison-type atomizer, operated at ~32 psi to generate an aerosol with a median diameter of 0.075 ± 0.020 micrometer. The aerosol stream passes through a diffusion dryer to remove excess water and an X-ray neutralizer to neutralize electrical surface charge before being injected into a 38 m^3 testing chamber.

Sample fixture

For respirator and mask testing, the sample is placed on a foam human headform and taped to seal any potential gaps between the respirator/mask and headform. A total flow rate of 15 LPM is passed through the sample to be tested and supplied to the particle sizing instrumentation: a Scanning Mobility Particle Sizer (TSI Inc.), measuring particles 11- 514 nm in electrical mobility diameter, and an Aerodynamic Particle Sizer (TSI Inc.), measuring particles 0.54 - 18.3 µmin aerodynamic diameter.

Test duration

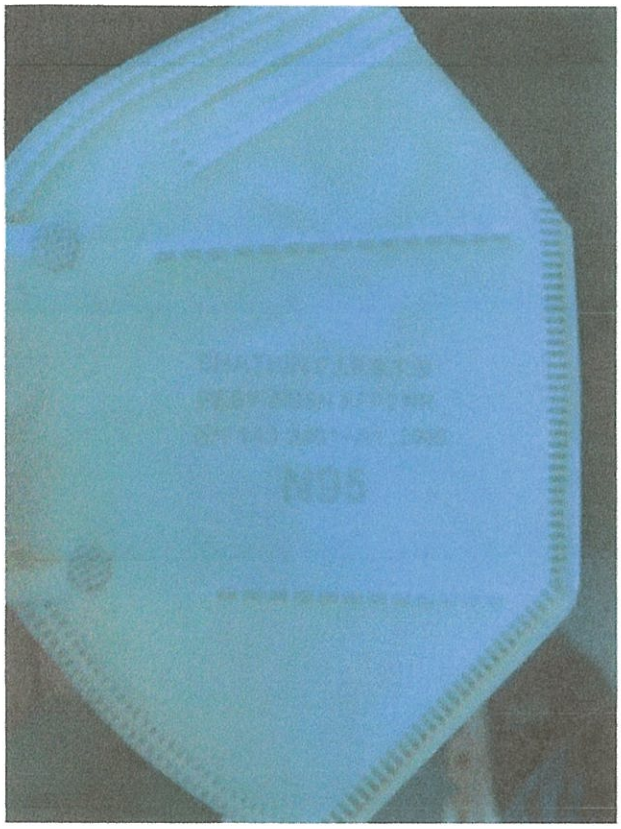
The test encompasses 234 min of total particle loading during a ~6-hour test, leading to ~0.2 mg particle loading. During this period, particle concentrations in the testing chamber and downstream of the sampling material are measured multiple times in order to provide a filtration efficiency over time.

Accordance to NIOSH procedures
This filtration efficiency test is not performed in complete accordance with the NIOSH N95 filtration efficiency procedure. Please see Table 1, in the Appendix of this report, for details on which steps are in accordance to the NIOSH procedure.

Inhalation resistance
The test for the determination of inhalation resistance is performed according to NIOSH procedure TEB-APR-STP-0007-508, which states: "The resistance for non-powered, air-purifying particulate respirators upon initial inhalation shall not exceed 35 mm water-column height."

3. Results

Sample description
Sample ID: 2020-002-002



Filtration efficiency over time

As a function of particle number:

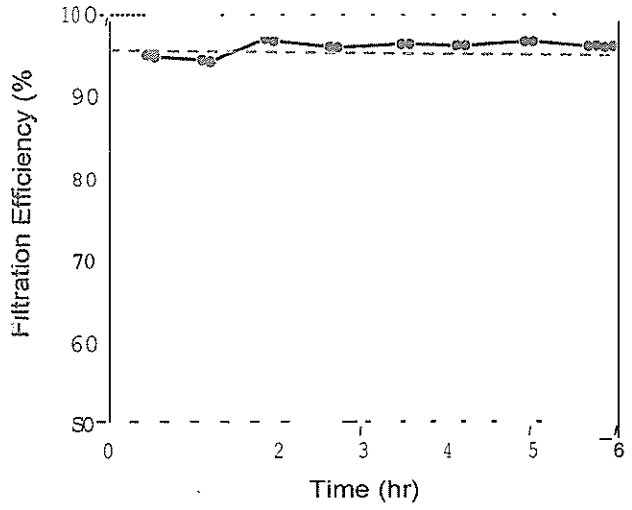


Figure 1. Filtration efficiency calculated using total particle number concentration over time.

As a function of particle mass:

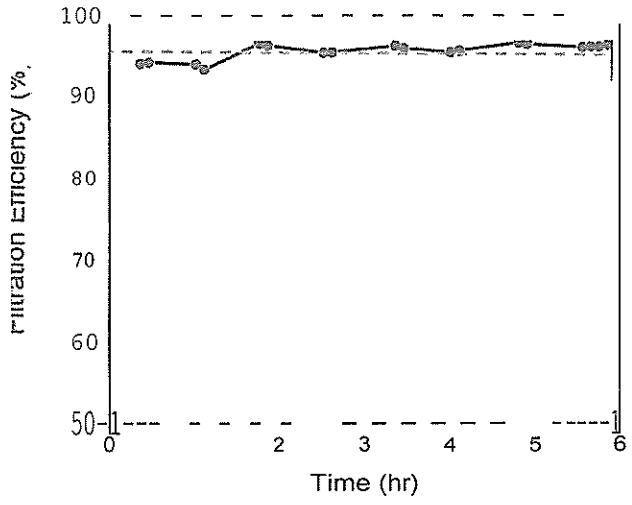


Figure 2. Filtration efficiency calculated using total particle mass concertation over time.

Size-resolved filtration efficiency

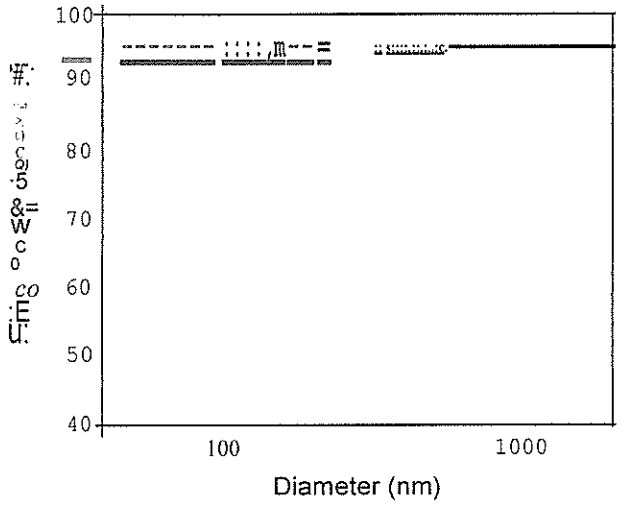


Figure 3. Size-resolved filtration efficiency calculated as a function of particle number distribution. The whiskers represent standard error (N=16).

As a function of particle mass:

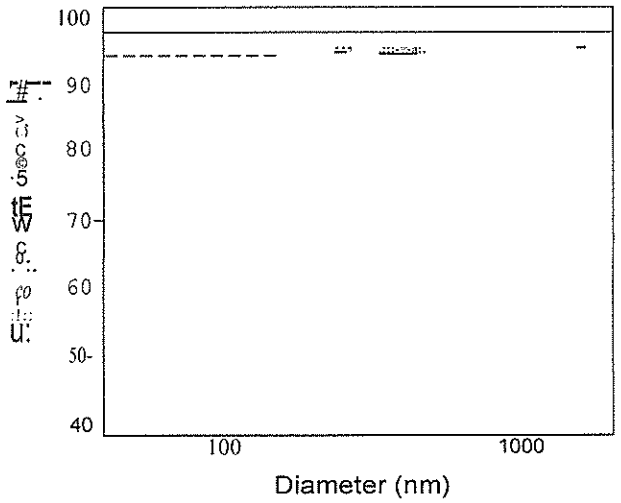


Figure 4. Size-resolved filtration efficiency calculated as a function of particle mass distribution. The whiskers represent standard error (N=16).

Inhalation resistance

Total inhalation resistance= 18.6 ± 0.2 mm H2O. Does not exceed the limit of 35 mm.

4. References

(1) NIOSH. *Determination of Particulate Filter Efficiency Level for N95 Series Filters against Solid Particulates for Non-Powered, Air-Purifying Respirators Standard Testing Procedure (STP).;* TEB-APR-STP-0059; Pittsburgh, MA, 2019.

(2) NIOSH. *Determination of Inhalation Resistance Test, Air-Purifying Respirators. Standard Testing Procedure (STP).;* TEB-APR-STP-0007; Pittsburgh, MA, 2019.

(3) Konda, A.; Prakash, A.; Moss, G. A.; Schmoldt, M.; Grant, G.D.; Guha, S. Aerosol Filtration Efficiency of Common Fabrics Used in Respiratory Cloth Masks. ACS *Nano* **2020** . https://doi.org/10.1021/acsnano.0c03252.

(4) EPA. Exposure Factors Handbook. EPA 2011.

Appendix

Table 1. Compliance according to NIOSH filtration efficiency testing procedure.

Procedure/Material	Following NIOSH N95 filtration efficiency procedure?	Details/comments
Pre-conditioning	YES	The NIOSH procedure states: "Respirator filters will be preconditioned at 85 ± 5% relative humidity and 38 ± 2.5 °C for 25 ± 1 hours. After conditioning, filters shall be sealed in a gas tight container and tested within 10 hours."
Aerosol material	**NO**	The NIO H procedure describes the use of sodium chloride (NaCl, table salt). We use ammonium sulfate to protect our laboratory instrumentation from rust. Results are unlikely to be affected by this substitution.
Aerosol size (0.075 ± 0 .020 micrometer)	YES	The NIOSH procedure states: "The particle size distribution will be a count median diameter of 0.075 ± 0.020 micrometer and a geometric standard deviation not exceeding 1.86."
Test flow rate	**NO**	The NIOSH procedure states: "single air purifying respirator filters will be tested at a challenge flow rate of 85 ± 4 Lpm." Our test flow rate is 15 l/min, which is comparable to the flow rate of human breath at light intensity activity level for most of the age groups.[4]
Aerosol mass loading	**NO**	The NIOSH procedure describes that filters will be loaded until 200 ± 5 mg loading is reached. At our testing flow rate of 15 l/min, this would take an amount of time that is impractical. Instead, we are performing tests for 6 hours to simulate an average work day.
Testing temperature and relative humidity	**YES**	The NIOSH procedure describes testing at 25 ± 5 °C and a relative humidity of 30 ± 10%. Our testing chamber is kept at ~22 °C and ~37%.

SGS IBR LABORATORIES **TEST REPORT**

IBR JN: 22699

Test Date: 11 September 2020

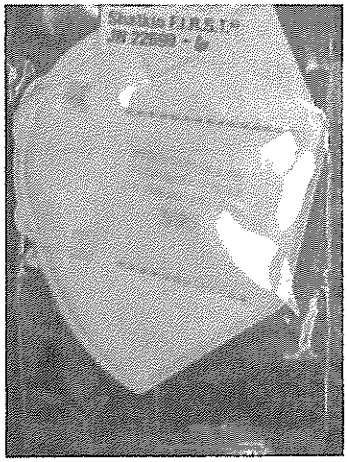
Performed for: Shatkin First LLC
Customer Contact: Kim Wiesmore
Customer Location: Amherst, NY

Test Method: NIOSH TEB-APR-STP-0059 Initial Filtration Efficiency with Airflow Resistance

Sample Description: White, non-powered respirator, Shatkin F.I.R.S.T.,PESF-N95H
Sample Source: Shatkin First LLC - Amherst, NY
Date Received: 19 Aug 2020

Fluid: Air
Flow rate: 85 ± 2 1pm
Contaminant: NaCl Aerosol Count Median Diameter 0.075 ± 0.020 µm (Neutralized)
All testing conducted within the required temperature and humidity ranges

Sample ID	Airflow Resistance (mmH2O) Inhalation	Exhalation	Particle Filtration Penetration (%)	Efficiency (%)
22699-6	15.5	15.2	1.6	**98.4**
22699-7	16.3	16.2	1.4	**98.6**
22699-8	17.0	16.5	2.1	**97.9**
22699-9	18.3	18.0	1.3	**98.7**
22699-10	14.5	13.7	2.5	**97.5**



CFR 42 84.180 and 181 requirements
Filtration Efficiency: 95%
Modifications to the test: Initial Efficiency Only
Inhalation Resistance: ≤35 mmH2O
Exhalation Resistance: ≤35 mmH2O

Notice: These data relate only to the samples tested. This report may be copied only in its entirety.
Performed By: NML Data Location: NML-06

Reviewed by: _____
Daniel R. Miller, Air Labs Manager

Revision	Editorial or Technical	Description	Approved by	Release Date
[illegible]	[illegible]	Initial release	DRM	9/11/2020

3M Science. Applied to Life /M

Technical Bulletin

May, 2020
Revision 4

Comparison of FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes

Description

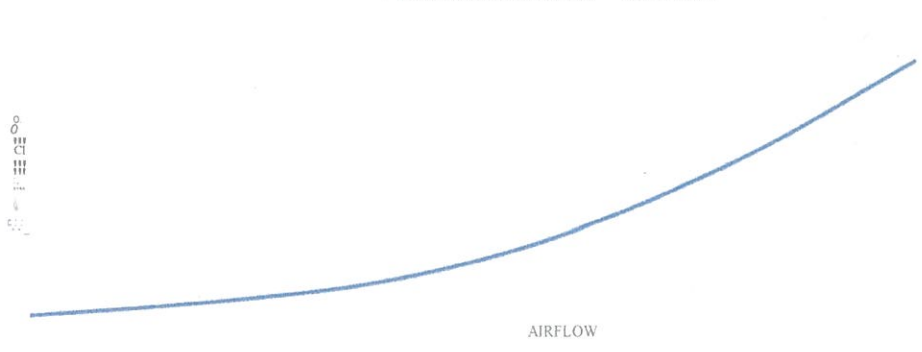
Filtering facepiece respirators (FFR), which are sometimes called disposable respirators, are subject to various regulatory standards around the world. These standards specify certain required physical properties and performance characteristics in order for respirators to claim compliance with the particular standard. During pandemic or emergency situations, health authorities often reference these standards when making respirator recommendations, stating, for example, that certain populations should use an "N95 , FFP2, or similar" respirator.

This document is only intended to help clarify some key similarities between such references, specifica lly to the following FFR performance standa rds:

- N95 (United States NIOSH-42CF R84)
- FFP2 (Europe EN 149-2001)
- KN95 (China GB2626-2006)
- P2 (Australia / Ne w Zealand AS/NZA 1716:201)2
- Korea 1st class (Korea KMOEL - 2017-64)
- D82 (Japan JMHLW-Notification 214, 2018)

As shown in the following summary table, respirators certified as meeting these standards can be expected to function very similarl y to one another, based on the performance requirements stated in the standards and confirmed during conformity testing.

One notable comparison point is the flow rates specified by these standards for the inhalation and exhalation resistance tests. Inhalation resistance testing flow rates range from 40 to 160L/ min. Exhalation resistance testing flow rates range from 30 to 95 Umin. Some count ries require testing to be performed at multiple flow rates, others at only the high or low end of those ranges. Although this appears to suggest thatthe standards ' requirements for breathing resistance (also called "pressure drop") differ from each other, it's important to understand that pressure drop across any filter will naturally be higher at higher flow rates and lower at lower flow rates. Given typic al pressure curves for respirator filters, the standards ' various pressure drop requirements are actually quite similar. This chart shows a representative filter pressure drop curve. If one filter is tested at a high flow rate, the pressure drop performance will be relatively high. If that same filter is tested at a lo w flow rate, the pressure drop performance will be relatively low.



Based on this comparison, it is reasonable to consider China KN95, AS/NZ P2, Korea 1st Class , and Japan DS2 FFRs as "similar" to US NIOSH N95 and European FFP2 respirators, for filtering non-oil-based particles such as those resulting from wildfires, PM 2.5 air pollution, volcanic eruptions, or bioaerosols {e.g. viruses). Howeve r, prior to selecting a respirator, users should consult their local respirato ry protection regulations and requirements or check with their locar pub lic health authorities for selection guidance.

Certification/ Class (Standard)	N95 (NIOSH-42C FR84)	FFP2(EN 149-2001)	KN95 (GB.2626-20 06)	P2(AS/NZ 1716:2012)	Ko lfea 1 s.t Class {KMOEL-2017-64)	DS2{Japan JMHLW-Notification 214,2018)
Filter p erformance - (must be 2 X% effi ci ent)	?: 95 %	2: 94%	2:95%	?:94%	?:9 4 %	2: 95%
Test agent	NaC l	NaC l and paraffin oil	NaCl	NaCl	NaCl and paraffin oil	NaCl
Flow rate	85l/min	951/mfn	85 l/ min	95! /min	95Umin	BS U min
Total inward leakage (TIL)* - tested on human subjects each performing exercises	NIA	s 8 % leakage (arithmetic mean)	s 8% Je akage (arithmetic mean}	s 8% 1e akage {individuat and arithmeti c mean)	s 8% 1eakage (arithmetic mean}	Inward Leakage measured and included in User Instruc tions
tnhalation resistance - max pressure drop	s 343 Pa	s7Q Pa(at30 Umin) s 240 Pa (at 95 Umin) s S00 Pa (clogging)	s 350 Pa	s 70 Pa{at30 Umin) s 240 Pa (at 95 Umin)	s70Pa(at30 Umin) s 240 Pa (at 95 Umin)	s 70 Pa (w/ valve) sS0 Pa(no valve)
Flow rate	85 L/m,n	Varied - s.e e ab o ve	8 5 1/ mi n	Varied - see above	Varie d - se e above	401/min
Exhalation resistance - max pressure drop	s 245 Pa	s300Pa	s 250 Pa	s120 Pa	s 3 00 Pa	s?0 Pa (w/ valve) s 50 Pa (no valve)
Flow rate	85 L/ min	160 Umin	85L/min	85Umin	160 L/min	40 L/min
Exhalation valve leakage requirement	Leak rat e s 30 ml/min	N/A	Depre ssuri zat fo n to 0 Pa 2: .2 0 sec	Le ak rate s 30 mUmfn	visual inspection after 300 Umin for 30 sec	Depressurizatio n to O Pa 2: 15 sec
Force applied	-2 45 Pa	NIA	-t180Pa	-250Pa	NIA	-1,470 Pa
CO_2 clearance requirement	NIA	S1 %	S i %	S j o/.,	S "\%	s t%

*Japan JMHLW-Notific at ion 214 requires an Inward l eakage test rather than a Tfl te st.

Definitions

Filter performance - the fifter is evaluated to measure the reduction in concentrations of specffic aerosols in air that passes through the filter.

Test agent - the aerosol that is generated during the filter performance test.

Tot al inward fe akage (TfL) - the amount of a specifi c aeroso l tha t enters the tested respirator facepiece via both filter penetration and faceseaf leakage,while a wearer performs a series of exercises in a test chamber.

Inw ard leakage (IL)- theamount of a spec ific aerosol that enters the tested respirator facepiece, white a wearer performs a normal breathin g for 3 minu tes in a test chamb er. The test aerosol size (count median diameter) is about 0.5 micro meter.

Pressuredrop - the resistance air is subjected to as it m o ves throug h a m edium, such as arespirator filter.

IMPORTANT: Always read and follow respirator user instructions.

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