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

Dear Valued Customer,

July, 2020

Pure Environments by Shatkin F.I.R.S.T., Inc. is/will be manufacturing USA Made N95 disposable face masks in Amherst, NY USA! The quality and manufacturing practices are second to none. We have built a clean room environment for the manufacturing of these masks and have received our approvals for use of the facility here in Amherst, NY.
In the spirit of full transparency, here is the current standing on the N95/FFP2 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.

These face masks will be available in approximately 1-2 weeks and orders will be shipped on a first come first served basis.

These masks are currently listed as FDA Class 1 device listing number 401288. The masks we are manufacturing have been laboratory tested (see attached testing documents and technical data sheet). We are currently having further testing done by 2 USA Testing facilities, ICS Labs and Vance Laboratory. We are also having additional testing done by SGS Laboratory, (the world's leading inspection, verification, testing and certification company) under European standard EN 149.

Currently, these masks are at ICS Labs awaiting pre-NIOSH Certification testing. We have received the Vance Laboratory pre-NIOSH Certification test results confirming that our masks do comply with the stringent NIOSH requirements for both particulate filtration efficiency and inhalation resistance. These results are included in this document. The masks will be sold as laboratory tested N95 filtration masks, conforming to N95 standards prior to NIOSH approval which can take up to 6 months. After NIOSH approval, the masks will then be listed with the FDA and CDC as USA made N95 NIOSH respirator masks. The pre-certification testing is 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.

NIOSH: Due to the 6 month lead time for NIOSH approval, these masks will not be NIOSH approved. However, the FDA now accepts these test reports under the standard of EN 149 for N95/FFP2 registration.

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 + A1:2009.

- Masks are model PESF-N95H FFP2 NR: Designed to protect the wearer against the 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.
- Our masks have passed stringent laboratory testing and are undergoing additional testing at USA and European Laboratories including ICS Labs as well as SGS Laboratory, for European Standards (See testing results and technical data sheets below)

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

PURE Environments by Shatkin F.I.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	<.0.7mbar
			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 Air Cotton	30g/m2	
	3rd Filter Layer	PP melt blown	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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Technical Report #2020-002
Vance Lab - University of Colorado Boulder
www.colorado.edu/lab/vance

Laboratory Testing for Respirators, Masks, and Filter Media

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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%	96% ± 1%	18.6 ± 0.2 mm H_2O

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)[1] 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 [$(NH_4)_2SO_4$] 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 µm in 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:

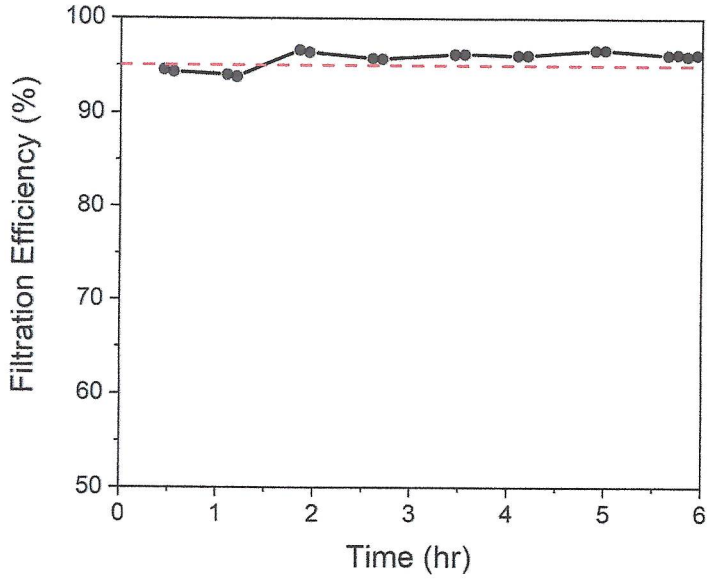


Figure 1. Filtration efficiency calculated using total particle number concentration over time.

As a function of particle mass:

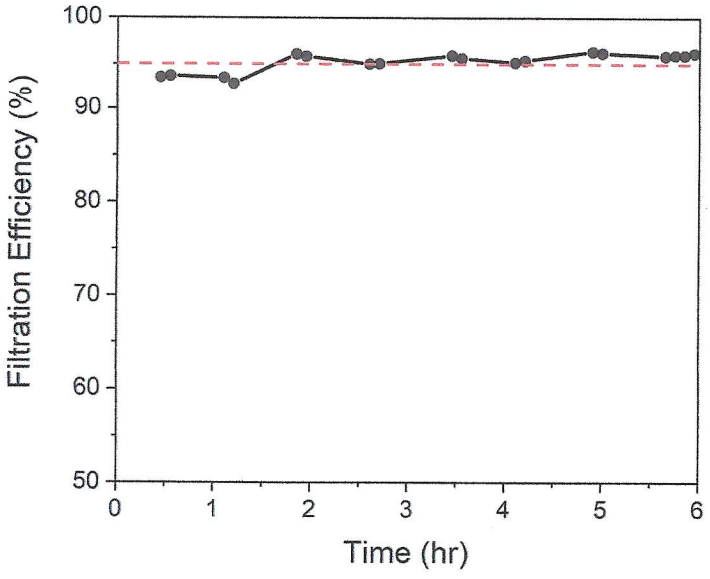


Figure 2. Filtration efficiency calculated using total particle mass concertation over time.

Size-resolved filtration efficiency

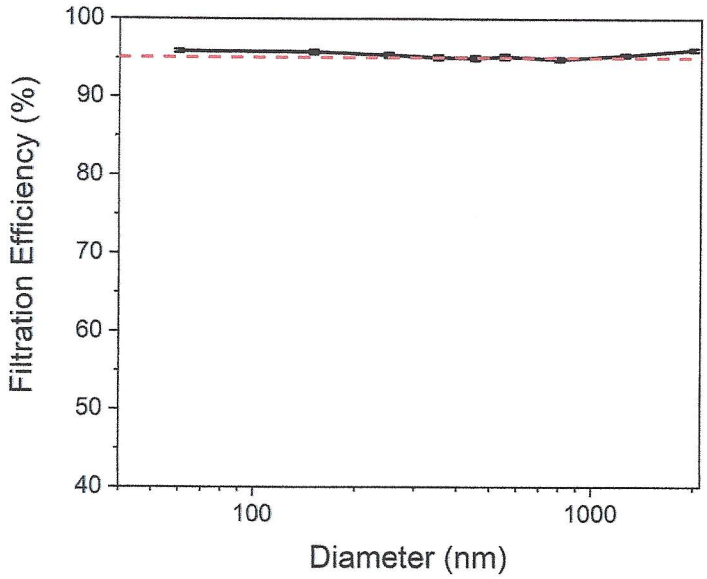


Figure 3. Size-resolved filtration efficiency calculated as a function of particle number distribution. The whiskers represent standard error (N=16).

As a function of particle mass:

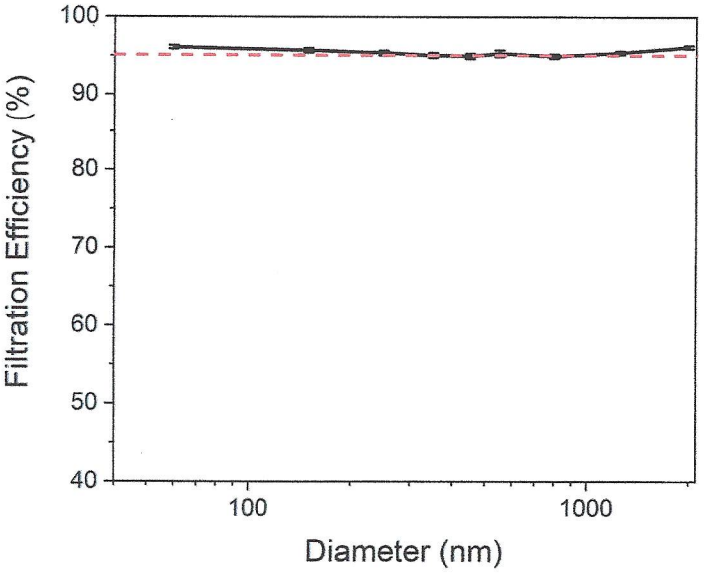


Figure 4. Size-resolved filtration efficiency calculated as a function of particle mass distribution. The whiskers represent standard error (N=16).

Inhalation resistance

Total inhalation resistance = 18.6 ± 0.2 mm H_2O. 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 NIOSH 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%.

TEST REPORT

EN 149

Respiratory protective devices. Filtering half masks to protect against particles.Requirements,testing,marking

Report Reference No	
Checked by (printed name and signature)	Kevin Yang
Approved by (printed name and signature)	King Hu
Date of issue	Mar. 30, 2020

Testing laboratory	Shenzhen ZCT Technology Co., Ltd.
Address	3F. 5th Building, Bao'an Road 4336, Bao'an District, Shenzhen, China
Applicant's name	Dongguan Huabao New Material Co., Ltd.
Address	Room 502, unit 2, building 1, No.7 qiaolonghe East Road, Tangxia Town, Dongguan City, Guangdong Province
Manufacturer's name	Pure Environments by Shatkin F.I.R.S.T., Inc
Address	2500 Kensington Avenue Amherst, NY 14226
Factory's name	Pure Environments by Shatkin F.I.R.S.T., Inc
Address	2500 Kensington Avenue Amherst, NY 14226
Test specification:	
Standard	☒ EN 149; 2001+ A1:2009
Test procedure	CE
Non-standard test method	N/A
Test Report Form No	
TRF Originator	ZCT
Master TRF	Dated 2019-01
Test item description	Daily protective mask
Trade Mark	N/A
Model/Type reference	N95
Ratings	FFP2 NR

Possible test case verdicts:

- test case does not apply to the test object ..... N (Not apply)

- test object does meet the requirement ..... P (Pass)

- test object does not meet the requirement ..... F (Fail)

Testing

Date of receipt of test item ..... Mar 23, 2020

Date(s) of performance of tests ..... Mar 23, 2020 to Mar 30, 2020

General remarks:

The test results presented in this report relate only to the object tested

This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.

"(See Enclosure #)" refers to additional information appended to the report.

"(See appended table)" refers to a table appended to the report.

General product information:

N/A

Copy of marking plate:

Daily protective mask
Model N95
Classification FFP2 NR
Standard EN 149:2001+A1:2009

Dongguan Huabao New Material Co., Ltd. - Material Made in China

Pure Environments by Shatkin F.I.R.S.T., Inc. - Masks Manufactured in USA

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
5	Classification		–
	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage There are three classes of devices		P
	- FFP1		N
	- FFP2	>95%	P
	- FFP3		N
6	Designation		–
	Particle filtering half masks meeting the requirements of this European Standard Year of publication classification option	Particle filtering half mask EN 149 2001+A1 2009 FFP2 NR	P
7	**Requirements**		–
7 1	General		P
	All test all test samples shall meet the requirements	Compled the requirement see bellow	P
7 2	Nominal values and tolerances		P
	Unless otherwise specified the values stated in this European Standard are experature limits		P
7 3	Visual inspection		P
	The visual inspection shall also include the marking and the information supplied by the manufacturer	Clear marking is provided see sample body	P
7 4	Packaging		P
	Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use		P
7 5	Material		P
	Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer	Comfortable wearing when releasing no hazards is produced	P
7 6	Cleaning and disinfecting		N
	If the particle filtering half mask is designed to be re-usable the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer	It's is not re-usable	N
7 7	Practical performance		P
	The particle filtering half mask shall undergo practical performance tests under realistic conditions	Complied see append test	P
7 8	Finish of parts		P
	come into contact with the wearer shall have no sharp edges or burrs		P
7 9	Leakage	See append table 8 5	P
7 9 1	Total inward leakage		P
	The laboratory tests shall wearer to protect with high probability against the potential hazard to be expected	Enough safe condition is Provide	P

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
	Exercise results for total inward leakage shall be not greater than		P
	25 % for FFP1 11% for FFP2 5% for FFP3	FFP2. Not exceed 11%	P
	And, in addition, at least 8 out of the 10 individual wearer anthmetic means for the total inward leakage shall be not greater than		P
	22 % for FFP1 8 % for FFP2 2 % for FFP3	FFP2. Not exceed 8%	P
7 9 2	Penetration of filter matenal		P
	The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1	see append table 7 92	P
7 10	Compatibility with shin		P
	Matenals that may come into contact with the wearer s skin shall not be known to be likely to cause imtation or any other adverse effect to health		P
7 11	Flammability		P
	The matenal used shall not present a danger for the wearer and shall not be of highly flammable nature		P
7 12	Carbon dioxide content of the inhalation air		P
	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1 0% (by volume)	<1 0%	P
7 13	Head harness		P
	Head harness shall be designed can be donned and removed easily and adjustable or selfadjusting and sufficiently robust to hold the particle	Head harness is donned and removed easily	P
7 14	Field of vision		P
	Field of vision is acceptable in practical performance tests	Clear field of vsion when weanng	P
7 15	Exhalation valve(s)		N
	A particle filtering half mask may have one or more exhalation valve(s) and shall function correctly in all onentations	One valve provided	N
	Exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device	Clearly function	N
	Exhalation valve(s) shall continue to operate correctly after a continuous exhalation flow of 300 l/mn over a penod of 30 s		N
	Exhalation valve housing is attached to the faceblank, and withstand axially a tensile force of 10 N applied for 10 s		N
7 16	Breathing resistance		P
	Ereathing resistances apply to valved and valveless and shall meet the requirements		P
7 17	Clogging		N
	General		N
	For single-use devices clogging test is an optional test		N
	Devices designed to be resistant to clogging, shown by a slow increase		N

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
	The specified breathing resistances shall not be exceeded before the required dust load of 833 mg·h/m³		N
7.17.2	Breathing resistance		N
7.17.2.1	Valved particle filtering half masks		N
7.17.2.2	Valveless particle filtering half masks		N
7.17.3	Penetration of filter material		N
	All types claimed to meet the clogging requirement shall also meet the penetration requirements given in 7.9.2 after the treatment		N
7.18	Demountable parts		N
	All demountable parts (if fitted) shall be readily connected and secured where possible by hand	No such demountable part	N
8	Testing		–
8.1	General		P
	No special measuring devices and methods are specified, commonly used devices and methods shall be used		P
8.2	Visual inspection		P
	The visual inspection is carried out appropriate by the test house prior to laboratory or practical performance tests		P
8.3	Conditioning		P
8.3.1	Simulated wearing treatment		P
	A breathing machine is adjusted to 25 cycles/min and 2.0 l/stroke	25 cycles/min 2.0 l/stroke	P
	For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head	A saturator incorporated by breathing machine and the dummy head	P
	The spilling out of the dummy's mouth and contaminating the particle filtering half mask the head shall be incline	Incline considered	P
8.3.2	Temperature conditioning		P
	Exposet masks to the following thermal cycle		P
	a) for 24 h to a dry atmosphere of (70 ± 3) °C.		P
	b) for 24 h to a temperature of (-30 ± 3) °C.		P
	Allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing	4 h to paid for	P
8.3.4	Flow conditioning		P
	A total of 3 valved particle filtering half masks shall be tested, one as received and two temperature conditioned in accordance with 8.3.2		P
9	Marking		–
9.1	Packaging		P
	The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent	Complied, clearly marked	P
9.1.1	The name, trademark or other means of identification of the manufacturer or supplier		P

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
9 1 2	Type-identifying marking		P
9 1 3	Classification FFP1, FFP2, FFP3	FFP2 NR	P
9 1 4	The number and year of publication of this European Standard		P
9 1 5	At least the year of end of shelf life		P
9 1 6	The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b		P
9 1 7	The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d	See product manual	P
9 1 8	The packaging of those particle filtering half masks passing the dolomite clogging test shall beadditionally marked with the letter "D"		N
9 2	Particle filtering half mask		P
	Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following		P
9 2 1	The name, trademark or other means of identification of the manufacturer or supplier	Dongguan Huabao New Material Co., Ltd	P
9 2 2	Type-identifying marking		P
9 2 3	The number and year of publication of this European Standard		P
9 2 4	The symbols FFP1, FFP2 or FFP3 according to class	FFP2 NR	P
9 2 5	If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the class designation (see 9 2 4)		N
9 2 6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified		N

Attachments: Test table

Table 7 9 2	Penetration of test aerosol test					P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Sodium chloride test 95 l/min	5 6	5 7	5 5	5 6	5 7	5 6
Paraffin oil test 95 l/min	5 4	5 6	5 7	5 7	5 6	5 5

Table 8 5	Leakage test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
NaCl flow rate (L/min)	90	100	120	110	120
NaCl aerosol (um)	0 3	0 3	0 3	0 3	0 3
0 3Pumping flow rate (L/min)	30	30	30	30	30
NaCl concentration before mask (Mg/m3)	2	2	2	2	2
NaCl concentration after mask (Mg/m3)	0 05	0 06	0 07	0 08	0 06
Note Test ark volume is $2m^3$ Average Leakage ratio is 8%<11% Calculation formula as below $P(\%)=\frac{C_2}{C_1}\times\frac{{}^1N+{}^1EX}{{}^1N}\times 100$					

Table 8 9 2	Exhalation resistance test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)	160	160	160	160	160
Maximum resistance (mbar)	2 45	2 47	2 45	2 46	2 46
Conclusion Maximum permitted resistance < 3 0 mbar					

Table 8 9 3	Inhalation resistance test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)	30	30	30	30	30
Maximum resistance (mbar)	0 42	0 44	0 44	0 45	0 43
Conclusion Maximum Inhalation resistance < 0 7 mbar					

3M Science. Applied to Life.™

Technical Bulletin

May, 2020
Revision 4

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

Description

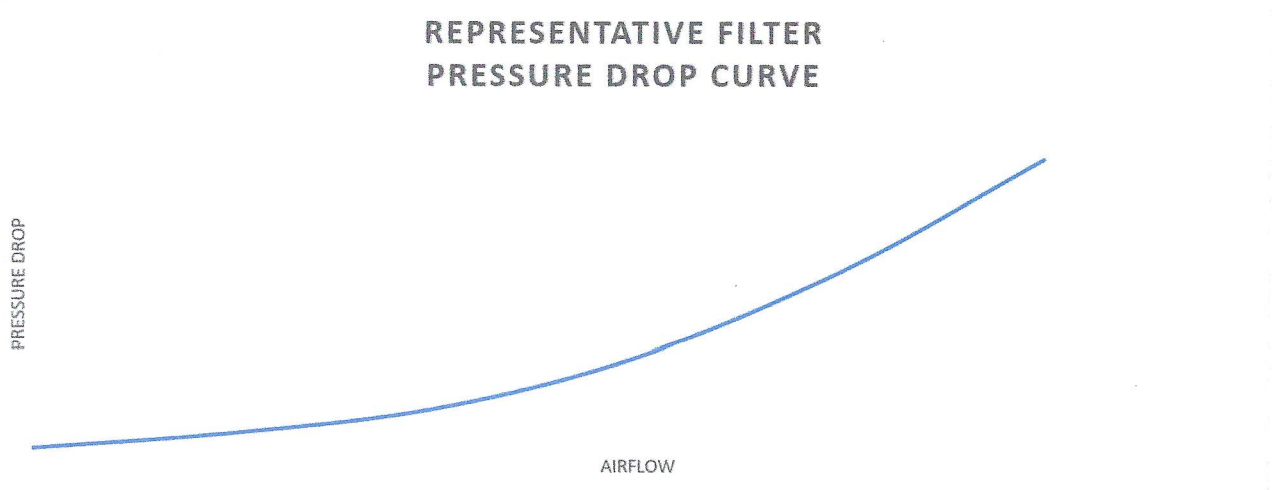
Filtering facepiece respirators (FFR), which are sometimes called disposable respirators, are subject to various regulatory standards around the world. These standards specify certain required physical properties and performance characteristics in order for respirators to claim compliance with the particular 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, specifically to the following FFR performance standards:

- N95 (United States NIOSH-42CFR84)
- FFP2 (Europe EN 149-2001)
- KN95 (China GB2626-2006)
- P2 (Australia/New Zealand AS/NZA 1716:2012)
- Korea 1st class (Korea KMOEL - 2017-64)
- DS2 (Japan JMHLW-Notification 214, 2018)

As shown in the following summary table, respirators certified as meeting these standards can be expected to function very similarly 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 L/min. Some countries 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 that the 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 typical 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 low 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). However, prior to selecting a respirator, users should consult their local respiratory protection regulations and requirements or check with their local public health authorities for selection guidance.

Certification/ Class (Standard)	N95 (NIOSH-42C FR84)	FFP2 (EN 149-2001)	KN95 (GB2626-2006)	P2 (AS/NZ 1716:2012)	Korea 1st Class (KMOEL - 2017-64)	DS2 (Japan JMHLW-Notification 214, 2018)
Filter performance – (must be ≥ X% efficient)	≥ 95%	≥ 94%	≥ 95%	≥ 94%	≥ 94%	≥ 95%
Test agent	NaCl	NaCl and paraffin oil	NaCl	NaCl	NaCl and paraffin oil	NaCl
Flow rate	85 L/min	95 L/min	85 L/min	95 L/min	95 L/min	85 L/min
Total inward leakage (TIL)* – tested on human subjects each performing exercises	N/A	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (individual and arithmetic mean)	≤ 8% leakage (arithmetic mean)	Inward Leakage measured and included in User Instructions
Inhalation resistance – max pressure drop	≤ 343 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min) ≤ 500 Pa (clogging)	≤ 350 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	Varied – see above	85 L/min	Varied – see above	Varied – see above	40 L/min
Exhalation resistance - max pressure drop	≤ 245 Pa	≤ 300 Pa	≤ 250 Pa	≤ 120 Pa	≤ 300 Pa	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	160 L/min	85 L/min	85 L/min	160 L/min	40 L/min
Exhalation valve leakage requirement	Leak rate ≤ 30 mL/min	N/A	Depressurization to 0 Pa ≥ 20 sec	Leak rate ≤ 30 mL/min	visual inspection after 300 L /min for 30 sec	Depressurization to 0 Pa ≥ 15 sec
Force applied	-245 Pa	N/A	-1180 Pa	-250 Pa	N/A	-1,470 Pa
CO_2 clearance requirement	N/A	≤ 1%	≤ 1%	≤ 1%	≤ 1%	≤ 1%

*Japan JMHLW-Notification 214 requires an Inward Leakage test rather than a TIL test.

Definitions

Filter performance – the filter is evaluated to measure the reduction in concentrations of specific aerosols in air that passes through the filter.

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

Total inward leakage (TIL) – the amount of a specific aerosol that enters the tested respirator facepiece via both filter penetration and faceseal leakage, while a wearer performs a series of exercises in a test chamber.

Inward leakage (IL)– the amount of a specific aerosol that enters the tested respirator facepiece, while a wearer performs a normal breathing for 3 minutes in a test chamber. The test aerosol size (count median diameter) is about 0.5 micro meter.

Pressure drop – the resistance air is subjected to as it moves through a medium, such as a respirator filter.

IMPORTANT: Always read and follow respirator user instructions.

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