Respiratory Face Mask General Classification

The classification of N95, KN95, KF94, and FFP2 is given to the mask after it passes the tests and falls within the filtering performance range.

- N95 & KN95 --> given when filtering performance (with NaCl) is greater than 95%

- KF94 & FFP2 --> given when filtering performance (with NaCl) is greater than 94%

TECHNICAL SHEET PUBLISHED BY 3M SCIENCE APPLIED TO LIFE states that

"Based on this comparison, it is reasonable to consider China KN95, AS/NZ P2, Korea 1st Class, and Japan DSFFRs as "**equivalent**" to **US NIOSH N95** and European FFP2 respirators,"

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Technical Bulletin

January, 2020
Revision 2

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

Description

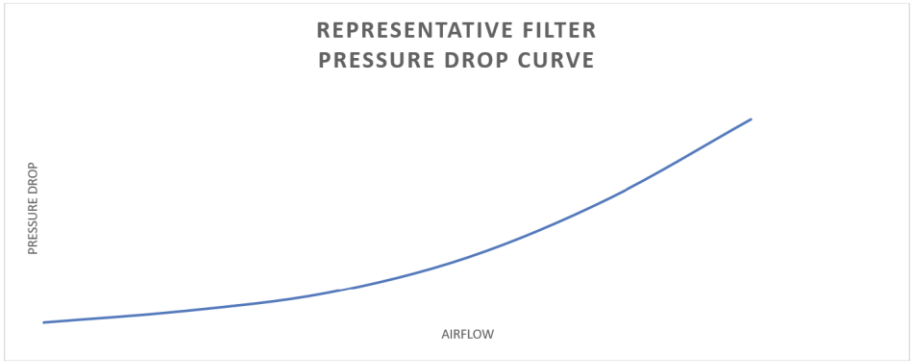
Filtering facepiece respirators (FFR), which are sometimes called disposable respirators, are subject to various regulatory standards around the world. These standards specify certain required physical properties and performance characteristics in order for respirators to claim compliance with the particular 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 equivalent" 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)
- DS (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 DS FFRs as "equivalent" 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 (GB2626-20 06)	P2 (AS/NZ 1716:2012)	Korea 1st Class (KMOEL - 2017-64)	DS (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	Depressurizatio n to 0 Pa ≥ 20 sec	Leak rate ≤ 30 mL/min	visual inspection after 300 L /min for 30 sec	Depressurizatio n 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.

Air Queen Nano Mask Classification

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRsearch.cfm?FR=878.4040

New Search | Help | More About 21CFR

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2019]
[CITE: 21CFR878.4040]

See Related Information

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 878 -- GENERAL AND PLASTIC SURGERY DEVICES

Subpart E--Surgical Devices

Sec. 878.4040 Surgical apparel.

(a) *Identification.* Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns. Surgical suits and dresses, commonly known as scrub suits, are excluded.

(b) *Classification.* (1) Class II (special controls) for surgical gowns and surgical masks. A surgical N95 respirator or N95 filtering facepiece respirator is not exempt if it is intended to prevent specific diseases or infections, or it is labeled or otherwise represented as filtering surgical smoke or plumes, filtering specific amounts of viruses or bacteria, reducing the amount of and/or killing viruses, bacteria, or fungi, or affecting allergenicity, or it contains coating technologies unrelated to filtration (e.g., to reduce and or kill microorganisms). Surgical N95 respirators and N95 filtering facepiece respirators are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 878.9, and the following conditions for exemption:

(i) The user contacting components of the device must be demonstrated to be biocompatible.

(ii) Analysis and nonclinical testing must:

(A) Characterize flammability and be demonstrated to be appropriate for the intended environment of use; and

(B) Demonstrate the ability of the device to resist penetration by fluids, such as blood and body fluids, at a velocity consistent with the intended use of the device.

(iii) NIOSH approved under its regulation.

(2) Class I (general controls) for surgical apparel other than surgical gowns and surgical masks. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 878.9.

[53 FR 23872, June 24, 1988, as amended at 65 FR 2317, Jan. 14, 2000; 83 FR 22849, May 17, 2018]

FDA classified the Air Queen NANO mask as 'SURGICAL N95 RESPIRATOR MASK'

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=668298&lpcd=FXX

U.S. Department of Health & Human Services

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Proprietary Name:	Air Queen; PM95; Pure MSK; Technoweb
Classification Name:	MASK, SURGICAL
Product Code:	FXX
Device Class:	2
Regulation Number:	878.4040
Medical Specialty:	General & Plastic Surgery
Registered Establishment Name:	Nano Filter Asan Manufacturing Facility
Premarket Submission Number:	K172500
Owner/Operator:	Nano Filter, Inc
Owner/Operator Number:	10069865
Establishment Operations:	Manufacturer

TEST REPORT

The filtering tests performed by KFDA designated and creditable Korean Testing Agency, **the filtering performance of the Nano Mask with NaCl agent always exceeds 98% or higher**.

시험 · 검사성적서

○ 성적서번호 : MY20-00102
○ 발 급 번 호 : 200200134
○ 의 뢰 업 체
- 업 체 명 : (주) 톰텍 [대표자:이재환(연락처:)]
- 소 재 지 : 충남 아산시 둔포면 아산밸리로 122
○ 제 품 명 : 에어퀸브리즈마스크 대형 (KF94) (Airqueen Breeze Mask)
○ 접 수 일 자 : 2020.03.11
○ 품 목 유 형 : KF94
○ 검 사 완 료 일 : 2020.03.12.
○ 품목제조보고(신고)번호 :
○ 검 사 목 적 : 제품 허가용
○ 제 조 원
○ 제 조 일 : 2020.03.10
- 업 체 명 : (주)톰텍
- 제 조 국 : 한국
- 소 재 지 : 충남 아산시

○ 시험 · 검사결과
- 세부 시험검사결과는 별지(시험결과) 참조

- 이 하 여 백 -

시험검사원: 이재호	시험검사책임자: 이상문

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「식품 · 의약품분야 시험 · 검사 등에 관한 법률」 제 11조 제 2항 및 같은 법 시행규칙 제 12조 제 4항 제 1호에 따라 위와 같이 시험 · 검사성적서를 발급합니다.

2020.03.13.

식품의약품안전처지정 시험 · 검사기관(지정번호 제22호)
한국건설생활환경시험연구원

27876 충청북도 진천군 덕산면 여안로 13 (재)한국건설생활환경시험연구원 종합안전환경시험장
결과문의 : 건물에너지센터 ☎ (043-753-3105)

- Page 1 of 3 -

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시험성적서

성적서번호 : MY20-00102

○ 시험결과

시험·검사항목		단 위	기 준			시험·검사 결과	항목판정
성상		-	육안관찰 [흰색의 3단 가로접이식 본체에 코편이 있고, 양 측면에 흰색의 끈 및 끈 연결용 고리가 있는 부직포 마스크]			이상 없음	적합
형상		mm	본체	가로	마스크가 3단 가로접이식으로 접혀진 상태에서의 가로로 가장 긴 길이 ≥10 ± 10	209	적합
				세로	마스크를 펼친 후 좌우 대칭이 되도록 세로로 접은 후 세로로 가장 긴 길이 155 ± 10	155	
			머리끈	길이	본체 접합부에서 머리끈을 분리한 후 접합부를 제외한 끈의 길이 160 ± 16	좌 : 165 우 : 163	
				폭	마스크 머리끈 길이의 수직 방향 길이 3 ± 1	2.5	
순도	색소	-	관찰하여 색을 나타내지 않음			색 나타내지 않음	적합
	산 또는 알칼리	-	홍색을 나타내지 않음(페놀프탈레인 시액) 적색을 나타내지 않음(메틸오렌지 시액)			홍색, 적색 나타내지 않음	적합
	형광	-	자외선(350~370 nm)에서 형광을 나타내지 않음			형광 없음	적합
	포름알데히드	-	검액의 색이 비교액의 색보다 진하지 않음			진하지 않음	적합
인장강도		N	절단하중(N) 평균(3회)이 10 N 이상			평균값 32.9	적합
안면부흡기저항		Pa	6개 각각의 결과가 70 Pa (KF94) 이하			본품 40.4 37.3 39.0 전처리 36.6 38.2 34.7	적합
포집효율(NaCl)		%	본품 3개, 전처리 3개 결과가 94 % (KF94) 이상			본품 98.6 98.6 98.2 전처리 98.0 98.5 98.6	적합

w/ NaCl agent

- Page 2 of 3 -

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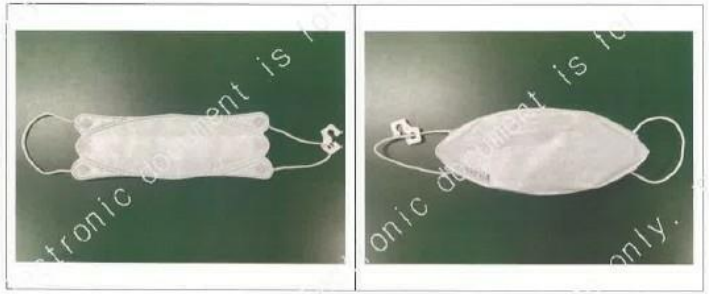
시험성적서

성적서번호 : MY20-00102

시험·검사항목	단 위	기 준	시험·검사 결과			항목판정
포집효율(파라핀오일)	%	본품 3개, 전처리 3개 결과가 94 % (KF94) 이상	본품 97.0 97.6 95.9 전처리 97.4 96.1 97.3			적합
누설률	%	시험대상자 10명의 5가지 운동결과인 총 50번 누설률 시험값 중 48번 이상이 기준값 이하 - KF94 : 11 % 이하	구분 / 운동 1 / 운동 2 / 운동 3 / 운동 4 / 운동 5			적합
			본품-1	3.2	3.7 / 4.4 / 3.4 / 3.6	
			본품-2	1.7	1.7 / 2.6 / 2.0 / 2.2	
			본품-3	3.4	1.5 / 1.0 / 0.7 / 0.8	
			본품-4	3.2	3.0 / 2.5 / 1.7 / 2.4	
			본품-5	6.6	4.3 / 3.4 / 2.1 / 4.1	
			전처리-1	11.0	10.1 / 9.6 / 4.2 / 6.6	
			전처리-2	8.1	9.6 / 11.5 / 8.1 / 13.3	
			전처리-3	3.4	1.8 / 1.8 / 1.4 / 1.9	
			전처리-4	1.8	2.2 / 2.4 / 2.5 / 3.3	
			전처리-5	2.1	2.0 / 2.0 / 2.6 / 1.9	
종 합 판 정			적합			
시험·검사방법			자사 기준 및 시험방법			

w/ Paraffin Oil

○ 시료사진



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QDL-QTI-01-04

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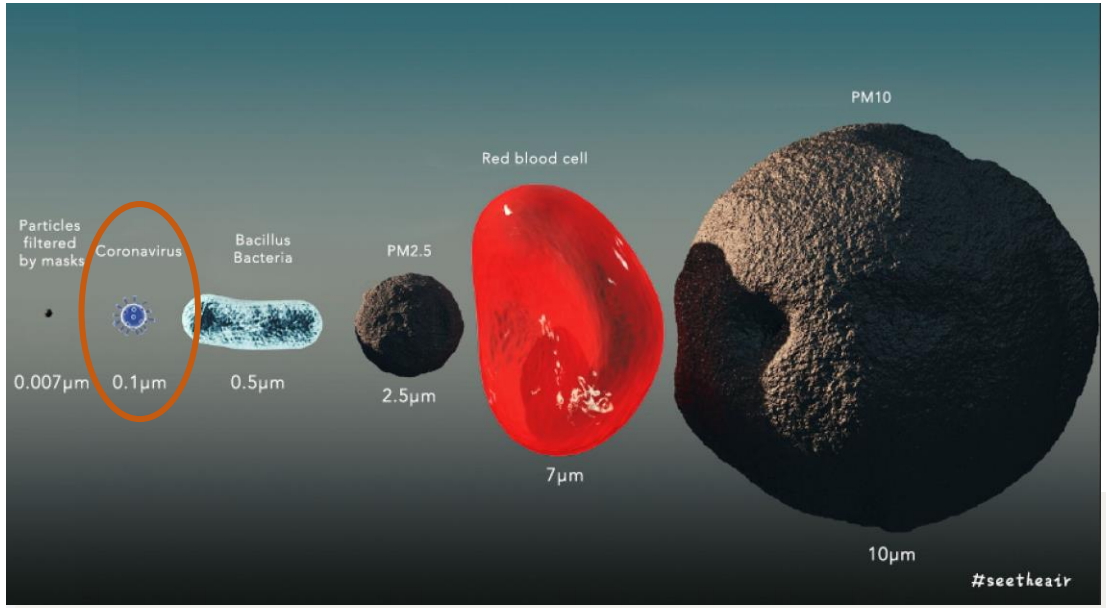
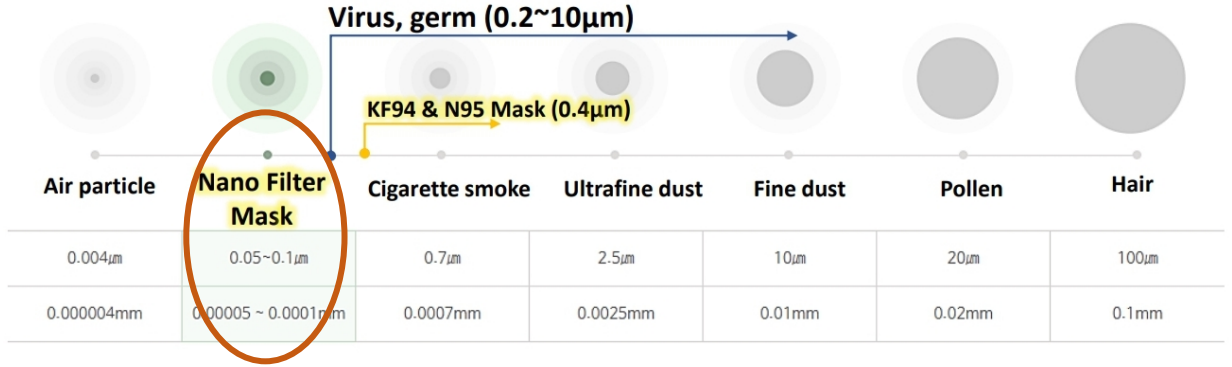
Air Queen Filtering Performance

Nano technology provides absolute blocking performance of the particles as small as **0.1 micron** in diameter. **The Air Queen Nano Mask outperforms any N-95 masks in the market when it comes to blocking small particles such as viruses and germs, which far exceeds N-95 standards.**

We are proud to present the NANO mask from Korea. This is a must-have face mask during the unprecedented pandemic situation.

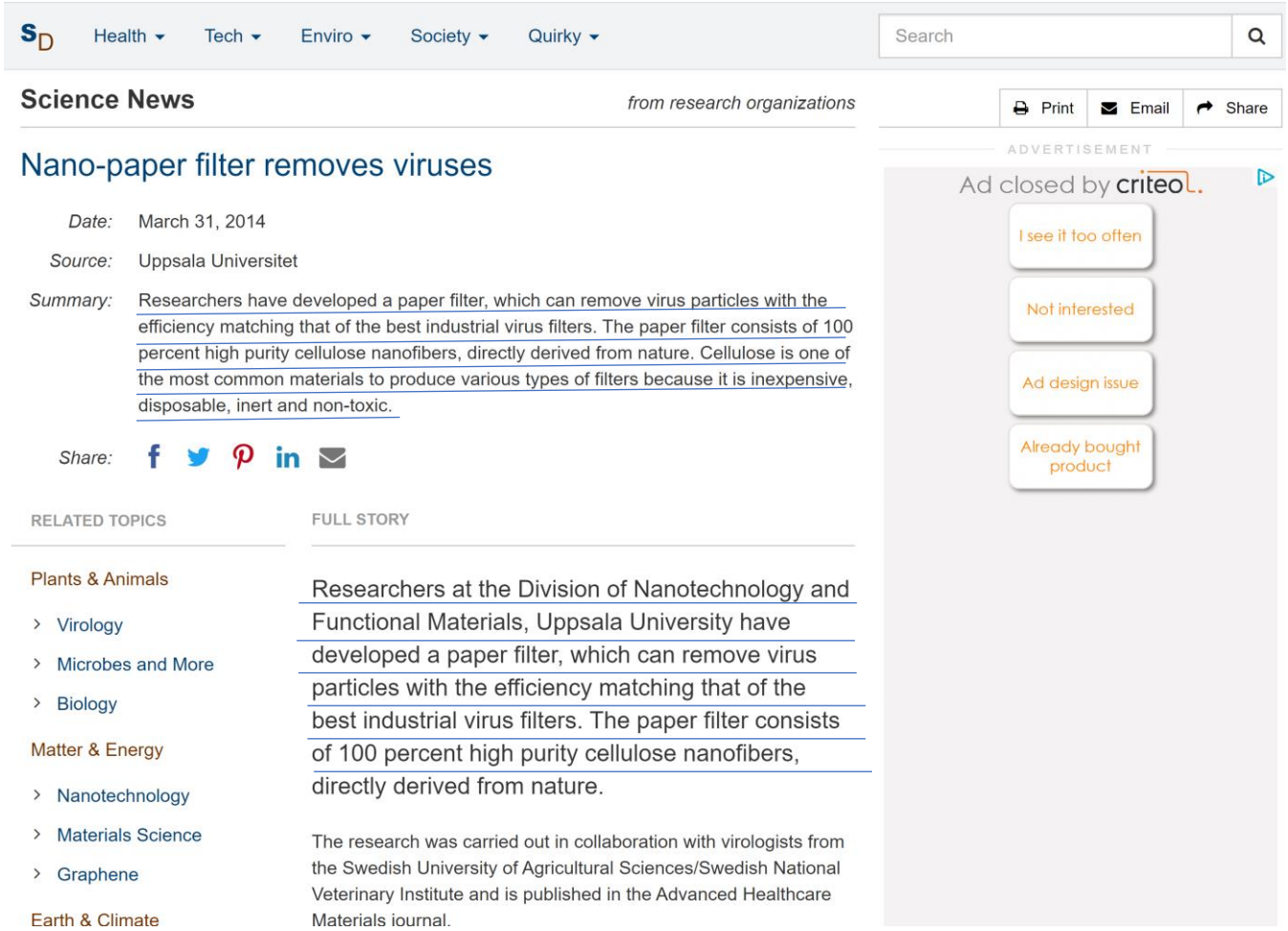


Filtering Performance Comparison



NANO FILTERATION TECHNOLOGY (Media)

https://www.sciencedaily.com/releases/2014/03/140331083738.htm



https://www.youtube.com/watch?v=3XE3OgcgXyE

Great Video, allows the viewers to see microscopic image of nano fiber. Must Watch!!!

https://www.youtube.com/watch?v=qwSncZVslJY

The scientists around the world are researching about the nano filber and it's capability of filtering. Even after few washes, it doesn't loose any filtering performance!!!

https://www.youtube.com/watch?v=TwT8uUJMabc