INTRODUCING

AOP-KF®

Kills Bacteria and Viruses

MEDICAL DEVICE

EN 14683

SANS 1866/1

infodoc HEALTH

"Your partner in Healthcare Marketing"

PRESENTED BY:

NANETTE DA FONSECA

DIRECTOR OF INFODOC HEALTH CC

2112 Eagle Trace Estate

1 Stork Road, Fourways, 2055

Vat no. 4010258764

Co. Reg. 2010/097191/23

Email: nanette@infodoc.co.za

Safe

Efficient

Sterilization

Deodorization

5-Layer Plus Filtering

PM2.5 Defense

KF-N95

For Adults

PM 2.5

EN14683

99% FILTRATION

Similar / Equal to FFP3

NEW GENERATION OF BIO TECHNOLOGY RESPIRATORS

Safe
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Deodorization
5-Layer Plus Filtering
PM2.5 Defense

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CERTIFICATE INDEX

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Similar / Equal to FFP3

Key Points

- New medical respirator with patented technology
- Kills bacteria
- Destroys viruses including COVID-19
- High breathability
- Filtrate over 98% PM2.5 particles
- Can be used for up to 7 days
- 3D design for comfort and tight fit

Safe
Efficient
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1
New Influenza Respirator

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KF-N95

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Similar / Equal to FFP3

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- The AOP-KF95 Respirator is a new generation of respirators designed specifically for the use against Influenza types viruses including the COVID-19
- It uses Solid Alkali with patented technology to disinfect, sterilize, deodorize effectively and continuously
- The Solid Alkali is certified as non-toxic by the world's leading examination organization SGS and is 100% harmless to humans, animals and plants
- It is infused into the masks with the effect of slowly emitting a low level of Chlorine Dioxide to eliminate pathogenic micro-organisms such as bacteria, viruses and fungus resulting in the relief of common fever
- Chlorine Dioxide has been classified by the World Health Organization (WHO) as the most safe, green and effective sterilizer
- Due to the anti-bacteria/virus, it can be used effectively for up to 7 days
- The mask is constructed from 5 layers of non-woven fabric to provide an effective defence against PM2.5 particles while retaining high breathability
- The 3D design is highly comfortable to wear and with limited restrictions to talking

Safe
Efficient
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Deodorization
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PM2.5 Defense

KF-N95

EN14683

99% FILTRATION

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For Adults

PM 2.5

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2
Field Tested

Safe
Efficient
Sterilization
Deodorization
5-Layer Plus Filtering
PM2.5 Defense

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Similar / Equal to FFP3

For Adults

PM 2.5

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- The AOP-KF95 Respirator was used effectively during the outbreak of the COVID-19 virus in China
- Care takers from hospitals in China reported faster recovery of patients due to the unique nature of the slow emitting Dioxides which kills bacteria and destroys viruses beyond the mask
- Hundreds of thousands of masks were also donated to hospitals in China
- Great reviews from end users as compared to traditional N95 masks
- On going demands from hospitals due to it's unique virus killing properties

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Deodorization
5-Layer Plus Filtering
PM2.5 Defense

KF-N95

For Adults

PM 2.5

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3
What is AOP-KF Solid Alkali ?

Safe
Efficient
Sterilization
Deodorization
5-Layer Plus Filtering
PM2.5 Defense

KF-N95
EN14683
99% FILTRATION
Similar / Equal to FFP3

For Adults

PM 2.5

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- New Bio-clean Material; Micro-nano Green Material; Advanced Catalytic Oxidation Material
- SGS tests showed "AOP-KF solid alkali does not produce harmful substance"
- Killing bacteria and virus effectively, but harmless to humans, animals and plants
- Slow generation of oxidation to effectively kill bacteria and destroys viruses over an extended period of time
- Superior performance compared to other technologies without harmful effects

Safe
Efficient
Sterilization
Deodorization
5-Layer Plus Filtering
PM2.5 Defense

KF-N95

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PM 2.5

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4
Respirator Construction

Safe
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Sterilization
Deodorization
5-Layer Plus Filtering
PM2.5 Defense

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Similar / Equal to FFP3

For Adults

PM 2.5

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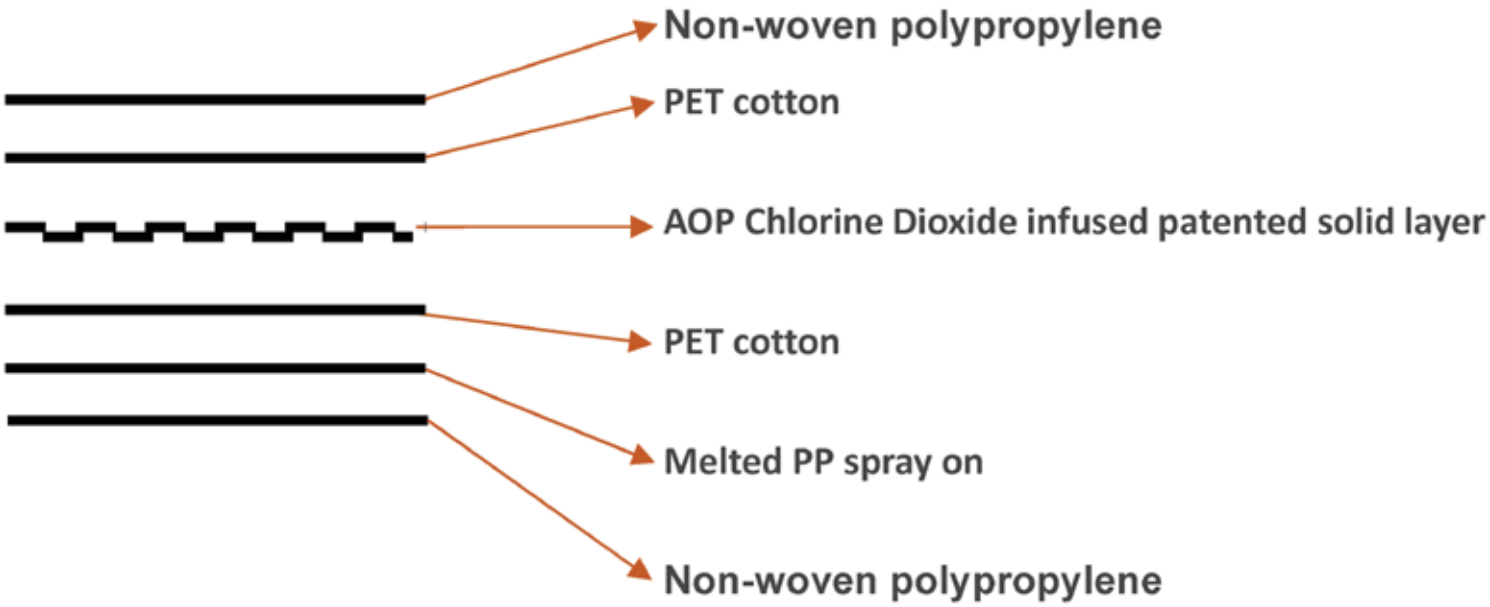
- The AOP-KF95 Respirator is made from 6 layers of non-woven fabric with a central infused Solid Alkali core layer to achieve high filtration and maximum protection:



Safe
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PM2.5 Defense

KF-N95

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Similar / Equal to FFP3

For Adults

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5
Packaging

Safe
Efficient
Sterilization
Deodorization
5-Layer Plus Filtering
PM2.5 Defense

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For Adults

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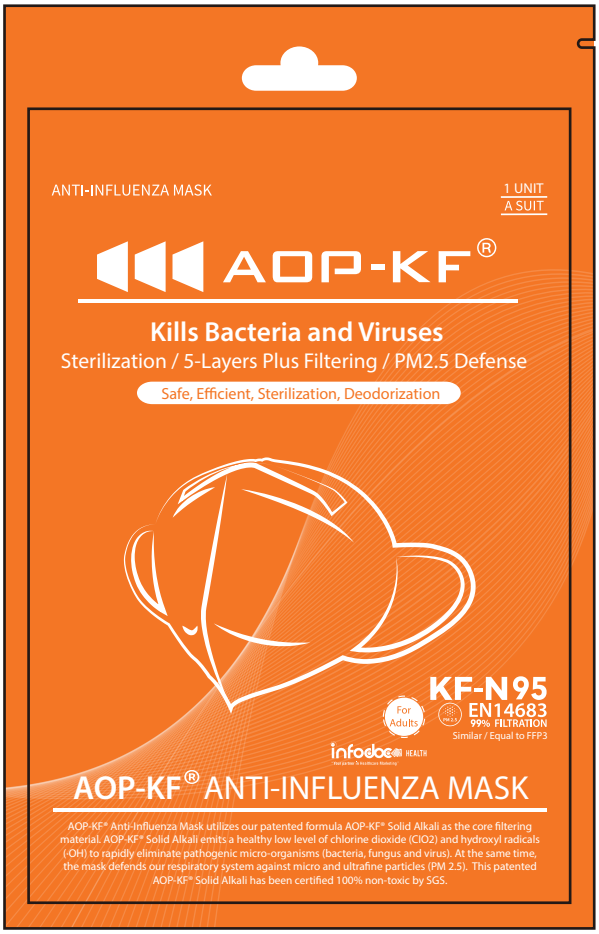
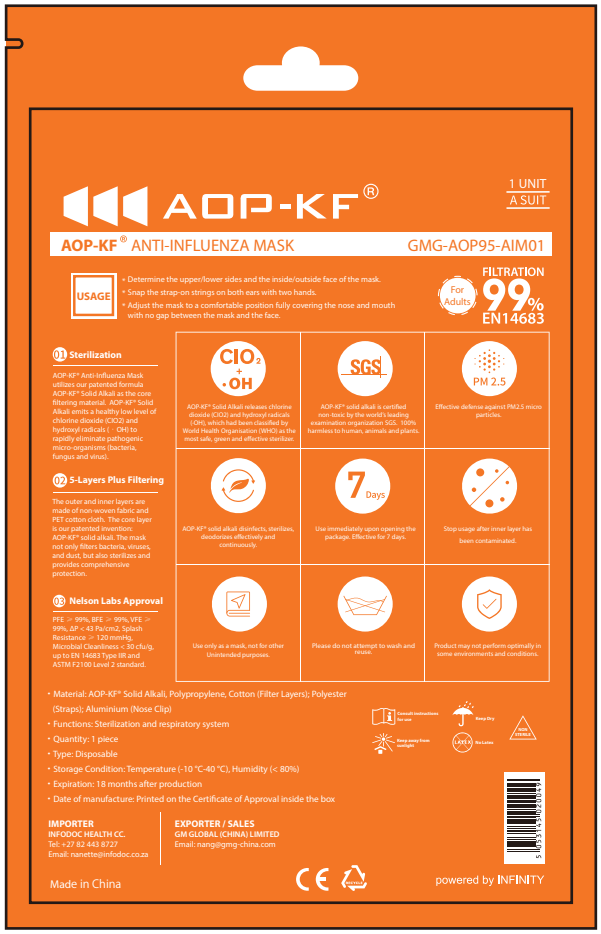
- Individual aluminum sleeves to retain the Solid Alkali for up to 2 years
- 50 sleeves per color box
- 8 boxes to a carton box
- 400 masks per carton box





Safe
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PM2.5 Defense

KF-N95
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99% FILTRATION
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For Adults

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6
Certification

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Sterilization
Deodorization
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PM2.5 Defense

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Similar / Equal to FFP3

For Adults

PM 2.5

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- SGS – Antibacterial Finishes on Textile Material – kills over 99.9%
- KF94 Korean standard equivalent to N95
- CE – end of March/early April 2020
- Nelson lab test reports PFE115, BFE110, FTS101, SBP210, MCM100, VFE110 - end of March/early April 2020
- EN 14683 planned
- Factory has ISO 9001
- HS Code 6307900000

Item Number	Description
PFE115	Particle Filtration Efficiency: Latex Particle Challenge *ASTM F2100* *Standard Turnaround Time: 12 days* *Sample Amount: AQL 4% sampling plan required for ASTM F2100, each sample must be 5 x 5 inches (12 x 12 cm) minimum or full face mask; specify particle size when submitting samples (0.1 for ASTM F2100, 0.3, 0.5 or 1.0 micron)*
BFE110	Bacterial Filtration Efficiency (BFE) w/ Diff. Pressure *EN 14683 & ASTM F2100* *Standard Turnaround Time: 12 days* *Sample Amount: separate samples for BFE and Delta P required, AQL 4% sampling plan required for ASTM F2100, minimum 5 samples up to AQL 4% required for EN 14683; each sample must be 4 x 4 inches minimum or full face mask*
FTS101	Flammability Test, 16 CFR part 1610 *ASTM F2100* *Price per sample set.* *Standard Turnaround Time: 8 days* *Sample Amount: Minimum of 14 replicate samples*
SBP210	Synthetic Blood Penetration for Face Masks (sets of 32), per set *EN 14683 & ASTM F2100* *Price is for the testing of 32 samples, one pressure* *Standard Turnaround Time: 10 days* *Sample Amount: 32 masks are required for each pressure, 1 extra for setup; specify pressure when submitting samples (80, 120 or 160 mmHg)*
MCM100	Microbial Cleanliness for Face Masks, EN 14683 (one mask type, set of 5) *EN 14683 & ASTM F2100* *Standard Turnaround Time: 18 days* *Sample Amount: Test is per mask type or configuration, set of 5 samples required*
VFE110	Virus Filtration Efficiency (VFE): Bacteriophage *Standard Turnaround Time: 12 days* *Sample Amount: Minimum 5 samples recommended; each sample must be 4 x 4 inches (10 x 10 cm) minimum*

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Nelson Labs - Viral Filtration Efficiency (VFE) Final Report

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Viral Filtration Efficiency (VFE) Final Report

Test Article:	AOP-KF
Study Number:	1279714-S01
Study Received Date:	21 Mar 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0007 Rev 16
Deviation(s):	None

Summary: The VFE test is performed to determine the filtration efficiency of test articles by comparing the viral control counts upstream of the test article to the counts downstream. A suspension of bacteriophage ΦX174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.1 - 3.3 x 10^3 plaque forming units (PFU) with a mean particle size (MPS) of 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. The VFE test procedure was adapted from ASTM F2101.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
Test Area:	~7.1 cm^2
VFE Flow Rate:	28.3 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Positive Control Average:	2.0 x 10^6 PFU
Negative Monitor Count:	<1 PFU
MPS:	2.8 µm

For GM Global (China) Limited Reference Only

Liang Liang for
Study Director

James W. Luskin

09 Apr 2020
Study Completion Date

1279714-S01

These results apply to the samples as received and relate only to the test article listed in this report. Reports may not be reproduced except in their entirety. Subject to NL terms and conditions at www.nelsonlabs.com.

Results:

Test Article Number	Percent VFE (%)
1	97.3
2	98.6
3	98.0
4	97.5
5	98.0

The filtration efficiency percentages were calculated using the following equation:

$$\%\,VFE = \frac{C - T}{C}\ x\ 100$$

C = Positive control average

T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

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Nelson Labs Synthetic Blood Penetration Resistance Final Report

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For Adults

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Synthetic Blood Penetration Resistance Final Report

Test Article:	AOP-KF
Study Number:	1279690-S01.1 Amended
Study Received Date:	21 Mar 2020
Study Completion Date:	31 Mar 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0012 Rev 09
Deviation(s):	None

For GM Global / China / Limited Release Only

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5°C and a relative humidity of 85 ± 10%. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested:	32
Number of Test Articles Passed:	30
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	23.7°C and 21% RH

Study Director — James W. Luskin

03 APR 2020
Amended Report Date

1279690-S01

*These results apply to the samples as received and relate only to the test article listed in this report. Reports may not be reproduced except in their entirety. Subject to NL terms and conditions at www.nelsonlabs.com

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥29 of 32 test articles show passing results.

Test Pressure: 120 mmHg (16.0 kPa)

Test Article Number	Synthetic Blood Penetration
1-6, 9-32	None Seen
7-8	Yes

Amendment Justification: At the request of the sponsor, the Sponsor Contact information was updated.

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Nelson Labs - Flammability of Clothing Textiles Final Report

Safe
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Flammability of Clothing Textiles Final Report

Test Article:	AOP-KF
Study Number:	1279716-S01.1 Amended
Study Received Date:	21 Mar 2020
Study Completion Date:	02 Apr 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0073 Rev 06
Deviation(s):	None

For Sale Global (China) Limited Free Trial Use Only

Summary: This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. The parameter of time is used to separate materials into different classes, thereby assisting in a judgment of fabric suitability for clothing and protective clothing material. The test procedure was performed in accordance with the test method outlined in 16 CFR Part 1610 (a) *Step 1 - testing in the original state*. Step 2 - *Refurbishing and testing after refurbishing*, was not performed. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Article Side Tested:	Outside Surface
Orientation:	Cross

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

Class	Plain Surface Textile Fabric
1	Burn time ≥3.5 seconds
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

The 16 CFR Part 1610 standard specifies that 10 replicates are to be tested if, during preliminary testing, only 1 test article exhibits flame spread and it is less than 3.5 seconds or the test articles exhibit an average flame spread less than 3.5 seconds. Five replicates are to be tested if no flame spread is observed upon preliminary testing, if only 1 test article exhibits flame spread and it is equal to or greater than 3.5 seconds, or if the average flame spread is equal to or greater than 3.5 seconds. In accordance with the standard, 5 replicates were tested for this study.

Curtis Gerow
Study Director — Curtis Gerow, B.S.

06 Apr 2020
Amended Report Date

1279716-S01

These results apply to the samples as received and relate only to the test article listed in this report. Reports may not be reproduced except in their entirety. Subject to NL terms and conditions at www.nelsonlabs.com.

Results:

Replicate Number	Time of Flame Spread
1	IBE
2	DNI
3	DNI
4	DNI
5	IBE

DNI = Test Article did not ignite
IBE = Test Article ignited, but extinguished

Amendment Justification: At the request of the sponsor, the sponsor information was changed to reflect the manufacturer and authorized distributer addresses.

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10 Nelson Labs - EN14683 Type IIR Test Reports

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[redacted]

Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article:	AOP-KF
Study Number:	1279715-S01
Study Received Date:	25 Mar 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

For Sinoglobal China Limited Reference Only

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
BFE Test Area:	~7.1 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~216 mm x ~156 mm
Positive Control Average:	2.6 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.0 µm

Study Director — James W. Luskin — Study Completion Date: 06 Apr 2020

1279715-S01

Test results apply to the samples as received and tested only as listed in this report. Reports may not be reproduced except in their entirety. Subject to the terms and conditions at www.nelsonlabs.com

Results:

Test Article Number	Percent BFE (%)
1	98.6
2	99.1
3	98.0
4	98.8
5	98.4

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	4.4	42.9
2	3.9	38.6
3	3.9	38.2
4	3.8	37.5
5	3.9	38.7

The filtration efficiency percentages were calculated using the following equation:

$$\%\ BFE = \frac{C - T}{C} \times 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

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Nelson Labs - Bacterial Filtration Efficiency (BFE) with Diff Pressure Final Report

Safe
Efficient
Sterilization
Deodorization
5-Layer Plus Filtering
PM2.5 Defense

KF-N95
EN14683
99% FILTRATION
Similar / Equal to FFP3

For Adults

PM 2.5

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Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article:	AOP-KF
Study Number:	1279715-S01
Study Received Date:	25 Mar 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

For GM Global / China / Limited Reference Only

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
BFE Test Area:	~7.1 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~216 mm x ~156 mm
Positive Control Average:	2.6 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.0 µm

ilac-MRA ANAB ACCREDITED TESTING LABORATORY

Study Director James W. Luskin 06 Apr 2020 Study Completion Date

1279715-S01

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Results:

Test Article Number	Percent BFE (%)
1	98.6
2	99.1
3	98.0
4	98.8
5	98.4

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	4.4	42.9
2	3.9	38.6
3	3.9	38.2
4	3.8	37.5
5	3.9	38.7

The filtration efficiency percentages were calculated using the following equation:

$$\%\,BFE = \frac{C - T}{C} \times 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

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Nelson Labs - Latex Particle Challenge Report

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KF-N95
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For Adults

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Manufacturer:
Zhong Shan Civil Tech Electronic Limited
No.6, Industrial Zone,
Nanlang Town,
Zhongshan, Guangdong,
CHINA

Authorized Distributor:
Max Excel Corporation Limited
Room 1104, Julibee Centre,
18 Fenwick Street, Wanchai,
HONG KONG

Latex Particle Challenge Final Report

Test Article:	AOP-KF	
Study Number:	1279708-S01	
Study Received Date:	21 Mar 2020	
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.	
Test Procedure(s):	Standard Test Protocol (STP) Number:	STP0005 Rev 07
Deviation(s):	Quality Event (QE) Number(s):	QE22125

Summary: This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized (atomized), dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

A one-minute count was performed, with the test article in the system. A one-minute control count was performed, without a test article in the system, before and after each test article and the counts were averaged. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the number of particles penetrating the test article compared to the average of the control values.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Side Labeled Back
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	21°C, 23% relative humidity (RH) at 1543; 21°C, 23% RH at 1646
Average Filtration Efficiency:	99.791%
Standard Deviation:	0.2543

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Study Director — for Curtis Gerow, B.S.

04 May 2020
Study Completion Date

1279708-S01

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Deviation Details: Controls and sample counts were conducted for one minute instead of an average of three one minute counts. This change shortens the total test time for each sample but will still provide an accurate determination of the particle counts. An equilibrate is a dwell period where the challenge is being applied to the test article for a certain period of time before test article counts are counted. The equilibrate period was reduced from 2 minutes to a minimum of 30 seconds which is sufficient time to clear the system of any residual particles, and establish a state of stable equilibrium before sample counts are taken. Test method acceptance criteria were met, results are valid.

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	24	11,385	99.79
2	5	11,521	99.957
3	7	11,660	99.940
4	75	11,573	99.35
5	9	11,047	99.919

13
Nelson Labs - Microbial Cleanliness

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Sterilization
Deodorization
5-Layer Plus Filtering
PM2.5 Defense

KF-N95
EN14683
99% FILTRATION
Similar / Equal to FFP3

For Adults

PM 2.5

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A Sotera Health company

Authorized Distributor:
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Room 1104, Julibee Centre,
18 Fenwick Street
Wanchai,
HONG KONG

Manufacturer:
Zhong Shan Civil Tech Electronic Limited
NO.6 Industrial Zone
Nanlang Town, Zhongshan
Guangdong
CHINA

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	AOP-KF	
Study Number:	1279700-S01	
Study Received Date:	21 Mar 2020	
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.	
Test Procedure(s):	Standard Test Protocol (STP) Number:	STP0036 Rev 15
	Customer Specification Sheet (CSS) Number:	202001695 Rev 01
Deviation(s):	None	

Summary: The testing was conducted in accordance with EN 14683:2019, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	6.6	<3	<3	5.8	0.9
2	7.0	<3	<3	5.9	0.8
3	6.5	<3	<3	5.9	0.9
4	6.8	<3	<3	5.9	0.9
5	6.4	3[a]	<3	6.1	1.0
Recovery Efficiency	24.8%[b]				

< = No Organisms Detected
Note: The results are reported as colony forming units per test article.
[a] Spreader. Count is considered a minimum estimate due to swarming of certain colonies on the membrane.
[b] The recovery efficiency may be impacted due to spreaders on the membrane.

Gabrielle Waldron electronically approved for — 13 Apr 2020 18:27 (+00:00)
Study Director — Robert Putnam — Study Completion Date and Time

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Method Suitability:

Organism	Percentage
Bacillus atrophaeus	98%

Test Method Acceptance Criteria: If applicable, anaerobic controls are acceptable for the bioburden test results. The number of masks to be tested shall be a minimum of 5 or more to meet an acceptable quality level of 4%. The bioburden of the medical mask shall be < 30 CFU/g tested.

Procedure:

Positive Controls/Monitors:	*Bacillus atrophaeus*
Extract Fluid:	Peptone Tween®
Extract Fluid Volume:	~300 mL
Extract Method:	Orbital Shaking for 15 minutes at 250 rpm
Plating Method:	Membrane Filtration
Agar Medium:	Potato Dextrose Agar Tryptic Soy Agar
Recovery Efficiency:	Exhaustive Rinse Method
Aerobic Bacteria:	Plates were incubated 3 days at 30-35°C, then enumerated.
Fungal:	Plates were incubated 7 days at 20-25°C, then enumerated.

14
SGS - Assessment of Antibacterial Finishes on Textiles

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Test Report

No. HKHC2001000563HC Date :Jan 31, 2020

Job No. : HKHC200100000272

The following sample was submitted and identified by the client as AOP-KF ® Fever Relief Mask Core Filter

Product Description	:	AOP-KF ® Fever Relief Mask Core Filter
Quantity Received	:	1 bag
Sample Appearance	:	White solid
SGS Sample No.	:	HKHC200100000272-101
Sample Receiving Condition	:	In unopened plastic bag under ambient condition
Country of Origin	:	China
Sample Receiving Date	:	Jan 20, 2020
Testing Period	:	Jan 20, 2020 – Jan 31, 2020

Test Requested, Test Method and Test Results
Please refer to the following page(s).

****

For GM Global (China) Limited Reference Only

Signed for and on behalf of
SGS Hong Kong Ltd.

WONG KIN MAN, GILMAN
ASSISTANT TECHNICAL DEVELOPMENT MANAGER
- COSMETICS, PERSONAL CARE & HOUSEHOLD SERVICES

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Test Requested, Test Method and Test Results

The analyses were performed with reference to:

Assessment of Antibacterial Finishes on Textile Material (AATCC 100-2012)

Test bacteria: *Staphylococcus aureus* (ATCC 6538)

Tested Specimen	Bacterial count (colony forming unit, CFU per ml) over contact period		Result: % of reduction of bacteria	Specified requirement	Comment
	0 hour	24 hours			
As received	1.60×10^5	<100	>99.94	Minimum 99 %	Pass
Untreated control sample	1.28×10^5	2.59×10^7	/	/	/

Test bacteria: *Klebsiella pneumoniae* (ATCC 4352)

Tested Specimen	Bacterial count (colony forming unit, CFU per ml) over contact period		Result: % of reduction of bacteria	Specified requirement	Comment
	0 hour	24 hours			
As received	1.20×10^5	<100	>99.92	Minimum 99 %	Pass
Untreated control sample	1.04×10^5	3.15×10^8	/	/	/

For CM Global (China) Limited Reference Only

Note:

1. Results reported on the submitted sample on an as received basis.
2. The untreated control sample is a 100% cotton fabric without fluorescent brighteners or other finish.

Remarks:

1 The number of circular swatches (4.8 +/- 0.1 cm in diameter) used per jar: 6
2 Sterilization of samples: By autoclave.
3 Culture medium used for bacterial culture preparation: Nutrient broth
4 Diluent used for inoculum dilution: 1:20 Nutrient broth
5 Surfactant used in inoculums: None
6 Neutralizing solution: 0.85% Saline + 0.1% Tween 80

****

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PHOTO APPENDIX

HKHC200100000272-101

SGS authenticate the Photo on original report only

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*** End of Report ***

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15
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检测报告
Test Report

报告编号：
Report No.: SHE17-51434

送交：
To: 吴朝佳

样品采样日期：
Sample date: 2017/8/14

客户名称：
Customer Name:

提交报告日期：
Submit report date: 2017/8/25

样品：
Sample: 室内空气(1)

项目编号：-

备注：

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2. Unless otherwise stated, this report is only responsible for sampling and test samples.
3. General standard Guangzhou Branch office of Environment Department.

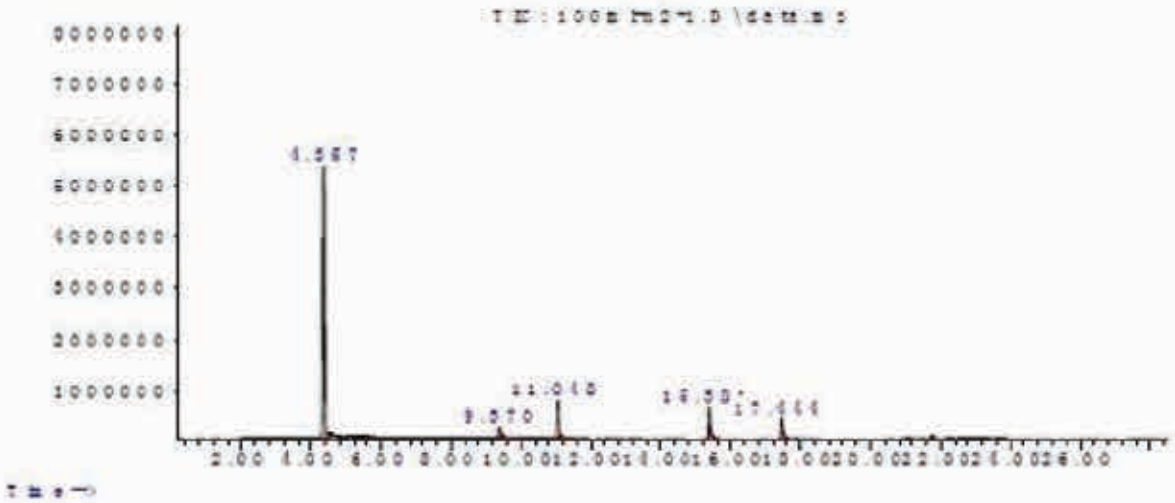
编制：
周敏

审核：
郑欣欣

批准：
沈咏洁
实验室经理

VOC 检索报告
VOC Analysis Report

样品用 TO-15 的方法测试，用 GC/MS 仪分析，用 NIST 谱库定性检索主要化合物，除备注化合物以标线定量外，其他以甲苯标线进行半定量，数据仅供参考。



Sample used TO-15 methods for testing. Analysis with GC/MS, use NIST qualitative search of main Compounds using mist spectral library. Except for remarks, compounds are quantified by the marked line, other semi-quantitative based on toluene marking, the data is for reference only.

6	6.485	0.68	乙醚	0.010mg/m³
			Ethyl ether	838 000060-29-7 76
			Ethane, 1,2-diethoxy-	8732 000629-14-1 59
			Ethane, 1,2-diethoxy-	8731 000629-14-1 59
7	6.592	0.55	1,3-戊二烯	0.008mg/m³
			1,3-Pentadiene	437 000504-60-9 95
			Cyclopropane, ethylidene-	464 018631-83-9 94
			1,3-Butadiene, 2-methyl-	459 000078-79-5 93
8	7.004	0.79	乙酸甲酯	0.012mg/m³
			Acetic acid, methyl ester	818 000079-20-9 50
			2-Propanone, 1-hydroxy-	812 000116-09-6 9
			Acetic acid, methyl ester	818 000079-20-9 9
9	7.198	1.62	二氯甲烷	0.019mg/m³（标线定量）
			Methylene Chloride	1517 000075-09-2 95
			Methylene Chloride	1516 000075-09-2 95
			Methylene Chloride	1519 000075-09-2 91
10	7.884	2.78	2-甲基戊烷	0.041mg/m³
			Pentane, 2-methyl-	1816 000107-83-5 90
			Pentane, 2-methyl-	1814 000107-83-5 86
			trans-2,3-Epoxydecane	27746 054125-39-2 59
11	8.271	1.00	3-甲基戊烷	0.015mg/m³
			Pentane, 3-methyl-	1817 000096-14-0 87
			Pentane, 3-methyl-	1815 000096-14-0 87
			Pentane, 3-methyl-	1818 000096-14-0 80
12	9.607	0.61	甲基环戊烷	0.009mg/m³
			Cyclopentane, methyl-	1487 000096-37-7 58
			Piperazine, 2-methyl-1,4-dinitroso	29242 055556-94-0 42
			1-Pentene, 2-methyl-	1481 000763-29-1 38
13	10.631	0.58	环己烷	0.009mg/m³
			Cyclohexane	1449 000110-82-7 83
			Cyclohexane	1451 000110-82-7 81
			Cyclohexane	1450 000110-82-7 81

14	13.421	1.23	甲苯	0.014mg/m³（标线定量）
			Toluene	2436 000108-88-3 95
			Toluene	2432 000108-88-3 94
			Toluene	2433 000108-88-3 93
15	21.865	0.60	肼基甲酸乙酯	0.009mg/m³
			Hydrazinecarboxylic acid, ethyl es ter	4614 004114-31-2 64
			Hydrazinecarboxylic acid, ethyl es ter	4611 004114-31-2 45
			Propanamide, 2-hydroxy-	2163 002043-43-8 39

备注：

检测方法不在 CMA 资质认定范围内，本检测报告仅用于客户科研、教学、内部质量控制、产品研发等目的，仅供内部参考。

Remarks:

The detection method is not within the scope of CMA qualification. This test report is only for the customer department, teaching, internal quality control, product development and other purposes. Internal reference only.

VOC Analysis Report

VOC 检索报告

序号	名称	浓度 mg/m³
1	异丁烷	0.048
2	丁烷	0.142
3	2-甲基丁烷	0.073
4	丙酮	0.116
5	戊烷	0.049
6	乙醚	0.010
7	1,3-戊二烷	0.008
8	乙酸甲酯	0.012
9	二氯甲烷	0.019
10	2-甲基戊烷	0.041
11	3-甲基戊烷	0.015
12	甲基环戊烷	0.009
13	环己烷	0.009
14	甲苯	0.014
15	肼基甲酸甲酯	0.009

本次检测并未发现康风九方 AOP-KF 固体碱材料产生有害物质。

The test did not find that Kang Feng Jiu Fang AOP-KF solid alkali materials (ClO2) produced harmful Substances.

通标标准技术服务有限公司

2017 年 8 月 25 日

The test did not find that Kang Feng Jiu Fang AOP-KF solid alkali materials (ClO2) produced harmful Substances.

16
SGS - SVHC Test Report

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Test Report (SVHC)

No. SZXEC2000834201 Date: 09 May 2020

SHENZHEN KANGFENG ENVIRONMENT SCIENCE & TECHNOLOGY DEVELOPMENT CO., LTD
ROOM 2101, FLOOR 21, BLOCK D, BUILDING 3, TIAN AN YUN GU INDUSTRIAL PARK(PHASE 1), BANTIAN SUB-DIST, SHENZHEN

The following sample(s) was/were submitted and identified on behalf of the clients as : Kangfeng AOP-KF®solid alkali

SGS Job No. :	RP20-007924 - SZ
Date of Sample Received :	30 Apr 2020
Testing Period :	30 Apr 2020 - 09 May 2020
Test Requested :	As requested by client, SVHC screening is performed according to: (i) Two hundred and five (205) substances in the Candidate List of Substances of Very High Concern (SVHC) for authorization published by European Chemicals Agency (ECHA) on and before Jan 16, 2020 regarding Regulation (EC) No 1907/2006 concerning the REACH. (ii) Five (5) substances in the Public Consultation List of potential Substances of Very High Concern (SVHC) published by European Chemicals Agency (ECHA) on Mar 3, 2020 regarding Regulation (EC) No 1907/2006 concerning the REACH.
Test Results :	Please refer to next page(s).

Summary :

According to the specified scope and evaluation screening, the test results of SVHC are ≤ 0.1% (w/w) in the submitted sample.	PASS

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Shenzhen Branch

Ford

Ford Shi
Approved Signatory

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Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

SGS-CSTC Standards Technical Services Co., Ltd. Shenzhen Branch
SGS Bldg, No.4, Jianghao Industrial Park, No.430, Jihua Road, Bantian, Longgang District, Shenzhen, China 518129 t (86-755) 25328888 f (86-755) 83106190 www.sgsgroup.com.cn
中国·深圳·龙岗区坂田吉华路430号江灏工业园4栋SGS大楼 邮编: 518129 t (86-755) 25328888 f (86-755) 83106190 e sgs.china@sgs.com

测试报告 (SVHC)

No. SZXEC2000834202　　日期: 2020年05月09日　第1页,共18页

深圳市康风环境科技发展有限公司
深圳市龙岗区坂田街道天安云谷产业园一期3栋D座21楼2101房

以下测试之样品是由申请者所提供及确认：康风AOP-KF®固体碱

SGS工作编号：	RP20-007924 - SZ
样品接收日期：	2020年04月30日
测试周期：	2020年04月30日 - 2020年05月09日
测试要求：	根据客户要求， (i) 基于欧洲化学品管理署截止2020年1月16日公布的供授权审议的高关注物质候选清单(根据欧盟第1907/2006号REACH法规)，对205种高关注物质(SVHC)进行筛分测试。 (ii) 基于欧洲化学品管理署于2020年3月3日公布的潜在的高关注物质咨询清单(根据欧盟第1907/2006号REACH法规)，对5种高关注物质(SVHC)进行筛分测试。
测试结果：	请参见下一页

总结：

根据具体的范围和筛分测试，所提交样品中SVHC测试结果≤0.1%(w/w)。	通过

通标标准技术服务有限公司深圳分公司
授权签名

石常福

Ford Shi石常福
批准签署人

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SGS Bldg, No.4, Jianghao Industrial Park, No.430, Jihua Road, Bantian, Longgang District, Shenzhen, China 518129 t (86-755) 25328888 f (86-755) 83106190 www.sgsgroup.com.cn
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INFINITY INTERNATIONAL STRATEGIC INVESTMENT GROUP LIMITED
ROOM 1104, 11/F, JUBILEE CENTRE,18 FENWICK STREET, WAN CHAI, HONG KONG

The following samples were submitted and identified on behalf of the client as:

PROTECTIVE FACE MASK

SGS Case No.	:	CA320202626169
Lot No. / Batch Code	:	NOT PROVIDED
Sample Description	:	WHITE RESPIRATOR
Quantity Submitted	:	40 PCS
Style / Item No.	:	1) AOP-KF MASK (BRAND NEW) 2) AOP-KF MASK (USED FOR 7 DAYS)
Quantity Submitted	:	40 PCS. (2 STYLES)
Manufacturer	:	ZHONGSHAN XINKE MEDICAL DEVICE LIMITED
Country of Origin	:	CHINA
Sample Receiving Date	:	JUN 18, 2020 AND JUL 03, 2020
Test Performing Date	:	JUN 18 TO JUL 09, 2020

Test Requested : Please refer to the result summary.

Test Method & Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
Microbial cleanliness (Bioburden) (EN 14683:2019+AC:2019 Annex D)	See Result

****

Signed for and on behalf of
SGS Hong Kong Ltd.

Au Kam Chi, Gigi
Technical Manager

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Microbial cleanliness (Bioburden) (EN 14683:2019+AC:2019 Annex D)

Test Methods

Bioburden

The analyses were performed according to EN 14683:2019+AC:2019 Annex D and ISO 11737-1:2018

Test Results

AOP-KF Mask (Brand New)
SGS Sample No.:HKHC200600002184-101

Article Number	Mask Weight	Total Bioburden, cfu/mask	Total Bioburden, cfu/g
1	6.73g	15	2.23
2	7.66g	6	0.78
3	6.96g	9	1.29
4	6.87g	6	0.87
5	6.87g	15	2.18
	Mean:	10.2	1.5

Recovery Efficiency	Correction Factor
62.7%	1.6

Microbial Cleanliness (Bioburden): 2.3 cfu/g

Standard requirement#: ≤30 cfu/g

Note:

1. Results reported on the submitted sample on an as received basis.
2. < = less than
3. cfu = Colony Forming Units
4. Extraction method: by stomacher at 250rpm for 5 minutes
5. # EN 14683:2019+AC:2019 - Medical face masks - Requirements and test methods – Performance requirements for medical face masks – Microbial cleanliness

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Microbial cleanliness (Bioburden) (EN 14683:2019+AC:2019 Annex D)

Test Methods

Bioburden

The analyses were performed according to EN 14683:2019+AC:2019 Annex D and ISO 11737-1:2018

Test Results

AOP-KF Mask (Used for 7 Days)
SGS Sample No.:HKHC200600002184-102

Article Number	Mask Weight	Total Bioburden, cfu/mask	Total Bioburden, cfu/g
1	7.17g	72	10.04
2	6.93g	39	5.63
3	6.69g	27	4.04
4	6.59g	33	5.01
5	7.14g	27	3.78
	Mean:	39.6	5.7

Recovery Efficiency	Correction Factor
62.7%	1.6

Microbial Cleanliness (Bioburden): 9.1 cfu/g

Standard requirement#: ≤30 cfu/g

Note:

1. Results reported on the submitted sample on an as received basis.
2. < = less than
3. cfu = Colony Forming Units
4. Extraction method: by stomacher at 250rpm for 5 minutes
5. # EN 14683:2019+AC:2019 - Medical face masks - Requirements and test methods – Performance requirements for medical face masks – Microbial cleanliness

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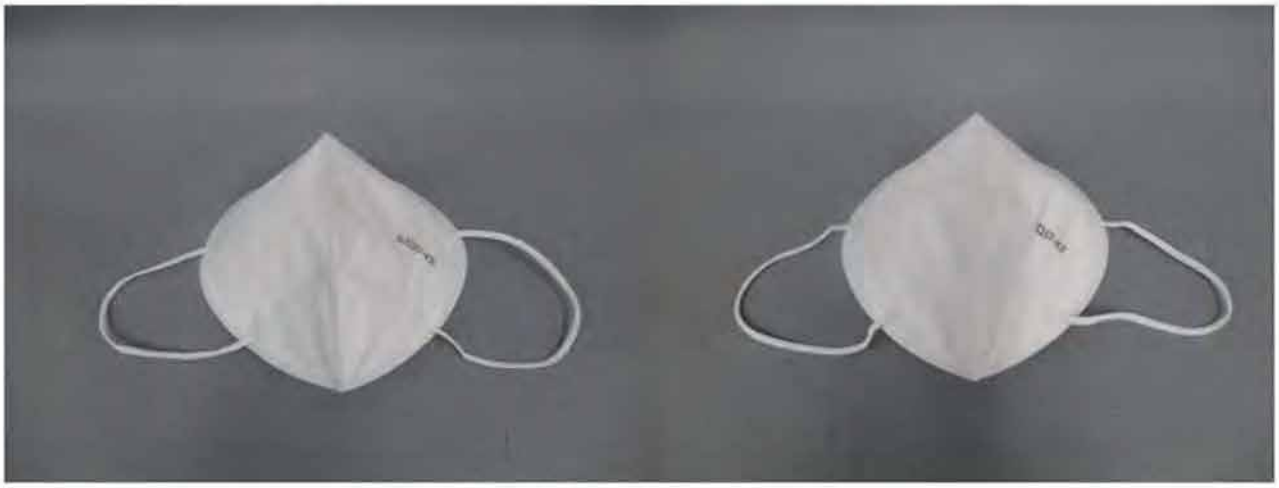
Photo Appendix



Sample as received

*** End of Report ***

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18
SGS - Bacterial Filtration Efficiency (BFE)

Safe
Efficient
Sterilization
Deodorization
5-Layer Plus Filtering
PM2.5 Defense

KF-N95
EN14683
99% FILTRATION
Similar / Equal to FFP3

For Adults

PM 2.5

infodoc HEALTH
"Your partner in Healthcare Marketing"

Test Report

No.: T32020260466SN Date: JUL 14, 2020

INFINITY INTERNATIONAL STRATEGIC INVESTMENT GROUP LIMITED
ROOM 1104, 11/F, JUBILEE CENTRE,18 FENWICK STREET, WAN CHAI, HONG KONG

The following samples were submitted and identified on behalf of the client as:

PROTECTIVE FACE MASK

SGS Case No.	:	CA320202626169
Lot No. / Batch Code	:	NOT PROVIDED
Sample Description	:	WHITE RESPIRATOR
Quantity Submitted	:	40 PCS
Style / Item No.	:	1) AOP-KF MASK (BRAND NEW) 2) AOP-KF MASK (USED FOR 7 DAYS)
Quantity Submitted	:	40 PCS. (2 STYLES)
Manufacturer	:	ZHONGSHAN XINKE MEDICAL DEVICE LIMITED
Country of Origin	:	CHINA
Sample Receiving Date	:	JUN 18, 2020 AND JUL 09, 2020
Test Performing Date	:	JUN 18 TO JUL 14, 2020

Test Requested : Please refer to the result summary.

Test Method & Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
Bacterial filtration efficiency (BFE) (EN14683:2019+AC:2019 Appendix B)	See Result

****

Signed for and on behalf of
SGS Hong Kong Ltd.

Au Kam Chi, Gigi
Technical Manager

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Bacterial filtration efficiency (BFE) (EN14683:2019+AC:2019 Appendix B)

Test Side	:	White Colour (Inside)
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Test Condition	:	21±2 °C and 30-50% R.H.
Dimensions of test specimen	:	157 mm x 204 mm
BFE Test Area	:	49 cm^2
BFE Flow Rate	:	28.3 l/min
Test bacteria	:	Staphylococcus aureus ATCC 6538
Positive Control Average	:	2.9 x 10^3 CFU
Negative Monitor Count	:	< 1 CFU

AOP-KF Mask (Brand New)

Test Specimen	Percent BFE (%)
1	99.9
2	99.9
3	99.9
4	99.9
5	99.9

AOP-KF Mask (Used for 7 Days)

Test Specimen	Percent BFE (%)
1	99.9
2	99.9
3	99.9
4	99.9
5	99.9

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19

CNAS - Passes all tests of Chinese GB 2626 and meets the KN95 standard

Safe
Efficient
Sterilization
Deodorization
5-Layer Plus Filtering
PM2.5 Defense

KF-N95

For Adults

PM 2.5

EN14683
99% FILTRATION
Similar / Equal to FFP3

infodoc HEALTH
"Your partner in Healthcare Marketing"

广检集团 GTTC

202019124876

检验检测报告 （电子版）

防伪查询网址：www.gttc.net.cn

防伪码：KLUF-7801-04

No:200103111

扫码下载报告

委托单位	中山市信科医疗器械有限公司 地址：广东省中山市南朗镇第六工业区				
客户认定信息	口罩 50个 号型规格：AOP-KF口罩 生产单位：中山市信科医疗器械有限公司 ----------				
检验性质	委托检测	样品受理/测试开始日期	2020-04-25	报告签发日期	2020-05-15
判定依据	GB 2626-2006 《呼吸防护用品 自吸过滤式防颗粒物呼吸器》				
综合检验结论	---				

检验检测结果

检验检测项目	判定依据	判定
视野	GB 2626-2006	符合
NaCl颗粒物过滤效率	GB 2626-2006	符合
吸气阻力	GB 2626-2006	符合
呼气阻力	GB 2626-2006	符合
可燃性	GB 2626-2006	符合
头带	GB 2626-2006	符合
外观检查[2个]	GB 2626-2006	符合

备注

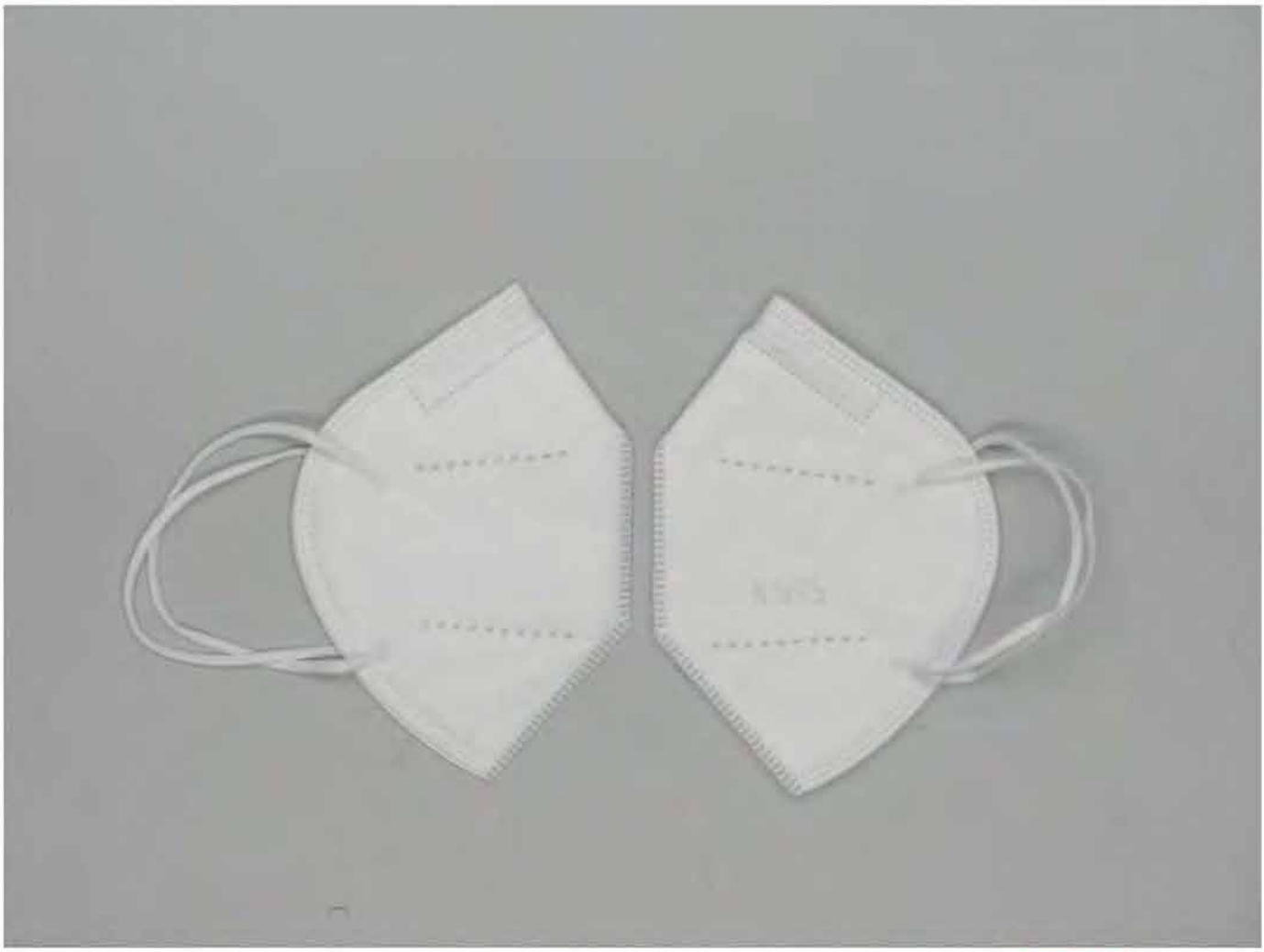
外观检查项目暂未获得CNAS认可。
本报告中检验检测项目均在相应标准规定的环境条件下进行（有注明的除外）。
复印件、副本未重新加盖报告书确认章无效。
本报告检验检测地址为广州市番禺区珠江路1号。

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

签发：刘圆 工程师 刘圆

样品图片 （电子版）

No:200103111



广州检验检测认证集团有限公司 检验检测专用章 (GF2)

检验检测报告附页 （电子版）

No:200103111

检验检测项目（计量单位）[样品识别]	测试方法	标准值及允差	检验检测结果	判定	备注
●视野(°)	GB 2890-2009 6.8	≥60	70	符合	
●NaCl颗粒物过滤效率(%)	GB 2626-2006 6.3 空气流量:85L/min 气溶胶颗粒:NaCl 气溶胶浓度:15mg/m³ 温度:23.2℃ 湿度:36.9%	过滤效率: ≥95.0 (KN95)	过滤效率: 未处理样品 1# 99.071 2# 99.111 3# 99.491 4# 99.471 5# 99.304 6# 99.207 7# 99.564 8# 99.347 9# 99.293 10# 99.033 温湿度预处理后样品 1# 98.97 2# 99.351 3# 99.037 4# 99.149 5# 99.133	符合	
●吸气阻力(Pa)	GB 2626-2006 6.5 头模：中号	≤350	未处理样品: 1# 188.9 2# 187.1 预处理样品: 1# 184.3 2# 173.8	符合	
●呼气阻力(Pa)	GB 2626-2006 6.6 头模：中号	≤250	未处理样品: 1# 169.9 2# 166.2 预处理样品: 1# 166.2 2# 155.4	符合	
●可燃性(s)	GB 2626-2006 6.15	续燃时间 ≤5	续燃时间 未处理样品 1# 0.0 2# 0.0 温湿度预处理后样品 3# 0.0 4# 0.0	符合	
●头带	GB 2626-2006 6.11	面罩的每条头带、带扣及其他调节部件在承受10N的拉力，持续10s，不应出现滑脱或断裂。	未处理样品: 1# 符合要求 温湿度预处理后样品: 1# 符合要求	符合	
●外观检查[2个]	GB 2626-2006 6.1	按标准5.2条要求	符合要求	符合	
备注	(本栏空白)				

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

——本报告结束——

广检集团
GTTC

202019124876

TEST REPORT

(Electronic version)

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VERIFICATION WEBSITE: www.gttc.net.cn

VERIFICATION CODE: BVDA-5163-53

No:200103112

ISSUE DATE:2020-05-15

APPLICANT: ZHONGSHAN XINKE MEDICAL DEVICE LIMITED
ADDRESS: NO.6, INDUSTRIAL ZONE, NANLANG TOWN, ZHONGSHAN, GUANGDONG, CHINA

INFORMATION CONFIRMED BY APPLICANT:

MASK

QUANTITY: FIFTY PIECES

SIZE: AOP-KF MASK

MANUFACTURE'S NAME: ZHONGSHAN XINKE MEDICAL DEVICE LIMITED

DATE RECEIVED/DATE TEST STARTED: 2020-04-25

CONCLUSION:

VISUAL FIELD	M
FILTRATION EFFICIENCY TO NaCl PARTICULATE MATTER	M
INSPIRATORY RESISTANCE	M
EXPIRATORY RESISTANCE	M
FLAMMABILITY	M
HEAD BAND	M
APPEARANCE INSPECTION[2 PIECES]	M

NOTE: "M" -MEET THE STANDARD'S REQUIREMENT "F" -FAIL TO MEET THE STANDARD'S REQUIREMENT
"---" -NO COMMENT

REMARK:
THE AUTHORIZATION OF APPEARANCE INSPECTION IS NOT RECEIVED FROM CNAS.
THIS REPORT IS THE ENGLISH TRANSLATION VERSION OF THE REPORT 200103111.
ALL THE TESTED ITEMS ARE TESTED UNDER THE STANDARD CONDITION (EXCEPT FOR INDICATION).
COPIES OF THE REPORT ARE VALID ONLY RE-STAMPED.
THE EXPERIMENT WAS CARRIED OUT AT No.1, ZHUJIANG ROAD, PANYU DISTRICT, GUANGZHOU, GUANGDONG, P.R.CHINA.

APPROVED BY: 刘圆

Yuan Liu ENGINEER

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

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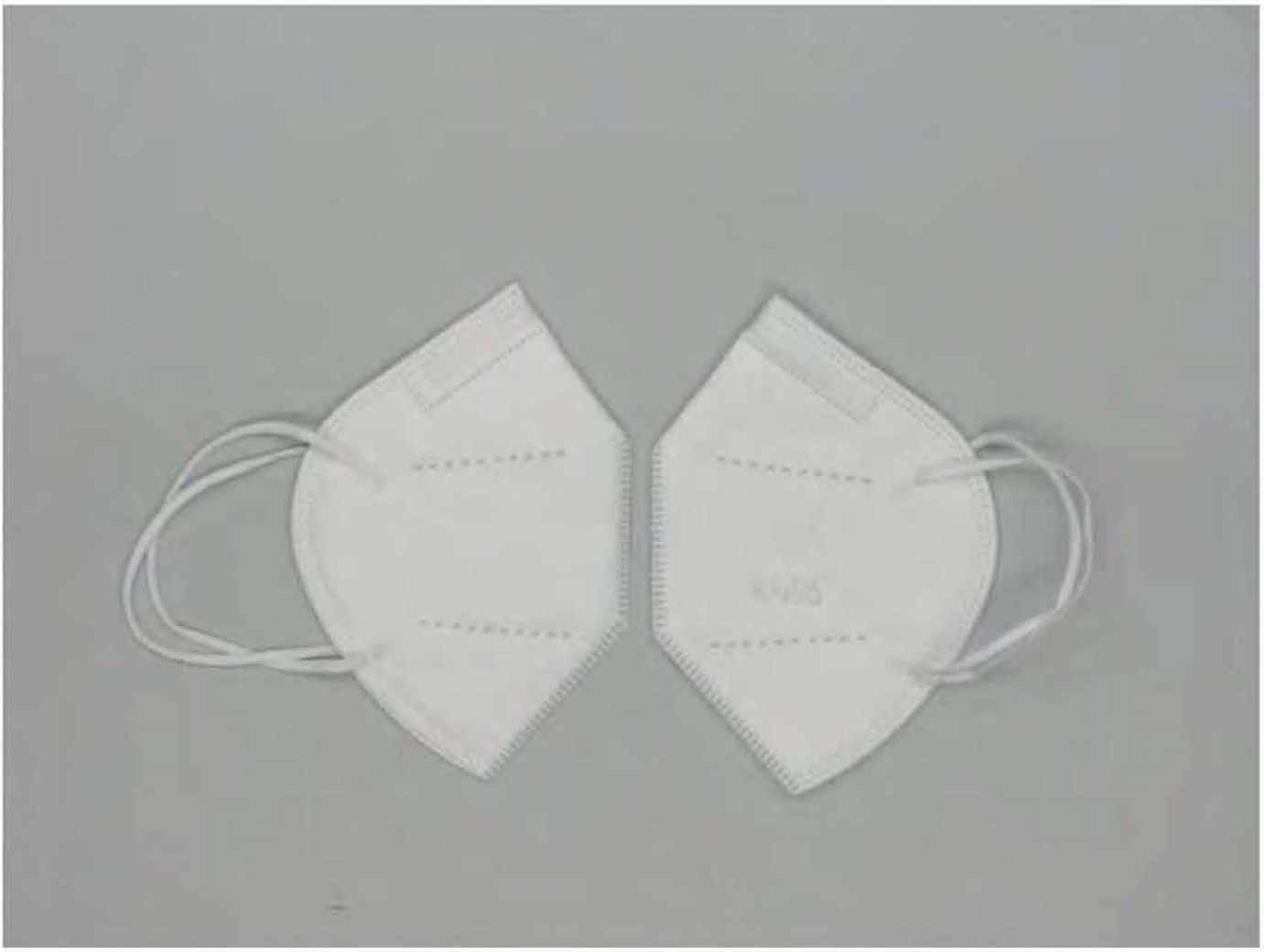
花都实验室：广州市花都区狮岭镇旗岭河滨西路1号
电话:020-61994598/61994599
电话:020-37721161

TEST REPORT

(Electronic version)

No:200103112



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花都实验室： 广州市花都区狮岭镇旗岭河滨西路1号
电话:020-61994598/61994599
电话:020-37721161

TEST REPORT

(Electronic version)

No:200103112

VISUAL FIELD(°)

(GB 2890-2009 6.8)

	REQUIREMENT
70	≥60
	(GB 2626-2006)

FILTRATION EFFICIENCY TO NaCl PARTICULATE MATTER(%)

(GB 2626-2006 6.3, AIR FLOW:85L/min, AEROSOL:NaCl, AEROSOL CONCENTRATION:15mg/m^3, TEMP:23.2℃ RH:36.9%)

	REQUIREMENT
FILTRATION EFFICIENCY:	FILTRATION EFFICIENCY:
UNTREATED SAMPLE	≥95.0
1# 99.071	(KN95)
2# 99.111	(GB 2626-2006)
3# 99.491	
4# 99.471	
5# 99.304	
6# 99.207	
7# 99.564	
8# 99.347	
9# 99.293	
10# 99.033	
CONDITIONING TREATED	
1# 98.97	
2# 99.351	
3# 99.037	
4# 99.149	
5# 99.133	

INSPIRATORY RESISTANCE(Pa)

(GB 2626-2006 6.5, HEAD SIZE: MEDIUM)

	REQUIREMENT
UNTREATED SAMPLE:	≤350
1# 188.9	(GB 2626-2006)
2# 187.1	
PRETREATMENT SAMPLE:	
1# 184.3	
2# 173.8	

EXPIRATORY RESISTANCE(Pa)

(GB 2626-2006 6.6, HEAD SIZE: MEDIUM)

	REQUIREMENT
UNTREATED SAMPLE:	≤250
1# 169.9	(GB 2626-2006)
2# 166.2	
PRETREATMENT SAMPLE:	
1# 166.2	
2# 155.4	

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TEST REPORT

(Electronic version)

No:200103112

FLAMMABILITY(s)

(GB 2626-2006 6.15)

	REQUIREMENT
AFTERFLAME TIME	AFTERFLAME TIME
UNTREATED SAMPLE	≤5
1# 0.0	(GB 2626-2006)
2# 0.0	
CONDITIONING TREATED	
3# 0.0	
4# 0.0	

HEAD BAND

(GB 2626-2006 6.11)

	REQUIREMENT
UNTREATED SAMPLE:	EACH HEAD BAND, BUCKLE AND OTHER ADJUST
1# PASS	PARTS OF MASK SHOULD NOT SLIP OR BREAK
CONDITIONING TREATED:	UNDER 10N TENSION FOR 10S.
1# PASS	(GB 2626-2006)

APPEARANCE INSPECTION[2 PIECES]

(GB 2626-2006 6.1)

	REQUIREMENT
PASS	ACCORDING TO THE CLAUSE 5.2 OF THE PRODUCT STANDARD (GB 2626-2006)

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

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电话:020-61994598/61994599
电话:020-37721161

20
CNAS - Bacterial Filtration Efficiency (BFE)

Safe
Efficient
Sterilization
Deodorization
5-Layer Plus Filtering
PM2.5 Defense

KF-N95
EN14683
99% FILTRATION
Similar / Equal to FFP3

For Adults

PM 2.5

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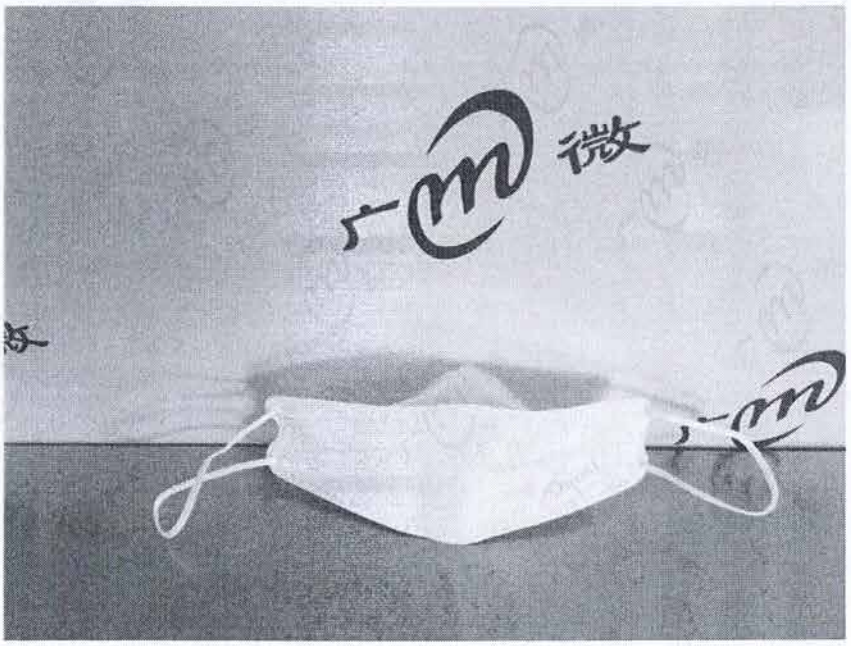
检测编号：KJ20192796
Test No.

广州市微生物研究所
GUANG ZHOU INSTITUTE OF MICROBIOLOGY

检 测 报 告
TEST REPORT

收样日期：2019 年 12 月 24 日
Date Received

检测日期：2019 年 12 月 26 日
Date Analyzed

样品名称 Name of Sample	康风 AOP-KF 固体碱抗流感防感染口罩	样品来源 Source of Sample	送检
委托单位 Applicant	深圳市康风环境科技发展有限公司	委托人 Client	郭旭芳
生产单位 Manufacturer	——	商标 Brand	康风 KFIAO
型号规格 Type and Specification	防细菌口罩	样品数量 Quantity of Sample	30 片
生产日期 Date of Production	2019 年 12 月	样品描述 State of Sample	片状
生产批号 Batch Number	——	样品包装 Packing of Sample	袋装
样品图片 Sample Picture			
检验依据和方法 Standard and Methods	YY 0469-2011 医用外科口罩		
检测项目 Items of Analysis	细菌过滤效率（BFE）		
备注 Remarks	——		

接下页/To be continued

广州市微生物研究所
GUANG ZHOU INSTITUTE OF MICROBIOLOGY

检 测 报 告
TEST REPORT

收样日期：2019 年 12 月 24 日
Date Received

检测日期：2019 年 12 月 26 日
Date Analyzed

细菌过滤效率试验：

1. 试验器材
   1) 菌种：金黄色葡萄球菌 ATCC 6538
   2) 微生物气溶胶发生器：PLG 2000
   3) 培养基：胰蛋白酶大豆琼脂（TSA）
   4) 采样器：六级筛孔空气撞击式采样器
2. 试验条件
   1) 环境温度：23.5℃
   2) 环境湿度：57%RH
3. 测试步骤
   1) 先不放样品，利用采样器和喷雾器调整细菌气溶胶浓度为（2200±500）CFU，作为阳性质控值。
   2) 将试验样品夹在采样器上端，被测试面向上并采样。
   3) 待样品测试完成后，再测试一次阳性质控。然后收集 2 min 气溶胶室中的空气样品，作为阴性质控，在此过程中不能向喷雾器中输送细菌悬液。
4. 计算公式

   细菌过滤效率BFE=$\frac{c-T}{c}$×100%（c 为阳性质控平均值，T 为试验样品计数之和）

检测结果：

样品编号	试验菌种	细菌过滤效率（BFE）（%）
KJ20192796-1	金黄色葡萄球菌	99.12

结论：由深圳市康风环境科技发展有限公司送检的型号为防细菌口罩的康风 AOP-KF 固体碱抗流感防感染口罩，细菌过滤效率（BFE）检测结果为 99.12%。

报告结束/End of report

编制：徐国洋 Editor　审核：王伯长 Checker　签发：李明 Issuer　签发日期（公章）：2020.2.3 Date Reported

广州市微生物研究所 检验检测专用章

中国认可
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检测
TESTING
CNAS L0823

201719001121

声　明

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联系地址：广州市黄埔区科学城尖塔山路 1 号

检验地址：（与联系地址不同时填写此项）

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检测报告(Test Report)

报告编号(Report No.)：WTH20H04023047C 日期(Date)：2020/5/6 页数(Page)：1 of 6

委托单位： 深圳市康风环境科技发展有限公司

Applicant: Shenzhen Kangfeng Environment Science & Technology Development Co., Ltd

单位地址： 深圳市龙岗区坂田街道天安云谷产业园一期 3 栋 D 座 21 楼 2101 房

Address: Room 2101, Floor 21, Block D, Building 3, Tian An Yun Gu Industrial Park(Phase 1), Bantian Sub-dist, Shenzhen

样品信息(Sample Information)：

样品名称(Sample Name)： 康风 AOP-KF®固体碱 Kangfeng AOP-KF®solid alkali

样品描述(Sample Description)： 白色物质(White substance)

样品编号(Sample No.)： WTH20H04023047C01

委托日期(Sample Received Date)： 2020/4/28

检测日期(Testing Period)： 2020/4/28 - 2020/5/6

检测结果(Test Result)： 请参见后续页(Please refer to following page(s).)。

检测要求(Test Requested)：	**结论(Conclusion)**
根据客户要求，参照欧盟 RoHS 指令 2011/65/EU 及其修订指令 EU 2015/863，检测样品中的铅、镉、汞、六价铬、多溴联苯、多溴二苯醚、DBP、BBP、DEHP、DIBP 的含量(As specified by client, to determine the Pb, Cd, Hg, Cr(VI), PBBs, PBDEs, DBP, BBP, DEHP, DIBP content in the sample with reference to EU RoHS Directive 2011/65/EU and its amendment Directive EU 2015/863.)。	合格(PASS)

授权签字人
Signed for and on behalf of HCT

Michael Huang

Shenzhen Hongcai Testing Technology Co., Ltd 深圳市虹彩检测技术有限公司 报告专用章

未CMA标识报告中的结果仅用于客户科研、教学、内部质量控制、产品研发等目的，仅供内部参考，对社会不具有证明作用。
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시점확인필 진본 2020-04-27 09:55:19 KST 전북시점확인센터

시험 · 검사성적서

의약품안전처 지정번호 : 의약품 제21호

발행번호	R20200427-0001	접수번호	200200030-001
검사완료일	2020-04-27	접수연월일	2020-03-23
제품명	크린 에어		
(품목)제조번호		품목제조신고번호	
유형 · 재질 · 품목명	보건용마스크		
제조(수입)일		유통(품질유지)기한	
의뢰자 성명	이영호	업체명	주식회사 골든베리
의뢰자 소재지	(38428)경상북도 경산시 하양읍 가마실길 50 산학협력관 702호(경일대학교) 전화번호: 02 - 3784 - 3936 팩스번호: 전자우편: jingyuan71@hanmail.net		
제조원 업체명	AOP-KF®	제조국	중국
제조원 소재지	Room 1004. 11/F. jubiles centre. 18 Fenwick Street. Wanchai. Hong kong		
시험 · 검사목적	의약품 | 허가.인증 신청 및 신고 검사		

시험 · 검사 항목 및 결과

시험 · 검사 항목	시험 · 검사 기준	시험 · 검사 결과	판정	비고
성상	해당 품목의 기준 및 시험 방법에 따름	백색의 부직포 재질 마스크로서 안면부와 백색의 머리끈 등으로 구성되어 있다.	적합	
형상시험(mm)	해당 품목의 기준 및 시험 방법에 따름	본체-가로(접은상태)107.57본체-세로(접은상태)157.78본체-가로(펼친상태)139.36본체-세로(펼친상태)141.32머리끈-길이(좌)182.04머리끈-길이(우)187.86	적합	
산또는알칼리	적합 부적합	페놀프탈레인:무색/메틸오렌지:주황색	적합	
색소	적합 부적합	색이 나타나지 않음.	적합	
형광	적합 부적합	UV램프 아래에서 형광을 나타내지 않음.	적합	
포름알데하이드	적합 부적합	크롬산칼륨 비교액보다 검액의 색이 연하다.	적합	
고정용 머리끈 접합부의 인장강도(N)	10N 이상	20.0	적합	
안면부 흡기저항 - KF94(Pa)	70 Pa 이하	15.7/16.4/14.9/15.0/15.6/14.9	적합	

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시험검사원 : 김수용 시험검사책임자 : 박재원

비고 : DCRF-2003-109

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2020년04월27일

단국대학교 천안캠퍼스 산학협력단 (인)

31116 충청남도 천안시 동남구 단대로 119 단국대학교 산학협력관 공동기기센터 T:041-550-1652 F:041-559-7929

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检测报告

客户：深圳市康风环境科技发展有限公司
地址：深圳市龙岗区坂田街道天安云谷产业园一期 3 栋 D 座 2101

以下测试样品由申请人提供及确认：

样品名称：	康风 AOP-KF 固体碱
检验类别：	送检
样品数量：	1
型号：	/
批号：	/
商标：	康风 KFIAQ
生产单位：	深圳市康风环境科技发展有限公司
到样日期：	2020/2/13
检测周期：	2020/2/15-2020/3/13
测试要求：	请参见下页
检测方法：	请参见下页
检测结果：	请参见下页
样品描述：	固体
备注：	1）相关项目不在资质认定范围内，仅供委托方内部使用。 2）报告显示的测试结果是在广州呼研所医药科技有限公司进行，报告证书编号为 HYS202002111.

编辑：　　批准：

审核：　　盖章：

广州中科检测技术服务有限公司 检验检测专用章

试验方法：

1. 试验用品

1） 毒株：冠状病毒 HCoV -229E

2） 细胞：Huh7 细胞

2. 测试条件

1）温　　度：23～25 ℃

2）相对湿度：50～60 %

3）试验时间：60、120 和 360 分钟

3. 测试方法

称取一定重量的样品备用，滴加病毒悬液，分别作用 60、120 和 360 分钟，回收载体片中的病毒，试验设对照组。试验重复 3 次。

试验结果：

在本测试设置的实验条件下，测试样品对冠状病毒 HCoV-229E 作用 60、120 和 360 分钟，测试样品对病毒有一定杀灭作用（表 1）。

表 1. 康风 AOP-KF 固体碱在规定设置下对冠状病毒的杀灭作用和杀灭负对数值

病毒	时间	组别	第一次试验 Log ($TCID_{50}$/ml)	第二次试验 Log ($TCID_{50}$/ml)	第三次试验 Log ($TCID_{50}$/ml)	平均值 Log ($TCID_{50}$/ml)	平均病毒灭活负对数值
冠状病毒 HCoV-229E	60 分钟	测试组	3.67	3.67	3.67	3.67	0.41
		对照组	4.00	4.00	4.33	4.11	
	120 分钟	测试组	3.33	3.00	3.33	3.22	0.45
		对照组	3.67	3.67	3.67	3.67	
	360 分钟	测试组	0.00	0.00	0.00	0.00	3.50
		对照组	3.50	3.50	3.50	3.50	

******** 接下页 ********

样品图片

******** 报告结束 ********

声 明

1. 本报告由广州中科检测技术服务有限公司（以下简称本公司）出具。
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2019_0119

深圳市康风环境科技发展有限公司　殿

試 験 報 告 書

「AOP-KF ボール」の抗ウイルス試験

(シェーク法)

北生発 2019_0119 号
2019 年 9 月 24 日

神奈川県相模原市南区北里 1 丁目 15 番 1 号
一般財団法人 北里環境科学センター
理事長　山　田　陽　城

試験内容を公表する際は、結果の表記等について専門的な立場から確認させていただいております。
なお、確認目的と申込様式は、ホームページに収載しております。
(http://www.kitasato-e.or.jp/?page_id=87)

1. 表題

「AOP-KF ボール」の抗ウイルス試験（シェーク法）

2. 報告書番号

北生発 2019_0119 号

3. 目的

「AOP-KF ボール」による大腸菌ファージに対する抗ウイルス性能を、抗菌製品技術協議会試験法である「シェーク法」を参考に評価した。

4. 依頼者

名　称：深圳市康风环境科技发展有限公司

所在地：深圳市龙岗区坂田街道雪岗北路天安云谷产业园一期 3 栋 D 座 2101

5. 試験機関

名　称: 一般財団法人 北里環境科学センター

所在地: 〒252-0329 神奈川県相模原市南区北里 1-15-1

6. 試験期間

2019 年 7 月 22 日 ~ 2019 年 7 月 25 日

7. 試験品

AOP-KF ボール（直径約 2 mm）・・・写真 a

※表面積が約 320 cm^2 となるよう、約 250 個のボール（＝6.18 g）を 1 組とした。

（6.18 g は、25 個のボールを 10 組測定した平均値 0.618 g の 10 倍量である）

写真 a. AOP-KF ボール

8. 試験条件

①自然減衰（コントロール）；試験ウイルス液のみを振とうした際の試験ウイルス数の経時変動

②対照ボール；試験品の代わりに対象ボール（ガラスビーズ）を入れ、振とうした際の試験ウイルス数の経時変動

③AOP-KF ボール; 試験品を入れ、振とうした際の試験ウイルス数の経時変動

9. 試験微生物

ウイルス：*Escherichia coli* phage φX174 NBRC 103405（大腸菌ファージ）

宿 主 菌：*Escherichia coli* NBRC 13898（大腸菌）

10. 試薬および機器・器材

1）主な試薬

- Nutrient Broth（Difco）
- 普通ブイヨン（栄研）
- 塩化ナトリウム（和光、特級）
- Agar（Difco）
- 普通寒天培地（日水）
- リン酸緩衝生理食塩液（エルメックス）

2）主な機器・器材

- インキュベータ（MIR-153、MIR-553、三洋）
- ネオシェーカー（NS-LR、アズワン）
- ガラスビーズ（BZ-2、アズワン、直径約 2 mm）

11. 方法

1）試験操作

試験品をアルミホイルで包み、121℃、15 分間で高圧蒸気滅菌後、乾燥させた。試験ウイルスを 1/50 濃度の普通ブイヨン培地に懸濁し、約 2×10^4 PFU/mL の試験ウイルス液とし、110 mL 容量滅菌コップ（φ50×H60 mm）に 10 mL の試験ウイルス液を入れ、蓋をした。コップを水平振とう数 150±10 rpm、振幅 30±5 mm の条件で、35±1 ℃、24±1 時間振とうした。1、6、24 時間後、各コップ内の試験液を遠沈管に取り、3,000 rpm で 1 分間遠心し、上清の 8 mL を採り、試料原液とした。また、試験品なし、および対照ボールを入れ、同様の操作をし、それぞれ自然減衰、対照とした。

2）試験ウイルス液の調製

Nutrient Broth で、36±2 ℃にて一晩培養した宿主菌液に、試験ウイルスを接種し、半流動寒天（Nutrient Broth＋0.5%塩化ナトリウム＋0.5%Agar）と混合して普通寒天培地に重層した。36±2℃で 18 時間培養後、宿主菌を遠心除去し、孔径 0.22 μm のメンブランフィルタでろ過して約 10^{10} PFU/mL の試験ウイルス液を得た。これを 1/50 濃度の Nutrient Broth で 1,000,000 倍に希釈し、試験に供した。

3）試験ウイルス数の測定

試料原液について、リン酸緩衝生理食塩液で 10 倍段階希釈列を作製した。その試料原液、または希釈液と宿主菌を半流動寒天に混合して普通寒天培地に重層し、36±2 ℃で 21～22 時間培養した。培養後、発生したプラークを数え、1 mL あたりの試験ウイルス数を求めた。

4）減少率の算出

コントロールの試験ウイルス数および各試験液の試験ウイルス数から、減少率を算出した。算出方法については、表3の脚注に示した。

12. 結果

表 1 および、図 1 に経過時間ごとの試験ウイルス数を示した。

表 2 に経過時間ごとの試験ウイルス数の対数値を示した。

表 3 に経過時間ごとの対数減少値と減少率を示した。

試験品において、6 時間作用後の試験ウイルス数は定量下限値未満（<5 PFU／mL）となり、減少率は＞99.9%であった。

以上

表 1. 経過時間ごとの試験ウイルス数　　（単位：PFU/20 mL）

試験条件	時間(h)			
	0	1	6	24
①自然減衰 (コントロール)	18,000	17,000	15,000	5,100
②対照ボール	18,000	22,000	20,000	6,500
③AOP-KFボール	18,000	75	<5	<5

試験ウイルス：*Escherichia coli* phage φX174 NBRC 103405（大腸菌ファージ）

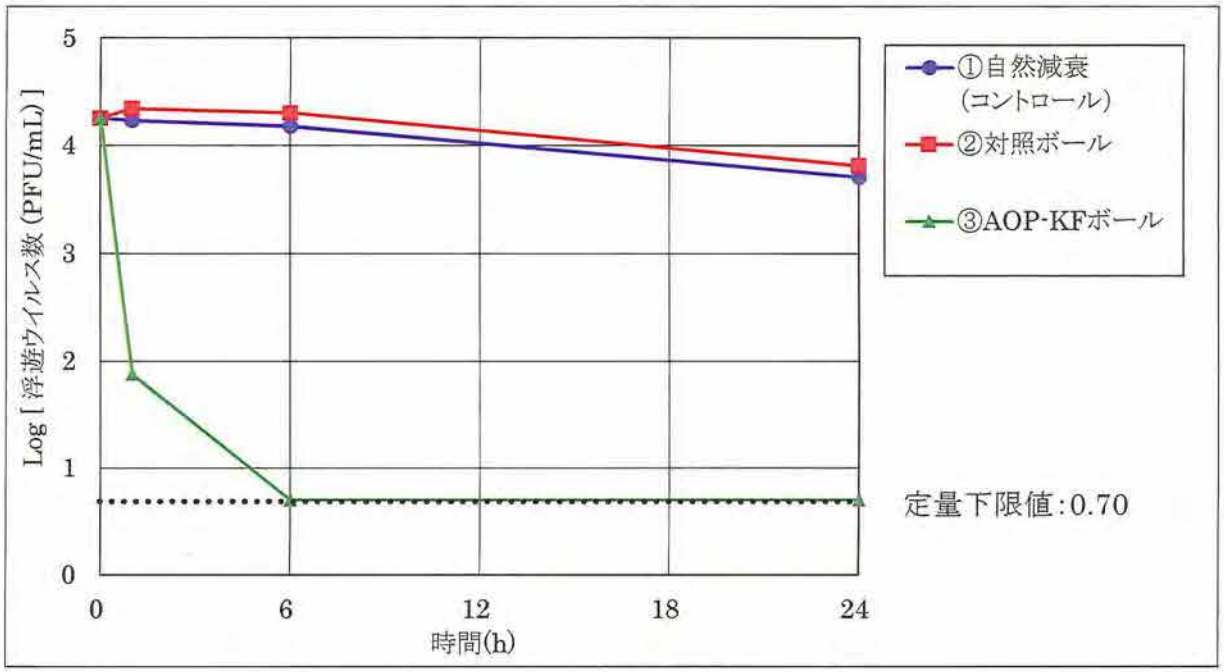

図 1. 経過時間ごとの試験ウイルス数

表 2. 経過時間ごとの試験ウイルス数の対数値

試験条件	時間(h)			
	0	1	6	24
①自然減衰 (コントロール)	4.26	4.23	4.18	3.71
②対照ボール	4.26	4.34	4.30	3.81
③AOP-KFボール	4.26	1.88	＜0.70	＜0.70

表 3. 経過時間ごとの対数減少値と減少率

試験条件	1h作用後		6h作用後		24h作用後	
	A	B (減少率)	A	B (減少率)	A	B (減少率)
①自然減衰 (コントロール)	0.03		0.08		0.55	
②対照ボール	(0.08)	−	(0.04)	−	0.44	−
③AOP-KFボール	2.38	2.35 (99.5%)	>3.56	>3.48 (>99.96%)	>3.56	>3.01 (>99.90%)

・初期値を基準とした時の対数減少値 A

$=\mathrm{Log}_{10}$（0 時間のウイルス数）$-\mathrm{Log}_{10}$（所定時間作用後のウイルス数）

・A（①自然減衰）を基準とした時の所定時間作用後の A（②試験品）の対数減少値 B

＝A（②試験品）－A（①自然減衰）

・減少率（%）$= \left(1 - \dfrac{1}{10^{(\text{対数減少値})}}\right) \times 100$ （%）

25
ISO 13485

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Deodorization
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EN14683
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PM 2.5

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CERTIFICATE OF REGISTRATION

The Medical Devices Quality Management Systems of

[redacted]

Unified Social Credit Code:91441900651824904

No.47 B District, Swan road Industrial Park, Li Wu village, Qiao Tou Town, Dong Guan, China

has been assessed by GIC and complying with

YY/T0287-2017/ISO13485:2016

For the following activities

Production and sales of plastic blister boxes for medical devices

Date of Issue: **02 November 2017** Date of Expiry: **01 November 2020**

Date of Initial Certification: **02 November 2017**

Certificate No.: G17Q2GZ0145R0S

Scan for certificate status

The granting of this certificate does not mean that the certificate holder can avoid any legal obligation. If the products or activities covered in the scope of certification require administrative license, the certificate shall be only valid within the scope of administrative licensing. The registered organization shall be subject to regular annual supervision by GIC, and the continual validity of the certificate is base upon conformity of audit. Please scan two-dimension code at lift to find the certificate information. This certificate can be queried at the National Certification and Accreditation Commission official website (www.cnca.gov.cn) & GIC website (www.gicg.com.cn)

GIC WeChat public number

Signature: Helen

Guardian Independent Certification (Beijing) Co., Ltd.
1-6D,6F, 1st Building, 2nd Courtyard, Dajiaoting Middle Street,
Chaoyang District, Beijing City
Post Code: 100124

11010514583 17

26
CAS - Antibacterial Test

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CNAS 检测 CNAS L0691

Test Center of Antimicrobial Materials

Technical Institute of Physics and Chemistry, Chinese Academy of Sciences

FOR INFORMATION ONLY
PROFIT ROYAL PHARMACEUTICAL LIMITED

Test Report

Report Number: LHKJ-1505-37-1/1

Sample Name * Antibacterial sheet

Sample Clients * Nano and Advanced Materials Institute Limited

Test Sort Application Test

Date of Report May 22, 2015

Address: 29#, East Road, Zhongguancun, Haidian District, Beijing, PRC
Tel: +8610 82543775, Fax: +8610 82543776
Post code: 100190
Web: www.ipc.ac.cn
E-mail: lhjc@mail.ipc.ac.cn

27
US FDA Registration

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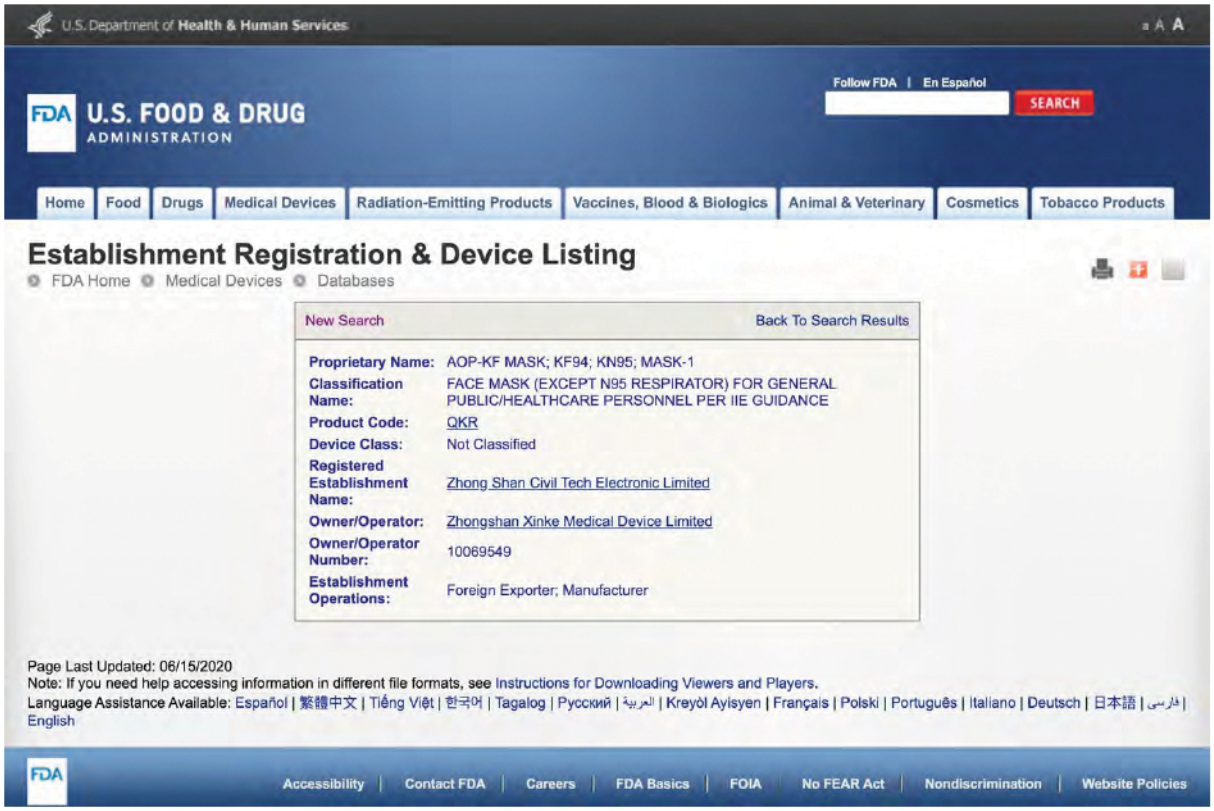
美國 FDA 註冊
US FDA Registration

連結 Link：
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=667355&lpcd=QKR



28
CE Certificate

Safe
Efficient
Sterilization
Deodorization
5-Layer Plus Filtering
PM2.5 Defense

KF-N95
EN14683
99% FILTRATION
Similar / Equal to FFP3

For Adults

PM 2.5

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AOP-KF®

EU DECLARATION OF CONFORMITY

Reference Number:

Y-LW0888

1) PPE Product

Product Name:	MASK
Model Number:	AOP-KF MASK
Type:	Non-sterile protective mask

2) Name and address of the manufacturer and authorized representative:

Manufacturer

Name:	ZHONGSHAN XINKE MEDICAL DEVICE LIMITED (former name: Zhong Shan Civil Tech Electronic Limited)
Address:	NO.6, INDUSTRIAL ZONE, NANLANG TOWN, ZHONGSHAN, GUANGDONG, CHINA

Authorized Representative

Name:	TO Hak Mau
Nationality:	Swedish
Personal ID Number:	551116-2090
Address:	Lönebostallsgatan, 1B 31, 00240, Helsingfors, Finland

3) This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer):

Manufacturer Name: ZHONGSHAN XINKE MEDICAL DEVICE LIMITED

4) Object of the declaration:

(identification of product allowing traceability. It may include a colour image of sufficient clarity to enable the identification of the product, where appropriate.)

5) The object of the declaration described in point 4 is in conformity with the relevant Union harmonization legislation:

REGULATION (EU) 2016/425

6) References to the relevant harmonized standards used, or references to the specifications in relation to which conformity is declared:

EN 14683:2009+AC:2019

7) Additional information:

None

CE

Signed for and on behalf of:

Yang Lin Wei
Director
Zhongshan Xinke Medical Device Limited
20 April 2020