Kaze Disposable Face Mask

Light

Certificate and test reports

Directory

Nelson Labs
A Sotera Health company

Sponsor:
Michael Wong
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Xinnan 1st Road, Xianan Village,
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Huizhou City, Guangdong Province
CHINA

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

Test Article:	Kaze Disposable Face Mask
Study Number:	1329616-S01
Study Received Date:	10 Aug 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

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:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~173 mm x ~168 mm
Positive Control Average:	2.4 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

James Luskin electronically approved — 14 Sep 2020 17:48 (+00:00)
Study Director James Luskin — Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	>99.9[a]
2	>99.9
3	>99.9[a]
4	>99.9
5	>99.9

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	6.5	63.5
2	6.1	59.7
3	6.3	61.3
4	5.0	48.8
5	5.0	48.6

The filtration efficiency percentages were calculated using the following equation:

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

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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Latex Particle Challenge Final Report

Test Article:	Kaze Disposable Face Mask
Study Number:	1329612-S01
Study Received Date:	10 Aug 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 08
Deviation(s):	None

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. 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. During testing and controls, the air flow rate is maintained at 1 cubic foot per minute (CFM) ± 5%.

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:	Inside
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	21°C, 32% relative humidity (RH) at 1003; 21°C, 31% RH at 1232
Average Filtration Efficiency:	99.946%
Standard Deviation:	0.0224

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Trang Truong electronically approved for — 18 Sep 2020 14:58 (+00:00)
Study Director — Curtis Gerow — Study Completion Date and Time

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	6	12,893	99.953
2	10	11,886	99.916
3	9	13,305	99.932
4	3	11,374	99.974
5	5	11,223	99.955

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Viral Filtration Efficiency (VFE) Final Report

Test Article:	Kaze Disposable Face Mask
Study Number:	1329615-S01
Study Received Date:	10 Aug 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:	~40 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:	1.9 x 10^3 PFU
Negative Monitor Count:	<1 PFU
MPS:	2.9 µm

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Trang Truong electronically approved for — 24 Sep 2020 21:20 (+00:00)
Study Director James Luskin — Study Completion Date and Time

Results:

Test Article Number	Percent VFE (%)
1	99.9
2	>99.9
3	>99.9[a]
4	99.9
5	>99.9[a]

[a] There were no detected plaques on any of the Andersen sampler plates for this test article.

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

HUIZHOU BOWEN MANUFACTURING LIMITED
XINNAN 1ST ROAD, XIANAN VILLAGE, YUANZHOU TOWN, BOLUO COUNTY, HUIZHOU CITY, GUANGDONG PROVINCE, P.R.CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)Kaze Disposable Face Mask (Claimed Type IIR)
Composition	:	(A)25% Color non-woven fabric; 25% skin friendly non-woven fabric; 20%melt blown fabric; 18%ear thread, 12%nose clip
Sample Color	:	(A)Sandy beige
Style No.	:	KAZE-04
Lot No.	:	2020-10
Manufacturer	:	HUIZHOU BOWEN MANUFACTURING LIMITED
Country of Destination	:	United States,EUR
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Nov 09, 2020
Testing Period	:	Nov 09, 2020 - Nov 19, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Comment:

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods **Clause 5.2 Performance Requirement**	(A)
Clause 5.2.2 Bacterial filtration efficiency (BFE)	M
Clause 5.2.3 Breathability	M
Clause 5.2.4 Splash Resistance	EXCLUDED
Clause 5.2.5 Microbial Cleanliness	M
Clause 5.2.6 Biocompatibility	EXCLUDED

Remark: M=Meet EN 14683:2019+AC:2019 Performance Requirement (Type IIR)
F=Below EN 14683:2019+AC:2019 Performance Requirement (Type IIR)

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)

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Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods

Clause 5.2 Performance Requirement

Clause 5.2.2 Bacterial Filtration Efficiency (BFE)
(EN 14683:2019+AC:2019 Annex B)

Sample: A

Test Side	:	Inside
Test Area	:	Approximately 60 cm^2
Flow Rate	:	28.3 L/min
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	~202mm x 156mm
Positive Control Average	:	2356 CFU
Negative Monitor Count	:	< 1 CFU
Mean Particle Size	:	3.0 ±0.3μm
Test bacteria	:	Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Result
Bacterial Filtration Efficiency (BFE)	1	99.9%
	2	99.9%
	3	99.9%
	4	99.9%
	5	99.9%

Remark:
1) Performance Requirement: Type I≥95%, Type II≥98%, Type IIR ≥98%
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

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Clause 5.2.3 Breathability
(EN 14683 :2019+AC:2019 Annex C)

Sample: A
Test Side : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Test Area : 4.9 cm^2
Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm^2)	The average value for each test specimen (Pa/cm^2)
1	1-1	44.5	49
	1-2	52.2	
	1-3	46.9	
	1-4	53.9	
	1-5	47.6	
2	2-1	50.3	48
	2-2	47.0	
	2-3	48.7	
	2-4	51.8	
	2-5	44.6	
3	3-1	55.2	49
	3-2	47.3	
	3-3	45.5	
	3-4	50.6	
	3-5	47.6	
4	4-1	49.1	50
	4-2	53.9	
	4-3	44.2	
	4-4	52.1	
	4-5	51.5	
5	5-1	47.2	49
	5-2	47.3	
	5-3	51.7	
	5-4	49.9	
	5-5	51.0	

Remark:
1) Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	5.83	138	23.67
2#	5.89	123	20.88
3#	5.87	99	16.87
4#	5.89	87	14.77
5#	5.87	84	14.31

Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

Sample Photo

The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)Kaze Disposable Face Mask (Claimed Type IIR)
Composition	:	(A)25% Color non-woven fabric; 25% skin friendly non-woven fabric; 20%melt blown fabric; 18%ear thread, 12%nose clip
Sample Color	:	(A)Sandy beige
Style No.	:	KAZE-04
Lot No.	:	2020-10
Manufacturer	:	HUIZHOU BOWEN MANUFACTURING LIMITED
Country of Destination	:	United States,EUR
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Nov 09, 2020
Testing Period	:	Nov 09, 2020 - Nov 19, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Comment:

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods **Clause 5.2 Performance Requirement**	(A)
Clause 5.2.2 Bacterial filtration efficiency (BFE)	EXCLUDED
Clause 5.2.3 Breathability	EXCLUDED
Clause 5.2.4 Splash Resistance	M
Clause 5.2.5 Microbial Cleanliness	EXCLUDED
Clause 5.2.6 Biocompatibility	EXCLUDED

Remark: M=Meet EN 14683:2019+AC:2019 Performance Requirement (Type IIR)
F=Below EN 14683:2019+AC:2019 Performance Requirement (Type IIR)

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

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Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods

Clause 5.2 Performance Requirement

Clause 5.2.4 Splash Resistance
(ISO 22609 :2004)

Sample: A
Test Blood Pressure : 16.0kPa
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Distance of the mask to the tip of cannula : 300±10mm

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	None Seen	Pass
4	None Seen	Pass	20	None Seen	Pass
5	None Seen	Pass	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	None Seen	Pass
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	Pass
Number of Pass:		32			
Overall result:		Acceptable			

Remark:
1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
2) Test was conducted within 60s after removal from conditioning chamber.
3) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results.

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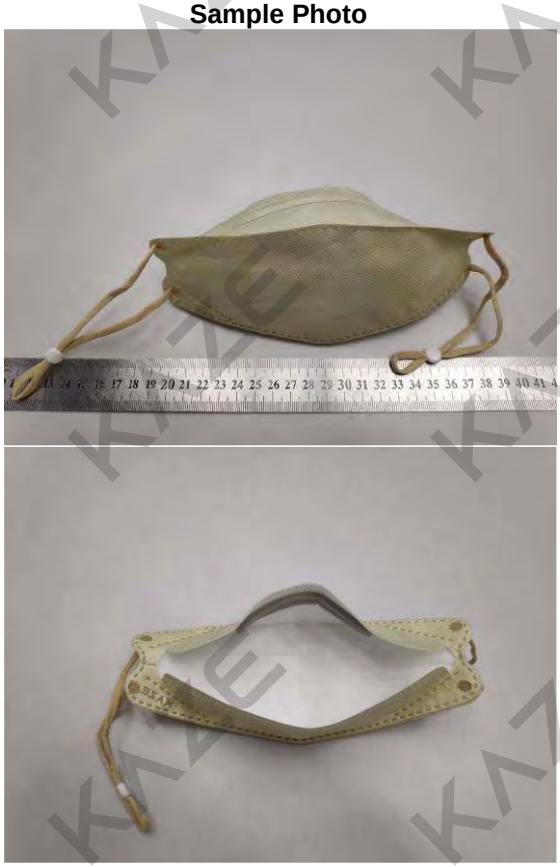
Sample Photo



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The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)Kaze Disposable Face Mask
Sample Color	:	(A)Arctic Blue
Composition	:	(A)28%Non-woven fabric 22%Melt blown cloth 22%Skin friendly non-woven fabric 20%ear band(spandex) 8%nose clip
Style No.	:	KAZE
Model No.	:	KAZE-04
Lot No.	:	2021.07
Manufacturer	:	Huizhou Bowen Manufacturing Limited
Country of Destination	:	Europe, USA
Sample Dimension	:	205mm * 83mm
Claimed Type/Level	:	type IIR
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Jul 14, 2021
Testing Period	:	Jul 14, 2021 - Jul 27, 2021
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)

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Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods

Clause 5.2 Performance Requirement

Clause 5.2.2 Bacterial Filtration Efficiency (BFE)
(EN 14683:2019+AC:2019 Annex B)

Sample: A

Test Side	:	Inside
Test Area	:	Approximately 60 cm^2
Flow Rate	:	28.3 L/min
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	~192mm x 160mm
Positive Control Average	:	2633.5 CFU
Negative Monitor Count	:	< 1 CFU
Mean Particle Size	:	3.0 ±0.3μm
Test bacteria	:	Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Result
Bacterial Filtration Efficiency (BFE)	1	99.9%
	2	99.9%
	3	99.9%
	4	99.9%
	5	99.9%

Remark:
1) Performance Requirement: Type I≥95%, Type II≥98%, Type IIR ≥98%
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

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Clause 5.2.3 Breathability
(EN 14683 :2019+AC:2019 Annex C)

Sample: A
Test Side : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Test Area : 4.9 cm^2
Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm^2)	The average value for each test specimen (Pa/cm^2)
1	1-1	54.3	53
	1-2	50.3	
	1-3	44.1	
	1-4	59.9	
	1-5	54.8	
2	2-1	44.8	42
	2-2	43.8	
	2-3	38.2	
	2-4	41.7	
	2-5	40.7	
3	3-1	40.1	43
	3-2	42.6	
	3-3	40.1	
	3-4	35.9	
	3-5	53.8	
4	4-1	53.2	52
	4-2	51.9	
	4-3	59.9	
	4-4	44.7	
	4-5	51.2	
5	5-1	51.6	48
	5-2	42.7	
	5-3	46.7	
	5-4	49.6	
	5-5	50.8	

Remark:
1) Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

Clause 5.2.4 Splash Resistance
(ISO 22609 :2004)

Sample: A
Test Blood Pressure : 16.0kPa
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Distance of the mask to the tip of cannula : 300±10mm

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	None Seen	Pass
4	None Seen	Pass	20	None Seen	Pass
5	None Seen	Pass	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	None Seen	Pass
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	Pass
Number of Pass:		32			
Overall result:		Acceptable			

Remark:
1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
2) Test was conducted within 60s after removal from conditioning chamber.
3) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results.

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Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1	6.56	28.08	4.28
2	6.62	28.08	4.24
3	6.61	17.55	2.66
4	6.58	17.55	2.67
5	6.62	21.06	3.18

Recovery Efficiency : 85.4 %
Correction Factor : 1.2

Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

Sample Photo

The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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HUIZHOU BOWEN MANUFACTURING LIMITED
XINNAN 1ST ROAD, XIANAN VILLAGE, YUANZHOU TOWN, BOLUO COUNTY, HUIZHOU CITY, GUANGDONG PROVINCE, P.R.CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)Kaze Disposable Face Mask
Sample Color	:	(A)Seaglass
Composition	:	(A)67%Non-woven fabric 21%Melt blown cloth 8%ear thread 4%nose dip
Sample Dimension	:	205mm * 83mm
Claimed Type/Level	:	type IIR
Style No.	:	KAZE
Model No.	:	KAZE-04
Lot No.	:	2021.07
Factory	:	Huizhou Bowen Manufacturing Limited
Country of Destination	:	Europe, USA
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Jul 23, 2021
Testing Period	:	Jul 28, 2021 - Aug 11, 2021
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)

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Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods

Clause 5.2 Performance Requirement

Clause 5.2.2 Bacterial Filtration Efficiency (BFE)
(EN 14683:2019+AC:2019 Annex B)

Sample: A

Test Side	:	Inside
Test Area	:	Approximately 60 cm^2
Flow Rate	:	28.3 L/min
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	~191mm x 166mm
Positive Control Average	:	2698.5 CFU
Negative Monitor Count	:	< 1 CFU
Mean Particle Size	:	3.0 ±0.3μm
Test bacteria	:	Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Result
Bacterial Filtration Efficiency (BFE)	1	99.9%
	2	99.9%
	3	99.9%
	4	99.9%
	5	99.9%

Remark:
1) Performance Requirement: Type I≥95%, Type II≥98%, Type IIR ≥98%
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

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Clause 5.2.3 Breathability

(EN 14683 :2019+AC:2019 Annex C)

Sample: A

Test Side : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks

Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.

Test Area : 4.9 cm^2

Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm^2)	The average value for each test specimen (Pa/cm^2)
1	1-1	37.9	38
	1-2	38.7	
	1-3	34.3	
	1-4	39.8	
	1-5	39.6	
2	2-1	39.5	37
	2-2	38.9	
	2-3	35.4	
	2-4	33.8	
	2-5	37.9	
3	3-1	33.9	35
	3-2	37.4	
	3-3	30.2	
	3-4	39.6	
	3-5	34.7	
4	4-1	36.8	38
	4-2	38.7	
	4-3	36.8	
	4-4	37.5	
	4-5	38.9	
5	5-1	37.8	38
	5-2	39.3	
	5-3	39.7	
	5-4	34.7	
	5-5	38.5	

Remark:

1) Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

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Clause 5.2.4 Splash Resistance
(ISO 22609 :2004)

Sample: A
Test Blood Pressure : 16.0kPa
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Distance of the mask to the tip of cannula : 300±10mm

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	None Seen	Pass
4	None Seen	Pass	20	None Seen	Pass
5	None Seen	Pass	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	None Seen	Pass
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	Pass
Number of Pass:		32			
Overall result:		Acceptable			

Remark:
1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
2) Test was conducted within 60s after removal from conditioning chamber.
3) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results.

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Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1	5.82	12.02	2.07
2	5.86	24.04	4.10
3	5.89	20.04	3.40
4	5.81	20.04	3.45
5	5.83	16.03	2.75

Recovery Efficiency : 74.9 %
Correction Factor : 1.3

Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

Sample Photo

The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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National Clothing Quality Inspection & Supervision Center(Tianjin)
国家针织产品质量监督检验中心
National Knitted Product Quality Inspection & Supervision Center

检验检测报告
Test Report

TTTS-WT202526700A

客户提供信息及要求 Information Provided by Client	委托单位/地址 Applicant	惠州博文制造有限公司 Huizhou Bowen Manufacturing Limited 广东省惠州市博罗县园洲镇下南村新南一路 Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China　送样人：Contact / 电话：Tel. /
	生产单位/地址 Manufacturer	惠州博文制造有限公司 Huizhou Bowen Manufacturing Limited 广东省惠州市博罗县园洲镇下南村新南一路 Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China
	样品信息 Information of Submitted Sample	样品名称：Sample Name Kaze 一次性口罩 Kaze Disposable Face Mask　商标：Trademark KAZE 样品总数：Sample Count 50个 50Pieces 号型规格：Size 鱼形口罩 Fish shaped mask(Kaze-04)　颜色：Colour / 质量等级：Quality Grade /　安全类别：Safety Category /
		产品款号或货号：Style No. or Order No. 2020-10
	判定标准：Test Standards	GB/T 32610-2016 日常防护型口罩技术规范 Technical specification of daily protective mask
样品描述 Test Part Description		1# 口罩-浅蓝色 Mask-Light Blue 2# 口罩-深粉色 Mask-Deep Pink 3# 口罩-米黄色 Mask-Beige 4# 口罩-黄色 Mask-Yellow 5# 口罩-蓝色 Mask-Blue

检验性质 Test Type	委托检验 Commission Test	样品接收日期 Date of Submission	2020-10-10	报告发布日期 Date of Checking	2020-11-05
检验日期 Test Date	2020-10-10	到 To	2020-10-15		
执行标准 Test Standards	见附页 See next page(s)				
检验结论 Conclusion	检验结果及符合性见附页。 Test results and compliance refer to next page(s). 检验单位盖章 Stamp of Inspection Unit				
备注 Remarks	见第2页 See Page 2				

天纺标检测认证股份有限公司 检测专用章 (c)

批准：Approver　审核：Checker　编制：Editor

备注 Remarks

客户要求过滤效率测试初始过滤效率，并按GB/T 32610-2016标准判定。
As per client's request that the Filtration Efficiency is required to test initial filtration efficiency and judged according to the standard GB/T 32610-2016.
本报告基于原报告TTTS-WT20252670，修改了“样品名称”。自本报告签发之日起，替代原报告TTTS-WT20252670，原报告作废。
The report is based on the original report TTTS-WT20252670 and has modified the “Sample Name”. As of the date of issue,replace the original report TTTS-WT20252670,the original report will be invalid.

检验检测报告
Test Report

TTTS-WT20252670A

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
1# 口罩-浅蓝色 Mask-Light Blue						
耐摩擦色牢度 Colour Fastness to Rubbing	干摩 Dry	级 Grade	≥4	4-5	符合 Pass	GB/T 29865-2013
耐摩擦色牢度 Colour Fastness to Rubbing	湿摩 Wet	级 Grade	/	4-5	/	GB/T 29865-2013
外观要求 Appearance Requirement	/	/	口罩表面不应有破损、油污斑渍、变形及其他明显缺陷 The mask surface shall have no damage, oil stain, deformation and other obvious defects.	+	符合 Pass	GB/T 32610-2016
2# 口罩-深粉色 Mask-Deep Pink						
甲醛含量 Formaldehyde Content	/	mg/kg	≤20	未检出 (低于检出限20mg/kg) Undetected (< 20mg/kg)	符合 Pass	GB/T 2912.1-2009
pH值 pH Value	氯化钾萃取 KCl Extract	/	4.0～8.5	6.6	符合 Pass	GB/T 7573-2009
3# 口罩-米黄色 Mask-Beige						
可分解致癌芳香胺染料 Azo	/	mg/kg	禁用 Not Used	未检出 (低于检出限5mg/kg) Undetected (< 5mg/kg)	符合 Pass	GB/T 17592-2011
环氧乙烷残留量 Ethylene Oxide Residual	/	μg/g	≤10	未检出 (低于检出限2μg/g) Undetected (< 2μg/g)	符合 Pass	GB/T 14233.1-2008
4# 口罩-黄色 Mask-Yellow						

检验检测报告
Test Report

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
吸气阻力 Inspiratory Resistance	/	Pa	≤175	未预处理样品 Samples Without Pretreatment: 1：117 2：88 预处理样品 Samples With Pretreatment: 1：101 2：85	符合 Pass	GB/T 32610-2016
呼气阻力 Expiratory Resistance	/	Pa	≤145	未预处理样品 Samples Without Pretreatment: 1：66 2：64 预处理样品 Samples With Pretreatment: 1：83 2：60	符合 Pass	GB/T 32610-2016
5# 口罩-蓝色 Mask-Blue						

检验检测报告
Test Report

TTTS-WT20252670A

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
过滤效率（III级） Filtration Efficiency （Grade III）	盐性介质 Salt Medium	%	≥90	初始过滤效率 Initial Filtration Efficiency: 未预处理样品 Samples Without Pretreatment: 1：97.4 2：97.1 3：97.4 4：97.4 5：97.4 预处理样品 Samples With Pretreatment: 1：92.9 2：93.4 3：96.4 最小值Minimum：92.9	符合 Pass	GB/T 32610-2016
	油性介质 Oiliness Medium	%	≥80	初始过滤效率 Initial Filtration Efficiency: 未预处理样品 Samples Without Pretreatment: 1：88.2 2：84.8 3：88.0 4：87.9 5：90.5 预处理样品 Samples With Pretreatment: 1：83.4 2：81.0 3：83.5 最小值Minimum：81.0		

表中“+”为符合标准要求，“×”表示不符合标准要求。
+ Meet the standard requirements, X Not Meet the standard requirements.

检验检测报告
Test Report

样 品 Sample

检验检测报告
Test Report

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----------报告结束 End of report----------

注意事项以中文为准The English edition is for reference only

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检验报告

TTTS-WF20000039

客户提供信息及要求 Information Provided by Client	委托单位/地址 Applicant	惠州博文制造有限公司 Huizhou Bowen Manufacturing Limited 广东省惠州市博罗县园洲镇下南村新南一路 Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China 送样人: Contact / 电话: Tel. /
	生产单位/地址 Manufacturer	惠州博文制造有限公司 Huizhou Bowen Manufacturing Limited 广东省惠州市博罗县园洲镇下南村新南一路 Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China
	样品信息 Information of Submitted Sample	样品名称: Sample Name: Kaze 一次性口罩 Kaze Disposable Face Mask 商标: Trademark: KAZE 样品总数: Sample Count: 50个 50Pieces 号型规格: Size: 鱼形口罩 Fish shaped mask(Kaze-04) 颜色: Colour: / 质量等级: Quality Grade: / 安全类别: Safety Category: / 产品款号或货号: Style No. or Order No.: 2020-11
	判定标准: Test Standards	GB/T 32610-2016 日常防护型口罩技术规范 Technical specification of daily protective mask
样品描述 Test Part Description		1# 口罩Mask-深灰色Espresso 2# 口罩Mask-浅杏色Light Blush 3# 口罩Mask-浅灰色Silver Grey 4# 口罩Mask-米白色Champagne 5# 口罩Mask-杏色Natural Sand 6# 口罩Mask-黑灰色Dark Grey 7# 口罩Mask-黑色Black 8# 口罩Mask-黑色十字纹Black Cross

检验性质 Test Type	委托检验 Commission Test	样品接收日期 Date of Submission	2020-11-23	报告发出日期 Date Of Checking	2020-11-27
检验日期 Test Date	2020-11-23	到 To	2020-11-27		
执行标准 Test Standards	见附页 See next page(s)				
检验结论 Conclusion	检验结果及符合性见附页。 Test results and compliance refer to next page(s). 检验单位盖章 Stamp of Inspection Unit				
备注 Remarks	/				

天纺标检测认证股份有限公司 检测专用章 (c)

批准: Approver 审核: Checker 编制: Editor

检验报告

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
1# 口罩Mask-深灰色Espresso						
外观要求 Appearance Requirement	/	/	口罩表面不应有破损、油污斑渍、变形及其他明显缺陷 The mask surface shall have no damage, oil stain, deformation and other obvious defects.	+	符合 Pass	GB/T 32610-2016
2# 口罩Mask-浅杏色Light Blush						
耐摩擦色牢度 Colour Fastness to Rubbing	干摩 Dry	级 Grade	≥4	4-5	符合 Pass	GB/T 29865-2013
耐摩擦色牢度 Colour Fastness to Rubbing	湿摩 Wet	级 Grade	/	4-5	/	GB/T 29865-2013
3# 口罩Mask-浅灰色Silver Grey						
吸气阻力 Inspiratory Resistance	/	Pa	≤175	未预处理样品 Samples Without Pretreatment: 1：148 2：132 预处理样品 Samples With Pretreatment: 1：114 2：109	符合 Pass	GB/T 32610-2016
呼气阻力 Expiratory Resistance	/	Pa	≤145	未预处理样品 Samples Without Pretreatment: 1：122 2：120 预处理样品 Samples With Pretreatment: 1：76 2：84	符合 Pass	GB/T 32610-2016
4# 口罩Mask-米白色Champagne						

检验报告

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
过滤效率（III级） Filtration Efficiency （Grade III）	盐性介质 Salt Medium	%	≥90	加载过滤效率: Loading Filtration Efficiency: 未预处理样品 Samples Without Pretreatment: 1：98.5 2：98.6 3：98.7 4：98.8 5：98.9 预处理样品 Samples With Pretreatment: 1：97.7 2：97.8 3：97.7 最小值Minimum：97.7	符合 Pass	GB/T 32610-2016
	油性介质 Oiliness Medium	%	≥80	加载过滤效率: Loading Filtration Efficiency: 未预处理样品 Samples Without Pretreatment: 1：89.4 2：89.7 3：88.9 4：89.7 5：89.7 预处理样品 Samples With Pretreatment: 1：87.7 2：87.3 3：88.1 最小值Minimum：87.3		
5# 口罩Mask-杏色Natural Sand						
可分解致癌芳香胺染料 Azo	/	mg/kg	禁用 Not Used	未检出 (低于检出限5mg/kg) Undetected (＜ 5mg/kg)	符合 Pass	GB/T 17592-2011
6# 口罩Mask-黑灰色Dark Grey						
环氧乙烷残留量 Ethylene Oxide Residual	/	μg/g	≤10	未检出 (低于检出限2μg/g) Undetected (＜ 2μg/g)	符合 Pass	GB/T 14233.1-2008
7# 口罩Mask-黑色Black						

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检验报告

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
甲醛含量 Formaldehyde Content	/	mg/kg	≤20	未检出 (低于检出限20mg/kg) Undetected (< 20mg/kg)	符合 Pass	GB/T 2912.1-2009
8# 口罩Mask-黑色十字纹Black Cross						
pH值 pH Value	氯化钾萃取 KCl Extract	/	4.0～8.5	6.7	符合 Pass	GB/T 7573-2009

表中“+”为符合标准要求，“×”表示不符合标准要求。
+ Meet the standard requirements, X Not Meet the standard requirements.

检验报告

样 品 Sample

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检验报告

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6.委托检验仅对来样负责，不承担其他连带责任。
Unless otherwise stated the results shown in this report refer only the sample(s) tested.

7.对于检验结果若有异议，应于收到报告之日起十五日内向本机构提出，逾期不予受理。
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----------**报告结束 End of report**----------

注意事项以中文为准The English edition is for reference only

天纺标集团检测单位与地址 Tianfangbiao Groups Others Testing Location
天纺标检测认证股份有限公司 Tianfangbiao Standardization Certification & Testing Co., Ltd. 国家服装质量监督检验中心（天津） China National Clothing Quality Inspection & Supervision Center (Tianjin) 国家针织产品质量监督检验中心 China National Knitted Product Quality Supervision Testing Center 地址：天津市南开区鹊桥路25号 Address: No.25, Queqiao Road, Nankai District, Tianjin, China

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National Clothing Quality Inspection & Supervision Center(Tianjin)
国家针织产品质量监督检验中心
National Knitted Product Quality Inspection & Supervision Center

检验检测报告
Test Report

TTTS-WF210000286

客户提供信息及要求 Information Provided by Client	委托单位/地址 Applicant	惠州博文制造有限公司 Huizhou Bowen Manufacturing Limited 广东省惠州市博罗县园洲镇下南村新南一路 Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China	送样人： Contact / 电话：Tel. /	
	生产单位/地址 Manufacturer	惠州博文制造有限公司 Huizhou Bowen Manufacturing Limited 广东省惠州市博罗县园洲镇下南村新南一路 Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China		
	样品信息 Information of Submitted Sample	样品名称：Sample Name：Kaze 一次性口罩 Kaze Disposable Face Mask 样品总数：Sample Count：50个 50Pieces 号型规格：Size：鱼形口罩 Fish shaped mask (Kaze-04) 质量等级：Quality Grade：/	商标：Trademark：KAZE 颜色：Colour：/ 安全类别：Safety Category：/	
		产品款号或货号：Style No. or Order No.：2021-01		
	判定标准：Test Standards	GB/T 32610-2016 日常防护型口罩技术规范 Technical specification of daily protective mask		
样品描述 Test Part Description		1# 口罩Mask-大紅色 Racing Red 2# 口罩Mask-深蓝色 Royal Blue 3# 口罩Mask-橘色 Citrus Orange 4# 口罩Mask-棕色 Maroon 5# 口罩Mask-深綠色 Forest Pine		
检验性质 Test Type	委托检验 Commission Test	样品接收日期 Date of Submission	2021-01-15	报告发布日期 Date of Checking：2021-01-22
检验日期 Test Date	2021-01-15	到 To	2021-01-21	
执行标准 Test Standards	见附页 See next page(s)			
检验结论 Conclusion	检验结果及符合性见附页。 Test results and compliance refer to next page(s). 检验单位盖章 Stamp of Inspection Unit			
备注 Remarks	/			

批准：Approver 审核：Checker 编制：Editor

检验检测报告
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TTTS-WF21000286

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
1# 口罩Mask-大紅色 Racing Red						
甲醛含量 Formaldehyde Content	/	mg/kg	≤20	未检出 (低于检出限20mg/kg) Undetected (< 20mg/kg)	符合 Pass	GB/T 2912.1-2009
外观要求 Appearance Requirement	/	/	口罩表面不应有破损、油污斑渍、变形及其他明显缺陷 The mask surface shall have no damage, oil stain, deformation and other obvious defects.	+	符合 Pass	GB/T 32610-2016
2# 口罩Mask-深蓝色 Royal Blue						
耐摩擦色牢度 Colour Fastness to Rubbing	干摩 Dry	级 Grade	≥4	4-5	符合 Pass	GB/T 29865-2013
	湿摩 Wet	级 Grade	≥4	4-5		
3# 口罩Mask-橘色 Citrus Orange						
可分解致癌芳香胺染料 Azo	/	mg/kg	禁用 Not Used	未检出 (低于检出限5mg/kg) Undetected (< 5mg/kg)	符合 Pass	GB/T 17592-2011
吸气阻力 Inspiratory Resistance	/	Pa	≤175	未预处理样品 Samples Without Pretreatment: 1：89 2：85 预处理样品 Samples With Pretreatment: 1：76 2：84	符合 Pass	GB/T 32610-2016

检验检测报告
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TTTS-WF21000286

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
呼气阻力 Expiratory Resistance	/	Pa	≤145	未预处理样品 Samples Without Pretreatment: 1：76 2：67 预处理样品 Samples With Pretreatment: 1：47 2：46	符合 Pass	GB/T 32610-2016
4# 口罩Mask-棕色 Maroon						
过滤效率（III级） Filtration Efficiency （Grade III）	盐性介质 Salt Medium	%	≥90	加载过滤效率: Loading Filtration Efficiency: 未预处理样品 Samples Without Pretreatment: 1：99.9 2：99.9 3：99.9 4：99.9 5：99.9 预处理样品 Samples With Pretreatment: 1：99.8 2：99.8 3：99.8 最小值Minimum：99.8	符合 Pass	GB/T 32610-2016
	油性介质	%	≥80	加载过滤效率: Loading Filtration Efficiency: 未预处理样品 Samples Without Pretreatment: 1：98.9 2：99.0 3：99.2 4：99.1 5：99.0 预处理样品 Samples With Pretreatment: 1：97.8 2：98.0 3：97.8 最小值Minimum：97.8		
pH值 pH Value	氯化钾萃取 KCl Extract	/	4.0～8.5	6.6	符合 Pass	GB/T 7573-2009

检验检测报告
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TTTS-WF21000286

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
5# 口罩Mask-深綠色 Forest Pine						
环氧乙烷残留量 Ethylene Oxide Residual	/	μg/g	≤10	未检出 (低于检出限2μg/g) Undetected (＜ 2μg/g)	符合 Pass	GB/T 14233.1-2008

表中“+”为符合标准要求，“×”表示不符合标准要求。
+ Meet the standard requirements, X Not Meet the standard requirements.

样　品　Sample

天纺标检测认证股份有限公司
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国家服装质量监督检验中心（天津）
National Clothing Quality Inspection & Supervision Center(Tianjin)
国家针织产品质量监督检验中心
National Knitted Product Quality Inspection & Supervision Center

检验检测报告
Test Report

TTTS-FH21002003

客户提供信息及要求 Information Provided by Client	委托单位/地址 Applicant	惠州博文制造有限公司 Huizhou Bowen Manufacturing Limited 广东省惠州市博罗县园洲镇下南村新南一路 Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China	送样人： Contact / 电话：Tel. /	
	生产单位/地址 Manufacturer	惠州博文制造有限公司 Huizhou Bowen Manufacturing Limited 广东省惠州市博罗县园洲镇下南村新南一路 Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China		
	样品信息 Information of Submitted Sample	样品名称：Sample Name：Kaze 一次性口罩 Kaze Disposable Face Mask 样品总数：Sample Count：115个 115Pieces 号型规格：Size or Specification：Light (Kaze-04) 质量等级：Quality Grade：/	商标：Trademark：KAZE 颜色：Colour：/ 安全类别：Safety Category：/	
		产品款号或货号：Style No. or Order No.：2021-04		
	判定标准：Test Standards	GB/T 32610-2016 日常防护型口罩技术规范 Technical specification of daily protective mask		
样品描述 Test Part Description		1# 口罩Mask-蓝色 Cobalt Blue 2# 口罩Mask-紫色 Purple Berry 3# 口罩Mask-深綠色 Spearmint 4# 口罩Mask-淺綠色 Key Lime 5# 口罩Mask-粉紅色 Bubblegum 6# 口罩Mask-黑色 Onyx 7# 口罩Mask-白色 Ivory		
检验性质 Test Type	委托检验 Commission Test	样品接收日期 Date of Submission：2021-04-20	报告发布日期 Date of Checking：2021-04-28	
检验日期 Test Date		2021-04-20 到 To 2021-04-25		
执行标准 Test Standards	见附页 See next page(s)			
检验结论 Conclusion	检验结果及符合性见附页。 Test results and compliance refer to next page(s). 检验单位盖章 Stamp of Inspection Unit			
备注 Remarks	/			

天纺标检测认证股份有限公司 检测专用章

批准：Approver 方倩　审核：Checker 张涛　编制：Editor 鲍子宁

检验检测报告
Test Report

TTTS-FH21002003

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
1# 口罩Mask-蓝色 Cobalt Blue						
外观要求 Appearance Requirement	/	/	口罩表面不应有破损、油污斑渍、变形及其他明显缺陷 The mask surface shall have no damage, oil stain, deformation and other obvious defects.	+	符合 Pass	GB/T 32610-2016
2# 口罩Mask-紫色 Purple Berry						
过滤效率（III级） Filtration Efficiency （Grade III）	盐性介质 Salt Medium	%	≥90	未预处理样品 Samples Without Pretreatment: 1：99.7 2：99.4 3：99.6 4：99.6 5：99.6 预处理样品 Samples With Pretreatment: 1：99.1 2：99.1 3：99.1 最小值Minimum：99.1	符合 Pass	GB/T 32610-2016
	油性介质 Oil Medium	%	≥80	未预处理样品 Samples Without Pretreatment: 1：95.3 2：94.8 3：94.7 4：94.9 5：95.0 预处理样品 Samples With Pretreatment: 1：93.8 2：92.4 3：92.4 最小值Minimum：92.4		
3# 口罩Mask-深綠色 Spearmint						

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检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
甲醛含量 Formaldehyde Content	/	mg/kg	≤20	未检出 (低于检出限20mg/kg) Undetected (< 20mg/kg)	符合 Pass	GB/T 2912.1-2009
4# 口罩Mask-淺綠色 Key Lime						
pH值 pH Value	氯化钾萃取 KCl Extract	/	4.0～8.5	6.9	符合 Pass	GB/T 7573-2009
5# 口罩Mask-粉紅色 Bubblegum						
吸气阻力 Inspiratory Resistance	/	Pa	≤175	未预处理样品 Samples Without Pretreatment: 1：58 2：75 预处理样品 Samples With Pretreatment: 1：55 2：64	符合 Pass	GB/T 32610-2016
呼气阻力 Expiratory Resistance	/	Pa	≤145	未预处理样品 Samples Without Pretreatment: 1：51 2：50 预处理样品 Samples With Pretreatment: 1：49 2：45	符合 Pass	GB/T 32610-2016
6# 口罩Mask-黑色 Onyx						
耐摩擦色牢度 Colour Fastness to Rubbing	干摩 Dry	级 Grade	≥4	4-5	符合 Pass	GB/T 29865-2013
耐摩擦色牢度 Colour Fastness to Rubbing	湿摩 Wet	级 Grade	/	4-5	/	GB/T 29865-2013
可分解致癌芳香胺染料 Azo	/	mg/kg	禁用 Not Used	未检出 (低于检出限5mg/kg) Undetected (< 5mg/kg)	符合 Pass	GB/T 17592-2011
7# 口罩Mask-白色 Ivory						
环氧乙烷残留量 Ethylene Oxide Residual	/	μg/g	≤10	未检出 (低于检出限2μg/g) Undetected (< 2μg/g)	符合 Pass	GB/T 14233.1-2008

样　品　Sample

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National Clothing Quality Inspection & Supervision Center(Tianjin)
国家针织产品质量监督检验中心
National Knitted Product Quality Inspection & Supervision Center

检验检测报告
Test Report

TTTS-FH21002047

客户提供信息及要求 Information Provided by Client	委托单位/地址 Applicant	惠州博文制造有限公司 Huizhou Bowen Manufacturing Limited 广东省惠州市博罗县园洲镇下南村新南一路 Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China	送样人：/ Contact 电话：Tel. /	
	生产单位/地址 Manufacturer	惠州博文制造有限公司 Huizhou Bowen Manufacturing Limited 广东省惠州市博罗县园洲镇下南村新南一路 Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China		
	样品信息 Information of Submitted Sample	样品名称：Kaze 一次性口罩 Sample Name Kaze Disposable Face Mask	商标：KAZE Trademark	
		样品总数：95个 Sample Count 95Pieces		
		号型规格：Light (Kaze-04) Size or Specification	颜色：/ Colour	
		质量等级：/ Quality Grade	安全类别：/ Safety Category	
		产品款号或货号：2021-04 Style No. or Order No.		
	判定标准：Test Standards	GB/T 32610-2016 日常防护型口罩技术规范 Technical specification of daily protective mask		
样品描述 Test Part Description		见第2页 See Page 2		

检验性质 Test Type	委托检验 Commission Test	样品接收日期 Date of Submission	2021-04-23	报告发布日期 Date of Issuing	2021-04-30
检验日期 Test Date	2021-04-23	到 To	2021-04-30		
执行标准 Test Standards	见附页 See next page(s)				
检验结论 Conclusion	检验结果及符合性见附页。 Test results and compliance refer to next page(s). 检验单位盖章 Stamp of Inspection Unit				
备注 Remarks	/				

天纺标检测认证股份有限公司 检测专用章 (c)

批准：Approver 审核：Checker 编制：Editor

样品描述Test Part Description

01# 口罩Mask-深藍色 Royal Blue
02# 口罩Mask-深綠色 Forest Pine
03# 口罩Mask-藍色 Powder Blue
04# 口罩Mask-橘色 Citrus Orange
05# 口罩Mask-淺綠色 Sweet Pea
06# 口罩Mask-紫色 Ultraviolet
07# 口罩Mask-米色 Sandy Beige
08# 口罩Mask-棕色 Maroon
09# 口罩Mask-桃紅色 Fuchsia
10# 口罩Mask-大紅色 Racing Red
11# 口罩Mask-粉紅色 Rose Quartz
12# 口罩Mask-米灰色 Dove Grey

检验检测报告
Test Report

TTTS-FH21002047

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
01# 口罩Mask-深蓝色 Royal Blue						
外观要求 Appearance Requirement	/	/	口罩表面不应有破损、油污斑渍、变形及其他明显缺陷 The mask surface shall have no damage, oil stain, deformation and other obvious defects.	+	符合 Pass	GB/T 32610-2016
02# 口罩Mask-深綠色 Forest Pine						
耐摩擦色牢度 Colour Fastness to Rubbing	干摩 Dry	级 Grade	≥4	4-5	符合 Pass	GB/T 29865-2013
耐摩擦色牢度 Colour Fastness to Rubbing	湿摩 Wet	级 Grade	/	4-5	/	GB/T 29865-2013
03# 口罩Mask-藍色 Powder Blue						
耐摩擦色牢度 Colour Fastness to Rubbing	干摩 Dry	级 Grade	≥4	4-5	符合 Pass	GB/T 29865-2013
耐摩擦色牢度 Colour Fastness to Rubbing	湿摩 Wet	级 Grade	/	4-5	/	GB/T 29865-2013
04# 口罩Mask-橘色 Citrus Orange						
环氧乙烷残留量 Ethylene Oxide Residual	/	μg/g	≤10	未检出 (低于检出限2μg/g) Undetected (< 2μg/g)	符合 Pass	GB/T 14233.1-2008
05# 口罩Mask-淺綠色 Sweet Pea						
耐摩擦色牢度 Colour Fastness to Rubbing	干摩 Dry	级 Grade	≥4	4-5	符合 Pass	GB/T 29865-2013
耐摩擦色牢度 Colour Fastness to Rubbing	湿摩 Wet	级 Grade	/	4-5	/	GB/T 29865-2013
06# 口罩Mask-紫色 Ultraviolet						

检验检测报告
Test Report

TTTS-FH21002047

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
过滤效率（III级） Filtration Efficiency （Grade III）	盐性介质 Salt Medium	%	≥90	未预处理样品 Samples Without Pretreatment: 1：99.9 2：99.9 3：99.9 4：99.9 5：99.9 预处理样品 Samples With Pretreatment: 1：99.9 2：99.8 3：99.8 最小值Minimum：99.8	符合 Pass	GB/T 32610-2016
	油性介质 Oil Medium	%	≥80	未预处理样品 Samples Without Pretreatment: 1：96.5 2：97.6 3：96.5 4：96.6 5：96.6 预处理样品 Samples With Pretreatment: 1：96.0 2：95.7 3：95.9 最小值Minimum：95.7		
07# 口罩Mask-米色 Sandy Beige						
甲醛含量 Formaldehyde Content	/	mg/kg	≤20	未检出 (低于检出限20mg/kg) Undetected (< 20mg/kg)	符合 Pass	GB/T 2912.1-2009
08# 口罩Mask-棕色 Maroon						
pH值 pH Value	氯化钾萃取 KCl Extract	/	4.0～8.5	6.5	符合 Pass	GB/T 7573-2009
09# 口罩Mask-桃紅色 Fuchsia						
耐摩擦色牢度 Colour Fastness to Rubbing	干摩 Dry	级 Grade	≥4	4-5	符合 Pass	GB/T 29865-2013
耐摩擦色牢度 Colour Fastness to Rubbing	湿摩 Wet	级 Grade	/	4-5	/	GB/T 29865-2013
10# 口罩Mask-大紅色 Racing Red						

检验检测报告
Test Report

TTTS-FH21002047

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
可分解致癌芳香胺染料 Azo	/	mg/kg	禁用 Not Used	未检出 (低于检出限5mg/kg) Undetected (< 5mg/kg)	符合 Pass	GB/T 17592-2011
11# 口罩Mask-粉紅色 Rose Quartz						
吸气阻力 Inspiratory Resistance	/	Pa	≤175	未预处理样品 Samples Without Pretreatment: 1：62 2：85 预处理样品 Samples With Pretreatment: 1：66 2：68	符合 Pass	GB/T 32610-2016
12# 口罩Mask-米灰色 Dove Grey						
呼气阻力 Expiratory Resistance	/	Pa	≤145	未预处理样品 Samples Without Pretreatment: 1：43 2：40 预处理样品 Samples With Pretreatment: 1：37 2：45	符合 Pass	GB/T 32610-2016

表中“+”为符合标准要求，“×”表示不符合标准要求。
+ Meet the standard requirements, X Not Meet the standard requirements.

样　品　Sample

天纺标检测认证股份有限公司
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国家服装质量监督检验中心（天津）
National Clothing Quality Inspection & Supervision Center(Tianjin)
国家针织产品质量监督检验中心
National Knitted Product Quality Inspection & Supervision Center

检验检测报告
Test Report

TTTS-FH21002583

客户提供信息及要求 Information Provided by Client	委托单位/地址 Applicant	惠州博文制造有限公司 Huizhou Bowen Manufacturing Limited 广东省惠州市博罗县园洲镇下南村新南一路 Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China 送样人：Contact / 电话：Tel. /
	生产单位/地址 Manufacturer	惠州博文制造有限公司 Huizhou Bowen Manufacturing Limited 广东省惠州市博罗县园洲镇下南村新南一路 Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China
	样品信息 Information of Submitted Sample	样品名称：Sample Name Kaze 一次性口罩 Kaze Disposable Face Mask 商标：Trademark KAZE 样品总数：Sample Count 100个 100Pieces 号型规格：Size or Specification Light(Kaze-04) 颜色：Colour / 质量等级：Quality Grade / 安全类别：Safety Category / 产品款号或货号：Style No. or Order No. 2021-07
	判定标准：Test Standards	GB/T 32610-2016 日常防护型口罩技术规范 Technical specification of daily protective mask
样品描述 Test Part Description		1# 口罩Mask-绿色花纹- photosynthesis 2# 口罩Mask-棕紫色花纹- dreamweaver 3# 口罩Mask-蓝色花纹- seaglass 4# 口罩Mask-红色花纹- sweet nectar 5# 口罩Mask-橙色花纹- bloomington

检验性质 Test Type	委托检验 Commission Test	样品接收日期 Date of Submission	2021-07-15	报告发布日期 Date of Checking	2021-07-23
检验日期 Test Date	2021-07-15	到 To	2021-07-20		
执行标准 Test Standards	见附页 See next page(s)				
检验结论 Conclusion	检验结果及符合性见附页。 Test results and compliance refer to next page(s). 检验单位盖章 Stamp of Inspection Unit				
备注 Remarks	/				

天纺标检测认证股份有限公司 检测专用章

批准：Approver 方倩　审核：Checker 张涛　编制：Editor 赵晓晓

检验检测报告
Test Report

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
1# 口罩Mask-绿色花纹- photosynthesis						
外观要求 Appearance Requirement	/	/	口罩表面不应有破损、油污斑渍、变形及其他明显缺陷 The mask surface shall have no damage, oil stain, deformation and other obvious defects.	+	符合 Pass	GB/T 32610-2016
吸气阻力 Inspiratory Resistance	/	Pa	≤175	未预处理样品 Samples Without Pretreatment: 1：72 2：89 预处理样品 Samples With Pretreatment: 1：91 2：58	符合 Pass	GB/T 32610-2016
呼气阻力 Expiratory Resistance	/	Pa	≤145	未预处理样品 Samples Without Pretreatment: 1：61 2：58 预处理样品 Samples With Pretreatment: 1：85 2：51	符合 Pass	GB/T 32610-2016
2# 口罩Mask-棕紫色花纹- dreamweaver						
耐摩擦色牢度 Colour Fastness to Rubbing	干摩 Dry	级 Grade	≥4	4-5	符合 Pass	GB/T 29865-2013
耐摩擦色牢度 Colour Fastness to Rubbing	湿摩 Wet	级 Grade	/	4-5	/	GB/T 29865-2013
3# 口罩Mask-蓝色花纹- seaglass						
甲醛含量 Formaldehyde Content	/	mg/kg	≤20	未检出 (低于检出限20mg/kg) Undetected (< 20mg/kg)	符合 Pass	GB/T 2912.1-2009

检验检测报告
Test Report

TTTS-FH21002583

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
可分解致癌芳香胺染料 Azo	/	mg/kg	禁用 Not Used	未检出 (低于检出限5mg/kg) Undetected (< 5mg/kg)	符合 Pass	GB/T 17592-2011
4# 口罩Mask-红色花纹- sweet nectar						
环氧乙烷残留量 Ethylene Oxide Residual	/	μg/g	≤10	未检出 (低于检出限2μg/g) Undetected (< 2μg/g)	符合 Pass	GB/T 14233.1-2008
5# 口罩Mask-橙色花纹- bloomington						
过滤效率（III级） Filtration Efficiency （Grade III）	盐性介质 Salt Medium	%	≥90	未预处理样品 Samples Without Pretreatment 1：99.8 2：99.8 3：99.8 4：99.8 5：99.8 预处理样品 Samples With Pretreatment: 1：99.7 2：99.7 3：99.7 最小值Minimum：99.7	符合 Pass	GB/T 32610-2016
	油性介质 Oil Medium	%	≥80	未预处理样品 Samples Without Pretreatment: 1：97.2 2：95.1 3：96.5 4：96.3 5：97.1 预处理样品 Samples With Pretreatment: 1：92.8 2：91.7 3：92.4 最小值Minimum：91.7		

表中“+”为符合标准要求，“×”表示不符合标准要求。
+ Meet the standard requirements, X Not Meet the standard requirements.

检验检测报告
Test Report

样 品 Sample

天纺标检测认证股份有限公司
TianFangBiao Standardization Certification & Testing Co.,Ltd.
国家服装质量监督检验中心（天津）
National Clothing Quality Inspection & Supervision Center(Tianjin)
国家针织产品质量监督检验中心
National Knitted Product Quality Inspection & Supervision Center

检验检测报告
Test Report

TTTS-FH21002652

客户提供信息及要求 Information Provided by Client	委托单位/地址 Applicant	惠州博文制造有限公司 Huizhou Bowen Manufacturing Limited 广东省惠州市博罗县园洲镇下南村新南一路 Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China	送样人： Contact / 电话：Tel. /	
	生产单位/地址 Manufacturer	惠州博文制造有限公司 Huizhou Bowen Manufacturing Limited 广东省惠州市博罗县园洲镇下南村新南一路 Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China		
	样品信息 Information of Submitted Sample	样品名称：Sample Name：Kaze 一次性口罩 Kaze Disposable Face Mask 样品总数：Sample Count：100个 100Pieces 号型规格：Size or Specification：Light (Kaze-04) 质量等级：Quality Grade：/	商标：Trademark：KAZE 颜色：Colour：/ 安全类别：Safety Category：/	
		产品款号或货号：Style No. or Order No.：2021-07		
	判定标准：Test Standards	GB/T 32610-2016 日常防护型口罩技术规范 Technical specification of daily protective mask		
样品描述 Test Part Description		见第2页 See Page 2		
检验性质 Test Type	委托检验 Commission Test	样品接收日期 Date of Submission	2021-07-24	报告发布日期 Date of Issuing：2021-07-30
检验日期 Test Date		2021-07-24 到 To	2021-07-29	
执行标准 Test Standards	见附页 See next page(s)			
检验结论 Conclusion	检验结果及符合性见附页。 Test results and compliance refer to next page(s). 检验单位盖章 Stamp of Inspection Unit			
备注 Remarks	/			

天纺标检测认证股份有限公司 检测专用章

批准：Approver 方倩　审核：Checker 于洋　编制：Editor 鲍子宇

样品描述Test Part Description

01# 口罩Mask-浅紫色-Light Purple
02# 口罩Mask-浅绿色-Light Green
03# 口罩Mask-紫色- Purple
04# 口罩Mask-蓝色-Blue
05# 口罩Mask-棕色- Brown
06# 口罩Mask-黄色- Yellow
07# 口罩Mask-粉色-Pink
08# 口罩Mask-红色- Red
09# 口罩Mask-浅蓝色-Light Blue
10# 口罩Mask-绿色- Green

检验检测报告
Test Report

TTTS-FH21002652

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
01# 口罩Mask-浅紫色-Light Purple						
外观要求 Appearance Requirement	/	/	口罩表面不应有破损、油污斑渍、变形及其他明显的缺陷。The mask surface shall have no damage, oil stain, deformation and other obvious defects.	+	符合 Pass	GB/T 32610-2016
02# 口罩Mask-浅绿色-Light Green						
甲醛含量 Formaldehyde Content	/	mg/kg	≤20	未检出 (低于检出限20mg/kg) Undetected (< 20mg/kg)	符合 Pass	GB/T 2912.1-2009
03# 口罩Mask-紫色- Purple						
过滤效率（III级） Filtration Efficiency （Grade III）	盐性介质 Salt Medium	%	≥90	未预处理样品 Samples Without Pretreatment 1：99.6 2：99.7 3：99.7 4：99.6 5：99.6 预处理样品 Samples With Pretreatment: 1：99.3 2：99.2 3：99.3 最小值Minimum：99.2	符合 Pass	GB/T 32610-2016

检验检测报告
Test Report

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检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
过滤效率（III级） Filtration Efficiency （Grade III）	油性介质 Oil Medium	%	≥80	未预处理样品 Samples Without Pretreatment: 1：91.7 2：90.2 3：91.6 4：91.4 5：90.6 预处理样品 Samples With Pretreatment: 1：88.0 2：87.2 3：87.6 最小值Minimum：87.2	符合 Pass	GB/T 32610-2016
04# 口罩Mask-蓝色-Blue						
pH值 pH Value	氯化钾萃取 KCl Extract	/	4.0～8.5	6.4	符合 Pass	GB/T 7573-2009
05# 口罩Mask-棕色- Brown						
耐摩擦色牢度 Colour Fastness to Rubbing	干摩 Dry	级 Grade	≥4	4-5	符合 Pass	GB/T 29865-2013
耐摩擦色牢度 Colour Fastness to Rubbing	湿摩 Wet	级 Grade	/	4-5	/	GB/T 29865-2013
06# 口罩Mask-黄色- Yellow						
可分解致癌芳香胺染料 Azo	/	mg/kg	禁用 Not Used	未检出 (低于检出限5mg/kg) Undetected (＜ 5mg/kg)	符合 Pass	GB/T 17592-2011
07# 口罩Mask-粉色-Pink						
环氧乙烷残留量 Ethylene Oxide Residual	/	μg/g	≤10	未检出 (低于检出限2μg/g) Undetected (＜ 2μg/g)	符合 Pass	GB/T 14233.1-2008
08# 口罩Mask-红色- Red						
吸气阻力 Inspiratory Resistance	/	Pa	≤175	未预处理样品 Samples Without Pretreatment: 1：63 2：57 预处理样品 Samples With Pretreatment: 1：81 2：65	符合 Pass	GB/T 32610-2016

检验检测报告
Test Report

TTTS-FH21002652

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
09# 口罩Mask-浅蓝色-Light Blue						
呼气阻力 Expiratory Resistance	/	Pa	≤145	未预处理样品 Samples Without Pretreatment: 1：46 2：39 预处理样品 Samples With Pretreatment: 1：43 2：48	符合 Pass	GB/T 32610-2016
10# 口罩Mask-绿色- Green						
甲醛含量 Formaldehyde Content	/	mg/kg	≤20	未检出 (低于检出限20mg/kg) Undetected (＜ 20mg/kg)	符合 Pass	GB/T 2912.1-2009

表中“+”为符合标准要求，“×”表示不符合标准要求。
+ Meet the standard requirements, X Not Meet the standard requirements.

样　品　Sample

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/16062020.20

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

Huizhou Bowen Manufacturing Limited
Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County,
Huizhou City, Guangdong Province, P.R.China

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/1437/2020**

CE

Issued on: 16/06/2020

Valid until: 24/05/2022

Authorized Signatory
CMC Medical Devices & Drugs SL

EC REP CERTIFICATE

ANNEX I Medical Device Products

Kaze Disposable Face Mask

CE

CE Declaration of Conformity

Manufacturer: SRN:	Huizhou Bowen Manufacturing Limited Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China Tel:+86-752-5895333 /
European Representative: SRN:	CMC Medical Devices & Drugs S.L. Horacio Lengo Nº 18, CP 29006, Málaga, Spain /
Product Name: Specification: UMDN Code:	Kaze Disposable Face Mask 20.5cm×8.3cm 12-458
Classification (MDR, Annex VIII): Class I, Rule 1. Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.	
We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the Huizhou Bowen Manufacturing Limited .is exclusively responsible for the declaration of conformity.	
General applicable regulations, directives: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.	
Applied standards, common specification, guidance: EN 14683:2019+AC:2019, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ASTM D4169-2016, MDCG 2019-15.	
Signature: Name: Wun Chun Hung Position: General Manager	Date: 26 May, 2020

191020340175

中国认可
国际互认
检测
TESTING
CNAS L13034

In Vitro Cytotoxicity Test

MTT Method

Final Report

Verification

Report Number: CSTBB20100408

Article Name: Kaze Disposable Face Mask

Method Standard: ISO 10993-5：2009

Sponsor

Huizhou Bowen Manufacturing Limited

Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China

Test Facility

CCIC Huatongwei international inspection (Suzhou) Co., Ltd

Room 101, Building G, Ruoshui Road 388, Suzhou, Jiangsu, China

CONTENTS

Notices

1. Please apply for rechecking within 15 days of receiving the report if there is any objection.
2. Any erasure or without special testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The report is only responsible for the test results of the tested samples.
5. The report shall not be reproduced except in full without the written approval of the company.

Abstract

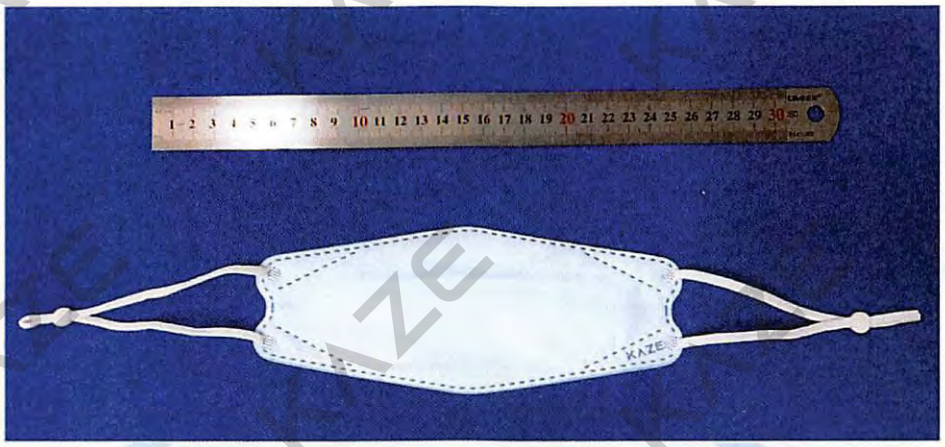
In this study, mammalian L-929 cells were cultured in vitro according to ISO 10993-5:2009 to test the potential cytotoxicity of the test article.

The test articles and the control material were separately placed in MEM medium containing 10% fetal bovine serum, and extracted in a 37 ℃ incubator for 24 hours. After the end of the extraction, the cell culture medium in the 96-well plate (10^4 cells/well) cultured for 24 hours was removed and replaced with the corresponding extract, cultured in 37 ℃, 5% CO_2, >90% humidity for 24 hours. After the culture, the morphology and cell lysis of the cells were observed under the microscope, and the cytotoxicity of the test samples was determined by MTT assay.

The results showed that the cells in the blank control group and the negative control group (high density polyethylene) were well-formed throughout the experiment and showed no cytotoxic reaction. A severe cytotoxic response was shown in the positive control group (ZDEC). The 100% concentration of the test extract retained a normal appearance after 24 hours of incubation, and the cell viability was 86.6%. The data of each group met the acceptance criteria, and the results of this test were valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article have no potential toxicity to L-929 in the MTT method.

Study Verification and Signature



Protocol Number	SST2010021601BB
Protocol Effective Date	2020-10-29
Technical Initiation Date	2020-10-30
Technical Completion Date	2020-11-04
Final Report Completion Date	2020-12-14

Personnel Betty 2020-12-14
Date Completed

Approved
Study Director 2020-12-14
Date Completed

Supervisory
Test Facility Manager 2020-12-14
Date Completed

CCIC Huatongwei international inspection (Suzhou) Co., Ltd.

1.0 Purpose

The purpose of the test is to determine the potential cytotoxicity toxicity of a mammalian cell culture (mouse fibroblast L-929 cells) in response to the test article.

2.0 Reference

Biological evaluation of medical devices-Part 5: Tests for In Vitro Cytotoxicity (ISO 10993-5：2009)

Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12：2012)

3.0 Test and control articles

Groups	Test article	Negative Control Article	Positive Control Article	Blank Control
Name	Kaze Disposable Face Mask	High Density Polyethylene Film	ZDEC	MEM medium, with addition 10% FBS
Manufacture	Huizhou Bowen Manufacturing Limited	Hatano Research Institute. FDSC	Sigma-Aldrich.	Hyclone
Size	205mm * 83mm	3 cm×10 cm (5 sheets)	25 g	500 ml
Model	KAZE-04	/	/	/
Lot Batch#	2020/10/1	C-161	BCBQ6847V	AF29549370
Test Article Material	Color non-woven fabric 25%; melt blown fabric 20%; skin friendly non-woven fabric 25%; ear thread 18%, nose clip 12%	/	/	/
Physical State	Solid	Solid	Solid	Liquid
Color	Light Blue	White	White	Pink
Packaging Material	Biodegradable OPP/VMPET/CPP Card Box, Carton	/	/	/
Sterilized or Not	No	No	No	Yes
Concentration	/	/	0.1%	/
Total Surface or weight	170 cm^2	/	/	/
Storage Condition	Room Temp.	Room Temp.	Room Temp.	4℃
Note：The information about the test article was supplied by the sponsor wherever applicable.				

4.0 Identification and justification of test system

L-929 mouse fibroblast cells obtained from American Type Culture Collection (ATCC).

L-929 cells have been used for cytotoxicity studies because they demonstrate sensitivity to extractable

cytotoxic articles. Also, the test article is extracted and administered in vitro to mouse fibroblast L929 cells through a solvent compatible with the test system, which is the optimal route of administration available in this test system as recommended in ISO 10993-5.

5.0 Equipment and reagents

5.1 Instruments

Vertical pressure steam sterilizer (SHB026), Ethylene oxide sterilizer (SHB109), CO_2 Incubator (SHB002), Steel Straight Scale (SHB076), Electronic Balance (SHB016), Clean bench (SHB014), Multiskan Spectrum Microplate Spectrophotometer (SHB003), Bench type low speed centrifuge (SHB022), Inverted microscope (SHB005)

5.2 Reagents

MEM (Hyclone, AF29549370), FBS (Clark, JC65941), Penicillin-Streptomycin (Gibco, 2145469), Tryps in (Gibco, 2120734), PBS (meilunbio, MA0015-Dec-19E1), MTT (3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyle trazolium bromide) (Sigma, MKBG2038V), Isopropyl alcohol (Macklin, C10954717)

6.0 Experiment design and dose

6.1 Sample preparation

According to the table below, aseptic extraction of the test article sealed and incubated in MEM medium (10% FBS) at 37 ℃, 5% CO_2 and 60 rpm for 24 hours.

Groups	Sampling		Sterilization	Aseptic Extraction In Inert Container				Final Extract
	Sampling Manner	Actually sampling	Method	Ratio	Extracts	Condition	pH	Clear or Not
Test article	Whole	340.0 cm^2	EO	6 cm^2: 1 ml	56.7 ml	37 ℃ 24 h	7.4	Clear
Negative Control	Random	60.0 cm^2	EO	3 cm^2: 1 ml	20.0 ml	37 ℃ 24 h	7.4	Clear
Positive Control	Random	0.02 g	/	0.1 g: 100 ml	20.0 ml	37 ℃ 24 h	7.4	Clear
Blank Control	/	/	/	/	20.0 ml	37 ℃ 24 h	7.4	Clear

The changes of the leaching solution was observed after extraction. No particulates or color changes were observed in pre- and post-extraction, and the extract were immediately be used in the follow-up experiment after leaching. The color and pH of the extraction solution did not change before and after use, and the pH value was 7.4 after leaching.

6.2 Test method

Aseptic procedures were used for handling cell cultures. L-929 cells were cultured in MEM medium (10% FBS, 1% Penicillin-Streptomycin solution) at 37 ℃ in a humidified atmosphere of 5% CO_2, then digested by 0.25% trypsin containing EDTA to get single cell suspension. 1×10^5 cells/ml suspension were obtained by centrifuging (1000 rpm, 5 min) and re-dispersing in MEM medium.

The suspended cells were dispensed at 100 μl per well in 96-well plate, and cultured in cell incubator (5% CO_2,

37 ℃, >90% humidity). Cell morphology was evaluated to verify that the monolayer was satisfactory.

After the cells grew to about 70% and form a monolayer, original culture medium was discarded. The 96-well plates were then treated with 100 µl of extract of test article (100%、75%、50%、25%), control article, negative article and positive article respectively. The 96-well plate was incubated at 37 ℃ in cell incubator of 5% CO_2 for 24 h. Six replicates of each test were tested.

After incubation, observe the cell morphology first and then discard the culture medium. Add 50 µl MTT (1mg/ml) to each well and then incubated at 37 ℃ in a humidified atmosphere of 5% CO_2 for 2 hours. The liquid in each well was tipped out and 100 µl Isopropyl alcohol was added to each well to suspend the cell layer.

Evaluate the suspension above with a dual-wavelength spectrophotometer with the measurement wavelength at 570 nm.

7.0 Statistical method

Mean±standard deviation ($\bar{x}\pm s$)

The cell cytotoxicity ratio = OD_{570} of test (or positive or negative) article group/ OD_{570} of blank control group×100%.

8.0 Evaluation criteria

8.1 The 50% extract of the test article should have at least the same or a higher viability than the 100% extract. Otherwise the test should be repeated.

8.2 The lower the Viab.% value, the higher the cytotoxic potential of the test article is.

8.3 If viability is reduced to < 70% of the blank, it has a cytotoxic potential.

8.4 The Viab.% of the 100% extract of the test article is the final result.

9.0 Results of the test

9.1 Results of the cell morphology

Table 1 Observation of the cell morphology

Group	Before inoculation	Before treated with extract	24 h after treatment
Blank control	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
Negative control			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
Positive control			Nearly complete or complete destruction of the cell layers.
100% Test article extract			The cells showed a round shape and a change in cell morphology occasionally, and there were particles in the cytoplasm, occasionally cell lysis and slight growth inhibition.
75% Test article extract			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.

50% Test article extract			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
25% Test article extract			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.

9.2 Results of the cell vitality

Table2 Results of the cell vitality

Group	OD value								Viab. (%)
	1	2	3	4	5	6	$\bar{x}$	s	
Blank control	0.618	0.613	0.618	0.625	0.613	0.623	0.618	0.005	100.0
Negative control	0.612	0.617	0.610	0.618	0.633	0.625	0.619	0.009	100.2
Positive control	0.059	0.059	0.060	0.058	0.055	0.055	0.058	0.002	9.3
100% test article extract	0.533	0.545	0.547	0.526	0.532	0.527	0.535	0.009	86.6
75% test article extract	0.578	0.572	0.572	0.570	0.572	0.568	0.572	0.003	92.6
50% test article extract	0.591	0.585	0.580	0.584	0.593	0.582	0.586	0.005	94.7
25% test article extract	0.605	0.604	0.611	0.612	0.617	0.613	0.610	0.005	98.7

10.0 Conclusion

Under the conditions of this study, the test article have no potential toxicity to L-929 cells.

11.0 Record

All raw data pertaining to this study and a copy of the final report are to be stored in the designated archive files at Huatongwei.

12.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

191020340175

中国认可
国际互认
检测
TESTING
CNAS L13034

Skin Sensitization Test

Guinea Pig Maximization

Final Report

Verification

Report Number: CSTBB20100414

Article Name: Kaze Disposable Face Mask

Method Standard: ISO 10993-10: 2010

Sponsor

Huizhou Bowen Manufacturing Limited

Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China

Test Facility

CCIC Huatongwei international inspection (Suzhou) Co., Ltd

Room 101, Building G, Ruoshui Road 388, Suzhou, Jiangsu, China

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Notices

1. Please apply for rechecking within 15 days of receiving the report if there is any objection.
2. Any erasure or without special testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The report is only responsible for the test results of the tested samples.
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Abstract

In this study, we took guinea pigs to observe the skin sensitization of the test article according to ISO 10993-10: 2010.

The test article were extracted in Constant Temperature Vibrator at 50 ℃, 60 rpm for 72 h by 0.9 % Sodium Chloride Injection and Sesame Oil. Mix 50:50 (by volume) stable emulsion of Freund's complete adjuvant with selected solvent. Intradermal induction and topical induction were operated in the clipped intrascapular region of each animal. After the topical induction phase was completed on day 14, all test and control animals were challenged with the test sample. The erythema and edema of the challenge site were observed to test the sensitization response of the test article. According to the Magnusson and Kligman scales, the response to erythema and edema at each application site of the skin was described and scored 24 hours and 48 hours after the challenge phase.

The results showed that the guinea pigs in the negative control group (0.9 % Sodium Chloride Injection, Sesame Oil) retained a normal appearance throughout the test and showed no skin irritants. A severe skin reactions for erythema and oedema were shown in the positive control group (DNCB). While in test article group, the response of skin on testing side did not exceed that on the control side. The skin reactions for erythema and oedema were not observed in test article group. The data of each group met the acceptance criteria, and the results of this test were considered valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article has no potential skin sensitization on guinea pigs in the extraction method.

Study Verification and Signature

Protocol Number	SST2010021602BB
Protocol Effective Date	2020-10-29
Technical Initiation Date	2020-10-30
Technical Completion Date	2020-11-27
Final Report Completion Date	2020-12-14

Personnel Betty 2020-12-14
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Approved
Study Director
2020-12-14
Date Completed

Supervisory
Test Facility Manager
2020-12-14
Date Completed

CCIC Huatongwei international inspection (Suzhou) Co., Ltd.

1.0 Purpose

The test was designed to evaluate the potential of a test article to cause skin sensitization. The test is used as a procedure for screening of contact allergens in guinea pigs and extrapolating the results to humans, but it does not establish the actual risk of sensitization.

2.0 Reference

Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization (ISO 10993-10: 2010)

Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2012)

Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

3.0 Test and control articles

Groups	Test article	Negative Control Article(Polar)	Negative Control Article(Non-Polar)	Positive Control
Name	Kaze Disposable Face Mask	0.9% Sodium Chloride Injection(SC)	Sesame Oil (SO)	2, 4-Dinitrochlorobenzene (DNCB)
Manufacture	Huizhou Bowen Manufacturing Limited	Guangxi Yuyuan Pharmaceutical Co., Ltd	Ji'an Lv yuan natural flavor oil refinery, Qingyuan District	TOKYO CHEMICAL INDUSTRY CO., LTD
Size	205mm * 83mm	500 ml	5L	25 g
Model	KAZE-04	/	/	/
Lot Batch#	2020/10/1	H20070606	20200528	H2UKD-DM
Test Article Material	Color non-woven fabric 25%; melt blown fabric 20%; skin friendly non-woven fabric 25%; ear thread 18%, nose clip 12%	/	/	/
Physical State	Solid	Liquid	Liquid	Solid
Color	Light Blue	Colorless	Light yellow	Light yellow
Package material	Biodegradable OPP/VMPET/CPP Card Box, Carton	/	/	/
Sterilized or Not	No	/	/	/
Concentration	/	0.9 %	/	Induction Concentration: 0.5 %

				Challenge Concentration: 0.1 % Dissolved in ethanol
Total Surface/Weight	170 cm^2	/	/	/
Storage Condition	Room Temp.	Room Temp.	Room Temp.	Room Temp.
The information about the test article was supplied by the sponsor wherever applicable.				

4.0 Identification of test system

4.1 Test animal

Species: Hartley Guinea Pig (Cavia Porcellus)

Number: 30 (20 Test +10 Control)

Sex: either sex

Initial body weight: 300.0~500.0 g

Health status: Healthy, not previously used in other experimental procedures. Female animals were nul liparous and not pregnant.

Animal identification: Ear tag

Cages: Plastic cage

Acclimation Period: 7 days under the same conditions as for the actual test

4.2 Justification of test system

The albino guinea pig has been used historically for sensitization studies (Magnusson and Kligman, 1 970). The guinea pig is believed to be the most sensitive animal model for this type of study. DNCB is the positive control article recommended in the test instructions. To ensure the sensitivity of the experime ntal system, the positive control article should be verified every three months.

5.0 Animal Management

Animal purchase: Wuxi hengtai experimental animal breeding co. LTD SCXK (SU) 2020-0003

Bedding: Corncob, Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd.

Feed: Guinea pigs were fed with full-price pellets, Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd.

Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006

Animal room temperature: 18-26 ℃

Animal room relative humidity: 30 %-70 %

Lights: 12 hours light/dark cycle, full-spectrum lighting

Personnel: Associates involved were appropriately qualified and trained

Selection: Only healthy, previously unused animals were selected

There were no known contaminants present in the feed, water, or bedding expected to interfere with the test data.

6.0 Equipment and reagents

6.1 Instruments

Constant Temperature Vibrator (SHB007, calibration data: 2020/3/16), Autoclave (SHB026, calibration data:

2020/3/16), Electronic scale (SHB017, calibration data: 2020/3/16)

6.2 Reagents

Freund's adjuvant Complete liquid (SIGMA, Lot No: SLCD4457), Sodium dodecyl sulfate (SDS SIGMA, Lot No: SLBL2304V)

7.0 Experiment design

7.1 Sample preparation

The extracts of test article will be prepared according to the following steps:

Aseptic Sampling			Extraction in sterile vessels				
Sampling Manner	Actually sampling	Ratio	Reagent		Temperature	Time	pH
Whole	340.0 cm^2	6 cm^2: 1 ml	SC	56.7 ml	50 ℃	72 h	5.5
	340.0 cm^2		SO	56.7 ml		72 h	/

Both inducements and excitations were prepared by the number of times. The state of the leaching solution did not change visually after the leaching was advanced. After extraction, the samples were stored at room temperature for no more than 24 h. The extraction solution is clear, and the pH value has not been adjusted, filtered, centrifuged, diluted and other processes. The control solution was prepared under the same conditions.

7.2 Test method

7.2.1 Intradermal induction phaseI

A pair of 0.1ml intradermal injections was made for each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.

Site A: A 50:50 (volume ratio) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent.

Site B: The test sample (undiluted extract); the control animals were injected with the solvent alone.

Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent (50 %); the control animals were injected with an emulsion of the blank liquid with adjuvant.

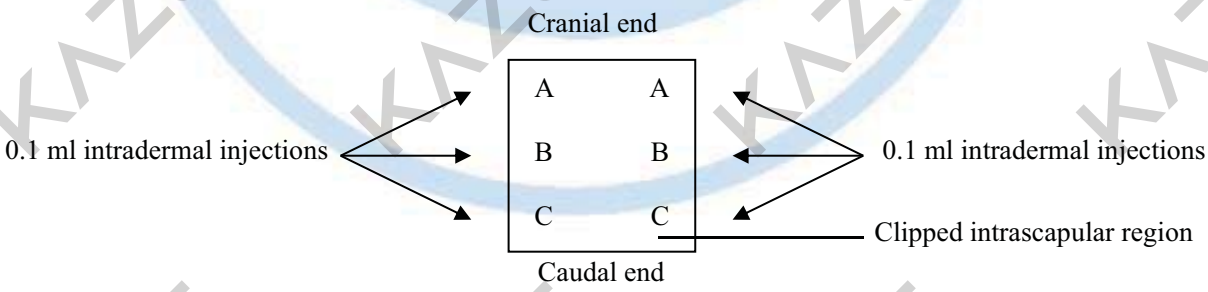

Figure 1 Location of intradermal injection sites

7.2.2 Topical induction phaseII

The maximum concentration that can be achieved in Intradermal induction phase Ⅰ did not produce irritation, animals are pretreated with 10% sodium dodecyl sulfate 24(±2) hours before the topical induction application.

At 7 d after completion of the intradermal induction phase, administer test article extract by topical application to the intrascapular region of each animal, using a patch of area approximately 8 cm^2 (absorbent gauze), so as to

cover the intradermal injection sites. Secure the patches with an occlusive dressing. Remove the dressings and patches after (48±2) h.

Treat the control animals similarly, using the blank liquid alone.

7.2.3 Challenge phase

At 14d after completion of the topical induction phase, challenge all test and control animals with the test sample. Fourteen days after removal of induction patches, the right and left flank areas of each guinea pig are to be shaved or clipped prior to the test extract for convenience of dermal score. Absorbent gauzes (2.5 cmx2.5 cm) were soaked respectively with test article and control article. Apply the test article extract and control article topically to two sites that were not treated during the induction stage. Secure with an occlusive dressing. Remove the dressings and patches after (24±2) h.

8.0 The results observed

The day after challenge exposure, the patch will be removed and the area cleaned gently with gauze if necessary. The site will be wiped gently with a 0.9 % saline soaked gauze sponge prior to each scoring period. The challenge sites will be observed for signs of irritation and sensitization reaction, as indicated by erythema and edema. If necessary, the fur will be shaved or clipped in advance for the convenience of dermal score.

Daily challenge observation scores will be recorded approximately 24, and 48 hours after patch removal in accordance with the following classification system for skin reactions:

Table 1 Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

9.0 Evaluation criteria

Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals.

If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization.

If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge.

The outcome of the test is presented as the frequency of positive challenge results in test and control animals.

10.0 Results of the test

All animals were survived and no abnormal signs were observed during the study.Individual results of dermal scoring for the challenge appear in Table 2.

11.0 Conclusion

The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor’s responsibility.

12.0 Record

All raw data pertaining to this study and a copy of the final report are retained in designated Huatongwei archive.

13.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

Table 2 Guinea pig Sensitization Dermal Reactions

Group		No.	Pretest weight(g)	Finished weight(g)	The Challenge patch was removed 24h later		The Challenge patch was removed 48h later		Positive rate
					Erythema	Swelling	Erythema	Swelling	
SC	Test	1	304.4	370.4	0	0	0	0	0%
		2	316.9	363.7	0	0	0	0	
		3	310.4	371.6	0	0	0	0	
		4	306.0	367.2	0	0	0	0	
		5	310.2	382.6	0	0	0	0	
		6	313.1	358.0	0	0	0	0	
		7	317.2	362.9	0	0	0	0	
		8	302.4	353.2	0	0	0	0	
		9	303.1	365.4	0	0	0	0	
		10	315.0	376.0	0	0	0	0	
	Control	11	316.6	374.2	0	0	0	0	0%
		12	313.3	361.0	0	0	0	0	
		13	305.5	380.3	0	0	0	0	
		14	315.0	353.4	0	0	0	0	
		15	303.1	354.8	0	0	0	0	
SO	Test	16	302.7	364.7	0	0	0	0	0%
		17	314.4	374.2	0	0	0	0	
		18	306.1	360.7	0	0	0	0	
		19	316.4	362.3	0	0	0	0	
		20	318.8	384.6	0	0	0	0	
		21	304.9	359.8	0	0	0	0	
		22	318.0	365.0	0	0	0	0	
		23	312.0	366.5	0	0	0	0	
		24	314.6	357.8	0	0	0	0	
		25	306.6	363.5	0	0	0	0	
	Control	26	304.1	380.8	0	0	0	0	0%
		27	316.6	386.2	0	0	0	0	
		28	303.9	364.9	0	0	0	0	
		29	314.0	384.6	0	0	0	0	
		30	318.0	354.6	0	0	0	0	

Table 3 Positive control

Group	No.	Pretest weight(g)	Finished weight(g)	The Challenge patch was removed 24 h later		The Challenge patch was removed 48 h		Positive rate
				Erythema	Swelling	Erythema	Swellin	
Test	1	309.8	354.0	1	0	1	0	100%
	2	307.2	352.1	2	0	2	0	
	3	306.3	360.2	1	0	1	0	
	4	314.1	382.9	1	0	1	0	
	5	307.1	351.0	1	0	2	0	
	6	318.7	352.9	1	0	2	0	
	7	312.1	374.0	1	0	1	0	
	8	310.4	358.6	1	0	1	0	
	9	303.3	366.1	2	0	2	0	
	10	308.7	354.2	1	0	2	0	
Control	11	312.9	353.0	0	0	0	0	0%
	12	307.7	359.0	0	0	0	0	
	13	303.7	353.7	0	0	0	0	
	14	307.9	372.3	0	0	0	0	
	15	310.8	380.9	0	0	0	0	

Note：The positive control was CSTBB20080001P1 (Finish date：2020-09-11)

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TESTING
CNAS L13034

Skin Irritation Test

Extraction Method

Final Report

Verification

Report Number: CSTBB20100415

Article Name: Kaze Disposable Face Mask

Method Standard: ISO 10993-10: 2010

Sponsor

Huizhou Bowen Manufacturing Limited

Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China

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Abstract

In this study, we took New Zealand white Rabbits to observe the skin irritation of the test article according to ISO10993-10:2010.

The test article were extracted in Constant Temperature Vibrator at 50 ℃, 60 rpm for 72 h by 0.9 % Sodium Chloride Injection and Sesame Oil. Apply 0.5 ml extracts of test article or control to 2.5 cm×2.5 cm absorbent gauze patches, and then apply the patch soaked with the extract of test article or control directly to the skin on each side of each rabbit, and then wrap the application sites with a bandage for a minimum of 4 h. At the end of the contact time, remove the dressing. The describe and score the skin reaction for erythema and oedema for each application site at each time interval. Record the appearance of each application site at (1±0.1) h, (24±2) h, (48±2) h and (72±2) h following removal of the patches.

The results showed that the rabbits in the negative control group (0.9 % Sodium Chloride Injection, Sesame Oil) retained a normal appearance throughout the test and showed no skin irritants. A severe skin reactions for erythema and oedema were shown in the positive control group (SDS). While in test article group, the response of skin on testing side did not exceed that on the control side. The skin reactions for erythema and oedema were not observed in test article group. The data of each group met the acceptance criteria, and the results of this test were considered valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article has no potential skin irritation on rabbit in the extraction method.

Study Verification and Signature

Protocol Number	SST2010021603BB
Protocol Effective Date	2020-10-29
Technical Initiation Date	2020-10-30
Technical Completion Date	2020-11-06
Final Report Completion Date	2020-12-14

Personnel Betty 2020-12-14
Date Completed

Approved
Study Director 2020-12-14
Date Completed

Supervisory
Test Facility Manager 2020-12-14
Date Completed

CCIC Huatongwei international inspection (Suzhou) Co., Ltd.

1.0 Purpose

To evaluate the potential skin irritation caused by test article contact with the skin surface of rabbits and extrapolating the results to humans, but it does not establish the actual risk of irritation.

2.0 Reference

Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization (ISO 10993-10: 2010)

Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2012)

Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

3.0 Test and control articles

Groups	Test article	Negative Control Article(Polar)	Negative Control Article(Non-Polar)	Positive Control
Name	Kaze Disposable Face Mask	0.9% Sodium Chloride Injection(SC)	Sesame Oil (SO)	10 % sodium dodecyl sulfate (SDS)
Manufacture	Huizhou Bowen Manufacturing Limited	Guangxi Yuyuan Pharmaceutical Co., Ltd	Ji'an Lv yuan natural flavor oil refinery, Qingyuan District	SIGMA
Size	205mm * 83mm	500 ml	5L	25 g
Model	KAZE-04	/	/	/
Lot Batch#	2020/10/1	H20070606	20200528	SLBL2304V
Test Article Material	Color non-woven fabric 25%; melt blown fabric 20%; skin friendly non-woven fabric 25%; ear thread 18%, nose clip 12%	/	/	/
Physical State	Solid	Liquid	Liquid	Solid
Color	Light Blue	Colorless	Light yellow	Colorless
Package material	Biodegradable OPP/VMPET/CPP Card Box, Carton	/	/	/
Sterilized or Not	No	/	/	/
Concentration	/	0.9 %	/	10 %
Total Surface/Weight	170 cm^2	/	/	/

Storage Condition	Room Temp.	Room Temp.	Room Temp.	Room Temp.
The information about the test article was supplied by the sponsor wherever applicable.				

4.0 Identification of test system

4.1 Test animal

Species: New Zealand white Rabbit

Number: 6

Sex: either sex

Weight: >2 kg

Health status: Healthy, not previously used in other experimental procedures. Female animals were nul liparous and not pregnant.

Animal identification: Ear tattoo

Cages: Stainless steel cage

Acclimation Period: 7 days under the same conditions as for the actual test

4.2 Justification of test system

The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the c urrent testing standards. Positive control 10% sodium dodecyl sulfate has been substantiated at HTW with this method.

5.0 Animal Managment

Animal purchase: Wuxi hengtai experimental animal breeding co. LTD SCXK (SU) 2020-0003

Feed: Experimental rabbits were fed a maintenance diet, Wuxi hengtai experimental animal breeding co. LTD

Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006

Animal room temperature: 18-26 ℃

Animal room relative humidity: 30 %-70 %

Lights: 12 hours light/dark cycle, full-spectrum lighting

Personnel: Associates involved were appropriately qualified and trained

Selection: Only healthy, previously unused animals were selected

There were no known contaminants present in the feed, water, or bedding expected to interfere with the test data

6.0 Equipment and reagents

6.1 Instruments

Constant Temperature Vibrator (SHB007, calibration data: 2020/3/16), Electronic scale (SHB020, calibration data: 2020/3/16)

7.0 Experiment design

7.1 Sample preparation

The extracts of test article will be prepared according to the following steps:

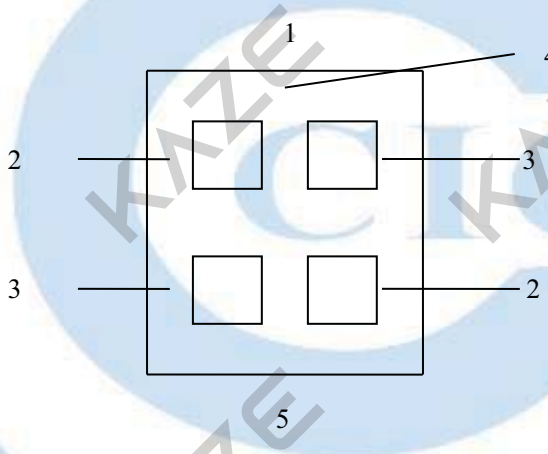
Aseptic Sampling			Extraction in sterile vessels				
Sampling Manner	Actually sampling	Ratio	Reagent		Temperature	Time	pH
Whole	340.0 cm^2	6 cm^2: 1 ml	SC	56.7 ml	50 ℃	72 h	5.5
	340.0 cm^2		SO	56.7 ml		72 h	/

The state of the leaching solution did not change visually after the leaching was advanced. The extractions were clear, and the pH value has not been adjusted, filtered, centrifuged, diluted and other processes, before dosing stored at room temperature no more than 24 h. The control solution was prepared under the same conditions

7.2 Test method

Use the rabbits with healthy intact skin. Fur was generally clipped within 24 h period before testing on the backs of the rabbits, a sufficient distance on both sides of the spine for application and observation of all test sites (approximately 10×15 cm).

Apply 0.5 ml extract (s) of test article or control to 2.5 cm×2.5 cm absorbent gauze patches, and then apply the patch soaked with the extract of test article or control directly to the skin on each side of each rabbit as shown in Figure 1, and then wrap the application sites with a bandage (semi-occlusive or occlusive) for a minimum of 4h. At the end of the contact time, remove the dressing.



1- Cranial end, 2- Test site, 3- Control site, 4- Clipped dorsal region, 5- Caudal end

Figure1 Location of skin application sites

8.0 The results observed

The Describe and score the skin reaction for erythema and oedema according to the scoring system given in Table 1 for each application site at each time interval. Record the appearance of each application site at (1±0.1) h, (24±2) h, (48±2) h and (72±2) h following removal of the patches.

Table 1 Classification System for Skin Reaction

Erythema and Eschar Formation:	Numerical Grading
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3

Severe erythema (beet redness) to eschar formation preventing grading of erythema	4
Edema Formation:	
No edema	0
Very slight edema (barely perceptible)	1
Well-defined edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond exposure area)	4
Maximal possible score for irritation	8
Irritation Response Categories in the Rabbit	
Response Category	Mean score
Negligible	0 to 0.4
Slight	0.5 to 1.9
Moderate	2 to 4.9
Severe	5 to 8

9.0 Evaluation criteria

Use only (24±2) h, (48±2) h and (72±2) h observations for calculation.

After the 72 h grading, all erythema grades plus oedema grades (24±2) h, (48±2) h and (72±2) h were totalled separately for each test article and blank for each animal. The primary irritation score for an animal was calculated by dividing the sum of all the scores by 6 (two test/observation sites, three time points).

To obtain the primary irritation index for the test article, add all the primary irritation scores of the individual animals and divide by the number of animals.

When blank or negative control was used, calculate the primary irritation score for the controls and subtract that score from the score using the test material to obtain the primary irritation score.

10.0 Results of the test

All animals were survived and no abnormal signs were observed during the study. According to what observed, the response of skin on testing side did not exceed that on the control side. Thus, the primary irritation index for the test article was calculated to be 0. See table 2.

11.0 Conclusion

The test result showed that the response of the test article extract was categorized as negligible under the test condition.

12.0 Record

All raw data pertaining to this study and a copy of the final report are retained in designated Huatongwei archive.

13.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

Table 2 Skin irritation response observation

Reagent	Rabbit No	Pretest weight(kg)	Finished weight(kg)	Group	Reaction	Interval (hours): score=left/right			
						1±0.1 h	24±2 h	48±2 h	72±2 h
SC	1	2.17	2.29	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	2	2.06	2.19	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	3	2.14	2.26	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
Primary irritation index						0			
SO	4	2.20	2.33	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	5	2.18	2.29	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	6	2.12	2.25	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
Primary irritation index						0			

Table 3 Positive control

Rabbit No	Group	Reaction	Interval (hours): score=left site/right site			
			1±0.1 h	24±2 h	48±2 h	72±2 h
1	Positive control	Erythema	0/1	2/1	2/3	3/3
		Oedema	1/0	2/2	3/2	4/3
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
2	Positive control	Erythema	0/0	1/2	3/3	4/4
		Oedema	1/1	3/2	3/4	3/4
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
3	Positive control	Erythema	1/1	2/3	4/3	4/4
		Oedema	1/0	2/2	4/4	4/3
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
Primary irritation index			5.8			

Positive control performed once every six months see CSTBB20070001P3(Finish date：2020-07-31)