## Kaze Disposable Face Mask

## Light

## Certificate and test reports

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ISO 10993-10:2010 - CSTBB20100415



Sponsor: Michael Wong Huizhou Bowen Manufacturing Ltd. Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County Huizhou City, Guangdong Province

### 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

> Nelson Laboratories, LLC Testing Facility:

> > 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 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<sup>3</sup> colony forming units (CFU) with a mean particle size (MPS) of  $3.0 \pm 0.3 \mu m$ . The aerosols were drawn through a sixstage, 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  $\sim 40 \text{ cm}^2$ BFE Test Area:

28.3 Liters per minute (L/min) BFE Flow Rate: 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

 $2.4 \times 10^{3}$  CFU Positive Control Average: Negative Monitor Count: <1 CFU

> MPS: 2.9 µm





James Luskin electronically approved

Study Director

James Luskin

14 Sep 2020 17:48 (+00:00) Study Completion Date and Time

801-290-7500 nelsonlabs.com sales@nelsonlabs.com FRT0004-0001 Rev 22



#### Results:

Test Article Number	er	Percent BFE (%)	
1		>99.9 <sup>a</sup>	>
2		>99.9	
3		>99.9 <sup>a</sup>	
4		>99.9	
5	$A \bigvee$	>99.9	

<sup>&</sup>lt;sup>a</sup> There were no detected colonies on any of the Andersen sampler plates for this test article.

Test Article Number	Delta P (mm H <sub>2</sub> O/cm <sup>2</sup> )	Delta P (Pa/cm²)
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:

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

C = Positive control average

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





Sponsor:
Michael Wong
Huizhou Bowen Manufacturing Ltd.
Xinnan 1st Road, Xianan Village,
Yuanzhou Town, Boluo County
Huizhou City, Guangdong,
CHINA

### 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)  $\pm$  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<sup>2</sup>
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





Trang Truong electronically approved for

Study Director

Curtis Gerow

18 Sep 2020 14:58 (+00:00)

Study Completion Date and Time

801-290-7500 | nelsonlabs.com | sales@nelsonlabs.com

FRT0005-0001 Rev 7



#### 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



Sponsor:
Michael Wong
Huizhou Bowen Manufacturing Limited
Xinnan 1st Road, Xianan Village,
Yuanzhou Town, Boluo County
Huizhou City, Guangdong,
CHINA

## 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  $\Phi$ X174 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<sup>3</sup> 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<sup>2</sup>

VFE Flow Rate: 28.3 Liters per minute (L/min)

Conditioning Parameters:  $85 \pm 5\%$  relative humidity (RH) and  $21 \pm 5$ °C for a minimum of 4 hours

Positive Control Average: 1.9 x 10<sup>3</sup> PFU Negative Monitor Count: <1 PFU

MPS: 2.9 µm





Trang Truong electronically approved for

Study Director

James Luskin

24 Sep 2020 21:20 (+00:00)

Study Completion Date and Time

801-290-7500

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FRT0007-0001 Rev 16
Page 1 of 2



#### Results:

Test Article Number	Percent VFE (%)
1	99.9
2	>99.9
3	>99.9 <sup>a</sup>
4	99.9
5	>99.9 <sup>a</sup>

<sup>&</sup>lt;sup>a</sup> 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



#### SL52045312143301TX



Date: November 19,2020



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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 (Claimed Type IIR)

(A)25% Color non-woven fabric; 25% skin friendly non-woven fabric; 20%melt Composition

blown fabric; 18%ear thread, 12%nose clip

Sample Color (A)Sandy beige

KAZE-04 Style No. Lot No. 2020-10

HUIZHOU BOWEN MANUFACTURING LIMITED Manufacturer

Country of Destination United States, EUR

**Test Performed** Selected test(s) as requested by applicant

Sample Receiving Date Nov 09, 2020

Nov 09, 2020 - Nov 19, 2020 **Testing Period** 

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	(A)	
Clause 5.2 Performance Requirement		
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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Date: November 19,2020

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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<sup>2</sup>

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
	. (1)	99.9%
Destarial Filtration Efficiency	2	99.9%
Bacterial Filtration Efficiency (BFE)	3	99.9%
(DFE)	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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Date:November 19,2020

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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<sup>2</sup> Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm²)	The average value specimen (F	
	1-1	44.5		
. [ ]	1-2	52.2		
1	1-3	46.9	49	
	1-4	53.9		
	1-5	47.6		
	2-1	50.3		
	2-2	47.0		
2	2-3	48.7	48	
	2-4	51.8		
	2-5	44.6		
	3-1	55.2		
	3-2	47.3		, v
3	3-3	45.5	49	
	3-4	50.6		
	3-5	47.6		
_	4-1	49.1		
	4-2	53.9		
4	4-3	44.2	50	
	4-4	52.1		
	4-5	51.5		
	5-1	47.2		
	5-2	47.3		
5	5-3	51.7	49	
	5-4	49.9		
	5-5	51.0		

#### Remark:

1) Performance Requirement: Type I<40 Pa/cm², Type II<40 Pa/cm², Type IIR<60 Pa/cm²

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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Date: November 19,2020

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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#	5.83	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





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 (Claimed Type IIR)

(A)25% Color non-woven fabric; 25% skin friendly non-woven fabric; 20%melt Composition

blown fabric; 18%ear thread, 12%nose clip

Sample Color (A)Sandy beige Style No. KAZE-04 Lot No. 2020-10

HUIZHOU BOWEN MANUFACTURING LIMITED Manufacturer

Country of Destination United States, EUR

**Test Performed** Selected test(s) as requested by applicant

Sample Receiving Date Nov 09, 2020

Nov 09, 2020 - Nov 19, 2020 **Testing Period** 

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	(A)	
Clause 5.2 Performance Requirement		
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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Date: November 19,2020

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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	Penetration on	Conclusion	Test	Penetration on	Conclusion
Specimen#	inside surface		Specimen#	inside surface	
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:			3	32	
Overal	l result:		Acce	ptable	
12 13 14 15 16 Number	None Seen None Seen None Seen None Seen None Seen of Pass:	Pass Pass Pass Pass	28 29 30 31 32	None Seen None Seen None Seen None Seen None Seen	Pass Pass Pass Pass

#### 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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\*\*\*End of Report\*\*\*



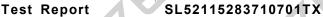
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Date: July 27,2021



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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)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<sup>2</sup>

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
. (/)	1	99.9%
Destarial Filtration Efficiency	2	99.9%
Bacterial Filtration Efficiency	3	99.9%
(BFE)	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<sup>2</sup> Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm²)	The average value specimen (Pa	
	1-1	54.3	- Promising	
	1-2	50.3		
1	1-3	44.1	53	
	1-4	59.9		
	1-5	54.8		
	2-1	44.8		
	2-2	43.8		
2	2-3	38.2	42	
	2-4	41.7		
	2-5	40.7		
	3-1	40.1	1	
	3-2	42.6		
3	3-3	40.1	43	
	3-4	35.9		
	3-5	53.8		
	4-1	53.2		
	4-2	51.9		
4	4-3	59.9	52	
	4-4	44.7		
	4-5	51.2		
	5-1	51.6		
	5-2	42.7		
5	5-3	46.7	48	
	5-4	49.6		
	5-5	50.8		

#### Remark:

1) Performance Requirement: Type I<40 Pa/cm<sup>2</sup>, Type II<40 Pa/cm<sup>2</sup>, Type IIR<60 Pa/cm<sup>2</sup>

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	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			
Overal	l 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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Date: August 11,2021



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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 KAZE Style No. Model No. KAZE-04 Lot No. 2021.07

Factory Huizhou Bowen Manufacturing Limited

Europe, USA Country of Destination

**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<sup>2</sup>

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
	. (1)	99.9%
Destarial Filtration Efficiency	2	99.9%
Bacterial Filtration Efficiency (BFE)	3	99.9%
(DFE)	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<sup>2</sup> Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each	The average value	
		tested area (Pa/cm²)	specimen (P	a/cm²)
	1-1	37.9		
	1-2	38.7		
1	1-3	34.3	38	
	1-4	39.8		
	1-5	39.6		
	2-1	39.5		
	2-2	38.9		
2	2-3	35.4	37	
	2-4	33.8		
	2-5	37.9		
	3-1	33.9		
	3-2	37.4		
3	3-3	30.2	35	
	3-4	39.6		
	3-5	34.7		
	4-1	36.8		
	4-2	38.7		
4	4-3	36.8	38	
	4-4	37.5		
	4-5	38.9		
	5-1	37.8		
	5-2	39.3		
5	5-3	39.7	38	
	5-4	34.7		
	5-5	38.5		

#### Remark:

1) Performance Requirement: Type I<40 Pa/cm<sup>2</sup>, Type II<40 Pa/cm<sup>2</sup>, Type IIR<60 Pa/cm<sup>2</sup>

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			
Overal	l 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)

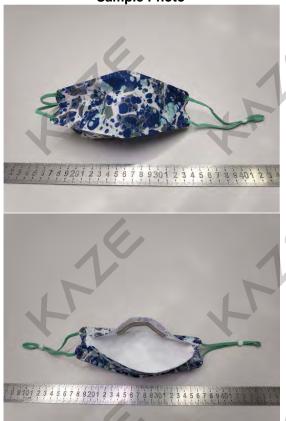
Sample: A

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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### 天纺标检测认证股份有阻公司

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



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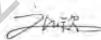
第1页 共7页 Page 1 of 7

	1113 W I		Page 1	01 (
	委托单位/地址 Applicant	惠州博文制造有限公司 送样人: Huizhou Bowen Manufacturing Limited Contact  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		
岁 岁 Client	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, Guangdong Province, P.R.China	Huizhou Ci	ty,
万提供信息及要求 Information brovided by	样品信息 Information of Submitted Sample	样品名称: Kaze 一次性口罩 商标: KAZE Sample Name Kaze Disposable Face Mask Trademark 样品总数: 50个 Sample Count 50Pieces 号型规格: 鱼形口罩	+	1
	判定标准: Test Standards	产品款号或货号: 2020-10 Style No. or Order No.  GB/T 32610-2016 日常防护型口罩技术规范 Technical specification of daily protective mask		4
T	样品描述 est Part escription	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	股份	
Т	检验性质 est Type 检验日期 est Date	委托检验 Commission Test		1-05
Tes	执行标准 st Standards 检验结论 onclusion	见附页 See next page(s)  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		
	备注 Remarks	Stamp of Inspection Unit 见第2页 See Page 2		4

批准: Approver



审核: Checker



编制: Editor 子舒荔

















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## 检验检测报告

Test Report

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#### TTTS-WT20252670A

#### 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.



















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## 检验检测报告 Test Report

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TTTS-WT20252670A	1			▼		Page 3 of 7
检测项目	项目描述	单位	标准值	实测值	评价	执行标准/备注
Test Items	Description	Unit	Standard	Results	Conclu	Test Method/
rest Items	Description	UIII t	Requirement	Results	sions	Remarks
1# 口罩-浅蓝色	Mask-Light Blue			.6,		.6
耐摩擦色牢度	干摩	级	$\Lambda \times$	1	符合	
Colour Fastness to	Dry	Grade	≥4	4-5	Pass	GB/T 29865-2013
Rubbing	D1 y	oraue			Tass	
耐摩擦色牢度	湿摩	级				
Colour Fastness to	Wet	Grade	/	4-5	/	GB/T 29865-2013
Rubbing	wet	Grade				
			口罩表面不应有			
			破损、油污斑			
			渍、变形及其他			
			明显缺陷			
			The mask			
外观要求			surface shall			
Appearance	/	/	have no	+	符合	GB/T 32610-2016
Requirement		· /	damage, oil		Pass	GB/ 1 G2G10 2G16
Requirement			stain,			
			deformation			
,			and other			
~			obvious	*		·
			defects.			
2# 口罩-深粉色	Mask-Deep Pink					
甲醛含量				未检出		
Formaldehyde		mg/kg	€20	(低于检出限20mg/kg)	符合	GB/T 2912.1-2009
Content		mg/ kg	220	Undetected	Pass	0D/1 2312.1 2003
				(< 20mg/kg)		
pH值	氯化钾萃取	/	4.0~8.5	6.6	符合	GB/T 7573-2009
pH Value	KC1 Extract	/	4.0.00.0	0.0	Pass	GD/1 1913-2009
3# 口罩-米黄色	Mask-Beige	F				
▼		_		未检出		₩
可分解致癌芳香胺染料	,	/1	禁用	(低于检出限5mg/kg)	符合	OD /W 18500 0011
Azo	/	mg/kg	Not Used	Undetected	Pass	GB/T 17592-2011
				(< 5 mg/kg)		
				未检出		
环氧乙烷残留量				(低于检出限2 μ g/g)	符合	
Ethylene Oxide		μg/g	€10	Undetected	Pass	GB/T 14233. 1-2008
Residual				$(< 2 \mu g/g)$	1 433	
	sk-Yellow	7		( ~ 2 × 6/ 6/	I	

















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## 检验检测报告

Test Report

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TI	TTS-WT20252670	A					Page 4 of 7
	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 Conclu sions	执行标准/备注 Test Method/ Remarks
	吸气阻力 Inspiratory Resistance		Pá	≤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	<b>≤</b> 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 Ma	sk-Blue					

























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# 检验检测报告

Test Report

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检测项目	项目描述	单位	标准值	实测值	评价	执行标准/备注
Test Items	Description	Unit	Standard	Results	Conclu	
1000 I tomb	Description	OHIU	Requirement		sions	Remarks
			The	初始过滤效率 Initial Filtration Efficiency: 未预处理样品 Samples Without Pretreatment:		. NE
		N.		1: 97.4		
·	盐性介质 Salt Medium	%	≥90	2: 97. 1 3: 97. 4 4: 97. 4		
1		4	16	5: 97.4 预处理样品 Samples With Pretreatment: 1: 92.9 2: 93.4		16
过滤效率(III级) Filtration		1		3: 96.4 最小值Minimum: 92.9	符合	GD (T. 00010, 0010
Efficiency (Grade III)				初始过滤效率 Initial Filtration Efficiency: 未预处理样品 Samples Without	Pass	GB/T 32610-2016
	油性介质 Oiliness Medium	%	≥80	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		4 TE
				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.

















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## 检验检测报告 Test Report

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TTTS-WT20252670A



样 品 Sample

















检验检测报告

Test Report



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(注意事项)

POINTS FOR ATTENTION

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--报告结束 End of report---

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国家服装质量监督检验中心(天津)

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#### 170011260277



# 检验报告





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CNAS L0608

			Page 1 of 6
		惠州博文制造有限公司                  送样人: Huizhou Bowen Manufacturing Limited Contact	,
	委托单位/地址		
	Applicant	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	
	iip p 11 c an c	Town, Boluo County, Huizhou City, Guangdong 电话: Tel. /	
	•	Province, P. R. China	
		惠州博文制造有限公司	
	4- <del>2- 2- 2- 2- 2- 2- 2- 2- 2- 2- 2- 2- 2- 2</del>	Huizhou Bowen Manufacturing Limited	
ent	生产单位/地址 Manufacturer	广东省惠州市博罗县园洲镇下南村新南一路	
友 Z Client	Manuracturer	Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County	y, Huizhou City,
户 fc		Guangdong Province, P.R.China	
尸提供信息及要求 Information Drovided by		样品名称: Kaze 一次性口罩 商标: KAZE	
供 pi.v		Sample Name Kaze Disposable Face Mask Trademark	
自 lo la		样品总数: 50个	
及 uo		Sample Count 50Pieces	
盖ati	样品信息	号型规格: 鱼形口罩 颜色: /	
求品	Information	Size Fish shaped mask(Kaze-04) Colour	
Inf	of Submitted	完全米別.	
	Sample	原里寺级: Sofoty /	
		Quality Grade Category	
		产品款号或货号: 2020-11	
		Style No. or	
	\(\ldots \ldots	Order No.	
	判定标准:	GB/T 32610-2016 日常防护型口罩技术规范	
	Test Standards	Technical specification of daily protective mask	
	5 tandar d5	1# 口罩Mask-深灰色Espresso	
		2# 口罩Mask-浅杏色Light Blush	
	样品描述	3# 口罩Mask-浅灰色Silver Grey	
Т	Cest Part	4# 口罩Mask-米白色Champagne	
	escription	5# 口罩Mask-杏色Natural Sand	il <i>M</i>
		6# 口罩Mask-黑灰色Dark Grey 7# 口罩Mask-黑色Black	THE PARTY OF THE P
		8# 口罩Mask-黑色十字纹Black Cross 118	
	扒扒糾岳	<b>                                      </b>	
,	检验性质 Test Type	委托检验 Date of 2020-11-23  Commission Test  Submission  Date of Date of Date of Checking Dat	
		Submission	<b>Y</b>
,	检验日期	2020-11-23 到 To 2020-11-27	安用章
	Test Date 执行标准	见附页	(6)
Те	st Standards	See next page(s)	
		检验结果及符合性见附页。	
	检验结论	Test results and compliance refer to next page(s).	
C	Conclusion	检验单位盖章	
		Stamp of Inspection Unit	
	备注		
	Remarks		$_{\perp}$ G

批准: Approver



审核: Checker My Sh

编制: Editor

子舒荡

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检测项目	项目描述	单位	标准值	实测值	评价	执行标准/备注
Test Items	Description	Unit	Standard	Results	Conclu	Test Method/
1050 Itoms	Description		Requirement	Robalts	sions	Remarks
1# 口罩Mask-深刻	灰色Espresso					
			口罩表面不应有			
			破损、油污斑			
		\ \	渍、变形及其他			
			明显缺陷			
Al server IV			The mask			
外观要求	,	,	surface shall		符合	CD /T 00C10 001C
Appearance	/	/	have no	+	Pass	GB/T 32610-2016
Requirement			damage, oil stain,			
			deformation			
			and other			
			obvious			
			defects.			
2# 口罩Mask-浅石	李色Light Blush				•	
耐摩擦色牢度					l	
Colour Fastness to	干摩	级	≥4	4-5	符合	GB/T 29865-2013
Rubbing	Dry	Grade			Pass	
耐摩擦色牢度	湿摩	级				
Colour Fastness to	Wet	级 Grade	/	4-5	/	GB/T 29865-2013
Rubbing	wet	Graue				
3# 口罩Mask-浅刻	灰色Silver Grey					
				未预处理样品		
				Samples Without		
				Pretreatment:		
吸气阻力				1:\148	6-6- A	
Inspiratory	/	Pa	≤175	2: 132	符合	GB/T 32610-2016
Resistance				预处理样品 Samples With	Pass	
				Pretreatment:		
				1: 114		
				2: 109		
				未预处理样品		
				Samples Without		
			$A \times$	Pretreatment:		
呼气阻力				1: 122		
Expiratory	/	Pa	≤145	2: 120	符合	GB/T 32610-2016
Resistance	,		1110	预处理样品	Pass	33/1 33310 2010
		N		Samples With		V
₩		_		Pretreatment:		▼
				1: 76 2: 84		
7# 口罩Maal, 业点	L 与在Champa ~ na	1	l	<b>2;</b> 04		
4# 口罩Mask-米自	白色Champagne					

## 天纺标检测认证股份有阻公司 国家针织产品质量监督检验中心

检验报告









#### 170011263663





中国认可 国际互认 检测 TESTING CNAS L0608

TTTS-WF20000039

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TTTS-WF20000039						Page 3 of 6
检测项目	项目描述	单位	标准值	实测值	评价	执行标准/备注
Test Items	Description	Unit	Standard	Results	Conclu	
过滤效率(III级) Filtration Efficiency (Grade III)	盐性介质 Salt Medium 油性介质 Oiliness Medium	%	Requirement  ≥90  ≥80	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 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	Sions 符合 Pass	Remarks  GB/T 32610-2016
4				最小值Minimum: 87.3		
5# 口罩Mask-杏色	色Natural Sand		47	12		47
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-黑力	灰色Dark Grey			<b>V</b>		
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	<u>—</u> Black		17	1,7		1,7

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检验报告













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#### TTTS-WE20000030

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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 Conclu sions	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1	oss					
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。

 $<sup>^{+}</sup>$  Meet the standard requirements, X Not Meet the standard requirements.



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检验报告













TTTS-WF20000039

第5页 共6页 Page 5 of 6

### 样 品 Sample



ME

ME

ME



ME

# 天纺标检测认证股份有阻公司国家针织产品质量监督检验中心







# 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。

Objection should be issued in 15 days upon receiving the report, overdue opinion is inadmissible.

8.未经本机构书面批准,部分复制报告无效。

Part copy report is invalid without the approval of the written documents of the testing organization.

#### 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, Quegiao Road, Nankai District, Tianjin, China



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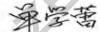
#### 检验检测报告 Test Report

第1页 共5页

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

批准: Approver

Remarks



审核: Checker



编制: Editor

















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

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_1	TTS-WF21000286						Page 2 of 5
	检测项目	项目描述	单位	标准值		评价	执行标准/备注
	Test Items	Description	Unit	Standard Requirement	Results	Conclu sions	Test Method/ Remarks
H				Requirement		STOIIS	Kemarks
	1# 口罩Mask-大約	I色 Racing Red					
1	甲醛含量			1	未检出 (低于检出限20mg/kg)	符合	
ı	Formaldehyde	/	mg/kg	≤20	Undetected	Pass	GB/T 2912.1-2009
ı	Content				(<20 mg/kg)	1 455	
Г			1	口罩表面不应有			
ı				破损、油污斑			
ı				渍、变形及其他			
ı				明显缺陷			
ı	外观要求			The mask surface shall			
ı	Appearance	/	/	have no	+	符合	GB/T 32610-2016
	Requirement		/	damage, oil		Pass	GD/ 1 02010 2010
				stain,			
ı			4	deformation			
ı			1	and other			
ı				obvious			
H				defects.			
	2# 口罩Mask-深藍	蓝色 Royal Blue					
ı	耐摩擦色牢度	干摩 Dry	级 Grade	≥4	4-5	符合	
C	Colour Fastness to	 湿摩	级 级			Pass	GB/T 29865-2013
	Rubbing	Wet	Grade	≥4	4-5	1 33 5	
Τ	3# 口罩Mask-橘包	在 Citrus Orange		N.Y			1
					未检出		
Ī	可分解致癌芳香胺染料	/	mg/kg	禁用	(低于检出限5mg/kg)	符合	GB/T 17592-2011
	Azo	/	mg/ Kg	Not Used	Undetected	Pass	35/1 11032 2011
$\perp$					(< 5mg/kg)		
					未预处理样品 Samples Without		
					Pretreatment:		
	HTT				1: 89		
	吸气阻力		D -	1-7 E	2: 85	符合	GB/T 32610-2016
	Inspiratory Resistance		Pa	≤175	预处理样品	Pass	GD/1 32010-2010
	Restaudice			$N \sim 1$	Samples With		12
					Pretreatment:		
					1: 76 2: 84		
L					2: 04		

















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# 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 Conclu sions	执行标准/备注 Test Method/ Remarks
呼气阻力 Expiratory Resistance		Pá	≪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# □罩Mask-棕色	鱼 Maroon					
过滤效率 (III级) Filtration	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	GB/T 32610-2016
Efficiency (Grade III)	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	Pass	
pH Value	KC1 Extract	/	4.0~8.5	6.6	Pass	GB/T 7573-2009

















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# 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 Conclu sions	执行标准/备注 Test Method/ Remarks
5# □罩Mask-深終	泉色 Forest Pine		.6,	.6	<b>,</b>	
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。

 $<sup>^{\</sup>scriptscriptstyle +}$  Meet the standard requirements, X Not Meet the standard requirements.

















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### 检验检测报告 Test Report

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#### 检验检测报告 Test Report

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			Page 1 of 4
	委托单位/地址 Applicant	惠州博文制造有限公司 送样人: Huizhou Bowen Manufacturing Limited Contact 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	
女 S Client	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, Guangdong Province, P.R.China	Huizhou City,
尸提供信息及要求 Information Drovided by	样品信息 Information of Submitted Sample	样品名称: Kaze 一次性口罩 商标: KAZE Sample Name Kaze Disposable Face Mask Trademark 样品总数: 115个 Sample Count 115Pieces	
	判定标准: Test Standards 样品描述	产品款号或货号: 2021-04 Style No. or Order No.  GB/T 32610-2016 日常防护型口罩技术规范 Technical specification of daily protective mask  1# 口罩Mask-藍色 Cobalt Blue 2# 口罩Mask-紫色 Purple Berry 3# 口罩Mask-深綠色 Spearmint	
D€	est Part escription 检验性质 Test Type	4# 口罩Mask-淺線色 Key Lime 5# 口罩Mask-粉紅色 Bubblegum 6# 口罩Mask-黑色 Onyx 7# 口罩Mask-白色 Ivory  委托检验 Commission Test Rate of Submission  Application  We will a part of Submission  Application  We will a part of Submission  We will a part of Submission  Application Test Rate of Submission	-2021-04-28
Te	检验日期 Test Date 执行标准 st Standards 检验结论 onclusion	2021-04-20 到To 2021-04-20 UND To  2021-04-20 And Complete to next page(s)  Accepted to next page(s).	· 川章
	备注 Remarks	(6, 6, 6,	. 6

批准: Approver



审核: Checker



编制: Editor

















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# 检验检测报告

Test Report

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检测项目	项目描述	单位	标准值 Standard	实测值	评价 Conclu	执行标准/备注 Test Method/
Test Items	Description	Unit	Requirement	Results	sions	Remarks
	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	+	符合 Pass	GB/T 32610-2016
2# 口罩Mask-紫色	上 Purple Berry		defects.			
过滤效率 (III级) Filtration	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	GB/T 32610-2016
Efficiency (Grade III)	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	Pass	GB/ 1 32010 2010
	L 录色 Spearmint		. ()	取小但MINIMUM: 92.4		
On H-Mask (A.S.	are obearmine		AV	AV		

















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# 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	实测值 Results	评价 Conclu	执行标准/备注 Test Method/
rest Items	Description	UIII t	Requirement		sions	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
	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 未预处理样品	符合 Pass	GB/T 32610-2016
呼气阻力 Expiratory Resistance		Pa	≤145	不顶处理样的 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			<b>V</b>		<b>V</b>
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

















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### 检验检测报告 Test Report

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#### 检验检测报告 Test Report

第1页 共6页

Page 1 of 6 惠州博文制造有限公司 送样人: Huizhou Bowen Manufacturing Limited Contact 委托单位/地址 广东省惠州市博罗县园洲镇下南村新南一路 Applicant Applicant Xinnan 1st Road, Xianan Village, Yuanzhou 电话: Tel. Town, Boluo County, Huizhou City, Guangdong Province, P.R.China 惠州博文制造有限公司 Huizhou Bowen Manufacturing Limited 生产单位/地址 广东省惠州市博罗县园洲镇下南村新南一路 nformation Provided by Client Manufacturer Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R. China 样品名称: Kaze 一次性口罩 商标: KAZE 供 Trademark Sample Name Kaze Disposable Face Mask 样品总数: 95个 Sample Count 95Pieces 样品信息 号型规格: Light (Kaze-04) 颜色: Information Size or Colour of Submitted Specification Sample | 安全类别: 质量等级: Safety Quality Grade Category 产品款号或货号: 2021-04 Style No. or Order No. 判定标准: GB/T 32610-2016 日常防护型口罩技术规范 Test Technical specification of daily protective mask Standards 样品描述 Test Part 见第2页 See Page 2 Description 样品接收日期 检验性质 委托检验 Date of 2021-04-23 -04 - 30Commission Test Date Test Type Submission 检验日期 到 2021-04-23 Test Date То 见附页 执行标准 See next page(s) Test Standards 检验结果及符合性见附页。 检测专用章 检验结论 Test results and compliance refer to next page(s). Conclusion 检验单位盖章 Stamp of Inspection Unit 备注 Remarks

批准: Approver

审核: Checker

编制: Editor

















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TianFangBiao Standardization Certification & Testing Co., Ltd.

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### 检验检测报告

Test Report

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# TTTS-FH21002047 2 of Page 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

















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### 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 Conclu sions	执行标准/备注 Test Method/ Remarks
01# 口罩Mask-深	藍色 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	+	符合 Pass	GB/T 32610-2016
			and other obvious defects.	16		
02# □罩Mask-深	綠色 Forest Pin	е				
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
	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# □罩Mask-橘	色 Citrus Orang	е		*		*
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# □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# □罩Mask-紫	色 Ultraviolet					

















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# 检验检测报告

Test Report

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检测项目 Test Items	项目描述 Description	単位 Unit	标准值 Standard	实测值 Results	评价 Conclu	执行标准/备注 Test Method/
	盐性介质 Salt Medium	%	Requirement  ≥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:	sions	Remarks
过滤效率 (III级) Filtration Efficiency (Grade III)		1	16	1: 99.9 2: 99.8 3: 99.8 最小值Minimum: 99.8 未预处理样品 Samples Without Pretreatment: 1: 96.5 2: 97.6	符合 Pass	GB/T 32610-2016
	油性介质 Oil Medium	%	≥80	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		
	色 Sandy Beige			ду Лушинтнин. 30.1		
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			1	1		
pH值 pH Value	氯化钾萃取 KCl Extract	1	4.0~8.5	6.5	符合 Pass	GB/T 7573-2009
	紅色 Fuchsia (	1	T			
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
	紅色 Racing Red		1	1,7		

















国家服装质量监督检验中心(天津) National Clothing Quality Inspection & Supervision Center(Tianjin)

# 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 Conclu sions	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 Quart	z				
吸气阻力 Inspiratory	/	Pa	<b>≤</b> 175	未预处理样品 Samples Without Pretreatment: 1: 62 2: 85	符合	GB/T 32610-2016
Resistance	4	4	16	预处理样品 Samples With Pretreatment: 1: 66 2: 68	Pass	16
12# □罩Mask-米	灰色 Dove Grey	1 1				
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	符合 Pass	GB/T 32610-2016
				Pretreatment:  1: 37  2: 45		

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.



TTTS-FH21002047















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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)

### 检验检测报告 Test Report

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样 밂 Sample





















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`TTS-FH21002583



### 检验检测报告 Test Report

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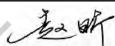
惠州博文制造有限公司 送样人: Huizhou Bowen Manufacturing Limited Contact  委托单位/地址	
Town, Boluo County, Huizhou City, Guangdong Province, P.R.China	1
惠州博文制造有限公司 生产单位/地址 Manufacturer 客 10 A P A D A E Manufacturer S 2 A D A E Manufacturer Manufacturer S 3 A D	,
横品名称: Kaze 一次性口罩 商标: KAZE Sample Name Kaze Disposable Face Mask  样品总数: 100个 Sample Count 100Pieces  特品信息 Information of Submitted Sample Sample  「競量等级: Quality Grade 「产品款号或货号: 2021-07 Style No. or Order No.	15
判定标准: Test Standards  Technical specification of daily protective mask	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   様品接收日期   最近後年月期   最近後年月日   日本日本日本日本日本日本日本日本日本日本日本日本日本日本日本日本日本日本	
Test Type Commission Test Date of Submission Date	-23
检验结果及符合性见附页。	
备注 Remarks	

批准: Approver



审核: Checker 强和

编制: Editor



















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### 检验检测报告 Test Report

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检测项目	项目描述	单位	标准值	实测值	评价	执行标准/备注
Test Items	Description	Unit	Standard Requirement	Results	Conclu sions	Test Method/ Remarks
	<b>5</b> 1145		Kequifement		STOIIS	Kelliat KS
1♯ 口罩Mask-绿色	色花纹- photosyn	thesis				
外观要求		4	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	KAL	符合	
Appearance Requirement		/	have no damage, oil stain, deformation and other obvious defects.	+	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	紫色花纹- dreamwe	eaver	.0,			
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	色花纹- seaglass					
甲醛含量 Formaldehyde Content	<b>(</b> , '	mg/kg	€20	未检出 (低于检出限20mg/kg) Undetected (< 20mg/kg)	符合 Pass	GB/T 2912.1-2009
						7 1 7

















国家服装质量监督检验中心(天津) National Clothing Quality Inspection & Supervision Center(Tianjin)

# Test Report

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						第3次 光生火
TTTS-FH21002	583			<u> </u>		Page 3 of 4
检测项目	项目描述	单位	标准值	实测值	评价	执行标准/备注
			Standard		Conclu	Test Method/
Test Items	Description	Unit	Requirement	Results	sions	Remarks
可分解致癌芳香胺 Azo	:染料 /	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Mas	k-红色花纹- sweet i	nectar				
环氧乙烷残留 Ethylene Oxic 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Mas	k-橙色花纹- bloomin	ngton				
4	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		ME
过滤效率(III级 Filtration Efficiency (Grade III)		4	16	预处理样品 Samples With Pretreatment: 1: 99.7 2: 99.7 3: 99.7 最小值Minimum: 99.7 未预处理样品 Samples Without Pretreatment: 1: 97.2	符合 Pass	GB/T 32610-2016
+	油性介质 Oil Medium	%	≥80	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.

















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### 检验检测报告 Test Report

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	1113-4	H 2 1 0 0 2 6 5 2				Page 1 of 6
	委托单位/地址 Applicant	广东省惠州市博 Xinnan 1st Roa	Manufacturing L 罗县园洲镇下南村弟 ad, Xianan Villa ounty, Huizhou C	f南一路 ge, Yuanzhou	送样人: Contact 电话: Tel. /	
多 b client	生产单位/地址 Manufacturer	广东省惠州市博 Xinnan 1st Roa	Manufacturing L 罗县园洲镇下南村新	<b>「南一路</b>	wn, Boluo County,	Huizhou City,
厂提供信息及要求 Information Drovided by	样品信息 Information of Submitted Sample	Ample Name 样品总数: Sample Count 号型规格: Size or Specification 质量等级: Quality Grade 产品款号或货号: Style No. or	Kaze 一次性口罩 Kaze Disposable 100个 100Pieces Light (Kaze-04)	Face Mask I	商标: KAZE Trademark	
	判定标准: Test Standards	Order No.  GB/T 32610-2016 Technical specif		7 11	k	1
De	样品描述 est Part escription 检验性质 fest Type	见第2页 See Page 2 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 Callering	021-07-30
Те	检验日期 fest Date 执行标准 st Standards 检验结论	见附页 See next page(s) 检验结果及符合性见 Test results and		到 To r to next page(	2011 — 29 — 29 — 检测 [	
C	onclusion 备注 Remarks	/	+	检验单 Stamp of Insp		+

批准: Approver

审核: Checker

编制: Editor

















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检验检测报告 Test Report

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#### TTTS-FH21002652

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

















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### 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	实测值 Results	评价 Conclu	执行标准/备注 Test Method/
			Requirement		sions	Remarks
01# 口罩Mask-浅	紫色-Light Purp	1e				
外观要求		+	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	4N		41
Appearance Requirement	/	/	have no damage, oil stain, deformation and other	+	符合 Pass	GB/T 32610-2016
			obvious defects.			10
02# □罩Mask-浅	绿色-Light Gree	n				
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# □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	符合 Pass	GB/T 32610-2016
			16	Pretreatment: 1: 99.3 2: 99.2 3: 99.3 最小值Minimum: 99.2		16

















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# 检验检测报告

Test Report

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TTTS-FH21002652		1	标准值		评价	Page 4 of 6 执行标准/备注
检测项目 Test Items	项目描述	单位 Unit	Standard	实测值	Conclu	Test Method/
lest Items	Description	Unit	Requirement	Results	sions	Remarks
			10	未预处理样品 Samples Without Pretreatment: 1: 91.7 2: 90.2		1
过滤效率(III级) Filtration Efficiency (Grade III)	油性介质 Oil Medium	%	≥80	3: 91.6 4: 91.4 5: 90.6 预处理样品 Samples With Pretreatment:	符合 Pass	GB/T 32610-2016
	6		16	1: 88.0 2: 87.2 3: 87.6 最小值Minimum: 87.2		16
04# 口罩Mask-蓝	i色-Blue					
pH值 pH Value	氯化钾萃取 KC1 Extract	1	4.0~8.5	6.4	符合 Pass	GB/T 7573-2009
05# □罩Mask-楊	₹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	竞色- Yellow	1				
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# □罩Mask-粉	}色-Pink					
环氧乙烷残留量 Ethylene Oxide Residual	<b>(</b> )	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# □罩Mask-约	L色- Red					
		1		未预处理样品 Samples Without Pretreatment:		1
吸气阻力 Inspiratory Resistance	(,)	Pa	≤175	1: 63 2: 57 预处理样品 Samples With Pretreatment:	符合 Pass	GB/T 32610-2016
				1: 81		

















国家服装质量监督检验中心(天津)

# Test Report

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世紀 Test Items Description Unit Requirement Results Conclusions Remains Remains Results Results Results Results Results Results Remains Results Remains Remai	- 0 OT (						
平气阻力 Expiratory Resistance  / Pa ≤145  Fa Samples Without Pretreatment: 1: 46 2: 39 预处理样品 Samples With Pretreatment: 1: 43 2: 48	准/备注 Method/ marks						
呼气阻力 Expiratory Resistance  / Pa ≤145  Samples Without Pretreatment:  1: 46 2: 39 预处理样品 Samples With Pretreatment:  1: 43 2: 48							
10# □罩Mask-绿色- Green	2610-2016						
甲醛含量 Formaldehyde Content  / mg/kg ≤20	12. 1-2009						

表中"+"为符合标准要求, "×"表示不符合标准要求。

 $<sup>^{\</sup>rm +}$  Meet the standard requirements, X Not Meet the standard requirements.

















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### 检验检测报告 Test Report

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### 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

GE

Issued on: 16/06/2020

Valid until: 24/05/2022

CMC Medical Devices & Drugs SI

### EC REP CERTIFICATE



ANNEX I Medical Device Product

**Kaze Disposable Face Mask** 

# **C** E Declaration of Conformity

Huizhou Bowen Manufacturing Limited

Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo

Manufacturer: County, Huizhou City, Guangdong Province, P.R.China

Tel:+86-752-5895333

SRN: /

European CMC Medical Devices & Drugs S.L.

Representative: Horacio Lengo Nº 18, CP 29006, Málaga, Spain

SRN: /

Product Name: Kaze Disposable Face Mask

Specification: 20.5cm×8.3cm

UMDN Code: 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





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

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

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Study Verification and Signature	4
1.0 Purpose	
2.0 Reference	
3.0 Test and control articles	
4.0 Identification and justification of test system	
5.0 Equipment and reagents	
6.0 Experiment design and dose	
7.0 Statistical method.	
8.0 Evaluation criteria.	
9.0 Results of the test.	Action 1
10.0 Conclusion.	
11.0 Record.	
12.0 Confidentiality Agreement	
12.0 Confidentiality Agreement.	······

#### 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.



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#### **Abstract**

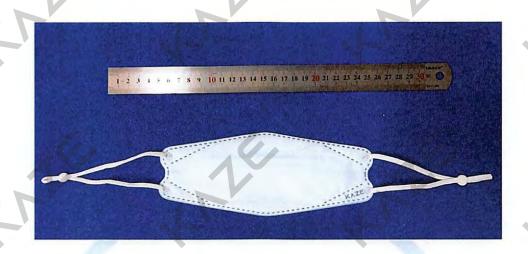
In this study, mammalian L-929 cells were cultured in vitro according to ISO 10993-5:2009 to test the potential cytotoxicity of the test article.

The test articles and the control material were separately placed in MEM medium containing 10% fetal bovine serum, and extracted in a 37 °C incubator for 24 hours. After the end of the extraction, the cell culture medium in the 96-well plate (10<sup>4</sup> cells/well) cultured for 24 hours was removed and replaced with the corresponding extract, cultured in 37 °C, 5% CO<sub>2</sub>, >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

Date Completed

Date Completed

Approved

Study Director

Supervisory

Test Facility Manager

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	ZDEC	MEM medium, with					
T (dance	Traze Bisposacie i uce iviasir	Polyethylene Film	ZDZC	addition 10% FBS					
Manufacture	Huizhou Bowen	Hatano Research	Sigma-Aldrich.	Hyclone					
Tytattataetate	Manufacturing Limited	Institute. FDSC		==y >10110					
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	Color non-woven fabric 25%; melt blown fabric 20%; skin								
Material Material	friendly non-woven fabric	/	/_	/					
Material	25%; ear thread 18%, nose		A						
A	clip 12%		1/1/1						
Physical State	Solid	Solid	Solid	Liquid					
Color	Light Blue	White	White	Pink					
	Biodegradable	. 1							
Packaging Material	OPP/VMPET/CPP	/							
· ·	Card Box, Carton			·					
Sterilized or Not	No	No	No	Yes					
Concentration	1	/	0.1%	/					
Total Surface or weight	170 cm <sup>2</sup>	/		/					
Storage Condition	Room Temp.	Room Temp.	Room Temp.	4°C					
Note: The information about the test article was supplied by the sponsor wherever applicable.									

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<sub>2</sub> 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 °C, 5% CO<sub>2</sub> and 60 rpm for 24 hours.

	Sampling		Sterilization	Aseptic Extraction In Inert Container			Final Extract	
Groups	Sampling Manner	Actually sampling	Method	Ratio	Extracts	Condition	рН	Clear or Not
Test article	Whole	340.0 cm <sup>2</sup>	ЕО	6 cm <sup>2</sup> : 1 ml	56.7 ml	37 °C 24 h	7.4	Clear
Negative Control	Random	60.0 cm <sup>2</sup>	ЕО	3 cm <sup>2</sup> : 1 ml	20.0 ml	37 °C 24 h	7.4	Clear
Positive Control	Random	0.02 g		0.1 g: 100 ml	20.0 ml	37 °C 24 h	7.4	Clear
Blank Control	/	1	1	1	20.0 ml	37 °C 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 °C in a humidified atmosphere of 5% CO<sub>2</sub>, then digested by 0.25% trypsin containing EDTA to get single cell suspension.  $1 \times 10^5$  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<sub>2</sub>,

37 °C, >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  $\mu$ l of extract of test article (100%  $\sim$  75%  $\sim$  50%  $\sim$  25%), control article, negative article and positive article respectively. The 96-well plate was incubated at 37 °C in cell incubator of 5% CO<sub>2</sub> 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 °C in a humidified atmosphere of 5% CO<sub>2</sub> 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 $\pm$ standard deviation ( $x\pm s$ )

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.
Negative control  Positive control  100% Test article extract  75% Test article extract	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.  Nearly complete or complete destruction of the cell layers.  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.  Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.

50% Test article		Discrete intracytoplasmatic granules, no cell
extract	1	lysis, no reduction of cell growth.
25% Test article		Discrete intracytoplasmatic granules, no cell
extract		lysis, no reduction of cell growth.

#### 9.2 Results of the cell vitality

Table2 Results of the cell vitality

Group				OD	value				Vial (0/)
Sieup	1	2	3	4	5	6	$\bar{x}$	S	Viab. (%)
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.





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.
- 5. The report shall not be reproduced except in full without the written approval of the company.



Page 3 of 12

#### **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 °C, 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

Date Completed

Approved

Study Director

Supervisory

Test Facility Manager

Date Completed

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

Article(Polar)  Article(Polar)  Article(Polar)  Article(Polar)  Article(Polar)  Article(Non-Polar)  O.9% Sodium Chloride Injection(SC)  Huizhou Bowen Manufacturing Limited  Manufacturing Limited  Size  205mm * 83mm  500 ml  Liquid  Color non-woven fabric 25%; ear thread 18%, nose clip 12%  Physical State  Article(Polar)  Article(Non-Polar)  Sesame Oil (SO)  Halding Tokyo  CHEMICAL  Industry O  CHEMICAL  Ind					
Name  Kaze Disposable Face Mask  Mask  Manufacture  Manufacture  Manufacture  Manufacture  Manufacturing Limited  Size  205mm * 83mm  Model  Lot Batch#  Color non-woven fabric 25%; ear thread 18%, nose clip 12%  Physical State  Color  Color  Color Light Blue  Color Light Blue  Color Card Box, Carton  Article(Polar)  Article(Polar)  Article(Non-Polar)  Sesame Oil  (SO)  Bound Tokyo  Chemical  Color natural flavor oil  refinery, Qingyuan  natural flavor oil  refinery, Qingyuan  District  LTD  //  //  //  //  //  //  //  //  Lot Batch#  Color non-woven fabric  25%; melt blown fabric  25%; ear thread 18%, nose clip  12%  Physical State  Color  Light Blue  Colorless  Light yellow  Light yellow  Light yellow  Article(Non-Polar)  2,  4-Dinitrochlorod  ne (DNCB)  Tokyo  CHEMICAl  refinery, Qingyuan  natural flavor oil  refinery, Qingyuan  Pharmaceutical  Plavorofolo  CHEMICAl  Refinery, Qingyuan  District  LTD  //  //  //  //  Light Solid  Liquid  Liquid  Liquid  Liquid  Liquid  Liquid  Liquid  Liquid  Light yellow  Light yellow	Groups	Test article			Positive Control
Name  Kaze Disposable Face Mask  Mask  Chloride Injection(SC)  Huizhou Bowen Manufacturing Limited  Size  Co., Ltd  Guangxi Yuyuan Pharmaceutical Co., Ltd  Co., Ltd  District  LTD  Size  205mm * 83mm  500 ml  SL  25 g  Model  KAZE-04  Lot Batch#  Color non-woven fabric 25%; ear thread 18%, nose clip 12%  Physical State  Solid  Color  Light Blue  Colorless  Light yellow  Light yellow  Light yellow  Light yellow  A-Dinitrochlorot ne (DNCB)  Guangxi Yuyuan Pharmaceutical refinety, Qingyuan District  LTD  TOKYO  CHEMICAL TOK	Joseph		Article(Polar)	Article(Non-Polar)	
Manufacture  Huizhou Bowen Manufacturing Limited  Huizhou Bowen Manufacturing Limited  Co., Ltd  District  LTD  Size  205mm * 83mm  500 ml  SL  25 g  Model  KAZE-04  Lot Batch#  Color non-woven fabric 25%; melt blown fabric 25%; ear thread 18%, nose clip 12%  Physical State  Solid  Color  Light Blue  Colorless  Light yellow  Biodegradable Package material  OPP/VMPET/CPP Card Box, Carton	Name		Chloride		4-Dinitrochlorobenze
Manufacture  Manufacturing Limited  Manufacturing Limited  Size  205mm * 83mm  S00 ml  Lot Batch#  Color non-woven fabric 25%; melt blown fabric 20%; skin friendly non-woven fabric 25%; ear thread 18%, nose clip 12%  Physical State  Solid  Color  Light Blue  Colorless  Light yellow  Biodegradable Package material  Co., Ltd  Color limited  Color limited  Color natural flavor oil refinery, Qingyuan District  LTD  CHEMICAL INDUSTRY Color Instruction Industry Qingyuan District INDUSTRY Color Instruction Industry Qingyuan District INDUSTRY Color Instruction INDUSTRY Color Instruction INDUSTRY Color Instruction Industry Qingyuan District Industry Qingyuan In			Injection(SC)		ne (DNCB)
Size 205mm * 83mm 500 ml 5L 25 g  Model KAZE-04 / / / /  Lot Batch# 2020/10/1 H20070606 20200528 H2UKD-DN  Color non-woven fabric 25%; melt blown fabric 25%; ear thread 18%, nose clip 12%  Physical State Solid Liquid Liquid Solid Color Light Blue Colorless Light yellow Light yellow Biodegradable OPP/VMPET/CPP / / Card Box, Carton	Manufacture		Pharmaceutical	natural flavor oil	TOKYO CHEMICAL INDUSTRY CO.,
Model KAZE-04 / / / / / / / / / / / / / / / / / / /			Co., Lta	District	LTD
Lot Batch# 2020/10/1 H20070606 20200528 H2UKD-DN  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 OPP/VMPET/CPP / Card Box, Carton	Size	205mm * 83mm	500 ml	5L	25 g
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 yellov  Biodegradable Package material OPP/VMPET/CPP Card Box, Carton	Model	KAZE-04	/	1	/
Test Article Material  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  Biodegradable Package material  OPP/VMPET/CPP Card Box, Carton	Lot Batch#	2020/10/1	H20070606	20200528	H2UKD-DM
ear thread 18%, nose clip 12%  Physical State Solid Liquid Liquid Solid  Color Light Blue Colorless Light yellow Light yellow  Biodegradable  Package material OPP/VMPET/CPP / / / Card Box, Carton		25%; melt blown fabric 20%; skin friendly	1		
Color Light Blue Colorless Light yellow Light yellow  Biodegradable Package material OPP/VMPET/CPP / / / Card Box, Carton	Material	ear thread 18%, nose clip			
Biodegradable Package material OPP/VMPET/CPP / / / Card Box, Carton	Physical State	Solid	Liquid	Liquid	Solid
Package material OPP/VMPET/CPP / / / / / / / / / / / / / / / Card Box, Carton	Color	Light Blue	Colorless	Light yellow	Light yellow
Card Box, Carton		Biodegradable			
	Package material	OPP/VMPET/CPP	/		/
Sterilized or Not No / / /	\ <u>\</u>	Card Box, Carton	•	-	
	Sterilized or Not	No	/	/	<b>P</b>
Concentration / 0.9 % /	Concentration	/	0.9 %	/	
Concentration: 0				_	Concentration: 0.5 %

Report No.: CSTBB20100414

	()		. ()	Challenge
		17	1	Concentration: 0.1 %
	1			Dissolved in ethanol
Total Surface/Weight	170 cm <sup>2</sup>	/		1
Storage Condition	Room Temp.	Room Temp.	Room Temp.	Room Temp.
T1 : C4:1.		11 11 1	1. 1.1	•

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 °C

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:

	Extraction in sterile vessels						
Sampling Manner	Actually sampling	Ratio	Reagent		Temperature	Time	рН
Whole	340.0 cm <sup>2</sup>	6 cm <sup>2</sup> : 1 ml	SC	56.7 ml	50 °C	72 h	5.5
whole	$340.0 \text{ cm}^2$	o cm : 1 mi	SO	56.7 ml	30 °C	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.

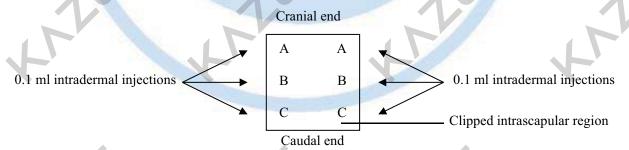


Figure 1 Location of intradermal injection sites

#### 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<sup>2</sup> (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:

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

Table 1 Magnusson and Kligman scale

#### 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

			Table 2 G	umea pig	Schsitizatio	n Dei mai i	teactions		
G	broup	No.	Pretest	Finished		enge patch ed 24h later	The Challe was remove		Positive
	1		weight(g)	weight(g)	Erythema	Swelling	Erythema	Swelling	rate
		1	304.4	370.4	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	
	T4	5	310.2	382.6	0	0	0	0	00/
	Test	6	313.1	358.0	0	0	0	0	0%
		7	317.2	362.9	0	0	0	0	
SC		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	
		11	316.6	374.2	0	0	0	0	
		12	313.3	361.0	0	0	0	0	
	Control	13	305.5	380.3	0	0	0	0	0%
		14	315.0	353.4	0	0	0	0	
		15	303.1	354.8	0	0	0	0	
		16	302.7	364.7	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	
	T	20	318.8	384.6	0	0	0	0	00/
	Test	21	304.9	359.8	0	0	0	0	0%
		22	318.0	365.0	0	0	0	0	
SO		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	
		26	304.1	380.8	0	0	0	0	
		27	316.6	386.2	0	0	0	0	]
	Control	28	303.9	364.9	0	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	Finished	The Challe was remove		The Challen		Positive
\-\'		weight(g)	weight(g)	Erythema	Swelling	Erythema	Swellin	rate
	1	309.8	354.0	1	0	1	0	
	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	
Test	5	307.1	351.0	1	0	2	0	100%
Test	6	318.7	352.9	1	0	2	0	10076
	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	
	11	312.9	353.0	0	0	0	0	
	12	307.7	359.0	0	0	0	0	
Control	13	303.7	353.7	0	0	0	0	0%
	14	307.9	372.3	0	0	0	0	
	15	310.8	380.9	0	0	0	0	
) I		1 0	CED DO COO	200151 (5)		000 00 11)		

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





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## **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 °C, 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

Date Completed

Approved

Study Director

**美田寺服侍衛侍** 

ate Completed

Supervisory

Test Facility Manager

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

Test article   Negative Control Article(Polar)   Positive Control Article(Non-Polar)   Positive Control Article(Non-Polar)					
Name  Kaze Disposable Face Mask  Manufacture  Huizhou Bowen Manufacturing Limited  Size  205mm * 83mm  Model  KAZE-04  Lot Batch#  Color non-woven fabric 25%; melt blown fabric 25%; ear thread 18%, nose clip 12%  Physical State  Package material  Opp/VMPET/CPP Card Box, Carton  Sesame Oil (SO)  Guangxi Yuyuan Pharmaceutical Co., Ltd  Guangxi Yuyuan Pharmaceutical Co., Ltd  Guangxi Yuyuan Pharmaceutical Co., Ltd  Color pharmaceutical Co., Ltd  Color non-woven fabric 25 g  SLBL2304V  Color non-woven fabric 25%; ear thread 18%, nose clip 12%  Physical State  Opp/VMPET/CPP Card Box, Carton  Sterilized or Not  No  / Concentration  /  Total  170 cm²  /  Chloride (SO)  Goal  Sesame Oil dodecyl sulfate (SO)  Slian Lv yuan natural flavor oil refinery, Qingyuan District  SIGMA  **Clor oil refinery, Qingyuan Pharmaceutical Co., Ltd  Color   Light Blue   Color066  Color066  Subject of the session of the s	Groups	Test article			Positive Control
Manufacture  Manufacturing Limited  Manufacturing Limited  Size  205mm * 83mm  500 ml  5L  25 g  Model  KAZE-04  Lot Batch#  2020/10/1  H20070606  20200528  SLBL2304V  Color non-woven fabric 25%; ear thread 18%, nose elip 12%  Physical State  Solid  Color  Light Blue  Colorless  Biodegradable  Package material  OPP/VMPET/CPP  Card Box, Carton  Sterilized or Not  Concentration  /  Total  No  Manufacturing Limited  Guangxi Yuyuan Pharmaceutical Co., Ltd  refinery, Qingyuan District  SIGMA  SIGMA  SIGMA  SIGMA  Plarmaceutical Co., Ltd  refinery, Qingyuan District  SIGMA  Plarmaceutical Co., Ltd  Color l  Sterilized or Not No  One of loss  No  Inatural flavor oil refinery, Qingyuan District  SIGMA  SIGMA  SIGMA  Color  Sterilized or Not  Inatural flavor oil refinery, Qingyuan District  Sterilized or Not  / / / / / / / / / / / / / / / / / /	Name		Chloride	(SO)	dodecyl sulfate
Model KAZE-04 / / / /  Lot Batch# 2020/10/1 H20070606 20200528 SLBL2304V  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  Biodegradable OPP/VMPET/CPP / / / / / / / / / / / / / / / / / /	Manufacture		Pharmaceutical Co.,	natural flavor oil refinery, Qingyuan	SIGMA
Lot Batch# 2020/10/1 H20070606 20200528 SLBL2304V  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  Biodegradable OPP/VMPET/CPP / / / / / / / / / / / / / / / / / /	Size	205mm * 83mm	500 ml	5L	25 g
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  Biodegradable Package material OPP/VMPET/CPP / / / Card Box, Carton  Sterilized or Not No / / /  Concentration / 0.9 % / 10 %  Total 170 cm² / /	Model	KAZE-04	/	1	/
Test Article Material  Material  Physical State  Color  Light Blue  Package material  OPP/VMPET/CPP  Card Box, Carton  Sterilized or Not  Total  Color  Concentration  25%; melt blown fabric 20%; skin friendly non-woven fabric 25%; ear thread 18%, nose clip 12%  Liquid  Liquid  Liquid  Liquid  Solid  Colorless  Light yellow  Colorless  A colorless  Diodegradable A colorl	Lot Batch#	2020/10/1	H20070606	20200528	SLBL2304V
Color Light Blue Colorless Light yellow Colorless  Biodegradable OPP/VMPET/CPP / / / / / / / / / / Card Box, Carton  Sterilized or Not No / / / / / / / / / / / / Concentration / 0.9 % / 10 %  Total 170 cm² / / / / / / / / / / / / / / / / / / /		25%; melt blown fabric 20%; skin friendly non-woven fabric 25%; ear thread 18%, nose clip			
Biodegradable	Physical State	Solid	Liquid	Liquid	Solid
Package material         OPP/VMPET/CPP         /         /         /           Card Box, Carton         No         /         /         /           Sterilized or Not         No         /         /         /           Concentration         /         0.9 %         /         10 %           Total         170 cm²         /         /         /	Color	Light Blue	Colorless	Light yellow	Colorless
Concentration         /         0.9 %         /         10 %           Total         170 cm²         /         /         /         /	Package material	OPP/VMPET/CPP	/		/
Total 170 cm <sup>2</sup> / /	Sterilized or Not	No	/	/	
$170 \text{ cm}^2$ / / / / / /		/	0.9 %	/	10 %
		170 cm <sup>2</sup>	/	/	/

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 °C

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:

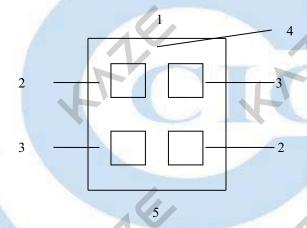
Aseptic Sampling			Extraction in sterile vessels				
Sampling Manner	Actually sampling	Ratio	Re	agent	Temperature	Time	pН
Whala	340.0 cm <sup>2</sup>	6 cm <sup>2</sup> : 1 ml	SC	56.7 ml	50 °C	72 h	5.5
Whole	340.0 cm <sup>2</sup>	o chi. 1 iiii	SO	56.7 ml	30 C	72 h	1

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

Figure 1 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  $(1\pm0.1)$  h,  $(24\pm2)$  h,  $(48\pm2)$  h and  $(72\pm2)$  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  $(24\pm2)$  h,  $(48\pm2)$  h and  $(72\pm2)$  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

			ble 2 Skin		1	bservatio			
Reagent Rabbit		Pretest	Finished	Group	Reaction	Interval (hours): score=left/right			
Reagent	No	weight(kg)	weight(kg)	Group	Reaction	1±0.1 h	24±2 h	48±2 h	72±2 h
			2.29	Test Article	Erythema	0/0	0/0	0/0	0/0
	1	1 2.17			Oedema	0/0	0/0	0/0	0/0
	1			Negative Control	Erythema	0/0	0/0	0/0	0/0
	4	0,			Oedema	0/0	0/0	0/0	0/0
				Test Article	Erythema	0/0	0/0	0/0	0/0
SC	2	2.06	2.19		Oedema	0/0	0/0	0/0	0/0
SC	2	2.00		Negative	Erythema	0/0	0/0	0/0	0/0
				Control	Oedema	0/0	0/0	0/0	0/0
				Test	Erythema	0/0	0/0	0/0	0/0
	3 2.14	2.14	14 2.26	Article	Oedema	0/0	0/0	0/0	0/0
		2.26	Negative Control	Erythema	0/0	0/0	0/0	0/0	
				Oedema	0/0	0/0	0/0	0/0	
		Primary i	irritation index				0		
			Test Article	Erythema	0/0	0/0	0/0	0/0	
1	4	2 20 2 22		Oedema	0/0	0/0	0/0	0/0	
4		2 20	2 22		o va viina			and the same of th	
	4	2.20	2.33	Negative	Erythema	0/0	0/0	0/0	0/0
	4	2.20	2.33	Negative Control		V.	0/0		0/0
	4	2.20	2.33	_	Erythema	0/0		0/0	
80	- 4			Control	Erythema Oedema	0/0	0/0	0/0	0/0
SO	5	2.20	2.33	Control  Test	Erythema Oedema Erythema	0/0 0/0 0/0	0/0	0/0 0/0 0/0	0/0
SO	- 4			Control  Test Article	Erythema Oedema Erythema Oedema	0/0 0/0 0/0 0/0	0/0 0/0 0/0	0/0 0/0 0/0 0/0	0/0 0/0 0/0
SO	- 4			Control  Test Article  Negative	Erythema Oedema Erythema Oedema Erythema	0/0 0/0 0/0 0/0 0/0	0/0 0/0 0/0 0/0	0/0 0/0 0/0 0/0 0/0	0/0 0/0 0/0 0/0
SO	5	2.18	2.29	Control  Test Article  Negative Control	Erythema Oedema Erythema Oedema Erythema Oedema	0/0 0/0 0/0 0/0 0/0 0/0	0/0 0/0 0/0 0/0 0/0	0/0 0/0 0/0 0/0 0/0 0/0	0/0 0/0 0/0 0/0 0/0
so	5		2.29	Control  Test Article  Negative Control  Test Article  Negative	Erythema Oedema Erythema Oedema Erythema Oedema Erythema	0/0 0/0 0/0 0/0 0/0 0/0 0/0	0/0 0/0 0/0 0/0 0/0 0/0	0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0	0/0 0/0 0/0 0/0 0/0 0/0
so	5	2.18	2.29	Test Article  Negative Control  Test Article	Erythema Oedema Erythema Oedema Erythema Oedema Erythema Oedema	0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0	0/0 0/0 0/0 0/0 0/0 0/0 0/0	0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0	0/0 0/0 0/0 0/0 0/0 0/0 0/0
so	5	2.18	2.29	Control  Test Article  Negative Control  Test Article  Negative Control	Erythema Oedema Erythema Oedema Erythema Oedema Erythema Oedema Erythema	0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0	0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0	0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0	0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0

**Table 3 Positive control** 

D-1-1-14-NJ-	Constant	D'antinu	Interval (hours): score=left site/right site			
Rabbit No	Group	Reaction	1±0.1 h	24±2 h	48±2 h	72±2 h
	Positive control	Erythema	0/1	2/1	2/3	3/3
1		Oedema	1/0	2/2	3/2	4/3
1	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
	Desiring a sector 1	Erythema	0/0	1/2	3/3	4/4
2	Positive control	Oedema	1/1	3/2	3/4	72±2 h 3/3 4/3 0/0 0/0
2	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
	Davidina a sutual	Erythema	1/1	2/3	4/3	4/4
2	Positive control	Oedema	1/0	2/2	4/4	4/3
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)

