Kaze Disposable Face Mask

Basic

Certificate and test reports

Directory

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	:	Kaze Disposable Face Mask
Style No.	:	KAZE-02
Manufacture	:	Huizhou Bowen Manufacturing Limited
Country of Destination	:	Europe,United States
COLOR		Tile
Composition		Non-woven fabric 67%; Melt blown cloth 21%; ear thread 8%,nose clip 4%
Sample Receiving Date	:	Jun 25, 2021
Testing Period	:	Jun 25, 2021 - Jul 05, 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).
Test Performed	:	Selected test(s) as requested by applicant

Overall Conclusion: PASS

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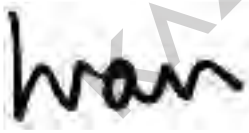
Conclusion		Remark
European Regulation POPs (EU) 2019/1021 - Pentachlorophenol (PCP)	PASS	
Entry 43 of Regulation (EC) No 552/2009 amending Annex XVII of REACH Regulation (EC) No 1907/2006 - Azo Dyes(Direct reduction approach)	PASS	
Entry 23 of Commission Regulation (EU) No 835/2012, (EU) No 494/2011 and (EU) 2016/217 amending Annex XVII of REACH Regulation (EC) No 1907/2006 - Cadmium(Cd)	PASS	
Entry 46a of Commission Regulation (EU) 2016/26 amending Annex XVII of REACH Regulation (EC) No 1907/2006 - Nonylphenol Ethoxylates(NPEOs)	PASS	
Entry 20 of Regulation (EC) No 276/2010 amending Annex XVII of REACH Regulation (EC) No 1907/2006 - Organotin Compounds	PASS	
European Regulation POPs (EU) 2019/1021 - Short Chain Chlorinated Paraffins (SCCP)	PASS	
Entry 51 of Commission Regulation (EU) 2018/2005 amending Annex XVII Regulation (EC) No 1907/2006 - Phthalates	PASS	

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



Ivan Xie (Technical Manager)

Sample Photo

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COMPONENT LIST / List of Materials

Sample No.	Component No.	Description	Material	Color	Remark
A	1	Outer non woven fabric	Synthetic Fibers	Dark grey	
A	2	Melt-blown non woven fabric	Synthetic Fibers	White	
A	3	Lining non woven fabric	Synthetic Fibers	White	
A	4	Round band	Synthetic Fibers	Dark grey	
A	5	Nose clip	Plastics	White	
A	6	Fabric interlining	Synthetic Fibers	Black	

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Test Result

European Regulation POPs (EU) 2019/1021 - Pentachlorophenol (PCP)

Test Method: Modified §64 LFGB, BVL, B 82.02.8-2001 Alkaline (KOH) digestion, analysis was performed by GC-ECD or GC-MS.

Test Item(s)	CAS NO.	1+2+3	4+6
Pentachlorophenol (PCP)	87-86-5	ND	ND
Comment		**PASS**	**PASS**

Notes :

RL (Reporting limit): 0.15 mg/kg
ND = Not Detected(< RL)
Requirement: Banned(< 0.5 mg/kg)

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Entry 43 of Regulation (EC) No 552/2009 amending Annex XVII of REACH Regulation (EC) No 1907/2006 - Azo Dyes(Direct reduction approach)

Test Method : According to EN ISO 14362-1:2017, analysis was performed by GC-MS/ HPLC-DAD. Determination of 4-aminoazobenzene (CAS No.:60-09-3) – EN ISO 14362-3:2017, analysis was performed by GC-MS/ HPLC-DAD.

Test Item(s)	CAS NO.	1+4
4-Aminobiphenyl	92-67-1	ND
Benzidine	92-87-5	ND
4-chloro-o-toluidine	95-69-2	ND
2-naphthylamine	91-59-8	ND
o-aminoazotoluene	97-56-3	ND
5-nitro-o-toluidine / 2-Amino-4-nitrotoluene	99-55-8	ND
4-chloroaniline	106-47-8	ND
4-methoxy-m-phenylenediamine / 2,4-Diaminoanisole	615-05-4	ND
4,4'-diaminodiphenylmethane, MDA	101-77-9	ND
3,3'-dichlorobenzidine	91-94-1	ND
3,3'-dimethoxybenzidine	119-90-4	ND
3,3'-dimethylbenzidine	119-93-7	ND
4,4'-methylenedi-o-toluidine/3,3'-Dimethyl-4,4'-diaminodiphenylmethane	838-88-0	ND
p-cresidine	120-71-8	ND
4,4'-methylene-bis-(2-chloroaniline)	101-14-4	ND
4,4'-oxydianiline	101-80-4	ND
4,4'-thiodianiline	139-65-1	ND
o-toluidine	95-53-4	ND
4-methyl-m-phenylenediamine / 2,4-Toluylendiamine, TDA	95-80-7	ND
2,4,5-trimethylaniline	137-17-7	ND
4-aminoazobenzene	60-09-3	ND
O-Anisidine	90-04-0	ND
Comment		**PASS**

Notes :

RL (Reporting limit): 5 mg/kg (for individual compound)

ND = Not Detected(< RL)

Requirement: 30 mg/kg (for individual compound)

1. Direct reduction (Method A) refers to the extraction and reduction according to EN ISO 14362-1:2017 clause 10.2 and relevant clauses. Colorant extraction (Method B) refers to the colourant extraction and subsequent reduction according to EN ISO 14362-1:2017 Clause 10.1 and relevant clauses.
2. 4-Aminodiphenyl (CAS No. 92-67-1), 2-Naphthylamine (CAS No. 91-59-8) and 2,4-Diaminoanisole (CAS No. 615-05-4) can be indirectly generated from some colorants which do not contain these amines azo bound. The use of banned azo colorants cannot be reliably ascertained without additional information.
3. In case PU is used, e.g. PU Foams or coatings, it cannot be ruled out that MDA (CAS No. 101-77-9) and TDA (CAS No. 95-80-7) can be released from PU material, not from banned azo colorant. Similarly, for pigment prints, MDA will be released from a chemical fixing agent.
4. EN ISO 14362-1:2017 will enable further cleavage of 4-AAB (CAS No. 60-09-3) to non-forbidden amines: aniline and p-phenylenediamine. If aniline and/or p-phenylenediamine is not found, 4-AAB is considered as “ND” (i.e. <5.0 mg/kg). Otherwise, EN ISO 14362-3:2017 will be employed to verify the presence of 4-AAB.

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Entry 43 of Regulation (EC) No 552/2009 amending Annex XVII of REACH Regulation (EC) No 1907/2006 - Azo Dyes(Colorant extraction approach)

Test Method : According to EN ISO 14362-1:2017, analysis was performed by GC-MS/ HPLC-DAD.
Determination of 4-aminoazobenzene (CAS No.:60-09-3) – EN ISO 14362-3:2017, analysis was performed by GC-MS/ HPLC-DAD.

Test Item(s)	CAS NO.	1+4
4-Aminobiphenyl	92-67-1	ND
Benzidine	92-87-5	ND
4-chloro-o-toluidine	95-69-2	ND
2-naphthylamine	91-59-8	ND
o-aminoazotoluene	97-56-3	ND
5-nitro-o-toluidine / 2-Amino-4-nitrotoluene	99-55-8	ND
4-chloroaniline	106-47-8	ND
4-methoxy-m-phenylenediamine / 2,4-Diaminoanisole	615-05-4	ND
4,4'-diaminodiphenylmethane, MDA	101-77-9	ND
3,3'-dichlorobenzidine	91-94-1	ND
3,3'-dimethoxybenzidine	119-90-4	ND
3,3'-dimethylbenzidine	119-93-7	ND
4,4'-methylenedi-o-toluidine/3,3'-Dimethyl-4,4'-diaminodiphenylmethane	838-88-0	ND
p-cresidine	120-71-8	ND
4,4'-methylene-bis-(2-chloroaniline)	101-14-4	ND
4,4'-oxydianiline	101-80-4	ND
4,4'-thiodianiline	139-65-1	ND
o-toluidine	95-53-4	ND
4-methyl-m-phenylenediamine / 2,4-Toluylendiamine, TDA	95-80-7	ND
2,4,5-trimethylaniline	137-17-7	ND
4-aminoazobenzene	60-09-3	ND
O-Anisidine	90-04-0	ND
Comment		**PASS**

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Notes :

RL (Reporting limit):5 mg/kg (for individual compound)

ND = Not Detected(< RL)

Requirement: 30 mg/kg (for individual compound)

1. Direct reduction (Method A) refers to the extraction and reduction according to EN ISO 14362-1:2017 clause 10.2 and relevant clauses. Colorant extraction (Method B) refers to the colourant extraction and subsequent reduction according to EN ISO 14362-1:2017 Clause 10.1 and relevant clauses.
2. 4-Aminodiphenyl (CAS No. 92-67-1), 2-Naphthylamine (CAS No. 91-59-8) and 2,4-Diaminoanisole (CAS No. 615-05-4) can be indirectly generated from some colorants which do not contain these amines azo bound. The use of banned azo colorants cannot be reliably ascertained without additional information.
3. In case PU is used, e.g. PU Foams or coatings, it cannot be ruled out that MDA (CAS No. 101-77-9) and TDA (CAS No. 95-80-7) can be released from PU material, not from banned azo colorant. Similarly, for pigment prints, MDA will be released from a chemical fixing agent.
4. EN ISO 14362-1:2017 will enable further cleavage of 4-AAB (CAS No. 60-09-3) to non-forbidden amines: aniline and p-phenylenediamine. If aniline and/or p-phenylenediamine is not found, 4-AAB is considered as “ND” (i.e. <5.0 mg/kg). Otherwise, EN ISO 14362-3:2017 will be employed to verify the presence of 4-AAB.

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Entry 23 of Commission Regulation (EU) No 835/2012, (EU) No 494/2011 and (EU) 2016/217 amending Annex XVII of REACH Regulation (EC) No 1907/2006 - Cadmium(Cd)

Test Method : With reference to EN 1122: 2001, Method B, analysis was performed by AAS.

Test Item(s)	5
Cadmium (Cd)	ND
Comment	**PASS**

Notes :

RL (Reporting limit): 5 mg/kg
ND = Not Detected(< RL)
Requirement: 100 mg/kg

Entry 46a of Commission Regulation (EU) 2016/26 amending Annex XVII of REACH Regulation (EC) No 1907/2006 - Nonylphenol Ethoxylates(NPEOs)

Test Method: With reference to ISO 18254-1:2016, analysis was performed by LC-MS

Test Item(s)	1+2+3	4+6
Nonylphenol Ethoxylate (NPEO)	ND	ND
Comment	**PASS**	**PASS**

Notes :

RL (Reporting limit) :30 mg/kg
ND = Not Detected(< RL)
Requirement: 100 mg/kg

Entry 20 of Regulation (EC) No 276/2010 amending Annex XVII of REACH Regulation (EC) No 1907/2006 - Organotin Compounds

Test Method : SGS In-house method (GZTC CHEM-TOP-031, with reference to ISO 17353:2004), analysis was performed by GC-MS.

Test Item(s)	1+2+3
Dibutyl tin (DBT) by weight of Tin	ND
Dioctyl tin (DOT) by weight of Tin	ND
Tributyl tin (TBT) by weight of Tin	ND
Triphenyl tin (TPhT) by weight of Tin	ND
Tricyclohexyltin (TCyT) by weight of Tin	ND
Trioctyltin (TOT) by weight of Tin	ND
Tripropyltin (TPT) by weight of Tin	ND
Trimethyltin(TMT) by weight of Tin	ND
Σ of Tri substituted organotin compounds calculated as tin	ND
Comment	**PASS**

Test Item(s)	4+6
Dibutyl tin (DBT) by weight of Tin	ND
Dioctyl tin (DOT) by weight of Tin	ND
Tributyl tin (TBT) by weight of Tin	ND
Triphenyl tin (TPhT) by weight of Tin	ND
Tricyclohexyltin (TCyT) by weight of Tin	ND
Trioctyltin (TOT) by weight of Tin	ND
Tripropyltin (TPT) by weight of Tin	ND
Trimethyltin(TMT) by weight of Tin	ND
Σ of Tri substituted organotin compounds calculated as tin	ND
Comment	**PASS**

Test Item(s)	5
Dibutyl tin (DBT) by weight of Tin	ND
Dioctyl tin (DOT) by weight of Tin	ND
Tributyl tin (TBT) by weight of Tin	ND
Triphenyl tin (TPhT) by weight of Tin	ND
Tricyclohexyltin (TCyT) by weight of Tin	ND
Trioctyltin (TOT) by weight of Tin	ND
Tripropyltin (TPT) by weight of Tin	ND
Trimethyltin(TMT) by weight of Tin	ND
Σ of Tri substituted organotin compounds calculated as tin	ND
Comment	**PASS**

Notes :

RL (Reporting limit): 100 mg/kg (for individual compound)
ND = Not Detected (< RL)
Requirement:
Tri substituted Organotin compound (TBT,TPhT,TCyT,TPT,TOT,TMT): 1000 mg/kg by weight of tin
(sum)
DBT: 1000 mg/kg by weight of tin
DOT: 1000 mg/kg by weight of tin

European Regulation POPs (EU) 2019/1021 - Short Chain Chlorinated Paraffins (SCCP)

Test Method : With reference to ISO 18219: 2015, analysis was performed by GC-NCI-MS / GC-ECD.

Test Item(s)	5
Alkanes C10-C13, chloro (short-chain chlorinated paraffins) (SCCPs)	ND
Comment	**PASS**

Notes :

RL (Reporting limit): 50 mg/kg
ND = Not Detected(< RL)
Requirement: 1500 mg/kg

Entry 51 of Commission Regulation (EU) 2018/2005 amending Annex XVII Regulation (EC) No 1907/2006 - Phthalates

Test Method : With reference to EN14372: 2004. Analysis was performed by GC-MS.

Test Item(s)	CAS NO.	5
Dibutyl Phthalate (DBP)	84-74-2	ND
Benzylbutyl Phthalate (BBP)	85-68-7	ND
Bis(2-ethylhexyl) Phthalate (DEHP)	117-81-7	ND
Diisobutyl Phthalate (DIBP)	84-69-5	ND
Total (DBP + BBP + DEHP+DIBP)	-	ND
Comment		**PASS**

Notes :

RL (Reporting limit): 30 mg/kg (each)
ND = Not Detected(< RL)
Requirement: Total (BBP+DBP+DEHP+DIBP) <1000 mg/kg

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

End of Report

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

Sample Description	:	(A)Disposable face mask
Composition	:	(A)67% Non-woven fabric + 33% Melt blown cloth
Sample Color	:	(A)white
Style No.	:	KAZE-02
Lot No.	:	202008
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Aug 24, 2020
Testing Period	:	Aug 24, 2020 - Sep 07, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

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

Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)

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Test Result

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

Clause 5.2 Performance Requirement

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

Sample: A

Test Side	:	Inside
Test Area	:	Approximately 60 cm^2
Flow Rate	:	28.3 L/min
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	~175mm x 165mm
Positive Control Average	:	2744 CFU
Negative Monitor Count	:	< 1 CFU
Mean Particle Size	:	3.0 ±0.3μm
Test bacteria	:	Staphylococcus aureus ATCC 6538

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

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

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

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

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm^2)	The average value for each test specimen (Pa/cm^2)
1	1-1	33.0	37
	1-2	36.5	
	1-3	39.2	
	1-4	35.5	
	1-5	39.9	
2	2-1	34.4	35
	2-2	32.4	
	2-3	34.5	
	2-4	37.3	
	2-5	38.3	
3	3-1	36.5	36
	3-2	35.2	
	3-3	33.6	
	3-4	34.8	
	3-5	38.7	
4	4-1	39.0	37
	4-2	33.8	
	4-3	37.2	
	4-4	36.5	
	4-5	37.4	
5	5-1	35.6	37
	5-2	35.2	
	5-3	39.6	
	5-4	38.7	
	5-5	36.4	

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

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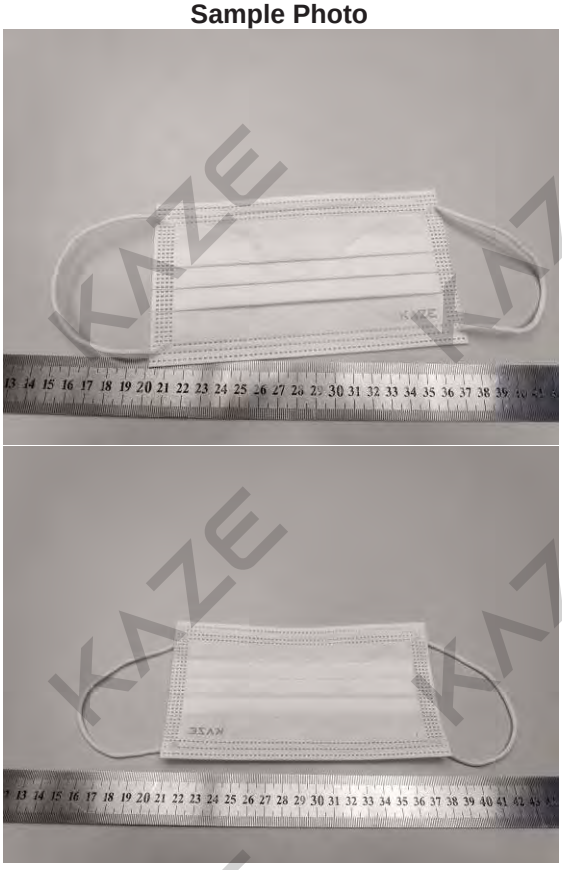
Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	3.31	57	17.22
2#	3.27	33	10.09
3#	3.27	57	17.43
4#	3.30	75	22.73
5#	3.29	27	8.21

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

Sample Photo



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

End of Report

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

Sample Description	:	(A)Kaze Disposable Face Mask
Sample Color	:	(A)Tile
Composition	:	(A)67%Non-woven fabric; 21%Melt blown cloth; 8%ear thread, 4%nose clip
Style No.	:	KAZE
Model No.	:	KAZE-02
Lot No.	:	2021.06
Manufacturer	:	HUIZHOU BOWEN MANUFACTURING LIMITED
Country of Destination	:	Europe, USA
Sample Dimension	:	175mm * 95mm
Claimed Type/Level	:	Type IIR
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Jul 16, 2021
Testing Period	:	Jul 19, 2021 - Jul 30, 2021
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

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

Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)

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Test Result

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

Clause 5.2 Performance Requirement

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

Sample: A

Test Side	:	Inside
Test Area	:	Approximately 60 cm^2
Flow Rate	:	28.3 L/min
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	~176mm x 170mm
Positive Control Average	:	2782.5 CFU
Negative Monitor Count	:	< 1 CFU
Mean Particle Size	:	3.0 ±0.3μm
Test bacteria	:	Staphylococcus aureus ATCC 6538

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

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

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

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

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm^2)	The average value for each test specimen (Pa/cm^2)
1	1-1	36.4	37
	1-2	37.6	
	1-3	33.4	
	1-4	38.2	
	1-5	39.7	
2	2-1	38.6	38
	2-2	39.7	
	2-3	37.5	
	2-4	33.4	
	2-5	39.7	
3	3-1	39.4	38
	3-2	39.8	
	3-3	36.5	
	3-4	34.3	
	3-5	38.7	
4	4-1	35.8	38
	4-2	38.6	
	4-3	35.6	
	4-4	38.6	
	4-5	39.4	
5	5-1	38.9	38
	5-2	37.7	
	5-3	38.5	
	5-4	36.9	
	5-5	35.9	

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

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Clause 5.2.5 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	4.42	30.33	6.86
2	4.39	34.67	7.90
3	4.35	26.00	5.98
4	4.41	39.00	8.84
5	4.38	47.67	10.88

Recovery Efficiency : 69.2 %
Correction Factor : 1.4

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

Sample Photo

Product information is provided by applicant without verification of authentication of the brand.

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.

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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)Tile
Composition	:	(A)67%Non-woven fabric 21%Melt blown cloth 8%ear thread 4%nose clip
Style No.	:	KAZE
Model No.	:	KAZE-02
Lot No.	:	2021.06
Manufacturer	:	HUIZHOU BOWEN MANUFACTURING LIMITED
Country of Destination	:	Europe, USA
Sample Dimension	:	175mm * 95mm
Claimed Type	:	type IIR
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Jun 28, 2021
Testing Period	:	Jul 01, 2021 - Jul 13, 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)

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Test Result

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

Clause 5.2 Performance Requirement

Clause 5.2.4 Splash Resistance
(ISO 22609 :2004)

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

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

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

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Sample Photo

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

检验报告
Test Report

TTTS-WT20216596

客户提供信息及要求 Information Provided by Client	委托单位/地址 Applicant	惠州博文制造有限公司 Huizhou Bowen Manufacturing Limited 广东省惠州市博罗县园洲镇下南村新南一路 Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China 送样人：Contact / 电话：Tel. /
	生产单位/地址 Manufacturer	惠州博文制造有限公司 Huizhou Bowen Manufacturing Limited 广东省惠州市博罗县园洲镇下南村新南一路 Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China
	样品信息 Information of Submitted Sample	样品名称：Sample Name 一次性平面口罩 Disposable Face Mask 商标：Trademark KAZE 样品总数：Sample Count 50个 50Pieces 号型规格：Size KAZE05 175mm×95mm 颜色：Colour / 质量等级：Quality Grade / 安全类别：Safety Category / 产品款号或货号：Style No. or Order No. 2020-07
	判定标准：Test Standards	GB/T 32610-2016 日常防护型口罩技术规范 Technical specification of daily protective mask
样品描述 Test Part Description		1# 白色口罩White Mask
检验性质 Test Type	委托检验 Commission Test	样品接收日期 Date of Submission 2020-07-25 / 报告发布日期 Date of Checking 2020-08-01
检验日期 Test Date	2020-07-25 到 To 2020-07-30	
执行标准 Test Standards	见附页 See next page(s)	
检验结论 Conclusion	检验结果及符合性见附页。 Test results and compliance refer to next page(s). 检验单位盖章 Stamp of Inspection Unit	
备注 Remarks	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, the initial filtration efficiency is tested for Filtration Efficiency, and judged according to the standard GB/T 32610-2016.	

天纺标检测认证股份有限公司 检测专用章

批准：Approver 审核：Checker 编制：Editor

检验报告
Test Report

TTTS-WT20216596

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
1# 白色口罩White Mask						
过滤效率（III级） Filtration Efficiency (Grade III)	盐性介质 Salt Medium	%	≥90	初始过滤效率 Initial Filtration Efficiency: 未预处理样品 Samples Without Pretreatment: 1：95.4 2：95.5 3：95.5 4：95.6 5：95.6 预处理样品 Samples With Pretreatment: 1：94.6 2：94.0 3：94.4 最小值Minimum：94.0	符合 Pass	GB/T 32610-2016
过滤效率（III级） Filtration Efficiency (Grade III)	油性介质 Oiliness Medium	%	≥80	初始过滤效率 Initial Filtration Efficiency: 未预处理样品 Samples Without Pretreatment: 1：82.8 2：83.0 3：82.7 4：82.7 5：82.8 预处理样品 Samples With Pretreatment: 1：81.4 2：82.7 3：82.3 最小值Minimum：81.4	符合 Pass	GB/T 32610-2016
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
甲醛含量 Formaldehyde Content	/	mg/kg	≤20	未检出 (低于检出限20mg/kg) Undetected (< 20mg/kg)	符合 Pass	GB/T 2912.1-2009
pH值 pH Value	氯化钾萃取 KCl Extract	/	4.0～8.5	6.5	符合 Pass	GB/T 7573-2009

天纺标检测认证股份有限公司 检测专用章

检验报告
Test Report

TTTS-WT20216596

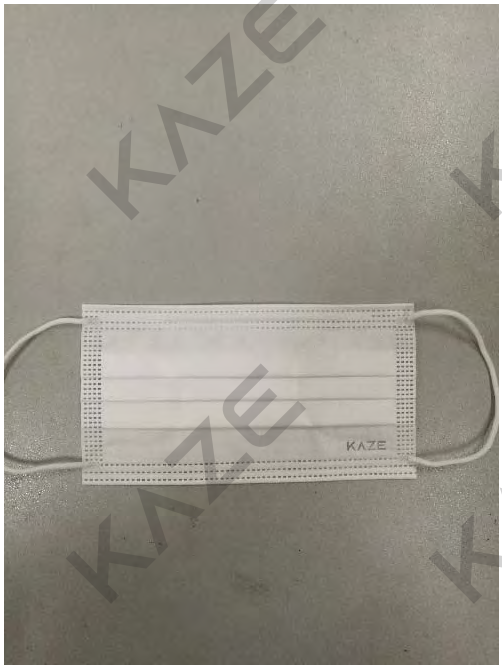
检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
可分解致癌芳香胺染料 Azo	/	mg/kg	禁用 Not Used	未检出 (低于检出限5mg/kg) Undetected (< 5mg/kg)	符合 Pass	GB/T 17592-2011
环氧乙烷残留量 Ethylene Oxide Residual	/	μg/g	≤10	未检出 (低于检出限2μg/g) Undetected (< 2μg/g)	符合 Pass	GB/T 14233.1-2008
外观要求 Appearance Requirement	/	/	口罩表面不应有破损、油污斑渍、变形及其他明显缺陷 The mask surface shall have no damage, oil stain, deformation and other obvious defects.	+	符合 Pass	GB/T 32610-2016
吸气阻力 Inspiratory Resistance	/	Pa	≤175	未预处理样品 Samples Without Pretreatment: 1：77 2：72 预处理样品 Samples With Pretreatment: 1：71 2：70	符合 Pass	GB/T 32610-2016
呼气阻力 Expiratory Resistance	/	Pa	≤145	未预处理样品 Samples Without Pretreatment 1：53 2：50 预处理样品 Samples With Pretreatment: 1：54 2：51	符合 Pass	GB/T 32610-2016

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

天纺标检测认证股份有限公司 检测专用章

检验报告
Test Report

样 品 Sample



天纺标检测认证股份有限公司 检测专用章

检验报告
Test Report

【注意事项】
POINTS FOR ATTENTION

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Report and copy report is invalid without stamp of “Paging Seal” (When the page number more than 1).

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

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

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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
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报告编号(Report No)：ZFLJ2627311	Page 1 of 6

Applicant Information (客户信息)

Applicant Name(委托单位) : Huizhou Bowen Manufacturing Limited(惠州博文制造有限公司)
Applicant Address(委托单位地址) : Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China(广东省惠州市博罗县园洲镇下南村新南一路)
Manufacturer(生产单位) : Huizhou Bowen Manufacturing Limited(惠州博文制造有限公司)

Sample Information (样品信息)

Sample Description(样品描述) : Disposable Face Mask(一次性平面口罩)
Sample Quantity(样品数量) : 50 pieces(50 个)
Colour(颜色) : Blue white white(蓝色夹白色)
Size specification(号型规格) : KAZE01
Material Components(原料成分): Non-woven fabric 50%;Melt-blown fabric 26%;Ear band 12.7%; Nose clip 11.3%(50%无纺布,26%熔喷布,12.7%耳帶,11.3%鼻夹)

- Sample Receiving date (收到样品的日期) : 2020-06-03
- Report date (报告日期) : 2020-06-07
- The original sample is sticked on the last paper. (送检样品原样粘贴在本报告的末页)

Test Performed (检验标准)

Judgement according to(评定依据):
GB/T 32610-2016 Technical Specification of daily protective mask .
日常防护型口罩技术规范 .

- Selected test(s) as requested by applicants. (本实验室根据客户要求完成以下检测内容)

Pronounce (声明)

The results shown in this report refer only to sample(s) tested unless otherwise stated.All the items are performed in the standard conditions, except the noted cases.(除非特别说明，测试结果只对来样负责。所有测试项目均在标准规定的环境下进行，有注明除外。)

Except for the requirement of the client, the test results and the conformity judgement of this report do not take the uncertainty of the test results into account.(除非客户要求，本报告检测结果及符合性判定不考虑测量结果的不确定度。)

Signed for and on behalf of
CNTAC Testing Service Co.,Ltd.(Foshan)
Approved by
（批准）

张志荣

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--- **Test Result (测试结果)** ---

	Test Result(测试结果)	Requirements(评定条件)	Judgement(判定)

1. Color Fastness to Rubbing(耐摩擦色牢度) *GB/T 29865-2013*

Unit(单位): <**grade(级)**>

Dry(干摩擦)	4	Dry friction ≥ 4(干摩擦 ≥ 4)	Pass(合格)
Wet(湿摩擦)	4-5	Wet friction ≥ 4(湿摩擦 ≥ 4)	

2. Tensile Strength of the mask belt and the connection between the mask belt and the mask body(口罩带及口罩带与口罩体的连接处断裂强力) *GB/T 32610-2016 Section 6.9(条款 6.9)*

Unit(单位): <**N**>

Result(测试结果)	49	≥ 20	Pass(合格)

3. Filtration Efficiency(过滤效率(盐性介质)) *GB/T 32610-2016 Appendix A(附录 A)*

Air flow: 85L/min，Aerosol: Nacl(气体流量：85L/min，气溶胶颗粒：NaCl)

Unit(单位): <**%**>

Minimum value(最小值)	98.5	(Level Ⅱ) ≥ 95((Ⅱ级) ≥ 95)	Pass(合格)

4. pH Value(pH 值) *GB/T 7573-2009*

Using KCl solution as the extracting solution.(萃取介质：氯化钾溶液)

Result(测试结果)	6.6	4.0~8.5	Pass(合格)

5. Formaldehyde Content(甲醛含量) *GB/T 2912.1-2009*

Water extraction method,lower limit of quantitation:20mg/kg(水萃取法，检出限：20mg/kg)

Unit(单位): <**mg/kg**>

Result(测试结果)	Not Detectable (未检出)	≤ 20	Pass(合格)

Remark(备注):Not Detectable，Less than 20 mg/kg(“未检出”指小于 20 mg/kg。)

6. Azo Colourants(可分解致癌芳香胺染料) *GB/T 17592-2011*

Use GC/MSD method,limit of detection :5mg/kg(使用 GC/MSD 分析方法，检出限：5mg/kg)

Unit(单位): <**mg/kg**>

Result(测试结果)	Not Detectable (未检出)	Forbidden (≤ 20)(禁用(≤ 20))	Pass(合格)

Remark(备注):1) Not Detectable,Less than the Limit of detection.(“未检出”指小于方法检出限)

2) Banned arylamines substances are listed in Annex.(禁用芳香胺物质清单见附页)

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	Test Result(测试结果)	Requirements(评定条件)	Judgement(判定)
7. Appearance Requirement(外观要求) *GB/T 32610-2016 Section 6.1(条款 6.1)*			
Result(测试结果)	Accordance(符合)	Mask surface should not be damaged, oil stains, deformation and other obvious defects(口罩表面不应有破损、油污斑渍、变形及其他明显的缺陷)	Pass(合格)
8. Basic Requirement(基本要求) *GB/T 32610-2016 Section 5.1(条款 5.1)*			
Result(测试结果)	Accordance(符合)	The mask should be able to cover the mouth and nose securely(口罩应能安全牢固地护住口、鼻。)	Pass(合格)
	Accordance(符合)	Mask raw materials should not be reworked materials,not contain highly toxic or potentially carcinogenic substances and materials known to cause skin irritation or other adverse reactions, residues of other substances that are restricted in use should meet the relevant requirement, no odor(口罩原材料不应使用再生料，含高毒性或潜在致癌性物质以及已知的可导致皮肤刺激或其他不良反应的材料，其他限制使用物质的残留量应符合相关要求，无异味。)	
	Accordance(符合)	The mask should not have a palpable sharp angle or sharp edge and should not pose a hazard to the wearer(口罩不应存在可触及的锐利角和锐利边缘，不应对佩戴者构成危害)	
	Accordance(符合)	Masks should be easy to wear and remove, no obvious constriction or tenderness in the wearing process, the impact on the head movement is small(口罩应便于佩戴和摘除，在佩戴过程中无明显压迫感或压痛现象，对头部活动影响较小。)	

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	Test Result(测试结果)	Requirements(评定条件)	Judgement(判定)
9. Exhalation Resistance(呼气阻力) *GB/T 32610-2016 Section 6.8(条款 6.8)*			
Air flow: 85L/min(通气量 85 L/min)			
Unit(单位): <**Pa**>			
Maximum value(最大值)	89.1	≤ 145	Pass(合格)
10. Inhalation Resistance(吸气阻力) *GB/T 32610-2016 Section 6.7(条款 6.7)*			
Air flow: 85L/min(通气量 85 L/min)			
Unit(单位): <**Pa**>			
Maximum value(最大值)	96.9	≤ 175	Pass(合格)
11. Residual Ethylene Oxide(环氧乙烷残留量) *GB/T 14233.1-2008 Section 9.4 Gas chromatography(Limit extraction)(条款 9.4 气相色谱法（极限浸提法）)*			
Unit(单位): <**μg/g**>			
Ethylene oxide relative content(环氧乙烷相对含量)	<0.7	≤ 10	Pass(合格)

Remark(备注):1.Detection limit is 0.7μg/g(检出限为 0.7μg/g)
2.Sample not sealed(样品没有密封)

Remark(备注):The inhalation resistance and exhalation resistance items are unauthorized for CNAS.
(CNAS 未授权吸气阻力和呼气阻力项目。)

检 测 报 告(Testing Report)	防伪查询网址(Security website)：www.fcl-sz.org.cn 防伪码(Security code)：4407154121
报告编号(Report No)：ZFLJ2627311	Page 5 of 6

Appendix(附页)：

No. （编号）	CAS No. （化学文摘编号）	Forbidden Arylamine （化学名称）
1	92-67-1	4-aminobiphenyl（4-氨基联苯）
2	92-87-5	benzidine（联苯胺）
3	95-69-2	4-chloro-o-toluidine（4-氯邻甲苯胺）
4	91-59-8	2-naphthylamine（2-萘胺）
5	97-56-3	o-aminoazotoluene（邻氨基偶氮甲苯）
6	99-55-8	5-nitro-o-toluidine（5-硝基-邻甲苯胺）
7	106-47-8	p-chloroaniline（对氯苯胺）
8	615-05-4	2,4-diaminoanisole（2,4-二氨基苯甲醚）
9	101-77-9	4,4’-diaminobiphenylmethane（4,4’-二氨基二苯甲烷）
10	91-94-1	3,3’-dichlorobenzidine（3,3’-二氯联苯胺）
11	119-90-4	3,3’-dimethoxybenzidine（3,3’-二甲氧基联苯胺）
12	119-93-7	3,3’-dimethylbenzidine（3,3’-二甲基联苯胺）
13	838-88-0	3,3’-dimethyl-4,4’-diaminobiphenylmethane（3,3’-二甲基-4,4’-二氨基二苯甲烷）
14	120-71-8	p-cresidine（2-甲氧基-5-甲基苯胺）
15	101-14-4	4,4’-methylene-bis-（2-chloroaniline）（4,4’-亚甲基-二-（2-氯苯胺））
16	101-80-4	4,4’-oxydianiline（4,4’-二氨基二苯醚）
17	139-65-1	4,4’-thiodianiline（4,4’-二氨基二苯硫醚）
18	95-53-4	o-toluidine（邻甲苯胺）
19	95-80-7	2,4-toluylenediamine（2,4-二氨基甲苯）
20	137-17-7	2,4,5-trimethylaniline（2,4,5-三甲基苯胺）
21	90-04-0	o-anisidine（邻氨基苯甲醚）
22	60-09-3	4-aminoazobenzene （4-氨基偶氮苯）
23	95-68-1	2,4-xylidine（2,4-二甲基苯胺）
24	87-62-7	2,6-xylidine（2,6-二甲基苯胺）

检 测 报 告(Testing Report)	防伪查询网址(Security website)：www.fcl-sz.org.cn 防伪码(Security code)：4407154121
报告编号(Report No)：ZFLJ2627311	Page 6 of 6

Original (送检样品原样)

======= End of Report (检测报告结束) ======

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

检验检测报告
Test Report

TTTS-FH21002545

客户提供信息及要求 Information Provided by Client	委托单位/地址 Applicant	惠州博文制造有限公司 Huizhou Bowen Manufacturing Limited 广东省惠州市博罗县园洲镇下南村新南一路 Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China	送样人：/ Contact 电话：Tel. /	
	生产单位/地址 Manufacturer	惠州博文制造有限公司 Huizhou Bowen Manufacturing Limited 广东省惠州市博罗县园洲镇下南村新南一路 Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China		
	样品信息 Information of Submitted Sample	样品名称：Kaze 一次性口罩 Sample Name Kaze Disposable Face Mask	商标：KAZE Trademark	
		样品总数：70个 Sample Count 70Pieces		
		号型规格：175mm*95mm (Kaze-02) Size or Specification	颜色：/ Colour	
		质量等级：/ Quality Grade	安全类别：/ Safety Category	
		产品款号或货号：2021-06 Style No. or Order No.		
	判定标准：Test Standards	GB/T 32610-2016 日常防护型口罩技术规范 Technical specification of daily protective mask		
样品描述 Test Part Description		1# 口罩Mask-牛仔蓝色 Tile 2# 口罩Mask-中灰色 Steel 3# 口罩Mask-浅灰色 Cement 4# 口罩Mask-浅黄色 Concrete 5# 口罩Mask-卡其色 Bamboo		

检验性质 Test Type	委托检验 Commission Test	样品接收日期 Date of Submission	2021-07-08	报告发布日期 Date of Checking	2021-07-14
检验日期 Test Date	2021-07-08	到 To	2021-07-14		
执行标准 Test Standards	见附页 See next page(s)				
检验结论 Conclusion	检验结果及符合性见附页。 Test results and compliance refer to next page(s). 检验单位盖章 Stamp of Inspection Unit				
备注 Remarks	/				

天纺标检测认证股份有限公司 检测专用章

批准：Approver 方倩　审核：Checker 千泽　编制：Editor 赵晓

检验检测报告
Test Report

TTTS-FH21002545

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
1# 口罩Mask-牛仔蓝色 Tile						
外观要求 Appearance Requirement	/	/	口罩表面不应有破损、油污斑渍、变形及其他明显缺陷 The mask surface shall have no damage, oil stain, deformation and other obvious defects.	+	符合 Pass	GB/T 32610-2016
2# 口罩Mask-中灰色 Steel						
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-淺灰色 Cement						
甲醛含量 Formaldehyde Content	/	mg/kg	≤20	未检出 (低于检出限20mg/kg) Undetected (< 20mg/kg)	符合 Pass	GB/T 2912.1-2009
pH值 pH Value	氯化钾萃取 KCl Extract	/	4.0～8.5	6.2	符合 Pass	GB/T 7573-2009
可分解致癌芳香胺染料 Azo	/	mg/kg	禁用 Not Used	未检出 (低于检出限5mg/kg) Undetected (< 5mg/kg)	符合 Pass	GB/T 17592-2011
4# 口罩Mask-淺黄色 Concrete						
吸气阻力 Inspiratory Resistance	/	Pa	≤175	未预处理样品 Samples Without Pretreatment: 1：75 2：74 预处理样品 Samples With Pretreatment: 1：86 2：83	符合 Pass	GB/T 32610-2016

检验检测报告
Test Report

TTTS-FH21002545

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
呼气阻力 Expiratory Resistance	/	Pa	≤145	未预处理样品 Samples Without Pretreatment: 1：56 2：53 预处理样品 Samples With Pretreatment: 1：67 2：71	符合 Pass	GB/T 32610-2016
5# 口罩Mask-卡其色 Bamboo						
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 1：99.3 2：99.3 3：99.3 4：99.3 5：99.4 预处理样品 Samples With Pretreatment: 1：99.2 2：99.1 3：99.2 最小值Minimum：99.1	符合 Pass	GB/T 32610-2016
	油性介质 Oil Medium	%	≥80	未预处理样品 Samples Without Pretreatment: 1：92.9 2：92.4 3：93.0 4：92.5 5：92.4 预处理样品 Samples With Pretreatment: 1：91.2 2：89.5 3：90.8 最小值Minimum：89.5		
环氧乙烷残留量 Ethylene Oxide Residual	/	μg/g	≤10	未检出 (低于检出限2μg/g) Undetected (＜ 2μg/g)	符合 Pass	GB/T 14233.1-2008

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

样　品　Sample

EC REP CERTIFICATE

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

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

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

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

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

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

CE

Issued on: 16/06/2020

Valid until: 24/05/2022

Authorized Signatory
CMC Medical Devices & Drugs SL

EC REP CERTIFICATE

ANNEX I Medical Device Products

Kaze Disposable Face Mask

CE

EU Declaration of Conformity

Manufacturer:	Huizhou Bowen Manufacturing Limited Xinnan 1st Road, Xianan Village, Yuanzhou Town, Boluo County, Huizhou City, Guangdong Province, P.R.China Tel:+86-752-5895333
SRN:	CN-MF-000009940
European Representative:	CMC Medical Devices & Drugs S.L.
SRN:	Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Product Name:	Kaze Disposable Face Mask
Specification:	17.5cm×9.5cm
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 premises of the manufacturer.
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

Place/date 26th may, 2020

191020340175

中国认可
国际互认
检测
TESTING
CNAS L13034

In Vitro Cytotoxicity Test

MTT Method

Final Report

Verification

Report Number: CSTBB20051119

Article Name: Disposable Face Mask

Method Standard: ISO 10993-5：2009

Sponsor

Huizhou Bowen Manufacturing Limited

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

Test Facility

CCIC Huatongwei international inspection (Suzhou) Co., Ltd

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

CONTENTS

Notices

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

Abstract

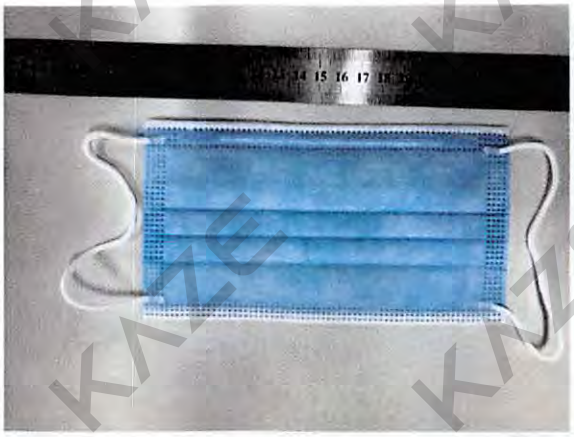
In this study, mammalian L-929 cells were cultured in vitro according to ISO 10993-5:2009 to test the potential cytotoxicity of the test article.

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

The results showed that the cells in the blank control group and the negative control group (high density polyethylene) were well-formed throughout the experiment and showed no cytotoxic reaction. A severe cytotoxic response was shown in the positive control group (ZDEC). The 100% concentration of the test extract retained a normal appearance after 24 hours of incubation, and the cell viability was 79.8%. 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 Disposable Face Mask have no potential toxicity to L-929 in the MTT method.

Study Verification and Signature



Protocol Number	SST2005032701BB
Protocol Effective Date	2020-05-22
Technical Initiation Date	2020-05-25
Technical Completion Date	2020-05-27
Final Report Completion Date	2020-06-01

Personnel Na Yang — 2020-06-01 Date Completed

Approved

Xiong Ling — Study Director

2020-06-01 Date Completed

Supervisory

Test Facility Manager

Date Completed

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	Disposable Face Mask	High Density Polyethylene Film	ZDEC	MEM medium, with addition 10% FBS
Manufacture	Huizhou Bowen Manufacturing Limited	Hatano Research Institute. FDSC	Sigma-Aldrich.	Hyclone
Size	17.5cmX9.5cm	3 cm×10 cm (5 sheets)	25 g	500 ml
Model	KAZE01	/	/	/
Lot Batch#	2020-05	C-161	BCBQ6847V	AE29441978
Test Article Material	Non-woven fabric 50%; Melt-blown fabric 26%; Ear band 12.7%; Nose clip 11.3%	/	/	/
Physical State	Solid	Solid	Solid	Liquid
Color	Blue with white	White	White	Pink
Packaging Material	Packaging of plastic bags and cartons	/	/	/
Sterilized or Not	No	No	No	Yes
Concentration	/	/	0.1%	/
Total Surface or weight	Not provided	/	/	/
Storage Condition	Room Tep.	Room Tep.	Room Tep.	4℃
Note：The information about the test article was supplied by the sponsor wherever applicable.				

4.0 Identification and justification of test system

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

L-929 cells have been used for cytotoxicity studies because they demonstrate sensitivity to extractable cytotoxic articles. Also, the test article is extracted and administered in vitro to mouse fibroblast L929 cells through a solvent compatible with the test system, which is the optimal route of administration available in this test system

as recommended in ISO 10993-5.

5.0 Equipment and reagents

5.1 Instruments

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

5.2 Reagents

MEM (Hyclone, AE29441978), FBS (Clark, JC65116), Penicillin-Streptomycin (Gibco, 2145453), Trypsin (Gibco, 2048080), PBS (Hyclone, AE29451445), MTT (3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyletrazolium bromide) (Sigma, MKBG2038V), Isopropyl alcohol (Macklin, C10394867)

6.0 Experiment design and dose

6.1 Sample preparation

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

Groups	Sampling		Sterilization	Aseptic Extraction In Inert Container				Final Extract
	Sampling Manner	Actually sampling	Method	Ratio	Extracts	Condition	pH	Clear or Not
Test article	Whole	570.0 cm^2	EO	6 cm^2: 1 ml	95.0 ml	37 ℃ 24 h	7.4	Clear
Negative Control	Random	60.0 cm^2	UV	3 cm^2: 1 ml	20.0 ml	37 ℃ 24 h	7.4	Clear
Positive Control	Random	0.02 g	Filter	0.1 g: 100 ml	20.0 ml	37 ℃ 24 h	7.4	Clear
Blank Control	/	/	/	/	20.0 ml	37 ℃ 24 h	7.4	Clear

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

6.2 Test method

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

The suspended cells were dispensed at 100 µl per well in 96-well plate, and cultured in cell incubator (5% CO_2, 37 ℃, >90% humidity). Cell morphology was evaluated to verify that the monolayer was satisfactory.

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

h. Six replicates of each test were tested.

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

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

7.0 Statistical method

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

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

8.0 Evaluation criteria

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

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

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

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

9.0 Results of the test

9.1 Results of the cell morphology

Table 1 Observation of the cell morphology

Group	Before inoculation	Before treated with extract	24 h after treatment
Blank control	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
Negative control			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
Positive control			Nearly complete or complete destruction of the cell layers.
100% Test article extract			The cells showed a round shape and a change in cell morphology occasionally, and there were particles in the cytoplasm, occasionally cell lysis and slight growth inhibition.
75% Test article extract			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.
50% Test article extract			The cells showed a round shape and a change in cell morphology occasionally, and there

			were particles in the cytoplasm, occasionally cell lysis and slight growth inhibition.
25% Test article extract			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.

9.2 Results of the cell vitality

Table2 Results of the cell vitality

Group	OD value								Viab. (%)
	1	2	3	4	5	6	$\bar{x}$	s	
Blank control	0.612	0.628	0.627	0.633	0.631	0.632	0.627	0.008	100.0
Negative control	0.634	0.615	0.620	0.623	0.612	0.613	0.620	0.008	98.8
Positive control	0.053	0.050	0.051	0.057	0.060	0.054	0.054	0.004	8.6
100% test article extract	0.503	0.507	0.496	0.498	0.492	0.505	0.500	0.006	79.8
75% test article extract	0.511	0.518	0.511	0.511	0.517	0.515	0.514	0.003	82.0
50% test article extract	0.558	0.535	0.562	0.561	0.535	0.536	0.548	0.014	87.4
25% test article extract	0.574	0.588	0.565	0.584	0.572	0.594	0.580	0.011	92.4

10.0 Conclusion

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

11.0 Record

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

12.0 Confidentiality Agreement

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

191020340175

中国认可
国际互认
检测
TESTING
CNAS L13034

Skin Sensitization Test

Guinea Pig Maximization

Final Report

Verification

Report Number: CSTBB20051120

Article Name: 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

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Abstract

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

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

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

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

Study Verification and Signature

Protocol Number	SST2005032702BB
Protocol Effective Date	2020-05-20
Technical Initiation Date	2020-05-22
Technical Completion Date	2020-06-19
Final Report Completion Date	2020-06-19

Personnel Na Yang 2020-06-19
Date Completed

Approved
Study Director 2020-06-19
Date Completed

Supervisory
Test Facility Manager 2020.06.19
Date Completed

Huatongwei international inspection (Suzhou) Co., Ltd.

1.0 Purpose

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

2.0 Reference

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

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

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

3.0 Test and control articles

Groups	Test article	Negative Control Article(Polar)	Negative Control Article(Non-Polar)	Positive Control
Name	Disposable Face Mask	Sodium Chloride Injection (SC)	Sesame Oil (SO)	2, 4-Dinitrochlorobenzene (DNCB)
Manufacture	Huizhou Bowen Manufacturing Limited	Shijiazhuang No.4 Pharmaceutical	Jiangxi xinsen natural vegetable oil co., Ltd.	TOKYO CHEMICAL INDUSTRY CO., LTD
Size	17.5cmX9.5cm	500 ml	25 kg	25 g
Model	KAZE01	/	/	/
Lot Batch#	2020-05	1912121907	181120	H2UKD-DM
Test Article Material	Non-woven fabric 50%; Melt-blown fabric 26%; Ear band 12.7%; Nose clip 11.3%	/	/	/
Physical State	Solid	Liquid	Liquid	Solid
Color	Blue with white	Colorless	Light yellow	Light yellow
Package material	Packaging of plastic bags and cartons	/	/	/
Sterilization state	No	/	/	/
Concentration	/	0.9 %	/	Induction Concentration: 0.5 % Challenge Concentration: 1.0 % Dissolved in ethanol

Total Surface/Weight	Not provided	/	/	/
Storage Condition	Room Tep.	Room Tep.	Room Tep.	Room Tep.
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: 15 ♀， 15 ♂

Initial body weight: 300~500 g

Health status: Healthy, not previously used in other experimental procedures

Animal identification: Ear tag

Cages: Plastic cage

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

4.2 Justification of test system

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

5.0 Animal Management

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

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

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

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

Animal room temperature: 18-26 ℃

Animal room relative humidity: 30 %-70 %

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

Personnel: Associates involved were appropriately qualified and trained

Selection: Only healthy, previously unused animals were selected

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

6.0 Equipment and reagents

6.1 Instruments

Constant Temperature Vibrator (SHB007, calibration data: 2020/3/16), Autoclave (SHB026, calibration data: 2020/3/16), Electronic scale (SHB017, calibration data: 2020/3/16)

6.2 Reagents

Freund’s adjuvant Complete liquid (SIGMA, Lot No: SLBR3877V), Sodium dodecyl sulfate (SDS SIGMA, Lot No: SLBL2304V)

7.0 Experiment design

7.1 Sample preparation

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

Aseptic Sampling			Extraction in sterile vessels				
Sampling Manner	Actually sampling	Ratio	Reagent		Temperature	Time	pH
Whole	570.0 cm^2	6 cm^2: 1 ml	SC	95.0 ml	50 ℃	/	
	570.0 cm^2		SO	95.0 ml			5.5

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

7.2 Test method

7.2.1 Intradermal induction phaseI

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

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

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

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

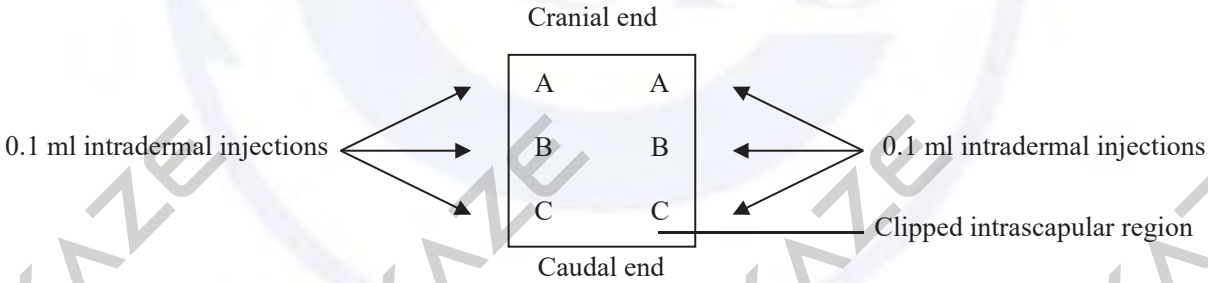

Figure 1 Location of intradermal injection sites

7.2.2 Topical induction phaseII

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

At 7 d after completion of the intradermal induction phase, administer test article extract by topical application to the intrascapular region of each animal, using a patch of area approximately 8 cm^2 (absorbent gauze), so as to cover the intradermal injection sites. Secure the patches with an occlusive dressing. Remove the dressings and patches after (48±2) h.

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

7.2.3 Challenge phase

At 14d after completion of the topical induction phase, challenge all test and control animals with the test sample. Absorbent gauzes (2.5 cmx2.5 cm) were soaked respectively with test article and control article. Apply the test article extract and control article topically to two sites that were not treated during the induction stage. Secure with an occlusive dressing. Remove the dressings and patches after (24±2) h.

8.0 The results observed

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

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

Table 1 Magnusson and Kligman scale

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

9.0 Evaluation criteria

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

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

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

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

10.0 Results of the test

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

11.0 Conclusion

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

12.0 Record

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

13.0 Confidentiality Agreement

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

Table 2 Guinea pig Sensitization Dermal Reactions

Group		No.	Pretest weigh(g)	Finished weigh(g)	The Challenge patch was removed 24h later		The Challenge patch was removed 48h later		Positive rate
					Erythema	Swelling	Erythema	Swelling	
SC	Test	1	314.7	378.8	0	0	0	0	0%
		2	318.0	366.0	0	0	0	0	
		3	304.3	382.3	0	0	0	0	
		4	308.8	384.3	0	0	0	0	
		5	317.0	367.1	0	0	0	0	
		6	315.3	370.4	0	0	0	0	
		7	317.6	364.5	0	0	0	0	
		8	315.8	355.5	0	0	0	0	
		9	305.0	354.1	0	0	0	0	
		10	304.7	375.2	0	0	0	0	
	Control	11	316.3	383.3	0	0	0	0	—
		12	304.6	384.4	0	0	0	0	
		13	314.8	371.9	0	0	0	0	
		14	314.2	372.7	0	0	0	0	
		15	304.6	378.6	0	0	0	0	
SO	Test	16	304.4	383.1	0	0	0	0	0%
		17	310.9	358.1	0	0	0	0	
		18	309.2	377.8	0	0	0	0	
		19	314.4	376.6	0	0	0	0	
		20	317.1	357.7	0	0	0	0	
		21	302.4	367.9	0	0	0	0	
		22	318.2	355.3	0	0	0	0	
		23	315.4	351.2	0	0	0	0	
		24	308.5	354.8	0	0	0	0	
		25	302.6	354.3	0	0	0	0	
	Control	26	318.5	364.7	0	0	0	0	—
		27	314.3	352.4	0	0	0	0	
		28	311.6	376.0	0	0	0	0	
		29	310.9	366.4	0	0	0	0	
		30	315.5	368.1	0	0	0	0	

Table 3 Positive control

Group	No.	Pretest weigh(g)	Finished weigh(g)	The Challenge patch was removed 24 h later		The Challenge patch was removed 48 h later		Positive rate
				Erythema	Swelling	Erythema	Swelling	
Test	1	310.4	377.0	1	0	1	0	100%
	2	302.3	384.4	1	0	1	0	
	3	303.0	350.5	2	0	2	0	
	4	315.8	384.3	1	0	1	0	
	5	313.1	381.0	1	0	1	0	
	6	308.7	361.1	1	0	2	0	
	7	302.7	360.5	2	0	1	0	
	8	312.9	354.3	1	0	1	0	
	9	316.1	379.6	1	0	1	0	
	10	311.4	369.8	2	0	1	0	
Control	11	306.4	373.9	0	0	0	0	—
	12	303.6	378.2	0	0	0	0	
	13	316.4	383.8	0	0	0	0	
	14	318.6	351.7	0	0	0	0	
	15	311.9	358.4	0	0	0	0	

Note：The positive control was CSTBB20040001P1(Finish date：2020-05-08).

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检测
TESTING
CNAS L13034

Skin Irritation Test

Extraction Method

Final Report

Verification

Report Number: CSTBB20051121

Article Name: 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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Abstract

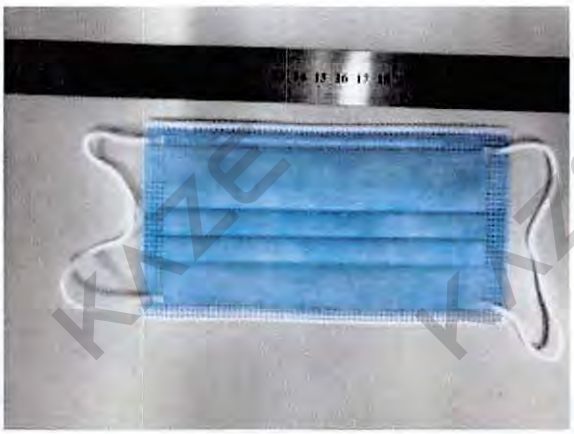
In this study, we took New Zealand white Rabbits to observe the skin irritation of the test article according to ISO10993-10:2010.

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

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

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

Study Verification and Signature



Protocol Number	SST2005032703BB
Protocol Effective Date	2020-05-22
Technical Initiation Date	2020-05-22
Technical Completion Date	2020-05-29
Final Report Completion Date	2020-06-19

Personnel — Na Yang — 2020-06-19 (Date Completed)

Approved — Study Director — 2020-06-19 (Date Completed)

Supervisory — Test Facility Manager — Date Completed

Huatongwei international inspection (Suzhou) Co., Ltd.

1.0 Purpose

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

2.0 Reference

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

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

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

3.0 Test and control articles

Groups	Test article	Negative Control Article(Polar)	Negative Control Article(Non-Polar)	Positive Control
Name	Disposable Face Mask	Sodium Chloride Injection (SC)	Sesame Oil (SO)	10 % sodium dodecyl sulfate (SDS)
Manufacture	Huizhou Bowen Manufacturing Limited	Shijiazhuang No.4 Pharmaceutical	Jiangxi xinsen natural vegetable oil co., Ltd.	SIGMA
Size	17.5cmX9.5cm	500 ml	25 kg	25 g
Model	KAZE01	/	/	/
Lot Batch#	2020-05	1912121907	181120	SLBL2304V
Test Article Material	Non-woven fabric 50%; Melt-blown fabric 26%; Ear band 12.7%; Nose clip 11.3%	/	/	/
Physical State	Solid	Liquid	Liquid	Solid
Color	Blue with white	Colorless	Light yellow	Colorless
Package material	Packaging of plastic bags and cartons	/	/	/
Sterilization state	No	/	/	/
Concentration	/	0.9 %	/	10 %
Total Surface/Weight	Not provided	/	/	/
Storage Condition	Room Tep.	Room Tep.	Room Tep.	Room Tep.
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: 3 ♀, 3 ♂

Weight: >2 kg

Health status: Healthy, not previously used in other experimental procedures

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 current 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

Bedding: /

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

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

Animal room temperature: 18-26 ℃

Animal room relative humidity: 30 %-70 %

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

Personnel: Associates involved were appropriately qualified and trained

Selection: Only healthy, previously unused animals were selected

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

6.0 Equipment and reagents

6.1 Instruments

Constant Temperature Vibrator (SHB007, calibration data: 2020/3/16), Autoclave (SHB026, calibration data: 2020/3/16), Electronic scale (SHB017, calibration data: 2020/3/16)

7.0 Experiment design

7.1 Sample preparation

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

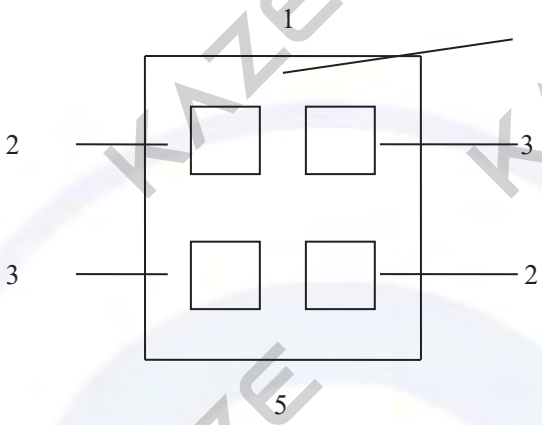
Aseptic Sampling			Extraction in sterile vessels				
Sampling Manner	Actually sampling	Ratio	Reagent		Temperature	Time	pH
Whole	570.0 cm^2	6 cm^2: 1 ml	SC	95.0 ml	50 ℃	72 h	5.5
	570.0 cm^2		SO	95.0 ml			/

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

7.2 Test method

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

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



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

Figure1 Location of skin application sites

8.0 The results observed

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

Table 1 Classification System for Skin Reaction

Erythema and Eschar Formation:	Numerical Grading
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet redness) to eschar formation preventing grading of erythema	4
Edema Formation:	
No edema	0
Very slight edema (barely perceptible)	1
Well-defined edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond exposure area)	4

Maximal possible score for irritation	8
Irritation Response Categories in the Rabbit	
Response Category	Mean score
Negligible	0 to 0.4
Slight	0.5 to 1.9
Moderate	2 to 4.9
Severe	5 to 8

9.0 Evaluation criteria

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

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

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

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

10.0 Results of the test

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

11.0 Conclusion

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

12.0 Record

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

13.0 Confidentiality Agreement

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

Table 2 Skin irritation response observation

Reagent	Rabbit No	Pretest weigh(g)	Finished weigh(g)	Group	Reaction	Interval (hours): score=left/right			
						1h	24h	48h	72h
SC	1	2.21	2.28	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	2	2.16	2.24	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	3	2.11	2.20	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
Primary irritation index						0			
SO	4	2.15	2.22	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	5	2.09	2.15	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	6	2.13	2.20	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
Primary irritation index						0			

Table 3 Positive control

Rabbit No	Group	Reaction	Interval (hours): score=left site/right site			
			1h	24h	48h	72h
1	Positive control	Erythema	0/0	1/2	2/3	3/3
		Oedema	0/0	2/1	2/2	3/3
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
2	Positive control	Erythema	0/1	2/1	3/3	4/3
		Oedema	1/0	2/2	3/3	3/4
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
3	Positive control	Erythema	1/0	1/2	3/3	4/3
		Oedema	0/1	2/1	3/4	3/4
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
Primary irritation index			5.2			

Positive control performed once every six months see CSTBB20020001P3(Finish date：2020-02-21)