EU Type Examination Certificate

This is to certify that:

Huizhou Bowen Manufacturing Ltd
Xinnan 1st Road, Xianan Village
Yuanzhou Town, Boluo County
Huizhou City
Guangdong
516123
China

Holds Certificate Number: CE 729875

In respect of:

Model: Kaze-05 Face mask
To technical specification Annex II (EHSR) of the PPE Regulation (EU) 2016/425
PPE for use by healthcare professionals as per Commission recommendation 2020/403

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Drs. Dave Hagenaars, Managing Director

First Issued: 2021-01-25
Latest Issue: 2021-01-25

Effective Date: 2021-01-25
Expiry Date: 2022-01-25

PRODUCTS
RvA C 646

...making excellence a habit.™

EU Type Examination Certificate

No. CE 729875

Product Specification

Product Name:	Kaze Protective Respirator.
Product Type:	Particulate filtering half masks for use by Healthcare professionals.
Model:	**Kaze-05**
Colour Variants:	18 Colour Variants - White, Dove Grey, Forest Pine, Sweet Pea, Powder Blue, Royal Blue, Racing Red, Fuchsia, Maroon, Ultraviolet, Rose Quartz, Sandy Beige, Citrus Orange, Champagne, Natural Sand, Light Blush, Espresso and Silver Grey
Classification:	FFP2 NR
Technical Specification:	Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425.
Product Description:	The respirator is non-reusable, secured to the face of the user by a pair of elasticated ear straps, and has no exhalation valve. The respirator is FFP2 NR class, vertical fold flat type. The Respirator has 18 Colour Variants; White, Dove Grey, Forest Pine, Sweet Pea, Powder Blue, Royal Blue, Racing Red, Fuchsia, Maroon, Ultraviolet, Rose Quartz, Sandy Beige, Citrus Orange, Champagne, Natural Sand, Light Blush, Espresso and Silver Grey. The respirator listed on this certificate is for use by healthcare workers, first responders and other personnel involved in the efforts to contain the COVID-19 virus and avoid its further spread. The product covered by this certificate is not approved for industrial applications and the certificate is only valid as long as EU Commission recommendation sheet 2020/403 remains applicable.
Product Assessments:	BSI's PPE for Healthcare Professionals 2020/403 – RPE Technical Specification.

KAZE

First Issued: 2021-01-25
Latest Issue: 2021-01-25

Effective Date: 2021-01-25
Expiry Date: 2022-01-25

EU Type Examination Certificate

No. CE 729875

Certificate Administration Details

Technical File Reference: Huizhou Bowen Manufacturing Ltd, Kaze-05

Certificate Amendment Record:

Issue date	Comments	BSI Review No.
January 2021	First issue.	2797:20:3218633

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

The validity of the Certificate for the products is also dependent on the maintenance of the EU Conformity to Type based on Internal Production Control plus supervised product checks at random intervals, Annex VII (Module C2) as referenced on BSI issued Certificate CE 729876.

KAZE

First Issued: 2021-01-25
Latest Issue: 2021-01-25

Effective Date: 2021-01-25
Expiry Date: 2022-01-25

Conformity to Type based on Internal Production Control plus supervised product checks at random intervals

This is to certify that:

Huizhou Bowen Manufacturing Ltd
Xinnan 1st Road, Xianan Village
Yuanzhou Town, Boluo County
Huizhou City
Guangdong
516123
China

Holds Certificate Number: CE 729876

In respect of:

For the manufacture of particulate respirators to technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425.

on the basis that BSI carried out the supervised production checks at random intervals under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex VII (Module C2)

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Drs. Dave Hagenaars, Managing Director

First Issued: 2021-01-25
Latest Issue: 2021-01-25

Effective Date: 2021-01-25
Expiry Date: 2022-01-25

PRODUCTS
RvA C 646

...making excellence a habit.™

Conformity to Type based on Internal Production Control plus supervised product checks at random intervals

No. CE 729876

Product manufactured by:

Huizhou Bowen Manufacturing Ltd.
Xinnan 1st Road, Xianan Village
Yuanzhou Town, Boluo County
Huizhou City
Guangdong
516123
China

Product details

The respiratory protective device covered by the scope of this Module C2 Certificate and the Technical Specification to which the product is manufactured are as follows:

Product type:	Particulate filtering half masks for use by Healthcare professionals.
Model and classifications:	Kaze-05 FFP2 NR
Colour Variants:	18 Colour Variants - White, Dove Grey, Forest Pine, Sweet Pea, Powder Blue, Royal Blue, Racing Red, Fuchsia, Maroon, Ultraviolet, Rose Quartz, Sandy Beige, Citrus Orange, Champagne, Natural Sand, Light Blush, Espresso and Silver Grey.
Technical Specification:	Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425. BSI's PPE for Healthcare Professionals 2020/403 – RPE Technical Specification.

KAE

First Issued: 2021-01-25
Latest Issue: 2021-01-25

Effective Date: 2021-01-25
Expiry Date: 2022-01-25

Conformity to Type based on Internal Production Control plus supervised product checks at random intervals

No. CE 729876

Certificate Administration Details:

Certificate Amendment Record and BSI internal Review relating to this Certificate

Issue date	Comments	BSI Review No.
January 2021	First issue.	2797:20:3218634

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspects of the overall quality system utilized in the manufacture of the products, failure to do so could invalidate the Certificate in respect of product manufactured after the introduction of such changes.

KAZE

First Issued: 2021-01-25
Latest Issue: 2021-01-25

Effective Date: 2021-01-25
Expiry Date: 2022-01-25

Nelson Labs
A Sotera Health company

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

Sodium Chloride (NaCl) Aerosol Test Final Report

Test Article:	KAZE Protective Respirator
Study Number:	1306452-S01
Study Received Date:	03 Jun 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: STP0014 Rev 09
Deviation(s):	None

Summary: This procedure was performed to evaluate particulate filter penetration as specified in 42 CFR Part 84 and TEB-APR-STP-0059 for requirements on a N95 respirator. Respirators were conditioned then tested for particle penetration against a polydispersed, sodium chloride (NaCl) particulate aerosol. The challenge aerosol was dried, neutralized, and passed through the test article at a concentration not exceeding 200 mg/m^3. The initial airflow resistance and particle penetration for each respirator was determined.

According to 42 CFR Part 84.64, pretesting must be performed by all applicants as part of the application process with NIOSH. Results seen below are part of that pretesting and must be submitted to and accepted by NIOSH for respirator approval.

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.

Robert Dieker electronically approved for	17 Jul 2020 17:58 (+00:00)
Study Director Curtis Gerow	Study Completion Date and Time

Results: The NIOSH N95 filter efficiency as stated in 42 CFR Part 84.181 is a minimum efficiency for each filter of ≥95% (≤5% penetration). The test articles submitted by the sponsor conform to the NIOSH N95 criteria for filter efficiency.

Test Article Number	Corrected[a] Initial Airflow Resistance (mm H_2O)	Maximum Particle Penetration (%)	Filtration Efficiency (%)
1	14.5	0.790	99.210
2	15.0	1.00	99.00
3	15.7	0.825	99.175
4	15.8	0.888	99.112
5	15.4	0.775	99.225
6	15.4	0.461	99.539
7	16.0	0.724	99.276
8	15.8	1.03	98.97
9	17.7	0.936	99.064
10	17.7	0.868	99.132
11	17.6	0.677	99.323
12	18.7	0.935	99.065
13	16.8	0.628	99.372
14	16.0	0.719	99.281
15	16.0	0.629	99.371
16	14.7	1.14	98.86
17	16.1	0.742	99.258
18	15.9	0.761	99.239
19	14.8	0.701	99.299
20	14.9	0.887	99.113

[a] The final airflow resistance value for each test article was determined by subtracting out the background resistance from the system.

Test Method Acceptance Criteria: The filter tester must pass the "Tester Set Up" procedure. The airflow resistance and particle penetration of the reference material must be within the limits set by the manufacturer.

Filter Test Procedure: Prior to testing, respirators were taken out of their packaging and placed in an environment of 85 ± 5% relative humidity (RH) and 38 ± 2.5°C for 25 ± 1 hours.

The filter tester used in testing was a TSI® CERTITEST® Model 8130 Automated Filter Tester that is capable of efficiency measurements of up to 99.999%. It produces a particle size distribution with a count median diameter of 0.075 ± 0.020 microns (µm) and a geometric standard deviation not exceeding 1.86 µm. The mass median diameter was approximately 0.26 µm, which is generally accepted as the most penetrating aerosol size. The reservoir was filled with a 2% NaCl solution and the instrument allowed a minimum warm-up time of 30 minutes. The main regulator pressure was set to 75 ± 5 pounds per square inch (psi). The filter holder regulator pressure was set to approximately 35 psi. The NaCl aerosol generator pressure was set to approximately 30 psi and the make-up airflow rate was set to approximately 70 liters per minute (L/min).

The NaCl concentration of the test aerosol was determined in mg/m^3 by a gravimetric method prior to the load test assessment. An entire respirator was mounted on a test fixture, placed into the filter holder, and the NaCl aerosol passed through the outside surface of the test article at a continuous airflow rate of 85 ± 4 L/min. In accordance with NIOSH policy, three respirators were challenged until 200 ± 5 mg of NaCl had contacted each test article. Based upon the load pattern of NIOSH Type 1, the initial penetration reading of the remaining 17 respirators was recorded.

Nelson Labs
A Sotera Health company

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

Determination of Inhalation and Exhalation Resistance for Air-Purifying Respirators Final Report

Test Article:	KAZE Protective Respirator
Study Number:	1306453-S01
Study Received Date:	03 Jun 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: STP0145 Rev 05
Deviation(s):	None

Summary: This procedure was performed to evaluate the differential pressure of non-powered air-purifying particulate respirators in accordance with 42 CFR Part 84.180. The air exchange differential or breathability of respirators was measured for inhalation resistance using NIOSH procedure TEB-APR-STP-0007 and exhalation resistance with NIOSH procedure TEB-APR-STP-0003. The differential pressure technique is a simple application of a basic physical principle employing a water manometer differential upstream and downstream of the test material, at a constant flow rate.

According to 42 CFR Part 84.64, pretesting must be performed by all applicants as part of the application process with NIOSH. Results seen below are part of that pretesting and must be submitted to and accepted by NIOSH for respirator approval.

The inhalation resistance criteria as stated in 42 CFR Part 84.180 is an initial inhalation not exceeding 35 mm water column height pressure. The test articles submitted by the sponsor conform to this NIOSH criterion for airflow resistance.

The exhalation resistance criteria as stated in 42 CFR Part 84.180 is an initial exhalation not exceeding 25 mm water column height pressure. The test articles submitted by the sponsor conform to this NIOSH criterion for airflow resistance.

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.

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Sean Shepherd electronically approved for Curtis Gerow	30 Jun 2020 18:54 (+00:00)
Study Director	Study Completion Date and Time

Results:

Test Article Number	Inhalation Resistance (mm H_2O)	Exhalation Resistance (mm H_2O)
1	11.5	10.2
2	10.3	10.3
3	10.3	10.3

Test Method Acceptance Criteria: The resistance measurement for the reference plate must be within ± 3 standard deviations of the mean established in the control chart.

Procedure: A complete respirator was mounted to a test fixture comprised of a metal plate with an approximate 3.5 inch diameter hole in the center to allow airflow to reach the mask. The sample holder was assembled by placing a Plexiglas collar around the test fixture and topping with another metal disc with a 3.5 inch opening in the center. The sample holder is held tightly together with clamps and connected to an air source. The manometer is attached to the sample holder by a connection port on the Plexiglas collar.

Before testing, the manometer was zeroed and the back pressure in the sample holder checked and verified to be acceptable. Resistance measurements were taken with a manometer capable of measuring at least 6 inches of water. For inhalation testing, a negative airflow (vacuum) was applied. For exhalation testing, a positive airflow (compressed air) was used. Airflow was passed through the sample holder at approximately 85 ± 2 liters per minute (L/min).

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

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

Sample Description	:	COLOR NON-WOVEN FABRIC 16%;MELT BLOWN FABRIC 22%;HOT AIR COTTON 12%;SKIN FRIENDLY NON-WOVEN FABRIC 10%;EAR THREAD 25%,NOSE CLIP 15% KN95 PROTECTIVE RESPIRATOR IN ORANGE
Sample Color	:	(A)ORANGE
Composition	:	(A)COLOR NON-WOVEN FABRIC 16%;MELT BLOWN FABRIC 22%;HOT AIR COTTON 12%;SKIN FRIENDLY NON-WOVEN FABRIC 10%;EAR THREAD 25%,NOSE CLIP 15%
Style No.	:	KAZE
Manufacturer	:	HUIZHOU BOWEN MANUFACTURING LIMITED
Country of Destination	:	United States,EUR
Sample Receiving Date	:	Jul 16, 2020
Testing Period	:	Jul 16, 2020 - Jul 22, 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).
Test Performed	:	Selected test(s) as requested by applicant

KAZE

198 Kezhu Road,Scientech Park Guangzhou Economic&Technology Development District,Guangzhou,China 510663 t (86-20) 82155555 f (86-20) 82075169 www.sgsgroup.com.cn
中国·广州·经济技术开发区科学城科珠路198号 邮编: 510663 t (86-20) 82155555 f (86-20) 82075169 e sgs.china@sgs.com

Conclusion	A	Remark
Pentachlorophenol (PCP)	PASS	
Cadmium(Cd)	PASS	
Nonylphenol Ethoxylates (NPEOs)	PASS	
Short Chain Chlorinated Paraffins (SCCP)	PASS	
Phthalates	PASS	
Azo Dyes	PASS	
Organotin Compounds	PASS	
Polycyclic Aromatic Hydrocarbons(PAHs)	PASS	

Remark(s) : PASS=Meet Client's Requirement

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

Lily Wang (Account Manager)

KAZE

198 Kezhu Road,Scientech Park Guangzhou Economic&Technology Development District,Guangzhou,China 510663 t (86-20) 82155555 f (86-20) 82075169 www.sgsgroup.com.cn
中国·广州·经济技术开发区科学城科珠路198号 邮编: 510663 t (86-20) 82155555 f (86-20) 82075169 e sgs.china@sgs.com

COMPONENT LIST / List of Materials

Sample No.	Component No.	Description	Material	Color	Remark
A	1	Outer non woven fabric	Synthetic Fibers	Orange	Finished product
A	2	Round band	Synthetic Fibers	Orange	Finished product
A	3	Hot air cotton fabric	Blended Fibers	White	Finished product
A	4	Melt-blown non woven fabric	Synthetic Fibers	White	Finished product
A	5	Lining non woven fabric	Synthetic Fibers	White	Finished product
A	6	Foam	Foam	Black	Finished product
A	7	Round band buckle	Plastics	White	Finished product
A	8	Nose clip	Plastics	White	Finished product

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)	Unit	MDL	*1+2*	*3+4+5*
Pentachlorophenol (PCP)	mg/kg	0.15	**ND**	**ND**
Comment			**PASS**	**PASS**

Notes :

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

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)	Unit	MDL	*6+7+8*
Cadmium (Cd)	mg/kg	5	**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)	Unit	MDL	*1+2*	*3+4+5*
Nonylphenol ethoxylates (NPEOs)	mg/kg	30	**ND**	**ND**
Comment			**PASS**	**PASS**

Notes :

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

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)	Unit	MDL	*6+7+8*
Alkanes C10-C13, chloro (short-chain chlorinated paraffins) (SCCPs)	mg/kg	50	**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	Unit	MDL	*6+7+8*
Dibutyl Phthalate (DBP)	84-74-2	mg/kg	30	ND
Benzylbutyl Phthalate (BBP)	85-68-7	mg/kg	30	ND
Bis(2-ethylhexyl) Phthalate (DEHP)	117-81-7	mg/kg	30	ND
Diisobutyl Phthalate (DIBP)	84-69-5	mg/kg	30	ND
Total (DBP + BBP + DEHP+DIBP)	-	mg/kg	30	ND
Comment				**PASS**

Notes :

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

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	Unit	MDL	*1+2*
4-Aminobiphenyl	92-67-1	mg/kg	5	ND
Benzidine	92-87-5	mg/kg	5	ND
4-chloro-o-toluidine	95-69-2	mg/kg	5	ND
2-naphthylamine	91-59-8	mg/kg	5	ND
o-aminoazotoluene	97-56-3	mg/kg	5	ND
5-nitro-o-toluidine / 2-Amino-4-nitrotoluene	99-55-8	mg/kg	5	ND
4-chloroaniline	106-47-8	mg/kg	5	ND
4-methoxy-m-phenylenediamine / 2,4-Diaminoanisole	615-05-4	mg/kg	5	ND
4,4'-diaminodiphenylmethane	101-77-9	mg/kg	5	ND
3,3'-dichlorobenzidine	91-94-1	mg/kg	5	ND
3,3'-dimethoxybenzidine	119-90-4	mg/kg	5	ND
3,3'-dimethylbenzidine	119-93-7	mg/kg	5	ND
4,4'-methylenedi-o-toluidine/3,3'-Dimethyl-4,4'-diaminodiphenylmethane	838-88-0	mg/kg	5	ND
p-cresidine	120-71-8	mg/kg	5	ND
4,4'-methylene-bis-(2-chloroaniline)	101-14-4	mg/kg	5	ND
4,4'-oxydianiline	101-80-4	mg/kg	5	ND
4,4'-thiodianiline	139-65-1	mg/kg	5	ND
o-toluidine	95-53-4	mg/kg	5	ND
4-methyl-m-phenylenediamine / 2,4-Toluylendiamine	95-80-7	mg/kg	5	ND
2,4,5-trimethylaniline	137-17-7	mg/kg	5	ND
4-aminoazobenzene	60-09-3	mg/kg	5	ND
O-Anisidine	90-04-0	mg/kg	5	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)Method A is direct reduction, direct reduction refers to the extraction and reduction according to ISO 14362-1:2017 clause 10.2 and relevant clauses. Method B is colorant extraction, colorant extractionrefers to the colourant extraction and subsequent reduction according to ISO 14362-1:2017 clause 10.1 and relevant clauses.(2)The ISO 14362-1:2017 methods will enable further cleavage of 4 aminoazobenzene to non forbidden amines: aniline and 1,4 phenylenediamine, therefore, the test method of ISO 14362-3:2017 was employed to verify the presence of 4 aminoazobenzene.

(3) Max. limit specified by entry 43 of Regulation (EC) No 552/2009 amending Annex XVII of REACH Regulation (EC) No 1907/2006 (previously restricted under Directive 2002/61/EC).

(4)Whenever 4-aminodiphenyl (CAS number 92-67-1), 2-naphylamine (CAS number 91-59-8) and 4-methoxy-m-phenylene-diamine (CAS number 615-05-4) is found, the use of banned azo colorants cannot be reliably ascertained without additional information, e.g. the chemical structure of the colorants used. In case polyurethane materials are used, e.g. PU foams and coatings and in prints, it cannot be ruled out that certain amines, e.g. 4,4'-methylene-dianiline (MDA, CAS number 101-77-9) and 2,4-toluylen-diamine (TDA, CAS number 95-80-7) are released from the PU component and not from a banned azo colorant. In case of pigment prints care has to be taken that 4,4'-methylene-dianiline (MDA, CAS number 101-77-9) is not released from a source of banned azo colorants but from e.g. a chemical fixing agent.

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	Unit	MDL	*1+2*
4-Aminobiphenyl	92-67-1	mg/kg	5	ND
Benzidine	92-87-5	mg/kg	5	ND
4-chloro-o-toluidine	95-69-2	mg/kg	5	ND
2-naphthylamine	91-59-8	mg/kg	5	ND
o-aminoazotoluene	97-56-3	mg/kg	5	ND
5-nitro-o-toluidine / 2-Amino-4-nitrotoluene	99-55-8	mg/kg	5	ND
4-chloroaniline	106-47-8	mg/kg	5	ND
4-methoxy-m-phenylenediamine / 2,4-Diaminoanisole	615-05-4	mg/kg	5	ND
4,4’-diaminodiphenylmethane	101-77-9	mg/kg	5	ND
3,3’-dichlorobenzidine	91-94-1	mg/kg	5	ND
3,3’-dimethoxybenzidine	119-90-4	mg/kg	5	ND
3,3’-dimethylbenzidine	119-93-7	mg/kg	5	ND
4,4'-methylenedi-o-toluidine/3,3'-Dimethyl-4,4' -diaminodiphenylmethane	838-88-0	mg/kg	5	ND
p-cresidine	120-71-8	mg/kg	5	ND
4,4’-methylene-bis-(2-chloroaniline)	101-14-4	mg/kg	5	ND
4,4’-oxydianiline	101-80-4	mg/kg	5	ND
4,4’-thiodianiline	139-65-1	mg/kg	5	ND
o-toluidine	95-53-4	mg/kg	5	ND
4-methyl-m-phenylenediamine / 2,4-Toluylendiamine	95-80-7	mg/kg	5	ND
2,4,5-trimethylaniline	137-17-7	mg/kg	5	ND
4-aminoazobenzene	60-09-3	mg/kg	5	ND
O-Anisidine	90-04-0	mg/kg	5	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)Method A is direct reduction, direct reduction refers to the extraction and reduction according to ISO 14362-1:2017 clause 10.2 and relevant clauses. Method B is colorant extraction, colorant extractionrefers to the colourant extraction and subsequent reduction according to ISO 14362-1:2017 clause 10.1 and relevant clauses.(2)The ISO 14362-1:2017 methods will enable further cleavage of 4 aminoazobenzene to non forbidden amines: aniline and 1,4 phenylenediamine, therefore, the test method of ISO 14362-3:2017 was employed to verify the presence of 4 aminoazobenzene.

(3) Max. limit specified by entry 43 of Regulation (EC) No 552/2009 amending Annex XVII of REACH Regulation (EC) No 1907/2006 (previously restricted under Directive 2002/61/EC).

(4)Whenever 4-aminodiphenyl (CAS number 92-67-1), 2-naphylamine (CAS number 91-59-8) and 4-methoxy-m-phenylene-diamine (CAS number 615-05-4) is found, the use of banned azo colorants cannot be reliably ascertained without additional information, e.g. the chemical structure of the colorants used. In case polyurethane materials are used, e.g. PU foams and coatings and in prints, it cannot be ruled out that certain amines, e.g. 4,4'-methylene-dianiline (MDA, CAS number 101-77-9) and 2,4-toluylen-diamine (TDA, CAS number 95-80-7) are released from the PU component and not from a banned azo colorant. In case of pigment prints care has to be taken that 4,4'-methylene-dianiline (MDA, CAS number 101-77-9) is not released from a source of banned azo colorants but from e.g. a chemical fixing agent.

198 Kezhu Road,Scientech Park Guangzhou Economic&Technology Development District,Guangzhou,China 510663 t (86-20) 82155555 f (86-20) 82075169 www.sgsgroup.com.cn
中国·广州·经济技术开发区科学城科珠路198号 邮编: 510663 t (86-20) 82155555 f (86-20) 82075169 e sgs.china@sgs.com

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)	Unit	MDL	*1+2*	*3+4+5*	*6+7+8*
Dibutyl tin (DBT) by weight of Tin	mg/kg	100	**ND**	**ND**	**ND**
Dioctyl tin (DOT) by weight of Tin	mg/kg	100	**ND**	**ND**	**ND**
Tributyl tin (TBT) by weight of Tin	mg/kg	100.00	**ND**	**ND**	**ND**
Triphenyl tin (TPhT) by weight of Tin	mg/kg	100.00	**ND**	**ND**	**ND**
Tricyclohexyltin (TCyT) by weight of Tin	mg/kg	100.00	**ND**	**ND**	**ND**
Trioctyltin (TOT) by weight of Tin	mg/kg	100.00	**ND**	**ND**	**ND**
Tripropyltin (TPT) by weight of Tin	mg/kg	100	**ND**	**ND**	**ND**
Trimethyltin(TMT) by weight of Tin	mg/kg	100.00	**ND**	**ND**	**ND**
Σ of Tri substituted organotin compounds calculated as tin	mg/kg	100	**ND**	**ND**	**ND**
Comment			**PASS**	**PASS**	**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

Entry 50 of Commission Regulation (EU) No 1272/2013 amending Annex XVII of REACH Regulation (EC) No 1907/2006 - Polycyclic Aromatic Hydrocarbons(PAHs)

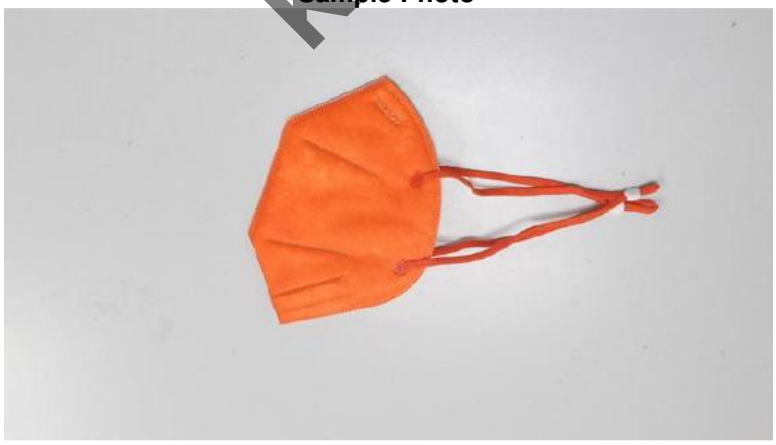
Test Method : With reference to AfPS GS 2019:01 PAK, analysis was performed by GC-MS.

Test Item(s)	CAS NO	Unit	MDL	*6+7*
Benzo(a)anthracene(BaA)	56-55-3	mg/kg	0.1	**ND**
Chrysene(CHR)	218-01-9	mg/kg	0.1	**ND**
Benzo(b)fluoranthene(BbF)	205-99-2	mg/kg	0.1	**ND**
Benzo(j)fluoranthene(BjF)	205-82-3	mg/kg	0.1	**ND**
Benzo(k)fluoranthene(BkF)	207-08-9	mg/kg	0.1	**ND**
Benzo(a)pyrene(BaP)	50-32-8	mg/kg	0.1	**ND**
Benzo(e)pyrene(BeP)	192-97-2	mg/kg	0.1	**ND**
Dibenzo(a,h)anthracene(DBA)	53-70-3	mg/kg	0.1	**ND**
Comment				**PASS**

Notes :

RL (Reporting limit): 0.1 mg/kg (each)
ND = Not Detected(< RL)
Requirement: 1 mg/kg (each)

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

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-WT20214907

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 KN95防护口罩 KN95 Protective Respirator 商标：Trademark KAZE 样品总数：Sample Count 45个 45Pieces 号型规格：Size 折叠型口罩 FOLD MASK 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 2626-2019 呼吸防护 自吸过滤式防颗粒物呼吸器 Respiratory protection-Non-powered air-purifying particle respirator
样品描述 Test Part Description		1# 口罩Mask-红色Red；2# 口罩Mask-深蓝色Dark Blue；3# 口罩Mask-米黄色Beige； 4# 口罩Mask-蓝色Blue；5# 口罩Mask-紫色Purple；6# 口罩Mask-深绿色Dark Green
检验性质 Test Type	委托检验 Commission Test	样品接收日期 Date of Submission 2020-07-23 — 报告发布日期 Date of Checking 2020-07-29
检验日期 Test Date	2020-07-23 到 To 2020-07-28	
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，并按照GB 2626-2019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 2626-2019.	

KAZE

批准：Approver 审核：Checker 编制：Editor

检验报告
Test Report

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
1# 口罩Mask-红色Red						
呼吸阻力 Respiratory Resistance	呼气阻力 Expiratory Resistance	Pa	≤210	未预处理样品 Samples Without Pretreatment: 1：204 2：210 预处理样品 Samples With Pretreatment: 1：174 2：187	符合 Pass	GB 2626-2019
	吸气阻力 Inspiratory Resistance	Pa	≤210	未预处理样品 Samples Without Pretreatment: 1：206 2：209 预处理样品 Samples With Pretreatment: 1：179 2：191		
2# 口罩Mask-深蓝色Dark Blue						

检验报告
Test Report

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
过滤效率 Filtration Efficiency (KN95)	氯化钠颗粒物 NaCl Particle	%	≥95.0	初始过滤效率 Initial Filtration Efficiency: 未预处理样品 Samples Without Pretreatment: 1：99.67 2：99.78 3：99.77 4：99.72 5：99.78 6：99.76 7：99.75 8：99.70 9：99.78 10：99.76 11：99.76 12：99.79 13：99.74 14：99.73 15：99.75 预处理样品 Samples With Pretreatment: 1：98.17 2：98.41 3：98.06 4：97.97 5：97.76	符合 Pass	GB 2626-2019
3# 口罩Mask-米黄色Beige						

检验报告
Test Report

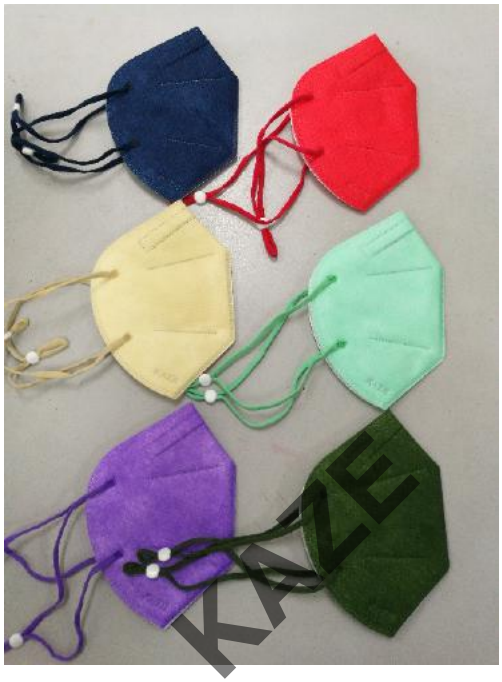
检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
外观检查 Appearance Inspection	样品表面 Surface of The Sample	/	按标准要求 As per standard requirement	+	符合 Pass	GB 2626-2019
	部件材料和结构 Component Material and Construction	/	按标准要求 As per standard requirement	+		
	部件经过温度湿度预处理后 The components after the temperature and humidity pretreatment	/	按标准要求 As per standard requirement	+		
	标识和制造商所提供的各种信息 Label and various information provided by manufacturer	/	按标准要求 As per standard requirement	+		
4# 口罩Mask-蓝色Blue						
可燃性 Flammability	续燃时间 Afterflame Time	s	≤5	0	符合 Pass	GB 2626-2019
5# 口罩Mask-紫色Purple						
头带 Head Harness	/	/	呼吸器的每条头带、带扣及其他调节部件在承受10N，持续10s的拉力时，不应出现滑脱或断裂 Each head harness, buckle and other adjustment components of the respirator should not have slippage or breaking for 10s under 10N loading	10N负荷持续10秒，头带未出现滑脱、断裂 The head harness have no slippage or breaking for 10s under 10N loading	符合 Pass	GB 2626-2019

检验报告
Test Report

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
6# 口罩Mask-深绿色Dark Green						
视野 View	下方视野 View Blow	°	≥35	61	符合 Pass	GB 2890-2009
	双目视野 Binocular View	%	≥65	>65		

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.

样 品 Sample



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

检验报告
Test Report

【注意事项】
POINTS FOR ATTENTION

1.检验报告无“检验专用章”无效。
Report is invalid without stamp of "special seal for the test report".

2.复制报告未重新加盖“检验专用章”无效。
Copy report is invalid without re-stamp of "special seal for the test report".

3.报告无编写、审核、批准人签字无效。
Report is invalid without collective signatures by editor, checker and approver.

4.检验报告涂改无效。
Report is invalid if altered.

5.检验报告或复制报告未加盖骑缝章无效（报告页数多于1页时）。
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。
Part copy report is invalid without the approval of the written documents of the testing organization.

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

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

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

扫码下载电子报告

扫码关注天纺标

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-WT20207761

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 KN95防护口罩 KN95 Protective Respirator 商标：Trademark KAZE 样品总数：Sample Count 50个 50Pieces 号型规格：Size 折叠型口罩 FOLD MASK 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 2626-2019 呼吸防护 自吸过滤式防颗粒物呼吸器 Respiratory protection-Non-powered air-purifying particle respirator
样品描述 Test Part Description		1# 浅灰色口罩 Light Grey Mask 2# 酒红色口罩 Wine Mask 3# 粉色口罩 Pink Mask 4# 浅蓝色口罩 Light Blue Mask 5# 玫红色口罩 Rose Mask 6# 橙色口罩 Orange Mask
检验性质 Test Type	委托检验 Commission Test	样品接收日期 Date of Submission 2020-07-13 — 报告发布日期 Date of Checking 2020-07-18
检验日期 Test Date	2020-07-13 到 To 2020-07-17	
执行标准 Test Standards	见附页 See next page(s)	
检验结论 Conclusion	检验结果及符合性见附页。 Test results and compliance refer to next page(s). 检验单位盖章 Stamp of Inspection Unit	
备注 Remarks	/	

批准：Approver 方倩 审核：Checker 编制：Editor 子舒芳

检验报告
Test Report

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
1# 浅灰色口罩 Light Grey Mask						
外观检查 Appearance Inspection	样品表面 Surface of The Sample	/	按标准要求 As per standard requirement	+	符合 Pass	GB 2626-2019
	部件材料和结构 Component Material and Construction	/	按标准要求 As per standard requirement	+		
	部件经过温度湿度预处理后 The components after the temperature and humidity pretreatment	/	按标准要求 As per standard requirement	+		
	标识和制造商所提供的各种信息 Label and various information provided by manufacturer	/	按标准要求 As per standard requirement	+		
2# 酒红色口罩 Wine Mask						

检验报告
Test Report

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
过滤效率 Filtration Efficiency (KN95)	氯化钠颗粒物 NaCl Particle	%	≥95.0	初始过滤效率 Initial Filtration Efficiency: 未预处理样品 Samples Without Pretreatment 1：99.37 2：99.43 3：99.38 4：99.41 5：99.47 6：99.49 7：99.38 8：99.40 9：99.33 10：99.34 11：99.40 12：99.33 13：99.35 14：99.35 15：99.40 预处理样品 Samples With Pretreatment: 1：95.99 2：96.24 3：96.52 4：96.24 5：95.78	符合 Pass	GB 2626-2019
3# 粉色口罩 Pink Mask						

检验报告
Test Report

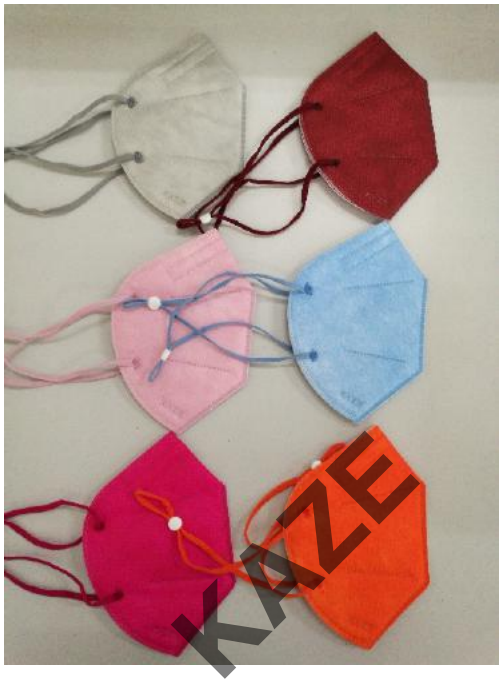
检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
呼吸阻力 Respiratory Resistance	呼气阻力 Expiratory Resistance	Pa	≤210	未预处理样品 Samples Without Pretreatment: 1：131 2：135 预处理样品 Samples With Pretreatment: 1：114 2：120	符合 Pass	GB 2626-2019
	吸气阻力 Inspiratory Resistance	Pa	≤210	未预处理样品 Samples Without Pretreatment: 1：139 2：143 预处理样品 Samples With Pretreatment: 1：127 2：121		
4# 浅蓝色口罩 Light Blue Mask						
视野 View	下方视野 View Blow	°	≥35	61	符合 Pass	GB 2890-2009
	双目视野 Binocular View	%	≥65	>65		
5# 玫红色口罩 Rose Mask						
头带 Head Harness	/	/	呼吸器的每条头带、带扣及其他调节部件在承受10N，持续10s的拉力时，不应出现滑脱或断裂 Each head harness, buckle and other adjustment components of the respirator should not have slippage or breaking for 10s under 10N loading.	10N负荷持续10秒，头带未出现滑脱、断裂 The head harness have no slippage or breaking for 10s under 10N loading	符合 Pass	GB 2626-2019
6# 橙色口罩 Orange Mask						

检验报告
Test Report

检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	执行标准/备注 Test Method/ Remarks
可燃性 Flammability	续燃时间 Afterflame Time	s	≤5	0	符合 Pass	GB 2626-2019

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.

样 品 Sample



检验报告
Test Report

【注意事项】
POINTS FOR ATTENTION

1.检验报告无“检验专用章”无效。
Report is invalid without stamp of "special seal for the test report".

2.复制报告未重新加盖“检验专用章”无效。
Copy report is invalid without re-stamp of "special seal for the test report".

3.报告无编写、审核、批准人签字无效。
Report is invalid without collective signatures by editor, checker and approver.

4.检验报告涂改无效。
Report is invalid if altered.

5.检验报告或复制报告未加盖骑缝章无效（报告页数多于1页时）。
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。
Part copy report is invalid without the approval of the written documents of the testing organization.

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

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

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

扫码下载电子报告

扫码关注天纺标