









Certificate

LKKS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

No. Q6 001517 0003 Rev. 00

Holder of Certificate:

Ningbo Tianbo First Aid Product Co., Ltd., Yushan Tou Village, Dongqiao Town

315156 Yinzhou, Ningbo PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Production and Distribution of First Aid Kit, Wound Plaster, Applicator, Gauze Sponges, Gauze Roll, Medical Tape, Medical Bandage, Alcohol Pads, Gloves, Wipe, Wound Fluid Plaster, Wound Dressing, Emergency Blanket, Medical Mask, First Aid Scissors

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q6 001517 0003 Rev. 00_

Report No.:

SH20120601

Valid from: Valid until: 2021-01-14 2023-12-20

Date.

2021-01-14

Christoph Dicks Head of Certification/Notified Body

Page 1 of 2 TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany





Certificate

No. Q6 001517 0003 Rev. 00

Applied Standard(s):	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) DIN EN ISO 13485:2016

Facility(ies):

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

> Ningbo Tianbo First Aid Product Co., Ltd., Yushan Tou Village, Dongqiao Town, 315156 Yinzhou, Ningbo, PEOPLE'S REPUBLIC OF CHINA

> > See Scope of Certificate.



EU-KONFORMITÄTSERKLÄRUNG

EU DECLARATION OF CONFORMITY (Gemäß/in accordance with EN ISO/IEC 17050-1)

Name und Anschrift des	KSi International GmbH
Importeurs und Händlers in	Zellescher Weg 3
Europa	01609 Dresden
Name and address of	Deutschland
importer and distributor responsible in Europe	Germany
responsible in Europe	
DIESE KONFORMITÄTSERKLÄRUNG	WIRD UNTER DER ALLEINIGEN VERANTWORTUNG UND
PRODUKTHAFTUNG ERSTELLT VON:	
THIS DECLARATION OF CONFORMITY	' IS ISSUED UNDER THE SOLE AND PRODUCT LIABILITY RESPONSIBILITY
OF:	
Name und Anschrift des	TAIZHOU DONGHAIXIANG PROTECTIVE EQUIPMENT CO., LTD
Herstellers	No.3091 Du Nan Avenue Dugiao Town Linhai City Zhejiang Province
name and address of	P.R. China
manufacturer	
Produktidentifikation	Produktname: Atemschutzmaske
Product identification	Description of product: Protective mask Marke: DHX
	Brand: DHX
	Modell Nr: DHX9001
	Model no.: DHX9001
	Produktfarbe und -typ: Weiß, nicht wiederverwendbar, gefaltet,
	partikelfilternde Halbmaske
	Product colour and type: White, Non-reusable, folded, filtering half
	mask
Die Konformitätsbewertung orfelgte	nach den wesentlichen Anforderungen vom Hersteller gemäß
	g to the essential requirements has been done by manufacturer
according to	g to the essential requirements has been done by manufacturer
EU-Rechtsvorschriften der	Verordnung über persönliche Schutzausrüstung (PSA) (EU)
Gemeinschaft EU Community Legislation	2016/425 Personal Protective Equipment (PPE) Regulation (EU) 2016/425
EO community Legislation	Personal Protective Equipment (PPE) Regulation (EO) 2010/425
	Anhang II Kategorie III in Verbindung mit
	Annex II Category III in connection with
	Anhang V (Modul B EU-Baumusterprüfungsbescheinigung)
	Annex V (Module B EU Type Examination Certification)
	SGS CertNr. / SGS Cert. no.:
	FI20/967053 und/ and
	Antone VIII (Medul C2 Dredultionsüberruschung)
	Anhang VII (Modul C2 Produktionsüberwachung) Annex VII (Module C2 Production Monitoring)
	SGS CertNr. / SGS Cert. no.:
	CN20/42527



	Persönliche Schutzausrüstung EN 149:2001+A1:2009
Harmonised standards	Personal protective equipmentEN 149:2001 +A1:2009
	SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing
	Center - Test Report Nr./no.: SL52035261876901TX
Weitere Spezifikationen	Partikelfiltermaske, FFP2 NR
Other specifications	Particle filtering mask, FFP2 NR
In Zusammenarbeit mit	
in cooperation with	
Benannte Stelle	SGS FIMKO OY, Notified Body 0598
Notified Body	Takomotie 8, FI-00380, Helsinki, Finland
	t +358 9 696 361 f +358 9 692 5474 www.sgs.com
Diese Erklärung ist gültig bis zun This declaration is valid until 26 th	
UNTERZEICHNET FÜR UND IM NA SIGNED FOR AND ON BEHALF OF	
Ort und Datum der Ausgabe: Place and date of issue:	Linhai City, 26 th January 2021
Unterschrift:	zhu Maifei
Signature:	
Signature.	
Name, Funktion:	Zhu Haifei, Management Bepresentative
5	Zhu Haifei, Managendent Representative
Name, Funktion:	Zhu Haifei, Managendent Representative



取得国外标准认证或注册的医疗物资和非医用口罩生产企业检索

	东海明	东海明 检索				
企业名称(中文)	企业名称(英文)	产品类别	产品名称/型号	统一社会信用代码	国外注册认证情况	
台州东海和防护用品有限公司	Taizhou donghaixiang Protective Equipment Co.,Ltd	医用口罩	Disposable medical mask (non-sterile)	91331082MA2DYPQ87Y	R <u>t盟</u> CE	
台州东海南防护用品有限公司	Taizhou Donghaixiang Protective Equipment Co.,Itd	非医用口室	DHX9001	91331082MA2DYPQ87Y	BT22CE	

友情链接



Certificate FI20/967053

Taizhou Donghaixiang Protective Equipment Co.,Ltd

NO.3091 DU NAN AVENUE DUQIAO TOWN LINHAI CITY ZHEJIANG PROVINCE CHINA

It is certified that the manufacturer's technical file and the PPE product detailed on page 2 have been assessed and found to be in accordance with

Regulation (EU) 2016/425 Module B, EU type-examination

This certificate is valid from 29 October 2020 until 29 October 2025 1. Certified since 29 October 2020



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Certificate FI20/967053, continued

Taizhou Donghaixiang Protective Equipment Co.,Ltd

Regulation (EU) 2016/425

Module B, EU type-examination

Issue 1

PPE Product

DHX (logo) DHX9001, single use particle filtering half mask.

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 Personal Protective Equipment

The following have been applied:

EN 149:2001+A1:2009 (Respiratory protective devices - filtering half masks to protect against particles) device classification: FFP2 NR.

This certificate is issued on the strict condition that appropriate checks on manufactured PPE, as detailed in Article 19 (c) of the Regulation are implemented and maintained while the model is in production

Certification is based on technical file reference:

Protective mask / DHX9001, Version 1, dated: 2020-09-03.

SGS Reference Number UK/CRS 242107.

This certificate remains the property of SGS Fimko Oy to whom it must be returned on request



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Certificate CN20/42527

The management system of

Taizhou Donghaixiang Protective Equipment Co.,Ltd

NO.3091 DU NAN AVENUE DUQIAO TOWN LINHAI CITY ZHEJIANG PROVINCE CHINA

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425

Module C2

For the following activities

Manufacture of DHX (logo) DHX9001, single use particle filtering half mask.

(Note: All products marked CE0598 must have a valid EU typeexamination certificate issued under Module B or a valid EC typeexamination certificate issued under Article 10 of Directive 89/686/EEC.)

> This certificate is valid from 14 November 2020 and remains valid subject to satisfactory surveillance audits. Issue 1. Certified since 14 November 2020

> > Authorised by

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SGS





The Statement

Our "Donghaixiang Protective equipment Co.,Ltd.", hereby declare, "Ningbo Tianbo First Aid Product Co.,Ltd" is our investment shareholders, we are their masks production base factory, about the face mask FFP2 and 3 ply the disposable mask which will be produced in our factory for Ningbo Tianbo First Aid Product Co.,Ltd.The product could be considered as produced in Ningbo Tianbo First Aid Product Co.,Ltd., the whole production process can be supervised by the final customer.

Donghaixiang Protective equipment Co.,Ltd.

台州东海翔防护用品有限公司	21-01-16
台州东海翔防护用品有限公司 TAIZHOU DONGHAIXIANG PROTECTIVE EQUIPMENT CO.LTD.	

	KSI	Care	
SGS	Contraction of the second s		中国认可 国际互认 检测 TESTING CNAS L0599
Test Report	SL52035261876901TX	Date:July 10,2020	Page 1 of 10
NO.3091 DU NAN AVE	was/were submitted and ident	CITY ZHEJIANG PROVINCE CH	INA
Sample Description	: (A)Protective mask		
Style No.	: DHX9001		
Sample Color	: (A)WHITE		
Test Performed	: Selected test(s) as req	uested by applicant	
Sample Receiving Date	: Jun 30, 2020		
Testing Period	: Jun 30, 2020 - Jul 10, 2	2020	
Test Result(s)		d the results shown in this test re rther details, please refer to the f	

-			

Recommendation Level

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

FFP2 NR

1 STA

Conclusion: Sample No.

(A)

Sara Guo (Account Executive)



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Date:July 10,2020

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Test Report Test Result

Personal Protective Equipment - Respiratory Protective Devices- Filtering Half Masks to Protect against Particles- Requirements, Testing, Marking EN 149:2001+A1:2009

EN 149:2001+A1:2009

Clause 7.4 Packaging

(EN 149:2001+A1:2009 Clause 8.2)

Test Requirement	Results	Comment
Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Comply	Pass

Clause 7.5 Material

(EN 149:2001+A1:2009, Clause 8.2 & 8.3.1 & 8.3.2)

Test Requirement	Results	Comment
Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.	Comply	
After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Comply	Pass
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Comply	
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Comply	

Clause 7.6 Cleaning and Disinfecting

(EN 149:2001+A1:2009, Clause 8.4 & 8.5 & 8.11)

Test Requirement	Results	Comment
If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.	Not applicable (Not designed to be re-usable)	N.A.

Clause 7.7 Practical Performance

(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard.	No imperfections	Pass



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Test Report

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Clause 7.8 Finish of Parts (EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
Parts of the device likely to come into contact with the wearer shall have no	No sharp	Pass
sharp edges or burrs.	edges or burrs	

Clause 7.9.1 Total Inward Leakage

(EN 149:2001+A1:2009, Clause 8.5)

Test Requirement	Results	Comment
The total inward leakage consists of three components: face seal leakage, exhalation value leakage(i exhalation value fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25% for FFP1, 11% for FFP2, 5% for FFP3 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than: 22% for FFP1, 8% for FFP2, 2% for FFP3	Detail refer to Appendix 1	Meet FFP1, Meet FFP2

Appendix 1: Summarization of Test Data

Inward Leakage Test Data

Subject	Sample	Condition	Walk(%)	Head	Head	Talk(%)	Walk(%)	Mean(%)
,	No.			Side/side(%)	up/down(%)			
Zhou	1	A.R.	5.68	6.28	6.79	5.60	6.45	6.16
Luo	2	A.R.	6.48	7.46	7.89	8.10	5.61	7.11
Lu	3	A.R.	6.28	4.89	6.09	6.59	6.35	6.04
Wang	4	A.R.	5.36	5.37	5.88	4.34	5.14	5.22
Bao	5	A.R.	7.33	7.76	6.98	6.03	7.49	7.12
Ding	6	T.C.	6.19	5.14	4.87	6.57	5.55	5.66
Li	7	T.C.	8.54	7.83	6.25	7.15	7.02	7.36
Chen	8	T.C.	4.34	4.42	7.18	6.35	5.85	5.63
Song	9	T.C.	5.80	5.99	7.42	7.34	6.53	6.62
Ye	10	T.C.	7.59	6.97	7.42	7.62	7.22	7.36

Facial Dimension(mm)

Subject	Face length	Face Width	Face Depth	Mouth Width
Chen	125	150	120	58
Lu	115	132	107	48
Zhou	115	135	106	52
Li	125	130	107	46
Luo	125	136	100	43
Zheng	128	140	112	55
Wang	120	147	103	48
Song	120	140	100	50
Bao	130	134	104	50
Ding	134	150	110	52



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Test Re	port SL520	SL52035261876901TX Date:July 10,202		Page 4 of 10
Liu	120	135	117	50
Ye	126	137	105	52

Clause 7.9.2 Penetration of Filter Material

(EN 149:2001+A1:2009, Clause 8.11 & EN 13274-7:2019)

		Test Requirement		Results	Comment		
		of the filter of the particle filte the following table.	the				
	Classifica Maximum penetration of test aerosol						
	tion	Sodium chloride test 95	Paraffin oil test 95 l/min		Detail refer to Meet FFP		
		l/min					
		%	%		Appendix 2	Meet FFP2	
		max.	max.				
	FFP1	20	20				
1	FFP2	6	6				
1	FFP3	1	1				

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)
		1	0.447
	As received	2	0.502
		3	0.479
		4	0.518
Sodium chloride test	Simulated wearing treatment	5	0.461
		6	0.453
	Machanical strength . Tomperature	7	0.674
	Mechanical strength +Temperature conditioned	8	0.734
	conditioned	9	0.694
		10	1.508
	As received	11	1.406
		12	1.473
		13	1.428
Paraffin oil test	Simulated wearing treatment	14	1.469
		15	1.527
	Marchanical stars attain Tanan anatoma	16	1.987
	Mechanical strength +Temperature conditioned	17	1.862
	conditioned	18	1.794
	Flow conditioning : Single fil	ter: 95.0 L/min	



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Clause 7.10 Compatibility with Skin (EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	No irritation or any other adverse effect to health	Pass

Clause 7.11 Flammability

(EN 149:2001+A1:2009, Clause 8.6)

Test Requirement	Results	Comment
The material used shall not present a danger for the wearer and shall not be of highly flammable nature	Detail refer to	Daga
When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.	Appendix 3	Pass

Appendix 3: Summarization of Test Data

Flammability

Condition	Sample No.	Result
	1	NIL
As received	2	NIL
	3	NIL
Temperature conditioned	4	NIL

Clause 7.12 Carbon Dioxide Content of The Inhalation Air

(EN 149:2001+A1:2009, Clause 8.7)

Test Requirement	Results	Comment
The carbon dioxide content of the inhalation air (dead space) shall not	Detail refer to	Pass
exceed an average of 1,0 % (by volume)	Appendix 4	. 1.00

Appendix 4: Summarization of Test Data

Carbon Dioxide Content of The Inhalation Air

Condition	Sample No.	Resul	Result(%)		
		0.4870			
	1				
As received		0.4867	Mean value:0.49		
As received	2		Weart value.0.49		
		0.4865			
	3				



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Test Report

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Clause 7.13 Head Harness (EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.	Comply	
The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.	Comply	Pass

Clause 7.14 Field of Vision

(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The field of vision is acceptable if determined so in practical performance tests.	Comply	Pass

Clause 7.15 Exhalation Valve(s)

(EN 149:2001+A1:2009, Clause 8.2 & 8.9.1 & 8.3.4 & 8.8)

Test Requirement	Results	Comment		
(a) A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	Not applicable due to No exhalation valve			
(b) If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.	Not applicable due to No exhalation valve	N.A.		
(c) Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.	Not applicable due to No exhalation valve			
(d) When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10N applied for 10 s.	Not applicable due to No exhalation valve			



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Test Report

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Clause 7.16 Breathing Resistance

(EN 149:2001+A1:2009, Clause 8.9)

	Tes	Results	Comment			
The penetration requirements of						
Classification	Maxim	um permitted resista	ance (mbar)			Meet FFP1,
	Ini	nalation	Exhalation		Detail refer to	Meet FFP2,
	30 l/min	95 l/min	160 l/min		Appendix 5	Meet FFP3
FFP1	0.6	2.1	3.0			
FFP2	0.7	2.4	3.0			
FFP3	1.0	3.0	3.0			

Appendix 5: Summarization of Test Data

Breathing resistance (mbar)

					1					2					3		
	Flow rate(I/min)		Α	В	С	D	Е	Α	В	С	D	E	Α	В	С	D	Е
As received	Inhalation	30	0.4	0.5	0.4	0.4	0.4	0.4	0.5	0.4	0.5	0.5	0.4	0.5	0.5	0.5	0.4
	Initialation	95	1.6	1.8	1.7	1.6	1.7	1.8	1.7	1.7	1.8	1.6	1.6	1.7	1.7	1.8	1.6
	Exhalation	160	2.5	2.7	2.6	2.5	2.5	2.6	2.7	2.6	2.5	2.6	2.6	2.7	2.6	2.7	2.6
	E 1 . 4				4					5					6		
Simulated	Flow rate(1/	Flow rate(I/min)	Α	В	С	D	Е	Α	В	С	D	E	Α	В	С	D	Е
wearing		30	0.4	0.5	0.4	0.5	0.5	0.5	0.4	0.5	0.5	0.4	0.5	0.4	0.5	0.5	0.4
treatment		95	1.7	1.9	1.8	1.7	1.7	1.8	1.7	1.8	1.9	1.7	1.7	1.8	1.7	1.9	1.7
	Exhalation	160	2.6	2.7	2.6	2.7	2.7	2.6	2.7	2.7	2.7	2.6	2.7	2.7	2.6	2.7	2.6
			7			8			9								
	Flow rate(l	/min)	Α	В	С	D	Е	Α	В	С	D	Е	Α	В	С	D	Е
Temperature	Inholation	30	0.3	0.4	0.3	0.4	0.3	0.4	0.3	0.4	0.3	0.4	0.3	0.4	0.3	0.4	0.4
conditioned	ed Inhalation 95	95	1.6	1.8	1.7	1.6	1.6	1.6	1.7	1.7	1.8	1.7	1.8	1.7	1.8	1.8	1.7
	Exhalation	160	2.5	2.6	2.7	2.5	2.5	2.6	2.7	2.5	2.6	2.6	2.7	2.7	2.5	2.7	2.5

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side



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Test Report

Clause 7.17 Clogging (EN 149:2001+A1:2009, Clause 8.9 & 8.10)

	Test Requirement		Results	Comment
Valved particle fill After clogging the FFP1: 4 mbar, Ff The exhalation re flow. Valveless particle After clogging the	eathing resistance tering half masks: a inhalation resistances shall noi FP2: 5 mbar, FFP3: 7 mbar at 95 asistance shall not exceed 3 mb <u>a filtering half masks:</u> a inhalation and exhalation resis FP2: 4 mbar, FFP3: 5 mbar at 95	Optional for single shift device only	N.A.	
All types (valvec meet the cloggin Classificatio n	enetration of filter material and valveless) of particle filte g requirement shall also meet th Maximum penetratio Sodium chloride test 95 l/min % max.	Optional for single shift device only	N.A.	
FFP1	20	20		
FFP2	6	6		
FFP3	1	1		

Clause 7.18 Demountable Parts (EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand	Comply	Pass

Test	Uncertainty
Total inward leakage	3.4%
Penetration of filter material	4.8%
Carbon dioxide content of the inhalation air	3.9%
Breathing resistance (30L/min)	5.9%
Breathing resistance (95L/min)	4.9%
Breathing resistance (160L/min)	4.3%



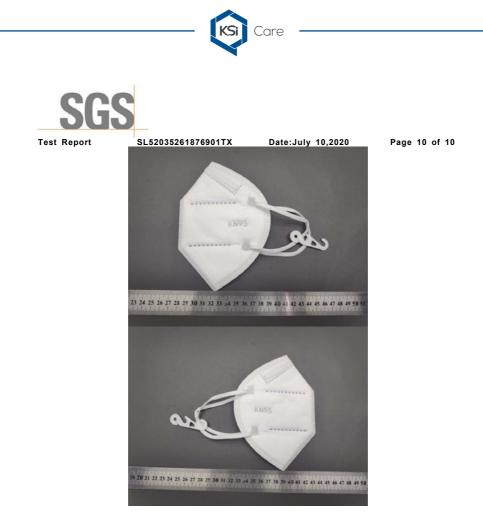
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 Sample Receiving Date
 :
 Oct 15, 2020

 Testing Period
 :
 Oct 30, 2020 - Nov 04, 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)



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SL52045301486001TX

Date:November 04,2020

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Test Report Test Result

Penetration of Filter Material

(EN 13274-7:2019, Flow rate: 95 l/min)

Sample: A

As received (One layer)

Penetration of filter material (%)									
Aerosol	1#	2#	3#						
Paraffin oil	0.730	0.703	0.549						

After temperature conditioned and exposure test with a specified mass of test aerosol of 120mg) (One layer) Penetration of filter material (%)

renetration of intermaterial (76)								
Aerosol	1#	2#	3#					
Paraffin oil	2.296	3.134	3.035					

Remark:

Number of specimens, flow rate, temperature condition and exposure test refer to parameter of EN 149:2001+A1:2009 clause 7.9.2 penetration of filter material.

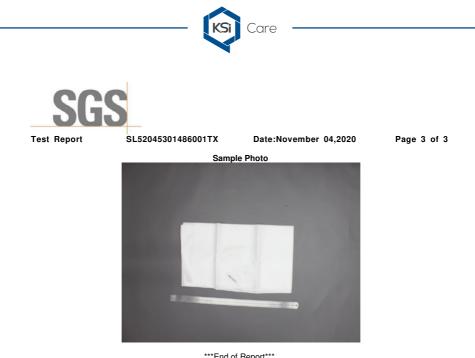


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