GREENCARE®

Face Masks Expert Since 2003

Model: MP9011

KN95 Particulate Respirator

FDA Authorized Imported Respirator
EUA listed Appendix A

Appendix A: Authorized Imported, Non-NIOSH Approved Respirators Manufactured in China (Updated: September 14, 2020)

The table below includes a list of non-NIOSH respirators authorized by this Umbrella EUA for emergency use during the COVID-19 public health emergency.

As stated in the EUA, authorized respirators should be used in accordance with CDC's recommendations. For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: Strategies for Optimizing the Supply of N95 Respirators.

Search: MP9011 Show 100 entries

Manufacturer	Respirator Model(s)	Instructions for Use
XIAMEN PROBTAIN NONWOVEN INC.	MP9011	• IFU

Greencare MP9011 KN95 Respirators are authorized by FDA for use in healthcare settings by healthcare personnel.

Please verify at FDA website: https://www.fda.gov/media/136663/download

Package: 5 pcs/bag, 4bags into a box, 20pcs/box

20pcs/box, 25boxes/case, 500pcs/case

Case dimensions: 570x495x190 mm / 22.5x19.5x7.5 inch

Case weight: 13.3 Lbs

ISO13485 Accredited Professional Medical Devices Manufacturer

MEDICAL DEVICES-QUALITY MANAGEMENT SYSTEMS CERTIFICATE

Certificate No.: CQC19QY20047R0S/46500

We hereby certify that

Xiamen Probtain Nonwoven INC./ Xiamen Probtain Medical Technology Co, LTD.

Unified Social Credit Code: 91350200776019243B

4th Floor,A Area 2th Floor,1th Building,Ji'An Road,Tong'An District, Xiamen,Fujian Province,P.R.China /4th Floor,1th Building,Ji'An Road,Tong'An District,Xiamen,Fujian Province,P.R.China

by reason of its

Quality Management System

has been awarded this certificate for compliance with the standard

YY/T 0287-2017 / ISO 13485:2016

The Quality Management System Applies in the following area:

Manufacture of Disposable Medical Sanitary Materials and Nursing Supplies Within Qualifications

Certified since: November 20, 2019 **Valid from:** November 20, 2019 **Valid until:** November 19, 2022

After a surveillance cycle, the certificate is valid only when used together with an Acceptance Notice of Surveillance Audit issued by CQC. Please access www.cqc.com.cn for checking validity of the certificate.

Signed by: Lu Mei

CHINA QUALITY CERTIFICATION CENTRE 中国质量认证中心

CHINA QUALITY CERTIFICATION CENTRE

Section 9, No.188, Nansihuan(the South Fourth Ring Road) Xilu(West Road), Beijing 100070,China

http://www.cqc.com.cn

D 0005167

2018年版

FDA Registration Confirmation

This is to confirm that, as the US Agent, we have completed the registration activation confirmation for the **FDA Establishment Registration and Device Listing** with the US Food & Drug Administration for the **Fiscal Year 2020** of

XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO., LTD
4th Floor, No.1 Building, No.6 Ji'an Road, Tong'an District Xiamen, Fujian, 361100, CHINA

The facility registration and device listing information:

The Owner/Operator Number: 10062942		
Device Listing No.	Product Code	Product Name(s)
D374915	FYF	Caps
D374916	FRL	Bed Sheet
D374917	EYQ	Adult Nursing Pad, Baby Care Mat, Adult Diapers, Baby Diapers, Adult Insert Diapers
D374918	KHA	Face Mask
D374919	FYE	Surgical Gown
D374920	KME	Bed Mattress
D374921	OEA	Isolation Gown
D389717	LYU	Disposable mask
D389718	QKR	Disposable mask

SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this attestation until the end of the calendar year stated above, unless said registration is terminated after issuance of this attestation. SUNGO Technical Service Inc. makes no other representations or warranties, nor does this attestation make any representations or warranties to any person or entity other than the named attestation holder, for whose sole benefit it is issued. ***This attestation does not denote endorsement or approval of the attestation-holder's device or establishment by the U.S. Food and Drug Administration.*** *SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.*

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." ***The U.S. Food and Drug Administration does not issue a attestation of registration, nor does the U.S. Food and Drug Administration recognize a attestation of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.***

Reference Number: 2007US069518-1
Reissue date: Apr.27, 2020

For and on behalf of
SUNGO Technical Service Inc.

Authorized Signature
Only used for the US Agent Signature

CMA
170020131613

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0118

TEST REPORT

CASST

Report No:	**WLH0411-2020(E)**
Product Name:	**KN95 Particulate Respirator**
Product Model:	**Folding Type 15.5*10.5(±0.5cm)**
Client:	**Xiamen Probtain Medical Technology Co., Ltd.**
Manufacturer:	**Xiamen Probtain Medical Technology Co., Ltd.**

Test Unit:	**China Academy of Safety Science and Technology**
Test Category:	**Company Consigned Test**
Date of tests:	**2020/05/09-2020/05/16**

China Academy of Safety Science and Technology
Test Report of Non-powered air-purifying particle respirator

No.: WLH0411-2020(E)

Product Name	KN95 Particulate Respirator	Model	Folding Type 15.5*10.5(±0.5cm)
Product Type	Disposable Respirator (Without Valve, KN95)		
Manufacturer	Xiamen Probtain Medical Technology Co., Ltd.	Trade Mark	Greencare
Address	No.6, Ji'an Road, Tong'an District, Xiamen City, Fujian Province, 361100, China	Postcode	/
Contact Person	Mu Jining	Telephone No.	13940828984
Sample Quantity	50 pcs of Respirators	Production Date	29th Apr, 2020
Sample Status	Intact appearance and complete packaging	Sample Received	09th May, 2020
Test Category	Company Consigned Test	Arrival Mode	Mailing
Consigned by	Xiamen Probtain Medical Technology Co., Ltd.	Identification No. of LA mark	/
Test Specification	GB 2626-2006 "Respiratory protective equipment—Non-powered air-purifying particle respirator"		
Test Items	General Requirements, Visual Inspection, Filter Efficiency, Total Inward Leakage, Inhalation Resistance, Exhalation Resistance, Dead Space, Visual Field, Head Harness, Flammability		
Sample Photos			
Test Conclusion	The samples were tested according to Chinese National standard GB 2626-2006 "Respiratory protective equipment—Non-powered air-purifying particle respirator", after inspection, all the test results of above items meet the standard technical requirements. Issued date 2020-05-16		
Remarks	①Sample No.: WLH0411-2020 ②Record number: WLH0411-2020 ③Sample appearance: folding type facepiece, with built-in nose clip and white ear straps.		
Approval:	Auditor:	Tester:	

Test Result Summary					
No.	Test Items	Standard Requirements	Test Results	Assessment	Remark
1	General Requirements	Parts that may directly contact wearer's face shall not be harmful to skin; Filter material shall not be harmful to people;	Filter material and parts directly contact face are not harmful	Pass	/
		Materials used should have sufficient strength, and there shall be no damage or distortion in the normal life cycle.	Materials used have sufficient strength		
		Structural design should conform to: a) structural disaggregation shall not likely occur, and the design, components and assembly shall not be harmful to the user; b) The head harness should be adjustable, convenient for wearing and removal, be able to fix the facepiece on wearer's face securely without apparent pressure and hurt feeling; the head harness design of the replaceable half facepiece and full facepiece should be replaceable; c) There shall be relatively small dead space and bigger visual field as much as possible;	Meet the requirements		
		d) the visor of full facepiece shall not fog and affecting vision when in use; e) replaceable filter elements, valves and head harness shall be facilitating for replacement and facial seal check during use. f) breathing hose shall not limit head and body movement, shall not affect face seal or limit and block air flow.	/		
		g) Disposable facepiece shall provide proper face seal, shall not deform during normal use.	Provide proper face seal, and are not liable to deform		
2	Visual Inspection	The sample surface shall not be damaged, deformation, or with other obvious defects	No damage, deformation and other obvious defects	Pass	/
		the component materials and structure should be able to stand normal use conditions and possible temperature, humidity and mechanical impact that may encounter	Meet the requirements		

China Academy of Safety Science and Technology
Test Report of Non-powered air-purifying particle respirator

Test Result Summary							
No.	Test Items	Standard Requirements		Test Results		Assessment	Remark
2	Visual Inspection	the head harness should be adjustable; the head harness design of the replaceable facepiece should be replaceable.		Head harness is adjustable		Pass	/
		the eyeglass of full facepiece shall not be foggy that affect the vision when wearing.		/			
		After temperature and humidity pretreatment and mechanical strength pretreatment, the components shall not fall off, be damaged or deformation.		After pretreatment, no fall off, damage and deformation			
3	Filter Efficiency	KN	≥90.0% (KN90)	/		Pass	/
			≥95.0% (KN95)	As Received			
				98.1%	98.2%		
				98.6%	98.9%		
				98.4%	99.0%		
				98.5%	98.7%		
				98.4%	98.7%		
				Temperature and Humidity Conditioning	Mechanical Strength Conditioning		
				99.6%	/		
				97.7%	/		
				98.2%	/		
				98.6%	/		
				98.9%	/		
			≥99.97% (KN100)	/			
			Ambient temperature: (25±5)℃; Relative humidity: (30±10)%	25℃ 36%			
		KP	≥90.0% (KP90)	/			
			≥95.0% (KP95)	/			
			≥99.97% (KP100)	/			
			Ambient temperature: (25±5)℃;	/			

China Academy of Safety Science and Technology
Test Report of Non-powered air-purifying particle respirator

Test Result Summary

No.	Test Items	Standard Requirements	Test Results	Assessment	Remark
4-1	Total Inward Leakage (TIL) (Disposable Respirator)	When TIL of each action is taken as basis of evaluation (10 people x 5 actions), TIL of at least 46 actions of the 50 should <13% (KN90/KP90) <11% (KN95/KP95) <5% (KN100/KP100) And, When the overall TIL of a person is taken as basis for evaluation, the total TIL of at least 8 people of the 10 subjects should <10% (KN90/KP90) <8% (KN95/KP95) <2% (KN100/KP100)	See detailed table below	Pass	KN95
4-2	Inward Leakage (IL) (Replaceable Half facepiece Respirator)	When the IL of each action is taken as basis of evaluation (that is, 10 people x 5 actions), the IL of at least 46 actions of the 50 actions <5%.	/	/	/
		when the overall IL of a person is taken as basis for evaluation, the total IL of at least 8 people of the 10 subjects <2%	/		
4-3	Inward Leakage (IL) (Replaceable Full facepiece Respirator)	When the IL of each action is taken as basis of evaluation (that is, 10 people x 5 actions), the IL of each action < 0.05%	/	/	/

Test Results for 4-1:

	No.	Head Still	Side to Side	Up and Down	Talking	Head Still	Avg.
A.R.	-01	6.1	6.4	7.3	6.8	3.2	6.0
	-02	6.1	4.5	10.9	3.8	2.9	5.7
	-03	7.0	13.2	13.1	10.8	10.4	10.9
	-04	3.5	5.4	5.2	5.9	4.4	4.9
	-05	10.0	4.4	13.4	6.8	5.3	8.0
T.H.C	-06	2.5	5.8	7.7	8.0	3.9	5.6
	-07	8.1	5.4	10.4	7.2	6.1	7.4
	-08	5.2	4.7	5.8	4.9	6.7	5.5
	-09	7.7	7.3	5.2	7.4	10.0	7.5
	-10	2.8	6.7	6.3	4.0	4.0	4.8

47 out of 50 actions TIL values are less than 11%; 8 out of 10 subjects overall TIL values are less than 8%

(A.R.: Sample as Received
T.H.C.: Temperature and Humidity Conditioning)

China Academy of Safety Science and Technology
Test Report of Non-powered air-purifying particle respirator

Test Result Summary						
No.	Test Items	Standard Requirements	Test Results		Assessment	Remark
11	Head Harness	Each head harness, buckling and other adjustable components of the disposable facepiece should not slip or break when it is subjected to a tensile force of 10N for 10s.	10N tensile force pulling for 10s without slippage or break		Pass	/
		Each head harness, buckling and other adjustable components of the replaceable half facepiece should not slip or break when it is subjected to a tensile force of 50N for 10s.	/			
		Each head harness, buckling and other adjustable components of the full facepiece should not slip or break when it is subjected to a tensile force of 150N for 10s.	/			
12	Connection and connector	All the connections and connecting parts between the replaceable filter element and the half facepiece should not be no slide, break or distortion when subjected to an axial tensile force of 50N for 10s.	/		/	/
		All connections and connection parts between the replaceable filter element and the full facepiece, and between the breathing hose and the filter element and the full facepiece should not be no slide, break or distortion when subjected to an axial tensile force of 250N for 10s.	/			
13	Visor (Full facepiece)	After each sample is impacted by a steel ball, No eyeglass of the sample shall be broken or in crack;	/		/	/
		Tested by the air tightness of the sample after the impact of the steel ball, the negative pressure drop in each sample within 60s should not be greater than 100Pa	/			
14	Air Tightness (Full facepiece)	The negative pressure drop in each sample within 60s should not be greater than 100Pa	/		/	/
15	Flammability	After being removed from the flame, Various parts exposed to the flame should not burn; if burned, the after burning time should not exceed 5s.	As Received	Temperature and Humidity Conditioning	Pass	/
			0.5s	0.3s		
			0.8s	0.6s		

Test Result Summary					
No.	Test Items	Standard Requirements	Test Results	Assessment	Remark
16	Information Supplied by the Manufacturer	Such information should be supplied along with the minimum package for sales; There shall be Chinese explanation. The information should be clear, and help explanations such as explanations, part numbers, and labels can be added.	/	/	/
		Include the following information that users must know: a) Scope of application and restriction; b) For replaceable filter elements, there should be explanations on the method for use together with full or half facepiece, and if multiple filer materials, there should be indications; c) Method of assemblage of the replaceable facepiece; d) Method of inspection before use; e) Method of wearing and method of inspection of the wearing air tightness; f) Suggestions as to when to replace the filter elements; g) If applicable, the method of maintenance (for instance, method of cleaning and sterilization); h) Methods of storage; i) Meaning of any of the symbols and icons used;			
		Provide warnings about problems that may be encountered during use, such as: a) Adaptability b) Hair under the close frame can cause the mask to leak c) Air quality (pollutants, hypoxia, etc.)	/		
17	Mark	The product body should have the product name, trademark or other manufacturer's identification, type or model (if applicable), implementation standard and year number, filter element filter grade	/	/	/
		Product packaging should have the product name, trademark, or other manufacturer-identifiable label, type or model number (if applicable), implementation standard and year number, filter element filter grade, product license number, production date, or production batch number , Storage life, "see information provided by manufacturer", manufacturer's recommended storage conditions.	/		

Test Result Summary			
Main Test Equipment	Equipment No.	Equipment Name	Verification Period
	2010072S	High and Low Temperature Humidity Test Chamber SH-641	2020.04.18~2021.04.17
	GJ-SB353	TSI8130 Filtration Efficiency Tester	/
	GJ-SB413	Inward leakage test cabin	/
	GJ-SB369	TSI9306A Aerosol Generator	/
	GJ-SB371	TSI8587A Aerosol Photometer	/
	GJ-SB372	TSI8587A Aerosol Photometer	/
	GJ-SB415	Breathing Resistance Test Device	2020.02.14~2021.02.13
	GJ-SB505	Microcomputer Controlled Universal Testing Machine	2020.04.18~2021.04.17
	GJ-SB380	INSPEC Apertometer	/
	GJ-SB417	Dead Space Test Device	2020.02.17~2021.02.16
	GJ-SB381	Face Mask Flammability Rig	2020.02.03~2021.02.02

Test Period: May 09 2020 ~ May 16 2020

End of Test Report.

----------The following is blank.

广检集团 GTTC

202019124876 CNAS 中国认可 国际互认 检测 TESTING CNAS L10314

TEST REPORT (Electronic version)

扫码下载报告

VERIFICATION WEBSITE: www.gttc.net.cn

VERIFICATION CODE: CICN-0423-04

No:200166006 ISSUE DATE:2020-06-30

APPLICANT: XIAMEN PROBTAIN NONWOVEN INC.
ADDRESS: NO.6 JI'AN ROAD TONGAN DISTRICT ,XIAMEN,FUJIAN, 361100 CHINA

INFORMATION CONFIRMED BY APPLICANT:

KN95 PARTICULATE RESPIRATOR

QUANTITY: 60 PIECES

BRAND: GREENCARE

MANUFACTURE'S NAME: XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO., LTD

DATE RECEIVED/DATE TEST STARTED: 2020-06-13

CONCLUSION:

FILTRATION EFFICIENCY TO NaCl PARTICULATE MATTER	M
INSPIRATORY RESISTANCE	M
EXPIRATORY RESISTANCE	M
VISUAL FIELD UNDER MASK	M
BINOCULAR VISUAL FIELD	M
FLAMMABILITY	M
DEAD SPACE	M
APPEARANCE[2 PIECES]	M

NOTE: "M" -MEET THE STANDARD'S REQUIREMENT "F" -FAIL TO MEET THE STANDARD'S REQUIREMENT
"---" -NO COMMENT

REMARK:
THIS REPORT IS THE ENGLISH TRANSLATION VERSION OF THE REPORT 200166005.
ALL THE TESTED ITEMS ARE TESTED UNDER THE STANDARD CONDITION (EXCEPT FOR INDICATION).
COPIES OF THE REPORT ARE VALID ONLY RE-STAMPED.
THE EXPERIMENT WAS CARRIED OUT AT No.1, ZHUJIANG ROAD, PANYU DISTRICT, GUANGZHOU, GUANGDONG, P.R.CHINA.

APPROVED BY: 郭子山

ZiShan Guo SENIOR ENGINEER

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

总部:广州市番禺区珠江路1号
花都实验室:广州市花都区狮岭镇旗岭河滨西路1号
电话:020-61994598/61994599
电话:020-37721161/66348638

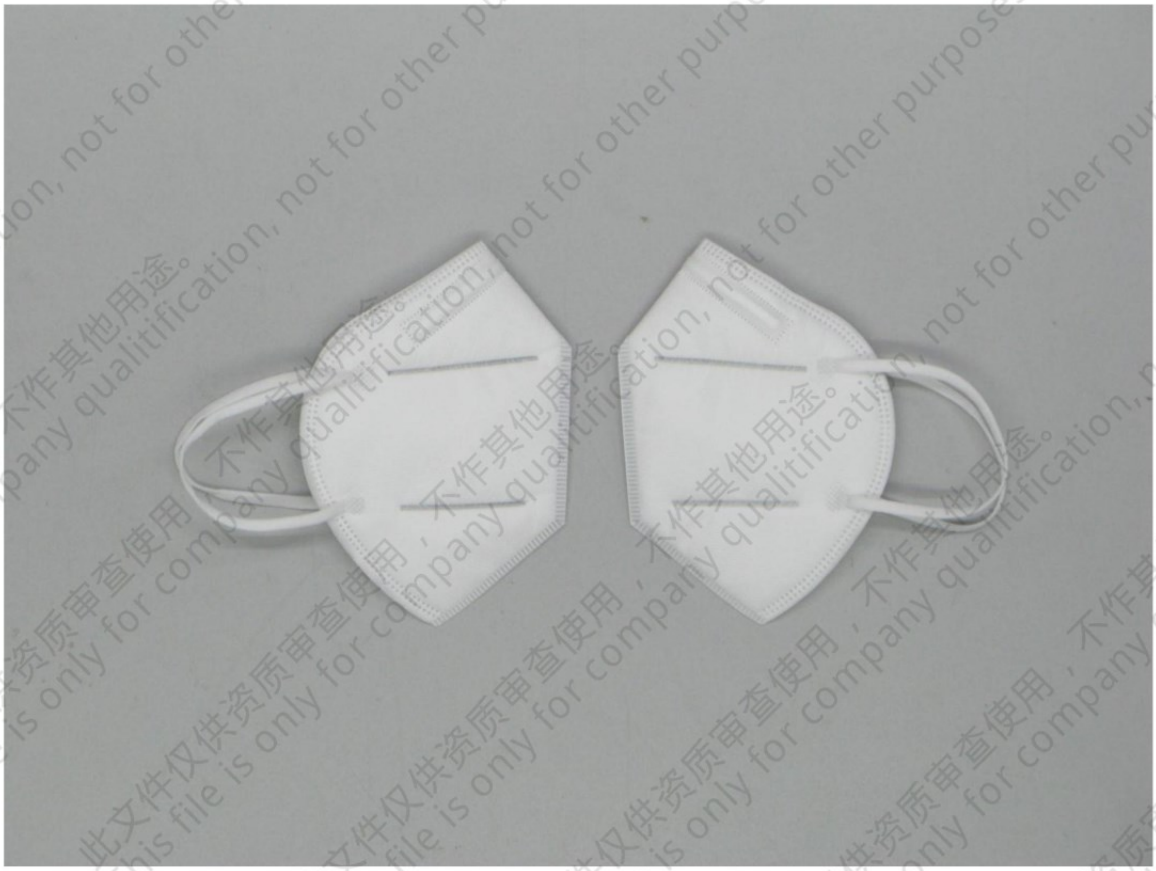
广检集团 GTTC

202019124876

TEST REPORT

(Electronic version)

No:200166006



广州检验检测认证集团有限公司 检验检测专用章 (GF2)

PAGE: 1/10

总部：广州市番禺区珠江路1号
花都实验室：广州市花都区狮岭镇旗岭河滨西路1号
电话：020-61994598/61994599
电话：020-37721161/66348638

TEST REPORT

(Electronic version)

No:200166006

FILTRATION EFFICIENCY TO NaCl PARTICULATE MATTER(%)

(GB 2626-2019 6.3, AIR FLOW:85L/min, AEROSOL:NaCl, AEROSOL CONCENTRATION:15mg/m^3, TEMP:23.7℃ RH:36.6%)

FILTRATION EFFICIENCY:	REQUIREMENT FILTRATION EFFICIENCY:
UNTREATED SAMPLE	≥95.0
1# 99.971	(KN95)
2# 99.918	(GB 2626-2019)
3# 99.936	
4# 99.940	
5# 99.952	
6# 99.876	
7# 99.790	
8# 99.913	
9# 99.850	
10# 99.764	
11# 99.678	
12# 99.702	
13# 99.674	
14# 99.803	
15# 99.617	
CONDITIONING TREATED	
1# 99.149	
2# 99.860	
3# 99.253	
4# 99.368	
5# 99.476	

INSPIRATORY RESISTANCE(Pa)

(GB 2626-2019 6.5, HEAD SIZE: MEDIUM)

UNTREATED SAMPLE:	REQUIREMENT ≤210
1# 131.6	(GB 2626-2019)
2# 124.5	
PRETREATMENT SAMPLE:	
1# 128.5	
2# 126.1	

EXPIRATORY RESISTANCE(Pa)

(GB 2626-2019 6.6, HEAD SIZE: MEDIUM)

UNTREATED SAMPLE:	REQUIREMENT ≤210
1# 115.9	(GB 2626-2019)
2# 111.4	
PRETREATMENT SAMPLE:	
1# 112.4	
2# 109.5	

VISUAL FIELD UNDER MASK(°)

(GB 2890-2009 6.8)

	REQUIREMENT
65	≥35
	(GB 2626-2019)

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

总部:广州市番禺区珠江路1号
花都实验室:广州市花都区狮岭镇旗岭河滨西路1号
电话:020-61994598/61994599
电话:020-37721161/66348638

TEST REPORT

(Electronic version)

No:200166006

BINOCULAR VISUAL FIELD(%)

(GB 2890-2009 6.8)

88	REQUIREMENT ≥65 (GB 2626-2019)

FLAMMABILITY(s)

(GB 2626-2019 6.15)

AFTERFLAME TIME UNTREATED SAMPLE 1# 0.0 2# 0.0 CONDITIONING TREATED 3# 0.0 4# 0.0	REQUIREMENT AFTERFLAME TIME ≤5 (GB 2626-2019)

DEAD SPACE

(GB 2626-2019 6.9)

CARBON DIOXIDE VOLUME FRACTION: 0.8%	REQUIREMENT CARBON DIOXIDE VOLUME FRACTION SHOULD NOT BE MORE THAN 1% (GB 2626-2019)

APPEARANCE[2 PIECES]

(GB 2626-2019 6.1)

PASS	REQUIREMENT ACCORDING TO THE CLAUSE 5.2 OF THE PRODUCT STANDARD (GB 2626-2019)

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

———End of Report———

总部:广州市番禺区珠江路1号
花都实验室:广州市花都区狮岭镇旗岭河滨西路1号
电话:020-61994598/61994599
电话:020-37721161/66348638

PRODUCTION LINE

Who Cares?
We Care.

GREENCARE®

Safeguard Personal & Public Health

Face Masks Expert Since 2003

Face Masks

Kids Face Masks

Surgical Masks

KN95 Respirators

FFP2 Respirator

Manufactured by

Xiamen Probtain Medical Technology Co., Ltd.

ISO13485 Accredited Professional Medical Devices Manufacturer