GREENCARE®

Dispositivi di protezione individuale

MASCHERINE FFP2 NR

Involucro singolo

Mascherina filtrante 5 strati con supporto nasale omaggio

(confezione da 20 pezzi, ciascun pezzo con proprio involucro)

Produttore:

Xiamen Probtain Nonwoven Inc.
No. 6, Ji an Road, Tong An District,
Xiamen, Fujian, China 361100

MASCHERINE DI PROTEZIONE

My Benefit Mask PRO

MASCHERINE FFP2 NR

CARATTERISTICHE

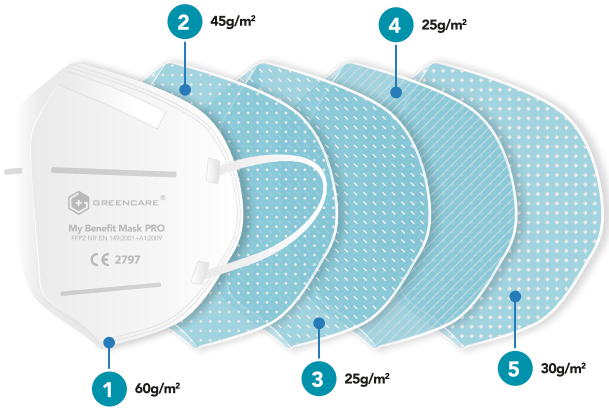
La mascherina FFP2 My Benefit Mask PRO è un dispositivo di protezione individuale è un dispositivo di protezione individuale capace di filtrare il 99,9% delle microparticelle sospese nell'aria, proteggendo le vie respiratorie. Protegge da batteri, virus, allergeni, nebbia, polveri, fumo, gas di scarico di auto ed altri agenti contaminanti. Plasmabile, assicura un ottimo livello di aderenza e comfort, grazie anche al supporto nasale incluso con ogni mascherina.

Forma: le mascherine FFP2 sono realizzate con materiali anallergici, e sono sagomate per rispettare l'ergonomia e la perfetta adesione al volto.

Certificazione: le mascherine sono dotate di attestato di certificazione CE e rispettano i requisiti delle norme tecniche armonizzate EN 149:2001+A1:2009.

Confezionamento: Confezione da 20 mascherine, ciascuna mascherina ha il proprio involucro

DETTAGLI TECNICI



Materiale (5 strati):

1. **Superficie esterna:** Polipropilene tessuto-non-tessuto 60 g/m²
2. **Imbottitura morbida:** tessuto-non-tessuto 45 g/m²
3. **Filtro:** Polipropilene melt-blown 25 g/m²
4. **Filtro:** Polipropilene melt-blown 25 g/m²
5. **Superficie interna:** Polipropilene tessuto-non-tessuto 30 g/m²

Dimensioni: Pieghevole 15.5 x 10.5 (± 0.5 cm)
Standard Filtrazione: FFP2 NR – EN149:2001+A1:2009
Condizioni di conservazione: mantenere in condizione buie, secche e ben ventilate, lontano da fiamme libere e fonti di inquinamento.
Shelf life: 3 anni dalla data di produzione

SUPPORTO NASALE
OMAGGIO

+ ADERENZA
+ COMFORT

FUNZIONI

Le Mascherine FFP2 vengono utilizzate frequentemente per prevenire contagi batterici / virali e per prevenire la respirazione di particelle dannose in ambito edile, nell'industria chimica, oppure come dispositivo di protezione da allergeni.

CE **EN 149:2001+A1:2009**

MASCHERINE FFP2 NR

ISTRUZIONI PER L'USO

1. Aprire la maschera, apporre il supporto nasale in corrispondenza del ponte nasale
2. Appoggiare la maschera sul mento e tirare l'elastico alle orecchie, regolare fino ad un'indossatura confortevole
3. Aggiustare il clip nasale alla forma del naso
4. Premere entrambi gli indici sul clip nasale per creare aderenza e impedire fuoriuscite d'aria

INDICAZIONI

- Seguire attentamente le figure illustrative e le istruzioni per l'uso per il corretto utilizzo della maschera e controllare il livello di aderenza al viso.
- La maschera non è efficace per prevenire l'inalazione di gas, vapori e fumiganti tossici o se indossata in un'area con una concentrazione di ossigeno inferiore al 19,5%.
- Indossare solo in aree adeguatamente ventilate e ossigenate.
- Non va indossata e non costituisce una protezione adeguata in casi di concentrazione letale di agenti tossici o contaminanti.
- Abbandonare immediatamente l'attività in corso e cercare assistenza sanitaria se:
    - Si incontrano difficoltà respiratorie;
    - Si avverte un principio di vertigini, nausea o altro malessere fisico;
- Maschera monouso, non riutilizzare.
- Alterare, modificare, o riparare la maschera in modo improprio ne renderà nulla l'azione filtrante.
- Quando la si getta, ripiegarla rivolgendo l'esterno verso il centro.

IMPORTANTE

La maschera è in grado di filtrare alcuni agenti contaminanti, ma un utilizzo scorretto può causare contagio e conseguente malattia, fino alla morte. Materiali in diretto contatto con la pelle possono causare una reazione allergica in certi individui ipersensibili.

CE **EN 149:2001+A1:2009**

Formato: Box (20 pezzi)
8 055519 881178

Formato: involucro singolo
8 055519 881208

My Benefit Mask PRO

GREENCARE®

5 veli
5 strati di protezione

MASCHERINE FFP2
MONOUSO/NON-STERILE

Conf. 20 pz. - Involucro singolo

SUPPORTO NASALE OMAGGIO

+ ADERENZA
+ COMFORT

1. **Superficie esterna:** Polipropilene tessuto-non-tessuto **60 g/m²**
2. **Imbottitura morbida:** tessuto-non-tessuto **45 g/m²**
3. **Filtro:** Polipropilene melt-blown **25 g/m²**
4. **Filtro:** Polipropilene melt-blown **25 g/m²**
5. **Superficie interna:** Polipropilene tessuto-non-tessuto **30 g/m²**

Capacità Filtrante
≥95%
Particelle oleose fino a 0,6 µm

CE **EN 149:2001+A1:2009**

Scheda tecnica produttore

公司简介Company Profile

美润股份
PROBTAIN

美润股份是一家专门研究和开发无纺布和无纺布产品在医疗和航空及各个领域的应用的集团公司。公司成立于2005年，拥有三家全资子公司，厦门美润医疗科技有限公司、厦门美润合悦卫生材料有限公司、和江西美润环保制品有限公司，拥有约8000平方米的厂房，员工总数为166人。

PROBTAIN GROUP is company specialized in developing & manufacturing of nonwoven fabric & nonwoven products for various industries including airlines & healthcare. Established in 2005, the company has three wholly-owned subsidiaries, Xiamen Probtain Medical Technology Co., Ltd., Xiamen Probtain Heyue Hygienic Materials Co., Ltd. and Jiangxi Ruijin Greenfibre Daily Products Co., ltd., with our own premises of approx 80,000 Square meters and recruiting total 466 employees.

公司通过了ISO9001和ISO 14001认证，拥有相应的资质和高素质的员工队伍，在过去的10年里，我们在设备和设施方面投入了大量的资金，现在我们可以以有竞争力的价格为客户提供高质量的产品/服务。

The Company is ISO9001 & ISO 14001 certified, with relevant qualifications and high caliber staffs in place and significant investment in equipment and facilities over the past 10 years, we're now in a good position to supply our clients with high quality products/services at competitive prices.

Your reliable partner in Aviation Products

格林特卫 GREENCARE | 美润股份 PROBTAIN

PACKAGE PHOTOS

SINGLE PACK/ 20 PCS/BOX ,30 BOX/CTN, 50*43*33M

Certificazioni / Test report

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

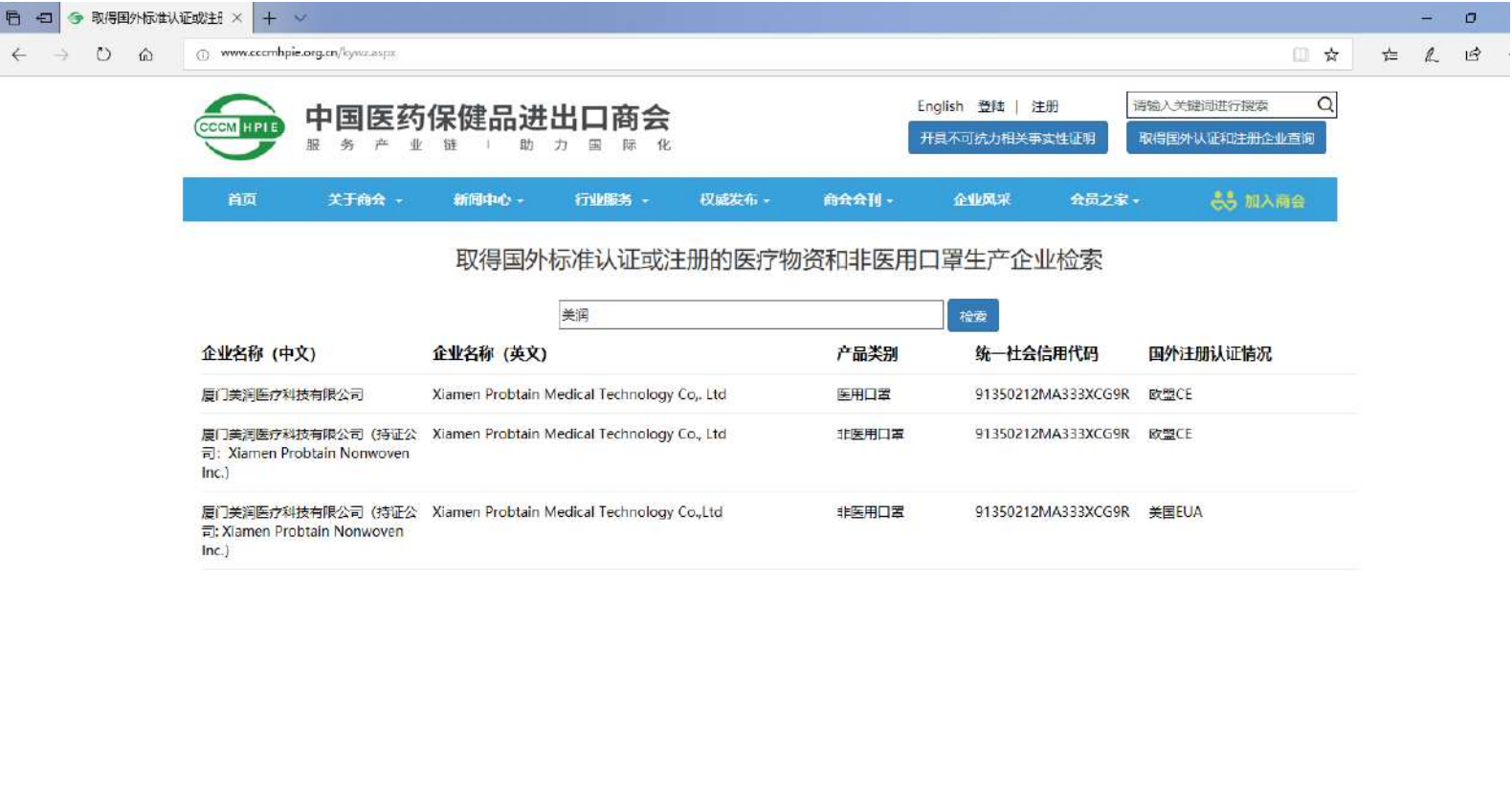
Section 9, No.188, Nansihuan(the South Fourth Ring Road) Xilu(West Road), Beijing 100070,China
http://www.cqc.com.cn

D 0005167

2018年版

格林特卫® GREENCARE | 美润股份 PROBTAIN

White list of Chamber Commerce



企业名称（中文）	企业名称（英文）	产品类别	统一社会信用代码	国外注册认证情况
厦门美润医疗科技有限公司	Xiamen Probtain Medical Technology Co,. Ltd	医用口罩	91350212MA333XCG9R	欧盟CE
厦门美润医疗科技有限公司（持证公司：Xiamen Probtain Nonwoven Inc.）	Xiamen Probtain Medical Technology Co., Ltd	非医用口罩	91350212MA333XCG9R	欧盟CE
厦门美润医疗科技有限公司（持证公司：Xiamen Probtain Nonwoven Inc.）	Xiamen Probtain Medical Technology Co.,Ltd	非医用口罩	91350212MA333XCG9R	美国EUA

EU DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer:

Manufacturer and address	XIAMEN PROBTAIN NONWOVEN INC. No.6 Ji'an Road,Tong'an District,Xiamen, Fujian,361100, China
Product name	PARTICULATE RESPIRATOR
Model/ Serial No.	MP9011
Technical Reference:	BSI's PPE Technical Specification for Healthcare Professionals during the Covid-19 Pandemic
Applicable Regulation:	PPE Regulation 2016/425
Notified body for EU type-examination (Module B)	BSI Group - NB 2797 The Netherlands BV, Say Building, John M Keynesplein 9, 1066 EP, Amsterdam, Netherlands
Notified body for EU type-examination (Module C2)	BSI Group - NB 2797 The Netherlands BV, Say Building, John M Keynesplein 9, 1066 EP, Amsterdam, Netherlands
Certificate number	CE728105

We declared that given information on the above statement and attached documents/records are true and correct to the best of our knowledge.

Signed for and on behalf of: XIAMEN PROBTAIN NONWOVEN INC.

May 22,2020

EU Type Examination Certificate

This is to certify that:

XIAMEN PROBTAIN NONWOVEN INC.
No.6 Ji'an Road
Tong'an District
Xiamen
Fujian
361100
China

Holds Certificate Number: CE 728105

In respect of:

Model MP9011 Particulate Respirator.
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

Previous Notified Body: BSI 0086

First Issued: 2020-06-01

Effective Date: 2020-06-01

Latest Issue: 2020-06-01

Expiry Date: 2021-06-01

PRODUCTS
RvA C 646

...making excellence a habit.™

EU Type Examination Certificate

No. CE 728105

Product Specification

Product Name:	Particulate Respirator.
Product Type:	Particulate filtering half masks for use by Healthcare professionals.
Model:	**MP9011.**
Classification:	FFP2 NR un-valved.
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 class, vertical fold flat type. 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.

First Issued: 2020-06-01
Latest Issue: 2020-06-01

Effective Date: 2020-06-01
Expiry Date: 2021-06-01

EU Type Examination Certificate

No. CE 728105

Certificate Administration Details

Technical File Reference: Xiamen Probtain Nonwoven Inc. Technical Files.

Certificate Amendment Record:

Issue date	Comments	BSI Review No.
June 2020	First issue.	2797:20:3201474

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 728110.

First Issued: 2020-06-01
Latest Issue: 2020-06-01

Effective Date: 2020-06-01
Expiry Date: 2021-06-01

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

This is to certify that:

XIAMEN PROBTAIN NONWOVEN INC.
No.6 Ji'an Road
Tong'an District
Xiamen
Fujian
361100
China

Holds Certificate Number: CE 728110

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

Previous Notified Body: BSI 0086

First Issued: 2020-06-01

Effective Date: 2020-06-01

Latest Issue: 2020-06-01

Expiry Date: 2021-06-01

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 728110

Product manufactured by:

XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD
4th Floor, No.1 Building
No.6 Ji'an Road
Tong'an District
Xiamen
Fujian
361100
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:	MP9011 FFP2 NR
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.

First Issued: 2020-06-01
Latest Issue: 2020-06-01

Effective Date: 2020-06-01
Expiry Date: 2021-06-01

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

No. CE 728110

Certificate Administration Details:

Certificate Amendment Record and BSI internal Review relating to this Certificate

Issue date	Comments	BSI Review No.
June 2020	First issue.	2797:20:3201475

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.

First Issued: 2020-06-01
Latest Issue: 2020-06-01

Effective Date: 2020-06-01
Expiry Date: 2021-06-01

Test Report 3201467.

Xiamen Probtain Nonwoven Inc.

Introduction.

This report has been prepared by Paul Waller and relates to the activity detailed below:

Job/Registration Details		Client Details
Job number:	**3201467**	Xiamen Probtain Nonwoven Inc. No.6 Ji'an Road Tong'an District Xiamen Fujian 361100 China
Job type:	Testing Samples Submitted	
Start Date:	05/05/2020	
Test type:	Type	
Sample ID:	10189485	
Registration:	**CE 728105**	
Scheme:	Negative pressure RPE	
Protocol:	PP123	
Scheme Manager:	Nathan Shipley	

The report has been approved for issue by T Wicksey – Senior Test Engineer

Approved For Issue	
	Issue Date: 20 May 2020

Objectives.

This is an independent test evaluation to only certain clauses or sub-clauses of the agreed specification in accordance with the following test programme:

BSI COVID-19 filtering face piece technical specification, for COVID-19 masks for use by healthcare workers

Product Scope.

COVID-19 masks for use by healthcare workers

Report Summary.

The samples were received on 30 April 2020 and the testing was started on 5 May 2020.

The samples submitted complied with the requirements of the test work conducted.

Test Samples.

Sample ID	ER Number	Description
1 to 19	10189485	Model: MP9011 FFP2

Description of Test Samples.

Sample Description
COVID-19 masks for use by healthcare workers: Model: MP9011 FFP2

Test Requirements.

Testing in accordance with BSI COVID-19 filtering face piece technical specification
Technical testing specification for COVID-19 masks for use by healthcare workers

EN 149:2001+A1:2009 Performance requirement	EN 149:2001+A1:2009 Test method clause	Requirement	Assessment
7.7 Practical performance 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. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections. *2 test subjects, masks tested 'As received'*	Testing shall be done in accordance with 8.4.	During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded: a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.	Pass
7.9 Leakage **7.9.1 Total inward leakage** *5 test subjects, masks tested 'As received'*	Testing shall be done in accordance with 8.5.	All samples must achieve All individual exercise results tests shall be not greater than 11 % (for FFP2) and, in addition, all arithmetic means for the total inward leakage shall be not greater than 8 % (for FFP2)	Pass
7.9 Leakage **7.9.2 Penetration of filter material** *3 test samples masks tested 'As received', for NaCl (Sodium Chloride) and PO (Paraffin oil), 3min test*	Testing shall be done in accordance with 8.11	6% for both PO and NaCl	Pass
7.12 Carbon dioxide content of the inhalation air *3 test samples, masks tested 'As received'*	Testing shall be done in accordance with 8.7.	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).	Pass
7.16 Breathing resistance *3 test samples, masks tested 'As received'*	Testing shall be done in accordance with 8.9	The breathing resistances shall meet the requirements of; 30l/min – 0.7mbar (inhale) 95l/min – 2.4mbar (inhale) 160l/min – 3.0mbar (exhale)	Pass
Appendix A - Test Panel Data			
Product Photographs			

Glossary of Terms.

Pass: Complies. Tested by BSI engineers at BSI laboratories
Pass 1: Complies. Witnessed by BSI engineers in manufacturers laboratory.
Pass 2: Complies. Tests carried out by third party lab; results accepted by BSI.
Pass*: Report resulted in uncertainty and states that Compliance is more probable than non-compliance.
Fail: Non-compliance. Product does not meet the requirements of this clause.
Fail*: Report resulted in uncertainty and states that Non-compliance is more probable than compliance.
N/T: Not Tested
N/A: Not Applicable
AR: As Received
TC: Temperature Conditioned
SW: Simulated Wear
FT: Flow Tested
MS: Mechanical strength
MMDF: Manufactures Minimum Design Flow
MMDC: Manufactures Minimum Design Condition

Conditions of Issue.

This Test Report is issued subject to the conditions stated in current issue of 'BSI Terms of Service'. The results contained herein apply only to the particular sample(s) tested and to the specific tests carried out, as detailed in this Test Report. The issuing of this Test Report does not indicate any measure of Approval, Certification, Supervision, Control or Surveillance by BSI of any product. No extract, abridgement or abstraction from a Test Report may be published or used to advertise a product without the written consent of BSI, who reserve the absolute right to agree or reject all or any of the details of any items or publicity for which consent may be sought.

Should you wish to speak with BSI in relation to this report, please contact Customer Services on +44 (0)8450 80 9000.

BSI
Kitemark House
Maylands Avenue
Hemel Hempstead
Hertfordshire
HP2 4SQ

UKAS TESTING
0135

Opinions and Interpretations expressed herein are outside the scope of our UKAS accreditation.
Unless otherwise stated, any results not obtained from testing in a BSI laboratory are outside the scope of our UKAS accreditation.

Test Results.

Testing in accordance with BSI COVID-19 filtering face piece technical specification

BS EN 149:2001 +A1:2009 Technical testing specification for COVID-19 masks for use by healthcare workers

CLAUSE	REQUIREMENTS	ASSESSMENT
7.7	**Practical performance** 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. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections. Test in accordance with clause 8.4 of the standard. ***Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers*** *During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded:* *a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.*	Pass

Table A: Practical performance

Test candidate	Sample	Comments				Assessment
		Head harness comfort	Security of fastenings	Field of vision	Any other comments	
LM2	1 AR	OK	OK	Good	Air leak around nose	Pass
JS3	2 AR	OK	OK	OK	Air leak around nose	Pass

7.9 Leakage

7.9.1 Total inward leakage

The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected.

The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration.

Test in accordance with clause 8.5 of the standard. Pass

Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers

5 test subjects, masks tested 'As received'. All individual exercise results tests shall be not greater than 11 % (for FFP2) and, in addition, all arithmetic means for the total inward leakage shall be not greater than 8 % (for FFP2).

Table B: Clause 7.9.1 - Total inward leakage

Test candidate	Sample	Pre test condition	Inward Leakage (%)						Assessment
			A	B	C	D	E		
			Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking	Average	
JS2	3	AR	3.63	5.63	6.23	1.04	3.30	3.97	Pass
CB1	4	AR	6.71	7.97	8.66	3.52	6.22	6.62	Pass
JB1	5	AR	1.73	1.47	1.75	0.89	1.12	1.39	Pass
AA1	6	AR	2.31	4.00	3.05	2.04	6.69	3.62	Pass
RF1	7	AR	2.01	4.64	7.23	2.62	2.59	3.82	Pass

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT

7.9.2 Penetration of filter material

Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers

3 test samples masks tested 'As received', for NaCl (Sodium Chloride) and PO (Paraffin oil), 3 min test. Testing shall be done in accordance with 8.11. 6% limit for both PO and NaCl

Pass

Table C: Clause 8.11 - Sodium Chloride penetration test

Sample number	Pre-test condition	Flow through filter (l/min)	Penetration (%)	
			Limit	Actual
8	AR	95	< 6	0.036
9	AR			0.031
10	AR			0.023

Table D: Clause 8.11 - Paraffin oil penetration test

Sample number	Pre-test condition	Flow through filter (l/min)	Penetration (%)	
			Limit	Actual
11	AR	95	< 6	0.261
12	AR			0.130
13	AR			0.162

7.12 Carbon dioxide content of inhalation air

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0% (by volume).

Test in accordance with clause 8.7 of the standard.

Pass

Table E: Clause 8.7 - Carbon Dioxide content of the inhalation air

Sample	Pre-test condition	Dead space CO_2 (%)	
		Limit	Measured
14	AR	< 1.0	0.52
15	AR		0.54
16	AR		0.52

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.16	**Breathing resistance** ***Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers*** *3 test samples masks tested 'As received'. Test in accordance with clause 8.9 of the standard.* *The breathing resistances shall meet the requirements of FFP2;* *30l/min – 0.7mbar (inhale), 95l/min – 2.4mbar (inhale), 160l/min – 3.0mbar (exhale)*	Pass

Table F: Clause 8.9 – Breathing resistance. Inhalation resistance at a continuous flow

Sample	Pre-test condition	Continuous flow (l/min)	Inhalation resistance (mbar)	
			Limit	Measured
17	AR	30	< 0.7	0.36
18	AR			0.35
19	AR			0.33
17	AR	95	< 2.4	1.13
18	AR			1.13
19	AR			1.08

Table G: Clause 8.9 – Breathing resistance. Exhalation resistance at a continuous flow, measured in five orientations with the worst case reported

Sample	Pre-test condition	Continuous flow (l/min)	Exhalation resistance (mbar)	
			Limit	Measured
17	AR	160	< 3.0	1.76
18	AR			1.76
19	AR			1.71

Appendix A. – Test Panel Data

Test Candidate	Facial Dimensions (mm)					Sex
	Length of face	Width of face	Face depth	Width of mouth	Head Circumference	
LM2	110	148	125	44	589	Male
JS3	126	134	124	49	600	Male
JS2	126	142	125	57	575	Male
CB1	117	147	130	57	566	Male
JB1	114	144	108	59	574	Male
AA1	125	144	130	47	581	Male
RF1	104	122	121	55	549	Male

Note: All candidates were clean shaven

Product photographs.

Front view

Side View

Inside View

End of Report

APAVE SUDEUROPE SAS Siège social : 8 rue Jean-Jacques Vernazza - Z.A.C. Saumaty-Séon - CS 60193 - 13322 MARSEILLE CEDEX 16 • Tél. : 04 96 15 22 60 - Fax : 04 96 15 22 61 - www.apave.com
Société par Actions Simplifiée au Capital de 6 648 544 € - N° SIREN 518 720 925

In enforcement of Regulation 2016/425 of the European Parliament and of the Council of 9th March 2016 on Personal Protective Equipment and repealing the Directive 89/686/EEC and in compliance with the Module B Certification Scheme of Apave 'M.MEPI.45' in force,
En exécution du Règlement 2016/425 du Parlement Européen et du Conseil du 9 mars 2016 relatif aux Equipements de Protection Individuelle et abrogeant la Directive 89/686/CEE et en respect du Programme de Certification Module B de l'Apave 'M.MEPI.45' en vigueur,

APAVE Sudeurope SAS, notified body identified under number 0082, awards the
APAVE Sudeurope SAS, organisme notifié identifié sous le numéro 0082, attribue l'

EU TYPE-EXAMINATION CERTIFICATE

Attestation d'examen UE de type

N° 0082/3584/079/08/20/0395

The following PPE type complies with the applicable essential health and safety requirements
Le type de l'EPI suivant est conforme aux exigences essentielles de santé et de sécurité applicables

PPE: PPE category III – Filtering half mask to protect against particles
EPI : EPI de catégorie III – Demi-masque filtrant contre les particules

Type: FFP2 NR
Type

Trademark: **GREENCARE**
Marque commerciale

Model: **MP9011**
Modèle

Manufacturer: XIAMEN PROBTAIN NONWOVEN INC. - No.6, Ji an Road, Tong an District - XIAMEN - Fujian - China
Fabricant

Description: Filtering half mask to protect against particles class FFP2 NR without exhalation valve, limited to single shift use only. The half mask is foldable with a vertical fold flat shape, designed with a nose clip in iron wire and polypropylene, a nose foam in polyurethane and two self-adjusting ear loop harnesses in spandex and polyester. The filter media is composed of 5 layers in polypropylene (detailed description in EU type examination report 20.0194).

Description : Demi-masque filtrant contre les particules de classe FFP2 NR sans soupape expiratoire, à usage unique. Le demi-masque est pliable en forme plate à pliage vertical, conçu avec une barrette nasale en fil de fer et polypropylène, une mousse nasale en polyuréthane et deux brides auto-réglables en spandex et polyester portées derrière les oreilles. Le média filtrant est composé de 5 couches en polypropylène (description détaillée dans le rapport d'examen UE de type 20.0194).

Technical referential in use: EN 149:2001 + A1:2009
Référentiel technique utilisé

CE CERTIFICATE BY APAVE CE 0082

Date of signature (day/month/year): 09/11/2020
Date de signature (jour/mois/année)

Date of issue (day/month/year): 09/11/2020
Date de délivrance (jour/mois/année)

Date of renewal (day/month/year): first edition
Date de renouvellement (jour/mois/année) 1ère édition

Date of expiry (day/month/year): 09/11/2025
Date d'expiration (jour/mois/année)

PPE Certification Manager
Le Responsable de la Certification EPI
Immaterial original

Vincent Maillocheau
Validation électronique

cofrac
CERTIFICATION DE PRODUITS ET SERVICES
Accréditation N° 5-0596
Scope available on
Portée disponible sur
www.cofrac.fr

Apave Sudeurope SAS
Centre d'Essais et de Certification EPI
17, Boulevard Paul Langevin
38600 FONTAINE - France
Tél. +33.(0)4.76.53.52.22

M.MEPI.74.V5

For category III PPE, the certificate shall only be used in conjunction with one of the conformity assessment procedures referred in point c) of Article 19
Pour les EPI de catégorie III, l'attestation ne doit être utilisée qu'en liaison avec l'une des procédures d'évaluation de la conformité visées à l'article 19, point c).
The manufacturer shall inform the notified body of all modifications to the approved type and of all modifications of the technical documentation that may affect the conformity of the PPE with the applicable essential health and safety requirements or the conditions for validity of that certificate *(article 7.2 – annex V)*
Le fabricant informe l'organisme notifié de toutes les modifications du type approuvé et de toutes les modifications de la documentation technique qui peuvent remettre en cause la conformité de l'EPI aux exigences essentielles de santé et de sécurité applicables ou les conditions de validité de cette attestation (article 7.2 – annexe V)

This certificate includes one page - *Cette attestation comporte une page*

APAVE SUDEUROPE SAS, organisme notifié, identifié sous le numéro 0082
APAVE SUDEUROPE SAS, notified body, identified under number 0082

Centre d'Essais et de Certification de Fontaine
17, Boulevard Paul Langevin
38600 FONTAINE - France
Tél. +33.(0)4.76.53.52.22

XIAMEN PROBTAIN NONWOVEN INC.
No.6, Ji an Road, Tong an District,
XIAMEN
Fujian
China

PPE REGULATION 2016/425 – ANNEX V
MODULE B – EU TYPE EXAMINATION
ASSESSMENT REPORT
Respiratory protective device

Report n°	**20.0194**
Technical referential	**EN 149:2001 + A1:2009**
Type of device	**PPE category III** **Filtering half mask to protect against particles**
Class	**FFP2 NR**
Trade mark	**GREENCARE**
Model	**MP9011**

Fontaine, the 21/10/2020
Report sent for the attention of XIE JIAN YOU to the email address jianyou@probtain.com
This report includes 15 pages

The technical assessment manager
Immaterial original

M.MEPI.324.V1

VILA COBARSI
Validation électronique

PAGE 22-36
TECHNICAL SPECIFICATION AND TEST REPORT

Summary

1.Introduction - Description of the service

This assessment report concerns PPE category III – Filtering half mask to protect against particles as defined in EN 149:2001 + A1:2009.

Its purpose is to assess the conformity of the PPE with the PPE REGULATION 2016/425, with a view to be placed on the European market exclusively.

The assessment was conducted in accordance with purchase order signed on 31/03/2020 placed by XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO., LTD.

Company: XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO., LTD. - No.6, Ji an Road, Tong an District - XIAMEN - Fujian - China

2.Use of the report

This assessment report only concerns the equipment identified in clause 4 and described in clause 7.

Only an integral reproduction of this assessment report is authorized.

The manufacturer, or his representative, commits himself not to use this assessment report for equipment that is not strictly identical to the equipment covered by this assessment report.

3.Economical operator(s)

Manufacturer:	XIAMEN PROBTAIN NONWOVEN INC. - No.6, Ji an Road, Tong an District - XIAMEN - Fujian – China
Manufacturing site:	XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO., LTD. - No.6, Ji an Road, Tong an District - XIAMEN - Fujian - China

4.Identification of the equipment

Class:	FFP2 NR
Trade mark:	GREENCARE
Model:	MP9011

5.Conditions for use of the equipment

This filtering half mask is intended to be used as respiratory protective devices to protect against particles except for escape purposes.

6.Reference specification

The assessment of conformity with Regulation 2016/425 of 9th march 2016 "Personal Protective Equipment" was conducted taking into account the provisions of European standard EN 149:2001 + A1:2009 "Respiratory protective devices – Filtering half masks to protect against particles".

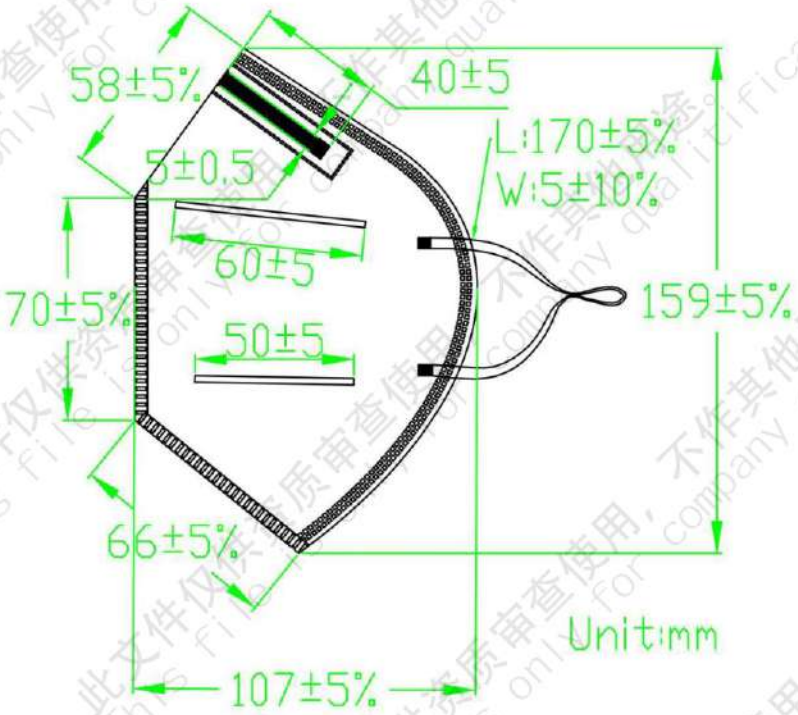
7.Technical Documentation

7.1.Identification

Identification of the assessed Technical Documentation:

1. Authorized representative – Company: XIE JIAN YOU - XIAMEN PROBTAIN NONWOVEN INC.
2. Commitment signature date: 27/04/2020, last update received on 16/10/2020
3. Technical Documentation reference: PM/WI-TD-34 B/2

7.2.Drawing



7.3.Description

Filtering half mask to protect against particles class FFP2 NR without exhalation valve, limited to single shift use only. The half mask is foldable with a vertical fold flat shape, designed with a nose clip in iron wire and polypropylene, a nose foam in polyurethane and two self-adjusting ear loop harnesses in spandex and polyester. The filter media is composed of 5 layers in polypropylene.

7.4.Description of components

Detailed description of components in the Technical Documentation.

7.5.CE Marking

× Notified body in charge of assessment control to article 19c) of PPE regulation (module C2 or D):

APAVE SUDEUROPE SAS

× CE mark: **CE 0082**

× Graphic of letters C and E: **Conform**

× Height of mark: **6 mm**

× Marking clear and permanent: **Conform**

× Location of the marking: **On the outer side of the mask**

7.6.Packaging

Month and year of manufacture and month and year of obsolescence are indelibly and unambiguously marked on the packaging.

8.Correlation between the articles of PPE Regulation 2016/425 and the reference standard

The following table shows the correlation between the essential health and safety requirements of Regulation 2016/425 of 9th march 2016 "Personal Protective Equipment" and the articles of the European standard EN 149:2001 + A1:2009 "Respiratory protective devices – Filtering half masks to protect against particles".

PPE Regulation 2016/425 Annex II	**Clauses of the standard**
1.1.1	5 ; 7.8 ; 7.9
1.1.2.1	5 ; 7.8 ; 7.9
1.1.2.2	7.8 ; 7.9
1.2.1	7.6
1.2.1.1	7.6 ; 7.7 ; 7.10 ; 7.11
1.2.1.2	7.8
1.2.1.3	7.8 ; 7.13
1.3.1	7.8 ; 7.13
1.3.2	7.8 ; 7.13 ; 7.15.2
1.4	10
2.1	7.13
2.3	7.14
2.4	9 ; 10
2.6	10
2.8	10
2.9	7.13 ; 7.18
2.12	9
3.10.1	7.6 ; 7.7 ; 7.8 ; 7.9 ; 7.12 ; 7.16 ; 7.17 ; 9 ; 10

WARNING: Other requirements and other EU Directives maybe applicable to the products falling within the scope of this European Standard.

9.Examination report

Article of the standard EN 149+A1	Content	Conformity			Comments
		Yes	No	N-A	
Art. 7	**Requirements**				
Art 7.1	**Visual inspection** The visual inspection shall also include the marking and the information supplied by the manufacturer	✓			
Art 7.4	**Packaging** 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.	✓			
Art 7.5	**Material** 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. After undergoing the simulated wearing treatment none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. Three particle filtering half masks shall be tested. When conditioned, the particle filtering half mask shall not collapse. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	✓			Date of test: 04/06/2020
Art 7.6	**Cleaning and disinfecting** 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." After cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.			✓	

Article of the standard EN 149+A1	Content	Conformity* Yes	No	N-A	Comments
Art 7.7	**Practical performance** 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. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test houses hall provide full details of those parts of the practical performance tests which revealed these imperfections.	✓			Date of test: 11/06/2020 No imperfection determined
	Here are the comments of the test subjects:				
	a) head harness comfort				No comment
	b) security of fastenings				No comment
	c) field of vision				No comment
	d) any other comments reported by the wearer on request				No comment
Art 7.8	**Finish of parts** Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs	✓			
Art 7.9	**Leakage**				
Art 7.9.1	**Total inward leakage** The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected. The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve 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: 11 % for FFP2 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than: 8 % for FFP2	✓			Date of test: 11/06/2020 50 results ≤ 11% 10 averages ≤ 8%

Exercice	Test subject reference									
	1	2	3	4	5	6	7	8	9	10
Walk	0,092	0,086	0,928	0,238	1,599	<0,01	0,219	0,195	0,198	2,768
Left-Right	0,200	0,263	1,425	0,779	3,388	<0,01	0,261	0,272	0,454	4,404
Up-Down	0,306	0,596	1,116	0,853	4,948	0,476	0,506	0,553	0,570	3,763
Alphabet	0,349	1,238	1,107	0,622	1,296	0,010	0,189	0,263	0,211	3,018
Walk	0,138	0,966	1,436	0,365	1,525	<0,01	0,184	0,307	0,270	3,132
average	**0,217**	**0,630**	**1,202**	**0,571**	**2,551**	**0,076**	**0,272**	**0,318**	**0,341**	**3,417**

* Total inward leakage values in %

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<table>
<tr><th rowspan="2">Article of the standard EN 149+A1</th><th rowspan="2">Content</th><th colspan="3">Conformity*</th><th rowspan="2">Comments</th></tr>
<tr><th>Yes</th><th>No</th><th>N-A</th></tr>
<tr><td>Art 7.9.2</td><td>Penetration of filter material
The penetration of the filter of the particle filtering half mask shall meet the requirements of Table1.

Tableau 1 – Penetration of filter material
<table><tr><th rowspan="2">Classification</th><th colspan="2">Maximum penetration of test aerosol</th></tr><tr><th>Sodium chloride test 95 l/min % max.</th><th>Paraffin oil test 95 l/min % max.</th></tr><tr><td>FFP1</td><td>20</td><td>20</td></tr><tr><td>FFP2</td><td>6</td><td>6</td></tr><tr><td>FFP3</td><td>1</td><td>1</td></tr></table></td><td>✓</td><td></td><td></td><td>Date of test:
05/06/2020</td></tr>
<tr><td>Art 7.10</td><td>Compatibility with skin
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.</td><td>✓</td><td></td><td></td><td>Manufacturer statement</td></tr>
<tr><td>Art 7.11</td><td>Flammability
The material used shall not present a danger for the wearer and shall not be of highly flammable nature.
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.
The particle filtering half mask does not have to be usable after the test.</td><td>✓</td><td></td><td></td><td>Date of test:
10/06/2020
The mask doesn't burn 5s after removal from the flame</td></tr>
<tr><td>Art 7.12</td><td>Carbon dioxide content of the inhalation air
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)</td><td>✓</td><td></td><td></td><td>Date of test:
02/06/2020
CO_2
<table><tr><td>0,53%</td><td>0,64%</td><td>0,62%</td></tr></table></td></tr>
</table>

Paraffin oil penetration of filter material tests results

Conditioning	AR			SWT		
Penetration (3min)	1,040	0,470	0,550	1,810	0,840	1,850

Conditioning	MS+TC		
Exposure (120mg)	1,170	1,050	1,080
Penetration (3min) after storage	N-A	N-A	N-A

Sodium chloride penetration of filter material tests results

Conditioning	AR			SWT		
Penetration (3min)	0,080	4,770	2,450	0,540	1,200	2,260

Conditioning	MS+TC		
Exposure (120mg)	0,150	0,190	0,140
Penetration (3min) after storage	N-A	N-A	N-A

As Received (AR), Simulated Wearing Treatment (SWT), Mechanical Strength (MS), Temperature Conditioning (TC), Cleaning and disinfecting cycle (CLEAN)

Article of the standard EN 149+A1	Content	Conformity* Yes	No	N-A	Comments
Art 7.13	**Head harness** The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. 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.	✓			Self-Adjusting ear loop harness
Art 7.14	**Field of vision** The field of vision is acceptable if determined so in practical performance tests	✓			See Art 7.7
Art 7.15	**Exhalation valve(s)**			✓	
	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations				
	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.			✓	
	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.			✓	
	When the exhalation valve housing is attached to the face blank, it shall withstand axially a tensile force of 10 N applied for 10s.			✓	
Art 7.16	**Breathing resistance** The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2.				Date of test: 05/06/2020

Tableau 2 – Breathing resistance

Classification	Maximum permitted resistance (mbar)		
	inhalation		exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1	3	3.0

Breathing resistance tests results

Conditioning	AR			SWT			TC			300l/min during 30s Art 7.15		
at 30l/min	0,23	0,20	0,21	0,30	0,33	0,43	0,38	0,35	0,36	N-A	N-A	N-A
at 95l/min	0,91	0,95	0,91	1,04	1,02	1,39	1,16	1,07	1,05	N-A	N-A	N-A
at 160l/min	1,93	1,86	1,88	1,66	1,63	2,22	1,70	1,65	1,48	N-A	N-A	N-A

Values in mbar

Article of the standard EN 149+A1	Content	Conformity*			Comments
		Yes	No	N-A	
Art 7.17	**Clogging**			✓	
Art 7.17.1	**General**				
	For single shift use devices, the clogging test is an optional test. For re-usable devices the test is mandatory. Devices designed to be resistant to clogging, shown by a slow increase of breathing resistance when loaded with dust, shall be subjected to the treatment described in 8.10. The specified breathing resistance shall not be exceeded before the required dust load of 833 mg.h/m3 is reached			✓	
Art 7.17.2	**Breathing resistance**				
Art 7.17.2.1	**Valved particle filtering half masks**			✓	
	After clogging the inhalation resistances shall not exceed : — FFP1 : 4 mbar ; — FFP2 : 5 mbar ; — FFP3 : 7 mbar ; at 95 l/min continuous flow The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow				
Art 7.17.2.2	**Valveless particle filtering half masks**			✓	
	After clogging the inhalation and exhalation resistances shall not exceed : — FFP1 : 3 mbar — FFP2 : 4 mbar — FFP3 : 5 mbar ; at 95 l/min continuous flow				
Art 7.17.3	**Filter penetration**			✓	
	All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements given in 7.9.2, for the Penetration test according to EN 13274-7, after the clogging treatment.				
Art 7.18	**Demountable parts**			✓	
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.				

* The measurement uncertainties are not taken into account for the assessment of conformity.

Article of the standard EN 149+A1	Content	Conformity			Comments
		Yes	No	N-A	
Art. 9	**Marking**				
Art 9.1	**Packaging** The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent	✓			
Art 9.1.1	The name, trademark or other means of identification of the manufacturer or supplier	✓			
Art 9.1.2	Type-identifying marking	✓			
Art 9.1.3	Classification The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.	✓			
Art 9.1.4	The number and year of publication of this European Standard	✓			
Art 9.1.5	At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure12a, where yyyy/mm indicates the year and month.	✓			
Art 9.1.6	The sentence "see information supplied by the manufacturer", at least in the official language(s) of the country of destination, or by using the equivalent pictogram.	✓			
Art 9.1.7	The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram	✓			
Art 9.1.8	The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". This letter shall follow the classification marking preceded by a single space.			✓	

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Article of the standard EN 149+A1	Content	Conformity			Comments
		Yes	No	N-A	
Art. 9	**Marking (continuation)**				
Art 9.2	**Particle filtering half mask**				
	Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:	✓			
Art 9.2.1	The name, trademark or other means of identification of the manufacturer or supplier	✓			
Art 9.2.2	Type-identifying marking	✓			
Art 9.2.3	The number and year of publication of this European Standard	✓			
Art 9.2.4	Classification	✓			
	The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then:				
	"NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR,	✓			
	or				
	"R" if the particle filtering half mask is re-usable. Example: FFP2 R D."			✓	
Art 9.2.5	If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space (see 9.2.4).			✓	
Art 9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified			✓	
Regulation	CE Marking (CE + Notified body in charge of module C2 or D) ;	✓			
	The CE marking shall be affixed visibly, legibly and indelibly to the PPE ;	✓			
	For PPE subject to ageing: the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging ;	✓			
	Name and address of the manufacturer ;	✓			Address on the packaging and on the IfU
	Type, batch or serial number or other means of identification	✓			

Article of the standard EN 149+A1	Content	Conformity			Comments
		Yes	No	N-A	
	Concerning the instruction for use: Only the English version has been checked. It is the responsibility of the manufacturer to supply the instruction for use in the official languages of the country of destination				
Art. 10	**Information to be supplied by the manufacturer**				
Art 10.1	Information supplied by the manufacturer shall accompany every smallest commercial available package			✓	
Art 10.2	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination			✓	
Art 10.3	The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on:				
	— application/limitations ;	✓			
	— the meaning of any colour coding ;			✓	
	— checks prior to use ;	✓			
	— donning, fitting ;	✓			
	— use ;	✓			
	— maintenance (e.g. cleaning , disinfecting),if applicable;			✓	
	— storage ;	✓			
	— the meaning of any symbols/pictogram used of the equipment	✓			
Art 10.4	The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.	✓			
Art 10.5	Warning shall be given against problems likely to be encountered, for example:				
	— fit of particle filtering half mask (check prior to use);	✓			
	— it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal;	✓			
	— air quality (contaminants, oxygen deficiency);	✓			
	— use of equipment in explosive atmosphere.	✓			
Art 10.6	The information shall provide recommendations as to when the particle filtering half mask shall be discarded.	✓			
Art 10.7	For devices marked "NR", a warning shall be given that the particle filtering half mask shall not be used for more than one shift.	✓			
Regulation	Name and address of the manufacturer;	✓			
	Name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE (module B and module C2 or D) ;	✓			
	EU declaration of conformity or the internet address where the EU declaration of conformity can be accessed ;	✓			
	The risk against which the PPE is designed to protect ;	✓			
	The reference to this Regulation	✓			
	The references to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used.	✓			

10.Conclusion

The PPE category III – Filtering half mask to protect against particles identified in paragraph 4 meets the Essential Health and Safety Requirements of PPE Regulation 2016/425 of 9th march 2016.

The assessment of conformity takes into account the compliance of the PPE with the provisions of European standard EN 149:2001 + A1:2009, and with the conformity of manufacturer's technical documentation.

M.MEPI.325.V1

Certificate FI20/967127

Xiamen Probtain Medical Technology Co.,Ltd

No.6, Ji an Road, Tong an District,
Xiamen, Fujian,
.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 04 November 2020 until 04 November 2025
1. Certified since 04 November 2020

Authorised by

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

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Xiamen Probtain Medical Technology Co.,Ltd

Regulation (EU) 2016/425

Module B, EU type-examination

Issue 1

PPE Product

GREENCARE (logo) MP9011 particle filtering half mask, consisting of a five layer (Polypropylene/Hot air cotton) disposable face mask, with Polypropylene covered iron wire nose clip, Polyurethane sponge nose bridge pad and Polyester/Spandex Ear loop.

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.

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

This certificate is issued on 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:

Filtering half mask/MP9011, Dated 11.09.2020

SGS Reference Number UK/CRS 242124

XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD.
4F, NO.1 FACTORY BUILDING, NO.6 JI'AN ROAD,TONG'AN DISTRICT, XIAMEN, FUJIAN, CHINA

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

Sample Description	:	(A)Particulate Respirator without valve
Sample Color	:	(A)WHITE
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Jun 18, 2020
Testing Period	:	Jun 23, 2020 - Jul 08, 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).

Conclusion:

Sample No.	Recommendation Level
(A)	FFP2 NR

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

Sara Guo (Account Executive)

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SGS TEST REPORT EN149:2001+A1:2009

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Test Result

Personal Protective Equipment - Respiratory Protective Devices- Filtering Half Masks to Protect against Particles- Requirements, Testing, Marking

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	Pass
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	
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

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 sharp edges or burrs.	No sharp edges or burrs	Pass

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(if 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 No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Zhou	1	A.R.	5.55	6.12	6.03	6.40	7.04	6.23
Luo	2	A.R.	5.65	7.09	7.57	7.00	8.02	7.07
Lu	3	A.R.	7.42	6.66	5.26	6.09	6.28	6.34
Wang	4	A.R.	5.34	5.15	6.35	5.62	5.49	5.59
Bao	5	A.R.	6.70	7.42	5.93	6.99	8.85	7.18
Ding	6	T.C.	5.94	5.16	4.66	6.41	6.66	5.77
Li	7	T.C.	7.27	7.49	6.83	7.29	7.25	7.23
Chen	8	T.C.	6.72	5.71	5.19	5.17	5.24	5.61
Song	9	T.C.	5.68	7.36	6.91	6.55	6.67	6.63
Ye	10	T.C.	7.53	5.94	7.98	7.57	7.53	7.31

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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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
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.	Detail refer to Appendix 2	Meet FFP1, Meet FFP2

Classification	Maximum penetration of test aerosol	
	Sodium chloride test 95 l/min % max.	Paraffin oil test 95 l/min % max.
FFP1	20	20
FFP2	6	6
FFP3	1	1

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)
Sodium chloride test	As received	1	0.841
		2	0.855
		3	0.896
	Simulated wearing treatment	4	0.852
		5	0.849
		6	0.846
	Mechanical strength +Temperature conditioned	7	1.073
		8	1.026
		9	1.104
Paraffin oil test	As received	10	0.975
		11	0.966
		12	0.983
	Simulated wearing treatment	13	0.985
		14	0.986
		15	0.976
	Mechanical strength +Temperature conditioned	16	2.346
		17	2.079
		18	2.148
Flow conditioning：Single filter: 95.0 L/min			

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 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.	Detail refer to Appendix 3	Pass

Appendix 3: Summarization of Test Data

Flammability

Condition	Sample No.	Result
As received	1	NIL
	2	NIL
Temperature conditioned	3	NIL
	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 exceed an average of 1,0 % (by volume)	Detail refer to Appendix 4	Pass

Appendix 4: Summarization of Test Data

Carbon Dioxide Content of The Inhalation Air

Condition	Sample No.	Result(%)	
As received	1	0.4743	Mean value:0.47
	2	0.4740	
	3	0.4752	

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	Pass
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	

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	N.A.
(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	
(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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Clause 7.16 Breathing Resistance
(EN 149:2001+A1:2009, Clause 8.9)

Test Requirement	Results	Comment
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.	Detail refer to Appendix 5	Meet FFP1, Meet FFP2, Meet FFP3

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
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)

	Flow rate(l/min)		1					2					3				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
As received	Inhalation	30	0.2	0.2	0.3	0.2	0.3	0.3	0.3	0.2	0.3	0.3	0.2	0.3	0.3	0.3	0.2
		95	0.9	1.1	1.0	0.9	0.9	0.9	1.0	1.1	1.1	1.0	0.9	0.9	1.0	1.1	1.1
	Exhalation	160	2.7	2.6	2.7	2.7	2.6	2.7	2.8	2.7	2.8	2.6	2.6	2.7	2.7	2.8	2.7
	Flow rate(l/min)		4					5					6				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Simulated wearing treatment	Inhalation	30	0.3	0.3	0.2	0.3	0.3	0.2	0.3	0.3	0.3	0.2	0.3	0.3	0.2	0.3	0.3
		95	0.9	1.1	1.1	1.0	1.0	1.1	1.1	0.9	1.1	1.1	0.9	1.1	1.1	1.0	1.0
	Exhalation	160	2.6	2.7	2.6	2.6	2.7	2.6	2.6	2.7	2.6	2.7	2.6	2.7	2.6	2.7	2.6
	Flow rate(l/min)		7					8					9				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Temperature conditioned	Inhalation	30	0.3	0.3	0.2	0.2	0.3	0.2	0.2	0.3	0.3	0.2	0.2	0.2	0.3	0.2	0.2
		95	0.8	1.0	0.9	0.9	0.8	0.8	0.9	1.0	1.0	0.9	1.0	0.8	0.9	1.0	0.9
	Exhalation	160	2.5	2.6	2.6	2.5	2.5	2.6	2.6	2.5	2.6	2.5	2.6	2.6	2.5	2.6	2.6

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

Test Requirement	Results	Comment
Clause 7.17.2 Breathing resistance Valved particle filtering half masks: After clogging the inhalation resistances shall not exceed: FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow. Valveless particle filtering half masks: After clogging the inhalation and exhalation resistances shall not exceed: FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow	Optional for single shift device only	N.A.
Clause 7.17.3 Penetration of filter material All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements.	Optional for single shift device only	N.A.

Classification	Maximum penetration of test aerosol	
	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
	%	%
	max.	max.
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	No demountable parts	N.A.

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%

Sample Photo

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XIAMEN PROBTAIN MEDICAL TECHNOLOGYCO., LTD
NO.6, JI' AN ROAD , TONG' AN DISTRICT, XIAMEN, FUJIAN ,361100, CHINA

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

Sample Description	:	(A)Medical face mask
Sample Color	:	(A)White
Roll/ Lot No.	:	FR20200517
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Jun 23, 2020
Testing Period	:	Jun 22, 2020 - Jul 13, 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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SGS TEST REPORT FOR
MEDICAL PROTECTIVE MASK EN14683

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	:	182 mm x 157 mm
Positive Control Average	:	247 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	58.9	55
	1-2	51.2	
	1-3	52.9	
	1-4	57.2	
	1-5	52.7	
2	2-1	55.0	57
	2-2	56.7	
	2-3	57.0	
	2-4	54.8	
	2-5	59.8	
3	3-1	57.9	56
	3-2	53.6	
	3-3	49.8	
	3-4	59.6	
	3-5	59.0	
4	4-1	56.8	56
	4-2	55.4	
	4-3	50.5	
	4-4	59.9	
	4-5	58.1	
5	5-1	55.3	56
	5-2	55.0	
	5-3	53.0	
	5-4	59.8	
	5-5	57.4	

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%.

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
Target plate method used : No

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.

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

Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	5.63	72	12.79
2#	5.62	99	17.62
3#	5.69	99	17.40
4#	5.68	81	14.26
5#	5.66	84	14.84

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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PAGE 54-56
EUA CERTIFIED MASK FOR IMPORT
PERMISSION TO The U.S.

Appendix A: Authorized Imported, Non-NIOSH Approved Respirators Manufactured in China (Updated: July 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: Probtain

Show 100 entries

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

Showing 1 to 1 of 1 entries (filtered from 73 total entries)

Previous 1 Next

July 15, 2020

XIAMEN PROBTAIN NONWOVEN INC.
NO. 6 JI'AN ROAD, TONG'AN DISTRICT
XIAMEN FUJIAN, CN 361100

EUA201704

Re: FFRs Made in China

Dear Raymond Luo:

This letter is in response to your request that the Food and Drug Administration (FDA) add your respirator model MP9011 as an authorized respirator to the Emergency Use Authorization (EUA) for non-NIOSH-approved filtering facepiece respirators manufactured in China[1], which was revised and reissued under Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) on June 6, 2020. We have reviewed your request to be added to Appendix A of this EUA and determined that model included meets the eligibility criteria in the June 6, 2020 EUA for non-NIOSH approved respirators made in China. As such, your respirator(s) is hereby added to Appendix A as an authorized respirator.

Having concluded that the eligibility criteria are met, I am adding your respirators to Appendix A, as described in the Scope of Authorization (Section II). As such, these respirator models are authorized for use by healthcare personnel in healthcare settings in accordance with CDC recommendations and subject to the Conditions of Authorization (Section IV) of the attached letter. We remind you that, among other things, you are required to meet the following labeling requirements:

Manufacturers

A. Manufacturers of authorized respirators are required to publish the intended use and other instructions (such as fit testing, etc.) about all authorized models that are imported and authorized under this EUA on their website in English. Additionally, manufacturers must notify FDA by emailing FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov of the website address (URL) that meets this condition. The subject line of this email should read "URL for FFR Made in China." FDA will make this information available to the public on its EUA website at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas. Manufacturers must notify FDA of any changes to this page.

B. In addition to the above electronic labeling condition, manufacturers of authorized respirators are additionally required to include a letter, in English, that can be distributed to each end user facility (e.g., each hospital, etc.) that receives the authorized respirator model. This letter must include the authorized respirator's manufacturer, model, intended use, manufacturer's webpage (if applicable), etc.

[1] The EUA Letter of Authorization is available at, https://www.fda.gov/media/136664/download.

Additionally, please be advised that if your firm does not have the appropriate fluid resistance testing, the respirator should not be labeled as "surgical."

Import information can be found on the Information for Filing Personal Protective Equipment and Medical Devices During COVID-19 page. If you need to resolve entry issues for shipments, please contact 301-796-0356 or COVID19FDAIMPORTINQUIRIES@fda.hhs.gov.

Sincerely,

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Linda Ricci, MME, MPH
Director
Division of All Hazard Response, Science and Strategic Partnerships (DARSS)
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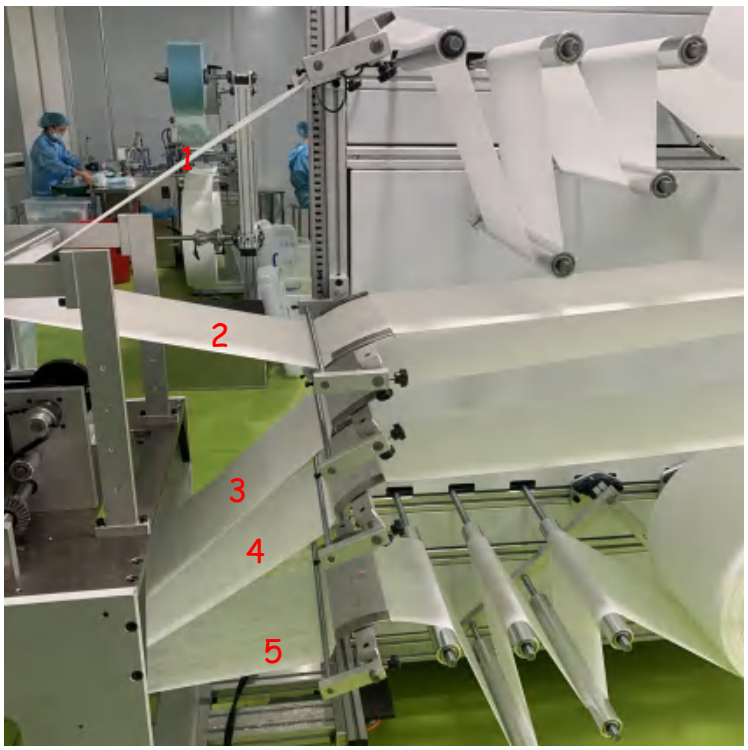

THE END

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