My Benefit Mask PRO

MASCHERINE FPP2 NR

DOCUMENTAZIONE

My Benefit®
il benessere della salute

GREENCARE®

Dispositivi di protezione individuale

My Benefit Mask PRO

MASCHERINE FFP2 NR

Conf. 20 pezzi

Involucro singolo

Mascherina filtrante 5 strati

con gancio di estensione e supporto nasale incluso

disponibile in 4 colori: **bianco, nero, blu e rosa**

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

My Benefit®
il benessere della salute

Importatore:
My Benefit Srl
Via Giacomo Leopardi, 46/a - 41123 Modena MO
www.mybenefit.it info@mybenefit.it

My Benefit Mask PRO

MASCHERINE FFP2 NR

CARATTERISTICHE

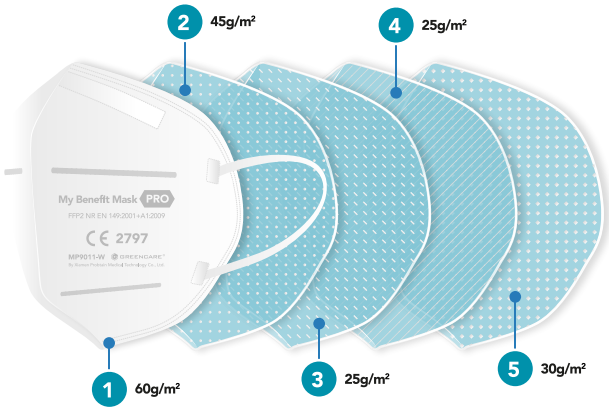
La mascherina FFP2 My Benefit Mask PRO BLACK è un dispositivo di protezione individuale capace di filtrare almeno il 95% delle microparticelle di diametro pari a 2,5 um. Rivestite in tessuto nero, la loro qualità è avvalorata da numerosi test che ne certificano la capacità filtrante.
Plasmabile, assicura un ottimo livello di aderenza ed eccellente comfort, grazie anche al gancio di estensione e supporto nasale inclusi con ogni mascherina, che permettono di regolare l'indossatura e alleviano il fastidio dato da un uso prolungato.

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. L'applicazione del colore è certificata EN ISO 14362-1:2017.

Confezionamento: Box in cartone da 20 mascherine; ogni 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

Modello: MP9011
Dimensioni: Pieghevole 15.5 x 10.5 (± 0.5 cm)
Standard Filtrazione: FFP2 – 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

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**

My Benefit Mask PRO

MASCHERINE FFP2 NR

ISTRUZIONI PER L'USO

Controllare l'integrità dell'involucro in plastica prima dell'uso. Se la confezione è rotta, non utilizzare.

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**

GREENCARE®

My Benefit Mask PRO

MASCHERINE FFP2 NR

WHITE

Conf. singola	8 055519 881208
Conf. 20 pezzi	8 055519 881178

BLACK

Conf. singola	8 055519 881444
Conf. 20 pezzi	8 055519 881437

PINK

Conf. singola	8 055519 881581
Conf. 20 pezzi	8 055519 881598

BLUE

Conf. singola	8 055519 881611
Conf. 20 pezzi	8 055519 881611

RED

Conf. singola	8 055519 881949
Conf. 20 pezzi	8 055519 881932

GREY

Conf. singola	8 055519 881895
Conf. 20 pezzi	8 055519 881888

My Benefit Mask PRO

GREENCARE®

WHITE

5 veli
5 strati di protezione

MASCHERINE FFP2 NR
MONOUSO/NON-STERILE
WHITE

Conf. 20 pz. - Involucro singolo

SUPPORTO NASALE
+ ADERENZA
+ COMFORT
GANCIO
DI ESTENSIONE

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

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

CE EN 149:2001+A1:2009

My Benefit®
il benessere della salute

Scheda tecnica produttore

My Benefit®
il benessere della salute

格林特卫® GREENCARE | 美润股份 PROBTAIN

COMPANY PROFILE

厦门美润无纺布股份有限公司（简称美润股份）成立于2005年，位于厦门市同安区，是国内从业最早、产业链最为完整的无纺布企业之一.,美润股份自创立起始终坚持以无纺布为基础材料，研究和开发无纺布产品对环境改善、医疗及职业健康防护、卫生用品、农业园艺的积极影响，参与和分享了中国无纺布产业的进步和市场增长。

XIAMEN PROBTAIN NONWOVEN INC. (hereinafter referred to as Probtain) was established in 2005 and ever since then, Probtain has been concentrating itself on the research and technological applications of PP spunbond non-woven fabrics for more than ten years as one of the earliest players in the industry domestically.

There are four wholly-owned subsidiaries of Probtain:

厦门美润医疗科技有限公司（即格林特卫GREENCARE®），工厂位于美润股份厂区，拥有4500㎡十万级洁净车间及万级无菌生化实验室，建立严格的管理体系，配套完善的检测设备，长期关注无纺布在医疗卫生及航空一次性耗材、个人防护、公共应急、呼吸安全的应用技术，代表产品格林特卫医用及劳动安全口罩入选全国安全防护用品领先品牌。
美润医疗拥有22条自动化医用平面口罩生产线，医用平面口罩日生产能力300万片，已安装调试自动化KN95立体口罩生产线20条，日生产能力100万片。

Xiamen Probtain Medical Technology Co.,Ltd.(GREENCARE), located in Probtain’ s factory zone, possessesa 4500㎡ of100,000 grade clean workshop and 1,0000 grade clean sterile biochemical laboratory.It implements strict quality management system and is well equipped with a complete set of testing facilities. For years, Probtain has focused on the applications & technological development of nonwoven fabric on medical, hygiene, personal care, public health emergency, respiratory health and safety. Its representative product of GREENCARE medical and personal protective masks are selected as the leading brand of national security protection products
There are 22 automatic production lines for disposable medical masks, with a daily production capacity of 3 million pieces. And 20 automatic production lines for KN95 foldable mask, providing adaily capacity of 1 million pieces.

江西美润环保制品有限公司位于瑞金，厂房面积16124㎡，共拥有5条全自动PP纺粘生产线：320cm（SSS建设中）、240cm（SSMS）、160cm SS，240cm S，180cm S，年产量合计约18000吨，广泛服务和应用于医疗卫生制品、环保包装、农业覆盖、日用家居制品，是国内重要无纺布新材料提供商。生产的SSMS、SSS、SMS等无纺布，具有强力高、无毒无味，高效隔菌。通过设备特殊处理，能达到抗静电，抗酒精，抗血浆，阻燃，拒水和亲水等性能。

Probtain（Jiangxi）Eco-Products Co.,Ltdis located in Ruijin City Jiangxi Province, covering a 16124㎡.It owns 5 automatic PP spun-bonded nonwoven production lines: 320cm (SSS, under construct-ion) ,240cm(SSMS), 160cm(SS), 240cmS, 180cmS, with a total annual output of 18000 metric tons, products have been widelyap-plied in medical and hygiene products,environmentally friendly packaging, agric-ultural covering and daily household products.

厦门美润合悦卫生材料有限公司（即格林特维GreenFibre®），23000平方米厂房建设，专业研发和生产复合膜、无纺布复合膜技术卫生用品材料的生产企业，产品广泛应用于妇女，婴儿，医疗等一次性个人护理领域。与美润医疗形成资源共享，相互促进。

XiamenProbtain Heyue Hygienic Mat-erials Co., LTD. (GreenFibre) occupiesa 23,000㎡work-shop. It is expertised in R& D and pro-duction of laminated nonwoven, nonwoven composite fabric, material application in hygienic products. Products are widely used in women and baby,medical and other disposablepersonal care fields.

厦门美润防护用品有限公司（即格林唯纳Greenneat），工厂位于美润股份厂区，拥有4000m²洁净车间，集印刷、裁剪、缝制和二十年从业经验，有300多名熟练缝制员工，代表产品有：手术衣、防护服、隔离衣等，月生产达300万套。另外还有生产无纺布环保袋、环保包装制品、创意家用无纺布收纳用品等。

Xiamen ProbtainProtective Products Co., Ltd.(greenneat), a wholly-owned subsidiary of Probtain, is located in the factory zone of Probtain, with a clean workshop of 4000m2. It has more than 300 skilled sewing workers and owns a vertical production structure of printing, cutting, and sewing, with 20 years experience and development in this trade. Its representative products issurgical gowns, protective gowns and isolation gowns, with a monthly capacity of 3 million sets. Besides,it also produces non-woven environmental friendly shopping bags, Eco friendly packaging products, creative non-woven storage goods of household etc.

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PACKAGE PHOTOS

INDIVIDUALLY PACKED,20 PCS/BOX,30 BOXES/CTN,60*40*35CM

Certificazioni / Test report

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RAPPORTO DI PROVA PPE343RP3090 A1

Il presente documento costituisce una correzione del rapporto di prova PPE343RP3090 del 30/04/2021, dovuta ad una errata identificazione dei campioni 4, 5 e 6 nella tabella a pagina 2.

METODO DI PROVA	*Le prove sono state condotte in base ai metodi di prova e requisiti espressi dalla norma UNI EN 149:2009 (EN 149:2001 + A1:2009) con alcune deviazioni di seguito indicate*
RICHIEDENTE	*My Benefit S.r.l.* *Via Leopardi, 26/A* *41123 Modena*
CAMPIONI DI PROVA	
Tipo	*Dispositivi di protezione delle vie respiratorie – Semimaschere filtranti*
Identificazione dei campioni	*La campionatura consegnata consiste nel modello dei semimaschera filtrante denominato MY BENEFIT MASK PRO, nelle due varianti di colore bianco (lotto M21-0183) e nero (lotto M21-0182). Le semimaschere riportano la marcatura CE 2797.*
Classificazione	*Le confezioni e/o i facciali citano la classificazione FFP2*
Data ricevimento campioni	*12/04/2021*
Data termine prove	*26/04/2021*
Rif. offerta ITALCERT	*PPE001BT784*

Note

1. *Come indicato nella proposta di ITALCERT, i test sono stati svolti su campioni come ricevuti, senza effettuare i pre condizionamenti richiesti dalla norma di riferimento.*
2. *Se non diversamente specificato, a tutti i valori espressi nel presente Rapporto si applicano le tolleranze previste nella norma di riferimento.*
3. *L'eventuale utilizzo dei risultati delle prove per valutare la conformità degli altri prodotti da cui i campioni sono stati selezionati è di esclusiva pertinenza del richiedente e non è oggetto della valutazione da parte di ITALCERT.*
4. *Il campionamento è stato effettuato a cura del richiedente. Sono stati consegnati 10 esemplari per tipo.*
5. *Per la valutazione dei risultati vengono riportati i riferimenti relativi ai requisiti previsti dalla norma EN 149 per la relativa classificazione.*
6. *Salvo dove differentemente specificato le prove sono state svolte presso la sede di ITALCERT S.r.l.*

REPORT FOTOGRAFICO

Figura 1: modello bianco

Figura 2: modello nero

PROVE

Penetrazione del materiale filtrante

Prove eseguite secondo EN 149 § 7.9.2. La norma EN 149 prevede di effettuare due tipi di test, utilizzando il metodo di prova descritto dalla norma EN 13274-7, detti “penetrazione”, noto anche come “breve durata”, ed “esposizione”, noto anche come “lunga durata”, utilizzando due tipologie di aerosol: olio di paraffina e NaCl. Tutti i valori ottenuti devono rientrare nei limiti massimi previsti per la classificazione dichiarata.

Il programma di prove previsto prevedeva di effettuare la prova di penetrazione (breve durata) con olio di paraffina su tre campioni come ricevuti.

I risultati sono riportati nella tabella sottostante in riferimento al valore massimo ammissibile per la classificazione FFP2.

ID campione	Test “penetrazione” olio di paraffina	Limite EN 149 per FFP2
# 01 - bianco	2.5 %	≤ 6 %
# 02 - bianco	0.7 %	≤ 6 %
# 03 - bianco	1.8 %	≤ 6 %
# 04 – nero	4.0 %	≤ 6 %
# 05 – nero	4.8 %	≤ 6 %
# 06 - nero	2.7 %	≤ 6 %

ITALCERT S.r.l.
Settore Dispositivi di Protezione Individuale

Ing. Flavio BANFI

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	PARTICLE FILTERING HALF MASK
Model/ Serial No.	MP9011/My Benefit Mask PRO
Technical Reference:	EN 149:2001+A1:2009-Respiratory Protective Devices. Filtering half masks to protect against particles.
Applicable Regulation:	PPE Regulation 2016/425
Notified body for EU type-examination (Module B)	BSI Group - NB 2797 The Netherlands B.V.， John M Keynesplein 9, 1066 EP, Amsterdam, Netherlands
Notified body for EU type-examination (Module D)	BSI Group - NB 2797 The Netherlands B.V.， John M Keynesplein 9, 1066 EP, Amsterdam, Netherlands
Certificate number	CE746812(Mould B), CE746813(Mould D)

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.

XIAMEN PROBTAIN NONWOVEN INC 厦门美润无纺布股份有限公司 单证专用章

Oct 14, 2021

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 746812

In respect of:

Particulate filtering half mask to EN149:2001+A1:2009 Non-Valved, Non-Reusable, FFP2

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

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

Drs. Dave Hagenaars, Managing Director

First Issued: 2021-10-12
Latest Issue: 2021-10-12

Effective Date: 2021-10-12
Expiry Date: 2026-10-12

PRODUCTS RvA C 646

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EU Type Examination Certificate

No. CE 746812

Product Specification

Product Type:	Filtering half masks to protect against particles.	
Model:	MP9011	
Product description:	The particulate respirators are designed to protect against solid and non-volatile liquid particles. The masks are held on the face by a pair of elasticated ear straps. The models are single shift devices denoted by the classification symbol NR.	
Technical specifications:	EN 149:2001+A1:2009 – Respiratory Protective Devices. Filtering half masks to protect against particles.	
EN 149 Classification	**Model**	**Classification**
	MP9011	**FFP2 NR Un-Valved**

Certificate Administration Details

Technical File reference: PM-PPE-FHM-01-01.

Certificate Amendment Record:

Issue date	Comments	BSI Review Number
Sept 2021	First issue under PPE Regulation (EU) 2016/425	2797:21:3408932

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall processes utilized 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 Quality Assurance of the Production Process, Annex VIII (Module D), as referenced on BSI issued Certificate CE 746813.

First Issued: 2021-10-12
Latest Issue: 2021-10-12

Effective Date: 2021-10-12
Expiry Date: 2026-10-12

Conformity to Type based on Quality Assurance of the Production Process

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 746813

In respect of:

For the manufacture of Respiratory Protective Equipment to the standards listed on the continuation sheet.

on the basis that BSI carried out the quality assurance assessment under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex VIII (Module D)

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

Drs. Dave Hagenaars, Managing Director

First Issued: 2021-10-12
Latest Issue: 2021-10-12

Effective Date: 2021-10-12
Expiry Date: 2026-10-12

PRODUCTS RvA C 646

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Conformity to Type based on Quality Assurance of the Production Process

No. CE 746813

Manufacturing Site

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

Product Specification

The products covered by the scope of this Module D certificate conform to the following standard:

Standard	Product Type
EN 149:2001+A1:2009	Respiratory protective devices. Filtering half masks to protect against particles.

Certificate Amendment Record

Issue date	Comments	BSI Project Number
October 2021	First issue of Module D under PPE Regulation (EU) 2016/425	2797:21:308963

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 products, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes

First Issued: 2021-10-12
Latest Issue: 2021-10-12

Effective Date: 2021-10-12
Expiry Date: 2026-10-12

Test Report 3408960.

Xiamen Probtain Nonwoven Inc.

Introduction.

This report has been prepared by Jordon Archer and relates to the activity detailed below:

Job/Registration Details		Client Details
Job number:	**3408960**	Xiamen Probtain Nonwoven Inc. No.6 Ji'an Road Tong'an District Xiamen Fujian 361100 China
Job type:	Testing Samples Submitted	
Start Date:	06/05/2021	
Test type:	Type	
Sample ID:	10196914	
Registration:	**CE 746812**	
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: 25 June 2021

Objectives.

This is an independent Type Test evaluation to BS EN 149:2001+A1:2009. This report covers the gap testing from the BSI COVID-19 filtering face piece technical specification, for COVID-19 masks for use by healthcare workers.
See BSI Test Report 3201467 for the BSI COVID-19 filtering face piece technical specification test results.

Product Scope.

Respiratory protective device- Filtering half masks to protect against particles.

Report Summary.

The samples were received on 25 March 2021 and the testing was started on 6 May 2021.

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

Test Samples.

Sample ID	ER Number	Description
1 to 37	10196914	Model: MP9011

Description of Test Samples.

Sample Description
Model: MP9011. FFP2 valveless vertical fold flat particle filtering half mask.

Test Requirements.

BS EN 149:2001 + A1:2009
Respiratory protective devices - Filtering half masks to protect against particles.

CLAUSE	REQUIREMENTS	ASSESSMENT
7	**Requirements**	-
7.1	**General**	-
7.2	**Nominal values and tolerances**	-
7.3	**Visual Inspection**	Pass (1)
7.4	**Packaging**	N/T (1)
7.5	**Material**	Pass
7.6	**Cleaning and disinfecting**	N/A (2)
7.7	**Practical performance**	N/T (3)
7.8	**Finish of parts**	Pass
7.9	**Leakage**	-
7.9.1	Total inward leakage	Pass (3)
7.9.2	Penetration of filter material	Pass (3)
7.10	**Compatibility with skin**	Pass
7.11	**Flammability**	Pass
7.12	**Carbon dioxide content of inhalation air**	N/T (3)
7.13	**Head harness**	Pass
7.14	**Field of vision**	Pass
7.15	**Exhalation valves**	N/A (4)
7.16	**Breathing resistance**	Pass (3)
7.17	**Clogging**	N/A (4)
7.18	**Demountable parts**	N/A (4)
9	**Marking**	N/T (1)
10	**Information to be supplied by the manufacturer**	N/T (1)
Appendix A - Test Panel Data		
Product Photographs		

(1) Packaging, Marking and Information not assessed as requested by BSI Product Certification
(2) Single use mask
(3) See also results from BSI COVID-19 filtering face piece technical specification testing, BSI Test Report number 3201467.
(4) Not a design feature of this product

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: Manufacturer's Minimum Design Flow

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.

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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.

BS EN 149:2001 + A1:2009
Respiratory protective devices - Filtering half masks to protect against particles.

CLAUSE	REQUIREMENTS	ASSESSMENT
7.1	**General**	
	In all tests all samples shall meet the requirements.	-
7.2	**Nominal values and tolerances**	
	Unless otherwise specified, the values stated in this European Standard are expressed as nominal values. Except for temperature limits, values, which are not stated as maxima or minima, shall be subject to a tolerance of ±5%. Unless otherwise specified, the ambient temperature for testing shall be (16 – 32) °C, and the temperature limits shall be subject to an accuracy of ± 1°C.	-
7.3	**Visual Inspection**	
	The visual inspection shall also include the marking and the information supplied by the manufacturer.	Pass (1)
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.	Pass
	After undergoing the conditioning described in clause 8.3.1 of the standard 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.	Pass
	When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Pass
	Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Pass
	Testing shall be done in accordance with 8.2.	
7.8	**Finish of parts**	
	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Pass
	Testing shall be done in accordance with 8.2.	

(1) Marking and user information were not assessed as requested by BSI Product Certification

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
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. 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 Testing shall be done in accordance with 8.5.	Pass (1) See Table A

Table A: Clause 7.9.1 - Total inward leakage.

Test candidate	Sample	Pre-test condition	Inward leakage (%).					
			A	B	C	D	E	Average
			Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking	
LM1	8	TC	0.1179	0.1616	0.2765	0.2088	0.1290	0.1787
BH1	9	TC	1.5427	3.1596	4.3119	2.7587	1.9150	2.7376
PM1	10	TC	1.1117	1.3777	1.6619	1.6811	1.9719	1.5608
JW1	11	TC	2.0255	2.8818	2.8609	1.6711	2.4798	2.3838
RS1	12	TC	14.7305	23.944	23.0359	7.0184	21.4645	18.0388

(1) Results for the 'as received' samples are covered in BSI Test Report number 3201467 for the BSI COVID-19 filtering face piece technical specification testing.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.9.2	Penetration of filter material	
	The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1	
	A total of 9 samples of particle filtering half masks shall be tested for each aerosol. Testing in accordance with 8.11 using the Penetration test according to EN 13274-7, shall be performed on:	Pass (1) See Tables B and C
	3 samples as received,	
	3 samples after the simulated wearing treatment described in 8.3.1.	
	Testing in accordance with 8.11 using the Exposure test with a specified mass of test aerosol of 120 mg, and for particle filtering devices claimed to be re-usable additionally the Storage test, according to EN 13274-7, shall be performed:	Pass See Table D and E
	for non-re-usable devices on:	
	3 samples after the test for mechanical strength in accordance with 8.3.3 followed by temperature conditioning in accordance with 8.3.2.	
	for re-usable devices on:	
	3 samples after the test for mechanical strength in accordance with 8.3.3 followed by temperature conditioning in accordance with 8.3.2 and followed by one cleaning and disinfecting cycle according to the manufacturer's instruction.	N/A (2)

Table B: Clause 8.11 - Sodium Chloride penetration test.

Sample	Pre-test condition	Continuous flow (l/min)	Penetration (%)	
			Limit	Measured
16	SW	95	6.0	0.0596
17	SW	95	6.0	0.1171
18	SW	95	6.0	0.0860

Table C: Clause 8.11 - Paraffin oil penetration test.

Sample	Pre-test condition	Continuous flow (l/min)	Penetration (%)	
			Limit	Measured
22	SW	95	6.0	0.5160
23	SW	95	6.0	0.4475
24	SW	95	6.0	0.4615

(1) Results for the remaining 'as received' samples are covered in BSI Test Report number 3201467 for the BSI COVID-19 filtering face piece technical specification testing.
(2) Not a design feature of this product.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.9.2	Penetration of filter material (continued)	

Table D: Clause 8.11. Exposure test Sodium Chloride.

	Sample 28 MS TC	Sample 29 MS TC	Sample 30 MS TC
Flow through filter	95 l/min		
Elapsed time (minutes)	Measured penetration % (Maximum permitted penetration 6.0 %)		
5	0.0934	0.0622	0.0823
10	0.0921	0.0636	0.0826
15	0.0935	0.0626 (1)	0.0836
20	0.0896 (1)	0.0582	0.0804 (1)
25	0.0857	0.0538	0.0778
30	0.0843	0.0471	0.0713
35	0.0766	0.0426	0.0668
40	0.0753		0.0592
45	0.0674		0.0538
Result	Pass	Pass	Pass

(1) The reading at which 5 subsequent sampling intervals showed a declining filter penetration. The testing was terminated without the 120mg exposure limit being reached, as permitted by BS EN 13274-7.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT

7.9.2 Penetration of filter material (continued)

Table E: Clause 8.11 Paraffin oil exposure test.

	Sample 25 MS TC	Sample 26 MS TC	Sample 27 MS TC
Flow through filter	95 l/min		
Elapsed time (minutes)	Measured penetration % (Maximum permitted penetration 6.0 %)		
3	0.4480	0.3945	0.3940
5	0.4625	0.4055	0.3940
10	0.4905	0.4265	0.4225
15	0.5130	0.4635	0.4405
20	0.5360	0.4750	0.4745
25	0.5485	0.4830	0.4680
30	0.5710	0.5005	0.4885
35	0.5835	0.5270	0.5065
40	0.6045	0.5235	0.5150
45	0.6175	0.5385	0.5290
50	0.6325	0.5605	0.5430
55	0.6500	0.5665	0.5555
60	0.6700	0.5785	0.5745
(1)	0.6690	0.5825	0.5715
Result	Pass	Pass	Pass

(1) A loading of 120 mg was achieved after a period of 63 minutes, 10 seconds had elapsed.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.10	**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.	Pass
	Testing shall be done in accordance with 8.4 and 8.5.	
7.11	**Flammability**	
	The material used shall not present a danger for the wearer and shall not be of a highly flammable nature.	
	When tested, the particle filtering half mask shall not burn or not continue to burn for more than 5 seconds after removal from the flame.	Pass See Table F
	The particle filtering half mask does not have to be usable after the test.	
	Testing shall be done in accordance with 8.6.	

Table F: Clause 8.6 – Flammability.

Sample	Area exposed	Comments
34 AR	Noseband, earloop.	Did not ignite
35 AR	Filter material.	Did not ignite
36 TC	Noseband, earloop.	Did not ignite
37 TC	Filter material.	Did not ignite

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.	Pass
	Testing shall be done in accordance with 8.4 and 8.5.	
7.14	**Field of vision**	
	The field of vision is acceptable if determined so in practical performance tests.	Pass
	Testing shall be done in accordance with 8.4.	

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.16	**Breathing resistance**	
	The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2.	
	Testing shall be done in accordance with 8.9.	
	A total of 9 valveless particle filtering half masks shall be tested: 3 as received, 3 after temperature conditioning in accordance with 8.3.2 and 3 after the test for simulated wearing in accordance with 8.3.1.	Pass (1) See Tables G, H and I
	Testing shall be done in accordance with 8.9.	
	A total of 12 valved particle filtering half masks shall be tested: 3 as received, 3 after temperature conditioning in accordance with 8.3.2, 3 after the test for simulated wearing in accordance with 8.3.1, and 3 after the flow conditioning in accordance with 8.3.4.	N/A (2)
	Testing shall be done in accordance with 8.9.	

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

Sample	Pre-test condition	Flow (l/min)	Limit (mbar)	Measured (mbar)
16	SW	30	0.7	0.34
17	SW	30	0.7	0.34
18	SW	30	0.7	0.34
31	TC	30	0.7	0.33
32	TC	30	0.7	0.36
33	TC	30	0.7	0.35

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

Sample	Pre-test condition	Flow (l/min)	Limit (mbar)	Measured (mbar)
16	SW	95	2.4	1.13
17	SW	95	2.4	1.12
18	SW	95	2.4	1.13
31	TC	95	2.4	1.08
32	TC	95	2.4	1.11
33	TC	95	2.4	1.11

(1) Results for the remaining 'as received' samples are covered in BSI Test Report number 3201467 for the BSI COVID-19 filtering face piece technical specification testing.
(2) Not a design feature of this product.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.16	**Breathing resistance (continued)**	

Table I: Clause 8.9 – Breathing resistance. Exhalation resistance at a continuous flow, measured in five orientations with the highest value recorded.

Sample	Pre-test condition	Flow (l/min)	Limit (mbar)	Measured (mbar)
16	SW	160	3.0	1.86
17	SW	160	3.0	1.87
18	SW	160	3.0	1.86
31	TC	160	3.0	1.72
32	TC	160	3.0	1.69
33	TC	160	3.0	1.75

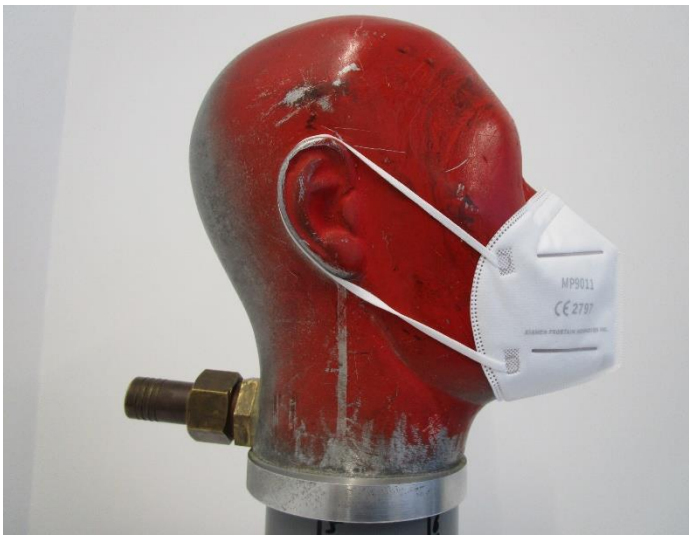
Appendix A. – Test Panel Data

Test Candidate	Facial Dimensions (mm)					Gender
	Length of face	Width of face	Face depth	Width of mouth	Head Circumference	
LM1	114	127	117	46	570	Male
BH1	114	139	120	50	570	Male
PM1	122	154	130	54	615	Male
JW1	116	126	122	48	570	Male
RS1	109	141	120	50	545	Male

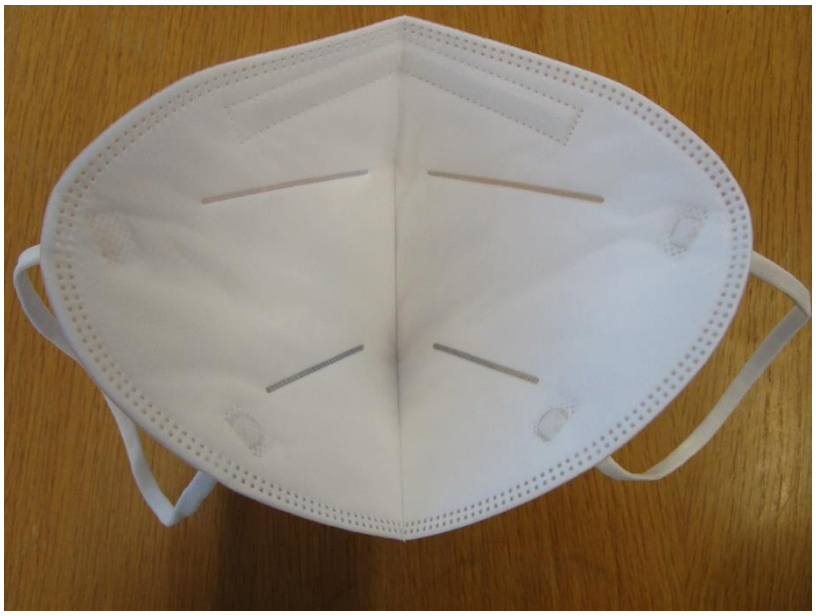
Note: All candidates were clean shaven

Product photographs.

Front view



Side view



Inside view

*** End of Report ***

EU DECLARATION OF CONFORMITY

Manufacturer

Name: Xiamen Probtain Medical Technology Co.,Ltd.

Address: No.6,Ji an Road,Tong an District,Xiamen,Fujian,China.

declares that the new PPE described here after

Description of products	Filtering half mask
Product style/order No	MP9011
Product colour and type	White\black\blue\pink\red\grey; Non-reusable, folded

are in conformity with the Regulation (EU) 2016/425 and with harmonized standard

EN 149:2001 + A1:2009

SGS Fimko Oy

Takomotie 8, FI-00380 Helsinki, Finland

Notified Body No. 0598

performed the EU type-examination (Module B) and issued the EU type-examination certificate FI20/967127

The PPE is subject to the conformity assessment procedure conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body SGS Fimko Oy, Notified Body No. 0598.

Signed for on behalf of Company

Name:Jianyou Xie

Position: R.D manager

Signature: Jianyou Xie

Date: 2021.7.8

DECLARATION OF MATERIAL INNOCUOUSNESS

The manufacturer or his authorized representative established in the Community:

Manufacturer: Xiamen Probtain Medical Technology Co.,Ltd.

Address: No.6,Ji an Road,Tong an District,Xiamen,Fujian,China.

declares that the materials which are coming into contact with the human skin and body used on the new PPE described hereafter

Product description:

Description of products	Filtering half mask
Product style/order No	MP9011
Product colour and type	White\black\blue\pink\red\grey; Non-reusable, folded

are known not to undergo appreciable alteration from contact with sweat or with substances likely to be found in toiletries and are known not to cause any harm to human skin and body.

Done at No.6,Ji an Road,Tong an District,Xiamen,Fujian,China.

Signed for on behalf of Company

Name:Jianyou Xie

Position: R.D manager

Signature: Jianyou Xie

Date: 2021.7.8

Certificate CN21/42547

The management system of

Xiamen Probtain Medical Technology Co., Ltd.

No.6, Ji'an Road, Tong'an District,
Xiamen City, Fujian Province, P.R. China

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425

Module D

For the following activities

Manufacture of FFP2 Protective Respirators
(Note: all products marked CE0598 must have a valid EU Type Examination Certificates issued under Module B or a valid EC type-examination certificate issued under Article 10 of the PPE Directive 89/686/EEC.)

This certificate is valid from 21 July 2021 until 20 July 2024
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 22 June 2024
Issue 1. Certified since 21 July 2021

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

Authorised by

SGS FIMKO OY, Notified Body 0598
Takomotie 8, FI-00380 Helsinki, Finland
t +358 9 696 361 f +358 9 692 5474 www.sgs.com

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)

SGS FIMKO OY, Notified Body 0598
Takomotie 8, FI-00380, Helsinki, Finland
t +358 9 696 361 f +358 9 692 5474 www.sgs.com

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

Documentation No.: *Filtering half mask /MP9011*

Creation Date: *2020-09-11*

Revision No.: *Version 1*

Revision Date: */*

Technical File to comply with the requirements of the Personal Protective Equipment Regulation (EU) 2016/425

Respiratory protective devices - Filtering half masks to protect against particles

EN 149:2001 +A1:2009

Section 1

Section	Contents
1	Contents
2	Applicant/Manufacture & Product General Information
3	Product Specifications
4	Manufacture Information (Sequence of Manufacture & Quality Control Procedure)
5	Essential Health and Safety Requirements
6	Manufacturer's Instructions and Information
7	Markings
8	Test Reports
9	Declaration of Conformity
10	Declaration of Material Innocuousness

Section 2

Applicant/Manufacture & Product General Information

1. Manufacturer General Information

Manufacturer Name	Xiamen Probtain Medical Technology Co.,Ltd.
Manufacturer Address	No.6,Ji an Road,Tong an District,Xiamen,Fujian,China.
Supplier/Factory Name	Xiamen Probtain Medical Technology Co.,Ltd.
Supplier/Factory Address	No.6,Ji an Road,Tong an District,Xiamen,Fujian,China.
Brand name (if any)	GREENCARE
Destination Country	European countries

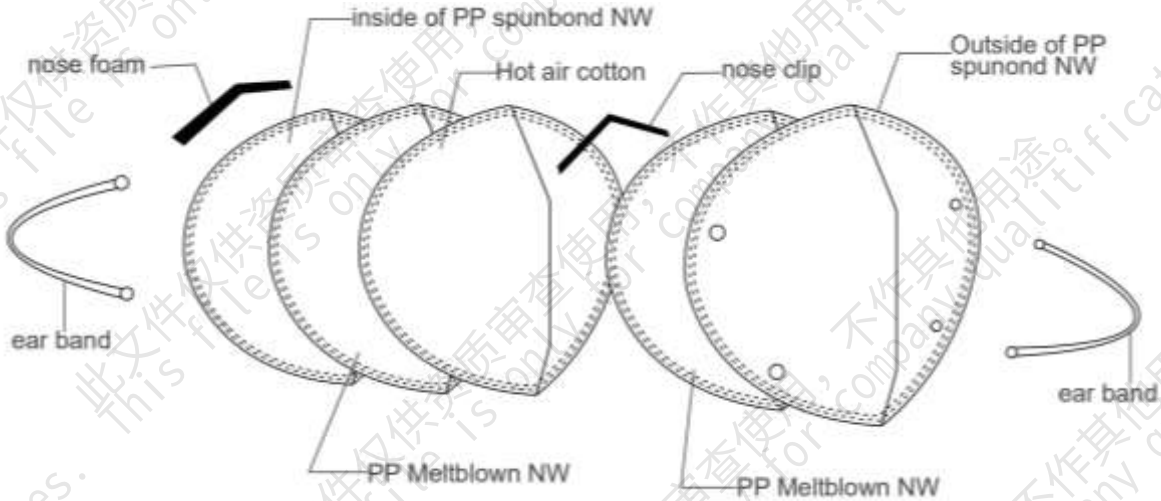
Section 3

Product Specifications

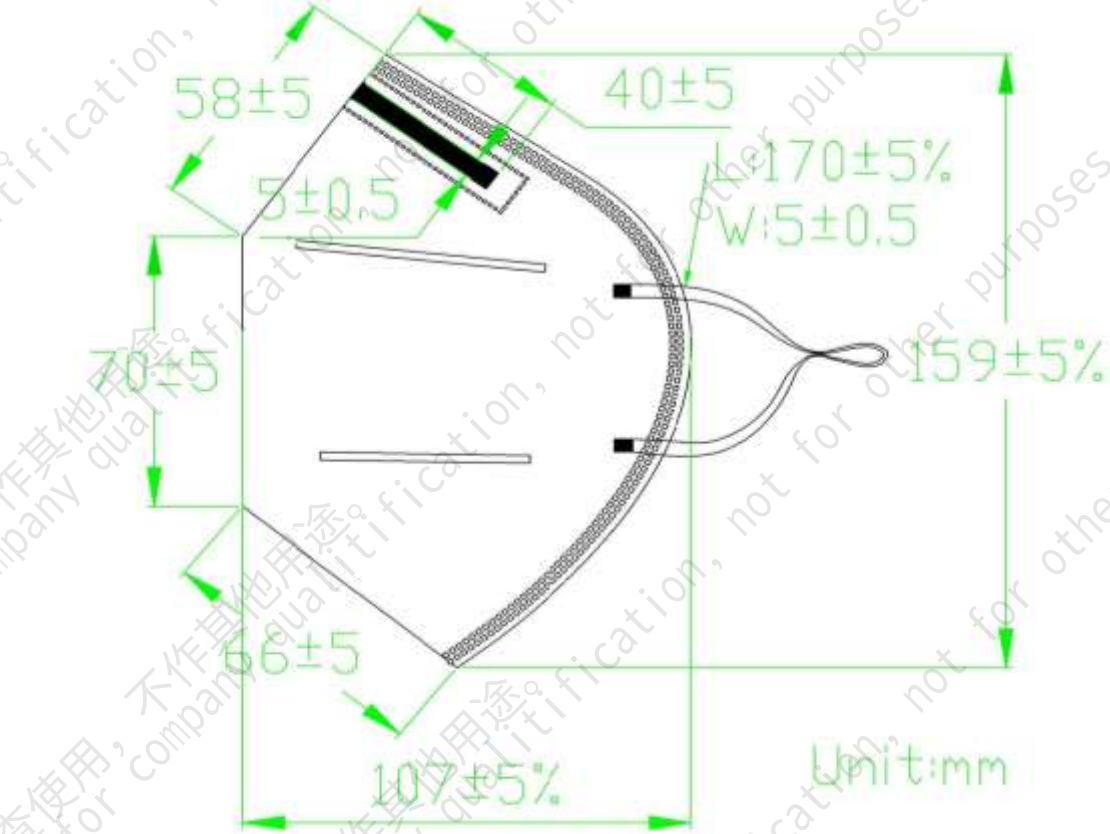
1. Product General Information

Description of products	Filtering half mask
Products Colour	White
Product style/order No	MP9011
Product Type	Non-reusable, folded
Standard	EN 149:2001+A1:2009
Classification	FFP2 NR

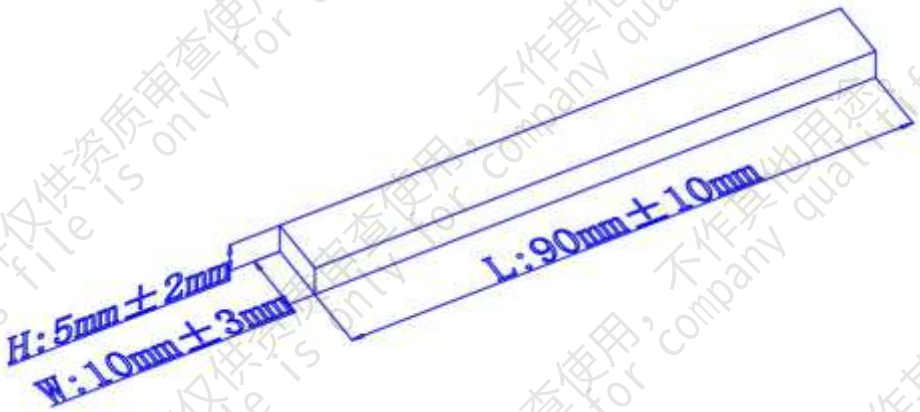
2. Product Photograph(s)



4. Product(s) Dimension



Nose bridge pad：



Section 4

Manufacture Information

1. Sequence of Manufacture

1	Incoming materials inspection
2	Shaping Facepiece and Welding ear loop
4	Fixture of nosepiece
5	Add sponge strip
5	Performance Test
8	Pressing mask marking
3	In-process inspection
6	Packaging: 6 pcs by polybag. User information in each package
10	Finished product inspection
7	Storage before shipment

2. Quality Control Procedure

No.	Procedure	Quality Control
1	Raw material control	Supplier should submit the "Declaration of Innocuousness" of raw materials.
2	In house lab testing	The basic testing e.g. Penetration of filter material, breathing resistance, strength of Exhalation valve (if any) will be checked by own lab. The test method is EN 149. Reject the raw materials and products if they cannot meet the minimum requirement.
3	Mould and cut	Mould and cut as per the specification, make sure the working site is clear to avoid pollution.
4	Nosepiece set up	Set up the nosepiece and check the strength of the attachment. Adjust the procedure if any failure.
5	Seal the ear loop	The ear loop should be sealed with durability. For tensile test of the samples, each ear loop of the folding mask must conform to the requirements. No slippage or fracture shall occur when each ear loop bear the tension of 10N and 10S. And take notes.
6	Install sponge strip	Install sponge strip as required to ensure correct concealed installation position of sponge strip

7	Breath Inspiratory resistance, filtration efficiency	Check reference to EN 149, Breath resistance and filtration efficiency meet the product specification. Filtration efficiency is the most critical index of masks, once there is an unqualified situation, immediately seal this batch of goods, is strictly prohibited to send to the customer. Analyse the causes and find solutions.
8	Total inward leakage	Total inward leakage is the critical criteria for final respirator, bulk production respirator will be sent to 3rd party lab to test TIL according to EN 149 from batch to batch/year to year.
9	Appearance inspection	the basic structure, surface and parts of the product shall be inspected in detail, and all information provided by the manufacturer shall be complete.
10	Ergonomics	The QC will carry out the fitting test for the final products. Make sure the fitting is correct.
11	Packaging	check the outgoing products against the production specifications to see if the packaging method is correct. Including pp bag, color box, outer box and packing quantity is correct.
12	Identification	check whether the name, trademark, model, production date and other information is complete and correct.
13	Finished product inspection report	all inspections must be conducted according to the requirements and the finished product inspection report must be filled in. Place in the specified area.

The Third Party Tests

Material performance and final products performance (especially the filtration efficiency, breathability, Total inward leakage) will be carried out batch to batch/year to year by an external independent ISO 17025 accredited test house (or equivalent). See Section 8: Test reports.

Section 5

Essential Health and Safety Requirements

In accordance with Personal Protective Equipment Regulation (EU) 2016/425 - Annex II

Essential Health and Safety Requirements of Regulation (EU) 2016/425, Annex II	Clause of EN149:2001+A1:2009 And Section of this Technical File
1. General requirements applicable to all PPE (PPE must provide adequate protection against the risks against which it is intended to protect)	See section 6, Manufacturer`s Instructions and Information
1.1. Design principles	-
1.1.1. Ergonomics	5, 7.7, 7.9
1.1.2. Levels and classes of protection	See section 2, Product Specifications
1.1.2.1. Optimum level of protection possible	5, 7.7, 7.9, 7.12
1.1.2.2. Classes of protection appropriate to different levels of risk	7.9
1.2. Innocuousness of PPE	-
1.2.1. Absence of inherent risk and other nuisance factors	7.6; 7.12; 7.14; 7.16
1.2.1.1. Suitable constituent materials	7.5; 7.6; 7.7; 7.10; 7.11
1.2.1.2. Satisfactory surface conditions of all PPE parts in contact with the User	7.7; 7.8
1.2.1.3. Maximum permissible user impediment	7.7; 7.14
1.3. Comfort and effectiveness	-
1.3.1. Adaptation of PPE to user morphology	7.7
1.3.2. Lightness and design strength	7.4; 7.5; 7.7
1.3.3. Compatibility of different classes or types of PPE designed for simultaneous use	N/A
1.3.4. Protective clothing containing removable protectors	N/A
1.4. Manufacturer`s instructions and information	10
2. Additional Requirements Common to Several Types of PPE	-
2.1. PPE incorporating adjustment systems	7.13
2.2. PPE enclosing the parts of the body to be protected	N/A
2.3. PPE for the face, eyes and respiratory system	7.14
2.4. PPE subject to ageing	7.6; 9; 10
2.5. PPE which may be caught up during use	N/A
2.6. PPE for use in potentially explosive atmospheres	10
2.7. PPE intended for rapid intervention or to be put on or removed	N/A

Essential Health and Safety Requirements of Regulation (EU) 2016/425, Annex II	Clause of EN149:2001+A1:2009 And Section of this Technical File
rapidly	
2.8. PPE for intervention in very dangerous situations	10
2.9. PPE incorporating components which can be adjusted or removed by the user	7.13; 7.18
2.10. PPE for connection to complementary equipment external to the PPE	N/A
2.11. PPE incorporating a fluid circulating system	N/A
2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	9
2.13. PPE capable of signaling the user`s presence visually	N/A
2.14. 'Multi-risk' PPE	N/A
3. Additional Requirements Specific to Particular Risks	-
3.1. Protecting against mechanical impact	-
3.1.1. Impact caused by falling or ejected objects and collision of parts of the body with an obstacle	N/A
3.1.2. Falls	N/A
3.1.2.1. Prevention of falls due to slipping	N/A
3.1.2.2. Prevention of falls from a height	N/A
3.1.3. Mechanical vibration	N/A
3.2. Protection against static compression of a part of the body	N/A
3.3. Protection against mechanical injuries (abrasion, perforation cuts, bites)	N/A
3.4. Protection in liquids	-
3.4.1. Prevention of drowning	N/A
3.4.2. Buoyancy aids	N/A
3.5. Protection against the harmful effects of noise	N/A
3.6. Protection against heat and/or fire	-
3.6.1. PPE constituent materials and other components	N/A
3.6.2. Complete PPE ready for use	N/A
3.7. Protection against cold	-
3.7.1. PPE constituent materials and other components	N/A
3.7.2. Complete PPE ready for use	N/A

Essential Health and Safety Requirements of Regulation (EU) 2016/425, Annex II	Clause of EN149:2001+A1:2009 And Section of this Technical File
3.8. Protection against electric shock	-
3.8.1. Insulating equipment	N/A
3.8.2. Conductive equipment	N/A
3.9. Radiation protection	-
3.9.1. Non-ionising radiation	N/A
3.9.2. Ionising radiation	N/A
3.9.2.1. Protection against external radioactive contamination	N/A
3.9.2.2. Protection against external irradiation	N/A
3.10. Protection against substances and mixtures which are hazardous to health and against harmful biological agents	-
3.10.1. Respiratory protection	7.6; 7.7; 7.8; 7.9; 7.12; 7.16; 7.17; 9; 10
3.10.2. Protection against cutaneous and ocular contact	N/A
3.11. Diving equipment	N/A

Section 6

Manufacturer's Instructions and Information

Product name: Filtering half mask
Class: FFP2 NR DISPOSABLE
Specification: Foldable 15.9*10.7(±0.5cm)
Type No: MP9011

Please read this User Information Sheet carefully before using this product. This product complies with the requirements of EU Regulation (EU) 2016/425 for Personal Protective Equipment and meets the requirements of European standard EN 149:2001+A1:2009.

Check prior to use

The respirator must be selected properly for intended application. An individual risk assessment must be evaluated. Check the respirator that it is undamaged with no visible defects. Check that the expiry date has not been reached (see the packaging). Check the protection class (FFP1 NR/ FFP2 NR/ FFP3 NR) is appropriate for the product used and its concentration. Do not use the mask if a defect is present or the expiry date has been exceeded.

Intend use of this PPE:

These devices are designed to protect against both solid and liquid aerosols. And be used in industries such as Textile, abattoirs, metallurgy, construction, iron and steel industries, hospitals etc. To Protects against dusts, mists and fumes containing calcium carbonate, clay, kaolin, cellulose, cotton, flour, ferrous metals, vegetal and mineral oils, metal-working fluids.

This product is designed to protective against the risks:

Risk	Standard Clause	Assessment method
Penetration of particle	EN 149:2001+A1:2009, clause 7.9.1 and 7.9.2	Total inward leakage test, Penetration of filter material

Application/ Limitations

This respirator is suitable for use in protection against the non-toxic solid and liquid aerosols. Do not use out of the scope of use defined in the warnings. Failure to properly use this product may result in serious health damage or death.

FFP1 NR: Filter Efficiency 80%; Allocated Protection Factor (FPA) is 4; Examples of applications are Handling of stone / rubble / cellulose.

FFP2 NR: Filter Efficiency 94%; Allocated Protection Factor (FPA) is 10, Examples of applications are Sanding of soft wood, composite materials, rust, putty, plaster, plastics / cutting, deburring, grinding, drilling of metal.

FFP3 NR: Filter Efficiency 99%; Allocated Protection Factor (FPA) is 20; Examples of applications are Sanding of hard wood (beech, oak) / treatment of wood using copper, chrome or arsenic based products / impact stripping of paint / sanding of cement.

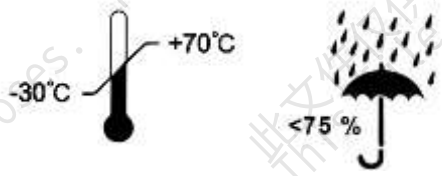
Explanation of marking

Marking	Description on label	Explanation
格林特卫 GREENCARE MP9011 FFP2 NR EN 149:2001+A1:2009 CE 0598	格林特卫® GREENCARE	trademark
	MP9011	Type-identifying marking, style No
	EN 149:2001+A1:2009	Number of European standards
	FFP2 NR	Classification Filter Efficiency 94%, non reusable
	CE 0598	CE marking

Easy to Use/Donning and fitting

	1. Hold the mask in hand with the nosepiece up. Allow ear loop to hang freely.		2. Position the mask under the chin covering mouth and nose. pull elastic loops to ears, wear mask as comfortable as possible.
	3. Adjust nose clip to fit the nose shape. Press soft nosepiece to conform snugly around the nose.		
	4. To check fit, cup both hands over the mask and exhale vigorously. If air flows around nose, tighten the nosepiece. If air leaks around the edge, reposition the ear loop for better fit. Re-check the seal and repeat the procedure until the mask is sealed properly.		

Temperature and humidity range of Storage Condition



End of shelf life

Date of manufacture: 2020/06

	**Don't Litter**

Warnings

1. Failure to follow all instructions and limitations on the use of this product, or failure to achieve proper fit, may result in damage to your health or death or will not provide the expected level of protection
2. This product does not supply oxygen. Use only in adequately ventilated areas containing sufficient oxygen to support life. Do not use this respirator when the oxygen concentration is less than 19.5%.
3. Do not use when concentrations of contaminants are immediately dangerous to health or life. Do not use this product in an explosive atmosphere.
4. Facial hair, beards and certain facial characteristics may reduce the effectiveness of this respirator.
5. "NR" means non reusable, this particle filtering half mask shall not be used for more than one shift.

The length of time this respirator can be used depends on contaminants present but should not exceed one shift. The respirator should be replaced sooner if breathing becomes difficult.

6. Respirator should be discarded after use or when it becomes damaged or deformed in any way; no longer forms an effective seal to the face; becomes wet or visibly dirty; breathing becomes difficult.
7. The respirators must be stored and transported in their original package and protected by the storage temperature and humidity as suggested by the manufacturer.

Manufacturer: Xiamen Probtain Medical Technology Co.,Ltd.

Address: No.6,Ji an Road,Tong an District,Xiamen,Fujian,China 361100

EU declaration of conformity can be accessed at: www.probtain.com

Made in China

Detailed content of the Instructions and information notice is the responsibility for manufacture

EU type-examination for Regulation (EU)
2016/425 by Notified Body Number: 0598

SGS Fimko Oy, Takomotie 8, FI-00380 Helsinki, Finland.

Section 7

Markings

1. Product Marking

Height of CE marking : 8 mm

2. Package Marking

Please see in appendix bag package.

Height of CE 0598 : 5.7 mm

Section 8

Test reports

	Test Report No.
EN 149:2001 + A1:2009	SL52035297675301TX

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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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

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

Test Requirement	Results	Comment
Parts of the device likely to come into contact with the wearer shall have no 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			

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

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

Clause 7.11 Flammability

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

Test Requirement	Results	Comment
The material used shall not present a danger for the wearer and shall not be of highly flammable nature 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	

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

Test Requirement	Results	Comment
The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.	Comply	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%

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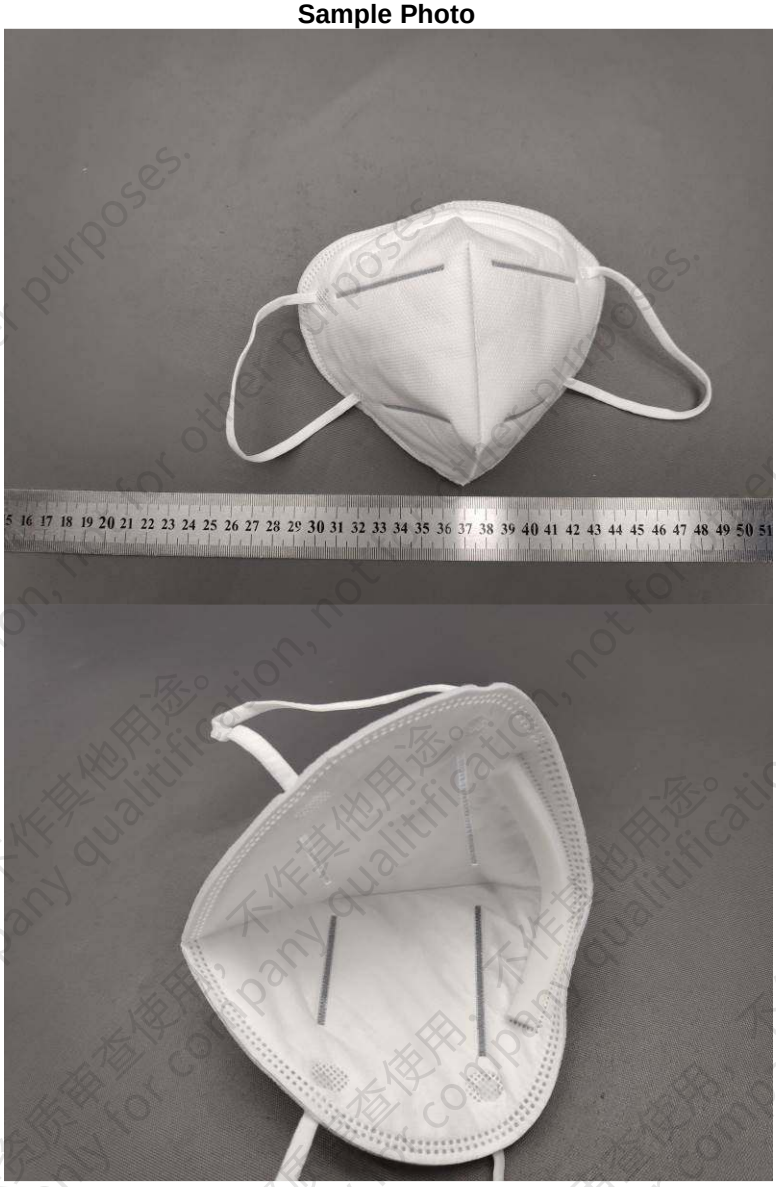
Sample Photo



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End of Report

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XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD
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-C)Particulate Respirator
Sample Color	:	(A)black; (B)pink; (C)blue
Composition	:	(A)Spunbond non-woven fabric, hot air cotton, melt-blown non-woven fabric; (B)Spunbond non-woven fabric, hot air cotton, melt-blown non-woven fabric; (C)Spunbond non-woven fabric, hot air cotton, melt-blown non-woven fabric
Style No.	:	MP9011-B、MP9011-P、MP9011-BL
Manufacturer	:	XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD
Country of Origin	:	China
Sample Size	:	15.5*10.5 (±0.5cm)
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Mar 22, 2021
Testing Period	:	Mar 24, 2021 - Apr 02, 2021
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

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)

SGS does not verify authenticity of any Brand/Trademark of products. Buyers must check if the product is genuine with the Brand/Trademark owner directly.

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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)
A

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)
A

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)
A

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)
A

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)

A

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)

A

Test Requirement	Results	Comment
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: 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.	3.86	3.60	4.65	4.71	4.37	4.24
Luo	2	A.R.	5.53	5.18	5.05	5.85	4.83	5.30
Lu	3	A.R.	4.84	4.45	4.20	4.90	3.72	4.42
Wang	4	A.R.	3.47	3.31	3.24	3.63	3.16	3.36
Bao	5	A.R.	5.04	5.62	5.50	5.93	4.58	5.33
Ding	6	T.C.	3.17	3.99	3.01	4.16	3.20	3.51
Li	7	T.C.	5.69	5.63	5.35	5.83	5.36	5.57
Chen	8	T.C.	3.25	3.22	3.91	4.35	3.38	3.62
Song	9	T.C.	4.68	4.44	4.37	4.89	4.63	4.60
Ye	10	T.C.	5.30	5.98	6.14	6.18	5.57	5.83

Facial Dimension

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
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)

A

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, Meet FFP3

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	0.356
		2	0.367
		3	0.389
	Simulated wearing treatment	4	0.369
		5	0.407
		6	0.383
	Mechanical strength +Temperature conditioned	7	0.575
		8	0.558
		9	0.563
Paraffin oil test	As received	10	0.650
		11	0.671
		12	0.655
	Simulated wearing treatment	13	0.641
		14	0.639
		15	0.645
	Mechanical strength +Temperature conditioned	16	0.745
		17	0.786
		18	0.835
Flow conditioning：Single filter: 95.0 L/min			

Clause 7.10 Compatibility with Skin

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

A

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)

A

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)

A

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	0.5724	Mean value:0.57
	2	0.5715	
	3	0.5720	

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Clause 7.13 Head Harness

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

A

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)

A

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)

A

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)

A

Test Requirement	Results	Comment
The breathing resistances apply to valved and valveless particle filtering half masks and 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	0.3	0.4	0.4	0.4	0.4	0.3	0.3	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.4
		95	1.5	1.6	1.6	1.6	1.6	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.5	1.5	1.6
	Exhalation	160	2.5	2.5	2.6	2.6	2.6	2.6	2.5	2.5	2.5	2.5	2.6	2.6	2.6	2.6	2.6
	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	0.3	0.4	0.4	0.4	0.4	0.4	0.4	0.3	0.3	0.4	0.4	0.4	0.4
		95	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.5	1.5	1.5	1.6	1.6	1.6
	Exhalation	160	2.5	2.5	2.5	2.6	2.6	2.6	2.6	2.5	2.5	2.5	2.6	2.6	2.6	2.6	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	0.4	0.4	0.3	0.4	0.4	0.4	0.4	0.4	0.3	0.3	0.3	0.3	0.4	0.4	0.4
		95	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.5	1.5	1.5	.1.5	1.5	1.6	1.6
	Exhalation	160	2.5	2.6	2.6	2.6	2.6	2.6	2.6	2.5	2.5	2.5	2.6	2.6	2.6	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)

A

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)

A

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%

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COMPONENT LIST / List of Materials

Sample No.	Component No.	Description	Material	Color	Remark
B	1	pink face cover			
B	2	pink ear loop			
C	3	blue face cover			
C	4	blue ear loop			

Azo Dyes (Direct Reduction & Colorant Extraction)

Textile: According to EN ISO 14362-1:2017 – Analysis was conducted with GC-MS/HPLC-DAD.

Test Item(s)	Cas No	Result (mg/kg)			
		1+2		3+4	
		Direct Reduction	Colorant Extraction	Direct Reduction	Colorant Extraction
4-Aminobiphenyl	92-67-1	ND	ND	ND	ND
Benzidine	92-87-5	ND	ND	ND	ND
4-Chlor-o-toluidine	95-69-2	ND	ND	ND	ND
2-Naphthylamine	91-59-8	ND	ND	ND	ND
o-Aminoazotoluene	97-56-3	ND	ND	ND	ND
5-Nitro-o-Toluidine/2-Amino-4-Nitrotoluene	99-55-8	ND	ND	ND	ND
4-Chloroaniline	106-47-8	ND	ND	ND	ND
4-Methoxy-m-Phenylenediamine/2,4-Diaminoanisole	615-05-4	ND	ND	ND	ND
4,4'-Diaminodiphenylmethane, MDA	101-77-9	ND	ND	ND	ND
3,3'-Dichlorobenzidine	91-94-1	ND	ND	ND	ND
3,3'-Dimethoxybenzidine	119-90-4	ND	ND	ND	ND
3,3'-Dimethybenzidine	119-93-7	ND	ND	ND	ND
4,4'-methylenedi-o-Toluidine/3,3'-Dimethyl-4,4'-Diaminodiphenylmethane	838-88-0	ND	ND	ND	ND
p-Cresidine	120-71-8	ND	ND	ND	ND
4,4'-Methylene-bis-(2-chloroaniline)	101-14-4	ND	ND	ND	ND
4,4'-Oxydianiline	101-80-4	ND	ND	ND	ND
4,4'-Thiodianiline	139-65-1	ND	ND	ND	ND
o-Toluidine	95-53-4	ND	ND	ND	ND
4-Methyl-m-Phenylenediamine/2,4-Toluylendiamine, TDA	95-80-7	ND	ND	ND	ND
2,4,5-Trimethylaniline	137-17-7	ND	ND	ND	ND
4-Aminoazobenzene	60-09-3	ND	ND	ND	ND
O-Anisidine	90-04-0	ND	ND	ND	ND
Conclusion		#	#	#	#

Requirement: 30mg/kg

Note:
ND = Not Detected

Reporting Limit = 5 mg/kg (for individual compound)

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Remark:
+Direct reduction refers to the extraction and reduction according to EN ISO 14362-1:2017 clause 10.2 and relevant clauses.

+Colorant extraction refers to the colourant extraction and subsequent reduction according to ISO 14362-1:2017 Clause 10.1 and relevant clauses

4-Aminodiphenyl (CAS No. 92-67-1), 2-Naphthylamine (CAS No. 91-59-8) and 2,4-Diaminoanisole (CAS No. 615-05-4) can be indirectly generated from some colorants which do not contain these amines azo bound. The use of banned azo colorants cannot be reliably ascertained without additional information.

In case PU is used, e.g. PU Foams or coatings, it cannot be ruled out that MDA (CAS No. 101-77-9) and TDA (CAS No. 95-80-7) can be released from PU material, not from banned azo colorant. Similarly, for pigment prints, MDA will be released from a chemical fixing agent.

EN ISO 14362-1:2017 will enable further cleavage of 4-AAB (CAS No. 60-09-3) to non-forbidden amines: aniline and p-phenylenediamine. If aniline and/or p-phenylenediamine is not found, 4-AAB is considered as “n.d.” (i.e. <5.0 mg/kg). Otherwise, EN ISO 14362-3:2017 will be employed to verify the presence of 4-AAB.

pH Value

(ISO 3071:2020; 0.1mol/L KCL extraction)

-	Unit	1	2	3
pH Value	-	6.6	6.5	6.3

-	Unit	4
pH Value	-	6.3

Note:
1) pH value of extraction medium: 5.7
2) Temperature of the extraction solution: 20.3ºC

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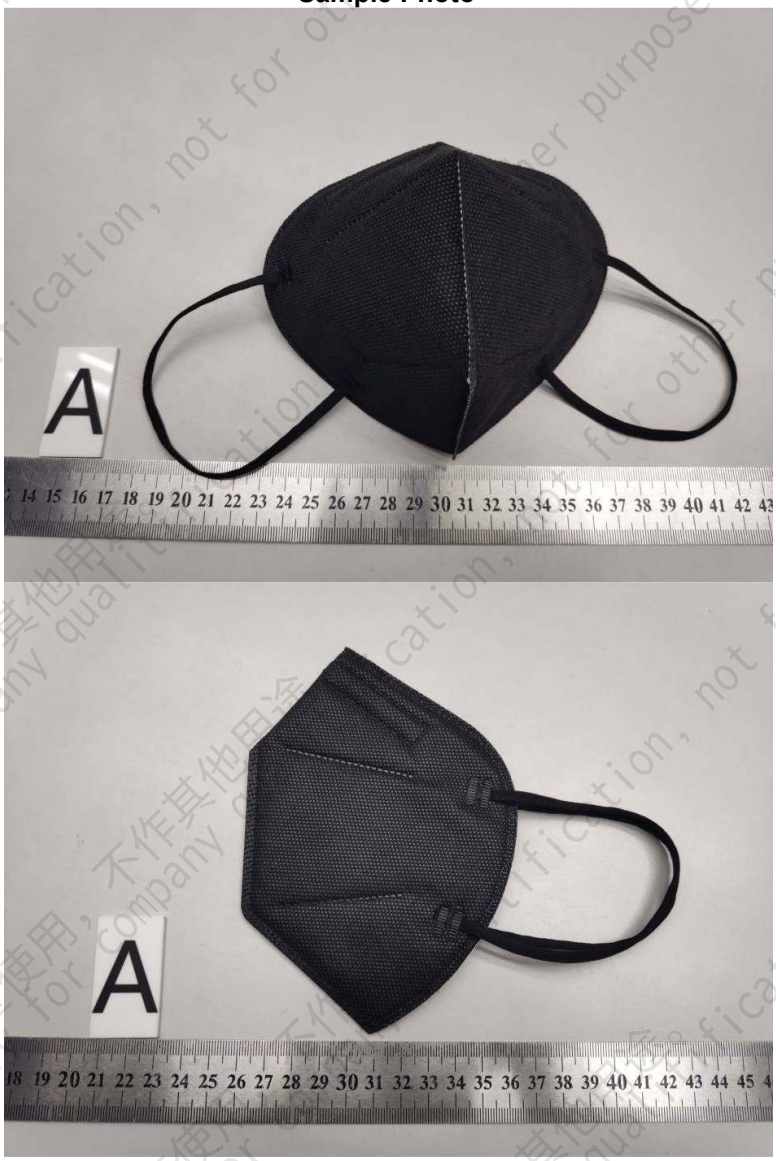
Sample Photo



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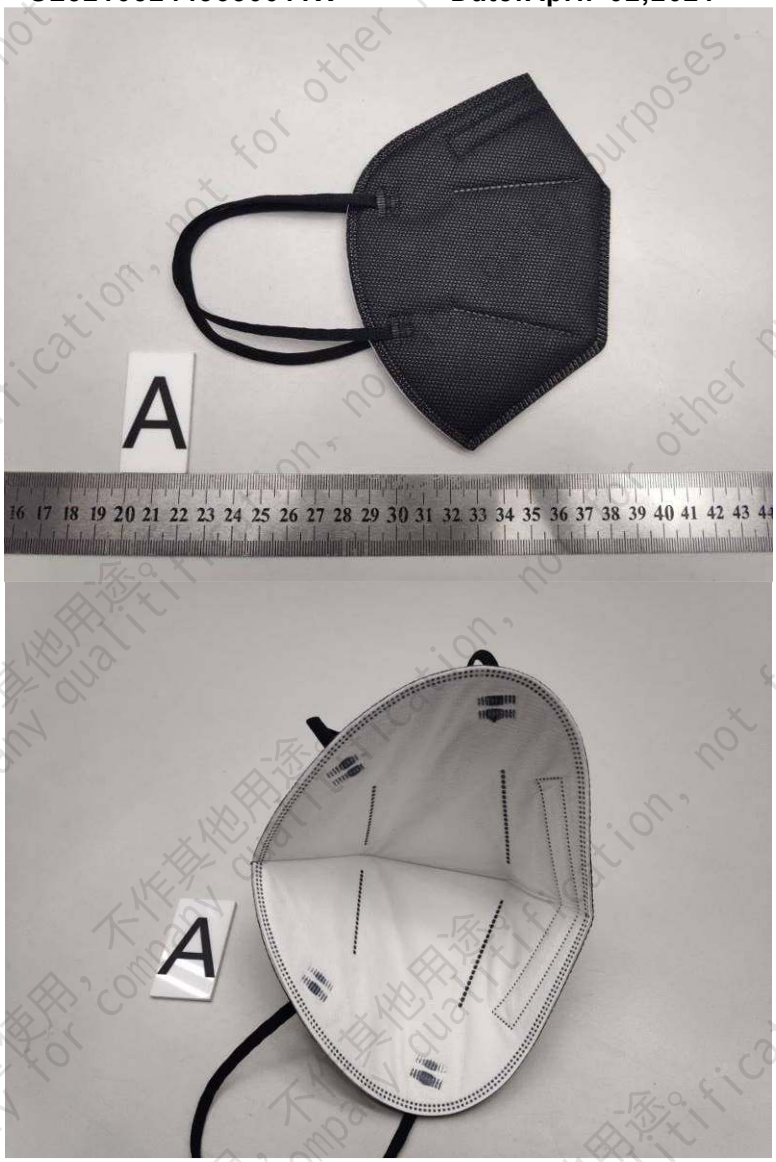

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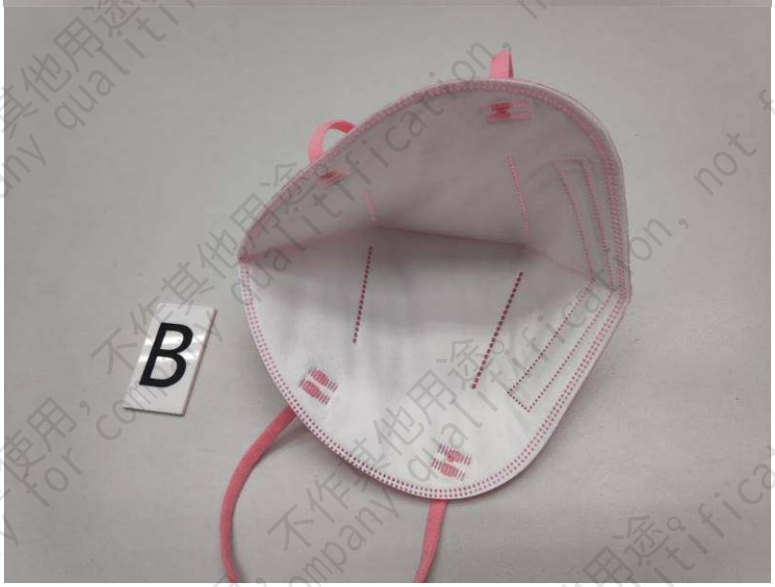

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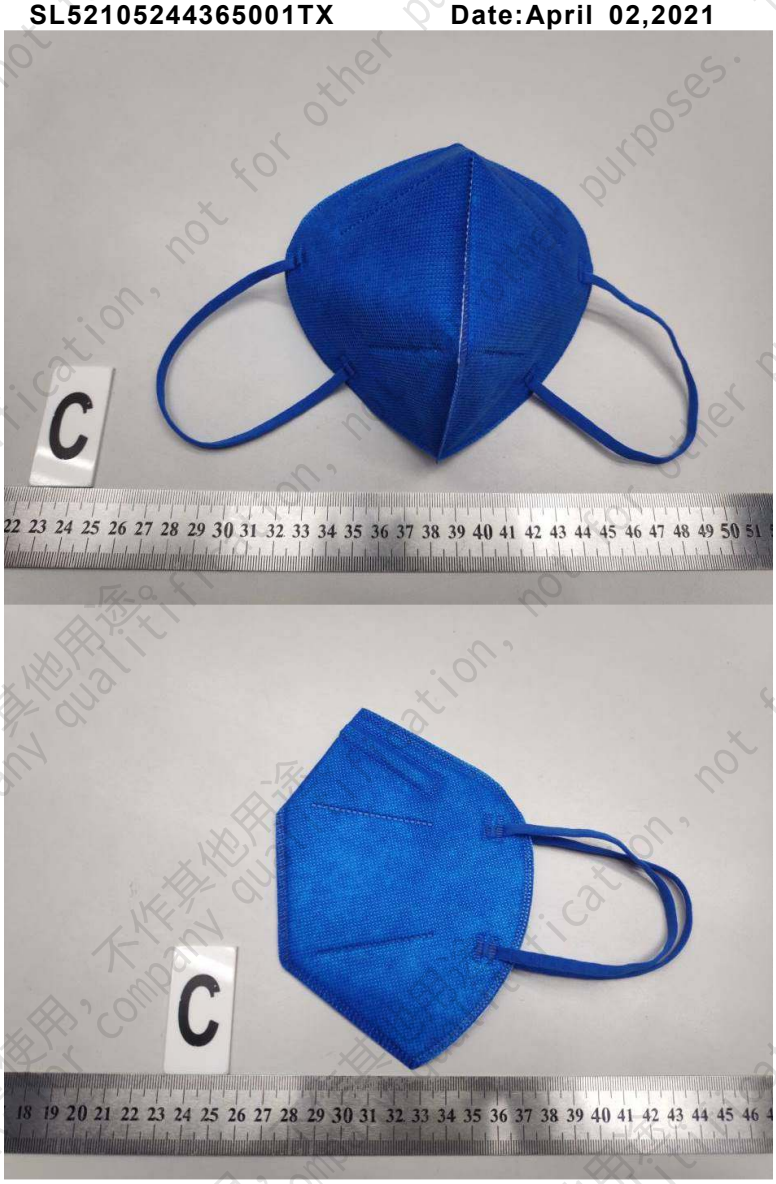

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End of Report

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XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD
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-C)Particulate Respirator
Sample Color	:	(A)BLACK; (B)PINK; (C)BLUE
Composition	:	(A)Spunbond non-woven fabric, hot air cotton, melt-blown non-woven fabric; (B)Spunbond non-woven fabric, hot air cotton, melt-blown non-woven fabric; (C)Spunbond non-woven fabric, hot air cotton, melt-blown non-woven fabric
Style No.	:	MP9011-P(pink), MP9011-B(black), MP9011-BL(blue)
Manufacturer	:	XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD
Country of Origin	:	China
Sample Size	:	15.5*10.5 (±0.5cm)
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Mar 23, 2021
Testing Period	:	Mar 25, 2021 - Mar 30, 2021
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

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

Sara Guo (Account Executive)

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COMPONENT LIST / List of Materials

Sample No.	Component No.	Description	Material	Color	Remark
A	1	black face cover			
A	2	black ear loop			
B	3	pink face cover			
B	4	pink ear loop			
C	5	blue face cover			
C	6	blue ear loop			

Test Result

Azo Dyes (Direct Reduction & Colorant Extraction)

Textile: According to EN ISO 14362-1:2017 – Analysis was conducted with GC-MS/HPLC-DAD.

Test Item(s)	Cas No	Result (mg/kg)			
		1+2+3		4+5+6	
		Direct Reduction	Colorant Extraction	Direct Reduction	Colorant Extraction
4-Aminobiphenyl	92-67-1	ND	ND	ND	ND
Benzidine	92-87-5	ND	ND	ND	ND
4-Chlor-o-toluidine	95-69-2	ND	ND	ND	ND
2-Naphthylamine	91-59-8	ND	ND	ND	ND
o-Aminoazotoluene	97-56-3	ND	ND	ND	ND
5-Nitro-o-Toluidine/2-Amino-4-Nitrotoluene	99-55-8	ND	ND	ND	ND
4-Chloroaniline	106-47-8	ND	ND	ND	ND
4-Methoxy-m-Phenylenediamine/2,4-Diaminoanisole	615-05-4	ND	ND	ND	ND
4,4'-Diaminodiphenylmethane, MDA	101-77-9	ND	ND	ND	ND
3,3'-Dichlorobenzidine	91-94-1	ND	ND	ND	ND
3,3'-Dimethoxybenzidine	119-90-4	ND	ND	ND	ND
3,3'-Dimethybenzidine	119-93-7	ND	ND	ND	ND
4,4'-methylenedi-o-Toluidine/3,3'-Dimethyl-4,4'-Diaminodiphenylmethane	838-88-0	ND	ND	ND	ND
p-Cresidine	120-71-8	ND	ND	ND	ND
4,4'-Methylene-bis-(2-chloroaniline)	101-14-4	ND	ND	ND	ND
4,4'-Oxydianiline	101-80-4	ND	ND	ND	ND
4,4'-Thiodianiline	139-65-1	ND	ND	ND	ND
o-Toluidine	95-53-4	ND	ND	ND	ND
4-Methyl-m-Phenylenediamine/2,4-Toluylendiamine, TDA	95-80-7	ND	ND	ND	ND
2,4,5-Trimethylaniline	137-17-7	ND	ND	ND	ND
4-Aminoazobenzene	60-09-3	ND	ND	ND	ND
O-Anisidine	90-04-0	ND	ND	ND	ND
Conclusion		#	#	#	#

Requirement: 30mg/kg

Note:
ND = Not Detected

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Reporting Limit = 5 mg/kg (for individual compound)

Remark:
+Direct reduction refers to the extraction and reduction according to EN ISO 14362-1:2017 clause 10.2 and relevant clauses.

+Colorant extraction refers to the colourant extraction and subsequent reduction according to ISO 14362-1:2017 Clause 10.1 and relevant clauses

4-Aminodiphenyl (CAS No. 92-67-1), 2-Naphthylamine (CAS No. 91-59-8) and 2,4-Diaminoanisole (CAS No. 615-05-4) can be indirectly generated from some colorants which do not contain these amines azo bound. The use of banned azo colorants cannot be reliably ascertained without additional information.

In case PU is used, e.g. PU Foams or coatings, it cannot be ruled out that MDA (CAS No. 101-77-9) and TDA (CAS No. 95-80-7) can be released from PU material, not from banned azo colorant. Similarly, for pigment prints, MDA will be released from a chemical fixing agent.

EN ISO 14362-1:2017 will enable further cleavage of 4-AAB (CAS No. 60-09-3) to non-forbidden amines: aniline and p-phenylenediamine. If aniline and/or p-phenylenediamine is not found, 4-AAB is considered as “n.d.” (i.e. <5.0 mg/kg). Otherwise, EN ISO 14362-3:2017 will be employed to verify the presence of 4-AAB.

pH Value

(ISO 3071:2020; 0.1mol/L KCL extraction)

-	Unit	**1**	**2**	**3**
pH Value	-	6.7	6.5	6.2
-	Unit	**4**	**5**	**6**
pH Value	-	6.2	6.2	6.3

Note:
1) pH value of extraction medium: 5.7
2) Temperature of the extraction solution: 20.3ºC

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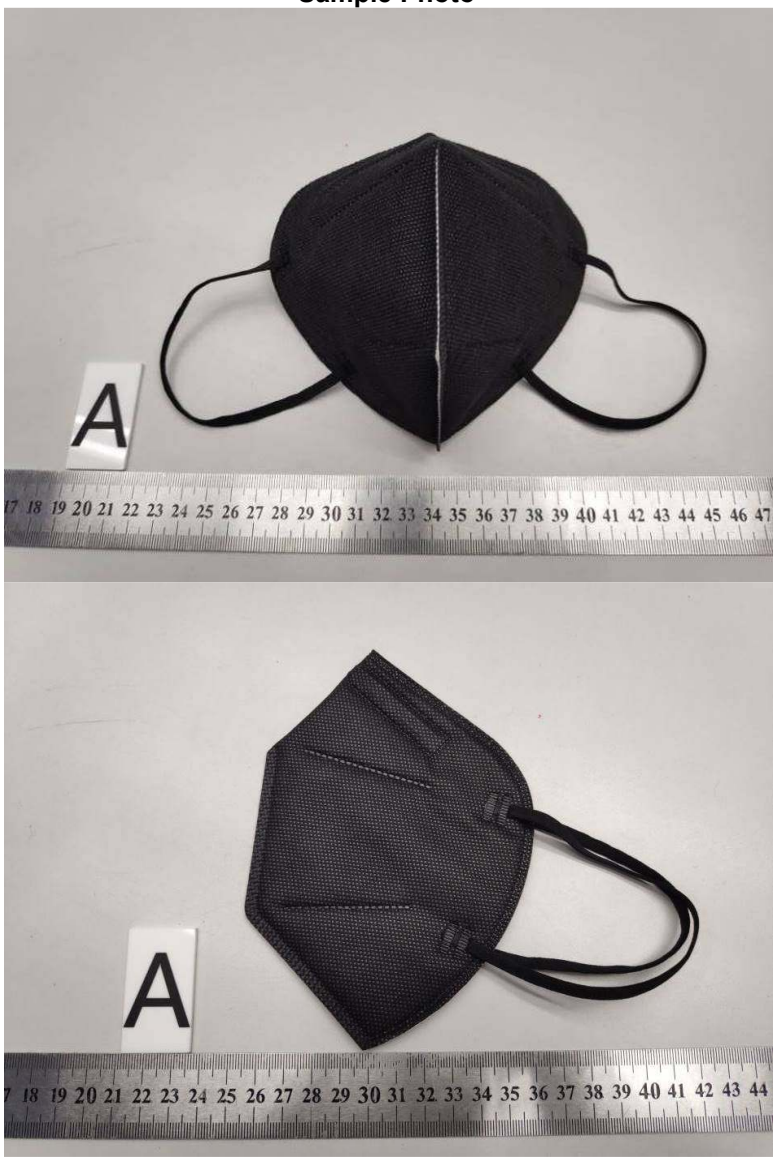
Sample Photo



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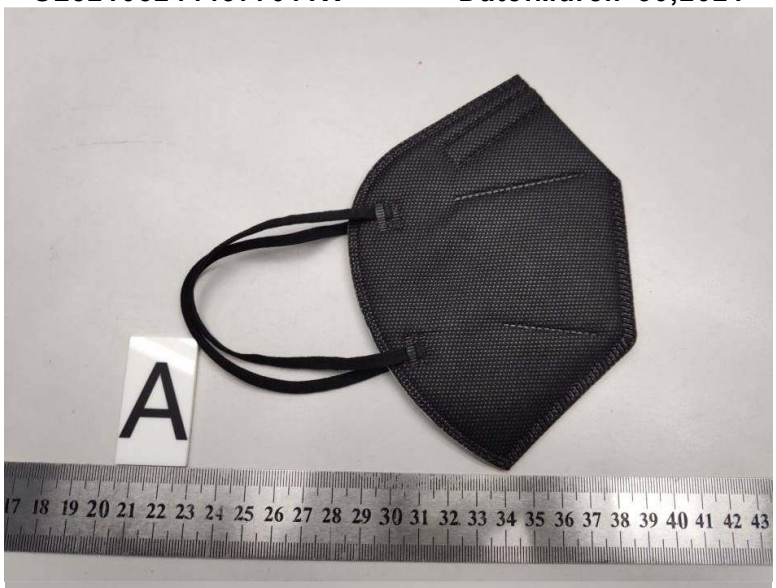

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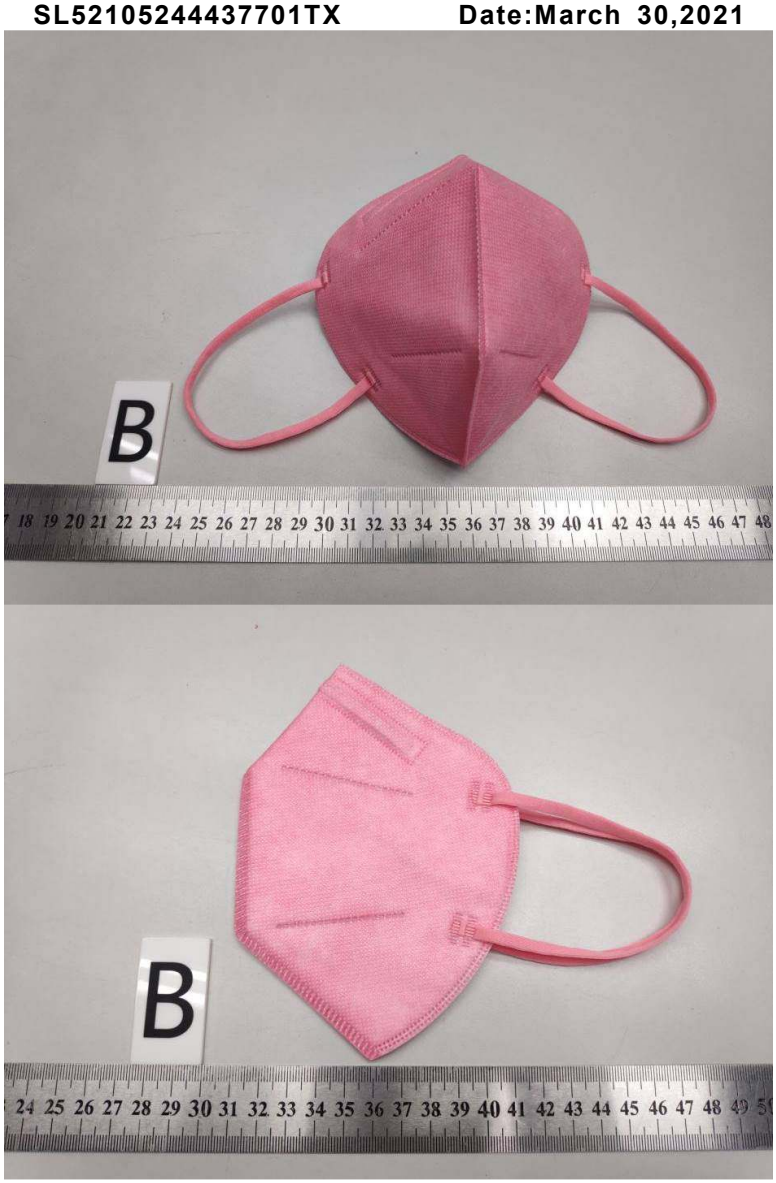

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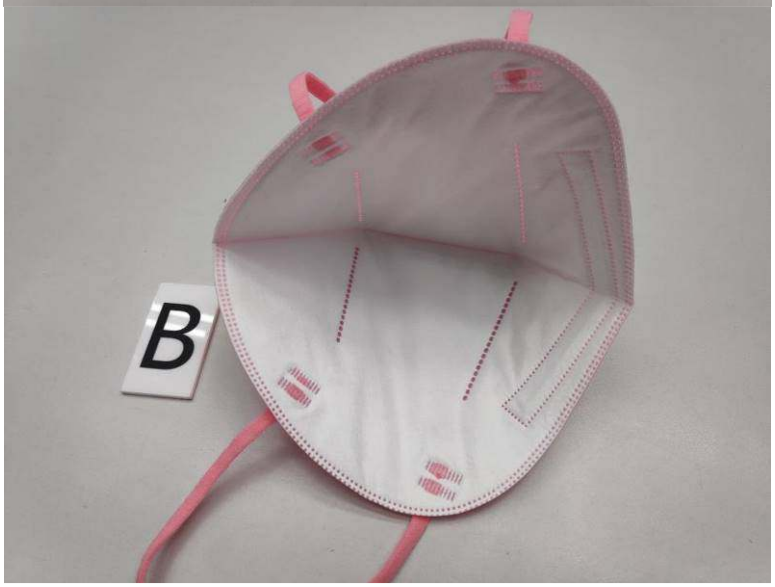

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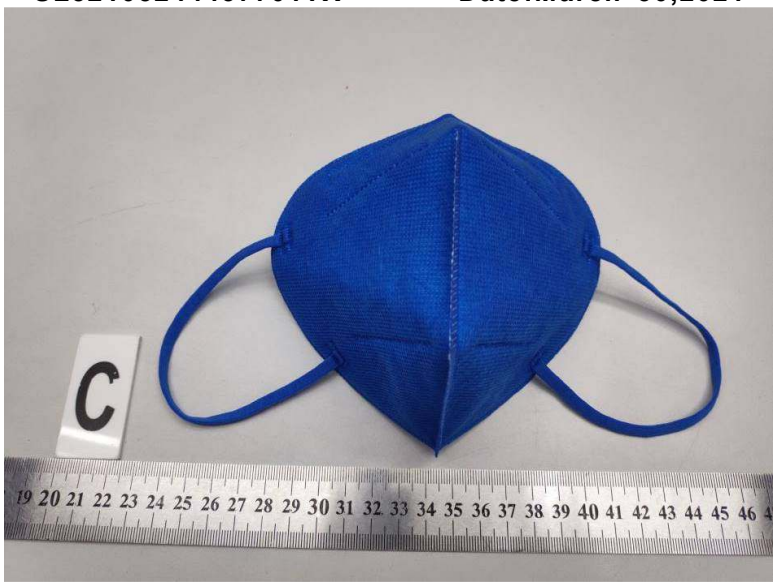

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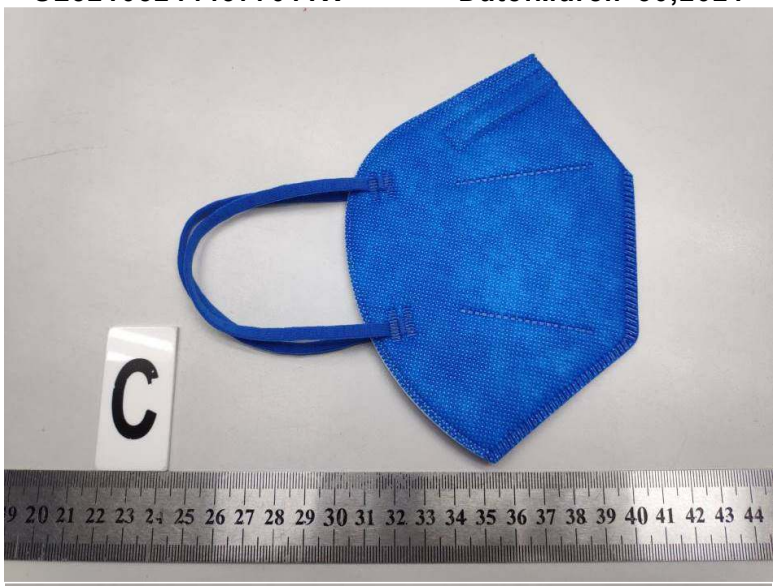

End of Report

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XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD
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,B)Particulate Respirator
Sample Color	:	(A)MP9011-R (red);(B)MP9011-G (gray)
Composition	:	(A)spunbond non-woven fabric, hot air cotton, melt-blown non-woven fabric;(B)spunbond non-woven fabric, hot air cotton, melt-blown non-woven fabric
Style No.	:	MP9011-R (red), MP9011-G (gray)
Manufacturer	:	XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD
Country of Origin	:	China
Sample Size	:	15.5*10.5 (±0.5cm)
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Jul 05, 2021
Testing Period	:	Jul 08, 2021 - Jul 13, 2021
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

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

Sara Guo (Account Executive)

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COMPONENT LIST / List of Materials

Sample No.	Component No.	Description	Material	Color	Remark
A	1	red face cover			
A	2	red ear loop			
B	3	gray face cover			

Test Result

Azo Dyes (Direct Reduction & Colorant Extraction)

Textile: According to EN ISO 14362-1:2017 – Analysis was conducted with GC-MS/HPLC-DAD.

Test Item(s)	Cas No	Result (mg/kg) 1+2+3	
		Direct Reduction	Colorant Extraction
4-Aminobiphenyl	92-67-1	ND	ND
Benzidine	92-87-5	ND	ND
4-Chlor-o-toluidine	95-69-2	ND	ND
2-Naphthylamine	91-59-8	ND	ND
o-Aminoazotoluene	97-56-3	ND	ND
5-Nitro-o-Toluidine/2-Amino-4-Nitrotoluene	99-55-8	ND	ND
4-Chloroaniline	106-47-8	ND	ND
4-Methoxy-m-Phenylenediamine/2,4-Diaminoanisole	615-05-4	ND	ND
4,4'-Diaminodiphenylmethane, MDA	101-77-9	ND	ND
3,3'-Dichlorobenzidine	91-94-1	ND	ND
3,3'-Dimethoxybenzidine	119-90-4	ND	ND
3,3'-Dimethybenzidine	119-93-7	ND	ND
4,4'-methylenedi-o-Toluidine/3,3'-Dimethyl-4,4'-Diaminodiphenylmethane	838-88-0	ND	ND
p-Cresidine	120-71-8	ND	ND
4,4'-Methylene-bis-(2-chloroaniline)	101-14-4	ND	ND
4,4'-Oxydianiline	101-80-4	ND	ND
4,4'-Thiodianiline	139-65-1	ND	ND
o-Toluidine	95-53-4	ND	ND
4-Methyl-m-Phenylenediamine/2,4-Toluylendiamine, TDA	95-80-7	ND	ND
2,4,5-Trimethylaniline	137-17-7	ND	ND
4-Aminoazobenzene	60-09-3	ND	ND
O-Anisidine	90-04-0	ND	ND
Conclusion		**#**	**#**

Requirement: 30mg/kg

Note:
ND = Not Detected

Reporting Limit = 5 mg/kg (for individual compound)

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Remark:
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+Colorant extraction refers to the colourant extraction and subsequent reduction according to ISO 14362-1:2017 Clause 10.1 and relevant clauses

4-Aminodiphenyl (CAS No. 92-67-1), 2-Naphthylamine (CAS No. 91-59-8) and 2,4-Diaminoanisole (CAS No. 615-05-4) can be indirectly generated from some colorants which do not contain these amines azo bound. The use of banned azo colorants cannot be reliably ascertained without additional information.

In case PU is used, e.g. PU Foams or coatings, it cannot be ruled out that MDA (CAS No. 101-77-9) and TDA (CAS No. 95-80-7) can be released from PU material, not from banned azo colorant. Similarly, for pigment prints, MDA will be released from a chemical fixing agent.

EN ISO 14362-1:2017 will enable further cleavage of 4-AAB (CAS No. 60-09-3) to non-forbidden amines: aniline and p-phenylenediamine. If aniline and/or p-phenylenediamine is not found, 4-AAB is considered as “n.d.” (i.e. <5.0 mg/kg). Otherwise, EN ISO 14362-3:2017 will be employed to verify the presence of 4-AAB.

pH Value

(ISO 3071:2020; 0.1mol/L KCL extraction)

-	Unit	1	2	3
pH Value	-	6.3	6.3	6.2

Note:
1) pH value of extraction medium: 5.7
2) Temperature of the extraction solution: 23.2ºC

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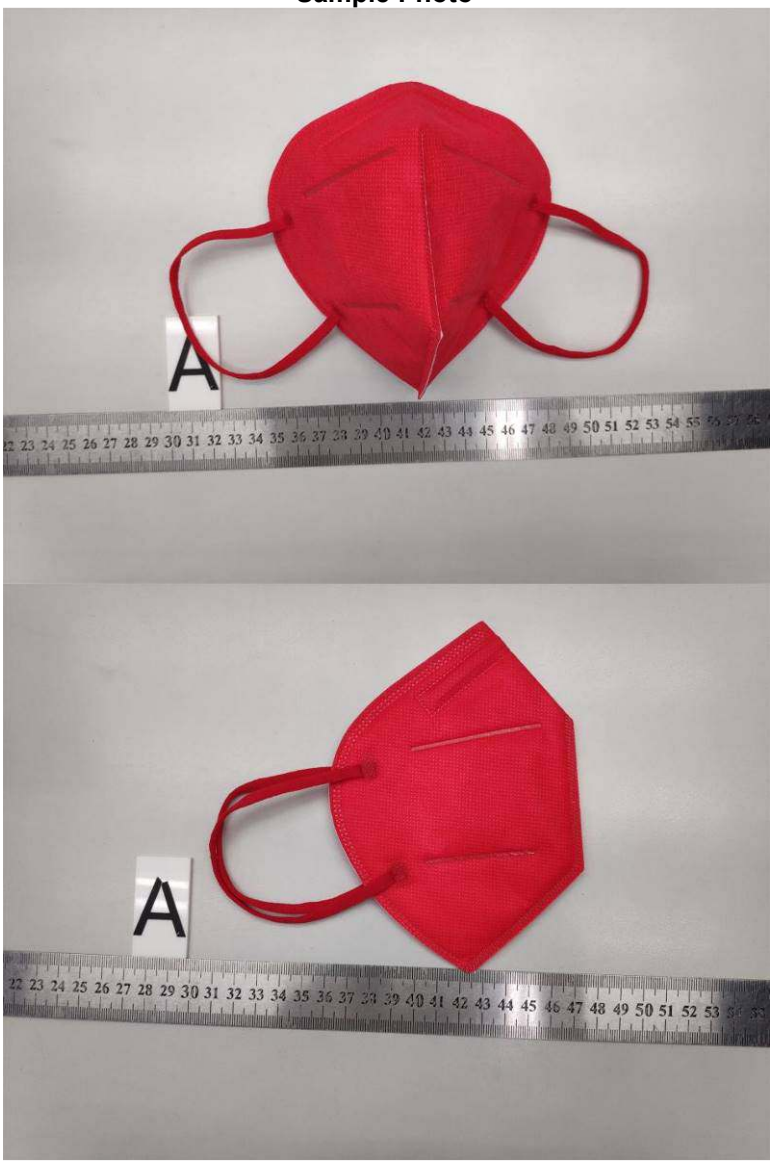
Sample Photo



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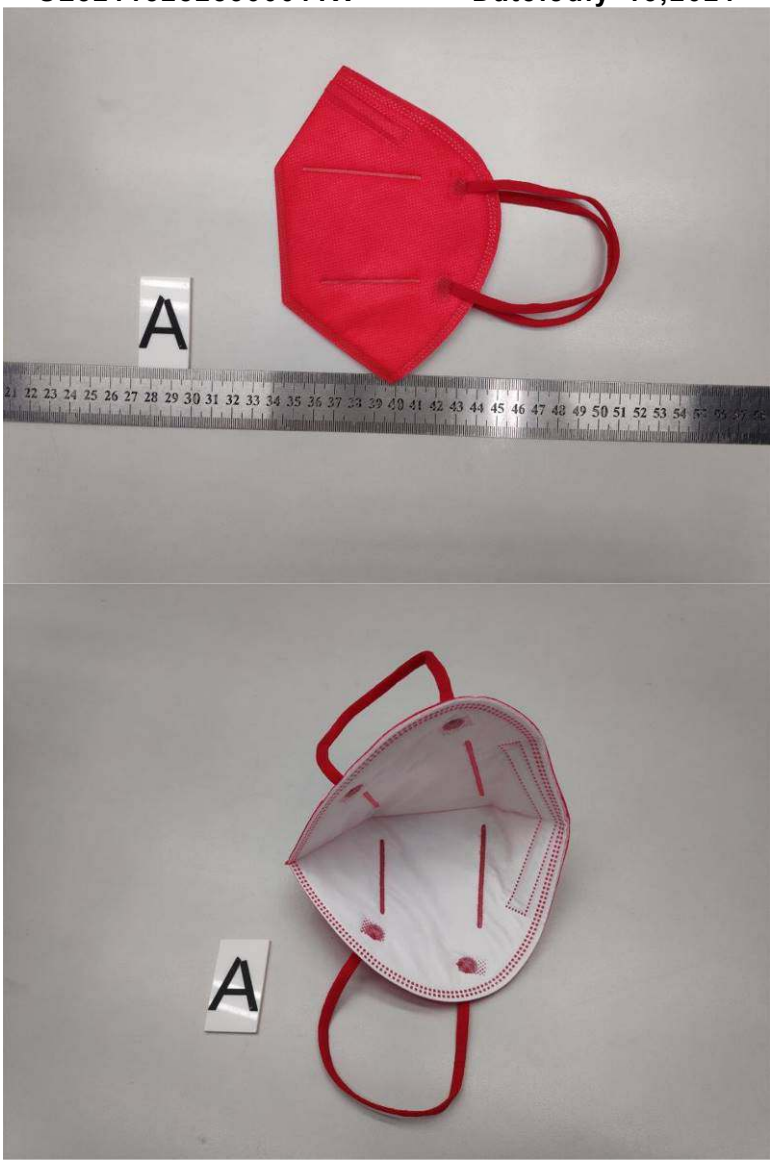

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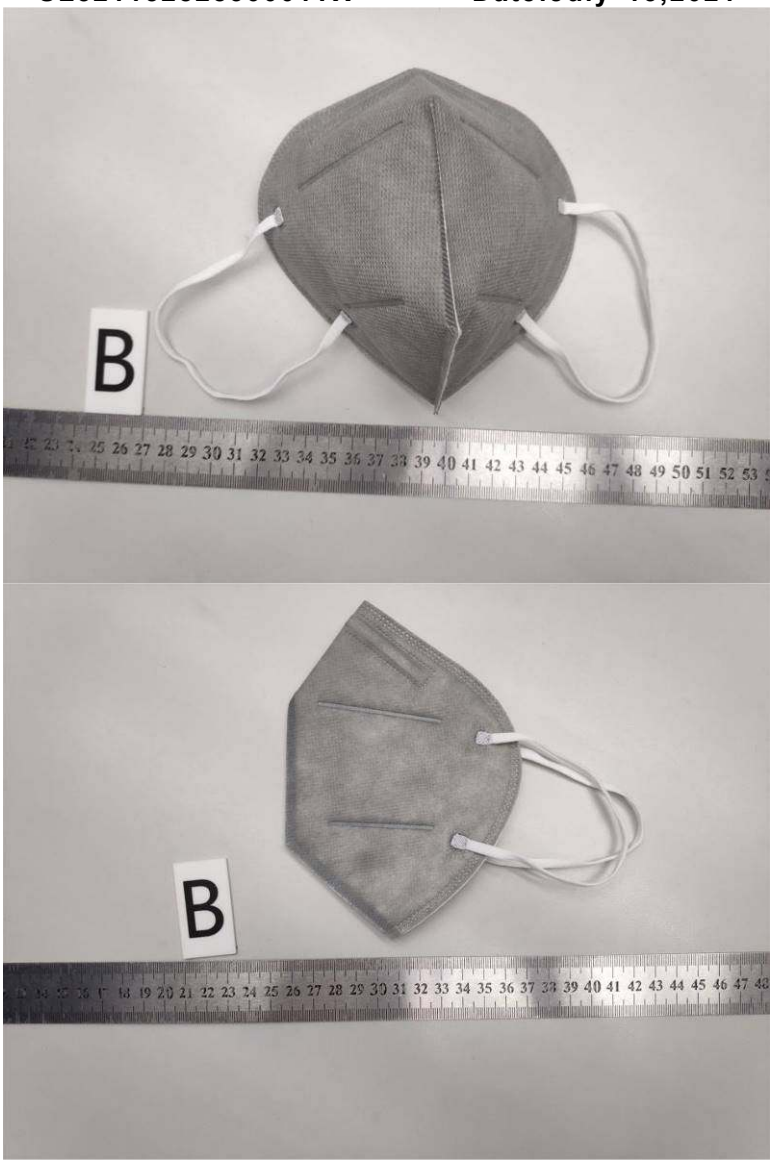

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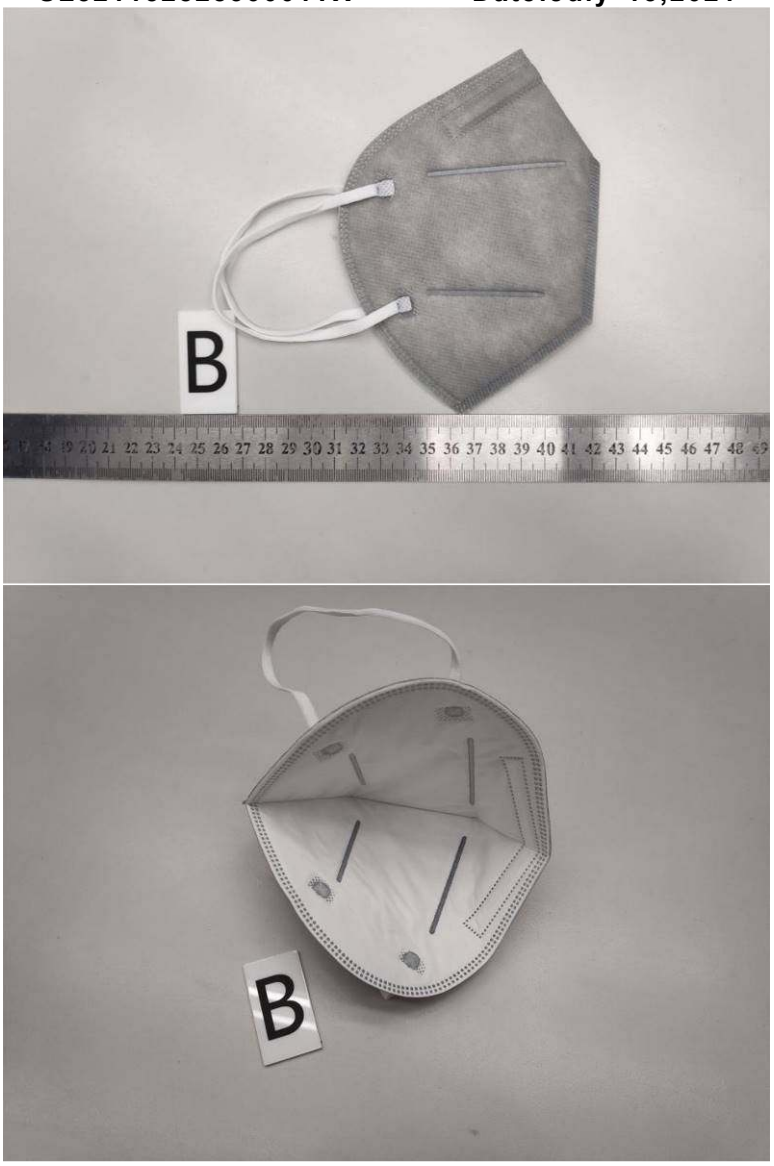

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