

My Benefit Mask

MASCHERINE FPP2 NR - COLORE ROSA

DOCUMENTAZIONE

My Benefit Mask **PRO**

MASCHERINE FFP2 NR



Mascherina filtrante 5 strati (rosa)
con gancio di estensione e supporto nasale incluso
(confezione da 20 pezzi, ciascun pezzo con proprio involucro)

My Benefit Mask PRO

MASCHERINE FFP2 NR

CARATTERISTICHE

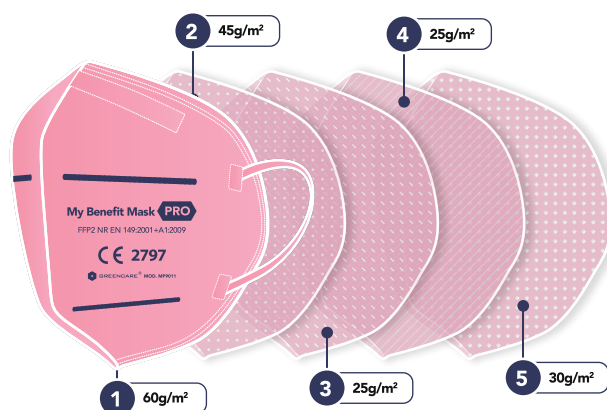
La mascherina FFP2 My Benefit Mask PRO Pink è un dispositivo di protezione individuale capace di filtrare almeno il 95% delle microparticelle di diametro pari a 2,5 µm. Protegge le vie respiratorie da batteri, allergeni, nebbia, polveri, fumo, gas di scarico di auto ed altri agenti contaminanti. Plasmabile, 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.

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

DETTAGLI TECNICI



Materiale (5 strati):

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

Disponibile nelle varianti colore: bianca, nera, rosa, blu

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



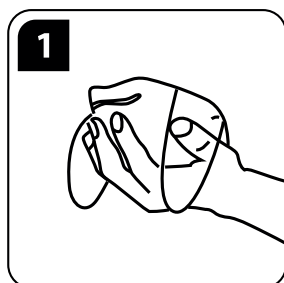
FUNZIONI

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.

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.

GREENCARE^R

My Benefit Mask

PRO

PINK



5 veli
5 strati di protezione

MASCHERINE FFP2 NR

MONOUSO/NON-STERILE
BLUE

Conf. 20 pz. - Involucro singolo

SUPPORTO NASALE

+ ADERENZA
+ COMFORT

GANCIO
DI ESTENSIONE



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

Capacità Filtrante

≥95%

Particelle oleose
fino a 0,6 µm

Scheda tecnica produttore



COMPANY PROFILE

There are four wholly-owned subsidiaries of Probtain:

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.



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4500m²十万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, possesses a 4500m² of 100,000 grade clean workshop and 1,000 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 a daily capacity of 1 million pieces.



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。

Xiamen Probtain Heyue Hygienic Materials Co., LTD. (GreenFibre®) occupies a 23,000m² workshop. It is expertised in R&D and production of laminated nonwoven, nonwoven composite fabric, material application in hygienic products. Products are widely used in women and baby, medical and other disposable personal care fields.



江西美润环保制品有限公司位于瑞金，厂房面积16124m²，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，拒水和亲水性等性能。

Probtain (Jiangxi) Eco-Products Co., Ltd. is located in Ruijin City Jiangxi Province, covering a 16124m². It owns 5 automatic PP spunbonded nonwoven production lines: 320cm (SSS, under construction), 240cm (SSMS), 160cm (SS), 240cm S, 180cm S, with a total annual output of 18000 metric tons, products have been widely applied in medical and hygiene products, environmentally friendly packaging, agricultural covering and daily household products.



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 Probtain Protective 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 are surgical 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.



PACKAGE PHOTOS



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



美润股份
PROBTAIN

STOCK CODE: 836267

XIAMEN PROBTAIN NONWOVEN INC.

Letter of Declaration

Date: Jan 23, 2021

To whom it may concern,

We Xiamen Probtain Nonwoven Inc., address No.6 Ji'an Road, Tong'an District, Xiamen, Fujian 361100 China. Our FFP2 particle filtering half mask Model MP9011 black color meets, Technical specification Annex II(EHSR) of the PPE regulation(EU)2016/425 PPE for use by healthcare professionals as per Commission recommendation 2020/403.

All our CE certifications and test reports are valid for our black FFP2 mask Model MP9011. The quality and technical data will not change with different colors. A request of indicating black FFP2 mask on CE certification has been sent to Notified Body BSI.

XIAMEN PROBTAIN NONWOVEN INC.

He Yimian



Add: No.6 Ji an Road, Tong an District, Xiamen, Fujian, 361100 China
Tel: +86-592-7266376 | Email: yimian@probtain.com | www.probtain.com

Certificazioni / Test report





MEDICAL DEVICES-QUALITY MANAGEMENT SYSTEMS CERTIFICATE

Certificate No.: CQC19QY20047R0S/46500

We hereby certify that
**Xiamen Probtain Nonwoven INC./ Xiamen Probtain Medical
Technology Co, LTD.**

Unified Social Credit Code: 91350200776019243B

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

by reason of its
Quality Management System
has been awarded this certificate for compliance with the standard
YY/T 0287-2017 / ISO 13485:2016
The Quality Management System Applies in the following area:
Manufacture of Disposable Medical Sanitary Materials and Nursing Supplies Within Qualifications

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

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

Signed by: Lu Mei



CHINA QUALITY CERTIFICATION CENTRE

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

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2018年版



White list of Chamber Commerce

取得国外标准认证或注册

www.cccmhpie.org.cn/kywz.aspx

English 登陆 | 注册

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开良不可抗力相关事实性证明

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首页 关于商会 新闻中心 行业服务 权威发布 商会会刊 企业风采 会员之家 加入商会

取得国外标准认证或注册的医疗物资和非医用口罩生产企业检索

美润 检索

企业名称 (中文)	企业名称 (英文)	产品类别	产品名称/型号	统一社会信用代码	国外注册认证情况
厦门美润医疗科技有限公司	Xiamen Probtain Medical Technology Co., Ltd	医用口罩	Disposable Medical Face Mask Sterile Single Use Surgical masks (type I, Type II, Type IIR)	91350212MA333XCG9R	欧盟CE
江西美润环保制品有限公司	Probtain (Jiangxi) Eco-Products Co.,Ltd.	医用口罩	Disposable Surgical Mask	91360781558479655U	欧盟CE
厦门美润医疗科技有限公司	Xiamen Probtain Medical Technology Co.,Ltd	医用口罩	Disposable Surgical Mask	91350212MA333XCG9R	美国FDA
厦门美润医疗科技有限公司 (持证公司: Xiamen Probtain Nonwoven Inc.)	Xiamen Probtain Medical Technology Co., Ltd	非医用口罩	MP9011	91350212MA333XCG9R	欧盟CE
厦门美润医疗科技有限公司 (持证公司: Xiamen Probtain Nonwoven Inc.)	Xiamen Probtain Medical Technology Co.,Ltd	非医用口罩	MP9011	91350212MA333XCG9R	美国EUA

EU TYPE-EXAMINATION CERTIFICATE

N° 0082/3584/079/08/20/0395

Vincent Maillocheau



For category III PPE, the certificate shall only be used in conjunction with one of the conformity assessment procedures referred in point c) of Article 19.
Pour les EPI de catégorie III, l'attestation ne doit être utilisée qu'en liaison avec l'une des procédures d'évaluation de la conformité visées à l'article 19, point c).

The manufacturer shall inform the notified body of all modifications to the approved type and of all modifications of the technical documentation that may affect the conformity of the PPE with the applicable essential health and safety requirements or the conditions for validity of that certificate
 (article 7.2 – annexe V)

Le fabricant informe l'organisme notifié de toutes les modifications du type approuvé et de toutes les modifications de la documentation technique qui peuvent remettre en cause la conformité de l'EPI aux exigences essentielles de santé et de sécurité applicables ou les conditions de validité de cette attestation (article 7.2 – annexe V)



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

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

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

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

Respiratory protective device

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

Fontaine, the 21/10/2020

Report sent for the attention of XIE JIAN YOU to the email address jianyou@probtain.com

This report includes 15 pages

The technical assessment manager
Immaterial original

M.MEPI.324.V1



VILA COBARESI
Validation électronique

Summary

1. Introduction - Description of the service
2. Use of the report
3. Economical operator(s)
4. Identification of the equipment
5. Conditions for use of the equipment
6. Reference specification
7. Technical Documentation
8. Correlation between the articles of PPE Regulation 2016/425 and the reference standard
9. Examination report
10. Conclusion

1.Introduction - Description of the service

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

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

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

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

2.Use of the report

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

Only an integral reproduction of this assessment report is authorized.

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

3.Economical operator(s)

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

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

4.Identification of the equipment

Class: FFP2 NR

Trade mark: GREENCARE

Model: MP9011

5.Conditions for use of the equipment

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

6.Reference specification

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

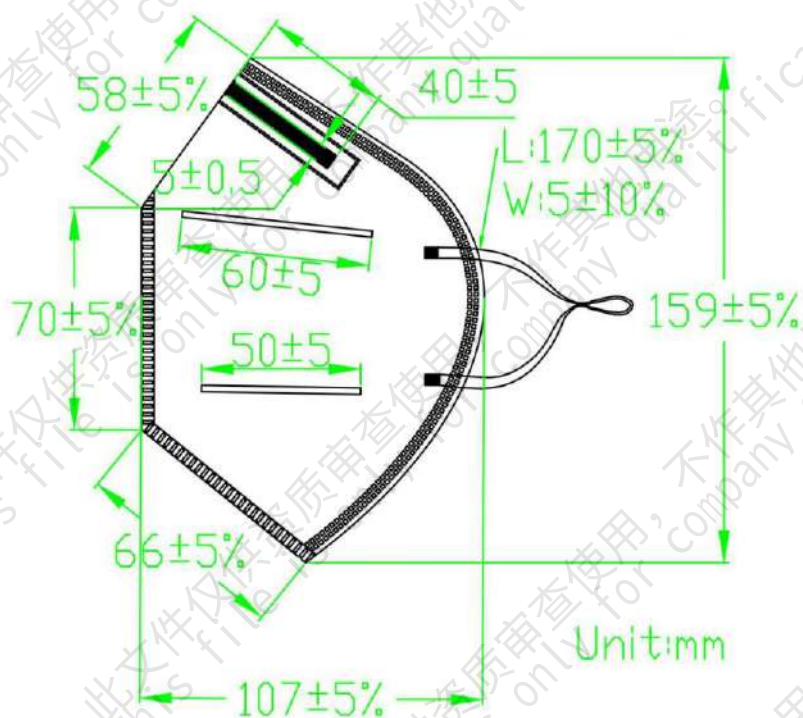
7. Technical Documentation

7.1. Identification

Identification of the assessed Technical Documentation:

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

7.2. Drawing



7.3.Description

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

7.4.Description of components

Detailed description of components in the Technical Documentation.

7.5.CE Marking

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

APAVE SUDEUROPE SAS

✖ CE mark:

CE 0082

✖ Graphic of letters C and E:

Conform

✖ Height of mark:

6 mm

✖ Marking clear and permanent:

Conform

✖ Location of the marking:

On the outer side of the mask

7.6.Packaging

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

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

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

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

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

9.Examination report

Article of the standard EN 149+A1	Content	Conformity			Comments
		Yes	No	N-A	
Art. 7	Requirements				
Art 7.1	Visual inspection The visual inspection shall also include the marking and the information supplied by the manufacturer	✓			
Art 7.4	Packaging Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	✓			
Art 7.5	Material Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used. After undergoing the simulated wearing treatment none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. Three particle filtering half masks shall be tested. When conditioned, the particle filtering half mask shall not collapse. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	✓			Date of test: 04/06/2020
Art 7.6	Cleaning and disinfecting If the particle filtering half mask is designed to be re-Usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer." After cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.			✓	

Article of the standard EN 149+A1	Content	Conformity*			Comments
		Yes	No	N-A	
Art 7.7	Practical performance The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test houses shall provide full details of those parts of the practical performance tests which revealed these imperfections. Here are the comments of the test subjects: a) head harness comfort b) security of fastenings c) field of vision d) any other comments reported by the wearer on request	✓			Date of test: 11/06/2020 No imperfection determined No comment No comment No comment No comment
Art 7.8	Finish of parts Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs	✓			
Art 7.9	Leakage				
Art 7.9.1	Total inward leakage The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected. The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e.10 subjects x 5 exercises) for total inward leakage shall be not greater than: 11 % for FFP2 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than: 8 % for FFP2	✓			Date of test: 11/06/2020 50 results ≤ 11% 10 averages ≤ 8%

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

* Total inward leakage values in %

Article of the standard EN 149+A1	Content	Conformity*			Comments														
		Yes	No	N-A															
Art 7.9.2	Penetration of filter material The penetration of the filter of the particle filtering half mask shall meet the requirements of Table1. Tableau 1 – Penetration of filter material <table><tr><th rowspan="2">Classification</th><th colspan="2">Maximum penetration of test aerosol</th></tr><tr><th>Sodium chloride test 95 l/min % max.</th><th>Paraffin oil test 95 l/min % max.</th></tr><tr><td>FFP1</td><td>20</td><td>20</td></tr><tr><td>FFP2</td><td>6</td><td>6</td></tr><tr><td>FFP3</td><td>1</td><td>1</td></tr></table>	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	✓			Date of test: 05/06/2020
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																	
Art 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.	✓			Manufacturer statement														
Art 7.11	Flammability The material used shall not present a danger for the wearer and shall not be of highly flammable nature. When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame. The particle filtering half mask does not have to be usable after the test.	✓			Date of test: 10/06/2020 The mask doesn't burn 5s after removal from the flame														
Art 7.12	Carbon dioxide content of the inhalation air The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)	✓			Date of test: 02/06/2020 CO ₂ <table><tr><td>0,53%</td><td>0,64%</td><td>0,62%</td></tr></table>	0,53%	0,64%	0,62%											
0,53%	0,64%	0,62%																	

Paraffin oil penetration of filter material tests results

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

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

Sodium chloride penetration of filter material tests results

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

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

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

Date of test:
05/06/2020

Breathing resistance tests results

Values in mbar

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

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

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

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

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

10.Conclusion

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

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

M.MEPI.325.V1

Certificate FI20/967127

Xiamen Probtain Medical Technology Co., Ltd

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

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

Regulation (EU) 2016/425

Module B, EU type-examination

This certificate is valid from 04 November 2020 until 04 November 2025

1. Certified since 04 November 2020

Authorised by

Tom Jörn

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

SGS FIMKO OY, Notified Body 0598

Takomatie 8, FI-00380, Helsinki, Finland
t +358 9 696 361 f +358 9 692 5474 www.sgs.com

Page 1 of 2



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Certificate F120/967127, continued

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

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

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

Section 2**Applicant/Manufacture & Product General Information**

1. Manufacturer General Information

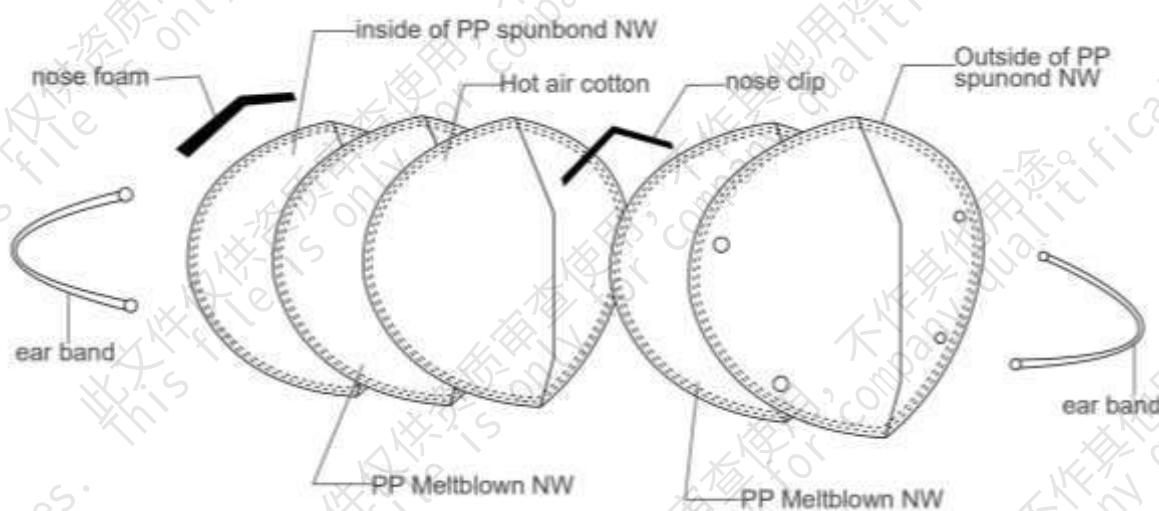
Manufacturer Name	Xiamen Probtain Medical Technology Co.,Ltd.
Manufacturer Address	No.6,Ji an Road,Tong an District,Xiamen,Fujian,China.
Supplier/Factory Name	Xiamen Probtain Medical Technology Co.,Ltd.
Supplier/Factory Address	No.6,Ji an Road,Tong an District,Xiamen,Fujian,China.
Brand name (if any)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

Section 3**Product Specifications**

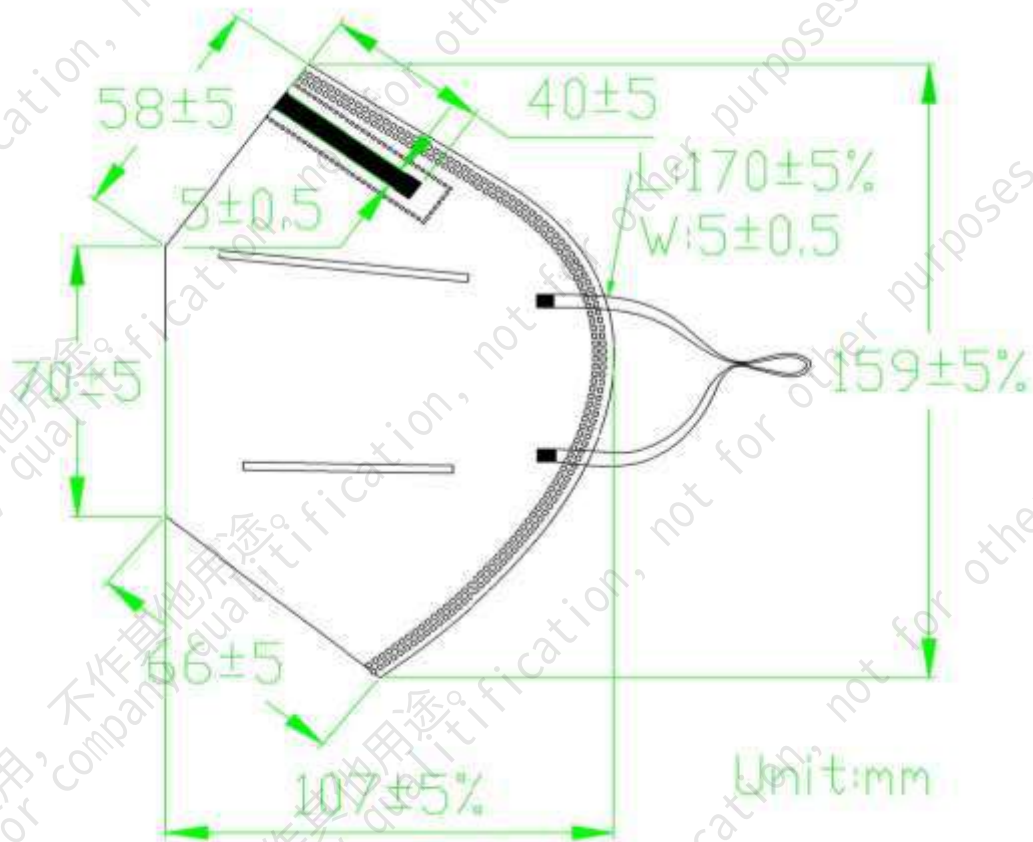
1. Product General Information

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

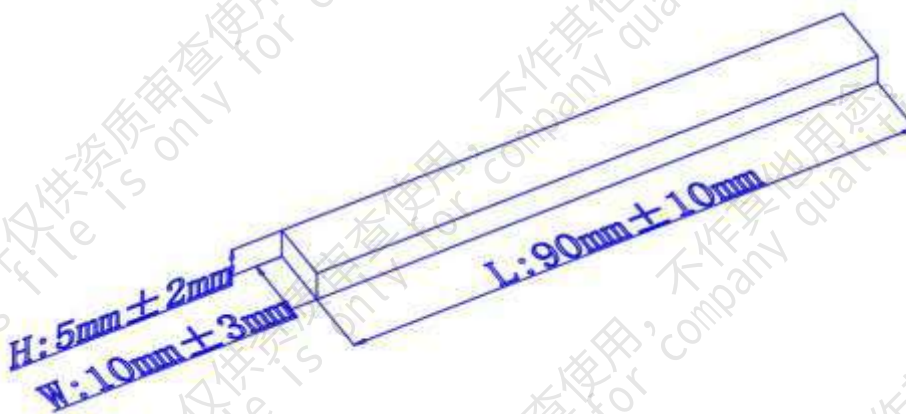
2. Product Photograph(s)



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.

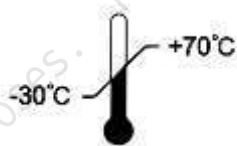
Explanation of marking

Marking	Description on label	Explanation
 		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



2023/06

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

Section 9

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 hereafter

Description of products	Filtering half mask
Product style/order No	MP9011
Product colour and type	White; Non-reusable, folded

are in conformity with the Regulation (EU) 2016/425 and with harmonized standard
EN 149:2001 + A1:2009

SGS Fimko Oy

Takomatie 8, FI-00380 Helsinki, Finland

Notified Body No. 0598

performed the EU type-examination (Module B) and issued the EU type-examination certificate
FI2222

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: 2020.9.9



Section 10

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; 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: 2020.9.9



Test Report **SL52105244437701TX**
XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD
NO.6.JI'AN ROAD, TONG'AN DISTRICT, XIAMEN, FUJIAN, CHINA.

Date: March 30, 2021

Page 1 of 9

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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Testing Center - Shanghai 中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com

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	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'-Dimethylbenzidine	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-Toluyldiamine, 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: 20.3°C

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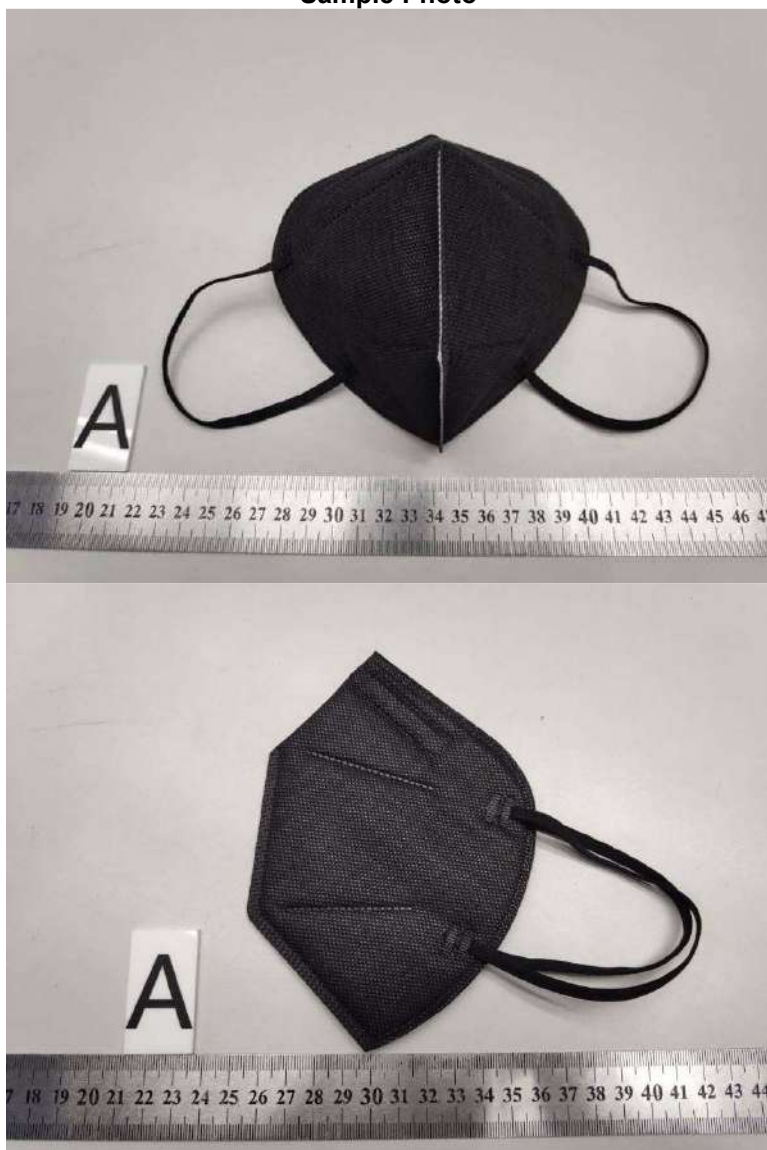
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Sample Photo



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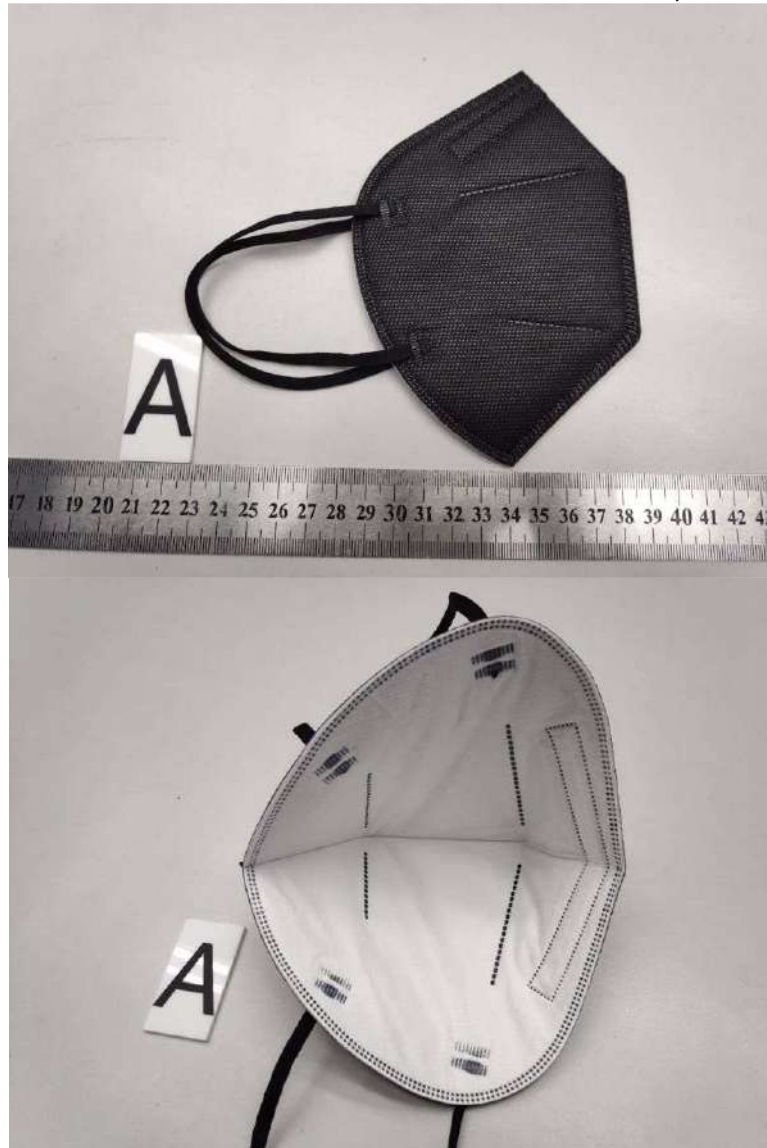
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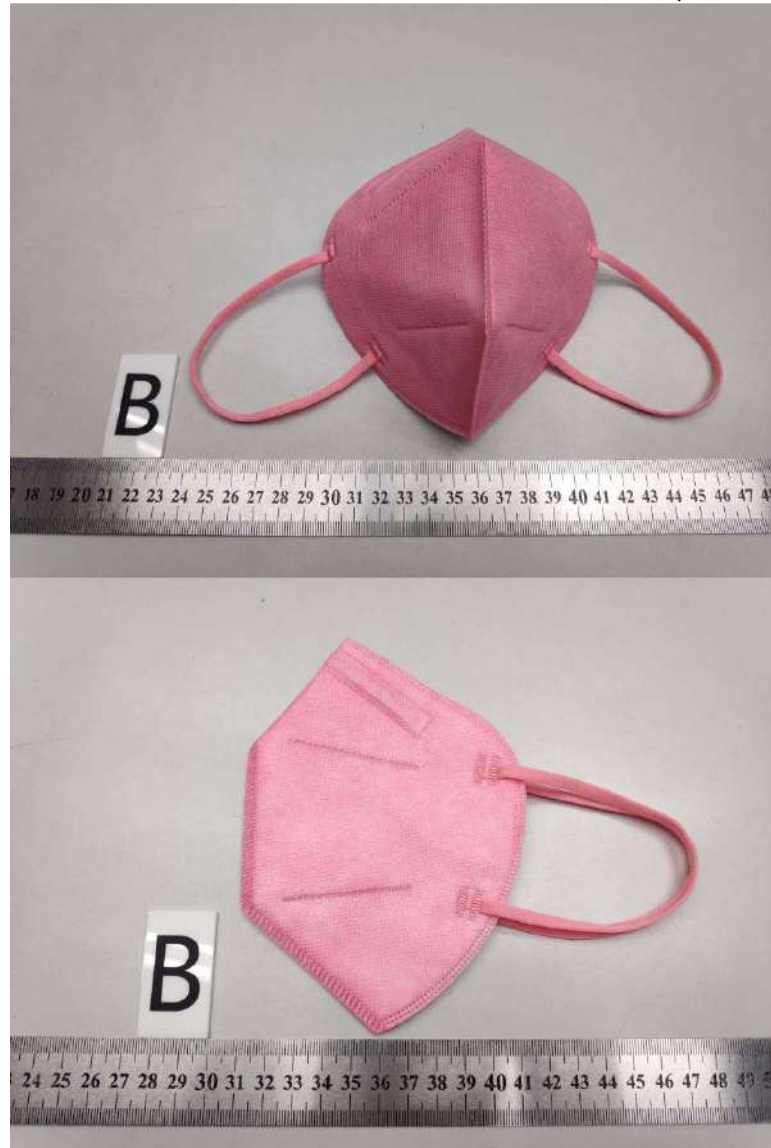
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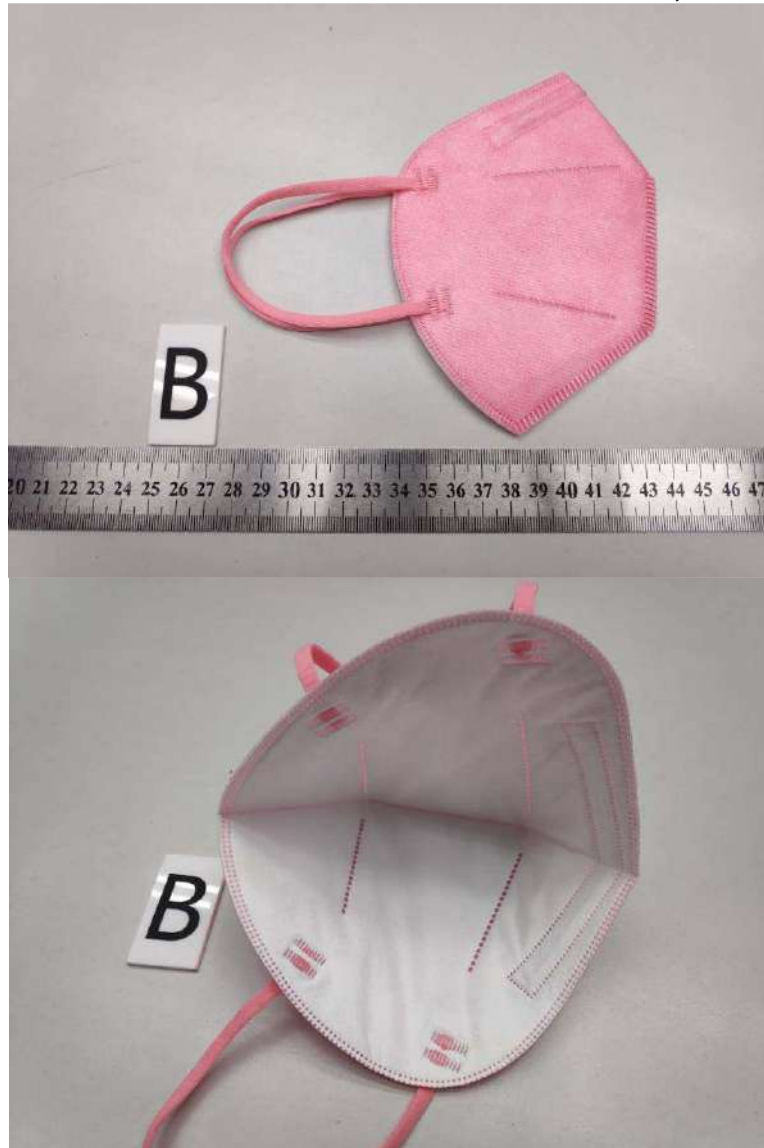
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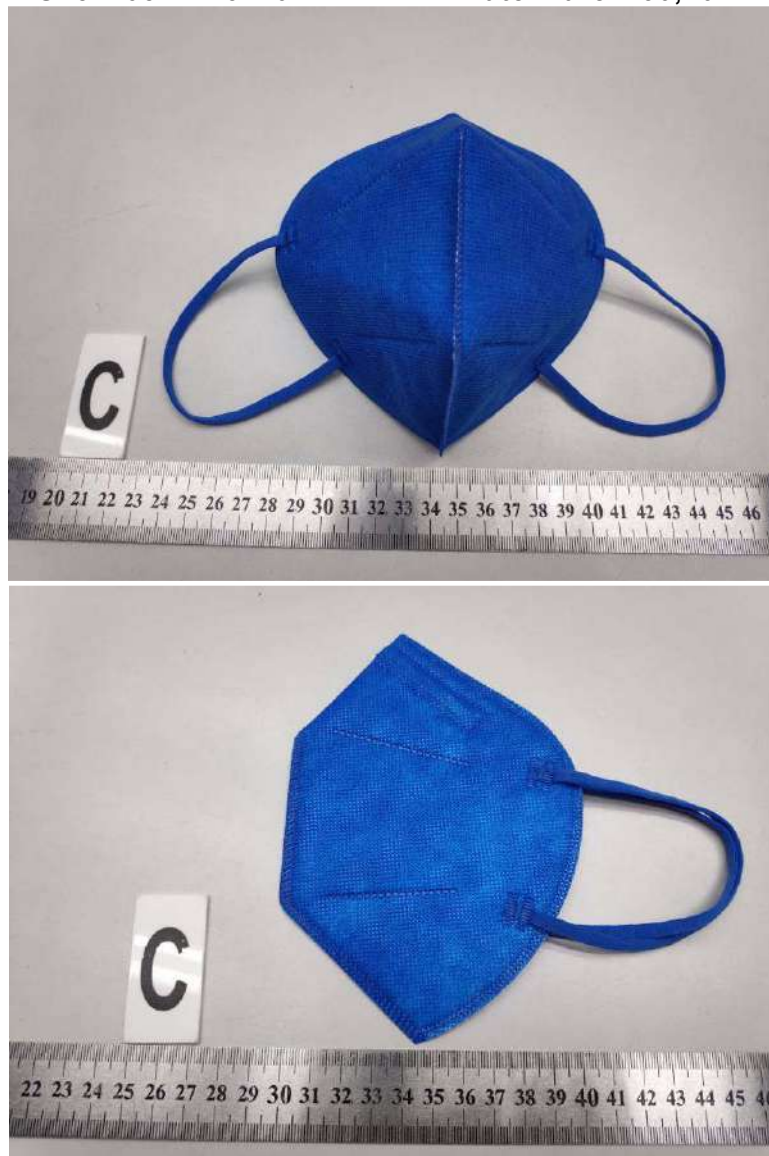
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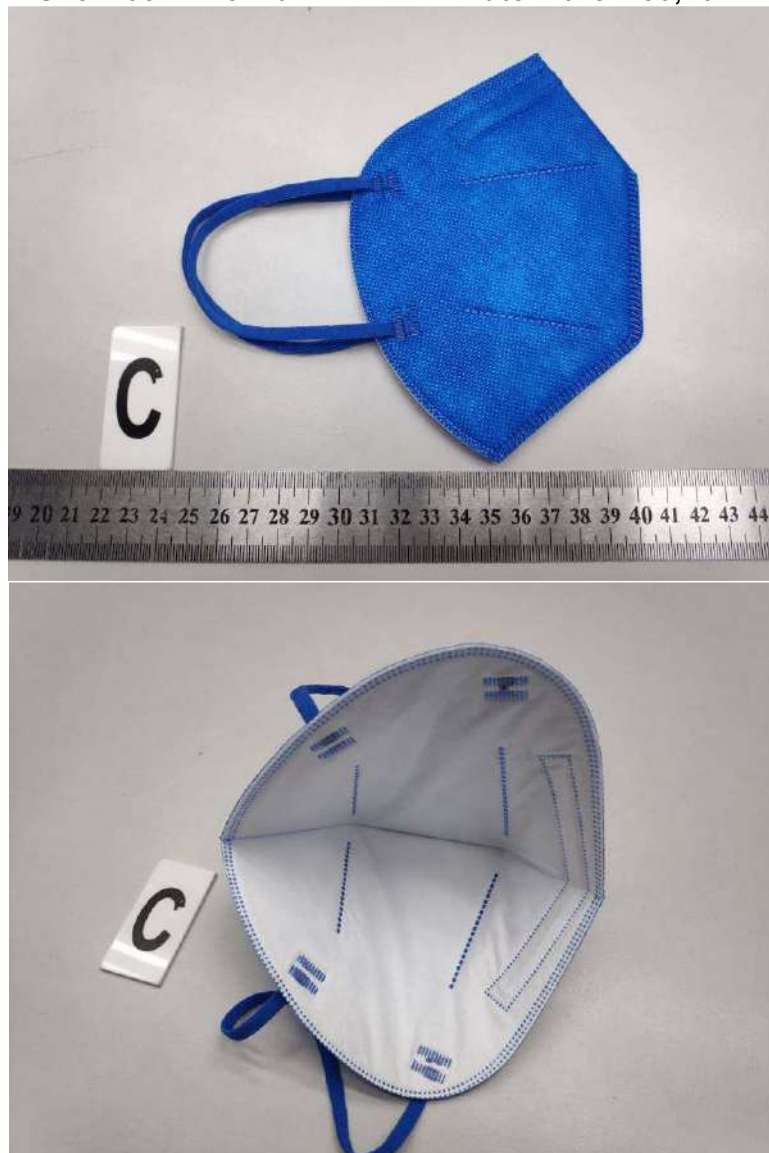
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End of Report



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

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

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

Search:

Show

100



entries

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

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

Previous

1

Next

July 15, 2020

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

EUA201704

Re: FFRs Made in China

Dear Raymond Luo:

This letter is in response to your request that the Food and Drug Administration (FDA) add your respirator model MP9011 as an authorized respirator to the Emergency Use Authorization (EUA) for non-NIOSH-approved filtering facepiece respirators manufactured in China¹, which was revised and reissued under Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) on June 6, 2020. We have reviewed your request to be added to Appendix A of this EUA and determined that model included meets the eligibility criteria in the June 6, 2020 EUA for non-NIOSH approved respirators made in China. As such, your respirator(s) is hereby added to Appendix A as an authorized respirator.

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

Manufacturers

- A. Manufacturers of authorized respirators are required to publish the intended use and other instructions (such as fit testing, etc.) about all authorized models that are imported and authorized under this EUA on their website in English. Additionally, manufacturers must notify FDA by emailing FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov of the website address (URL) that meets this condition. The subject line of this email should read "URL for FFR Made in China." FDA will make this information available to the public on its EUA website at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas>. Manufacturers must notify FDA of any changes to this page.
- B. In addition to the above electronic labeling condition, manufacturers of authorized respirators are additionally required to include a letter, in English, that can be distributed to each end user facility (e.g., each hospital, etc.) that receives the authorized respirator model. This letter must include the authorized respirator's manufacturer, model, intended use, manufacturer's webpage (if applicable), etc.

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



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

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

Sincerely,

Linda Ricci, MME, MPH
Director
Division of All Hazard Response, Science and Strategic
Partnerships (DARSS)
Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health

EU DECLARATION OF CONFORMITY

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

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

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

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



EU Type Examination Certificate

This is to certify that:

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

Holds Certificate Number:

CE 728105

In respect of:

Model MP9011 Particulate Respirator.

To technical specification Annex II (EHSR) of the PPE Regulation (EU) 2016/425

PPE for use by healthcare professionals as per Commission recommendation 2020/403.

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



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

Previous Notified Body: BSI 0086

First Issued: 2020-06-01

Latest Issue: 2020-06-01

Drs. Dave Hageraars, Managing Director

Effective Date: 2020-06-01

Expiry Date: 2021-06-01

Page: 1 of 3



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EU Type Examination Certificate

No. CE 728105

Product Specification

Product Name:	Particulate Respirator.
Product Type:	Particulate filtering half masks for use by Healthcare professionals.
Model:	MP9011.
Classification:	FFP2 NR un-valved.
Technical Specification:	Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425.

Product Description: The respirator is non-reusable, secured to the face of the user by a pair of elasticated ear straps, and has no exhalation valve. The respirator is FFP2 class, vertical fold flat type.

The respirator listed on this certificate is for use by healthcare workers, first responders and other personnel involved in the efforts to contain the COVID-19 virus and avoid its further spread.

The product covered by this certificate is not approved for industrial applications and the certificate is only valid as long as EU Commission recommendation sheet 2020/403 remains applicable.

Product Assessments: BSI's PPE for Healthcare Professionals 2020/403 – RPE Technical Specification.

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

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

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A member of BSI Group of Companies.

EU Type Examination Certificate

No. CE 728105

Certificate Administration Details

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

Certificate Amendment Record:

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

Certificate validity

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

The validity of the Certificate for the products is also dependent on the maintenance of the EU Conformity to Type based on Internal Production Control plus supervised product checks at random intervals, Annex VII (Module C2) as referenced on BSI issued Certificate CE 728110.

First Issued: 2020-06-01

Latest Issue: 2020-06-01

Effective Date: 2020-06-01

Expiry Date: 2021-06-01

Page: 3 of 3

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To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated [online](#).

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
A member of BSI Group of Companies.

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

This is to certify that:

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

Holds Certificate Number:

CE 728110

In respect of:

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

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

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

Previous Notified Body: BSI 0086

First Issued: 2020-06-01

Latest Issue: 2020-06-01



Drs. Dave Hageraars, Managing Director

Effective Date: 2020-06-01

Expiry Date: 2021-06-01

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

No. CE 728110

Product manufactured by:

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

Product details

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

Product type:	Particulate filtering half masks for use by Healthcare professionals.
Model and classifications:	MP9011 FFP2 NR
Technical Specification:	Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425. BSI's PPE for Healthcare Professionals 2020/403 – RPE Technical Specification.

First Issued: 2020-06-01

Latest Issue: 2020-06-01

Effective Date: 2020-06-01

Expiry Date: 2021-06-01

Page: 2 of 3

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No. CE 728110

Certificate Administration Details:

Certificate Amendment Record and BSI internal Review relating to this Certificate

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

Certificate validity

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

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Test Report 3201467.

Xiamen Probtain Nonwoven Inc.

Introduction.

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

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

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

Approved For Issue	
	Issue Date: 20 May 2020

Objectives.

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

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

Product Scope.

COVID-19 masks for use by healthcare workers

Report Summary.

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

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

Test Samples.

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

Description of Test Samples.

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

Test Requirements.

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

Technical testing specification for COVID-19 masks for use by healthcare workers

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

Glossary of Terms.

Pass: Complies. Tested by BSI engineers at BSI laboratories

Pass 1: Complies. Witnessed by BSI engineers in manufacturers laboratory.

Pass 2: Complies. Tests carried out by third party lab; results accepted by BSI.

Pass*: Report resulted in uncertainty and states that Compliance is more probable than non-compliance.

Fail: Non-compliance. Product does not meet the requirements of this clause.

Fail*: Report resulted in uncertainty and states that Non-compliance is more probable than compliance.

N/T: Not Tested

N/A: Not Applicable

AR: As Received

TC: Temperature Conditioned

SW: Simulated Wear

FT: Flow Tested

MS: Mechanical strength

MMDF: Manufactures Minimum Design Flow

MMDC: Manufactures Minimum Design Condition

Conditions of Issue.

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

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

Test Results.

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

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

CLAUSE	REQUIREMENTS	ASSESSMENT
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7.7

Practical performance

The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard.

Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections.

Test in accordance with clause 8.4 of the standard.

Pass

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

During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded:

a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.

Table A: Practical performance

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

7.9

Leakage

7.9.1

Total inward leakage

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

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

Test in accordance with clause 8.5 of the standard.

Pass

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

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

Table B: Clause 7.9.1 - Total inward leakage

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

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
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7.9.2

Penetration of filter material

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

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

Pass

Table C: Clause 8.11 - Sodium Chloride penetration test

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

Table D: Clause 8.11 - Paraffin oil penetration test

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

7.12

Carbon dioxide content of inhalation air

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

Test in accordance with clause 8.7 of the standard.

Pass

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

Sample	Pre-test condition	Dead space CO ₂ (%)	
		Limit	Measured
14	AR	< 1.0	0.52
15	AR		0.54
16	AR		0.52

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
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7.16

Breathing resistance

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

3 test samples masks tested 'As received'. Test in accordance with clause 8.9 of the standard.

Pass

The breathing resistances shall meet the requirements of FFP2;
30l/min – 0.7mbar (inhale), 95l/min – 2.4mbar (inhale), 160l/min – 3.0mbar (exhale)

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

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

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

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

Appendix A. – Test Panel Data

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

Note: All candidates were clean shaven

Product photographs.



Front view



Side View



Inside View

End of Report

Test Report **SL52035260890301TX** **Date: July 08, 2020** **Page 1 of 10**
 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

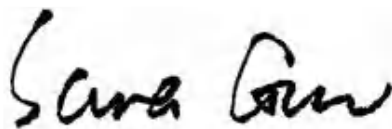
Testing Period : Jun 23, 2020 - Jul 08, 2020

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
Classifica tion	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
	2	0.4740
	3	0.4752
		Mean value: 0.47



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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.					
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)

As received	Flow rate(l/min)		1					2					3				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	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
Simulated wearing treatment	Inhalation	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
		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
	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
Temperature conditioned	Flow rate(l/min)		4					5					6				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	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
Temperature conditioned	Inhalation	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
		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
	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
Temperature conditioned	Flow rate(l/min)		7					8					9				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	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
Temperature conditioned	Inhalation	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
		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
	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																			
<u>Clause 7.17.2 Breathing resistance</u> <u>Valved particle filtering half masks:</u> 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. <u>Valveless particle filtering half masks:</u> 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.																			
<u>Clause 7.17.3 Penetration of filter material</u> All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements. <table border="1"> <thead> <tr> <th rowspan="3">Classification</th><th colspan="2">Maximum penetration of test aerosol</th></tr> <tr> <th>Sodium chloride test 95 l/min</th><th>Paraffin oil test 95 l/min</th></tr> <tr> <th>%</th><th>%</th></tr> </thead> <tbody> <tr> <td></td><td>max.</td><td>max.</td></tr> <tr> <td>FFP1</td><td>20</td><td>20</td></tr> <tr> <td>FFP2</td><td>6</td><td>6</td></tr> <tr> <td>FFP3</td><td>1</td><td>1</td></tr> </tbody> </table>	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	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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Test Report

SL52035261134901TX

Date: July 13, 2020

Page 1 of 5

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

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

Sample Description : (A)Medical face mask

Sample Color : (A)White

Roll/ Lot No. : FR20200517

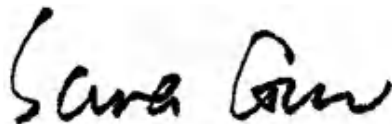
Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Jun 23, 2020

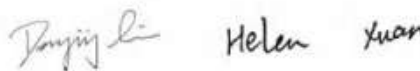
Testing Period : Jun 22, 2020 - Jul 13, 2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

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



Sara Guo (Account Executive)



Dongjing Liu / Hailian Xuan (Authorized Signatory)

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Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods**Clause 5.2 Performance Requirement****Clause 5.2.2 Bacterial Filtration Efficiency (BFE)**

(EN 14683:2019+AC:2019 Annex B)

Sample: A

Test Side : Inside
 Test Area : Approximately 60 cm²
 Flow Rate : 28.3 L/min
 Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Dimensions of test specimen : 182 mm x 157 mm
 Positive Control Average : 247 CFU
 Negative Monitor Count : < 1 CFU
 Mean Particle Size : 3.0 ±0.3µm
 Test bacteria : Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Result
Bacterial Filtration Efficiency (BFE), %	1	99.9
	2	99.9
	3	99.9
	4	99.9
	5	99.9

Remark:

- 1) Performance Requirement: Type I ≥95%, Type II ≥98%, Type IIR ≥98%
- 2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.



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Clause 5.2.3 Breathability

(EN 14683 :2019+AC:2019 Annex C)

Sample: A

Test Side : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks

Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.

Test Area : 4.9 cm²

Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm ²)	The average value for each test specimen (Pa/cm ²)
1	1-1	58.9	55
	1-2	51.2	
	1-3	52.9	
	1-4	57.2	
	1-5	52.7	
2	2-1	55.0	57
	2-2	56.7	
	2-3	57.0	
	2-4	54.8	
	2-5	59.8	
3	3-1	57.9	56
	3-2	53.6	
	3-3	49.8	
	3-4	59.6	
	3-5	59.0	
4	4-1	56.8	56
	4-2	55.4	
	4-3	50.5	
	4-4	59.9	
	4-5	58.1	
5	5-1	55.3	56
	5-2	55.0	
	5-3	53.0	
	5-4	59.8	
	5-5	57.4	

Remark:

- 1) Performance Requirement: Type I<40 Pa/cm², Type II<40 Pa/cm², Type IIR<60 Pa/cm²
- 2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.



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Clause 5.2.4 Splash Resistance

(ISO 22609 :2004)

Sample: A

Test Blood Pressure

: 16.0kPa

Pre-Conditioning

: Minimum of 4 hours at 21±5°C and 85±5% R.H.

Distance of the mask to the tip of cannula

: 300±10mm

Target plate method used

: No

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	None Seen	Pass
4	None Seen	Pass	20	None Seen	Pass
5	None Seen	Pass	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	None Seen	Pass
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	Pass
Number of Pass:		32			
Overall result:		Acceptable			

Remark:

- 1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
- 2) Test was conducted within 60s after removal from conditioning chamber.
- 3) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results.

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3rd Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233

t (86-21) 61402666

f (86-21) 64958763

www.sgs.com.cn

中国·上海·徐汇区宜山路889号3号楼 邮编: 200233

t (86-21) 61402666

f (86-21) 64958763

e sgs.china@sgs.com

Clause 5.2.5 Microbial Cleanliness

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

Sample: A

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

Remark: Performance Requirement: Type I ≤ 30 CFU/g, Type II ≤ 30 CFU/g, Type IIR ≤ 30 CFU/g

Sample Photo

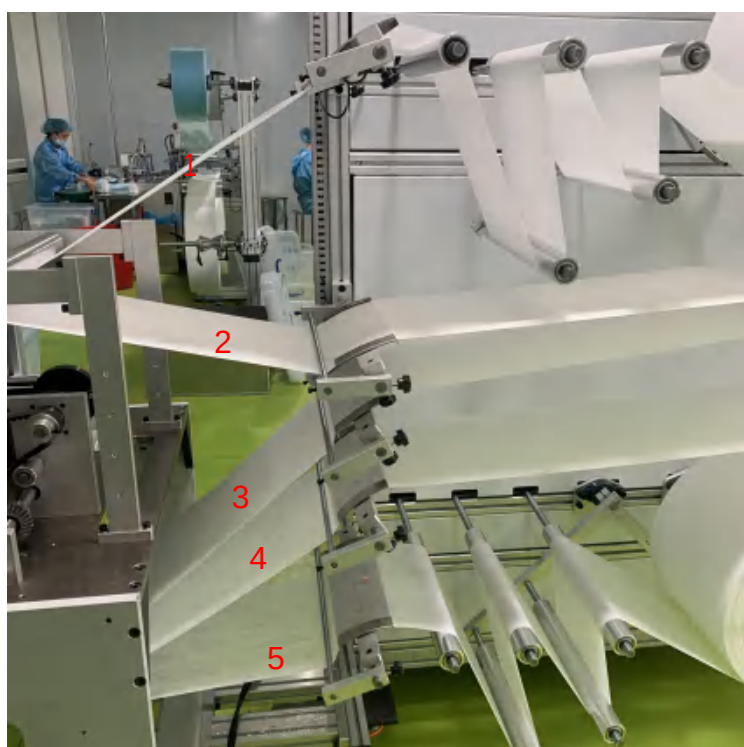
The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report



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 中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t: (86-21) 61402666 f: (86-21) 64958763 e: sgs.china@sgs.com



THE END

