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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White list of Chamber Commerce

EU DECLARATION OF CONFORMITY

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

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

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

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

May 22,2020

EU Type Examination Certificate

This is to certify that:

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

Holds Certificate Number: CE 728105

In respect of:

Model MP9011 Particulate Respirator.
To technical specification Annex II (EHSR) of the PPE Regulation (EU) 2016/425
PPE for use by healthcare professionals as per Commission recommendation 2020/403.

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

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

Drs. Dave Hagenaars, Managing Director

Previous Notified Body: BSI 0086

First Issued: 2020-06-01

Effective Date: 2020-06-01

Latest Issue: 2020-06-01

Expiry Date: 2021-06-01

PRODUCTS
RvA C 646

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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

EU Type Examination Certificate

No. CE 728105

Certificate Administration Details

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

Certificate Amendment Record:

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

Certificate validity

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

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

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

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

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

This is to certify that:

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

Holds Certificate Number: CE 728110

In respect of:

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

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

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

Drs. Dave Hagenaars, Managing Director

Previous Notified Body: BSI 0086

First Issued: 2020-06-01

Effective Date: 2020-06-01

Latest Issue: 2020-06-01

Expiry Date: 2021-06-01

PRODUCTS
RvA C 646

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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

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

No. CE 728110

Certificate Administration Details:

Certificate Amendment Record and BSI internal Review relating to this Certificate

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

Certificate validity

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

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

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

Test Report 3201467.

Xiamen Probtain Nonwoven Inc.

Introduction.

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

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

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

Approved For Issue	
	Issue Date: 20 May 2020

Objectives.

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

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

Product Scope.

COVID-19 masks for use by healthcare workers

Report Summary.

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

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

Test Samples.

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

Description of Test Samples.

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

Test Requirements.

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

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

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

Glossary of Terms.

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

Conditions of Issue.

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

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

BSI
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Hertfordshire
HP2 4SQ

UKAS TESTING
0135

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

Test Results.

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

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

CLAUSE	REQUIREMENTS	ASSESSMENT
7.7	**Practical performance** The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections. Test in accordance with clause 8.4 of the standard. ***Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers*** *During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded:* *a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.*	Pass

Table A: Practical performance

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

7.9	**Leakage**	
7.9.1	Total inward leakage The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected. The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration. Test in accordance with clause 8.5 of the standard. ***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).*	Pass

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
7.9.2	Penetration of filter material ***Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers*** *3 test samples masks tested 'As received', for NaCl (Sodium Chloride) and PO (Paraffin oil), 3 min test. Testing shall be done in accordance with 8.11. 6% limit for both PO and NaCl*	Pass

Table C: Clause 8.11 - Sodium Chloride penetration test

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

Table D: Clause 8.11 - Paraffin oil penetration test

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

7.12	**Carbon dioxide content of inhalation air** The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0% (by volume). Test in accordance with clause 8.7 of the standard.	Pass

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

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

Test Results. (Continued)

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

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

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

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

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

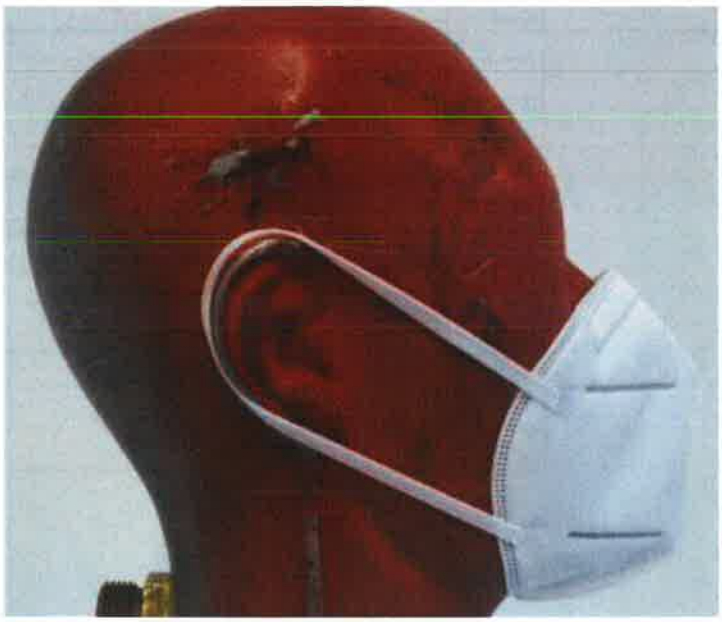
Appendix A. – Test Panel Data

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

Note: All candidates were clean shaven

Product photographs.

Front view



Side View

Inside View

End of Report

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)

Test Result

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

EN 149:2001+A1:2009

Clause 7.4 Packaging
(EN 149:2001+A1:2009 Clause 8.2)

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

Clause 7.5 Material
(EN 149:2001+A1:2009, Clause 8.2 & 8.3.1 & 8.3.2)

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

Clause 7.6 Cleaning and Disinfecting
(EN 149:2001+A1:2009, Clause 8.4 & 8.5 & 8.11)

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

Clause 7.7 Practical Performance
(EN 149:2001+A1:2009, Clause 8.4)

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

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

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

Clause 7.9.1 Total Inward Leakage
(EN 149:2001+A1:2009, Clause 8.5)

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

Appendix 1: Summarization of Test Data

Inward Leakage Test Data

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

Facial Dimension(mm)

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

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Liu	120	135	117	50
Ye	126	137	105	52

Clause 7.9.2 Penetration of Filter Material

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

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

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

Appendix 2: Summarization of Test Data

Penetration of filter material

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

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Clause 7.10 Compatibility with Skin

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

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

Clause 7.11 Flammability

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

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

Appendix 3: Summarization of Test Data

Flammability

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

Clause 7.12 Carbon Dioxide Content of The Inhalation Air

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

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

Appendix 4: Summarization of Test Data

Carbon Dioxide Content of The Inhalation Air

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

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

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

Clause 7.14 Field of Vision
(EN 149:2001+A1:2009, Clause 8.4)

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

Clause 7.15 Exhalation Valve(s)
(EN 149:2001+A1:2009, Clause 8.2 & 8.9.1 & 8.3.4 & 8.8)

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

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Clause 7.16 Breathing Resistance

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

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

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

Appendix 5: Summarization of Test Data

Breathing resistance (mbar)

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

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

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Clause 7.17 Clogging

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

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

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

Clause 7.18 Demountable Parts

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

Test Requirement	Results	Comment
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand	No demountable parts	N.A.

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

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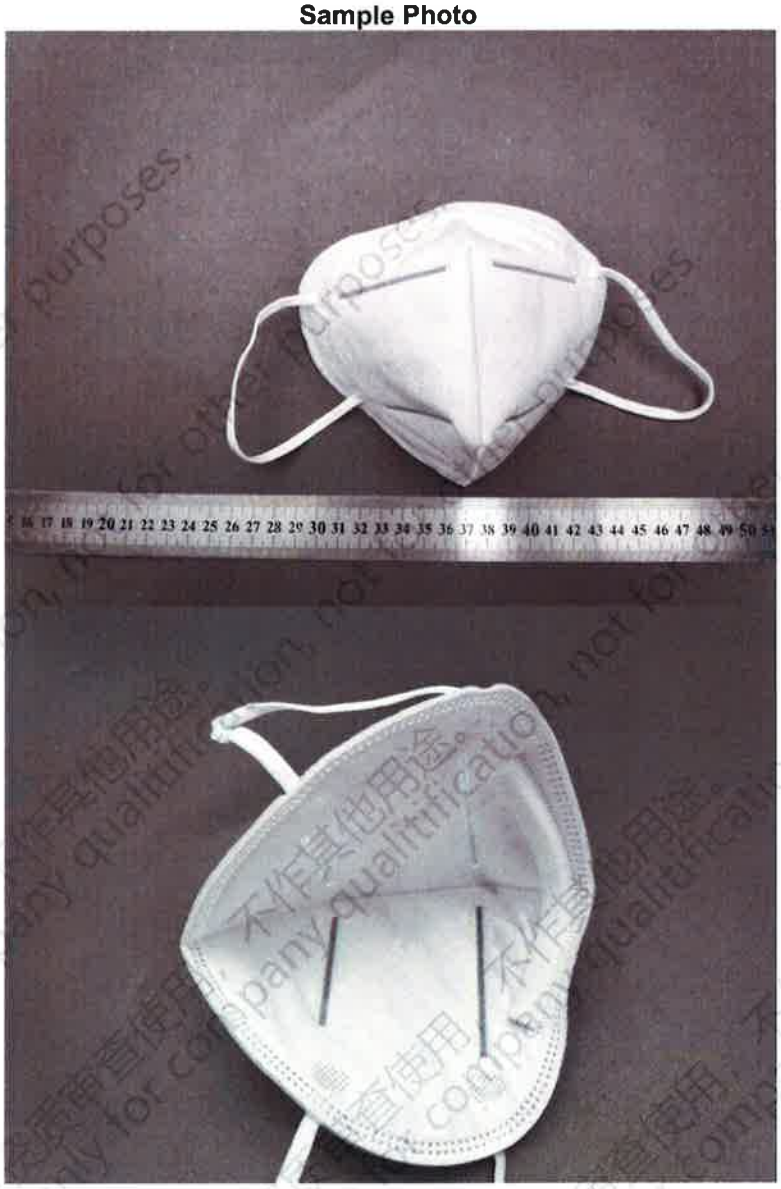
Sample Photo



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Test Report **SL52035261134901TX** **Date:July 13,2020**

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

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

Sample Description	:	(A)Medical face mask
Sample Color	:	(A)White
Roll/ Lot No.	:	FR20200517
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Jun 23, 2020
Testing Period	:	Jun 22, 2020 - Jul 13, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

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

Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)

Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods

Clause 5.2 Performance Requirement

Clause 5.2.2 Bacterial Filtration Efficiency (BFE)
(EN 14683:2019+AC:2019 Annex B)

Sample: A

Test Side	:	Inside
Test Area	:	Approximately 60 cm^2
Flow Rate	:	28.3 L/min
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	182 mm x 157 mm
Positive Control Average	:	247 CFU
Negative Monitor Count	:	< 1 CFU
Mean Particle Size	:	3.0 ±0.3μm
Test bacteria	:	Staphylococcus aureus ATCC 6538

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

Remark:

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

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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 cm^2
Flow Rate : 8 l/min

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

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

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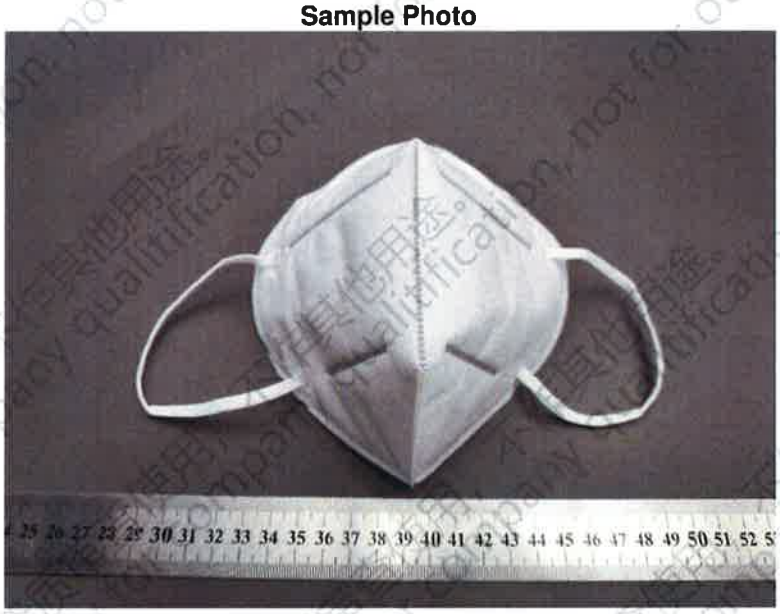
Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

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.

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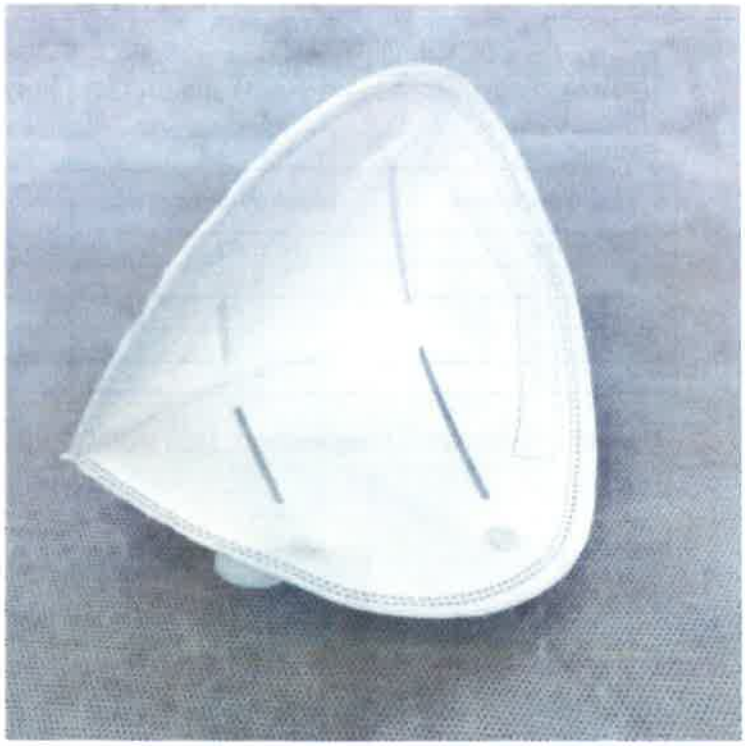

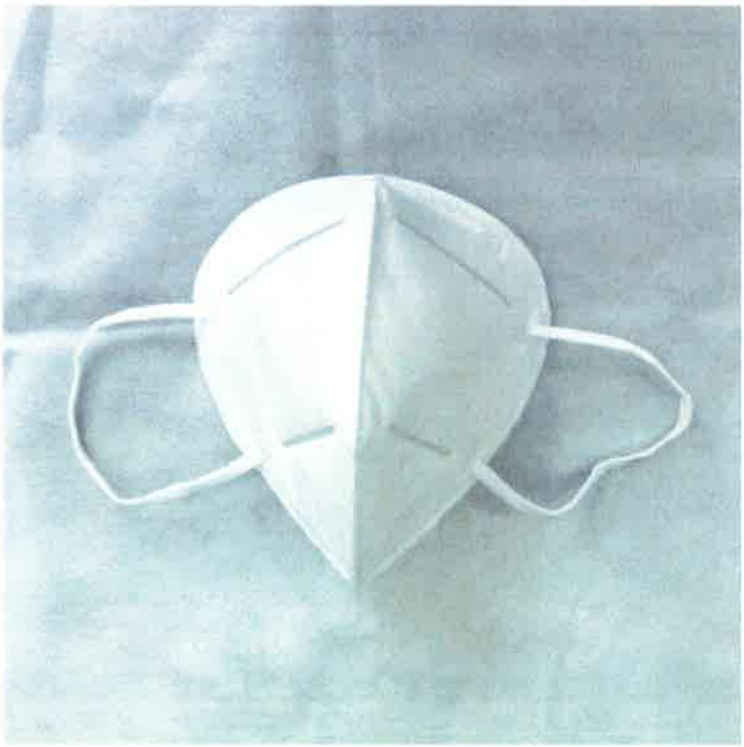

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