CE Test Report

Test Report No. :AS20032301PPE

Type / Model Name	:	**Folding Type 16.5cm*10cm (±1cm)**
Filter Grade	:	**FFP2**
Product Name	:	**KN95 mask (external bridge of nose)**
Applicant	:	**GUIZHOU BOCAI MEDICAL DEVICES CO., LTD.**

P P E -- T E S T R E P O R T

Test Report No. : AS20032301PPE	10-Apr.-2020 Date of issue

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Filter Grade : FFP2

Product Name : KN95 mask (external bridge of nose)

Applicant : GUIZHOU BOCAI MEDICAL DEVICES CO., LTD.

Address : 4 / F, Building 24, Intelligent terminal (mobile phone) Industrial Park, Intersection of Huaxia Avenue and Donghai Road, Zhengzhou Airport Economic Comprehensive Experimental Zone, China

Manufacturer : GUIZHOU BOCAI MEDICAL DEVICES CO., LTD.

Address : 4 / F, Building 24, Intelligent terminal (mobile phone) Industrial Park, Intersection of Huaxia Avenue and Donghai Road, Zhengzhou Airport Economic Comprehensive Experimental Zone, China

Prepared By : Shenzhen AS Technology Co., Ltd.

Address : Building A3,Digital Technology Park, Gao Xin South 7# Road High-Tech Industrial Park,Nanshan District, Shenzhen,China

Test Result according to the standards listed in clause 1 test standards:	**POSITIVE**

The test report merely corresponds to the test sample.
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1 TEST STANDARDS

The tests were performed according to following standards:

EN 149:2001+A1:2009	Respiratory protective devices-Filtering half masks to protect against Particles-Requirements, testing, marking

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2 SUMMARY

GENERAL REMARKS:

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Masks (sanitary products used to filter the air entering the nose and mouth)

Mask is a kind of sanitary product, which is generally used to filter the air entering the mouth and nose by wearing it on the mouth and nose, so as to block harmful gases, smells and droplets from entering and leaving the mouth and nose of the wearer. It is made of gauze or paper, etc.

Masks have a certain filtering effect on the air entering the lungs. When respiratory infectious diseases are prevalent, and when working in dust and other polluted environment, wearing masks has a very good effect.

FINAL ASSESSMENT:

Suction protection device, anti-debris filter half mask, tested in full compliance with EN149:2001+A1:2009 standard requirements.

Date of receipt of test sample	:	02-04-2020
Testing commenced on	:	02-04-2020
Testing concluded on	:	10-04-2020

Tested By:

Antany/ Engineer
10-04-2020

Approved By:

Davis/Technical Manager
10-04-2020

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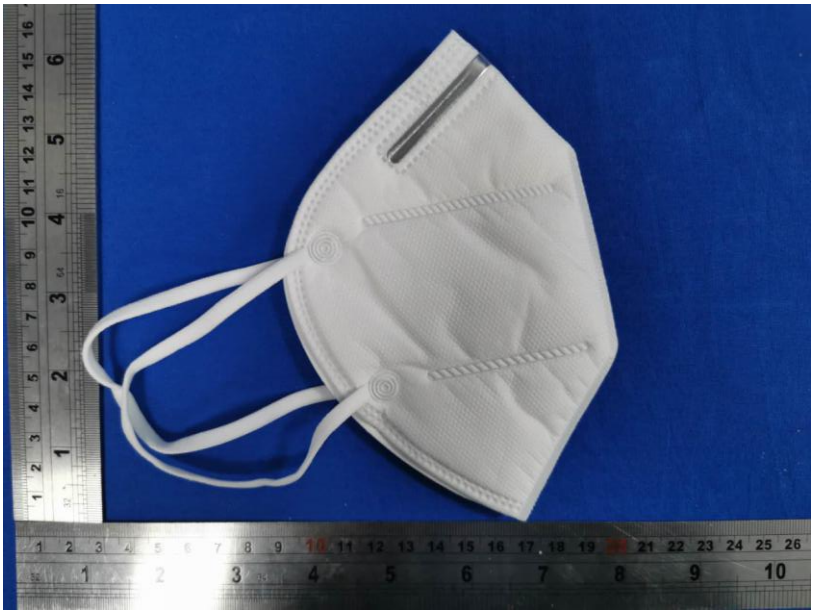
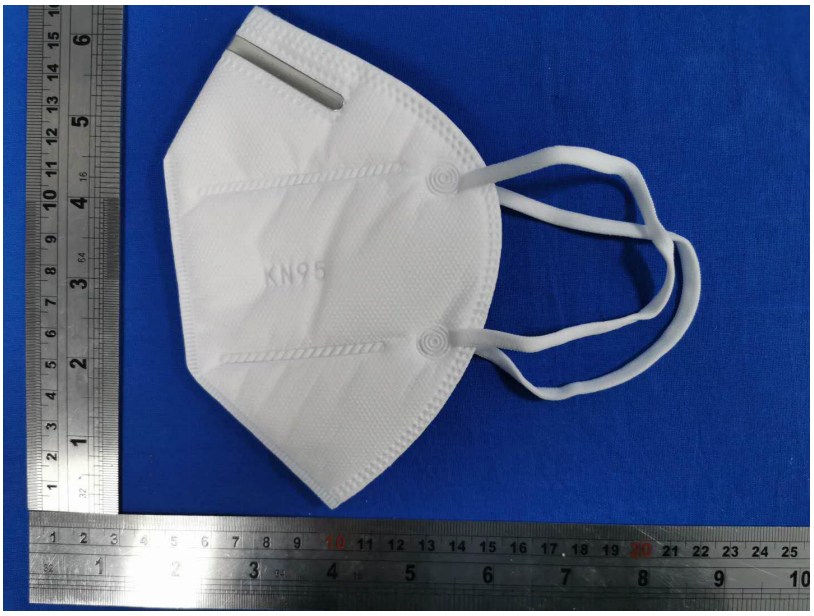
3 PRODUCT UNDER TEST

3.1 Photo documentation of the Product





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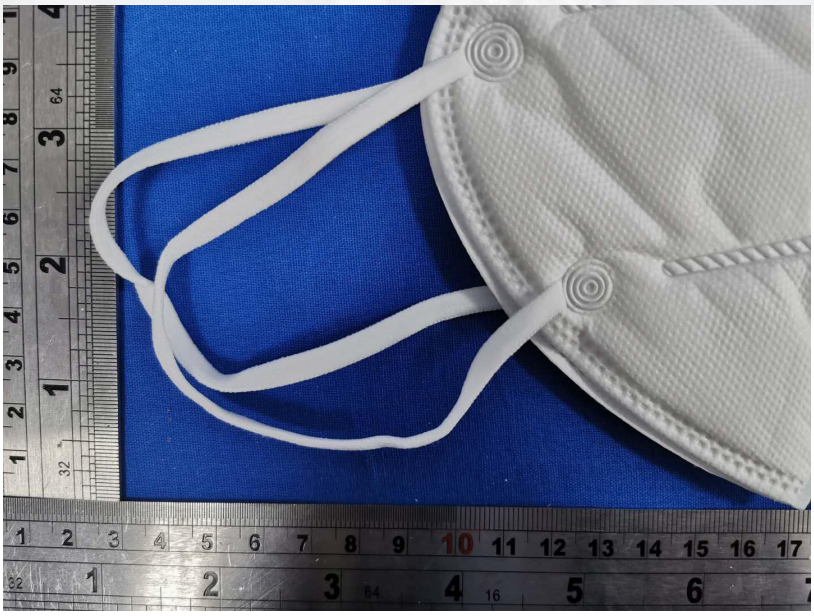

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3.2 Correlation parameter

FFP1 type mask: minimum filtering effect 80%

FFP2 type mask: minimum filtering effect 94%

FFP3 type mask: minimum filtering effect 99%

Medical or not

Masks are divided into medical masks and non-medical masks.

Item classification edit

N series: no time limit for protection of non oil suspended particles

R Series: eight hours for protection of non oil and sweat oil suspended particles

P Series: no time limit for the protection of non oil suspension particles and sweat oil suspension particles

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4 TEST ENVIRONMENT

4.1 Address of the test laboratory

Shenzhen AS Technology Co., Ltd.
Building A3,Digital Technology Park, Gao Xin South 7# Road
High-Tech Industrial Park,Nanshan District, Shenzhen,
P.R.China. P.C. 518000

Subcontractor: NIL

4.2 Environmental conditions

During the measurement the environmental conditions were within the listed ranges:

Temperature:	20-25 ° C
Humidity:	55-60 %
Atmospheric pressure:	100-106 kPa

5 TEST CONDITIONS AND RESULTS

Possible test case verdicts:

- test case does not apply to the test object.....N(Not apply)

- test object does meet the requirement.....P(Pass)

- test object does not meet the requirement.....F(Fail)

Copy of marking plate:

KN95 mask (external bridge of nose)

Model: Folding Type 16.5cm*10cm (±1cm)

Standard: EN149:2001+A1:2009

GUIZHOU BOCAI MEDICAL DEVICES CO., LTD.

Made in China

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EN 149:2001+A1:2009			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
5	**Classification**		--
	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage.There are three classes of devices:		P
	- FFP1		N
	- FFP2	>95%	P
	- FFP3		N

6	Designation		--
	Particle filtering half masks meeting the requirements of this European Standard. Year of publication, classification, option	Particle filtering half mask EN149:2001+A1:2009 FFP2 NR.	P

7	Requirements		--
7.1	General		P
	All test samples shall meet the requirements.	Compled the requirement, see bellow	P
7.2	Nominal values and tolerances		P
	Unless otherwise specified, the values stated in this European Standard are experature limits.		P
7.3	Visualin spection		P
	The visual inspection shall also include the marking and the information supplied by the manufacturer.	Clear marking is provided, see sample body	P
7.4	Packaging		P
	Particle filtering half masks shall be offered for sale packaged in such away that they are protected against mechanical damage and contamination before use.	Comfortable wearing,when releasing no hazards is produced.	P
7.6	Cleaning and disinfecting		N
	If the particle filtering half mask is designed to be re-usable,the materials used shall with stand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.	It’s not re-usable.	N
7.7	Practical performance		P
	The particle filtering half mask shall undergo practical performance tests under realistic conditions.	Complied,see append test	P

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EN 149:2001+A1:2009			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
7.8	Finishofparts		P
	comeintocontactwiththewearershallhavenoshar pedgesorburrs		P
7.9	Leakage	Seeappendtable8.5	P
7.9.1	Total inward leakage		P
	The laboratory tests shall wearer to protect with high probability against the potential hazard to be expected.	Enough safe condition is Provide.	P
	Exercise results for total inward leakage shall be not greater than		P
	25％ for FFP1 11％ for FFP2 5％ for FFP3	FFP2, Not exceed 11%	P
	And,inaddition,at least 8 out of the10 individual wearer arithmetic means for the total inward leakage shall be not greater than.		P
	22% for FFP1 8% for FFP2 2% for FFP3.	FFP2, Not exceed 8%	P
7.9.2	Penetration of filtermaterial		P
	The penetration of the filter of the particle filtering half mask shall meet the requirements of Table1.	See append table 7.92	P
7.10	Compatibility with shin		P
	Materials that may comein to contact with the wearer’s skin shall not be known to be likely to cause irritation or any other adverse effect to health.		P
7.11	Flammability		P
	The material used shall not present a danger for the wearer and shall not be of highly flammable nature.		P
7.12	Carbon dioxide content of the inhalation air		P
	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0% (by volume).		P
7.13	Head harness		P
	Head harness shall be designed can be donned and removed easily and adjustable or self adjusting and sufficiently robust to hold the particle.	Head harness is donned and removed easily	P

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EN 149:2001+A1:2009			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
7.14	Field of vision		P
	Field of vision is acceptable in practical performance tests.	Clear field of vsion when wearing	P
7.15	Exhalation valve(s)		N
	A particle filtering half mask may have one or more exhalation valve(s) and shall function correctly in all orientations.	One valve provided	N
	Exhalation valve is provided it shall be protected against or be resistant to dirtandme chanical damage and may be shrouded or may include any other device.	Clearly function	N
	Exhalation valve(s) shall continue to operate correctly after a continuous exhalation flow of 300l/min over a period of 30s.		N
	Exhalation valve housing is attached to the face blank,and withstand axially a tensile force of 10N applied for 10s.		N
7.16	Breathing resistance		P
	Breathing resistances apply to valved and valve less and shall meet the requirements.		P
7.17	Clogging		N
	General		N
	Forsingle-use devices clogging test is an optional test.		N
	Devices designed to be resistant to clogging, shown by a slow increase		N
	The specified breathing resistances shall not be exceeded before the required dust load of 833mg.h/m³.		N
7.17.2	Breathing resistance		N
7.17.2.1	Valved particle filtering half masks		N
7.17.2.2	Valveless particle filtering half masks		N
7.17.3	Penetration of filter materia		N
	All types claimed to meet the clogging requirement shall also meet the penetration requirements given in 7.9.2 after the treatment.		N
7.18	Demount able parts		N
	All demount able parts (if fitted) shall be readily connected and secured, where possible by hand.	No such demount able part	N
8	Testing		--

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EN 149:2001+A1:2009			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.1	General		P
	No special measuring devices and methods are specified, commonly used devices and methods shall be used.		P
8.2	Visual inspection		P
	The visual inspection is carried out appropriate by the test house prior to laboratory or practical performance tests.		P
8.3	Conditioning		P
8.3.1	Simulated wearing treatment		P
	A breathing machine is adjusted to 25 cycles/min and 2.0l/stroke.	25cycles/min 2.0l/stroke.	P
	For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head,	A saturator incorporated by breathing machine and the dummy head.	P
	The spilling out of the dummy's mouth and contaminating the particle filtering half mask the head shall be incline	Incline considered	P
8.3.2	Temperature conditioning		P
	Exposet masks to the following thermal cycle:		P
	a) For 24h to a dry atmosphere of (70±3)℃;		P
	b) For 24h to a temperature of (-30±3)℃;		P
	Allow to return to room temperature for at least 4h between exposures and prior to subsequent testing.	5h to paid for	P
8.3.4	Flow conditioning		P
	A total of 3 valved particle filtering half masks shall be tested, one as received and two temperature conditioned in accordance with 8.3.2.		P
9	Marking		--
9.1	Packaging		P
	The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.	Complied,clearly marked	P
9.1.1	The name, trademark or other means of identification of the manufacturer or supplier.	GUIZHOU BOCAI MEDICAL DEVICES CO., LTD.	P
9.1.2	Type-identifying marking.		P
9.1.3	Classification:FFP1,FFP2,FFP3.	FFP2 NR	P

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EN 149:2001+A1:2009			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
9.1.4	The number and year of publication of this European Standard.		P
9.1.5	At least they ear of end of shelf life.		P
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 pictogram as shown in Figure12b.		P
9.1.7	The manufacturer’ s recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures12c and 12d.	See product manual	P
9.1.8	The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D".		N
9.2	Particle filtering half mask		P
	Particle filtering half masks complying with this European Standards hall be clearly and durably marked with the following:		P
9.2.1	The name,trademark or other means of identification of the manufacturer or supplier.	GUIZHOU BOCAI MEDICAL DEVICES CO., LTD.	P
9.2.2	Type-identifying marking.		P
9.2.3	The number and year of publication of this European Standard.		P
9.2.4	The symbols FFP1,FFP2 or FFP3 according to class.	FFP2 NR	P
9.2.5	If appropriate the letter D (dolomite) in accordance with clogging performance.This letter shall follow the class designation (see 9.2.4).		N
9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.		N

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6 Attachments: Test table

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

Table 1 — Penetration of filter material

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

Table7.9.2	Penetration of test aerosol test					P
Item \ Models	Sample1	Sample2	Sample3	Sample4	Sample5	Sample6
Sodium chloride test 95 l/min	5.6	5.6	5.7	5.6	5.5	5.6
Paraffin oil test 95 l/min	5.5	5.7	5.6	5.5	5.6	5.7

Table8.5	Leakage test					P
Item \ Models	Sample1	Sample2	Sample3	Sample4	Sample5	Sample6
NaCl flow rate (L/min)	90	100	120	110	120	100
NaCl aerosol (um)	0.3	0.3	0.3	0.3	0.3	0.3
0.3 Pumping flow rate (L/min)	30	30	30	30	30	30
NaCl concentration before mask (Mg/m3)	2	2	2	2	2	2
NaCl concentration after mask (Mg/m3)	0.6	0.8	0.6	0.7	0.6	0.7

Note:Test ark volume is 2m³

Average Leakage ratio is 8%<11%

Calculation formula as below:

$$P(\%) = \frac{C_2}{C_1} \times \left(\frac{t_{IN} + t_{EX}}{t_{IN}} \right) \times 100$$

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Table 8.9.2	Exhalation resistance test					P
Item \ Models	Sample1	Sample2	Sample3	Sample4	Sample5	Sample6
Inhalation gas velocity(L/min)	160	160	160	160	160	160
Maximum resistance(mbar)	2.45	2.46	2.47	2.45	2.46	2.45
Conclusion: Maximum permitted resistance <3.0 mbar						

Table 8.9.3	Inhalation resistance test					P
Item \ Models	Sample1	Sample2	Sample3	Sample4	Sample5	Sample6
Inhalation gas velocity(L/min)	30	30	30	30	30	30
Maximum resistance (mbar)	0.42	0.43	0.45	0.43	0.42	0.43
Conclusion: Maximum Inhalation resistance <0.7 mbar						

Table 8.9.3.2	Inhalation resistance test					P
Item \ Models	Sample1	Sample2	Sample3	Sample4	Sample5	Sample6
Inhalation (L/min)	95	95	95	95	95	95
Maximum resistance (mbar)	2.12	2.14	2.14	2.13	2.12	2.13
Conclusion: Maximum Inhalation resistance <2.4 mbar						

-----End of Test Report------

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