



APPLICATION FOR TEST REPORT

On Behalf of

Prepared For : Shenzhen Qingxin Medical Equipment Biotechnology Co., Ltd.
4/F YAHUA LANE NO.5, QINGSHUI ROAD, LONGGANG STREET,
LONGGANG DISTRICT, SHENZHEN

Product Name : FFP2 / FFP3 Personal non-woven face masks
Model : FFP2 N95, FFP1 01, FFP2 01, FFP2 N95V, FFP3 N95, FFP2 KN95

Prepared By : Shenzhen CTO Technology Service Co., Ltd
9/F, Block B, 196 Tangtou Avenue, Langxin Community, shiyan Street,
Baoan District, Shenzhen, China

Test Date : Mar. 02, 2020 to Mar. 23, 2020
Date of Report : Mar. 24, 2020
Report No. : CTO200328025GRS

TEST REPORT EN 149 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking	
Report Reference No.....	CTO200328025GRS
Compiled by (+ signature).....	Gary hu
Approved by (+ signature).....	Mike Wang
Date of issue.....	Mar. 24, 2020
Testing Laboratory	Shenzhen CTO Technology Service Co., Ltd
Address.....	9/F, Block B, 196 Tangtou Avenue, Langxin Community, shiyan Street, Baoan District, Shenzhen, China
Applicant's name	Shenzhen Qingxin Medical Equipment Biotechnology Co., Ltd.
Address.....	4/F YAHUA LANE NO.5, QINGSHUI ROAD, LONGGANG STREET, LONGGANG DISTRICT, SHENZHEN
Test specification:	
Standard.....	EN 149:2001+A1:2009
Non-standard test method.....	N/A
Test item description.....	FFP2 / FFP3 Personal non-woven face masks
Trade Mark.....	N/A
Model/Type reference.....	FFP2 N95, FFP1 01, FFP2 01, FFP2 N95V, FFP3 N95, FFP2 KN95
Manufacturer.....	Shenzhen Qingxin Medical Equipment Biotechnology Co., Ltd.
Address.....	4/F YAHUA LANE NO.5, QINGSHUI ROAD, LONGGANG STREET, LONGGANG DISTRICT, SHENZHEN
Classification	FFP2 NR



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)

Testing

Date of receipt of test item Mar. 01, 2020

Date(s) of performance of tests Mar. 02, 2020 to Mar. 23, 2020

General remarks:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.
“(See Enclosure #)” refers to additional information appended to the report.
“(See appended table)” refers to a table appended to the report.

General product information:

The all models are same except their model number, and all tests are based on FFP2 N95

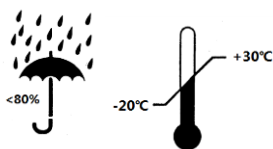
Copy of marking plate:**Packaging:**

FFP2 /FFP3 Personal non-woven face masks

Model: FFP2 N95

Classification: FFP2 NR

Standard: EN 149:2001+A1:2009

Shenzhen Qingxin Medical Equipment Biotechnology Co., Ltd.
End of shelf life:YYYY/MM**Made in China**

Marking shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent

Particle filtering half mask:

FFP2 /FFP3 Personal non-woven face masks

Model: FFP2 N95

Classification: FFP2 NR

Standard: EN 149:2001+A1:2009



Shenzhen Qingxin Medical Equipment Biotechnology Co., Ltd.

EN149			
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		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 EN 149:2001+A1:2009 FFP2 NR	P

7	Requirements		--
7.1	General		P
	All test 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 exeperature limits.		P
7.3	Visual inspection		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 a way that they are protected against mechanical damage and contamination before use.	Testing in accordance with 8.2	P
7.5	Material		P
	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. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	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 withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.	It's is not re-usable.	N
7.7	Practical performance		P
	The particle filtering half mask shall undergo practical performance tests under realistic conditions.	Complied, Testing in accordance with 8.4.	P
7.8	Finish of parts		P
	come into contact with the wearer shall have no sharp edges or burrs	Testing in accordance with 8.2	P
7.9	Leakage	See append table 8.5	P
7.9.1	Total inward leakage		P

EN149			
Clause	Requirement – Test	Result - Remark	Verdict
	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, 7.1% Not exceed 11%	P
	And, in addition, at least 8 out of the 10 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, 5.2% Not exceed 8%	P
7.9.2	Penetration of filter material		P
	The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.	see table 7.9.2	P
7.10	Compatibility with shin		P
	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.		P
7.11	Flammability		P
	The material used shall not present a danger for the wearer and shall not be of highly flammable nature.	Testing in accordance with cl 8.6	P
7.12	Carbon dioxide content of the inhalation air	Testing in accordance with cl 8.7	P
	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0% (by volume).	<1.0%	P
7.13	Head harness	Testing in accordance with cl 8.4 and cl 8.5	P
	Head harness shall be designed can be donned and removed easily and adjustable or selfadjusting and sufficiently robust to hold the particle.	Head harness is donned and removed easily	P
7.14	Field of vision	Testing in accordance with cl 8.4	P
	Field of vision is acceptable in practical performance tests.	Clear field of vision when wearing	P
7.15	Exhalation valve(s)	No Exhalation valve	N
	A particle filtering half mask may have one or more exhalation valve(s) and shall function correctly in all orientations.		N
	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.		N
	Exhalation valve(s) shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.		N
	Exhalation valve housing is attached to the faceblank, and withstand axially a tensile force of 10 N applied for 10 s.		N
7.16	Breathing resistance	Testing in accordance with cl 8.9	P
	Ereathing resistances apply to valved and valveless and shall meet the requirements.	see table 7.16	P
7.17	Clogging		N

EN149			
Clause	Requirement – Test	Result - Remark	Verdict
	General		N
	For single-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 833 mg·h/m ³ .		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	Demountable parts		N
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	No such demountable part	N

8	Testing		--
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 2,0 l/stroke.	25 cycles/min 2,0 l/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 24 h to a dry atmosphere of (70 ± 3) °C;	71.5°C	P
	b) for 24 h to a temperature of (-30 ± 3) °C;	-30.9°C	P
	Allow to return to room temperature for at least 4 h 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

EN149			
Clause	Requirement – Test	Result - Remark	Verdict
	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.		P
9.1.2	Type-identifying marking.		P
9.1.3	Classification: FFP1, FFP2, FFP3.		P
	"NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or	FFP2 NR	P
	"R" if the particle filtering half mask is re-usable. Example: FFP2 R D		N
9.1.4	The number and year of publication of this European Standard.	EN 149:2001+A1:2009	P
9.1.5	At least the year of end of shelf life.	End of shelf life:YYYY/MM	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 Figure 12b.		P
9.1.7	The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.		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 Standard shall 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.		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.		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
10	Information to be supplied by the manufacturer		P
10.1	Information supplied by the manufacturer shall accompany every smallest commercial available package		P
10.2	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination		P
10.3	The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on		P
	- application/limitations		P
	the meaning of any colour coding		P

EN149			
Clause	Requirement – Test	Result - Remark	Verdict
	checks prior to use		P
	donning, fitting		P
	use		P
	maintenance (e.g. cleaning, disinfecting), if applicable		N
	storage		P
	the meaning of any symbols/pictograms used		P
10.4	The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.		P
10.5	Warning shall be given against problems likely to be encountered, for example:		P
	fit of particle filtering half mask (check prior to use)		P
	it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal		P
	air quality (contaminants, oxygen deficiency)		P
	use of equipment in explosive atmosphere		N
10.6	The information shall provide recommendations as to when the particle filtering half mask shall be discarded.		P
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.		P

Attachments: Test table

Table 7.9.2	Penetration of test aerosol test									P
	3 samples as received			described in 8.3.1			described in 8.3.2 and 8.3.3			
Sodium chloride test 95 l/min	2.4%	1.9%	2.1%	3.0%	2.9%	2.9%	2.9%	3.1%	2.9 %	
Paraffin oil test 95 l/min	2.2%	2.2%	2.2%	3.1%	3.0%	3.0%	2.8%	3.0%	3.1%	

table 7.16	Maximum permitted resistance (mbar)			P
FFP2	inhalation		exhalation	
	30 l/min	95 l/min	160 l/min	
	0.7	2.4	3.0	

A total of 9 valveless particle filtering half masks shall be tested:
 3 as received, 3 after temperature conditioning in accordance with 8.3.2 and 3 after the test for simulated wearing in accordance with 8.3.1
 The above result is the Maximum value

ANNEX A: Photo-documentation



<p>Photo 1</p>	
<p>Photo 2</p>	

Photo 3

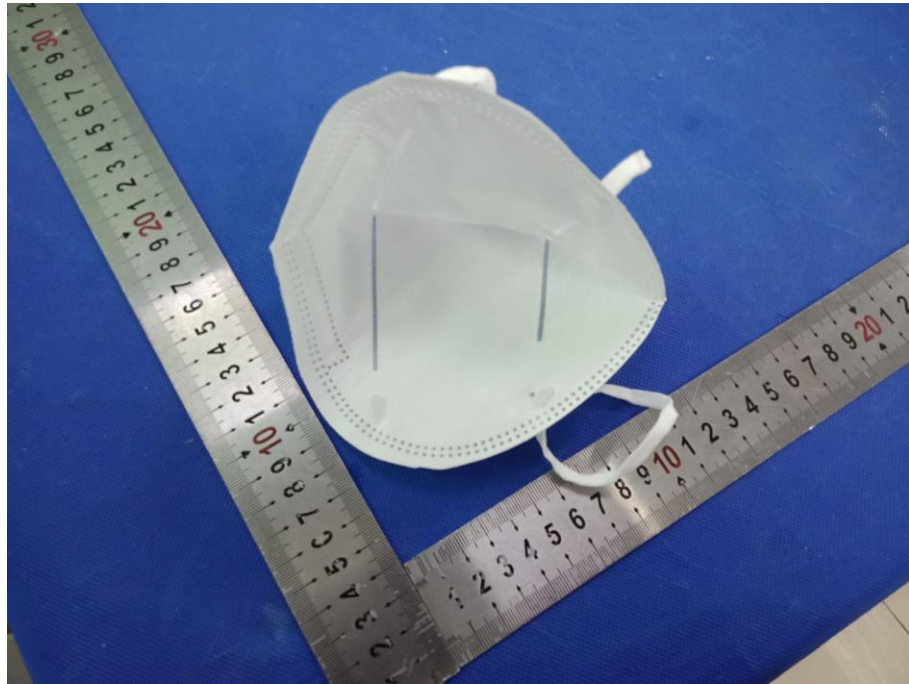


Photo 4

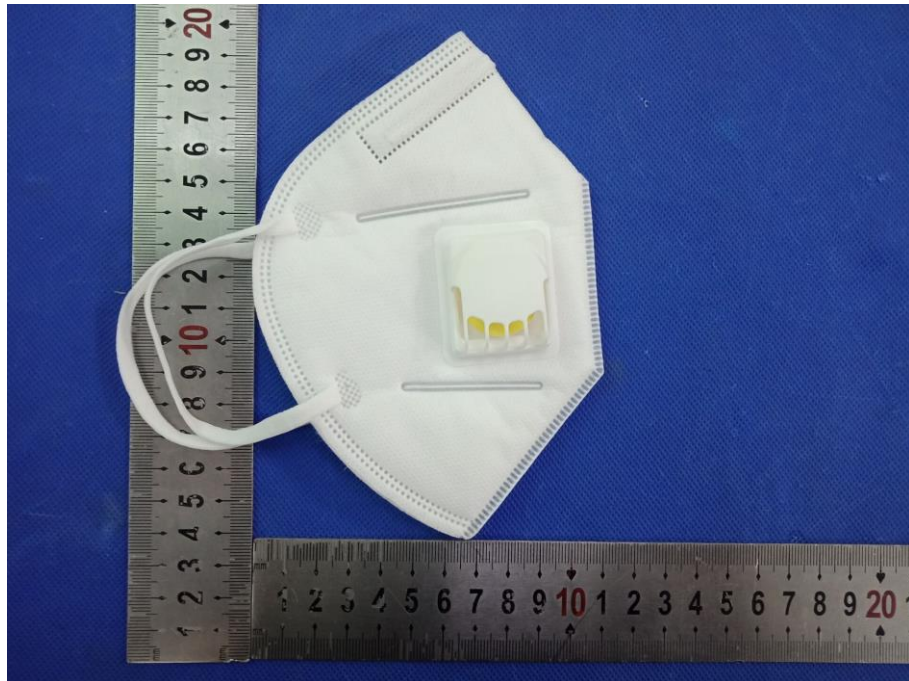


Photo 5



Photo 6

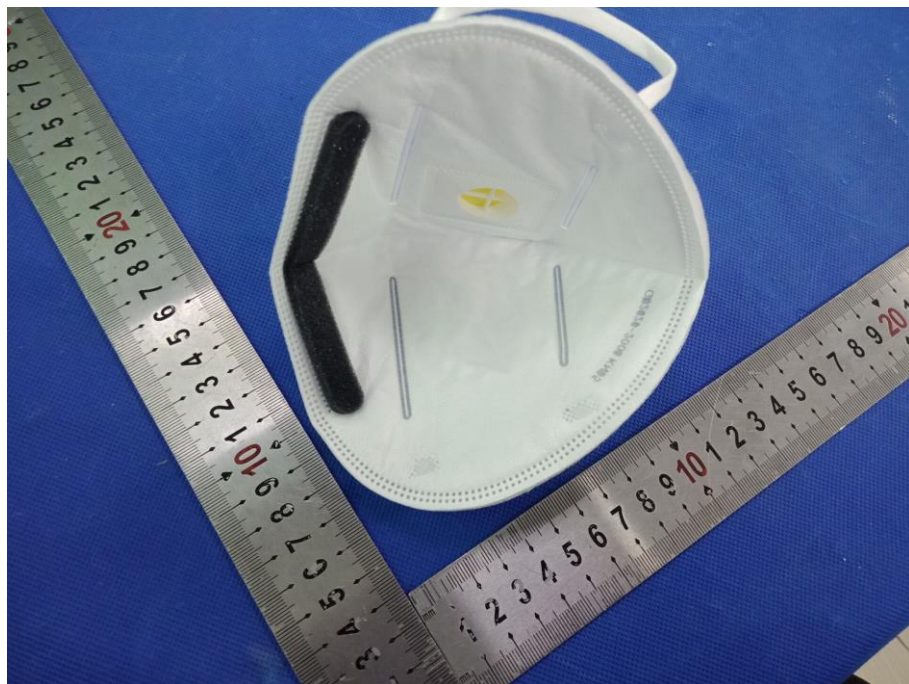


Photo 7



Photo 8



Photo 9

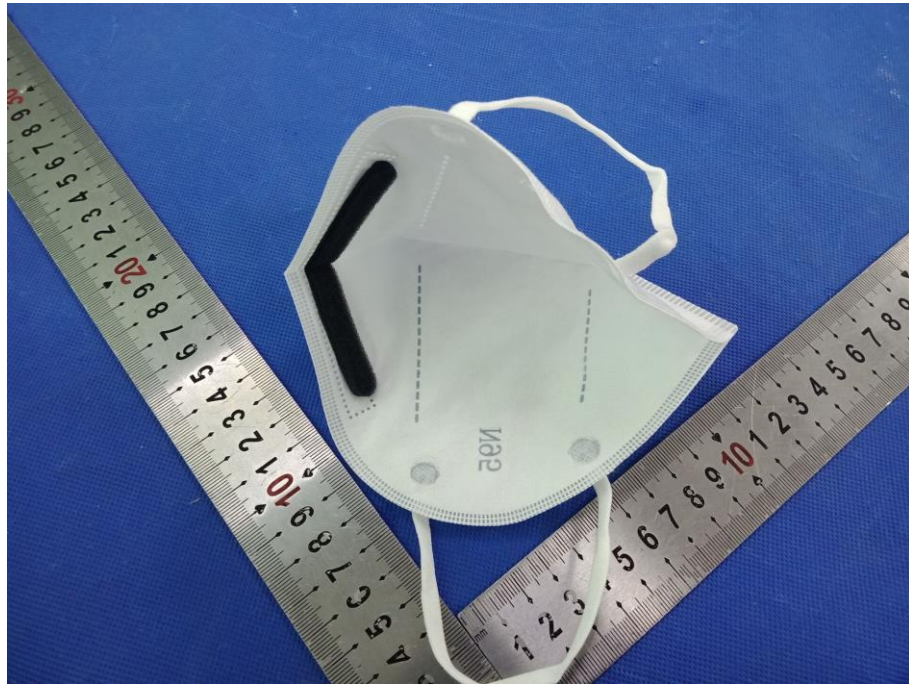
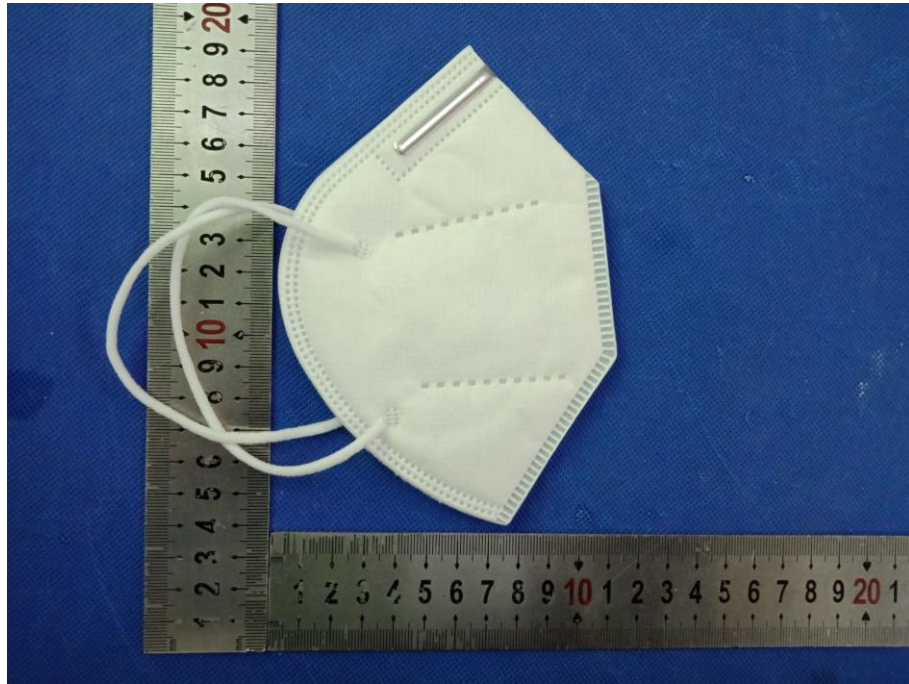


Photo 10



Photo 11



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