

PPE Report

ON BEHALF OF

FOSHAN NANHAI PLUS MEDICAL CO., LTD

Disposable Protective Face Mask

Main Model: VM-01

Prepared For : FOSHAN NANHAI PLUS MEDICAL CO., LTD
Shatou, Jiujiang Town,Nanhai District,Foshan
City,Guangdong,China

Prepared By : OCT TECHNOLOGY TESTING CO., LTD.
637,No. 56, zhongyun Road,Panyu
District,Guangzhou,Guangdong Province,China

Date Of Test : 2020,3.15-3.19

Date Of Issue : 2020,3.19

<p>PPE Report</p> <p>EN 149</p> <p>Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking</p>	
Testing laboratory	Oct Technology Testing Co., Ltd.
Address	637, No. 56, zhongyun Road, Panyu District, Guangzhou, Guangdong Province, China
Report body.....	Oct Technology Testing Co., Ltd.
Address	637, No. 56, zhongyun Road, Panyu District, Guangzhou, Guangdong Province, China
Applicant	FOSHAN NANHAI PLUS MEDICAL CO., LTD.
Address	Shatou, Jiujiang Town, Nanhai District, Foshan City, Guangdong, China
Standard	EN 149:2001+A1:2009
Test Result	Compliance with EN 149:2001+A1:2009
Procedure deviation	N.A.
Trade Mark.....	N.A.
Non-standard test method	N.A.
Type of test object	Disposable Protective Face Mask
Model/type reference	VM-01
Manufacturer	FOSHAN NANHAI PLUS MEDICAL CO., LTD.
Address	Shatou, Jiujiang Town, Nanhai District, Foshan City, Guangdong, China

General remarks

This report shall not be reproduced except in full without the written approval of the testing laboratory.

The test results presented in this report relate only to the item(s) tested.

"(see appended table)" refers to a table appended to the report.

"(see remark #)" refers to a remark appended to the report.

"(see Annex #)" refers to an annex appended to the report.

Throughout this report a comma (point) is used as the decimal separator.

Remark:

Photos view:

(See appendix 1)

Copy of marking plate:

(See appendix 2)

Possible test case verdicts :	
test case does not apply to the test object	: N (.A.)
test object does meet the requirement	: P(ass)
test object does not meet the requirement	: F(ail)
Name and address of the testing laboratory: <u>Oct Technology Testing Co., Ltd.</u> <u>637, No. 56, zhongyun Road, Panyu District, Guangzhou, Guangdong Province, China</u>	
Reported by :  _____ Signature	_____ 2020.3.19 Date
Approved by :   _____ Signature	_____ 2020.3.19 Date

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
5	Classification		P
	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices: FFP1, FFP2 and FFP3.	FFP3	P
6	Designation		P
	Particle filtering half masks meeting the requirements of this European Standard shall be designated in the following manner:		P
	Particle filtering half mask EN 149, year of publication, classification, option (where "D" is an option for a non re-useable particle filtering half mask and mandatory for re-useable particle filtering half mask).		P
7	Requirements		P
7.1	General		P
	In all tests all test samples shall meet the requirements.		P
7.2	Nominal values and tolerances		P
	Unless otherwise specified, the values stated in this European Standard are expressed as nominal values. Except for temperature limits, values which are not stated as maxima or minima shall be subject to a tolerance of $\pm 5\%$. Unless otherwise specified, the ambient temperature for testing shall be (16 - 32) °C, and the temperature limits shall be subject to an accuracy of $\pm 1\text{ }^{\circ}\text{C}$.	+ 5°C to +38°C	P
7.3	Visual inspection		P
	The visual inspection shall also include the marking and the information supplied by the manufacturer.		P
7.4	Packaging		P

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
	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.		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.	Melt blown filter	P
	A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke. The particle filtering half mask is mounted on a Sheffield dummy head. For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head, the saturator being set at a temperature in excess of 37 °C to allow for the cooling of the air before it reaches the mouth of the dummy head. The air shall be saturated at (37 ± 2) °C at the mouth of the dummy head. In order to prevent excess water spilling out of the dummy's mouth and contaminating the particle filtering half mask the head shall be inclined so that the water runs away from the mouth and is collected in a trap.		P
7.6	Cleaning and disinfecting		P
	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.		P
	Testing shall be done in accordance with 8.4 and 8.5.		P
	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.		P
	Testing shall be done in accordance with 8.11.		P

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Clause	Requirement – Test	Result - Remark	Verdict
	Walking test		P
	The subjects wearing normal working clothes and wearing the particle filtering half mask shall walk at a regular rate of 6 km/h on a level course. The test shall be continuous, without removal of the particle filtering half mask, for a period of 10 min.		P
7.7	Practical performance		P
	Work simulation test		P
	The particle filtering half mask shall be tested under conditions which can be expected during normal use. During this test the following activities shall be carried out in simulation of the practical use of the particle filtering half mask. The test shall be completed within a total working time of 20 min. The sequence of activities is at the discretion of the test house. The individual activities shall be arranged so that sufficient time is left for the comments prescribed.	The particle filtering half mask could undergo practical performance tests under realistic condition	P
	a) walking on the level with headroom of $(1,3 \pm 0,2)$ m for 5 min;		P
	b) crawling on the level with headroom of $(0,70 \pm 0,05)$ m for 5 min;		P
	c) filling a small basket (see Figure 1, approximate volume = 8 l) with chippings or other suitable material from a hopper which stands 1,5 m high and has an opening at the bottom to allow the contents to be shovelled out and a further opening at the top where the basket full of chippings is returned.		P
	The subject shall stoop or kneel as he wishes and fill the basket with chippings. He shall then lift the basket and empty the contents back into the hopper. This shall be done 20 times in 10 min.		P
7.8	Finish of parts		P
	Parts of the device likely to come into contact with	no sharp edges and burrs.	P

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	the wearer shall have no sharp edges or burrs.		
	The visual inspection is carried out where appropriate by the test house prior to laboratory or practical performance tests.		P
7.9	Leakage		P
7.9.1	Total inward leakage	Total inward leakage is 9%	P
	1) walking for 2 min without head movement or talking;		P
	2) turning head from side to side (approx. 15 times), as if inspecting the walls of a tunnel for 2 min;		P
	3) moving the head up and down (approx. 15 times), as if inspecting the roof and floor for 2 min;		P
	4) reciting the alphabet or an agreed text out loud as if communicating with a colleague for 2 min;		P
	5) walking for 2 min without head movement or talking.		P
	Expression of results		P
	<p>The leakage P shall be calculated from measurements made over the last 100 s of each of the exercise periods to avoid carry over of results from one exercise to the other.</p> $P(\%) = \frac{C_2}{C_1} \times \left(\frac{t_{IN} + t_{EX}}{t_{IN}} \right) \times 100$ <p>where C 1 is the challenge concentration C 2 is the measured mean concentration in the breathing zone of the test subject t IN is the total duration of inhalation t EX is the total duration of exhalation</p>		P

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Clause	Requirement – Test	Result - Remark	Verdict														
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.	Penetration of paraffin oil test is 0.4%. The penetration of sodium chloride testis 0.3%	P														
<p align="center">Table 1 — Penetration of filter material</p> <table border="1"> <thead> <tr> <th rowspan="2">Classification</th> <th colspan="2">A₁ Maximum penetration of test aerosol A₁</th> </tr> <tr> <th>Sodium chloride test 95 l/min % max.</th> <th>Paraffin oil test 95 l/min % max.</th> </tr> </thead> <tbody> <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	A ₁ Maximum penetration of test aerosol A ₁		Sodium chloride test 95 l/min % max.	Paraffin oil test 95 l/min % max.	FFP1	20	20	FFP2	6	6	FFP3	1	1	P
Classification	A ₁ Maximum penetration of test aerosol A ₁																
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7.10	Compatibility with skin		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.	Inner and out layer Nonwoven pet fabric	P														
7.11	Flammability	The particle filtering half mask does not to continue to burn for more than 5s After removal from the flame	P														
	A total of four particle filtering half masks shall be tested: two in the state as received and two after temperature conditioning in accordance with 8.3.2.		P														
	The facepiece is put on a metallic dummy head which is motorized such that it describes a horizontal circle with a linear speed, measured at the tip of the nose, of (60 ± 5) mm/s.		P														
	The head is arranged to pass over a propane burner the position of which can be adjusted. By means of a suitable gauge, the distance between the top of the burner, and the lowest part of the facepiece (when positioned directly over the burner) shall be set to (20 ± 2) mm.		P														
	With the head turned away from the area adjacent		P														

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Clause	Requirement – Test	Result - Remark	Verdict
	to the burner, the propane gas is turned on, the pressure adjusted to between 0,2 bar and 0,3 bar and the gas ignited. By means of a needle valve and fine adjustments to the supply pressure, the flame height shall be set to (40 ± 4) mm. This is measured with a suitable gauge. The temperature of the flame measured at a height of (20 ± 2) mm above the burner tip by means of a 1,5 mm diameter mineral insulated thermocouple probe, shall be (800 ± 50) °C.		
	The head is set in motion and the effect of passing the facepiece once through the flame shall be noted.		P
	The test shall be repeated to enable an assessment to be made of all materials on the exterior of the device. Any one component shall be passed through the flame once only.		P
7.12	Carbon dioxide content of the inhalation air	The Carbon dioxide content of the inhalation air (dead space) does not exceed an average of 1.0%	P
	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume).		P
	For this test the particle filtering half mask shall be fitted securely in a leak-tight manner but without deformation to a Sheffield dummy head (see Figure 6).		P
	Air shall be supplied to it from a breathing machine adjusted to 25 cycles/min and 2,0 l/stroke and the exhaled air shall have a carbon dioxide content of 5 % by volume.		P
	The CO ₂ is fed into the breathing machine via a control valve, a flowmeter, a compensating bag		P

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Clause	Requirement – Test	Result - Remark	Verdict
	and two non-return valves.		
	Immediately before the solenoid valve a small quantity of exhaled air is preferably continuously withdrawn through a sampling line and then fed into the exhaled air via a CO 2 analyser.		P
	To measure the CO 2 content of the inhaled air, 5 % of the stroke volume of the inhalation phase of the breathing machine is drawn off at the marked place by an auxiliary lung and fed to a CO 2 analyser. The total dead space of the gas path (excluding the breathing machine) of the test installation should not exceed 2000 ml.		P
	Measure the carbon dioxide content of the inhaled air and record continuously.		P
7.13	Head harness		P
	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.		P
	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.		P
7.14	Field of vision		P
	The field of vision is acceptable if determined so in practical performance tests.		P
7.15	Exhalation valve(s)		N
	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.		N
	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.		N
	When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.		N

EN 149																									
Clause	Requirement – Test	Result - Remark	Verdict																						
7.16	Breathing resistance	Inhalation resistance at 30 l/min :1 mbar. Inhalation resistance at 95 l/min :3 mbar. Inhalation resistance at 160 l/min :3.0 mbar.	P																						
	The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2.		P																						
<p style="text-align: center;">Table 2 — Breathing resistance</p> <table border="1"> <thead> <tr> <th rowspan="3">Classification</th> <th colspan="3">Maximum permitted resistance (mbar)</th> </tr> <tr> <th colspan="2">inhalation</th> <th>exhalation</th> </tr> <tr> <th>30 l/min</th> <th>95 l/min</th> <th>160 l/min</th> </tr> </thead> <tbody> <tr> <td>FFP1</td> <td>0,6</td> <td>2,1</td> <td>3,0</td> </tr> <tr> <td>FFP2</td> <td>0,7</td> <td>2,4</td> <td>3,0</td> </tr> <tr> <td>FFP3</td> <td>1,0</td> <td>3,0</td> <td>3,0</td> </tr> </tbody> </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	P
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FFP3	1,0	3,0	3,0																						
	Seal the particle filtering half mask on the Sheffield dummy head. Measure the exhalation resistance at the opening for mouth of the dummy head using the adapter shown in Figure 6 and a breathing machine adjusted to 25 cycles/min and 2.0 l/stroke or a continuous flow 160 l/min. Use a suitable pressure transducer.		P																						
	Measure the exhalation resistance with the dummy head successively placed in 5 defined positions:		P																						
	facing directly ahead		P																						
	facing vertically upwards		P																						
	facing vertically downwards		P																						
	lying on the left side		P																						
	lying on the right side		P																						
	Test the inhalation resistance at 30 l/min and 95 l/min continuous flow		P																						
7.17	Clogging		P																						

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Clause	Requirement – Test	Result - Remark	Verdict
7.17.1	General		P
	For single shift use devices, the clogging test is an optional test. For re-usable devices the test is mandatory		P
	Convey dust from the distributor to the dust chamber where it is dispersed into the air stream of 60 m ³ /h.		P
	Fit the sample particle filtering half mask in a leak tight manner to a dummy head or a suitable filter holder located in the dust chamber. Connect the breathing machine and humidifier to the sample and operate for the specified testing time.		P
	The concentration of dust in the test chamber may be measured by drawing air at 2 l/min through a sampling probe equipped with a pre-weighed, high efficiency filter (open face, diameter 37 mm) located near the test sample, as shown in Figure 10.		P
	Calculate the dust concentration from the weight of dust collected, the flow rate through the filter and the time of collection.		P
7.18	Demountable parts	No Demountable parts	N
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	Not applicable	N

Appendix 1

Photo of EUT

