

Test Report

EN 149:2001+A1:2009

For

Product Name :Non-Medical KN95 Daily Protected Mask

Model :SH-ZK12

Report No. :E04302013

Date of Issue :4.30.2020

Prepared For

Zhejiang shaohua medical equipment co. LTD


**West floor 1, building 2, beiyuan science park, 968 xuefeng west road,
beiyuan street, yiwu city, zhejiang province**

Prepared By

Europen Test Lab.Inc

STATUS CENTER, 81,ATHINAS AV.VOULIAGMENI GR-16671,ATHENS, GREECE

Remark: This document issued on a voluntary basis and upon request of the manufacturer.It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of EUTLAB. The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body.

Test Report	
EN 149:2001+A1:2019 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles-Requirements,Testing,Marking	
Report reference No.:	E04302013
Test by	Sam
Review by.....	Ray
Approved by(+ Signature).....	Yemig 
Date of Issue	Apr.30,2020
Contents.....	Total 12 pages
Application	
Name	Zhejiang shaohua medical equipment co. LTD
Address	West floor 1, building 2, beiyuan science park, 968 xuefeng west road, beiyuan street, yiwu city, zhejiang province
Manufacturer	
Name	Zhejiang shaohua medical equipment co. LTD
Address	West floor 1, building 2, beiyuan science park, 968 xuefeng west road, beiyuan street, yiwu city, zhejiang province
Test Item	
Description.....	Non-Medical KN95 Daily Protected Mask
Brand Name	N/A
Model.....	SH-ZK12
Test Specification	
Standard	EN 149:2001+A1:2009
Test Procedure.....	CE
Procedure deviation.....	N/A
Non-Standard test method	N/A
Test Report Form/Blank test report	
Test Report From No.....	E149-A2
TRF originator	EUTLAB
Testing Laboratory	
Name	Euopen Test Lab.Inc
Address	STATUS CENTER, 81,ATHINAS AV.VOULIAGMENI GR-16671,ATHENS, GREECE
Test Location.....	Same as above
Testing	
Date of receipt of test item.....	Apr.20,2020
Date(s) of performance of test	Apr.20,2020--Apr.30,2020



Test case verdicts

Test case does not apply to the test object.....: N(/A)
 Test item meet the requirement.....: P(ass)
 Test item does not meet the requirement.....: F(ail)

General remarks

This test 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 tested. "(see remark #)" refers to a remark appended to the report. "(see appended table)" refers to a table appended to the report.

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

When determining the test result, measurement uncertainty has been considered.

Note:

This report shall not be altered, increase and deleted.

The results relate only to the items tested.

This report shall not be published as advertisement without the approval of EUT.

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Should any objections to the test reports occurred, should submit it to the Company within ten days since the issuing of the report, Fail to accept .

Summary of testing

All tests were found satisfactory in accordance with Personal Protective Equipment (PPE) - (EU) 2016/425

Copy of Marking Plate



EN 149:2001+A1:2009			
Clause	Requirement - Test	Result	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:	Complied with standard, see appended.	P
	-FFP1		N
	-FFP2		P
	-FFP3		N

5.1	Bacterial filtration efficiency (BFE)	Sample 1: 96.9% Sample 2: 95.9% Sample 3: 95.8% Sample 4: 95.0% Sample 5: 95.1% Sample 6: 95.2%	P
5.2	Breathability	Sample 1: 29.4Pa/cm ² Sample 2: 29.0Pa/cm ² Sample 3: 26.8Pa/cm ² Sample 4: 27.4Pa/cm ² Sample 5: 28.1Pa/cm ² Sample 6: 27.7Pa/cm ²	P
5.3	Microbial cleanliness (Bioburden)	Sample 1: 21cfu/g Sample 2: 21cfu/g Sample 3: 20cfu/g Sample 4: 21cfu/g Sample 5: 19cfu/g Sample 6: 17cfu/g	P

6	Designation		P
	Particle filtering half masks meeting the requirements of this European Standard. Year of publication, classification	2020; FFP2 NR D	P

7	Requirements		P
7.1	In all tests all test samples shall meet the requirements	Complied see bellow	P
7.2	Nominal values and tolerances		P
	Unless otherwise specified, the values stated in this European Standard are expressed as normal values.	Actual using value is clear	P

EN 149:2001+A1:2009			
Clause	Requirement - Test	Result	Verdict
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
	Masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use	Distinct design and warning are made on packaging,see sample body	P
7.5	Material		P
	Materials used shall be suitable to withstand handling and wear over the period. Any material from the filter media released 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
	The materials used shall withstand the cleaning and disinfecting	Single-use equipment	N
7.7	Practical performance		P
	The particle filtering half mask shall undergo practical performance tests under realistic conditions.	Complied, see bellow test	P
7.8	Finish of parts	Soft equipment	N
	Parts likely to come into contact with the wearer shall have no sharp edges or burrs		N
7.9	Leakage		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 25% for FFP1,11% forFFP2,5% for FFP3	FFP2, See below test table	P
7.9.2	Penetration of filter material		P
	Meet the requirements of Table 1	FFP2 Sodium chloride test: 3.5% Paraffin oil test: 3.3%	P
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.	Have no irritation or adverse effect to skin and health	P

EN 149:2001+A1:2009			
Clause	Requirement - Test	Result	Verdict
7.11	Flammability	Have no such hazard	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).	<1.0%	P
7.13	Head harness		P
	Head harness shall be designed so that mask can be donned and removed easily.	The design is considered	P
	Head harness shall be adjustable or self- adjusting and sufficiently robust to hold the mask firmly in position.	Non-adjustable	N
7.14	Field of vision		P
	The field of vision is acceptable if determined so in practical performance tests.	Clear field of vision when wearing	P
7.15	Exhalation valve(s)	No exhalation valve(s)	N
	A particle filtering half mask may have one or more exhalation valve(s) and shall function correctly in all orientations.		N
	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		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		P
	The breathing resistances apply to valved and valveless and shall meet the requirements	Complied, see below test table	P
7.17	Clogging		N
7.17.1	General	Single-use device	N
	For single-use devices dogging test is an optional test.		N
	Devices designed to be resistant to dogging, shown by a slow increase		N
	specified breathing resistances not be exceeded before the required dust load of 833mg·h/m ³		N

EN 149:2001+A1:2009			
Clause	Requirement - Test	Result	Verdict
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
	After clogging the inhalation and exhalation resistances shall not exceed - FFP1: 3 mbar - FFP2: 4 mbar - FFP3: 5 mbar		N
	at 95 l/min continuous flow.		N
7.17.3	Penetration of filter material		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 any such par	N

EN 149:2001+A1:2009			
Clause	Requirement - Test	Result	Verdict
8.1	General		P
	No special measuring devices and methods are specified, commonly used devices and methods shall be used.	Common methods	P
8.2	Visual inspection		P
	The visual inspection is carried out appropriate by the test house prior to laboratory or practical performance tests	Considered	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
	Expose masks to the following thermal cycle:	Complied	P
	a) for 24 h to a dry atmosphere of $(70 \pm 3) ^\circ\text{C}$;		P
	b) for 24 h to a temperature of $(-30 \pm 3) ^\circ\text{C}$;		P
	Allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing.	5h	P

9	Marking		P
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.	See user manual	P
9.1.2	Type-identifying marking.		P
9.1.3	Classification: FFP1, FFP2. FFP3.		P
9.1.4	The number and year of publication of this European Standard.	See above	P

EN 149:2001+A1:2009			
Clause	Requirement - Test	Result	Verdict
9.1.5	At least the year of end of shelf life.	2 years	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	English used	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.	See user 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".		P
9.2	Particle filtering half mask		P
	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.	See above	P
9.2.4	The symbols FFP1, FFP2 or FFP3 according to class.	FFP2	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).		P
9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.		P

10	Information to be supplied by the manufacturer		P
10.1	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.	English	P

EN 149:2001+A1:2009			
Clause	Requirement - Test	Result	Verdict
10.3	The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on <ul style="list-style-type: none"> - 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/pictograms used of the equipment. 	See user manual	P
10.4	The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.	Clearly considered	P
10.5	Warning shall be given against problems likely to be encountered, for example: <ul style="list-style-type: none"> - 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. 	See user manual	P
10.6	The information shall provide recommendations as to when the particle filtering half mask shall be discarded.		P

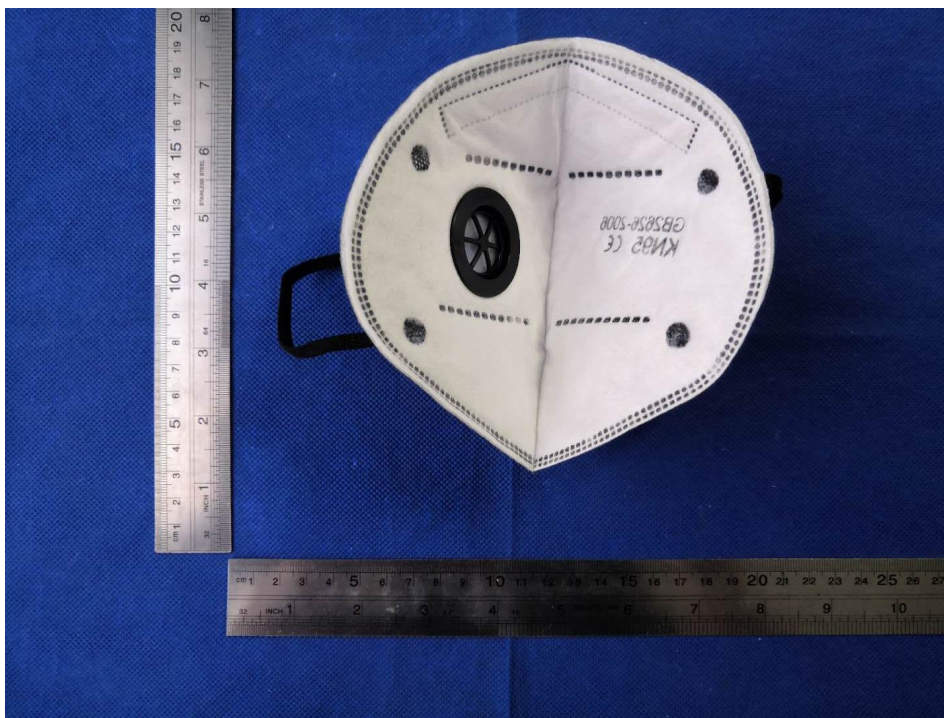
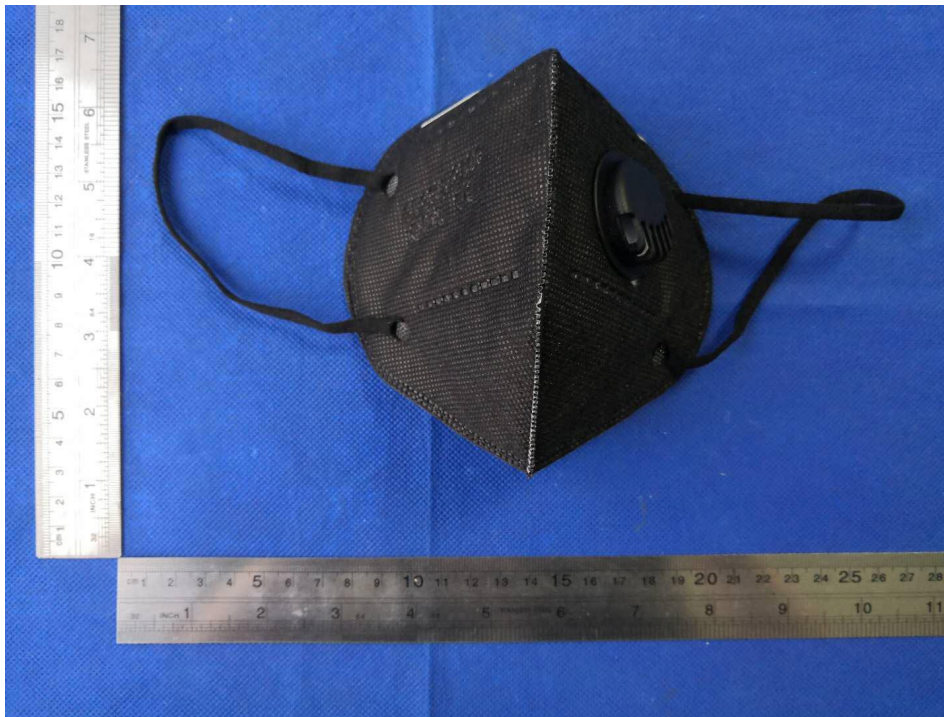
Table 8.5	Leakage test				P
Item	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Test subject walk (km/h)	6	6	6	6	6
Particle size distribution(μ m)	0.08-1.5	0.08-1.5	0.08-1.5	0.08-1.5	0.08-1.5
NaCl flow rate (L/min)	98-101	98-101	98-101	98-101	98-101
NaCl concentration before mask (mg/m^3)	7.9-83	7.9-83	7.9-83	7.9-83	7.9-83
NaCl concentration after mask (mg/m^3)	0.49	0.48	0.48	0.49	0.49
Note: Test ark volume is 2m ³					
Test result total inward Leakage is 6.1%<11%					

EN 149:2001+A1:2009						
Clause	Requirement - Test	Result				Verdict
Table 8.9-1		Inhalation breathing resistance test at 30 L/min				P
Item		Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)		30	30	30	30	30
Maximum resistance (mbar)		0,60	0.62	0.61	0.61	0.62
Note: Maximum permitted resistance <0.7 mbar						

Table 8.9-2	Inhalation breathing resistance test at 95 L/min				P
Item	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)	95	95	95	95	95
Maximum resistance (mbar)	1.94	1.95	1.92	1.93	1.94
Note: Maximum permitted resistance <2.4 mbar					

Table 8.9-3	Inhalation breathing resistance test at 160 L/min				P
Item	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)	160	160	160	160	160
Maximum resistance (mbar)	2.20	2.22	2.21	2.19	2.21
Note: Maximum permitted resistance <2.4 mbar					

APPENDIX A
PHOTO(S) OF PRODUCT



*** End of Report ***