

TEST REPORT EN 149 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking	
Report reference No.....	: A20032468SR-01
Tested by (+signature).....	: Steven  see cover page.....
Approved by (+ signature)...	: Liuze  see cover page.....
Date of issue.....	: Mar.,24, 2020
Testing laboratory	
Name.....	: United Testing Technology (Hong Kong) Limited
Address.....	: Unit 04,7/F,Bright Way Tower,No.33 Mong Kok Road, Kowloon, HK.
Test location.....	: (Same as above)
Client	
Name.....	: Zhejiang Shengbai Medical Equipment Co. LTD
Address.....	: 68# Shangcheng Road,Shangxi Town,Yiwu City, China
Test specification	
Standard.....	: EN 149: 2001+ A1: 2009
Test procedure.....	: CE-PPE
Procedure deviation.....	: N.A.
Non-standard test method..	: N.A.
Test Report Form No.....	: EN_149
Test item	
Description.....	: Disposable mask
Model No.	: 17.5*9.5
Trade Mark.....	: ASUSI
Manufacturer.....	: Zhejiang Shengbai Medical Equipment Co. LTD
Address.....	: 68# Shangcheng Road,Shangxi Town,Yiwu City, China
Classification.....	: FFP2



Test case verdicts

Test case does not apply to the test object..... : N(.A.)

Test item does meet the requirement..... : P(ass)

Test item does not meet the requirement..... : F(ail)

Testing

Date of receipt of test item: Feb., 15, 2020

Date(s) of performance of test: Feb., 15, 2020 - Mar., 23, 2020

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.

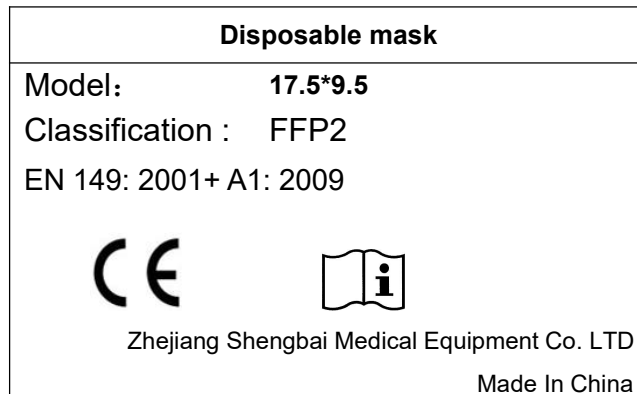
"(see remark #)" refers to a remark appended to the report.

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

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

Remark :

The EUT complies with the standard EN 149 requirement.

Copy of marking plate:

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:	Complied with standard, see appended.	P
	- FFP1		N
	- FFP2		P
	- FFP3		N
6	Designation		P
	Particle filtering half masks meeting the requirements of this European Standard. Year of publication, classification		P
7	Requirements		P
7.1	In all tests all test samples shall meet the requirements	Complied see bellow	P
7.2	Nomial 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
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

EN 149			
Clause	Requirement + Test	Result - Remark	Verdict
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% for FFP2 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: 9.2% Paraffin oil test: 9.7%	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
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		N
	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		
	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 .	The design is considered	P
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)		N
	A particle filtering half mask may have one or more exhalation valve(s) and shall function correctly in all orientations.		N

EN 149			
Clause	Requirement + Test	Result - Remark	Verdict
	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		P
7.17.1	General	Single-use device	P
	For single-use devices clogging test is an optional test.		P
	Devices designed to be resistant to clogging, shown by a slow increase		P
	The specified breathing resistances shall not be exceeded before the required dust load of 833 mg·h/m ³ .		P
7.17.2	Breathing resistance		P
7.17.2.1	Valved particle filtering half masks		N
7.17.2.2	Valveless particle filtering half masks		P
	After clogging the inhalation and exhalation resistances shall not exceed - FFP1: 3 mbar - FFP2: 4 mbar - FFP3: 5 mbar	FFP2: <4 mbar	P
	at 95 l/min continuous flow.		P
7.17.3	Penetration of filter materia		P
	All types claimed to meet the clogging requirement shall also meet the penetration requirements given in 7.9.2 after the treatment.		P
7.18	Demountable parts	No any such part	N
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.		
8	Testing		P
8.1	General		P

EN 149			
Clause	Requirement + Test	Result - Remark	Verdict
	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
	Exposet 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		--
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.	FFP2	P
9.1.4	The number and year of publication of this European Standard.	See above	P
9.1.5	At least the year of end of shelf life.	3 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	

EN 149			
Clause	Requirement + Test	Result - Remark	Verdict
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
	Particle filtering half masks		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).		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 be at least in the official language(s) of the country of destination.	English	P
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 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

EN 149			
Clause	Requirement + Test	Result - Remark	Verdict
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

Attachments: test table

Table 8.5	Leakage test					P
Item	Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
	Test subject walk (km/h)					
Particle size distribution(um)		0.08~1.6	0.08~1.6	0.08~1.6	0.08~1.6	0.08~1.6
NaCl flow rate (L/min)		99~104	99~104	99~104	99~104	99~104
NaCl concentration before mask (mg/m ³)		7.9~8.3	7.9~8.3	7.9~8.3	7.9~8.3	7.9~8.3
NaCl concentration after mask (mg/m ³)		0.46	0.47	0.47	0.50	0.46
Note: Test ark volume is 2m ³ Test result total inward Leakage is 6.2%<11%						

Table 8.9-1	Inhalation breathing resistance test at 30 L/min					P
Item	Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
	Inhalation gas velocity (L/min)					
Maximum resistance (mbar)		0.60	0.62	0.65	0.62	0.61
Note: Maximum permitted resistance <1.0 mbar						

Table 8.9-2	Inhalation breathing resistance test at 95 L/min					P
Item	Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
	Inhalation gas velocity (L/min)					
Maximum resistance (mbar)		3.46	3.39	3.40	3.36	3.36
Note: Maximum permitted resistance < 4.0 mbar						

Table 8.9-3	Exhalation breathing resistance test at 160 L/min					P
Models Item	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	
Exhalation (L/min)	160	160	160	160	160	
Maximum resistance (mbar)	3.42	3.43	3.51	3.40	3.53	
Note: Maximum permitted resistance < 4.0 mbar						

Appendix
Photo documentation

Photo 1

View:

- front
- rear
- right side
- left side
- top
- bottom
- internal

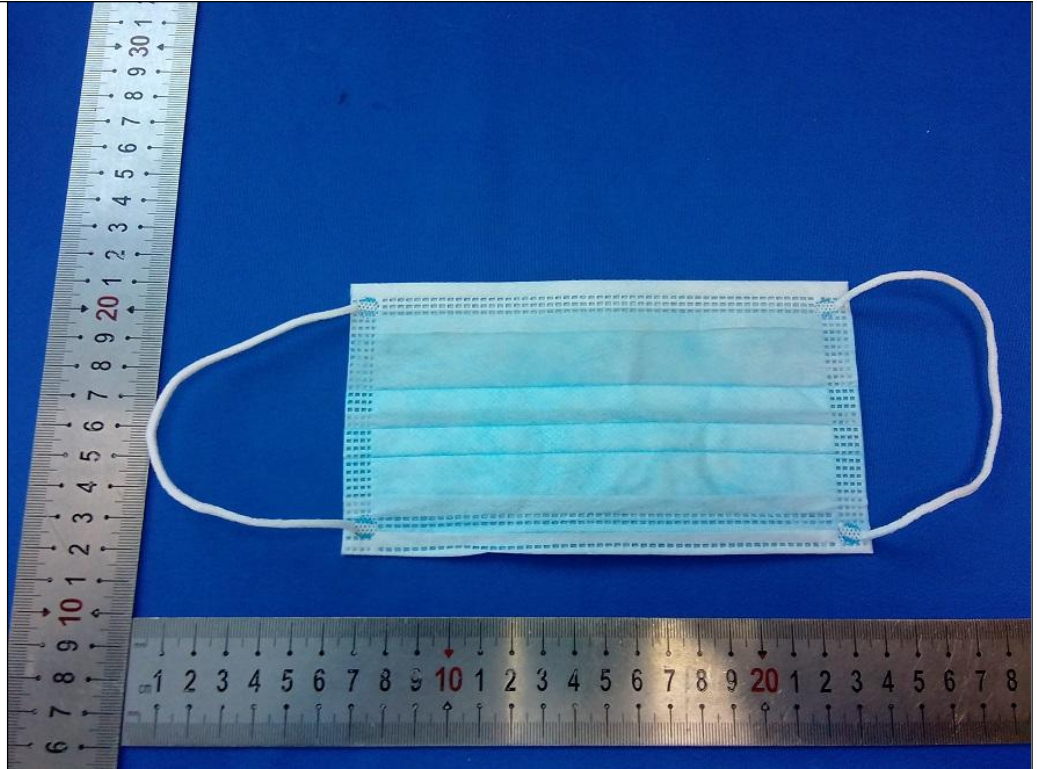


Photo 2

View:

- front
- rear
- right side
- left side
- top
- bottom
- internal

