



PPE TEST REPORT

For
Shandong kangertai Protective Equipment Co., Ltd

Daily disposable mask

Model: 175mm×95mm

Prepared For : Shandong kangertai Protective Equipment Co., Ltd.

Address : South of Xinxing street, industrial park, Shanghe County, Jinan City,
Shandong Province, east of the planned West Ring Road .

Prepared By : STS INSPECTION & CERTIFICATION LIMITED

MarAddress : UNIT G25 WATERFRONT STUDIOS , 1 DOCK ROAD , LONDON ,
UNITED KINGDOM , E16 1AH



Report Number : STS- kangertai-2020001-PPE

Date of Test : 20th Mar , 2020

Date of Report : 20th Mar , 2020

TEST REPORT DECLARATION

Applicant : **Shandong kangertai Protective Equipment Co., Ltd**

Address : **South of Xinxing street , industrial park, Shanghe County, Jinan City,
Shandong Province, east of the planned West Ring Road.**

Manufacturer : **Shandong kangertai Protective Equipment Co., Ltd**

Address : **South of Xinxing street, industrial park, Shanghe County, Jinan City,
Shandong Province, east of the planned West Ring Road**

EUT Description : **Daily Disposable Mask**

Model No. : **175mm×95mm**

Remark : N/A

Test Procedure Used : EN 149:2001+A1:2009

The results of this test report are only valid for the mentioned equipment under test. The test report with all its sub-reports, e.g. tables, photographs and drawings, is copyrighted. Unauthorized utilization, especially without permission of the test laboratory, is not allowed and punishable. For copying parts of the test report, a written permission by the test laboratory is needed.

The test results of this report relate only to the tested sample identified in this report.

Tested By :



Date: 20th Mar, 2020



Approved By : Sunny Yang

Date: 20th Mar, 2020

EN 149:2001 +A1:2009

Possible test case verdicts :	
test case does not apply to the test object	N/A
test object does not meet the requirement	p
test object does meet the requirement	P
General remarks:	
<p>“(see remark #)” refers to a remark appended to the report</p> <p>“(see appended table)” refers to a table appended to the report.</p> <p>Throughout this report a comma is used as the decimal separator.</p> <p>The test results presented in this report relate only to the object tested.</p> <p>This report shall not be reproduced except in full without the written approval of the testing laboratory.</p> <p>Until otherwise specified, all tests are done under normal ambient condition 25°C±10°C, Max RH: 75% and air pressure of 860 mbar to 1060 mbar</p>	<p>Attached with: Attachment - Photo Documentation</p>
<p>The test samples were pre-production samples without serial numbers. This report shall not be reproduced except in full without the written approval of the testing laboratory.</p> <p>This report covers 175mm×95mm</p> <p>The test result presented in this report relate only to the object tested. The samples tested comply with the requirements of this standard.</p> <p>All tests were performed by model 175mm×95mm to represent the other identical models.</p> <p>The test result presented in this report relate only to the object tested. The samples tested comply with the requirements of this standard.</p>	

EN 149:2001 +A1:2009

1	Scope		
2	Normative references		-
3	Terms and definitions		-
3.1	re-useable particle filtering half mask particle filtering half mask intended to be used for more than a single shift		-
	<p>Description</p> <p>A particle filtering half mask covers the nose and mouth and the chin and may have inhalation and/or exhalation valve(s). The half mask consists entirely or substantially of filter material or comprises a facepiece in which the main filter(s) form an inseparable part of the device. It is intended to provide adequate sealing on the face of the wearer against the ambient atmosphere, when the skin is dry or moist and when the head is moved.</p> <p>Air enters the particle filtering half mask and passes directly to the nose and mouth area of the facepiece or, via an inhalation valve(s) if fitted. The exhaled air flows through the filter material and/or an exhalation valve (if fitted) directly to the ambient atmosphere.</p> <p>These devices are designed to protect against both solid and liquid aerosols.</p>		P
5	<p>Classification</p> <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.</p> <p>The protection provided by an FFP2 - or FFP3 - device includes that provided by the device of lower class or classes.</p>	FFP1	P
6	<p>Designation</p> <p>Particle filtering half masks meeting the requirements of this European Standard shall be designated in the following manner: 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>	Particle filtering half mask FFP1	P
7	Requirements		P
7.1	<p>General</p> <p>In all tests all test samples shall meet the requirements.</p>		P
7.2	<p>Nominal values and tolerances</p> <p>Unless otherwise specified, the values stated in this European Standard are expressed as</p>		P

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	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 ± 1 °C.		
7.3	Visual inspection The visual inspection shall also include the marking and the information supplied by the manufacturer.	Shandong kangertai protective equipment Co., Ltd	P
7.4	Packaging 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 shall be done in accordance with 8.2.		P
7.5	Material 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. After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. Three particle filtering half masks shall be tested. When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer. Testing shall be done in accordance with 8.2.		P
7.6	Cleaning and disinfecting 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." BS EN 149:2001+A1:2009	Disposable products	N/A
	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. Testing shall be done in accordance with 8.11."	Disposable products	N/A
7.7	Practical performance The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard. Where practical performance tests show the		P

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	<p>apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections.</p> <p>Testing shall be done in accordance with 8.4.</p>		
7.8	<p>Finish of parts</p> <p>Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.</p> <p>Testing shall be done in accordance with 8.2.</p>		P
7.9	<p>Leakage</p>		P
	<p>The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected.</p> <p>The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration.</p>		P
7.10	<p>Compatibility with skin</p> <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> <p>Testing shall be done in accordance with 8.4 and 8.5.</p>		P
7.11	<p>Flammability</p> <p>The material used shall not present a danger for the wearer and shall not be of highly flammable nature.</p> <p>When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.</p> <p>The particle filtering half mask does not have to be usable after the test.</p> <p>Testing shall be done in accordance with 8.6.</p> <p>BS EN 149:2001+A1:2009</p>		P
7.12	<p>Carbon dioxide content of the inhalation air</p> <p>The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).</p> <p>Testing shall be done in accordance with 8.7.</p>	0.5%	P
7.13	<p>Head harness</p> <p>The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.</p> <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</p>	Hanging ear type	NA

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	the device. Testing shall be done in accordance with 8.4 and 8.5		
7.14	Field of vision The field of vision is acceptable if determined so in practical performance tests. Testing shall be done in accordance with 8.4.		P
7.15	Exhalation valve(s) A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations. Testing shall be done in accordance with 8.2 and 8.9.1. 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 that may be necessary for the particle filtering half mask to comply with 7.9. Testing shall be done in accordance with 8.2. 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. Testing shall be done in accordance with 8.3.4. When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s. Testing shall be done in accordance with 8.8.	No such parts	N
7.16	Breathing resistance The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2		P
7.17	Clogging		P
7.17.1	General For single shift use devices, the clogging test is an optional test. For re-usable devices the test is mandatory ." Devices designed to be resistant to clogging, shown by a slow increase of breathing resistance when loaded with dust, shall be subjected to the treatment described in 8.10. The specified breathing resistances shall not be exceeded before the required dust load of 833 mg • h/m ³ is reached.	No such parts	N
7.17.2	Breathing resistance		P
7.17.2.1	Valved particle filtering half masks	<4 mbar at 95 l/min continuous flow	P
7.17.2.2	Valveless particle filtering half masks	<3 mbar at 95 l/min continuous flow	P
7.17.3	Penetration of filter materia		P
	All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement		P

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	shall also meet the requirements given in 7.9.2, for the Penetration test according to EN 13274-7, after the clogging treatment.		
7.18	Demountable parts All demountable parts (if fitted) shall be readily connected and secured, where possible by hand. Testing shall be done in accordance with 8.2.	No such parts	N
8	Testing		P
8.1	General If no special measuring devices and methods are specified, commonly used devices and methods shall be used. NOTE For a summary of testing, see Table 4. Before performing tests involving human subjects account should be taken of any national regulations concerning the medical history, examination or supervision of the test subjects.	-	-
8.2	Visual inspection The visual inspection is carried out where appropriate by the test house prior to laboratory or practical performance tests.		P
8.3	Conditioning		P
8.3.1	Simulated wearing treatment		P
	Conditioning by simulated wearing treatment shall be carried out by the following process. 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. The breathing machine is brought into operation, the saturator switched on and the apparatus allowed to stabilize. The particle filtering half mask under test shall then be mounted on the dummy head. During the test time at approximately 20 min intervals the particle filtering half mask shall be completely removed from the dummy head and refitted such that during the test period it is fitted ten times to the dummy head.		P
8.3.2	Temperature conditioning		P

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	Expose the particle filtering half masks to the following thermal cycle: a) for 24 h to a dry atmosphere of $(70 \pm 3) ^\circ\text{C}$;		
	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.		P
8.3.3	Mechanical strength	Conditioning shall be done in accordance with EN 143.	P
8.3.4	Flow conditioning	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
8.4	Practical performance		P
8.4.1	<p>General</p> <p>A total of 2 particle filtering half masks shall be tested: both as received.</p> <p>All tests shall be carried out by two test subjects at ambient temperature and the test temperature and humidity shall be recorded.</p> <p>Prior to the test there shall be an examination to assure that the particle filtering half mask is in good working condition and that it can be used without hazard.</p> <p>Examination shall be done in accordance with 8.2.</p> <p>For the test, persons shall be selected who are familiar with using such or similar equipment.</p> <p>During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded:</p> <p>a) head harness comfort;</p> <p>b) security of fastenings;</p> <p>c) field of vision;</p> <p>d) any other comments reported by the wearer on request.</p>		P
8.4.2	<p>Walking test</p> <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>		P
8.4.3	<p>Work simulation test</p> <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.</p> <p>The test shall be completed within a total working</p>		P

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	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.		
	a) walking on the level with headroom of $(1,3 \pm 0,2)$ m for 5 min; BS EN 149:2001+A1:2009		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
8.5	Leakage		P
8.5.1	General test procedure		P
8.5.1.1	<p>Total inward leakage A total of 10 test specimens shall be tested: 5 as received and 5 after temperature conditioning in accordance with 8.3.2. The total inward leakage shall be tested using sodium chloride aerosol. Prior to the test there shall be an examination to ensure that the particle filtering half mask is in good working condition and that it can be used without hazard. Examination shall be done in accordance with 8.2.</p> <p>For the test, persons shall be selected who are familiar with using such or similar equipment. A panel of ten clean-shaven persons (without beards or sideburns) shall be selected covering the spectrum of facial characteristics of typical users (excluding significant abnormalities). It is to be expected that exceptionally some persons cannot be satisfactorily fitted with a particle filtering half mask. Such exceptional subjects shall not be used for testing particle filtering half masks.</p>		P
8.5.1.2	<p>Test equipment The test atmosphere shall preferably enter the top of the enclosure through a flow distributor, and be directed downwards over the head of the test subject at a minimum flow rate of 0,12 m/s. The concentration of the test agent inside the effective working volume shall be checked to be homogeneous. The flow rate should be measured close to the subject's head. A level treadmill is required capable of working at 6 km/h.</p>		P

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8.5.1.3	<p>Test procedure Ask the test subjects to read the manufacturer's fitting information and if more than one size of particle filtering half mask is manufactured, ask the test subject to select the size deemed by him to be the most appropriate. If necessary the test supervisor shall show the test subjects how to fit the particle filtering half mask correctly in accordance with the fitting information. Inform the test subjects that if they wish to adjust the particle filtering half mask during the test they may do so. However if this is done, repeat the relevant section of the test, having allowed the system to re- settle. The test subjects shall have no indication of the results as the test proceeds.</p>		P
8.7	Carbon dioxide content of the inhalation air		P
	<p>A total of 3 particle filtering half masks shall be tested: all 3 as received. The apparatus consists essentially of a breathing machine with solenoid valves controlled by the breathing machine, a connector, a CO 2 flowmeter and a CO 2 analyser.</p>		P
8.8	<p>Strength of attachment of exhalation valve housing A total of three particle filtering half masks shall be tested: one as received, one temperature conditioned in accordance with 8.3.2 and one after the test described for mechanical strength in EN 143. Mount the particle filtering half mask securely to a fixture as shown in Figure 9. Apply an axial tensile</p>		P
8.9	force of 10 N to the valve (housing) for 10 s, and note the results.		P
	Breathing Resistance		

Documentation

Test data

Ambient temperature: 24 °C
Relative Humidity (RH): 32%

Sample	Items	Limits(%)	Initial filtration efficiency(%)	Loading filter efficiency(%)	Conclusion
Non- temperature conditioning samples					
#1	Filtration Efficiency	Test gas flow single filter element 085 ± 4) l / min >80	85.3	85.2	PASS
#2			85.2	85.2	PASS
#3			85.3	85.3	PASS
#4			85.2	85.1	PASS
#5			85.3	85.2	PASS
#6			85.3	85.2	PASS
Temperature conditioning samples					
#7	Filtration Efficiency	Test gas flow single filter element 085 ± 4) l / min >80	84.3	84.3	PASS
#8			84.2	84.1	PASS
#9			84.3	84.2	PASS
#10			84.3	84.2	PASS
Sample	Items	Limits(%)	Data (Pa)		Conclusion
Non- temperature conditioning samples					
#11	Inspiratory resistance	The total gas resistance of each sample should be ≤ 350Pa	141		PASS
#12			141		PASS
#13			142		PASS
#14			145		PASS
#15			141		PASS
#16			144		PASS
Temperature conditioning samples					
#17	Inspiratory resistance	The total gas resistance of each sample should be ≤ 350Pa	152		PASS
#18			154		PASS
#19			158		PASS

Documentation

#20			156	PASS
#21			157	PASS
Non- temperature conditioning samples				
#22	Expiratory resistance	The total gas resistance of each sample should be $\leq 250\text{Pa}$	65	PASS
#23			68	PASS
#24			85	PASS
#25			65	PASS
#26			65	PASS
#27			65	PASS
Temperature conditioning samples				
#28	Expiratory resistance	The total gas resistance of each sample should be $\leq 250\text{Pa}$	92	PASS
#29			91	PASS
#30			89	PASS
#31			92	PASS
#32			93	PASS
#33			91	PASS
#34			90	PASS
Note:	Temperature conditions a) 24 hours at 38 °C and 85% b) At 70 °C for 24 hours c) 24 hours at -30 °C			

Documentation

EC Declaration



Manufacture : Shandong Kangertai Protective Equipment Co., Ltd

**Address : South of Xinxing street, industrial park, Shanghe County, Jinan City,
Shandong Province, east of the planned West Ring Road.**

**Description of product
Disposable Protective Mask**

**Model(s)
175mm×95mm**

Standards used, including number, title, issue date and other relative documents

EN 149:2001 +A1:2009

Declaration:

I declare that as the authorised representative, the above information in relation to the supply / manufacture of this product, is in conformity with the stated standards and other related documents following the provisions of the above Directives and their amendments.

Signature Of Manufacturers Authorized:

Documentation

Photo Documentation