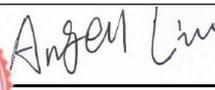
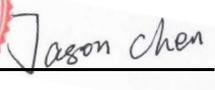




<b>TEST REPORT</b> <b>EN149:2001+A1:2009</b> <b>Respiratory protective devices</b> <b>Filtering half masks to protect against particles</b> <b>Requirements, testing, marking</b>	
Report reference NO.....	CTE2020030508
Tested by (+signature).....	Angell Liu 
Approved by(+signature).....	Jason Chen 
Date of issue.....	2020,03.05
Contents.....	10 pages
Testing Laboratory Name.....	<b>Shenzhen Coffee-T Electronics Technology Co., Ltd</b>
Address.....	4th Floor,Bldg A3,Digital Tech Park,7th GaoXin South Blvd, Tech Park,NanShan,ShenZhen,China
Testing location.....	Same as above
Applicant's Name.....	<b>Chang zhou tiantian ai medical device co.ltd</b>
Address.....	135 hongxi road,niutang.wujin district.changzhou city. jangsu province.china
Test spacification	
Standard.....	EN 149:2001+A1:2009
Test procedure.....	CCA-scheme
Non-standard test method.....	N/A
Test Report Form No.....	EN 149
Date of performance of tests .....	2020,03.05
Test item description.....	<b>Disposable protective mask</b>
Model and/or type reference.....	<b>kn95, kf94</b>
Classification.....	FFP2
Manufacturer.....	<b>Chang zhou tiantian ai medical device co.ltd</b>
Address.....	135 hongxi road,niutang.wujin district.changzhou city. jangsu province.china



Test Property	Test Method	Test Principle / Requirements	Test Result
Classification	EN 149:2001+ A1:2009 Clause 5	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.	Pass. FFP2 >95%.
Designation	EN 149:2001+ A1:2009 Clause 6	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).	Pass. re-useable particle filtering half mask
Nominal values and tolerances	EN 149:2001+ A1:2009 Clause 7.2	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 $\pm 1$ ° C.	Pass. +5°C to +38°C.
Visual inspection	EN 149:2001+ A1:2009 Clause 7.3	The visual inspection shall also include the marking and the information supplied by the manufacturer.	Pass
Packaging	EN 149:2001+ A1:2009 Clause 7.4& Clause 8.2	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. The visual inspection is carried out where appropriate by the test house prior to laboratory or practical performance tests.	Pass
Material	EN 149:2001+ A1:2009 Clause 7.5& Clause 8.3	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 $\pm$ 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. Expose the particle filtering half masks to the	Pass. None of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. The particle filtering half mask shall not collapse.

Test Property	Test Method	Test Principle / Requirements	Test Result
		<p>following thermal cycle:</p> <p>a) for 24 h to a dry atmosphere of <math>(70 \pm 3) ^\circ \text{C}</math>;</p> <p>b) for 24 h to a temperature of <math>(-30 \pm 3) ^\circ \text{C}</math>;</p> <p>and allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing.</p> <p>The conditioning shall be carried out in a manner which ensures that no thermal shock occurs.</p>	
Cleaning and disinfecting	EN 149:2001+A1:2009 Clause 7.6& Clause 8.4& Clause 8.5	<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> <p>Testing shall be done in accordance with 8.4 and 8.5.</p> <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> <p>Testing shall be done in accordance with 8.11.</p>	Pass
Practical performance	EN 149:2001+A1:2009 Clause 7.7& Clause 8.4	<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>Work simulation test</p> <p>The individual activities shall be arranged so that sufficient time is left for the comments prescribed.</p> <p>a) walking on the level with headroom of <math>(1,3 \pm 0,2) \text{ m}</math> for 5 min;</p> <p>b) crawling on the level with headroom of <math>(0,70 \pm 0,05) \text{ m}</math> for 5 min;</p> <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> <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</p>	Pass. The particle filtering half mask could undergo practical performance tests under realistic conditions.

Test Property	Test Method	Test Principle / Requirements	Test Result																	
		times in 10 min.																		
Finish of parts	EN 149:2001+ A1:2009 Clause 7.8& Clause 8.2	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs. Testing shall be done in accordance with 8.2.	Pass. No sharp edges and burrs.																	
Total inward leakage	EN 149:2001+ A1:2009 Clause 7.9.1& Clause 8.5	<p>1)walking for 2 min without head movement or talking;</p> <p>2) turning head from side to side (approx. 15 times), as if inspecting the walls of a tunnel for 2 min;</p> <p>3) moving the head up and down (approx. 15 times), as if inspecting the roof and floor for 2 min;</p> <p>4) reciting the alphabet or an agreed text out loud as if communicating with a colleague for 2 min;</p> <p>5)walking for 2 min without head movement or talking.</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            C1 is the challenge concentration            C2 is the measured mean concentration in the breathing zone of the test subject            tIN is the total duration of inhalation            tEX is the total duration of exhalation</p>	Total inward leakage is 7%.																	
Penetration of filter material	EN 149:2001+ A1:2009 Clause 7.9.2	<p>The device shall be mounted in a leaktight manner on a suitable adaptor and subjected to the test(s), ensuring that components of the device that could affect filter penetration values such as valves and harness attachment points are exposed to the challenge aerosol.</p> <p>Testing of penetration, exposure and storage shall be done in accordance with EN 13274-7.</p> <p>The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.</p> <table border="1" data-bbox="609 1921 1179 2063"> <caption>Table 1 — Penetration of filter material</caption> <thead> <tr> <th rowspan="2">Classification</th> <th colspan="2">Maximum penetration of test aerosol (%)</th> </tr> <tr> <th>Sodium chloride test 95 l/min</th> <th>Paraffin oil test 95 l/min</th> </tr> <tr> <td></td> <td>% max.</td> <td>% max.</td> </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	Maximum penetration of test aerosol (%)		Sodium chloride test 95 l/min	Paraffin oil test 95 l/min		% max.	% max.	FFP1	20	20	FFP2	6	6	FFP3	1	1	<p>Pass</p> <p>See the ANNEX I.</p> <p>The penetration of paraffin oil test is 0.94%.</p> <p>The penetration of sodium chloride test is 0.25%.</p>
Classification	Maximum penetration of test aerosol (%)																			
	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min																		
	% max.	% max.																		
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Test Property	Test Method	Test Principle / Requirements	Test Result
Compatibility with skin	EN 149:2001+ A1:2009 Clause 7.10	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.	Pass
Flammability	EN 149:2001+ A1:2009 Clause 7.11& Clause 8.6	<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 <math>(60 \pm 5)</math> mm/s.</p> <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 <math>(20 \pm 2)</math> mm.</p> <p>With the head turned away from the area adjacent 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 <math>(40 \pm 4)</math> mm. This is measured with a suitable gauge. The temperature of the flame measured at a height of <math>(20 \pm 2)</math> mm above the burner tip by means of a 1,5 mm diameter mineral insulated thermocouple probe, shall be <math>(800 \pm 50)</math> ° C.</p> <p>The head is set in motion and the effect of passing the facepiece once through the flame shall be noted.</p> <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>	<p>Pass.</p> <p>The particle filtering half mask does not burn or not to continue to burn for more than 5 s after removal from the flame.</p>
Carbon dioxide content of the inhalation air	EN 149:2001+ A1:2009 Clause 7.12& Clause 8.7	<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> <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> <p>The CO<sub>2</sub> is fed into the breathing machine via a control valve, a flowmeter, a compensating bag and two non-return valves. Immediately before the solenoid valve a small quantity of exhaled air is preferably continuously withdrawn through a sampling</p>	<p>Pass.</p> <p>The carbon dioxide content of the inhalation air (dead space) does not exceed an average of 1,0 %</p>

Test Property	Test Method	Test Principle / Requirements	Test Result
		<p>line and then fed into the exhaled air via a CO2 analyser.</p> <p>To measure the CO2 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 CO2 analyser. The total dead space of the gas path (excluding the breathing machine) of the test installation should not exceed 2000 ml.</p> <p>Measure the carbon dioxide content of the inhaled air and record continuously.</p>	
Head harness	EN 149:2001+ A1:2009 Clause 7.13	<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 the device.</p>	Pass
Field of vision	EN 149:2001+ A1:2009 Clause 7.14	The field of vision is acceptable if determined so in practical performance tests.	Pass
Exhalation valve(s)	EN 149:2001+ A1:2009 Clause 7.15	<p>A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.</p> <p>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.</p> <p>When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.</p>	Pass
Breathing resistance	EN 149:2001+ A1:2009 Clause 7.16& Clause 8.9	<p>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> <p>Measure the exhalation resistance with the dummy head successively placed in 5 defined positions:</p> <ul style="list-style-type: none"> <li>- facing directly ahead</li> <li>- facing vertically upwards</li> <li>- facing vertically downwards</li> </ul>	<p>Pass.</p> <p>Inhalation resistance at 30 l/min:&lt;0.6mbar.</p> <p>Inhalation resistance at 95 l/min:&lt;2.1mbar.</p> <p>Exhalation resistance at 160 l/min:&lt;3.0mbar.</p>

Test Property	Test Method	Test Principle / Requirements	Test Result																						
		<ul style="list-style-type: none"> <li>- lying on the left side</li> <li>- lying on the right side</li> </ul> <p>Test the inhalation resistance at 30 l/min and 95 l/min continuous flow.</p> <p>The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2.</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <caption>Table 2 — Breathing resistance</caption> <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	
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FFP3	1,0	3,0	3,0																						
Clogging	EN 149:2001+A1:2009 Clause 7.17& Clause 8.10	<p>Convey dust from the distributor to the dust chamber where it is dispersed into the air stream of 60 m /h.</p> <p>Fit the sample particle filtering half mask in a leaktight 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> <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> <p>Calculate the dust concentration from the weight of dust collected, the flow rate through the filter and the time of collection.</p>	<p>Pass.</p> <p>After clogging the inhalation resistances does not exceed 5 mbar at 95 l/min continuous flow; The exhalation resistance does not exceed 3 mbar at 160 l/min continuous flow.</p>																						
Demountable parts	EN 149:2001+A1:2009 Clause 7.18	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	Pass.																						

## ANNEX I The Paraffin Oil Test

Air Flow	Exhalation resistance(mm of H <sub>2</sub> O)	Penetration(%)
F 95.0	19.30	0.926
F 95.1	18.90	0.914
F 95.1	19.00	0.931
F 95.1	19.10	0.902
F 95.0	19.20	0.957
F 95.1	19.10	0.928
F 95.0	19.00	0.933
F 95.0	18.80	0.964
F 94.9	19.10	0.938
F 95.0	19.00	0.967
F 94.9	19.30	0.942
F 95.1	18.80	0.921
F 95.0	19.10	0.909
F 95.0	18.90	0.912
F 95.1	19.40	0.941
F 94.9	18.70	0.919
F 95.1	19.10	0.957
F 95.0	19.20	0.989
F 95.1	18.90	0.994
F 95.0	19.00	0.962

EN149: 2001+A2009 FFP2 standard : Air Flow = F95 , Penetration  $\leq$  1% , Exhalation resistance(mm of H<sub>2</sub>O)  $\leq$  24 .

ANNEX II EUT Photos



