



# Certificate Of FDA Registration

2020

This is certified that:

At The Address Stated Below Has Completed U.S. FOOD AND DRUG ADMINISTRATION Medical Device Registration Through MANTONG.

GUANGDONG YONGCHUANG MEDICAL TECHNOLOGY CO., LTD.  
NO.8,3 BUILDING,SOUTH STREET STONE,DONGGUAN,  
GUANGDONG 523000,CHINA

**Proprietary Device Name** KN95  
Disposable Medical Mask  
Disposable Mask

**Device Listing Number** D380466

**Product Code** LYU

**Owner/Operator Number** 10064995

The FDA annual establishment registration fee must be paid between Oct. 1 and Dec. 31 of every year.



*Jacky M. Chuang*

Executive Director

Date: 03-28-2020

**MTG STANDARDS TESTING & CERTIFICATION CENTER** [www.fdacn.org](http://www.fdacn.org)

*This certification affirms that the above device and company was registered with U.S. Food and Drug Administration pursuant to section 305 of the United States Public Health and Disaster Preparedness and Response Act of 2002, P.L. 107-188, on the date stated above, and makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. MTG CO., Inc. assumes no liability to any person or entity in connection with the foregoing. MTG is a private registration agent not affiliated with the U.S. Food and Drug Administration.*





**Certificate Number: HW20200317055S**  
**Personal Protective Equipment Regulation**  
**(EU) 2016/425**

## Certificate Of Compliance

Applicant : Dongguan Nancheng Yongchuang Labor Protection Products Factory  
Address : No. 8, 3 Building, South Street stone, Dongguan, Guangdong, China  
Manufacturer : Dongguan Nancheng Yongchuang Labor Protection Products Factory  
Address : No. 8, 3 Building, South Street stone, Dongguan, Guangdong, China  
Product : KN95  
Model : KN95

The submitted products have been tested by us with the following standard(s) and found to be in compliance with the listed European Directives.

EN 149: 2001+A1:2009

The test results apply only to the particular sample tested and to the specific tests carried out. Technical Report and documentation are at the Holder's disposal.

This certificate applies specifically to the sample investigated in our test reference number only. The CE markings as shown below can be affixed on the product after preparation of necessary technical documentation. Other relevant Directives have to be observed.

**CE**



Manager: Guy Su

Date: March 17, 2020

Shenzhen Huawin Testing Certification Co., Ltd.

Add: 7F, Building A, Shenye U Center, No. 743, Zhoushi Road, Bao'an District, Shenzhen, China

Http://www.huawinlab.com E-mail: info@huawinlab.com



PPE TEST REPORT  
For

Dongguan Nancheng Yongchuang Labor Protection Products Factory

KN95

Model No.: KN95

Prepared for : Dongguan Nancheng Yongchuang Labor Protection Products Factory  
Address : No. 8, 3 Building, South Street stone, Dongguan, Guangdong

Prepared by : SHENZHEN HUAWIN TESTING CERTIFICATION CO., LTD.  
Address : 7F, Building A, Shenye U Center, No. 743, Zhoushi Road, Bao' an  
District, Shenzhen, China

Tel: +86-755-29703209  
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Report Number : HW20200317055S  
Date of Test : March 10, 2020 to March 17, 2020  
Date of Report : March 17, 2020



**Test Report**  
**EN 149:2001+A1:2009**

**Respiratory protective devices — Filtering half masks to protect  
against particles — Requirements, testing, marking**

Testing laboratory .....	Shenzhen Huawin Testing Certification Co., Ltd.
Address .....	7F, Building A, Shenye U Center, No. 743, Zhoushi Road, Bao'an District, Shenzhen, China
Report body.....	Shenzhen Huawin Testing Certification Co., Ltd.
Address .....	7F, Building A, Shenye U Center, No. 743, Zhoushi Road, Bao'an District, Shenzhen, China
Applicant .....	Dongguan Nancheng Yongchuang Labor Protection Products Factory
Address .....	No. 8, 3 Building, South Street stone, Dongguan, Guangdong
Standard .....	EN 149: 2001+A1:2009
Test Result .....	Compliance with EN 149: 2001+A1:2009
Procedure deviation .....	N.A.
Non-standard test method .....	N.A.
Type of test object .....	KN95
Trademark .....	YZX
Model/type reference .....	KN95
Rating .....	FFP2
Manufacturer .....	Dongguan Nancheng Yongchuang Labor Protection Products Factory
Address .....	No. 8, 3 Building, South Street stone, Dongguan, Guangdong



## 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.

### Summary of testing:

1, Full tests were performed on model KN95.

### Attached with:

#### Photo-document:


(See appendix 1)



<b>Possible test case verdicts :</b>	
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)

**Test by : Shenzhen Huawin Testing Certification Co., Ltd.  
7F, Building A, Shenye U Center, No. 743, Zhoushi  
Road, Bao' an District, Shenzhen, China**

**Reported by :**

  
\_\_\_\_\_  
Signature

2020.03.17  
Date

Allen / Project Engineer  
Name and Title

**Approved by :**

  
\_\_\_\_\_  
Signature

2020.03.17  
Date

Robert / Manager  
Name and Title





EN 149:2001+A1:2009			
Clause	Requirement – Test	Remark	Verdict
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.	FFP2	P
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).		P
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 $\pm 1\text{ }^{\circ}\text{C}$		P
7.3	The visual inspection shall also include the marking and the information supplied by the manufacturer The visual inspection is carried out where appropriate by the test house prior to laboratory or practical performance test		P
7.4	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		P





## EN 149:2001+A1:2009

Clause	Requirement – Test	Result - Remark	Verdict
7.5	<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> <p>Expose the particle filtering half masks to the following thermal cycle:</p> <p>a) for 24 h to a dry atmosphere of (70±3) °C; b) for 24 h to a temperature of (-30±3)°C; 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>	Melt blown filter	P
7.6	<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>		P





## EN 149:2001+A1:2009

Clause	Requirement – Test	Result - Remark	Verdict
7.7	<p>Walking test 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 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)</math> m for 5 min; b) crawling on the level with headroom of <math>(0,70 \pm 0,05)</math> m for 5 min; 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 times in 10 min</p>	The particle filtering half mask could undergo practical performance tests under realistic conditions	P
7.8	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.	No sharp edges and burrs	P



EN 149:2001+A1:2009																	
Clause	Requirement – Test	Result - Remark	Verdict														
7.9.1	<p>1) walking for 2 min without head movement or talking;            2) turning head from side to side (approx. 15 times), as if inspecting the walls of a tunnel for 2 min;            3) moving the head up and down (approx. 15 times), as if inspecting the roof and floor for 2 min;            4) reciting the alphabet or an agreed text out loud as if communicating with a colleague for 2 min;            5) walking for 2 min without head movement or talking. The leakage P shall be calculated from measurements made over the last 100s 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            tIN is the total duration of inhalation            t EX is the total duration of exhalation</p>	Total inward leakage is 9%															
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. Testing of penetration, exposure and storage shall be done in accordance with EN13274-7.            The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.</p> <table border="1"> <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 % 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	Maximum penetration of test aerosol		Sodium chloride test 95 l/min % max.	Paraffin oil test 95 l/min % max.	FFP1	20	20	FFP2	6	6	FFP3	1	1	<p>The penetration of paraffin oil test is 4 %            The penetration of sodium chloride test is 3.3%</p>	P
Classification	Maximum penetration of test aerosol																
	Sodium chloride test 95 l/min % max.	Paraffin oil test 95 l/min % max.															
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FFP2	6	6															
FFP3	1	1															
7.10	<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>Inner and out layer :            Nonwoven pet fabric</p>	P														



## EN 149:2001+A1:2009

Clause	Requirement – Test	Result - Remark	Verdict
7.11	<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. 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>	The particle filtering half mask does not to continue to burn for more than 5 s after removal from the flame.	P





EN 149:2001+A1:2009

Clause	Requirement – Test	Result - Remark	Verdict
7.12	<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.</p> <p>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<sub>2</sub> analyser. To measure the CO<sub>2</sub> 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<sub>2</sub> 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>	<p>The carbon dioxide content of the inhalation air (dead space).does not exceed an average of 1,0%</p>	P
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>		P
7.14	<p>The field of vision is acceptable if determined so in practical performance tests</p>		N/A
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>		P



EN 149:2001+A1:2009																									
Clause	Requirement – Test	Result - Remark	Verdict																						
7.16	<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> <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;"> <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>Inhalation resistance at 30 l/min:&lt;0.7mbar.</p> <p>Inhalation resistance at 95 l/min:&lt;2.4mbar.</p> <p>Exhalation resistance at 160 l/min:&lt;3.0mbar.</p>	P
Classification	Maximum permitted resistance (mbar)																								
	inhalation		exhalation																						
	30 l/min	95 l/min	160 l/min																						
FFP1	0.6	2.1	3.0																						
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FFP3	1.0	3.0	3.0																						
7.17	<p>Convey dust from the distributor to the dust chamber where it is dispersed into the air stream of 60 m<sup>3</sup>/h. 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>		N/A																						
7.18	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand		N/A																						

# Appendix 1

