

# Certificate of Compliance

No. 4L200407.ZGNT017

Test report no. CTL2003209031-S

&amp; H U W L I L F D W H · V

New Material

Holder:

Co., Ltd.

400 Meters East of Xiangang Toll Station, Xianer Village, Xiangang Town, Gaoyao District, Zhaoqing City (No.2 Workshop of Xianer Village Committee), China

Certification ECM

Mark:



Product:

FFP2(KN95) Respirator Mask

Model(s):

GL-01

Verification to:

Standard:

EN 149:2001+A1:2009

related to CE Directive(s):  
R 2016/425 (Personal Protective Equipment)

Remark: This document has been 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 the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:

The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01\_ECM rev.3 available at: [www.entecerma.it](http://www.entecerma.it)

Issuance date: 07 April 2020

Expiry date: 06 April 2025

Reviewer  
Technical expert  
Amanda Payne

Approver  
ECM Service Director  
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SHT-LAB



## CERTIFICATION OF REGISTRATION

2020

SHT2003030FD1

This certifies that:

**ZHAOQING GUANGLUN NEW MATERIAL CO., LTD**

**400 meters east of xiangang toll station, xianer village, xiangang town, gaoyao district, zhaoping city (no.2 workshop of xianer village committee) , Zhaoqing, Guangdong, 526107, CHINA**

*Was registered with US Food and Drug Administration, Center for Devices and Radiological Health, pursuant to the Code of Federal Regulations 21 CFR 807, by Shenzhen SHT Testing Technology Co., Ltd.*

**Owner / Operator Number: 10065080**  
**Device Listing #: See Annex**  
**Expiration Date: Dec. 31, 2020**

*SHT will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate.*

*SHT 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. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S.*

*Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, SHT is not affiliated with the U.S. Food and Drug Administration.*



Mar. 28, 2020

(Date)

Ryan MA  
Lab Supervisor

Shenzhen SHT Testing Technology Co., Ltd.

Tel: 0755-23318846 Fax: 0755-23318846 <http://www.sht-lab.com>

**SHT-LAB**



**Annex to Device Listing #:**

Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
KN95 Respirator Mask	MSH	2	D380624	Manufacturer



.....  
Mar 28, 2020  
.....  
(Date)  
.....  
  
.....  
Ryan MA  
Lab Supervisor



<b>TEST REPORT</b> <b>EN 149</b> <b>Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking</b>	
<b>Report Reference No</b> .....:	BD-PPE407110VV
<b>Tested by (name + signature)</b> .....	Vivi Wang
<b>Compiled by (name + signature)</b> .....	Chard Li
<b>Approved by (name + signature)</b> .....	Tom Zhang
<b>Date of issue</b> .....:	Apr. 07, 2020
<b>Total number of pages</b> .....	6 Pages
<b>Testing Laboratory</b> .....	<b>Shenzhen Beyon Certification Co.,Ltd.</b>
<b>Address</b> .....	<b>4F Jiayunda Bulid Xinhua 1rd Baoan Shenzhen China</b>
<b>Testing location</b> .....	As above
<b>Applicant's name</b> .....:	Zhaoqing Guanglun New Material Co., Ltd
<b>Address</b> .....	400 meters east of xiangang toll station, xianer village, xiangang town, gaoyao district, zhaoqing city (no.2 workshop of xianer village committee), China
<b>Test specification:</b>	
<b>Standard</b> .....	EN 149:2001+A1:2009
<b>Test procedure</b> .....	Type approved
<b>Non-standard test method</b> .....:	N/A
<b>Test item description</b> .....	FFP2(KN95) Respirator Mask
<b>Trade Mark</b> .....	GuangLun
<b>Manufacturer</b> .....	Zhaoqing Guanglun New Material Co., Ltd
<b>Address</b> .....	400 meters east of xiangang toll station, xianer village, xiangang town, gaoyao district, zhaoqing city (no.2 workshop of xianer village committee), China
<b>Model/Type reference</b> .....	GL-01





<b>Summary of testing:</b>	
<b>Tests performed (name of test and test clause):</b> All clauses.	<b>Testing location:</b> 10 buildings 1-5 floors of Xinligang Bay Industrial Zone, Huangtian Street, Baoan District, Shenzhen
<b>Test item particulars</b> .....:	
Relative Humidity.....: 56% RH	
Air Pressure .....: 97.9 kPa	
Temperature by measurement .....: 25 °C	
Information for safety use.....: N/A	
<b>Possible test case verdicts:</b>	
– test case does not apply to the test object.....: N/A	
– test object does meet the requirement.....: P (Pass)	
– test object does not meet the requirement.....: F (Fail)	
<b>Testing:</b>	
Date of receipt of test item .....: Apr. 01, 2020	
Date (s) of performance of tests .....: Apr. 01, 2020 – Apr. 03, 2020	
<b>General remarks:</b>	
<p>The test results presented in this report relate only to the object tested.                  This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.                  "(See Enclosure #)" refers to additional information appended to the report.                  "(See appended table)" refers to a table appended to the report.                  Throughout this report a comma (point) is used as the decimal separator.                  List of test equipment must be kept on file and available for review.</p>	
<b>General product information:</b>	
<p>The following test were carried out according to EN 149:2001+A1:2009 and manufacturer specification requirement.</p>	



EN 149			
Clause	Requirement - Test	Result - Remark	Verdict
4	Description		P
5	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage.	FFP2	P
6	Particle filtering half masks meeting the requirements of this European Standard shall be designated in the following manner		P
7	Requirements		P
7.1	In all tests all test samples shall meet the requirements.		P
7.2	Unless otherwise specified, the values stated in this European Standard are expressed as nominal values		P
7.3	The visual inspection shall also include the marking and the information supplied by the manufacturer.		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.		P
7.5	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.		P
7.6	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
7.7	The particle filtering half mask shall 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.	No sharp edges and burrs	P
7.9	Leakage		
7.9.1	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.	11 %	P
7.9.2	The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.	FFP2	P
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.		P
7.11	The material used shall not present a danger for the wearer and shall not be of highly flammable nature.		P
7.12	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average		P



EN 149			
Clause	Requirement - Test	Result - Remark	Verdict
7.13	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.		P
7.14	The field of vision is acceptable if determined so in practical performance tests.		P
7.15	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.		P
7.16	The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2.	Inhalation: 0.5 Exhalation: 2.1	P
7.17	Clogging		P
7.17.1	For single shift use devices, the clogging test is an optional test.		P
7.17.2	Breathing resistance		P
7.17.2.1	Valved particle filtering half masks	3 mbar	P
7.17.2.2	Valveless particle filtering half masks	3 mbar	P
7.17.3	Penetration of filter material		P
7.18	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.		P

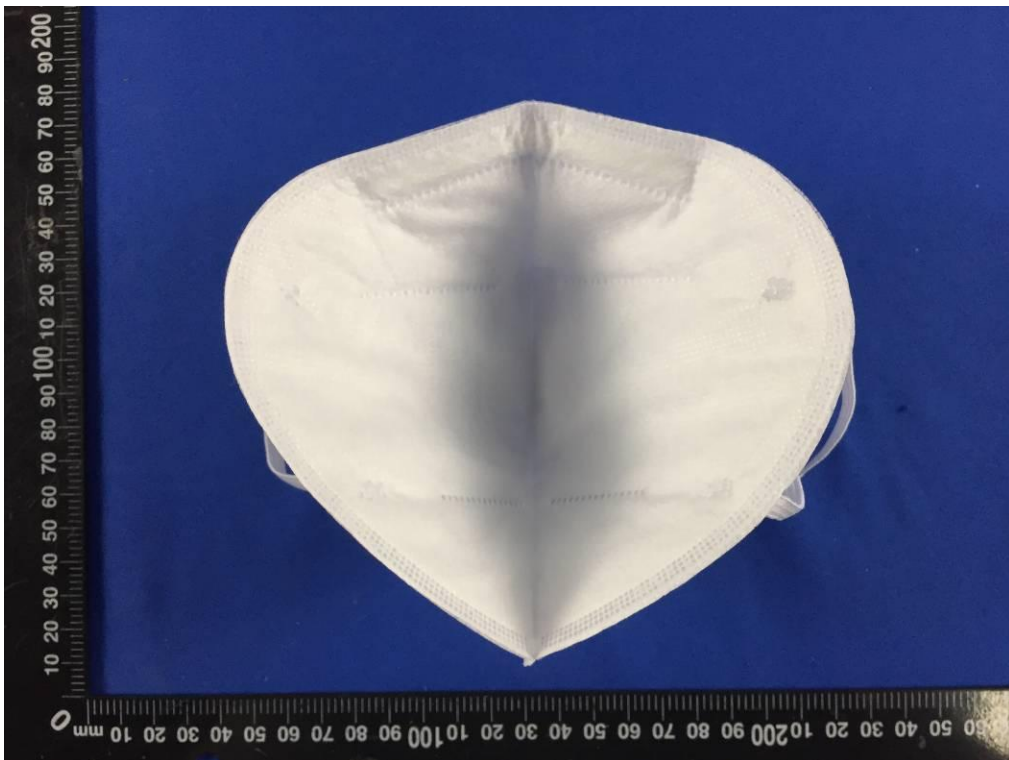


Test	Required level	Test Date	Average value
Paraffin Oil penetration	≤6% after 120mg exposure	Apr. 01, 2020	5,10%
Sodium chloride penetration	≤6% after 120mg exposure	Apr. 01, 2020	0,83%
Inward leakage	46 results ≤11% 8 averages in 10 ≤8%	Apr. 01, 2020	Compliant
Air permeability inhalation 30l/min	≤0,7 mbars	Apr. 02, 2020	0,16 mbar*
Air permeability inhalation 95l/min	≤2,4 mbars	Apr. 02, 2020	0,64 mbar*
Air permeability exhalation 160l/min	≤3,0 mbars	Apr. 03, 2020	1,18 mbar*
Carbon dioxide content	≤1,0%	Apr. 03, 2020	0,60%
Flammability	Must not burn or continue to burn for more than 5 seconds after the withdrawal of the flame	Apr. 03, 2020	Compliant
<p>Remark:</p> <p>Protection(D): protection against solid and liquid aerosols, combined with resistance higher to clogging tested with dolomite dust</p> <p>*Average of the test results (Receiving State + Simulated port processing)</p>			





**Photo document of product**



-----End of test report-----