



中国认可
国际互认
检测
TESTING
CNAS L0218



Test Report



Test Report No. : 轻委2020-05-0955

Applicant: Hunan Kangweining Medical Devices Co., Ltd

Sample Name: Disposable medical mask (non-sterile)

Type and Specification: Flat Ear hanging 17.5cm×9.5cm

Completion Date: 2020-06-02



Guangzhou Quality Supervision and Testing Institute (GQT)

Important Statement

1. Guangzhou Quality Supervision and Testing Institute (GQT) is the products quality supervision and testing organization that is set up by the Government and in charge by Guangzhou Administration for Market Regulation. GQT is a social public welfare institution that providing technical support for the government to strengthen the market supervision and administration, and also accepting commissioned inspection.
2. GQT and the National Quality Supervision and Testing center (center) and the Products Quality Supervision and Testing Station (station) guarantee that the inspection is scientific, impartial and accurate and are responsible for the testing result and also keep confidentiality of the samples and technical information provided by the applicants.
3. Any report without the signatures of the tester, checker and approver, or altered, or without the special chapter for Inspection and Testing of the Institute (center/station), or without the special testing seal , will be taken as invalid. The test shall not be partial copied, picked up and tampered without the authorization of GQT (Center/ Station).
4. The entrusted testing is only valid to the provided samples. The applicant shall not use the inspection results without authorization of GQT (Center/ Station) for undue publicity.
5. The sample and relevant information provided by the applicant, GQT (Center/Station) is not responsible for its authenticity and integrity.
6. If there is any objection to the inspection report, it shall be submitted to GQT (Center/Station) within fifteen days since the report is received. It will not be accepted after the deadline.

Business Contact

Food	020-83390395	020-83655806	020-83187077	
Chemical Product	020-83186957	020-83193967	020-83392709	020-31002536
Light Industrial and Packaging Products	020-83354114	020-83398676	020-83183524	020-82022363
Construction Material				
Fire Protection	020-83334528	020-82022335	020-83355302	020-83380817
Environmental Protection				
Light Industrial Products		020-82022358	020-83398701	
Electrical & Mechanical Equipments				
Complaint Handling: Quality Assurance Review Department			020-83179105	
Sample Returning: Sample Warehouse			020-83186557	

Address: No.1-2, Zhujiang Road, Chaotian Industrial Area, Shilou, Panyu District, Guangzhou, Guangdong Province, PR China (Headquarters) . Zip code: 511447

No.38 Erma Road, Baqi, Yuexiu District, Guangzhou, Guangdong Province, PR China (Branch) . Zip code: 510110

Report Progress, True and False Inquiries

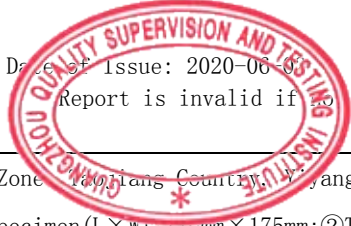
Website: www.qmark.com.cn

Quick Response Code(QR Code): On the lower right corner of the report' s first page

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Sample Name	Disposable medical mask (non-sterile)	Production Date	----
Trademark	----	Lot No.	MN2020051401
Type/Specification/Grade	Flat Ear hanging 17.5cm×9.5cm Type IIR	Expiration Date	----
Applicant	Hunan Kangweining Medical Devices Co., Ltd	Contract No.	CLW2002497-1
		Contract Category	Applicant Test
Manufacturer	Hunan Kangweining Medical Devices Co., Ltd	Sample Quantity	60 pieces
		Sampling Date	2020-05-21
Sampling Way	Submit by applicant	Completion Date	2020-06-02
Test Reference	EN 14683:2019+AC:2019 Medical face masks-Requirements and test methods		
Judge Reference	EN 14683:2019+AC:2019 Medical face masks-Requirements and test methods		
Condition of Sample	Normal		
Test Environment	As the requirements of test reference.		
Test Conclusion	The test items meet the requirements of EN 14683:2019+AC:2019 (Type IIR) .		
Remarks	 <p style="text-align: right;">Date of Issue: 2020-06-03 Report is invalid if not sealed.</p>		
	<p>1. The address of applicant: Building No. 31, Economic Development Zone Chaotian Country, Yang City, Hunan Province, China.</p> <p>2. Bacterial filtration efficiency (BFE): ①Dimension of the test specimen(L×W):170mm×175mm;②Test area of specimen(cm²):44cm²;③The side of the test specimen was facing towards the challenge aerosol:inside;④Flow rate:28.3L/min</p> <p>3. All tests are carried out on finished products or samples cut from finished products.</p> <p>4. The Chinese version of this test report is the standard one, the English version is only for reference.</p>		

Approved by

程小焯

Verified by

李石欣

Tested by

田育涛



(----/2020.06.15)

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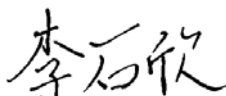
Test Report

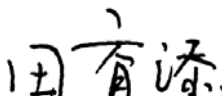
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No.	Test Items	Unit	Reference Requirement	Test Results	Assess
			----	----	
1	Materials and construction	----	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	Meet the requirements	Pass
			The medical face mask shall not disintegrate, split or tear during intended use.	Meet the requirements	
			In the selection of the filter and layer materials, attention shall be paid to cleanliness.	Meet the requirements	
2	Design	----	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.	Meet the requirements	Pass
			Medical face masks may have different shapes and constructions as well as additional features such as a face shield(to protect the wearer against splashes and droplets)with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).	Meet the requirements	
3	Differential pressure	Pa/cm ²	Classification: Type IIR: <60 Test method: EN 14683:2019+AC:2019 Annex C Air flow: 8l/min Test area:4.9cm ² Supplementary information: 1.Pretreatment: Condition each specimen for 4h by exposure to a temperature of (21±5)°C and a relative humidity of (85±5)% 2.General location of the areas of the mask the differential measurement: specimen center 3.Test equipment: a) Test apparatus for measuring differential pressure ZR-1200 b) Programmable Temperature and Humidity Chamber	Classification: Type IIR No.1: 46.9 No.2: 47.1 No.3: 45.9 No.4: 46.4 No.5: 47.3 Average: 46.7	Pass

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No.	Test Items	Unit	Reference Requirement	Test Results	Assess
			----	----	
4	Splash resistance pressure	----	Classification: Type IIR: $\geq 16.0\text{kPa}$ Test method: ISO 22609:2004 Supplementary information: 1. Pretreatment: Condition each specimen for 4h by exposure to a temperature of $(21\pm 5)^{\circ}\text{C}$ and a relative humidity of $(85\pm 10)\%$ 2. The temperature and relative humidity for testing: $(21\pm 5)^{\circ}\text{C}$ and $(85\pm 10)\%$ 3. The description of target area tested: specimen center 4. Any technique used to enhance visual detection of synthetic blood: talcum powder on the normal inside surface of the medical face mask 5. An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show "pass" results. 6. Test equipment: a) Test apparatus for synthetic blood penetration FYY182 b) Programmable Temperature and Humidity Chamber c) Graduated cylinder d) Electronic Balance e) Targeting plate	Classification: Type IIR Pressure: 16.0kPa Velocity: 550cm/s No. 1: pass No. 2: pass No. 3: pass No. 4: pass No. 5: pass No. 6: pass No. 7: pass No. 8: pass No. 9: pass No. 10: pass No. 11: pass No. 12: pass No. 13: pass No. 14: pass No. 15: pass No. 16: pass No. 17: pass No. 18: pass No. 19: pass No. 20: pass No. 21: pass No. 22: pass No. 23: pass No. 24: pass No. 25: pass No. 26: pass No. 27: pass No. 28: pass No. 29: pass No. 30: pass No. 31: pass No. 32: pass	Pass
5	Bacterial filtration efficiency (BFE)	%	Type IIR: ≥ 98	No. 1: 99.80 No. 2: 99.92 No. 3: 99.28 No. 4: 99.96 No. 5: 99.72 Mean plate colony counts of two positive controls: 2.50×10^3 CFU Mean plate colony counts of negative controls: 0 CFU	Pass

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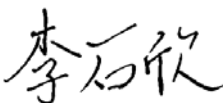
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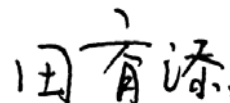
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No.	Test Items	Unit	Reference Requirement	Test Results	Assess
			----	----	
6	Microbial cleanliness	CFU/g	≤30	No. 1: 9 No. 2: 9 No. 3: 17 No. 4: 6 No. 5: 4	Pass

Approved by 

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Tested by 



(----/2020.06.15)

