

# **CAROLEN GROUP FOR COVID-19 HELP**

## **5-Ply Face Masks**

**Labeled for non-medical use, but performance exceeds N95 specs**

**Available for immediate shipment from our warehouse in NJ**

**KN95**

**DISPOSABLE MASK**



# 5 LAYER FILTER



**Effectively protect  
respiratory health**



Respiratory  
Resistance

**<100**pa

Filtration  
Efficiency

**≥95**%

Methanol  
Content

**0**%

# PRODUCT PHOTOS

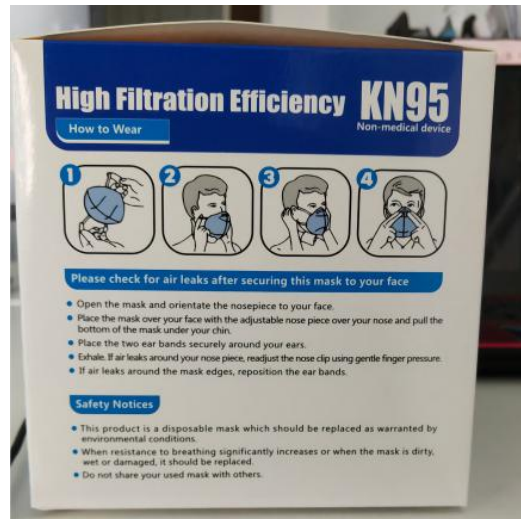


26(cm)


16(cm)



# PRODUCT PACKAGE



# CERTIFICATE KN95

  
**Fiscal Year 2020**  
**CERTIFICATION OF REGISTRATION**

This certifies that:



[REDACTED]


has completed the FDA Establishment Registration (as manufacturer, contract manufacturer) and Device Listing with the US Food & Drug Administration, through

**Owner/Operator Number: 10064790**  
**Device Listing#: See annex**  
**Expiration Date: Dec. 31 2020**

CMC Testing 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. CMC Testing 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. Food and Drug Administration. CMC Testing assumes no liability to any person or entity in connection with the foregoing.

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**Fiscal Year 2020**  
**CERTIFICATION OF REGISTRATION**

Annex to Device Listing#

Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
Disposable Medical Mask (YYC), Protective Face Mask (MYC)	KHA	1	D380064	Manufacturer
Respiratory Mask N95 (MNG5, MKNG)	MSH	2	D380066	Manufacturer

END OF THE ANNEX

   
CMC Testing International (Shenzhen) Co., Ltd.  
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Review Report - 审查报告 - 검토 보고서 - Rapport d'Evaluation

Form QAT\_10-M06, version 00, effective since March 25<sup>th</sup>, 2020

**CE Documentation Review** 

No. 08200331 IDC37

**Review goal:** Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

**Product:** Protective Mask N95 (Not Sterile)  
**Model(s):** M9510

**Classification:** Class I (Not Sterile) (accordingly to the Manufacturer's declaration)

**Review output:** This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices. The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. 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)

Date of issue 31 March 2020  
Approver  
ECM Service Director  
Luca Redonni

Expiry date 30 March 2025  
Technical Expert  
Amanda Pina

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# TEST REPORT

## Test Report

[2020] WSZ FHL NO.W0065

Page 1 of 4

Product name	Protective Mask KN95	Specification	—
		Brand	—
Client/Add/Tel	INJEOLLY CO.,LTD./38th, Xinye Road, Wuping, Longyan, Fujian Province, 364300, China/—		
Manufacturer/Add/Tel	—/—/—		
Sample grade	KN95	Sample number	GW W0065-2020
Sample quantity	60 pcs	Receiving date of sample	08/04/2020
Test type	Entrusted inspection	Article number/Batch number/Style number	YJ10
Test date	16/04/2020~19/04/2020	Testing sites	Testing room
State	Meeting the requirements of testing		
Test standard(s)	GB 2626-2006 Respiratory protective equipment -Non-powered air-purifying particle respirator		
Test items	General requirements, appearance requirements, respiratory resistance, flammability, filter efficiency, head harness, dead space, vision, total inward leakage		
Test conclusion	The sample upon testing, the test items meet the requirements of the GB 2626-2006 standard. The detail of test results see on Pages 2-4.		
Note	For the entrusted sample test, the technical responsibilities are undertaken for the test results of the supplied samples only.		

Approver: 

Reviewer: 

Chief Tester: 

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## Test Report

[2020] WSZ FHL NO.W0065

Page 2 of 4

S.No.	Test item	Unit	Technical requirements	Test result	Single item decision	
1	General requirements	—	<p>Materials shall have sufficient strength and shall not break or deform during the service life.</p> <p>The design shall be less prone to structural damage; the design, composition and installation of components shall not pose any danger to the user; headband design shall be adjustable, easy to wear and removal, able to hold the mask firmly on the face and not show significant compression or tenderness when worn; The mask shall have a small dead space and a larger field of view as much as possible; disposable mask structure shall be able to ensure close contact with the face, and shall not be deformed during the service life.</p>	Meeting the requirements	Qualified	
2	Appearance requirements	—	The surface of the sample shall not be damaged, deformed and have obvious other defects; components and structures shall be able to withstand normal conditions of use and the temperature, humidity and mechanical impact possibly encountered; headband shall be adjustable, and the replaceable mask headband design shall be replaceable; after the pretreatments of temperature, humidity and mechanical strength, the parts shall not fall off, be damaged and deformed.	Meeting the requirements	Qualified	
3	Respiratory resistance	Pa	Total inspiratory resistance $\leq 350$	Untreated	72.3	Qualified
					74.1	
			Total expiratory resistance $\leq 250$	Pretreated	73.0	Qualified
					71.5	
	Untreated	54.1	Qualified			
	58.3					
	Pretreated	57.6				
	56.3					

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# TEST REPORT

## Test Report

[2020] WSZ FHL NO.W0065

Page 3 of 4

S.No.	Test item	Unit	Technical requirements	Test result		Single item decision	
4	Flammability	—	Parts exposed to the flame shall not burn after having been removed from the flame, if burned, the afterflame time shall not exceed 5s.	Untreated	The mask burned. The afterflame time is 0.1s.	Qualified	
				Pretreated	The mask burned. The afterflame time is 0.1s.		
5	Head harness	—	Not appearing slippage or breakage to withstand 10N tensile force lasting 10s .	Untreated	No slippage or breakage occurred		Qualified
				Pretreated	No slippage or breakage occurred		
6	Dead space	—	≤1%	0.08%		Qualified	
7	Vision	—	View below ≥60°	78.6°		Qualified	
8	Filter efficiency	—	≥95.0%	Untreated	99.6%	Qualified	
					99.8%		
					99.7%		
					99.5%		
					99.6%		
					99.5%		
					99.4%		
				Pretreated	99.5%		
					99.6%		
					99.5%		
					99.6%		
					99.5%		
					99.6%		
					99.7%		

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## Test Report

[2020] WSZ FHL NO.W0065

Page 4 of 4

S.No.	Test item	Unit	Technical requirements	Test result							Single item decision	
S.No.	Test item	Unit	Technical requirements	Subjects	E1	E2	E3	E4	E5	TIL	Single item decision	
					(%)	(%)	(%)	(%)	(%)	(%)		
9	Total inward leakage	—	TIL <11% for at least 46 actions in 50 actions, and TIL <8 %for at least 8 of 10 subjects.	Untreated	1 <sup>st</sup>	2.4	3.2	3.4	3.1	2.6	2.9	Qualified
					2 <sup>nd</sup>	2.6	3.7	3.7	3.5	3.0	3.3	
					3 <sup>rd</sup>	2.9	3.9	3.8	3.7	3.3	3.5	
					4 <sup>th</sup>	2.3	2.8	2.9	2.7	2.3	2.6	
					5 <sup>th</sup>	3.0	3.7	3.5	3.5	3.1	3.4	
				Pretreated	6 <sup>th</sup>	1.9	3.1	3.0	3.0	2.4	2.7	
					7 <sup>th</sup>	2.7	3.4	3.5	3.7	3.1	3.3	
					8 <sup>th</sup>	2.4	3.5	3.4	3.4	2.8	3.1	
					9 <sup>th</sup>	2.8	3.4	3.4	3.2	2.8	3.1	
					10 <sup>th</sup>	3.1	3.6	3.6	3.9	3.2	3.5	
Note												

————— The end —————

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## PRODUCT DETAILS:

1. COLOR BOX SIZE:14.0\*12.5\*13.5 CM, 25 pcs in a color box
2. MASTER CARTON SIZE:68\*44\*55cm/0.165cbm, 1500pcs/ctn, 13.6kg/ctn  
Total:KN95/487500PCS/325ctns/4420 KGS/53.625 CBM
3. Material:
  - 5 ply (100% new material)
  - 1st ply: 50g/m2 SSS non-woven fabric
  - 2nd ply: 25g/m2 melt blown filter
  - 3rd ply: 25g/m2 melt blown filter
  - 4th ply: 45g/m2 hot air cotton
  - 5th ply: 25g/m2 SSS non-woven fabric
4. Usage:In restaurants, beauty salons, nail shops, pet shops, and general cleaning, as well as other environments that require face mask protection.