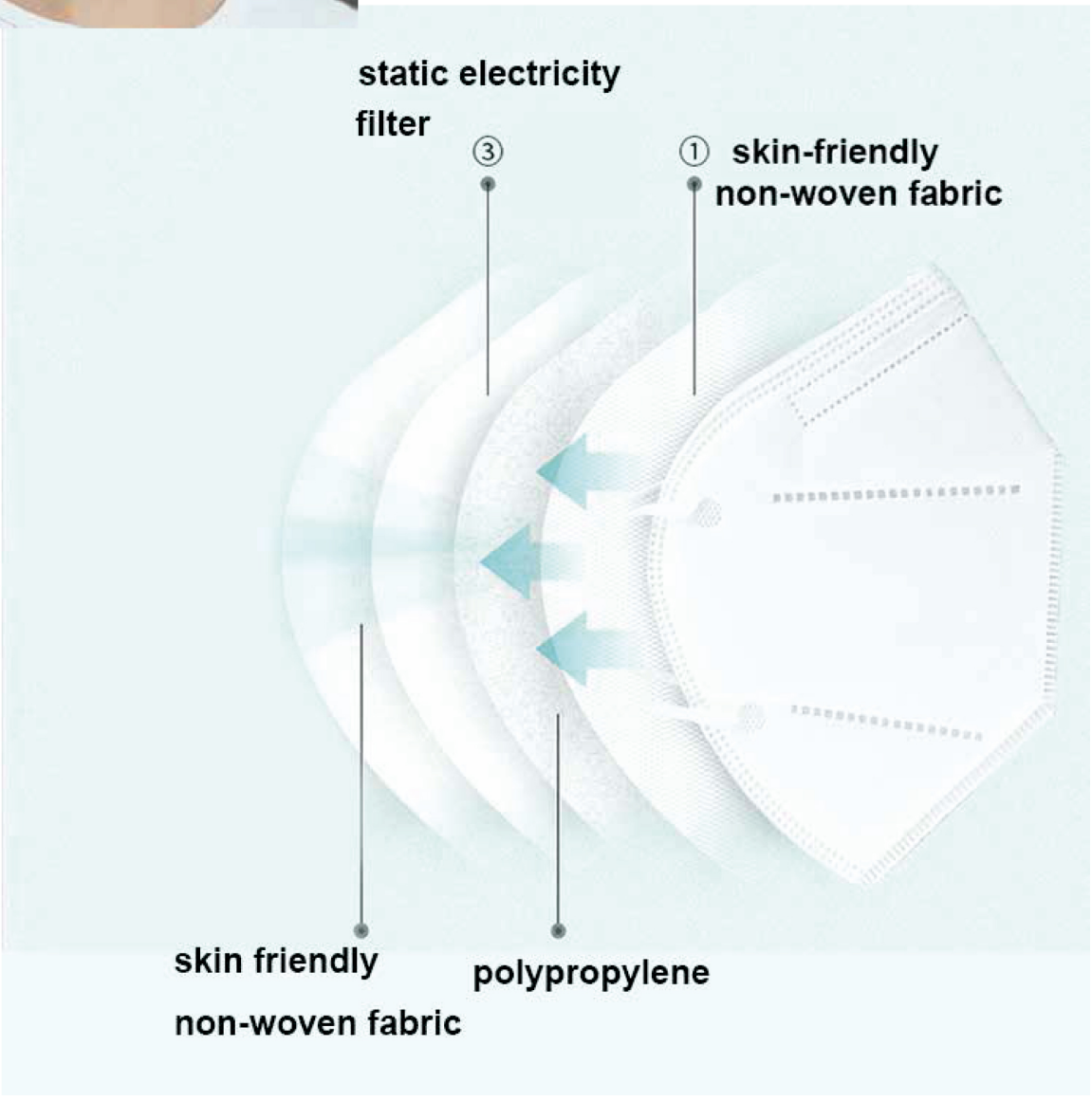


Ficha Técnica

TAPABOCAS KN95

KN95 Protective Mask Estándar GB2626-2006

5 CAPAS





Ficha Técnica
TAPABOCAS KN95

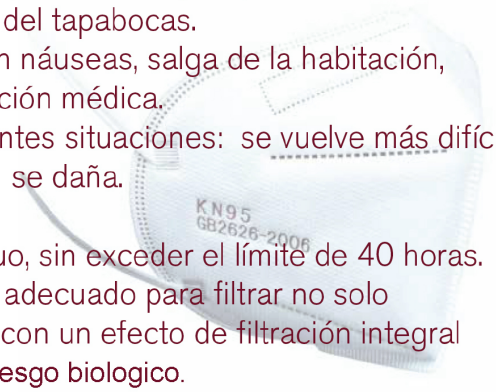
KN95 Protective Mask Estándar GB2626-2006

Producto: Tapabocas KN95 (KN95 Protective Mask GB2636-2006)

Elaborado: 5 capas de telas no tejidas, unidas por punzonado al calor.
1ra Capa Tela no tejida SS 50G/M2
2da Capa Algodón de alta densidad 45G/M2
3ra Capa Tela no tejida soplada por fusión PP 25G/M2 (Nivel 95)
4ta Capa Tela no tejida soplada por fusión PP 25G/M2 (Nivel 95)
5ta Capa Tela no tejida agradable a la piel 25G/M2

Usos: Para protección personal, filtra efectivamente las partículas finas (PM25) y las bacterias en la contaminación del aire.

Modo de uso: Los tapabocas sólo deben ser utilizados por un usuario.
Colóquese el tapabocas sobre la nariz y por debajo del mentón.
El tapabocas tiene dos correas de ajuste, ponga una correa debajo de las orejas y una por encima.
El tapabocas tiene un clip nasal, use las puntas de los dedos de ambas manos para moldear este clip de manera firme contra la nariz y la cara. No lo haga con una mano.
Asegúrese de realizar una autoverificación del sellado hermético cada vez que use el tapabocas.
El vello facial puede hacer que el tapabocas tenga filtraciones, por lo que de preferencia los usuarios deben estar bien rasurados.
Algunos tipos de vello facial son aceptables siempre que no estén a lo largo del área de sellado hermético del tapabocas.
Si se siente mareado, aturdido o con náuseas, salga de la habitación, quítese el tapabocas y busque atención médica.
Deseche el tapabocas en las siguientes situaciones: se vuelve más difícil respirar a través de él, se ensucia o se daña.



Rango de aplicación: Esta recomendado para uso continuo, sin exceder el límite de 40 horas. Para filtrar partículas en el aire y es adecuado para filtrar no solo partículas tambien virus y bacterias con un efecto de filtración integral de más del 95%. Proteccion contra riesgo biologico.



Ficha Técnica
TAPABOCAS KN95

KN95 Protective Mask Estándar GB2626-2006

Precauciones: ¡NO TOQUE la parte de adelante del tapabocas! Puede estar contaminada.
Mantenga su tapabocas limpio y seco.
Asegúrese de leer y seguir las recomendaciones del fabricante sobre el uso y almacenamiento.
El uso en niños debe estar supervisador por un adulto.
No se recomienda su uso en niños menores de tres años.

Advertencias: No usar donde halla exposición a vapores orgánicos, gases ácidos, neblinas o partículas toxicas para las cuales es apropiado usar un respirador con carbón activo. (manupulación de plomo, mercurio, etc.)
El tapabocas no es una fuente de oxígeno, no lo use en ambientes que contengan menos de 19,5% de oxígeno por volumen.
Ante de usarlo, el usuario deberá determinar si el producto es apropiado para el uso pretendido, ni el fabricante ni el vendedor se hacen responsables por el uso inapropiado que se le dé a este producto.

Presentaciones: Caja x 50 unidades - contienen10 bolsas x 5 unidades C/U.
Bulto x 40 cajas de 50 unidades cada una.

Almacenar: Almacenar en un lugar limpio, con una humedad inferior al 80% y buena ventilación.

Elaborado por: Guangzhou Medical Supplies Store Medical Technology CO, LTDA.

Vida Útil: 5 años.

Trazabilidad: Lote y fecha de vencimiento impresos en la factura y empaques.



Codigos de Barra: EAN13 0610452919388 Caja x 50 unidades
EAN 13 0610452919395 Bolsa x 5 Unidades

检 测 报 告(Testing Report)	防伪查询网址(Security website)：www.fcl-sz.org.cn 防伪码(Security code)：4475432837
报告编号(Report No)：ZFLJ2616857A	Page 1 of 4

Applicant Information (客户信息)

Applicant Name(委托单位) : Guangzhou medical supplies store medical technology Co., Ltd
(广州医耗店医疗科技有限公司)

Applicant Address(委托单位地址) : No.32 11-4F, Lida Road, Shiling Town, Huadu District, Guangzhou
（广州市花都区狮岭镇利达路 32 号之十一 4F）

Manufacturer(生产单位) : Guangzhou medical supplies store medical technology Co., Ltd
(广州医耗店医疗科技有限公司)

Sample Information (样品信息)

Sample Description(样品描述) : KN95 protective masks（KN95 防护口罩）

Sample Quantity(样品数量) : 40 pieces（40 个）

- Sample Receiving date (收到样品的日期) : 2020-04-26
- Report date (报告日期) : 2020-05-08
- The original sample is sticked on the last paper. (送检样品原样粘贴在本报告的末页)

Test Performed (检验标准)

Judgement according to(评定依据):

GB 2626-2006 Respiratory protective equipment—— Non-powered air-purifying particle respirator .
呼吸防护用品 自吸过滤式防颗粒物呼吸器 .

- Selected test(s) as requested by applicants. (本实验室根据客户要求完成以下检测内容)

Pronounce (声明)

The results shown in this report refer only to sample(s) tested unless otherwise stated.All the items are performed in the standard conditions, except the noted cases.(除非特别说明，测试结果只对来样负责。所有测试项目均在标准规定的环境下进行，有注明除外。)

Except for the requirement of the client, the test results and the conformity judgement of this report do not take the uncertainty of the test results into account.(除非客户要求，本报告检测结果及符合性判定不考虑测量结果的不确定度。)

Signed for and on behalf of
CNTAC Testing Service Co.,Ltd.(Foshan)

Approved by
（批准）

张志荣

佛山中纺联检验技术服务有限公司 检验检测专用章 (02)

检 测 报 告(Testing Report)	防伪查询网址(Security website)：www.fcl-sz.org.cn 防伪码(Security code)：4475432837
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--- Test Result (测试结果) ---

	Test Result(测试结果)	Requirements(评定条件)	Judgement(判定)
1. Filtration Efficiency(过滤效率) *GB 2626-2006 Section 6.3(条款 6.3)*			
Air flow: 85L/min, Aerosol: NaCl(气体流量 85L/min，气溶胶颗粒：NaCl)			
Unit(单位): <**%**>			
Before pretreatment (未经处理)		(KN95) ≥ 95.0	Pass(合格)
sample 1#(样品 1)	97.7		
sample 2#(样品 2)	98.8		
sample 3#(样品 3)	99.0		
sample 4#(样品 4)	98.6		
sample 5#(样品 5)	98.3		
sample 6#(样品 6)	98.3		
sample 7#(样品 7)	98.6		
sample 8#(样品 8)	98.2		
sample 9#(样品 9)	98.7		
sample 10#(样品 10)	98.3		
After pretreatment(经预处理)			
sample 1#(样品 1)	98.6		
sample 2#(样品 2)	98.8		
sample 3#(样品 3)	98.7		
sample 4#(样品 4)	98.7		
sample 5#(样品 5)	98.3		
2. Head harness(头带) *GB 2626-2006 Section 6.11(条款 6.11)*			
For disposable facepiece, , tension 10N for 10s(随弃式面罩，拉力 10N，持续 10s)			
Result(测试结果)	No slippage or fracture (未出现滑脱或断裂)	There should be no slippage or fracture(不应出现滑脱或断裂)	Pass(合格)
3. Exhalation Resistance(呼气阻力) *GB 2626-2006 Section 6.6(条款 6.6)*			
Air flow: 85 L/min(通气量 85 L/min)			
Unit(单位): <**Pa**>			
Before pretreatment(未经处理)		≤ 250	Pass(合格)
sample 1#(样品 1)	48.4		
sample 2#(样品 2)	40.7		
After pretreatment(经预处理)			
sample 1#(样品 1)	57.0		
sample 2#(样品 2)	50.4		
4. Inhalation Resistance(吸气阻力) *GB 2626-2006 Section 6.5(条款 6.5)*			
Air flow: 85 L/min(通气量 85 L/min)			
Unit(单位): <**Pa**>			
Before pretreatment(未经处理)		≤ 350	Pass(合格)
sample 1#(样品 1)	60.2		
sample 2#(样品 2)	57.2		
After pretreatment(经预处理)			
sample 1#(样品 1)	60.6		
sample 2#(样品 2)	55.7		

佛山中纺联检验技术服务有限公司 检验检测专用章 (02)

检 测 报 告(Testing Report)	防伪查询网址(Security website)：www.fcl-sz.org.cn 防伪码(Security code)：4475432837
报告编号(Report No)：ZFLJ2616857A	Page 3 of 4

	Test Result(测试结果)	Requirements(评定条件)	Judgement(判定)

5. Appearance Inspection(外观检查) *GB 2626-2006 Section 6.1~6.2(条款 6.1~6.2)*

Result(测试结果)	Accordance （符合）	The surface should not be damaged, deformation and other obvious defects. (样品表面不应破损、变形和有明显的其他缺陷。)	Pass(合格)
	Accordance （符合）	Component materials and structures shall be able to withstand normal operating conditions and possible temperature, humidity and mechanical shocks.（部件材料和结构应能耐受正常使用条件及可能遇到的温度、湿度和机械冲击。）	
	Accordance （符合）	Headband should be adjustable（头带应可调）	
	Accordance （符合）	After temperature and humidity pretreatment and mechanical strength pretreatment, components should not fall off, damage and deformation.(经温度湿度预处理和机械强度预处理后，部件不应脱落、损坏和变形。)	

6. Flammability(可燃性) *GB 2626-2006 Section 6.15(条款 6.15)*

Unit(单位): <**s**>

After flame time(续燃时间)

Before pretreatment(未经处理)		After flame time(续燃时间) ≤ 5	Pass(合格)
sample 1#(样品 1)	0		
sample 2#(样品 2)	0		
After pretreatment(经预处理)			
sample 1#(样品 1)	0		
sample 2#(样品 2)	0		

Remark（备注）：1. The filtration efficiency item is unauthorized for CMA and have no valid in law.
（CMA 未授权过滤效率项目，不具有对社会证明作用。）
2. The filtration efficiency、 inhalation resistance and exhalation resistance items are unauthorized for CNAS.（CNAS 未授权过滤效率、吸气阻力和呼气阻力项目。）
3. This report is a supplement to the report number ZFLJ2616857.
（此报告是对报告编号 ZFLJ2616857 的补充。）

佛山中纺联检验技术服务有限公司 检验检测专用章 (02)

检 测 报 告(Testing Report)	防伪查询网址(Security website)：www.fcl-sz.org.cn 防伪码(Security code)：4475432837
报告编号(Report No)：ZFLJ2616857A	Page 4 of 4

Original (送检样品原样)



======= End of Report (检测报告结束) ======

International Certification Registrar International Certification Registrar International Certification Registrar International Certification Registrar

Certificate

No. ICR Polska/P4440142

CE

Name and address of manufacturer:	Guangzhou medical supplies store medical technology Co., Ltd 4f, no.32-11, Lida Road, Shiling Town, Huadu District, Guangzhou
Product name:	Protective masks
Product types:	KN95;N95;FFP1;FFP2;FFP3;PM2.5
Product trademark:	n/a

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425

EN 149:2001+A1:2009

The certification process has been carried out in accordance with the program PC-P-07-07. Evaluation has been carried out in accordance with test reports made by UAC Quality Techno logy Service（UK） Ltd

No. of test reports:	TCF-UAC-20200322022PPE
Certificate issue date:	25.03.2020
Expiration date:	24.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3109.

This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standard.

Director: Rafał Kalinowski

Warsaw, 25. 03. 2020

ICR Polska Co. Ltd.
ul. Plac Przymierza 6, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrqa.com

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

GUANGZHOU MEDICAL SUPPLIES STORE MEDICAL TECHNOLOGY CO., LTD
No.32 11-4F, Lida Road, Shiling Town, Huadu District,Guangzhou, Guangdong, 510000, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Owner/Operator Number: 10063522

Device Listing#: See annex

ATL 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. ATL 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. ATL assumes no liability to any person or entity in connection with the foregoing.

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. ATL is not affiliated with the U.S. Food and Drug Administration.

FDA

Chief engineer

Issued: March 22, 2020
Expiration Date: December 31, 2020

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Owner/Operator Number: 10063522

Listing No.	Code	Device Name	Proprietary Names	Activities
D376656	KHA	MASK,SCAVENGING	Manufacturer	

END OF THE ANNEX

Chief engineer
Issued: March 22, 2020
Expiration Date: December 31, 2020

HKGCC

Hong Kong General Chamber of Commerce
香港總商會1861

Reference Number

5473280

Certificate
證明書

THIS IS TO CERTIFY THAT:

The annexed **FREE SALE CERTIFICATE** is submitted to the Chamber for certification; and

Specimens of authorized signature and company chop of the applicant company are recorded in the Chamber.

茲證明：

附件 **FREE SALE CERTIFICATE** 已提交予本會作商事證明；及

申請公司的授權人簽署及印章式樣已在本會記錄備案。

THE HONG KONG GENERAL CHAMBER OF COMMERCE
FOUNDED 1861

.....

Signature of Authorized Officer

Name of Signatory
Ms. Sheryl LEUNG Ho Laam

Date: 13 May 2020

.....

Certification Chop
The Hong Kong General Chamber of Commerce

Authorized by the Government of the Hong Kong SAR to issue Certificates of Origin (Chapter 324 of the laws of HK)

Issuing Office: Mongkok Certification Branch, HKGCC
18/F Hang Seng Mongkok Building, 677 Nathan Road,
Mongkok, Kowloon, Hong Kong

Authentication Code **65302679**

http://cert.chamber.org.hk/verify

自 由 销 售 证 书

CERTIFICATE OF FREE SALE

产品名称：KN95 防护口罩
Product(s)：KN95 MASK

型号： KN95
Model: KN95

规格：无
Specifications：N/A

销往国家：哥伦比亚
Export to：COLOMBIA

出口商：广州医耗店医疗科技有限公司
Exporter: Guangzhou Medical Supplies Store Medical Technology Co., Ltd

出口商地址：广州市花都区狮岭镇利达路 32 号之十一 4F
Address: No.32 11-4F,Lida Road, Shingling Town, Huadu District, Guangzhou

制造商：广州医耗店医疗科技有限公司
MANUFACTURE: Guangzhou Medical Supplies Store Medical Technology Co., Ltd
制造商地址：广州市花都区狮岭镇利达路 32 号之十一 4F
ADDRESS: No.32 11-4F, Lida Road, Shingling Town, Huadu District, Guangzhou

兹声明广州医耗店医疗科技有限公司，产品: KN95 防护口罩，允许在中国境内销售并出口。

IT IS HEREBY DECLARED THAT GUANGZHOU MEDICAL SUPPLIES STORE MEDICAL TECHNOLOGY Co., Ltd CAN SELL KN95 MASK , WHICH ARE ALLOWED TO BE SOLD AND EXPORTED IN CHINA.

广州医耗店医疗科技有限公司
Guangzhou Medical Supplies Store Medical Technology Co., Ltd
日期：2020 年 5 月 11 日
DATE：2020/05/11


THE HONG KONG GENERAL CHAMBER OF COMMERCE
FOUNDED 1861

El progreso es de todos | Mincomercio | VUCE Importaciones

VISTO BUENO

Instituto Nacional de Vigilancia de Med, Alim

Número solicitud:	TMR-M-0018345-20200831		
Número Visto Bueno:	VINVIMA-20-0093198	Fecha aprobación o negación:	2020-09-01 03:45:02 PM
Concepto de visto bueno:	Aprobado	Fecha vencimiento aaaa-mm-dd:	

DESCRIPCIÓN y/o OBSERVACIONES

OK TECNICO
SE ACEPTA MODIFICACION DE SUBPARTIDA

EL CONCEPTO NO CAMBIA

OK
NO REQUIERE AUTORIZACION COMO DISPOSITIVO MEDICO VITAL NO DISPONIBLE POR LO TANTO NO SE AMPARA BAJO LA RESOLUCION 522 DE 2020, DE ACUERDO A LA FICHA TECNICA EMITIDA POR EL FABRICANTE: GUANGZHOU MEDICAL SUPPLIES STORE MEDICAL TECHNOLOGY CO.,LTD. ÉSTA INDICA UN USO DIFERENTE AL MEDICO.
PRODUCTO: MASCARA PROTECTORA CON FILTRO KN95
USO: NO MEDICA .ESTE PRODUCTO NO ES DE USO MEDICO

A7gL WChZ Jxiq +zoi t1ld 6iup GxI=