

Mascarilla KN95

Protección | Alta Eficiencia

Healthy

KN95



Filtra + 95%

10
uds.

Anti Polvo ✓ Anti Niebla ✓ Anti Spray ✓ Anti Virus ✓

KN95

Healthy

Ficha Técnica

PRODUCTO

Nombre KN95

Marca Healthy

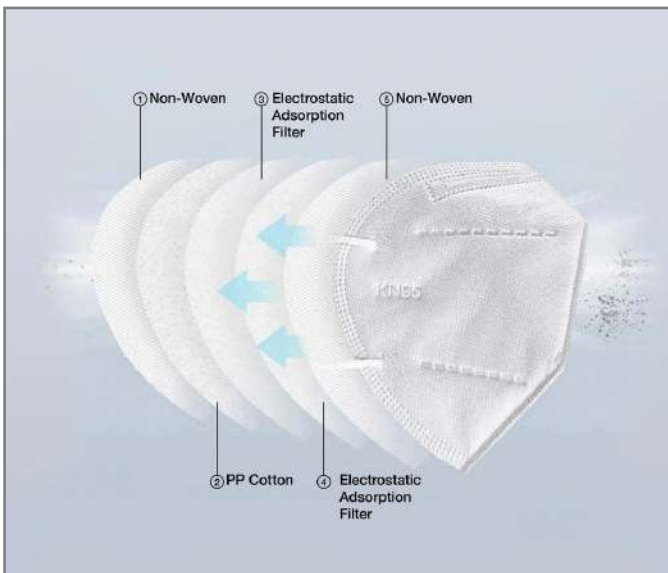
Color Blanco / Negro

Envase Caja 10 unidades

ESPECIFICACIONES TÉCNICAS

La mascarilla KN95 ha sido íntegramente fabricada en PP no tejido de varias capas proporcionando una protección total y una eficiencia aproximada del 95,9 %. Es capaz de retener humo, partículas en suspensión, gotas, olores, etc.

Dado su diseño 360°, correas elásticas para un ajuste universal, clip nasal para un sellado perfectamente hermético y su construcción en material suave de alta calidad, permite utilizarla por un prolongado tiempo.





Fiscal Year 2020

CERTIFICATION OF FDA REGISTRATION

This certifies that:

HUNAN HEALTHY FOREVER MEDICAL TECHNOLOGY CO.,LTD
1101, 11F, Building A1, LuGu Science&Technology Innovation Park,
1698 Yuelu West Ave., High-Tech Development Z, changsha, Hunan,
414000, CHINA

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

Shenzhen CCT Testing Technology Co., Ltd.

Owner/Operator Number: 10063568



Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D376721	KHA	MASK, SCAVENGING	Disposable medical face mask. Protective face mask .KN-95/N-95 KBN-0068.KBN-0 088. KBN-0099, KBN-KN95-01,KBN-N95-02

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



Chief engineer
Issued: 03/20/2020
Expiration Date:12/31/2020

Shenzhen CCT Testing Technology Co., Ltd.
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شهادة - Certificate - 證明書 - Сертификат - Certificate

Form QAT_10-M04, version 00, effective since March 6th, 2020

Certificate of Compliance



No. 0B200323M.HHF0086

Certificate's Holder:

Hunan Healthy Forever Medical Technology Co., Ltd.
1101, 11F, Building A1, LuGu Science&Technology Innovation Park, 1698 Yuelu West Ave., High-Tech Development Zone, Changsha, Hunan, China

Certification ECM Mark:



Product Model(s):

Medical Mask
KBN-0068, KBN-0088, KBN-KN95-01, KBN-N95-02

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. 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

Issuance date: 23 March 2020

Expiry date: 22 March 2025

Reviewer
Technical expert
Amanda Payne



Approver
ECM Service Director
Luca Bedonni



Ente Certificazione Macchine Srl

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Certificate

ICR Polska/VC/PC00255

Name and address of certificate owner:	Hunan Healthy Forever Medical Technology Co., Ltd 1101, 11F, Building A1, LuGu Science&Technology Innovation Park, 1698 Yuelu West Ave., High-Tech Development Zone, Changsha, Hunan, China
Name and address of manufacturer:	Hunan Healthy Forever Medical Technology Co., Ltd 1101, 11F, Building A1, LuGu Science&Technology Innovation Park, 1698 Yuelu West Ave., High-Tech Development Zone, Changsha, Hunan, China
Product name:	KN95 Protective Mask
Product types:	KBN-KN95
Product trademark:	N/A

- This certificate confirms that the product: meets the requirements of the following standard(s):
EN 149:2001+A1:2009

The certification has been carried out in accordance with individual rules and conditions agreed with the applicant. Evaluation has been carried out in accordance with:

Test report(s) No.:	CTO200409021MRS
Test conducted by:	Shenzhen CTO Technology Service Co., Ltd
Certificate issue date:	20.04.2020
Expiration date:	19.04.2025

- This certificate refers to the above mentioned product and its conformity in regards of above mentioned standard(s) was proven on test sample
- This certificate does not imply meeting all essential requirements, assessment of the series-production or any other restricted Notified Bodies conformity assessment procedure appropriate for the product
- This certificate holder shall use this certificate in connection to declaration of conformity and technical data relevant for the product the certificate was issued
- This certificate does not constitute legal base to affix **CE** marking on the product

Certificate modifications:

- n/a



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Director: Rafał Kalinowski

Warsaw, 20.04.2020



Check certificate status: <https://cert.icrpolska.com/>