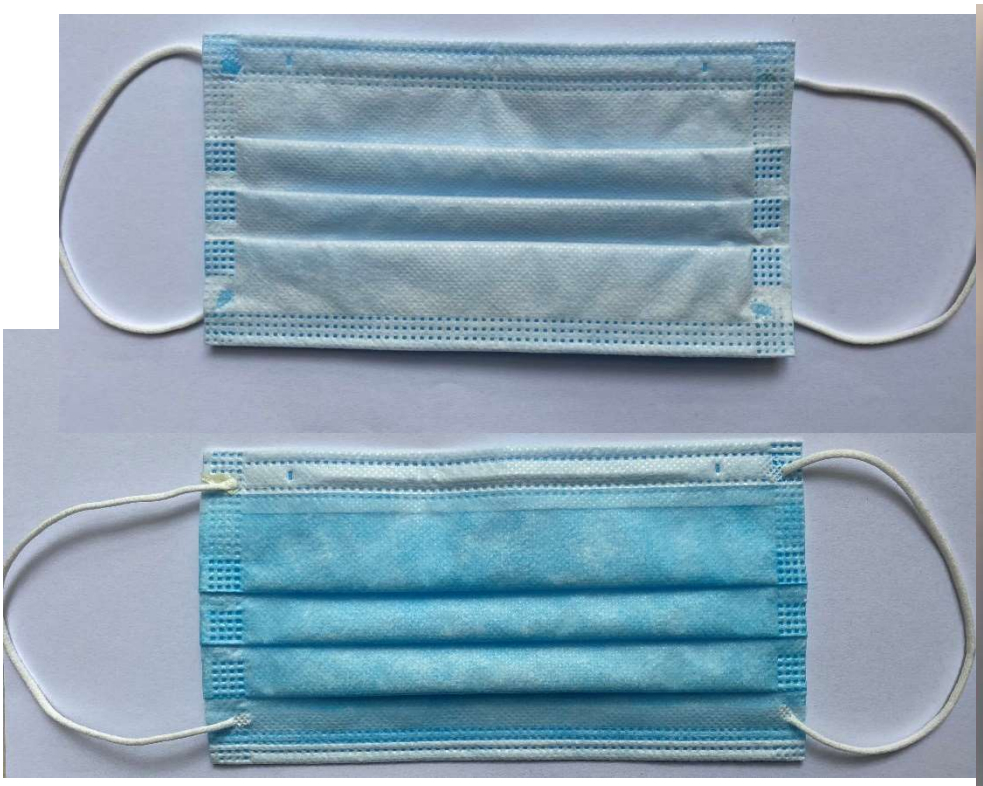
CUBREBOCAS-STD-CGC/10

CUBREBOCAS USO MEDICO DE 3 CAPAS DESECHABLE



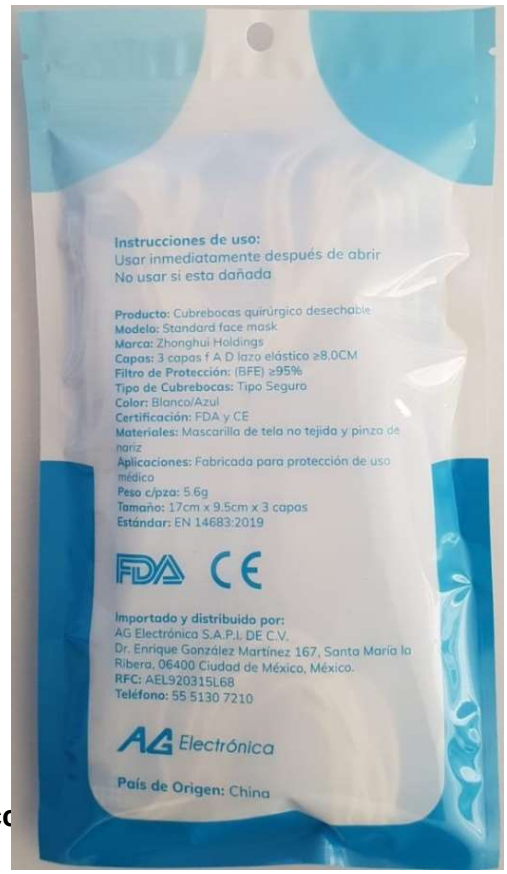
Tratamiento: Para mayor seguridad a este producto se le practicaron procedimientos de esterilización con luz UV-C y ozono gaseoso.

Tipo de Cubrebocas: Tipo Seguro
Aplicaciones: Fabricada para protección de uso médico

Forma: Rectangular
Materiales: Mascarilla de tela no tejida, pinza de nariz y lazo elástico.
Capas: 3 Capas f A D lazo elástico ≥8.0CM
Color: Blanco/Azul

Eficiencia de Filtración Bacteriana (BFE) ≥95%
Certificación: CE & FDA
Estándar: EN 14683:2019

Peso/pza: 5.6g
Tamaño: 17x9.5cm x 3 Capas
Empaque: 10pzas/bolsa
Lugar de Origen: China
Código HS: 6307900000



b-ok.cc

AG Electrónica
¿Qué vamos a innovar hoy?

Attestation of Conformity

No. ICR Polska/M3100166

CE

Name and address of Registered Manufacturer:	CHINA GREEN CONTAINER CO.,LTD 5 / F, 1st floor, 18 Xinyue Road, Wusha Neighborhood Committee, Daliang Street, Shunde District, Foshan
Product name:	FACE MASK
Product type/model:	175mm*95mm
Trade mark:	n/a

This Attestation confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption of conformity with essential requirements of Directive 93/42/EEC.

Relevant EC Directive:	Medical Device Directive 93/42/EEC
Conformity assessment procedure:	EC Declaration of Conformity (Annex VII of Directive 93/42/EEC)
Classification:	Class I according Rule 1 of Annex IX of Directive 93/42/EEC
Applied normative documents:	EN 14683:2019
Applied Quality Management System	n/a

This AoC will remain valid only if Quality Management System Certificate remains valid.
The assessment process has been carried out in accordance with the program PC-P-07-07.
Evaluation has been carried out in accordance with test report made by:

- Shenzhen Circle Testing Certification Technology Service Co., Ltd.

No. of test report:	CTC200339008RR
Issue date:	24.03.2020
Expiration date:	23.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3125.

This Attestation 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, 24. 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 FDA REGISTRATION

This certifies that:

CHINA GREEN CONTAINER CO.,LTD

5 / F, 1st floor, 18 Xinyue Road, Wusha Neighborhood Committee, Daliang Street, Shunde District, Foshan (residence declaration) 528399, 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: 10065225

Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D380939	KHA	MASK, SCAVENGING	FACE MASK 17.5cm*9.5cm

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.

Tony

Chief engineer
Issued: 03/21/2020
Expiration Date:12/31/2020

SHENZHEN CCT TESTING TECHNOLOGY CO.,LTD CCT Testing Service

Shenzhen CCT Testing Technology Co.,Ltd.
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