

Certificate

CERTIFICATE of CONFORMITY

APPLICANT : AN BINH EXPORT GARMENT JOINT STOCK COMPANY
Truc Cau Hamlet, Nghia Dan Commune, Kim Dong District, Hung Yen Province, Vietnam

MANUFACTURER : AN BINH EXPORT GARMENT JOINT STOCK COMPANY
Truc Cau Hamlet, Nghia Dan Commune, Kim Dong District, Hung Yen Province, Vietnam

Product Name : *Non sterile face mask*

Trade mark : *Face Mask*

Product Classification : *Class I*

Applied Directive(s) : *93/42/EEC Medical Device Directive*

This certificate has been issued according to the voluntary application of the manufacturer. This certificate is valid only for the product(s) in above mentioned. This certificate confirms that the declaration of conformity which is prepared by manufacturer is available. It's manufacturer's sole responsibility to meet all the necessary conformity assessment activities according to 93/42/EEC Medical Devices Directive and related standards or the mentioned product(s) before placing them on the market. It is the manufacturer's responsibility to comply a full technical file according to Annex VII of 93/42/EEC and the manufacturer is the responsible to take all necessary actions before affixing CE mark on the product(s)

Date of issue of this certificate : 03.04.2020

Expiry date : 02.04.2021

Certificate Number : 20.02.528-CE



CE


General Manager

*İncilipınar mahallesi 57 nolu sokak Ekip İş Mrk. Kat: 6 No: 33
Şehitkâmil/Gaziantep*



TỔ CHỨC CHỨNG NHẬN VÀ GIÁM ĐỊNH QUỐC TẾ ISOCERT
"HẢI HÒA CÙNG THỊNH VƯỢNG"

GIẤY CHỨNG NHẬN

Số 1869293400402-MED

CHỨNG NHẬN HỆ THỐNG QUẢN LÝ CHẤT LƯỢNG CHO LĨNH VỰC
TRANG THIẾT BỊ Y TẾ CỦA:

CÔNG TY CỔ PHẦN MAY XUẤT KHẨU AN BÌNH

Địa chỉ: Thôn Trúc Cầu, Xã Nghĩa Dân, Huyện Kim Động, Tỉnh Hưng Yên, Việt Nam.

Được đánh giá và xác nhận phù hợp với yêu cầu của tiêu chuẩn:

TIÊU CHUẨN

ISO 13485:2016

PHẠM VI CHỨNG NHẬN:

Sản xuất và kinh doanh khẩu trang y tế, bộ trang phục phòng dịch.

Ngày chứng nhận : 29/02/2020
Ngày phát hành : 29/02/2020
Ngày hết hạn : 28/02/2023
Chi tiết tại quyết định số : 1869293400402-MED

Được phép sử dụng dấu chứng nhận



Mã Truy Xuất Chứng Chỉ
1869293400402



ISO 13485:2016



ThS. Vũ Văn Thao

Tra cứu hiệu lực chứng chỉ tại: <https://isocert.org.vn>

CÔNG TY CỔ PHẦN CHỨNG NHẬN VÀ GIÁM ĐỊNH QUỐC TẾ ISOCERT

Số 40 dãy A, lô 12 KĐT mới Định Công, Phường Định Công, Quận Hoàng Mai, Thành phố Hà Nội

Hotline: 1900.636.538, VP HN: 02473.036.538, VP HCM: 02873.056.538, Email: contacts@isocert.org.vn, Website: <https://isocert.org.vn>

GIẤY CHỨNG NHẬN ISO 13485:2016

Certificate of Conformity

GuangZhou Runjia Industrial Co.,Ltd

#1218 Longjiao Road,Long Hu town,Baiyun River,Baiyun district,GuangZhou

The following products have been tested by us with the listed standards and found in compliance with the European Community Directive (EU) 2016/425
Assessment of compliance of the product with the requirements relating to was based on the following standards:

EN 149:2001 +A1:2009

Product: **KN-95 MASK**

Model No.: **2020-1XG**

Parameters: **FFP2**

The statement is based on a single evaluation of one sample of above mentioned products. It does not imply an assessment of the whole production and does not permit the use of the test lab. Logo.

The manufacture should ensure that all product in series production are in conformity with the product sample detailed in this report. The applicant should hold the whole technical report at disposal of the competent all the right.



After preparation of the necessary technical documentation as well as the conformity declaration the required CE marking can be affixed on the product.

Other relevant directives have to be observed.

Marks Licence No.: ACT20030611
Ref. Test Report: 68.5.13.10.2800.2689
Issued Date: 2020-03-06



Steve
Chief Director

Approved by: ACT Testing Technology Co., Ltd.
Tel:(86)020-82317089 Fax:(86)020-82317089
Website: www.act-ce.com Email:info@act-ce.com

FDA Certificate



The certificate features a decorative border with a central eagle and American flag motif. The title "CERTIFICATION OF REGISTRATION 2020" is prominently displayed in blue and black text, with a registration number "No. 2020190200" to the right. Below the title, it states "This certifies that:" followed by a redacted area. The address "No. 35 Lihui Road, Qingxi Town, Dongguan, Guangdong, 523660, CHINA" is listed. A paragraph explains the registration process with the USFDA. Key details include: Owner/Operator Number: 1006; Device Listing#: See annex; Expiration Date: December 31, 2020. A disclaimer states that F&W does not endorse the device. The bottom section includes the FDA logo, a signature for the executive director, and contact information for F&W (Shanghai) Certification Co., Ltd.

CERTIFICATION OF REGISTRATION
2020 No. 2020190200

This certifies that:

No. 35 Lihui Road, Qingxi Town, Dongguan, Guangdong, 523660, CHINA

Was registered with US Food and Drug Administration, Center for Devices and Radiological Health, pursuant to the Code of Federal Regulations 21 CFR 807, by F&W (Shanghai) Certification Co., Ltd.

Owner/Operator Number: 1006.
Device Listing#: See annex
Expiration Date: December 31, 2020

F&W 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. F&W 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. F&W 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. F&W is not affiliated with the U.S. Food and Drug Administration.

FDA

for and on behalf of
F&W (Shanghai) Certification Co., Ltd.

[Signature]
Executive Director

Dated: March 11, 2020

F&W (Shanghai) Certification Co., Ltd. TEL: 021-62950771 E-MAIL: sales@fz-lab.com
Website: www.fz-lab.com Add: 201-202, No. 2, Lane 1015, Yangping Road, Jiading District, Shanghai, China

CE Certificate

شهادة – 증명서 – 證明書 – Сертификат – Certificat – Certificate

Certificate of Compliance



No. 3N200311.K
Test Report no. ZJ0024

Certificate's Holder: [Redacted]
No. 35 Lihui Road, Qingxi Town, Dongguan, Guangdong, China

Certification ECM Mark: 

Product: U KN95 particle respirator
Model(s): (this certificate certifies only the product without its own specific models)

Verification to: Standard: EN 149:2001+A1:2009
related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it.
This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the CE Marking:
We attest that a TCF for the CE Marking process is in place. Whereas the Manufacturer is Responsible to start the CE Marking Certification Procedure through an appointed Notified Body and the perform of the necessary activities, as required by the Directive and accepted by the Notified Body, before placing the CE Mark on the product(s).

CE

Date of issue 11 March 2020
Expiry date 10 March 2025

Chief Manager
Marta Maria


Deputy Manager
Amanda Payne


Ente Certificazione Macchine Srl
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