



# Certificate of Compliance



No. 4M200324T.DZH0D67

Technical Construction File no. 20ZCTS0310025SP

**Certificate's Holder:** Dongguan Zmiao Health Technology Co., Ltd  
Building 118, No.22 Xinghong Road, Xintaiyang Industrial City, Lincun, Tangxia Town, Dongguan City, China

**Manufacturer:** Dongguan Zmiao Health Technology Co., Ltd  
Building 118, No.22 Xinghong Road, Xintaiyang Industrial City, Lincun, Tangxia Town, Dongguan City, China

**Certification ECM Mark:**



**Product:** Disposable daily protective mask  
**Model(s):** ZM025

**Verification to:** Standard: EN149-2001+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](http://www.entecerma.it)

**Issuance date:** 24 March 2020

**Expiry date:** 23 March 2025

Reviewer  
Technical expert  
Amanda Payne

Approver  
ECM Service Director  
Luca Bedonni

**Ente Certificazione Macchine Srl**

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QCC  
www.qcc-cn.com

CERTIFICATE No.:10137240Q

WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM  
OPERATED BY

**Dongguan Zhengmiao Health S&T Co.,Ltd.**  
Bldg 82,No.6,Xinfa Road,New Solar Industrial City,Lin  
Village,Tangxia Town,Dongguan City,Guangdong Province,China

IS IN COMPLIANCE WITH THE STANDARD

**ISO13485: 2016**

This system is valid for the

**R&D and sales of medical apparatus and instruments(The  
second category),drugs,electronic products and hardware  
plastic(Excluding products refer to qualification)**

First issue:**Sep.12,2017**

Expiring data:**Sep.11,2020**

The use and the validity of this certificate shall satisfy the requirements of the rules for the certification of quality management systems.

This certificate will not remain valid only if the certified organization accepts at least one surveillance audit annually within the validity period of the certificate in which the surveillance audit conforming mark is in the designated position on the certificate.

Issued by:

*Timothy*

QCC Co.,Limited



0236









Fiscal Year 2020

### CERTIFICATE OF FDA REGISTRATION

This certifies that:

**DONGGUAN ARUN INDUSTRIAL CO., LTD**

**NO.18Xingfeng st, Changlong, Huangjiang Dongguan, Guangdong, 523766, CHINA**

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through UCL-REG SERVICE INC.

**Owner/Operator Number: 10062866**

Listing No.	Product Code:	Device Name:
D374605	KHA	MASK, SCAVENGING

*UCL-REG SERVICE INC. 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. UCL-REG SERVICE INC. 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. UCL-REG SERVICE INC. 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. UCL-REG SERVICE INC. is not affiliated with the U.S. Food and Drug Administration.*



UCL-REGSERVICE INC.  
602 ROCKWOOD ROAD WILMINGTON,  
NEW CASTLE, DE 19802 USA

Cert. No.: M20596  
Issued Date: 12 March 2020  
Expiration Date: 31 December 2020