Fiscal Year 2020
FDA REGISTRATION CERTIFICATE
FDA注册证明

This certifies that:

No. [redacted] **ng**

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

Owner/Operator Number: 10066324

Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
Disposable Protective Face Mask	QKR	1	D383639	Manufacturer

This is a formal notice upon your company that your product applied has been successfully registered by the U.S. Food and Drug Administration. The registration remains effective unless the said registration is terminated by the U.S. Food and Drug Administration. We makes no other representations or warranties, nor does this certificate make sole benefit as it is issued. This notice does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. We assumes no liability to any person or entity in connection with the foregoing. 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. We are not affiliated with the U.S. Food and Drug Administration.

这是向贵公司发出的正式通知，告知您所申请的产品已获得美国食品药品监督管理局的成功注册。除非该注册已被美国食品药品监督管理局终止，否则注册将保持有效。我们不做任何其他陈述或保证，并且此证明在发行时也不具有唯一利益。此通知并不表示美国食品药品监督管理局对证明持有者的设备或机构的认可或认可。对于以上任何方面，我们不对任何个人或实体承担任何责任。美国食品药品监督管理局不颁发注册证书，美国食品药品监督管理局也不承认注册证书。我们不隶属于美国食品药品监督管理局。

Jimmy engineer _____ For and on behalf of UGK-LVM UNITED INC.

Authorized Signature

Issued: April. 16, 2020

Expiration Date: Dec31, 2020

US Food & Drug Administration

Web: http://www.fda.gov Tel: 1-888-INFO-FDA (1-888-463-6332) e-mail: webmail@oc.fda.gov

EC Declaration of Conformity

according to the Medical Devices Directive 93/42/EEC

***Class I** Medical Device*

(non-sterile, without measuring function)

Manufacturer:

Address:
Tel:
Fax

TEL: [redacted] E-mail: [redacted]om

EC Rep: Wellkang Ltd
16 Castle Street, Dover, CT16 1PW, England, UK

We, the manufacturer, declare under our sole responsibility that

the medical device(s)	Product Name	Medical Face Mask
	Type/model, identification of product allowing traceability (Where applicable)	175mm×95mm
of class	according to annex IX of directive 93/42/EEC :	**Class I** Medical Device (non-sterile, without measuring function)

is/are in conformity with the relevant provisions and requirements of directive 93/42/EEC, as amended by Directive 2007/47/EC.

Applied harmonised standards, national standards or other normative documents	EN ISO 15223-1:2016	EN ISO10993-1：2009
	EN 1041:2008	EN ISO10993-10：2010
	EN ISO 14971:2012	EN ISO10993-5：2009
	EN 14683：2019	
Conformity assessment procedure	**Module A (EC Declaration of Conformity (Annex VII) + Technical Files)**	
Notified Body (name & number) Certificate & number	**NOT applicable**	

Signed on: 4 June 2020. Place: Jiaxing, Zhejiang, China

Signature (on behalf of the manufacturer) : Zhejiang [redacted] Co. Ltd

Name of authorized signatory: Shi cheng you

Position held in the company: general manager

Official Seal: