

CERTIFICATION OF REGISTRATION

This certifies that:

Name: HUNAN ZHENHEYIKANG MEDICAL INSTRUMENT CO.,LTD Add: No.6 Building Jingxiang Energy,No.55 Xiaguang east road,Gaoxin district, xiangtan, Hunan, 411100, CHINA

has completed the FDA Establishment Registration (as manufacturer and foreign exporter) and Device Listing with the US Food & Drug Administration, through Registration/FEI Number: 3016726450 Owner/Operator Number: 10063717

ABmed will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. ABmed 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. ABmed assumes no liability to any person or entity in connection with foregoing.

Date of verification: Feb.23, 2022 Date of expiration: Dec.31, 2022

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Fiscal Year 2022

Listing No	Premarket	Code	Device Name
	Submission NO.		
D400441	Enforcement	QKR	Face mask per enforcement
	Discretion		policy for face masks and
		1	respirators during the declared
			public health emergency
D424899	510(k) exempt	HOY	Shield, eye, ophthalmic
		1	(including sunlamp protective
		1	eyewear and post-mydriatic
			eyewear)
D414980	510(k) exempt	MSH	Respirator, surgical
D377025	510(k) exempt	OEA	Non-surgical isolation gown
D377026	510(k) exempt	LYU	ACCESSORY, SURGICAL
			APPAREL
D377028	510(k) exempt	FXO	SUIT, SURGICAL
D424901	510(k) exempt	FXP	COVER, SHOE, OPERATING
			ROOM
D431473	Enforcement	LYZ	Vinyl patient examination glove
	Discretion	1	
D470308	K220066	LZA	Polymer patient examination glove - Medical
			Nitrile Examination Gloves
D467317	K213724	FXX	Mask, surgical - Medical Surgical Mask