

FDA

Fiscal Year 2022

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

SH OFFICE

TEL:0086-21-50313932 Boyle Wang Phone:0086-18930777676 info@truthful.com.cn

ABMED SERVICE INC.

1312 17th Street Suite 692 Denver, CO 80202

TEL:303-800-0162 info@abmed.com.cn

FDA

Fiscal Year 2022

Listing No	Premarket Submission NO.	Code	Device Name
D400441	Enforcement Discretion	QKR	Face mask per enforcement policy for face masks and respirators during the declared public health emergency
D424899	510(k) exempt	HOY	Shield, eye, ophthalmic (including sunlamp protective eyewear and post-mydratic 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 Discretion	LYZ	Vinyl patient examination glove
D470308	K220066	LZA	Polymer patient examination glove - Medical Nitrile Examination Gloves
D467317	K213724	FXX	Mask, surgical - Medical Surgical Mask