

FDA registration certificate

FDA 注册证明

Fiscal Year 2020

Shen zhen Hefangyuan Molding Technology Co., Ltd.

Building 2, no. 246, East Pinglong Road, Fenghuang Community, Pinghu Street, Longgang District, Shenzhen City, 518000, China

Owner/Operator Number: : 10064967

Registration Number: 3016812269

Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D380411	LYU	ACCESSORY, SURGICAL APPAREL	Filter Cotton, Protective Mask, Surgical Mask, Self-priming Mask, Protective filter mask, Isolation Mask
D380414	FQZ	THERMOMETER, CLINICAL COLOR CHANGE	Non-contact Infrared Thermometer
D387376	IWP	Radiographic Protective Glove	Latex Gloves, Medical Gloves
D387378	OEA	Non-Surgical Isolation Gown	Protective Clothing, SCRUBS, Isolation Clothing
D387381	HQY	Sunglasses (Non-Prescription Including Photosensitive)	Protective Goggles, Isolation Eye Mask
D387383	JRS	PURIFIER, WATER (ABSORPTION, DEIONIZATION, MEMBRANE FILTER, REVERSE OSMOSIS)	Air Purifier

D387386	FXW	SHOES, OPERATING-ROOM	Protective Boot
D387389	FYF	CAP, SURGICAL	Disposable Work Cap,Protective Cowl

CCTC 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. CCTC 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. CCTC 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, CCTC is not affiliated with the U.S. Food and Drug Administration.

Issued Date: 03/27/2020

Expiration Date有效日期: 12/31/2020

查询网址 : <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>

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