

FDA registration certificate

FDA 注册证明

Fiscal Year 2020

HANGZHOU SHIJIE HEALTH TECHNOLOGY CO.,LTD
No.428 QIANZHANGZIRANG VILLAGE,HUANGJIAZHANG,
SHUSHAN STREET, XIAOSHAN DISTRICT, HANGZHOU,
Zhejiang, 33012, CHINA

Owner/Operator Number: 10062985
Registration Number: 3016710474

Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D393218	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance	Disposable medical mask(non-sterile),SJM206,Disposable medical mask (sterile),SJM207
D404417	MSH	Respirator, surgical	Non-powered air-purifying particle respirator,SJY101

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.

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

Issued Date: 04/17/2020
Expiration Date有效日期: 12/31/2020

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