



Model conventional market: **N95**



Business Management in HealthCare





Fiscal Year 2020 CERTIFICATION OF REGISTRATION

This certifies that:

RIZHAO SANQI MEDICAL & HEALTH ARTICLES CO., LTD
Heshan Industrial Area Rizhao Shandong, 276800, CHINA

has completed the FDA Establishment Registration (as manufacturer) and Device Listing with the US Food & Drug Administration, through

U.S. Agent for FDA Communications: **SUNGO TECHNICAL SERVICE INC.**
6050 W EASTWOOD AVE APT 201, CHICAGO,
ILLINOIS 60630, USA
Telephone: +1-855-957-7779 / E-mail: sungogroup@yahoo.com

Registration Number: 3010374972
Device Listing#: See annex

SUNGO Technical Service Inc. 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. SUNGO Technical Service Inc. 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. SUNGO Technical Service Inc. 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. SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.



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Annex to Cert. No.: 2006US530538

Listing No	Code	Device Name
D197937	KHR	ABSORBER, SALIVA, PAPER (Absorber, Saliva, Paper)
D197938	FXP	COVER, SHOE, OPERATING-ROOM (Check Pants, Sleeve Cover, Cover, Shoe, Operating-Room)
D197939	LYU	ACCESSORY, SURGICAL APPAREL (Accessory, Surgical Apparel; Check Pants, Sleeve Cover)
D197940	OEA	NON-SURGICAL ISOLATION GOWN (Non-Surgical Isolation Gown, Gowns, Coverall, Medical Gown, Isolation Gowns, Protection Gown/Coverall, Lab Coat, Patient Cloth)
D197941	FYF	CAP, SURGICAL (Caps, Hood, Surgical Cap, Surgical Cap, Doctor Cap, Nurse Cap, Clip Cap, Protection Hood, Cap, Surgical,)
D197942	NAB	GAUZE/SPONGE, NONRESORBABLE FOR EXTERNAL USE (Gauze/Sponge, Nonresorbable For External Use, Medical Gauzes, Medical Gauzes Roll)
D197943	KME	BEDDING, DISPOSABLE, MEDICAL (Medical Bed Sheets, Medical Pillow Cover, Medical Drape, Underpad, Bedding, Disposable, Medical)
D197945	NEC	BANDAGE, LIQUID, SKIN PROTECTANT (Wet Tissues, Bandage, Liquid, Skin Protectant)
D216807	KHA	MASK, SCAVENGING (Face Masks, Face Cover)
D283004	FQM	BANDAGE, ELASTIC (Dressing Kit For Medical Use)
D283005	IWO	APRON, PROTECTIVE (Dental Apron /Shawl, Bib, Apron)
D311639	LRJ	DISINFECTANT, MEDICAL DEVICES (Wet Wipes)

END OF THE ANNEX

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营业执照
(副本)

1-1

统一社会信用代码 91371100168371999W

名称 日照三奇医疗卫生用品有限公司

类型 有限责任公司(自然人投资或控股)

住所 山东省日照市东港区河山国际工业园(河山镇许家官庄村南)

法定代表人 王常中

注册资本 壹仟万元整

成立日期 1993年03月29日

营业期限 1993年03月29日至2023年03月29日

经营范围 生产第二类医用卫生材料及敷料(6864)(凭《医疗器械生产许可证》经营,有效期至许可证为准);特种劳动防护用品生产(凭获得《山东省特种劳动防护用品经营单位备案证书》经营,并依照备案证书标准范围从事经营活动);第二类医疗器械生产、销售;普通货物进出口;但国家限定公司经营或禁止进出口的商品除外。(依法须经批准的项目,经相关部门批准后方可开展经营活动)

登记机关 日照市工商行政管理局

2020年(2)月6日

企业信用信息公示系统网址:

中华人民共和国国家工商行政管理总局监制

**Fiscal Year 2020
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Communications: 6050 W EASTWOOD AVE APT 201, CHICAGO, ILLINOIS 60630, USA
Telephone: +1-855-957-7779 / E-mail: sungogroup@sungo.com

Registration Number: 3018374972
Device Listing: See annex

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Sungo FDA

SUNGO CHINA OFFICE Tel: 021-69620052 Email: sungochina@126.com Website: www.sungoglobal.com
Add: 17th Floor, No. 1500 Century Avenue, Shanghai 200122, P.R. China

医疗器械生产许可证

许可证编号: 鲁食药监械生产 201100029

企业名称: 日照三奇医疗卫生用品有限公司 生产地址: 日照市东港区河山国际工业园(河山镇许家官庄村南)

法定代表人: 王常中 生产范围: 第二类: 6864 医用卫生材料及敷料

企业负责人: 王常中

住所: 日照市东港区河山国际工业园(河山镇许家官庄村南)

有效期至: 第三〇二一 年 月 日 发证日期: 第二〇一 年 月 日

国家食品药品监督管理局监制

[illegible][illegible][illegible][illegible][illegible]

ISO13485 证书



**Business
Management**
in **HealthCare**



**222 W. Las Colinas Blvd, Suite 1650E
Irving, TX 75039, Phone:(972) 363-6278**

