

Fiscal Year 2020 CERTIFICATION OF REGISTRATION

This certifies that:

JIANGSU HANHENG MEDICAL TECHNOLOGY CO., LTD #401, Unit B, Building #16, 1 North Qingyang Rd., Tianning District Changzhou, Jiangsu, 213017, CHINA

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

U.S. Agent for FDA SUNGO TECHNICAL SERVICE INC.

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Owner/Operator Number: 10061791

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.



Executive Director Issued: Nov. 20 2019 Cert. No.: 2006US779518 Expiration Date: Dec. 31 2020



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Annex to Cert. No.: 2006US779518

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Listing No	Code	Device Name
D362513	JOL	CATHETER AND TIP, SUCTION (Disposable suction catheter, Disposable suction connecting tubes with Yankauer)
D362514	GCY	APPARATUS, SUCTION, SINGLE PATIENT USE, PORTABLE, NONPOWERED (Disposable mucus extrators)
D362515	CAT	CANNULA, NASAL, OXYGEN (Disposable nasal oxygen cannula)
D362516	FOD	DEVICE, OCCLUSION, UMBILICAL (Disposable Umbilical Cord Clamp)
D362517	FZZ	MARKER, SKIN (Disposable I.D. bracelet)
D362518	KXG	APPLICATOR, ABSORBENT TIPPED, STERILE (Disposable Sterile Cervical Sampler; Disposable Sterile Sampling Brush, Disposable Sampling Swab, Disposable Sterile Scraper)
D362519	GDG	HOOK, SURGICAL, GENERAL & PLASTIC SURGERY (Disposable Amniotic hook)
D362520	HIB	Speculum, vaginal, nonmetal (Disposable vaginal expander)
D362521	OKU	Emergency obstetrical kit (Disposable Endometrial Sampling Kit)
D362522	ERY	Drape, surgical, ent (Disposable medical pad)
D362523	KNX	COLLECTOR, URINE, (AND ACCESSORIES) FOR INDWELLING CATHETER (Disposable urine drainage bags)
D362524	NNI	CONTAINER, SPECIMEN, NON-STERILE (Disposable Sampling spoon)
D362525	oow	Applicator for rectal suppository (Disposable rectal tube)
D362526	EYK	CONNECTOR, URETERAL CATHETER (Disposable nelaton catheter)
D362527	GBS	CATHETER, VENTRICULAR, GENERAL & PLASTIC SURGERY (Disposable feeding tube, Disposable stomach tube)
D362528	IWP	Radiographic protective Glove (Disposable medical gloves)
D362529	GEC	BRUSH, SCRUB, OPERATING-ROOM (Medical hand wash brush)

END OF THE ANNEX