



Fiscal Year 2020 CERTIFICATION OF REGISTRATION

This certifies that:

Ningbo Luke Medical Devices Co., Ltd.
Gujiayan, Yangming Road, 315400 Yuyao City, Zhejiang Province,
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has completed the FDA Establishment Registration (as manufacturer , foreign exporter, contract manufacturer) and Device Listing with the US Food & Drug Administration, through

U.S. Agent for FDA
Communications:

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Registration Number: 3013909820
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.: 2006US310598

Listing No	Code	Device Name
D306796	EYI	ADAPTOR, URETERAL CATHETER (Urethral Catheters)
D306797	CAE	AIRWAY, OROPHARYNGEAL, ANESTHESIOLOGY (Laryngeal Mask Airways)
D306798	GCB	NEEDLE, CATHETER (pvc wound drainage tube)
D306801	JAY	SUPPORT, BREATHING TUBE (Endotracheal Tubes)
D306815	BYG	MASK, OXYGEN (Oxygen Masks; CPAP Mask; Aerosol)
D306816	EBR	UNIT, SUCTION OPERATORY (Suction Catheters)
D306817	CAT	CANNULA, NASAL, OXYGEN (Nasal Oxygen Cannulas)
D306819	EYD	STIRRUPS (Heat and Moisture Exchangers)
D306821	BYP	MOUTHPIECE, BREATHING (Silicone/SEBS/PVC Manual Resuscitators (Reservoir); Silicone/ SEBS/PVC Manual Resuscitators (Mask); Silicone/SEBS/ PVC Manual Resuscitators (Oxygen tube))
D306823	GCY	APPARATUS, SUCTION, SINGLE PATIENT USE, PORTABLE, NONPOWERED (Wound Drainage Systems; PVC wound drainage system, PVC reservoirs)
D306824	GBX	CATHETER, IRRIGATION (Silicone Reservoirs)
D306825	HHE	CUP, MENSTRUAL (First greener cup; Canack Cup, Luke Cup, Vivi Cup, Inna Cup, Menstrual; Pee Safe Menstrual cup; Sirona- menstrual cups; Cuttie cup)
D357613	PRM	Enteral administration kit (adult & pediatric) (stomach tube (Gastric Calibration Tube))
D372633	KXQ	Vibrator for therapeutic use, genital (Kegel Ball)
D372882	GEA	CANNULA, SURGICAL, GENERAL & PLASTIC SURGERY (CPAP Tube; Disposable Breathing Circuits)
D372883	KGB	MASK, OXYGEN, NON-REBREATHING (CPR Mask; Non-breathing Oxygen Mask)



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Listing No	Code	Device Name
D372884	KGZ	ACCESSORIES, CATHETER (Drainage Bag; Drainage Tubes)
D373014	BSJ	MASK, GAS, ANESTHETIC (Anesthesia Mask)
D373015	BTK	STRAP, HEAD, GAS MASK (Headgear)
D373016	BTQ	AIRWAY, NASOPHARYNGEAL (Nasopharyngeal Airway)
D373017	BYF	MASK, OXYGEN, LOW CONCENTRATION, VENTURI (Venturi Mask)
D373018	CCQ	NEBULIZER, MEDICINAL, NON-VENTILATORY (ATOMIZER) (Nebulize Mask)
D373019	EPE	BRUSH, CLEANING, TRACHEAL TUBE (Tracheal Tube)
D373020	GAE	SNARE, SURGICAL (Silicone Loops)
D373021	JZY	KNIFE, LARYNGEAL (Laryngeal Mask)
D373022	HOY	Shield, eye, ophthalmic (including sunlamp protective eyewear and post-mydratic eyewear) (Protective Goggles)
D373023	LYU	ACCESSORY, SURGICAL APPAREL (Face Shield)

END OF THE ANNEX