

Fiscal Year 2020 CERTIFICATION OF REGISTRATION

This certifies that:

Celecare Medical Wenzhou Co., Ltd No.401 Xiajin Road, nanbaixiang Jinzhu Industrial Zone, Ouhai District, Wenzhou City Zhejiang 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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ILLINOIS 60630, USA

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Registration Number: 3013530949

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: Dec. 30 2019 Cert. No.: 2006US285558 Expiration Date: Dec. 31 2020



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Annex to Cert. No.: 2006US285558

Listing No	Code	Device Name
D285187	EZQ	POUCH, COLOSTOMY
		(Ostomy Care Accessories; colostomy bag; ostomy bag)
D285189	EXG	BAG, URINE COLLECTING, URETEROSTOMY
		(Urine Bag; Water Proof Bag; Dry Bag)
D285190	NAC	DRESSING, WOUND, HYDROPHILIC
		(Hydrocolloid Dressing; Wound Dressing; Foam Dressing; Alginate
		Dressing)
D285191	NAD	DRESSING, WOUND, OCCLUSIVE
		(Transparent Dressing)
D285192	NAE	DRESSING, WOUND, HYDROGEL W/Out Drug And/Or Biologic
		(Medical Wound Cream; Spray Lidocaine; Cream Lidocaine;
		Hydrogel Dressing)
D285193	MDA	ELASTOMER, SILICONE, FOR SCAR MANAGEMENT
		(silicone dressing; Silicone gel)
D285194	KGX	TAPE AND BANDAGE, ADHESIVE
		(Blister Plaster; Medical Tape; Ag Dressing; Corn Plaster; Bandage;
		Protection Of Diapers; Band-Aid; Skin Closure Stripe; Acne Pimple
		Patch)
D285195	НОҮ	SHIELD, EYE, OPHTHALMIC (INCLUDING SUNLAMP
		PROTECTIVE EYEWEAR AND POST-MYDRIATIC
		EYEWEAR)
		(phototherapy diaper; Blu-Ray Eye Mask)
D374801	LYU	ACCESSORY, SURGICAL APPAREL
		(Face Mask)
D374802	OEA	Non-surgical isolation gown
		(Protective Suit(Protective Coverall Safety Suit))

END OF THE ANNEX