



EC Declaration of Conformity



Regarding Medical Device Regulation (EU)2017/745

Manufacturer:

Name: Shandong Zhushi Pharmaceutical Group Co., LTD

Address: No.6 Shande Road, Shan County, Heze City, Shandong, China 274300

European Authorized Representative:

Name: SUNGO Europe B.V

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product::

Name: Face Mask

Model: Bandage type, Fat type, Folding type, Child

type; 22cm*9.5cm, 20cm*9cm, 18cm*9.3cm, 17.5cm*9.5cm, 16.5cm*9.5cm, 14.5*9.5cm, 1

4.5cm*9cm, 12cm*8.7cm; or customized

Classification: Class I

Rule: According to Rule 1, Annex VIII, Chapter III of EU Medical Device Regulation (EU)2017/745

Conformity assessment procedure: Annex II+III

SRN: -

UDI-DI:

Product Mod - Size	UDI-DI	Product Mod - Size	UDI-DI

We confirm our product can meet the requirement of Medical Device Regulation and the following harmonized standards:

EN ISO 14971:2012

EN ISO 15223-1:2016

EN 1041:2008

ISO 10993-1:2018

EN ISO 10993-5:2009

EN ISO 10993-10:2010

EN 14683:2014

Signature:

Date: 2020/8/18

Position:

Jerry



CERTIFICATE

ZERTIFIKAT

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CERTIFICATE

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Fiscal Year 2020 CERTIFICATION OF REGISTRATION

This certifies that:

Shandong Zhushi Pharmaceutical Group Co., Ltd
South Fanlou Road, Shan County Development Zone, Heze,
Shandong, China 274300

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: sungo.group@yahoo.com

Registration Number: 3013496867

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.





Fiscal Year 2020 CERTIFICATION OF REGISTRATION

Annex to Cert. No.: 2006US666548

Listing No	Code	Device Name
D273335	LYG	MASSAGER, THERAPEUTIC, MANUAL (Acupoint Therapy Patch / Detox Foot Patch / Foot Pad) 穴位貼敷治療貼/足貼
D273336	IMD	PACK, HOT OR COLD, DISPOSABLE (Heat Pads; Cooling Gel Patch) 熱療貼/退熱貼
D324618	MDA	ELASTOMER, SILICONE, FOR SCAR MANAGEMENT (Silicone Gel For Scar; Silicone Scar Patch) 疤痕凝膠/疤痕貼
D334868	ITG	BANDAGE, CAST (Fiberglass Casting Tape) 高分子繃帶
D334869	NOC	SPLINT, EXTREMITY, NON-INFLATABLE, EXTERNAL, NON-STERILE (Medical Polymer Splint) 高分子夾板
D366904	IME	PACK, HOT OR COLD, REUSABLE (Pain Relief Cream; Pain Relief Patch) 疼痛緩解膏/疼痛緩解貼
D366905	HHE	CUP, MENSTRUAL (Menstrual Cup) 月經杯
D366906	HED	DOUCHE APPARATUS, VAGINAL, THERAPEUTIC (Vaginal Scrubber) 阴道洗滌器
D374392	KHA	MASK, SCAVENGING (Face Mask) 面罩
D374393	OEA	Non-surgical isolation gown (Isolation Gown; Protective Suit) 隔離衣/防護服
D374394	PXH	Thermometer kit (Thermometer) 額溫槍

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