

CERTIFICATE OF CONFORMITY

No. : HX1706161658
Applicant : SHENZHEN XMD TECHNOLOGY CO.,LTD.
Address : Room701, Jingkai building, Longhua District, Shenzhen, China
Manufacturer : SHENZHEN XMD TECHNOLOGY CO.,LTD.
Address : Room701, Jingkai building, Longhua District, Shenzhen, China
Product : Anti snore mouthpiece
Models : XMD-1
Trademark : N/A
Test Standard(s) : EN71 Part 1: 2014;
EN71 Part 2: 2011+A12014;
EN71 Part 3: 2013+A1:2014

The EUT described above has been tested by us with the listed standards and found in compliance with the Council TOYS Directive 2009/48/EC. It is possible to use CE marking to demonstrate the compliance with this TOYS Directive.

The certificate applies to the tested sample above mentioned only and shall not imply an assessment of the whole production. It is only valid in connection with the test report number: HX1706161658



Andy

(Manager)
Oct. 20, 2023



Shenzhen HX certification testing Co., Ltd.

8F, Haoyunlai Building B, 2 Baomin Road, Xixiang Street, Baoan District, Shenzhen, China

HOTLINE: 0755-29116082 Email: huaxunprc@163.com [Http://www.hx-lab.com](http://www.hx-lab.com)



Fiscal Year 2025 CERTIFICATION OF REGISTRATION

This certifies that:

NANCHANG WHITE TECHNOLOGY CO., LTD.

101, building A3, No.88, Dongyang Avenue, Anyi County Industrial Park, Nanchang, Jiangxi, 330500, CHINA

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

U.S. Agent for FDA Regrek LLC
Communications: 19

Dover, Delaware, 19901, UNITED STATES

Telephone: +1-302-6089028 / E-mail: regrek.cs@hotmail.com

Owner/Operator Number: 10073848

Registration Number: 3017248108

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 2025 CERTIFICATION OF REGISTRATION

Annex to Cert. No.: 2007US000528

Listing No	Code	Device Name
D402364	KXF	APPLICATOR, ABSORBENT TIPPED, NON-STERILE (Vitamin E Swab)
D402365	LWF	DILATOR, NASAL (Stop Snoring Chin Strap/Anti Snore Jaw Supporter/Stop Snoring Solution/Anti Snore Belt/Chin Strap Belt)
D402366	EHY	TRAY, IMPRESSION, PREFORMED (Thermoplastic Mouth Tray/Mouth Piece/Teeth Whitening Mouth Tray, /Foam Strip Mouth Tray/Gel Prefilled Mouth Tray)
D402367	EIG	RETRACTOR, ALL TYPES (Cheek Retractor/Mouth Opener/Lip Retractor)
D402368	EFW	TOOTHBRUSH, MANUAL (Bamboo toothbrush; Plastic toothbrush; Toothbrush, Bamboo Toothbrush; Teeth Wipes, Brush Ups, Finger Brush, Oral Brush Ups)
D402370	BYP	MOUTHPIECE, BREATHING (Anti Snore Mouth Piece/Snoring Stopper/Anti Snore Mouth Tray/Stop Snoring Solution; Anti Snore Kit/Stop Snoring Device)
D402371	EIE	DAM, RUBBER (Dental Dam/Dental Gum Dam/ Gum Protector Gel/ Gingival Protection Gel)
D402372	MAU	ERASER, DENTAL STAIN (Remineralization Gel/Desensitizing Gel/Teeth Whitening Kit/Teeth Whitening Home Kit; Teeth Bleaching System/Teeth Bleaching Kit/Teeth Whitening Strips/Double Elastic Gel Strips/Dry Strips; Teeth Whitening Gel 3ml/5ml/10ml/PROFESSIONAL WHITENING GEL, teeth whitening powder; PearlSmile Teeth Whitening Kit; Charcoal Teeth Whitening Strips, Dual Barrel Gel; Dissolving Strips;charcoal teeth whitening powder,coconut oil pulling;coconut oil sachet; Teeth Whitening System;; Teeth Whitening Pen/Bleaching Pen/Teeth Whitener; teeth whitening foam)
D402373	EEG	HEAT SOURCE FOR BLEACHING TEETH (Teeth Whitening Accelerator; Plusma Light; Teeth Whitening Light; Teeth Whitening Mini Light; Mini Light 11led/5led;Teeth Whitening Light 8led/16led; ProLite LED Teeth Whitening Device; Smart Teeth Whitening Device; Smart Teeth Whitening Light; Teeth Whitening Lamp; Teeth Whitening Mouth Tray Led Light; Teeth Whitening Mouth Tray Light; Teeth whitening Led Light; Portable Teeth Whitening Light; Teeth Whitening Led Light 8led/16led)



Fiscal Year 2025 CERTIFICATION OF REGISTRATION

Annex to Cert. No.: 2006US830528

Listing No	Code	Device Name
D402374	JEQ	TOOTHBRUSH, POWERED (Electric Toothbrush, Sonic Toothbrush, Electric Led Toothbrush, Sonic Led Toothbrush)
D402376	EFT	CLEANSER, DENTURE, OVER THE COUNTER (Denture Cleansing Tablet)
D402378	EID	SYRINGE, RESTORATIVE AND IMPRESSION MATERIAL (dental impression material)
D522809	KOT	CARBOXYMETHYLCELLULOSE SODIUM OR POLYVINYL METHYLETER MALEIC ACID CALCIUM-SODIUM (denture adhesive cream; denture adhesive powder)
D522810	LYU	ACCESSORY, SURGICAL APPAREL (Face Mask, Face Shield)

END OF THE ANNEX

Sungo
GLOBAL SERVICE