Certification of FDA Registration Service

The establishment stated below has completed registering for the establishment and listing information for FDA FY 2027.

For more information about registration number and listing, please refer to the following:

Establishment:	ZHONGSHAN XINWEI WEAVING CO., LTD.
Address:	30#Jinhong Rd, Pingnan Industrial Zone, Sanxiang Town Zhongshan, Guangdong, 528463, CHINA
Owner/Operator No.:	10094811
Registration No.:	3039440874
Issue / Update date:	2026-11-09

No	Listing No.	Premarket Submission No.	Product Codes	Device Name	Proprietary Name	Activities
1.	D586498	510(k) exempt	FQM	BANDAGE, ELASTIC	VTAPE, Medical Fixation Strips, Model: E1, E2, E3, E4, E5, E6, E7, E8, E9, E10, F1, F2, F3, F4, F5, F6, F7, F8, F9, F10, G1, G2, G3, G4, G5, G6, G7, G8, G9, G10, H1, H2, H3, H4, H5, H6, H7, H8, H9, H10 Wellempire, Medical Fixation Strips, Model: E1, E2, E3, E4, E5, E6, E7, E8, E9, E10, F1, F2, F3, F4, F5, F6, F7, F8, F9, F10, G1, G2, G3, G4, G5, G6, G7, G8, G9, G10, H1, H2, H3, H4, H5, H6, H7, H8, H9, H10	Manufacturer
2.	D586499	510(k) exempt	KGX	Tape and bandage, adhesive	VTAPE, Catheter Fixation Device, Model: A1, A2, A3, A4, A5, A6, A7, A8, A9, A10, B1, B2, B3, B4, B5, B6, B7, B8, B9, B10, C1, C2, C3, C4, C5, C6, C7, C8, C9, C10	Manufacturer
3.	D586500	510(k) exempt	NAC	Dressing, wound, hydrophilic	VTAPE, Medical Adhesive bandage, Model: D1, D2, D3, D4,	Manufacturer

No	Listing No.	Premarket Submission No.	Product Codes	Device Name	Proprietary Name	Activities
					D5, D6, D7, D8, D9, L1, L2, L3, L4, L5, L6, L7, L8, L9	
					VTAPE, Self-adhesive silicone tape, Model: T1, T2, T3, T4, T5, T6, T7, T8, T9, T10	
4.	D586501	510(k) exempt	BYG	MASK, OXYGEN	VTAPE, CPAP replacement headgear and accessories, Model: CP-N20, CP-F20, CP-P10, CP-F30, CP-F40, CP-P10i, CP-N30, CP-N30i, CP-F30i, CP-FX, CP-PH1, CP-PH2, CP-PH3, CP-PH4, CP-PH5, CP-PH6, CP-FP1, CP-FP2, CP-FP3, CP-FP4, RSM-01, RSM-02, RSM-03, RSM-04, RSM-05, RSM-06, RSM-07, RSM-08, RSM-09	Manufacturer Repackager /Relabeler
					VTAPE, CPAP MASK, OXYGEN, Model: BMZ-01, BMZ-02, BMZ-03, BMZ-04, KBZ-01, KBZ-02, KBZ-03, KBZ-04, KBZ-05, QNM-01, QNM-02 QNM-03	
					Wellempire, CPAP replacement headgear and accessories, Model: CP-N20, CP-F20, CP-P10, CP-F30, CP-F40, CP-P10i, CP-N30, CP-N30i, CP-F30i, CP-FX, CP-PH1, CP-PH2, CP-PH3, CP-PH4, CP-PH5, CP-PH6, CP-FP1, CP-FP2, CP-FP3, CP-FP4, RSM-01, RSM-02, RSM-03, RSM-04, RSM-05, RSM-06, RSM-07, RSM-08, RSM-09	
					KOEYNUE, CPAP replacement headgear and accessories, Model: CP-N20, CP-F20, CP-P10, CP-	

No	Listing No.	Premarket Submission No.	Product Codes	Device Name	Proprietary Name	Activities
					F30, CP-F40, CP-P10i, CP-N30, CP-N30i, CP-F30i, CP-FX, CP-PH1, CP-PH2, CP-PH3, CP-PH4, CP-PH5, CP-PH6, CP-FP1, CP-FP2, CP-FP3, CP-FP4, RSM-01, RSM-02, RSM-03, RSM-04, RSM-05, RSM-06, RSM-07, RSM-08, RSM-09	
5.	D586503	510(k) exempt	GAX	TOURNIQUET, ONPNEUMATIC	VTAPE, TOURNIQUET, NONPNEUMATIC (Tourniquet, Silicone tourniquet), Model: ZXD-01, ZXD-02, ZXD-03, ZXD-04, ZXD-05	Manufacturer
6.	D586504	510(k) exempt	BZB	CATHETER, NASAL, OXYGEN	VTAPE, CATHETHER, NASAL, OXYGEN, (nasal oxygen cannula, oxygen tube), Model: BYG-01, BYG-02, BYG-03, BYG-04, BYG-05, BYG-06, BYG-07, BYG-08, BYG-09	Repackager /Relabeler

Note:

Pursuant to 21 CFR 807.39, the U.S. Food and Drug Administration does not issue a certificate of registration or recognize a certificate of registration which is not affiliated with U.S. Food and Drug Administration.

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 any impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

Field Fu

Mr. Field Fu

SHENZHEN JOYANTECH CONSULTING CO., LTD

www.cefda.com

Certification No.: FDA 202611-311 Validity: Oct. 1st, 2026 - Sep. 30th, 2027