

Fiscal Year 2023 FDA REGISTRATION INFORMATION

To whom it may concern,

Establishment: Xiamen WeiYou Intelligent Technology Co., Ltd. Registered Address: Unit 101-401, No.6 Xianghong Road, Xiang'an District, xiamen, Fujian, 361021, CHINA

Registration Number: 3011539161/3011539161 Owner/Operator Number: 10059059

has completed the FDA Establishment Registration (as manufacturer) and Device Listing with the US Food & Drug Administration, and the U.S. Agent information is:

U.S. Agent for FDA: SPICA MEDTECH CORP Communications: 1020 LINCOLN ST Denver,CO,80203, United States Phone: 720 6176666 Ext ,Email: spica_us@yahoo.com

Establishments that are involved in the production and distribution of medical devices intended for commercial distribution in the United States (U.S.), including those that are imported for export only, are required to register annually with the FDA under section 510(g) of the Federal Food, Drug, and Cosmetic Act; And annual registration for each fiscal year is required for all establishments. Annual registration shall take place during the period beginning on October 1 and ending on December 31 of each fiscal year.

The FDA does not issue registration certificates to medical device facilities nor does the FDA certify information for facilities that have registered their establishments and listed their medical devices.

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.



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Listing No	Code	Device Name
D346836	FNM	Air Pressure Therapy System, Item No.VU-NIPC02H, VU-IPC04H, VU-IPC06H
D346837	ISA	AC Compression Machine: VU-IPC01, VU-IPC02, VU-NIPC01, VU-NIPC02, VU-IPC03, VU-IPC04, VU-IPC06; Cuffs:ACF-04, WCF-04, LBT-04, SPT-04, ACF-06, WCF-06, LBT-06, SPT-06, LPT-06, ACF-08, WCF-08, LBT-08, SPT-08, LPT-08; RECHARGEABLE&PORTABLE INTERMITTENT PNEUMATIC COMPRESSION (Model: VU-IPCU6); Air Pressure Therapy System; TRC-02; DC Compression Machine: VU-IPC04B,VU-IPCS4,VU-IPCS6,VU-IPCS8, VU-IPCA8,VU-IPC05, VU-IPC05B
D446119	IRP	Air Pressure Therapy System (Model: VU-IPC04), Air Pressure Therapy System (Model: IPC06), Air Pressure Therapy System (Model: VU-IPC03), Air Pressure Therapy System (Model: VU-IPC12), Air Pressure Therapy System (Model: VU-IPC06), Air Pressure Therapy System (Model: VU-AMP02), Air Pressure Therapy System (Model: VU-AMP01), Air Pressure Therapy System (Model: VU-NIPC02), Air Pressure Therapy System (Model: VU-IPC01), Air Pressure Therapy System (Model: VU-IPC02)
D450574	IRP	Air Pressure Therapy System:VU-IPCRB8, Air Pressure Therapy System:VU-IPC12B, Air Pressure Therapy System:VU-IPC04B, Air Pressure Therapy System:VU-IPC05D, Air Pressure Therapy System:VU-IPCU8, Air Pressure Therapy System:VU-IPCM4, Air Pressure Therapy System:VU-IPCV5, Air Pressure Therapy System:VU-IPC05B, Air Pressure Therapy System:VU-IPCA8, Air Pressure Therapy System:VU-IPCS8
D469895	FNL	Medical parallel transport beds : XW-PTB-8S
D470079	JOM	Circul8 Luxe
D478837	ВХВ	Hand Rehabilitation Device (Model: SL-FR01S), Hand Rehabilitation Device (Model: SL-FR02MS), Hand Rehabilitation Device (Model: SL-FR01), Hand Rehabilitation Device (Model: SL-FR03), Hand Rehabilitation Device (Model: SL-FR02)

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