



FISCAL YEAR 2023

CONFIRMATION OF FDA REGISTRATION

Dear Official Correspondent:

This document provides notification of the registration number assigned to your establishment:

Establishment: **SHENZHEN S-HANDE TECHNOLOGY CO., LTD**

Address: **2/F, Building 8, XinXintian Industrial Park, Xinsha Road,
Shajing Street, Baoan District, Shenzhen, CN
Shenzhen, Guangdong, 518104, China**

Registration/FEI No.: **3014686987**

Listing Number	Premarket Submission Type	Product Code(s)	Device Name(s)
D342399	510(k) exempt	ISA	MASSAGER, THERAPEUTIC, ELECTRIC
D342400	510(k) exempt	LYG	MASSAGER, THERAPEUTIC, MANUAL
D422999	510(k) exempt	HHE	CUP, MENSTRUAL
D422997	510(k) exempt	KMJ	LUBRICANT, PATIENT
D357171	510(k) exempt	FCE	ENEMA KIT
D376409	510(k) exempt	KHA	MASK, SCAVENGING
D376410	510(k) exempt	LYU	ACCESSORY, SURGICAL APPAREL
D465100	510(k) exempt	KXQ	VIBRATOR FOR THERAPEUTIC USE, GENITAL
D465101	510(k) exempt	LKY	DEVICE, EXTERNAL PENILE RIGIDITY

Conclusion:

This certificate makes no other representations or warranties, nor does it make any representations and warranties to any person or entity other than the named certificate holder. New Risen assumes no liability to any person or entity in connection with the foregoing. 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. New Risen is not affiliated with the U.S. Food and Drug Administration.

FDA registration means the manufacturer registered the factory and certain products with FDA, which does not mean that their products meet certain quality specifications unless the manufacturer shows you the quality certificates.

Helen Nan

Executive Director
Expiration Date: Dec. 31st, 2023



CERTIFICATE

CERTIFICATE