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Annual Registration Successful

Facility: WELLMIEN HEALTHCARE TECH.(SUZHOU) CO., LTD., Suzhou, Jiangsu, CHINA

You have successfully updated your registration and listing information for 2023.

Your registration will be valid through Dec 31, 2023.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2023.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 10080621.

Facility Information

Registration Number:

3014819517

Initial Importer:

N

Facility Name:

WELLMIEN HEALTHCARE TECH.(SUZHOU) CO., LTD.

Legal Name:

Address:

**1-3603, Global 188, NO.88 Suhui Road, Suzhou Industrial Park,
Suzhou, Jiangsu, 215000, CHINA**

DUNS Number:

Foreign Trade Zone:

N

Facility URL:

Other Business Trade Name(s):

Establishment located on a campus:

Owner/Operator Information

Owner/Operator Number:

10080621

Contact Name:

Charles Shen

Company:

WELLMEN HEALTHCARE TECH.(SUZHOU) CO., LTD.

Address:1-3603, Global 188, NO.88 Suhui Road, Suzhou Industrial Park
Suzhou, JIANGSU, 215000, CHINA**Telephone:**

086 - 512 - 65953508

Fax:

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E-mail:

cyshe@aol.com

DUNS Number:**Official Correspondent Information****Contact Name:**

Charles Shen

Company:

WELLMEN HEALTHCARE TECH.(SUZHOU) CO., LTD.

Address:1-3603, Global 188, NO.88 Suhui Road, Suzhou Industrial Park
Suzhou, JIANGSU, 215000, CHINA**Telephone:**

086 - 512 - 65953508

Fax:

-

E-mail:

cyshe@aol.com

DUNS Number:**United States Agent Information****Contact First Name**

Charles

Contact Last Name

Shen

Contact Title:

Mr

Business Name:

Manton Business and Technology Services

Address:37 Winding Ridge
Oakland, New Jersey, 07436, UNITED STATES**Phone:**

608 - 2179358

Fax:**DUNS Number:****E-mail:** cyshe@aol.com**Device Listings**

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities	Importers
D436340		510(k) exempt	LRJ	Disinfectant, medical devices	Foreign Exporter	
D446429		510(k) exempt	FRL	FIBER, MEDICAL, ABSORBENT	Foreign Exporter	
D436329		510(k) exempt	FYF	CAP, SURGICAL	Foreign Exporter	M. C. JOHNSON CO., INC.
D436327		510(k) exempt	FME	Gown, examination	Foreign Exporter	M. C. JOHNSON CO., INC.
D436328		510(k) exempt	OEA	Non-surgical isolation gown	Foreign Exporter	M. C. JOHNSON CO., INC.
D436325	Enforcement Discretion		QKR	Face mask per enforcement policy for face masks and respirators during the declared public health emergency	Foreign Exporter	M. C. JOHNSON CO., INC.
D436345	K110981		LZA	Polymer patient examination glove	Foreign Exporter	
D436324	K101000		FXX	Mask, surgical	Specification Developer Foreign Exporter	M. C. JOHNSON CO., INC. ANATOMY SUPPLY PARTNERS, LLC
D436343		510(k) exempt	LYU	ACCESSORY, SURGICAL APPAREL	Foreign Exporter	M. C. JOHNSON CO., INC.
D436344	K182575		LYZ	Vinyl patient examination glove	Foreign Exporter	

D436341		510(k) exempt	HMP	PAD, EYE	Foreign Exporter	
D436342		510(k) exempt	KME	BEDDING, DISPOSABLE, MEDICAL	Foreign Exporter	
D436338		510(k) exempt	KGX	Tape and bandage, adhesive	Foreign Exporter	M. C. JOHNSON CO., INC.
D436339		510(k) exempt	NAB	Gauze / sponge, nonresorbable for external use	Foreign Exporter	
D436337		510(k) exempt	KPY	Shield, protective, personnel	Foreign Exporter	
D436334		510(k) exempt	IWO	Apron, protective	Foreign Exporter	
D436335		510(k) exempt	HOY	Shield, eye, ophthalmic (including sunlamp protective eyewear and post-mydratic eyewear)	Foreign Exporter	
D436333	K183665		FMI	Needle, hypodermic, single lumen	Foreign Exporter	M. C. JOHNSON CO., INC.
			MEG	SYRINGE, ANTISTICK		
			FMF	Syringe, piston		
D436330		510(k) exempt	FXP	COVER, SHOE, OPERATING-ROOM	Foreign Exporter	M. C. JOHNSON CO., INC.
D436331		510(k) exempt	NTX	NURSING PAD, POLYURETHANE PAD WITH STARCH COPOLYMER, GLYCERIN, AND SURFACTANT (F-68)	Foreign Exporter	M. C. JOHNSON CO., INC.

Date of Initial Registration: 2021-02-15 11:09:38.0