

5/29/2020

FDA | U.S. Food and Drug Administration



Registration Confirmation

Facility: VISION MEDICAL TECHNOLOGY CO., LIMITED, Kunshan City, Jiangsu, CHINA

You have successfully entered your facility registration and device listing information. You should print a copy of this page for your records. Listing numbers appear below for the products manufactured, developed, or processed at this facility.

As a manufacturer, specification developer, or single-use device reprocessor, you are required to pay an annual fee for medical device facility registration.

You will receive another e-mail providing you with your registration number in approximately 30 to 90 days. Until your registration number is assigned, reference your Owner/Operator number in any correspondence with the Center for Devices and Radiological Health.

Your registration will be valid through Dec 31, 2020. An e-mail will be sent to the Owner/Operator and the Official Correspondent 90 days before the facility is required to re-register for Fiscal Year 2020 with instructions on how and when to re-register.

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

Should you have any questions, please send an e-mail to reglist@cdrh.fda.gov (<mailto:reglist@cdrh.fda.gov>).

The Owner/Operator Number for this Registration is: 10074745

Facility Information

Initial Importer:	N
Facility Name:	VISION MEDICAL TECHNOLOGY CO., LIMITED
Address:	F4, Building 4, No.99 Shuntie Rd., Lujia, Kunshan, China Kunshan City, Jiangsu, 215300, CHINA
Foreign Trade Zone:	N

Owner/Operator Information

Owner/Operator Number: 10074745
Contact Name: Jeff Zhang
Company: VISION MEDICAL TECHNOLOGY CO., LIMITED
Address: F4, Building 4, No.99 Shuntie Rd., Lujia, Kunshan, China
Kunshan City, JIANGSU, 215300, CHINA
Telephone: 086 - 949 - 9817497
Fax: -
E-mail: info@visionmedtech.com

Official Correspondent Information

Contact Name: David Lennarz
Company: Registrar Corp
Address: 144 Research Drive
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DUNS Number: 139242874

United States Agent Information

Contact Name: David Lennarz
Contact Title: Mr
Business Name: Registrar Corp
Address: 144 Research Drive
Hampton, Virginia, 23666, UNITED STATES
Phone: 757 - 2240177
Fax: 757 -2240179
DUNS Number: 139242874
E-mail: david.lennarz@registrarcorp.com

Device Listings

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	Importers
D405694	Exempt	OEA	Non-surgical isolation gown	Manufacturer Contract Manufacturer Repackager/Relabeler Remanufacturer	CG ONCOLOGY INC.

Date of Initial Registration: Fri May 29 13:08:55 EDT 2020