

4/8/2020

FDA | U.S. Food and Drug Administration



Registration Confirmation

Facility: MAINE-LEE TECHNOLOGY GROUP, LLC, Wells, Maine, UNITED STATES

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: 10068288

Facility Information

Initial Importer:	Y
Facility Name:	MAINE-LEE TECHNOLOGY GROUP, LLC
Address:	952 Post Road - Unit 22 Wells, Maine, 04090, UNITED STATES
Foreign Trade Zone:	N
Facility URL:	http://www.mltgllc.com

Owner/Operator Information

Owner/Operator Number: 10068288
Contact Name: Bill Kimball
Company: MAINE-LEE TECHNOLOGY GROUP, LLC
Address: 952 Post Road - Unit 22
Wells, MAINE, 04090, UNITED STATES
Telephone: 1 - 207 - 3600194
Fax: -
E-mail: bk@mltgllc.com

Official Correspondent Information

Contact Name: David Lennarz
Company: Registrar Corp
Address: 144 Research Drive
Hampton, VIRGINIA, 23666, UNITED STATES
Telephone: 1 - 757 - 2240177
Fax: 1 - 757 - 2240179
E-mail: david.lennarz@registrarcorp.com
DUNS Number: 139242874

No Listings Required.

Imported Products and Manufacturers

Manufacturer(s) Name	Address	Product Code	Device Name	Premarket Submission Number
HENAN JOINKONA MEDICAL PRODUCTS STOCK CO.,LTD	Xinxing Road, The South of Industry District, Lushan County, Pingdingshan, Henan, 467300, CHINA	OEA	Non-surgical isolation gown	
HUBEI ZHONGJIAN MEDICAL PRODUCTS CO., LTD.	NO.20 JINCHENG ROAD TIANCHENG TOWN CHONGYANG COUNTY, XIANNING, Hubei, 437500, CHINA	OEA	Non-surgical isolation gown	
JIANGSU SUNSHINE GROUP CO., LTD.	Xinqiao Town, Jiangyin City, Wuxi, Jiangsu, 214426, CHINA	OEA	Non-surgical isolation gown	
GRAND WORK PLASTIC PRODUCTS CO., LTD.	DONGGAO INDUSTRIAL ZONE, ZANHUANG, HEBEI, Hebei, 050000, CHINA	LYZ	Vinyl patient examination glove	K061562
GRAND WORK PLASTIC PRODUCTS CO., LTD.	DONGGAO INDUSTRIAL ZONE, ZANHUANG, HEBEI, Hebei, 050000, CHINA	LYZ	Vinyl patient examination glove	K042830
GRAND WORK PLASTIC PRODUCTS CO., LTD.	DONGGAO INDUSTRIAL ZONE, ZANHUANG, HEBEI, Hebei, 050000, CHINA	LYZ	Vinyl patient examination glove	K040682
GRAND WORK PLASTIC PRODUCTS CO., LTD.	DONGGAO INDUSTRIAL ZONE, ZANHUANG, HEBEI, Hebei, 050000, CHINA	LYZ	Vinyl patient examination glove	K040681
GRAND WORK PLASTIC PRODUCTS CO., LTD.	DONGGAO INDUSTRIAL ZONE, ZANHUANG, HEBEI, Hebei, 050000, CHINA	LYZ	Vinyl patient examination glove	K040702
GRAND WORK PLASTIC PRODUCTS CO., LTD.	DONGGAO INDUSTRIAL ZONE, ZANHUANG, HEBEI, Hebei, 050000, CHINA	LYZ	Vinyl patient examination glove	K102089

GRAND WORK PLASTIC PRODUCTS CO., LTD.	DONGGAO INDUSTRIAL ZONE, ZANHUANG, HEBEI, Hebei, 050000, CHINA	LYZ	Vinyl patient examination glove	K102094
GRAND WORK PLASTIC PRODUCTS CO., LTD.	DONGGAO INDUSTRIAL ZONE, ZANHUANG, HEBEI, Hebei, 050000, CHINA	LYZ	Vinyl patient examination glove	K142409

Date of Initial Registration: Wed Apr 08 13:51:17 EDT 2020