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Registration Confirmation

Facility: NEO-NOSTICS (SUZHOU) BIOENGINEERING CO., LTD., Suzhou, 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: 10063051

Facility Information

Registration Number:

Initial Importer:

N

Facility Name:

NEO-NOSTICS (SUZHOU) BIOENGINEERING CO., LTD.

Address:

2F, #3 building, #52 Yingang Road, TaiCang
Suzhou, Jiangsu, 215435, CHINA

DUNS Number:

Foreign Trade Zone:

N

Facility URL:

Other Business Trade Name(s) :

Owner/Operator Information

Owner/Operator Number:

10063051

Contact Name:

Ji Liu

Company:

NEO-NOSTICS (SUZHOU) BIOENGINEERING CO., LTD.

Address:

2F, #3 building, #52 Yingang Road, TaiCang
Suzhou, JIANGSU, 215435, CHINA

Telephone:

086 - 512 - 33022698 - 808

Fax:

-

E-mail:

wallace.xu@zuoce.org

DUNS Number:

Official Correspondent Information

Contact Name:

Ji Liu

Company:

NEO-NOSTICS (SUZHOU) BIOENGINEERING CO., LTD.

Address:

2F, #3 building, #52 Yingang Road, TaiCang
Suzhou, JIANGSU, 215435, CHINA

Telephone:

086 - 512 - 33022698 - 808

Fax:

-

E-mail:

wallace.xu@zuoce.org

DUNS Number:

United States Agent Information

Contact Name:

Jerry Xu

Contact Title:

Mr

Business Name:

Address:

39 Worthington Ct Unit 1
Freehold, New Jersey, 07728, UNITED STATES

Phone:

501 - 3059107

Fax:

DUNS Number:

E-mail: xuhfr@163.com

Device Listings

| Listing Number | Premarket Submission Number/Type | Product Code(s) | Device Name(s) | Activities | Importers |
|----------------|----------------------------------|-----------------|--|-------------------------------------|-----------|
| D375194 | Exempt | CDH | Acid, uric, phosphotungstate reduction | Manufacturer Foreign Exporter | |

Date of Initial Registration: Mon Mar 16 00:50:29 EDT 2020