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DRLM Home (mainMenu.htm) > Register a New Medical Device Facility

✔ Facility

✔ Products Listing

Registration Confirmation

Facility: ZHEJIANG HAIPAI PHARMACEUTICAL CO.,LTD, Wenzhou City, Zhejiang, 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: 10069196

Facility Information

Registration Number:

Initial Importer:
N

Facility Name:
ZHEJIANG HAIPAI PHARMACEUTICAL CO.,LTD

Address:
Floor 1 And Floor 2,Building 2,Xixiang Jinyuan,Nanbaixiang Street, Ouhai District
Wenzhou City, Zhejiang, 325000, CHINA

DUNS Number:

Foreign Trade Zone:
N

Facility URL:

Other Business Trade Name(s):

Owner/Operator Information

Owner/Operator Number:
10069196

Contact Name:
Xiaolian Cai

Company:
ZHEJIANG HAIPAI PHARMACEUTICAL CO.,LTD

Address: Floor 1 And Floor 2,Building 2,Xixiang Jinyuan,Nanbaixiang Street , Ouhai District
Wenzhou City, ZHEJIANG, 325000, CHINA

Telephone:
86 - 173 - 57756688

Fax:
-

E-mail: zhejianghaipaiyl@sft-lab.cn

DUNS Number:

Official Correspondent Information

Contact Name:
Xiaolian Cai

Company:
ZHEJIANG HAIPAI PHARMACEUTICAL CO.,LTD

Address: Floor 1 And Floor 2,Building 2,Xixiang Jinyuan,Nanbaixiang Street , Ouhai District
Wenzhou City, ZHEJIANG, 325000, CHINA

Telephone:
86 - 173 - 57756688

Fax:
-

E-mail: zhejianghaipaiyl@sft-lab.cn

DUNS Number:

United States Agent Information

Contact Name:
Jack Zhang

Contact Title:
Mr

Business Name:

Address: 1942 Broadway St , STE 314C
Boulder, Colorado, 80302, UNITED STATES

Phone:
720 - 7791888

Fax:

DUNS Number:

E-mail: us.fw@fda-registered.com

Device Listings

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	Importers
D390073	Enforcement Discretion	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance	Manufacturer	

Date of Initial Registration: Sat Apr 11 11:07:52 EDT 2020

CERTIFICATE

Certificate Number

AI-MDD-0012/03/2020

Manufacturer	:	Zhejiang Haipai Pharmaceutical Co., Ltd.
Address	:	Floor 1 And Floor 2, Building 2, Xixiang Jinyuan, Nanbaixiang Street, Ouhai District, Wenzhou City, Zhejiang Province,China
Product(s)	:	Disposable medical mask

Model(s) :

Standard sizes	Length (±5%)	Width (±5%)	Layers
17.5×9.5cm	17.5	9.5	3 layers

Product Classification	:	Class I
Related Directive	:	93/42/EEC Medical Device Directive
Technical File Document Number	:	TCF-ZJHP-001
First Issue Date and Place	:	2020.03.24 & Istanbul
Revision Number and Date	:	00 / --
Validity Date	:	2024.05.26

This certificate has been issued according to the voluntary application of the manufacturer. NOTICE confirms that a technical file exists for the above mentioned product(s) and Declaration of Conformity prepared by the manufacturer is available. This certificate is valid only for the product(s) described in above mentioned tehcnical file. It is manufacturer's sole responsibility to fullfill all necessary conformity assessment activities according to 93/42/EEC Medical Devices Directive and related standards for the mentioned product(s) before placing them on the market. It is the manufacture's responsibility to compile a full Technical File according to Annex VII of 93/42/EEC in order to comply with the requirements of 93/42/EEC and to appoint a European Representative before placing the products on the European Market. Additionally, the manufacturer is responsible to take necessary actions, such as internal production controls to fullfill the essential requirements of the related Directive(s), before affixing CE mark on the product(s).

Özgür Vicdan
General Manager

NOTİCE BELGELENDİRME MUAYENE VE DENETİM HİZMETLERİ A.Ş.
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