Aries Medical Management

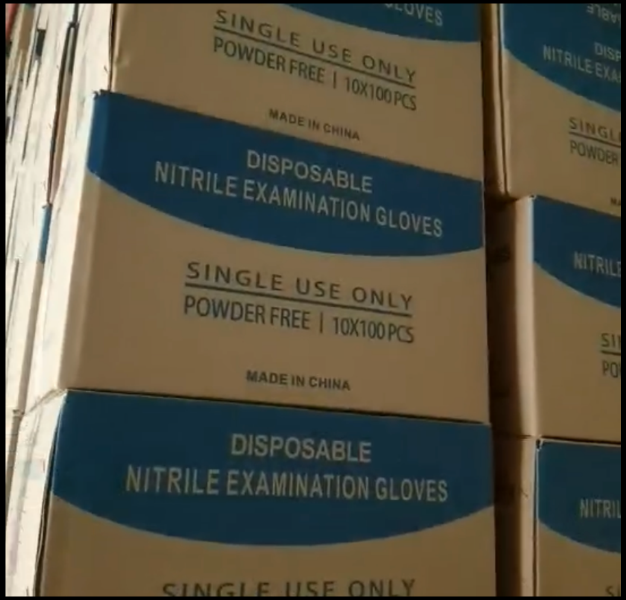
Dongtai Huayi / Perfect Fit

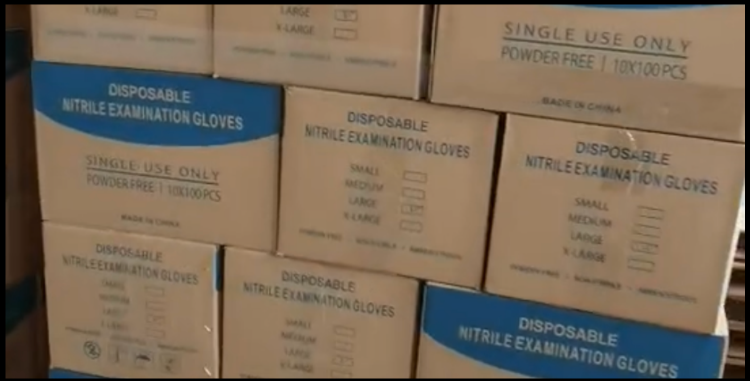
Disposable Nitrile Examination Glove | 510K + Chemo Rated


Perfect Fit
by Aries Medical Management
M
100
Disposable Nitrile Examination Gloves
Single Use Only
Non-Sterile
Latex-Free
Powder-Free


Perfect Fit
by Aries Medical Management
Disposable Nitrile Examination Gloves
Single Use Only
Non-Sterile
Latex-Free
Powder-Free
M
100


Perfect Fit
by Aries Medical Management
Disposable Nitrile Examination Gloves
Single Use Only
Non-Sterile
Latex-Free
Powder-Free
M
100


SINGLE USE ONLY
POWDER FREE | 10X100 PCS
MADE IN CHINA
DISPOSABLE
NITRILE EXAMINATION GLOVES
SINGLE USE ONLY
POWDER FREE | 10X100 PCS
MADE IN CHINA
DISPOSABLE
NITRILE EXAMINATION GLOVES


SINGLE USE ONLY
POWDER FREE | 10X100 PCS
DISPOSABLE
NITRILE EXAMINATION GLOVES
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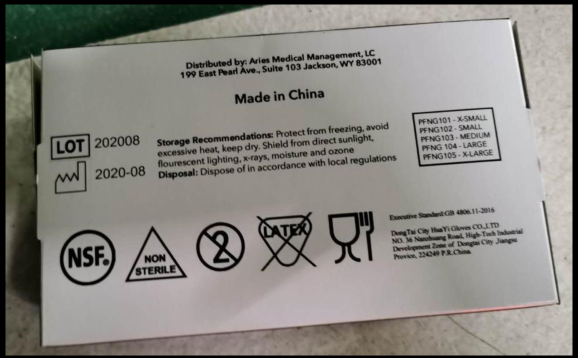
NITRILE EXAMINATION GLOVES
DISPOSABLE
NITRILE EXAMINATION GLOVES


Distributed by: Aries Medical Management, LC
199 East Pearl Ave., Suite 103 Jackson, WY 83001
Made in China
LOT 202008
2020-08
Storage Recommendations: Protect from freezing, avoid excessive heat, keep dry. Shield from direct sunlight, flourescent lighting, x-rays, moisture and ozone
Disposal: Dispose of in accordance with local regulations
PFNG101 - X-SMALL
PFNG102 - SMALL
PFNG103 - MEDIUM
PFNG 104 - LARGE
PFNG105 - X-LARGE
NSF
NON STERILE
LATEX
Executive Standard:GB 4806.11-2016
DongTai City HuaYi Gloves CO.,LTD
NO. 36 Nanzhuang Road, High-Tech Industrial Development Zone of Dongtai City ,Jiangsu Provice, 224249 P.R.China


Perfect Fit
by Aries Medical Management
M
100
Disposable Nitrile Examination Gloves
Single Use Only
Non-Sterile
Latex-Free
Powder-Free

DONG TAI CITY HUAYI GLOVES CO.,LTD
NO.36 NANZHANG ROAD,DONGTAI HIGH-TECH
INDUSTRIAL DEVELOPMENT ZONE JIANGSU PROVINCE

The following sample(s) was/were submitted and identified by the client as:

Sample Description	: DISPOSABLE NITRILE GLOVES
Lot No.	: NOT PROVIDED
Lot Size	: NOT PROVIDED
Sample Quantity	: 300PCS
Sample Receiving Date	: JUN.28,2020
Final Information Date	: JUN.30,2020
Testing Period	: JUN.28,2020 TO JUL.15,2020

Test Requested	Result
ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application (Clause 5, 6.1.2, 6.1.3, 6.1.4, 6.1.5)	Pass

Remark: Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

SGS-CSTC Standards
Technical Services (Qingdao)
Co., Ltd.

scan to see the report

QDHL2006006094MD

Jessica Gao
Approved Signatory

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 68999088 f (86-532) 80991955
www.sgsgroup.com.cn
e sgs.china@sgs.com

Test Conducted:

ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application

Number of test sample	:	231 Pieces
Size	:	L

Clause	Test Items	Result
5	Sampling	See Result 1
6	Performance Requirements	---
6.1.2	Freedom from Holes	Pass (See Result 2)
6.1.3	Physical dimensions	Pass (See Result 3)
6.1.4	Physical property characteristics	Pass (See Result 4)
6.1.5	Powder Residue for Powder Free Gloves	Pass (See Result 5)

Test Result:

Result 1: Sampling

The number of specimen:

	Sample size	Ac	Re
Freedom from Holes	200	10	11
Dimensions	13	1	2
Physical property	13	1	2

Result 2: Freedom from Holes

Sample Quantity: 200 Pieces

AQL=2.5 Ac: 10 Re: 11 Found: 0

Result 4: Physical property characteristics

Sample Quantity: 13 Pieces

AQL=4.0 Ac: 1 Re: 2

Size: L					
Before Aging			After Aging		
Sample No.	Tensile strength (Mpa)	Ultimate Elongation (%)	Sample No.	Tensile strength (Mpa)	Ultimate Elongation (%)
1	30.8	557	1	27.5	509
2	27.6	550	2	31.2	513
3	30.8	558	3	31.3	526
4	28.6	548	4	23.2	493
5	31.0	557	5	28.5	513
6	30.3	552	6	27.6	505
7	30.7	557	7	26.4	498
8	28.0	540	8	28.8	506
9	27.3	538	9	29.0	514
10	29.3	544	10	23.7	492
11	32.0	551	11	28.6	517
12	25.0	530	12	30.1	489
13	30.5	545	13	34.0	517
Standard requirement	≥14	≥500	Standard requirement	≥14	≥400
Found	0	0	Found	0	0

Result 5: Powder Residue For Powder Free Gloves

The average mass per glove(mg)	0.02
Standard requirement(mg)	≤2.0

Remark: The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

Result 3: Physical dimensions

Sample Quantity: 13 Pieces

AQL=4.0 Ac:1 Re: 2

Sample No.	Size: L			
	Length/mm	Width/mm	Median value/mm	
			Thickness-finger	Thickness-palm
1	245	110	0.131	0.104
2	245	110	0.138	0.108
3	245	110	0.133	0.104
4	240	110	0.131	0.107
5	243	111	0.131	0.106
6	243	110	0.131	0.107
7	245	110	0.138	0.108
8	242	110	0.138	0.105
9	240	110	0.132	0.103
10	242	110	0.133	0.093
11	241	110	0.134	0.105
12	240	110	0.135	0.104
13	240	110	0.134	0.104
Standard requirement	≥230	110±10	≥0.05	≥0.05
Found	0	0	0	0

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 68999888 f (86-532) 80991955
www.sgsgroup.com.cn
e sgs.china@sgs.com

Sample Photo:

Received sample

SGS authenticate the photo on original report only

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 68999088 f (86-532) 80991955
www.sgsgroup.com.cn
e sgs.china@sgs.com

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Dongtai City Huayi Gloves Co., Ltd.
No. 36 Nanzhuang Road, East New District
Dongtai City, Jiangsu, P.R. China
Post Code: 224200

Unified social credit code: 91320981064501824X

has established and applies
a Quality Management System for

Production and Distribution of Nitrile Examination Gloves.

An audit was performed, Order No. **7482274766.**

Proof has been furnished that the requirements
according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2020-04-11** until **2023-04-10.**

The certified organization shall undergo and pass
the regular surveillance audit to maintain the validity of this certificate.

Certificate Registration No.: **12 100 47761 TMS.**

Information about this certificate can be inquired at the official website
of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn).

Product Compliance Management
Munich, 2020-03-10

IAF

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

VISOI-07/10

TÜV®

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/15062020.37

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

DongTai City HuaYi Gloves CO.,LTD.
NO. 36 Nanzhuang Road, High-Tech Industrial Development Zone of Dongtai City, Jiangsu Provice, CHINA

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/1418/2020**

CE

Issued on: 15/06/2020

Valid until: 14/06/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

EC REP CERTIFICATE

ANNEX I Medical Device Products

Nitrile Examination Gloves

CE

DEC - 9 2013

Section 6 510(k) Summary

510(K) Summary

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: K131823 "

Premarket Notification [510(k)] Summary

1.0 Submitter:

Submitter's name :	Dong Tai City Huayi Gloves Co., Ltd.
Submitter's address :	No.68 Jingyi Road, ChengDong New District, DongTai, Jiangsu, 224200, China
Phone number :	0086-515-85332088
Fax number :	0086-515-85332688
Name of contact person:	Ms.Zhu Ya Fen
Date of preparation :	2013-10-07

2.0 Name of the Device

Device Name:	Powder Free Nitrile Patient Examination Gloves, Blue Color
Proprietary/Trade name:	DongTai
Common Name:	Exam gloves
Classification Name:	Patient examination glove
Device Classification:	I
Regulation Number:	21 CFR 880.6250
Panel:	General Hospital (80)
Product Code:	LZA

3.0 Predicate device

Device Name:	Powder Free Nitrile Patient Examination Gloves, Blue Color
Company name:	Jiangsu Dongling Plastic & Rubber Co., Ltd.
510(K) Number:	K110247

4.0 Device Description:

4.1 **How the device functions:**
Nitrile films form a barrier to body fluids and bloodborne Pathogens

4.2 **Scientific concepts that form the basis for the device**

The nitrile rubber is water tight under normal conditions of use. It's tensile properties cause it to conform to the hand, allowing movements necessary for a medical procedure.

4.3 **Physical and performance characteristics such as design, materials and physical properties:**
Nitrile glove is known to create a barrier to bloodborne pathogens and body fluids. ASTM conforming tensile properties create a glove that is strong and flexible. The leaching process removes traces of chemical accelerants that may be chemically irritating. The glove is manufactured in accordance with the requirements of ASTM D6319 and ASTM D5151 requirements.

5.0 Device Intended Use (Indication for use):

Powder Free Nitrile Patient Examination Gloves, Blue Color is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6.0 Summary of the Technological Characteristics of the Device:

The Powder Free Nitrile Patient Examination Gloves, Blue Color, non sterile are summarized with the following technological characteristics compared to ASTM or equivalent standard.

Characteristics	Standard	Device performance
Dimension	ASTM standard D 6319-10.	Meets
Physical Properties	ASTM standard D 6319-10.	Meets
Freedom from pinholes	21 CFR 800.20	Meets
Powder Residual	ASTM standard D 6319-10 and D6124-06(Reapproved 2011).	Meets <2mg/glove
Biocompatibility	Primary Skin Irritation in rabbits ISO 10993-10:2002 /Amd.1:2006	Passes Not a Primary Skin Irritant
	Dermal sensitization in the guinea pig ISO 10993-10: 2002 /Amd.1:2006	Passes Not a Dermal Sensitizer

7.0 Substantial Equivalent Based on Assessment ofNon-ClinicalPerformance Data:

Powder Free Nitrile Patient Examination Gloves, Blue Color, meet requirements per ASTM D6319-10.per ASTM D6124-06(Reapproved 2011), per 21 CFR 800.20 and ISO 10993-10: 2002/Amd.1:2006.

The performance test data of the non clinical tests that support a determination of substantial equivalent is the same as mentioned immediately above.

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data:

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

9.0 Substantial Equivalence Comparison:

Features & Description	Predicate Device	Medical Glove Guidance Manual	Subject Device	Result of Comparison
Company	Jiangsu Dongling Plastic & Rubber Co., Ltd.		Dong Tai City Huayi Gloves Co., Ltd.	--
510(K) Number	K110247		K131823	
Product name	Powder Free Nitrile Patient Examination Gloves, Blue Color		Powder Free Nitrile Patient Examination Gloves, Blue Color	same
Product Code	LZA	LZA	LZA	same
Size	Small/ Medium/ Large/X large		Small/ Medium/ Large/X large	same
Intend for use	Powder Free Nitrile Patient Examination Gloves, Blue Color is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Powder Free Examination Gloves: A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Powder Free Nitrile Patient Examination Gloves, Blue Color is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Substantially equivalent
Device Description and Specifications	Meets ASTM D6319-10	If nitrile gloves: Does the above data for your nitrile examination glove meet all the current specifications listed under the applicable ASTM standard D6319 or an equivalent consensus standard?	Meets ASTM D6319-10	Substantially equivalent
Dimensions --Length	Meets ASTM D6319-10 ≥230mm min	ASTM D6319	230mm min for all sizes	Substantially equivalent

Dimensions – Width	Meets ASTM D6319-10 Small 70-90 mm Medium 85-105mm Large 100-120mm Xlarge 110-130 mm	ASTM D6319	 Small 82-86 mm Medium 94-98mm Large 107-113mm X large 115-121 mm	Substantially equivalent
Dimensions --Thickness	Meets ASTM D6319-10 Finger 0.05mm min. Palm 0.05mm min.		 Thickness (mm) min. Finger 0.09-0.13 Palm 0.09-0.13	Substantially equivalent
Physical Properties	Meets ASTM D D6319-10 Before aging/after aging Elongation ≥500% Tensile Strength≥ 14MPa	ASTM D6319	 Before aging/after aging Elongation :540-600% Tensile Strength:19-23 MPa	Substantially equivalent
Freedom from Pinholes	Meets • 21 CFR 800.20 • ASTM D6319-10 • ASTM D 5151-06 (Reapproved 2011)	21 CFR 800.20 ASTM D5250 ASTM D 5151	Meets ASTM D5151-06 (Reapproved 2011) Holes at Inspection Level I AQL2.5	Substantially equivalent
Residual Powder	Meets ASTM D 6124-06 (Reapproved 2011) below 2mg of residual powder	ASTM D 6124	Meets ASTM D 6124-06 (Reapproved 2011) Results generated values below 2mg of residual powder	Substantially equivalent
Materials used to fabricate the devices	Nitrile	If the glove is made of a polymer or other type of material. identify the material.	Nitrile	Substantially equivalent
Dusting or Donning Powder:	PU	If a donning lubricant is used, state the composition and include biocompatibility data for the lubricant in an identified attachment; also state the name, manufacturer, and address below	PU-120C	Substantially equivalent
Dusting or Donning Powder: name	PU	Lubricant Generic Name/ Lubricant Brand Name	Surface Coating Agent	Substantially equivalent
Compare performance data supporting substantial equivalence	Meets ASTM D5151-06 (Reapproved 2011) ASTM D6319-10 ASTM D6124-06 (Reapproved 2011)	At this time FDA recognizes the following standards: Patient Examination Gloves(PVC)ASTM D5151(Detection of Holes in Medical Gloves)ASTM D6124(Residual Powder on Medical Gloves)ASTM	Meets ASTM D5151-06 (Reapproved 2011) ASTM D6319-10 ASTM D6124-06 (Reapproved 2011)	Substantially equivalent

		D6319 (Nitrile Gloves)		
Single Patient Use	Single Patient Use	Single Patient Use	Single Patient Use	Substantially equivalent
Biocompatibility	SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10:2002/Amd.1: 2006	SKIN IRRITATION DERMAL and SENSITIZATION STUDIES ISO 10993-10	The test article was a non-irritant and non-sensitizer. SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10:2002 /Amd.1:2006	Substantially equivalent
Labeling for the legally marketed device to which substantial equivalence is claimed.	-Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot - Blue color - Non-sterile	Chapter 4	-Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot - Blue color - Non-sterile	Substantially equivalent

10.0 Substantial Equivalence Comparison:

It can be concluded that the Powder Free Nitrile Patient Examination Gloves, Blue Color meet the ASTM standard or equivalent standard and FDA requirements for waterleak test on pinhole AQL., meet labeling claims.

It can be concluded that the Powder Free Nitrile Patient Examination Gloves, Blue Color is as safe, as effective, and performs as well as the predicate device, Powder Free Nitrile Patient Examination Gloves, Blue Color, Jiangsu Dongling Plastic & Rubber Co., Ltd. K110247

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 9, 2013

Dong Tai City Huayi Gloves Company, Limited
C/O Mr. Chu Xiaoan
Official Correspondent
Beijing Easy-Link Co.
Room 1606 Bldg. 1 Jianxiang Yuan #209
Bei Si Huan Zhong Road, Haidian District
Beijing 100083
CHINA

Re: K131823
Trade/Device Name: Powder-Free Nitrile Patient Examination Gloves, Blue Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: October 7, 2013
Received: October 24, 2013

Dear Mr. Xiaoan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131823

Device Name
Powder Free Nitrile Patient Examination Gloves, Blue Color

Indications for Use *(Describe)*

Powder Free Nitrile Patient Examination Gloves, Blue Color is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth F. Claverie -S
2013.12.06 15:33:05 -05'00'

June 9,2021

· TEST REPORT ·

PN 13326

CHEMICAL ANALYTICAL SERVICES

DongTai City HuaYi Gloves CO.,Ltd
NO.36 Nanzhuang Road,High-Tech Industrial Development Zone of Dongtai City
Jiangsu Provice,224249 P.R.
China

Prepared By: _____
Tiffany L. Heller
Assistant Manager, Pharmaceutical Services

Approved By: _____
Ana C. Barbur, M.S.
Manager, Chemical, Microbiological, & Pharmaceutical Services

June 9,2021

DongTai City HuaYi Gloves CO.,Ltd.

SUBJECT: Permeation testing per ASTM D 6978-05 on sample submitted by the above company.

RECEIVED: Glove sample identified as Nitrile Powder Free Glove, Blue, Lot# ZP161212.

TESTING CHEMOTHERAPY DRUGS:

Table 1. List of the Testing Chemotherapy Drugs, Sources, and Expiration Dates

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	Sigma Aldrich; Lot# 016M4028V; Expires 09/2017
Cisplatin, 1.0 mg/ml (1,000 ppm)	Fresenius Kabi; Lot# 6114286; 01/2018
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	Sigma Aldrich; Lot# BCBM8984V; Expiration 04/2017
Cytarabine, 100 mg/ml (100,000 ppm)	Sigma Aldrich; Lot# LRAA8717; Expiration 01/2018
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Teva; Lot# 31318323B; Expiration 10/8/2017
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	Sigma Aldrich; Lot# SLBM7382V; Expiration 08/2017
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	Teva; Lot# 31321666B; Expiration 09/2019
Fluorouracil, 50.0 mg/ml (50,000 ppm)	Accord; Lot# PT04300; Expiration 10/2018
Ifosfamide, 50.0 mg/ml (50,000 ppm)	Sigma Aldrich; Lot# 106K1063V; Expiation 12/2017
Methotrexate, 25 mg/ml, (25,000 ppm)	Teva; Lot# 16A28MA, Expiration 01/2018
Mitomycin C, 0.5 mg/ml (500 ppm)	Sigma; Lot# MKBR2210V; Expiration 03/2017
Mitoxantrone, 2.0mg/ml (2,000ppm)	Sigma Aldrich; Lot# MKBR2210V; Expiration 11/2017
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	Hospira; Lot# C126865AA; Expiration 12/2017
Thiotepa, 10.0 mg/ml (10,000 ppm)	Sigma Aldrich; Lot# SLBQ8871V; Expiration 02/2018
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Sigma Aldrich; Lot# SLBQ9329V; Expiration 01/2018

COLLECTION MEDIA:

The collection media, which were selected, are listed in Table 2.

Table 2. Collection Media for Testing Chemotherapy Drugs

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	Distilled Water
Cytarabine, 100 mg/ml (100,000 ppm)	Distilled Water
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	Distilled Water
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Ifosfamide, 50.0 mg/ml (50,000 ppm)	Distilled Water
Methotrexate, 25 mg/ml, (25,000 ppm)	Distilled Water
Mitomycin C, 0.5 mg/ml (500 ppm)	Distilled Water
Mitoxantrone, 2.0mg/ml (2,000ppm)	Distilled Water
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Thiotepa, 10.0 mg/ml (10,000 ppm)	Distilled Water
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978-05
Deviation From Standard Test Method:	Used 1" Permeation Cell
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area

DETECTION METHOD OF CHEMICAL PERMEATION; UV/VIS ABSORPTION SPECTROMETRY:

Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 ml/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING CHEMOTHERAPY DRUGS	WAVELENGTH (nm)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	200
Cytarabine, 100 mg/ml (100,000 ppm)	272
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	320
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	232
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	205
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269
Ifosfamide, 50.0 mg/ml (50,000 ppm)	200
Methotrexate, 25 mg/ml, (25,000 ppm)	303
Mitomycin C, 0.5 mg/ml (500 ppm)	217
Mitoxantrone, 2.0mg/ml (2,000ppm)	242
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	231
Thiotepa, 10.0 mg/ml (10,000 ppm)	199
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	220

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested specimens Glove sample identified as Nitrile Powder Free Glove, Blue, Lot# ZP161212

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m2)
	Sample 1	Sample 2	Sample 3		
Carmustine (BCNU)	0.046	0.049	0.047	0.047	
Cisplatin	0.045	0.050	0.046	0.047	
Cyclophosphamide (Cytoxan)	0.047	0.043	0.048	0.046	
Cytarabine	0.047	0.044	0.048	0.046	
Dacarbazine (DTIC)	0.048	0.049	0.045	0.047	
Doxorubicin Hydrochloride	0.050	0.052	0.046	0.049	
Etoposide (Toposar)	0.048	0.052	0.046	0.049	
Fluorouracil	0.048	0.047	0.045	0.047	52.3
Ifosfamide	0.044	0.049	0.048	0.047	
Methotrexate	0.045	0.047	0.054	0.049	
Mitomycin C	0.047	0.050	0.044	0.047	
Mitoxantrone	0.046	0.047	0.053	0.049	
Paclitaxel (Taxol)	0.048	0.042	0.044	0.045	
Thiotepa	0.047	0.049	0.043	0.047	
Vincristine Sulfate	0.045	0.044	0.048	0.046	

RESULTS:

Table 5. Permeation Test Results on: Glove sample identified as Nitrile Powder Free Glove, Blue, Lot# ZP161212.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm²/minute)	OTHER OBSERVATIONS
Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	14.7 (15.1,14.7,16.8)	0.6 (0.5,0.5,0.7)	Moderate swelling and no degradation
Cisplatin 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytoxan) 20 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cytarabine, 100 mg/ml (100,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Etoposide (Toposar) 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Fluorouracil 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Ifosfamide, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Methotrexate 25 mg/ml (25,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitomycin C 0.5 mg/ml (500 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitoxantrone, 2.0mg/ml (2,000ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min.	N/A	Moderate swelling and no degradation
Thiotepa 10.0 mg/ml (10,000 ppm)	58.8 (110.0,58.8,67.0	0.5 (0.3,0.5,0.6)	Slight swelling and no degradation
Vincristine Sulfate 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation

Tiffany L. Heller
Assistant Manager
Pharmaceutical Services
AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Ana C. Barbur, M.S,
Manager
Chemical, Microbiological and Pharmaceutical Services

Test Report

No.: QDHL2004003544MD_EN Date: MAY.18,2020 Page: 1 of 6

Client name	:	DONG TAI CITY HUAYI GLOVES CO.,LTD
Client address	:	NO.36 NANZHUANG ROAD, EAST NEW DISTRICT, 224200 DONGTAI CITY, JIANGSU, PEOPLE'S REPUBLIC OF CHINA
Sample Description	:	DISPOSABLE NITRILE GLOVES
Lot No.	:	NOT PROVIDED
Lot Size	:	NOT PROVIDED
Sample Quantity	:	360PCS

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

****

Sample Receiving Date	:	APR.29,2020
Test Performing Date	:	APR.29,2020 TO MAY.18,2020

****

Test Requested	Result
1. BS EN 455-1:2000 MEDICAL GLOVES FOR SINGLE USE – PART 1: REQUIREMENTS AND TESTING FOR FREEDOM FROM HOLES (CLAUSE 5.1)	Pass
2. BS EN 455-2:2015 MEDICAL GLOVES FOR SINGLE USE – PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIES (CLAUSE 4.2, 4.3, 5.2, 5.3)	Pass
3. BS EN 455-3:2015 MEDICAL GLOVES FOR SINGLE USE—PART 3: REQUIREMENTS AND TESTING FOR BIOLOGICAL EVALUATION (CLAUSE 4.4)	Pass

Remark: - Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. This document cannot be used for publicity, without prior written approval of the SGS.

SGS-CSTC Standards
Technical Services (Qingdao)
Co., Ltd.

scan to see the report
QDHL2004003544MD

Jessica Gao
Approved Signatory

Test Conducted:

1. **BS EN 455-1:2000 Medical gloves for single use – Part 1: Requirements and testing for freedom from holes**

Number of test sample	:	200 Pieces
Sample size	:	M
Number of non-conforming gloves	:	1pc

Clause	Test Items	Result
5	Watertightness test for detection of holes	---
5.1	Referee testing	Pass (See note 1)

Note : 1 Sample quantity: 200pcs, AQL:1.5, Ac:7, Re:8, Found:1. See refer photo. The sample selecting amount for this clause is deviated to 200 pcs as assessed by SGS.

2. **BS EN 455-2:2015 Medical gloves for single use – Part 2: Requirements and testing for physical properties**

Number of test sample	:	26 Pieces
Type	:	examination/procedure gloves b)
Size	:	Examination/procedure gloves: M

Clause	Test Items	Result
4	Dimensions	---
4.2	Length	Pass (See result 1)
4.3	Width	Pass (See result 1)
5	Strength	---
5.2	Force at break	Pass (See result 2)
5.3	Force at break after challenge testing	Pass (See result 2)

Result 1: Dimensions

Size	M	
No.	Length (mm)	Width (mm)
1	240	96
2	241	96
3	246	97
4	246	96
5	245	97
6	240	97
7	244	96
8	241	97
9	241	96
10	245	96
11	245	96
12	247	96
13	243	95
Standard requirement	≥240	95±10
Median value	244	96

Result 2: Strength

Size: M			
Force at break (N)			
Before aging		After aging	
No.	/	No.	/
1	16.5	1	16.3
2	17.1	2	16.0
3	15.0	3	16.2
4	16.9	4	14.7
5	18.2	5	17.7
6	15.1	6	16.5
7	17.0	7	16.7
8	16.7	8	17.1
9	12.1	9	12.2
10	15.6	10	14.8
11	13.4	11	12.2
12	17.2	12	14.6
13	13.0	13	15.7
Standard requirement	≥6.0	Standard requirement	≥6.0
Median value	16.5	Median value	16.0

3. BS EN 455-3:2015 Medical gloves for single use – Part 3: Requirements and testing for biological evaluation

Number of test sample	:	5 Pieces
Sample size	:	M
Finishes of gloves	:	Powdered-free gloves other than surgeon's gloves

Clause	Test Items	Result
4.4	Powder-free gloves	Pass (See note 1)

Note : 1 Test according to EN ISO 21171:2006, the average mass of powder per glove is 0.18mg. (Requirement: ≤2mg per powder-free glove)

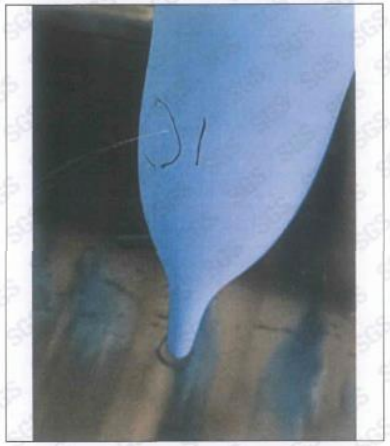
Remark: The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

Sample Photo:

Received Sample

SGS authenticate the photo on original report only

Refer Photo (Watertightness test):



End of Report

MANUFACTURING PLANT

- Established in 2013, new recent investment of $7 Million into extra production capacity.
- Current production of over 45 Million nitrile gloves a year.
- 7,452 square meters and consisting of 3 production lines.
- Fully compliant with EU requirements and regulations.
- Focusing on top of the range equipment, improving technical processes and passing on cost savings to customers whilst never diminishing on quality.
- Our research and development department produces innovative designs and focuses on new cutting-edge technology.

MANUFACTURING PLANT

FDA Registration & Device Listing

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Device Classification Name	Polymer Patient Examination Glove
510(k) Number	K131823
Device Name	PROPRIETARY / DONGTAI/ OTHER CLIENTS PRIVATE LABELING
Applicant	DONG TAI CITY HUAYI GLOVES CO., LTD. RM 1606 BLDG, 1 JIAN XIANG YUAN NO. 209 BEI SI HUAN ZHONG RD HAI DI Beijing, CN 100083
Applicant Contact	Chu Xiaoan
Correspondent	DONG TAI CITY HUAYI GLOVES CO., LTD. RM 1606 BLDG, 1 JIAN XIANG YUAN NO. 209 BEI SI HUAN ZHONG RD HAI DI Beijing, CN 100083
Correspondent Contact	Chu Xiaoan
Regulation Number	880.6250
Classification Product Code	LZA
Date Received	06/20/2013
Decision Date	12/09/2013
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

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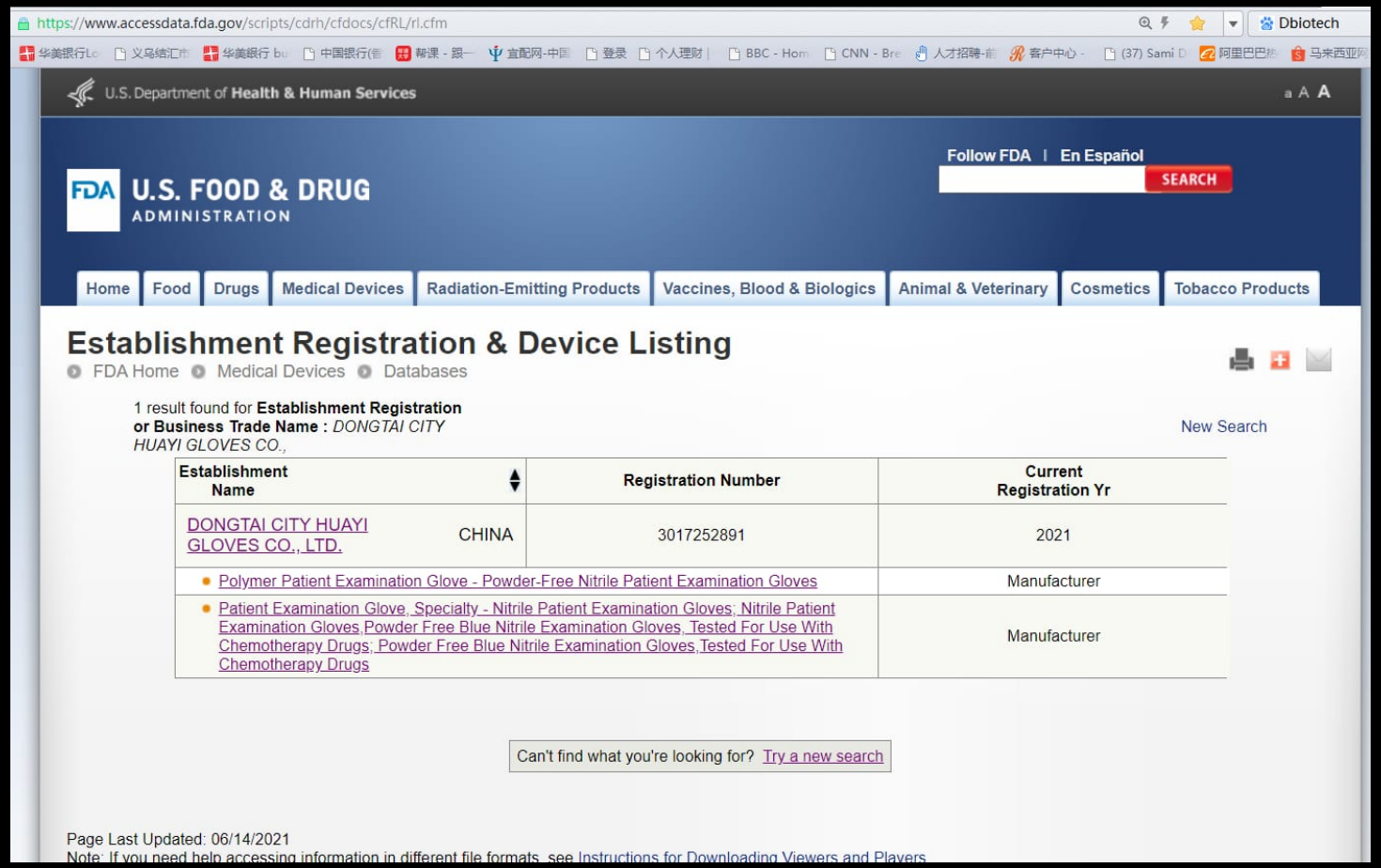
FDA Registration & Device Listing



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1 result found for **Establishment Registration or Business Trade Name :** *DONGTAI CITY HUAYI GLOVES CO.,*

New Search

Establishment Name		Registration Number	Current Registration Yr
DONGTAI CITY HUAYI GLOVES CO., LTD.	CHINA	3017252891	2021
• Polymer Patient Examination Glove - Powder-Free Nitrile Patient Examination Gloves			Manufacturer
• Patient Examination Glove, Specialty - Nitrile Patient Examination Gloves; Nitrile Patient Examination Gloves,Powder Free Blue Nitrile Examination Gloves, Tested For Use With Chemotherapy Drugs; Powder Free Blue Nitrile Examination Gloves,Tested For Use With Chemotherapy Drugs			Manufacturer

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Establishment:
DONGTAI CITY HUAYI GLOVES CO., LTD.
NO. 36 Nanzhuang Road, High-Tech Industrial Development Zone Of
Dongtai , CN 224200
Registration Number: 3017252891
FEI Number*: 3017252891
Status: Active
Date Of Registration Status: 2021

Owner/Operator:
DONGTAI CITY HUAYI GLOVES CO., LTD.
NO. 36 Nanzhuang Road, High-Tech Industrial Development Zone Of
Dongtai, CN 224200
Owner/Operator Number: 10073578

Official Correspondent:
Yun Gao
NO. 36 Nanzhuang Road, High-Tech Industrial Development Zone Of
Dongtai, CN 224200
Phone: 086-515-89517999

US Agent:
Hui Hong
ABMED SERVICE INC
1312 17th Street Suite 692
Denver , CO US 80202
Phone: 303 8000162 Ext
Email: Info@Abmed.Com.Cn

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