



InnovatePLUS

Nitrile Examination Gloves

The InnovatePLUS glove is manufactured by one of the largest plants in China and distributed to North America and APAC regions (3.5g), and throughout Europe (4.5g). This world-class medical examination glove is tested for use with Chemotherapy drugs and meets ISO, ASTM, and EN standards with FDA 510(k) and CE approvals.



Multi-Purpose



Technical Data Sheet

Type	Powder Free, Examination Glove
Specification	Non-Sterile/Disposable/Ambidextrous
Cuff	Beaded
Colour	Blue
Internal Surface	Chlorinated
External Surface	Finger textured 35mm from tip
Primary	Acrylonitrile Butadiene
Packaging	100 pcs/box – 10 boxes/carton



Size	Weight Per Size	Width	Length	Finger Thickness	Palm Thickness	Product Code
Small	4.0g (3.0g) ± 0.3g	80±10mm	≥245mm (9.5")	≥0.10mm (3.94mils)	≥0.07mm (2.75mils)	NG-INPL-001
Medium	4.5g (3.5g) ± 0.3g	95±10mm	≥245mm (9.5")	≥0.10mm (3.94mils)	≥0.07mm (2.75mils)	NG-INPL-002
Large	5.0g (4.0g) ± 0.3g	110±10mm	≥245mm (9.5")	≥0.10mm (3.94mils)	≥0.07mm (2.75mils)	NG-INPL-003
Extra-Large	5.5g (4.5g) ± 0.3g	120±10mm	≥245mm (9.5")	≥0.10mm (3.94mils)	≥0.07mm (2.75mils)	NG-INPL-004

Product Properties (Size Medium)

Test Method	Characteristics	Requirements	Median
EN 455-2 (ASTM D6319)	Width (mm)	95±10	96 (3.78")
	Length (mm)	≥240 (230)	245 (9.65")
	Thickness Single (mm) Finger	≥ 0.08 (0.05)	0.112 (4.41mils)
	Thickness Single (mm) Palm	≥ 0.06 (0.05)	0.074 (2.91mils)
EN 455-1 (ASTM D515)	Freedom from holes	AQL 1.5 (2.5)	PASS (AQL 1.5)
EN 455-2 (ASTM D412)	(Before accelerated ageing)		
	Tensile Strength - N (MPa)	≥ 6.0 (14)	17.4 (37)
	Ultimate elongation (%)	≥ 500	650 (817)
EN 455-2 (ASTM D573)	(After accelerated aging at (70±2° C 166±2 hr)).		
	Tensile Strength - N (MPa)	≥ 6.0 (14)	25.7 (25.3)
	Ultimate elongation (%)	≥ 400	689 (676.1)
EN 455-3 (ASTM D6124)	Powder Control (mg/glove)	≤2.0	0.30

Chemotherapy Drug Permeation Resistance Tested

Chemical Tested	Avg. Time in minutes
Carmustine (BCNU), 3.3mg/ml (3,300 ppm)	15.1
Cisplatin, 1.0 mg/ml (1,000 ppm)	>240
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	>240
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	>240
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	>240
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	>240
Fluorouracil, 50.0 mg/ml (50,000 ppm)	>240
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	>240
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	>240
Mechlorethamine HCl, 1.0mg/ml (1,00 ppm)	>240
Methotrexate, 25.0mg/ml (25,000ppm)	>240
Mitomycin C, 0.5 mg/ml (500ppm)	>240
Thiotepa, 10.0 mg/ml (1,000 ppm)	15.1

Certifications

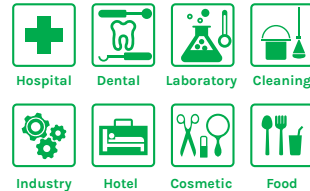


InnovatePLUS Examination Gloves

Specifications & Certifications



Multi-Purpose



The InnovatePLUS glove is manufactured by one of the largest plants in China and distributed to North America and the Asia Pacific. The 3.5g medical examination glove meets ISO and ASTM standards with FDA 510(k) approval.

Product Technical Data Sheet

Type	Powder-Free, Examination Glove		
Specification	Non-Sterile/Disposable		
Cuff	Beaded		
	3.5g +/- 0.3g (0.12 oz)		
Colour	Blue		
Primary Material	Nitrile (Acrylonitrile-butadiene)		
Surface	Finger textured 35mm from tip.		
Powder Control	<=0.51mg/glove (M)		
Packaging	100 pcs/box		
Size & Product Code	Small:	NG-INPL-001	
	Medium:	NG-INPL-002	
	Large:	NG- 003	
	Extra-large:	NG-INPL-004	
Product Name	InnovatePLUS Examination Glove		
Origin of Manufacturer			
Application Distribution	North America Asia Pacific		

Product Properties

Test Method	Characteristics			Requirement	Median
ASTM D6319	Dimensions (mm)	Width (L)		110 ± 10	106 (4.1")
		Length (L)		Min 230	244 (9.6")
		Thickness single (mm)	Finger	Min 0.05	0.14 (5.5mils)
			Palm	Min 0.05	0.09 (3.3mils)
ASTM D5151	Freedom from holes			No leakage	NA
ASTM D412	Before accelerated aging.				
	Tensile Strength (MPa)			Min 14	16.5
	Ultimate elongation (%)			Min 500	697.7
ASTM D573	After accelerated aging at (70±2 °C 166±2 hr).				
	Tensile Strength (MPa)			Min 14	25.3
	Ultimate elongation (%)			Min 400	676.1

Certifications



US Standards	ASTM D6319, ASTM D6978 - Tested for use with Chemotherapy Drugs
FDA Information	FDA 510(k) - K171782 Click here for FDA Website
Quality Standards	ISO 9001, ISO 13485, GMP, QSR & NSF Compliant

June 22, 2020

▪TEST REPORT▪

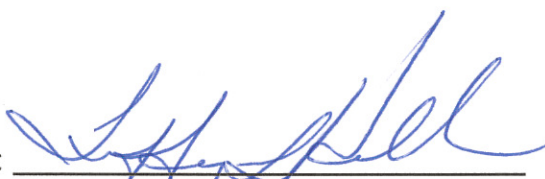
PN 154230A

PHARMACEUTICAL SERVICES

Prepared For:

Coco Wang
He Chuang Plastic & Rubber Co., Ltd.
6-27, Qilu International Plastic Park
Linzi, Zibo, CN 255400

Prepared By:


Tiffany Heller
Manager, Pharmaceutical Services

Approved By:


Ana C Barbur, M.S.
Vice President, Analytical & Chemical Services

Rev 101218



An A2LA ISO 17025 Accredited Testing Laboratory — Certificate Numbers 255.01 & 255.02
ISO 9001:2015 Registered

ISO 9001:2015
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June 22, 2020

Coco Wang
He Chuang Plastic & Rubber Co., Ltd.

Page 2 of 3
PN 154230A

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

RECEIVED: One (1) glove type identified as; Disposable Nitrile Examination Gloves, Powder Free – Blue, Lot# 20200402, Size Medium.

TEST CHEMICALS:

Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Fentanyl Citrate Injection, 100mcg/2mL	WestWard; Lot# 059420; Expiration 06/2022

COLLECTION MEDIA:

Table 2. Collection Media for Test Chemicals

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Fentanyl Citrate Injection, 100mcg/2mL	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978
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 cm ²
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff

*ARDL is ISO 17025 accredited by A2LA for the test methods listed on the certificates referenced on page one. Unless specified, the current specification version is used.

NOTE: Non-ISO 17025 accredited test methods are designated with the ^ symbol to differentiate from ISO 17025 accredited methods in the body of the test report. *

www.ardl.com | 2887 Gilchrist Rd. | Akron, Ohio 44305 | answers@ardl.com | Toll Free (800) 830-ARDL

Fax (330) 794-6610 | Worldwide (330) 794-6600

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 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 DRUG	WAVELENGTH (nm)
Fentanyl Citrate Injection, 100mcg/2mL	199

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested: Disposable Nitrile Examination Gloves, Powder Free – Blue, Lot# 20200402, Size Medium.

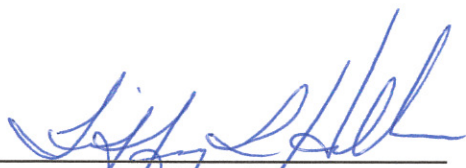
Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Fentanyl Citrate Injection	0.057	0.059	0.053	0.056
Weight/Unit Area (g/m2)	51.8			

RESULTS:

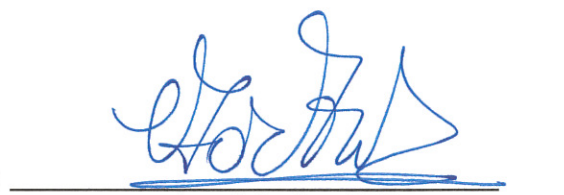
Table 5. Permeation Test Results on Testing of: Disposable Nitrile Examination Gloves, Powder Free – Blue, Lot# 20200402, Size Medium.

TEST CHEMOTHERAPY DRUGS	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen 1/2/3) ($\mu\text{g}/\text{cm}^2/\text{minute}$)	OTHER OBSERVATIONS
Fentanyl Citrate Injection, 100mcg/2mL	>240 min.	N/A	Slight swelling and no degradation

Prepared By:


 Tiffany Heller
 Manager, Pharmaceutical Services

Approved By:


 Ana C Barbur, M.S.
 Vice President, Analytical & Chemical Services



October 12, 2017

Blue Sail Medical Co.,Ltd
Robin Liu
RA/QA Department Manger
No. 21 Qingtian Road, Qilu Chemical Industrial Park
Zibo, 255414 CN

Re: K171782

Trade/Device Name: Powder Free Nitrile Examination Gloves, Blue, Tested for Use with
Chemotherapy drugs

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: I

Product Code: LZA, LZC

Dated: July 31, 2017

Received: August 10, 2017

Dear Robin Liu:

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 Industry and Consumer Education (DICE) 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" (21 CFR 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 Industry and Consumer Education (DICE) 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,


Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K171782

Device Name

Powder Free Nitrile Examination Gloves, Blue, Tested for Use with Chemotherapy Drugs

Indications for Use (Describe)

The Powder Free Nitrile Examination Gloves, Blue, Tested for Use with Chemotherapy Drugs 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.

The proposed device was tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

The following chemicals have been tested with proposed device.

Test Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
*Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	35.3
Cisplatin	1.0 mg/ml(1,000 ppm)	>240
Cyclophosphamide (Cytosan)	20 mg/ml(20,000 ppm)	>240
Doxorubicin Hydrochloride	2.0 mg/ml(2,000 ppm)	>240
Etoside (Toposar)	20.0 mg/ml(20,000 ppm)	>240
Fluorouracil	50.0 mg/ml(50,000 ppm)	>240
Mechlorethamine HCl	1.0 mg/ml(1,000 ppm)	>240
Methotrexate	25.0 mg/ml(25,000 ppm)	>240
Mitomycin C	0.5 mg/ml(500 ppm)	>240
Paclitaxel (Taxol)	6.0 mg/ml(6,000 ppm)	>240
*Thiotepa	10.0 mg/ml(10,000 ppm)	29.2
Vincristine Sulfate	1.0 mg/ml(1,000 ppm)	>240

Please note that the following drugs have lower permeation times:

Carmustine (BCNU): 35.3 minutes and Thiotepa: 29.2 minutes.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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BLUE SAIL MEDICAL CO., LTD
Add: Qilu Chemical Industrial Park, Zibo,
Shandong 255414 China

CoShield Global Trading Limited
5 Noel Rodgers Place, Milson, Palmerston North, 4414, NZ

June 9,2021

Statement on Blue Sail Companies

We hereby to confirm that the companies listed below are related companies. Blue Sail Medical Co.,LTD is the parent firm of He Chuang Plastic & Rubber Co.,Ltd which is the exam nitrile glove factory of Blue Sail Medical Co.,Ltd.

He Chuang Plastic & Rubber Co.,Ltd
6-27, Qilu International Plastic Park,Linzi,Zibo,Shandong

Thanks,

Signature: *Robin Liu*

Robin Liu
RA/QA Department Manager

Date.2021/6/9



Medical Device Licence

* AMENDED *

Licence Number: 102741
First Issue Date: 2019/04/15
Amended Date: 2020/04/05

Homologation d'un instrument médical

* MODIFIÉE *

No d'homologation:
Première date de délivrance:
Date de modification:

Device Class/Classe de l'instrument: 2

This Licence is issued in accordance with the Medical Devices Regulations, Section 36, for the following medical device:

La présente homologation est délivrée en vertu de l'article 36 du Règlement sur les instruments médicaux pour l'instrument médical suivant:

Licence Name/Nom de l'homologation:

POWDER FREE NITRILE EXAMINATION GLOVES

Licence Type/Type d'homologation:

Family / Famille

Reason for Amendment/Raison de la modification

ADDITION OF A DEVICE

Manufacturer Name & Address/Nom du fabricant & adresse

BLUE SAIL MEDICAL CO., LTD

NO. 21 QINGTIAN ROAD
QILU CHEMICAL INDUSTRIAL PARK
ZIBO, SHANDONG
CHINA
255414

Colin Foster, Director, Bureau of Medical Device Licensing Services
Directeur, Bureau des services d'homologation des instruments médicaux

Application Number: 312852
Numéro de la demande:

Manufacturer ID: 127677
Identificateur du fabricant:



Components/Parts/Accessories/Devices for this Licence
Les composantes, parties, accessoires et instruments médicaux pour cette homologation

POWDER FREE NITRILE EXAM GLOVES

Device ID/No de l'instrument: 1010853

Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):

0102016-BLUE-XS
0102017-BLUE-S
0102018-BLUE-M
0102019-BLUE-L
0102020-BLUE-XL
0102026-VIOLET-XS
0102027-VIOLET-S
0102028-VIOLET-M
0102029-VIOLET-L
0102030-VIOLET-XL
0102036-COBALT-XS
0102037-COBALT-S
0102038-COBALT-M
0102039-COBALT-L
0102040-COBALT-XL
0102046-WHITE-XS
0102047-WHITE-S
0102048-WHITE-M
0102049-WHITE-L
0102050-WHITE-XL
0102056-BLACK-XS
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0102058-BLACK-M
0102059-BLACK-L
0102060-BLACK-XL
0102136-VIOLET-XS
0102137-VIOLET-S
0102138-VIOLET-M
0102139-VIOLET-L
0102140-VIOLET-XL
0102156-COBALT-XS
0102157-COBALT-S



0102158-COBALT-M
0102159-COBALT-L
0102160-COBALT-XL
0102196-BLUE-XS
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0102199-BLUE-L
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0102349-WHITE-L
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0102736-BLACK-XS
0102737-BLACK-S
0102738-BLACK-M
0102739-BLACK-L
0102750-BLACK-XL

SYNTHETIC POWDER FREE NITRILE EXAMINATION GLOVES

Device ID/No de l'instrument: 1020825

**Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):**

0122006-BLUE-XS
0122007-BLUE-S
0122008-BLUE-M
0122009-BLUE-L
0122010-BLUE-XL
0122016-VIOLET-XS
0122017-VIOLET-S
0122018-VIOLET-M
0122019-VIOLET-L
0122020-VIOLET-XL
0122026-COBALT-XS
0122027-COBALT-S
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0122126-COBALT-XS
0122127-COBALT-S
0122128-COBALT-M
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0122130-COBALT-XL



0122136-WHITE-XS
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0122190-WHITE-XL
0122196-BLACK-XS
0122197-BLACK-S
0122198-BLACK-M
0122199-BLACK-L
0122200-BLACK-XL
0122206-BLUE-XS
0122207-BLUE-S
0122208-BLUE-M
0122209-BLUE-L
0122210-BLUE-XL
0122216-VIOLET-XS



0122217-VIOLET-S
0122218-VIOLET-M
0122219-VIOLET-L
0122220-VIOLET-XL
0122226-COBALT-XS
0122227-COBALT-S
0122228-COBALT-M
0122229-COBALT-L
0122230-COBALT-XL
0122236-WHITE-XS
0122237-WHITE-S