Vinyl Synmax Exam Gloves

Features

- Easier donning than standard vinyl gloves
- Longer wearing time than nitrile gloves
- Increased cost performance
- PU Coating with no protein, limiting allergy risk
- Increased protection, resisting acid, alkali and oil

Quality Standards

- Complies with EN 455 and EN 374
- Complies with ASTM D5250 (USA Related Product)

Physical Properties

Characteristic	Tensile Strength(MPa)	Elongation	Standard
Before Aging	14	350	ASTM D5250 EN455
After Aging	14	350	ASTM D5250 EN455

Size Guide

SIZE	Reorder No.	Glove Length	Palm Width	Cuff Thickness	Finger Thickness	Palm Thickness
Small	BMPF 3001	235±5mm	85±5mm	0.05±0.03mm	0.07±0.03mm	0.08±0.03mm
Medium	BMPF 3002	235±5mm	95±5mm	0.05±0.03mm	0.07±0.03mm	0.08±0.03mm
Large	BMPF 3003	235±5mm	105±5mm	0.05±0.03mm	0.07±0.03mm	0.08±0.03mm
X-Large	BMPF 3004	235±5mm	115±5mm	0.05±0.03mm	0.07±0.03mm	0.08±0.03mm

Package

Size	Small	Medium	Large	X-Large
QTY Per Box	100Pcs			
Box Per Carton	10Boxes			
QTY Per Carton	1,000Pcs			
Carton Demission	315mm*258mm*245mm			
Carton Gross Weight	5.5Kg	6.0Kg	6.5Kg	6.8Kg
QTY/40HQ(no Pallet)	3,200 ctn			
QTY/Pallet	98 ctn			
QTY/53 truck（Palletized)	30 * 98 ctn			

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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

February 5, 2016

Zibo Huiying Medical Products, Co. Ltd.
% Sophie Hao
Official Correspondent
Basic Medical Industries, Inc.
12390 East End Ave
Chino, California 91710

Re: K153028
Trade/Device Name: Synmax Synthetic Patient Examination Vinyl Gloves, Powder Free, Blue
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: December 18, 2015
Received: December 18, 2015

Dear Sophie Hao:

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 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 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

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

Enclosure

INTCO
英科医疗

Document Number ：INTCO-CE-DC-PVC-001 Version: A/1

EU DECLARATION OF CONFORMITY

Manufacturer

Name: **Shandong Intco Medical Products Co., Ltd.**
Address: **Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China**

Authorized Representative

Name: **Lotus NL B.V.**

Address: **Koningin Julianaplein 10, le Verd, 2595AA， The Hague，Netherlands**

Declares that the MDR described hereafter

Product name and model:

Synmax Vinyl Exam Gloves

UMDNS code：11882

Model: XS/ S /M /L /XL

UDI-DI:

Meet the provisions of the Council Regulation EU 2017/745 and Annex I which apply to them.

The medical device has been assigned to Class I, based on rule 1 of Annex VIII Chapter III of the Regulation EU 2017/745 MDR. It bears the mark

CE

This Declaration of conformity is valid for five years: 6 / October / 2020 to 6 / October / 2025. If there is a change in the declaration information, this declaration is invalid.

The above mentioned declaration of conformity is exclusively under the responsibility of
Company: Shandong Intco Medical Products Co., Ltd.
Address: Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China.

Shandong 2020-10-06

Place , date

Cui Zhongqiang Quality Manager

Legally binding signature, Function

INTCO
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VINYL SYNMAX POWDER FREE EXAMINATION GLOVES

Permeation Resistance to Chemotherapy Drugs

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

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 pe specimens into the collection medium. The collection medium was circulated in a closed loop throu Data collection was performed according to the programmed schedule by means of UV Winlab soft Elmer Corporation. The list of the characteristic wavelengths is shown below.

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

TESTING DRUG	WAVELENGT
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 (20,000 ppm)	200
Dacarbazine, 10.0 mg/ml (10,000 ppm)	320
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	232
Etoposide, 20.0 mg/ml (20,000 ppm)	205
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269
Paclitaxel, 6.0 mg/ml (6,000 ppm)	232
ThioTepa, 10.0 mg/ml (10,000 ppm)	199

Table 5. Permeation Test Results on testing of: One (1) glove type identified as; Synmax Vinyl Exam Glove.

TEST CHEMOTHERAPY DRUGS	AVERAGE BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) (µg/cm²/minute)	OTHER OBSERVATIONS
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	12.6 (12.6,13.3,12.7)	0.2 (0.2,0.2,0.1)	Slight swelling and no degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Dacarbazine, 10.0 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Etoposide, 20.0 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Fluorouracil, 50.0 mg/ml (50,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Paclitaxel, 6.0 mg/ml (6,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
ThioTepa, 10.0 mg/ml (10,000 ppm)	15.4 (15.4,16.3,17.6)	0.6 (0.7,0.6,0.6)	Slight swelling and no degradation

SAMPLES RECEIVED:

One (1) glove type (2 boxes) identified as; Synmax Vinyl Exam Gloves 100 pieces Size M, 100 Pieces Size Lg

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