VINYL GLOVES

SYNMAX

PRODUCT INFO

* Available in blue and black colors

PRODUCT INFO

* Available in blue and black colors

PRODUCT INFO

Features

- 100% Brand-new formula to enhance softness and fitness
- Higher tensile strength and more tactile sensitivity
- DOP or DEHP free
- No latex protein to cause allergy
- Dry and smooth coating to avoid dermatitis
- A variety of colors available for different people or industries

Quality Standards

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

Applications

Medical Purpose / Examination

Industrial purpose / PPE

Laboratory

Healthcare and nursing

General housekeeping

IT Industry

510(k)

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

November 27, 2013

Zibo Intco Medical Products Company, Limited
C/O Mr. John Zhao
Official Correspondent
Basic Medical Industries, Inc.
12390 East End Avenue
CHINO CA 91710

Re: K132201
Trade/Device Name: Synmax Synthetic Examination Vinyl Gloves, Powder Free, Blue
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYZ
Dated: October 28, 2013
Received: October 31, 2013

Dear Mr. Zhao:

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.

510(k)

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,

Erin FDA ith

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

510(k)

510(K) SUMMARY

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

The assigned 510(K) number is: K132201

1. **Submitter's Identification:**
   Zibo Intco Medical Products, Co. Ltd.
   No. 18, Qingtian Road, Linzi District
   Qilu Chemical Industry Park
   Zibo City, Shandong Province
   China

   Contact Person
   John Zhao
   Tel: 909-548-4828, Fax: 909-548-4808

   NOV 27 2013

Date summary prepared: Nov. 4, 2013

2. **Name of the Device:**
   Synmax Synthetic Examination Vinyl Gloves,
   Powder Free, Blue

3. **Common Name:**
   Synmax Synthetic Examination Vinyl Gloves,
   Powder Free, Blue

4. **Predicate Device Information:**
   Shijiazhuang Eversharp Plastic Products Co., Ltd.
   Synthetic Powder Free (Yellow) Vinyl Examination Gloves (K011882)

5. **Device Description:**
   Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 880.6250, Examination Vinyl Glove, 80LYZ, and meets all requirements of ASTM Standard D5250-06.

6. **Intended Use:**
   A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner.(21 CFR 880.6250)

7. **Comparison to Predicate Devices:**
   Zibo Intco Medical Products, Co. Ltd.'s Synmax Synthetic Examination Vinyl Gloves, Powder Free, Blue is substantially equivalent in safety and effectiveness

510(k)

to Shijiazhuang Eversharp Plastic Products Co., Ltd. Synthetic Powder Free (Yellow) Vinyl Examination Gloves (K011882). Please see table 7-2 for comparison details.

8. **Discussion of Non-Clinical Test Performed for Determination of Substantial Equivalence are as Follows:**
The standards used for Zibo Intco Medical Products, Co. Ltd. glove production are based on ASTM-D-5250-06. All testing meets requirements for Physical and Dimensions Testing conducted on gloves, Inspection Level S-2, AOL 2.5.

   The FDA 1000 ml. Water Fill Test was also conducted with samplings of AOL 2.5, Inspection Level I, meeting these requirements, Primary Skin irritation and Skin Sensitization (allergic contact dermatitis) testing was conducted with results showing no primary skin irritant or sensitization reactions.

   There are no special labeling claims and we do not claim our gloves as hypoallergenic is conducted to insure that our gloves meet our "powder-free" claims (contain no more than 2 mg powder per glove).

9. **Sterilization**
There is no specific device for non-sterile examination gloves. Hand hygiene by rubbing with an alcohol-based hand rub or by washing with soap and water should be performed when appropriate.

10. **Discussion of Clinical Tests Performed:**
Not Applicable – There is no hypoallergenic Claim.

11. **Conclusions:**
Zibo Intco Medical Products, Co. Ltd. Synmax Synthetic Examination Vinyl Gloves, Powder Free, Blue, conform fully to ASTM-D-5250-06 standard as well as applicable 21 CFR references, and, meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data in Section 7. There are no safety/efficacy issues or new claims from the "substantial equivalence" products cited.

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Table 7-2. Side-by-Side Comparison of Intended Use, Design, Material, Physical, Biocompatibility, and Performance Testing

	Proposed Device	Predicate Device (K051662)
Description	Zibo Inteo Medical Products, Co. Ltd. Synmax Synthetic Examination Vinyl Gloves, Powder Free, Blue	Shijiazhuang Eversharp Plastic Products Co., Ltd. Synthetic Powder Free (Yellow) Vinyl Examination Gloves (K011882)
Indication for Use	A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner.	Substantially equivalent
Labeling: Instruction for use	A garment covering the hand and wrist area. That is a disposable device which is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner.	Substantially equivalent
Labeling: Labels on the carton	Labels include: Product name; color; "single use only" size, piece count, lot number, distributor name, and manufacturer address.	Substantially equivalent
Device Materials	Poly Vinyl Chloride Polyurethane Diisononyl Phthalate (DINP)	Substantially equivalent
Before Aging: Tensile Strength(Mpa) and Ultimate Elongations	Average Tensile Strength (Mpa): 16.9 Average Ultimate Elongations: 550%	Substantially equivalent
After Aging: Tensile Strength(Mpa) and Ultimate Elongations	Average Tensile Strength (Mpa): 14.4 Average Ultimate Elongations: 500%	Substantially equivalent
Overall Length on Medium Size	Average over 230mm	Substantially equivalent
Width of Palm on Medium Size	Average 95mm	Substantially equivalent
Palm Thickness	Average 0.095 mm	Substantially equivalent
Figure Thickness	Average 0.090 mm	Substantially equivalent

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Residual Powder	According to ASTM D6124-06 Standard Test Method for Residual Powder on Medical gloves for the determination of residual powder content. Testing result indicates the weight of all types of residual or powder on finished powder-free gloves as < 2 mg per glove and there is no defect glove found according to ASTM D6124-06.	Substantially equivalent
Pinhole Results	According to ASTM D5151-06, Testing result indicates pinhole were found less than two pieces gloves out of 125 pieces gloves. AQL 2.5 is met.	Substantially equivalent
Biocompatibility Result: Primary Skin Irritation	ISO 10993-10 passes	Substantially equivalent
Dermal Sensitization	ISO 10993-10 passes	Substantially equivalent
Summary of comparison	Zibo Intco Medical Products, Co. Ltd. Synmax Synthetic Examination Vinyl Gloves, Powder Free, Blue (subject device) and Shijiazhuang Eversharp Plastic Products Co., Ltd.Synthetic Powder Free (Yellow) Vinyl Examination Gloves (K011882) (predicate device) are substantially equivalent in all technological characteristics, including tensile strength, ultimate elongations size, thickness, residual powder and pinhole.	

TEST REPORT

AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Testing. Development. Problem Solving.

January 5, 2021

▪TEST REPORT▪

PN 156551

PHARMACEUTICAL SERVICES

Prepared For:

John Zhao
Intco Medical Industries Inc.
805 Barrington Avenue
Ontario, CA 91764

Prepared By: Tiffany Heller
Manager, Pharmaceutical Services

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

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TEST REPORT

January 5, 2021

John Zhao
Intco Medical Industries Inc.

SUBJECT: Permeation testing per ASTM D6978 on sample submitted by the above company.

RECEIVED: One (1) glove type identified as; Synmax Vinyl Exam Glove.

TEST CHEMICALS:
Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	Sigma Aldrich; Batch# 0000095754; Expiration 10/2021
Cisplatin, 1.0 mg/ml (1,000 ppm)	Accord; Lot# P2001296; Expiration 01/2022
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	Accord; Lot# 19112225; Expiration 10/2021
Dacarbazine, 10.0 mg/ml (10,000 ppm)	Teva; Lot# 31325414B; Expiration 09/2021
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	WestWard; Lot# BJ0051; Expiration 06/2021
Etoposide, 20.0 mg/ml (20,000 ppm)	Teva; Lot# 31325485B; Expiration 07/2021
Fluorouracil, 50.0 mg/ml (50,000 ppm)	Accord; Lot# P2001167; Expiration 01/2022
Paclitaxel, 6.0 mg/ml (6,000 ppm)	Teva; Lot# 19K24KA; Expiration 11/2021
ThioTepa, 10.0 mg/ml (10,000 ppm)	USP; Lot # R11380; Expiration 09/2021

COLLECTION MEDIA:
Table 2. Collection Media for Test Drug

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 (20,000 ppm)	Distilled Water
Dacarbazine, 10.0 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	Distilled Water
Etoposide, 20.0 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Paclitaxel, 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
ThioTepa, 10.0 mg/ml (10,000 ppm)	Distilled Water

TEST REPORT

January 5, 2021

John Zhao
Intco Medical Industries Inc.

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D6978
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 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)
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

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested: One (1) glove type identified as: Synmax Vinyl Exam Glove.

Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Carmustine (BCNU)	0.056	0.050	0.050	0.052
Cisplatin	0.055	0.057	0.054	0.056
Cyclophosphamide (Cytoxan)	0.056	0.057	0.054	0.056
Dacarbazine	0.051	0.051	0.053	0.052
Doxorubicin	0.051	0.052	0.054	0.052
Etoposide	0.049	0.054	0.051	0.051
Fluorouracil	0.053	0.051	0.055	0.053
Paclitaxel	0.052	0.050	0.054	0.052
ThioTepa	0.057	0.053	0.057	0.056
Weight/Unit Area (g/m2)	**62.2**			

TEST REPORT

January 5, 2021

John Zhao
Intco Medical Industries Inc.

RESULTS:

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

TEST REPORT

January 5, 2021

John Zhao
Intco Medical Industries Inc.

SAMPLES RECEIVED:

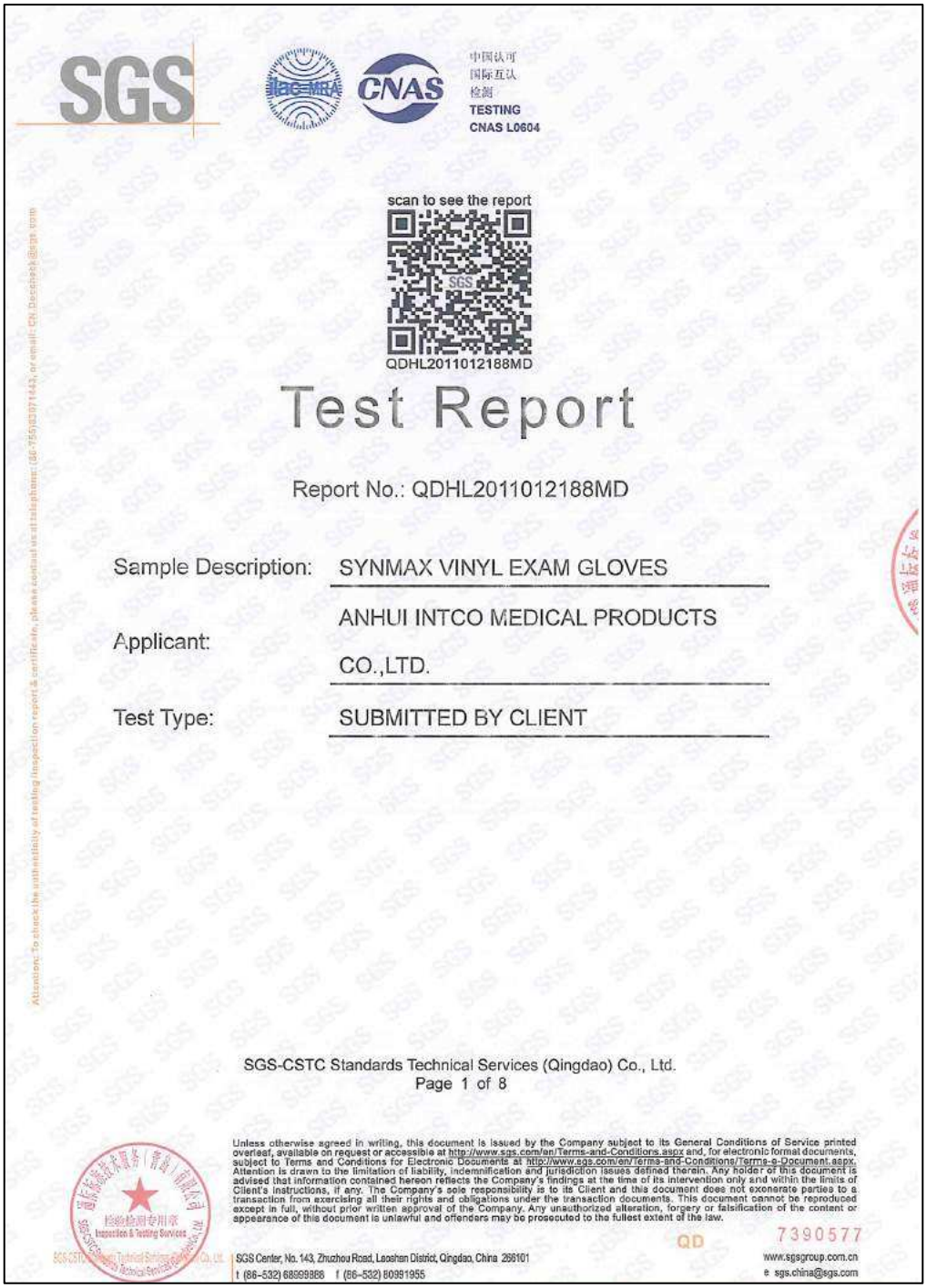
One (1) glove type (2 boxes) identified as: Synmax Vinyl Exam Gloves 100 pieces Size M, 100 Pieces Size Lg

Prepared By: _____
Tiffany Heller
Manager, Pharmaceutical Services

Approved By: _____
Ana C Barbur, M.S.
Vice President, Analytical & Chemical Services

**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.*

TEST REPORT



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Test Report

Report No.: QDHL2011012188MD

Sample Description:	SYNMAX VINYL EXAM GLOVES
Applicant:	ANHUI INTCO MEDICAL PRODUCTS CO.,LTD.
Test Type:	SUBMITTED BY CLIENT

QD 7390577

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CNAS L0604

Report No.: QDHL2011012188MD

Test Report

BLUE	Sample Description	SYNMAX VINYL EXAM GLOVES	Color	BLUE
	Received sample quantity/ Tested sample quantity	300PCS/ 235PCS	Type/Specifications	M
	Lot No.	NOT PROVIDED	Lot Quantity	NOT PROVIDED
	Manufacture Date	NOT PROVIDED	Expiration Date	NOT PROVIDED
	Material/Appearance	VINYL	Storage Condition	NOT PROVIDED
	Manufacturer	NOT PROVIDED		
Client information	Applicant	ANHUI INTCO MEDICAL PRODUCTS CO.,LTD.		
	Applicant address	(HAITANG ROAD WEST AND YINHUA ROAD NORTH) SUIXI WUHU MODERN INDUSTRIAL PARK, SUIXI TOWN,HUAIBEI CITY, ANHUI,CHINA		

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CNAS L0604

Report No.: QDHL2011012188MD

Test information	Sample Receiving Date	NOV.23,2020	Test Period Date	NOV.23,2020 TO DEC.08,2020
	Sample No.	QDHL2011012188MD	Test environment	Meet requirement
	Test items	Freedom from holes, Physical dimensions (length, width, thickness), Physical property characteristics (Tensile strength & Ultimate elongation before aging, Tensile strength & Ultimate elongation after aging), Powder residue for powder free gloves		
	Testing Accordance	ASTM D 5250-19 Standard Specification for Poly (Vinyl Chloride) Gloves for Medical Application Clause 6.1.2, 6.1.3, 6.1.4, 6.1.5		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: DEC.08,2020			
Remark	/			

Approver: Jessica Guo Auditor: Jessica Guo Compiler: Lillian Diao

Date: 2020.12.08 Date: 2020.12.08 Date: 2020.12.08

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TEST REPORT

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Report No.: QDHL2011012188MD

Sample Photo

QD 7390580

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Report No.: QDHL2011012188MD

Test Results

Test Items			Unit	Test Method	Requirement		Test Result	Assessment
Performance Requirements								
Freedom from Holes			/	ASTM D 5250-19 Clause 7.3	Sample quantity: 200pcs AQL: 2.5 Ac: 10 Re: 11		Found: 0	Pass
Physical dimensions	Length		mm	ASTM D 5250-19 Clause 7.4	≥230	Sample quantity: 13pcs AQL: 4.0 Ac: 1 Re: 2	See appendix 1 for details	Pass
	Width		mm		M: 95±5			Pass
	Thickness-finger		mm		Median Value ≥0.08			Pass
	Thickness-palm		mm		Median Value ≥0.08			Pass
Physical property characteristics	Before Aging	Tensile strength	Mpa	ASTM D 5250-19 Clause 7.5	≥11	Sample quantity: 13pcs AQL: 4.0 Ac: 1 Re: 2	See appendix 2 for details	Pass
		Ultimate Elongation	%		≥300			Pass
	After Aging	Tensile strength	Mpa		≥11			Pass
		Ultimate Elongation	%		≥300			Pass
Powder Residue For Powder Free Gloves			mg	ASTM D 5250-19 Clause 7.6	≤2.0		0.02	Pass

QD 7390581

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Report No.: QDHL2011012188MD

Appendix 1: Physical dimensions

Sample No.	Size: M			
	Length/mm	Width /mm	Median value /mm	
			Thickness-finger	Thickness-palm
1	236	98	0.085	0.084
2	239	97	0.093	0.083
3	238	98	0.088	0.086
4	235	97	0.080	0.083
5	240	97	0.086	0.088
6	238	97	0.096	0.088
7	235	98	0.081	0.089
8	238	98	0.080	0.094
9	234	98	0.099	0.087
10	238	97	0.099	0.087
11	240	98	0.085	0.089
12	237	97	0.110	0.084
13	239	97	0.080	0.086
Standard requirement	≥230	95±5	≥0.08	≥0.08
Found	0	0	0	0

QD 7390582

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Report No.: QDHL2011012188MD

Appendix 2: Physical property characteristics

Size: M					
Before Aging			After Aging		
Sample No.	Tensile strength (MPa)	Ultimate Elongation (%)	Sample No.	Tensile strength (MPa)	Ultimate Elongation (%)
1	16.9	340	1	17.2	344
2	16.3	341	2	16.4	338
3	17.5	308	3	17.1	340
4	19.8	390	4	16.2	323
5	17.3	365	5	17.8	371
6	14.8	310	6	16.7	331
7	18.4	379	7	18.0	340
8	18.4	394	8	16.8	343
9	16.6	340	9	16.6	332
10	16.9	344	10	16.7	330
11	17.0	354	11	14.9	324
12	14.9	313	12	17.2	352
13	18.9	369	13	16.3	325
Standard requirement	≥11	≥300	Standard requirement	≥11	≥300
Found	0	0	Found	0	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.

End of Report

QD 7390583

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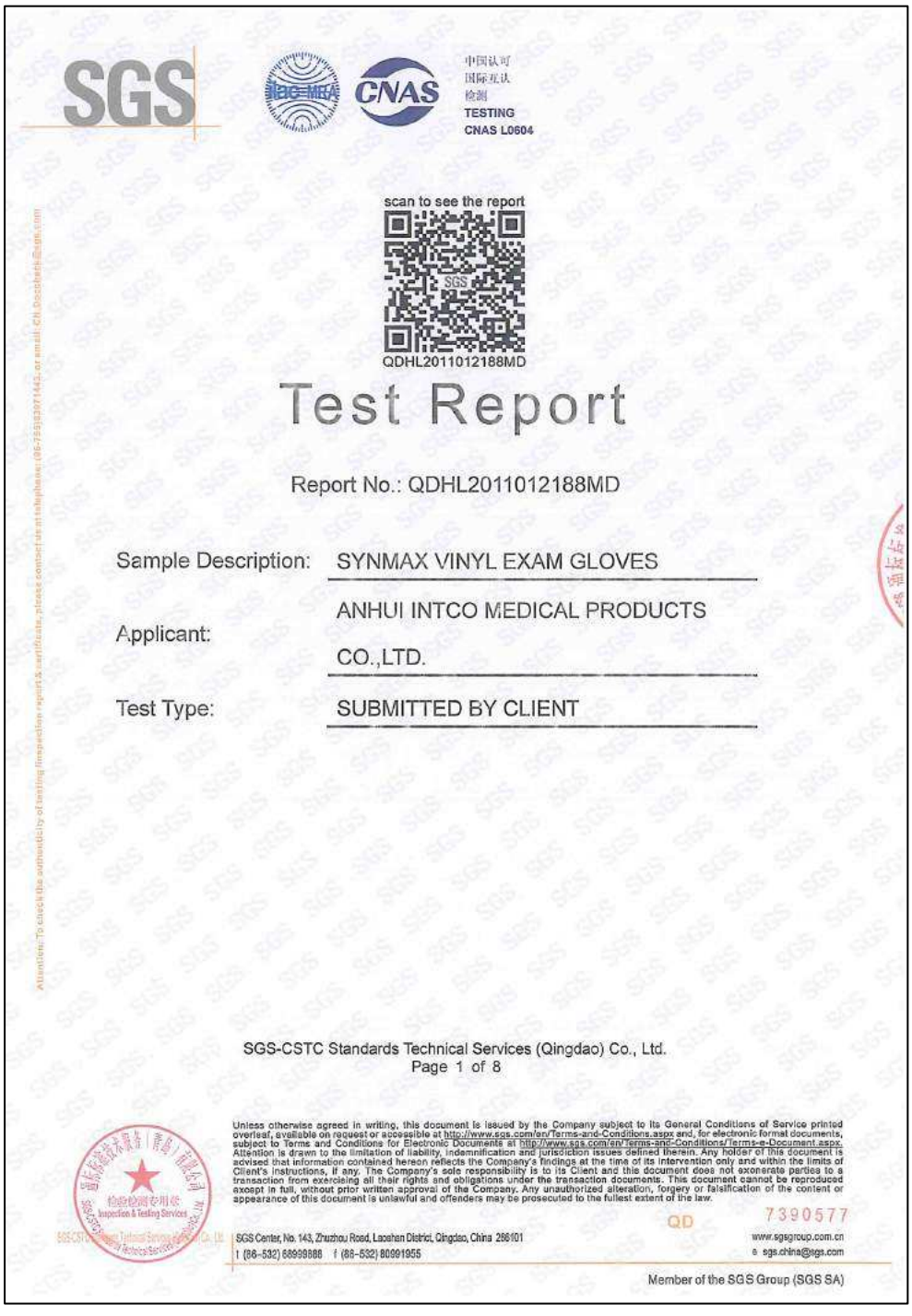
TEST REPORT



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QDHL2011012188MD

Test Report

Report No.: QDHL2011012188MD

Sample Description: SYNMAX VINYL EXAM GLOVES

Applicant: ANHUI INTCO MEDICAL PRODUCTS CO.,LTD.

Test Type: SUBMITTED BY CLIENT

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 1 of 8

QD 7390577

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