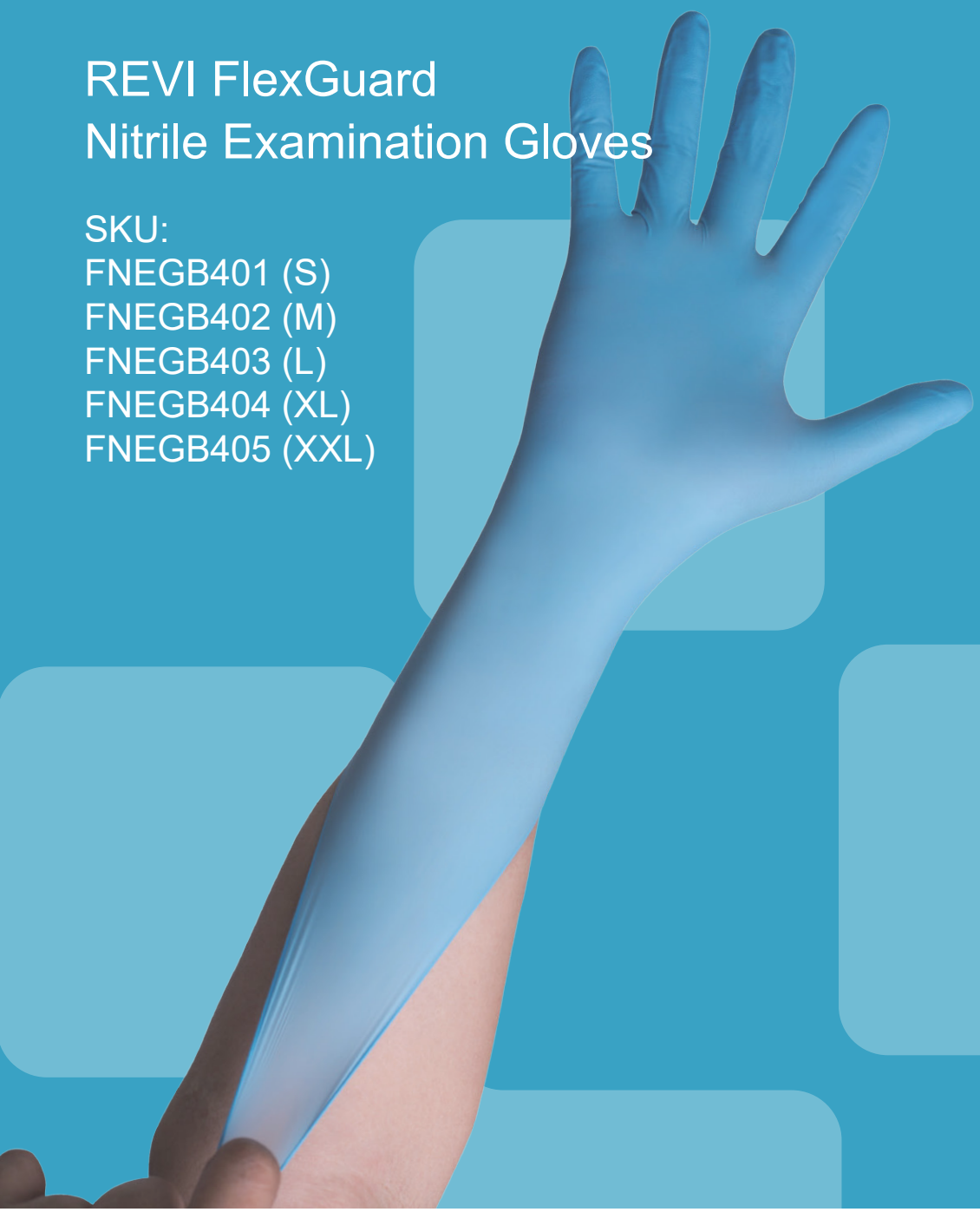
REVi

GUOYU GLOBAL, INC.

REVI FlexGuard
Nitrile Examination Gloves

SKU:
FNEGB401 (S)
FNEGB402 (M)
FNEGB403 (L)
FNEGB404 (XL)
FNEGB405 (XXL)



FDA U.S. FOOD & DRUG ADMINISTRATION

TÜV SÜD PSB Singapore

Nelson Labs. A Sotera Health company

SGS

CE

国检检测

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Nitrile Examination Gloves

General Description

Material	Nitrile	**Type**	Non-sterile
Color	Blue	**Usage**	Single Use
Shape	Ambidextrous	**Interior**	Powder Free
Sizes	S, M, L, XL, XXL	**Exterior**	Textured
Cuff	Beaded	**Process**	Chlorinated

Product SKU

Small	FNEGB401
Medium	FNEGB402
Large	FNEGB403
X-Large	FNEGB404
XX-Large	FNEGB405

Packaging

Box	100 Gloves Per Box
Box Dims	240 X 120 X 70 mm
Case	10 Boxes Per Case
Case Dims	370 X 255 X 255 mm

Physical Properties

Tensile Strength	14 Mpa (min)
Tensile Strength (Aged)	14 Mpa (min)
Powder Content	< 2 mg
FDA 510(k)	K 211914
Elongation	500%
Elongation (Aged)	400%
Protein Content	N/A
AQL Level	2.5

Dimensions

Weight	3.0 g	**Length**	240 ± 10 mm
Thickness		**Width**	
cuff	0.07 ± 0.03 mm	**Small**	85 ± 5 mm
palm	0.08 ± 0.03 mm	**Medium**	95 ± 5 mm
finger	0.09 ± 0.03 mm	**Large**	105 ± 5 mm
Nominal	3 mil	**X-Large**	115 ± 5 mm
		XX-Large	125 ± 5 mm

UPC Barcodes

S Case
M Case
L Case
XL Case
XXL Case

S Box
M Box
L Box
XL Box
XXL Box

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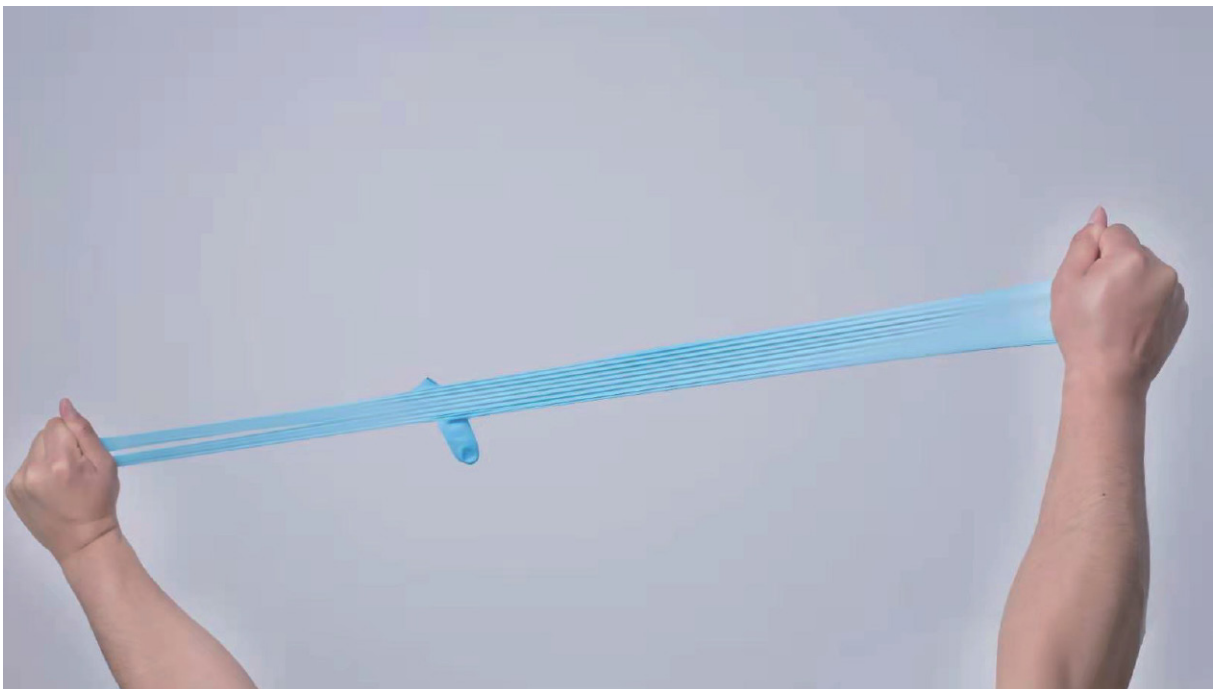
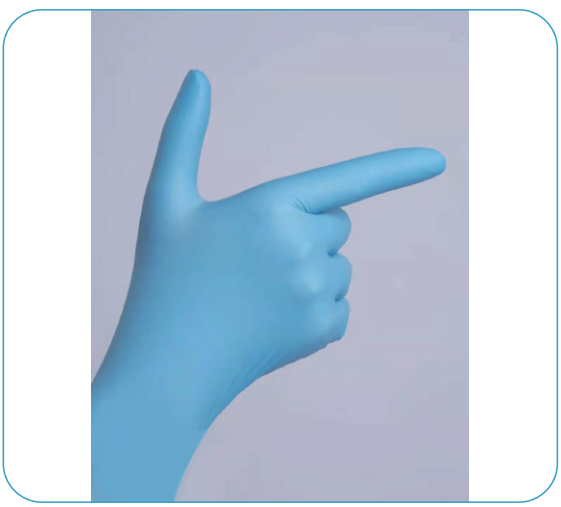
Nitrile Examination Gloves



Standard	**ASTM D6319**
Product Name	**Nitrile Examination Gloves**
Type	**Non-Sterile**
Color	**Blue**
Main Ingredients	**NBR , Zinc Oxide , Promoter BZ , Defoamer , Color Pulp , Active ABS**



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Nitrile Examination Gloves

Length	9.5" 240 ± 10 mm
Size	**Palm Width**
S 7.0 ~ 7.5	85± 5 mm
M 8.0 ~ 8.5	95± 5 mm
L 9.0 ~ 9.5	105± 5 mm
XL 10 ~ 10.5	115± 5 mm
XXL 11 ~ 11.5	125± 5 mm
Thickness	3 mil
Thickness Cuff	0.07 ± 0.03 mm
Thickness Palm	0.08 ± 0.03 mm
Thickness Finger	0.09 ± 0.03 mm

Tensile Strength (MPa)	Before Aging	14 MPa min.
Elongation Break%	Before Aging	500% min.
AQL	2.5%	
Shelflife	Min. 5 Years	

Packaging

Box 240 X 120 X 70 (mm)
Quantity 100 Pcs

Carton 370 X 255 X 255 (mm)
Quantity 1000 Pcs

October 14, 2021

Yingxiang Glove Products Co., Ltd.
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K211914
Trade/Device Name: Nitrile Patient Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: September 7, 2021
Received: September 13, 2021

Dear Boyle Wang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray, III, PhD
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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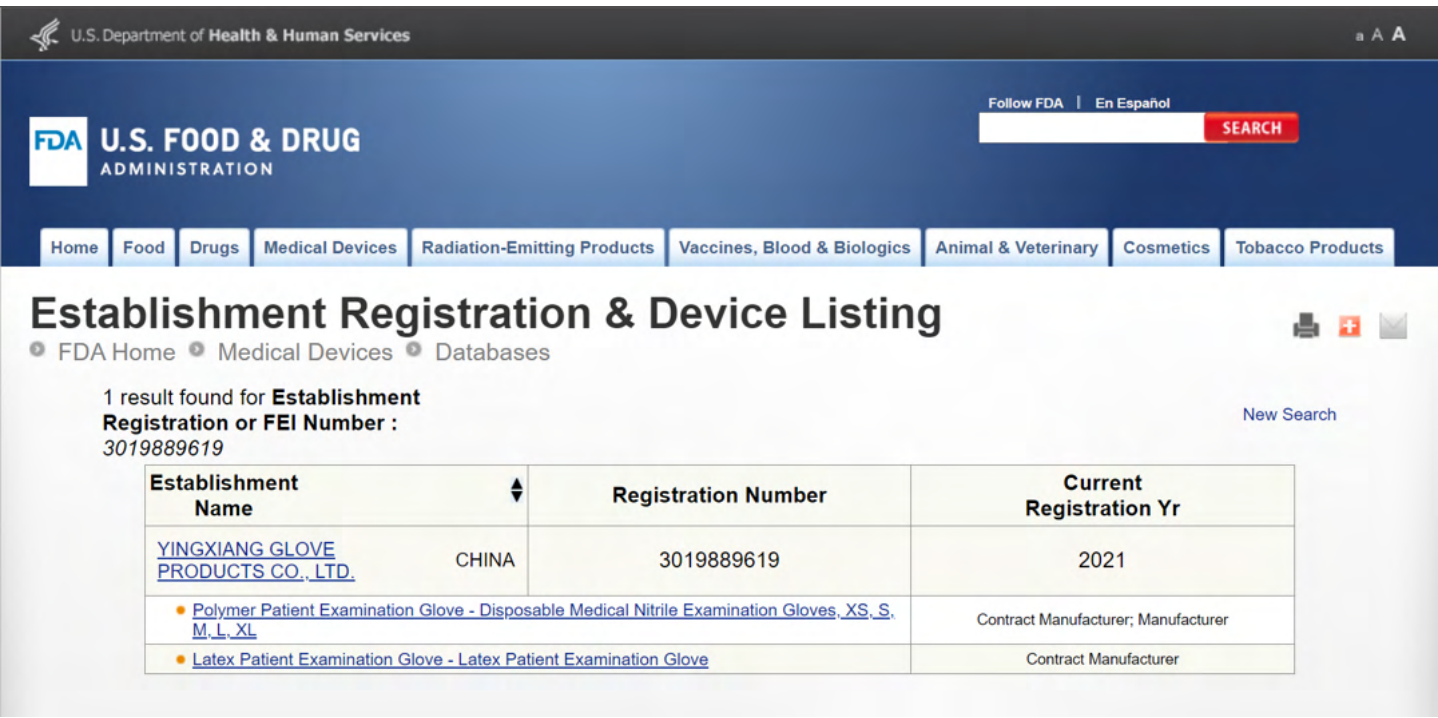
Nitrile Examination Gloves


U.S. Department of Health & Human Services

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Establishment Registration & Device Listing

FDA Home › Medical Devices › Databases

1 result found for **Establishment Registration or FEI Number :**
3019889619

New Search

Establishment Name		Registration Number	Current Registration Yr
YINGXIANG GLOVE PRODUCTS CO., LTD.	CHINA	3019889619	2021
• Polymer Patient Examination Glove - Disposable Medical Nitrile Examination Gloves, XS, S, M, L, XL			Contract Manufacturer; Manufacturer
• Latex Patient Examination Glove - Latex Patient Examination Glove			Contract Manufacturer

Properties Test

Final Report

Verification

Article Name: Nitrile Patient Examination Gloves

Report Number: CSTBB21040009

Sponsor

Yingxiang Glove Products Co., Ltd.

No. 1 , Zhendong Industrial Park, Huaqiao Town, Wuxue City, Huanggang City, Hubei Province

Test Facility

CCIC Huatongwei international inspection (Suzhou) Co., Ltd

Room 101, Building G, Ruoshui Road 388, Suzhou, Jiangsu, China

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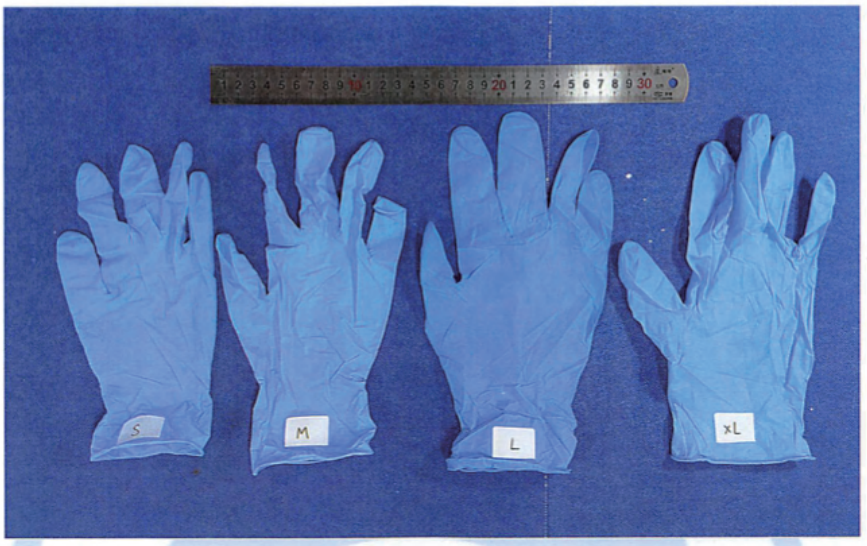
Notices

1. Please apply for rechecking within 15 days of receiving the report if there is any objection.
2. Any erasure or without special testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The report is only responsible for the test results of the tested samples.
5. The report shall not be reproduced except in full without the written approval of the company.
6. The results are not used to prove the society, and are only used for scientific research, teaching and internal quality control.

Study Verification and Signature



Protocol Number	SST2103000601BB
Protocol Effective Date	2021-03-16
Technical Initiation Date	2021-03-16
Technical Completion Date	2021-03-23
Final Report Completion Date	2021-04-19

Personnel — Betty — 2021-04-19 (Date Completed)

Approved — Yuheng Zhang (Study Director) — 2021-04-19 (Date Completed)

Supervisory — (Test Facility Manager) — (Date Completed)

Huatongwei international inspection (Suzhou) Co., Ltd.

Quality Assurance Statement and GLP Statement

Quality Assurance Statement

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to the HTW's Management.

The final report was reviewed to assure that the report accurately describes the methods and standard operating procedures. The reported results accurately reflect the raw data of the nonclinical study conducted per the protocol.

Phase Inspected	Date	Study Director	Management
Experiment	2021-03-16	2021-03-16	2021-03-16
Raw Data	2021-03-23	2021-03-23	2021-03-23
Final Report	2021-04-19	2021-04-19	2021-04-19

The findings of these inspections have been reported to Management and the Study Director.

Hui Tang
Quality Assurance

2021-04-19
Date

GLP Statement

This study was conducted in compliance with current U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of HTW, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Part 58.105 and 58.113.

Yuheng Zhang
Study Director

2021-04-19
Date

1.0 Purpose

The test was designed to validate the properties of the test glove.

Water tightness test for detection of holes, physical dimensions and physical properties were performed on the test glove to test its properties.

The results showed each property of the test glove was acceptable under this test condition.

2.0 Reference

Sampling procedures for inspection by attributes Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection (ISO 2859-1:1999).

Standard Specification for Nitrile Examination Gloves for Medical Application (ASTM D6319 - 19).

Standard Test Method for Detection of Holes in Medical Gloves (ASTM D 5151-19).

Standard Practice for Rubber—Measurement of Dimensions (ASTM D 3767-03(2014)).

Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension (ASTM D 412-06a(2013))

Standard Test Method for Rubber—Deterioration in an Air Oven (ASTM D 573-04(2015))

Medical gloves - Determination of removable surface powder ISO 21171-2006

Standard Test Method for Residual Powder on Medical Gloves ASTM D6124 - 06(2017)

3.0 Compliance

US FDA Good Laboratory Practice Regulations 21 CFR 58, effective June 20, 1979, as amended 52 FR 33780, Sept. 4, 1987, and subsequent amendments

Standard operating procedure of CCIC Huatongwei international inspection (Suzhou) Co., Ltd.

4.0 Test articles

Name	Nitrile Patient Examination Gloves
Manufacture	Yingxiang Glove Products Co., Ltd.
Size	S\M\L\XL
Model	S\M\L\XL
Lot Batch#	Not provided
Test Article Material	Not provided
Physical State	Solid
Color	Blue
Package material	Paper box
Sterilized or Not	Not Sterilized
Total Surface/Weight	Not provided
Storage Condition	Room Temp.
Note: The information about the test article was supplied by the sponsor wherever applicable.	

5.0 Equipment

Ruler (SHB076)

Digital display micrometer (SHB127)

Computer control tensile tester (SHB041)

Oven (SHB023)

6.0 Watertightness Test for Detection of Holes

6.1 Took 125 gloves to be test.

6.2 Vertically position the filling tube to fit the glove and attached the glove to the filling tube, overlapping the cuff by a maximum of 40 mm over the end of the tube and secured it to obtain a watertight seal without damaging the globe.

6.3 Added 1000 ml of water at a temperature of (15 to 35) ℃ into the open end of the filling tube, allowing the water to pass freely into the glove.

6.4 Immediately inspected the glove visually for water leakage. Let the glove hang for 2 min and again inspect for water leakage. Disregard leakages within 40 mm of the cuff.

6.5Criterion

Items	Batch size	Inspectional Level	AQL	Sample Demand	Criterion
Water leak	35000	I	2.5	125	≤7

6.6 Result

Number of Conforming	Number of Non-conforming
125 Glove	0 Glove

6.7 Conclusion: The test result was considered to be acceptable.

7.0 Physical Dimensions Test

7.1 Length: The length shall be expressed in millimeters as measured from the tip of the middle finger to the outside edge of the cuff.

7.2 Width: The width of the palm shall be expressed in millimeters as measured at a level between the base of the index finger and the base of the thumb.

7.3 Thickness: The minimum thickness shall be expressed in millimeters when using a dial micrometer and in the locations of finger and palm.

7.4 Criterion:

Items	Batch size	Inspectional Level	AQL	Sample Demand
Physical dimension test	35000	S-2	4.0	8

7.5 Results:

No.	Length (S)(mm)	Width (S) (mm)	Length (M)(mm)	Width (M) (mm)	Length (L)(mm)	Width (L) (mm)	Length (XL)(mm)	Width (XL) (mm)	Thickness (mm)	
									Finger	Palm
1	234	86	244	94	270	105	245	112	0.11	0.07
2	233	87	254	95	268	106	248	115	0.12	0.08
3	234	86	242	94	275	108	248	118	0.11	0.07
4	233	81	255	95	274	109	245	119	0.12	0.08
5	234	86	247	94	268	100	250	114	0.11	0.07

6	233	86	249	96	274	104	250	113	0.13	0.07
7	228	87	247	96	273	102	248	114	0.12	0.07
8	230	86	243	94	270	100	252	116	0.11	0.08
Criteria	≥220mm	80±10mm	≥230mm	95±10mm	≥230mm	110±10mm	≥230mm	120±10mm	≥0.05mm	≥0.05mm
Conclusion	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable

7.6 Conclusion: The test result was considered to be acceptable.

8.0 Determination of Physical Properties

8.1 Determined the physical properties of the 8 test pieces (medium gloves) after conditioning at 25 ℃ and 50% relative humidity for 24 hours under test condition.

8.2 Obtained one dumb-bell test piece from each of 8 gloves using a cutter.

8.3 With the cross-head speed of 500 mm/min, the specimen in the normal tensile strength was pulled to fracture.

8.4 Calculated the tensile strength and ultimate elongation.

8.5 Repeated the method after the specimen (medium gloves) being subjected to a temperature of 70 ℃ for 166 h.

8.6 Criterion:

Items	Before Aging		After Accelerated Aging	
	Tensile Strength	Ultimate Elongation	Tensile Strength	Ultimate Elongation
Physical Requirements	≥14MPa	≥500%	≥14MPa	≥400%
Inspection Level	S-2			
AQL	4.0			
Sample Size Code Letter	D			
Batch size	35000			
Sample Demand	8			
Number of Non-conforming	≤1	≤1	≤1	≤1

8.7 Result:

NO.	Before Aging		After Accelerated Aging	
	Tensile Strength (MPa)	Ultimate Elongation (%)	Tensile Strength (MPa)	Ultimate Elongation (%)
1	26.66	637.50	17.09	780.10
2	20.06	663.59	19.12	642.45
3	17.03	518.19	15.78	622.60
4	16.72	582.58	15.34	560.54
5	22.57	648.98	19.34	750.54
6	23.26	797.38	21.73	665.68
7	25.65	853.19	17.37	799.91
8	23.88	849.65	16.34	577.25
Criteria	≥14MPa	≥500%	≥14MPa	≥400%
Conclusion	Acceptable	Acceptable	Acceptable	Acceptable

8.8 Conclusion: The test result was considered to be acceptable.

9.0 Surface Powder Test of "powder-free" gloves

9.1 Before use, rinse all glassware and tweezers with water

9.2 Take a 47 mm, 2.7 μm pore size filter. Transfer it to the suction apparatus, rinse it with three portions of 50

cm^3 of water and suck free of water. Place the filter on a watch glass or Petri dish and dry it in an oven at 100℃ for 1 h. Transfer the filter to a desiccator to cool for at least 30 min before use. Remove the filter and immediately weigh it on the balance, determining the mass to the nearest 0,1 mg. Record the mass in grams (m_0).

9.3 Place the filter in the suction apparatus.

9.4 Carefully remove a glove from its packaging and insert it into a 1 L capacity conical flask, or other suitable container, containing 500 cm^3 of water so that 1 cm to 3 cm of the glove projects out round the rim of the flask. Pour approximately 250 cm^3 of water into the glove while holding a small portion of the cuff away from the rim of the flask to allow air to be vented from the flask. While pouring the water into the glove, make sure that the projecting part of the cuff is rinsed. Tightly seal the flask with a rubber stopper covered by a small piece of polypropylene sheet so that the flask does not leak. Place the sealed flask in the mechanical shaker and oscillate for 30 s at a speed of not less than 1 rpm/min. Ensure that all the surfaces of the glove are well washed

9.5 Take the flask from the shaker and remove the stopper. Pour the water inside the glove into a 600 cm^3 capacity beaker. Then remove the glove from the flask and pour any water still remaining in the glove into the beaker. Discard the glove.

9.6 Repeat the procedure of 9.4 and 9.5 using a fresh glove, but leaving the water already present in the flask and using the washing water in the 600 ml beaker to fill the inside of the glove.

9.7 Repeat the procedure of 9.4 and 9.5 for three more gloves, making a total of five

9.8 Pour the water in the 600 cm^3 beaker through the suction filter unit containing the weighed filter Remove the last glove from the flask and pour the remaining water from inside the glove through the filter followed by the water in the flask. Rinse the beaker, flask and stopper covering with fresh water to ensure that any remaining powder is transferred to the filter

9.9 Remove as much water from the filter as possible by suction. Discard the filtrate. Carefully remove the filter with the tweezers and transfer it to a washed and dried watch glass or Petri dish. Dry in the oven at 100 °C for 1 h then transfer to the desiccator to cool for not less than 30 min. Weigh the filter immediately after removal from the desiccator to minimize re-adsorption of moisture. Record the mass in grams to the nearest 0,1 mg (m_1).

9.10 Blank determination: Use flasks, stoppers, stopper coverings and a filter and beakers identical to those employed in 9.2 and 9.3. Determine the mass of the filter (m_F) as described in 9.2 and run the procedure described in 9.3 to 9.4 with 750 cm^3 of water as employed for the test but without gloves. After filtering the washings, dry the filter and weigh it as described in 9.9. Record the mass (m_B). The mass of any material retained on the filter is given by $m_B - m_F$.

9.11 Calculation of the result

The mass of powder, in milligrams, on the five gloves is given by:

$(m_1-m_0- m_B + m_F) \times 1000$

The average mass (ma) of powder, in milligrams, per glove is given by:

$m_A= (m_1-m_0- m_B + m_F) \times 200$

9.12 Result:

Analyte	Result (mg/glove)

Residual Powder	0.08

10.0 Conclusion

The results showed each property of the test glove was acceptable under this test condition.

11.0 Record

All raw data pertaining to this study and a copy of the final report are retained in designated HTW archive.

12.0 Confidentiality

All information regarding the test item and test results will be kept confidential by the test facility.

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检测
TESTING
CNAS L13034

In Vitro Cytotoxicity Test

MTT Method

Final Report

Verification

Report Number: CSTBB21030890

Article Name: Nitrile Patient Examination Gloves

Method Standard: ISO 10993-5：2009

Sponsor

Yingxiang Glove Products Co., Ltd.

No. 1 , Zhendong Industrial Park, Huaqiao Town, Wuxue City, Huanggang City, Hubei Provinc

Test Facility

CCIC Huatongwei international inspection (Suzhou) Co., Ltd

Room 101, Building G, Ruoshui Road 388, Suzhou, Jiangsu, China

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Abstract

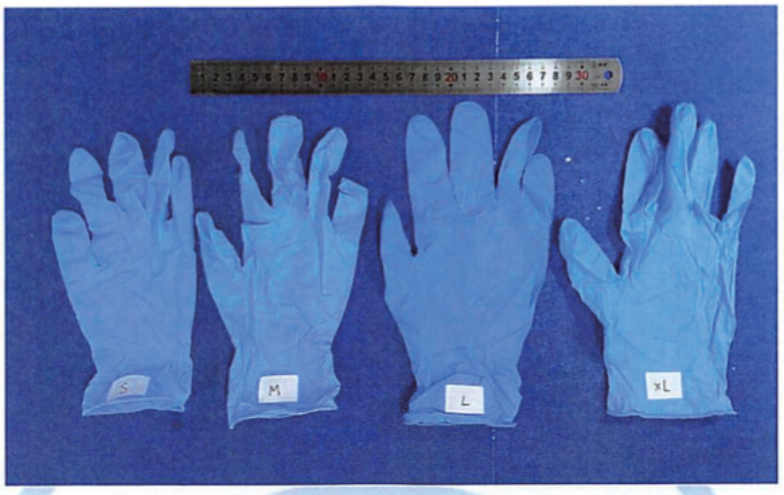
In this study, mammalian L-929 cells were cultured in vitro according to ISO 10993-5:2009 to test the potential cytotoxicity of the test article.

The test articles and the control material were separately placed in MEM medium containing 10% fetal bovine serum, and extracted in a 37 ℃ incubator for 72 hours. After the end of the extraction, the cell culture medium in the 96-well plate (10^4 cells/well) cultured for 24 hours was removed and replaced with the corresponding extract, cultured in 37 ℃, 5% CO_2, >90% humidity for 24 hours. After the culture, the morphology and cell lysis of the cells were observed under the microscope, and the cytotoxicity of the test samples was determined by MTT assay.

The results showed that the cells in the blank control group and the negative control group (high density polyethylene) were well-formed throughout the experiment and showed no cytotoxic reaction. A severe cytotoxic response was shown in the positive control group (ZDEC). While in test article group, after the cells were incubated for 24 hours, the cell layer was almost destroyed, most of the cells were lysed. The cell growth was inhibited and the cell viability was 30.3%. The data of each group met the acceptance criteria, and the results of this test were valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article have potential toxicity to L-929 in the MTT method.

Study Verification and Signature



Protocol Number	SST2103000602BB
Protocol Effective Date	2021-03-09
Technical Initiation Date	2021-03-15
Technical Completion Date	2021-03-19
Final Report Completion Date	2021-03-22

Personnel Betty 2021-03-22
Date Completed

Approved
Study Director 2021-03-22
Date Completed

Supervisory
Test Facility Manager Date Completed

CCIC Huatongwei international inspection (Suzhou) Co., Ltd.

Quality Assurance Statement and GLP Statement

Quality Assurance Statement

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to the HTW's Management.

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Phase Inspected	Date	Study Director	Management
Experiment	2021-03-15	2021-03-15	2021-03-15
Raw Data	2021-03-19	2021-03-19	2021-03-19
Final Report	2021-03-22	2021-03-22	2021-03-22

The findings of these inspections have been reported to Management and the Study Director.

Quality Assurance　　Date

GLP Statement

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The sections of the regulations not performed by or under the direction of HTW, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Part 58.105 and 58.113.

Study Director　　2021-03-22
Date

1.0 Purpose

The purpose of the test is to determine the potential cytotoxicity toxicity of a mammalian cell culture (mouse fibroblast L-929 cells) in response to the test article.

2.0 Reference

Biological evaluation of medical devices-Part 5: Tests for In Vitro Cytotoxicity (ISO 10993-5：2009)

Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12：2021)

Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

3.0 Test and control articles

Groups	Test article	Negative Control Article	Positive Control Article	Blank Control
Name	Nitrile Patient Examination Gloves	High Density Polyethylene Film	ZDEC	MEM medium, with addition 10% FBS
Manufacturer	Yingxiang Glove Products Co., Ltd.	Hatano Research Institute. FDSC	Sigma-Aldrich.	Hyclone
Size	S\M\L\XL	3 cm×10 cm (5 sheets)	25 g	500 ml
Model	S\M\L\XL	/	/	/
Lot Batch#	Not provided	C-161	BCBQ6847V	AF29549370
Test Article Material	Not provided	/	/	/
Physical State	Solid	Solid	Solid	Liquid
Color	Blue	White	White	Pink
Packaging Material	Paper box	/	/	/
Sterilized or Not	No	No	No	Yes
Concentration	/	/	0.1%	/
Total Surface or weight	Not provided	/	/	/
Storage Condition	Room Temp.	Room Temp.	Room Temp.	4℃
Note：The information about the test article was supplied by the sponsor wherever applicable.				

4.0 Identification and justification of test system

L-929 mouse fibroblast cells obtained from American Type Culture Collection (ATCC).

L-929 cells have been used for cytotoxicity studies because they demonstrate sensitivity to extractable cytotoxic articles. Also, the test article is extracted and administered in vitro to mouse fibroblast L929 cells through a solvent compatible with the test system, which is the optimal route of administration available in this test system as recommended in ISO 10993-5.

5.0 Equipment and reagents

5.1 Instruments

Vertical pressure steam sterilizer (SHB026), CO_2 Incubator (SHB002), Steel Straight Scale (SHB076), Electronic Balance (SHB016), Clean bench (SHB014), Multiskan Spectrum Microplate Spectrophotometer (SHB003), Bench type low speed centrifuge (SHB022), Inverted microscope (SHB005)

5.2 Reagents

MEM (Hyclone, AF29549370), FBS (Clark, JC65927), Penicillin-Streptomycin (Gibco, 2175429), Trypsin (Beyotime, C0201-100ml), PBS (meilunbio, MA0015-Nov-29E4), MTT (3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyletrazolium bromide) (Sigma, MKBG2038V), Isopropyl alcohol (Macklin, C10394867)

6.0 Experiment design and dose

6.1 Sample preparation

According to the table below, aseptic extraction of the test article sealed and incubated in MEM medium (10% FBS) at 37 ℃, 5% CO_2 and 60 rpm for 72 hours.

Groups	Sampling		Aseptic Extraction In Inert Container				Final Extract
	Sampling Manner	Actually sampling	Ratio	Extracts	Condition	pH	Clear or Not
Test article	Random (proportional)	120.0 cm^2	6 cm^2: 1 ml	20.0 ml	37 ℃ 72 h	7.4	Clear
Negative Control	Random	60.0 cm^2	3 cm^2: 1 ml	20.0 ml	37 ℃ 72 h	7.4	Clear
Positive Control	Random	0.02 g	0.1 g: 100 ml	20.0 ml	37 ℃ 72 h	7.4	Clear
Blank Control	/	/	/	20.0 ml	37 ℃ 72 h	7.4	Clear

The changes of the leaching solution was observed after extraction. No particulates or color changes were observed in pre- and post-extraction, the color and pH of the extraction solution did not change before and after use, and the pH value was 7.4, the status of the extract was shown in the figure below. The extraction solution and the pH value did not been adjusted, filtered, centrifuged, diluted and other processes before used.The extraction of the test article could be stored at 4℃ for no more than 24 h, but in our test, the test article extract were immediately be used after leaching.

Vehicle	Time Observed	Extracts	Condition of Final Extracts		
			Color	Clear or Not	Particulates
MEM medium (10% FBS)	Before Extraction	Test article	Pink	Clear	None
		Negative Control	Pink	Clear	None
		Positive Control	Pink	Clear	None
		Blank Control	Pink	Clear	None
	After Extraction	Test article	Pink	Clear	None
		Negative Control	Pink	Clear	None

		Positive Control	Pink	Clear	None
		Blank Control	Pink	Clear	None

6.2 Test method

Aseptic procedures were used for handling cell cultures. L-929 cells were cultured in MEM medium (10% FBS, 1% Penicillin-Streptomycin solution) at 37 ℃ in a humidified atmosphere of 5% CO_2, then digested by 0.25% trypsin containing EDTA to get single cell suspension. 1×10^5 cells/ml suspension were obtained by centrifuging (1000 rpm, 5 min) and re-dispersing in MEM medium.

The suspended cells were dispensed at 100 µl per well in 96-well plate, and cultured in cell incubator (5% CO_2, 37 ℃, >90% humidity). Cell morphology was evaluated to verify that the monolayer was satisfactory.

After 24 h incubation which made the cells grew to about 70% and form a monolayer, original culture medium was discarded. The 96-well plates were then treated with 100 µl of extract of test article (100%、75%、50%、25%), control article, negative article and positive article respectively. The 96-well plate was incubated at 37 ℃ in cell incubator of 5% CO_2 for 24 h. Six replicates of each test were tested.

After incubation, observe the cell morphology first and then discard the culture medium. Add 50 µl MTT (1mg/ml) to each well and then incubated at 37 ℃ in a humidified atmosphere of 5% CO_2 for 2 hours. The liquid in each well was tipped out and 100 µl Isopropyl alcohol was added to each well to suspend the cell layer.

Evaluate the suspension above with a dual-wavelength spectrophotometer with the measurement wavelength at 570 nm.

7.0 Statistical method

Mean±standard deviation ($\bar{x} \pm s$)

The cell cytotoxicity ratio = OD_{570} of test (or positive or negative) article group/ OD_{570} of blank control group×100%.

Table 1 Qualitative morphological grading of cytotoxicity of extracts

Grade	Conditions of all cultures
0	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth
1	Not more than 20 % of the cells are round, loosely attached and without intracytoplasmatic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.
2	Not more than 50 % of the cells are round, devoid of intracytoplasmatic granules, no extensive cell lysis; not more than 50 % growth inhibition observable.
3	Not more than 70 % of the cell layers contain rounded cells or are lysed; cell layers not completly destroyed, but more than 50 % growth inhibition observable.
4	Nearly complete or complete destruction of the cell layers.

8.0 Evaluation criteria

8.1 The 50% extract of the test article should have at least the same or a higher viability than the 100% extract. Otherwise the test should be repeated.

8.2 The lower the Viab.% value, the higher the cytotoxic potential of the test article is.

8.3 If viability is reduced to < 70% of the blank, it has a cytotoxic potential.

8.4 The Viab.% of the 100% extract of the test article is the final result.

9.0 Results of the test

9.1 Results of the cell morphology

Table 2 Observation of the cell morphology

Group	Before inoculation	Before treated with extract	24 h after treatment
Blank control	0	0	0
Negative control	0	0	0
Positive control	0	0	4
100% Test article extract	0	0	3
75% Test article extract	0	0	3
50% Test article extract	0	0	2
25% Test article extract	0	0	1

9.2 Results of the cell vitality

Table2 Results of the cell vitality

Group	OD value								Viab. (%)
	1	2	3	4	5	6	$\bar{x}$	s	
Blank control	0.624	0.628	0.633	0.624	0.629	0.626	0.627	0.004	100.0
Negative control	0.629	0.619	0.632	0.631	0.621	0.604	0.623	0.010	99.3
Positive control	0.058	0.057	0.056	0.058	0.053	0.054	0.056	0.002	8.9
100% test article extract	0.167	0.174	0.190	0.211	0.200	0.198	0.190	0.017	30.3
75% test article extract	0.290	0.292	0.289	0.300	0.291	0.309	0.295	0.008	47.1
50% test article extract	0.415	0.407	0.415	0.388	0.415	0.396	0.406	0.012	64.8
25% test article extract	0.474	0.483	0.481	0.479	0.483	0.481	0.480	0.004	77.1

10.0 Conclusion

Under the conditions of this study, the test article have potential toxicity to L-929 cells.

11.0 Compliance

US FDA Good Laboratory Practice Regulations 21 CFR 58, effective June 20, 1979, as amended 52 FR 33780, Sept. 4, 1987, and subsequent amendments

Standard operating procedure of CCIC Huatongwei international inspection (Suzhou) Co., Ltd.

12.0 Protocol amendment/deviations

There were no amendmentst or deviations that occurred during the course of this study.

13.0 Record

All raw data pertaining to this study and a copy of the final report are to be stored in the designated archive

files at Huatongwei.

14.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

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