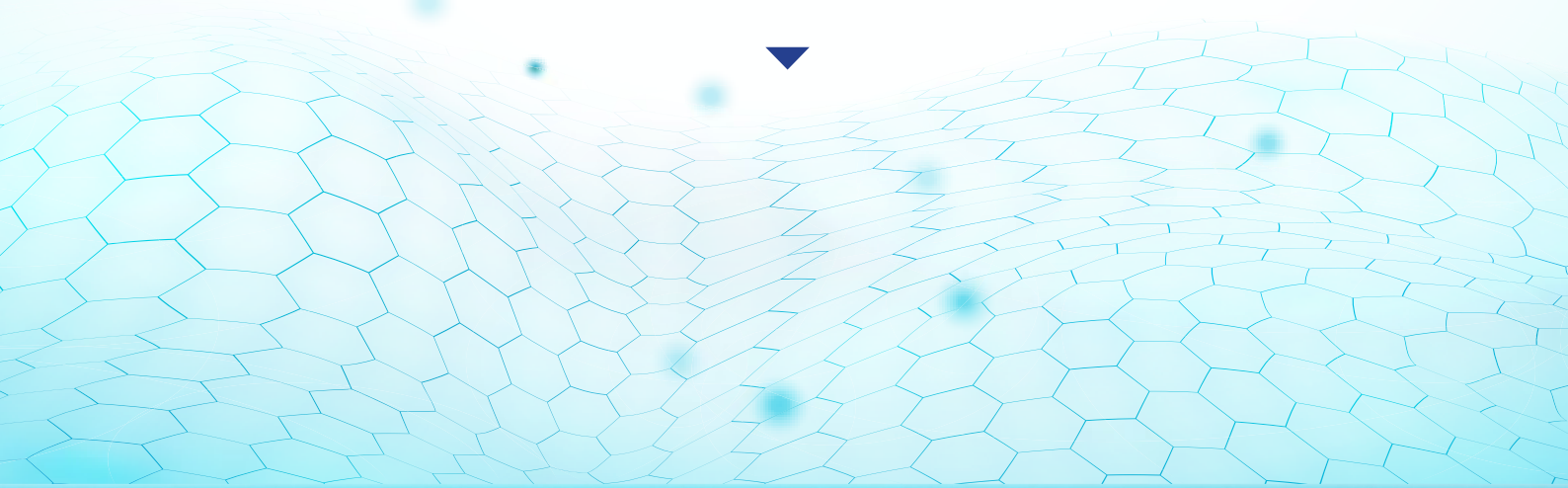


# NITRILE

## DISPOSABLE GLOVES





## ABOUT US

The selected approved manufactures produce premium quality healthcare gloves & cleanroom products, for safety and hygiene purposes. their products are widely used in industries like healthcare, semi conductors, manufacturing, bio tech, laboratory, pharmaceutical etc. Among the products they offer, it covers nitrile gloves, medical examination gloves, finger cots, cleanroom gloves, cleeanroom bags, packaging bags, face masks and growing. Each product goes through stringent test, to meet the highest industrial standards. These products are well recognized by local companies, as well as key countries around the globe.



# OUR VISION

## TO BUILD GLOBAL RELATIONSHIPS

WE SUPPLY MEDICAL PRODUCTS GLOBALLY.

ALL PRODUCTS CARRY ALL THE REQUIRED CERTIFICATIONS  
FOR EUROPE, USA AND THE REST OF THE WORLD.

HIGH QUALITY PRODUCTS AT AFFORDABLE PRICES.





# STATE OF THE ART MANUFACTURING

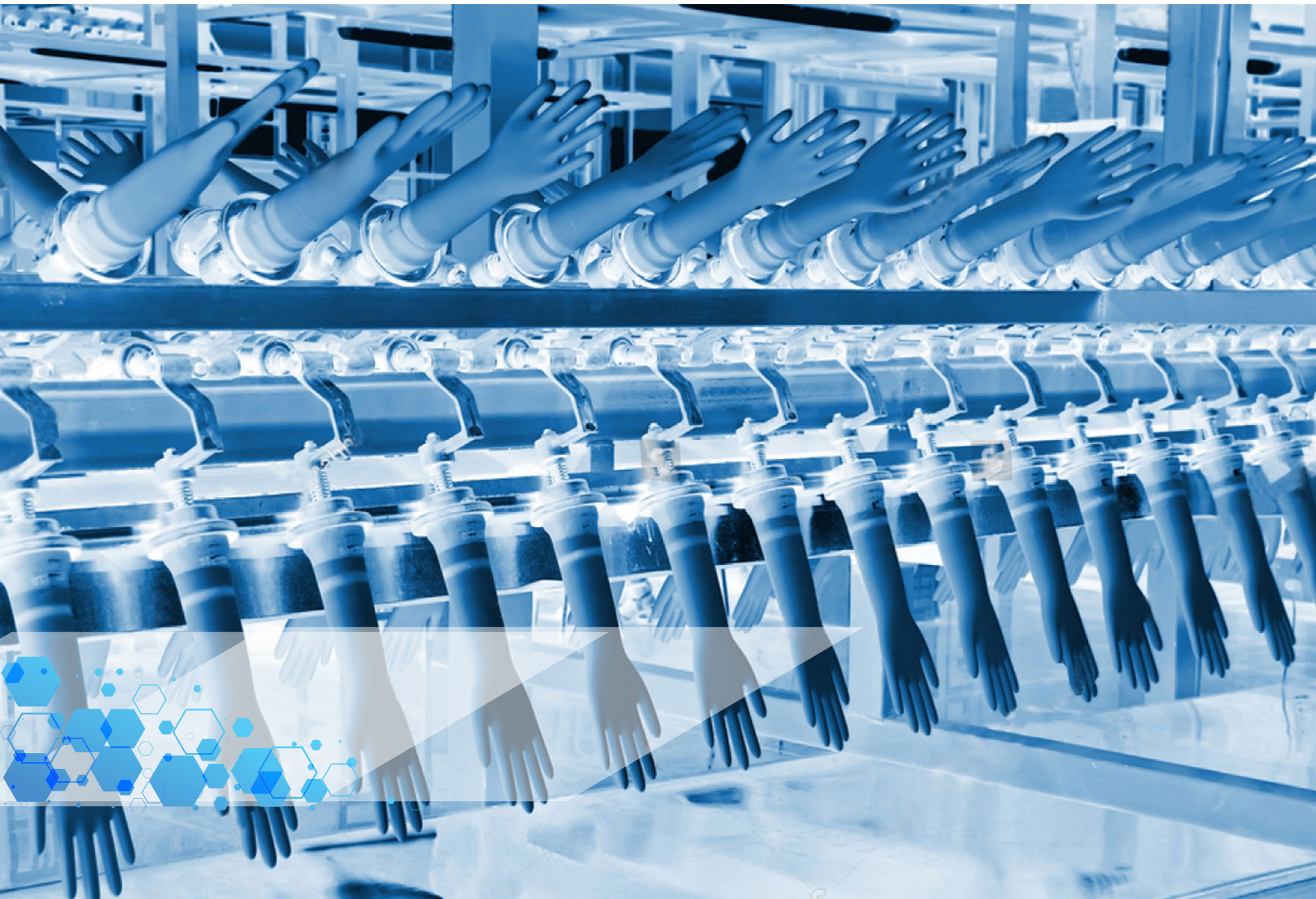
## THROUGH PEOPLE AND TECHNOLOGIES

### CLEANROOM GLOVES MANUFACTURING PROCESS AND FACILITIES

The manufacturer uses in-house special formulation in the compounding process. Their manufacturing facilities are specially designed and build with unique features to produce gloves to meet our customers' stringent requirement. The final stages of processes from D.I. water washing to packing are all performed in NEBB-certified Class 10 and Class 100 Cleanrooms. All operators are trained to adhere strictly to Cleanroom protocols.

### FINGERCOT MANUFACTURING PROCESS AND FACILITIES

They are one of the pioneers in the manufacturing of Nitrile fingercot in Asia. The production lines are specially built for manufacturing of Cleanroom Nitrile and Latex fingercots. Fingercots are free of Silicone Oil, Amide and DOP. In-house pre-shipment testings are carried out for each delivery. All operators are trained to adhere strictly to Cleanroom protocols.





# QUALITY CONTROL

Quality Control at the in-house laboratory is equipped with state-of-art facilities for carrying out tests commonly required in the Critical Environment. The quality control is carried out following international standards such as ASTM and IEST.

The manufacturers are ISO compliant and certified.  
All operators are trained to adhere strictly to Cleanroom protocols.

---

## TESTING FACILITIES

- Liquid Particle Count (LPC)
- Ion Chromatography ( Anion Testing )
- Ion Chromatography ( Cation Testing )
- Non Volatile Residue (NVR) Test
- Electrostatic Discharge (ESD) Tester
- Fourier Transform Infra Red Spectroscopy (FTIR)
- Gas Chromatography - Mass Spectrometry (GC - MS)
- Air Particle Count (APC)
- Tensile Strength Analysis
- Waterleak Test
- Scanning Eletron Microscope - Energy Dispersive X-ray (SEM - EDX)



# NITRILE DISPOSABLE GLOVES



It offers protection in the most sensitive area of the body. Hands are in constant contact with all types of materials and environments, therefore, the ideal way to isolate us is the use of gloves as a measure of protection.





# NITRILE DISPOSABLE GLOVES DATA SHEET

## Technical Data Sheet

### 5mg blue nitrile medical glove Sterile Non-Powdered

Blue Nitrile Medical Glove 5mg Sterile Non-Powdered EN455

#### Regulatory Compliance

FDA, CE, ANNEX IX Directive 93/42 EEC, EN455

UMDNS- Code: 11882

#### PRODUCT DESCRIPTION

Disposable Nitrile gloves are made from 100% synthetic rubber that provides superior resistance to a wide range of solvents and hazardous chemicals. Nitrile gloves are an alternative for people with a latex sensitivity. The glove features a textured finger that provides a secure grip.

#### Application setting

Low risk-medical, dental, procedures, chemotherapy, drugs, pathology lab and food handling.

#### PRODUCT BENEFITS

1. Comfortable
2. Chemical Resistant
3. Textured Finger
4. Fits either hand
5. No natural latex proteins

#### Physical Characters / Glove Dimensions

##### Thickness (Mils)

Finger	5.0mg
Palm	4.5mg
Finger	4.5mg
Thickness	0.8mm

ASTM 3767

ASTM 3767 Standard practice for rubber measurement of dimension (thickness)

#### Tensile Properties

Tensile strength, Mpa (minimum)	21
Elongation, % (minimum)	55
Elongation, % (minimum)	1.00 – 1.5 AQL

ASTM D412 Standard test Method for Vulcanized Rubber and thermoplastic Elastomers- tension (Tensile Strength) to access the breaking point of a glove when stretched

400% (4.0AQL)

# NITRILE DISPOSABLE GLOVES DATA SHEET

TENSIL	Tensil Strength (MPA) Before ageing ≥21 After ageing ≥20
	Ultimate elongation% Before aging 550% After Aging 500%
Powder Content	5mg / glove maximum
Protein Content	Free Protein

Specifications	
Sterility	Sterile
Intended Use	Medical
Basic Material	Nitrile Butadiene Rubber

Material Safety data	
Product	Nitrile 5mg Medical Non-sterile glove Blue
IARP/IACO	Not Restricted

Normal Precautions	Not necessary under normal conditions
Ventilation	Not necessary under normal conditions
Eyes	Not Applicable
Storage	Store in a cool dry place at a temperature of between 8° and 28° preferably to the lower degrees.

## Material Safety Data Sheet

Common Name 5mg blue nitrile medical glove Non-Sterile Non-Powdered	Chemical Family 100% synthetic rubber composed by acrylonitrile and butadiene allergy free semi biodegradable
--	--

Application  
Medical and dental

Hazardous Ingredients				
Hazardous Component	CAS#	%(WT)	TLV	PEL
N/A	N/A	N/A	N/A	N/A

## Chemical Composition

All chemicals used is non-Toxic and Non-Hazardous  
Butadiene-Acrylonitrile latex, sodium, Dodecylbenzenesulfonate , Sulphur, Zink, Oxide, Zink Di-n-Butyldithiocarbamate, Titanium Dioxide, Parrafin wax Emulsion.



# NITRILE DISPOSABLE GLOVES DATA SHEET

## First Aid Measure

In the case of reaction in the form of skin irritation and allergy is noticed. Remove the gloves immediately, wash the affected area with saline water. If there is no relieve found please see a physician.

## Fire Fighting

<b>Flashpoint</b> N/A	<b>Autoignition Temperature</b> N/A	<b>Flammable Limits in Air</b> N/A
<b>Extinguishing media</b> Chemical Foam and dry chemical		
<b>Fire-fighting procedures</b> Use standard procedures for combustion, material fires. Including self-contained breathing apparatus		
<b>Fire and Explosion Hazards</b> No fire or explosion hazards are associated with these products. They will melt under levitated temperatures		

## Accidental release Measure

The chemical formulation and surface lubrication of the glove does not contain any biochemical that can be potentially harmful to user

## Physical and chemical properties

Dimension	XS	S	M	L	XL
Length mm	230mm				
Width mm	76+4	86+4	98+4	107+4	115+4
<b>Thickness</b>					
Finger	0.9mm				
Palm	0.8mm				

## Other Information

Nitrile gloves is for single use only


Dispose in the correct manner as stated by countries law.

## General Information

Components used in the making of these gloves may cause allergic reaction in some very rare people. Don't use if you know or suspect that you might be allergic or have a sensitivity to the nitrile glove without consulting your physician. If allergic reaction occurs, discontinue use immediately and consult with a physician. These gloves are not made of natural rubber latex. According to (NIOSH) (National Institute for occupational safety and health) Alert, Use of non-Natural rubber latex gloves such as nitrile is an effective method of preventing an allergic reaction to natural rubber latex.

These gloves are made on the exact specifications as well-med

# NITRILE DISPOSABLE GLOVES CERTIFICATIONS



**医疗器械-质量管理体系认证证书**

证书编号: CQC20QY20016R0S/46500  
兹证明  
江西阿尔梅医疗器械有限公司  
统一社会信用代码: 91360122MA35HEW01Y

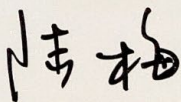
江西省南昌市新建区长堍镇工业五路69号1栋


建立的质量管理体系符合标准:  
YY/T 0287-2017 / ISO 13485:2016  
通过认证范围如下:

资质范围内的检查手套(一次性使用医用橡胶检查手套)、检查手套(一次性使用医用丁腈检查手套)、检查手套(一次性使用医用PVC检查手套)、检查手套(一次性使用医用PE薄膜手套)的生产

首次发证日期: 2020年4月15日 本次发证日期: 2020年4月15日 有效期至: 2020年10月14日

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Signed by: Lu Mei



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D 0006494 2018年版



# NITRILE DISPOSABLE GLOVES CERTIFICATIONS



# NITRILE DISPOSABLE GLOVES CERTIFICATIONS

CERTIFICATE

ZERTIFIKAT

認證證書

CERTIFICATE

ZERTIFIKAT

## EC DECLARATION OF CONFORMITY

Product name: Nitrile Examination Gloves  
Classification (MDD, Annex IX): class I, rule I.  
Conformity Assessment Route: Annex VII  
We, the manufacturer, herewith declare that the products

**Nitrile Examination Gloves**  
**UMDNS-Code: 11882**

Meet the provisions of Directive 93/42/EEC, which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark EN455



The product concerned has been manufactured under a quality management system according to Annex VII of Directive 93/42/EEC, following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

**Company: Jiangxi Aermei Medical Equipment Co., Ltd.**

**Address: Building 1, No. 69, Gongye 5th Road, Changleng Town, Xinjian District, Nanchang City, Jiangxi Province.**

Shanghai 2020-03-25

Place, date

Legally binding signature function


EC Declaration of Conformity



# NITRILE DISPOSABLE GLOVES TEST REPORT

## Test Report

IR number: AEM/OR-8.4-02

Product name	Disposable Nitrile medical examination glove		Production lot	200206	
Spec	XS/S/M/L		Model	Powder free	
Test type	Inspection lot by lot		Test standard	GB 10123 - 2006	
Test date	2/6/2020		Report date:	2/6/2020	
Test Items	Technical requirement			Test Result	Test Conclusion
Size	Width	(85±5) mm		88 mm	Pass
	Length	230-300mm		245 mm	Pass
	Thickness	0.07-0.08 mm		0.075 mm	Pass
Appearance	No appearance defects which influence the using functions			Meet requirement	Pass
Tensile property	The minimum elongation at break before aging is 650%			660%	Pass
Water impermeability	No any obvious leakage			Meet requirement	Pass
Test conclusion	Products tested based on GB 10123 - 2006 and result meet the requirement				
Remark					
Approved by:			Check by:	Xiao Gang	Test by: Dai Long



# SGS CERTIFICATIONS



Test Report

No.: SHHL1611069812MD

Date: DEC. 14, 2016

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

Sample Description : POWDER FREE NITRILE DISPOSABLE EXAM GLOVE  
SGS Ref. No. : QDHL1611008641OT  
Style/ Item No. : D5000  
Country of Origin : CHINA  
Sample Receiving Date : NOV. 23, 2016  
Testing Period : NOV. 23, 2016 TO DEC. 14, 2016  
Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT  
Test Requested : 1. EN 455-1:2000 MEDICAL GLOVES FOR SINGLE USE -  
PART 1: REQUIREMENTS AND TESTING FOR  
FREEDOM FROM HOLES  
2. EN 455-2: 2015 MEDICAL GLOVES FOR SINGLE USE -  
PART 2: REQUIREMENTS AND TESTING FOR  
PHYSICAL PROPERTIES(EXCEPT FOR CLAUSE 7  
LABELLING)  
3. POWDER-FREE GLOVES (EN 455-3: 2015 MEDICAL  
GLOVES FOR SINGLE USE - PART3:REQUIREMENTS  
AND TESTING FOR BIOLOGICAL EVALUATION  
CLAUSE 4.4)

Test Result(s) : FOR FURTHER DETAILS, PLEASE REFER TO THE  
FOLLOWING PAGE(S)

Conclusion : THE SUBMITTED SAMPLE MET THE TEST  
REQUIREMENT.

\*\*\*\*\*

Signed for and on behalf of  
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

Melody Zhang  
Authorized Signatory



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# SGS CERTIFICATIONS



## Test Report

No.: SHHL1611069812MD

Date: DEC. 14, 2016

### Test Conducted:

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

Number of test sample : 200 pcs  
The type of gloves : Examination glove  
Manufacturing batch code : /  
Batch size : /  
Sample size : S / M / L / XL  
Number of non-conforming gloves : 4 pcs  
Defects observed before testing : No defect  
Test Result : Pass

Clause	Test Items	Result	Note
5	Watertightness test for detection of holes	---	---
5.1	Referee testing	Pass	# 1 & 2

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

Number of test sample : 78 pcs  
Type : Examination glove  
Manufacturing batch code : /  
Size : S / M / L / XL  
Defects observed before testing : No defect  
Test Result : Pass

Clause	Test Items	Result	Note
4	Dimensions	Pass	#3
5	Strength	Pass	#2&4
7	Labeling	N/C	#5



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SGS CSTC (Shanghai) Technical Services Co., Ltd.  
Testing Center (Shanghai)

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# SGS CERTIFICATIONS



## Test Report

No.: SHHL1611069812MD

Date: DEC. 14, 2016

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

Number of test sample : 5 pcs  
Finishes of gloves : Powdered-free gloves other than surgeon's gloves  
Defects observed before testing : No defect  
Test Result : Pass

Clause	Test Items	Result	Note
4.4	Powder-free gloves	Pass	#2&6

#### Note:

1. See result 1.
2. As per client's request, only the glove of size M was tested.
3. See result 2.
4. See result 3.
5. N/C means not conducted as per client's request.
6. Test according to EN ISO 21171-2006, the powder of glove was 0.02 mg < 2.0 mg.



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# SGS CERTICATIONS



## Test Report

No.: SHHL1611069812MD

Date: DEC. 14, 2016

### Test Results:

#### 1. Watertightness test for detection of holes

Sample Quantity: 200 pcs

AQL: 1.5 Accept: 7 Reject: 8 Found: 4

Remark: The sample selecting amount for Watertightness test for detection of holes is deviated to 200 pcs as accessed by SGS.

#### 2. Dimensions

Sample Quantity: 52 pcs

Size	S												
Length (mm)	246	243	245	244	244	246	243	244	245	245	243	244	245
Width (mm)	83	87	87	87	87	87	87	88	88	87	88	88	87

Median value:

Length (mm): 244

Width (mm): 87

Size	M												
Length (mm)	245	249	247	245	244	245	245	244	247	245	245	247	245
Width (mm)	98	98	97	97	97	97	97	96	97	97	97	97	98

Median value:

Length (mm): 245

Width (mm): 97

Size	L												
Length (mm)	243	244	245	247	244	247	247	245	245	244	245	244	244
Width (mm)	110	110	109	110	107	109	109	109	109	110	110	111	109

Median value:

Length (mm): 245

Width (mm): 109



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# SGS CERTIFICATIONS



## Test Report

No.: SHHL1611069812MD

Date: DEC. 14, 2016

Size	XL												
Length (mm)	241	242	240	240	240	240	237	236	241	240	240	248	239
Width (mm)	115	115	114	116	115	115	115	115	115	116	117	114	115

Median value:

Length (mm): 240

Width (mm): 115

Requirements: see table 1 & 2

**Table 1 Dimensions for surgical gloves**

Size	Median length in mm	Median width in mm
5	≥250	67±4
5.5	≥250	72±4
6	≥260	77±5
6.5	≥260	83±5
7	≥270	89±5
7.5	≥270	95±5
8	≥270	102±6
8.5	≥280	108±6
9	≥280	114±6
9.5	≥280	121±6

**Table 2 Dimensions for  
examination/procedure gloves**

Size	Median length in mm	Median width in mm
Extra small	≥240	≤80
Small		80±10
Medium		95±10
Large		110±10
Extra Large		≥110



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# SGS CERTIFICATIONS



## Test Report

No.: SHHL1611069812MD

Date: DEC. 14, 2016

### 3. Strength

Sample Quantity: 26 pcs

Size	M												
Force at break (N)	5.4	8.3	8.4	8.5	7.2	7.0	7.9	9.0	3.3	8.6	1.1	3.7	7.9
Force at break after challenge testing (N)	2.8	8.8	7.7	5.8	6.1	2.3	5.7	7.4	9.5	6.0	9.6	7.3	7.0

Median value:

Force at break during shelf life (N): 7.9

Force at break after challenge testing (N): 7.0

Requirements: see table 3

Table 3 — Median values of force at break

	Force at break in Newton		
	Surgical gloves a)	Examination/procedure gloves b) c)	
Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3	≥ 9,0	≥ 6,0	≥ 3,6
a) Requirements for all surgical gloves. b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene). c) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).			



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# SGS TEST REPORT

# SGS

Test Report

No.: SHHL1611069812MD

Date: DEC. 14, 2016

Sample Photo:

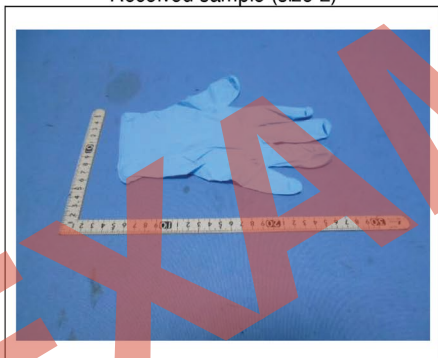
Received sample (size S)



Received sample (size M)



Received sample (size L)



Received sample (size XL)



SGS-CST (Shanghai) Technical Services (Shanghai) Co., Ltd.  
Testing Center Shanghai

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# NITRILE DISPOSABLE GLOVES TEST REPORT

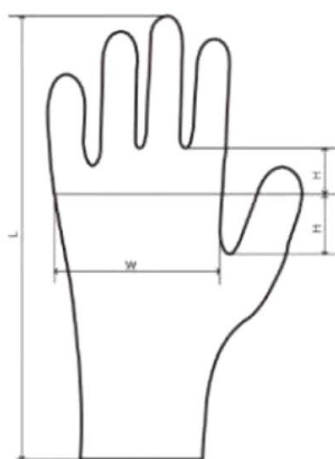


图 1

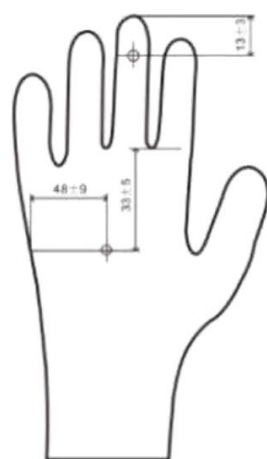


图 2

注：对于不同规格的手套，48mm±9mm所处位置大约在手掌中心处。

## 规格型号对应的尺寸和公差

单位：毫米

尺寸代码	规格	代码	宽度 (图1中尺寸W)	最小长度 (图1中尺寸L)	最大长度 (图1中尺寸L)	最小厚度 (按图2所示位置测量)	最大厚度 (大约在手掌的中心)
6和6以下	特小号	XS	<80	220	290	对所有尺寸： 光面：0.07 麻面：0.08	对所有尺寸： 光面：0.08 麻面：0.09
6.5	小号	S	80±5	220	290		
7	中号	M	85±5	230	300		
7.5	中号	M	95±5	230	300		
8	大号	L	100±5	230	300		
8.5	大号	L	110±5	230	300		
9和9以上	特大号	XL	>110	230	300		



# PACKAGING SPECIFICATIONS

100 Latex or Nitrile™ Exam Gloves

per Units 10 Individual units

Carton/1,000 Gloves/Pieces

Carton/Size Medium/Large

Carton Dimensions

UNITS PER CARTON EACH WEIGHT

BOX DIMENSIONS

10 packs

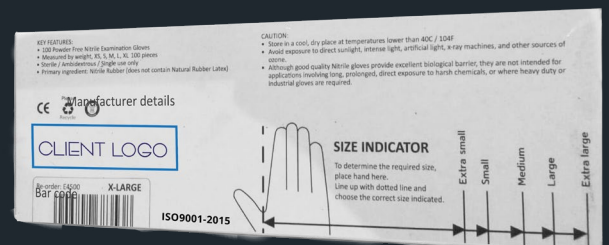
4.5 kg 32.5X25.8X26.5 cm

Shipping Data

UNITS PER CASE 10



# NITRILE DISPOSABLE GLOVE PACKAGING





**THANK YOU**

**FOR A SAFER  
TOMORROW**