

QUEEN GLOVES

GUANGDONG JUNAN MEDICAL TECHNOLOGY
CO.,LTD.

FDA OWNER OPERATOR: 10072701

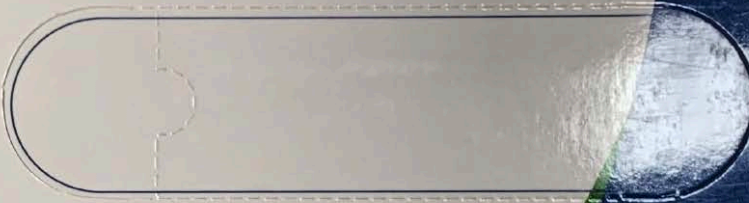


Queen®

DISPOSABLE
GLOVES

XL
Blue

100 PCS



Non-sterile/No powder/Ambidextrous

NITRILE



One time use

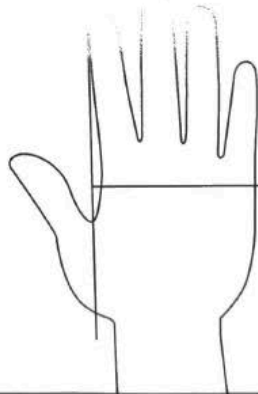


Read the instructions

XL
Blue

100 PCS

Most women use size S
and large hands use size M
Most men use size M
and large hands use size L



S M L XL XXL

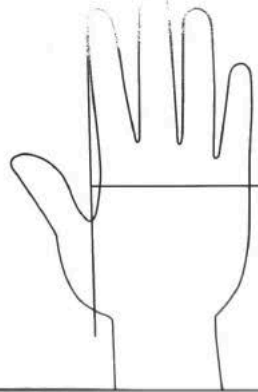
WARM PROMPT

Due to different measurement methods and methods there will be an error of 2-5 mm.

XL
Blue

100 PCS

Most women use size S
and large hands use size M
Most men use size M
and large hands use size L



S M L XL XXL

WARM PROMPT

Due to different measurement methods and methods there will be an error of 2-5 mm.

Product Name: Nitrile gloves
 Specifications: S, M, L, XL, XXL
 Product Record Certificate No.: Ysxb No. 20200731
 Product Technical Requirement No.: Ysxb No. 20200731
 Production Record Certificate No.: Yueshi food and Drug administration equipment production preparation 2020017
 Manufacturing Enterprise: Guangdong Junan Medical Technology Co., Ltd.
 Address: Room 1005, NO 301 huanshi zhong road, Yuexiu District, Guangzhou
 Production Address: 101, No. 66, Liangtian South Road, Zhongjia Town, Baiyun District, Guangzhou
 General Distributor: Guangzhou Difushi Garment Co., Ltd.
 Address: 5/F, building e, Huixin Science and Technology park, no. 8 T, Heta road, Helong Street, Baiyun District, Guangzhou City, Guangdong Province.
 Telephone: +86-020-29880472
 Storage Conditions: It shall be stored in a cool and dry warehouse (the indoor temperature is below 30 degrees, and the relative humidity is not more than 80%), and on the shelf 200 mm away from the ground, pay attention to waterproof, fire prevention, and prohibit direct sunlight
 Validity: Three years
 Production Batch No. / Production Date: See the certificate of approval



Matters Needing Attention

1. This product is disposable.
2. If it is damaged, please do not use it.
3. Please treat it as special waste after use.
4. Please wear it with your fingers to avoid the gloves from being scratched.
5. Use it with proper strength, and do not use too much force.
6. When removing the hand sleeve, please turn up the gloves at the wrist and remove them to the fingers



Queen®

DISPOSABLE NITRILE GLOVES

- Good elasticity
- Tensile strong sex
- Oil resistivity

XL
Blue



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XL
Blue





TEST REPORT

Report No.: SHC20090085-01E Date: 2020-09-04

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Test Results:

Test items	Test Method	Test conditions	Test Results
Thickness	Reference EN 455-2: 2015	Make measurements with a thickness gauge	See the table below

The sample number	The thickness of the wrist (mm)	Thickness of the palm of your hand (mm)	The thickness of the finger (mm)
#001	0.036	0.069	0.071
	0.047	0.084	0.102
	0.055	0.063	0.172
The average	0.046	0.072	0.115
#002	0.057	0.063	0.234
	0.041	0.052	0.179
	0.059	0.078	0.098
The average	0.052	0.064	0.170
#003	0.064	0.066	0.086
	0.032	0.049	0.189
	0.051	0.058	0.246
The average	0.049	0.058	0.174

Average wrist thickness of all samples: 0.049mm, Average palm thickness : 0.065mm, Average finger thickness : 0.153mm

Sample photos



Before thickness test



Thickness test

This photo is limited to ICAS used this report

End of the report



Product name: Disposable Inspection Gloves

Size production specifications: S, M, L, XL, XXL

Product Performance: Disposable inspection gloves have sufficient strength and barrier properties, non-sterile provision, disposable use

Intended Us: Used to wear on hand for inspection to protect hands from bacteria and virus

Scope of Use: Suitable for personal protection , daily use is ok.

Product Review, Test and Documentation, Yue Sui Machinery Equipment No. 20200731

Product Technical Number: Yue Sui Machinery Equipment No. 20200731

Production Case Certificate No: Guangdong Sui Food and Drug Administration Equipment:2020017

Manufacturer: Guangdong Junan Medical Technology Co., Ltd.

Address: 1005, Yidong Building, No.303 Badshi Middle Road, Guangzhou, CN

Production Address: 101, No.60, Liangtian South Road, Zhouluotan, Bai District, Guangzhou, CN

Product Technical Number: Yue Sui Machinery Equipment No. 20200731

Storage Instructions: Store in cool and dry warehouse with indoor temperature below 30°C and less than 80% Humidity. Keep on shelf 200mm from the ground, avoid direct sunlight

Validity: 3 years from production date



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2020

CERTIFICATE OF REGISTRATION

This certifies that:

GUANGDONG JUNAN MEDICAL TECHNOLOGY CO.,L
TD Room 1005, No 301 Huanshi Zhong Road Yuexiu
District Guangzhou Guangdong, CN 510000

Is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number:	10072701
Device Classification Name:	PATIENT EXAMINATION GLOVE
Product Code:	FMC
Regulation Number:	880.6250
Official Correspondent and U.S. Agent:	Registrar Corp 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

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Registrar Corp

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info@registrarcorp.com • www.registrarcorp.com

David Leunarz

 David Leunarz
 Executive Director
 Registrar Corp
 Dated: May 4, 2020

EC Declaration of Conformity

Manufacturer: Guangdong Junan Medical Technology Co., Ltd. Room 1005, No 301 huanshi zhong road, Yuexiu District ,Guangzhou	whose single Authorized Representative: Caretection GmbH Niederreinstr. 71, 40474 Düsseldorf, Germany DIMDI Code: DE/0000048026 Tel/Fax: 0211 3003 6618 Email: info@caretection.com
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We, the manufacturer, herewith declare that the products

Disposable examination gloves

MODEL: nitrile, latex, vinyl, PVC

Size :XS, S, M, L, XL, XXL

UMDNS-Code: 11-882

Meet the provisions of MDR 2017/745 EU which apply to them.
The medical device has been assigned to class I according to Annex VIII of the MDR 2017/745 EU



Applied harmonized standards :EN455-1:2015, EN455-2:2015, EN455-3:2015, EN ISO 14971:2012, EN ISO 13485:2016

The glove is a disposable non-sterile device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner

The product concerned has been manufactured under a quality management system according to Annex IX of MDR 2017/745 EU

Following the procedure relating to the EC Declaration of Conformity set out in Annex IV of MDR 2017/745 EU

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

Guangdong Junan Medical Technology Co., Ltd.
Room 1008, No 301 huanshi zhong road , Yuexiu District , Guangzhou

For and on behalf of
GUANGDONG JUNAN MEDICAL TECHNOLOGY CO., LTD
廣東君安醫用科技有限公司

Guangzhou China 2020-06-01
Place, date

GM:
Legally binding signature/ Function

Packing content (for reference only)

volume weight: 0.0613 Cubic, gross weight: 20.5 kg, net weight: 18 kg
Packing Size: 30 boxes per box, 100 gloves per box, a total of 3000 gloves per box.

Outer Box Size: 61.5 * 47.5 * 21CM inner box size: 23 * 12 * 6.5 cm.

61.5cm

47.5cm

61.5cm

47.5cm

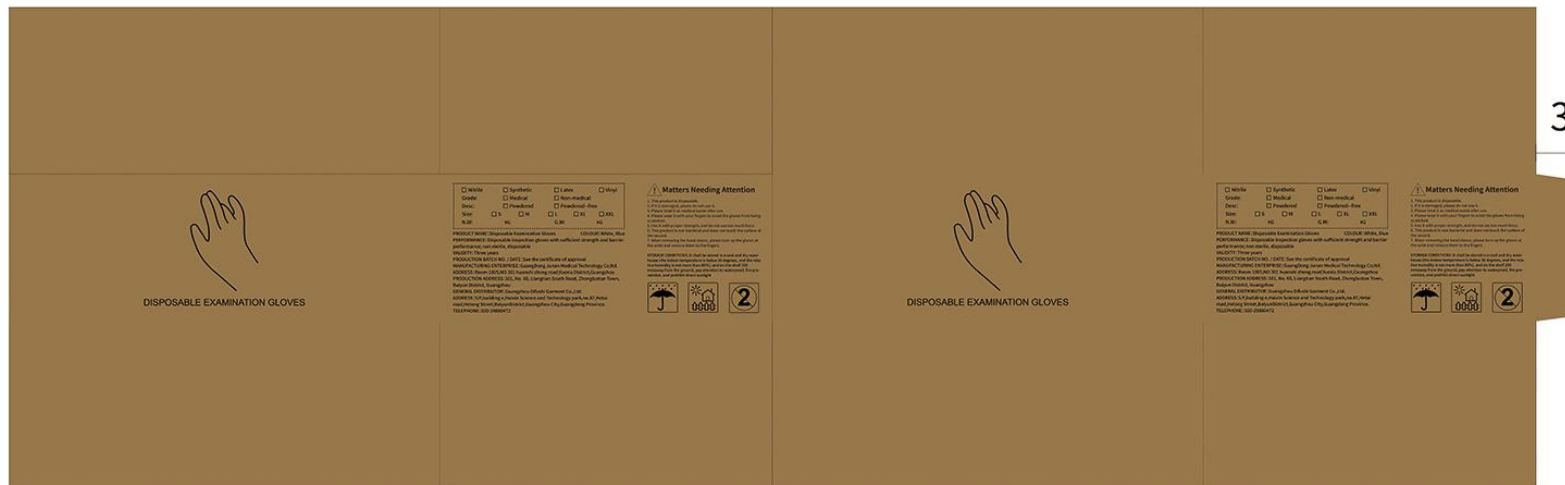
23.7cm

3cm

115.8cm

21cm

23.7cm



Production Facilities



Packing Facilities

