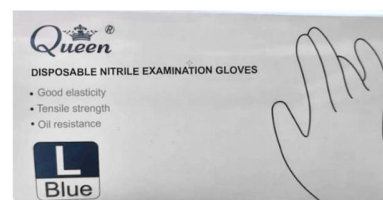
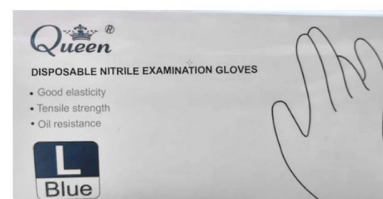
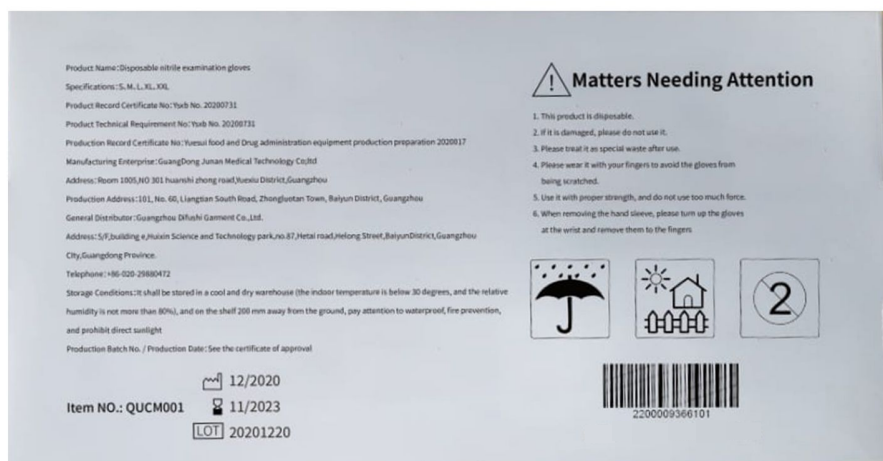


QUEEN GLOVES

GUANGDONG JUNAN MEDICAL TECHNOLOGY CO.,LTD
FDA OWNER OPERATOR: 10072701





Establishment Registration & Device Listing

[New Search](#)
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Classification Name:	PATIENT EXAMINATION GLOVE
Product Code:	<u>FMC</u> ⁶
Device Class:	1
Regulation Number:	<u>880.6250</u> ⁷
Medical Specialty:	General Hospital
Registered Establishment Name:	<u>GUANGDONG JUNAN MEDICAL TECHNOLOGY CO.,LTD</u> ⁸
Registered Establishment Number:	3017301373
Owner/Operator:	<u>Guangdong Junan Medical Technology Co.,Ltd</u> ⁹
Owner/Operator Number:	10072701
Establishment Operations:	Contract Manufacturer; Foreign Exporter; Manufacturer; Specification Developer; Foreign Private Label Distributor



2020

CERTIFICATE OF REGISTRATION

This certifies that:

GUANGDONG JUNAN MEDICAL TECHNOLOGY CO.,LTD
TD Room 1005, No 301 Huanshi Zhong Road Yueshi
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 Name: **10072701**
Product Code: **PATIENT EXAMINATION GLOVE**
Regulation Number: **FMC**
Official Correspondent: **880.6250**
and U.S. Agent: **144 Research Drive, Hampton, Virginia, 23666, USA**
Telephone: **+1-757-224-0179** • Fax: **+1-757-224-0179**

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info@registrarcorp.com • www.registrarcorp.com

David Lemire
Executive Director
Registrar Corp
Date: **11/19/2020**

Guangdong Junan Medical Technology Co., Ltd.
CE technical documents
effective date: 2020.06.01

EC Declaration of Conformity

Manufacturer: **Guangdong Junan Medical Technology Co., Ltd**
Room 1005, No 301 huanshi zhong road,
Yueshi District, Guangzhou

whose single Authorized Representative:

Carelection GmbH
Niedertreisstr. 71, 40174 Düsseldorf,
Germany
DIMDI Code: DE0000048026
Tel/Fax: 0211 3003 6618
Email: info@carelection.com

Disposable examination gloves

MODEL: nitrile, latex, vinyl, PVC
Size :XS, S, M, L, XL, XXL

UN205-Code: 11-882

We, the manufacturer, herewith declare that the products
Meet the provisions of MDR 2017/45 EU which apply to them.
The medical device has been assigned to class I according to Annex VIII of the MDR 2017/45 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 2017/45 EU

Following the procedure relating to the EC Declaration of Conformity set out in Annex IV of MDR 2017/45 EU

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

Guangdong Junan Medical Technology Co., Ltd.
Room 1005, No 301 huanshi zhong road, Yueshi District, Guangzhou

Guangzhou China 2020-06-01
Place , date

GM: **Guangdong Junan Medical Technology Co., Ltd**
Legal binding signature function
Date: **2020.06.01**



TEST REPORT

Report No.: SHC20121170-01E

Date: 2021-01-07

Page 1 of 5

Applicant : GUANGDONG JUNAN MEDICAL TECHNOLOGY CO. LTD.

Address : 101, No.60 Liangtian south road, Zhongluotan town, Baiyun District, Guangzhou.

Sample Information

Sample Name : Medical Examination Gloves

Sample Type/Specification : Size: M

Sample Qty. : 1 (200pcs)

Batch number : 20201220

Above information and sample(s) was/were submitted and certified by/on behalf of the applicant. ICAS was not responsible for the authenticity of the sample, and quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.

Sample No. : C20121170-01

Date of Sample Received : 2020-12-28

Sample Test Period : 2020-12-28~2021-01-07

Test content:

Test item(s) : Please refer to next page(s).

Test Method(s) : Please refer to next page(s).

Decision basis : Please refer to next page(s).

Test Results : Please refer to next page(s).

Prepared by:

陈南娟

(Nanjuan Chen)

Reviewed by:

张进杰

(Jinjie Zhang)

Approved by:

吴清

(Authorized signatory: Jason Wu)



TEST REPORT

Report No.:

SHC20121170-01E

Date:

2021-01-07

Page 2 of 5

Test Instrument:

Name of Test Equipment	Equipment Number
Universal material testing machine	E-023-01ITD
Ultraviolet aging testing machine	E-049-01PV

Test Results:

Test items		Test Method	Test conditions	Test Results	Limited Value	Item(s) Conclusion
Impervious*		EN 455-1: 2000	1. Vertical placement of an acrylic tube enables it to hold more than 1000ml of water in the natural volume of the glove. 2. Connect the gloves to the acrylic tube, overlap the cuffs at the end of the tube by up to 40mm, and secure them in an appropriate way to obtain a watertight seal without damaging the gloves. Add 1000ml+50ml of water to the open end of the acrylic tube to allow the water to enter the glove freely. 3. Immediately visually check if the gloves are leaking, hang them up and visually check again after 2 to 3 minutes	After the test, there was no leakage on the surface of the sample.	No water seepage	Pass
Size *	Length	EN 455-2: 2015	Ruler	240mm (median)	≥240mm	Pass
	Width			93mm (median)	(95±10) mm	Pass
Tensile force value*		EN 455-2: 2015	(23±2) °C, (50±5) %RH, 24h Tection speed: 500mm/min	7.24N	≥6.0N	Pass
Ultraviolet aging		GB/T 16422.3-2014	Lamp Type: UVA-340 Illumination phase: irradiance 0.76W/m²; BPT: 60℃, 8h Condensation stage: BPT: 50℃, 4h Detection period: 24h	The surface of the sample is obviously yellow and dark	/	/
Tensile force value after aging*		EN 455-2: 2015	70℃ hot air aging 168h Tection speed: 500mm/min	6.47N	≥6.0N	Pass

Note: As required by the client, the measured values are obtained from ultraviolet aging.

The remaining project limits are derived from EN 455-1:2000 and EN 455-2:2015.



TEST REPORT

Report No.:

SHC20121170-01E

Date:

2021-01-07

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Sample Photo



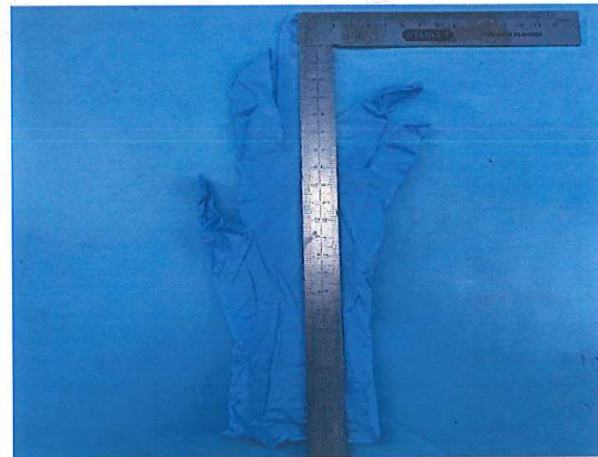
Before water impermeability test



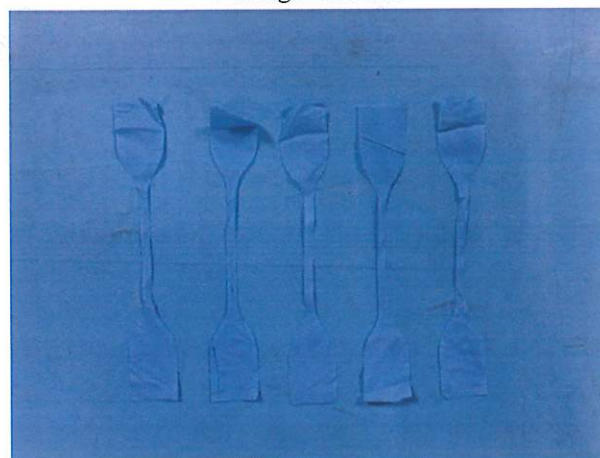
During water impermeability test



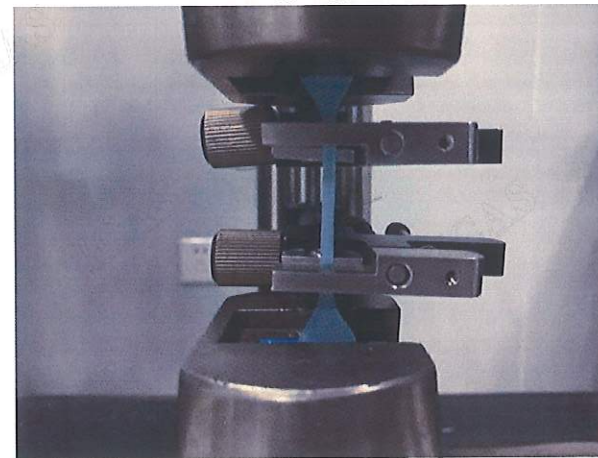
During width test



During length test



Before tensile test



During tensile test



TEST REPORT

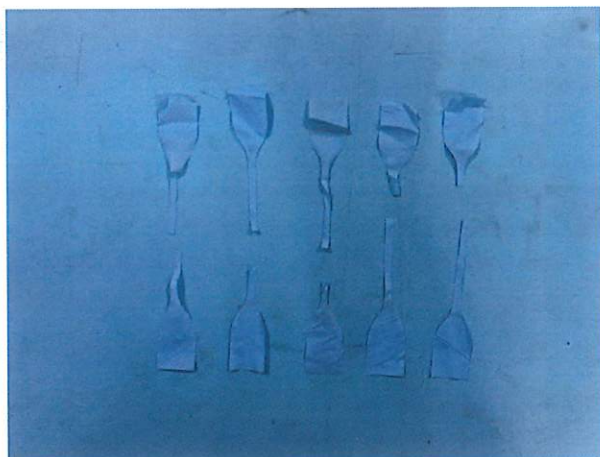
Report No.:

SHC20121170-01E

Date:

2021-01-07

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After tensile test



Before ultraviolet test



During ultraviolet test



After ultraviolet test



Sample packing box 1



Sample packing box 2



TEST REPORT

Report No.:

SHC20121170-01E

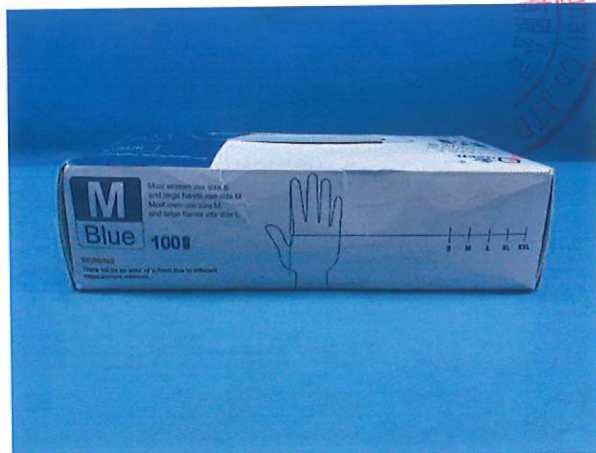
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2021-01-07

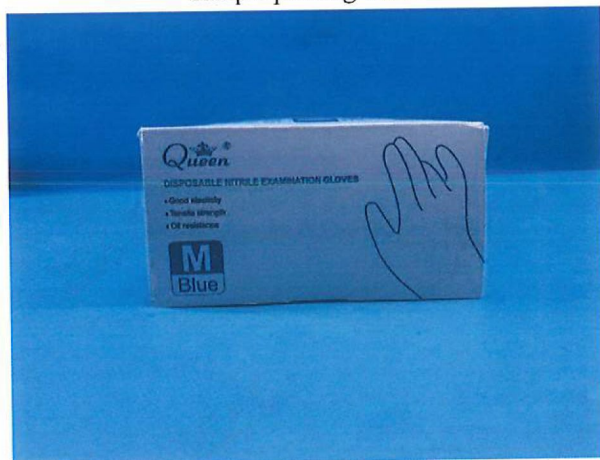
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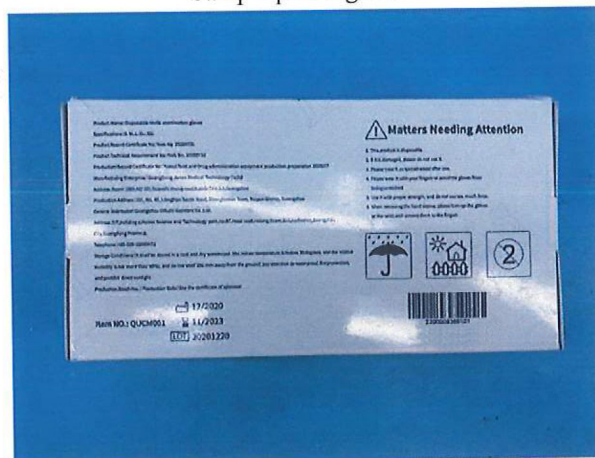
Sample packing box 3



Sample packing box 4



Sample packing box 5



Sample packing box 6

This photo is limited to ICAS used this report

End of the report

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