

Disposable nitrile gloves



KINGFA services worldwide



Inhouse Production
Personalized service and 24/7 online tracking system

Increased Efficiency
Raw Material supply chain management & control

Short Leadtime
Overseas Distribution Centers

Low Risk TermssGs
Inspection and quality control



We have been focusing on supplier management, new product design and quality control

Strong
supply system



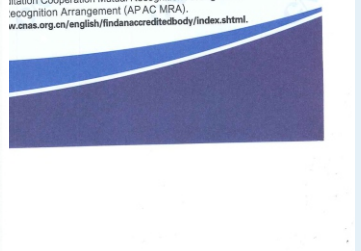
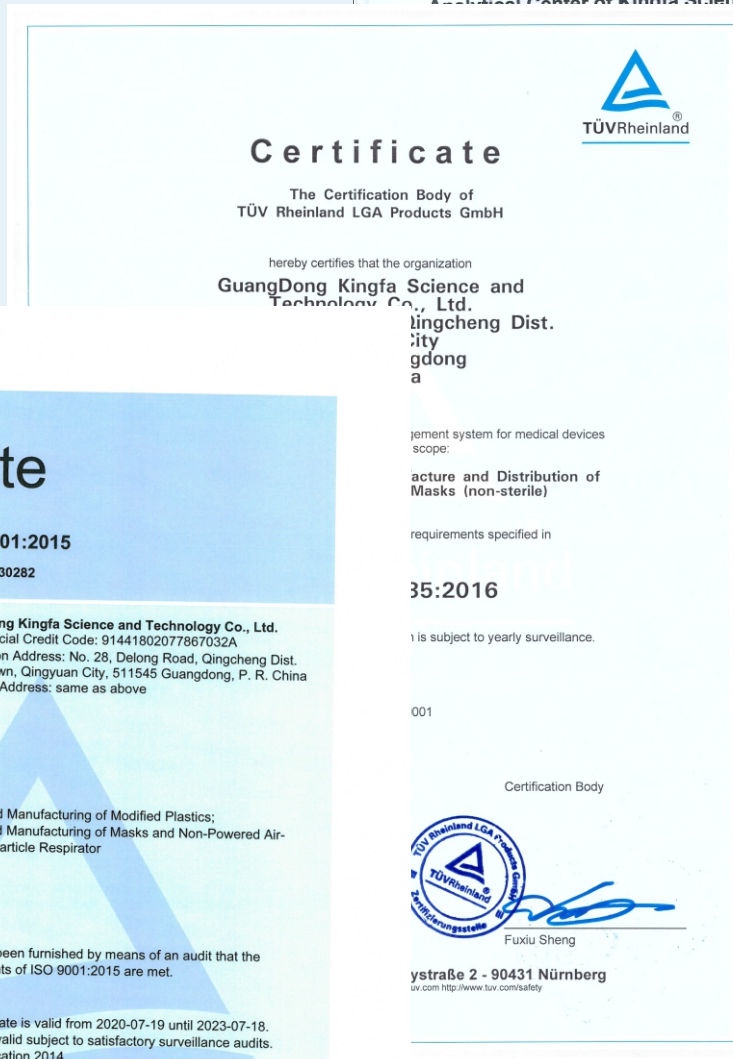
Excellent
technology
team

Ample varieties
of products

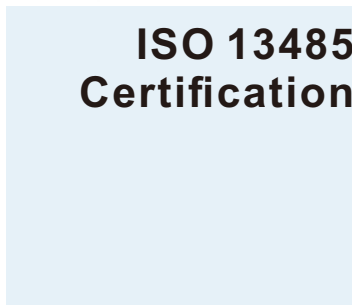


Kingfa makes full use of its own technology accumulated in the modified plastics industry for many years. With the experience and advantages of process control and test certifications, we have successfully developed nitrile gloves with excellent physical properties, tactile sensitivity, chemical resistance and virus resistance, which can provide effective protection for people.

Establish quality guarantying system and product test criteria



ISO 17025 Certification



ISO 13485 Certification

ISO 9001 Certification

MODEL:KS-ST RT021

STANDARD COMPLAINCE



Chemical	Letter	Level
40% Sodium hydroxide	K	2
Type	C	

INTENT USE

The disposable nitrile gloves is intended to be worn on the hands of health care and similar personnel to prevent contamination between health care personnel and the patient's body. This is a single-use, powder-free, non-sterile device.

- PPE Cat III according to Regulation (EU) 2016/425
- EN ISO 374-1:2016 Type C (K) chemical splash protection
- EN 16523-1:2015+A1:2018 Determination of material resistance to permeation by chemicals - Part 1: Permeation by potentially hazardous liquid chemicals under conditions of continuous contact
- ISO 21420:2020 Protective gloves — General requirements and test methods
- EN 374-4:2014 Resistance to degradation by chemicals
- EN ISO 374-5:2016 Micro Organism and VIRUS protection
- EN 455-1: Medical gloves for single use – Part 1: Requirements and testing for freedom from holes
- EN 455-2: Medical gloves for single use – Part 2: Requirements and testing for physical properties
- EN 455-3: Medical gloves for single use – Part 3: Requirements and testing for biological evaluation
- EN 455-4: Medical gloves for single use – Part 4: Requirements and testing for shelf life determination
- Food contact approved

FEATURE

- Fingertip textured
- Powder Free
- Not made with natural rubber latex
- Lab chemical tested
- Dawn blue colour



SGS Test Report

中国认可
国际互认
检测
TESTING
CNAS L0604

Report No.: QDHL2011011608MD

Sample Receiving Date	NOV.02.2020	Test Period Date	NOV.02.2020 TO NOV.17.2020
Test	Sample No. QDHL2011011608MD (SL920193013402FW)	Test environment	Meet requirement

中国认可
国际互认
检测
TESTING
CNAS L0604

scan to see the report

length (Force at break, Force at
le Use – Part 2: Requirements
se 4,2,4,3,5,2,5,3
nent, conclusion please see
e date: NOV.17.2020

Lillian Deao
2020.11.17

中国认可
国际互认
检测
TESTING
CNAS L0604

Report No.: QDHL2011011607MD

Sample Receiving Date	NOV.02.2020	Test Period Date	NOV.02.2020 TO NOV.17.2020
Test	Sample No. QDHL2011011607MD (SL920193013395FW)	Test environment	Meet requirement

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GLOVES
SCI.&TECH.

Co., Ltd.

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检测
TESTING
CNAS L0604

scan to see the report

QDHL2011011607MD

Test Report

Report No.: QDHL2011011607MD

Sample Description: NITRILE EXAMINATION GLOVES

Applicant: GUANGDONG KINGFA SCI.&TECH. CO.,LTD.

Test Type: SUBMITTED BY CLIENT

Co., Ltd.

Single Use – Part 1:
m from Holes Clause 5.1
nent, conclusion please see
e date: NOV.17.2020

er: Lillian Deao
2020.11.17

Co., Ltd.

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SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 1 of 6

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Test Report

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TEST REPORT
Tests Conducted (As Requested By The Applicant)



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8 Resistance To Degradation By Chemicals (BS EN 374-4:2013 / EN 374-4:2013)

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TEST REPORT
Tests Conducted (As Requested By The Applicant)



3 Glove Length (BS EN ISO 21420:2020 / ISO 21420:2020, 6.1)

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TEST REPORT



Applicant: GUANGDONG KINGFA SCI.&TECH.CO.,LTD.
NO.28 DELONG AVENUE, SHIJIAO TOWN,
QINGCHENG DISTRICT, QINGYUAN CITY,
GUANGDONG PROVINCE,CHINA
Attn: XIAOGE YU

Date: Oct 27, 2020

Sample Description:

Two Hundred (200) pairs of submitted samples protective gloves in Blue.
Standard : BS EN ISO 21420:2020 / ISO 21420:2020
EN ISO 374-1:2016+A1:2018
EN ISO 374-2:2019
EN 16523-1:2015+A1:2018
BS EN 374-4:2013 / EN 374-4:2013
Ref. No. : KS-ST RT021
Colors : --
Size Range : M/L
Manufacturer : GUANGDONG KINGFA SCI.&TECH.CO.,LTD.
Ref. : --
Palm : Nitrile
Back : Nitrile
Cuff : Nitrile
Cuff Binding : Nitrile
Lining : Nitrile
Country Of Origin : China
Goods Exported To : --
Date Received/Date Test Started: Oct 16, 2020
Date Final Information Confirmed/ --/--
Date Payment Received:

Test Result Please Refer To Attached Page(S).

Should you have any query on this report, you may contact at gzfootwear@intertek.com

Authorized By:
For Intertek Testing Services Shenzhen Ltd.
Guangzhou Branch

Authorized By:
For Intertek Testing Services Shenzhen Ltd.
Guangzhou Branch

Guiliang Dong
Senior Lab Manager

Vivian Li
Senior Technical Specialist

/ kayyu

Page 1 Of 11

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
深圳天祥质量技术服务有限公司
Room 02, 1-8/F. & Room 01, E101/E201/E301/E401/E501/E601/E701/E801 3/F., Hengqin Building, 235 Kaifa Ave., Guangzhou
No.7-2, Capin Road, Guangzhou Science City, GETDD, Guangzhou, Guangdong Province, China
Economic Technological Development District, Guangzhou,
广州经济技术开发区科学城彩虹岗7号之二第1-8层40房、01房101、102房
E201、E301、E401、E501、E601、E701、E801 3/F., Hengqin Building, 235 Kaifa Ave., Guangzhou
Economic Technological Development District, Guangzhou,
广州经济技术开发区开发大道235号恒垣大厦3楼
Tel: +86 20 83966868 Fax: +86 20 82228169 Postcode: 510730

itions
howed No Visible Damage
howed No Visible Damage
howed No Visible Damage

End Of Report

ou. It is not intended to be a responsibility to any person other than n the terms and conditions governing implied with respect to this report save refal basis and we do not accept any therwise, except in the event of our without the written approval by

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i523-1:2015+A1:2018

rough Time	Performance
0 Mins	1
0 Mins	2

Page 11 Of 11

, 235 Kaifa Ave., Guangzhou cal Development District, Guangzhou, 开发大道 235 号恒垣大厦 3 楼 Fax: +86 20 82228169 Postcode: 510730

Requirement	Pass/Fail
*	Pass
*1	Pass

Page 9 Of 11

, 235 Kaifa Ave., Guangzhou cal Development District, Guangzhou, 开发大道 235 号恒垣大厦 3 楼 Fax: +86 20 82228169 Postcode: 510730

Requirement	Pass/Fail
*	Pass
*1	Pass

Page 3 Of 11

, 235 Kaifa Ave., Guangzhou cal Development District, Guangzhou, 开发大道 235 号恒垣大厦 3 楼 Fax: +86 20 82228169 Postcode: 510730



CE Certification

EU TYPE EXAMINATION CERTIFICATE



Issued to : GUANGDONG KINGFA SCL&TECH.CO., LTD.
NO.28 DELONG AVENUE, SHIJIAO TOWN, QINGCHENG DISTRICT,
QINGYUAN CITY, GUANGDONG PROVINCE, CHINA

Issue Date : 12 November 2020

Expiry Date : 12 November 2025

Certificate No. : LECFI00381894

Product reference : Nitrile Gloves KS-ST RT021



APPROVED BODY 0362

The gloves detailed herein meets the criteria of an EU Type Examination in accordance with Annex V, including the applicable clauses of the Essential Health and Safety Requirements of the PPE Regulation EU 2016/425 for Category III products.

This has been shown through satisfactory testing to EN ISO 21420:2020, EN ISO 374-1:2016+A1 2018, EN ISO 374-2:2019, EN ISO 374-4:2013 and examination of the Technical File Documentation.

Following an EU Declaration of Product Conformity, you are hereby licensed to mark the product(s) detailed in accordance with Article 17 of the PPE Regulation EU 2016/425

ITS Testing Services (UK) Ltd.
Centre Court
Meridian Business Park
Leicester, LE19 1WD
United Kingdom
Phone: +44 (0)116 263 0330

EN ISO 21420:2020	Performance level achieved	
General requirements		
Dexterity		5
Sizes		M/L
EN ISO 374-1:2016+A1 2018		
Protective gloves against dangerous Chemicals and Micro-organisms		
Chemical	Letter	Level
Sodium hydroxide 40%	K	2
Type		C
EN ISO 374-2:2019		Pass/Fail
Determination of resistance to penetration		
Water leak		Pass
Air leak		Pass
EN 374-4:2013 Determination of resistance to degradation by chemicals		Pass / Fail
Perforation test		Pass

The products detailed above shall also be subject to regular assessments in accordance with Module C2 of the PPE Regulation 2016/425

Assessor: P. Williams Date: 12/11/2020

Certification Manager: J. Moore Date: 12/11/2020

For and on behalf of ITS Testing Services (UK) Limited

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DECLARATION OF CONFORMITY

Manufacturer: GUANGDONG KINGFA SCL&TECH. CO., LTD.
Address of manufacturer: No.28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
Product: Nitrile Examination Gloves
Model Ref.: KS-ST RT021
Class characteristics: Class I (not sterile or measuring according to Annex IX, Rule 1)
UMDNS-Code: 11882

The product is certified to meet the Essential requirements and relevant provisions of
EC Directive: Medical Devices Directive 93/42/EEC

Standard(s)/Directive(s): EN ISO 14971: 2012
 EN ISO 13485: 2016
 EN 1041: 2008
 EN ISO 15223-1: 2016
 EN ISO 10993-1: 2018
 EN 62366: 2015
 EN 455-1: 2000
 EN 455-2: 2015
 EN 455-3: 2015
 BS EN 455-4: 2009
 EC Declaration of Conformity (Annex VII) + Technical Files

Conformity assessment procedure: Share Info Consultant Service LLC Repräsentanzbüro
EC representative: Heerdtter Lohweg 83, 40549 Düsseldorf
Address: Heerdtter Lohweg 83, 40549 Düsseldorf

This DoC is valid from 11 Sep., 2020.
 Authorized by:



Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für Medizinprodukte, außer In-vitro-Diagnostika
 Form for Medical Devices except In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority	
Code DE/CA20	
Bezeichnung / Name Bezirksregierung Düsseldorf, Dezernat 24	
Staat / State Deutschland	Land / Federal state Nordrhein-Westfalen
Ort / City Düsseldorf	Postleitzahl / Postal code 40474
Straße, Haus-Nr. / Street, house no. Cecilienallee 2	
Telefon / Phone +49-211-4750	Telefax / Fax +49-211-4752671
E-Mail / E-mail dez24.mpg@brd.nrw.de	
Anzeige / Notification	
Registriertdatum bei der zuständigen Behörde Registration date at competent authority 26.10.2020	Registriernummer / Registration number DE/CA20/01-share-info-consultant-279/20
Typ der Anzeige / Notification type <input checked="" type="checkbox"/> Erstanzeige / Initial notification <input type="checkbox"/> Änderungsanzeige / Notification of change <input type="checkbox"/> Widerrufsanzeige / Notification of withdrawal	
Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn	
Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG <input type="checkbox"/> Hersteller / Manufacturer <input checked="" type="checkbox"/> Bevollmächtigter / Authorised Representative <input type="checkbox"/> Einführer / Importer <input type="checkbox"/> Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG / Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG <input type="checkbox"/> Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV <input type="checkbox"/> Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG	

PACKING INFORMATION



100 PCS
BY WEIGHT

Box

Size: 220*125*68mm
Gross weight: 390±10g



Carton

10 boxes/carton
Size: 365*235*270mm
Gross weight: 4470±500g

1000 PCS
BY WEIGHT



STORAGE AND DISPOSAL




Know you're protected.

Our gloves will go through rigorous testing and meets strict FDA guidelines. We follow the highest quality standards to make sure you get the protection you need.

We will have 96 product lines at the end of 2021, the daily output of each machine is about 1 million gloves.

Contact your KINGFA representative for more information.

GUANGDONG KINGFA SCI. & TECH. CO., LTD.

 NO.28, Delong Avenue, Shijiao Town,
Qingcheng District, Qingyuan City,
Guangdong Province, China

 medical@kingfa.com

 <http://www.kingfa.com.cn>



March 19, 2021

Guang Dong Kingfa SCI. & TECH.CO., LTD.
% Shelley Li
Director
Landlink Healthcare Technology (Shanghai) Co., Ltd.
Room 703, 705, Baohua International Plaza, West Guangzhong
Road 555, Jingan
Shanghai, 200071
China

Re: K203593

Trade/Device Name: 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: February 6, 2021
Received: February 16, 2021

Dear Shelley Li:

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,

Ryan Ortega -S

Ryan Ortega Ph D.
Acting 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



Total Quality. Assured.

TEST REPORT



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国际互认
检测
TESTING
CNAS L0220

Number: GZHT91004210

Date: Nov 26, 2020

Applicant: GUANGDONG KINGFA SCI.&TECH.CO.,LTD.
NO.28 DELONG AVENUE, SHIJIAO TOWN,
QINGCHENG DISTRICT, QINGYUAN CITY,
GUANGDONG PROVINCE,CHINA
Attn: XIAOGE YU

Sample Description:

Three Hundred (300) pieces of submitted samples said to be Nitrile examination gloves in Blue

Standard : ASTM D6319-19
Ref. No. : KG-1101
P.O. No. : 25007026
Colors : Blue
Size Range : KG-1101 M
Palm : Nitrile
Back : Nitrile
Cuff : Nitrile
Cuff Binding : Nitrile
Lining : Nitrile
Date Received/Date Test Started: Nov 13, 2020/--
Date Final Information Confirmed/ Nov 26, 2020/--
Date Payment Received:

Test Result Please Refer To Attached Page(S).

Should you have any query on this report, you may contact at gzfootwear@intertek.com

Authorized By:
For Intertek Testing Services Shenzhen Ltd.
Guangzhou Branch

Guiliang Dong
Senior Lab Manager



er / lynnyang

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

深圳天祥质量技术服务有限公司广州分公司

Room 02, 1-8/F. & Room 01, E101/E201/E301/E401/E501/E601/E701/E801,
No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, Guangdong, China
广州经济技术开发区科学城彩频路7号之二第1-8层02房、01房101、
E201、E301、E401、E501、E601、E701、E801
Tel: +86 208213 9001 Fax: +86 20 82089909 Postcode: 510663

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Economic & Technological Development District, Guangzhou,
China
中国广州经济技术开发区开发大道235号恒运大厦3楼
Tel: +86 20 83966868 Fax: +86 20 82228169 Postcode: 510730



1 Freedom From Holes (ASTM D6319-19, 7.3 & ASTM D5151-19)

Results			Requirement			Pass/Fail
Physical Performance	Failure	AQL	Physical Performance	AQL	n [Ac Re]	-
Water Leakage	1	< 2.5	No Leakage	2.5	200 (10 11)	Pass

Remark: n Means Sample Size, Ac Means Acceptance Number, Re Means Rejection Number.

2 Physical Dimensions (ASTM D6319-19, 7.4 & ASTM D3767-03 (2020))

Results			Requirement			Pass/Fail
Physical Performance	Failure	AQL	Physical Performance	AQL	n [Ac Re]	-
See Test Data	0	< 4.0	Size: M Width: (95 ± 10) mm Length: Min. 230 mm Finger Thickness: Min. 0.05 mm Palm Thickness: Min. 0.05 mm	4.0	13 (1 2)	Pass

Test Data:

Size	Specimen	Width (mm)	Length (mm)	Finger Thickness (mm)	Palm Thickness (mm)
M	1	97	245	0.13	0.11
	2	97	248	0.12	0.11
	3	97	245	0.12	0.11
	4	96	250	0.12	0.11
	5	97	250	0.12	0.11
	6	97	249	0.12	0.11
	7	96	250	0.12	0.11
	8	96	247	0.12	0.11
	9	97	248	0.12	0.11
	10	96	245	0.12	0.11
	11	96	249	0.12	0.11
	12	97	245	0.12	0.11
	13	96	248	0.12	0.11

Remark: n Means Sample Size, Ac Means Acceptance Number, Re Means Rejection Number.





3 Package Marking (ASTM D6319-19, 9.3)

Requirements		Pass	Fail	N/A
9.3.1	Sterile Packages Shall Bear Markings For The Contents To Include The Glove Size, Instructions For Opening, The Legend "Sterile," And A Manufacturing Lot Number.			X
9.3.2	Nonsterile And Bulk Packages Shall Bear Markings For The Contents To Include The Glove Size And A Manufacturing Lot Number.	X		
9.3.3	The Outermost Case Shall Be Labeled With The Glove Size And A Manufacturing Lot Number. Sterile Product Cases Shall Also Be Marked With The Legend "Sterile."	X		
9.3.4	All Levels Of Packaging Shall Conform To All Appropriate Government Labeling Regulations.	X		

Compliance: The Submitted Sample **MEETS** The Requirements Of ASTM D6319-19 Clause 9.3 For Package Marking.

4 Powder Residue For Powder Free Gloves (ASTM D6319-19, 7.6 & ASTM D6124-06 (2017))

Size	Result	Requirement	Pass/Fail
M	0.1 mg	Max. 2.0 mg	Pass



5 Physical Requirements Before Aging (ASTM D6319-19, 7.5 & ASTM D412-16)

Results			Requirement			Pass/Fail
Physical Performance	Failure	AQL	Physical Performance	AQL	n [Ac Re]	-
See Test Data	0	< 4.0	Tensile Strength Min. 14 Mpa Ultimate Elongation Min. 500%	4.0	13 (1 2)	Pass

Test Data:

Condition	Sample	Results	
		Tensile Strength (MPa)	Ultimate Elongation (%)
Before Aging	1	26.7	520
	2	33.7	552
	3	32.2	540
	4	33.3	560
	5	37.8	568
	6	31.3	540
	7	38.3	548
	8	36.1	560
	9	34.6	556
	10	39.8	564
	11	36.5	552
	12	33.0	548
	13	31.3	548

Remark: n Means Sample Size, Ac Means Acceptance Number, Re Means Rejection Number.



6 Physical Requirements After Accelerated Aging (ASTM D6319-19, 7.5 & ASTM D412-16 & ASTM D573-04 (2019))

Results			Requirement			Pass/Fail
Physical Performance	Failure	AQL	Physical Performance	AQL	n [Ac Re]	-
See Test Data	0	< 4.0	Tensile Strength Min. 14 Mpa Ultimate Elongation Min. 400%	4.0	13 (1 2)	Pass

Test Data:

Condition	Sample	Results	
		Tensile Strength (MPa)	Ultimate Elongation (%)
After Accelerated Aging (70°C For 166 h)	1	37.8	536
	2	29.6	520
	3	37.6	552
	4	37.4	552
	5	45.7	564
	6	32.6	536
	7	34.4	540
	8	36.1	536
	9	31.5	540
	10	37.0	540
	11	35.4	540
	12	29.6	528
	13	29.8	532

Remark: n Means Sample Size, Ac Means Acceptance Number, Re Means Rejection Number.





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TEST REPORT



中国认可
国际互认
检测
TESTING
CNAS L0220

Number: GZHT91004211

Date: Nov 26, 2020

Applicant: GUANGDONG KINGFA SCI.&TECH.CO.,LTD.
NO.28 DELONG AVENUE, SHIJIAO TOWN,
QINGCHENG DISTRICT, QINGYUAN CITY,
GUANGDONG PROVINCE,CHINA
Attn: XIAOGE YU

Sample Description:

Three Hundred (300) pieces of submitted samples said to be Nitrile examination gloves in Blue.

Standard : ASTM D6319-19
Ref. No. : KG-1101
P.O. No. : 25007031
Colors : Blue
Size Range : KG-1101 M
Palm : Nitrile
Back : Nitrile
Cuff : Nitrile
Cuff Binding : Nitrile
Lining : Nitrile
Date Received/Date Test Started: Nov 13, 2020/--
Date Final Information Confirmed/ Nov 26, 2020/--
Date Payment Received:

Test Result Please Refer To Attached Page(S).

Should you have any query on this report, you may contact at gzfootwear@intertek.com

Authorized By:
For Intertek Testing Services Shenzhen Ltd.
Guangzhou Branch

Guiliang Dong
Senior Lab Manager



er / lynnyang

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

深圳天祥质量技术服务有限公司广州分公司

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1 Freedom From Holes (ASTM D6319-19, 7.3 & ASTM D5151-19)

Results			Requirement			Pass/Fail
Physical Performance	Failure	AQL	Physical Performance	AQL	n [Ac Re]	-
Water Leakage	1	< 2.5	No Leakage	2.5	200 (10 11)	Pass

Remark: n Means Sample Size, Ac Means Acceptance Number, Re Means Rejection Number.

2 Physical Dimensions (ASTM D6319-19, 7.4 & ASTM D3767-03 (2020))

Results			Requirement			Pass/Fail
Physical Performance	Failure	AQL	Physical Performance	AQL	n [Ac Re]	-
See Test Data	0	< 4.0	Size: M Width: (95 ± 10) mm Length: Min. 230 mm Finger Thickness: Min. 0.05 mm Palm Thickness: Min. 0.05 mm	4.0	13 (1 2)	Pass

Test Data:

Size	Specimen	Width (mm)	Length (mm)	Finger Thickness (mm)	Palm Thickness (mm)
M	1	97	252	0.12	0.11
	2	96	253	0.12	0.11
	3	97	251	0.12	0.11
	4	97	250	0.12	0.11
	5	95	250	0.12	0.11
	6	96	253	0.12	0.11
	7	96	252	0.12	0.11
	8	95	251	0.12	0.11
	9	97	253	0.12	0.10
	10	96	253	0.12	0.10
	11	96	250	0.12	0.10
	12	97	248	0.12	0.11
	13	98	249	0.12	0.11

Remark: n Means Sample Size, Ac Means Acceptance Number, Re Means Rejection Number.





3 Package Marking (ASTM D6319-19, 9.3)

Requirements		Pass	Fail	N/A
9.3.1	Sterile Packages Shall Bear Markings For The Contents To Include The Glove Size, Instructions For Opening, The Legend "Sterile," And A Manufacturing Lot Number.			X
9.3.2	Nonsterile And Bulk Packages Shall Bear Markings For The Contents To Include The Glove Size And A Manufacturing Lot Number.	X		
9.3.3	The Outermost Case Shall Be Labeled With The Glove Size And A Manufacturing Lot Number. Sterile Product Cases Shall Also Be Marked With The Legend "Sterile."	X		
9.3.4	All Levels Of Packaging Shall Conform To All Appropriate Government Labeling Regulations.	X		

Compliance: The Submitted Sample **MEETS** The Requirements Of ASTM D6319-19 Clause 9.3 For Package Marking.

4 Powder Residue For Powder Free Gloves (ASTM D6319-19, 7.6 & ASTM D6124-06 (2017))

Size	Result	Requirement	Pass/Fail
M	0.7 mg	Max. 2.0 mg	Pass



5 Physical Requirements Before Aging (ASTM D6319-19, 7.5 & ASTM D412-16)

Results			Requirement			Pass/Fail
Physical Performance	Failure	AQL	Physical Performance	AQL	n [Ac Re]	-
See Test Data	0	< 4.0	Tensile Strength Min. 14 Mpa Ultimate Elongation Min. 500%	4.0	13 (1 2)	Pass

Test Data:

Condition	Sample	Results	
		Tensile Strength (MPa)	Ultimate Elongation (%)
Before Aging	1	29.0	568
	2	28.1	552
	3	30.9	560
	4	31.5	568
	5	30.2	552
	6	30.7	560
	7	28.2	580
	8	30.6	572
	9	26.7	548
	10	27.8	564
	11	30.2	572
	12	31.1	584
	13	29.3	588

Remark: n Means Sample Size, Ac Means Acceptance Number, Re Means Rejection Number.



6 Physical Requirements After Accelerated Aging (ASTM D6319-19, 7.5 & ASTM D412-16 & ASTM D573-04 (2019))

Results			Requirement			Pass/Fail
Physical Performance	Failure	AQL	Physical Performance	AQL	n [Ac Re]	-
See Test Data	0	< 4.0	Tensile Strength Min. 14 Mpa Ultimate Elongation Min. 400%	4.0	13 (1 2)	Pass

Test Data:

Condition	Sample	Results	
		Tensile Strength (MPa)	Ultimate Elongation (%)
After Accelerated Aging (70°C For 166 h)	1	29.3	524
	2	28.2	516
	3	29.3	508
	4	30.3	516
	5	30.5	512
	6	31.3	520
	7	29.8	516
	8	31.3	508
	9	32.5	500
	10	30.6	500
	11	27.5	480
	12	27.8	492
	13	25.8	488

Remark: n Means Sample Size, Ac Means Acceptance Number, Re Means Rejection Number.





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EU DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer:

Manufacturer and address	<p>GUANGDONG KINGFA SCI.&TECH. CO., LTD.</p> <p>NO.28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China</p>
Product name	Nitrile Gloves
Model/ Serial No.	KS-ST RT021
Applicable Regulation/Standard:	<p>Our glove products are accorded with Medical Devices Directive 93/42/EEC, and corresponding testing standards are as follows:</p> <p>EN ISO 14971: 2012</p> <p>EN ISO 13485: 2016</p> <p>EN 1041: 2008</p> <p>EN ISO 15223-1: 2016</p> <p>EN ISO 10993-1: 2018</p> <p>EN 62366: 2015</p> <p>EN 455-1: 2020</p> <p>EN 455-2: 2015</p> <p>EN 455-3: 2015</p> <p>BS EN 455-4: 2009</p> <p>Our glove products are accorded with PPE Regulation EU 2016/425 For Category III products, and corresponding testing standards are as follows:</p> <p>EN ISO 21420:2020</p> <p>EN ISO 374-1:2016+A1 2018</p> <p>EN ISO 374-2:2019</p> <p>EN ISO 374-4:2019</p> <p>EN ISO 374-5:2016</p> <p>EN16523-1: 2015+A1: 2018</p>

Notified body for EU type-
examination (Module B)

Certificate 2777/15747-01/E00-00 issued by SATRA
Technology Europe Limited.(NB 2777)

We declared that given information on the above statement and attached documents/records are true and correct to the best of our knowledge.

Signed for and on behalf of: GUANGDONG KINGFA SCI.&TECH. CO., LTD.

(date of signature):2021-02-09

(title of signatory):General Manager

(signature):



Test Report No. 7191250395-EEC21-WBH
dated 07 Jan 2021



PSB Singapore

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Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of Gloves submitted by Guangdong Kingfa Sci.& Tech. Co., Ltd.
on 10 Dec 2020.

TESTED FOR:

Guangdong Kingfa Sci.& Tech. Co., Ltd.
No. 28 Delong Avenue, Shijiao Town,
Qingcheng District,
Qingyuan City, Guangdong Province,
China

TEST DATE:

11 Dec 2020 to 02 Jan 2021

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Size	Colour	Lot No.	Expiry Date	Sample Received (pieces)	Manufacturer
1	Nitrile Examination Glove	KS-ST RT021	M	Blue	25007031	2023-07-15	444	Guangdong Kingfa Sci.& Tech. Co., Ltd.

Lot size as specified by client: 35,001 to 150,000 pieces

METHOD OF TEST:

1. EN 455-1:2020 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
3. EN 455-3:2015 Medical glove for single use
Part 3: Requirements and testing for biological evaluation



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Test Report No. 7191250395-EEC21-WBH
dated 07 Jan 2021



PSB Singapore

RESULTS:

Sample: Nitrile Examination Glove, KS-ST RT021, Blue, Size M

Table 1: Results for EN 455-1:2020

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	7	200	2	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	≥ 240	13	252	Passed
	b) Width (mm)	For Size M: 95 ± 10	13	96	Passed
5	Strength a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	10.6	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	9.3	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Comply	Passed

Test Report No. 7191250395-EEC21-WBH
dated 07 Jan 2021



PSB Singapore

RESULTS (cont'd):

Sample: Nitrile Examination Glove, KS-ST RT021, Blue, Size M

Table 4: Results for EN 455-3:2015 Clauses 4.2-4.5


Clause	Tests	Requirements	Results / Remarks	Inferred results
4.2	Chemicals	Gloves shall not be dressed with talcum powder (magnesium silicate).	Glove is talcum powder-free glove, based on client's declaration letter	Passed
		Other chemicals	Manufacturer shall disclose upon request a list of chemical ingredients	NA
4.3 5.1	Endotoxins	< 20 EU/pair for gloves labelled with 'low endotoxin content'.	Not labelled with 'low endotoxin content'	NA
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	0.18 mg per glove	Passed
4.5 5.3	Proteins, leachable	The manufacturer shall strive to minimize the leachable protein level for gloves containing natural rubber latex.	Not natural rubber latex glove	NA

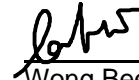
Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA		
Inferred results			Passed

REMARKS:

1. Labelling requirements are assessed based on the submitted packaging artwork by client.
2. NA: Not applicable for the submitted sample.


Yeo Poh Kwang
Associate Engineer


Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:



Photo 1: Nitrile Examination Glove, KS-ST RT021, Blue, Size M



Photo 2: Packaging artwork for Nitrile Examination Glove, KS-ST RT021, Blue, Size M

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Effective 01 January 2021

