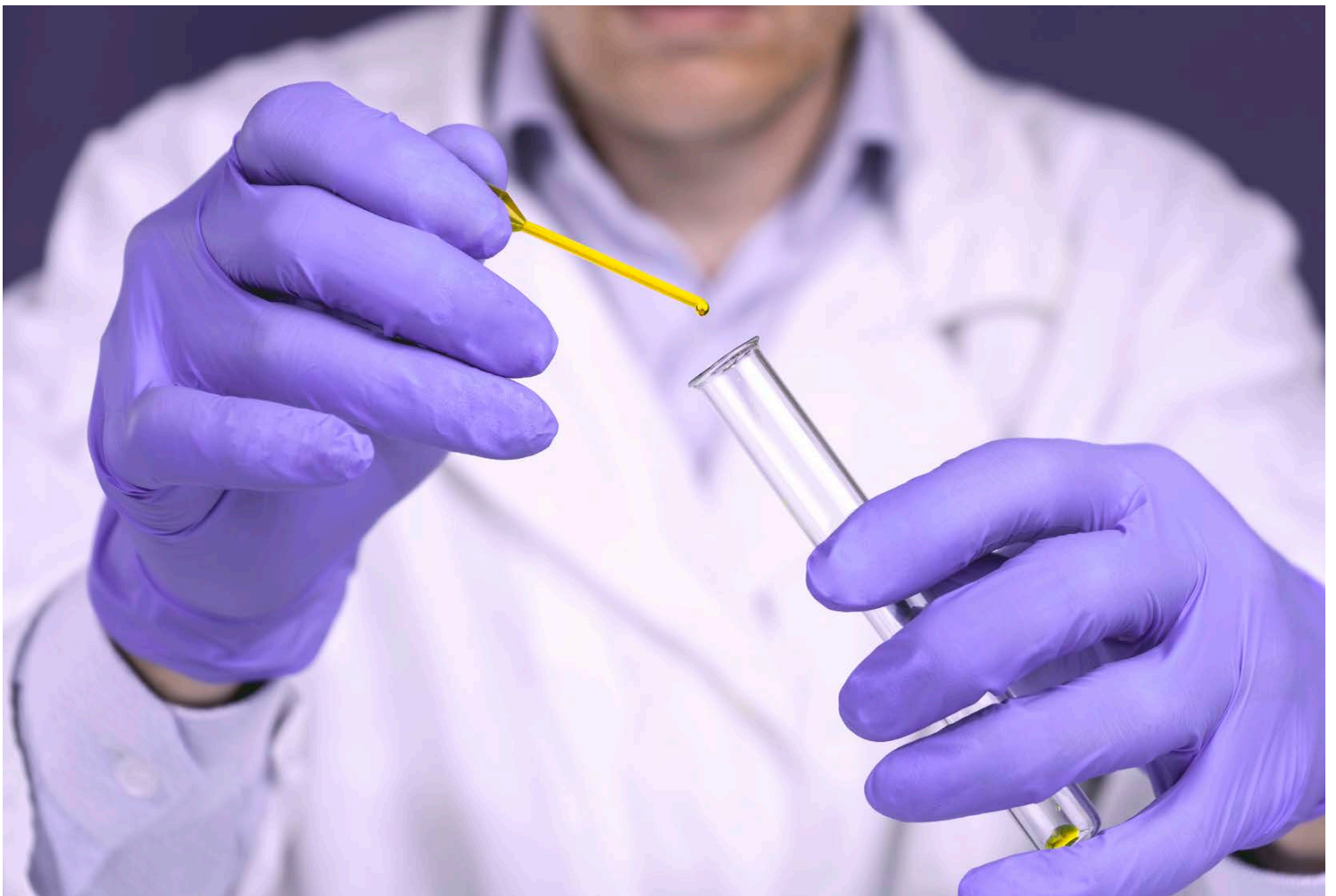


Powder Free Nitrile Examination Gloves

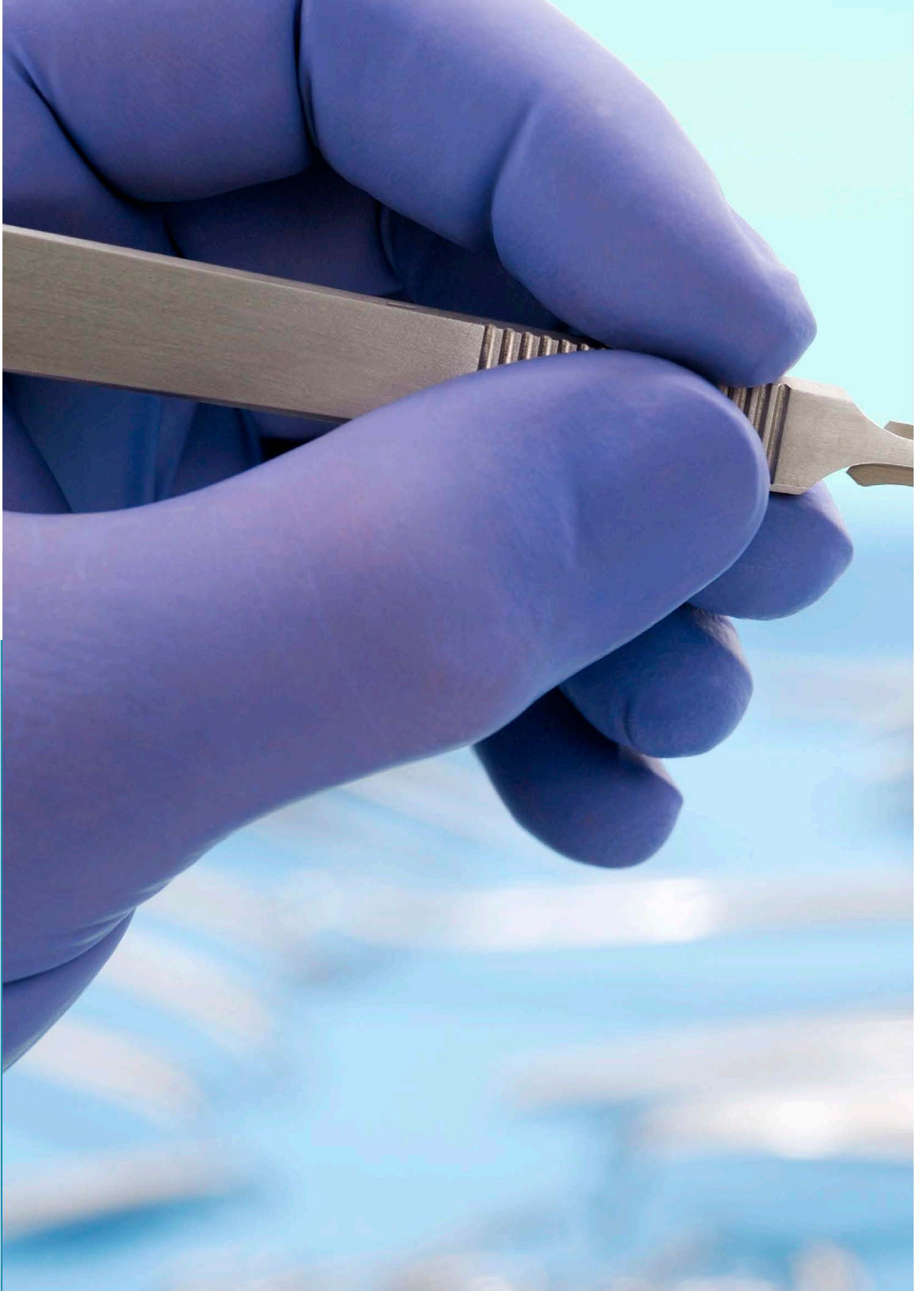
KG-1802



You're protected.

Our gloves are manufactured by overcoming numerous tests based on the corresponding regulations.

KINGFA has a daily production capacity of 1,000,000 units per line. At the end of 2021, KINGFA will have 96 functional production lines, reaching a total daily production capacity of over 100,000,000 units.



ABOUT KINGFA

KINGFA Group is established in 1993 and listed on the Shanghai Stock Exchange in 2004, is the world's leading high-tech manufacturing company committed to R&D, production and marketing of advanced polymer materials. KINGFA Group has been exported products to more than 130 countries, which is providing high-quality services to more than 1000 customers worldwide.



Founded
1993



Employees
10000+



Manufacturing Bases
16+



Invention
Patents
3000+



Countries
served
130+



Revenue of 2020
**5,400,000,000
USD**

KINGFA MEDICAL, establishing itself as an important industrial segment of KINGFA, focuses on the R&D, production and sales of medical and healthcare products. Utilizing KINGFA's technological innovations within the advanced polymer industry for more than 28 years, KINGFA MEDICAL established a vertically integrated supply chain. From the upstream production of polypropylene polymer to the downstream production of face masks, protective coveralls, surgical gowns and other similar products. Furthermore, KINGFA MEDICAL has developed the Nitrile Glove Project with a daily production capacity of 1,000,000 units per line. At the end of 2021, KINGFA will have 96 functional production lines, reaching a total daily production capacity of over 100,000,000 units.

KINGFA MEDICAL is committed to supply high-performance medical and healthcare protective devices to communities around the world.



Achievements & Honors

- 3 National Science and Technology Awards
- 15 China Patent Awards
- 93 Drafting and revision of national and industrial standards

Quality Control

- ISO/IEC 17025 State Accredited Laboratory
- ISO 9001 Quality Management System Certification
- ISO 13485 Medical Device Quality Management System
- QSR820 FDA Quality System Regulation
- ISO 14001 Environmental Management System

Innovation Team

- 5 State Council Special Allowance Experts
- 15 R&D Leading Academicians
- 108 Senior Experts
- 112 Senior Professional Titles
- 125 Doctors
- 651 Masters

Innovation Platform

- UL-CTDP Accredited Laboratory
- State Key Laboratory
- National Enterprise Technology Center
- Post-doctoral Research Center
- Academician Workstation

Focus on supplier management, new products development and quality control.

Production Lines



Strong Supply System



R&D Center



Excellent Technology Team



MODEL:KG-1802

PRODUCT INFORMATION	
Material	100% Nitrile
Color	Blue Violet
Cuff length	Standard
Glove length(mm/inches) min	240 / 9.5
Powder content	Powder-Free
External glove surface	Textured Finger
Freedom from holes(Inspection level I)	1.5 AQL
Palm thickness (mm/mil)	≥ 0.07 / 2.7
Finger thickness (mm/mil)	≥ 0.1 / 4.0
Tensile strength	≥ 14 Mpa
Elongation	≥ 500%
Application Temperature	≤ 40°C
Shelf Life	3 Years

Size	Median Length(mm)	Median Width(mm)
S	≥ 240	80±10
M	≥ 240	95±10
L	≥ 240	110±10
XL	≥ 240	≥ 110

INTENDED USE

The patient examination glove is a disposable device intended for medical purposes that is worn on the examiner’s hand to prevent contamination between patient and examiner.

FEATURES

- Powder free/Latex free
- Superior strength with better puncture resistance
- Excellent chemical resistance
- High chemotherapy drug resistance
- Excellent antiviral properties
- Skin irritation&sensitization tested

These gloves were tested for use with chemotherapy drugs per ASTM D6978-05 (2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. Tested chemotherapy drugs are as follows:

	Minimum Breakthrough Detection Time(minutes)
Carmustine (BCNU) 3.3 mg/ml	65.3 minutes
Cisplatin 1.0 mg/ml	>240 minutes
Cyclophosphamide (Cytoxan) 20.0 mg/ml	>240 minutes
Dacarbazine (DTIC)10.0 mg/ml	>240 minutes
Doxorubicin Hydrochloride 2.0 mg/ml	>240 minutes
Etoposide (Toposar) 20.0 mg/ml	>240 minutes
Fluorouracil 50.0 mg/ml	>240 minutes
Paclitaxel (Taxol) 6.0 mg/ml	>240 minutes
Thiotepa 10.0 mg/ml	58.3minutes

STANDARDS AND CERTIFICATIONS

EN374 TYPE B
 ASTM D6319(FDA 510K)
 ASTM D6978

MANUFACTURING ACCREDITATIONS

ISO/IEC 17025 State Accredited Laboratory
 ISO 9001 Quality Management System Certification
 ISO 13485 Medical Device Quality Management System
 QSR820 FDA Quality System Requirements
 ISO 14001 Environmental Management System

REGULATORY COMPLIANCE

21 U.S.C. ch.9
 MDD 93/42/EEC
 REACH

EU 2016/425
 EC 10/2011
 EC 1935/2004



Package Components

KG-1802

Exterior Package Design

- Size:225*120*63 mm



Carton Package Design

- 10 boxes/carton
- Size:330*250*240 mm



Container Loading (For Reference Only)

20GP	1500 cartons
40GP	3100 cartons
40HQ	3464 cartons

STORAGE INSTRUCTIONS



TEST REPORT

FDA 510K

510(k) Premarket Notification

[FDA Home](#) [Medical Devices](#) [Databases](#)



[510\(k\)](#) | [DeNovo](#) | [Registration & Listing](#) | [Adverse Events](#) | [Recalls](#) | [PMA](#) | [HDE](#) | [Classification](#) | [Standards](#)
[CFR Title 21](#) | [Radiation-Emitting Products](#) | [X-Ray Assembler](#) | [Medsun Reports](#) | [CLIA](#) | [TPLC](#)

New Search		Back To Search Results	
Device Classification Name	Polymer Patient Examination Glove	510(K) Number	K203593
Device Name	Patient Examination Gloves	Device Name	Patient Examination Gloves
Applicant	Guang Dong Kingfa SCI. & TECH CO., LTD. No. 28 Delong Ave., Shijiao Town, Qingcheng District Qingyuan, CN 511545	Applicant Contact	Xiaoge Yu
Correspondent	Landlink Healthcare Technology (Shanghai) Co., Ltd. Room 703, 705, Baohua International Plaza, West Guangzhong Road 555, Jingan Shanghai, CN 200071	Correspondent Contact	Shelley Li
Regulation Number	880.6250	Classification Product Code	LZA
Date Received	12/09/2020	Decision Date	03/19/2021
Decision	Substantially Equivalent (SESE)	Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital	Type	Traditional
Reviewed By Third Party	No	Combination Product	No

Establishment Registration & Device Listing

[FDA Home](#) [Medical Devices](#) [Databases](#)



New Search		Back To Search Results	
Proprietary Name:	Patient Examination Gloves:KG-1101; Patient Examination Gloves:KG-1601; Patient Examination Gloves:KG-1802		
Classification Name:	POLYMER PATIENT EXAMINATION GLOVE		
Product Code:	LZA		
Device Class:	1		
Regulation Number:	880.6250		
Medical Specialty:	General Hospital		
Registered Establishment Name:	GUANGDONG KINGFA SCI.&TECH.CO.,LTD.		
Registered Establishment Number:	3016785267		
Premarket Submission Number:	K203593		
Owner/Operator:	Guangdong KINGFA SCI.&TECH.Co.,Ltd.		
Owner/Operator Number:	10065634		
Establishment Operations:	Manufacturer		

TEST REPORT

ASTM D6319



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TESTING
CNAS L0220

Number: GZHT91004600

Date: Nov 28, 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-1802
P.O. No.	:	25007025
Colors	:	Blue
Size Range	:	KG-1802 S/M/L/XL
Palm	:	Nitrile
Back	:	Nitrile
Cuff	:	Nitrile
Cuff Binding	:	Nitrile
Lining	:	Nitrile
Date Received/Date Test Started	:	Nov. 16, 2020/--
Date Final Information Confirmed/	:	Nov. 27, 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



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wx / lynnyang

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

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Number: GZHT91004600

- 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	2	< 2.5	No Leakage	2.5	200 (10 11)	Pass

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

/ lynnyang

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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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CNAS L0220

Number: GZHT91004600

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: S Width: (80 ± 10) mm Length: Min. 220 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)
S	1	85	242	0.14	0.11
	2	83	237	0.15	0.12
	3	84	239	0.15	0.12
	4	84	235	0.15	0.12
	5	84	241	0.14	0.12
	6	86	243	0.14	0.11
	7	86	245	0.13	0.11
	8	86	235	0.14	0.11
	9	83	239	0.15	0.11
	10	85	230	0.15	0.10
	11	85	243	0.16	0.10
	12	87	241	0.15	0.10
	13	86	240	0.14	0.11





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Number: GZHT91004600

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

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	0.16	0.12
	2	97	233	0.15	0.11
	3	96	237	0.15	0.11
	4	96	239	0.14	0.11
	5	95	242	0.15	0.12
	6	95	243	0.15	0.11
	7	95	238	0.14	0.12
	8	96	239	0.14	0.11
	9	96	242	0.13	0.10
	10	93	241	0.14	0.11
	11	94	236	0.15	0.12
	12	96	242	0.14	0.11
	13	97	240	0.14	0.12





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Number: GZHT91004600

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

Results			Requirement			Pass/Fail
Physical Performance	Failure	AQL	Physical Performance	AQL	n [Ac Re]	-
See Test Data	0	< 4.0	Size: L Width: (110 ± 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)
L	1	106	245	0.17	0.11
	2	103	247	0.17	0.11
	3	103	242	0.18	0.11
	4	104	246	0.18	0.12
	5	107	244	0.17	0.12
	6	105	246	0.16	0.10
	7	105	247	0.16	0.11
	8	106	240	0.17	0.12
	9	106	237	0.17	0.12
	10	104	240	0.18	0.12
	11	106	239	0.17	0.13
	12	107	241	0.17	0.11
	13	105	242	0.16	0.11





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CNAS L0220

Number: GZHT91004600

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

Results			Requirement			Pass/Fail
Physical Performance	Failure	AQL	Physical Performance	AQL	n [Ac Re]	-
See Test Data	0	< 4.0	Size: XL Width: (120 ± 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)
XL	1	117	245	0.17	0.11
	2	116	243	0.16	0.11
	3	116	246	0.16	0.10
	4	115	246	0.16	0.11
	5	116	242	0.17	0.12
	6	115	247	0.16	0.11
	7	115	240	0.16	0.10
	8	113	243	0.16	0.09
	9	113	242	0.17	0.09
	10	114	240	0.17	0.11
	11	116	244	0.17	0.10
	12	117	244	0.18	0.12
	13	117	246	0.18	0.11

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





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Number: GZHT91004600

3 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	1	< 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	23.6	480
	2	32.4	540
	3	41.3	540
	4	38.1	532
	5	42.2	552
	6	40.4	548
	7	31.2	520
	8	28.6	532
	9	34.1	500
	10	44.8	500
	11	29.5	500
	12	37.4	520
	13	37.8	500

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





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Number: GZHT91004600

4 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	40.1	540
	2	47.1	520
	3	17.6	440
	4	40.3	500
	5	44.3	520
	6	38.4	552
	7	42.6	508
	8	42.1	532
	9	38.1	500
	10	43.2	500
	11	37.0	500
	12	44.1	520
	13	36.7	500

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





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Number: GZHT91004600

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

Size	Result	Requirement	Pass/Fail
XL	0.2 mg	Max. 2.0 mg	Pass

6 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.



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Number: GZHT91004600



End Of Report

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/ lynnyang

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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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TEST REPORT

ASTM D6978



Testing. Development. Problem Solving.

March 10, 2021

TEST REPORT


PN 157940

PHARMACEUTICAL SERVICES

Prepared For:

Yu Xiaoge
Guangdong Kingfa Sci. & Tech. Co., Ltd.
No. 28, Delong Avenue, Shijiao Town, Qingcheng District,
Qingyuan City, Guangdong Province
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Prepared By:


Tiffany Heller
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Approved By:


Ana C Barbur, M.S.
Vice President, Analytical & Chemical Services

Rev 101218



An A2LA ISO 17025 Accredited Testing Laboratory — Certificate Numbers 255.01 & 255.02
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Testing. Development. Problem Solving.

March 10, 2021

Yu Xiaoge
Guangdong Kingfa Sci. & Tech. Co., Ltd.

Page 2 of 5
PN 157940

SUBJECT: Permeation testing per ASTM D6978-05(2019) on sample submitted by the above company.

RECEIVED: One (1) glove type identified as; Nitrile Gloves, Style/Item No.: KG-1802, P.O./Ref No. 25007030.

TEST CHEMICALS:

Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	Sigma Aldrich; Batch# 0000098912; Expiration 02/2022
Cisplatin, 1.0 mg/ml (1,000 ppm)	Accord; Lot# P2001296; Expiration 01/2022
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	Accord; Lot# 19112225; Expiration 10/2021
Dacarbazine, 10.0 mg/ml (10,000 ppm)	Teva; Lot# 31325414B; Expiration 09/2021
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	WestWard; Lot# BJ0051; Expiration 06/2021
Etoposide, 20.0 mg/ml (20,000 ppm)	Teva; Lot# 31325485B; Expiration 07/2021
Fluorouracil, 50.0 mg/ml (50,000 ppm)	Accord; Lot# P2001167; Expiration 01/2022
Paclitaxel, 6.0 mg/ml (6,000 ppm)	Teva; Lot# 19K24KA; Expiration 11/2021
ThioTepa, 10.0 mg/ml (10,000 ppm)	USP; Lot # R11380; Expiration 01/2022

COLLECTION MEDIA:

Table 2. Collection Media for Test Drug

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	Distilled Water
Dacarbazine, 10.0 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	Distilled Water
Etoposide, 20.0 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Paclitaxel, 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
ThioTepa, 10.0 mg/ml (10,000 ppm)	Distilled Water

*ARDL is ISO 17025 accredited by A2LA for the test methods listed on the certificates referenced on page one. Unless specified, the current specification version is used.
NOTE: Non-ISO 17025 accredited test methods are designated with the ^ symbol to differentiate from ISO 17025 accredited methods in the body of the test report.*
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March 10, 2021

Yu Xiaoge
Guangdong Kingfa Sci. & Tech. Co., Ltd.

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TESTING CONDITIONS:

Standard Test Method Used: ASTM D6978-05(2019)
Analytical Method: UV/VIS Spectrometry
Testing Temperature: 35.0°C ± 2.0
Collection System: Closed Loop
Specimen Area Exposed: 5.067 cm²
Selected Data Points: 25/test
Number of Specimens Tested: 3/test
Location Sampled From: Cuff

DETECTION METHOD OF CHEMICAL PERMEATION:

UV/VIS ABSORPTION SPECTROMETRY:

Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING DRUG	WAVELENGTH (nm)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	200
Dacarbazine, 10.0 mg/ml (10,000 ppm)	320
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	232
Etoposide, 20.0 mg/ml (20,000 ppm)	205
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269
Paclitaxel, 6.0 mg/ml (6,000 ppm)	232
ThioTepa, 10.0 mg/ml (10,000 ppm)	199

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested: Nitrile Gloves, Style/Item No.: KG-1802, P.O./Ref No. 25007030.

Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Carmustine (BCNU)	0.095	0.107	0.096	0.099
Cisplatin	0.100	0.097	0.093	0.097
Cyclophosphamide (Cytoxan)	0.107	0.106	0.093	0.102
Dacarbazine	0.103	0.093	0.100	0.099
Doxorubicin	0.107	0.099	0.092	0.099
Etoposide	0.110	0.094	0.094	0.099
Fluorouracil	0.094	0.096	0.095	0.095
Paclitaxel	0.098	0.095	0.094	0.095
ThioTepa	0.100	0.095	0.098	0.098
Weight/Unit Area (g/m²)	98.3			

*ARDL is ISO 17025 accredited by A2LA for the test methods listed on the certificates referenced on page one. Unless specified, the current specification version is used.
NOTE: Non-ISO 17025 accredited test methods are designated with the ^ symbol to differentiate from ISO 17025 accredited methods in the body of the test report.*

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RESULTS:

Table 5. Permeation Test Results on testing of: Nitrile Gloves, Style/Item No.: KG-1802, P.O./Ref No. 25007030.

TEST CHEMOTHERAPY DRUGS	AVERAGE BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) ($\mu\text{g}/\text{cm}^2/\text{minute}$)	OTHER OBSERVATIONS
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	65.3 (68.6,66.3,65.3)	0.6 (0.6,0.5,0.6)	Moderate swelling and no degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytosan), 20.0 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Dacarbazine, 10.0 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Etoposide, 20.0 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Fluorouracil, 50.0 mg/ml (50,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Paclitaxel, 6.0 mg/ml (6,000 ppm)	>240 min.	N/A	Moderate swelling and no degradation
ThioTepa, 10.0 mg/ml (10,000 ppm)	58.3 (59.2,58.3,58.4)	0.1 (0.1,0.1,0.1)	Slight swelling and no degradation

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Guangdong Kingfa Sci. & Tech. Co., Ltd.

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SAMPLES RECEIVED:

Nitrile Gloves, Style/Item No.: KG-1802, P.O./Ref No. 25007030



Prepared By: _____

Jiffany Heller
Jiffany Heller
Manager, Pharmaceutical Services

Approved By: _____

Ana C Barbur
Ana C Barbur, M.S.
Vice President, Analytical & Chemical Services

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TEST REPORT

EN374 TYPE B

		<p>Issued to: Guangdong Kingfa Sci. & Tech. Co., Ltd NO.28 Delong Avenue Shijiao Town Qingcheng District Qingyuan City Guangdong Province 511500 China</p>												
<p>Notified Body: 2777</p>	<p>SATRA customer number: P21017</p>													
<h3>EU Type-Examination Certificate</h3>														
<p>Certificate number: 2777/16466-01/E00-00</p>														
<p>This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation: Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.</p>														
<p>Product reference: KG-1802</p>	<p>Description: Disposable Powder-Free Nitrile Examination Gloves</p>													
	<p>Colour: Blue violet</p>													
<p>Sizes: 6/S, 7/M, 8/L, 9/XL</p>	<p>Classification:</p> <table border="1"> <thead> <tr> <th>EN ISO 374-1:2016+A1:2018 /Type B</th> <th>Level</th> <th>EN ISO 374-4:2019 Degradation %</th> </tr> </thead> <tbody> <tr> <td>40% Sodium Hydroxide (K)</td> <td>6</td> <td>3.8</td> </tr> <tr> <td>30% Hydrogen Peroxide (P)</td> <td>3</td> <td>13.7</td> </tr> <tr> <td>37% Formaldehyde (T)</td> <td>6</td> <td>19.4</td> </tr> </tbody> </table>		EN ISO 374-1:2016+A1:2018 /Type B	Level	EN ISO 374-4:2019 Degradation %	40% Sodium Hydroxide (K)	6	3.8	30% Hydrogen Peroxide (P)	3	13.7	37% Formaldehyde (T)	6	19.4
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37% Formaldehyde (T)	6	19.4												
	<p>EN ISO 374-5:2016 Protection against Bacteria and Fungi: Pass Protection against Viruses: Pass</p>													
<p>Standards/Technical specifications applied: EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016</p>														
<p>Technical reports/Approval documents: SATRA: CHT0305030/2047, CHM0305280/2047/EN/A, CHM0305280/2047/EN/B</p>														
<p>Signed on behalf of SATRA:</p>		<p>Geoff Graham</p>												
		<p>Date first issued: 29/04/2021 Date of issue: 29/04/2021 Expiry date: 29/04/2026</p>												
<p>Page 1 of 2</p>														

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Contact your KINGFA representative for more information

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