

MEDICAL EXAMINATION NITRILE GLOVE

KG-1101



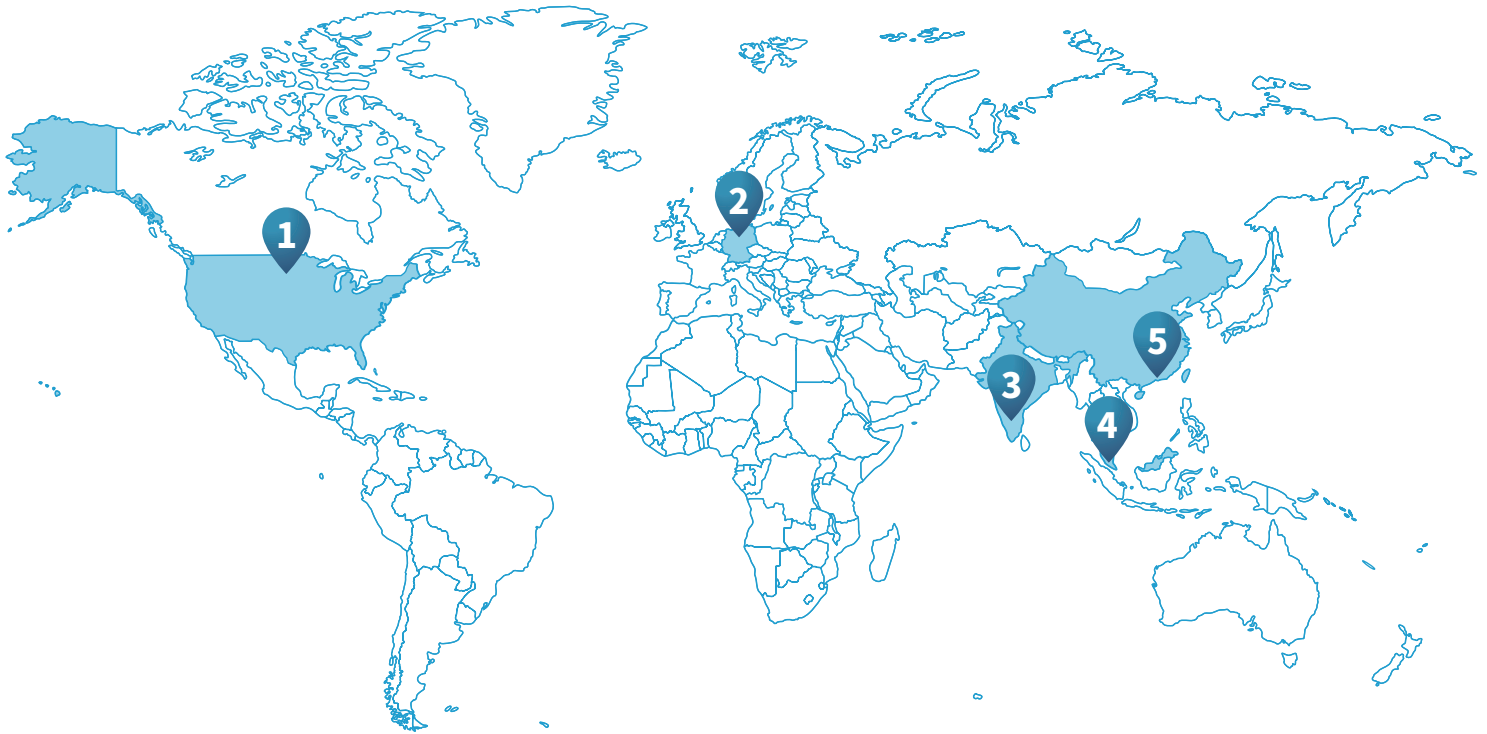
You're protected.

Our gloves will be manufactured through rigorous tests based on the corresponding regulations. We will ensure the demand and protection in accordance with the highest quality standards.

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.



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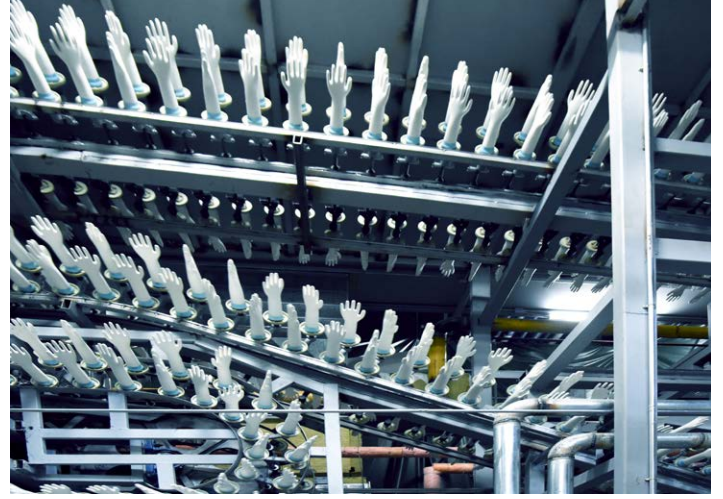
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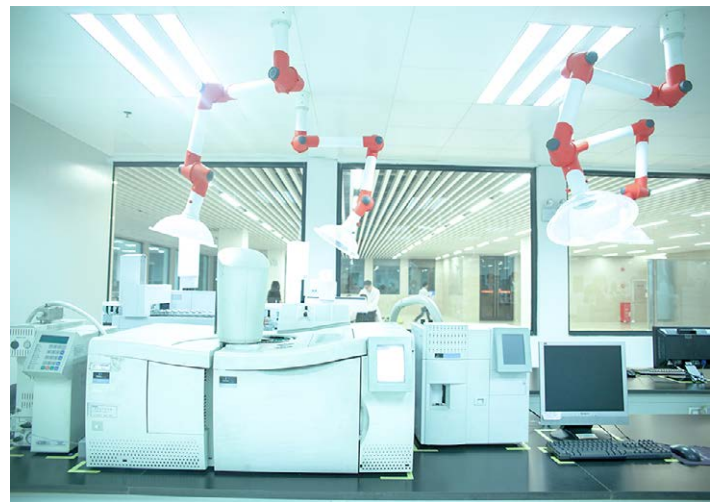
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Management & Control

Short Leadtime



Overseas Distribution Centers

Risk Control & Management



SGS Inspection and
Quality Control

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

Strong Supply System



Excellent Technology Team



Various Kinds 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.

MODEL:KG-1101

PRODUCT INFORMATION		
Material	100% Nitrile	
Color	Blue	
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)	≥ 0.05 / 2.0	
Finger thickness (mm/mil)	≥ 0.08 / 3.1	
Breakage force	≥ 6N	
Tensile strength	≥ 14 Mpa	
Elongation	≥ 500%	
Application Temperature	≤ 70°C	
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 nitrile examination gloves are intended to be worn on the hands of healthcare personnel to prevent contamination between patients and examiners. This is a single-use, powder-free, non-sterile device.

FEATURES

1. Excellent mechanical strength provides a high level of hand protection.
2. Textured in finger tips for a secure grip.
3. Protection against bacteria and fungi.
4. Skin irritation&sensitization tested.



STANDARDS AND CERTIFICATIONS

FDA Premarket
Notifications[510(K)]:
ASTM D6319
CE Certificate:
EN 455 part 1/2/3/4
EN 374 part 1/2/3/4/5

MANUFACTURING ACCREDITATIONS


ISO/IEC 17025 State Accredited Laboratory
ISO 9001:2008 Quality Management System Certification
ISO 13485 Medical Device Quality Management System
OHSAS 18001 Occupational Health and Safety Management
ISO 14001 Environmental Management System
IECQ QC080000:2012 Process Management System for Hazardous Substances

REGULATORY COMPLIANCE

21 U.S.C. ch.9
MDD 93/42/EEC
REACH
EU 2016/425
EC 10/011
EC 1935/2004

TEST REPORT

FDA 510K






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Device Classification Name	Polymer Patient Examination Glove
510(K) Number	K203593
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


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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

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TEST REPORT

ASTM D6319

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Number: GZHT91004206

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. : 25007036
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

Guliang Dong
Senior Lab Manager

er / lynnyang



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Number: GZHT91004206

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]	-
No Leakage	0	< 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	96	247	0.12	0.11
	2	95	250	0.12	0.11
	3	97	253	0.12	0.11
	4	96	253	0.12	0.11
	5	95	252	0.12	0.11
	6	96	250	0.12	0.11
	7	97	250	0.12	0.11
	8	97	253	0.12	0.11
	9	95	250	0.12	0.11
	10	98	250	0.12	0.11
	11	95	249	0.12	0.11
	12	98	248	0.12	0.11
	13	96	252	0.12	0.11

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





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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	0.8 mg	Max. 2.0 mg	Pass

/ lynnyang

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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	4.0	13 (1 2)	Pass
			Ultimate Elongation Min. 500%			

Test Data:

Condition	Sample	Results	
		Tensile Strength (MPa)	Ultimate Elongation (%)
Before Aging	1	30.6	600
	2	29.1	588
	3	27.0	564
	4	31.9	596
	5	29.9	556
	6	29.7	580
	7	29.9	568
	8	29.8	560
	9	28.0	592
	10	29.8	568
	11	28.6	560
	12	29.6	552
	13	27.3	556

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





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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	26.2	524
	2	28.4	500
	3	27.1	492
	4	24.4	500
	5	28.5	512
	6	27.8	504
	7	30.9	544
	8	30.1	580
	9	27.4	512
	10	36.7	516
	11	37.2	516
	12	32.1	516
	13	28.7	488

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

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Number: GZHT91004206



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EN 455 1-4

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QDHL2011011607MD

Test Report

Report No.: QDHL2011011607MD


Sample Description: NITRILE EXAMINATION GLOVES

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

Test Type: SUBMITTED BY CLIENT

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Report No.: QDHL2011011607MD

Test Report

Sample information	Sample Description	NITRILE EXAMINATION GLOVES	Color	BLUE
	Received sample quantity/	220PCS/	Type/Specifications	KG-1101 M
	Tested sample quantity	200PCS		
	Lot No.	NOT PROVIDED	Lot Quantity	NOT PROVIDED
	Manufacture Date	NOT PROVIDED	Expiration Date	NOT PROVIDED
	Material/Appearance	NITRILE	Storage Condition	NOT PROVIDED
	Manufacturer	NOT PROVIDED		
Client information	Applicant	GUANGDONG KINGFA SCI.&TECH. CO.,LTD.		
	Applicant address	NO.28 DELONG AVENUE, SHIJIAO TOWN, QINGCHENG DISTRICT, QINGYUAN CITY, GUANGDONG PROVINCE, CHINA		

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Report No.: QDHL2011011607MD

Test information	Sample Receiving Date	NOV.02,2020	Test Period Date	NOV.02,2020 TO NOV.17,2020
	Sample No.	QDHL2011011607MD (SL920193013395FW)	Test environment	Meet requirement
	Test items	Water tightness test		
	Testing Accordance	EN 455-1:2000 Medical Gloves for Single Use – Part 1: Requirements and Testing for Freedom from Holes Clause 5.1		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: NOV.17,2020			
Remark	/			

Approver: *Jessica Gao* Auditor: *Jessica Gao* Compiler: *Lillian Zhao*
 Date: *2020.11.17* Date: *2020.11.17* Date: *2020.11.17*

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Report No.: QDHL2011011607MD

Test Results

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Water tightness test	/	EN455-1: 2000 Clause 5.1	Sample quantity: 200pcs AQL: 1.5 Ac: 7 Re: 8	Found: 0	Pass

End of Report

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QDHL2011011608MD

Test Report

Report No.: QDHL2011011608MD

Sample Description: NITRILE EXAMINATION GLOVES
 Applicant: GUANGDONG KINGFA SCI.&TECH.
CO.,LTD.
 Test Type: SUBMITTED BY CLIENT

Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755)83071443, or email: CN.Doc@china.sgs.com

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Report No.: QDHL2011011608MD

Test Report

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Sample information	Sample Description	NITRILE EXAMINATION GLOVES	Color	BLUE
	Received sample quantity/ Tested sample quantity	80PCS/ 30PCS	Type/ Specifications	KG-1101 M
	Lot No.	NOT PROVIDED	Lot Quantity	NOT PROVIDED
	Manufacture Date	NOT PROVIDED	Expiration Date	NOT PROVIDED
	Material/Appearance	NITRILE	Storage Condition	NOT PROVIDED
	Manufacturer	NOT PROVIDED		
	Client information	Applicant	GUANGDONG KINGFA SCI.&TECH. CO.,LTD.	
Applicant address		NO.28 DELONG AVENUE, SHIJIAO TOWN, QINGCHENG DISTRICT, QINGYUAN CITY, GUANGDONG PROVINCE, CHINA		

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Test information	Sample Receiving Date	NOV.02,2020	Test Period Date	NOV.02,2020 TO NOV.17,2020
	Sample No.	QDHL2011011608MD (SL920193013402FW)	Test environment	Meet requirement
	Test items	Dimensions(Length, Width), Tensile strength (Force at break, Force at break after challenge testing)		
	Testing Accordance	EN 455-2:2015 Medical Gloves for Single Use – Part 2: Requirements and Testing for Physical Properties Clause 4.2,4.3,5.2,5.3		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: NOV.17,2020			
Remark	/			

Approver: *Jessica Gao* Auditor: *Jessica Gao* Compiler: *Lillian Zhao*

Date: *2020.11.17* Date: *2020.11.17* Date: *2020.11.17*

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Report No.: QDHL2011011608MD

Test Results

Test Items	Unit	Test Method	Requirement	Test Result	Assessment	
Dimensions	Length	mm	EN 455-2:2015 Clause 4.2	Median value: M:≥240	See appendix 1 for details	Pass
	Width	mm	EN 455-2: 2015 Clause 4.3	Median value: M:95±10		Pass
Tensile strength	Force at break	N	EN 455-2: 2015 Clause 5.2	Median value: b): ≥6.0	See appendix 2 for details	Pass
	Force at break after challenge testing	N	EN 455-2: 2015 Clause 5.3	Median value: b): ≥6.0		Pass

Appendix 1: Dimensions

Size	M	
	Length (mm)	Width (mm)
No.		
1	250	98
2	253	97
3	250	98
4	249	97
5	248	97
6	256	97
7	245	97
8	248	97
9	255	97
10	253	97
11	253	97
12	253	97
13	253	97
Standard requirement	≥240	95±10
Median value	253	97

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Report No.: QDHL2011011608MD

Appendix 2: Tensile Strength

Size: M			
Force at break (N)			
Before aging		After aging	
No.	/	No.	/
1	9.4	1	8.1
2	8.1	2	8.3
3	9.2	3	8.8
4	8.6	4	8.4
5	8.8	5	8.9
6	8.9	6	8.4
7	8.9	7	8.2
8	9.0	8	8.2
9	8.6	9	9.4
10	9.4	10	8.5
11	11.7	11	7.8
12	9.3	12	8.0
13	8.6	13	8.0
Standard requirement	≥6.0	Standard requirement	≥6.0
Median value	8.9	Median value	8.3

Remark: The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

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QDHL2011011609MD

Test Report

Report No.: QDHL2011011609MD

Sample Description: NITRILE EXAMINATION GLOVES

Applicant: GUANGDONG KINGFA

SCI.&TECH. CO.,LTD.

Test Type: SUBMITTED BY CLIENT

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Report No.: QDHL2011011609MD

Test Report

Sample information	Sample Description	NITRILE EXAMINATION GLOVES	Color	BLUE
	Received sample quantity/ Tested sample quantity	100PCS/ 5PCS	Type/ Specifications	KG-1101 M
	Lot No.	25007026	Lot Quantity	NOT PROVIDED
	Manufacture Date	2020-07-21	Expiration Date	2023-07-20
	Material/Appearance	NITRILE (POWDER FREE)	Storage Condition	NOT PROVIDED
	Manufacturer	NOT PROVIDED		
	Others	NOT PROVIDED		
	Client information	Applicant	GUANGDONG KINGFA SCI.&TECH. CO.,LTD.	
Applicant address		NO.28 DELONG AVENUE, SHIJIAO TOWN, QINGCHENG DISTRICT, QINGYUAN CITY, GUANGDONG PROVINCE, CHINA		

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Report No.: QDHL2011011609MD

Test information	Sample Receiving Date	DEC.17,2020; NOV.02,2020	Test Period Date	NOV.02,2020 TO DEC.21,2020
	Sample No.	QDHL2011011609MD (SL920193013392FW)	Test environment	Meet requirement
	Test items	Removable surface powder, Labelling		
	Testing Accordance	EN 455-3:2015 Medical Gloves for Single Use – Part 3: Requirements and Testing for Biological Evaluation Clause 4.4,4.6		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. <p style="text-align: right;">Issue date: DEC.21,2020</p>			
Remark	/			

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Approver: *Jessica Gu* Auditor: *Jessica Gu* Compiler: *Air tao*
 Date: 2020.12.21 Date: 2020.12.21 Date: 2020.12.21

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Report No.: QDHL2011011609MD

Test Results

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Removable surface powder	mg	EN 455-3: 2015 Clause 4.4 EN ISO 21171: 2006	≤2	0.10	Pass
Labelling	/	EN 455-3: 2015 Clause 4.6	The relevant requirement of EN 1041:2008+A1:2013 and EN ISO 15223-1:2012 The labelling shall include a prominent indication of whether the glove is powdered or powder-free	/	Pass

Remarks:

1. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.
2. Labelling assessment was based on the information provided by the customer, excluding the verification of the authenticity of the content. SGS is not responsible for verifying the accuracy of the information provided by customers.

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Final Report

Report Number: SDWH-M202005591-1(E)

Physical Properties Shelf Life Test of Nitrile gloves Accelerated Aged for 1 Year Accelerated Aged for 3 Years

Sponsor: GUANG DONG KINGFA SCI.& TECH.CO.,LTD

Address: No.28 Delong Ave.,Shijiao Town,Qingcheng District,Qing
yuan,Guangdong,China



Sanitation & Environment Technology Institute, Soochow University

Address: 199 Ren-Ai Road, Suzhou Industrial Park, Suzhou, Jiangsu 215123, P. R. China

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Supplementary Explanation

- (1) Please apply for rechecking within 15 days of receiving the report if there are any objections.
- (2) Any erasure or without special inspection and testing seal renders the report null and void.
- (3) The report is only valid when signed by the persons who edited, checked and approved it.
- (4) The results relate only to the articles tested.
- (5) The report shall not be reproduced except in full without the written approval of the institute.
- (6) Conclusion determination basis is not in the scope of accreditation.

Verification Dates

Test Article Receipt	2020-10-13
Protocol Effective Date	2020-10-21
Technical Initiation Date	2020-10-29
Technical Completion Date	2021-02-23
Final Report Completion Date	2021-03-08

Edited by: Wang Deheng 2021-03-08
Date

Reviewed by: Jiang Chongyuan 2021-03-08
Study Director Date

Approved by: Wang Lijie 2021-03-08
Authorized Signatory Date

Sanitation & Environment Technology Institute, Soochow University



Summary

1 Test Article

Test Article Name	Nitrile gloves
Manufacturer	GUANG DONG KINGFA SCI.& TECH.CO.,LTD
Address	No.28 DeLong Ave.,Shijiao Town,Qingcheng District,Qing yuan,Guangdong,China
Model	KG-1101
Lot/Batch	25007015/25007016/25007017

2 Main Reference

Medical gloves for single use Part 4: Requirements and testing for shelf life determination (EN455-4:2009)

Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices (ASTM F 1980-16)

3 Test Method

Watertightness test and physical property test were performed both before and after the test glove were accelerated aged for 33 days and 97 days.

Study protocol number: SDWH-PROTOCOL-M202005591-1.

4 Conclusion

The test glove could achieve the physical properties shelf life for 3 years under this test condition.

Test Report

1 Purpose

The test was designed to validate the physical properties shelf life of the test gloves.

2 Reference

Medical gloves for single use Part 4: Requirements and testing for shelf life determination (EN455-4:2009)

Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices (ASTM F 1980-16)

3 Compliance

ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories (CNAS—CL01 Accreditation criteria for the competence of testing and calibration laboratories) China National Accreditation Service for Conformity Assessment LABORATORY ACCREDITATION CERTIFICATE Registration No. CNAS L2954

RB/T 214—2017 Competence assessment for inspection body and laboratory mandatory approval—General requirements for inspection body and laboratory Certification and Accreditation Administration of the People's Republic of China INSPECTION BODY AND LABORATORY MANDATORY APPROVAL Certificate No. CMA 180015144061

4 Identification of Test Article

Test Article Name	Nitrile gloves
Manufacturer	GUANG DONG KINGFA SCI.& TECH.CO.,LTD
Address	No.28 Delong Ave.,Shijiao Town,Qingcheng District,Qingyuan,Guangdong,China
Test Article Initial State	Non-sterile
CAS Number	Not supplied by sponsor (N/S)
Model	KG-1101
Size	M
Lot/Batch	25007015/25007016/25007017
Raw Material	Nitrile
Packaging Material	N/A
Physical State	Solid
Color	BLUE
Density	N/A
Stability	N/A
Solubility	N/A
Storage Condition	Room temperature
Intended Use	N/A
Additional Information	N/A

The information about the test article was supplied by the sponsor wherever applicable.

5 Equipment and Reagents

5.1 Equipment

Equipment Name	Equipment Number	Calibration Expire
Ruler	SDWH463	2021-07-06
Computer control tensile tester	SDWH872	2021-03-11
High temperature and high humidity aging box	SDWH314	2021-09-29
High temperature and low humidity aging box	SDWH315	2021-09-02

6 Test Methods and Results

6.1 Accelerated Aging Test

6.1.1 Test condition: Accelerated Aging Temperature (60°C), High RH (70%), Low RH (20%), $Q_{10}=2$

6.1.2 Parameters:

Aging Time	Q_{10}	T_{AA}	T_{RT}	AAF	Desired RT	AAT
1 y	2	60°C	25°C	11.3	365Days	33 Days
3 y	2	60°C	25°C	11.3	1095Days	97 Days

Q_{10} : Arrhenius reaction rate function states that a 10°C increase or decrease in temperature of a homogeneous process results in approximately, a two times or 1/2-time change in the rate of a chemical reaction ($Q_{10}=2$).

T_{AA} : Selected Accelerated Aging Temperature (°C);

T_{RT} : Ambient Temperature (°C).

AAF (Accelerated Aging factor) = $Q_{10}^{(|T_{AA}-T_{RT}|/10)}$.

Desired RT: Desired simulated Real Time.

AAT: Accelerated Aging Time to simulate a Desired RT; AAT = Desired RT/AAF

6.1.3 Calculation for accelerated aging time:

Accelerated Aging factor (AAF) = $Q_{10}^{(|T_{AA}-T_{RT}|/10)} = 2^{[(60-25)/10]} = 11.3$

Accelerated Aging Time of 1y (AAT) = Desired (RT)/AAF = 365/11.3 = 33 days

Accelerated Aging Time of 3y (AAT) = Desired (RT)/AAF = 1095/11.3 = 97 days

6.1.4 Aging schedule:

1y Equivalent 33 Days	Date
High RH = 70%: 16 Days	From 2020-10-29 to 2020-11-14
Low RH = 20%: 17 Days	From 2020-11-14 to 2020-12-01
3y Equivalent 97 Days	Date
High RH = 70%: 48 Days	From 2020-10-29 to 2020-12-16
Low RH = 20%: 49 Days	From 2020-12-16 to 2021-02-03

6.1.5 Watertightness test and physical property test were performed both before and after the test glove were accelerated aged for 33 days and 97 days.

6.2 Watertightness Test

6.2.1 Test samples: 50 pieces/Batch.

6.2.2 Vertically positioned the filling tube to fit the glove and attached the glove to the filling tube, overlapping the cuff by a maximum of 40 mm over the end of the tube and secured it to obtain a watertight seal without damaging the globe.

6.2.3 Added 1000 ± 50 ml of water at a temperature of $(15 \text{ to } 35)^{\circ}\text{C}$ into the open end of the filling tube, allowing the water to pass freely into the glove.

6.2.4 Immediately inspected the glove visually for water leakage. Allowed the glove to hang and visually inspected the glove for water leakage again after a period of 2 min to 3 min.

6.2.5 Disregard leakages within 40 mm of the cuff.

6.2.6 Results: List in Table.

6.3 Physical property test

6.3.1 Obtained one dumb-bell test piece from each of 13 gloves/batch using a cutter from the palm, back of the hand or cuff areas of each glove in the test sample, avoiding textured areas if possible and taking the test pieces in the direction of the longitudinal axis of the glove;

6.3.2 Determined the force at break of the 13 test pieces after conditioning at $23 \pm 2^{\circ}\text{C}$ and $50 \pm 5\%$ relative humidity for 24 hours under test condition and cross-head speed of 500 mm/min;

6.3.3 Recorded the force at break, in Newtons, for each of the 13 samples.

6.3.4 Results: List in Table.

7 Conclusion

The test glove could achieve the physical properties shelf life for 3 years under this test condition.

8 Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated SDWH archive.

9 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

10 Deviation statement

There was no deviation from the approved study protocol which was judged to have any impact on the validity of the data.

Annex 1 Test Data

Table 1 The results of watertightness test (Lot/ Batch: 25007015)

	The Results (Zero-time)	The Results (1 year Aged)	The Results (3 years Aged)
Sample	50 Gloves	50 Gloves	50 Gloves
Number of Non-conforming	0 Glove	0 Glove	0 Glove
Criteria	≤2 Gloves	≤2 Gloves	≤2 Gloves
Conclusion	Acceptable	Acceptable	Acceptable

Table 2 The results of watertightness test (Lot/ Batch: 25007016)

	The Results (Zero-time)	The Results (1 year Aged)	The Results (3 years Aged)
Sample	50 Gloves	50 Gloves	50 Gloves
Number of Non-conforming	0 Glove	0 Glove	0 Glove
Criteria	≤2 Gloves	≤2 Gloves	≤2 Gloves
Conclusion	Acceptable	Acceptable	Acceptable

Table 3 The results of watertightness test (Lot/ Batch: 25007017)

	The Results (Zero-time)	The Results (1 year Aged)	The Results (3 years Aged)
Sample	50 Gloves	50 Gloves	50 Gloves
Number of Non-conforming	0 Glove	0 Glove	0 Glove
Criteria	≤2 Gloves	≤2 Gloves	≤2 Gloves
Conclusion	Acceptable	Acceptable	Acceptable

Table 4 The results of physical property test (Lot/ Batch: 25007015)

No.	Force at break (Zero-time) N	Force at break (1 year Aged) N	Force at break (3 years Aged) N
1	7.06	7.27	8.47
2	7.49	6.01	6.29
3	8.03	9.29	6.72
4	7.47	10.21	7.72
5	7.91	10.00	9.23
6	6.92	10.89	6.66
7	10.38	11.07	10.72
8	10.06	10.63	9.74
9	9.86	9.69	11.22
10	9.29	9.54	9.15
11	8.27	8.96	8.88
12	10.52	9.38	10.21
13	8.31	7.06	6.87
Median	8.27	9.54	8.88
Criteria	≥6.0	≥6.0	≥6.0
Conclusion	Acceptable	Acceptable	Acceptable

Sanitation & Environment Technology Institute, Soochow University Report No.: SDWH-M202005591-1(E)

Table 5 The results of physical property test (Lot/ Batch: 25007016)

No.	Force at break (Zero-time) N	Force at break (1 year Aged) N	Force at break (3 years Aged) N
1	9.34	11.01	10.80
2	10.47	8.34	8.57
3	11.51	9.79	9.44
4	7.58	9.80	10.23
5	7.94	8.76	7.84
6	10.78	6.80	9.28
7	8.52	7.86	7.51
8	9.44	6.28	10.56
9	8.94	8.36	11.69
10	10.07	11.18	8.83
11	9.03	12.31	9.09
12	10.02	9.95	9.19
13	11.29	6.77	8.53
Median	9.44	8.76	9.19
Criteria	≥6.0	≥6.0	≥6.0
Conclusion	Acceptable	Acceptable	Acceptable

Table 6 The results of physical property test (Lot/ Batch: 25007017)

No.	Force at break (Zero-time) N	Force at break (1 year Aged) N	Force at break (3 years Aged) N
1	10.57	7.81	7.15
2	9.68	6.17	11.16
3	8.75	8.40	10.02
4	9.11	6.89	8.79
5	11.10	6.63	6.43
6	9.11	7.59	5.45
7	10.95	7.65	11.73
8	9.60	9.21	8.79
9	9.72	7.51	9.35
10	10.17	7.47	6.10
11	10.85	7.38	7.47
12	10.20	6.19	8.46
13	8.81	11.01	9.74
Median	9.72	7.51	8.79
Criteria	≥6.0	≥6.0	≥6.0
Conclusion	Acceptable	Acceptable	Acceptable

Kingfa Medical

Annex 2 Photograph of Test Article



— 检测 —

Annex 3 Information Provided by Sponsor

1 Production Process

Not supplied by sponsor.

2 Other Information

Batch Size:2000 pieces/batch.

End of Report

TEST REPORT

EN 374 1-5



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Customer details: GUANGDONG KINGFA SCI.&TECH. CO., LTD SATRA reference: CHT0305029 /2047

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

Your reference: KG-1101

Date of report: 10 December 2020

Samples received: 17 November 2020

Date(s) work carried out: 17 November 2020 to 3 December 2020

TECHNICAL REPORT

Subject:

EN ISO 21420: 2020 size & dexterity & innocuousness test, EN ISO 374-2: 2019 air leak and water leak, EN ISO 374-5: 2016 viruses test on Disposable Powder Free Nitrile Examination Gloves, Color: Blue, Size: S (6), M (7), L (8), XL(9), Reference number: KG-1101

Conditions of Issue:

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Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides a coverage probability of approximately 95%.

Report signed by: Adam Zhang
Position: Technologist
Department: China Testing

(Page 1 of 10)



TECHNICAL REPORT

WORK REQUESTED

Samples described as Disposable Powder Free Nitrile Examination Gloves, Color: Blue, Size: S (6), M (7), L (8), XL(9), Reference number: KG-1101 were received by SATRA on 17 November 2020 for testing in accordance with EN ISO 21420: 2020, EN ISO 374-2: 2019 and EN ISO 374-5: 2016.

SAMPLE SUBMITTED



Samples described as Disposable Powder Free Nitrile Examination Gloves, Color: Blue, Reference number: KG-1101

TESTING REQUESTED

- EN ISO 21420: 2020 Clause 5.1 – Sizing and measurement of gloves
- EN ISO 21420: 2020 Clause 5.2 – Dexterity
- EN ISO 374-2: 2019 Clause 7.2 – Air leak
- EN ISO 374-2: 2019 Clause 7.3 – Water leak
- EN ISO 374-5: 2016 Clause 5.3 – Protection against viruses (ISO 16604: 2004 Procedure B)
- EN ISO 21420: 2020 Clause 4.2 – Innocuousness of protective gloves

CONCLUSION

The samples described as Disposable Powder Free Nitrile Examination Gloves, Color: Blue, Size: S (6), M (7), L (8), XL(9), Reference number: KG-1101 were found to achieve the following results:

- EN ISO 21420: 2020 Clause 5.1 – See below table
- EN ISO 21420: 2020 Clause 5.2 – Level 5
- EN ISO 374-2: 2019 Clause 7.2 – Pass
- EN ISO 374-2: 2019 Clause 7.3 – Pass
- EN ISO 374-5: 2016 Clause 5.3 – Pass
- EN ISO 21420: 2020 Clause 4.2 – Pass PAHs, DMFA and pH value

Detailed results are included on the following page(s)



TECHNICAL REPORT

Testing

Testing was carried out in accordance with EN ISO 21420:2020, EN ISO 374-2: 2019

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at (23±2) °C and (50±5) % relative humidity.

Requirements

Table 1 – Requirements for EN ISO 21420: 2020 Clause 5.2 Dexterity

Performance level	1	2	3	4	5
Diameter of dexterity pin /mm	11.0	9.5	8.0	6.5	5.0

Table 2 – Requirements for EN ISO 374-2: 2019

Clause 7.2 Air leak	No leak to be detected
Clause 7.3 Water leak	No leak to be detected

Test Results

Table 3 – EN ISO 21420:2020 Test Results

Clause / Test	Requirement	Test Results			UoM (See note ♣)	Result	
5.1 Glove length, comfort and fit	N/A	Size	Length /mm			± 1.10 mm	N/A
			1	2	3		
		6	241	241	240		
		Comfortable on fit					
		7	240	240	239		
		Comfortable on fit					
		8	242	235	245		
		9	235	240	240		
		Comfortable on fit					
5.2 Dexterity	See table 1	Size	Minimum pin diameter / mm			N/A	Level 5
		6	5.0				
		7	5.0				
		8	5.0				
		9	5.0				



TECHNICAL REPORT

Table 4 – EN ISO 374-2: 2019 Test Results

Clause / Test	Test Results		UoM (See note ♣)	Result
7.2 Air leak test	Total air pressure used	2.9 kPa	N/A	Pass
	Sample size	Leaks		
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		
7.3 Water leak test	Sample size	Leaks	N/A	Pass
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		
	9	No leaks detected		

Additional Information / Notes

Note ♣ – Estimated uncertainty of measurement applied at point of test (e.g. to applied force or to tolerance limits) to ensure product meets requirements of the standard



TECHNICAL REPORT

Protection Against Viruses Test Results

Testing was conducted at a third-party laboratory and reported under their reference 20R006810. The laboratory is CNAS accredited to ISO 17025: 2017 with ISO 16604: 2004 included in their accreditation schedule.

Table 1 – Resistance to penetration by blood-borne pathogens results

Sample description:		Disposable Powder Free Nitrile Examination Gloves, Color: Blue, Reference number: KG-1101				
Test method	Specimen	Step 1 (0 kPa, 5 min)	Step 2 (14 kPa, 1min)	Step 3 (0kPa, 4min)	Titre of phage Phi-X174 (PFU /mL)	Comment
ISO 16604: 2004	+ control	Penetration	Penetration	Penetration	Penetration	Acceptable
	- control	No penetration	No penetration	No penetration	< 1	Acceptable
Procedure B Using retaining screen	1	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	2	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	3	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass



TECHNICAL REPORT

Innocuousness Test Results

Testing was conducted at a third-party laboratory and reported under their reference A201123018001. The laboratory is CNAS accredited to ISO 17025: 2017.

Sample Item	Sample Description	Location	Style
I001	Blue Disposable Powder Free Nitrile Examination Gloves	Gloves	-

pH Value - EN ISO 21420:2020

Test Method I : With reference to EN ISO 4045:2018, analyzed by pH meter.

Test Method II: With reference to ISO 3071:2020, analyzed by pH meter.

Requirement:	3.5-9.5
--------------	---------

-	Unit	Result
Test Item(s)	-	I001
Test Method	-	II
Parameter	-	-
pH Value of Extracting Solution	-	5.50
Temp. of Aqueous Extract	deg. C	25.1
pH Value of Aqueous Extract	-	7.0
Difference Figure	-	-
Conclusion	-	PASS

Note / Key : deg. C = degree Celsius (°C) Temp. = Temperature

Remark: Result(s) was (were) reported the average value from two trials.
Tested part(s) was/were specified by client.

GUANGDONG KINGFA SCI.&TECH. CO., LTD
SATRA Reference: CHT0305029 /2047
Date: 10 December 2020

Signed: *Adam Zhang*
Technologist
China Testing

(Page 6 of 10)



TECHNICAL REPORT

Polycyclic Aromatic Hydrocarbons (PAHs) Content - EN ISO 21420:2020

Test Method : With reference to test method PD CEN ISO/TS 16190:2013

Maximum Allowable Limit:	Each of all listed PAHs: 1.0 mg/kg
---------------------------------	------------------------------------

Tested Item(s)	Result			Conclusion
	Detected Analyte(s)	Conc.	Unit	
I001	ND	ND	mg/kg	PASS

Note / Key : ND = Not detected(<Detection Limit) Detection Limit (mg/kg) : Each : 0.2;
mg/kg = milligram per kilogram = ppm = part per million

Remark: The list of polycyclic aromatic hydrocarbons is summarized in table of Appendix.
Tested part(s) was/were specified by client.

APPENDIX

List of Polynuclear Aromatic Hydrocarbons:

No.	Name of Analytes	CAS-No.	No.	Name of Analytes	CAS-No.
1	Chrysene	218-01-9	5	Dibenzo (a,h) anthracene	53-70-3
2	Benzo (a) pyrene	50-32-8	6	Benzo (b) fluoranthene	205-99-2
3	Benzo (e) pyrene	192-97-2	7	Benzo (j) fluoranthene	205-82-3
4	Benzo (a) anthracene	56-55-3	8	Benzo (k) fluoranthene	207-08-9

GUANGDONG KINGFA SCI.&TECH. CO., LTD
SATRA Reference: CHT0305029 /2047
Date: 10 December 2020

(Page 7 of 10)

Signed: *Adam Zhang*
Technologist
China Testing



TECHNICAL REPORT

Dimethylformamide(DMFA) Content - EN ISO 21420:2020

Test Method : With reference to EN 16778:2016, and then analyzed by Gas Chromatograph Mass Spectrometer.

Analyte	Unit	Result	Client's Requirement
		Test Item(s)	
		I001	
Dimethylformamide(DMFA)	mg/kg	ND	1000
Conclusion	-	PASS	-

Note / Key : ND = Not detected (<Detection Limit) Detection Limit (mg/kg) : 5
mg/kg = milligram per kilogram = ppm = part per million

*** End of Report ***



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DONGGUAN CITY
Guangdong Province
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523079

SATRA reference: CHM0305281/2047/EN
/A
Your reference: CHT0305029
Date of report: 23rd December 2020
Samples received: 20th November 2020
Date(s) work carried out: 23rd November to 16th December 2020

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:
Customer: GUANGDONG KINGFA SCI.&TECH. CO., LTD
NO.28 Delong Avenue, Shijiao Town
Qingcheng District
Qingyuan
Guangdong
China

Subject: EN 16523-1:2015+A1:2018 resistance to permeation by chemicals on gloves described as Disposable Powder Free Nitrile Examination Gloves, reference number: KG-1101

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

Tests marked # fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides a coverage probability of approximately 95%.

Report signed by: Emma Norris
Position: Technologist Team Leader
Department: Chemical & Analytical Technology

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TECHNICAL REPORT



WORK REQUESTED:

Samples of gloves described as Disposable Powder Free Nitrile Examination Gloves, reference number: KG-1101 were received on the 20th November 2020 for testing in accordance with EN 16523-1:2015+A1:2018 and assessment in accordance with the requirements of EN ISO 374-1:2016+A1:2018.

SAMPLES SUBMITTED:



Samples described as Disposable Powder Free Nitrile Examination Gloves, reference number: KG-1101

CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016+A1:2018 the samples of gloves described as Disposable Powder Free Nitrile Examination Gloves, reference number: KG-1101 achieved the following performance levels:

Chemical	Performance level
n-Heptane (CAS: 142-82-5)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
40% Sodium hydroxide (CAS: 1310-73-2)	6
30% Hydrogen peroxide (CAS: 7722-84-1)	2
37% Formaldehyde (CAS: 50-00-0)	6

Full results are reported in the following tables.

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SATRA Reference: CHM0305281/2047/EN/A
Date: 23rd December 2020 (Page 2 of 10)

Signed:



TECHNICAL REPORT



TESTING REQUIRED:

- EN 16523-1:2015+A1:2018 - Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact

RESULTS AND REQUIREMENTS:

EN ISO 374-1:2016+A1:2018 - Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks. Table 1: Permeation performance levels.

Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

Performance levels are based on the lowest individual result achieved per chemical.

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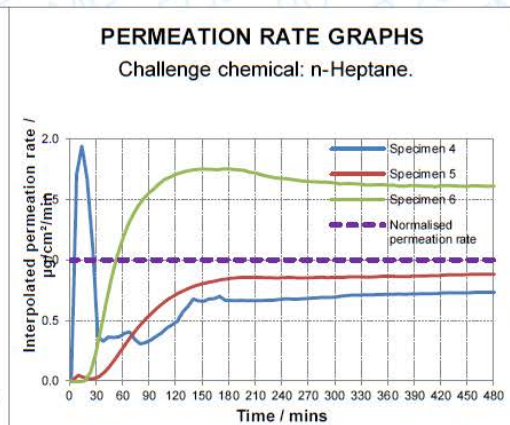
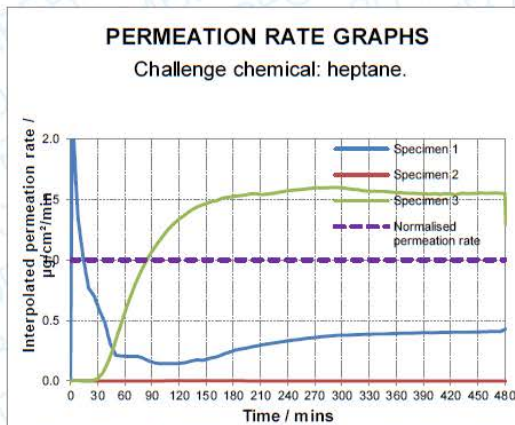
Signed:



TECHNICAL REPORT



Test/Property	Sample reference:	Disposable Powder Free Nitrile Examination Gloves, reference number: KG-1101		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-005 Using stainless steel permeation cells with standardised dimensions	Test information:	Chemical: n-heptane		The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique: GC-FID (periodic measurement)		
		Collection medium: Dry air (open loop)		
		Collection medium flow rate: 335 – 380 ml/min		
	Specimen	Test temperature: (23 ± 1) °C		
		Thickness (mm) ^Δ	Breakthrough time (mins) [▲]	
		1	<1	
		2	>480	
		3	84	
4		5		
5	>480			
6	52			
Test result:		<1		
UoM:		<1		
Visual appearance of specimens after testing:		Swollen		



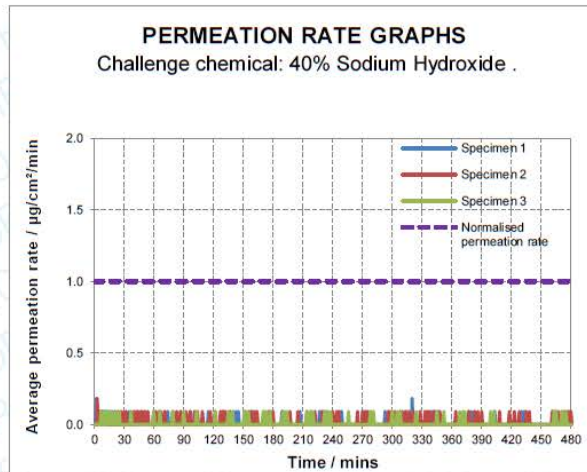
In accordance with clauses 8.5.1.2 and 8.5.1.4, the test results were outside the defined range and required an additional 3 specimens to be tested. All 6 results have been reported and the sample was found to not meet with the minimum breakthrough time for a performance level 1 to be achieved.



TECHNICAL REPORT



Test/Property	Sample reference:	Disposable Powder Free Nitrile Examination Gloves, reference number: KG-1101		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-009 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 40% Sodium hydroxide		Level 6
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique: Conductimetry (continuous measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature: (23 ± 1) °C		
	Specimen	Thickness (mm)^Δ	Breakthrough time (mins)	
	1	0.09	>480	
	2	0.09	>480	
	3	0.08	>480	
Test result:		>480		
UoM:		<1		
Visual appearance of specimens after testing:		No change		



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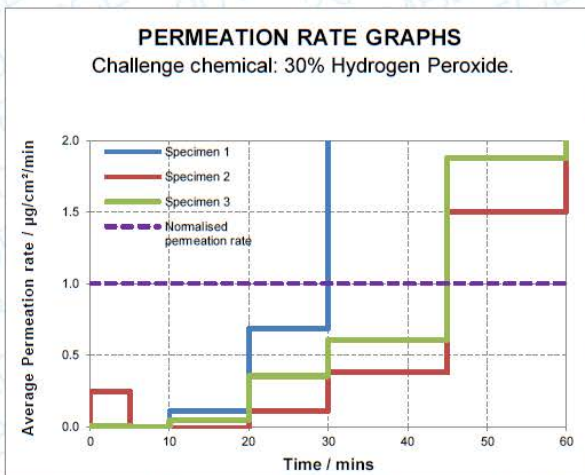


TECHNICAL REPORT



Test/Property	Sample reference:	Disposable Powder Free Nitrile Examination Gloves, reference number: KG-1101		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 30% Hydrogen peroxide		Level 2
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique: Electrochemical detector (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature: (23 ± 1) °C		
	Specimen	Thickness (mm)^Δ	Breakthrough time (mins)[▼]	
	1	0.10	Between 31 to 45	
	2	0.10	Between 46 to 60	
	3	0.09	Between 46 to 60	
	Test result:	Between 31 to 45		
	UoM:	See below		
Visual appearance of specimens after testing:	Swollen			

For SOP CAT-025, where both the P₁ and P₄ are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result.



Hydrogen peroxide is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

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Date: 23rd December 2020

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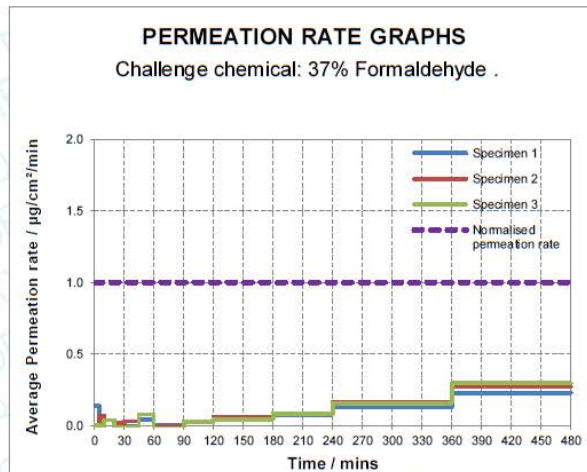
Signed:



TECHNICAL REPORT



Test/Property	Sample reference:	Disposable Powder Free Nitrile Examination Gloves, reference number: KG-1101		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 37% Formaldehyde		Level 6
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique: HPLC-DAD (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature: (23 ± 1) °C		
	Specimen	Thickness (mm)Δ	Breakthrough time (mins)▽	
	1	0.09	>480	
	2	0.09	>480	
	3	0.09	>480	
Test result:		>480		
UoM:		<1		
Visual appearance of specimens after testing:		Swollen and discoloured		



Formaldehyde is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.



TECHNICAL REPORT



- △ EN 16523-1:2015+A1:2018 does not require the test specimen thicknesses to be reported, this information is indicative only.
- ▲ The collection medium from each cell is analysed once every 6 minutes. Due to the complexity of the detection technique, the minimum sampling frequency for final results ≤ 60 minutes as specified in table 1 of EN 16523-1:2015+A1:2018 is not possible. Breakthrough time is calculated using linear interpolation between the discrete sampling points.
- ▼ Breakthrough expressed as a range between discrete sampling points where the average permeation rate exceeds the NPR. Due to the complexity of the detection technique, the minimum sampling frequency as specified in table 1 of EN 16523-1:2015+A1:2018 is not possible.

TECHNOLOGY

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Date: 23rd December 2020

Signed:

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SATRA reference: CHM0305281/2047/EN
/B
Your reference: CHT0305029
Date of report: 23rd December 2020
Samples received: 20th November 2020
Date(s) work carried out: 21st to 22nd December 2020

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:
Customer: GUANGDONG KINGFA SCI.&TECH. CO., LTD
NO.28 Delong Avenue, Shijiao Town
Qingcheng District
Qingyuan
Guangdong
China

Subject: EN ISO 374-4:2019 determination of resistance to degradation by dangerous chemicals on gloves described as Disposable Powder Free Nitrile Examination Gloves, reference number: KG-1101.

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

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A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides a coverage probability of approximately 95%.

Report signed by: Emma Norris
Position: Technologist Team Leader
Department: Chemical & Analytical Technology

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TECHNICAL REPORT



WORK REQUESTED:

Samples of gloves described as Disposable Powder Free Nitrile Examination Gloves, reference number: KG-1101 were received on the 20th November 2020 for testing in accordance with EN ISO 374-4:2019.

SAMPLE SUBMITTED:



Samples described as Disposable Powder Free Nitrile Examination Gloves, reference number: KG-1101

CONCLUSION:

When assessed in accordance with EN ISO 374-4:2019 the samples of gloves described as Disposable Powder Free Nitrile Examination Gloves, reference number: KG-1101 achieved the following degradation results:

Chemical	Mean degradation / %
n-Heptane (CAS: 142-82-5)	44.6
40% Sodium hydroxide (CAS: 1310-73-2)	-5.9
30% Hydrogen peroxide (CAS: 7722-84-1)	36.4
37% Formaldehyde (CAS: 50-00-0)	-3.1

TESTING REQUIRED:

- EN ISO 374-4:2019. Protective gloves against dangerous chemicals and micro-organisms. Part 4: Determination of resistance to degradation by chemicals.

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Signed: 



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RESULTS:

Sample description:	Disposable Powder Free Nitrile Examination Gloves, reference number: KG-1101		
Challenge chemical:	n-Heptane (CAS: 142-82-5)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	36.1	45.7	51.9
Mean degradation (DR) / %:	44.6		
Standard deviation (σ_{DR}) / %:	8.0		
UoM / ± %:	12.6		
Appearance of samples after testing:	No change		

Sample description:	Disposable Powder Free Nitrile Examination Gloves, reference number: KG-1101		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-1.5	-8.6	-7.7
Mean degradation (DR) / %:	-5.9		
Standard deviation (σ_{DR}) / %:	3.9		
UoM / ± %:	9.3		
Appearance of samples after testing:	No change		

Sample description:	Disposable Powder Free Nitrile Examination Gloves, reference number: KG-1101		
Challenge chemical:	30% Hydrogen peroxide (CAS: 7722-84-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	34.0	36.1	39.1
Mean degradation (DR) / %:	36.4		
Standard deviation (σ_{DR}) / %:	2.6		
UoM / ± %:	11.6		
Appearance of samples after testing:	No change		

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Date: 23rd December 2020

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Sample description:	Disposable Powder Free Nitrile Examination Gloves, reference number: KG-1101		
Challenge chemical:	37% Formaldehyde (CAS: 50-00-0)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	6.9	-13.7	-2.3
Mean degradation (DR) / %:	-3.1		
Standard deviation (σ_{DR}) / %:	10.4		
UoM / ± %:	9.3		
Appearance of samples after testing:	No change		

NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

SATRA Technology Services (Dongguan) Ltd
SATRA Reference: CHM0305281/2047/EN/B
Date: 23rd December 2020

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Signed:

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P R O T E C T I N G P E O P L E

Contact your KINGFA representative for more information

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