

NITRILE GLOVE

KS-ST RT021



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.

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: KS-ST RT021



Chemical	Letter	Level
	K	6
Type	C	

FEATURE

- Fingertip textured
- Powder Free
- Latex Free
- Multifunctional
- Blue colour

APPLICATION

The disposable nitrile gloves are designed for the health care personnel to prevent contamination during close contact with the patient. The products are single-use, powder-free and non-sterile.

STANDARD COMPLIANCE

PPE Cat III

according to Regulation (EU) 2016/425
 EN ISO 21420:2020 Protective gloves — General requirements and test methods
 EN ISO 374-1: 2016 Terminology and performance requirements for chemical risks
 EN 374-2:2014: Determination of resistance to penetration
 EN 16523-1:2015+A1:2018 Permeation by potentially hazardous liquid chemicals under conditions of continuous contact
 EN ISO 374-4:2019 Determination of resistance to degradation by chemicals
 EN ISO 374-5:2016 Terminology and performance requirements for microorganisms risks

Medical Device Class I

EN 455-1: Requirements and testing for freedom from holes
 EN 455-2: Requirements and testing for physical properties
 EN 455-3: Requirements and testing for biological evaluation
 EN 455-4: Requirements and testing for shelf life determination

Food contact approved



EN ISO 374-1:
2016/Type C



VIRUS
ISO 374-5:2016



EN ISO 21420









NON
STERILE



LATEX
FREE



AQL
1.5

Package Components

EN 374

Exterior Package Design

- Size: 225*120*63 mm
- Gross weight: 460±10 g



Carton Package Design

- 10 boxes/carton
- Size: 330*250*240 mm
- Gross weight: 4950±500 g



Container Loading

(For Reference Only/
Without Pallets)

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

STORAGE INSTRUCTIONS



Package Components EN 455

Exterior Package Design

- Size: 225*120*63 mm
- Gross weight: 460±10 g



100
units



Carton Package Design

- 10 boxes/carton
- Size: 330*250*240 mm
- Gross weight: 4950±500 g



1000
units



Container Loading

(For Reference Only/
Without Pallets)

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

STORAGE INSTRUCTIONS



TEST REPORT

EN 455 1-3

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



PSB Singapore

Add value.
Inspire trust.

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



Laboratory:
TÜV SÜD PSB Pte. Ltd.
TÜV SÜD @ IBP
15 International Business Park
Singapore 609937

Phone : +65-6778 7777
E-mail: info.sg@tuvsud.com
https://www.tuvsud.com/en-sg
Co. Reg : 199002667R

Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
TÜV SÜD @ IBP
15 International Business Park
Singapore 609937
TUV®

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



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



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

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

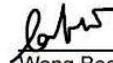


PSB Singapore

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

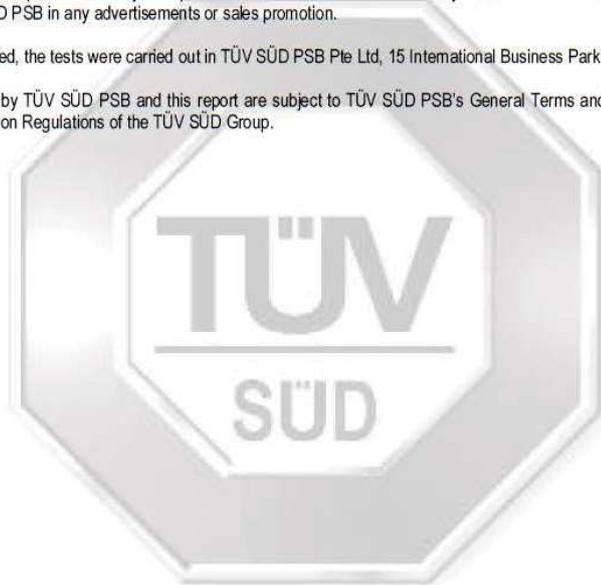
Test Report No. 7191250395-EEC21-WBH
dated 07 Jan 2021



Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.
2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.
3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.
4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.
5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, 15 International Business Park Singapore 609937.
6. The tests carried out by TÜV SÜD PSB and this report are subject to TÜV SÜD PSB's General Terms and Conditions of Business and the Testing and Certification Regulations of the TÜV SÜD Group.

Effective 01 January 2021



TEST REPORT

EN 455-4



中国认可
国际互认
检测
TESTING
CNAS L2954

Final Report

Report Number: SDWH-M202005587-1(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

Website: www.sudatest.com

Direct: +86 512 65880038

E-mail: med@sudatest.com

Free: 400 107 8828

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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 Changyuan

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,Qingyuan,Guangdong,China
Model	KS-ST RT021
Lot/Batch	25007018/25007019/25007020

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 F1980-16)

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-M202005587-1.

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 F1980-16)

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	KS-ST RT021
Size	M
Lot/Batch	25007018/25007019/25007020
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 to 35)°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: 25007018)

	The Results (Zero-time)	The Results (1 year Aged)	The Results (3 years Aged)
Sample Number of	50 Gloves	50 Gloves	50 Gloves
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: 25007019)

	The Results (Zero-time)	The Results (1 year Aged)	The Results (3 years Aged)
Sample Number of	50 Gloves	50 Gloves	50 Gloves
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: 25007020)

	The Results (Zero-time)	The Results (1 year Aged)	The Results (3 years Aged)
Sample Number of	50 Gloves	50 Gloves	50 Gloves
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: 25007018)

No.	Force at break (Zero-time) N	Force at break (1 year Aged) N	Force at break (3 years Aged) N
1	8.49	7.79	10.00
2	5.29	9.33	9.19
3	8.55	8.63	8.67
4	8.46	8.41	9.92
5	7.66	6.73	10.05
6	8.92	9.75	9.02
7	8.29	9.16	8.09
8	8.04	6.15	5.35
9	6.36	6.89	10.11
10	9.67	8.62	7.54
11	5.07	9.17	8.50
12	5.81	9.02	8.50
13	7.35	6.21	8.90
Median	8.04	8.62	8.90
Criteria	≥6.0	≥6.0	≥6.0
Conclusion	Acceptable	Acceptable	Acceptable

Table 5 The results of physical property test (Lot/ Batch: 25007019)

No.	Force at break (Zero-time) N	Force at break (1 year Aged) N	Force at break (3 years Aged) N
1	6.68	10.76	8.47
2	9.72	10.34	8.99
3	7.35	11.02	8.58
4	8.34	8.95	9.68
5	10.38	9.58	7.68
6	9.13	8.71	12.10
7	12.43	9.37	10.29
8	10.22	9.53	10.76
9	9.35	8.47	6.92
10	11.68	7.56	7.98
11	5.36	8.12	12.27
12	7.94	8.40	11.12
13	9.49	7.20	8.49
Median	9.35	8.95	8.99
Criteria	≥6.0	≥6.0	≥6.0
Conclusion	Acceptable	Acceptable	Acceptable

Table 6 The results of physical property test (Lot/ Batch: 25007020)

No.	Force at break (Zero-time) N	Force at break (1 year Aged) N	Force at break (3 years Aged) N
1	5.57	8.71	10.76
2	7.98	9.94	10.53
3	11.91	9.89	9.24
4	10.40	9.55	5.56
5	11.69	9.94	9.12
6	10.11	7.98	9.72
7	8.47	9.05	11.07
8	10.16	9.21	12.34
9	5.39	10.20	8.07
10	7.96	10.63	11.95
11	6.64	9.64	9.42
12	7.48	9.03	7.12
13	7.52	8.38	7.77
Median	7.98	9.55	9.42
Criteria	≥6.0	≥6.0	≥6.0
Conclusion	Acceptable	Acceptable	Acceptable

Annex 2 Photograph of Test Article



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 1186

Test Report No.: 68.431.21.0029.01
Dated: 2021-03-03



Applicant : GUANGDONG KINGFA SCI.&TECH. CO., LTD.
NO.28 Delong Avenue, Shijiao Town, Qingcheng District,
Qingyuan City, Guangdong Province, China

Sample Description : Nitrile gloves

Style No. / Name / Design No. : KS-ST RT021

Supplier/Manufacturer : GUANGDONG KINGFA SCI.&TECH. CO., LTD.

Test Sample Receipt Date, Location : 2021-02-04, Shenzhen

Test Period, Location : From 2021-02-04 to 2021-03-02, Shenzhen

Test Result(s) : Refer to Section 3



Test Report No.: 68.431.21.0029.01
Dated: 2021-03-03



Purpose Of Examination / Conclusion:

Test Requested:	As specified by client, to test per the selected requirement(s) for the tested item(s) as stated in the Regulation (EC) No.1935/2004
------------------------	---

No.	Test Item(s)	Conclusion
1.	Overall Migration	Pass

Remarks:

- (1) The results relate only to the items tested.
- (2) Samples are tested as received.
- (3) The test item and samples were specified by the client
- (4) "Pass" means the measured result is within a limit, even when extended by expanded uncertainty. "Fail" means the measured result is beyond a limit, even when extended by expanded uncertainty. "Inconclusive" means the measured result can be within or beyond a limit when extended by expanded uncertainty. The confidence level of the expanded uncertainty for "Pass", "Fail" and "Inconclusive" is 95%.

TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch
TÜV SÜD Group

Prepared by:

Simon

Simon Liu
Project Engineer

Reviewed by:

Angelina Wang

Angelina Wang
Supervisor



Any use for advertising purposes must be granted in writing. This technical report may only be quoted in full. This report is the result of a single examination of the object in question and is not generally applicable evaluation of the quality of other products in regular production. For further details, please see testing and certification regulation, chapter A-3.4.

Test Report No.: 68.431.21.0029.01
Dated: 2021-03-03



1. Description of the Test Sample:

Sample Description	Nitrile gloves
---------------------------	----------------

2. List of Materials as identified by the Laboratory:

T. No.	Sample No.	Colour and Description	Photograph
T1	001	Blue NBR rubber (Glove)	



Laboratory:
 TÜV SÜD Certification and
 Testing (China) Co., Ltd.
 Shenzhen Branch

Phone : +86 755 8828 6998
 Fax: +86 755 8828 5299
 E-mail: info@tuvsud.com
 Web : http://www.tuvsud.cn

Regd. Office:
 TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch
 Building 12&13, Zhiheng Wisdomland Business Park,
 Nantou Checkpoint Road 2, 518052, P. R. China



Test Report No.: 68.431.21.0029.01

Dated: 2021-03-03

3. Test Result

3.1 Overall Migration

Test method: As specified in Regulation (EU) No. 10/2011 ANNEX III and V then test with reference to:

EN 1186-1:2002(Guide to the selection of conditions and test methods for overall migration)

EN 1186-2:2002(Oil by Total Immersion method)

EN 1186-3:2002(Total Immersion method)

SIMULANT USED	TEST CONDITIONS	RESULT [mg/dm ²]			MAXIMUM PERMISSIBLE LIMIT [mg/dm ²]
		SAMPLE 001 1 st Migration	SAMPLE 001 2 nd Migration	SAMPLE 001 3 rd Migration	
3% Acetic acid	40°C for 2 Hours	<3	<3	<3	3 rd migration: 10, 3 rd < 2 nd < 1 st :
10% Ethanol	40°C for 2 Hours	<3	<3	<3	
Rectified olive oil	40°C for 2 Hours	4.1	<3	<3	

SIMULANT USED	TEST CONDITIONS	RESULT [mg/dm ²]			MAXIMUM PERMISSIBLE LIMIT [mg/dm ²]
		SAMPLE 001 1 st Migration	SAMPLE 001 2 nd Migration	SAMPLE 001 3 rd Migration	
3% Acetic acid	70°C for 2 Hours	<3	<3	<3	3 rd migration: 10, 3 rd < 2 nd < 1 st :
10% Ethanol	70°C for 2 Hours	<3	<3	<3	
Rectified olive oil	70°C for 2 Hours	5.8	<3	<3	

Note 1. "°C" denotes degree Celsius

2. "<" denotes less than

3. "mg/dm²" denotes milligram per square decimeter

4. The specification was quoted from Regulation (EU) No. 10/2011 and its amendment (EU) No. 2020/1245.

-- END OF TEST REPORT--

TEST REPORT

EN ISO 374 1-5



SATRA Technology Services (Dongguan) Ltd
Unit 110, Xinzhongyin Garden, Xiping
Nancheng District, Dongguan City
Guangdong Province, China
Tel: +86 (0) 769 22888020
email: info@satrafe.com

Customer details: Guangdong Kingfa Sci. & Tech. Co., Ltd
NO.28 DeLong Avenue
Shijiao Town
Qingcheng District
Qingyuan City
Guangdong Province
China

SATRA reference: CHT0305236 /2047/
Issue 2

Your reference: KS-ST RT021

Date of report: 29 January 2021

Samples received: 20 November 2020

Date(s) work carried out: 23 November 2020 to
1 December 2020

TECHNICAL REPORT

(This report replaces the technical report of CHT0305236 /2047 issued on 10 December 2020)

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: KS-ST RT021.

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.

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 9)



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: KS-ST RT021 were received by SATRA on 20 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: KS-ST RT021

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: KS-ST RT021 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
		6	242	243	245		
		7	250	245	245		
		8	245	240	244		
		9	247	245	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	3.0 kPa	N/A	Pass
	Sample size	Leaks		
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		
7.3 Water leak test	9	No leaks detected	N/A	Pass
	Sample size	Leaks		
	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 20R006813. 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

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		1	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
Using retaining screen		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 A201123020001. The laboratory is CNAS accredited to ISO 17025: 2017.

Sample Item	Sample Description	Location	Style
I001	KS-ST RT021 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
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-	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	-	6.7
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.



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

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 ***



SATRA Technology Centre Ltd
Wyndham Way, Telford Way, Kettering,
Northamptonshire, NN16 8SD United Kingdom
Tel: +44 (0) 1536 410000
Fax +44 (0) 1536 410626
email: info@satra.com
www.satra.com



Customer details: SATRA Technology Services (Dongguan) Ltd SATRA reference: CHM0305368/2048/LC
Unit 110, Xinzhongyin Garden /B
Hongwei Road Your reference: CHT0305236
Xiping, Nancheng District
DONGGUAN CITY Date of report: 21st December 2020
Guangdong Province Samples received: 23rd November 2020
China Date(s) work carried out: 16th to 21st December 2020
523079

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, Color: Blue, Reference number: KS-ST RT021.

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: Lucy Cove
Position: Technologist
Department: Chemical & Analytical Technology

(Page 1 of 5)



TECHNICAL REPORT



WORK REQUESTED:

Samples of gloves described as Disposable Powder Free Nitrile Examination Gloves, Color: Blue, Reference number: KS-ST RT021 were received on the 23rd November 2020 for testing in accordance with EN ISO 374-4:2019.

SAMPLE SUBMITTED:



Sample described as Disposable Powder Free Nitrile Examination Gloves, Color: Blue, Reference number: KS-ST RT021.

CONCLUSION:

When assessed in accordance with EN ISO 374-4:2019 the samples of gloves described as Disposable Powder Free Nitrile Examination Gloves, Color: Blue, Reference number: KS-ST RT021 achieved the following degradation results:

Chemical	Mean degradation / %
40% Sodium hydroxide (CAS: 1310-73-2)	-65.6

TESTING REQUIRED:

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



TECHNICAL REPORT



RESULTS:

Sample description:	Disposable Powder Free Nitrile Examination Gloves, Color: Blue, Reference number: KS-ST RT021		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-56.0	-61.2	-79.5
Mean degradation (DR) / %:	-65.6		
Standard deviation (σ_{DR}) / %:	12.4		
UoM / ± %:	9.1		
Appearance of samples after testing:	No change		

NOTE: Lining materials were removed from the specimen in order to perform the test.



SATRA Technology Centre Ltd
Wyndham Way, Telford Way, Kettering,
Northamptonshire, NN16 8SD United Kingdom
Tel: +44 (0) 1536 410000
Fax +44 (0) 1536 410626
email: info@satra.com
www.satra.com



0248

Customer details: SATRA Technology Services (Dongguan) Ltd SATRA reference: CHM0305368/2048/LC
Unit 110, Xinzhongyin Garden /A
Hongwei Road Your reference: CHT0305236
Xiping, Nancheng District
DONGGUAN CITY
Guangdong Province
China
523079
Date of report: 21st December 2020
Samples received: 23rd November 2020
Date(s) work carried out: 4th to 8th 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, Color: Blue, Reference number: KS-ST RT021.

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.

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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: Lucy Cove
Position: Technologist
Department: Chemical & Analytical Technology

(Page 1 of 6)



TECHNICAL REPORT



WORK REQUESTED:

Samples of gloves described as Disposable Powder Free Nitrile Examination Gloves, Color: Blue, Reference number: KS-ST RT021 were received on the 23rd 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, Color: Blue, Reference number: KS-ST RT021

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, Color: Blue, Reference number: KS-ST RT021 achieved the following performance levels:

Chemical	Performance level
40% Sodium hydroxide (CAS: 1310-73-2)	6

Full results are reported in the following tables.

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

SATRA Technology Services (Dongguan) Ltd
SATRA Reference: CHM0305368/2048/LC/A
Date: 21st December 2020

(Page 2 of 6)

Signed:



TECHNICAL REPORT



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

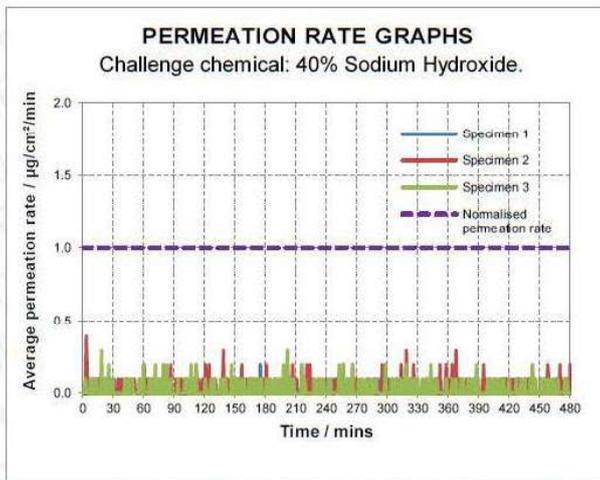
Performance levels are based on the lowest individual result achieved per chemical.



TECHNICAL REPORT



Test/Property	Sample reference:	Disposable Powder Free Nitrile Examination Gloves, Color: Blue, Reference number: KS-ST RT021		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)△	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:		Discoloured		



△ EN 16523-1:2015+A1:2018 does not require the test specimen thicknesses to be reported, this information is indicative only.

EU-Type-Examination Certificate

Notified Body 2777

		Issued to:	Guangdong Kingfa Sci. & Tech. Co., Ltd NO.28 Delong Avenue Shijiao Town Qingcheng District Qingyuan City Guangdong Province 511500 China									
Notified Body: 2777	SATRA customer number: P21017											
<h3>EU Type-Examination Certificate</h3>												
Certificate number: 2777/15747-02/E00-00												
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.												
Product reference: KS-ST RT021	Description: Disposable Nitrile Glove, Powder-Free											
	Colour: Blue											
Sizes: 6/S, 7/M, 8/L, 9/XL	Classification: <table border="0"> <tr> <td>EN ISO 374-1:2016+A1:2018 /Type C 40% Sodium Hydroxide (K)</td> <td>Level 6</td> <td>EN ISO 374-4:2019 Degradation % -65.6</td> </tr> <tr> <td>EN ISO 374-5:2016 Protection against Bacteria and Fungi</td> <td>Pass</td> <td></td> </tr> <tr> <td>Protection against Viruses</td> <td>Pass</td> <td></td> </tr> </table>			EN ISO 374-1:2016+A1:2018 /Type C 40% Sodium Hydroxide (K)	Level 6	EN ISO 374-4:2019 Degradation % -65.6	EN ISO 374-5:2016 Protection against Bacteria and Fungi	Pass		Protection against Viruses	Pass	
EN ISO 374-1:2016+A1:2018 /Type C 40% Sodium Hydroxide (K)	Level 6	EN ISO 374-4:2019 Degradation % -65.6										
EN ISO 374-5:2016 Protection against Bacteria and Fungi	Pass											
Protection against Viruses	Pass											
Standards/Technical specifications applied: EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016												
Technical reports/Approval documents: SATRA: CHT0305236/2047/Issue 2, CHM0305368/2048/LC/A, CHM0305368/2048/LC/B												
Signed on behalf of SATRA:		Quincey Brown	Date first issued: 08/02/2021 Date of issue: 19/02/2021 Expiry date: 08/02/2026									
			Page 1 of 2									

TEST REPORT

ISO 10993-10:2010



中国认可
国际互认
检测
TESTING
CNAS L2954

Amendment Report

Report Number: SDWH-M202004118-2(E) Amd01
(Replace SDWH- M202004118-2 (E))

Skin Sensitization Test of Single-use medical rubber examination gloves

According to ISO 10993-10:2010
Guinea Pig Maximization Test
0.9% Sodium Chloride Injection Extract

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

Website: www.sudatest.com

Direct: +86 512 65880038

E-mail: med@sudatest.com

Free: 400 107 8828

Summary

1 Test Article

Test Article Name	Single-use medical rubber examination gloves
Manufacturer	GUANG DONG KINGFA SCI.& TECH.CO.,LTD
Address	No.28 Delong Ave.,Shijiao Town,Qingcheng District,Qing yuan,Guangdong,China
Model	KS-ST RT021
Lot/Batch	25007011

2 Main Reference

ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization

3 Test Method

Potential skin sensitization of test article was evaluated using guinea pig maximization test in accordance with ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization.

Study protocol number: SDWH-PROTOCOL-GLP-M202004118-2.

4 Conclusion

Under the conditions of this study, the test article extract showed no significant evidence of causing skin sensitization in the guinea pig. The positive rate of sensitization was 0%. No evidence of skin sensitization in guinea pigs was found.

TEST REPORT

ISO 10993-10:2010



中国认可
国际互认
检测
TESTING
CNAS L2954

Amendment Report

Report Number: SDWH-M202004118-3(E) Amd01
(Replace SDWH- M202004118-3 (E))

Skin Sensitization Test of Single-use medical rubber examination gloves

According to ISO 10993-10:2010
Guinea Pig Maximization Test
Sesame Oil Extract

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

Website: www.sudatest.com

Direct: +86 512 65880038

E-mail: med@sudatest.com

Free: 400 107 8828



Summary

1 Test Article

Test Article Name	Single-use medical rubber examination gloves
Manufacturer	GUANG DONG KINGFA SCI.& TECH.CO.,LTD
Address	No.28 Delong Ave.,Shijiao Town,Qingcheng District,Qing yuan,Guangdong,China
Model	KS-ST RT021
Lot/Batch	25007011

2 Main Reference

ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization

3 Test Method

Potential skin sensitization of test article was evaluated using guinea pig maximization test in accordance with ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization.

Study protocol number: SDWH-PROTOCOL-GLP-M202004118-3.

4 Conclusion

Under the conditions of this study, the test article extract showed no significant evidence of causing skin sensitization in the guinea pig. The positive rate of sensitization was 0%. No evidence of skin sensitization in guinea pigs was found.

TEST REPORT

ISO 10993-10:2010



中国认可
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检测
TESTING
CNAS L2954

Amendment Report

Report Number: SDWH-M202004118-4(E) Amd01
(Replace SDWH- M202004118-4 (E))

Skin Irritation Test of Single-use medical rubber examination gloves

According to ISO 10993-10:2010
0.9% Sodium Chloride Injection Extract

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

Website: www.sudatest.com

Direct: +86 512 65880038

E-mail: med@sudatest.com

Free: 400 107 8828



Summary

1 Test Article

Test Article Name	Single-use medical rubber examination gloves
Manufacturer	GUANG DONG KINGFA SCI.& TECH.CO.,LTD
Address	No.28 DeLong Ave.,Shijiao Town,Qingcheng District,Qingyuan,Guangdong,China
Model	KS-ST RT021
Lot/Batch	25007011

2 Main Reference

ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization

3 Test Method

The extract of test article was evaluated for skin irritation. With ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization.
Study protocol number: SDWH-PROTOCOL- GLP-M202004118-4.

4 Conclusion

The test result showed that the response of the test article extract was categorized as negligible under the test condition.

TEST REPORT

ISO 10993-10:2010



中国认可
国际互认
检测
TESTING
CNAS L2954

Amendment Report

Report Number: SDWH-M202004118-5(E) Amd01
(Replace SDWH- M202004118-5 (E))

Skin Irritation Test of Single-use medical rubber examination gloves

According to ISO 10993-10:2010
Sesame Oil Extract

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

Website: www.sudatest.com

Direct: +86 512 65880038

E-mail: med@sudatest.com

Free: 400 107 8828



Summary

1 Test Article

Test Article Name	Single-use medical rubber examination gloves
Manufacturer	GUANG DONG KINGFA SCI.& TECH.CO.,LTD
Address	No.28 DeLong Ave.,Shijiao Town,Qingcheng District,Qingyuan,Guangdong,China
Model	KS-ST RT021
Lot/Batch	25007011

2 Main Reference

ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization

3 Test Method

The extract of test article was evaluated for skin irritation. With ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization.
Study protocol number: SDWH-PROTOCOL- GLP-M202004118-5.

4 Conclusion

The test result showed that the response of the test article extract was categorized as negligible under the test condition.