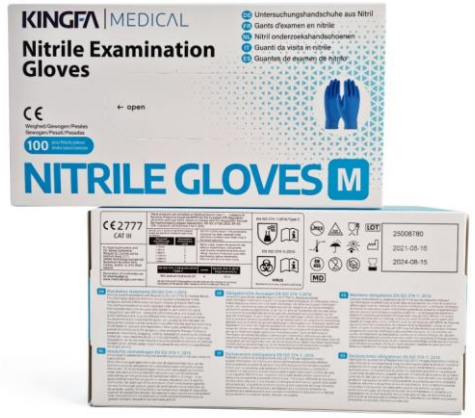
Technical Sheet



Product: KingFa Medical - Nitrile Examination Gloves
Manufacturer:
EC REP:

Product Description

Description

KINGFA MEDICAL nitrile examination gloves are intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Areas of use

- Hospitals, Laboratories, Clinics
- Health Care
- Dentistry and veterinary applications
- Food production and processing
- Cosmetics Industry

Features

- Powder free/Latex free
- Excellent mechanical strength provides
- a high level of hand protection.
- Comfortable fit with textured fingertips
- for excellent tactile sensitivity.
- Protection against bacteria and fungi
- Skin irritation & sensitization tested

Regulatory Compliance

- 21 U.S.C. ch.9
- EU 2017/745
- EU 2016/425
- REACH
- EC 10/2011
- EC 1935/2004

PRODUCT INFORMATION

Material			100%Nitrile, Sulphur and Pigments
Grade			Medical Grade
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)			0.06±0.02/2.4±0.8
Finger thickness (mm/mil)			0.1±0.02/4.0±0.8
Physical Requirement (median value)	Before Aging	Breakage Force(N)	⩾ 6N
	After Aging	Breakage Force(N)	⩾ 6N
Application Temperature			⩽ 40°C
Shelf Life			3 Years

Size	Median Length (mm)	Median Width (mm)	Unit Weight (gram)
S	⩾ 240	80±10	3.5±0.3
M	⩾ 240	95±10	3.7±0.3
L	⩾ 240	110±10	4.0±0.3
XL	⩾ 240	⩾ 110	4.3±0.3

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PROTECTING PEOPLE

EU DECLARATION OF CONFORMITY

We, the manufacturer,

GUANGDONG KINGFA SCI.&TECH. CO., LTD.
NO.28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
SRN: CN-MF-000009520

declare under our sole responsibility that following CE marked products,
Nitrile examination gloves

Sizes	XS	S	M	L	XL
Basic UDI –DI: 697316340KS-STRT021D9					
Intended Purpose: The nitrile examination gloves are intended to be worn on the hands of health care and similar personnel to prevent contamination between health care personnel and the patient's body.This is a single-use, powder-free, non-sterile device.					

KS-ST RT021

all belong to

- Class I according to Annex VIII of the Regulation (EU)2017/745 on medical devices
- Category III according to the Regulation (EU) 2016/425 on personal protective equipment

to which this declaration relates,are in conformity with Regulation (EU)2017/745 on medical devices as well as of the Regulation (EU) 2016/425 on personal protective equipment ,and with following harmonized standards and common specifications:

EN ISO 13485 :2016 Medical devices — quality management systems — requirements for regulatory purposes
EN ISO 14971 :2019 Medical devices — application of risk management to medical devices
EN 1041 :2008 Information supplied by the manufacturer of medical devices
EN ISO 15223-1 :2016 Medical devices — symbols to be used with medical device labels, labelling and information to be supplied — part 1: general requirements
EN 455-1:2020 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes

KINGFA | MEDICAL
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EN 455-2:2015 Medical gloves for single use - Part 2: Requirements and testing for physical properties
EN 455-3:2015 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
EN 455-4: 2009 Medical gloves for single use - Part 4: Requirements and testing for shelf life determination
EN ISO 21420 :2020 Protective gloves — general requirements and test methods
EN ISO 374-1 :2016+A1 :2018 Protective gloves against dangerous chemicals and micro-organisms — Part 1: Terminology and performance requirements for chemical risks
EN ISO 374-5 :2016 Protective gloves against dangerous chemicals and micro-organisms — Part 5: Terminology and performance requirements for micro-organisms risks

The products are subject to the conformity assessment procedure conformity to type based on Module C2 under the surveillance of the notified body 2777 SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin D15 YN2p Ireland, and issued the EU Type Examination Certificate No. 2777/15747-02/E00-00.Type C glove according to EN ISO 374-1 :2016.

Place and date of issue: Qingyuan, China 2021-08-31

Name and signature of authorized person:

Linanjing
General Manager

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.:	SX 2136111-1
Organization:	GuangDong Kingfa Science and Technology Co., Ltd. No. 28, Delong Road, Qingcheng Dist., Shijiao Town, Qingyuan City, 511545 Guangdong P.R. China
Scope:	Design and Development, Manufacture and Distribution of Disposable Medical Face Masks (non-sterile), Disposable Medical Gloves (non-sterile)

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	10918575-100
Effective date:	2021-06-04
Expiry date:	2023-07-12
Issue date:	2021-06-04

TÜV Rheinland LGA Products GmbH

Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

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

EU Type-Examination Certificate

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:

EN ISO 374-1:2016+A1:2018 /Type C	**Level**	**EN ISO 374-4:2019 Degradation %**
40% Sodium Hydroxide (K)	6	-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

PPE REGULATION (EU) 2016/425
MODULE C2 CERTIFICATE

Issued to:

Guangdong Kingfa Sci. & Tech. Co., Ltd
NO.28 Delong Avenue
Shijiao Town
Qingcheng District
Qingyuan City
Guangdong Province
China
511500

This is to certify that the following products tested under SATRA reports referenced: STE0310718 & CHM0311673/2115/LH have been found to satisfy the requirement of PPE Regulation (EU) 2016/425 Module C2 EU quality control system for the final product for and on behalf of SATRA Technology Europe Limited

EU TYPE EXAMINATION CERTIFICATE NUMBER	PRODUCT GROUP REFERENCE	PRODUCT TYPE	CLASSIFICATION
2777/15747-02/E00-00	KS-ST RT021	Disposable Nitrile Glove Powder free	EN ISO 374-1:2016+A1:2018 Type C & EN ISO 374-5:2016

Dated: 21st May 2021

This certificate is valid until: *May 2022*

Signed By (Alan Weston)

For and on behalf of SATRA Technology Europe Limited

The issuance of this certificate is subject to the company maintaining its manufacturing and quality system to the required standard.
SATRA Technology Europe Limited. Bracetown Business Park Clonee Dublin 15 D15 YN2P. Republic of Ireland.
(Notified Body number 2777)
Tel: +353 (0) 1 437 2484 Web: www.satraeurope.com

认证证书

标准	**ISO 9001:2015**
证书登记号码	**01 100 1430282**

证书持有者：

广东金发科技有限公司
统一社会信用代码：91441802077867032A
注册地址：
中国广东省清远市清城区石角镇德龙大道 28 号
邮编：511545
经营地址：同上述地址

认证范围：

改性塑料的设计和生产；
口罩、自吸过滤式防颗粒物呼吸器、防护服、手套、湿巾、卫生湿巾、化妆棉（纸、巾）、非织造布的设计和生产

证明完成了审核并满足了 ISO 9001:2015 标准的要求。

有效期：

证书有效期从 2021-07-09 至 2023-07-18。
此证书须经过符合要求的监督审核保持有效。
初次发证始于 2014 年
本证书信息可在国家认证认可监督管理委员会官方网站上查询
http://www.cnca.gov.cn

2021-07-09

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Certificate

Standard	**ISO 9001:2015**
Certificate Registr. No.	**01 100 1430282**

Certificate Holder:

GuangDong Kingfa Science and Technology Co., Ltd.
Unified Social Credit Code: 91441802077867032A
Registration Address:
No. 28, Delong Road, Qingcheng Dist., Shijiao Town, Qingyuan City, 511545 Guangdong, P.R. China
Operation Address: same as above

Scope:

Design and Manufacturing of Modified Plastics;
Design and Manufacturing of Masks, Non-powered Air-purifying Particle Respirator, Protective Coverall, Gloves, Wet Wipes, Sanitary Wet Wipes, Cotton Pad (Paper, Towels) and Non-Woven Fabric

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity:

The certificate is valid from 2021-07-09 until 2023-07-18.
It remains valid subject to satisfactory surveillance audits.
First certification 2014
This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2021-07-09

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

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中国认可
国际互认
检测
TESTING
CNAS L2954

Final Report

Report Number: 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,Qingyuan,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 E-mail: med@sudatest.com
Direct: +86 512 65880038 Free: 400 107 8828

Quality Assurance Statement

The Quality Assurance Unit inspected/audited this study in compliance with the following GLP regulations:
Good Laboratory Practice (GLP) Regulation 21 CFR Part 58, U.S. Food and Drug Administration (FDA). The laboratory is exempt from the following provisions: 21 CFR Part 58.105 Test and Control Article Characterization, and Part 58.113 Mixtures of Articles with Carriers.

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to the Testing Facility Management. The final report was reviewed by the Quality Assurance Unit. The final report accurately describes the test methods in accordance with standard operating procedures, and the results are consistent with raw data of non-clinical studies conducted according to the study protocol.

Inspections	Date of Inspection	Date Reported to Study Director	Date Reported to Testing Facility Management.
Study Protocol	2020-08-07	2020-08-07	2020-09-08
Study Procedure	2020-08-07	2020-08-07	2020-09-08
Raw Data	2020-09-08	2020-09-08	2020-09-08
Final Report	2020-09-08	2020-09-08	2020-09-08

Quality Assurance Unit: Zou Jing — Quality Assurance

2020-09-08 — Date

GLP Compliance Statement

This study was fully in accordance with the technical requirements of the study protocol.

This study was conducted in compliance with Good Laboratory Practice (GLP) Regulation 21 CFR Part 58, U.S. Food and Drug Administration (FDA).

The laboratory is exempt from the following provisions: 21 CFR Part 58.105 Test and Control Article Characterization, and Part 58.113 Mixtures of Articles with Carriers.

Verification Dates

Test Article Receipt	2020-07-30
Protocol Effective Date	2020-08-07
Technical Initiation Date	2020-08-07
Technical Completion Date	2020-08-14
Final Report Completion Date	2020-09-11

Edited by: Feng Yuntao 2020-09-04
Date

Reviewed by: [signature] 2020-09-11
Study Director Date

Approved by: Fangjingyi 2020-09-11
Authorized Signatory Date

Sanitation & Environment Technology Institute, Soochow University

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	KF-ST RT02
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.

Test Report

1 Purpose

The extract of test article was evaluated for skin irritation and extrapolating the results to humans, but it does not establish the actual risk of irritation.

2 Reference

ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
ISO 10993-12:2012 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
ISO 10993-2:2006 Biological evaluation of medical devices — Part 2: Animal welfare requirements

3 Compliance

Good Laboratory Practice Regulations, 21 CFR, Part 58.
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 and Control Articles

4.1 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
Test Article Initial State	Not Sterilized
CAS Code	Not supplied by sponsor (N/S)
Model	KF-ST RT02
Size	M
Lot/Batch	25007011
Test Article Material	Nitrile rubber
Packaging Material	N/S
Physical State	Solid
Color	Blue
Density	N/S
Stability	N/S
Solubility	N/S
Storage Condition	Room temperature
Intended Clinical Use	This product is used in medical examination and diagnosis, which helps to prevent cross infection between patients and users.

The information about the test article was supplied by the sponsor wherever applicable.
The Sponsor is responsible for all test article characterization data as specified in the GLP

regulations.

4.2 Control Article

4.2.1 Negative Control

Name: sesame oil (SO)
Manufacturer: Ji'an Qingyuan District luyuanxiangliao. Co. Ltd
Size: 5kg
Lot/ Batch#: 20200312
Physical State: Oily liquid
Color: Pale yellow
Storage Condition: Room Temperature

4.2.2 Positive Control

Name: sodium dodecyl sulfate
Manufacturer: Ron reagent
Size: 500g
Lot/ Batch#: RH178474
Physical State: Powder
Color: White
Storage Condition: Room Temperature
Solvent: Sesame Oil
Concentration: 20%
Date prepared: 2020-06-30

5 Equipment and Reagents

5.1 Equipment

Equipment Name	Equipment Number	Calibration Expire
Electronic Scale	SDWH2436	2021-05-21
Horizontal Large Capacity Constant Temperature Vibrator	SDWH2671	2021-01-13
Steel straight scale	SDWH463	2021-07-06
Vertical pressure steam sterilizer	SDWH2097	2021-03-25

5.2 Reagents

Reagent Name	Manufacturer	LOT
Sesame oil (SO)	Ji'an Qingyuan District luyuanxiangliao. Co. Ltd	20200312
Sodium dodecyl sulfate (SDS)	Ron reagent	RH178474

6 Identification of Test System

Species: New Zealand white Rabbit (single strain).
Number: 3
Sex: Female
Weigh: Initial body weight not less than 2kg
Health status: Healthy, not previously used in other experimental procedures, young adult, nulliparous and not pregnant.
Housing: Animals were housed in cages identified by a card indicating the lab number, test code and first treatment date.
Animal identification: Stain with dyeing liquid

Cages: Stainless steel cage
Acclimation Period: 7 days under the same conditions as for the actual test

7 Animal Care and Maintenance

Animal purchase: Provided by Suzhou Experimental Animal Sci-tech Co., Ltd. <Permit Code: SCXK (SU) 2015-0007>
Bedding: NA
Feed: Rabbit Diet, Suzhou Experimental Animal Sci-tech Co., Ltd.
Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006
Animal room temperature: 18-26°C
Animal room relative humidity: 30%-70%
Lights: 12 hours light/dark cycle, full-spectrum lighting
Personnel: Associates involved were appropriately qualified and trained.
Selection: Only healthy, previously unused animals were selected.
There were no known contaminants present in the feed, water expected to interfere with the test data.

8 Justification of Test System and Route of Administration

The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current testing standards. Positive control sodium dodecyl sulfate has been substantiated at SDWH with this method. See table 3.
The patches (about 2.5cm×2.5cm) which moistened by test article extract, and directly applying to the rabbit skin is considered to be the best mean of contact.

9 Experimental Design

9.1 Preparation of Extracts

9.1.1 Pretreatment

No pretreatment required.

9.1.2 Extraction

Under aseptic conditions, samples were taken according to the sampling method (Random sampling). The extraction was performed with agitation in closed inert containers according to the extraction ratio listed in the following table (sample: extraction vehicle). The extraction vehicle was SO.

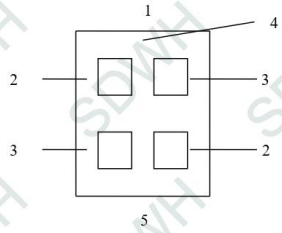
Test Period	Actual Sampling	Extract Procedure			Final Extract
		Extract Ratio	Extraction volume	Condition	
Non-polar test extract	Surface area 120 cm^2	6 cm^2 : 1 mL	20.0 mL	50°C, 72 h	Clear
Non-polar negative control	/	/	10.0 mL		Clear

The state of the extract did not change after extraction. The extract was stored at room temperature, and tested within 24 h, without the process of adjusting its pH value, filtering, centrifuging, diluting, etc. The vehicle (without the test article) was similarly prepared to serve as the control.

9.2 Experimental Procedure

Use the rabbits with healthy intact skin. Fur was generally clipped within 4-24 h of testing on the backs of the rabbits, a sufficient distance on both sides of the spine for application and observation of all test sites (approximately 10cm×15 cm).
Apply 0.5 mL extract (s) of test article or control to 2.5 cm×2.5 cm absorbent gauze patches, and

then apply the patch soaked with the extract of test article or control directly to the skin on each side of each rabbit as shown in Figure 1, and then wrap the application sites with a bandage (semi-occlusive or occlusive) for a minimum of 4 h. At the end of the contact time, remove the dressing and washing with lukewarm water or other suitable nonirritating solvent and careful drying.



1- Cranial end, 2- Test site, 3- Control site, 4- Clipped dorsal region, 5- Caudal end

Figure1 Location of skin application sites

9.3 Observation of Animals

Describe and score the skin reaction for erythema and oedema according to the scoring system given in Table 1 for each application site at each time interval. Record the appearance of each application site at (1±0.1) h, (24±2) h, (48±2) h and (72±2) h following removal of the patches.

Table 1 — Scoring system for skin reaction

Reaction	Irritation score
Erythema and Eschar Formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet redness) to eschar formation preventing grading of erythema	4
Oedema Formation	
No edema	0
Very slight edema (barely perceptible)	1
Well-defined edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond exposure area)	4
Maximal possible score for irritation	8
Other adverse changes at the skin sites shall be recorded and reported.	

9.4 Evaluation of Results

Use only (24±2) h, (48±2) h and (72±2) h observations for calculation.
After the 72 h grading, all erythema grades plus oedema grades (24±2) h, (48±2) h and (72±2) h were totalled separately for each test sample and blank for each animal. The primary irritation score for an animal was calculated by dividing the sum of all the scores by 6 (two test/observation sites, three time points).
To obtain the primary irritation index for the test article, add all the primary irritation scores of the individual animals and divide by the number of animals.

When blank or negative control is used, calculate the primary irritation score for the controls and subtract that score from the score using the test material to obtain the primary irritation score.
The primary irritation index (PII) for the test article was evaluated according to Table 2.

Table 2 — Primary or cumulative irritation index categories in a rabbit

Mean score	Response category
0~0.4	Negligible
0.5~1.9	Slight
2~4.9	Moderate
5~8	Severe

10 Results

All animals were survived and no abnormal signs were observed during the study. According to what observed, the skin reaction of non-polar extract on testing side did not exceed that on the control side. Thus, the final test article score was calculated to be 0. See table 4.

11 Conclusion

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

12 Record Storage

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

13 Confidentiality Agreement

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

14 Deviation Statement

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

Annex 1 Test Data

Table 3 Positive control

Extract	Rabbit No.	Group	Reaction	Interval (hours): score=left site/right site 24±2h	48±2h	72±2h
SO	1	Positive Control	Erythema	2/3	3/3	4/3
			Oedema	3/3	4/4	4/4
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
SO	2	Positive Control	Erythema	3/3	3/3	4/3
			Oedema	3/3	3/4	4/4
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
SO	3	Positive Control	Erythema	3/3	4/3	4/4
			Oedema	3/2	3/3	3/3
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
The primary irritation score.					6.6	

Note：Positive control performed once every six months, see SDWH-M202003007-2(Completed Date: 2020-07-03).

Table 4 Test Results of Dermal Observations

Extract	Rabbit No.	Group	Reaction	Interval (hours): score=left site/right site 24±2h	48±2h	72±2h
SO	1	Test Article	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
SO	2	Test Article	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
SO	3	Test Article	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
The primary irritation score.					0	

Annex 2 Photograph of Test Article

Annex 3 Information Provided by Sponsor

1 Production Process

Not supplied by sponsor.

2 Other Information

Not supplied by sponsor.

End of Report

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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,Qingyuan,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 E-mail: med@sudatest.com
Direct: +86 512 65880038 Free: 400 107 8828

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,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 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-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 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	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℃	25℃	11.3	365Days	33 Days
3 y	2	60℃	25℃	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±2°C and 50±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	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: 25007019）

	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: 25007020）

	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: 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

PSB Singapore

Add value.
Inspire trust.

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

TÜV SÜD PSB

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

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

PSB Singapore

RESULTS:

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

Table 1: Results for EN 455-1:2020

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

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

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

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

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

RESULTS (cont'd):

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

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

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

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

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

REMARKS:

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

Yeo Poh Kwang
Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

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

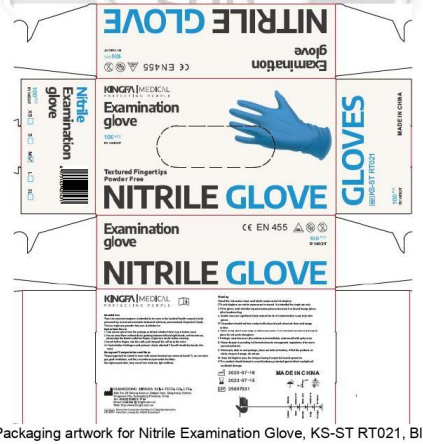


Photo 2: Packaging artwork for Nitrile Examination Glove, KS-ST RT021, Blue, Size M

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
Unit 110, Xinzhongyin Garden
Hongwei Road
Xiping, Nancheng District
DONGGUAN CITY
Guangdong Province
China
523079

SATRA reference: CHM0305368/2048/LC/B
Your reference: CHT0305236
Date of report: 21st December 2020
Samples received: 23rd November 2020
Date(s) work carried out: 16th to 21st 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, Color: Blue, Reference number: KS-ST RT021.

Report signed by: Lucy Cove
Position: Technologist
Department: Chemical & Analytical Technology

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.

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
Unit 110, Xinzhongyin Garden
Hongwei Road
Xiping, Nancheng District
DONGGUAN CITY
Guangdong Province
China
523079

SATRA reference: CHM0305368/2048/LC/A
Your reference: CHT0305236
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.

Report signed by: Lucy Cove
Position: Technologist
Department: Chemical & Analytical Technology

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

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.

SATRA TECHNOLOGY

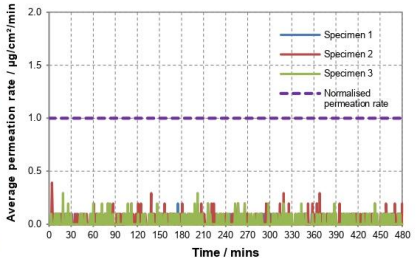
TECHNICAL REPORT

0248

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/cm²/min	
		Detection technique:	Conductimetry (continuous measurement)	
		Collection medium:	Deionised water (closed loop)	
		Collection medium stirring rate: (each cell constant to within ± 10%)	45 – 65 ml/min	
		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		

PERMEATION RATE GRAPHS

Challenge chemical: 40% Sodium Hydroxide.



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

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

Your reference: KS-ST RT021

Date of report: 10 December 2020

Samples received: 20 November 2020

Date(s) work carried out: 23 November 2020 to 1 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: KS-ST RT021.

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

SATRA TECHNOLOGY

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)

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	2	3	± 1.10 mm	N/A
		9	242	243	245		
		Comfortable on fit					
		7	250	245	245		
		Comfortable on fit					
		8	245	240	244		
		Comfortable on fit					
		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				

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		
	9	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

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

Sample description:		Disposable Powder Free Nitrile Examination Gloves, Color: Blue, Reference number: KS-ST RT021.				
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 Procedure B Using retaining screen	+ control	Penetration	Penetration	Penetration	Penetration	Acceptable
	- control	No penetration	No penetration	No penetration	< 1	Acceptable
	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

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

-	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.

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 hyrdocarbons 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 *****

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AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
SI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
Str. Av. Sănătescu nr. 48, sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

Catre ,

MEDPLAZA HEALTH SRL

Tel : 0737.552756
E-mail: office@medplaza.ro

Prin prezenta vă înaintăm anexa avizului de funcționare aferentă cererilor cu numerele DM 1272/04.03.2022 și DM 1304/07.03.2022.

Cu stimă,

VICEPREȘEDINTE
Ioana ȚENE

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
SI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
Str. Av. Sănătescu nr. 48, sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

ANEXA din data 29.03.2022
LA AVIZUL DE FUNCȚIONARE
Nr. 7111/19.08.2020 al MEDPLAZA HEALTH SRL

În conformitate cu art. 926 din Legea nr. 95/2006 privind reforma în domeniul sănătății, republicată și în baza documentației înaintate, Avizul de funcționare nr. 7111/19.08.2020 se completează după cum urmează:

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VICEPREȘEDINTE
Ioana ȚENE

Thank you!

comenzi@medplaza.ro
distributie@medplaza.ro

www.medplaza.ro
0316.30.66.90