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KS-ST RT021

SINGLE USE NITRILE PATIENT EXAMINATION GLOVES

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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.

There will be 96 product lines at the end of 2021, and the daily output of each machine will be approximately 1 million.

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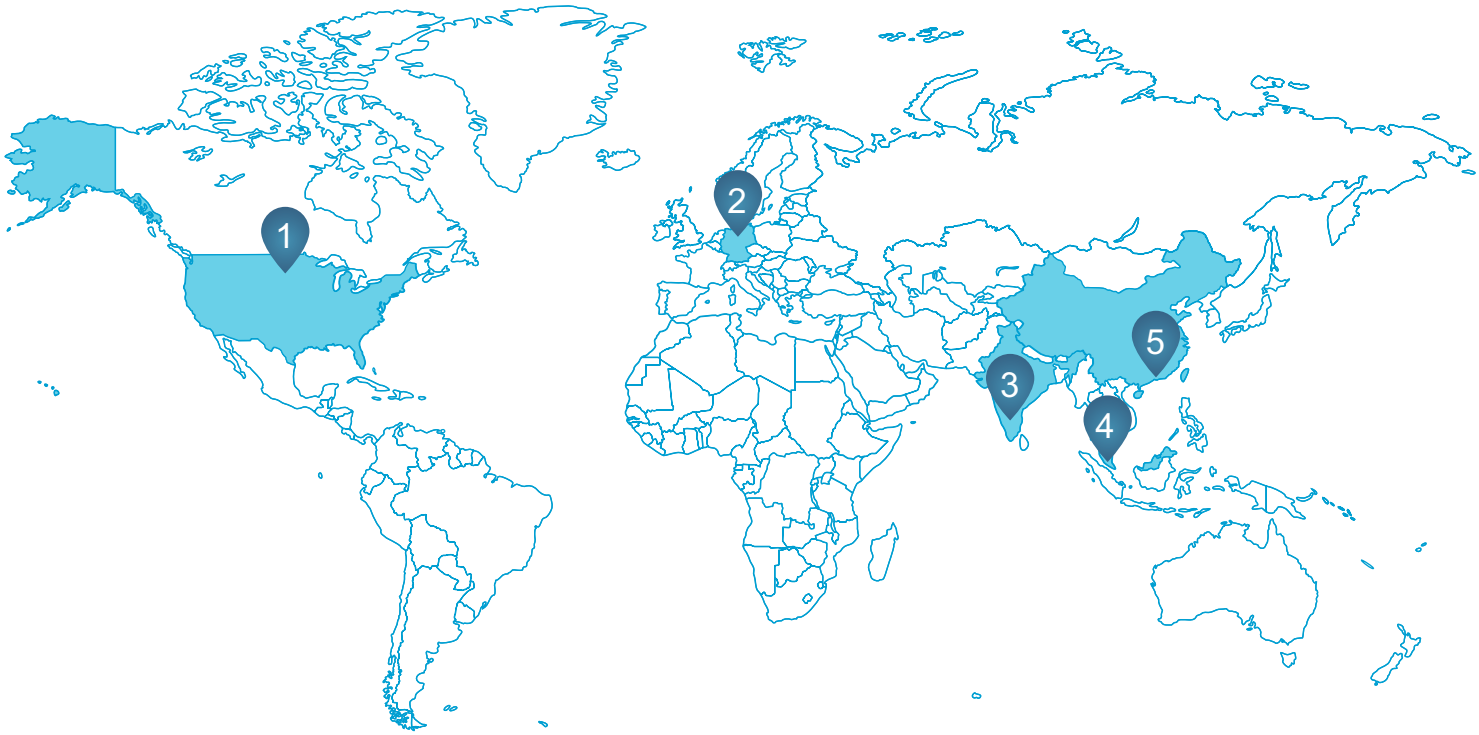
Serves Worldwide



1 United State

Canton,Michigan

2 Germany

Wiesbaden

3 India

Chennai

4 Malaysia

Kuala Lumpur

5 China

Konggang,Tianjin

Mianyang,Sichuan

Chengdu,Sichuan

Wuhan,Hubei

Kunshan,Jiangsu

Qinpu,Shanghai

Ningbo,Zhejiang

Qingyuan,Guangdong

Guangzhou,Guangdong

Zhuhai,Guangdong

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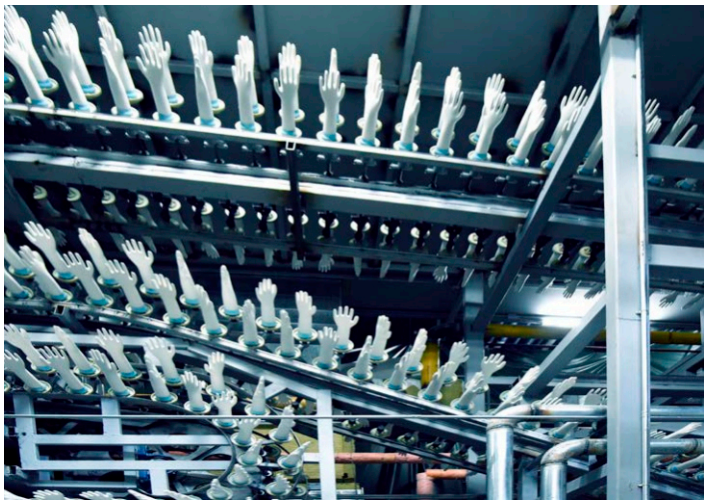
Inhouse Production

Personalized Service and

24/7 Online Tracking System

Increasing Efficiency



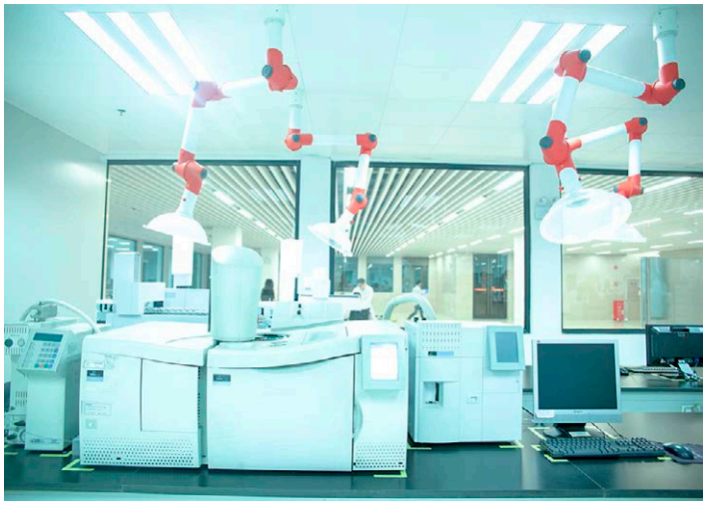
Raw Material Supply Chain

Management & Control

Short Leadtime

Overseas Distribution Centers

Risk Control & Management



SGS Inspection and

Quality Control

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

Strong Supply System

Excellent Technology Team

Various Kinds of Products

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

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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 COMPLIAINCE

PPE Cat III according to Regulation (EU) 2016/425

FDA 510K No: K203593
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 forbiological evaluation
EN 455-4: Requirements and testing for shelf life determination

Food contact approved

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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

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

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

TÜV SÜD
PSB Singapore

RESULTS (cont'd):

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

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

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

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

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

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

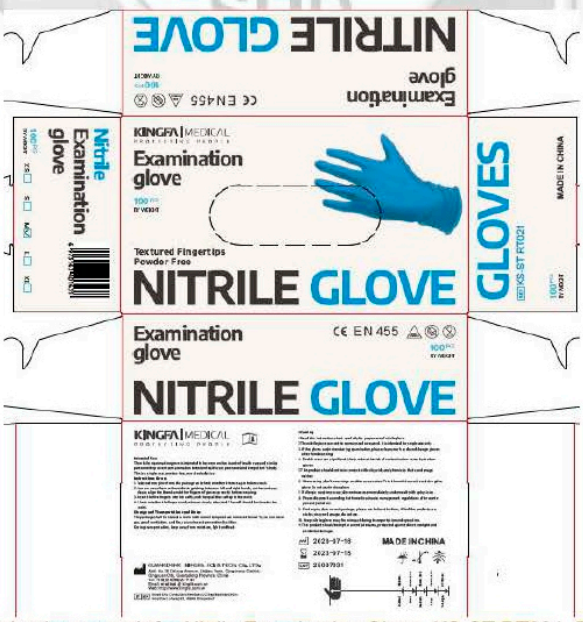

Photo 2: Packaging artwork for Nitrile Examination Glove, KS-ST RT021, Blue, Size M

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

PSB Singapore

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

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TEST REPORT

EN 455-4

CMA 180015144061

ilac-MRA CNAS 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,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

Content

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,Qing yuan,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℃), 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 (℃);

T_{RT}: Ambient Temperature (℃).

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

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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 expended uncertainty for "Pass", "Fail" and "Inconclusive" is 95%.

TüV SüD Certification and Testing (China) Co., Ltd. Shenzhen Branch
TüV SüD Group

Prepared by:

Simon Liu
Project Engineer

Reviewed by:

Angelina Wang
Supervisor

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)	

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/dm²]			MAXIMUM PERMISSIBLE LIMIT [mg/dm²]
		SAMPLE 001 1st Migration	SAMPLE 001 2nd Migration	SAMPLE 001 3rd Migration	
3% Acetic acid	40°C for 2 Hours	<3	<3	<3	3rd migration: 10, 3rd < 2nd < 1st
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/dm²]			MAXIMUM PERMISSIBLE LIMIT [mg/dm²]
		SAMPLE 001 1st Migration	SAMPLE 001 2nd Migration	SAMPLE 001 3rd Migration	
3% Acetic acid	70°C for 2 Hours	<3	<3	<3	3rd migration: 10, 3rd < 2nd < 1st
10% Ethanol	70°C for 2 Hours	<3	<3	<3	
Rectified olive oil	70°C for 2 Hours	5.8	<3	<3	

Note 1. "℃" 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--

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TEST REPORT

EN ISO 374 1-5

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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.

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

Adam Zhang

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)

SATRA TECHNOLOGY

TECHNICAL REPORT

Testing

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

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

Requirements

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

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

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

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

Test Results

Table 3 – EN ISO 21420:2020 Test Results

Clause / Test	Requirement	Test Results				UoM (See note ♣)	Result
5.1 Glove length, comfort and fit	N/A	Size	Length /mm			± 1.10 mm	N/A
			1	2	3		
		6	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				

SATRA TECHNOLOGY

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		
	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

SATRA TECHNOLOGY

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

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

SATRA TECHNOLOGY

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

-	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.

SATRA TECHNOLOGY

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 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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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.

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

SATRA TECHNOLOGY

TECHNICAL REPORT

UKAS TESTING 0248

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.

SATRA TECHNOLOGY

TECHNICAL REPORT

UKAS TESTING 0248

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.

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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.

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

SATRA TECHNOLOGY

TECHNICAL REPORT

UKAS TESTING 0248

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

TECHNICAL REPORT

UKAS TESTING 0248

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

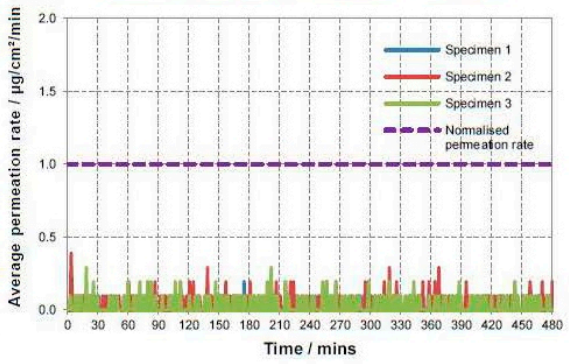
TECHNICAL REPORT

UKAS TESTING 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.

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EU-Type-Examination Certificate

Notified Body 2777

Issued to:

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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:	Description:
KS-ST RT021	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 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

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TEST REPORT

ISO 10993-10:2010

CMA 180015144061

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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,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

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.

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TEST REPORT

ISO 10993-10:2010

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,Qingyuan,Guangdong,China

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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.

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TEST REPORT

ISO 10993-10:2010

CMA 180015144061

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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,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

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

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.

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TEST REPORT

ISO 10993-10:2010

CMA 180015144061

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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,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

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

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.

ASTM D6319-19

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检测
TESTING
CNAS L0220

TEST REPORT

Number: GZHT91012916

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

Date: Jan 07, 2021

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

Standard	:	ASTM D6319-19
Ref. No.	:	KF-ST RT021
P.O. No.	:	25007031
Colors	:	Blue
Size Range	:	M
Palm	:	Nitrile
Back	:	Nitrile
Cuff	:	Nitrile
Cuff Binding	:	Nitrile
Lining	:	Nitrile
Date Received/Date Test Started:		Dec 21, 2020/--
Date Final Information Confirmed/		Jan 07, 2021/--
Date Payment Received:		

Test Result Please Refer To Attached Page(S).

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

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

Guiliang Dong
Senior Lab Manager

wx / lynnyang

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

Room 02, 1-8/F. & Room 01, E101/E201/E301/E401/E501/E601/E701/E801, No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, Guangdong, China
Tel: +86 208213 9001 Fax: +86 20 82089909 Postcode: 510663

3/F., Hengyun Building, 235 Kaifa Ave., Guangzhou Economic & Technological Development District, Guangzhou, China
Tel: +86 20 83966868 Fax: +86 20 82228169 Postcode: 510730

TEST REPORT Number: GZHT91012916

Tests Conducted (As Requested By The Applicant)

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

Results			Requirement			Pass/Fail
Physical Performance	Failure	AQL	Physical Performance	AQL	n [Ac Re]	-
No Leakage	0	< 2.5	No Leakage	2.5	200 (10 11)	Pass

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

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

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

Test Data:

Size	Specimen	Width (mm)	Length (mm)	Finger Thickness (mm)	Palm Thickness (mm)
M	1	96	247	0.12	0.11
	2	97	246	0.12	0.11
	3	97	246	0.12	0.11
	4	96	248	0.13	0.11
	5	95	248	0.12	0.11
	6	95	246	0.12	0.11
	7	97	245	0.13	0.11
	8	94	245	0.13	0.11
	9	94	247	0.13	0.10
	10	95	247	0.13	0.10
	11	97	246	0.13	0.11
	12	96	246	0.12	0.11
	13	96	248	0.12	0.11

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

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

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

Test Data:

Condition	Sample	Results	
		Tensile Strength (MPa)	Ultimate Elongation (%)
Before Aging	1	20.4	588
	2	25.5	600
	3	27.6	600
	4	22.7	600
	5	30.0	588
	6	26.2	600
	7	28.3	592
	8	35.2	640
	9	26.3	580
	10	28.1	600
	11	28.4	588
	12	24.3	580
	13	32.9	592

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

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

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

Test Data:

Condition	Sample	Results	
		Tensile Strength (MPa)	Ultimate Elongation (%)
After Accelerated Aging (70 For 166 h)	1	17.6	540
	2	14.3	500
	3	18.7	540
	4	15.8	480
	5	18.3	520
	6	25.3	532
	7	20.1	480
	8	**4.8**	**380**
	9	18.9	520
	10	27.9	540
	11	19.1	460
	12	23.8	540
	13	21.8	540

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

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

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

Size	Result	Requirement	Pass/Fail
M	0.4 mg	Max. 2.0 mg	Pass

6 Package Marking (ASTM D6319-19, 9.3)

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

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

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

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7 Packaging (ASTM D6319-19, 9.2 Nonsterile And Bulk Packaging)

	Requirements	Pass	Fail	N/A
9.1	Sterile Packaging:			
9.1.1	The Unit Of Packaging Shall Normally Be One Glove Or One Pair Of Gloves.			√
9.1.2	A Glove Or Pair Of Gloves, Normally, Shall Be Enclosed In An Inner Wallet Or Wrapper. The Wrapper Shall Be Of Sufficient Size When Opened To Provide A Field For Glove-Donning Purposes.			√
9.1.3	The Glove Or Pair Of Gloves, And Accompanying Wrapper If Utilized, Shall Be Totally Enclosed In An Outer Package That Will Allow Sterilization Of The Product.			√
9.1.4	The Outer Package Shall Have A Method Of Closure Sufficient To Ensure The Sterility Of The Product Until Opened Or Damaged.			√
9.1.5	The Outer Package Shall Have Sufficient Strength And Integrity To Withstand Normal Transportation And Storage Within The Intermediate Or Shipping Cartons, Or Both.			√
9.1.6	The Method Of Closure Of The Outer Package Shall Be Such That Prior Opening Will Be Detectable By The User.			√
9.1.7	None Of The Packaging Material Shall Contain Any Material Likely To Impair The Quality And Use Of The Gloves.			√
9.1.8	Intermediate Cartons And Shipping Cases Shall Be Of Sufficient Strength To Maintain The Quality And Sterility Of The Product During Normal Transportation And Storage.			√
9.2	Nonsterile And Bulk Packaging:			
9.2.1	The Gloves Shall Be Enclosed In An Outer Package That Has Sufficient Strength To Withstand Normal Transportation And Storage Within The Cartons Or Shipping Cases, Or Both.	√		
9.2.2	None Of The Packaging Material Shall Contain Any Material Likely To Impair The Quality And Use Of The Gloves.	√		
9.2.3	Cartons And Shipping Cases Shall Be Of Sufficient Strength To Maintain The Quality Of The Product During Normal Transportation And Storage.	√		

Compliance: The Submitted Sample **MEETS** The Requirements Of ASTM D6319-19 Clause 9.2 For Nonsterile And Bulk Packaging.

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

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End Of Report

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

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KINGFA MEDICAL
PROTECTING PEOPLE

MSDS for Disposable Nitrile Gloves

1. PRODUCT AND COMPANY IDENTIFICATION

1.1. Trade name: Nitrile Examination Glove, Powder-free

1.2. Application: Gloves for single use

1.3. Producer:

2. COMPOSITION / INFORMATION OF INGREDIENTS

Name	CAS number
Nitrile	109-74-0
Sulphur	7704-34-9
Zinc oxide	1314-13-2
Vulcanization accelerator ZDBC	136-23-2
Vulcanization accelerator ZDEC	14324-55-1
Titanium Dioxide	13463-67-7
Pigment	/

3. HAZARD IDENTIFICATION

not applicable

4. FIRST AID MEASURES

not required

5. FIRE FIGHTING MEASURES

In case of fire unidentified toxic and/or irritating vapours/gases can arise

Extinguishing media: CO_2, Foam, Dry extinguishing powder, Waterspray jet

6. ACCIDENTAL RELEASE MEASURES

not applicable

7. HANDLING AND STORAGE

Store in a dry, ventilated area

Avoid direct sunlight, fluorescent lighting, heat and moisture

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

not applicable

9. PHYSICAL AND CHEMICAL PROPERTIES

Odor: N/A

Physical state, odour: solid

10. STABILITY AND REACTIVITY

Stable under recommended storage and handling conditions. Hazardous decomposition products depend upon temperature, air supply and the presence of other materials.

Materials/conditions to avoid: at temperatures > 200°C decomposition starts

Hazardous decomposition products: hydrochloric acid (HCl), carbon monoxide (CO) and other toxic substances

11. TOXICOLOGICAL INFORMATION

Inhalation: not applicable

Skin contact: material is not hazardous

Eye contact: not applicable

Ingestion: not applicable

12. ECOLOGICAL INFORMATION

The material is practically insoluble in water and is not expected to biodegrade.

13. DISPOSAL CONSIDERATIONS

Disposable according to national regulations.

14. TRANSPORT INFORMATION

ADR/RID: not a dangerous load

IMDG: not a dangerous load

ICAO: not a dangerous load

UN-No.: not a dangerous load

15. REGULATORY INFORMATION

Symbol: none

R-phrases: none

S-phrases: none

16. OTHER INFORMATION

This listing of legal regulations is related to the valid version.

FDA 510K Acknowledgment Letter

Acknowledgment Letter

12/9/2020

Shelley Li, Director
Landlink Healthcare Technology (Shanghai) Co., Ltd.
Room 703, 705, Baohua International Plaza, West Guangzhong
Road 555, Jingan
Shanghai 200071
CHINA

Dear Shelley Li:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: K203593
Received: 12/9/2020
Applicant: Guang Dong Kingfa SCI. & TECH.CO., LTD.
Device: Patient Examination Gloves

We will notify you when the review of this document has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

FDA 510K Approval: K203593

March 19, 2021

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

Re: K203593
Trade/Device Name: Patient Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: February 6, 2021
Received: February 16, 2021

Dear Shelley Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ryan Ortega Ph D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510(k) Premarket Notification

FDA Home ▸ Medical Devices ▸ Databases

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

New Search | Back To Search Results

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

510(k) Premarket Notification

FDA Home ▸ Medical Devices ▸ Databases

1 to 4 of 4 Results
Applicant: *kingfa* **Decision Date To:**
03/22/2021

Results per Page 10

New Search | Export to Excel | Download Files | More About 510(k)

Device Name	Applicant	510(K) Number	Decision Date
Patient Examination Gloves	Guang Dong Kingfa SCI. & TECH.CO., LTD.	K203593	03/19/2021
Medical Protective Mask	Guangdong Kingfa Sci.&Tech.Co., Ltd.	K202107	01/15/2021
Medical Surgical Mask	Guangdong KINGFA Sci.&Tech.Co.,Ltd.	K201622	11/24/2020
Medical Surgical Mask	Guangdong Kingfa SCI.&Tech.Co., Ltd.	K202139	11/20/2020

Report No.: TAOWT00219823

INSPECTION REPORT

(Special for Epidemic prevention materials)

IMPORTANT INFORMATION REGARDING THE SCOPE AND LIMITATIONS OF THE INSPECTION AND REPORT

The scope of this report is limited to a **VISUAL INSPECTION ONLY** for the workmanship and basic function check of the product. Performance index and compliance of the product are NOT included in the scope of this report. This report is a reasonable attempt to identify any obvious or significant defects apparent in those areas of the product fully accessible and visible to the Inspector at the time of the inspection. This Report is made solely for the use and benefit of the Client named on the front of this report.

To :	AIM-X Global LLP	Date:	5-Mar-2021
Att :	Abdul Halim Choudhury		
From :	Elvis Dong	E-mail :	elvis.dong@sgs.com

SGS File No.:	CNTAO10334313
Buyer :	AIM-X Global LLP
Supplier :	GUANGDONG KINGFA SCI.&TECH CO.,LTD
Manufacturer :	GUANGDONG KINGFA SCI.&TECH CO.,LTD
Style Number:	L size, M size
Product description:	Single-use Nitrile Patient Examination Gloves
P.O. Number:	KFAIM20210203002
L/C Number:	N/A
Service performed :	FRI
Inspection Date :	04-Mar-2021
Inspection Location :	Qingyuan, Guangdong, China

Product family view

Inspection Criteria

Reference sample provided by	Not Available
Client instruction/specification	YES
SGS WI number	P-INSP-WI-HL-111
Other	N/A

Overall Inspection Conclusion:	**Subject to client's evaluation**

Inspection Summary:

1. Quantity :	Conform
2. Style, color :	Subject to client's evaluation
3. Workmanship appearance / function :	Conform
4. Data measurement / field tests:	Subject to client's evaluation
5. Packing :	Conform
6. Marking / label :	Conform
Problem Remark:	
1. No reference sample was available for comparison during inspection.	

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

1. Quantity: Conform

No	Style / Item/ Article	P.O. No.	Order Qty.	Inspection Qty. (Presented Qty. for insp.)		Number of Cartons	
				Packed	Not Packed	Packed	Not packed
1	L	KFAIM20210203002	1500000	1500000	0	1500	0
2	M	KFAIM20210203002	1500000	1500000	0	1500	0
		Total:	3000000	3000000	0	3000	0

2. Style & Color Conformity: Subject to client's evaluation

Comments:
No refer sample was available for comparison during inspection.

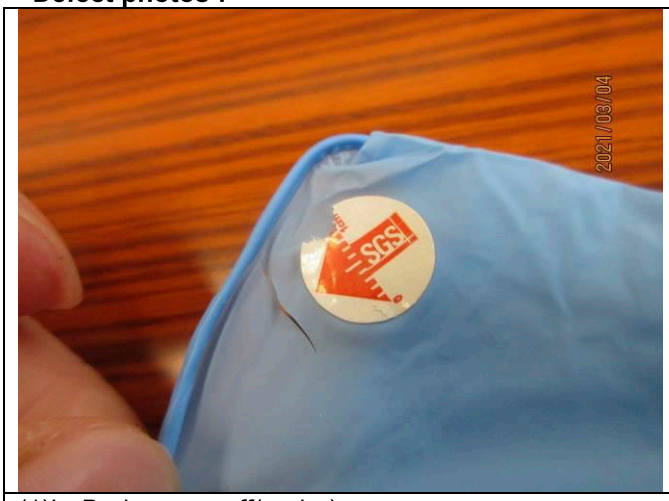
3. Workmanship Appearance / Functional Inspection Findings: Within AQL

Inspection Method Applied:
ANSI / ASQ Z1.4- 2003（R2018）, Single sampling plans for normal inspection,
Level II Sample size: 1250pcs
Acceptance Quality Limit (AQL) for: Critical: N/A Major: 1.0 Minor: 1.5

Defect description	Critical	Major	Minor
-For L S/S:625pcs			
Broken on cuff	0	1	0
Excessive material stuck to cuff	0	1	0
Black spot on surface	0	0	4
White mark on surface	0	0	4
-For M S/S:625pcs			
Broken on cuff	0	1	0
Hole on fingertip	0	1	0
Black spot on surface	0	0	4
White mark on surface	0	0	3
Total defectives:	0	4	15
Maximum allowed:	0	21	21

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

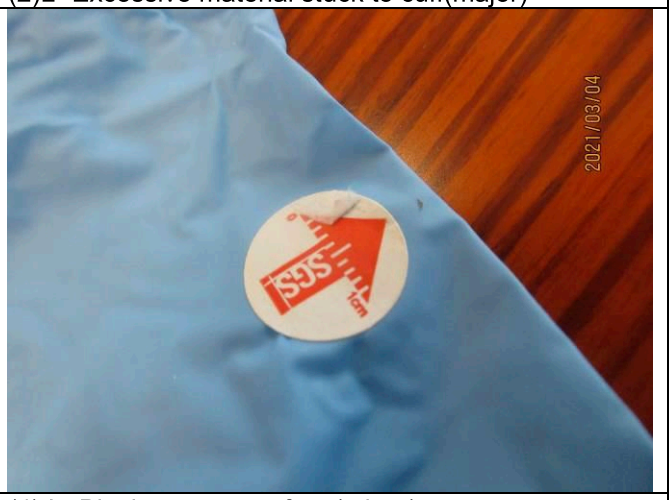
Defect photos :



(1)L- Broken on cuff(major)

(2)L- Excessive material stuck to cuff(major)

(3)L- Black spot on surface(minor)

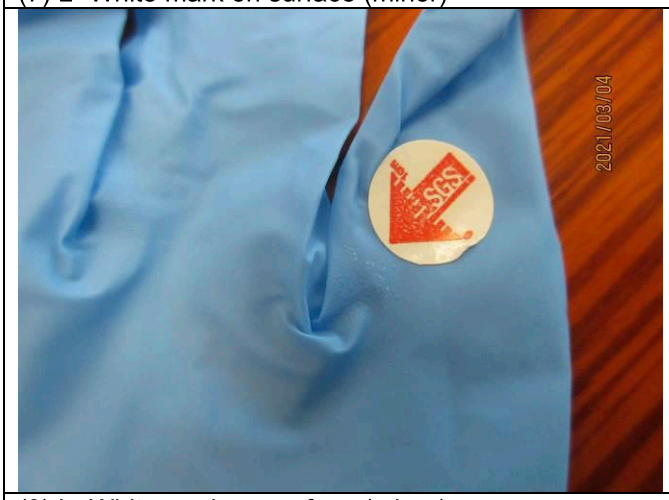


(4) L- Black spot on surface(minor)

(5) L- Black spot on surface(minor)

(6) L- Black spot on surface(minor)

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

	
(7) L- White mark on surface (minor)	(8) L- White mark on surface (minor)
	
(9) L- White mark on surface (minor)	(10) L- White mark on surface (minor)
	
(11)M- Broken on cuff (major)	(12)M- Hole on fingertip (minor)

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

	
(13)M- Black spot on surface (minor)	(14) M- Black spot on surface (minor)
	
(15) M- Black spot on surface (minor)	(16) M- Black spot on surface (minor)
	
(17) M- White mark on surface (minor)	(18) M- White mark on surface (minor)

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

	N/A
(19) M- White mark on surface (minor)	

4. Product-Specific Data Measurement / Field Test on Reduced Sample Size: Subject to client's evaluation

Check points	Qty	Test Result	Specification/Tolerance
Unit size check(mm)	5	L:242x107,240x108,242x107,240x108,242x108 M:243x98,245x97,245x98,246x97,246x98	L >=240x110+/-10mm M >=240x95+/-10mm
Unit thickness check	5	L: Cuff thickness: 2.28,2.40,2.48,2.40,2.44mil Palm thickness: 2.87,2.72,2.80,2.80,2.64mil Fingertip thickness:4.41,4.53,4.41,4.53,4.45mil M: Cuff thickness: 2.44,2.44,2.44,2.40,2.24mil Palm thickness: 2.91,2.80,2.91,2.80,2.76mil Fingertip thickness:4.33,4.72,4.65,4.65,4.92mil	Finger(mm) Palm(mm) Cuff(mm) ≥0.05 ≥0.08 N/A 1.97mil 3.15mil N/A
Unit weight check (g)	5	L:4.11,4.18,4.23,4.18,4.16 M:3.89,3.84,3.91,3.80,3.84	N/A
Box size check(cm)	1	L:23x12x6.5 M: 23x12x6.5	N/A
Number of pcs check per gift box	2	L: 100,100 M:100,101	100pcs
Carton size check(cm)	1	L:33x25x24.5 M: 33x25x24.5	N/A
Carton weight check	1	L:5.08, M:4.82	N/A
Carton drop test	1	Pass	76cmx10times
Barcode scan	5	Pass	Can be scan and corrected
Tensile strength test(N)	5	L:12.48,12.45,13.21,8.03,12.66 M:11.07,11.22,11.69,11.56,10.10	N/A
Water leakage test	125	2pcs leak	N/A
Wear check on 5pc per size	5	Pass	fit physical gloves on to check the fit, the fingers moved freely

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

5. Packing:

5.1 Individual packing conformity : Conform
Comments:
Each set (100 pcs) per color box.

5.2 Inner packing conformity : Not Applicable
Comments:
N/A

5.3 Export packing conformity : Conform
Comments:
10 sets per 3-ply corrugated cardboard export carton sealed with gummed tape

5.4 Samples selected from carton numbers:
Total selected 20 cartons for inspection and no carton number

6. Marking / Label:

6.1 Bar code: Conform
Please refer to photo

6.2 Shipping mark conformity: Conform
Comments:
Please refer to photo.

6.3 Marking & label conformity: Conform
Comments:
Please refer to photo.

7. Informative Remark:

Nil

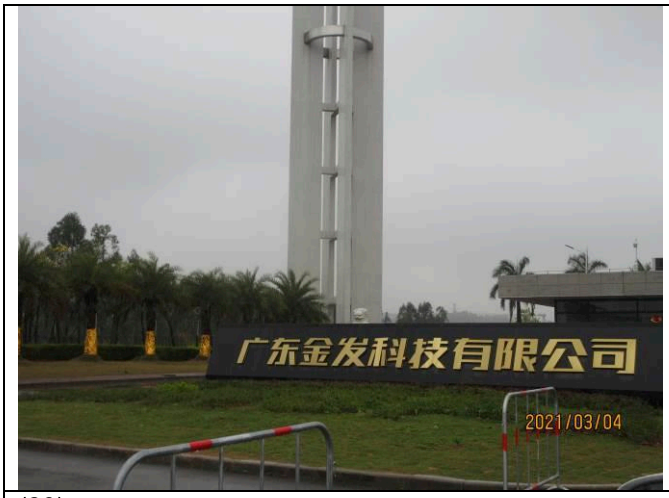
8. Inspection Environment:

Lighting :	Room lighting Sufficient
Inspection place :	Warehouse
Inspection done on:	Table
Cleanliness :	Clean
Weather condition:	Rainy
Cargo storage:	Orderly, easy to count

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

9. Attachment

L size



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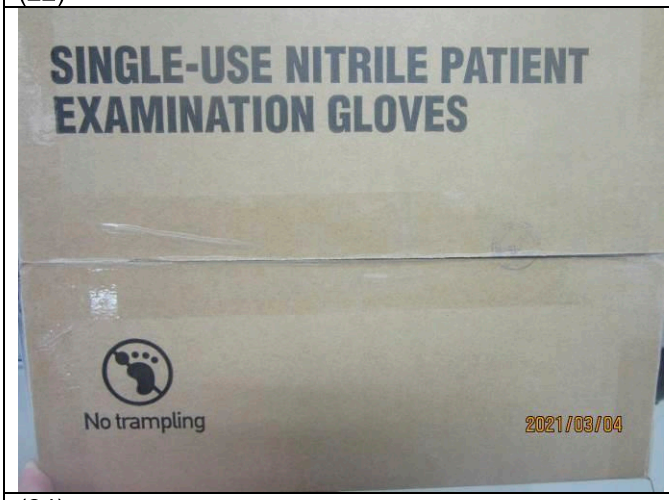

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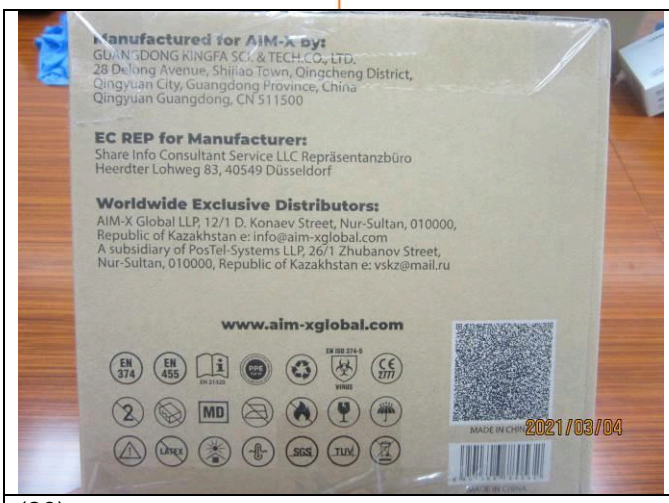
(25)

Inspector: Kaifang Zhang Factory Representative: Mr. Luo



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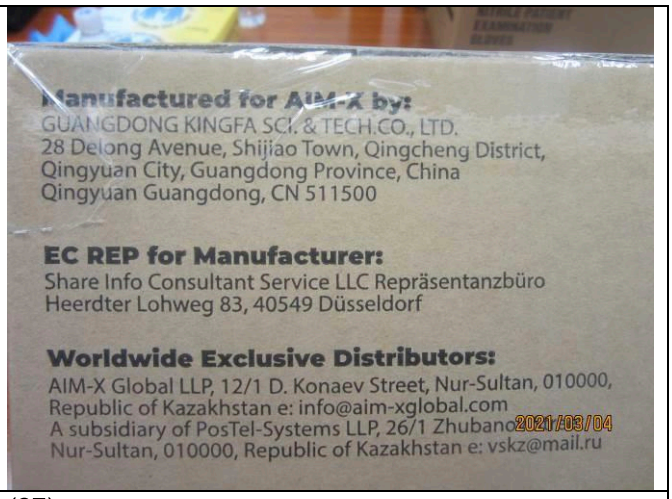

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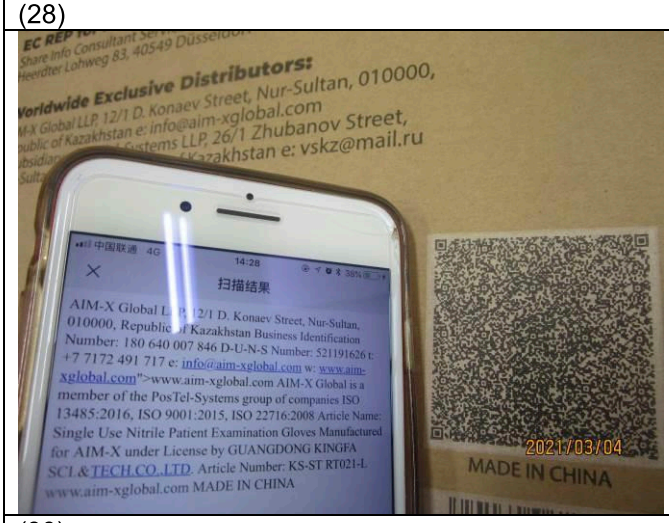

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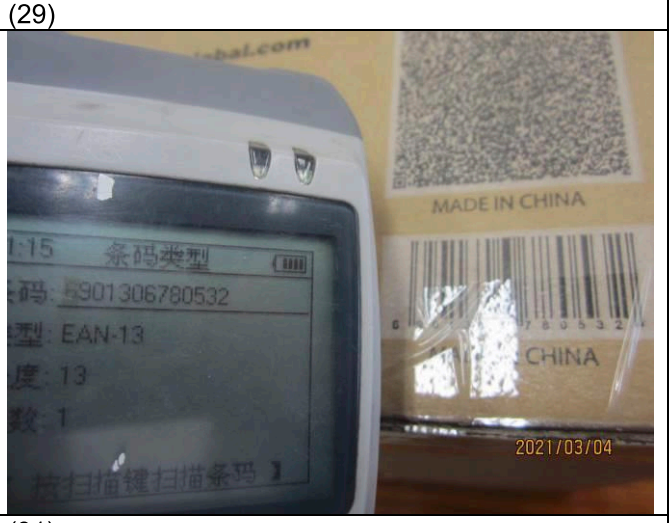

(31)

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

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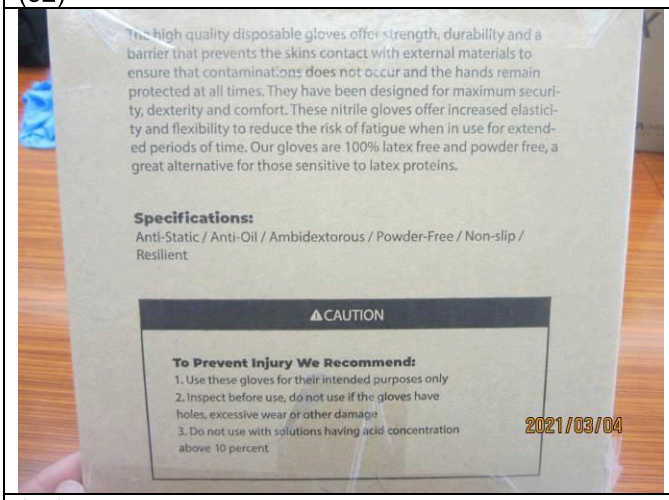
(33)



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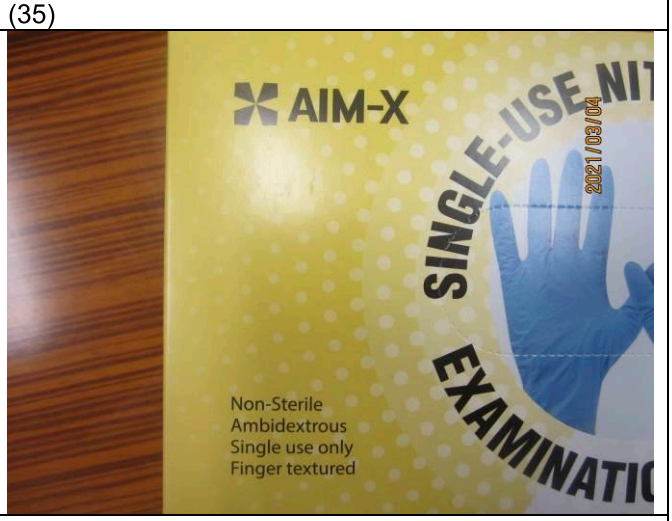

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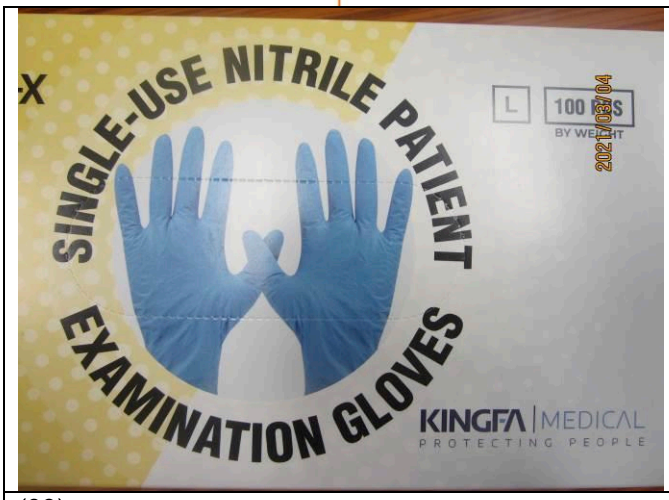
Inspector: Kaifang Zhang Factory Representative: Mr. Luo



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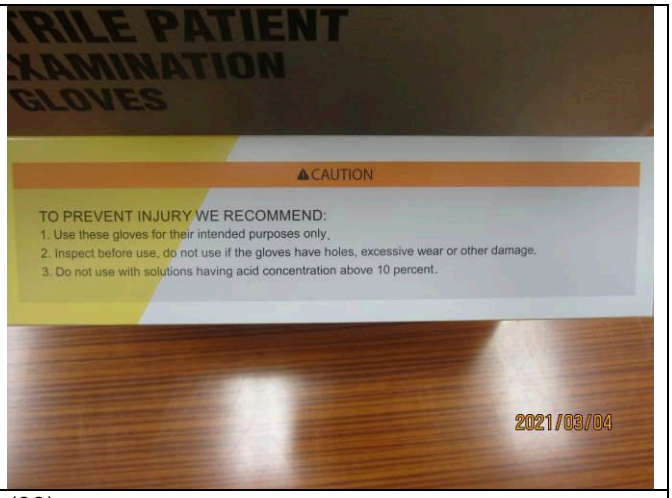

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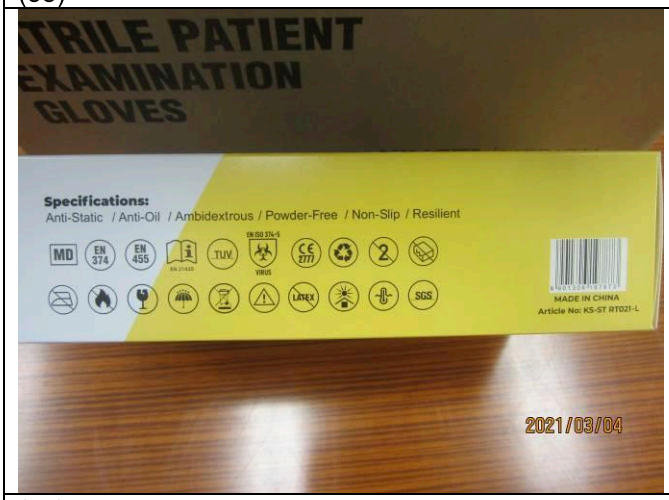

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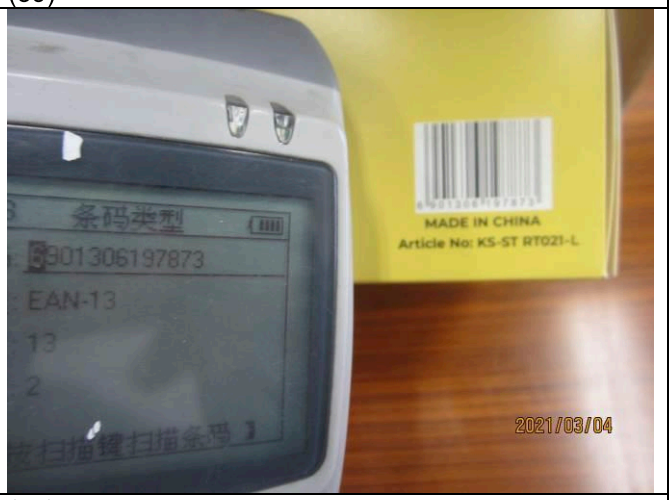

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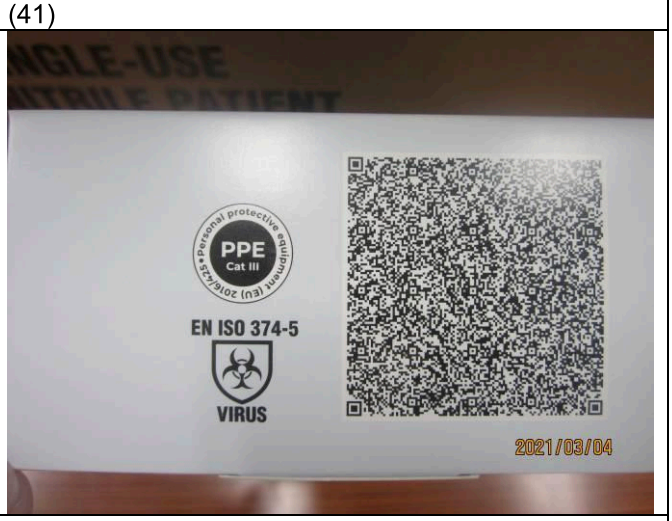
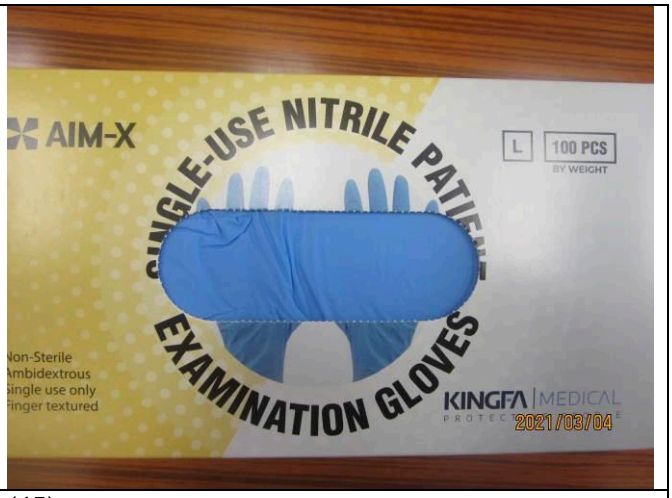


(43)

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

(44)



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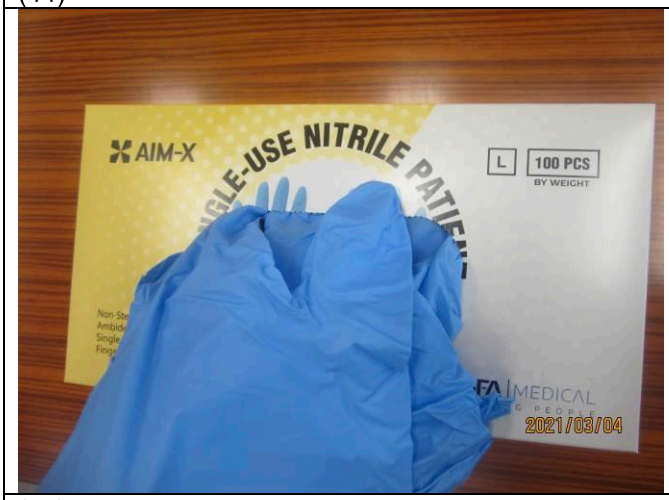


(46)

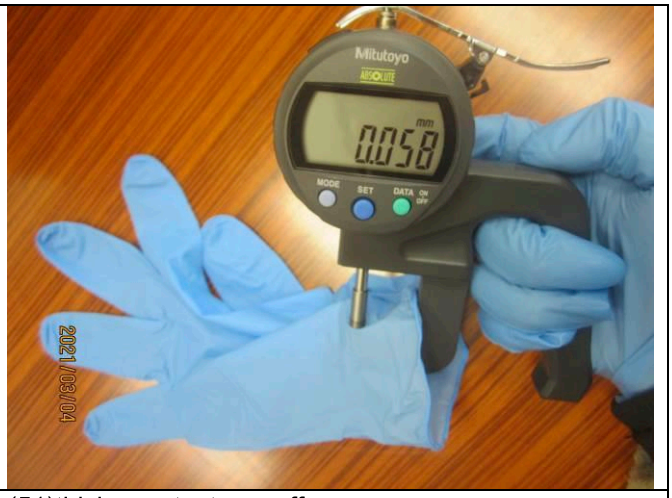
(47)

(48) Wear check

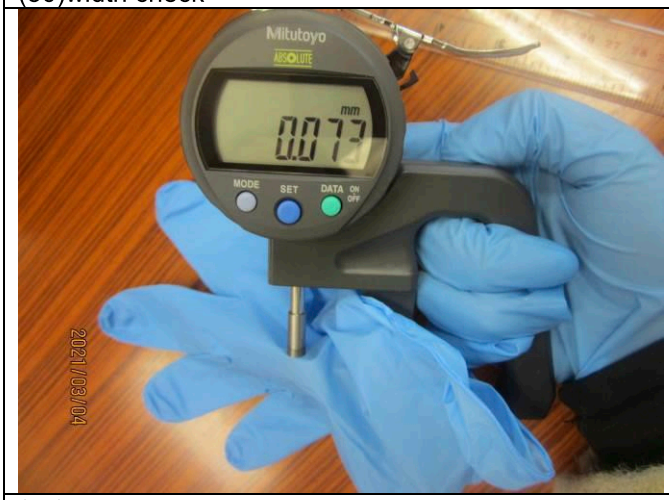
(49)length check

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

(50)width check



(51)thickness test on cuff



(52)thickness test on palm

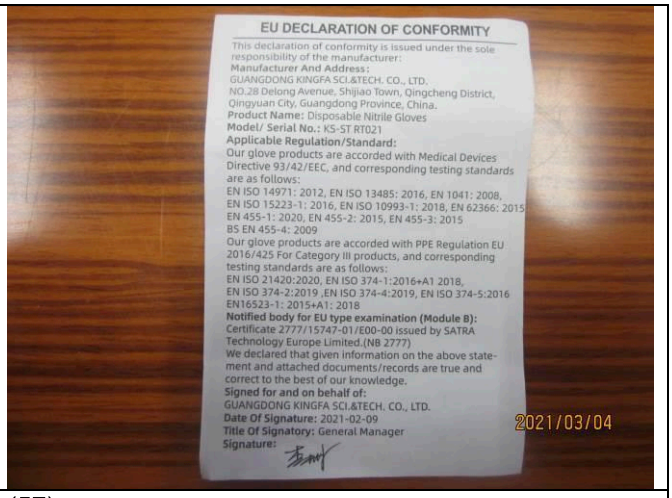
(53)thickness test on finger

(54) Unit weight check

(55) Number of pcs check per gift box

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

(56)



(57)

(58)weight check

(59)carton drop test

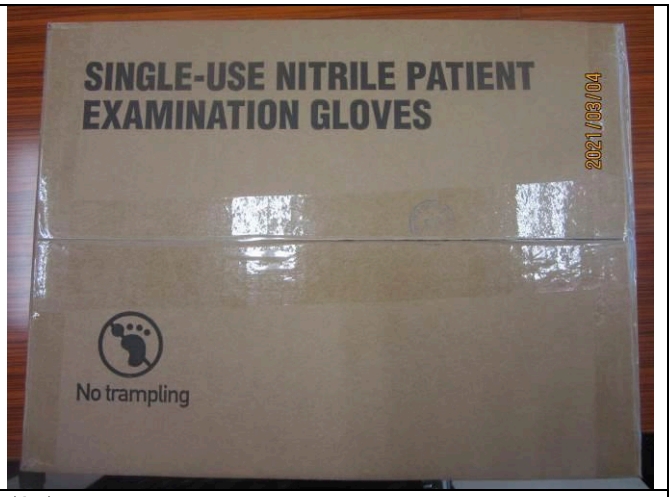
(60) Water leakage test

(61) Water leakage test

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

	
(62) Tensile strength test	(63) Tensile strength test

M Size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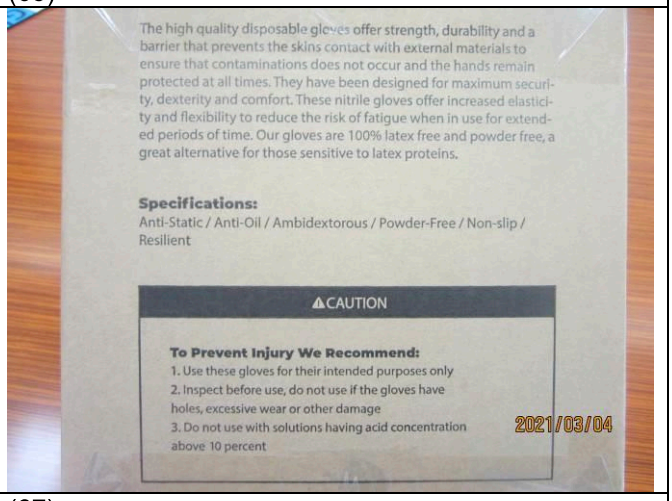
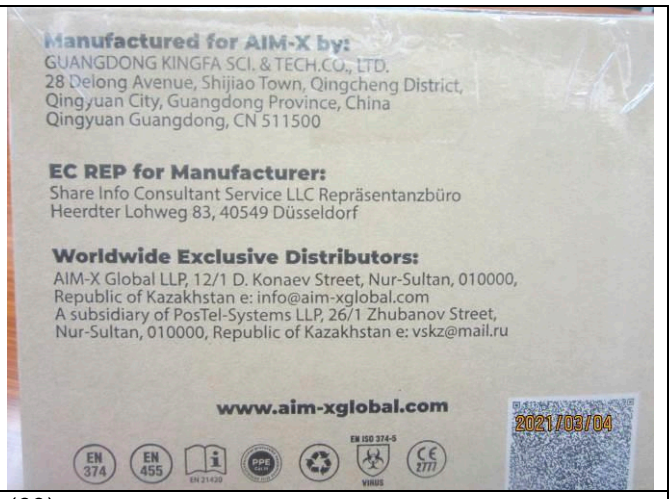
	
(66)	(67)

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

(68)



(69)

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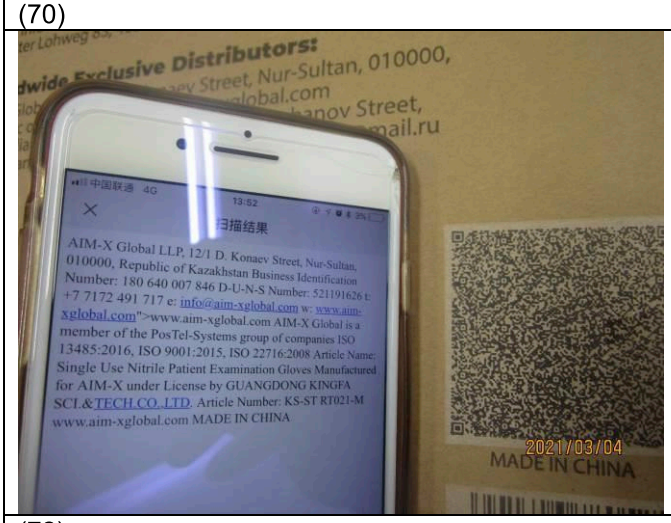
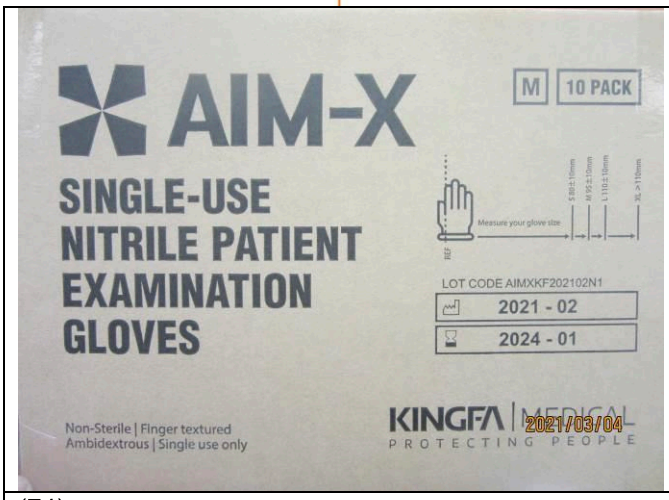


(72)

(73)

Inspector: Kaifang Zhang Factory Representative: Mr. Luo



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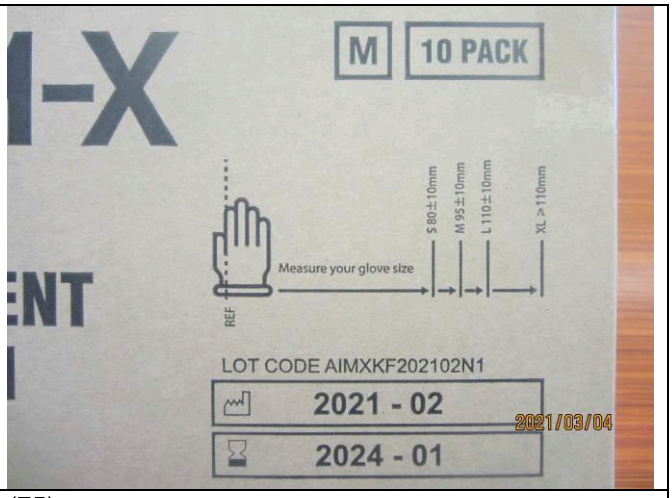

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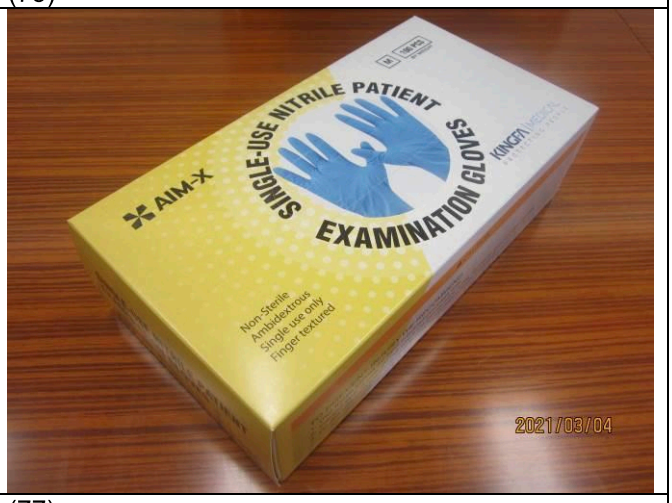
(76)



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Inspector: Kaifang Zhang Factory Representative: Mr. Luo

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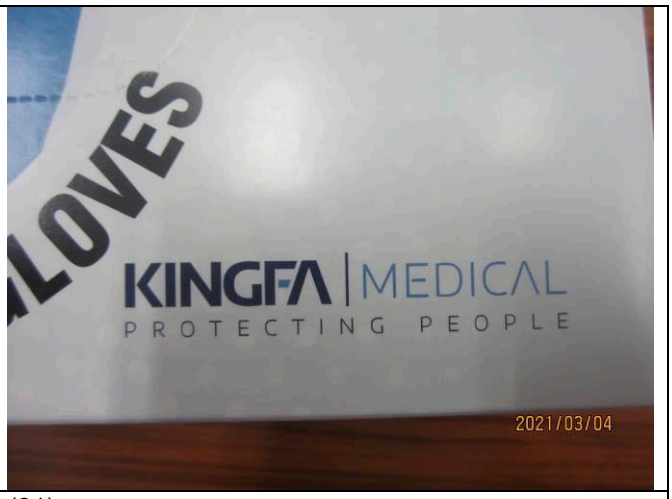

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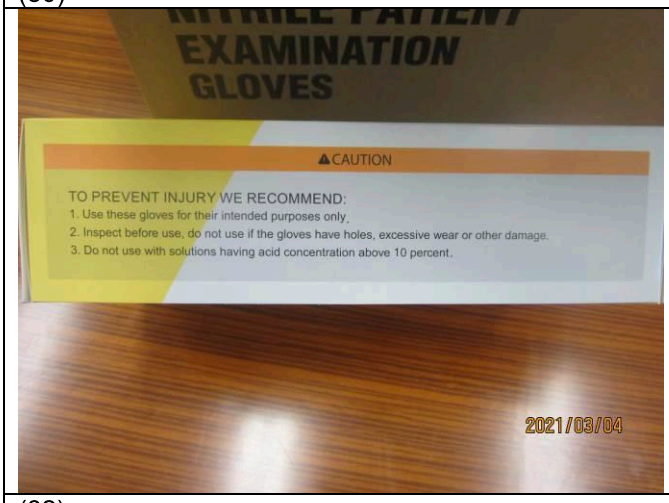

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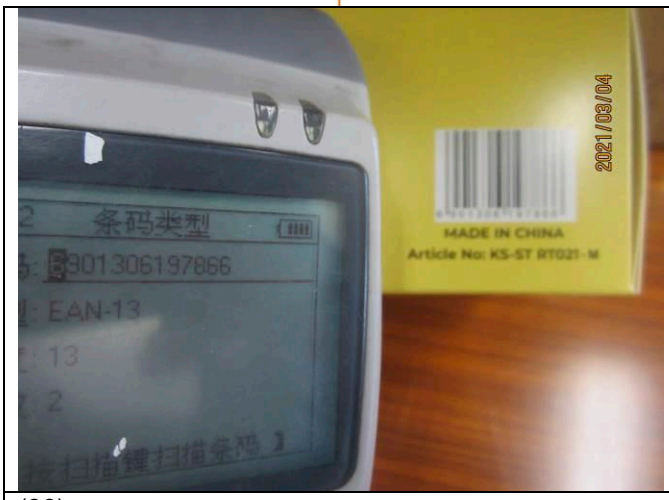
Inspector: Kaifang Zhang Factory Representative: Mr. Luo



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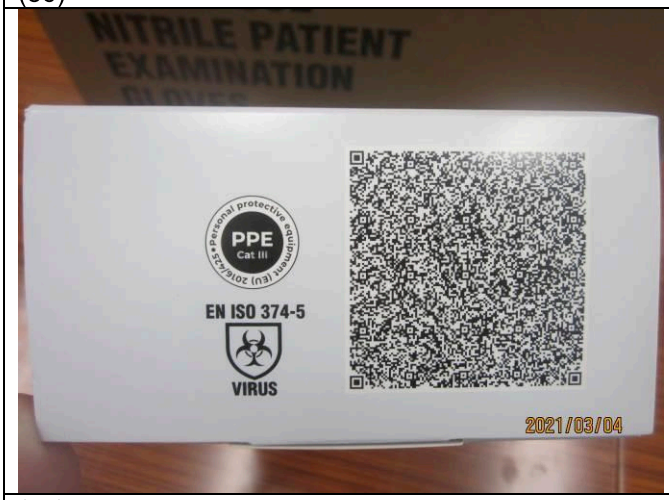

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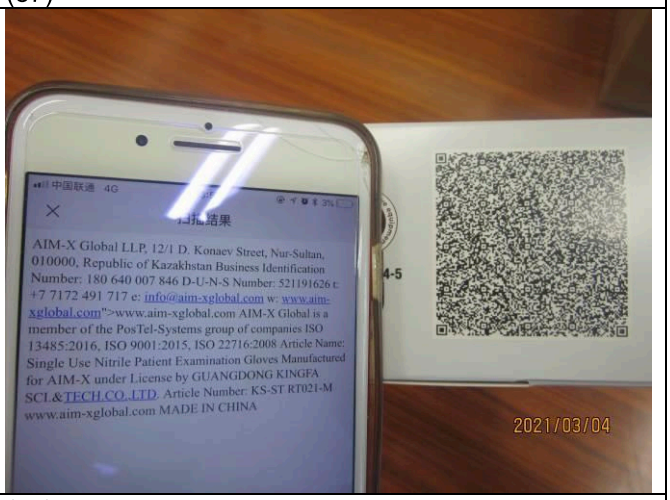

(89)

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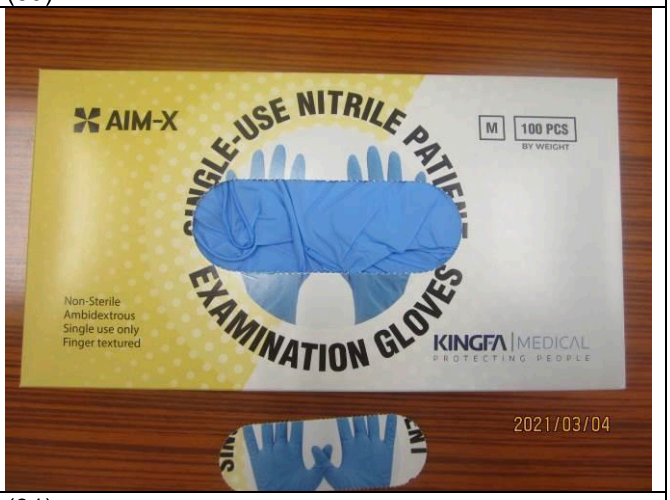
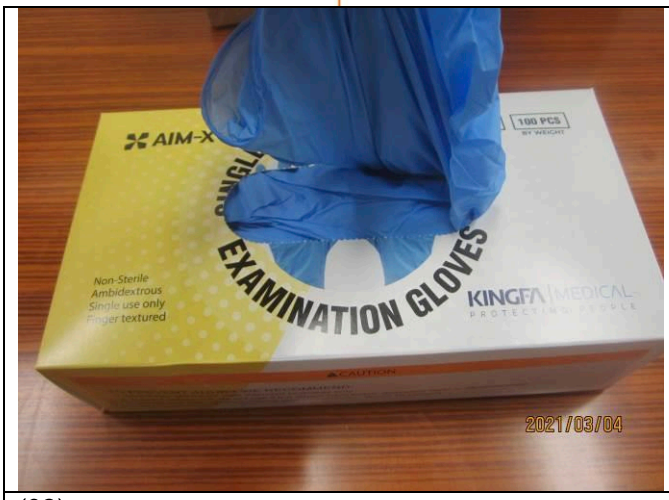


(91)

Inspector: Kaifang Zhang Factory Representative: Mr. Luo



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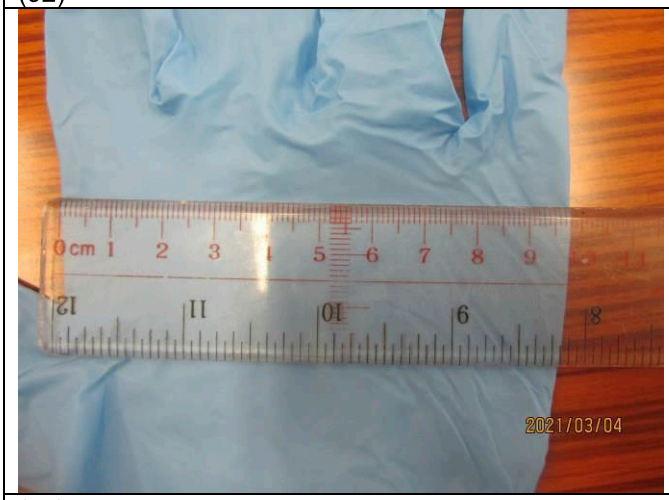
(93)



(94)width check

(95)length check

(96)thickness check on cuff

(97)thickness check on palm

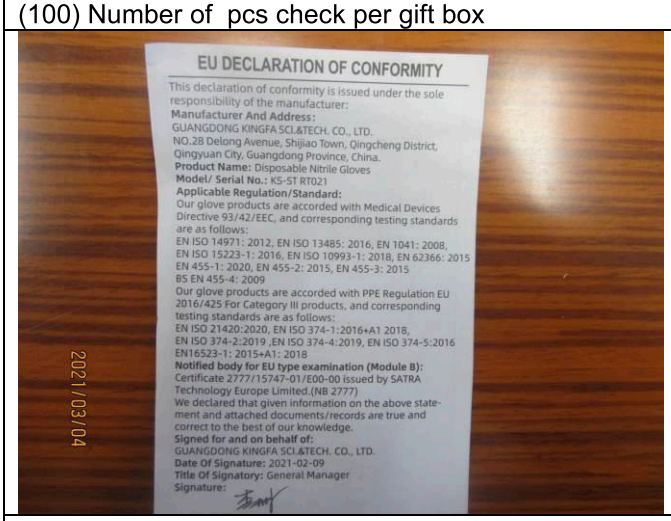
Inspector: Kaifang Zhang Factory Representative: Mr. Luo

(98)thickness check of finer

(99) Wear check

(100) Number of pcs check per gift box

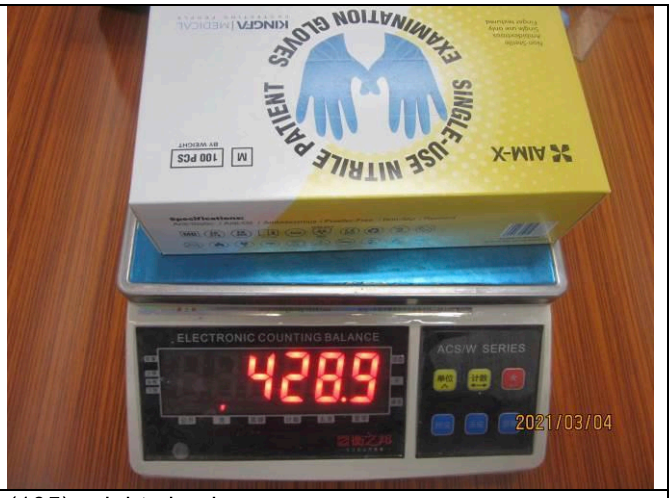
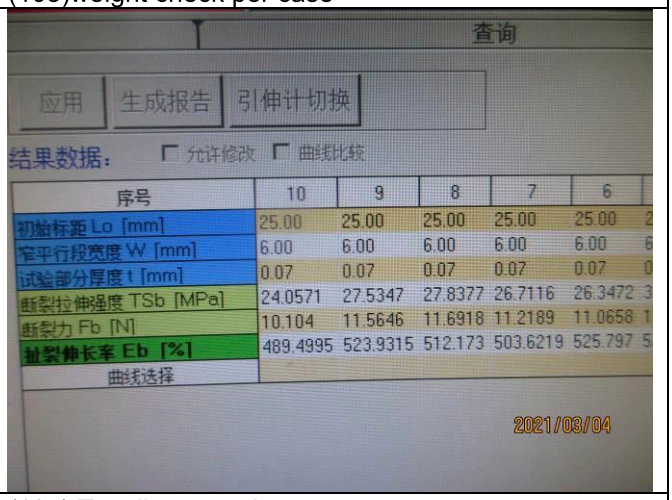
(101)



(102)

(103) Unit weight check

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

	
(104)carton drop test	(105)weight check per case
	
(106) Tensile strength test	(107) Tensile strength test

End of Report

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

Report No.: TAOWT00219821

INSPECTION REPORT

(Special for Epidemic prevention materials)

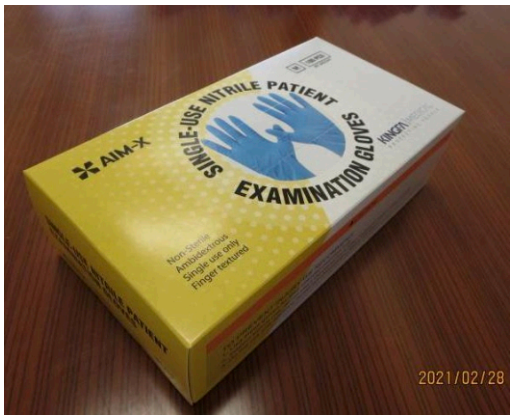
IMPORTANT INFORMATION REGARDING THE SCOPE AND LIMITATIONS OF THE INSPECTION AND REPORT

The scope of this report is limited to a **VISUAL INSPECTION ONLY** for the workmanship and basic function check of the product. Performance index and compliance of the product are NOT included in the scope of this report. This report is a reasonable attempt to identify any obvious or significant defects apparent in those areas of the product fully accessible and visible to the Inspector at the time of the inspection. This Report is made solely for the use and benefit of the Client named on the front of this report.

To :	AIM-X Global LLP	Date:	01-Mar-2021
Att :	Abdul Halim Choudhury		
From :	Elvis Dong	E-mail :	elvis.dong@sgs.com

SGS File No.:	CNTAO10334313
Buyer :	AIM-X Global LLP
Supplier :	GUANGDONG KINGFA SCI.&TECH CO.,LTD
Manufacturer :	GUANGDONG KINGFA SCI.&TECH CO.,LTD
Style Number:	0001
Product description:	Single-use Nitrile Patient Examination Gloves
P.O. Number:	KFAIM20210203001
L/C Number:	N/A
Service performed :	FRI
Inspection Date :	28-Feb-2021
Inspection Location :	Qingyuan, Guangdong, China

Product family view



Inspection Criteria

Reference sample provided by	Not Available
Client instruction/specification	YES
SGS WI number	P-INSP-WI-HL-111
Other	N/A

Overall Inspection Conclusion:	**Subject to client's evaluation**

Inspection Summary:

1. Quantity :	Conform
2. Style, color :	Subject to client's evaluation
3. Workmanship appearance / function :	Conform
4. Data measurement / field tests:	Subject to client's evaluation
5. Packing :	Subject to client's evaluation
6. Marking / label :	Conform
Problem Remark:	
1. No reference sample was available for comparison during inspection.	

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

1. Quantity: Conform

No	Style / Item/ Article	P.O. No.	Order Qty.	Inspection Qty. (Presented Qty. for insp.)		Number of Cartons	
				Packed	Not Packed	Packed	Not packed
1	M	KFAIM2021020	15000	15000	0	1500	0
		Total:	15000	15000	0	1500	0

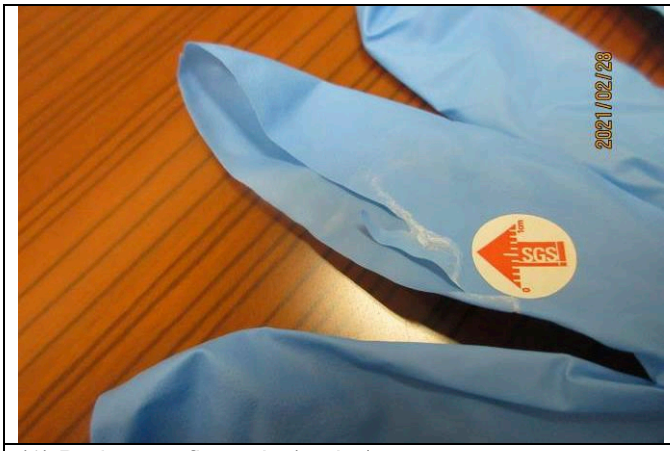
2. Style & Color Conformity: Subject to client's evaluation

Comments:
No refer sample was available for comparison during inspection.

3. Workmanship Appearance / Functional Inspection Findings: Within AQL

Inspection Method Applied:
ANSI / ASQ Z1.4- 2003（R2018）, Single sampling plans for normal inspection,
Level II Sample size: 1250pcs
Acceptance Quality Limit (AQL) for: Critical: N/A Major: 1.0 Minor: 1.5

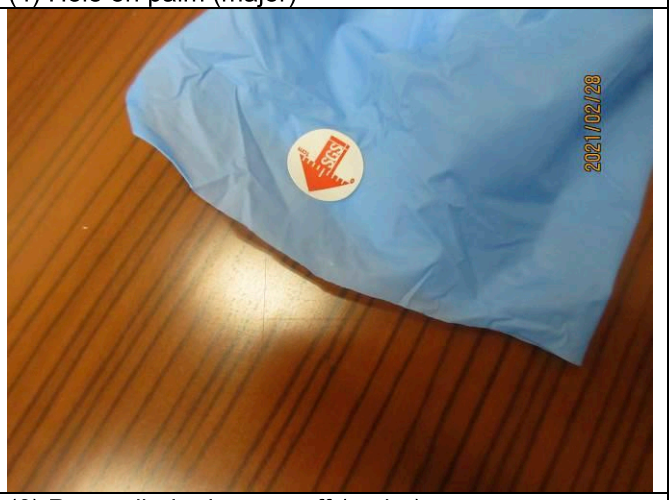
Defect description	Critical	Major	Minor
Broken on fingertip	0	1	0
Double layer product	0	1	0
Hole on palm	0	3	0
Poor rolled edge on cuff	0	2	0
Dirt stain on surface	0	0	10
White mark on surface	0	0	3
Total defectives:	0	7	13
Maximum allowed:	0	21	21



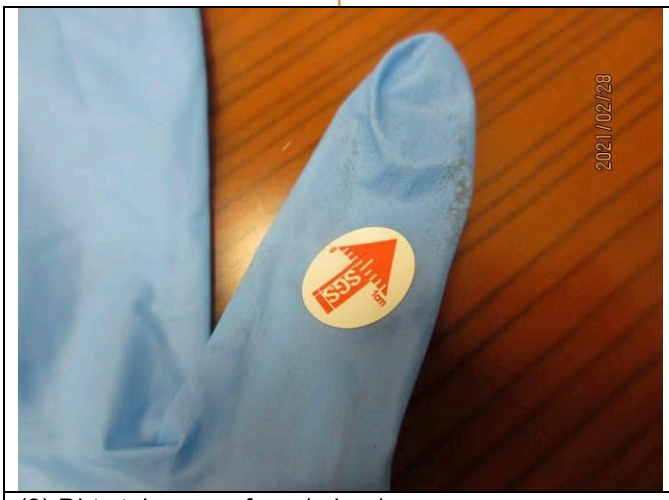
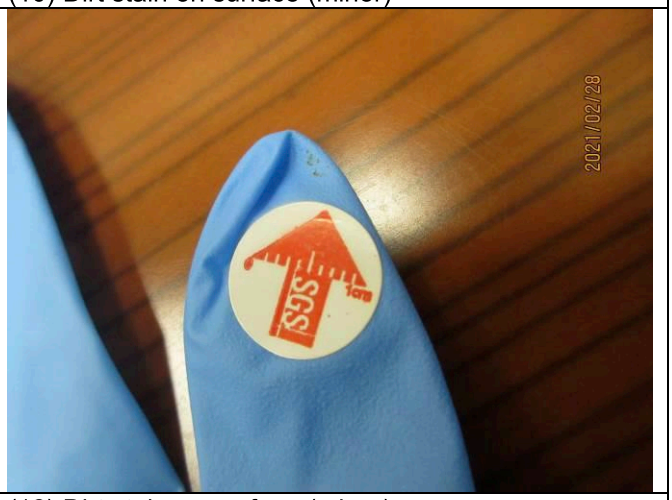
(1) Broken on fingertip (major)

(2) Double layer product (major)

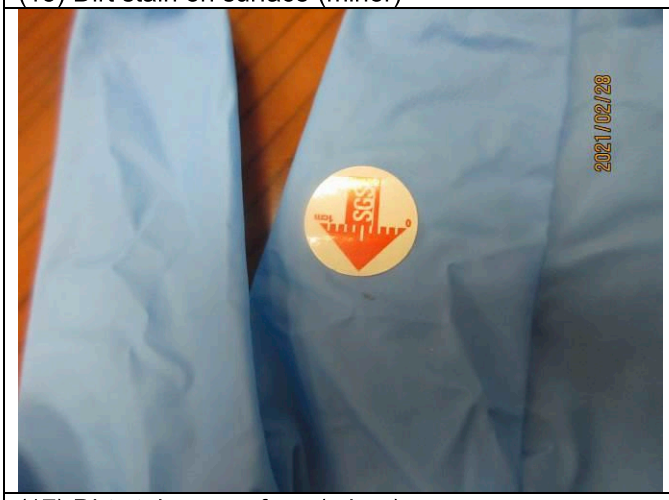
Inspector: Kaifang Zhang Factory Representative: Mr. Luo

	
(3) Hole on palm (major)	(4) Hole on palm (major)
	
(5) Hole on palm (major)	(6) Poor rolled edge on cuff (major)
	
(7) Poor rolled edge on cuff (major)	(8) Dirt stain on surface (minor)

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

	
(9) Dirt stain on surface (minor)	(10) Dirt stain on surface (minor)
	
(11) Dirt stain on surface (minor)	(12) Dirt stain on surface (minor)
	
(13) Dirt stain on surface (minor)	(14) Dirt stain on surface (minor)

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

	
(15) Dirt stain on surface (minor)	(16) Dirt stain on surface (minor)
	
(17) Dirt stain on surface (minor)	(18) White mark on surface (minor)
	
(19) White mark on surface (minor)	(20) White mark on surface (minor)

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

4. Product-Specific Data Measurement / Field Test on Reduced Sample Size: Subject to client's evaluation

Check points	Qty	Test Result	Specification/Tolerance
Unit size check(mm)	5	242x98,241x98,244x98,244x97,245x98	M >=240x95+/-10mm
Unit thickness check(mil)	5	Cuff thickness: 2.36, 2.28, 2.36, 2.36, 2.28 mil Palm thickness: 2.76, 2.87, 2.80, 2.76, 2.87 mil Fingertip thickness: 3.98, 4.21, 3.94, 4.33, 4.13 mil	Finger(mm) Palm (mm) Cuff (mm) ≥0.05 ≥0.08 N/A 1.97mil 3.15mil N/A
Unit weight check (g)	5	3.92,3.86,3.95,3.94,3.95	N/A
Box size check(cm)	1	23x12x6.5	N/A
Number of pcs check per gift box	2	100,102	100pcs
Carton size check	1	33.5x25x24.5	N/A
Carton weight check(kg)	1	4.67	N/A
Carton drop test	1	Passed	76cmx10times
Barcode scan	5	Passed	Can be scan and corrected
Tensile strength test(N)	5	10.45,12.83,10.40,10.46,10.47	N/A
Water leakage test	125	2pcs leak	N/A

5. Packing:

5.1 Individual packing conformity : Subject to client's evaluation
Comments:
Each set (100 pcs) per color box

5.2 Inner packing conformity : Not Applicable
Comments:
N/A

5.3 Export packing conformity : Conform
Comments:
10 sets per 3-ply corrugated cardboard export carton sealed with gummed tape.

5.4 Samples selected from carton numbers:
Total selected 5 cartons for inspection and no carton number

6. Marking / Label:

6.1 Bar code: Conform
Please refer to photo

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

6.2 Shipping mark conformity: Conform
Comments:
Please refer to photo

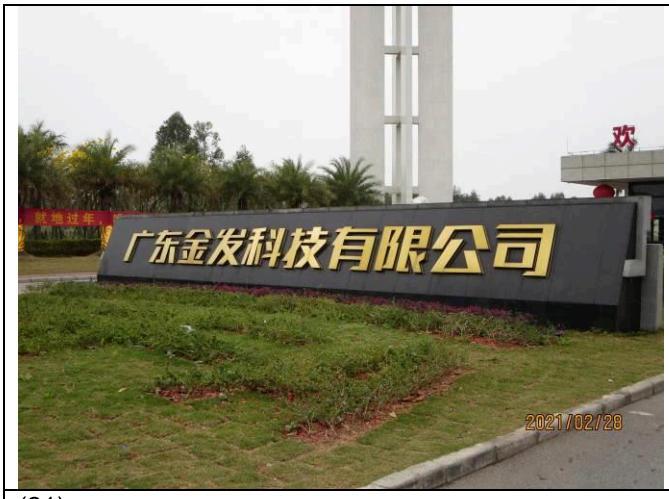
6.3 Marking & label conformity: Conform
Comments:
Please refer to photo

7. Informative Remark:
Nil

8. Inspection Environment:

Lighting :	Room lighting Sufficient
Inspection place :	Warehouse
Inspection done on:	Table
Cleanliness :	Clean
Weather condition:	Rainy
Cargo storage:	Orderly, easy to count

9. Attachment

	
(21)	(22)

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

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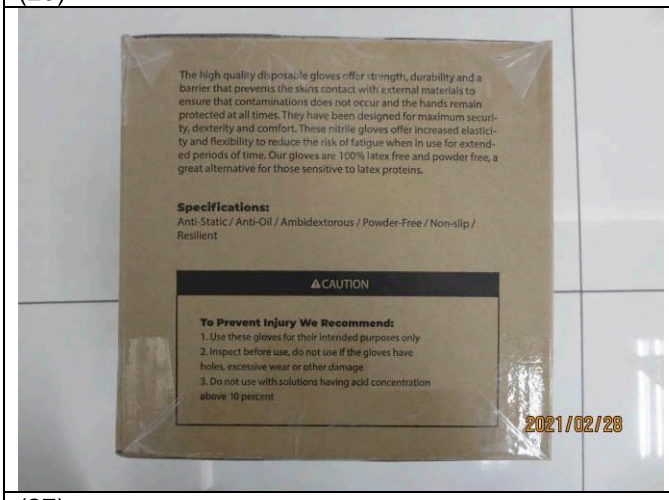

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Inspector: Kaifang Zhang Factory Representative: Mr. Luo

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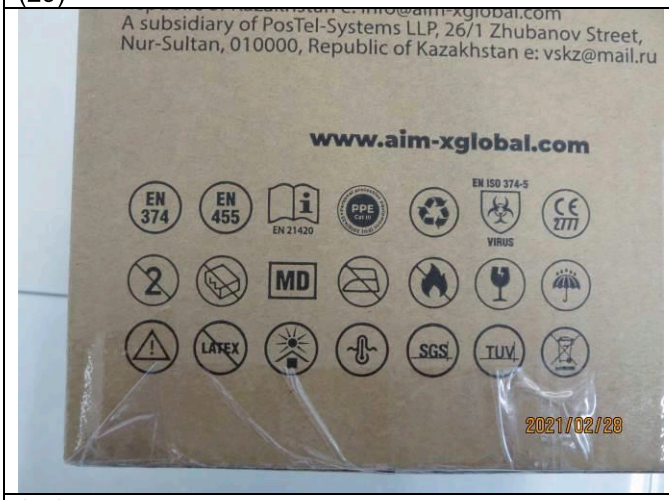

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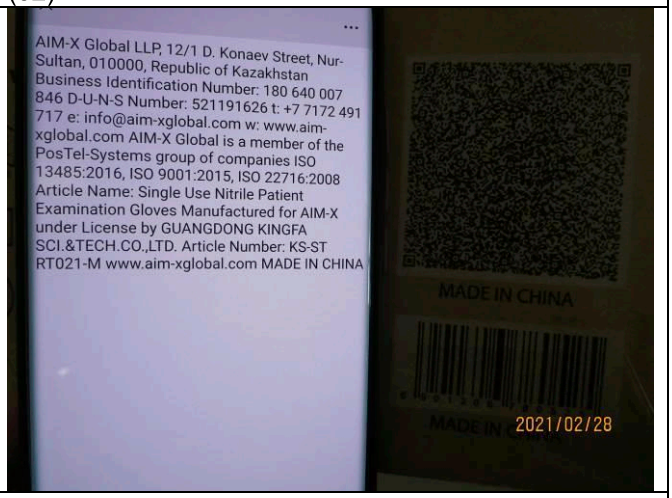

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Inspector: Kaifang Zhang Factory Representative: Mr. Luo

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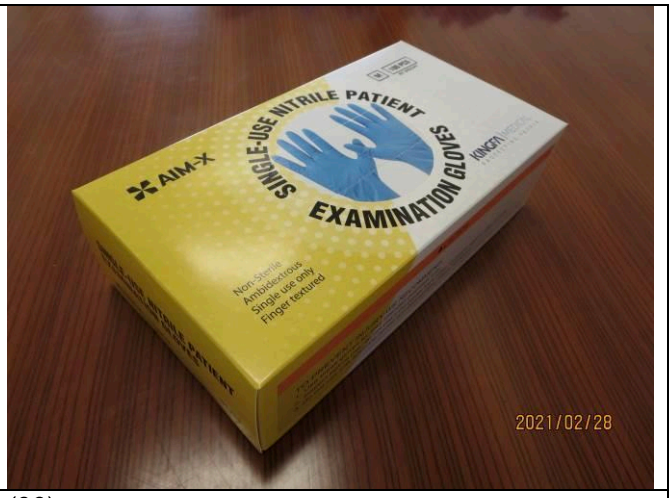

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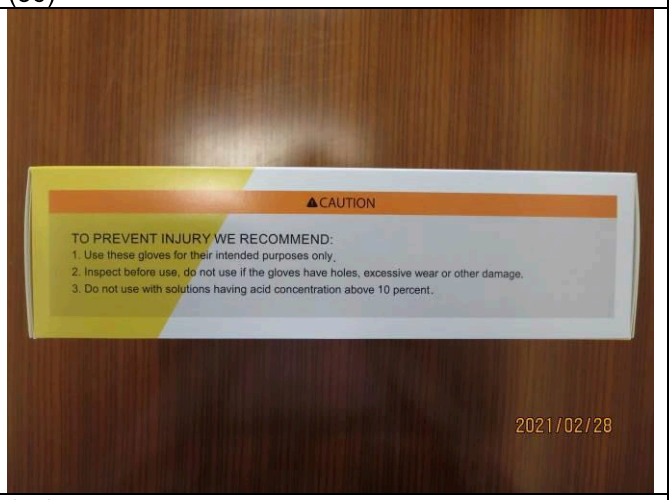

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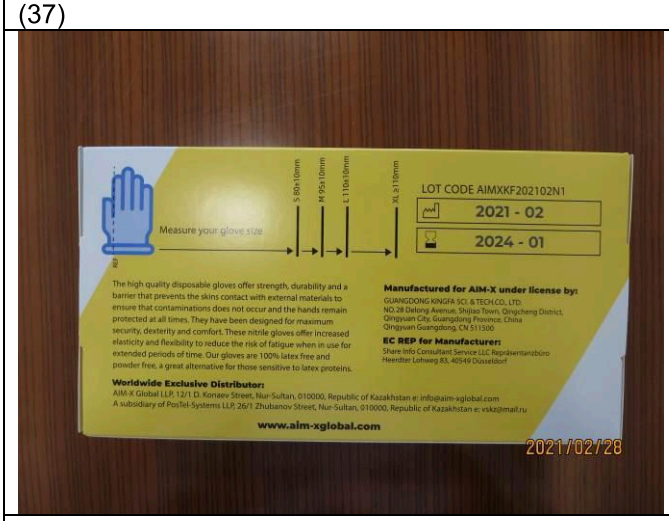

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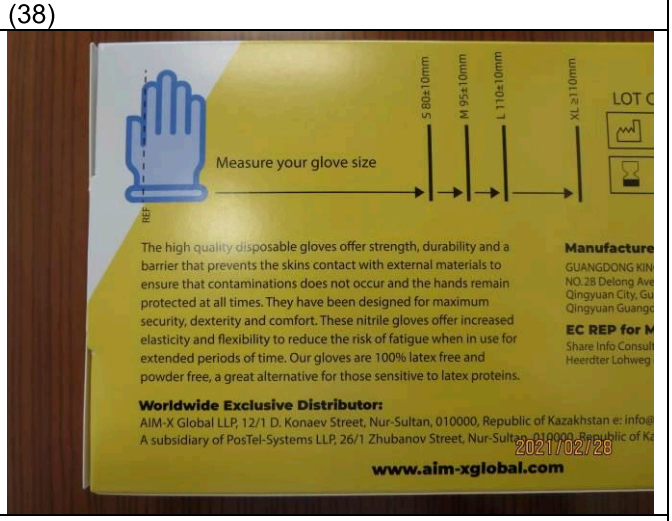

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Inspector: Kaifang Zhang Factory Representative: Mr. Luo

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Inspector: Kaifang Zhang Factory Representative: Mr. Luo

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Inspector: Kaifang Zhang Factory Representative: Mr. Luo

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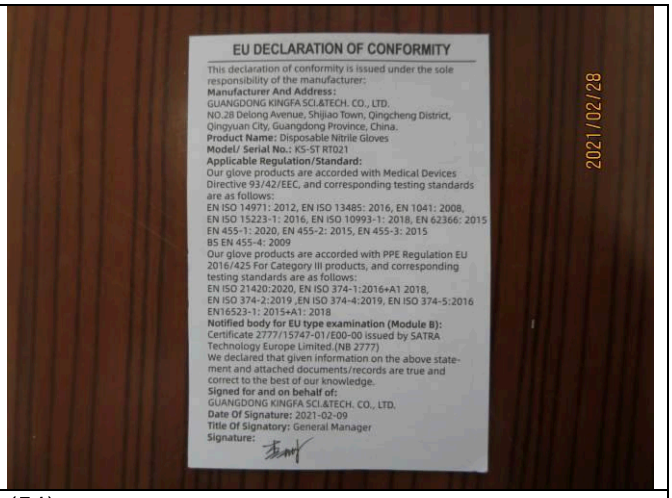
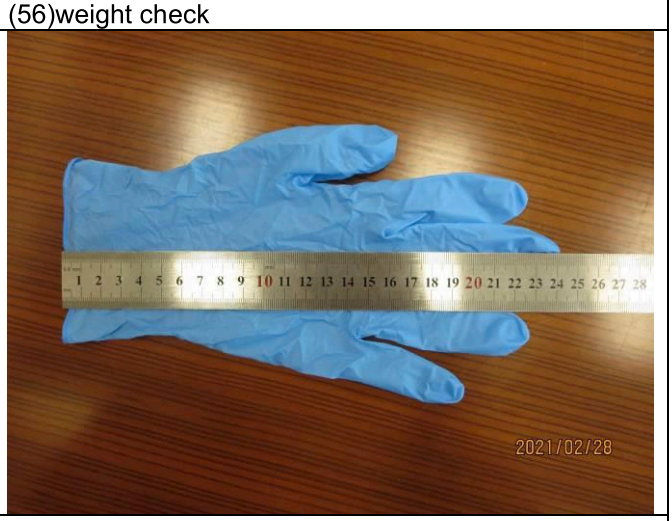


(54)

(55)

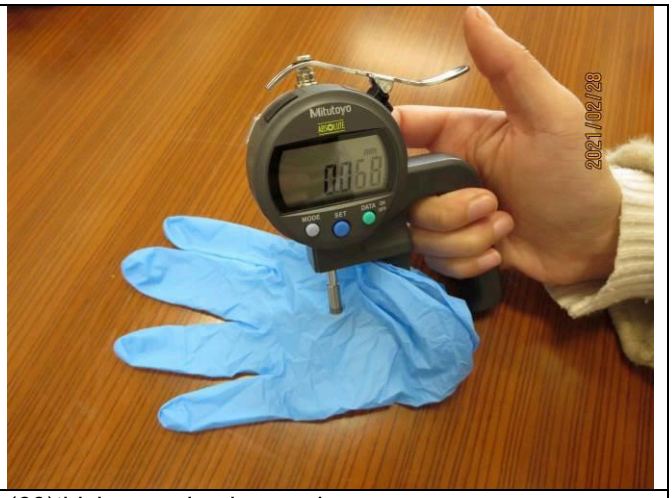
(56)weight check

(57)width check

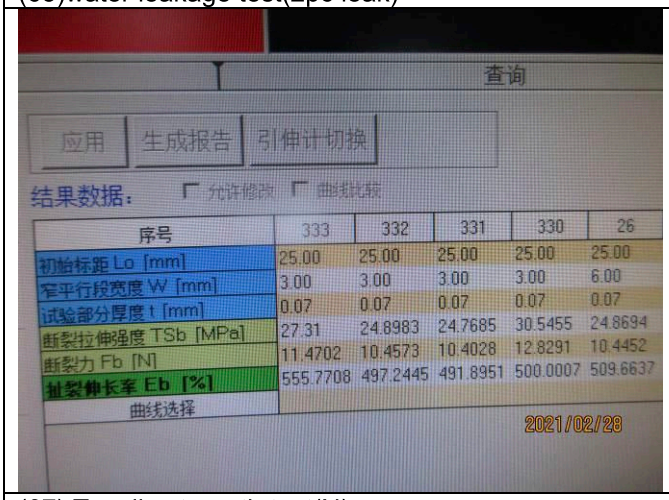


(58)length check

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

	
(59)thickness check on cuff	(60)thickness check on palm
	
(61)thickness check on fingertip	(62)quantity check
	
(63)carton drop test	(64)water leakage test

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

	
(65)water leakage test(2pc leak)	(66) Tensile strength test(N)
	N/A
(67) Tensile strength test(N)	

End of Report

Inspector: Kaifang Zhang Factory Representative: Mr. Luo

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

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.

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

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.

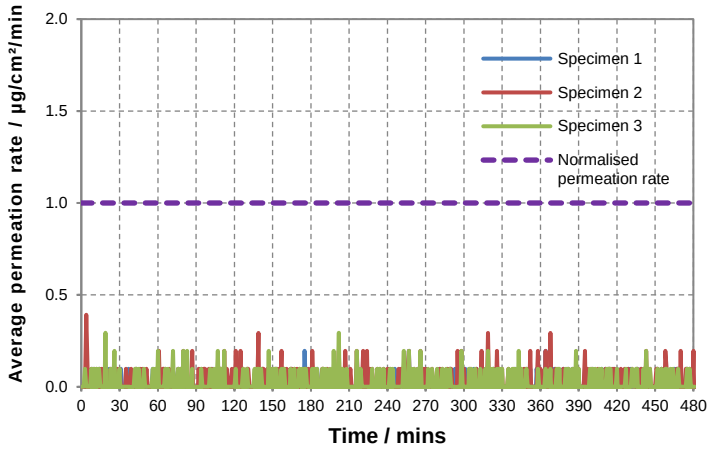
Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

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

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.

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

1. GENERAL

1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are hereby excluded.

1.2 SATRA Technology Centre Limited, its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.

1.3 These terms and conditions will apply to the Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealing

1.4 Unless otherwise agreed in writing no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.

1.5 All references in these terms and conditions to:

(a) the "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and
(b) "Services" are the work or services to be supplied or performed under the Contract (including where relevant the supply of software, components and consumables); and
(c) "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment).

1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the goods or services being described and shall not form part of the Contract.

1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

2. FEES AND PAYMENT

2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.

2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.

2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try and provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.

2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.

2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.

2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.

2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.

2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.

2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.

2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

3. INTELLECTUAL PROPERTY RIGHTS

3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.

3.2 In the event of certification services the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.

3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.

3.4 The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.

3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors. With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.

3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) Regulation (EU) 2016/679. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4. SUSPENSION OR TERMINATION OF SERVICES

4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.

4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Clients failure to comply with its obligations under the Contract.

5. LIABILITY AND INDEMNIFICATION

5.1 Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.

5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:

(a) death or personal injury caused by its negligence or the negligence of its employees or agents;
(b) fraud or fraudulent misrepresentation;
(c) breach of the terms implied by Section 12 of the Sale of Goods Act 1979;
(d) defective products under the Consumer Protection Act 1987; or
(e) any other liability which cannot be limited or excluded by applicable law.

5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.

5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or £100,000 whichever is the lower figure.

6. MISCELLANEOUS

6.1 If any one or more provisions of these conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.

6.3 The use of SATRAs corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.

6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.

6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.

6.6 All provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

7. CONFIDENTIALITY

7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.

7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.

7.3 Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.

7.4 The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client.

7.5 The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA.

8. AMENDMENT

8.1 No amendment to this Contract shall be effective unless it is in writing, expressly stated to amend this Contract and signed by an authorised signatory of both Parties.

9. DISPUTE RESOLUTION

9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.

9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a mediator.

9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twenty-eight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no connection with the mediator or the mediation proceedings, unless both parties have consented in writing. The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of the

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

Chartered Institute of Arbitrators (2000 Edition), or any amendments thereof, which Rules are deemed to be incorporated by reference into this clause. The seat of the arbitration shall be England and Wales.

9.4 The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.

10. PROVISION OF SERVICES

10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Clients specific instructions and as confirmed by SATRA as part of the Contract review process.

10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.

10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. 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.

10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.

10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRAs sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.

10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.

Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client. Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.

Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.

10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.

10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.

10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.

11. CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES

11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.

11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.

11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.

11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.

12. DELIVERY AND NON-DELIVERY OF GOODS

12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.

12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.

12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.

12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.

12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.

12.6 If for any reason the Client fails to accept delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).

13. RISK/TITLE OF GOODS

13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.

13.2 The Company shall not accept responsibility for loss or damage in transit unless:

a) In the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or

b) In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.

13.3 Title to the Goods shall not pass to the Client until the earlier of when: -

a) SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and

b) the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.

13.4 Until ownership of Goods has passed to the Client, the Client shall:

a) hold the Goods as SATRA's bailee;

b) store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);

c) not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and

d) maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.

13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.

13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:

a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and

b) SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and

c) if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.

13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.

13.8 On termination of the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.

14. PATENTS

14.1 SATRA gives no indemnity against any claim of infringement of Letters Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.

15. WARRANTY OF GOODS

15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.

16. DEFECTIVE GOODS

16.1 Subject to clauses 16.6 and 16.7 if:

a) the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and

b) SATRA is given a reasonable opportunity of examining such Goods; and

c) the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.

16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.

16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.

16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.

16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.

16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:

a) the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or

b) the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or

c) the Client has breached any of the terms of the Contract under which the Goods were supplied; or

d) the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;

16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:

a) SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;

b) nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.

16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Terms and conditions – September 2019

SATRA Technology Services (Dongguan) Ltd
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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

Adam Zhang

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 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	± 1.10 mm	N/A
5.2 Dexterity	See table 1	Size / Minimum pin diameter / mm 6: 5.0 7: 5.0 8: 5.0 9: 5.0	N/A	Level 5

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 *****

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

1. GENERAL

1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are, to the maximum extent permitted by law, hereby excluded.

1.2 SATRA Technology Services (Dongguan) Limited (东莞赛卓检测技术服务有限公司), its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for, or supply Goods to, persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.

1.3 These terms and conditions will apply to any Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealings.

1.4 Unless otherwise agreed in writing, no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.

1.5 All references in these terms and conditions to:

1.5.1 "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and

1.5.2 "Services" are the work or services to be supplied or performed under the Contract (including, where relevant the supply of software, components and consumables); and

1.5.3 "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment); and

1.5.4 "PRC" means the People's Republic of China.

1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the Goods or Services being described and shall not form part of the Contract.

1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

2 FEES AND PAYMENT

2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.

2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.

2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try to provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.

2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.

2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.

2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.

2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.

2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.

2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.

2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

3 INTELLECTUAL PROPERTY RIGHTS

3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.

3.2 In the event of certification services, the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.

3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.

3.4 The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.

3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors.

3.6 With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.

3.7 SATRA shall observe all statutory provisions with regard to data protection. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4 SUSPENSION OR TERMINATION OF SERVICES

4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.

4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Clients failure to comply with its obligations under the Contract.

5 LIABILITY AND INDEMNIFICATION

5.1 Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.

5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:

5.2.1 death or personal injury caused by its negligence or the negligence of its employees or agents;
5.2.2 fraud or fraudulent misrepresentation; or
5.2.3 any other liability which cannot be limited or excluded by applicable law.

5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.

5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or RMB500,000 whichever is the lower figure.

6 MISCELLANEOUS

6.1 If any one or more provisions of these terms and conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.

6.3 The use of SATRA's corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.

6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.

6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.

6.6 To the extent permitted by applicable laws and regulations, all provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

7 CONFIDENTIALITY

7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.

7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.

7.3 Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms and conditions and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.

7.4 The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client.

7.5 The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA.

8 AMENDMENT

8.1 No amendment to a Contract shall be effective unless it is in writing, expressly stated to amend the Contract and signed by an authorised signatory of both Parties.

9 DISPUTE RESOLUTION

9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.

9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, the terms of clause 9.3 shall apply.

9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, refer the dispute to the Shenzhen Court of International Arbitration for arbitration in accordance with its rules of arbitration then in force. The place of arbitration shall be Shenzhen. The number of arbitrators shall be one. Unless agreed otherwise, the language used for the arbitration shall be English and Chinese and each Party shall have the right to have its own interpreters and legal advisors present throughout the arbitration. The arbitral award shall be final and binding upon the Parties and the Parties agree to be bound thereby and to act accordingly. Application may be made to any court having jurisdiction for judicial acceptance of the award and an order of enforcement and execution.

9.4 Unless specified otherwise in a Contract, the laws of the PRC shall govern the interpretation of a Contract.

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

10 PROVISION OF SERVICES

10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Client's specific instructions and as confirmed by SATRA as part of the Contract review process.

10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.

10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. 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.

10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.

10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRA's sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.

10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.

Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client.

Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.

Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.

10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.

10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.

10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.

11 CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES

11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.

11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.

11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.

11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.

12 DELIVERY AND NON-DELIVERY OF GOODS

12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.

12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.

12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.

12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.

12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.

12.6 If for any reason the Client fails to take delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).

13 RISK/TITLE OF GOODS

13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.

13.2 The Company shall not accept responsibility for loss or damage in transit unless:

13.2.1 In the case of sales where delivery of Goods is made in the PRC, SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or

13.2.2 in all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.

13.3 Title to the Goods shall not pass to the Client until the earlier of when: -

13.3.1 SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and

13.3.2 the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.

13.4 Until ownership of Goods has passed to the Client, the Client shall:

13.4.1 hold the Goods as SATRA's bailee;

13.4.2 store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);

13.4.3 not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and

13.4.4 maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.

13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.

13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:

13.6.1 the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and

13.6.2 SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and

13.6.3 if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.

13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.

13.8 On termination of a Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause13 shall remain in effect.

14 PATENTS

14.1 SATRA gives no indemnity against any claim of infringement of any Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of a Patent, Registered Design, Trade Mark or Copyright published at the date of a Contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.

15 WARRANTY OF GOODS

15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.

16 DEFECTIVE GOODS

16.1 Subject to clauses 16.6 and 16.7 if:

16.1.1 the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and

16.1.2 SATRA is given a reasonable opportunity of examining such Goods; and

16.1.3 the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business,

then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.

16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.

16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.

16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.

16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.

16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:

16.6.1 the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or

16.6.2 the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or

16.6.3 the Client has breached any of the terms of the Contract under which the Goods were supplied; or

16.6.4 the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;

16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:

16.7.1 SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;

16.7.2 nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.

16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Terms and conditions – May 2017

CMA 180015144061

ilac-MRA CNAS 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,Qingch[illegible] District [illegible] yuan,Guangdong,China

Sanitation & Environment Technology Institute, [illegible]ochow U[illegible]ersity

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

Content

Supplementary Explanation

(1) Please apply for rechecking within 15 days of receiving the report if there are any objections.

(2) Any erasure or without special inspection and testing seal renders the report null and void.

(3) The report is only valid when signed by the persons who edited, checked and approved it.

(4) The results relate only to the articles tested.

(5) The report shall not be reproduced except in full without the written approval of the institute.

(6) Conclusion determination basis is not in the scope of accreditation.

Verification Dates

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

Edited by: Wang Deheng 2021-03-08
Date

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

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

Sanitation & Environment Technology Institute, Soochow University

Summary

1 Test Article

Test Article Name	Nitrile gloves
Manufacturer	GUANG DONG KINGFA SCI.& TECH.CO.,LTD
Address	No.28 Delong Ave.,Shijiao Town,Qingcheng District,Qing yuan,Guangdong,China
Model	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,Qing yuan,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)= $Q_{10}^{[(T_{AA}-T_{RT})/10]}=2^{\lceil(60-25)/10\rceil}$ =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)℃ 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

2021-03-31

To Whom It May Concern，

This is to confirm that 1st Surveillance Audit and Extension Audit was carried out on behalf of TÜV Rheinland LGA Product GmbH Notified Body (CE0197) as follows:

Applicant	:	GuangDong Kingfa Science and Technology Co., Ltd.
Address	:	No.28, Delong Road, Qingcheng Dist., Shijiao Town, Qingyuan City, 511545, Guangdong, P.R. China
Standards	:	EN ISO 13485:2016
Scope	:	Design and Development, Manufacture and Distribution of Disposable Medical Face Masks (non-sterile), Disposable Gloves (non-sterile).
Date	:	2021-03-25~26
Report No.	:	10918575-100

No nonconformities were established what would affect the overall effectiveness of the QM-system. Therefore the auditors will recommend that TÜV Rheinland LGA Product GmbH Notified Body (0197) Certificate for a Quality Assurance System should be issued.

Yours sincerely,

Mr. Raymond LIN

Lead Auditor

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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.

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

Adam Zhang

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 6: 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	± 1.10 mm	N/A
5.2 Dexterity	See table 1	Size / Minimum pin diameter / mm 6: 5.0 7: 5.0 8: 5.0 9: 5.0	N/A	Level 5

Signed: Adam Zhang
Technologist
China Testing

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 *****

Signed: Adam Zhang
Technologist
China Testing

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

1. GENERAL

1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are, to the maximum extent permitted by law, hereby excluded.

1.2 SATRA Technology Services (Dongguan) Limited (东莞赛卓检测技术服务有限公司), its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for, or supply Goods to, persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.

1.3 These terms and conditions will apply to any Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealings.

1.4 Unless otherwise agreed in writing, no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.

1.5 All references in these terms and conditions to:

1.5.1 "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and

1.5.2 "Services" are the work or services to be supplied or performed under the Contract (including, where relevant the supply of software, components and consumables); and

1.5.3 "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment); and

1.5.4 "PRC" means the People's Republic of China.

1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the Goods or Services being described and shall not form part of the Contract.

1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

2 FEES AND PAYMENT

2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.

2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.

2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try to provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.

2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.

2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.

2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.

2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.

2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.

2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.

2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

3 INTELLECTUAL PROPERTY RIGHTS

3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.

3.2 In the event of certification services, the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.

3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.

3.4 The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.

3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors.

3.6 With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.

3.7 SATRA shall observe all statutory provisions with regard to data protection. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4 SUSPENSION OR TERMINATION OF SERVICES

4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.

4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Clients failure to comply with its obligations under the Contract.

5 LIABILITY AND INDEMNIFICATION

5.1 Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.

5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:

5.2.1 death or personal injury caused by its negligence or the negligence of its employees or agents;
5.2.2 fraud or fraudulent misrepresentation; or
5.2.3 any other liability which cannot be limited or excluded by applicable law.

5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.

5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or RMB500,000 whichever is the lower figure.

6 MISCELLANEOUS

6.1 If any one or more provisions of these terms and conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.

6.3 The use of SATRA's corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.

6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.

6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.

6.6 To the extent permitted by applicable laws and regulations, all provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

7 CONFIDENTIALITY

7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.

7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.

7.3 Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms and conditions and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.

7.4 The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client.

7.5 The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA.

8 AMENDMENT

8.1 No amendment to a Contract shall be effective unless it is in writing, expressly stated to amend the Contract and signed by an authorised signatory of both Parties.

9 DISPUTE RESOLUTION

9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.

9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, the terms of clause 9.3 shall apply.

9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, refer the dispute to the Shenzhen Court of International Arbitration for arbitration in accordance with its rules of arbitration then in force. The place of arbitration shall be Shenzhen. The number of arbitrators shall be one. Unless agreed otherwise, the language used for the arbitration shall be English and Chinese and each Party shall have the right to have its own interpreters and legal advisors present throughout the arbitration. The arbitral award shall be final and binding upon the Parties and the Parties agree to be bound thereby and to act accordingly. Application may be made to any court having jurisdiction for judicial acceptance of the award and an order of enforcement and execution.

9.4 Unless specified otherwise in a Contract, the laws of the PRC shall govern the interpretation of a Contract.

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

10 PROVISION OF SERVICES

10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Client's specific instructions and as confirmed by SATRA as part of the Contract review process.

10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.

10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. 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.

10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.

10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRA's sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.

10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.

Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client.

Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.

Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.

10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.

10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.

10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.

11 CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES

11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.

11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.

11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.

11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.

12 DELIVERY AND NON-DELIVERY OF GOODS

12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.

12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.

12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.

12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.

12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.

12.6 If for any reason the Client fails to take delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).

13 RISK/TITLE OF GOODS

13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.

13.2 The Company shall not accept responsibility for loss or damage in transit unless:

13.2.1 In the case of sales where delivery of Goods is made in the PRC, SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or

13.2.2 in all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.

13.3 Title to the Goods shall not pass to the Client until the earlier of when: -

13.3.1 SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and

13.3.2 the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.

13.4 Until ownership of Goods has passed to the Client, the Client shall:

13.4.1 hold the Goods as SATRA's bailee;

13.4.2 store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);

13.4.3 not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and

13.4.4 maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.

13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.

13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:

13.6.1 the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and

13.6.2 SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and

13.6.3 if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.

13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.

13.8 On termination of a Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause13 shall remain in effect.

14 PATENTS

14.1 SATRA gives no indemnity against any claim of infringement of any Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of a Patent, Registered Design, Trade Mark or Copyright published at the date of a Contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.

15 WARRANTY OF GOODS

15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.

16 DEFECTIVE GOODS

16.1 Subject to clauses 16.6 and 16.7 if:

16.1.1 the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and

16.1.2 SATRA is given a reasonable opportunity of examining such Goods; and

16.1.3 the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business,

then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.

16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.

16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.

16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.

16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.

16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:

16.6.1 the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or

16.6.2 the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or

16.6.3 the Client has breached any of the terms of the Contract under which the Goods were supplied; or

16.6.4 the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;

16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:

16.7.1 SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;

16.7.2 nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.

16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Terms and conditions – May 2017

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

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

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

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

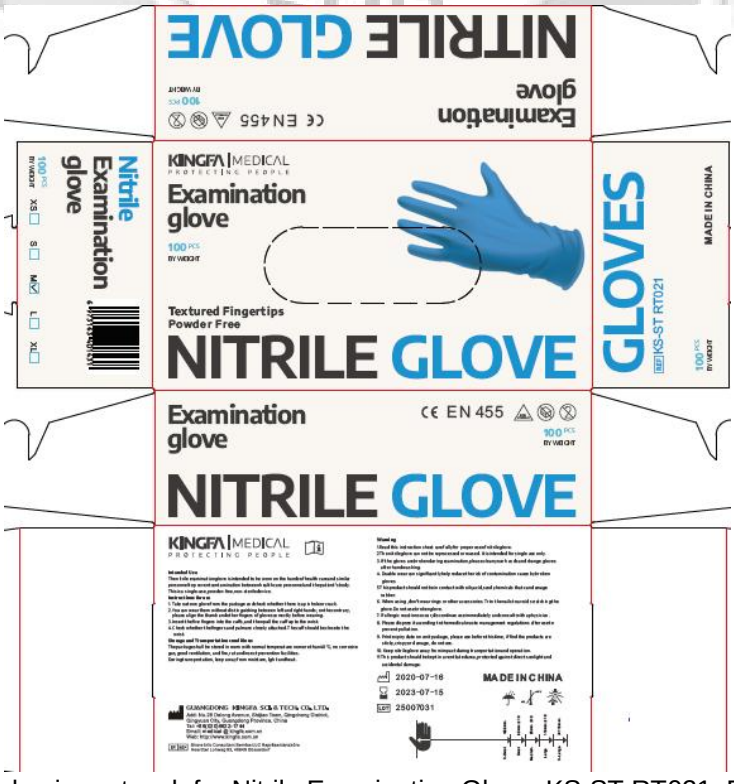


Photo 2: Packaging artwork for Nitrile Examination Glove, KS-ST RT021, Blue, Size M

PSB Singapore

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

PPE REGULATION (EU) 2016/425
MODULE C2 CERTIFICATE

Issued to:

Shijiazhuang Hongray Group Co., Ltd
South Tongda Road, East District
Jinzhou City
Hebei
052260
China

This is to certify that the following products tested under SATRA reports referenced:
CHT0271907/1823/SPT, CHT0271907/1823/JS/B & CHT0271907/1823/JS/A
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
2777/11050-02/E00-00	NPF2001-XS NPF2002-S NPF2003-M NPF2004-L NPF2005-XL	Disposable nitrile glove (blue beaded ambidextrous)	EN ISO 374-1:2016+A1:2018 Type B EN 374-2:2014 EN 374-4:2013 EN ISO 374-5:2016 EN 420:2003 +A1:2009

Dated: 27th November 2020

This certificate is valid until: *November 2021*

Signed By (Alan Weston)

For and on behalf of SATRA Technology Europe Limited

CE

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

KINGFA | MEDICAL
PROTECTING PEOPLE

EU Declaration of Conformity

according to the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

***Class I** Medical Device*

(non-sterile)

Manufacturer:	GUANGDONG KINGFA SCI.&TECH. CO., LTD.
Address:	No.28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
Single Registration Number (SRN) of the Manufacturer:	--
European Representative (ER):	Share Info GmbH
Address:	Heerdter Lohweg 83, 40549 Düsseldorf
Single Registration Number (SRN) of ER:	DE-AR-000005132

We, the manufacturer, declare under our sole responsibility that

the medical device(s)	**Product Name:**	Nitrile examination gloves
	Type/model, identification of product allowing traceability (Where applicable):	KS-ST RT021
	Intended Purpose:	The nitrile examination gloves are intended used for the health care personnel to prevent contamination during close contact with the patient. The products are single-use, powder-free and non-sterile.
	Classification: (Annex VIII of the MDR)	Class I Medical Device
	Basic UDI-DI:	697316340KS-STRT021D9
Conformity assessment route:		EU Declaration of Conformity + Technical Documentation (Annex II) + Technical Documentation on Post-Market Surveillance (Annex III)

KINGFA | MEDICAL
PROTECTING PEOPLE

is/are in conformity with the relevant provisions and requirements of the Council and the parliament regulation (EU) 2017/745 for medical device and all applicable harmonized standards and Common Specification. All supporting documents are retained under the premises of the manufacturer.

Applied harmonized standards and Common Specification	Regulation (EU) 2017/745	EN 455-1:2020
	EN ISO 14971:2019	EN 455-2:2015
	EN ISO 13485:2016	EN 455-3:2015
	EN 1041:2008	EN 455-4:2009
	EN ISO 10993-1:2018	EN ISO 15223-1:2016
	MEDDEV 2.7.1: 2016	EN 62366-1:2015
Notified Body:	Not Applicable	
Address:	Not Applicable	
Identification Number:	Not Applicable	
EC Certificate(s):	Not Applicable	

Signed on: Place: Qingyuan, China

2021-6-2

Signature (on behalf of the manufacturer) : GUANGDONG KINGFA SCI.&TECH CO., LTD.

Name of authorized signatory: Linanjing

Position held in the company: General Manager

CE

Test Report No.: 68.431.20.0384.01
Dated: 2021-01-08

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	:	2020-12-07, Shenzhen
Test Period, Location	:	From 2020-12-07 to 2021-01-06, Shenzhen
Test Result(s)	:	Refer to Section 3

Test Report No.: 68.431.20.0384.01
Dated: 2021-01-08

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
2	**Specific Migration of PAA**	Pass
3	**Specific Migration of Phthalates**	Pass
4	**Specific Migration of Butadiene (BU)**	Pass
5	**Phthalates Test**	Pass
6	**N-Nitrosamines and N-Nitrosatable substances Content**	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 expended uncertainty for "Pass", "Fail" and "Inconclusive" is 95%.

TüV SüD Certification and Testing (China) Co., Ltd. Shenzhen Branch
TüV SüD Group

Prepared by:

Hailey Tan
Project Engineer

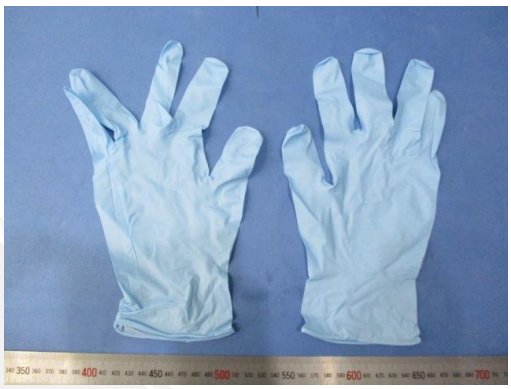
Reviewed by:

Angelina Wang
Supervisor

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 gloves (Rubber)	

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/dm²]	MAXIMUM PERMISSIBLE LIMIT [mg/dm²]
		SAMPLE 001	
3% Acetic acid	40 °C for 0.5 Hour	<3.0	<10
10% Ethanol	40 °C for 0.5 Hour	4.1	<10
Rectified olive oil	40 °C for 0.5 Hour	<3.0	<10

Note 1. "℃" 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

3.2 Specific Migration of PAA

Test method: With reference to EN 1186-1: 2002.follow by UV spectrophotometer
Test Conditions: 3% Acetic Acid: 40 °C for 0.5 Hour

TEST ITEM	RESULT [mg/kg foodstuff]	MAXIMUM PERMISSIBLE LIMIT [mg/kg foodstuff]
	SAMPLE 001	
Primary Aromatic Amine	<0.01	<0.01
Conclusion	Pass	-

Note 1. "℃" denotes degree Celsius
2. "<" denotes less than
3. "mg/kg" denotes milligram per kilogram
4. The specification was quoted from Regulation (EU) No. 10/2011

3.3 Specific Migration of Phthalates

Test method: As specified in Regulation (EU) No. 10/2011 ANNEX III and V, and followed by gas chromatography/Mass Spectrometry (GC-MS) analysis.

Test Conditions: 95% Ethanol: 40 °C for 0.5 Hour

TEST ITEM	RESULTS [mg/kg foodstuff]	MAXIMUM PERMISSIBLE LIMIT [mg/kg foodstuff]
	SAMPLE 001	
Dibutyl phthalate (DBP)	<0.30	0.3
benzyl butyl phthalate (BBP)	<1.0	30
Bis (2-ethylhexyl) phthalate (DEHP)	<0.30	1.5
adipic acid, bis(2-ethylhexyl) ester (DEHA)	<1.0	18
Bis(2-Ethylhexyl) Terephthalate (DEHTP)	<1.0	60
DINP+DIDP	<2.0	9
Conclusion	Pass	-

Note:
1. "mg/kg" denotes milligram per kilogram
2. "<" denotes less than

3.4 Specific Migration of Butadiene (BU)

Test method: As specified in Regulation (EU) No. 10/2011 ANNEX III and V, and followed by gas chromatography/Mass Spectrometry (GC-MS) analysis.

Test Conditions: 3% Acetic Acid: 40 °C for 0.5 Hour

TEST ITEM	RESULT [mg/kg foodstuff]	MAXIMUM PERMISSIBLE LIMIT [mg/kg foodstuff]
	SAMPLE 001	
Butadiene	<0.01	<0.01
Conclusion	Pass	-

Note 1. "℃" denotes degree Celsius
2. "<" denotes less than
3. "mg/kg" denotes milligram per kilogram

3.5 Phthalates Test

Solvent extraction in chloroform, followed by GC-MS
[Reporting Limit = 0.005%]

Test Items	CAS No.	Results [%]	Limit [%]
		Sample 001	
Benzyl butyl Phthalate, (BBP)	85-68-7	<0.005	<0.1
Di-isodecyl Phthalate, (DIDP)	26761-40-0 , 68515-49-1	<0.005	<0.1
Bis (2-ethylhexyl) Phthalate, (DEHP)	117-81-7	<0.005	<0.1
Di-isononyl Phthalate, (DINP)	28553-12-0 , 68515-48-0	<0.005	<0.1
Di-n-butyl Phthalate, (DnBP)	84-74-2	<0.005	<0.05
Conclusion		Pass	-

Note 1. "<" denotes less than
2. "%" denotes percent by weight
3. The specification was quoted from Regulation (EU) No. 10/2011

3.6 N-Nitrosamines and N-Nitrosatable substances Content

Test Method**:** As per EN12868:2017, analyzed by high performance liquid chromatography with mass spectrometer detector (HPLC-MS-MS)
Test Conditions: 40 °C for 24 Hours

Test Item	CAS No.	RESULT [mg/kg]	
		Sample 001	
		N-Nitrosamines	N-Nitrosatable substances
N-Nitrosodimethylamine (NDMA)	62-75-9	<0.01	<0.1
N-Nitrosodiethylamine (NDEA)	55-18-5	<0.01	<0.1
N-Nitrosodipropylamine (NDPA)	621-64-7	<0.01	<0.1
N-nitrosodibutylamine (NDBA)	924-16-3	<0.01	<0.1
N-nitrosodiisnonylamine (NDiNA)	1207995-62-7	<0.01	<0.1
N-nitrosomorpholine (NMOR)	59-89-2	<0.01	<0.1
N-nitrosopiperidine (NPIP)	100-75-4	<0.01	<0.1
N-nitrosodibenzylamine (NDBzA)	5336-53-8	<0.01	<0.1
N-nitroso N-ethyl N-phenylamine (NEPhA)	612-64-6	<0.01	<0.1
NPYR+NMPhA	-	<0.01	<0.1
Sum of above	--	<0.01	<0.1
Limit	--	<0.01	<0.1

Note:
1. “mg/L” denotes milligram per litre
2. “<” denotes less than

-- END OF TEST REPORT--

General Terms and Conditions

of TÜV SÜD Certification and Testing (China) Co., Ltd. and its affiliated branch offices in the P.R.C.
(hereinafter referred to as *the company*)

1. General Information and Definitions

(1.1) In the event that an order for any services is placed, the Client shall accept the General Terms and Conditions. The General Terms and Conditions shall be applicable to all orders ,resulting contracts and other arrangements, including all offers made or services provided by the Company or any of its affiliated companies They are not applicable if and as far as they are in conflict with the regulations on services performed on behalf of governments, government bodies or any other public entity, or they are in conflict with mandatory provisions of local law. The Client's placement of orders as well as the conclusion of contracts with the Company shall be regarded as awareness and acceptance of these General Terms and Conditions.

(1.2) The Company strongly recommends any Client or potential Client to read the full text of these General Terms and Conditions prior to placement of any order to or conclusion of any contract with the Company. Ancillary agreements, promises and other statements made on the part of the Company staff or the experts called upon by them shall be binding only if they are expressly confirmed by the Company in writing. This shall also apply to any modifications of this clause.

2. Provision of Services

(2.1) With due care and skill, the Company will provide services according to Client's specific instructions as made available by the Client. In the absence of Client's specific instructions, the following is deemed as instructions given to the Company:
- (a) The terms of any standard specification sheet or standard order form provided by the Company; and/or
- (b) Any relevant usage, practice or trade custom; and/or
- (c) Such methods the Company considers technically, operationally and/or on financial grounds appropriate.

(2.2) No other party is entitled to give any instructions particularly on the scope and type of the services or the reports delivered, or on the resulting certificates (the "Reports of Findings"), unless the Company receives prior written instructions to the contrary from the Client. The Client hereby irrevocably authorizes the Company to deliver Reports of Findings to a third party where so instructed by the Client or, at the Company's discretion, where it implicitly follows from circumstances, trade custom, usage or practice.

(2.3) The Information stated in the Report of Findings is derived from the results of inspection or testing procedures carried out in accordance with the instructions and/or Company's assessment of such results on the basis of any technical standards, trade custom or practice, or other circumstances which should in Company's professional experience be taken into account.

(2.4) Reports of Findings issued after the testing of samples refer the Company's opinion only on samples under testing and not to the lot from which the samples were drawn.

(2.5) Client agrees that the Company's sole responsibility is to be present at the time of the third party's intervention and to forward the results, or confirm the occurrence of the intervention, in case Client requests the Company to witness any third party's intervention. Client agrees that the Company will use the test methods for analysis as requested in the request form, and if none is stated in the form, the Company will choose the appropriate test methods for analysis.

(2.6) The Reports of Findings issued by the Company will reflect the facts as recorded by it at the time of its intervention only and within the limits of the instructions received or, in the absence of such instructions, within the limits of the alternative parameters applied as provided for in Clause 2.1. The Company is under no obligation to refer to, or report upon, any facts or circumstances, which are outside the specific instructions received or alternative parameters applied.

(2.7) The performance of all or part of the services may be delegated to an agent or subcontractor by the Company. The Client authorizes the Company to disclose all information necessary for such performance to the agent or subcontractor.

(2.8) Documents reflecting engagements contracted between the Client and third parties or third party documents, e.g. sales contract copies, letters of credit, bills of lading, etc. should be made available to the Company. These are considered to be for information only, and do not extend or restrict the scope of the services or the obligations accepted by the Company.

(2.9) The Company agrees that, by providing the services to the Client, it neither takes the place of Client or any third party, nor otherwise assumes, abridges, abrogates or undertakes to discharge any duty of the Client to any third party or that of any third party to the Client. Also, it does not release the Client or any third party from any of their obligations.

(2.10) Depending on the nature of each sample, all samples given to the Company shall be retained for a maximum of 3 months or for such other shorter time period as the nature of the sample permits, and then sent back to Client or otherwise disposed of at the Company's discretion. After that time the Company will not be responsible for the samples. Storage of samples for more than 3 months shall incur a storage fee payable by the Client. If samples are returned to the Client, the Client will be billed a handling and freight fees. Special disposal charges will be billed to the Client if incurred.

3. Client's Obligations

The Client shall:

(3.1) ensure that all required supporting documents, information and instructions as submitted are accurate, trueful and complete. These information are to be submitted in a timely not later than 2 working days from the date of which the services are requested by the Client

(3.2) ensure to give all necessary access for the Company's representatives to the premises where the services are to be performed and to take all necessary steps to eliminate or remedy any obstacles to, or interruptions in the performance of the services;

(3.3) make available any special equipment and personnel necessary for the performance of the services, if required;

(3.4) ensure that for the safety and security of working conditions, sites and installations, all necessary measures are taken during the performance of services. In this respect, the Client will not rely on the Company's advice whether required or not;

(3.5) inform the Company of any known hazards or dangers, actual or potential, associated with any order, samples, testing or any other service rendered by the Company well in advance. Those are, but are not limited to the presence or risk of radiation, environmental pollution or poisons-toxic or noxious or explosive elements or materials;

(3.6) fully exercise all its rights and discharge all its liabilities under any relevant sales or other contract with a third party.

4. Fees and Payment

(4.1) All Fees not agreed on between the Company and Client at the time the order is placed or a contract is concluded shall be determined by the Company's Schedule of Fees (which are subject to change). All applicable taxes shall be paid by Client, as far as mandatory laws do not provide otherwise.

(4.2) Unless a specific period is established in the invoice, the Client shall pay upon receiving the invoice, but not later than 30 days from the relevant invoice date or within such other period as may be established by the Company in the invoice (the "Due Date").

(4.3) The Client shall not be entitled to retain or defer due payment of any sums to the Company on account of any dispute, counter claim or set-off against the Company. The Company reserves the right to retain or defer any due payments if any dispute arises with or it raises any counterclaim against the Client. The Company is entitled to set off due payments against payments of the Client.

(4.4) For the collection of unpaid fees, the Company may decide to bring action in any court with competent jurisdiction. The corresponding collection costs, including attorney's fees and related costs, shall be borne by the Client, as far as the mandatory local law does not provide otherwise.

(4.5) In case of any unforeseen problems or expenses arise while carrying out the services, the Company informs the Client. In such cases, the Company shall be entitled to charge additional fees to cover extra time and to invoice extra costs necessarily incurred to complete the services.

(4.6) If the Company is unable to perform all or parts of the services for any cause whatsoever beyond the Company's control, including the failure by Client to comply with any of its obligations provided for in the foregoing Clause 3, the Company shall nevertheless be entitled to payments of:
- (1) The amount of all non-refundable expenses incurred by the Company; and
- (2) A proportion of the agreed fee equal to the proportion of the services actually carried out.

5. Suspension or Termination of Services

In any case mentioned below, the Company shall be entitled to either suspend or terminate the provisionof the services immediately and without any liability:

(5.1) Failure by the Client to comply with any of its obligations under these General Terms and Conditions and such failure is not remedied within 10 days after a notice of such failure has been delivered to the Client; or

(5.2) Any suspension of payment, arrangement with creditors, bankruptcy, insolvency, receivership or cessation of business by Client.

6. Liability and Indemnification

(6.1) Limitation of Liability:
- (1) Clients seeking a guarantee against loss or damage should obtain appropriate insurance. The Company is neither an insurer nor a guarantor and disclaims all liability in such capacity.
- (2) Reports of Findings are issued on the basis of the information, documents and/or samples provided by, or on behalf of the Client and solely for the benefit of the Client who is obliged to act on the basis of such Reports of Findings. Neither the Company nor any of its staff, agents or subcontractors shall be liable to the Client nor to any third party for any actions taken or not taken on the basis of such Reports of Findings, or for any incorrect results arising from unclear, erroneous, incomplete, misleading or false information provided to the Company.
- (3) For any delayed, total or partial non-performance of the services arising directly or indirectly from any event beyond the Company's control, including failure by Client to comply with any of its obligations hereunder, the Company shall not be liable.
- (4) The liability of the Company in respect of any claim for loss, damage or expense of any nature and howsoever arising shall in no circumstances exceed a total aggregate sum equal to 10 times the amount of the fee paid in respect of the specific service which gives rise to such claim, and shall in any case not exceed the equivalent of 25,000 EUR in CNY.
- (5) For any indirect or consequential loss (including loss of profits), the Company shall not have any liabilities.
- (6) In case of any claim, the Client must give written notice to the Company within 30 days of discovery of the facts with all necessary documents to justify such claim. In any case, the Company shall be discharged from all liability for all claims for loss, damage or expense unless a lawsuit is brought within three years from:
  - (i) the performance date of the Company for its services which refers to the claim; or
  - (ii) the date when the service should have been completed in the event of any alleged non-performance.

(6.2) Indemnification: Against all claims (actual or threatened) by any third party for loss, damage or expenses of whatsoever nature including all legal expenses and related costs and howsoever arising relating to the performance, purported performance or non-performance of any services, the Client shall guarantee, hold harmless and indemnify the Company and its officers, employees, agents or subcontractors.

7. Obligation of Confidentiality, Copyright, Data Privacy Protection

(7.1) The Company shall be authorized to make file copies of written documents, which have been made available to it for review and which are important for processing the order.

(7.2) Insofar as Reports of Findings are prepared in the course of processing the order and which are subject to the protection of copyright, then the Company shall grant the Client a simple, non-transferable right to use, insofar as this is necessary and in accordance with the contractually presupposed purpose. Other rights shall not be transferred; in particular, the customer shall not be entitled to modify and/or edit audit reports or to make use of such outside of his business premises.

(7.3) The Company and its staff which may be called in shall not disclose or use trade and business matters about which they have gained knowledge during the performance of their work without proper authorization, or unless instructed by a court or authorized body (e.g. regulatory authority, accreditation body or certification scheme owner) or otherwise legally required.

(7.4) For all nonpublic personal information, protected health information, other personal information, and personal data as each of those terms is defined in or by application of each respective privacy regulations under Governing Law (collectively, the "Personal Data"), the Client confirms that the Personal Data has been collected and processed and that consents required to provide the Personal Data to the Company have been obtained in accordance with the privacy regulations under Governing Law; and the Company shall only store, process, transfer and use the Clients' Personal Data for the proper implementation of orders, contracts and for its own purposes and shall observe the applicable privacy regulations. To this end, the Company will also use automated data processing systems.

8. Miscellaneous

(8.1) The validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired, even if any one or more provisions of these General Conditions are found to be illegal or unenforceable in any respect.

(8.2) Client shall not directly or indirectly entice, encourage or make any offer to Company's employees to leave their employment with the Company, during the course of providing the services and for a period of one year thereafter.

(8.3) Use of the Company's corporate name or registered marks for advertising purposes is not permitted without the Company's prior written authorization.

9. Governing Law, Jurisdiction and Dispute Settlement

(9.1) Unless specifically agreed otherwise, all disputes arising out or in connection with contractual relationship(s) hereunder shall be governed by the applicable laws and regulations of the People's Republic of China.

(9.2) Place of performance for any obligation arising out of this contract shall be Shanghai, the Place of the TÜV SÜD Certification and Testing (China) Co., Ltd., Shanghai branch, unless otherwise expressly agreed by the parties.

10. Languages

In the event of any discrepancy between the English and the Chinese version of these General Terms and Conditions, the English version shall prevail.

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

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement. This certificate has been issued in accordance with Annex V (Module B) of the applicable legislation (see note 11).

Please note:

1. Where the product is classified as category III then CE or UKCA Marking of production is reliant on current compliance with module C2 or Module D of the applicable legislation (See note 11). (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturer's technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate and an EU declaration of product conformity shall be made available in accordance with the applicable legislation (See note 11)
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state, or UK government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of the applicable legislation (See note 11).
11. These terms and conditions shall apply to the requirements set out in Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment or to UK legislation relating to UKCA Marking as defined within the issued certificate.

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

Usability Evaluation Report
of
Nitrile Examination Glove
Model: KS-ST RT021

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

Document Reference No **KF-T10-B001-002**

Issued Date **2020-07-08**

Compiled by: (Name/signature)	Pingxu Chen	Compiled Date:	2020-07-06
Reviewed by (Name/signature)	Xiaojun deng	Reviewed Date:	2020-07-08
Approved by: (Name/signature)	Shijun Zhao	Approved Date:	2020-07-08

Table of Content

1. Purpose

The purpose of this procedure is to define how usability will be performed in Nitrile Examination Glove (model: KS-ST RT021) in order to comply with EN 62366-1 and IEC 60601-1-6. It specifies a Usability Engineering Process (UEP) with respect to the user interface, the intended use and to risk management (control of risks due to normal use), in order to provide safety for the patient, users and others related to usability.

2. Reference standards

MDD 93/42/EEC
EN 62366-1:2015 Medical device – part 1: Application of usability engineering to medical devices

3. Reference Documents

<User Manual> Version: V1.0
< Risk Analysis Report of Nitrile Examination Glove > KF-T10--A008-002
< Usability Engineering Plan> KF-T10-B001-001

4. Basic Information

Company name:	GUANGDONG KINGFA SCI.&TECH. CO., LTD.
Company address:	NO. 28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
Products:	Nitrile Examination Glove
Model:	KS-ST RT021
Intended use	The nitrile examination glove is intended to be worn on the hands of health care and similar personnel to prevent contamination between health care personnel and the patient's body. This is a single-use, non-sterile device.
Expected service life	3 years

5. Personnel and Required Resources

5.1 Policy

There should be a diverse group of professionals to handle the whole usability engineering process, including:

- company, department, project, and product managers,
- design and engineering professionals (e.g. Usability engineers, industrial designers, technical writers, information designers, mechanical engineers, electrical engineers, packaging engineers),
- medical researchers and other interested clinicians, and
- Marketers and other business professionals in the MEDICAL DEVICE industry.

5.2 Usability evaluation members

Usability evaluation members include:

Name	Duty	Remark
Shijun Zhao	Management representative	--
Pingxu Chen	Chief engineer/Technical Manager	--
Xioajun Deng	Quality Manager	--
Min Ding	Sales Supervisor	--

6 Usability Engineering Evaluation

6.1 Risk Analysis

6.1.1. Relative priority of tasks

Please refer to < Usability Engineering Plan> and < Risk Analysis Report> for details.

6.1.2. Comprehensiveness Task

Please refer to < Usability Engineering Plan> and Section 6.3 for details.

6.2 Usability Verification

6.2.1 Background

The work products and other descriptive materials that characterize the design should be tested against criteria derived from the design requirements. Insufficient attention to verification activities can become apparent during tests of production models in the form of unsafe, inefficient medical device installation and operation. The cost of correcting problems identified during verification is much less than the cost of retrofitting production models.

6.2.2 Test Sample

The subject device Nitrile Examination Glove (model: KS-ST RT021) we claimed has the overview as below:

Figure 1 model: KS-ST RT021

6.3 Usability Validation Data and Analysis

6.3.1 Purpose

The purpose of this part is to provide an overview of the validation activities to be performed for Nitrile Examination Glove (model: KS-ST RT021). The activities shall validate that the user needs and the intended use are fulfilled.

The purposes of the validation study are: (1) to determine if the operators could correctly using the product; and to improve the labeling of the Packaging and Instruction Manual.

The study was broken down into 2 sections, each of which required a 95% pass rate to be considered acceptable (refer to <Usability Engineering Plan> for details):

1. Product operation.
2. Product/label designation.

6.3.2 Representative users

The users enrolled in the study should be representative users and not company employees. Therefore, the validation team should lunch a group of volunteers to run the usability validation. The study questions were designed for a doctor that responded to the ads was able to read English. Here is the plan about choosing volunteers:

Table 6-1 Representative Operators Information

Group	Job Title	Number of people	
		Male	Female
1	Doctor	10	10
2	Nurse	10	10

6.3.3 Labeling Test

6.3.3.1 General

The usability group organized a series tests to evaluate the usability of Nitrile Examination Glove. As the basis of operation, labeling is the most important part. To ensure users are able to operate Nitrile Examination Glove safely and efficiently, the usability group should confirm that all the labels are reasonable.

6.3.3.2 Data

Usability Study Questionnaire

1. Were you aware of this product before you agreed to participate in the study?		
Answer Options	**Response Percent**	**Response Count**
Yes	0.0%	0
No	100%	40
If Yes, Explain		0
answered question		40
skipped question		0

2. Are you familiar with GUANGDONG KINGFA SCI.&TECH. CO., LTD. ?		
Answer Options	**Response Percent**	**Response Count**
Yes	0.0%	0
No	100%	40
If Yes, Explain		0
answered question		40
skipped question		0

3. Are you have medical knowledges?		
Answer Options	**Response Percent**	**Response Count**
Yes	100%	40

No	100%	0
I yes, please say what you major with	100%	40
answered question		40
skipped question		0

4. Contact Information		
Answer Options	**Response Percent**	**Response Count**
Name	100%	40
Subject Number	100%	40
Age	100%	40
answered question		40
skipped question		0

5. What is this device used for. Explain:	
Answer Options	**Response Count**
answered question	40
skipped question	0

Item	Response text
1	Examination Glove
2	Nitrile Examination Glove
3	Examination Glove
4	Glove
5	Nitrile Examination Glove
6	Examination Glove
7	Nitrile Examination Glove
8	Nitrile Glove
9	Nitrile Examination Glove
10	Nitrile Glove
11	Glove
12	Nitrile Examination Glove
13	Nitrile Glove
14	Nitrile Examination Glove
15	Glove
16	Examination Glove
17	Nitrile Examination Glove
18	Nitrile Glove
19	Examination Glove
20	Nitrile Glove
21	Glove
22	Glove
23	Examination Glove
24	Nitrile Examination Glove
25	Nitrile Glove

26	Examination Glove
27	Nitrile Glove
28	Nitrile Glove
29	Nitrile Examination Glove
30	Examination Glove
31	Nitrile Glove
32	Nitrile Glove
33	Nitrile Examination Glove
34	Examination Glove
35	Nitrile Glove
36	Nitrile Glove
37	Nitrile Examination Glove
38	Nitrile Glove
39	Examination Glove
40	Nitrile Examination Glove

6. Are there any words or abbreviations in the Instruction Manual that you did not understand?

Answer Options	Response Percent	Response Count
Yes	5.00%	2
No	95.00%	38
answered question		40
skipped question		0

7. Did you have any difficulties in understanding how to use the device?

Answer Options	Response Percent	Response Count
Yes	0%	0
No	100%	40
Other (please specify)		0
answered question		40
skipped question		0

8. Is there anything that can be added or clarified in the Instruction Manual to help you better understand how to use the device?

Answer Options	Response Percent	Response Count
Yes	2.50%	1
No	97.50%	39
Other (please specify)		0
answered question		40
skipped question		0

9. Was there anything in the Packaging or Instruction Manual that would lead you to believe that you could or should be treating anything other than body temperature measurement?

Answer Options	Response Percent	Response Count
Yes	0%	0
No	100%	40

Other (please specify)	0
answered question	40
skipped question	0

10. After reading the packaging and the Instruction Manual, are you able to weigh the risks versus the benefits of using the device and make a decision on whether or not this is the correct device for you to use?		
Answer Options	**Response Percent**	**Response Count**
Yes	100.0%	40
No	0.0%	0
Other (please specify)		0
answered question		40
skipped question		0

11. It is correct to attempt to adjust or modify the Nitrile Examination Glove in any way?		
Answer Options	**Response Percent**	**Response Count**
Yes	0%	0
No	100%	40
Other (please specify)		0
answered question		40
skipped question		0

12. Do you understand the Risks, Warnings, Cautions, and Precautions sections of the Instruction Manual?		
Answer Options	**Response Percent**	**Response Count**
Yes	100%	40
No	0%	0
Other (please specify)		0
answered question		40
skipped question		0

13. If you noticed that the package are broken, what would you do?	
Answer Options	**Response Count**
	40
answered question	40
skipped question	0

Item	Use a new one
1	Use the another one
2	Throw it to ash bin
3	Dispose safely
4	Throw it to ash bin
5	Throw it to ash bin
6	Use the new one
7	Use the another one

8	Use the another one
9	Use a new one
10	Throw it to ash bin
11	Use the another one
12	Use the another one
13	Use a new one
14	Throw it to ash bin
15	Use a new one
16	Use the another one
17	Use the another one
18	Use the new one
19	Dispose safely
20	Throw it to ash bin
21	Use the another one
22	Use the another one
23	Use the new one
24	Throw it to ash bin
25	Use the another one
26	Use the new one
27	Use the new one
28	Dispose safely
29	Use the another one
30	Use the another one
31	Throw it to ash bin
32	Use a new one
33	Dispose safely
34	Use the another one
35	Dispose safely
36	Use the another one
37	Use the new one
38	Use the another one
39	Use a new one
40	Use the another one

14. Please explain how to use the device. How was it described?		
Answer Options	**Response Percent**	**Response Count**
Correctly	100%	40
Incorrectly	0%	0
Comments/Observations:		40
answered question		40
skipped question		0

15. Check before using		
Answer Options	**Response Percent**	**Response Count**
Correctly	100.0%	40
Incorrectly	0.0%	0
Comments/Observations:		40
answered question		40
skipped question		0

16. Operation for using		
Answer Options	**Response Percent**	**Response Count**
Correctly	100.0%	40
Incorrectly	0.0%	0
Comments/Observations:		40
answered question		40
skipped question		0

17. Discard safely		
Answer Options	**Response Percent**	**Response Count**
Correctly	100.0%	40
Incorrectly	0.0%	0
Comments/Observations:		40
answered question		40
skipped question		0

18. Explain how to dispose the device		
Answer Options	**Response Percent**	**Response Count**
Correctly	100.0%	40
Incorrectly	0.0%	0
Comments/Observations:		40
answered question		40
skipped question		0

6.3.4.3 Results of the Study

Part 1: 100% of the participants answered “No” to being aware of the Nitrile Examination Glove before the study. 100% of the participants were not familiar with GUANGDONG KINGFA SCI.&TECH. CO., LTD. before the study.

Part 2: 100% of the study participants were able to answer all other questions related to the Comprehension portion of the study. Based on feedback related to improvement of the User Manual for comprehension and readability, we have increased the font size to accommodate users.

Part 3: In the study group, 0 of 40 participants did not correctly complete the Demonstration portion of the study, since 100% of the total study group was able to complete the Demonstration portion of the study, no further changes were made.

6.3.4.5 Data Analysis

There are totally 40 representative users attended the test. Calculate the average accuracy in group.

Here is the result:
Analysis of the results from the final study group allows us to determine the following, based on a comprehension and demonstration above the 85% target:
(1) Target operators can correctly use the device to operate the device after training;
(3) Consumers can comprehend the Manual, weigh the risks and benefits of the device, and use it according to the instructions.
In conclusion, the results of the study demonstrate that target operators can comprehend the labeling and use the device in a safe and effective manner according to the labeling.

6.3.5 Satisfaction Test

6.3.5.1 General

To be a good medical device, not only it should be well-designed in function, but also are the users able to operate it easily, which should be concerned about the satisfaction of users. For perfecting the design of Nitrile Examination Glove, the usability group arranged a test or questionnaire to do some researches.

6.3.5.2 Data

Please rate the below questions on a scale of 1=Poor, unreasonable, to 10=Excellent, comfortable, reasonable.

(1) User Manual

User Number	1. The fonts	2. The word size	3. The picture size	4. The resolution of the picture	5. The content of comprehensiveness	6. The content of logicality
1	10	10	10	10	10	9
2	9	10	10	10	10	10
3	9	9	8	10	10	10
4	8	10	10	10	9	10
5	10	10	9	10	10	8
6	10	10	10	7	10	10
7	10	8	10	9	10	10
8	10	10	8	10	10	10
9	8	8	10	9	10	8
10	10	10	10	8	10	10
11	10	10	10	10	9	10
12	9	8	10	10	10	10
13	9	10	10	8	10	9
14	10	10	8	10	10	10
15	10	9	10	10	10	10
16	8	10	10	10	10	10
17	10	10	10	10	10	10
18	10	10	10	10	9	10
19	10	9	8	10	10	9
20	9	10	10	10	10	10
21	9	10	10	8	10	10
22	10	10	10	10	10	9
23	10	8	10	8	10	10

24	9	10	9	10	9	10
25	10	9	10	9	10	10
26	10	10	9	10	10	10
27	10	10	10	10	10	10
28	10	10	10	10	8	8
29	10	9	10	10	10	10
30	10	9	8	9	10	10
31	9	9	10	10	10	10
32	10	10	10	10	8	10
33	10	10	8	8	10	9
34	10	10	10	10	10	10
35	8	10	10	10	9	10
36	10	8	10	10	10	10
37	8	10	10	8	10	9
38	10	9	9	10	9	10
39	10	9	10	10	10	10
40	10	10	9	8	10	10

(2) Package

User Number	**1. The fonts**	**2. The word size**	**3. The picture size**	**4. The resolution of the picture**	**5. The content of comprehen siveness**	**6. The content of logicality**
1	10	10	10	10	9	10
2	9	10	8	8	10	10
3	10	10	10	10	10	9
4	10	8	10	10	10	10
5	10	10	9	10	9	10
6	10	10	10	8	10	10
7	10	10	10	10	9	9
8	9	10	10	10	10	10
9	10	8	10	10	10	10
10	8	10	10	7	10	10
11	10	9	10	10	8	10
12	10	10	8	10	10	9
13	9	7	10	10	10	10
14	10	10	10	10	10	10
15	10	10	8	10	10	10
16	10	9	10	10	10	10
17	10	10	8	10	9	10
18	9	10	10	9	10	10
19	10	9	10	10	10	10
20	9	10	10	10	10	10
21	10	8	8	10	10	10
22	10	10	10	10	10	10
23	10	10	10	10	10	8
24	10	8	10	8	10	10

25	9	10	10	10	9	10
26	10	10	10	9	9	10
27	10	10	8	10	10	10
28	10	7	10	10	10	8
29	9	10	9	10	10	10
30	10	10	10	9	10	10
31	10	10	8	10	8	10
32	8	8	10	10	10	10
33	8	10	10	10	10	10
34	10	8	10	9	10	10
35	9	10	8	10	10	10
36	10	10	10	10	9	9
37	10	9	10	10	10	9
38	10	10	10	8	10	10
39	8	8	8	10	10	9
40	10	10	10	10	10	10

(3) Operation

User Number	1. The operability	2. The size of Glove	3. The comfort of worn	4. The wearability
1	10	10	9	10
2	9	10	10	10
3	10	8	10	8
4	10	10	10	10
5	10	10	10	10
6	9	10	10	10
7	10	9	8	9
8	19	9	10	10
9	10	10	10	9
10	10	10	9	10
11	9	10	10	10
12	10	10	10	10
13	10	8	10	8
14	10	10	10	10
15	8	10	9	10
16	10	10	10	9
17	10	10	10	10
18	10	10	10	10
19	8	10	9	8
20	10	9	10	10
21	10	10	10	8
22	10	10	10	10
23	7	10	10	10
24	10	10	10	10
25	10	10	8	10
26	10	9	10	9
27	9	10	10	10

28	10	9	10	9
29	10	10	10	10
30	10	10	8	10
31	10	10	9	10
32	9	10	10	10
33	9	10	10	10
34	10	9	9	10
35	10	10	10	9
36	10	10	10	10
37	8	9	8	10
38	10	10	9	10
39	10	8	10	10
40	10	10	10	10

6.3.5.3 Data Analysis

There are totally 50 representative users attended the test. Calculate the average accuracy in group. Here is the result:

Table 6~3 The result of satisfaction test

Type	**Questions**	**Average Rate**	**Result**	**Remark**
User Manual	1. The fonts	9.55	Pass	--
	2. The word size	9.53	Pass	--
	3. The picture size	9.58	Pass	--
	4. The resolution of the picture	9.48	Pass	--
	5. The content of comprehensiveness	9.75	Pass	--
	6. The content of logicality	9.70	Pass	--
Package	1. The fonts	9.53	Pass	--
	2. The word size	9.50	Pass	--
	3. The picture size	9.40	Pass	--
	4. The resolution of the picture	9.63	Pass	--
	5. The content of comprehensiveness	9.73	Pass	--
	6. The content of logicality	9.75	Pass	--
Operation	1. The operability	9.85	Pass	--
	2. The size of Glove	9.68	Pass	--
	3. The comfort of worn	9.63	Pass	--
	4. The wearability	9.65	Pass	

As the result displayed above, the satisfactions to different parts of Nitrile Examination Glove all gained a rate over 8.5 points. The usability group evaluate that the design of the device is logical and reasonable, thoughtful.

7 Conclusion

The Nitrile Examination Glove (model: KS-ST RT021) can meet the usability goal of IEC 62366-1 standards. Hence it has the expected availability.

7.1 Modifications to the design

According to the results of the usability validation, there is no need to make modification to the original design.

7.2 Conclusions of Usability Validation

It was concluded that the external Usability Evaluation found no additional potential hazards. It was further noted that the worst case scenario already identified in the Usability Specification did not occur during this clinical evaluation. It was concluded that Usability Engineering analysis and evaluation of Nitrile Examination Glove has passed.

Risk Management Report
Of
Nitrile Examination Glove

Model: KS-ST RT021

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Edited by	**Pingxu Chen**

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Table of Content

1. Basic Information

This document is Risk management plan of Nitrile Examination Glove. In this plan all possible harm and its cause have been assessed, each harm severity degree and occurrence probability has been evaluated. We'll have harm decrease measure when a certain harm level is inacceptable. Meanwhile, all the remaining harm after taking harm measure have been assessed, all the remaining harm level have been changed to be acceptable.

Company name:	GUANGDONG KINGFA SCI.&TECH. CO., LTD.
Company address:	NO. 28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
Products:	Nitrile Examination Glove
Model:	KS-ST RT021
Criteria:	EN ISO 14971:2019 and ISO/TR 24971 + MDD 93/42/EEC Annex I, EN 455-1: 2000, EN 455-2: 2015, EN 455-3: 2015, EN 455-4: 2009
Description:	The risk analysis has been performed according to risk management system documented procedure, EN ISO 14971:2019 and MDD 93/42/EEC and 2007/47/EEC Annex I and covers all risks related to the products and its uses.
Conclusion:	All risks associated with the products and its uses have been analyzed and evaluated with regard to EN ISO 14971:2019 and ISO/TR 24971. The overall remaining risks have been deemed acceptable when weighed against the intended benefits to the patient.
Reference standards:	**Item** — Description **Performance** — EN 455-1: 2000, EN 455-2: 2015, EN 455-3: 2015, EN 455-4: 2009 **Quality System** — EN ISO 13485:2016/AC2016 **Risk Management** — EN ISO 14971:2019, ISO/TR 24971

2. Management Responsibility and Qualification of Personnel

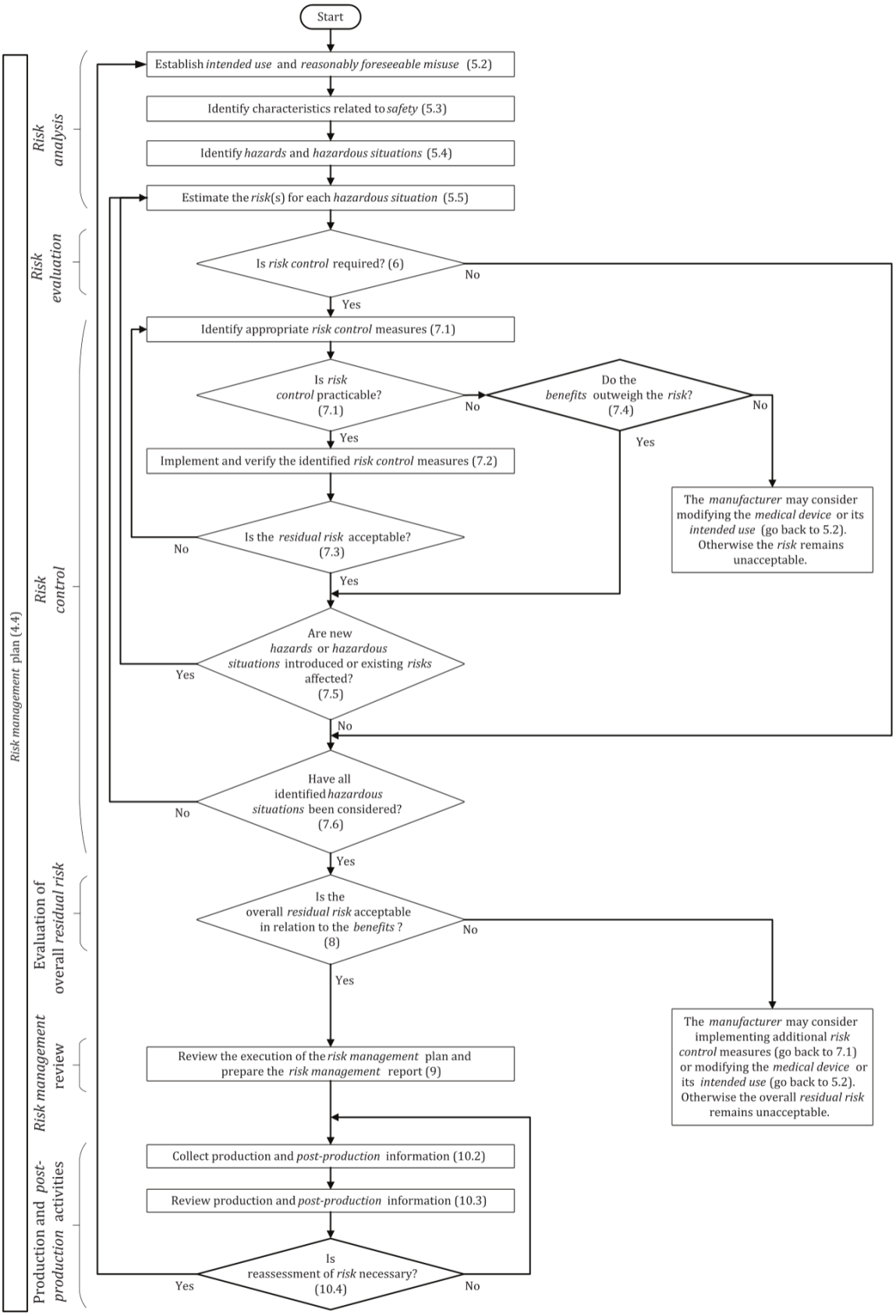
Name	Duty	Department	Backgrounds	Responsibility
Hongtao Ning	General Manager	--	Have 12 years' experience of ISO risk management system, very familiar with ISO 13485, the responsibility is instructing every department to work according to ISO 13485, ISO 14971:2007.	1) Provided the resources needed to risk management; 2) Guaranteed risk management executives had the corresponding knowledge and experience; 3) Approved Risk Management Procedure; 4) Approved Risk Management Report. 5) Review the suitability of the risk management process at planned intervals to ensure continuing effectiveness of the risk

				management process and documented any decisions and actions taken.
Shijun Zhao	Management Representative	Quality Department	Have 9 years' experience of ISO quality management system, very familiar with ISO 13485, ISO 14971:2007, the responsibility is instructing every department to work according to ISO 13485, ISO 14971:2007.	1) Review the suitability of the risk management process at planned intervals to ensure continuing effectiveness of the risk management process and documented any decisions and actions taken. 2) Responsible for overall risk management activities of the organization and implementation; 3) provide the resources needed to risk management; 4) Guaranteed risk management executives had the corresponding knowledge and experience; 5) Organized and implemented the products development of the whole process of the risk management activities; 6) Complied Risk Management Procedure; 7) Formation risk analysis risk evaluation risk control comprehensive residual risk analysis and evaluation of the relevant records, complied risk Management Reports; 8) Responsible for risk analysis and risk evaluation; 9) Verified the results of risk control measures; 10) Reviewed nonconforming products 11) Reviewed regularly the results of risk management activities and responsible for correctness and effectiveness
Min Ding	Sales manager	Market Department	Have 6 years' experience of sales, very familiar with sales and service of medical devices, has a profound acknowledgement	1) Provided information related risk about policy, market, client, cooperation, etc. of the project on quasi development and in the implementation; 2) Participated risk analysis and risk evaluation.

			of ISO 13485, ISO 14971:2007.	
Qing Cheng	Procurement Manager	Procurement Department	Have 12 years' experience of Procurement, very familiar with Procurement of medical devices, has a profound acknowledgement of ISO 13485, ISO 14971:2007.	1) Provided the information related risk in procurement; 2) Participated risk analysis and risk evaluation.
Zheng xiong Ma	Production Manager	Production Department	Have 8 years' experience of the management of production, especially for electronic products. Very familiar with ISO 13485, ISO 14971:2007.	1) Analyzed the risk on if the Manufacturing progress could satisfy the requirements; 2) Complied counterplan on the conflicts among the schedules of raw material, personnel, processing equipment, and other products; 3) Participated risk analysis and risk evaluation.
Pingxu Chen	R&D Manager	Research and Development Department	Have 9 years' experience of design of medical devices, especially for Infrared Thermometer, familiar with ISO 13485, ISO 14971:2007, IEC 60601-1, 3ed and harmonized standards of European.	1) Estimated the probability maybe occur form the design; 2) Participated in risk analysis and evaluation.
Ziqian g Song	Clinical doctor	Research and Development Department	Have 10 years' experience of clinical, very familiar with Nitrile Examination Glove	Estimated the clinical performance of the design.

3. Risk Management Process

Please refer to the following Risk Management Process chart. Please refer to "Risk Management Procedure of Nitrile Examination Glove" for details.


Start
Establish intended use and reasonably foreseeable misuse (5.2)
Identify characteristics related to safety (5.3)
Identify hazards and hazardous situations (5.4)
Estimate the risk(s) for each hazardous situation (5.5)
Is risk control required? (6)
No
Yes
Identify appropriate risk control measures (7.1)
Is risk control practicable? (7.1)
No
Do the benefits outweigh the risk? (7.4)
No
Yes
Yes
Implement and verify the identified risk control measures (7.2)
The manufacturer may consider modifying the medical device or its intended use (go back to 5.2). Otherwise the risk remains unacceptable.
Is the residual risk acceptable? (7.3)
No
Yes
Are new hazards or hazardous situations introduced or existing risks affected? (7.5)
Yes
No
Have all identified hazardous situations been considered? (7.6)
No
Yes
Is the overall residual risk acceptable in relation to the benefits ? (8)
No
Yes
The manufacturer may consider implementing additional risk control measures (go back to 7.1) or modifying the medical device or its intended use (go back to 5.2). Otherwise the overall residual risk remains unacceptable.
Review the execution of the risk management plan and prepare the risk management report (9)
Collect production and post-production information (10.2)
Review production and post-production information (10.3)
Is reassessment of risk necessary? (10.4)
Yes
No
Risk management plan (4.4)
Risk analysis
Risk evaluation
Risk control
Evaluation of overall residual risk
Risk management review
Production and post-production activities

4. Criteria for Acceptability

HazID	Hazard identification
S	S stands for the severity of harm
O	O stands for the probability of occurrence of harm
RL	RL: Risk Level RL = S &O (e.g. N & F stands for Negligible & Frequent, CR & F stands for Critical & Frequent)
ER	MDD 93/42/EEC Annex I essential requirements

PROBABILITY OF OCCURRENCE	**LEVEL**	**PROBABILITY RANGE**	**DESCRIPTION**
FREQUENT	5	≥ 10^{-3}	Occurring often or repeatedly
PROBABLE	4	< 10^{-3} and ≥ 10^{-4}	Reasonably likely to occur
OCCASIONAL	3	< 10^{-4} and ≥ 10^{-5}	Irregular occurrence, infrequent
REMOTE	2	< 10^{-5} and ≥ 10^{-6}	Not likely to occur
IMPROBABLE	1	< 10^{-6}	Unlikely to ever occur

Probability Range Definition: When uses the devices, if occurrence ≥ 0.8/800, that stands for FREQUENT;
When uses the devices, if occurrence ≥ 0.08/800 and ≤ 0.8/800, that stands for PROBABLE;
When uses the devices, if occurrence ≥ 0.008/800 and ≤ 0.08/800, that stands for OCCASIONAL;
When uses the devices, if occurrence ≥ 0.0008/800 and ≤ 0.008/800, that stands for REMOTE;
When uses the devices, if occurrence ≤ 0.0008/800, that stands for IMPROBABLE;
Use according to 800 times per year.

SEVERITY	**LEVEL**	**DESCRIPTION**
CATASTROPHIC	5	Results in patient death
CRITICAL	4	Results in permanent impairment or life-threatening injury
SERIOUS	3	Results in injury or impairment requiring professional medical intervention
MINOR	2	Low risk failure not expected to contribute to an injury
NEGLIGIBLE	1	Insignificant failure not serious enough to contribute to an injury

PROBABILITY OF OCCURRENCE	**SEVERITY**				
	NEGLIGIBLE	**MINOR**	**SERIOUS**	**CRITICAL**	**CATASTROPHIC**

FREQUENT	5	10	15	20	25
PROBABLE	4	8	12	16	20
OCCASIONAL	3	6	9	12	15
REMOTE	2	4	6	8	10
IMPROBABLE	1	2	3	4	5

HAZARD RISK LEVEL	ACCEPTANCE CRITERIA
1 to 4	Acceptable (ACC)
5 to 25	Unacceptable (UACC)

5. Products Specification Consideration

5.1 Intended Use

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

5.2 Device Description

The Nitrile Examination Glove is non-sterile disposable device made from Nitrile, those 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.

5.3 Expected Service Life

We define the expected service life of subject device is 3 years.

5.4 User Manual

Please refer to User Manual.

6. Risk Analysis

6.1 Information Sources for performing the Risk Analysis

The following sources were used as inputs to the risk analysis process for the products:
Customer complaints (PQR/CQA, PSR/FPR, CSO)
Program Team Brainstorming session(s). (A cross-functional team including Engineering, Marketing and Clinical Applications Specialists, at a minimum)
We use FMEA method as risk management policy

6.2 Intended use and identification of characteristics related to the safety of the medical device

Clause Ref.	Question	Answer/ Comments
A.2.1	What is the intended use and how is the medical device to be used?	The nitrile examination glove is intended to be worn on the hands of health care and similar personnel to prevent contamination between health care personnel and the patient's body. This is a single-use, non-sterile device.
A.2.2	Is the medical device intended to be implanted?	No, the medical device is not intended to be implanted.
A.2.3	Is the medical device intended to be in contact with the patient or other persons?	Yes. It is intended to be contact with the skin with patients and users.
A.2.4	What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	The product is mainly made of Nitrile.
A.2.5	Is energy delivered to or extracted from the patient?	No.
A.2.6	Are substances delivered to or extracted from the patient?	No.
A.2.7	Are biological materials processed by the medical device for sub-sequent re-use, transfusion or transplantation?	No.
A.2.8	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	No.
A.2.9	Is the medical device intended to be routinely cleaned and disinfected by the user?	No, this is a disposable device.
A.2.10	Dose the medical device intended to modify the patient environment?	No.
A.2.11	Are measurements taken?	No.
A.2.12	Is the medical device interpretative?	No.
A.2.13	Is the medical device intended for use in conjunction with other medical devices, medicines or	No.

	other medical technologies?	
A.2.14	Are there unwanted outputs of energy or substances?	No.
A.2.15	Is the medical device susceptible to environmental influences?	No.
A.2.16	Does the medical device influence the environment?	No.
A.2.17	Does the medical device require consumables or accessories?	No.
A.2.18	Is maintenance or calibration necessary?	No, this is a disposable device.
A.2.19	Does the medical device contain software?	No.
A.2.20	Does the medical device allow access to information?	No.
A.2.21	Does the medical device store data critical to patient care?	No.
A.2.22	Does the medical device have a restricted shelf life?	Yes. 3 years.
A.2.23	Are there any delayed or long-term use effects?	No.
A.2.24	To what mechanical forces will the medical device be subjected?	No.
A.2.25	What determines the lifetime of the medical device?	Aging of packaging materials and raw materials.
A.2.26	Is the medical device intended for single use?	Yes. It is intended for single use.
A.2.27	Is safe decommissioning or disposal of the medical device necessary?	Yes. Destroyed after use, treated with medical waste.
A.2.28	Does installation or use of the medical device require special training or special skills?	No. It can be used properly after reading the user manual.
A.2.29	How will information for safe use be provided?	The information for safe use will be provided in proposed labeling including Instruction for use, product label, safety symbol, package labeling.
A.2.30	Are new manufacturing processes established or introduced?	No.

A.2.31	Is successful application of the medical device critically dependent on human factors such as the user interface?	No.
A.2.31.1	Can the user interface design features contribute to use errors?	No
A.2.31.2	Is the medical device used in an environment where distractions can cause errors?	No
A.2.31.3	Does the medical device have connecting parts or accessories?	No
A.2.31.4	Does the medical device have a control interface?	No
A.2.31.5	Does the medical device display information?	No
A.2.31.6	Dose the medical device controlled by a menu?	No
A.2.31.7	Is the successful use of the medical device dependent on a user's knowledge, skills and abilities?	No
A.2.31.8	Will the medical device be used by persons with specific needs?	No
A.2.31.9	Can the user interface be used to initiate user actions?	N/A
A.2.32	Does the medical device use an alarm system?	No.
A.2.33	In what way(s) might the medical device be deliberately misused[1]?	The products might be deliberately misused in the wrong use without Instruction for use, the other use beyond the intended use.
A.2.34	Is the medical device intended to be mobile or portable?	Yes. It is a portable device.
A.2.35	Does the use of the medical device depend on essential performance?	Yes.
A.2.36	Does the medical device have a degree of autonomy?	No.
A.2.37	Does the medical device produce	No.

[1] In this context, misuse is intended to mean incorrect or improper use of the medical device such as incorrect use of connectors, disabling safety features or alarms, neglect of manufacturer's recommended maintenance.

	an output that is used as an input in determining clinical action?	

6.3 Process for Risk Analysis
Please refer to “Risk Management Plan”.

6.4 Possible hazard(s) analysis according to ISO/TR 24971
This document covers Risk Analysis, Risk Evaluation and Risk Control of the following types of risks: Engineering Products Design and Manufacturing Marketing, Service, Business liability, Antitrust/Government compliance, EHS, etc. of Nitrile Examination Glove.

For these products, the following hazard areas have been identified:
1) Energy Hazards;
2) Biological hazard(s);
3) Environmental hazard(s);
4) Hazards resulting from incorrect output of energy and substances
5) Hazards related to the use of the medical device
6) Inappropriate, inadequate or over-complicated user interface (man/machine communication);
7) Hazards arising from functional failure, maintenance and ageing
8) Self definition

For these products, the following hazard(s) have been identified in 6. Risk Evaluation, Risk Control, overall residual risk evaluation and the hazard ID of new hazard generated for hazard(s)

7. Risk Evaluation, Risk Control, Overall Residual Risk Evaluation

See Annex 1 for detail.

Note Annex 1:

Note [1]
The Risk Evaluation, Risk Control, and Overall Residual Risk Evaluation cover all known and foreseeable hazards associated with the medical device in both normal and fault conditions.

Note [2] Fault Condition
Reasonably foreseeable sequences or combinations of events that can result in a hazardous situation shall be considered and the resulting hazardous situation(s) shall be recorded.
It means in this report, we not only consider all the Single Fault Conditions (SFC), but also foreseeable Multiple Fault Conditions (MFC). The hazardous situation is defied in column “Identified risk(s)”.

NC: Normal Condition
FC: Fault Condition
SFC: Single Fault Condition
MFC: Multiple Fault Condition

Note [3] Failure Modes

D=Design
P=Process
U=Use/Application

Note [4] Risk Control Methods

HD=Hardware Design
SD=Software Design
M=Manufacturing
L=Labeling
S=Service
T=Training
FT=Final Testing

Note [5] Section

Section	***Hazard Description***
A	***Energy Hazards***
B	***Biological and Chemical Hazards***
C	***Environmental Hazards and Contributory Factors Operational Hazards***
D	***Hazards Resulting from Incorrect Output of Energy and Substances***
E	***Hazards Related to The Use of The Device and Contributory Factors***
F	***Hazards Arising From Functional Failure, Maintenance and Ageing***
G	***Reuse Hazards***

8. Post Product Information

Company has established and maintains a systematic procedure, Vigilance System Procedure, and Corrective Action Procedure, to review information gained about the medical device or similar devices in the post-production phase. The information shall be evaluated for possible relevance to safety, especially the following:
a) If previously unrecognized hazard(s) are present;
b) If the estimated risk(s) arising from a hazard is no longer acceptable;
c) If the original Evaluation is otherwise invalidated.

If any of the above conditions is satisfied, the results of the evaluation shall be fed back as an input to the risk management process.

In the light of this safety relevant information, a review of the appropriate steps of risk management process for the medical device shall be considered. If there is a potential that the residual risk(s) or its acceptability has changed, the impact on previously implemented risk control measures shall be evaluated. The results of this evaluation shall be recorded in the risk management file according to Risk Management procedure. And this file is a living file.

9. Risk Management Conclusion

9.1 Completeness of risk control

All identified hazardous situations have been considered. The results of activity are recorded by safety department.

9.2. Evaluation of overall residual risk acceptability

After all risk control measures have been implemented and verified, the overall residual risk posed by the Nitrile Examination Glove is acceptable using the criteria defined in the risk management plan. And all the risk control measures won't arise new risk.

So far, all risks have been found to be acceptable, the overall residual risk is evaluated to assure that the risk/benefit balance is still maintained.

Annex 1 - Risk Analysis Table of Nitrile Examination Glove

Hazard	Resultant Harm	Failure Mode	Cause	Trigger Event	Unmitigated Risk			Failure Mode	Mitigation Method	Risk Control Measures	Residual Risk			Verification evidence
					Severity	Likelihood	RPN				Severity	Likelihood	RPN	
A. Energy Hazards														
A1. Electromagnetic Energy Hazards	N/A	--	--	--	--	--	--	--	--	--	--	--	--	--
A2. Radiation Energy Hazards	N/A	--	--	--	--	--	--	--	--	--	--	--	--	--
A3. Thermal Energy Hazards	N/A	--	--	--	--	--	--	--	--	--	--	--	--	--
A4. Mechanical Energy Hazards	Elastic force	U	Improper use, overstretching	Overstretching the Surgical Gloves	1	2	2 ACC	--	--	--	--	--	--	--
B. Biological and Chemical Hazards														

Hazard	Resultant Harm	Failure Mode	Cause	Trigger Event	Unmitigated Risk			Failure Mode	Mitigation Method	Risk Control Measures	Residual Risk			Verification evidence
					Severity	Likelihood	RPN				Severity	Likelihood	RPN	
B1. Biological Hazards	--													

Hazard	Resultant Harm	Failure Mode	Cause	Trigger Event	Unmitigated Risk			Failure Mode	Mitigation Method	Risk Control Measures	Residual Risk			Verification evidence
					Severity	Likelihood	RPN				Severity	Likelihood	RPN	
B1.1 Bio-incompatibility	Allergy or infection	U	1. Use bio-incompatible raw materials; 2. The purchased raw materials do not meet the requirements of biocompatibility and physical and chemical properties.	Bio-incompatible materials may cause Allergy or infection	4	2	8 U A C C	U	M	1. Confirm product effectiveness performance Biocompatibility evaluation and physical and chemical performance evaluation of the selected material or the final product. 2. Perform full performance testing on the final product.	4	1	4 A C C	Biocompatibility test report of the final product

Hazard	Resultant Harm	Failure Mode	Cause	Trigger Event	Unmitigated Risk			Failure Mode	Mitigation Method	Risk Control Measures	Residual Risk			Verification evidence
					Severity	Likelihood	RPN				Severity	Likelihood	RPN	
B1.2 Bio-incompatibility	Allergy or infection	U	Powde, nitrite, endotoxin on gloves causes allergies	Bio-incompatible materials may cause Allergy or infection	4	2	8 U A C C	U	M	Choose powder-free materials with good biocompatibility	4	1	4 A C C	Biocompatibility test report; Performance test report
B1.3 Re-and/ or cross-infection	Allergy or infection	U	The patient re-used the product	The product has been re-used	4	2	8 U A C C	U	S T	Design product identification has a clear one-time use	4	1	4 A C C	User manual and Labeling
Same as above	Causes human infection and environmental damage	U D	Harmful substances pollute the environment	After the product is used, it is not treated as medical waste	4	2	8 U A C C	U D	M L	Design product identification has clear use as medical waste disposal regulations	3	1	3 A C C	User manual and Labeling
B1.4 Infection	Allergy or infection	D P	The patient used the product which has	Ruptured packaging causes gloves to become contaminat	4	2	8 U A C C	D P	M, FT	1. Choose appropriate materials for packing; 2. Add the warning	4	1	4 A C C	User manual and Labeling

Hazard	Resultant Harm	Failure Mode	Cause	Trigger Event	Unmitigated Risk			Failure Mode	Mitigation Method	Risk Control Measures	Residual Risk			Verification evidence
					Severity	Likelihood	RPN				Severity	Likelihood	RPN	
			polluted	ed with bacteria						information in user manual and labeling				
B1.5 Bio-incompatibility	Allergy or infection	U, P	Use bio-incompatible raw materials; The purchased raw materials do not meet the requirements	Skin allergy or infection	4	2	8 U A C C	U, P	L, M	1. Biocompatibility evaluation and physical and chemical performance evaluation of the selected material or the final product. 2. Perform protein test on the finished product	4	1	4 A C C	Biocompatibility test report; Performance test report
B2.1 Chemical Hazards	Allergy, local skin irritation, sensitization reaction.	U	The raw materials brings harmfl substances	1. Use bio-incompatible raw materials; 2. The purchased raw materials do not meet the requirements of biocompati	4	2	8 U A C C	U	M	1. Biocompatibility evaluation and physical and chemical performance evaluation of the selected material or the final product. 2. Test the toxicity of the single	4	1	4 A C C	Biocompatibility test report of the final product; Performance test report

Hazard	Resultant Harm	Failure Mode	Cause	Trigger Event	Unmitigated Risk			Failure Mode	Mitigation Method	Risk Control Measures	Residual Risk			Verification evidence
					Severity	Likelihood	RPN				Severity	Likelihood	RPN	
				bility and physical and chemical properties.						packaging material used or the inspection report provided by the subcontractor. 3. Testing of raw materials purchased in each batch or requiring subcontractors to provide relevant product inspection reports. 4. Perform full performance testing on the final product.				
Same as above	The patient is infected with bacteria, causing fever and shock in severe cases;	U P	The product is borne by bacteria, and the patient uses the product with	Use the over the aging period of packaging materials and raw materials, the product may	3	3	9 U A C C	U P	T	Add the waring information that “Don’t use the device expired.”	3	1	3 A C C	User manual and labeling

Hazard	Resultant Harm	Failure Mode	Cause	Trigger Event	Unmitigated Risk			Failure Mode	Mitigation Method	Risk Control Measures	Residual Risk			Verification evidence
					Severity	Likelihood	RPN				Severity	Likelihood	RPN	
	toxic substances harm patients' health		bacteria; harmful substances are brought into the human body	contain bacteria or physical and chemical indicators exceed the standard										
C. Environmental Hazards and Contributory Factors Operational Hazards														
C 1. Environmental Hazards and Contributory Factors Operational Hazards	Affect product effectiveness, safety and environmental pollution	U	Improper use, improper handling	Inappropriate labeling on the package or instruction manual;	3	2	6 ACC	U	M	To compile and review the format and content of all labels, instructions and languages in accordance with the requirements of the National Regulations on the Administration of Medical Devices, the European Union's "Medical Devices Directive" and	3	1	3 ACC	User manual and labelings

Hazard	Resultant Harm	Failure Mode	Cause	Trigger Event	Unmitigated Risk			Failure Mode	Mitigation Method	Risk Control Measures	Residual Risk			Verification evidence
					Severity	Likelihood	RPN				Severity	Likelihood	RPN	
										the "Management Regulations for Medical Device Instructions, Labels and Packaging Labels"; The label, description and language are to be confirmed and released according to the “Control Procedures for Final Inspection and Test”.				
Same as above	Causes human infection and environmental damage	U	Harmful substances pollute the environment	After the product is used, it is not treated as medical waste	4	2	8 U A C C	U	P	Design product identification has clear use as medical waste disposal regulations	4	1	4 A C C	User manual and labelings
D. Hazards Resulting from Incorrect Output of Energy and Substances														

Hazard	Resultant Harm	Failure Mode	Cause	Trigger Event	Unmitigated Risk			Failure Mode	Mitigation Method	Risk Control Measures	Residual Risk			Verification evidence
					Severity	Likelihood	RPN				Severity	Likelihood	RPN	
D. Hazards Resulting from Incorrect Output of Energy and Substances	The patient was infected with bacteria and caused severe fever and shock; cytotoxicity, local skin irritation, and sensitization reactions.	U	Excessive harmful substances enter the human body	Particulates, bacterial endotoxin, plasticizer exceeded	3	3	9 UACC	U	M	Radiation sterilization and analysis process confirmation; according to the confirmed process to develop sterilization analysis work instructions; operation records; production environment, process water has been verified; according to the confirmed operation instructions; daily monitoring; Confirm and follow the instructions. Purification plant and air purification system verification;	3	1	3 ACC	Biocompatibility test report of the final product; Performance test report

Hazard	Resultant Harm	Failure Mode	Cause	Trigger Event	Unmitigated Risk			Failure Mode	Mitigation Method	Risk Control Measures	Residual Risk			Verification evidence
					Severity	Likelihood	RPN				Severity	Likelihood	RPN	
										formulate purification plant hygiene regulations.				
E. Hazards Related to The Use of The Device and Contributory Factors														
E1.1 Inadequate Labeling	The patient was infected with bacteria and caused severe fever and shock	D	Bacterial contamination causes infection in patients	Product not operating according to instructions	3	3	9 UACC	D	L	1. Communicate the product instructions in time 2. Mark "Do not re-use" and "Do not use if the package is damaged or not properly sealed." in label	3	1	3 ACC	User manual and labelings
E2.1 Inadequate Operating Instructions	Causes human infection and environmental pollution	U	Harmful substances pollute the environment	Improper identification. After the product is used, it is not treated as medical waste.	4	3	UACC	U	T	Design product identification has clear use as medical waste disposal regulations	4	1	4 ACC	User manual and labelings

Hazard	Resultant Harm	Failure Mode	Cause	Trigger Event	Unmitigated Risk			Failure Mode	Mitigation Method	Risk Control Measures	Residual Risk			Verification evidence
					Severity	Likelihood	RPN				Severity	Likelihood	RPN	
Same as above	Affect product effectiveness	U P	Affect product performance	Improper use of operating products by untrained personnel	3	3	9 U A C C	U P	M	Prepare clear, easy-to-understand, clear and meet the requirements of the product manual to guide the operation	3	1	3 A C C	User manual and labelings
E2.2 Glove break	The patient was infected with bacteria and other contaminations, caused severe fever and shock; acute toxicity, cytotoxicity, hemolysis, local skin irritation, and	U	Protection performance failed	Gloves break in use.	4	2	8 U A C C	U	M T	Determine there is no perforation of the gloves to ensure operation safety Perform performance tests to ensure that the gloves keep intact during normal used.	4	1	4 A C C	Performance test report; User manual and labelings

Hazard	Resultant Harm	Failure Mode	Cause	Trigger Event	Unmitigated Risk			Failure Mode	Mitigation Method	Risk Control Measures	Residual Risk			Verification evidence
					Severity	Likelihood	RPN				Severity	Likelihood	RPN	
	sensitization reactions.													
F. Hazards Arising From Functional Failure, Maintenance and Ageing														
F1.1 Hazards Arising From Functional Failure, Maintenance and Ageing	Reduce the expected effect of preventing in operators	U	Not used as required	Not used as required	2	3	6 UACC	U	M	Prepare the clear, easy to understand manual	2	1	2 ACC	User manual and labelings
F1.2 Lack of Adequate Determination of End of Device Life	The patient was infected with bacteria and caused severe fever and shock	U	The product is borne by the patient and the patient uses the product	Products that exceed the expiration date may carry bacteria	3	3	9 UACC	U	M	The expiration date and warning information should be clear described in tha manual and labelings	3	1	3 ACC	User manual and labelings
F1.3 Hazards arising from unqualified product	Affect product performance	D	Failure to achieve stated performance	Dispersion grinding failed	4	2	8 UACC	D	M, FT	Confirm product effectiveness performance. Perform full performance	4	1	4 ACC	Performance test report

Hazard	Resultant Harm	Failure Mode	Cause	Trigger Event	Unmitigated Risk			Failure Mode	Mitigation Method	Risk Control Measures	Residual Risk			Verification evidence
					Severity	Likelihood	RPN				Severity	Likelihood	RPN	
quality			and unknown harm to patients							testing on the final product.				
G. Reuse Hazards														
G 1.1 Re-and/ or cross-infection	The patient was infected with bacteria and caused severe fever and shock	U	The patient used the product with bacteria	The product is reused	4	2	8 UACC	U	S T	Design product identification has a clear one-time use	4	1	4 ACC	User manual and labelings

Clinical Evaluation Report

Nitrile Examination Glove
Models: KS-ST RT021

Document Reference No **KF-T10-A013**

Issued Date **Sep 11, 2020**

Daft by: Ziqiang Song	Date: 09/11/2020
Reviewed by: Shijun Zhao	Date: 09/11/2020

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Preface

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Part 1 - Summary

1.1 Evaluation device

This clinical evaluation report is issued for below evaluation device:
Nitrile Examination Glove, Models: KS-ST RT021
Classification (MDD, Annex IX): Class I

1.2 Reference documents

Annex X of the Medical Device Directives (MDD) 93/42/EEC as Amended by 2007/47/EC
MEDDEV 2.7-1 rev.4 - CLINICAL EVALUATION: A GUIDE FOR ANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
MEDDEV 2.12-2, rev.2 - POST MARKET CLINICAL FOLLOW-UP STUDIES: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES

1.3 Objective of the clinical evaluation

Evaluate the clinical performance of evaluation device

1.4 Intended Use

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

1.5 Determination summary of benefit/risk profile

We conducted the literature search and clinical investigation for the Nitrile Examination Glove following the requirement of MEDDEV 2.7/1 revision 4. By taking all elements into consideration, including but not limited to intended target

groups, medical indications, device technology, we draw below conclusion for determination of benefit/risk profile.

1) No obvious technological updating that revealing the device technology contains risk or less medical effect;
2) Not serious risk discovered from the medical database in the worldwide context;
3) Not unacceptable complaints regarding performance and safety sent to the manufacturer, including the manufacturer's own evaluation and report;
4) No incident reports sent to the manufacturer.

In summary, we can conclude that the performance and safety of evaluation device as claimed have been established; and the risks associated with the use of the device are acceptable when weighed against the benefits to the user.

Part 2 - Scope of the clinical evaluation

2.1 Device Identification

(1) Device name

Nitrile Examination Glove

(2) Models

KS-ST RT021

(3) Proprietary name

Device 1: Nitrile Examination Glove, Model: KS-ST RT021

(4) Size

See below dimension drawing: (unit: mm)

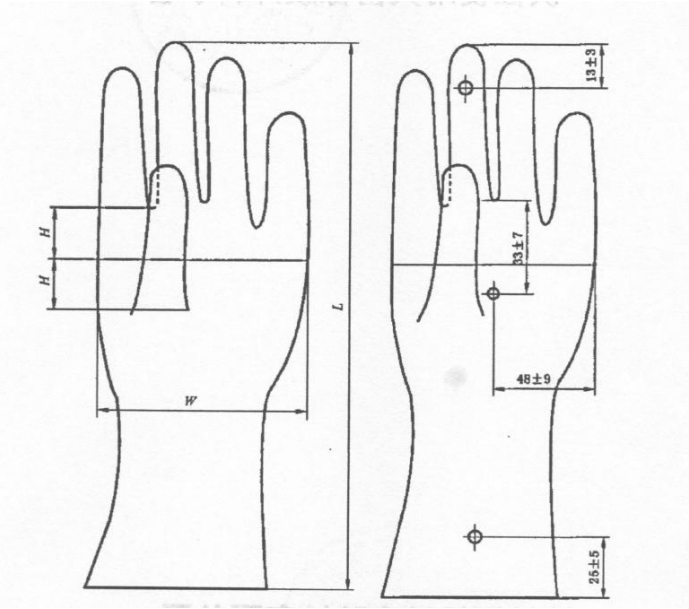


Figure 1 Model: KS-ST RT021

Glove specification sheet (unit: mm)

Size	Palm width (W in Figure 1)	Minimum length (L in Figure 1)
Extra Small	≤ 80 mm	≥240 mm
Small	80 ± 10 mm	
Medium	95±10 mm	
Large	110 ± 10 mm	
Extra Large	≥ 110 mm	

(5) Software version

N/A

(6) Accessory

N/A

(7) Manufacturer Information

Manufacturer Name: GUANGDONG KINGFA SCI.&TECH. CO., LTD.

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

2.2 Clinical evaluation compliance

This clinical evaluation is submitted to the MDD as amended by directive 2007/47/EC.

2.3 Physical and chemical description

Characteristics Table

Manufacturer:	GUANGDONG KINGFA SCI.&TECH. CO., LTD.
Address:	NO. 28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
Name:	Nitrile Examination Glove
Model:	KS-ST RT021

Intended use:	The nitrile examination glove is intended to be worn on the hands of health care and similar personnel to prevent contamination between health care personnel and the patient's body. This is a single-use, non-sterile device.
Components and materials	Nitrile
Width:	XS: ≤ 80mm, S: 80 ±10 mm, M: 95 ± 10 mm, L: 110 ± 10 mm, XL: ≥ 110 mm
Length:	≥240mm
Strength	≥6.0 N
Freedom from holes AQL:	1.5
Powder content	Powder free (≤2mg / glove)
Biocompatibility	EN ISO 10993-5, EN ISO 10993-10
Performance	EN 455-1; EN 455-2; EN455-3; EN 455-4

The product does NOT incorporate any medicinal substances, tissues, or blood products.

The product does NOT include any radioactivity.

All patient-contact material of the device is complied with biocompatibility standards ISO 10993. See below table for detailed.

Component of Device Requiring Biocompatibility	**Material of Component**	**Body Contact Category (ISO 10993-1)**	**Contact Duration (ISO 10993-1)**
The whole Nitrile Examination Glove	Ntrile	Skin	Less than 24 hours

Picture of the device

Fig.1. Nitrile Examination Glove (Model: KS-ST RT021)

Components

Bill of material and Qualitied supplier of Nitrile Examination Glove

Item	Materials	Manufacture
01	NBR Lates	Kumho Petrochemical Co., Ltd.
02	Vulcanization package	KINGFA SCI.&TECH.CO., Ltd.
03	Titanium package	KINGFA SCI.&TECH.CO., Ltd.
04	KOH	KINGFA SCI.&TECH.CO., Ltd.
05	$Ca(NO_3)_2$	KINGFA SCI.&TECH.CO., Ltd.

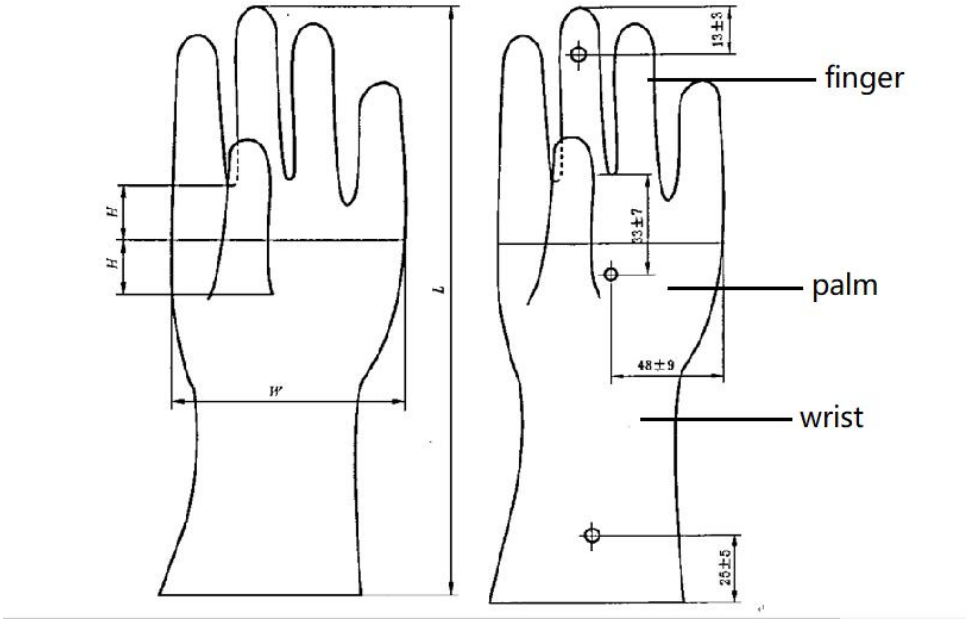


Fig.2. Nitrile Examination Glove (Construction View)

2.4 Technologies description

Principles of operation

Nitrile Examination Glove is coverings made to fit over health personnel's hands. It works by providing a physical barrier between patients and health personnel, so that to prevent contamination between health care personnel and the patient's body, if the device is used correctly and consistently.

The device is NOT based on a new technology, a new clinical application of an existing technology, or the result of incremental change of an existing technology. The Nitrile Examination Glove technology is traditional technology; the device does NOT include innovative aspects of technology.

2.5 Device group

The device is worn on the health care and similar personnel to prevent contamination between health care personnel and the patient's body, for single used only.

2.6 Intended purpose

Indications for Use

The nitrile examination glove is intended to be worn on the hands of health care and similar personnel to prevent contamination between health care personnel and the patient's body.

This is a single-use, non-sterile device.

Exact medical indications

Not applicable.

Contraindications

Not applicable.

Patient population

All kinds of patients (including adults / children / infants)

Intended user

The device can be used by medical professionals.

Parts of the body / tissues or body fluids contacted by the device

Skin

Others

The device is disposable, non- invasive devices

The maximum duration of use or contact with the body is less than 24 hours.

Precautions

(1) This product should be kept in a ventilated area, protected against direct sunlight and accidental damage.

(2) Print expiry date on unit pack, please use before this time, if found the products are sticky, crispy or damage, do not use.
(3) Beware of sharp object to slash this product, affecting the use.
(4) If the gloves are broken during examination, please clean your hands and change gloves after hand washing.
(5) After using this product, please dispose as medical waste.
(6) Double wear can significantly help reduce the risk of contamination cause by broken gloves.
(7) Don't not use the product if the package damaged.

2.7 Manufacturer claims

We (GUANGDONG KINGFA SCI.&TECH. CO., LTD.) claim that our evaluation device Nitrile Examination Glove (Model: KS-ST RT021) has the same clinical performance and clinical safety as our selected equivalent device during our clinical evaluation.

2.8 Marketing description

The device is our company's new product, which is not modified.

The device is not CE marketed, and it is NOT sale on the market in Europe.

2.9 Device changes

The device is our company's new product, which is not modified.

Part 3 - Clinical background, current knowledge, state of the art

3.1 Identification of medical fields

The Nitrile Examination Glove belongs to one kind of clinical products, which is fall in General Hospital.

And the evaluation device can be used by professionals in hospital.

3.2 Summary of the literature search

Literature sources

- Scientific literature databases

Source: MEDLINE / PubMed

Justification: MEDLINE is an international Integrated Biomedical Information Bibliographic Database from National Library of Medicine in U.S, and is the most authoritative biomedical literature database in the world. The literatures of clinical intended usage and use safety generated from this database represent the current latest medical technology state of Nitrile Examination Glove, and can be more comprehensive and correct to guide the manufacturers to conduct the clinical evaluation.

This literature search has included in the favorable and unfavorable literatures.

- Internet searches

Source: ClinicalTrials.gov

Justification: The database has plentiful data about the clinical trials and has well reprehensive for all the clinical trial in the world.

- Web of science:

Source: http://nsf.gov

Justification: The database has plentiful data including the SCI, SSCI and AHCI.

Search terms

We use below key words for in our search in scientific literature databases and Internet searches.

- Nitrile Examination Glove
- gloves
- glove perforation
- (((disposable glove) AND (nitrile)) AND (examination)))
-(((glove) AND (nitrile)) AND (examination)))
- medical exam gloves
- (((glove) AND (nitrile)) AND (sensitization)))
- (((glove) AND (nitrile)) AN D (allergy)))
- (((glove) AND (nitrile)) AND (cross infection)))
- (((Glove) AND (Perforation) AND (nitrile)))
- ((EXAM GLOVE) AND (NITRILE)))
- ((disposable glove) AND (non-sterile))

Selection criteria

We select literatures which have below same or similar characteristic with our evaluation device.

- Indication for Use
- Operation principle
- Physical parameter (e.g. material)

Quality control measures

- In order to control the quality of selected literatures, we will filter out the literatures which do not use the same operation principle and indication for Use.

Searches results

The pertinent literatures found are listed below.

- Pubmed and ClinicalTrials

Keywords	Number of search results	
	Pubmed	Sciencedirect
- Nitrile Examination Glove	54	713
- gloves	11321	189372
- glove perforation	346	5128
- (((disposable glove) AND (nitrile)) AND (examination))	4	291
-(((glove) AND (nitrile)) AND (examination))	47	1020
- medical exam gloves	16	3606
- (((glove) AND (nitrile)) AND (sensitization))	21	530
- (((glove) AND (nitrile)) AN D (allergy))	53	385
- (((glove) AND (nitrile)) AND (cross infection))	6	364
- (((Glove) AND (Perforation) AND (nitrile))	5	106
- ((EXAM GLOVE) AND (NITRILE))	13	181
- ((disposable glove) AND (non-sterile))	15	2569

3.3 Applicable standards and guidance documents

MEDDEV 2.7-1 rev.4 - CLINICAL EVALUATION: A GUIDE FOR ANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC

MEDDEV 2.12-2, rev.2 - POST MARKET CLINICAL FOLLOW-UP STUDIES: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES

3.4 Natural course and consequences of the medical conditions

For this device, there are no different clinical forms, stages and severities of the conditions.

Please see below description for frequency in the general population.

Age group: Not specified.

Gender: Male or female

Ethnicity: White, yellow, black

Familiar predispositions: Not applicable

Genetic aspects: Not applicable

3.5 Therapeutic, benefits and risks

As the Nitrile Examination Glove is for providing a barrier against potentially infectious material and other contaminants, after clinical evaluation and risk management, we consider that there is no found disadvantage in clinical trial and literatures record.

We can conclude that the risks associated with the use of the device are acceptable when weighed against the benefits to the user after our risk analysis. Please see the risk management report (File no.: KF-T10-A008) for detailed.

3.6 Hazards due to substances and technologies

Please see the risk management report (File no.: KF-T10-A008) for detailed.

3.7 Types of users

The device can be used by professionals in hospital.

Part 4 - Device under evaluation

4.1 Type of evaluation

We mainly use literature in this clinical evaluation. The clinical evaluation is based on below database sources:

- Scientific literature databases: MEDLINE / PubMed / Web of science
- ScienceDirect

The demonstration of conformity with essential requirements based on clinical data is deemed appropriate after our evaluation.

4.2 Demonstration of equivalence (only when equivalence is claimed)

4.2.1 Identification of equivalent device

We claim below devices to be the equivalent devices for our evaluation devices.

Equivalent Device

Manufacturer: Ansell Healthcare Products LLC

Device name: MICRO-TOUCH NITRAFREE™ Nitrile examination gloves

Model: --

Size: XS, S, M, L, XL

Accessories: N/A

Software: N/A

Relationship to the device under evaluation: N/A

Regulatory status: CE-marked

4.2.2 Comparison Table of evaluation device and equivalent device

	Subject device	Equivalent Device	Notes
Device name	Nitrile Examination Glove	MICRO-TOUCH NITRAFREE™ Nitrile examination gloves	--
Product Certification (CE)	Pending	CE-marked	--
Model	KS-ST RT021	/	--
Operation principle	Nitrile Examination Gloves are coverings made to fit over health care and similar personnel's hands. It works by providing a physical barrier to prevent contamination between health care personnel and the patient's body, if the device is used correctly and consistently.		Equivalent
Clinical Parameter			
Intended purpose	The nitrile examination glove is intended to be worn on the hands of health care and similar personnel to prevent contamination between health care personnel and the patient's body. This is a single-use, non-sterile device.	This is a medical glove to be worn on the hands of health care and similar personnel to prevent contamination between health care personnel and the patient's body, fluids, waste or environment, and tested for use with chemotherapy drugs.	Equivalent
Supplement information: *- used for the same clinical condition (including when applicable similar severity and stage of disease, same medical indication);* *- used for the same intended purpose;* *- used at the same site in the body;* *- used in a similar population;* *- not foreseen to deliver significantly different performances (in the relevant critical performances such as the expected clinical effect, the specific intended purpose, the duration of use, etc.).*			
Technical characteristics			

Components	Nitrile	Nitrile	Equivalent
Warranty shelf life	3 years	3 years	Equivalent
Size	XS, S, M, L, XL	XS, S, M, L, XL	Equivalent
Power free	Yes	Yes	Equivalent
Single use	Yes	Yes	Equivalent
Non-sterile	Yes	Yes	Equivalent
Pinhole AQL	1.5	1.5	Equivalent
Length	≥240mm	240mm	Equivalent
Width:	For XS: ≤80mm For S: 80±10mm For M: 95±10mm For L: 110±10mm For XL: ≥110mm	For XS: 5.5-6 (≤80mm) For S: 6.5-7 (80±10mm) For M: 7.5-8 (95±10mm) For L: 8.5-9 (110±10mm) For XL: 9.5-10 (≥110mm)	Equivalent
Strength	≥6.0N	≥6.0N	Equivalent
Textured Fingers	Yes	Yes	Equivalent
Supplement information: *- be of similar design;* *- used under the same conditions of use;* *- have similar specifications and properties;* *- have similar principles of operation and critical performance requirements.*			
Biological Parameter			
Patient contact materials	Nitrile	Nitrile	Equivalent
Biocompatibility	ISO 10993	ISO 10993	Equivalent
Supplement information: *-Use the same materials or substances in contact with the same human tissues or body fluids.*			

Conclusion

The equivalence is demonstrated that the differences between evaluation device and equivalent device are not expected to affect the clinical performance and clinical safety.

4.2.3 Identification of pre-clinical studies carried out and literature used

Summary of studies and literature

We only use literature of equivalence device for this evaluation.

Item	Literature Title	Literature Results & Conclusions

Appendix 1-1 Equivalent Device MICRO-TOUCH NITRAFREE ™ Nitrile examination glove	A preliminary report on the incidence of pre-existing pinhole defects in nitrile dental gloves	All glove types examined met the European Standard (EN 455-1) and there was no statistically significant difference between glove types. However, the nitrile gloves generally exhibited less pre-existing pinhole defects than the latex examination gloves.

Evaluation of the methodological quality & scientific validity

Because the device in the literature is our selected Equivalent Device, they have the same technical parameters, so below factors will not affect the methodological quality and scientific validity of clinical evaluation.

- Confounding influences: No effect
- Bias: Slight effect
- Random error: Slight effect
- Inadequate disclosure of information: No effect
- Misinterpretation: No effect

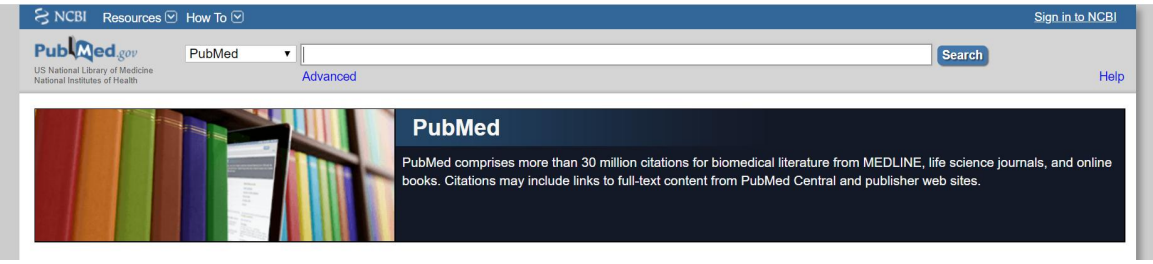
4.3 Clinical data generated and held by the manufacturer

There is no clinical data generated and held by the manufacturer.

All the data is got from Internet database.

4.4 Clinical data from literature

We search the clinical literature from PubMed below link which including MEDLINE database.
https://www.ncbi.nlm.nih.gov/pubmed/



Item	Literature Title	Appendix
1	A preliminary report on the incidence of pre-existing pinhole defects in nitrile dental gloves	Appendix 1-1: full document Appendix 1-2: abstract Appendix 1-3: search record
2	Comparison of blood transmission through latex and nitrile glove materials	Appendix 2-1: full document Appendix 2-2: abstract Appendix 2-3: search record
3	Transfer efficiency of Staphylococcus aureus between nitrile exam gloves and nonporous fomites	Appendix 3-1: full document Appendix 3-2: abstract Appendix 3-3: search record
4	Assessment of the Durability of Medical Examination Gloves	Appendix 4-1: full document Appendix 4-2: abstract Appendix 4-3: search record
5	Latex and synthetic rubber glove usage in UK general dental practice: changing trends	Appendix 5-1: full document Appendix 5-2: abstract Appendix 5-3: search record

4.5 Summary and appraisal of clinical data

4.5.1 Summary of clinical data

Item	Data Content	Data Summary
Appendix 1-1	A preliminary report on the incidence of pre-existing pinhole defects in nitrile dental gloves	All glove types examined met the European Standard (EN 455-1) and there was no statistically significant difference between glove types. However, the nitrile gloves generally exhibited less pre-existing pinhole defects than the latex examination gloves.
Appendix 2-1	Comparison of blood transmission through latex and	Our study found that the wiping of nitrile glove material was modestly superior to single latex material and that double layer gloves provided better protection than single

	nitrile glove materials	layer latex and nitrile gloves. Nitrile is associated with promising biomechanical performance and has been recommended as an alternative to latex.
Appendix 3-1	Transfer efficiency of Staphylococcus aureus between nitrile exam gloves and nonporous fomites	This report describes fomite transmission of Staphylococcus aureus amongst various surfaces. A contact transfer protocol was completed to evaluate the movement of S aureus between a person wearing nitrile gloves and either: handshaking with another person with gloved hands, touching a plastic cellular telephone back, or touching a stainless steel rod. The data in this preliminary study imply that the highest bacterial transfer is with metal surfaces followed by plastic. Interestingly, glove-to-glove transfer occurred but transfered less bacteria than a plastic or metal surface. The observations from this study point to the need to clearly define hygiene behaviors to reduce the potential of hand- and surface-mediated transmission.
Appendix 4-1	Assessment of the Durability of Medical Examination Gloves	The results of this study demonstrate that all medical exam gloves are not equal in durability. The durability depends on the type of glove material. Vinyl gloves are not as durable as latex and this may be an important factor when choosing an alternative to latex. Nitrile and chloroprene gloves appear to be as durable as latex gloves and may provide a better alternative.
Appendix 5-1	Latex and synthetic rubber glove usage in UK general dental practice: changing trends	Nitrile examination gloves are replacing NRL gloves in general dental practice. Non-latex containing dental dam also appears to be replacing latex containing dental dam. These changes are in line with changes in other healthcare settings where latex free products are now being used. This reduction in latex use will help reduce the incidence of new cases of latex allergy and also reduce the risk of an allergic reaction to latex occurring in the dental setting. If current trends continue it is likely that NRL examination gloves will be

		completely replaced by nitrile gloves in general dental practice. This change is to be encouraged.

4.5.2 Appraisal of clinical data

4.5.2.1 Method of Appraisal

We use below two tables' test items to appraise the clinical data.

Appraisal Criteria for Suitability

Suitability Criteria	**Description**	**Grading System**	
Appropriate device	Were the data generated from the device in question?	D1 D2 D3	Actual device Equivalent device Other device
Appropriate device application	Was the device used for the same intended use (e.g., methods of deployment, application, etc.)?	A1 A2 A3	Same use Minor deviation Major deviation
Appropriate patient group	Where the data generated from a patient group that is representative of the intended treatment population (e.g., age, sex, etc.) and clinical condition (i.e., disease, including state and severity)?	P1 P2 P3	Applicable Limited Different population
Acceptable report/data collation	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1 R2 R3	High quality Minor deficiencies Insufficient information

Appraisal Criteria for Data Contribution

Data Contribution Criteria	**Description**	**Grading System**	
Data source type	Was the design of the study appropriate?	T1 T2	Yes No
Outcome measures	Does the outcome measures reported reflect the intended performance of the device?	O1 O2	Yes No
Follow up	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1 F2	Yes No
Statistical	Has a statistical analysis of the data been	S1	Yes

significance	provided and is it appropriate?	S2	No
Clinical significance	Was the magnitude of the treatment effect observed clinically significant?	C1 C2	Yes No

(1) <u>Appendix 1-1: A preliminary report on the incidence of pre-existing pinhole defects in nitrile dental gloves</u>

a) Summary of the studies or references

The device under evaluation in this literature is MICRO-TOUCH NITRAFREE™ Nitrile examination gloves, which is our selected Equivalent Device.

<u>We used this literature to demonstrate physical performance of evaluation Nitrile Examination Gloves, provide a barrier against potentially infectious material and other contaminants.</u> See below:

- MICRO-TOUCH NITRAFREE™ Nitrile examination gloves

b) Methodological quality and scientific validity

Because the device in the literature is our selected Equivalent Device, they have the same technical parameters, so below factors will not affect the methodological quality and scientific validity of clinical evaluation.

- Confounding influences: No effect
- Bias: Slight effect
- Random error: Slight effect
- Inadequate disclosure of information: No effect
- Misinterpretation: No effect

c) Relevance to the clinical evaluation

The device under evaluation in this literature is MICRO-TOUCH NITRAFREE™ Nitrile examination gloves, which is our selected Equivalent Device.

d) Weighting attributed to the data

We use the method (describe in clause 4.5.2.1) to weight the clinical data. The result is as below.

Suitability Criteria	**Description**	**Grading System**	
Appropriate device	Were the data generated from the device in question?	D2	Equivalent device
Appropriate device application	Was the device used for the same intended use (e.g., methods of deployment, application, etc.)?	A1	Same use
Appropriate patient group	Where the data generated from a patient group that is representative of the intended treatment population (e.g., age, sex, etc.) and clinical condition (i.e., disease, including state and severity)?	P2	Limited
Acceptable report/data collation	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1	High quality

Data Contribution Criteria	**Description**	**Grading System**	
Data source type	Was the design of the study appropriate?	T1	Yes
Outcome measures	Do the outcome measures reported reflect the intended performance of the device?	O1	Yes
Follow up	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1	Yes
Statistical significance	Has a statistical analysis of the data been provided and is it appropriate?	S1	Yes
Clinical significance	Was the magnitude of the treatment effect observed clinically significant?	C1	Yes

(2) <u>Appendix 2-1: Comparison of blood transmission through latex and nitrile glove materials</u>

a) Summary of the studies or references

This literature demonstrates that in protecting against blood transmission in the context of needlestick injuries, single layer nitrile gloves are superior to single

layer gloves and the wiping quality of nitrile glove materials was modestly superior to single latex material.

b) Methodological quality and scientific validity

Because the device in the literature has the same technical parameters to evaluation the subject device, so below factors will not affect the methodological quality and scientific validity of clinical evaluation.

- Confounding influences: No effect
- Bias: Slight effect
- Random error: Slight effect
- Inadequate disclosure of information: No effect
- Misinterpretation: No effect

c) Relevance to the clinical evaluation

The device in this literature is the same use and principle as our evaluation device, which will support the theoretical foundation.

d) Weighting attributed to the data

We use the method (describe in clause 4.5.2.1) to weight the clinical data. The result is as below.

Suitability Criteria	**Description**	**Grading System**	
Appropriate device	Were the data generated from the device in question?	D3	Other device
Appropriate device application	Was the device used for the same intended use (e.g., methods of deployment, application, etc.)?	A1	Same use
Appropriate patient group	Where the data generated from a patient group that is representative of the intended treatment population (e.g., age, sex, etc.) and clinical condition (i.e., disease, including state and severity)?	P2	Limited

Acceptable report/data collation	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1	High quality

Data Contribution Criteria	**Description**	**Grading System**	
Data source type	Was the design of the study appropriate?	T1	Yes
Outcome measures	Do the outcome measures reported reflect the intended performance of the device?	O1	Yes
Follow up	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1	Yes
Statistical significance	Has a statistical analysis of the data been provided and is it appropriate?	S1	Yes
Clinical significance	Was the magnitude of the treatment effect observed clinically significant?	C1	Yes

(3) <u>Appendix 3-1: Transfer efficiency of Staphylococcus aureus between nitrile exam gloves and nonporous fomites</u>

a) Summary of the studies or references

This literature demonstrates that the transfer efficiency of S aureus between nitrile gloves and a model plastic surface and a model metal surface was examined to provide insight into differences in the transmission potential of bacteria across different types of surface contact events. The date in this preliminary study imply that the highest bacterial transfer is with metal surfaces followed by plastic, glove to glove transfer occured but transfered less bacteria the a plastic or metal surface.

b) Methodological quality and scientific validity

Because the device in the literature has the same technical parameters to evaluation the subject device, so below factors will not affect the methodological quality and scientific validity of clinical evaluation.

- Confounding influences: No effect
- Bias: Slight effect

- Random error: Slight effect
- Inadequate disclosure of information: No effect
- Misinterpretation: No effect

c) Relevance to the clinical evaluation

The device in this literature is the same use and principle as our evaluation device, which will support the theoretical foundation.

d) Weighting attributed to the data

We use the method (describe in clause 4.5.2.1) to weight the clinical data. The result is as below.

Suitability Criteria	**Description**	**Grading System**	
Appropriate device	Were the data generated from the device in question?	D3	Other device
Appropriate device application	Was the device used for the same intended use (e.g., methods of deployment, application, etc.)?	A1	Same use
Appropriate patient group	Where the data generated from a patient group that is representative of the intended treatment population (e.g., age, sex, etc.) and clinical condition (i.e., disease, including state and severity)?	P2	Limited
Acceptable report/data collation	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1	High quality

Data Contribution Criteria	**Description**	**Grading System**	
Data source type	Was the design of the study appropriate?	T1	Yes
Outcome measures	Do the outcome measures reported reflect the intended performance of the device?	O1	Yes
Follow up	Is the duration of follow-up long enough to assess whether duration of treatment	F1	Yes

	effects and identify complications?		
Statistical significance	Has a statistical analysis of the data been provided and is it appropriate?	S1	Yes
Clinical significance	Was the magnitude of the treatment effect observed clinically significant?	C1	Yes

(4) Appendix 4-1: Assessment of the Durability of Medical Examination Gloves

a) Summary of the studies or references

This literature demonstrates the durability of various types of medical examination golves, and the results suggest that nitrile appear to be as durable as latex gloves and may provide a better alternative.

b) Methodological quality and scientific validity

Because the device in the literature has the same technical parameters to evaluation the subject device, so below factors will not affect the methodological quality and scientific validity of clinical evaluation.

- Confounding influences: No effect
- Bias: Slight effect
- Random error: Slight effect
- Inadequate disclosure of information: No effect
- Misinterpretation: No effect

c) Relevance to the clinical evaluation

The device in this literature is the same use and principle as our evaluation device, which will support the theoretical foundation.

d) Weighting attributed to the data

We use the method (describe in clause 4.5.2.1) to weight the clinical data. The result is as below.

Suitability Criteria	**Description**	**Grading System**

Appropriate device	Were the data generated from the device in question?	D3	Other device
Appropriate device application	Was the device used for the same intended use (e.g., methods of deployment, application, etc.)?	A1	Same use
Appropriate patient group	Where the data generated from a patient group that is representative of the intended treatment population (e.g., age, sex, etc.) and clinical condition (i.e., disease, including state and severity)?	P2	Limited
Acceptable report/data collation	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1	High quality

Data Contribution Criteria	**Description**	**Grading System**	
Data source type	Was the design of the study appropriate?	T1	Yes
Outcome measures	Do the outcome measures reported reflect the intended performance of the device?	O1	Yes
Follow up	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1	Yes
Statistical significance	Has a statistical analysis of the data been provided and is it appropriate?	S1	Yes
Clinical significance	Was the magnitude of the treatment effect observed clinically significant?	C1	Yes

(5) <u>Appendix 5-1: Latex and synthetic rubber glove usage in UK general dental practice: changing trends</u>

<u>a)</u> Summary of the studies or references

This literature demonstrates nitrile gloves have been shown to be equally as resistant to puncture as NRL gloves, and due to their superior properties, nitriles gloves are the comment used gloves in general practice.

b) Methodological quality and scientific validity

Because the device in the literature has the same technical parameters to evaluation the subject device, so below factors will not affect the methodological quality and scientific validity of clinical evaluation.

- Confounding influences: No effect
- Bias: Slight effect
- Random error: Slight effect
- Inadequate disclosure of information: No effect
- Misinterpretation: No effect

c) Relevance to the clinical evaluation

The device in this literature is the same use and principle as our evaluation device, which will support the theoretical foundation.

d) Weighting attributed to the data

We use the method (describe in clause 4.5.2.1) to weight the clinical data. The result is as below.

Suitability Criteria	**Description**	**Grading System**	
Appropriate device	Were the data generated from the device in question?	D3	Other device
Appropriate device application	Was the device used for the same intended use (e.g., methods of deployment, application, etc.)?	A1	Same use
Appropriate patient group	Where the data generated from a patient group that is representative of the intended treatment population (e.g., age, sex, etc.) and clinical condition (i.e., disease, including state and severity)?	P1	Applicable
Acceptable report/data collation	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1	High quality

Data Contribution Criteria	Description	Grading System	
Data source type	Was the design of the study appropriate?	T1	Yes
Outcome measures	Do the outcome measures reported reflect the intended performance of the device?	O1	Yes
Follow up	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1	Yes
Statistical significance	Has a statistical analysis of the data been provided and is it appropriate?	S1	Yes
Clinical significance	Was the magnitude of the treatment effect observed clinically significant?	C1	Yes

4.6 Analysis of the clinical data

4.6.1 Requirement on safety (MDD ER1 / AIMDD ER1)

In summary, our evaluation device is complied with requirement on safety. We provide below test reports to evaluate the device safety conformity.

- Performance test according to EN 455-1, EN 455-2, EN 455-3, EN 455-4 (see Part B - B002 Performance Test Report)
- Biocompatibility test according to ISO 10993-1, ISO 10993-5, ISO 10993-10 (see Part B - B003 Biocompatibility Report)
- Usability test according to EN 62366-1: 2015 standard (see Part B - B001 Usability Test Report)

The detailed analysis for requirement and conformity assessment on safety is listed below.

Item	Requirement description on safety	Analysis
1	Whether there are special design features that pose special safety concerns	The Nitrile Examination Gloves is non - innovative technology. There are no special design features that pose special safety concerns.
2	Whether the risks identified in the risk management documentation and literatures have been adequately addressed	The risks identified in the risk management documentation and literatures have been adequately addressed.

		See Risk Management Report in Part A - A008 Risk Management.
3	Whether all the hazards and other clinically relevant information have been identified appropriately	All the hazards and other clinically relevant information have been identified appropriately. See Risk Management Report in Part A - A008 Risk Management.
4	Whether the safety characteristics and intended purpose of the device requires training of the end-user or other precautions	The safety characteristics and intended purpose of the device require professionals' usage. See Usability Engineering File in Part B B001 Usability Test Report.
5	Whether there is full consistency between current knowledge/ the state of the art, the available clinical data, the information materials supplied by the manufacturer, and the risk management documentation for the device.	We provide the literatures to support the clinical evaluation, which is our selected Equivalent Devices. The parameters of Evaluation Device and Equivalent Devices are nearly the same. So, there is full consistency between current knowledge/ the state of the art, the available clinical data, the information materials supplied by the manufacturer, and the risk management documentation for the device. See Risk Management File in Part A - A008 Risk Management.

4.6.2 Requirement on acceptable benefit/risk profile (MDD ER1 / AIMDD ER1)

The detailed analysis for requirement and conformity assessment on acceptable benefit/risk profile is listed below.

Item	Requirement on benefit/risk profile	Analysis
1	Estimated numbers and characteristics of patients exposed to the device in clinical investigations, PMCF	Evaluated by literature research, no clinical investigation done.
2	Nature, extent/severity, probability/frequency, duration of	All the hazards and other clinically relevant information have been

	benefits to the patients and of undesirable side-effects and other risks	identified appropriately. See Risk Management Report in Part A - A008 Risk Management.
3	For each aspect of the intended purpose, whether the benefit/risk profile including its uncertainties or unanswered questions is compatible with a high level of protection of health and safety, corresponding justifications.	There are no uncertainties or unanswered questions for each aspect of the intended purpose.

4.6.3 Requirement on performance (MDD ER3 / AIMDD ER2)

In summary, our evaluation device is complied with requirement on performance.

We provide below test reports to evaluate the device performance conformity.

- EN 455-1 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes (see Part B – B002 Performance test report)
- EN 455-2 Medical gloves for single use - Part 2: Requirements and testing for physical properties (see Part B – B002 Performance test report)
- EN 455-3 -Medical gloves for single use - Part 3: Requirements and testing for biological evaluation (see Part B – B002 Performance test report)

The reports show that all the samples meet the requirement of EN 455-1, EN 455-2 and EN 455-3:

1) Freedom of holes

Based on the performance testing, the freedom of holes of the Nitrile Examination Glove meet the requirement in EN 455-1.

2) Physical properties

Based on the performance testing, the physical properties of the Nitrile Examination Glove meet the requirement in EN 455-2.

3) Biological evaluation

Based on the performance testing, the Biological evaluation of the Nitrile Examination Glove meet the requirement in EN 455-3.

The detailed analysis for requirement and conformity assessment on performance is listed below.

Item	Requirement on benefit/risk profile	Analysis
1	Whether available data allows adequate evaluation of performance, limitations of the data, gaps, uncertainties or unanswered questions.	Available data shows adequate evaluation of performance, we consider there is no limitations of the data, gaps, uncertainties or unanswered questions based on.
2	Whether there is sufficient clinical evidence for every intended performance.	There is sufficient clinical evidence for every intended performance.

4.6.4 Requirement on acceptability of side-effects (MDD ER6 / AIMDD ER5)

There are three methods to collect cases of undesirable side-effect, including pre-market literature search, clinical investigation and post-market clinical follow-up.

As for the Nitrile Examination Gloves, the situation of the undesirable side-effect is:

1) Clinical investigation: There is no undesirable side-effect during the clinical investigation.

2) Follow-up: There is no incident report or complaint that has been found.

The detailed analysis for requirement and conformity assessment on acceptability of side-effects is listed below.

Item	Requirement on benefit/risk profile	Analysis
1	Whether the data available is of sufficient amount and quality for the detection of undesirable side-effects and their frequency, limitations of the data, description of gaps, uncertainties or unanswered questions, and assumptions.	The data available is of sufficient amount and quality for the detection of undesirable side-effects.

2	Whether the undesirable side-effects are acceptable and corresponding justifications.	Nitrile contains no protein, and hos no allergic reaction to human.

4.7 Clinical data generated and held by the manufacturer

4.7.1 Pre-market clinical verifications

We have collected many clinical data (including performance and safety) from our competitor's similar devices before this device bring to the market. These clinical data are also included in this clinical evaluation report. And we have completed below evaluations:

- Performance test according to EN 455-1, EN 455-2, EN 455-3, EN 455-4 (see Part B - B002 Performance Test Report)
- Biocompatibility test according to ISO 10993-1, ISO 10993-5, ISO 10993-10 (see Part B - B003 Biocompatibility Report)
- Usability test according to EN 62366-1: 2015 standard (see Part B - B001 Usability Test Report)

4.7.2 Clinical trial (not applicable)

Similar Nitrile Examination Gloves have been on the market for many years. It has been proved that these kinds of product are safe and effective by tracking the use of them. Data collected for years of comparison products have not been found to be unsafe or invalid. Therefore, we don't think that we need any new clinical trial.

4.7.3 Post Market Clinical Follow-Up

We had conducted clinical evaluation for Nitrile Examination Gloves, the clinical verification result indication that the device is safety and effectiveness. It is mature for the technology, and it has been on the market for many years without any unanswered questions.

Nitrile Examination Glove is classed into I, and the device is intended to be worn on the hands, usually in a examination setting, to provide a barrier against potentially infectious material and other contaminants, so we not need PMCF, and our company will take post-market surveillance activities to follow up product quality and safety.

4.7.3.1 PMCF (Post Market Clinical Follow-Up) Plan

We will set up the PMCF plan according to item 4.7.3.2 & 4.7.3.3 to collect post market clinical data based on the use our device.
The objective is to confirm clinical performance and safety throughout the expected lifetime of our device, the acceptability of identified risks and to detect emerging risks on the basis of factual evidence.
We will use below methods to collect clinical data.

Focus groups

The company's quality department takes the lead and set up a focus group composed of related departments, including R & D department, production department, quality department and marketing department. It can get market feedback and adverse events related to this product from all kinds of possible information channels.

Customer surveys

Our customer service staff will call back to their customers within a month after the sale of the product. In addition, in the life cycle of the product, the customer will also visit the customer for the use of the product every month.

User feedback via training programs

After the sale of the products, our company will arrange sales engineers to the customer on site to carry out the training of the products. After the training, the engineer will ask the customer to fill out the questionnaire used by the product to collect feedback on the use of the product.

Implant registries

We will join in several Implant Registry (IR) platforms of this kind product, which is formulated in an endeavor to provide patients, physicians, regulatory bodies and manufacturers with essential and updated information that would improve knowledge and ensure safety in the use of this kind product.

The application of any new device in medicine can generate short- and long-term unexpected adverse effects. The registry should provide the basic data needed to evaluate and compare the quality, to enable early detection of serial defects, to assess short- and long-term reactions and complications. The registry can shorten the time lapse before any health hazard is perceived.

Other bodies (e.g. CA)

The staff of marketing department will obtain more market trends and adverse events about these products through the websites of other bodies, e.g. Certification Authority (CA).

Media

Our company's marketing personnel will also collect customers' opinions and suggestions on products related questions through various media, including the official website of the company, the official website of the agent, the media advertising opinion collection, etc.

Experience with similar devices

The company's marketing personnel will collect and share relevant information about competitor similar devices (including customer use problems, product design problems, etc.) at monthly sales meetings.

Retrieval studies

The company's marketing personnel will search the major online search engines, network data retrieval center every two weeks; and they will search for industry information related to the product, including customer feedback, description of adverse events and new technology in the industry.

4.7.3.2 Criteria should be taken into account:

- innovation, e.g., where the design of the device, the materials, substances, the principles of operation, the technology or the medical indications are novel;
- significant changes to the products or to its intended use for which pre-market clinical evaluation and re-certification has been completed;

- high product related risk e.g. based on design, materials, components, invasiveness, clinical procedures;
- high risk anatomical locations;
- high risk target populations;
- severity of disease/treatment challenges;
- questions of ability to generalize clinical evaluation results;
- unanswered questions of long-term safety and performance;
- results from any previous clinical evaluation, including adverse events or from post-market surveillance activities;
- identification of previously unstudied subpopulations which may show different benefit/risk-ratio;
- continued validation in cases of discrepancy between reasonable premarket follow-up time scales and the expected life of the product;
- risks identified from the literature or other data sources for similar marketed devices;
- interaction with other medical products or treatments;
- verification of safety and performance of device when exposed to a larger and more varied population of clinical users;
- emergence of new information on safety or performance;
- Where CE marking was based on equivalence.

4.7.3.3 Elements of a PMCF study

4.7.3.3.1 Objective

- To verify the device's performance and effect

We will record and statistic the devices' performance and effect under normal condition. And we will determine any undesired side-effects, under normal conditions of use, and assess whether they constitute risks when weighed against the intended performance of the device.

- To record and analysis any incident event of the device

We will also record and statistic all the incident event under any normal and single fault condition. And we will analysis the reason of the incident event.

4.7.3.3.2 Incident Event Follow-up

1) Any event which meets all three basic reporting criteria A - C listed below is considered as an INCIDENT and will be reported to the relevant National Competent Authority. The criteria are that:

A: An event has occurred.

This also includes situations where testing performed on the device, examination of the information supplied with the device or any scientific information indicates some factor that could lead or has led to an event.

Typical events include, but are not limited to:

a) A malfunction or deterioration in the characteristics or performance.
b) Unanticipated adverse reaction or unanticipated side effect
c) Interactions with other substances or products
d) Degradation/destruction of the device (e.g. fire)

e) Inappropriate therapy
f) An inaccuracy in the labelling, instructions for use and/or promotional materials.

B: The device is suspected to be a contributory cause of the incident.
In assessing the link between the device and the incident the manufacturer should take account of:

- the opinion, based on available evidence, of healthcare professionals;
- the results of the manufacturer's own preliminary assessment of the incident;
- evidence of previous, similar incidents;
- Other evidence held by the manufacturer.

C: The event led, or might have led, to one of the following outcomes:

- death of a patient, user or other person
- Serious deterioration in state of health of a patient, user or other person.

A serious deterioration in state of health can include (non-exhaustive list):
a) life-threatening illness,
b) Permanent impairment of a body function or permanent damage to a body structure,
c) A condition necessitating medical or surgical intervention to prevent a) or b).
d) Any indirect harm
e) Fetal distress, fetal death or any congenital abnormality or birth defects.

For any incident event in item above, we will establish an ad hoc group, follow up, and analysis the reason of the incident event. And we will handle the event according to guideline MEDDEV 2.12-1 rev 8.

4.7.3.3.3 Incident Reports
N/A

4.7.3.3.4 Complaints
N/A

4.7.3.3.5 Relevant pre-clinical studies
Please refer to reports of EN 455-1, EN 455-2, EN 455-3, EN ISO 10993-1, EN ISO 10993-5 and EN ISO 10993-10 for details.

4.7.4 Market Tracking PMS

- Marketing data
  The product not in marketing now.

- PMS - Post-Market Surveillance
  The product not in marketing now. We will process the clinical evaluation once a year.

- Adverse events (including our products / competitor products)
  1) Query time: 2020-07-01.
  2) The time period covered by the query: January 2015 –Jul 01, 2020.
  3) Inquiry route:
     a) US FDA official website:
     http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM
     b) China CFDA official website：http://www.nmpa.gov.cn/WS04/CL2157/

  4) Discussion and evaluation of the query results (adverse events)
     No adverse events were found.

  5) Conclusion
     No adverse events were found, we consider the product is safe.

Part 5 - Conclusions

Through the above clinical appraisal and analysis, we conclude that the evaluation device is compliance to all essential requirements.

- The benefit/risk profile is acceptable according to current knowledge / the state of the art in the medical fields concerned and according to available medical alternatives.
- The information materials supplied by the manufacturer are adequacy; the intended purpose and risk reduction measures are adequate.
- The device, including its IFU, for the intended users and usability aspects is suitable.
- The claims foreseen by the manufacturer is adequacy.
- There is consistency between the clinical data, the information materials supplied by the manufacturer, the risk management documentation for the device under evaluation.
- There is consistency between these documents and the current knowledge/ the state of the art.
- There is no residual risks have been found until now. These are acceptable for CE-marking.

Part 6 - Date of the next clinical evaluation

We defined the date of the next clinical evaluation is when we modify the Intended Use or the design of the evaluation device or any condition as below happened:

- The device carries significant risks.
- There are risks and uncertainties or unanswered questions, in the medium or long-term, that would influence the frequency of updates.
- Design changes or changes to manufacturing procedures (if any).
- When the manufacturer receives new information from PMS that has the potential to change the current evaluation;
- If no such information is received, then
- At least annually if the device carries significant risks or is not yet well established;

If no any updated, we will process the clinical evaluation in one year.

Part 7 - Dates and signatures

The evaluate leader for this clinical evaluation has signature and date as below.

Name:	Ziqiang Song
Signature:	
Date:	09/11/2020

Part 8 - Qualification of the responsible evaluators

This clinical evaluation is conducted by our clinical evaluation team, including:

1. Product expert – Ziqiang Song
2. President Engineer – Pingxu Cheng;

Ziqiang Song product expert:

He has graduate from university more than 20 years, and keep working for medical device and clinical work more than 19 years, including working for masks more than 12 years.

His qualification certificate as below showed:

He is very experienced since:

- Working for disposed masks production for more than 12 years;
- Working for disposed medical masks production for more than 8 years;

He also has knowledge of:

- GMP for more than 5 years;
- Regulatory of medical device for more than 8 years.

Part 9 - References

During this clinical evaluation, we reference below document and guidance.

- MEDDEV 2.7-1 rev.4 - CLINICAL EVALUATION: A GUIDE FOR ANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
- MEDDEV 2.12-2, rev.2 - POST MARKET CLINICAL FOLLOW-UP STUDIES: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES

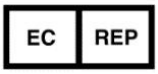
Manual, packaging, labels and language requirements

Our company developed the “Language and Labels Procedure” according to the requirements on laws and regulations, standards of EN ISO 15223-1: 2016, EN 1041: 2008, 93/42/EEC and 2007/47/EC. Every process of the product is strictly controlled and managed in accordance with the Procedure requirements.

1. Label and Symbol

1.1 Label please refer to “Part A / A010 Labeling and Instructions for Use-03 Package Box”

1.2 All of our medical products which are supplied for Europe market need to be marked in accordance with the above requirements of standards. Based on features of Nitrile Examination Glove (model: KS-ST RT021), the following logos in Chart 1 can be used:

1		Symbol for CE Mark. This symbol certifies that a product has met European Union consumer safety, health, or environmental requirements.
2		Non-sterilized
3		Indicates the medical device manufacturer, as defined in EU Directives 90/385/ EEC, 93/42/EEC and 98/79/EC.
4		Indicates the Authorized representative in the European Community.
5		Indicates that need for the user to consult the instructions for use
6		Indicates the date when the medical device was manufactured
7		Indicates a medical device that should not be used if the package has been damaged or open
8		Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
9		Indicates a medical device that needs protection from moisture
10		Indicates a medical device that needs protection from light sources
11		Indicated the date after which the medical device is not to be used

12		Indicated the manufacturer's batch codes so that the batch or lot can be identified
13		Caution
14		Temperature limit
15		Maximum number of stack levels
16		Product does not contain latex

1.2 The Label of Nitrile Examination Glove (KS-ST RT021) at least includes the following information: Name of Manufacture, Address of Manufacture, Name of Authorized representative, Address of Authorized representative, Serial number, do not re-use, warning information, etc.
Please see attached "02 Instruction for Use" and "03-07 Package box" for more details.

1.3 Other information that is not mentioned in the labels should be identified on the box or manual.
02 User Manual
03-07 Package Box

The packaging labels of our products meet the above requirements, if customers have any other requirement in this label, we will follow the request for additional content.

2. Instructions

See 02 User Manual.

3. Packaging

3.1 Packaging Method

The product packaged with 100 pcs / box.

3.2 Contents

Nitrile Examination Glove (Model: KS-ST RT021)

3.4 Packaging Quantity and Weight

100 pcs / box packaged

3.5 Protective Packaging Validation

We did the package integrity test for Nitrile Examination Glove (Model: KS-ST RT021), for more details, Read part B / B004 Package test report, the test can prove that the above-mentioned packaging achieve the desired protection.

4. Language

According to the language requirements based on the import, the company needs to decide whether to adopt one or more languages in the labeling of medical devices and information. For more information of the official language situations of the 27 EU member states and three candidates to join the EU (Deadline: 2009), you can read “The capital and official language of the 27 EU countries and the three candidates to join the nation”. The language translation can be seen in Flowchart 1.

Working step	Related dept (person)	Quality records
Design label, manual, language ↓ The translation company ↓ Viewed by customer or third party ↓ Control for label, manual and language		Labeling and Instruction

Flowchart 1

5. LANGUAGE AND LABEL CONTROL

5.1 According to the above requirements, R&D department design the labels, and the relevant design samples should be a part of the product technical documentation.

5.2 It is responsible for the product label and the language testing according to the procedural requirements and design samples, and The Quality Department is also responsible for the management and control of the label in order to use the label properly.

KINGFA MEDICAL
PROTECTING PEOPLE

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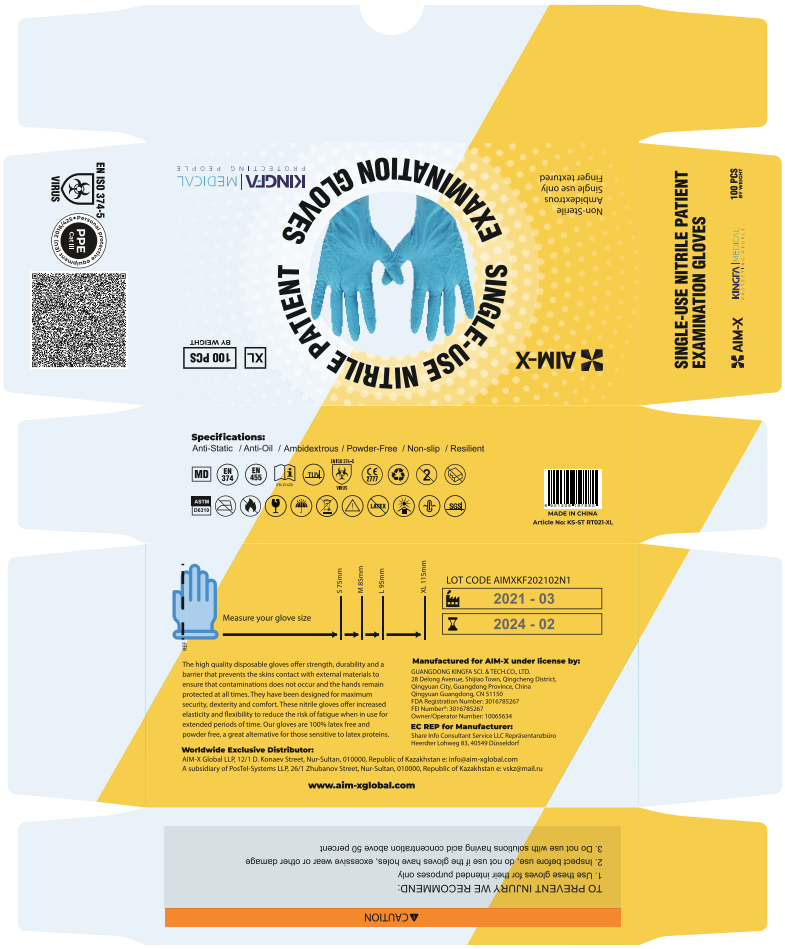
PACKING INFORMATION



STORAGE AND DISPOSAL

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PACKING INFORMATION

Paper Box

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

100
pcs

AIM-X Kingfa Co branded Single Use Nitrile Patient Examination Gloves

Carton

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

1000
pcs

STORAGE AND DISPOSAL

Know you're protected.

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

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