

TEST REPORT

EN 455 1-3

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



PSB Singapore

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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:

- EN 455-1:2020 Medical gloves for single use
Part 1: Requirements and testing for freedom from holes
- EN 455-2:2015 Medical gloves for single use
Part 2: Requirements and testing for physical properties
- EN 455-3:2015 Medical glove for single use
Part 3: Requirements and testing for biological evaluation



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TUV®

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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	Freedom from holes	Shall not leak	7	200	2	Passed
5						

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

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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

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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

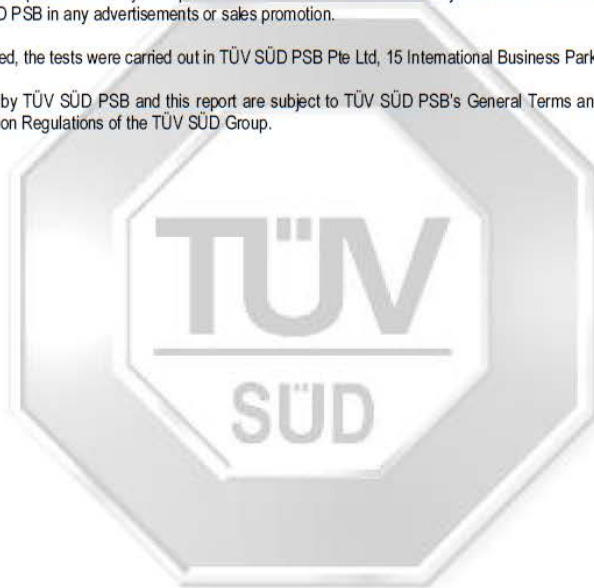
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Effective 01 January 2021



TEST REPORT

EN 455-4



180015144061



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TESTING
CNAS L2954

Final Report

Report Number: SDWH-M202005587-1(E)

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

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

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



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Supplementary Explanation

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

Verification Dates

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

Edited by: Wang Deheng 2021-03-08
 Date

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

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

Sanitation & Environment Technology Institute, Soochow University



Summary

1 Test Article

Test Article Name	Nitrile gloves
Manufacturer	GUANG DONG KINGFA SCI.& TECH.CO.,LTD
Address	No.28 Delong Ave.,Shijiao Town,Qingcheng District,Qingyuan,Guangdong,China
Model	KS-ST RT021
Lot/Batch	25007018/25007019/25007020

2 Main Reference

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

Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices (ASTM F1980-16)

3 Test Method

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

Study protocol number: SDWH-PROTOCOL-M202005587-1.

4 Conclusion

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

Test Report

1 Purpose

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

2 Reference

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

Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices (ASTM F1980-16)

3 Compliance

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

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

4 Identification of Test Article

Test Article Name	Nitrile gloves
Manufacturer	GUANG DONG KINGFA SCI.& TECH.CO.,LTD
Address	No.28 Delong Ave.,Shijiao Town,Qingcheng District,Qingyuan,Guangdong,China
Test Article Initial State	Non-sterile
CAS Number	Not supplied by sponsor (N/S)
Model	KS-ST RT021
Size	M
Lot/Batch	25007018/25007019/25007020
Raw Material	Nitrile
Packaging Material	N/A
Physical State	Solid
Color	BLUE
Density	N/A
Stability	N/A
Solubility	N/A
Storage Condition	Room temperature
Intended Use	N/A
Additional Information	N/A

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

5 Equipment and Reagents

5.1 Equipment

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

6 Test Methods and Results

6.1 Accelerated Aging Test

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

6.1.2 Parameters:

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

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

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

T_{RT} : Ambient Temperature (°C).

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

Desired RT: Desired simulated Real Time.

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

6.1.3 Calculation for accelerated aging time:

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

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

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

6.1.4 Aging schedule:

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

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

6.2 Watertightness Test

6.2.1 Test samples: 50 pieces/Batch.

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

6.2.3 Added 1000 ± 50 ml of water at a temperature of (15 to 35)°C into the open end of the filling tube, allowing the water to pass freely into the glove.

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

6.2.5 Disregard leakages within 40 mm of the cuff.

6.2.6 Results: List in **Table**.

6.3 Physical property test

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

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

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

6.3.4 Results: List in **Table**.

7 Conclusion

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

8 Record Storage

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

9 Confidentiality Agreement

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

10 Deviation statement

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

Annex 1 Test Data

Table 1 The results of watertightness test (Lot/ Batch: 25007018)

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

Table 2 The results of watertightness test (Lot/ Batch: 25007019)

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

Table 3 The results of watertightness test (Lot/ Batch: 25007020)

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

KINGFA MEDICAL

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