

Products



**TÜVRheinland®**  
Precisely Right.

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Client: TK Hitech Technology Co.,Ltd.

Contact Information: 1/221 Soi Watcharaphon 2/7, Tha Raeng, Bangkok, Bangkok 10220, Thailand.

Identification / Model No(s): Nitrile Glove

Sample Receiving date: 2020-06-11

Testing Period: 2020-06-11 to 2020-07-02

Reference Order No.: 242121264

Delivery condition: Apparent good, Samples tested as received

Test Specification:

Test result:

1. EN 455-1: 2000: Requirements for freedom from holes PASS
2. EN 455-2: 2015: Physical properties test;
  - Dimension test PASS
  - Force at break test PASS
3. EN 455-3: 2015 (E), Annex A : Proteins extraction by aqueous Refer to result page
4. US FDA 21 CFR 177.2600 (Rubber Articles) - Determination of Amount of Extractives PASS

Other Information:

Grade: MEDICAL GRADE

Manufacture: TK HITECH TECHNOLOGY CO., LTD.

Country of Origin: THAILAND

For and on behalf of TÜV  
Rheinland Thailand Ltd.





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2020-07-31

Wilawan Sriprom / Manager

Date

Name/Position

Test result is drawn according to the kind and extent of tests performed. This test report relates to the above mentioned Test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.

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**Sampling Information:**

Inspection Method: No inspection, submitted sample by client

Inspection level: N/A

AQL: N/A

Sample size: N/A

**Material list:**

Material No.	Material	Color	Location
M001	Nitrile Glove	Purple	Size S
M002	Nitrile Glove	Blue	Size M
M003	Nitrile Glove	Blue	Size L
M004	Nitrile Glove	Blue	Size XL



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Freedom from holes

Test method: With reference to EN 455-1: 2000

Test result:

Gloves Size	Tested samples	No. of samples for Non-compliance	Conclusion
S	200 pcs.	1	Pass
M	200 pcs.	0	Pass
L	200 pcs.	0	Pass
XL	200 pcs.	0	Pass

Remark:

- All samples were selected and supplied by the client.
- The batch size of the gloves supplied was not stated by the client. In accordance with BS EN 455-1, a batch size between 35,001 to 150,000 was chosen, and therefore 50 gloves per stage were tested for perforations using General Inspection Level I at an AQL of 1.5%. with reference to table;

Stage No.	Cumulative no. tested	Accept	Reject
First	50	0	4



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Second	100	1	6
Third	150	3	8
Fourth	200	5	9
Fifth	250	9	19

## Dimension test

Test method: EN 455-2: 2015

## Test results:

Test No.:	T001		T002	
Material No.:	M001		M002	
Tested no.	Length (mm)	Width (mm)	Length (mm)	Width (mm)
1	246	85	244	94
2	246	86	244	94
3	245	85	246	94
4	246	85	246	94
5	245	85	245	94
6	245	85	244	93
7	245	84	245	94
8	245	85	245	94
9	245	85	244	94
10	244	82	244	94



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11	245	85	244	94
12	243	85	244	95
13	244	85	244	94
Median result	245	85	245	94
Conclusion	Pass	Pass	Pass	Pass

Test No.:	T003		T004	
Material No.:	M003		M004	
Tested no.	Length (mm)	Width (mm)	Length (mm)	Width (mm)
1	245	110	245	116
2	246	110	244	116
3	245	110	245	119
4	245	110	244	116
5	245	110	245	116
6	245	110	245	115
7	245	111	245	116



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8	246	110	244	117
9	245	110	245	116
10	246	110	245	116
11	245	110	245	116
12	245	110	245	116
13	245	111	245	116
Median result	245	110	245	116
Conclusion	Pass	Pass	Pass	Pass

Abbreviation: mm denotes millimeter

Remark: Dimension limit reference to table

Size	Median length (mm)	Median width (mm)
Extra small	≥ 240	≤ 80
Small		80±10
Medium		95±10
Large		110±10
Extra large		≥ 110

Force at break

Test method: EN 455-2: 2015

Test results:

Test No.	T001	T002
Material No.	M001	M002



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Tested no.	Force at break Before ageing (N)	Force at break After ageing (N)	Force at break Before ageing (N)	Force at break After ageing (N)
1	6.31	6.33	10.11	10.98
2	7.22	6.81	9.45	8.67
3	6.47	5.92	9.75	10.57
4	7.46	6.72	8.33	9.41
5	5.56	5.35	10.80	8.94
6	5.47	5.93	8.48	10.75
7	6.18	6.70	8.80	9.46
8	6.32	4.80	10.00	8.65
9	5.72	6.21	9.95	9.83
10	6.71	5.87	9.12	9.58
11	6.45	6.68	9.11	8.90
12	5.87	5.95	11.02	8.40
13	6.53	6.52	8.97	10.54
Median result	6.33	6.14	9.53	9.59
Conclusion	Pass	Pass	Pass	Pass

Test No.	T003	T004
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Material No.	M003		M004	
	Force at break Before ageing (N)	Force at break After ageing (N)	Force at break Before ageing (N)	Force at break After ageing (N)
1	99.13	7.97	6.71	5.20
2	7.32	7.32	7.37	5.83
3	7.15	7060	6.57	5.49
4	8.16	7085	7.70	5.37
5	9.04	7072	7.16	5.57
6	8.59	7.84	6.40	5.34
7	7.86	7.33	7.70	4.48
8	8.33	8.29	5.73	4.68
9	7.74	7.39	7.05	5.85
10	9.65	9.11	7.58	4.45
11	7.89	9.26	7.27	5.33
12	7.84	6.87	6.35	4.58
13	9.59	7.73	8.26	5.73
Median result	8.33	7.87	7.06	5.22
Conclusion	Pass	Pass	Pass	Pass

Abbreviation: N denotes Newton

Remark:

1. Median values of force at break

Force at Break (newton)		
a)	b)	c)
≥ 9.0	≥ 6.0	≥ 3.0

- a) Requirements for all surgical gloves
- b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. Polyvinylchloride, Polyethylene)




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c) Requirements for gloves made from thermoplastic materials (e.g. Polyvinylchloride, Polyethylene) Proteins extraction

Test method: With reference to EN 455-3: 2015 (E), Annex A.

Test result:

Test No.	Material No.	Test parameter	Unit	MDL	Test result
T001	M001	Proteins	µg/g	3	n.d.
T002	M002	Proteins	µg/g	3	n.d.
T003	M003	Proteins	µg/g	3	n.d.
T004	M004	Proteins	µg/g	3	n.d.

Abbreviation: µg/g denotes Microgram per gram

MDL denotes Method Detection Limit

Remark: The leachable protein level shall be "As Low As Reasonable Practicable" (ALARP)

US FDA 21 CFR 177.2600 (Rubber Articles) – Determination of Amount of Extractives

Test Method: With reference to US FDA 21 CFR 177.2600.

For use in contact with aqueous foods:

Extractants	Test Condition	RL (mg/inch <sup>2</sup> )	Result (mg/inch <sup>2</sup> )	Permissible Limit (mg/inch <sup>2</sup> )
			M001	
Distilled Water	Reflux temperature for 7 hours	0.1	0.5	20
	Succeeding 2 hours of extraction	0.1	n.d.	1
Comment	--	--	Pass	--

For use in contact with fatty foods:

Extractants	Test Condition	RL (mg/inch <sup>2</sup> )	Result (mg/inch <sup>2</sup> )	Permissible Limit (mg/inch <sup>2</sup> )
			M001	
n-Hexane	Reflux temperature for 7 hours	0.1	0.2	175



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	Succeeding 2 hours of extraction	0.1	n.d.	4
Comment	--	--	Pass	--

For use in contact with aqueous foods:

Extractants	Test Condition	RL (mg/inch <sup>2</sup> )	Result (mg/inch <sup>2</sup> )	Permissible Limit (mg/inch <sup>2</sup> )
			M002	
Distilled Water	Reflux temperature for 7 hours	0.1	0.7	20
	Succeeding 2 hours of extraction	0.1	0.2	1
Comment	--	--	Pass	--

For use in contact with fatty foods:

Extractants	Test Condition	RL (mg/inch <sup>2</sup> )	Result (mg/inch <sup>2</sup> )	Permissible Limit (mg/inch <sup>2</sup> )
			M002	
n-Hexane	Reflux temperature for 7 hours	0.1	0.4	175
	Succeeding 2 hours of extraction	0.1	n.d.	4
Comment	--	--	Pass	--

For use in contact with aqueous foods:

Extractants	Test Condition	RL (mg/inch <sup>2</sup> )	Result (mg/inch <sup>2</sup> )	Permissible Limit (mg/inch <sup>2</sup> )
			M003	
Distilled Water	Reflux temperature for 7 hours	0.1	0.7	20
	Succeeding 2 hours of extraction	0.1	n.d.	1
Comment	--	--	Pass	--

For use in contact with fatty foods:



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Extractants	Test Condition	RL (mg/inch <sup>2</sup> )	Result (mg/inch <sup>2</sup> )	Permissible Limit (mg/inch <sup>2</sup> )
			M003	
n-Hexane	Reflux temperature for 7 hours	0.1	0.4	175
	Succeeding 2 hours of extraction	0.1	n.d.	4
Comment	--	--	Pass	--

For use in contact with aqueous foods:

Extractants	Test Condition	RL (mg/inch <sup>2</sup> )	Result (mg/inch <sup>2</sup> )	Permissible Limit (mg/inch <sup>2</sup> )
			M004	
Distilled Water	Reflux temperature for 7 hours	0.1	0.8	20
	Succeeding 2 hours of extraction	0.1	n.d.	1
Comment	--	--	Pass	--

For use in contact with fatty foods:

Extractants	Test Condition	RL (mg/inch <sup>2</sup> )	Result (mg/inch <sup>2</sup> )	Permissible Limit (mg/inch <sup>2</sup> )
			M004	
n-Hexane	Reflux temperature for 7 hours	0.1	0.4	175
	Succeeding 2 hours of extraction	0.1	n.d.	4
Comment	--	--	Pass	--

Abbreviation: n.d. denotes Not Detected (<RL)  
 RL denotes Reporting Limit  
 mg/inch<sup>2</sup> denotes Milligram per square inch Sample photo

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M001 – Size S



M002 – Size M



M003 – Size L



M004 – Size XL

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