

Report No.: 242123500-01

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Client: HN MEDICAL GROUP CO., LTD.

Contact Information: 498/188 Sammakorn Avenue Ramindra, Ta Raeng, Bangkhen,
Bangkok 10220 Thailand

Identification/ Refer to next page

Model No(s):

Sample Receiving date: 2020-11-04

Testing Period: 2020-11-04 to 2020-11-27

Delivery condition: Apparent good, Samples tested as received

Test Specification:

Test result:

- | | |
|--|-----------------------|
| 1. EN 455-1: 2020: 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, 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 |
| 5. Resolution ResAP (2004) 4 on rubber used for food contact applications Overall | Refer to result page. |

Other Information:

Material type: Nitrile Glove

Grade: Examination

Manufacture: HN Medical Group Co., Ltd.

Country of Origin: THAILAND

Country of Destination: US/Canada, UK, EU (Including Germany)

For and on behalf of

TÜV Rheinland Thailand Ltd.



2020-12-08

Wilawan Sriprom / Manager

Date

Name/Position

Sample information is provided by customer. 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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Identification/

NITRILE DISPOSABLE GLOVE

Model No(s):

MD Glove Model : HN202001

Kleanse Glove Model : HN20202

Excel Glove Model : HN202003

MD Plus Glove Model : HN202004

Plam Shield Glove Model : HN202005

Ezy Care Glove Model : HN202006

Safe Plus Glove Model : HN202007

Material list:

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

Remark: * No submitted sample, all test information were referred from test report no. 242122877-01
date 2020-11-27

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Freedom from holes *

Test method: With reference to EN 455-1: 2020

Test result:

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

Remark:

1. Information of batch size or sample size is not provided by client.
2. All samples were selected and supplied by the client.
3. According to test requirement, each lot shall be samples for single sampling plan using general inspection level I and corresponding acceptance/rejection number equivalent to sample size code letter L. The compliance level for freedom from holes shall be an AQL of 0.65 for surgical gloves and 1.5 for examination gloves.
4. A minimum sample size equivalent to sample size code letter L ensure that an adequate assessment of the quality of the lot is obtained when the lot size is small or unknown.

Inspection level	Sample size	AQL	Accept	Reject
G-I, code letter L	200	0.65	3	4
G-I, code letter L	200	1.5	7	8

5. * The test item is not under accreditation scope of ISO/IEC 17025.
6. Not perform test on submitted sample, the test result was referred from test report No. 242122877-01, date 2020-11-27

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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	251	82	245	95
2	245	83	244	97
3	248	84	237	95
4	246	84	247	95
5	246	83	251	95
6	247	84	250	96
7	247	83	242	95
8	242	83	245	96
9	247	84	242	95
10	250	83	246	96
11	247	83	245	96
12	246	84	244	95
13	250	83	245	96
Median result	247	83	245	96
Conclusion	Pass	Pass	Pass	Pass

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Test No.:	T003		T004	
Material No.:	M003		M004	
Tested no.	Length (mm)	Width (mm)	Length (mm)	Width (mm)
1	242	97	249	109
2	241	97	245	108
3	243	98	248	109
4	242	97	250	108
5	245	97	247	108
6	246	97	245	108
7	244	96	247	108
8	244	97	253	108
9	242	97	251	108
10	239	97	250	106
11	240	98	245	108
12	247	98	247	107
13	245	98	246	108
Median result	243	97	248	108
Conclusion	Pass	Pass	Pass	Pass

Abbreviation: mm denotes millimeter

Remark:

1. 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

2. Not perform test on submitted sample, the test result was referred from test report No. 242122877-01, date 2020-11-27

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Force at break

Test method: EN 455-2: 2015

Test results:

Test No.	T001		T002	
Material No.	M001*		M002	
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	11.54	10.52	8.40	8.86
2	10.68	11.76	7.10	7.71
3	13.07	10.81	7.69	8.19
4	8.31	9.73	7.05	6.81
5	9.77	11.32	7.65	6.86
6	12.67	9.72	8.28	8.61
7	11.89	10.66	6.93	8.36
8	11.46	9.38	8.24	8.62
9	8.63	9.62	7.71	7.71
10	12.12	10.98	6.61	7.60
11	10.70	11.71	7.52	6.87
12	8.39	11.09	6.53	6.49
13	8.68	11.64	8.94	7.53
Median result	10.61	10.69	7.59	7.71
Conclusion	Pass	Pass	Pass	Pass

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Test No.	T003		T004	
Material No.	M003		M004	
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	6.96	6.57	8.36	7.88
2	9.08	10.57	7.45	6.66
3	6.97	7.87	8.92	8.20
4	8.55	6.54	9.84	8.78
5	9.51	6.31	8.40	6.74
6	6.02	6.95	9.30	6.20
7	9.29	8.24	8.48	7.30
8	9.09	6.07	7.87	6.73
9	6.79	7.23	8.59	7.19
10	8.73	8.86	7.09	7.05
11	6.68	9.00	8.74	7.07
12	7.61	7.34	9.42	9.02
13	8.49	10.11	9.42	6.52
Median result	7.98	7.82	8.61	7.33
Conclusion	Pass	Pass	Pass	Pass

Abbreviation: N denotes Newton

Remark:

- Median values of force at break

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

- Requirements for all surgical gloves
 - Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. Polyvinylchloride, Polyethylene)
 - Requirements for gloves made from thermoplastic materials (e.g. Polyvinylchloride, Polyethylene)
- Not perform test on submitted sample, the test result was referred from test report No. 242122877-01, date 2020-11-27
- 3 * Except material M001 was performed from on submitted date 2020-11-04

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Proteins extraction

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

Test results:

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: n.d. denotes Not Detected (<MDL)

MDL denotes Method Detection Limit

µg/g denotes Microgram per gram

Remark:

1. The leachable protein level shall be "As Low As Reasonable Practicable" (ALARP)
2. All materials were composite test as according to client's requested.
3. Not perform test on submitted sample, the test result was referred from test report No. 242122877-01, date 2020-11-27

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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 ²)	Result (mg/inch ²)	Permissible Limit (mg/inch ²)
			M001	
Distilled Water	Reflux temperature for 7 hours	0.1	0.5	20
	Succeeding 2 hours of extraction	0.1	0.3	1
Comment	--	--	Pass	--

For use in contact with fatty foods:

Extractants	Test Condition	RL (mg/inch ²)	Result (mg/inch ²)	Permissible Limit (mg/inch ²)
			M001	
n-Hexane	Reflux temperature for 7 hours	0.1	0.2	175
	Succeeding 2 hours of extraction	0.1	0.1	4
Comment	--	--	Pass	--

Abbreviation: n.d. denotes Not Detected (<RL)
 RL denotes Reporting Limit
 mg/inch² denotes Milligram per square inch

Remark: Not perform test on submitted sample, the test result was referred from test report
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Overall migration test

Test method: The migratory behaviour is examined in accordance with Directive 82/711/EEC and Council Directive 85/572/EEC and its corresponding regulations. Deviating to the regulations the following tests were performed as orientating single tests.

Limit: Resolution AP (2004) 4 on rubber used for food contact applications

The following food simulants and conditions were applied:

Food simulant	Test duration / Temperature
Acetic acid 3 %	2 hour(s) / 40 °C
Ethanol 10 %	2 hour(s) / 40 °C
Ethanol 20 %	2 hour(s) / 40 °C
Isooctane	2 hour(s) / 40 °C

Test No.:	T001		
Sample No.:	M001		
Parameter	Unit	Result	Limit
Acetic acid 3 %	mg/kg	24	60
Ethanol 10 %	mg/kg	< 18	60
Ethanol 20 %	mg/kg	< 18	60
Isooctane	mg/kg	< 18	60

Abbreviations:

mg/kg = Milligram per kilogram

< = Less than

Remark: Not perform test on submitted sample, the test result was referred from test report No. 242122877-01, date 2020-11-27

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M001 – Size S



M002 – Size M



M003 – Size L



M004 – Size XL

- END -