

Testing of Powder Free Nitrile Examination Gloves

FİRMA ADI : **BAYRAKTAR YATIRIM İÇ VE DIŞ TİCARET A.Ş.**
Company Name

ADRESİ : **ALTINTEPSİ MAH. YAHYA KEMAL CAD. A-2 KULE NO: 112**
Address **BAYRAMPAŞA - İSTANBUL / TÜRKİYE**

TESTİN ADI : **Testing of Powder Free Nitrile Examination Gloves submitted by**
Test Name **Bayraktar Yatırım Company on 06.11.2020**

TEST METHODU : **1 EN 455-1:2000 Medical gloves for single use**
Method of Test **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

RAPOR NUMARASI: **2020-12/MGLV/1327-01**
Report Number

TEST TARİHİ: **10.11.2020 - 10.12.2020**
Test Date

RAPOR SAYFA SAYISI : **5**
Total Report Page Number

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/Model	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Nitrile Powder-Free Examination Gloves	Sogi-Gloves	Blue	01254511	XS	60	Bayraktar Yatırım İç Ve Dış Ticaret A.Ş.
				01254512	S	60	
				01264711	M	60	
				01264712	L	60	
				01264921	XL	400	

Lot size as specified by client: 35,001 to 150,000 pieces



Gökhan Efe Uysal
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Engineer

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RESULTS:

Sample: Disposable Nitrile Powder-Free Examination Gloves, Sogi-Gloves, Blue

Table 1: Results for EN 455-1:2000

Clause	Tests	Size	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	XS	Shall not leak	10	315	0	Passed
		S		10	315	1	Passed
		M		10	315	1	Passed
		L		10	315	1	Passed
		XL		10	315	1	Passed

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

Clause	Tests	Size	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	XS	≥ 240	13	243	Passed
		S		13	246	Passed
		M		13	242	Passed
		L		13	242	Passed
		XL		13	250	Passed
	b) Width (mm)	XS	≤ 80	13	80	Passed
		S	80 ± 10	13	84	Passed
		M	95 ± 10	13	95	Passed
		L	110 ± 10	13	105	Passed
		XL	≥ 110	13	115	Passed
5	Strength a) Force at break (N)	XS	For nitrile examination gloves: ≥ 6.0	13	10.8	Passed
		S		13	8.7	Passed
		M		13	8.0	Passed
		L		13	10.9	Passed
		XL		13	10.8	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	XS	For nitrile examination gloves: ≥ 6.0	13	9.6	Passed
		S		13	8.7	Passed
		M		13	8.0	Passed
		L		13	10.3	Passed
		XL		13	10.8	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.	Observed	Passed

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RESULTS (cont'd):

Sample: Disposable Nitrile Powder-Free Examination Gloves, Sogi-Gloves, Blue

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 powder-free glove, based on client's declaration letter version 2019001	NA	
		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.	XS	0.04 mg per glove	Passed
			S	0.17 mg per glove	Passed
			M	0.51 mg per glove	Passed
			L	0.14 mg per glove	Passed
			XL	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.	Non-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. Freedom from holes test for XS, S, M and L sizes were tested in manufacturer's site, witnessed by Medicert Certification Test Laboratories, İzmir Branch on 05 Dec 2020.
2. Labelling requirements are assessed based on submitted packaging artwork together with client's declaration letter version number 2020001.
3. NA: Not applicable for the submitted sample

PERFORMING ANALYSIS

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APPENDIX:



Photo : Disposable Nitrile Powder-Free Examination Gloves, Sogi-Gloves, Blue

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