

Test Standards & Limits for Nitrile Gloves as per ASTM & EN

Sl No	Parameters	Standard	Requirement / Acceptable Limit	
1	Freedom from Holes	ASTM D6319-19	AQL 2.5	
2	Physical Properties before aging	ASTM D6319-19	AQL 4.0	
	Physical Properties after aging	ASTM D6319-19	AQL 4.0	
	Tensile strength before aging	ASTM D3578	14 MPa, minimum	
	Tensile strength after aging	ASTM D3578	14 MPa, minimum	
	Elongation before aging	ASTM D412	500%, minimum	
	Elongation after aging	ASTM D412	400%, minimum	
	Force at Break, before aging	EN 455-2: 2015	≥ 6.0 N	
Force at Break, after Aging	EN 455-2: 2015	≥ 6.0 N		
3	Powder-free Residue	ASTM D6319-19	< 2 mg	
4	Puncture Resistance	ASTM F1342	To Pass	
5	Heat Aging Degradation Test	ASTM D573	To Pass	
6	Whole Glove viral barrier	NFPA 1999	To Pass	
7	Proteins Extraction g/g	EN 455-3:2015	3 µg/g	
8	pH Value	EN ISO 21420:2020	>3.5 & <9.5	
9	Dexterity, Level of Performance	EN ISO 21420:2020	Level of Performance	Smallest pin diameter fulfilling test conditions
			1	11 mm
			2	9.5 mm
			3	8 mm
			4	6.5 mm
10	Length of the Gloves in mm	ASTM D6319-19	5	5 mm
			XS	220
			S	220
			M	230
			L	230
			XL	230

Performance Requirements as per ASTM D6319, EN 455, EN ISO 21420

Dimensions & MOC

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Sl No	Parameters	Standard	Requirement / Acceptable Limit	Sl No
11	Width of the Gloves in mm	ASTM D6319-19 ASTM D5250	XS	70 ± 10
			S	80 ± 10
			M	95 ± 10
			L	110 ± 10
			XL	120 ± 10
12	Thickness of Gloves at finger in mm	ASTM D6319-19	0.05 minimum	
13	Thickness of Gloves at palm in mm		0.05 minimum	
14	Weight of the Gloves in gms**	As mentioned in the TDS		
15	Color of the Gloves**	As mentioned in the TDS		
16	Design	Ambidextrous with Beaded Cuff		
17	Food Grade US & EU – For use in contact with aqueous foods: Extractants: Distilled Water			
	Reflux temperature for 7 hours	US FDA 21 CFR 177.2600 (Rubber Articles)	20 mg/inch ²	
	Succeeding 2 hours of extraction		1 mg/inch ²	
18	Food Grade US & EU – For use in contact with fatty foods: Extractants: n-Hexane			
	Reflux temperature for 7 hours	US FDA 21 CFR 177.2600 (Rubber Articles)	175 mg/inch ²	
	Succeeding 2 hours of extraction		4 mg/inch ²	
19	Food Grade EU			
	Global Migration from Rubber	EN 1186	According to Directive 82/711/EEC & Council directive 85/572/EEC	
20	REACH SVHC	Not to be Detected		
21	REACH (EU specific)	Test report as per globally acceptable standards (EC 1907/2006)		
22	Packaging (EU specific)	Directive 94/62/EC		
23	Technical data sheet	As per Keymate Standard Format		
24	MSDS (Material safety data sheet)	For all of the whole pair of Gloves		
25	QMS	EN 13485, ISO 9001 or Equivalent		
26	Shade card for Color of gloves	Light, Standard, Dark Samples		
27	Biocompatibility of Gloves	ISO 10993-5		
28	Protective gloves against chemicals and micro organisms	EN ISO 374- 1/2/3/5		

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Compliance & Regulatory Documents for Nitrile Gloves:

1. Reach Compliance
2. QMS as per ISO 9001 or Equivalent
3. Shelf-Life Declaration
4. CE certification
5. FDA Registration

Fig: Image of Nitrile Glove



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