



3.5g White Powder-Free Nitrile Gloves

Powder-Free Nitrile Gloves (ASTM | EN) Specifications

Product Specification

Product Type	Powder-Free, Non-sterile, Single-use
Material	Nitrile Butadiene Rubber (NBR)
Color	White
Gloves Size	XS, S, M, L, XL
Weight (g)	3.5 ± 0.3
Design & Features	<ul style="list-style-type: none"> • Not made with natural rubber latex • Ambidextrous • Finger Textured • Beaded cuff
Shelf-life	3 years from the date of manufacturing

Quality Standards

- Conforms to ASTM D6319 and EN 455 Standards
 - Manufactured under ISO 9001:2015 and ISO 13485:2016 Quality Management System
- Medical**
- Conforms to Medical Device Regulation (EU) 2017/745 Class I
 - Cleared under FDA 510(k) Premarket Notification Class I
- PPE**
- Conforms to Personal Protective Equipment Regulation (EU) 2016/425 Category III (Type B) in accordance with EN ISO 21420 and EN ISO 374
- Food Contact**
- Conforms to Federal Legislation US FDA 21 CFR 177.2600
 - Conforms to Regulation (EU) No 1935/2004 (Italian D.M. 21/03/73, EC Directive 93/11/EEC & Council of Europe Resolution AP(2004)4)

Product Performance

EN ISO 374-1: 2016+A1:2018

Classification of Permeation Performance Level:

Level	1	2	3	4	5	6
Breakthrough (mins)	>10	>30	>60	>120	>240	>480

Code Letter	Chemical Permeation (EN ISO 374-1: 2016+A1:2018)	Level	Mean Degradation (%) (EN ISO 374-4:2019)
J	n-Heptane	6	52
K	Sodium hydroxide 40%	6	-21.7
P	Hydrogen peroxide 30%	5	43
T	Formaldehyde 37%	5	32.8

EN ISO 374-5: 2016 Protection against bacteria and fungi Pass
Protection against viruses Pass

Biocompatibility Testing Acute Systemic Toxicity (ISO 10993-11) Pass
Sensitization (ISO 10993-10) Pass
Irritation (ISO 10993-10) Pass

*All test reports are available upon request

Physical Properties

PROPERTY	STANDARDS			
	ASTM D6319		EN 455	
	Before Aging	After Aging	Before Aging	After Aging
Tensile Strength (MPa)	Min 14	Min 14	N/A	N/A
Elongation at Break (%)	Min 500	Min 400	N/A	N/A
Median Force at Break (N)	N/A	N/A	Min 6	Min 6
Powder Content (mg/glove)	≤ 2.0		≤ 2.0	
Protein Content (mg/glove)	N/A		Not detected	

Physical Dimension

DIMENSIONS		STANDARDS		
		One Glove	ASTM D6319	EN455
Length (mm)		Min 240	Min 220 (XS, S), Min 230 (M, L, XL)	Min 240
Palm Width (mm)	XS	75 ± 5	70 ± 10	≤80
	S	85 ± 5	80 ± 10	80 ± 10
	M	95 ± 5	95 ± 10	95 ± 10
	L	105 ± 5	110 ± 10	110 ± 10
Single Wall Thickness (mm)	XL	115 ± 5	120 ± 10	≥110
	Finger (13 ± 3 mm from finger tip)	Min 0.10	Min 0.05	N/A
	Palm (33 ± 5 mm from crotch)	Min 0.06	Min 0.05	N/A
	*Cuff (25 ± 5 mm from cuff edge)	Min 0.05	N/A	N/A

*For reference only.
Single Wall Thickness represents the typical thickness value measured.

Quality Assurance for Pre-Shipment Inspection

Characteristic	Dimension	Physical Properties	Freedom from Holes	Visual Defects	
				Major	Minor
Inspection Level	S2	S2	G1	G1	G1
AQL	4.0	4.0	1.5	2.5	4.0

*This pre-shipment inspection follows our standard guidelines and is subjected to change according to agreed requirements and specifications.
For further information, please contact our sales team.



One Glove Group Berhad

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