



3.5g Black | Blue | Midnight Violet 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	Black, Blue, Violet Blue
Gloves Size	XS, S, M, L, XL
Weight (g)	3.5 ± 0.3
Design & Features	• Tested for Chemotherapy Drugs & Fentanyl Resistance • Biocompatibility Tested • 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) • *Conforms to JETRO and Korea MFDS standards

*On selected color variants.

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
	XL	115 ± 5	120 ± 10	≥110
Single Wall Thickness (mm)	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.

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	

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
Protection against viruses

Pass
Pass

ASTM D6978

Resistance to Permeation by Chemotherapy Drugs and Fentanyl

Chemotherapy Drugs and Concentration	Breakthrough Time (Min)
Carboplatin (10 mg/ml)	>240
Carmustine (3.3 mg/ml)	Do not use
Cisplatin (1 mg/ml)	>240
Cyclophosphamide (20 mg/ml)	>240
Dacarbazine (10 mg/ml)	>240
Docetaxel (20 mg/ml)	>240
Doxorubicin HCl (2 mg/ml)	>240
Etoposide (20 mg/ml)	>240
Fluorouracil (50 mg/ml)	>240
Gemcitabine (38 mg/ml)	>240
*Glutaraldehyde (80 mg/ml)	>240
Ifosfamide (50 mg/ml)	>240
*Methotrexate (25 mg/ml)	>240
*Mitomycin C (0.5 mg/ml)	>240
Paclitaxel (6.0 mg/ml)	>240
Thiotepa (10 mg/ml)	Do not use
Vincristine Sulfate (1 mg/ml)	>240
Additional Agents	
Fentanyl Citrate Injection (100mcg/2ml)	>240
Gastric Acid Fluid/ Fentanyl Citrate Injection Mix 50/50 Solution	>240
Simulated Gastric Acid	>240

*FDA 510(k) clearance is currently in process for Glutaraldehyde, Methotrexate, Mitomycin C (Violet Blue, Black), and all Chemotherapy Drugs (Blue).

Biocompatibility Testing

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

Pass
Pass
Pass

*All test reports are available upon request



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