



MANUFACTURING SPECIFICATIONS



GENERAL PRODUCT DESCRIPTION

MATERIAL	LENGTH	FT THICKNESS	PROCESS	SURFACE	CUFF/FIT
Nitrile, examination grade; black or reflex blue with green interior	9.5"/240 mm minimum	6 mil/.15 mm	Interior surface powder-free	Full surface raised diamond pattern	Beaded/ambi

FENTANYL, HEROIN AND GASTRIC ACID PERMEATION TESTED

FENTANYL, HEROIN AND GASTRIC ACID THIRD-PARTY TESTED—SEE ADDENDUM

Contact the PH&S Products LLC main office at 888-688-6768 or sales@PHS-products.com for addendum.

CERTIFICATIONS/TEST STANDARDS

STANDARD/NUMBER	TITLE
ASTM D5712	Standard Test Method for Protein Content on Medical Gloves
ASTM D6319	Standard Specification for Nitrile Exam Gloves
ASTM D6124	Standard Test Method for Residual Powder on Medical Gloves
ASTM D5151	Standard Test Method for Detection of Holes in Medical Grade Gloves
ASTM D6978	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
EN ISO 374-1: 2016/Type B	Modified Standard for Chemical Protective Gloves
EN 388	European Standards for Protective Gloves

PHYSICAL DIMENSIONS AND TOLERANCES

DESIGNATION	TOLERANCE	S	M	L	XL	2XL	3XL
Width (mm)	±3	86	97	109	115	121	131
Length (mm)	Minimum	240	240	240	240	240	240
Thickness single wall (mm)—finger	±.02	0.15	0.15	0.15	0.15	0.15	0.15
Thickness single wall (mm)—palm	±.02	0.13	0.13	0.13	0.13	0.13	0.13
Thickness single wall (mm)—cuff	±.02	0.08	0.08	0.08	0.08	0.08	0.08

PERFORMANCE REQUIREMENTS—SAMPLING PLAN

All Products to Be Sampled in Accordance to ANSI/ASQ Z1.4-2008

Lot and Batch Control	Lot Size: NTE 900,000	Batch Size: NTE 40,000	
CHARACTERISTIC	RELATED DEFECT	INSP. LEVEL	AQL
Watertight	Holes—pinholes	G-1	1.5
Dimensions	Width, length, thickness	S-2	4.0
Physical properties	Before, after aging	S-2	4.0
Visual defects—major	Rips or tears, visible holes, sticking pleats (>10mm), embedded visual defects major foreign matter (>5mm), large lumps, permanent dirt, torn beads and/or cuffs, extreme thin spots, improper size, stickiness	G-1	2.5
Visual defects—minor	Stains and discoloration, sticking pleats (<10mm), embedded G-1 4.0 foreign matter (<5mm), small lumps, removable dirt, defective beads	G-1	4.0



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PHYSICAL REQUIREMENTS

TEST METHOD	TOLERANCE	TENSILE (MPa) +/-3%		ELONGATION +/-5%	
		BEFORE	AFTER	BEFORE	AFTER
ASTM D6319	MIN	26	28	550%	550%
EN 388 Force at Break (n)	+/-3	16n	16n	N/A	N/A

PACKAGING AND MARKING REQUIREMENTS

GENERAL REQUIREMENTS

- Each carton and inner box must be labeled with size, lot number, Summit Glove name and address, country of origin, product description and date of manufacture.
- Each box contains:
 - S-L:** 100 gloves by weight
 - XL-3XL:** 90 gloves by weight
 - 10 boxes per case
- All cases and boxes must be printed clearly.
- Inner box to be 450 gram weight box, dual fold, and able to withstand box ends opening during use. Outer carton to be a standard corrugated box and must be able to withstand crushing during container stacking and subsequent shipment.

STORAGE AND SHELF LIFE REQUIREMENTS

- Shelf Life:** If product is stored at optimum storage condition listed below, then product shelf life shall be no less than 5 years.
- Storage Temperature:** Do not store in temperatures >104 °F or in damp/high humidity areas.
- Optimum Storage Conditions:** Temperature-controlled environment with no exposure to direct sunlight.

CERTIFICATIONS

21 CFR	510K NO.
Meets Title 21 CFR Section 6250 Non-Powdered Patient Examination Glove requirements	K220371 K220373