

GENERAL PRODUCT DESCRIPTION

MATERIAL	LENGTH	THICKNESS	PROCESS	SURFACE	CUFF/FIT
Nitrile; accelerator, sulfur and zinc-free	12"/302 mm	FT: 8.0 mil/.20 mm Palm: 5.5 mil/.14 mm	Powder-free; examination grade; white/green color	Patented reduced fingertip region having a bullet-tip configuration	Beaded/ambi

FENTANYL, HEROIN AND GASTRIC ACID PERMEATION TESTED

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

Contact the PHS main office at 888-688-6768 or sales@phs-products.com for addendum.

CERTIFICATIONS/TEST STANDARDS

STANDARD/NUMBER	TITLE
NFPA 1999-2018	National Fire Protection Agency Standard on Protective Clothing and Ensembles for Emergency Operations
ASTM D6319	Standard Specification for Nitrile Exam Gloves
ASTM D412a	Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers—Tension 1
ASTM D412a (NFPA Modification)	Standard Test Method for Ultimate Elongation Percentage Following 100% Isopropanol Soak for 2 Hours
ASTM D573	Standard Test Method for Rubber—Deterioration in an Air Oven
ASTM D573 (NFPA Modification)	Standard Test Method for Ultimate Elongation Percentage Following Heat Aging at 70 °C for 166 Hours
ASTM F1671	Standard Test Method for Detection of Holes in Medical Grade Gloves
ASTM F1342	Standard Test Method for Protective Clothing Material Resistance to Puncture
ASTM D5151	Standard Test Method for Detection of Holes in Medical Grade Gloves
NFPA Dexterity Test	Standard Test Method for Crawford Small Parts Dexterity Test—Screws Technique
ASTM D7558-09	Standard Test Method for Extractable Accelerators
ASTM D6124	Standard Test Method for Residual Powder on Medical Gloves
ASTM D6978	Standard Test Method of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs Used for Fentanyl, Heroin and Gastric Acid Permeation

Manufactured under GMP, ISO 9001, and ISO 13485

PHYSICAL DIMENSIONS AND TOLERANCES

DESIGNATION	TOLERANCE	S	M	L	XL	2XL	3XL
Width (mm)	±3	85	95	105	115	124	128
Length (mm)	±3	302	302	302	302	302	302
Thickness single wall (mm)—finger	±.03	0.20	0.20	0.20	0.20	0.20	0.20
Thickness single wall (mm)—palm	±.03	0.14	0.14	0.14	0.14	0.14	0.14
Thickness single wall (mm)—cuff	±.03	0.11	0.11	0.11	0.11	0.11	0.11

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	0.65
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 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 foreign matter (<5mm), small lumps, removable dirt, defective beads	G-1	4.0

PHYSICAL REQUIREMENTS

TEST METHOD	TOLERANCE	TENSILE (MPa) +/-3%		ELONGATION +/-5%	
		BEFORE	AFTER	BEFORE	AFTER
ASTM D412a/D573	MIN	30	32	700%	600%
ASTM D412a NFPA IPA SOAK	MIN	N/A	N/A	N/A	550%
EN 388 Force at Break (n)	+/-3	14n	15n	N/A	N/A

PACKAGING AND MARKING REQUIREMENTS

GENERAL REQUIREMENTS

- Each carton and inner box must be labeled with size, lot number, American Nitrile name and address, country of origin, product description and date of manufacture.
- Each box contains:
 - S-2XL:** 100 gloves by weight | **3XL:** 90 gloves by weight | 10 boxes per case
- Each carton and inner box must conform to NFPA 1999 (2018) labeling requirements and UDI barcode requirements.
- 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:** No minimum temperature required. Do not store in temperatures >110 °F or in damp/high humidity areas.
- Optimum Storage Conditions:** Temperature-controlled environment with no exposure to direct sunlight.

CERTIFICATIONS

21 CFR	DEVICE LISTING NO.	510K NO.	UL NO.
Meets 21 CFR 880.6250 Patient Examination Glove Requirement	D471887	K220375	Private Labeler: MH48780