INTERCEPT Free®
MANUFACTURING SPECIFICATIONS

Summit Glove
HIGH-QUALITY GLOVES FOR TODAY'S WORKFORCE
An ISO 9001 (with Design) Certified Company

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, GASTRIC ACID AND XYLAZINE PERMEATION TESTED

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

Contact the Summit Glove main office at *800-245-7117* or *sales@summitglove.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 Bacteriophage Penetration Resistance*
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, Gastric Acid and Xylazine 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

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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**	**INSPEC. 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, Summit Glove 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: MH66887