

### GENERAL PRODUCT DESCRIPTION

MATERIAL	LENGTH	FT THICKNESS	PROCESS	SURFACE	CUFF/FIT
100% Nitrile, Examination Grade Orange, Black	9.5"/240 mm	5 Mil/.127 mm	Interior Surface Powder Free Non-Sterile Online Chlorinated	Summit Custom Pattern	Beaded / Ambi / Contoured Fingertips

### CERTIFICATIONS / TEST STANDARDS

STANDARD / NUMBER	TITLE
ASTM D412	Standard Test Method for Rubber Tensile Test Fixture
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 14971	Risk Management
EN 455	European Medical Device Reg. 2017/746 Class 1

### PHYSICAL DIMENSIONS AND TOLERANCES

DESIGNATION	TOLERANCE	S	M	L	XL	2XL
Width (mm)	±/5	86	95	105	115	125
Length (mm)	Minimum	240	240	240	240	240
Thickness Single Wall (mm) Finger	± .02	0.12	0.12	0.12	0.12	0.12
Thickness Single Wall (mm) Palm	± .02	0.09	0.09	0.09	0.09	0.09
Thickness Single Wall (mm) Cuff	± .02	0.07	0.07	0.07	0.07	0.07

### PERFORMANCE REQUIREMENTS - SAMPLING PLAN

#### ALL PRODUCT TO BE SAMPLED IN ACCORDANCE TO ANSI / ASQ Z1.4-2008

LOT & BATCH CONTROL:	LOT SIZE	NTE 900,000	BATCH SIZE	NTE 40,000	
CHARACTERISTIC	RELATED DEFECT			INSPEC. LEVEL	AQL
Watertight	Holes - Pinholes			G-1	1.5
Dimensions	Width, Length, Thickness			G-1	4.0
Physical Properties	Before, After Aging			G-1	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, removeable dirt, defective beads			G-1	4.0

### PHYSICAL REQUIREMENTS

TEST METHOD	TOLERANCE	TENSILE (MPa) +/-3%		ELONGATION +/-5%	
		BEFORE	AFTER	BEFORE	AFTER
ASTM D6319	MIN	21	20	650%	600%
EN 388 Force at Break (n)	+/-3	6n	6n		

### 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: 100 Gloves by weight S-L and 90 Gloves by weight XL-2XL/ 10 Boxes per Case
- All cases and boxes must be printed clearly.
- Inner box to be dual fold, 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 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

21CFR	510K NO.		
Meets 21 CFR 880.6250 Patient Examination Glove Requirement	Orange - K133193	Black - K112924	Blue - K10063