



GLOVES

PPE Product Information for the COVID-19 Response

All gloves may be powdered or powder-free. For powder-free gloves, the recommended limit is not more than 2 mg per glove. The recommended limit for powdered gloves is not more than 10 mg per glove.

NITRILE GLOVES

Testing

The following tests shall be conducted:

- Sterility Test
- Freedom from Holes
- Physical Dimensions Test - The gloves shall comply with the dimensions as shown in Table 2 (below). Dimensions should be shown in millimeters.
- Accelerated Aging—The gloves shall be tested with the following methods:
 - After being subjected to a temperature of $70 \pm 2^\circ\text{C}$ for 166 ± 2 h, the tensile strength and ultimate elongation shall not be less than the values specified in Table 3.
 - After being subjected to a temperature of $100 \pm 2^\circ\text{C}$ for 22 ± 0.3 h, the tensile strength and ultimate elongation shall not be less than the values specified in Table 3.
 - For gloves that are older than 6 months from the date of manufacture or for which the date of manufacture cannot be determined, no accelerated aging shall be performed. If such gloves are tested, their physical requirements for tensile strength and ultimate elongation shall not be less than the “After Accelerated Aging” values specified in Table 3.

Sterile Packaging

- The unit of packaging shall normally be one glove or one pair of gloves.
- A glove or pair of gloves, normally, shall be enclosed in an inner wallet or wrapper. The wrapper shall be of sufficient size when opened to provide a field for glove-donning purposes.
- The glove or pair of gloves, and accompanying wrapper if utilized, shall be totally enclosed in an outer package that will allow sterilization of the product.
- The outer package shall have a method of closure sufficient to ensure the sterility of the product until opened or damaged.
- The outer package shall have sufficient strength and integrity to withstand normal transportation and storage within the intermediate or shipping cartons, or both.
- The method of closure of the outer package shall be such that prior opening will be detectable by the user.
- None of the packaging material shall contain any material likely to impair the quality and use of the gloves.
- Intermediate cartons and shipping cases shall be of sufficient strength to maintain the quality and sterility of the product during normal transportation and storage.

NITRILE GLOVES CONT

Materials

- Any nitrile rubber polymer compound may be used.
- A lubricant that meets the current requirements of the U.S. Pharmacopeia for absorbable dusting powder may be applied to the glove. Other lubricants may be used if their safety and efficacy have been previously established.
- The inside and outside surface of the nitrile rubber examination gloves shall be free of talc.

Package Making

- Sterile packages shall bear markings for the contents to include the glove size, instructions for opening, a manufacturing lot number, and marked "sterile".
- The outermost case shall be labeled with the glove size and a manufacturing lot number. Sterile product cases shall also be marked "sterile."
- Nonsterile and bulk packages shall bear markings for the contents to include the glove size and a manufacturing lot number.

Nonsterile and Bulk Packaging

- The gloves shall be enclosed in an outer package that has sufficient strength to withstand normal transportation and storage within the cartons or shipping cases, or both.
- None of the packaging material shall contain any material likely to impair the quality and use of the gloves.
- Cartons and shipping cases shall be of sufficient strength to maintain the quality of the product during normal transportation and storage.

Materials and Manufacturing

- Any natural rubber compound that permits the glove to meet the requirements of this specification.
- A lubricant that meets the current requirements of the U.S. Pharmacopeia for Absorbable Dusting Powder may be applied to the glove. Other lubricants may be used if their safety and efficacy have been previously established.
- The inside and outside surface of the natural rubber examination gloves shall be free of talc.

Classification

- Type I—Gloves with a minimum tensile strength of 18 MPa and a maximum stress at 500 % elongation of 5.5 MPa.
- Type II—Gloves with a minimum tensile strength of 14 MPa and a maximum stress at 500 % elongation of 2.8 MPa.

Testing

-See *Nitrile Gloves testing*

Packaging

-See *Nitrile Gloves packaging standards*

POLY(VINYL CHLORIDE) GLOVES

Testing

- Testing Sterility Test
- Freedom from Holes
- Physical Dimensions Test - The gloves shall comply with the dimensions as shown in Table 2 (below). Dimensions should be shown in millimeters.
- Accelerated Aging—The gloves shall be tested with the following methods:
 - Accelerated aging tests shall be conducted on samples cut from the glove. It shall be exposed to $70 \pm 2^\circ\text{C}$ for 72 ± 2 h. The glove shall withstand these conditions without evidence of tackiness, exudation, or other deterioration.
 - For gloves that are older than 6 months from the date of manufacture or for which the date of manufacture cannot be determined, no accelerated aging shall be performed.

Materials and Manufacturing

- Any poly(vinyl chloride) polymer compound may be used that permits the glove to meet the requirements of this standard.
- A lubricant that meets the current requirements of the U.S. Pharmacopeia for absorbable dusting powder may be applied to the glove. Other lubricants may be used if their safety and efficacy have been previously established.
- The inside and outside surface of the poly(vinyl chloride) examination gloves shall be free of talc.

Packaging

-See *Nitrile Gloves packaging standards*

POLYCHLOROPRENE GLOVES

Materials and Testing

- Any polychloroprene rubber compound may be used that permits the glove to meet the requirements of this standard.
- A lubricant that meets the current requirements of the U.S. Pharmacopeia for absorbable dusting powder may be applied to the glove. Other lubricants may be used if their safety and efficacy have been previously established.
- The inside and outside surface of the polychloroprene rubber examination gloves shall be free of talc.

Testing

-See *Nitrile Glove testing*

Packaging

-See *Nitrile Gloves packaging standards*

GLOVE TABLES

TABLE 2 Dimensions and Tolerances

Note: 1---Sizing that falls within the tolerance overlaps between two sizes may be labeled as a size range including both sizes, for example, small/medium and medium/large.

Designation	Size								Tolerance, mm	
	6	6 1/2	7	7 1/2	8	8 1/2	9			
Width by size	75	83	89	95	102	108	114		±6	
Width by		x-small 70	small 80	Unize 85	medium 95	large 110	X-large 120	XX-large 70	±10	
Length		220	220	230	230	230	230	230	min	
Thickness, mm:	For All Sizes									
finger	0.05									min
palm	0.05									min

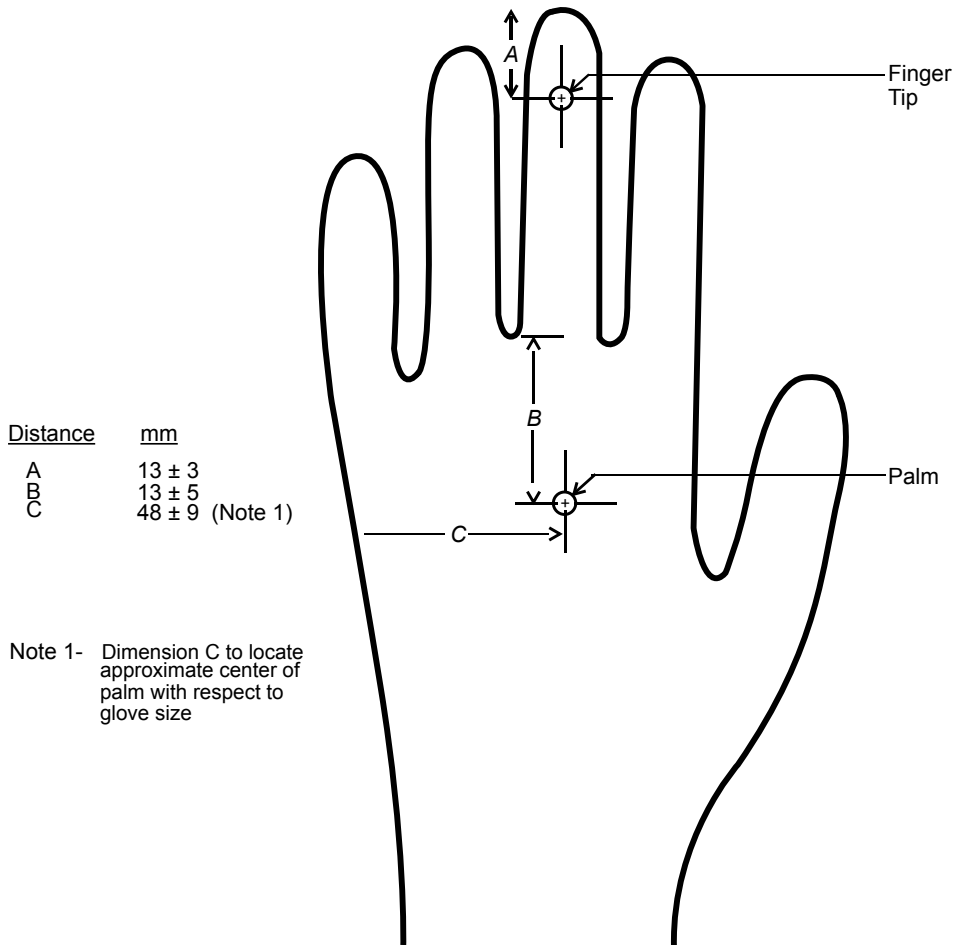


TABLE 3 Physical Requirements

Before Aging		After Accelerated Aging	
Tensile Strength	Ultimate Elongation	Tensile Strength	Ultimate Elongation
14 MPa, min	500 % min	14 MPa min	400% Min