

TECHNICAL SPECIFICATIONS FOR HI RISK 10" 9 MIL LATEX GLOVES

1.0 SCOPE

- 1.1 Purchase of 9.5", 7 mil exam double polymer coated / non chlorinated latex gloves for use primarily in medical applications city wide.

2.0 DEFINITIONS

- 2.1 **ASTM** – American Society for Testing and Materials
- 2.2 **Batch** – A quantity of gloves produced from a single, incoming shipment of incoming raw material – subset of a lot. Batch sizes must be traceable to production line, operators, packaging and the polymer coat process.
- 2.3 **Batch Number** – A unique number assigned to all gloves produced from a single batch used in tracking materials through the production process and in tracing quality problems to their source.
- 2.4 **Date of Manufacture** – A distinct and separate number that clearly identifies the date of manufacture – not the lot number – cannot be coded.
- 2.5 **Lot** – A quantity of gloves produced in a given time period based on a formula or recipe.
- 2.6 **Lot Number** – Unique number assigned to specific dates of production and utilized to trace quality problems to their source.
- 2.7 **Manufacturer** - A factory that operates the production line and controls the quality of the end product.
- 2.8 **Package** – The wrapping or enclosure directly containing the smallest number of gloves from which the user withdraws product for use, commonly referred to as a box.
- 2.9 **Private Labeler** - The entity that procures product from a manufacturer and whose name appears on the product labeling.
- 2.10 **Shall** – This term indicates a mandatory requirement.
- 2.11 **Standard** – The established requirements of NFPA 1999–2008 edition, ASTM D3578 or other standards as referenced and set forth in this document.
- 2.12 **Will** – This term indicates a mandatory requirement.

3.0 CERTIFICATIONS & SPECIFICATIONS

- 3.1 BIDDERS MUST MEET ALL CERTIFICATIONS AND SPECIFICATIONS CONTAINED IN THIS DOCUMENT. IF A BIDDER DOES NOT MEET A CERTIFICATION OR SPECIFICATION LISTED, THEY WILL BE DECLARED NON-RESPONSIVE. SEE ATTACHED SPECIFICATION WORKSHEET.
- 3.2 NFPA 1999-2008
- 3.3 ISO 9001-2000
- 3.4 FDA 510K Registration
- 3.5 Packaging
 - 3.5.1 Each box of 50 gloves, (of bid samples and on each post bid shipment) must be marked with a lot #, separate batch #, separate un-coded date of manufacture, model # and design, and glove size in package.

No labels or stickers will be accepted.

3.5.2 Each box will have printed legibly the shelf life warranty and recommended storage conditions.

3.5.3 All gloves (of bid samples and on each post bid shipment) must be in the original manufacturer's packaging. This packaging must not be tampered with. No area should be cut out or covered over by labels other than those put on by the manufacturer.

3.6 Shelf Life

3.6.1 The City will not accept any product that has a manufacturing date older than twenty-four (24) months from the date of manufacture.

6.0 DOCUMENTATION REQUIRED (All Technical Data Packages must include the following):

6.1 ALL REQUIRED DOCUMENTATION MUST BE PROVIDED AT THE TIME OF BID SUBMISSION. THE OMISSION OF ANY REQUIRED DOCUMENTATION OR SAMPLES WILL RESULT IN THE BIDDER BEING DECLARED NON-RESPONSIVE.

6.2 ISO 9001-2000 Certification for both manufacturer and private labeler.

6.3 FDA 510K Registration for manufacturer product submitted, including process and color.

6.4 Independent 3rd Party Laboratory Test Report showing gloves meet the following criteria:

6.4.1 Lot & Batch Control

6.4.1.1 Each test data must be for a lot < 900,000 gloves and > 500,000 gloves.

6.4.1.2 Manufacturer Lot & Batch Traceability Key

6.4.2 Chemical Exclusions

6.4.2.1 Chemicals tested less than below detectable levels for all chemicals referenced in Specification Worksheet.

6.4.2.2 Manufacturer letter confirming gloves are NOT manufactured using a chlorinated process.

6.4.2.3 Manufacturer flow chart outlining double polymer coating / non chlorination process.

6.4.3 Latex Protein & Powder Residue

6.4.3.1 Guthrie Institute, or other recognized institute, test data showing Modified Lowry ASTM D5712-95 has been performed with results <50 ug/g: Leap Assay test results showing Antigenic Protein Concentration did not exceed 40 ug/g of sample. (Minimum 2 samples.)

6.4.3.2 Particle Measurement Technology, or other recognized institute, test data showing average powder residue levels detected with results <2.0 mg/dm² powder level.

6.4.4 Physical Requirements

6.4.4.1 Data must clearly show that all physical and dimensions requirements, including tensile, elongation, length, thickness, box count and watertight AQL have been achieved.

6.4.4.2 Data Sets Required to Verify Physical Requirements are Adhered to:

6.4.4.2.1 1 Set

6.5 Literature Sheets

- 6.5.1 Bidders must submit literature sheets that declare minimum tolerances for thickness properties. Average thickness dimensions will not be allowed unless literature sheet declares +/- tolerances. If either minimum or average thickness is not declared, vendor will be deemed non-responsive and will be immediately disqualified. Literature sheets must not be altered.

7.0 SAMPLES

- 7.1 Bidder must submit for evaluation a minimum of 1 box of each size for each glove model considered for bid. All sample gloves must be submitted with all required documentation upon bid submission. Failure to submit samples will result in bidder being declared non-responsive.

8.0 EVALUATION

- 8.1 Gloves submitted will be tested by a panel of committee members. The gloves must meet the following criteria:

- 8.1.1 Less than 5% breakage while routinely trying on the gloves.
- 8.1.2 Gloves will be application tested to assure that the sizes conform to the needs of fire and various city department personnel.
- 8.1.3 Gloves shall provide maximum sensitivity so that the user can perform such medical tasks as feeling a pulse, intubation, and picking up small objects in the course of treating a patient. Gloves shall provide a secure grip of smooth, hard objects that are handled by field providers during patient treatment.

9.0 QUALITY ASSURANCE

- 9.1 Testing as specified by this standard in section 6.5 shall be conducted on a pre-shipment lot to lot basis. Test data shall be supplied for each shipment of gloves received by the City, upon request for pre-shipment approval. This test data shall be used to verify that:

- 9.1.1 All gloves received by the city are compliant with this standard
- 9.1.2 Gloves received are not "seconds" or otherwise substandard

10.0 WARRANTY

- 10.1 All products are to be warranted against all defects in parts or workmanship. The vendor shall replace any and all products which are found to be defective or substandard.

- 10.2 The City Procurement Department shall be notified immediately in the event of any of the following:

- 10.2.1 Problems regarding Good Manufacturing Practices in the production of the product
- 10.2.2 Any and all problems with compliance to this standard
- 10.2.3 Any changes affecting the form, fit or function of the product
- 10.2.4 Any and all recalls of the product.
- 10.2.5 Any gloves in possession of the City identified by lot and/or batch number as recalled will be replaced at no cost to the City.

.....**GLOVE SPECIFICATIONS**

Glove Specification Requirements	HANDS ON or Equivalent	BIDDER RESPONSE CHECKLIST ✓ FOR COMPLIANCE (Does not preclude submission of required data)
Material	100% Latex	
Minimum Length	9.5"	
Minimum Fingertip Thickness (Mils)	7	
Minimum Palm Thickness (Mils)	6	
Minimum Cuff Thickness (Mils)	3.5	
Palm Widths (Tolerance +5)	S - 82 // M - 94 L - 105 // XL- 112 2XL – 118	
Surface Properties	Full Texture	
Process Properties	Double Polymer Coated Non Chlorinated	
Watertight AQL NTE	1.5	
Avg Tensile Before Aging	21	
Avg Tensile After Aging	18	
Avg Elongation Before Aging %	750	
Avg Elongation After Aging %	700	
Excluded Chemicals (Cannot Be Used in the Manufacturing Process)	Mercaptobenzothiazole (MRT) Tetramethylthiuram disulfide (TMTD) Butylhydroxyanisole (BHA) Chlorine	
Controlled Chemicals (Must Test Below Detectable Levels)	Zinc dibutylthiocarbamate (ZDBC) Zinc diethylthiocarbamate (ZDEC)	
Lot Control	< 900,000	
Batch Control	< 40,000	
Sampling Plan	ANSI / ASQ Z1.4-2003	
Glove Color	Natural	
Sizes Available	S-2XL	
Box Count / Case Count	100 box / 10 box case	
Annual Case Usage Per Year		