

**SPECIFICATION
FOR
GLOVES, DISPOSABLE, EXAMINATION (MEDICAL), NONSTERILE**

SCOPE

This specification describes certain requirements for gloves used in conducting medical examinations and diagnostic and therapeutic procedures. It also covers gloves used in handling contaminated medical material.

I. APPLICABLE STANDARDS

The following documents of issue in effect on the date of the Invitation for Bids shall form a part of this specification:

ASTM D3578-05e1, Standard Specification for Rubber Examination Gloves

ASTM D3767-03, Standard Practice for Rubber-Measurement of Dimensions

ASTM D5151-06, Standard Test Method for Detection of Holes in Medical Gloves

ASTM D5250-06e1, Standard Specification for PVC (polyvinyl chloride) Gloves for Medical Application

ASTM D5712-05e1, Standard Test Method for Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method

ASTM D6124-06, Standard Test Method for Residual Powder on Medical Gloves

ASTM D6319-00a(2005)e1, Standard Specification for Nitrile Examination Gloves for Medical Application

ASTM D6499-07, Standard Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products

II. CLASSIFICATION

Type 1 - Gloves compounded primarily from natural rubber latex, Beaded Cuff, Ambidextrous

Class 1 - Regular Duty, 0.14 mm Minimum and 0.20 mm Maximum Thickness (finger and palm)

Smooth Gloves

Style 1 – Powdered – Category Discontinued on the QPL

Style 2 - Powder Free

Lightly Roughen Surface – Micro-Textured only.

Style 1 – Powdered - Category Discontinued on the QPL

Style 2 - Powder Free

Class 2 – Heavy Duty, 0.25 mm Minimum Thickness (finger and palm)

Style 1 - Powder Free

Type 2 - Gloves compounded primarily from a rubber cement or a synthetic polymer (e.g. "Nitrile"), Beaded Cuff, Ambidextrous

Class 1 - Regular Duty, 0.11mm Minimum Thickness (finger and palm)
Style 1 - Powder Free

Type 3 - Gloves compounded primarily from polyvinylchloride (PVC), Beaded cuff, Ambidextrous

Class 1 - Regular Duty, 0.11 mm Minimum Thickness (finger and palm)
Style 1 – Powdered - Category Discontinued for the QPL
Style 2 - Powder Free

III. REQUIREMENTS

A. MATERIALS

1. The gloves shall be compounded from virgin natural latex or any polymer compound that permits the glove to meet the requirements of this specification in addition to requirements of the Food and Drug Administration.
2. A donning 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.
3. Talc, cotton flock, and other non-absorbable materials are not acceptable as a lubricating, dusting or donning powder. Lycopodium (club moss spores) and ground pine pollen are toxic and are not acceptable as powder on or in any gloves.
4. Gloves shall be manufactured with the identical materials as submitted and evaluated for compliance to the requirements of the specifications herein.

B. DESIGN

1. The gloves shall be of seamless construction and designed as ambidextrous. Gloves shall be soft, flexible, non-toxic, moisture resistant, and shall allow a high degree of tactile sensitivity. Unless otherwise specified herein, the gloves shall be either (1) a smooth non-textured surface or (2) a lightly roughen surface or micro-textured surface. Heavily textured gloves are not acceptable for any of the above product categories. Gloves with micro-textured surfaces are considered as thin enough to detect a faint pulse while providing enough grip to handle laboratory glassware and small plastic intravenous devices when the gloves are wet.
2. The advisory committee for the QPL evaluation will judge the maximum acceptable glove surface texture of gloves submitted.
3. Gloves shall be available, as a minimum, in Small, Medium, Large and Extra Large sizes.
4. Gloves shall comply with the dimension and physical requirements specified in ASTM D3578-05e1, ASTM D5250-06e1, and ASTM D6319-00a(2005)e1.
5. The gloves shall be provided with a beaded cuff.

6. The glove minimum thickness shall be as indicated in the "Classification" section, as applicable for product type. The extra large gloves should measure a minimum 110 mm wide.
7. All gloves offered under this specification shall have been evaluated as a class I medical device as documented with a currently valid FDA 510K premarket certification number.
8. The powder free type gloves shall have a maximum 2.0 mg (milligrams) total per glove of residual donning powder as specified in ASTM D3578-05.
9. The powdered type gloves shall have a maximum 10 mg/dm² (milligrams of powder per square decimeter) of glove surface area OR 10 mg/g of glove (milligrams of powder per gram) of glove weight with a maximum of 120 mg total per glove of residual donning powder as specified in ASTM D3578-05e1.
10. The latex gloves shall have a maximum 200 µg/dm² (micrograms per square decimeter of surface area) OR 200 µg/gram (micrograms per gram of glove weight) with a maximum of 1200 (µg) micrograms per glove of Aqueous Soluble Protein Content as specified in ASTM D3578-05e1.
11. Compliance verification for the reduced latex protein glove content claim shall be confirmed by the manufacturer's statement of reduced latex protein claims as indicated in the FDA 510K summary statement or approval letter. The reduced protein claim may also be provided on the product labeling or markings on the smallest unit packaging. Referenced below is the FDA website for a posting of the 510K summary statement or approval letter.

Ref.: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>

C. PERFORMANCE

The gloves shall:

1. Be watertight when tested in accordance with III.D.1.
2. Be airtight when tested in accordance with III.D.2.
3. Meet minimum thickness requirements as indicated elsewhere herein when tested in accordance with III.D.3.

D. TEST METHODS

1. Watertight Test – Refer to the ASTM D5151-99 for complete details.
Fill glove with 1000ml water at room temperature.
Secure at the cuff and maintain in a vertical position for 2 minutes.
Observe for leaks. Emergence of water from glove constitutes a watertight failure.
2. Airtight Test
Position glove over a suitable inflation device and inflate the glove to a diameter of six to seven inches. Examine the inflated glove for air leakage while holding under water for one minute. Emergence of air bubbles from the glove constitutes an airtight failure.
3. Dimensional Analysis
Thickness measurements will be made in accordance with the ASTM D3578, ASTM D3767 and ASTM D5250 standards.

E. PHYSICAL INSPECTION

The gloves shall be free from the following defects:

- Tears and holes
- Latex chunks in palm and finger areas
- Insufficient powder or excessively powdered
- Dirt specks or foreign matter
- Blisters
- Bleeding
- String or Fisheye
- Mixed Sizes
- Torn or unsealed outer wrapper
- A strong or objectionable odor other than a slight "rubber" odor
- Tackiness or gumminess when wet
- Resist tearing when donning
- Slipperiness when wet
- Improper fit
- Inconsistent coloration
- Discoloration
- Difficulty quickly opening unit packaging (regardless of package perforations)
- Mold release powder

Note:

The physical inspection shall be done by an advisory committee comprised of members of the user community, such as paramedics, doctors, nurses, laboratory technicians, and other health care givers. The advisory committee may provide their recommendations for disqualification for each of the evaluated products.

The Division of Purchase & Contract, may reject any glove for (1) any one or more of the defects listed above, (2) recommendations of the advisory committee or (3) noncompliance with any of the specifications. Any glove rejected by this evaluation process will not be approved for listing on the Qualified Products List for these gloves.

F. PACKAGING

1. The smallest unit of packaging normally consists of a quantity of 90 to 100 gloves of one type and size, except for the Class 2, heavy duty latex gloves may provide 40 to 50 gloves per box.
2. 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.
3. None of the packaging material shall contain any material likely to impair the quality and use of the gloves.
4. Cartons and shipping cases shall be of sufficient strength to maintain the quality of the product during normal transportation and storage.
5. The quantity per unit box and the number of unit boxes per carton will be specified in the Invitation for Bids.

G. MARKING

1. The unit boxes, shelf boxes, and shipping cartons shall be marked with the brand name, size, quantity, and lot number.
2. The outermost case shall be labeled with the glove size and a manufacturing lot number.
3. The date of manufacture shall be readily visible on the unit boxes. This may be accomplished with the lot number by clearly indicating the month and year. In any case, the user must be furnished the appropriate information in which to readily determine the date of manufacture by inspection of the smallest unit packaging.

EFFECTIVE JANUARY 1, 2013: The date of manufacture shall be clearly indicated by month and year, as a readily visible marking on the unit boxes. A three digit marking to indicate the Julian Day of Year of the year is not sufficient to indicate the month of manufacture. The date of manufacture shall be a separate marking and NOT accomplished within the lot number marking. In any case, the user must be furnished the appropriate information in which to readily determine the date of manufacture by inspection of the smallest unit packaging.

4. All levels of packaging shall conform to all appropriate government labeling regulations, including any ASTM requirements for powder and protein content.

H. INVENTORY CONTROL

No gloves covered by this specification shall be accepted after more than eighteen (18) months from the date of manufacture. All gloves shall retain original physical performance and product specifications for a minimum of three (3) years from the date of manufacture. Glove showing any deterioration or defects during that period shall be immediately replaced or may result with the Division of Purchase and Contract proceeding as stipulated in the "Terms and Conditions" of the bid.

The state reserves the rights to have the glove vendor provide factory invoices and shipping documentation in English for specific lot numbers of products delivered under contract. Factory identification shall reference identical manufacturer for the 510K number submitted for the QPL.

Failure to provide documentation indicating the identical manufacturing source as originally indicated by the submitted 510K number may result with the Division of Purchase and Contract proceeding as stipulated in the "Terms and Conditions" of the bid.

IV. WARRANTY

The contractor warrants to the owner that all products furnished under this specification will be new, of good materials and workmanship, and agrees to replace promptly any product which by reason of defective material or workmanship shall fail this specification. Such replacement shall be free of any charge to the owner or representative, including shipping charges.

V. ACCEPTANCE EVALUATION AND QUALITY ASSURANCE

All gloves shall be new, not seconds, and constructed of appropriate first quality materials and workmanship in a manner acceptable in good industry practice for compliance with the full requirements of this specification.

Gloves submitted for a brand and model shall be identical except for size. This includes but is not limited to the following criteria consisting of manufacture, product type, construction, thickness, performance, color, product packaging and markings. Multiple brands, models, or other product differences will not be accepted for the different sizes for an individual brand and model of gloves. Any product packaging, markings, brand and model or reorder designations that have been relabeled or obscured will also not be accepted.

All glove samples, including packaging and markings submitted for evaluation shall be representative and identical to any products provided for that brand and model designation. The gloves and packaging shall not be marked with a different brand, model designation or reorder number than as submitted or represented for evaluation to the specifications herein.

Gloves manufactured for a brand and model shall be of a single manufacturer as designated by a single FDA 510K number. Only a single FDA 510K premarket number will be accepted for the manufacturer's identity of that brand and model of gloves..

If there is any reason to suspect that actual factory location is different from that recorded in the FDA database for the gloves provided, proof shall be requested such as the submittal of packing slips for significant quantities of gloves identifying the original manufacturer and the branded glove company. If the actual factory location can not be confirmed or is not in the FDA database for that product, the submitted gloves will not be accepted.

Gloves in this specification may be tested in accordance with the test procedures outlined in this specification. Any gloves failing these tests will be rejected and given no further consideration or evaluation.

Manufacturers offering gloves under this specification shall provide a current 510K number and the applicable documentation thereof. The manufacturer's name, brand name, description and product designation / part number may be verified to match information in the FDA registration database. The Division of Purchase and Contract reserves the right to request a copy of the submission document, any amended premarket summaries and equivalency evidence letters submitted to the Food and Drug Administration (FDA) to obtain the FDA 510K product registration.

Manufacturers shall also provide any product documentation or information (questionnaire) requested for product evaluation. The omission or failure to provide any required documentation or samples will be an immediate disqualification for that product.

Responses to the evaluation questionnaires shall indicate specific numerical dimensions or values where requested. A response indicating an equivalent strength or an equivalent thickness, an approximate value or other vague and obscure response will not be accepted for the purposes of determining compliance with the product specifications. Any value indicated with a tolerance specified that is greater than best industry practice will not be accepted.

During the QPL evaluation, award evaluation or contract administration, the state reserves the right to request testing by a third party independent laboratory to substantiate product compliance to the specifications listed within. Test results for the extractable aqueous soluble protein content and maximum residual powder may also be requested. The Division of Purchase & Contract shall approve the independent third party laboratory selected for the testing submitted. The bidder is responsible for providing samples for the verification tests. All cost associated with the samples, testing, product shipping shall be borne by the bidder.

No changes may be made in the products approved per this specification without prior approval by the NC Division of Purchase and Contract including product thickness, construction, material content, packaging, labeling and manufacturer.

If it is found that delivered products are not equal to or better than the samples originally submitted and evaluated for the QPL, the Division of Purchase and Contract may proceed as stipulated in the "General Terms and Conditions" of the bid.

Any glove manufactured by a factory, as designated by the FDA 510K number that has been currently placed on FDA Level II or Level III detention as posted on the FDA website, will be disqualified from the QPL evaluation. Refer to the following Internet links to search and review the FDA database for product deficiencies, adverse events, complaints, import refusals and product detentions.

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/R eportingAdverseEvents/ucm127891.htm>

http://www.accessdata.fda.gov/ImportAlerts/ora_import_ia8004.html

VI. DELIVERY AND PAYMENT

Delivery of and payment for commodities under this specification shall be in accordance with the terms and conditions of the Invitation for Bids. The contractor shall be responsible for any packing, packaging, or protection required to insure delivery in undamaged condition.

VII. ORDERING DATA (For Purchase & Contract Use Only)

Purchasers should exercise any desired option offered herein and should specify the following in the requisition and Invitation for Bids:

1. Title, number, and date of this specification.
2. Type, Class, and Style (See Classification).
3. Special packaging requirement.
4. Special sizes if requested in the Invitation For Bids.

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