

**SPECIFICATION
FOR
GLOVES, SURGICAL**

SCOPE

This specification covers the requirements for sterile latex surgical gloves used in conducting surgical procedures.

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 D 3577-91-Standard Specification for Rubber Surgical Gloves
U.S. Pharmacopeia

II. CLASSIFICATION

Type I - Gloves compounded primarily from natural rubber latex.

Class 1 - Regular Duty, 0.12mm Minimum Thickness, 10" Minimum Length, Beaded Cuff

Style 1 - Powdered
Style 2 - Allergy-Sensitive

Class 2 - Heavy Duty, 0.30mm Minimum Thickness, 11.5" Minimum Length, Beaded or Non-Beaded Cuff

Style 1 - Powdered
Style 2 - Allergy-Sensitive

III. REQUIREMENTS

A. MATERIALS

1. The gloves shall be compounded from virgin natural latex or any rubber polymer compound that permits the glove to meet the requirements of this specification and is approved by the Food and Drug Administration.
2. 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.
3. The gloves shall be talc free.

4. The gloves shall be sterilized according to the procedure given in the latest edition of the U.S. Pharmacopoeia.

B. DESIGN

1. The gloves shall be of seamless construction and designed as left and right hand sized gloves. Gloves shall be thin, soft, flexible, non-toxic, moisture resistant, and shall allow a high degree of tactile sensitivity. Gloves shall be available in sizes 6 thru 9 in half size increments.
2. Unless otherwise specified herein, or in the Invitation for Bids, the gloves shall comply with the dimension and physical requirements specified in ASTM D 3577-91.
3. The cuff shall be beaded or non-beaded as specified.
4. The glove length will be as specified herein, or in the Invitation for Bids.

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 when tested in accordance with III.D.3.
4. Comply with requirements for sterility when tested in accordance with the latest edition of U.S. Pharmacopoeia.

D. TEST METHODS

1. Watertight Test

Fill glove with 300 ± 25 ml water at room temperature.

Twist to close at cuff.

Maintain in a vertical position for 3 minutes.

Observe for leaks.

Emergence of water from glove constitutes a watertight failure.

2. Airtight Test

Position glove over a suitable inflation device. 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. Thickness measurements will be made in accordance with ASTM D 3577-91 and ASTM D 3767. The minimum thickness shall be 0.10 mm.

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

F. PACKAGING

1. Each pair of gloves shall be packaged as sterile product in an inner wrapper. The outer package shall have a method of closure sufficient to assure the sterility of the product until opened.
2. There shall be 50 pairs per unit box. 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.

G. MARKING

1. The unit boxes, shelf boxes, and shipping cartons shall be marked with the brand name, size, quantity, and lot number.
2. Packages shall bear markings for the contents to include the size, instruction for opening, the legend "sterile", and manufacturing lot number.
3. Inner wrappers shall bear a size marking to be located on the outside of the wrapper.
4. The date of manufacture must be shown on the unit boxes. This may be accomplished with the lot number. In any case, the user must be furnished the appropriate information in which to readily determine the date of manufacture by inspection of the unit box.

H. INVENTORY CONTROL

No products covered by this specification shall be shipped to the user more than twelve (12) months from the date of manufacture.

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 his representative.

V. ACCEPTANCE EVALUATION AND QUALITY ASSURANCE

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

Gloves that pass the tests outlined in Section III.D of this specification will be evaluated in accordance with the requirements outlined in Section III.E of this specification.

The purchaser reserves the right to use any additional available information to ascertain whether the product conforms to specification

Manufacturers offering gloves under this specification must provide a current 501(K) number and the applicable documentation thereof.

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 and 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 Section II CLASSIFICATION)
3. Special packaging requirements

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