

ZZ-C-001597A(GSA FSS)

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SUPERSEDING

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INTERIM FEDERAL SPECIFICATION

CONDOMS, RUBBER CONTRACEPTIVE

This Interim Federal Specification was developed by the General Services Administration, Federal Supply Service, Washington, DC 20406, based upon currently available technical information. It is recommended that Federal agencies use it in procurement and forward recommendations for changes to the preparing activity at the address shown above.

1. SCOPE AND CLASSIFICATION

1.1 Scope. This specification covers the requirements for natural rubber contraceptive condoms.

1.2 Classification. Condoms covered by this specification shall be the following types, styles, classes, and sizes, as specified (see 6.2).

Type I - Noncontoured

Type II - Contoured (style B, only; see 3.2.1)

Style A - Round End

Style B - Reservoir End

Class A - Nonlubricated (powdered)

Class B - Lubricated

Size 1 (large) - 180 ± 10 mm in length

Size 2 (small) - 160 ± 10 mm in length

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2. APPLICABLE DOCUMENTS

2.1 The following documents, of the issues in effect on date of invitation for bids or request for proposal, form a part of this specification to the extent specified herein.

Federal Standards:

Fed. Std. No. 123 - Marking for Shipment (Civil Agencies)

(Activities outside the Federal Government may obtain copies of Federal Specifications, Standards, and Handbooks as outlined under General Information in the Index of Federal Specifications and Standards and at the prices indicated in the Index. The Index, which includes cumulative monthly supplements as issued, is for sale on a subscription basis by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

(Single copies of this specification and other Federal Specifications required by activities outside the Federal Government for bidding purposes are available without charge from Business Service Centers at the General Services Administration Regional Offices in Boston, New York, Washington, DC, Atlanta, Chicago, Kansas City, MO, Fort Worth, Denver, San Francisco, Los Angeles, Seattle, WA.

(Federal Government activities may obtain copies of Federal Specifications, Standards, and Handbooks and the Index of Federal Specifications and Standards from established distribution points in their agencies.)

Military Standards:

MIL-STD-105 - Sampling Procedures and Tables for Inspection
by Attributes

(Copies of Military Specifications and Standards required by suppliers in connection with specific procurement functions should be obtained from the procuring activity or as directed by the contracting officer.)

2.2 Other publications. The following documents form a part of this specification to the extent specified herein. Unless a specific issue is identified, the issue in effect on date of invitation for bids or request for proposal shall apply.

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American Society for Testing and Materials (ASTM) Standards:

D 3492 - Rubber Contraceptives (Condoms), Standard
Specification for

(Application for copies should be made to the American Society
for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.)

National Motor Freight Traffic Association, Inc., Agent:

National Motor Freight Classification.

(Application for copies should be addressed to the American Trucking
Associations, Inc., Traffic Department, 1616 P Street, N.W., Washington,
DC 20036.)

Uniform Freight Classification.

(Application for copies should be addressed to the Uniform Classification
Committee, Room 1106, 222 South Riverside Plaza, Chicago, IL 60606.)

Laws and Regulations:

21 CFR 1 - The Federal Food, Drug, and Cosmetic Act and
the Fair Packaging and Labeling Act and
regulations promulgated thereunder.

(The Code of Federal Regulations (CFR) and the Federal Register (FR)
are for sale on a subscription basis by the Superintendent of Documents,
U.S. Government Printing Office, Washington, DC 20402. When indicated,
reprints of certain regulations may be obtained from the Federal agency
responsible for issuance thereof).

3. REQUIREMENTS

3.1 Materials.

3.1.1 Latex. Condoms shall be made of natural rubber latex, and shall be
capable of meeting all requirements and passing all tests specified herein.
The rubber latex used shall be free of embedded grit and discoloration.
Condoms shall be transparent and either clear (i. e. natural colored) or
colored, as specified (see 6.2). Colored condoms shall be available in the
following manufacturer's standard colors: Red, Blue, Green, Pink, Black,
and Yellow, as specified (see 6.2). The condoms shall not liberate toxic or
otherwise harmful substances under normal conditions of use, and shall be
in strict compliance with the applicable portions of 21 CFR 1 (see 4.4.8).

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3.1.2 Dressing and compounding materials. Dressing materials (e.g. powders, lubricants, etc.) and compounding materials (coloring agents and other additives) shall not have a deleterious effect on the condoms, nor shall they have a harmful or irritating effect on the human body. Such materials shall be in strict compliance with the applicable portions of 21 CFR 1 (see 4.4.8).

3.2 Construction. Condoms shall consist of smooth surfaced, essentially cylindrical, latex sheaths with one open end. The open end shall have a thin ring consisting of several layers of latex contiguous with the sheath. When tested as specified in 4.4.4, condoms shall have a maximum weight of 1.70 grams. When tested as specified in 4.4.2.1, condoms shall have an average wall thickness of from 0.040 mm (min.) to 0.070 mm (max.), and no individual wall thickness measurement shall exceed 0.090 mm.

3.2.1 Type I and Type II. Type I condoms shall be straight, without constrictions. The closed end of Type I condoms may be straight or expanded, according to the manufacturer's standard practice. Type II condoms shall have a formfitting profile, consisting of an essentially cylindrical sheath for one-half to two-thirds of its length (measured from the open end), followed by a constricted portion, followed in turn by an expanded portion, and in all cases, terminating with a definite shoulder and reservoir tip (style B, only; see 1.2). When condoms are tested as specified in 4.4.2.2, the laid flat width of the expanded portion (at its maximum) shall never be less than the laid flat width of the "shank."

3.2.2 Style A and Style B. Style A condoms shall have a smoothly rounded tip, without additional features. The closed end of Style B condoms shall have a visible shoulder leading to a reservoir pouch at the tip.

3.2.3 Length and width. When condoms are tested as specified in 4.4.2.2, their lengths shall be as specified in 1.2; their widths shall be as specified in Table 1.

TABLE I. Laid Flat Width Requirements

| Classification | Point of Measurement (i. e. distance from the open end.) | Width |
|----------------|--|---------------|
| Type I: | | |
| Size 1 | 80 ± 5 mm | 52 ± 3 mm |
| Size 2 | 80 ± 5 mm | 49 ± 2 mm |
| Type II: | | |
| Size 1 | 80 ± 5 mm | 52 ± 3 mm |
| | 130 ± 15 mm | 35 ± 5 mm |
| Size 2 | 80 ± 5 mm | 49 ± 2 mm |
| | 110 ± 15 mm | 35 ± 5 mm |

3.3 Class A and Class B condoms. Class A condoms shall be powdered to prevent the latex from sticking to itself, and to facilitate mechanical manipulation of the condoms. Class B condoms shall be dressed with a water based jelly or silicone oil type lubricant, as specified (see 6.2). When Class B condoms are tested as specified in 4.4.3, the amount(s) of lubricant used shall be as follows:

water-base jelly type - 350 mg (min.) to 550 mg (max.)
 silicone oil type - 250 mg (min.) to 500 mg (max.)

Powders and lubricants shall be applied directly to the condoms in accordance with the manufacturer's standard practice. Powders and lubricants shall be as specified in 3.1.2.

3.4 Tensile strength and elongation. When tested as specified in 4.4.5, the tensile strength and elongation at break characteristics of the condoms shall be as specified in Section 6 of ASTM D3492.

3.5 Pinholes. Condoms shall show no evidence of pinholes when tested by an electronic testing machine, as specified in 4.4.6.

3.6 Water leakage. Condoms shall show no evidence of water leakage when tested as specified in 4.4.7.

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3.7 Identification marking. Each individual condom shall have the manufacturer's name or symbol and the date (i. e. month/year) of manufacture imprinted on the condom, near the open end.

3.8 Workmanship. The workmanship shall be first class throughout. Condoms shall be free of defects which affect their durability, detract from their appearance, or which may impair their serviceability.

4. QUALITY ASSURANCE PROVISIONS

4.1 Responsibility for inspection. Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the Specification where such inspections are deemed necessary to assure that supplies and services conform to prescribed requirements.

4.2 Objective evidence. The supplier shall provide objective evidence acceptable to the contracting officer that the requirements of 3.1.1 and 3.1.2, for which specific inspection has not been provided, have been satisfied (see 4.4.8).

4.3 Sampling. Sampling plans in tables II and III for the water leakage test are matched to certain plans in MIL-STD-105. The normal, tightened, and reduced inspection provisions of MIL-STD-105 may be used, as applicable, as sampling plans in this specification.

4.4 Examination and tests.

4.4.1 Visual examination. A visual examination for defects in materials, construction, and workmanship shall be performed on condoms selected for the water leakage test (see 4.4.7). Sample sizes and acceptance/rejection (Ac/Re) numbers, expressed in terms of percent defective, shall be identical to those specified in table II. The presence of one or more imperfections in material, etc., in the same condom shall constitute a defective condom. Results of the visual examination shall be kept separately from the results of the tests.

4.4.2 Dimensions. Five condoms shall be selected at random from each lot for determination of compliance with the applicable thickness, and length and width requirements of 3.2, 3.2.1, 3.2.3, and table I. Wall thickness measurements shall be made on condoms from which all dressing materials have been removed with water or isopropanol and then dried to a constant mass. The acceptance number for dimensional tests shall be zero (i.e. any evidence of noncompliance with specified requirements shall be cause for rejection of the lot.).

4.4.2.1 Wall thickness. The wall thickness of condoms shall be measured at three points, 10 ± 2 mm from the open end, 30 ± 5 mm from the closed end, and at the mid-distance between those two points. Lateral measurements made from the closed end of style B condoms shall exclude the reservoir tip. The individual measurements and the average value of all three measurements shall be recorded for each condom.

4.4.2.2 Length and width. Measurement of condom length shall be made from the open end to the furthest extension of the closed end (exclusive of the reservoir tip on style B condoms). Width measurements shall be made on laid flat condoms. Width measurements shall be taken at the points specified in table I. The expanded portion of type II condoms shall be inspected to assure compliance with the applicable requirements of 3.2.1.

4.4.3 Quantity of lubricant. Twenty individual condoms, selected at random from each lot shall be tested for compliance with the quantity of lubricant requirements of 3.3, as applicable. The test procedure(s) shall be as follows:

(a) water-based lubricant; lubricated condoms, sealed in their individual packets, shall be weighed on an analytical balance. Each packet shall be opened taking care to retain all pieces thereof. The packet and condom shall be washed in denatured ethanol until all lubricant is removed, dried to a constant mass, and then weighed again; the condom without its packet shall also be weighed. All weights shall be recorded to the nearest milligram (mg). Compliance with the requirements of 3.3 shall be determined by subtracting the weight of the washed and dried sample (packet and condom) from the initial weight of the sample prior to removal of the lubricant.

(b) silicone oil lubricant; this procedure shall be identical to that specified in (a), except that the condom packet shall be discarded prior to the initial weighing and shall not be used in any of the procedural steps; i.e., only the lubricated condom shall be used in this procedure.

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4.4.3 In both (a) and (b), all procedural steps shall be completed for each sample before proceeding to subsequent samples. The acceptance number for this test shall be zero.

Individual condom weights recorded in (a) and (b), as applicable, shall be used to satisfy the requirements of 4.4.4.

4.4.4 Weight. The twenty condoms tested as specified in 4.4.3, from which all dressing materials have been removed, shall be dried to a constant mass and then weighed on an analytical balance to determine compliance with the applicable requirements of 3.2. The acceptance number for this test shall be zero.

4.4.5 Tensile strength and elongation test. Sample condoms shall be selected and tested as specified in Section 6 of ASTM D3402. The compliance and acceptance criterion shall be as specified therein.

4.4.6 Pinhole test. The test for pinholes shall be performed on a 100 percent basis (i.e. no sampling). The electronic testing shall be performed by utilizing an electronically charged liquid bath (wet method), or a gammeter test (dry method) which examines the product dry. Condoms failing to meet the requirements of 3.5 shall be removed.

4.4.7 Water leakage test. After the pinhole test specified in 4.4.6, and prior to shipment, condoms shall be sampled and inspected in accordance with tables II and III, as applicable. Sample condoms shall be placed in a funnel rack approximately twelve (12) inches above the base support, and each condom shall then be filled with 300 cubic centimeters (ml) of water. The open end of the condom(s) shall then be closed by squeezing the beaded portion together. The filled condom(s) shall be laid on a piece of dry filter paper, rolled from side to side, and examined for water leakage in compliance with 3.6. Lot acceptability shall be based upon the acceptance (Ac) and rejection (Re) numbers (representing defective condoms) in tables II and III, as applicable.

Table II. Sampling Plans for Water Leakage Test ^a, and for Visual Examination (see 4.4.1).

*Area of examination. Between 25 mm from the open end and the closed end.

Lot size 35,000 and less

| Type of Sampling Plan | Cumulative Sample Size | Ac | Re |
|-----------------------|------------------------|----|----|
| Single | 500 | 2 | 3 |
| Double | 315 | 0 | 3 |
| | 630 | 3 | 4 |
| Multiple | 125 | # | 2 |
| | 250 | 0 | 3 |
| | 375 | 0 | 3 |
| | 500 | 1 | 4 |
| | 625 | 2 | 4 |
| | 750 | 3 | 5 |
| | 875 | 4 | 5 |

Lot size 35,001 - 150,000

| | | | |
|----------|------|---|----|
| Single | 800 | 5 | 6 |
| Double | 500 | 2 | 5 |
| | 1000 | 6 | 7 |
| Multiple | 200 | # | 4 |
| | 400 | 1 | 5 |
| | 600 | 2 | 6 |
| | 800 | 3 | 7 |
| | 1000 | 5 | 8 |
| | 1200 | 7 | 9 |
| | 1400 | 9 | 10 |

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Table II continued

Lot size 150,001 - 500,000

| Type of Sampling Plan | Cumulative Sample Size | Ac | Re |
|-----------------------|------------------------|----|----|
| Single | 1250 | 7 | 8 |
| Double | 800 | 3 | 7 |
| | 1600 | 8 | 9 |
| Multiple | 315 | 0 | 4 |
| | 630 | 1 | 6 |
| | 945 | 3 | 8 |
| | 1260 | 5 | 10 |
| | 1575 | 7 | 11 |
| | 1890 | 10 | 12 |
| | 2205 | 13 | 14 |

Lot size 500,001 and over

| | | | |
|----------|------|----|----|
| Single | 2000 | 14 | 15 |
| Double | 1250 | 7 | 11 |
| | 2500 | 18 | 19 |
| Multiple | 500 | 1 | 7 |
| | 1000 | 4 | 10 |
| | 1500 | 8 | 13 |
| | 2000 | 12 | 17 |
| | 2500 | 17 | 20 |
| | 3000 | 21 | 23 |
| | 3500 | 25 | 26 |

Table III. Sampling Plan for Water Leakage Test in the area between the open end, and 25 mm from the open end. This plan is applicable to all lot sizes.

| Type of Sampling Plan | Cumulative Sample Size | Ac | Re |
|-----------------------|------------------------|----|----|
| Single | 500 | 21 | 22 |
| Double | 315 | 11 | 16 |
| | 630 | 26 | 27 |
| Multiple | 125 | 2 | 9 |
| | 250 | 7 | 14 |
| | 375 | 13 | 19 |
| | 500 | 19 | 25 |
| | 625 | 25 | 29 |
| | 750 | 31 | 33 |
| | 875 | 37 | 38 |

4.4.8 Added materials. Contractors shall provide adequate certification that the condoms, all dressing materials (powders, lubricants, etc.), and all compounding materials (coloring agents and other additives) are in compliance with the applicable portions of 21 CFR 1, and that they have been tested in accordance with applicable Food and Drug Administration regulations in force at the time of the manufacture of the condoms.

4.5 Inspection of preparation for delivery. An inspection shall be performed to insure that packaging, packing, and marking are in compliance with the requirements of Section 5. The inspection shall be conducted in accordance with MIL-STD-105. The lot size shall be the number of shipping containers and interior packages in the end item inspection lot. The inspection level shall be S-3, with an Acceptable Quality Level (AQL) of 2.5, expressed in terms of percent defective. For the purpose of exterior packing examination, the sample unit shall be one shipping container; for interior packaging examination, the sample unit shall be one package. Examination of interior packaging shall be performed on packages selected at random from sample shipping containers. Examination of defects of closure shall be performed on randomly selected shipping containers, fully prepared for delivery. Preparation for delivery defects shall be scored in accordance with table IV.

Table IV. Classification of Preparation for Delivery Defects

| Examine | Defects |
|---------------------------------|---|
| Contents | Number of condoms not as specified, packets or strips not as specified. |
| Marking (Exterior and Interior) | Omitted, incorrect; illegible; of improper size, location, sequence, or method of application. |
| Materials | Packaging/packing materials not as specified, missing, damaged, or nonserviceable. |
| Workmanship | Containers inadequately closed and secured, poor application or internal packaging and packing material, distorted intermediate packages. |

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5 PREPARATION FOR DELIVERY

5.1 Packaging. Packaging shall be level A or commercial, as specified (see 6.2).

5.1.1 Level A. Condoms shall be sealed in individual packets constructed of a suitable flexible metal foil, plastic film, or combination thereof. The sealed packets shall be provided in strips of three or four, separated by perforations to facilitate detachment. When colored condoms are specified in the contract or order, the sealed packets shall consist in part of transparent plastic film through which the color of the condom can be identified. One gross (144) of condoms shall be neatly packaged in a folding or set-up paperboard box.

5.1.2 Commercial. Condoms shall be preserved and packaged in accordance with normal commercial practice. The complete package shall be designed to protect the condoms against damage during shipment, handling, and storage.

5.2 Packing. Packing shall be level A or commercial, as specified (see 6.2).

5.2.1 Level A. Condoms, packaged as specified in 5.1.1, shall be packed in corrugated fiberboard boxes made from Weather-Resistant fiberboard with a bursting test strength of not less than 275 pounds per square inch. The box flaps shall be secured with water resistant adhesive applied to not less than 75 percent of the area of contact between the flaps or with 3 inch wide water resistant tape applied to the full length of the center seams and extending over the ends not less than 3 inches. Alternatively, wirebound, cleated plywood, or nailed wood boxes shall be acceptable shipping containers when lined with a waterproof barrier material. The barrier material shall be sealed at the edges with waterproof tape or adhesive.

5.2.2 Commercial. Condoms, packaged as specified in 5.1.2, shall be packed in fiberboard boxes to insure safe delivery at destination, to provide for safe redistribution by the initial receiving activity, and shall be acceptable by common carrier under National Motor Freight Classification or Uniform Freight Classification.

5.3 Unitization. When shipments to Government depots are full car or truckload, the shipping containers shall be unitized for shipment and handling in accordance with normal commercial practice. The unitized load shall not exceed 2,500 pounds in weight, 63 inches in height, 56 inches in length, and 45 inches in width.

5.4 Marking. In addition to markings required by the contract or order, packages, shipping containers, and unitized loads (when applicable) shall be marked in accordance with Fed. Std. No. 123.

6. NOTES

6.1 Intended use. Condoms covered by this specification are intended for use as contraceptive and prophylactic agents.

6.2 Ordering data. Purchasers should select the preferred options permitted herein, and include the following information in procurement documents.

- (a) Title, number, and date of this specification.
- (b) Type, style, class, and size condom required (see 1.2).
- (c) Whether clear (natural colored) or colored condoms are required (see 3.1.1); if colored condoms are required, what colors are required (see 3.1.1).
- (d) Whether the water-based or silicone oil type lubricant is required (see 3.3).
- (e) Selection of applicable levels of packaging and packing (see 5.1 and 5.2).
- (f) Unitization required (see 5.3).
- (g) Marking required (see 5.4).

6.3 Definitions. The following terms, as used in this specification shall be defined as indicated.

Laid flat width: one half of the circumference (of the condom) at the designated point.

Shank. that portion of the condom lying between the open end and the first visible constriction, convolution or contour, etc., (see 3.3).