COLOURED LATEX MALE CONDOM SINGLE USE
PROCUREMENT SPECIFICATION

1. GENERAL REQUIREMENTS

Manufacturers and Suppliers shall follow an appropriate code of quality management, including good
manufacturing practices (GMP) as required by the South African Bureau of Standards (SABS) Mark
Scheme and statistical process control, in the manufacture and packaging of condoms.

The methods used to test for compliance are:

- use of statistical samples; and
- subjective inspection; and
- documentary evidence, such as comprehensive reports of stability tests, certificates of purity from
  material suppliers, or certification by regulatory agency or an independent body.

Requirements marked with a star/* will be tested on each lot and will be seen as critical to the
fulfilment of the tender agreement. The remaining requirements will be tested on a random basis.
Should any of the condoms not meet the requirements when tested that particular lot will be
considered to be unfit for delivery and therefore in breach of the tender agreement and will be subject
to the conditions held therein.

1.1 Constituent materials

- The condoms shall be made from natural rubber latex.
- The latex shall be free of embedded solid impurities and discoloration.
- The condoms shall not liberate toxic or otherwise harmful substances in amounts that can be
  irritating, sensitising or otherwise harmful to the user of the condom under normal conditions of use.
- The compounding materials (colouring agents, antioxidants, accelerators, vulcanizing 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. The use and type of accelerators used should be stated. Excess
  accelerators and other leachable chemicals should be avoided.
- Careful attention shall be given in the formulation to suitable antioxidants in order to provide
  maximum protection under adverse storage conditions.
- All materials must comply strictly with the requirements of the applicable portions of the US Code of
  Federal Regulations (USCFR) 21 and/or latest updated version.

These requirements will be verified by documentary evidence.
1.2  Shelf-life

Condoms shall comply with the performance requirements of this specification throughout the stated shelf life of the condom.

It is intended that condoms purchased under this specification should retain their properties when exposed in their individual packages to an average temperature of 35°C for the stated shelf-life.

The manufacturer shall stipulate a shelf-life, measured from the month of manufacture, during which the packed products will be stable in properties, and will continue to meet the requirements of clause 2.1. (before oven conditioning). This shelf-life shall be at least 3 years. At the time of delivery at least 80% of the shelf-life must still be available to the procurer.

The manufacturer shall make available to the purchaser on request, data to support the stated shelf-life. This data may take the form of:

1. Real time stability studies conducted over the stated shelf-life at 35°C
2. Accelerated studies conducted over shorter times at higher temperatures. These should preferably be done at 70°C at multiple intervals over 21 days and at a temperature between 40°C and 50°C, at multiple intervals (e.g. every 2 weeks), for at least 6 months. The basis for any extrapolation to real environmental temperatures should be stated,

The maximum acceptable decrease in mean inflation properties should be 25%, and products should comply with the requirements in clause 2.1. at the end of the stated shelf-life.

Updated documentation on 35°C post-market trials must be made available to the purchaser on request. Validated expiry dates up to 5 years will be allowed.

1.3  Resistance to oxidation (independent of the package)

(i)  Sampling

One hundred (100) condoms per lot

(ii)  Testing

Remove the condoms from their packages. Place the rolled condoms in an oven at 70 ± 2°C.

After 2 days, remove 50 condoms from the oven, allow them to cool for 12-96 hours and test them by air inflation according to ISO 4074. After a further 7 days, remove the remainder from the oven and test them as above.

(iii)  Requirement

The ratio of the mean burst pressure at 9 days to the mean burst pressure at 2 days should not be less than 75%
Annexure A: South African Department of Health Coloured Male Latex Condom Specification:

1.4 Dressing materials

The dressing materials applied to the condoms (e.g. powders and lubricants) shall not have a deleterious effect on the condoms, nor shall they have a harmful or irritating effect on the human body.

These materials shall comply strictly with the requirements of the applicable portions of the US Code of Federal Regulations (USCFR) 21 or its equivalent.

The manufacturer shall use a suitable powder (e.g. cornstarch; silica, magnesium carbonate) to improve the "feel" of the condom and facilitate unrolling.

*Talc and lycopodium spores shall not be used.*

Documentary evidence is required to verify the quality of the dressing materials.

2 PERFORMANCE REQUIREMENTS

Condoms purchased under this specification must not leak or break during use, and must retain their properties when exposed in their individual packages to average temperatures of 35°C at maximum humidity for the stated shelf-life.

- Performance requirements will be tested for compliance by the use of statistical samples and prescribed test protocols.
- Tests or verifications in this section will generally be undertaken at the pre-qualification stage, and by lot-by-lot compliance testing carried out by the purchaser’s laboratory or by a third party laboratory selected by the purchaser prior to delivery.
- Unless otherwise indicated, test protocols will be according to ISO 4074 (version current at the time of contract).

2.1 Bursting volume and pressure*

(i) Sampling

For the test before oven conditioning: *ISO 2859-1 General Inspection Level G-1.*

For the test after oven conditioning: 80 condoms per lot. (The purpose of this test is to check for major formulation or vulcanisation errors.)

(ii) Testing

In accordance with the inflation test and oven conditioning procedure in *ISO 4074, Annexure G* and the relevant clause in *ISO 4074.*
(iii) Requirement

Before ageing, AQL 1.0% applied separately to volume and pressure non-compliers.

The minimum permitted bursting volume depends on the width of the condom.

For the test before oven conditioning, the specification prescribes a minimum limit for each condom tested. The minimum bursting pressure shall be 1kPa. The minimum volume is arrived at by the following formula:

\[
\text{minimum limit (litres)} = \frac{w^2}{150} \quad \text{(rounded off to the nearest 0.5 litres)}
\]

The width is the lot mean width of a sample of 13 condoms, rounded off to the nearest 0.5 mm, of the shank portion of the condom measured 70 ± 5 mm determined in accordance with ISO 4074.

After oven conditioning, neither the mean bursting pressure nor the mean bursting volume shall diminish by more than 20%.

2.2 Freedom from holes*

(i) Sampling

ISO 2859-1 General Inspection Level G-1, but at least code level M.

(ii) Testing

The test is carried out in accordance with ISO 4074, Annexure L.

Condoms breaking or tearing as a result of prescribed handling will be considered failures.

(iii) Requirement

AQL 0.25.

2.3 Package integrity*

(i) Sampling

ISO 2859-1 Special Inspection Level S-3.

(ii) Testing

In accordance with Package Integrity Test Method in ISO 4074 Annex M

Sample condoms in individual packages are placed in an airtight, transparent container (such as a laboratory Bell jar) and subjected to a vacuum of 90 ± 5 kPa (gauge) for a period of one minute.

Condom packs should inflate and remain inflated for the period of the test.

Packs that do not inflate or do not remain inflated are considered to be non-compliers. It is permissible to repeat the test on any packs not giving a clear result.

(iii) Requirement

AQL 2.5%
Annexure A: South African Department of Health Coloured Male Latex Condom Specification:

3 DESIGN REQUIREMENTS

The purchaser, as part of the purchase agreement or before delivery of the product, must approve any variances in these properties.

- The methods used to test these requirements for compliance will be:
  - visual inspection; or
  - the use of statistical samples and prescribed test protocols.

- Tests or verifications in this section will generally be:
  - at the pre-qualification\(^1\) stage;
  - compliance lot-by-lot testing carried out by the purchaser’s laboratory or by a third-party laboratory selected by the purchaser prior to delivery;
  - periodic audits other than the mandatory lot by lot testing if the quality of the product is in doubt once it has been purchased.

Unless otherwise indicated, test protocols will be according to ISO 4074 (version current at the time of contract).

3.1 Shape and texture*

The surface of the condoms shall be smooth throughout.

The condoms shall have straight and parallel sides, without constrictions, and with a visible shoulder leading to a reservoir pouch at the tip.

3.2 Bead*

The open end of the condom shall have a rolled ring of latex, called an integral bead.

3.3 Colour and clarity

Pigments to be added to the latex formulation as per required colours in the specifications (red strawberry, purple grape and yellow banana). They need to be selected so that they are not harmful to the users as demonstrated by biocompatibility studies conducted according to ISO 10993.

The condoms shall have the following pigments:

- red (strawberry)
- yellow (banana)
- purple (grape)

Appropriate methods of defining the colours shall be agreed upon between the manufacturers and the purchaser at the time of pre-qualification. The use of pantone charts may be useful. Strips that mix different coloured condoms are not recommended because they require the mixing of condoms from different LOTS. This complicates sampling for quality assurance as well as the tracing of defects.

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\(^1\) Pre-qualification is the process, which proceeds the tender during which the supplier provides condoms for testing and other appropriate documentation according to the requirements of this specification to gain entry in to the tender.
3.4 Odour and taste

Condoms have a characteristic odour of rubber, which tends to dissipate quickly once the package is opened. The condoms shall not give off an unpleasant odour when the package is opened at any time after manufacture and for the shelf life of the product.

The condoms shall be free from taste.

The coloured condoms shall have the following odour/s:

- Strawberry red: Strawberry odour
- Yellow: Banana odour
- Purple: Grape odour

The odours must be to the degree approved by the purchaser at pre qualification.
Annexure A: South African Department of Health Coloured Male Latex Condom Specification:

The manufacturer or the manufacturer’s agent will store 100 condoms for at least one year at room temperature from each certified lot\(^2\) for use in resolving disputes regarding odour.

The condoms shall be free from taste.

3.1 – 3.4 **verify by visual and other appropriate inspection methods**

3.5 **Length**

(i) **Sampling**

According to ISO 2859-1 Special Inspection Level S-2.

(ii) **Testing**

According to the length measurement procedure in ISO 4074 Annexure D

(iii) **Requirement**

*A minimum of 180 mm allowed.*

3.6 **Width**

(i) **Sampling**

According to ISO 2859-1 Special Inspection Level S-2.

(ii) **Testing**

According to the width measurement procedure in ISO 4074 Annexure E

(iii) **Requirement**

A width of 53 mm with a tolerance of ± 2 mm is allowed for individual condoms with an AQL of 1.0% and in addition a tolerance of ± 1 mm for the mean of the lot.

3.7 **Thickness**

(i) **Sampling**

ISO 2859-1 Special Inspection Level S-2.

(ii) **Testing**

*In accordance with test method in ISO 4074 annex F*

The measurement of thickness is done with a micrometer mounted on an anvil, with resolution of at least 0,002 mm, operating with a pressure of 22 ± 4 kPa on the sample.

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\(^2\) A certified lot is a lot of condoms, which has been tested and found to meet the requirements in this specification by the procurer’s testing agents.
Annexure A: South African Department of Health Coloured Male Latex Condom Specification:

For convenience, the double-wall thickness may be measured and divided by two. The samples should be wiped once with absorbent tissue, inside and out, before measuring.

The thickness measurements are taken at three points: 30 ± 5 mm from the open end, 30 ± 5 mm from the closed end (excluding the reservoir tip), and at the mid-distance between those two points.

The individual measurements, and the average of all three, are recorded for each sample.

(iii) Requirement

AQL 1%

The mean single-wall thickness (calculated from the three individual measurements) for each condom shall be 0.065 ± 0.015 mm.

3.8 Quantity of lubricant *

(i) Sampling

ISO 2859-1 Special Inspection Level S-2.

(ii) Testing

In accordance with test method in ISO 4074, Annex C

The condoms in their packages are weighed on an analytical balance. The packages are then opened and the condoms removed.

The condoms and packages are washed in denatured ethanol or isopropanol until all lubricant is removed, dried to a constant mass, and then weighed again. All weights shall be recorded to the nearest milligram (mg).

The weight of lubricant and dressing material will be the difference in weight of the condom and package before and after washing.

Washing and drying may be repeated up to a total of four times if necessary to assure complete removal of lubricant. Alternatively, an ultrasonic bath may be used for washing, provided the washing time has been validated against repeated manual washing. For initial validation of either method, weighing is conducted after each drying.

(iii) Requirement

The quantity of silicone lubricant, for translucent and coloured condoms, scented and unscented, including powder, in the package shall be 550 ± 150 mg. With an AQL of 4.0%. The viscosity of the silicone lubricant shall be between 200 and 350 centistokes at manufacture.

3.9 Individual package materials and markings*

(i) Sampling

ISO 2859- Special Inspection Level S-3.
(ii) **Testing**

The sample of condom packages is visually inspected to verify the required aspects of package quality.

**Any lot numbers on packages must be printed at the time of packaging - not pre-printed.**

In addition, the following shall apply:

- There shall be no evidence of leakage.
- The outside surface of the package shall be clean.
- There shall be no separation of the layers of laminate.
- Sealed packages are in strips of up to 4, the individual packages are separated by perforations or other means which allow the packages to be separated by hand without interfering with the seals.
- The package must be easy to open and will have a notch or serration to assist in opening.
- The packages shall have the following *indelible* markings:
  - Manufacturer’s name
  - Lot or lot identification code (printed at the time of packaging, not pre-printed);
  - Manufacturing date: Month and year- labelled Manufacturing Date
  - *Expiration Date: month and year of expiry labelled in full or Exp Date abbreviated* in English (the year shall be written as a four digit number, and the month as a two digit number);

**Requirement**

AQL 2.5%.

Verify by visual inspection

4. **Packaging for Delivery Requirements**

The properties listed below will be tested for compliance by inspection. Inspections or verifications in this section will generally be carried out at the pre-qualification stage, lot-by-lot compliance testing and during periodic inspections/audits.

4.1 **Cartons and Markings**

(i) **Sampling**

ISO 2859-1 Special Inspection Level S-3.

The lot size for the inspection of inner boxes or consumer packs is the number of inner boxes, and the sample unit is one inner box.

For the inspection of exterior shipping cartons, the lot size is the number of exterior shipping cartons, and the sample unit is one shipping carton.
Annexure A: South African Department of Health Coloured Male Latex Condom Specification:

Examination of inner boxes shall be done on boxes selected at random from sample shipping cartons. Examination of defects of closure shall be done on randomly selected shipping cartons fully prepared for delivery.

(ii) Testing

By inspection carried out at the time of sampling and/or testing.

(iii) Requirements

The individual requirements for the various packagings and packing for delivery are set out below. The AQL for these inspections is 2.5%.

Defects found in the packaging and the marking of packages for delivery shall be assessed in accordance with the following table:

| Classification of defects in packaging and marking of packages for delivery |
|-----------------------------|------------------------------------------------------------------|
| Examine                     | Defects                                                          |
| **Contents**                | Number of condoms not as specified; packages or strips not as specified. |
| **Marking**                 | Omitted; incorrect; illegible; of an improper size (exterior, interior), location, sequence, or method of application. |
| **Materials**               | Packaging/packing materials not as specified, missing, damaged or non-serviceable. |
| **Workmanship**            | Shipping cartons inadequately closed and secured; poor application of internal packaging and packing material; distorted intermediate packages. |

Exterior Shipping Cartons

Thirty dispenser boxes will be packed into plastic waterproof lining bags, which will be placed into three-wall corrugated fibreboard cartons (in three layers of ten dispenser boxes each) made from weather-resistant fibreboard with a bursting strength of not less than 1900 kPa.

The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75-mm-wide water-resistant tape applied to the full length of the centre seams and extending over the ends not less than 75 mm. The cartons will be secured by plastic strapping at not less than two positions.

Alternatively, wire-bound, cleated plywood or nailed wood boxes are acceptable when lined with a waterproof barrier material.

The barrier material must be sealed at the edges with waterproof tape or adhesive, and there must be no sharp protrusions inside the boxes.

The exterior shipping carton, like the bulk carton, shall be marked on the exposed face with information about the contents in a clearly legible manner. The information shall include:

− Lot or lot identification number.
Annexure A: South African Department of Health Coloured Male Latex Condom Specification:

- Month and year of manufacture (including the words *Date of Manufacture, Month, Year*) in English. The year shall be written as a four-digit number, and the month as a two-digit number.

- Month and year of expiry (including the words *Expiry Date, Month, Year*) in English. The year shall be written as a four-digit number, and the month as a two-digit number.

- Name and address of contractor.

- Nominal width.

- Number contained in the carton.

- Instructions for storage and handling.

4.2 Lot traceability

To facilitate monitoring of LOT quality during shipping and storage, all exterior-shipping cartons for each discrete LOT shall be assembled and shipped together.

Best efforts shall be made to ensure that shipments remain as discrete LOTS and that these LOTS remain intact as far down the distribution system as possible.

These efforts may include the use of very large lettering for LOT codes on the exterior shipping cartons, colour coding, palleting of discrete LOTS or otherwise physically linking all exterior shipping cartons from discrete lots, and issuing instructions to this effect to shippers and warehouse personnel.

Each LOT or LOT identification code shall start with the suppliers four digit SABS mark holder registration number followed by a three letter contractor identifier, followed by a unique lot number e.g. 1234/ABC/030001.
5.0 Summary of requirements for which tests are specified

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