

MALE CONDOMS

CONDOMS, MALE, FOR USE DURING INTERCOURSE

1. QUANTITIES REQUIRED:

As per the pricing schedule

2. DISAGGREGATED BY COLOUR AS FOLLOWS:

As per the pricing schedule

3. PACKAGING

3.1. INDIVIDUALLY PACKED;

3.2. SAMPLES TO BE SUBMITTED TO SABS, IN QUANTITIES REQUIRED AS PER SABS SPECIFICATIONS;

3.3. COST MUST INCLUDE DELIVERY COST. (non-compliant sample as will be at the cost of the supplier)

4. GENERAL REQUIREMENTS

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

4.2. The method used to test for compliance is: Availability of the SABS mark.

4.3. The Department reserves the right to request any additional information to verify reports (e.g. Certificate of analysis (COA) and/or material safety data sheet (MSDS).

4.4. Requirements marked with a star* will be confirmed and/or 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.

4.4.1. Constituent materials*

- a. The condoms shall be made from natural rubber latex.
- b. The latex shall be free of embedded solid impurities and discoloration.
- c. 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.

- d. The compounding materials (coloring agents, antioxidants, accelerators, vulcanising 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.
- e. Careful attention shall be given in the formulation to suitable antioxidants in order to provide maximum protection under adverse storage conditions.
- f. All materials must comply with the requirements of the applicable portions of the WHO/UNFPA Specifications 2010 or latest updated version.

These requirements may be verified by documentary evidence if and when necessary (eg COA and/or MSD).

4.4.2. Shelf-life

- a. Condoms shall comply with the performance requirements of the WHO/UNFPA 2010 specifications or latest updated version throughout the states shelf-life of the condom.
- b. It is intended that condoms purchased under this specifications should retain their properties when exposed in their individual packages to an average temperature of 35°C for the stated shelf-life.
- c. 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 the WHO/UNFPA 2010 specifications or latest updated version. The date of manufacture is the date that the condoms were dipped. This shelf-life shall be at least five (5) years. At the time of delivery at least 80% or three (3) years of the shelf-life must still be available to the procurer.
- d. the manufacturer shall make available to the purchaser on request, data to support the stated shelf-life. This data may take the form of:
 - i. Real time stability studies conducted over the stated shelf-life at 35°C, COA or declaration certificate;
 - ii. Use of the methods of WHO/UNFPA 2010 specification or latest updated version or /ISO 4074:2015.
 - iii. The maximum acceptable decrease in mean inflation properties should be 25%, and products should comply with the requirements of WHO/UNFPA 2010 specifications or latest updated version at the end of the stated shelf-life.

4.4.3. Dressing material

- a. The manufacturer shall use a suitable powder (e.g. cornstarch, silica, magnesium carbonate) to improve the “feel” of the condom and facilitate unrolling.
- b. *Talc* and *lycopodium* spores shall **not** be used.

These requirements may be verified by documentary evidence if and when needed e.g. COA and/or MSDS).

5. PERFORMANCE REQUIREMENTS*

5.1. Condoms purchased under this specification must not leak or brake 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.

5.1.1. Performance requirements will be tested for compliance by the use of statistical samples and prescribed test protocols.

5.1.2. Tests or verifications in this section will generally be undertaken 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.

5.1.3. Unless otherwise indicated, test protocols will be according to ISO 4074:2015 (version current at the time of contract).

5.2. Bursting volume of pressure*

5.2.1. Sampling

- a. For the test before oven conditioning: ISO 2859-1 General Inspection Level G-1.
- b. For the test after oven conditioning: 80 condoms per lot. The purpose of this test is to check for major formulation or vulcanisation errors.

5.2.2. Testing

- a. In accordance with the inflation test and oven conditioning procedure in ISO 4074:2015.

5.2.3. Requirement

- a. AQL 1.5% applied separately to volume and pressure non compliers.

5.2.4. Volume

- a. The minimum permitted bursting volume depends on the width of the condom. The minimum volume is arrived at by the following formula

$$\frac{\text{Minimum limited (litres)} = w^2 (\text{rounded of the nearest 0.5 litres})}{150}$$

5.2.5. Pressure

- a. The minimum bursting pressure shall be 1kPa.
- b. The width is defined as the t mean lay-flat width of a sample of 13 condoms measured in accordance with the relevant of ISO 4074:2015 at a point (75±5) mm from the closed end.

5.3. Freedom from holes*

5.3.1. Sampling

- a. ISO 2859-1 General Inspection Level G-1.

5.3.2. Testing

- a. The test is carried out in accordance with relevant annexure of ISO 4074:2015.

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

5.3.3. Requirements

- a. The test is carried out in accordance with relevant annexure of ISO 4074:2015.
 - i. Freedom from holes: AQL 0.25.
 - ii. Critical visible defects: AQL 0.4.
 - iii. Non critical visible defects: AQL 2.5.

5.4. Package seal integrity*

5.4.1. Sampling

- a. ISO 2859-1 Special Inspection Level S-3.

5.4.2. Testing

- a. In accordance with Package Integrity Test Method in the relevant annexure of ISO 4074:2015.

5.4.3. Requirement

- a. AQL 2.5.

6. DESIGN REQUIREMENTS

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

6.1.1. Test or verifications in this section will generally be:

- a. 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.
- b. Periodic audits other than the mandatory lot-by-lot testing if the quality of the product is in doubt once it has been purchased.

- 6.1.2. Unless otherwise indicated, test protocols will be according to ISO 4074:2015.

6.2. Shape and texture*

- 6.2.1. The surface of the condoms shall be smooth throughout.

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

6.3. Integral Bead*

- 6.3.1. The open end of the condom shall have a rolled ring of latex, called an Integral Bead.

6.4. Colour and clarity*

- 6.4.1. The condoms shall be colourless (natural) or coloured as per the items below. Pigments used for coloured condoms shall be suitable for use in medical devices. The coloured condoms shall be of three (3) different pigments: one (1) x pigment per stipulated quantity as per special conditions of contract requirements:

a. Natural (vanilla)

The condoms shall be translucent (clear) and without added colouring. The latex smell shall be scented with vanilla. Full details of the pigment, including MSDS and/or COA may be requested.

b. Red (Strawberry)

The condoms shall be of red (strawberry) colour: Full details of the pigment, including MSDS and/or COA may be requested.

c. Yellow (Banana)

The condoms shall be of yellow (banana) colour: Full details of the pigment, including MSDS and/or COA may be requested.

d. Purple (Grape)

The condoms shall be of purple (grape) colour: Full details of the pigment, including MSDS and/or COA may be requested.

The quantities of each item above will be as specified in the special conditions of contract. Bidders are allowed to bid for more than one item. Bidders shall clearly indicate which item/s they are bidding for.

6.5. Odour/fragrance*

6.5.1. 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.

a. The natural (colourless) condoms shall be of vanilla scent.

Vanilla must be used as a scent for the natural (colourless) condoms. The scent must be non-toxic, non irritant and not degrade the rubber.

b. Full details of the scent, including MSDS and/or COA may be requested.

6.5.2. The coloured condoms shall be of three (3) different fragrances/colour: One (1) x fragrance per colour per item as follows:

a. A red condom shall smell of strawberry (fruit);

b. A yellow condom shall smell of banana (fruit);

c. A purple condom shall smell of grape (fruit).

d. Full details of the scent, including MSDS and/or COA may be requested.

6.6. **All the condoms shall be tasteless.**

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

6.7. **Points 6.2.-6.5. may be verified by visual and other appropriate inspection methods including MSDS and/or COA.**

6.8. Length*

6.8.1. **Sampling**

- a. ISO 2859-1 Inspection Level S-2.

6.8.2. **Testing**

- a. According to the length measurement procedure in ISO 4074:2015.

6.8.3. **Requirement**

- a. AQL 1.0.
- b. **A minimum of 165 mm allowed.**

6.9. **Width***

6.9.1. **Sampling**

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

6.9.2. **Testing**

- a. According to the width measurement procedure in ISO 4074:2015.

6.9.3. **Requirement**

- a. A width stated 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.

6.10. **Thickness***

6.10.1. **Sampling**

- a. ISO 2859-1 Special Inspection Level S-2.

6.10.2. **Testing**

- a. In accordance with test method in ISO 4074:2015.
- b. 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.
- c. For convenience, the double-wall thickness may be measured and divided by two. The sample should be wiped once with absorbent tissue, inside and out, before measuring.
- d. The thickness measurements are taken at three points:
 - i. 30 ± 5 mm from the open end;
 - ii. 30 ± 5 mm from the closed end (excluding the reservoir tip); and
 - iii. At the mid-distance between those two points.
- e. The individual measurements, and the average of all three, are recorded for each sample.

6.10.3. **Requirement**

- a. **AQL 1%**

The mean single-wall thickness (calculated from the three individual measurements) for each condom shall be 0.065 ± 0.015 mm – 0.020 mm.

6.11. **Quantity of Lubricant***

6.11.1. **Sampling**

- a. In accordance with ISO 2859-1 Special Inspection Level S-2.

6.11.2. **Testing**

- a. In accordance with test method in ISO 4074:2015.
- b. The condoms in their packages are weighed on an analytical balance. The packages are then opened and the condoms removed.
- c. 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).
- d. The weight of lubricant and dressing material will be the difference in weight of the condom and package before and after washing.
- e. Washing and drying may be repeated several times if necessary to assure complete removal of lubricant.
- f. Alternatively, an ultrasonic bath may be used for washing, provided the washing time has been validated against repeated manual washing.
- g. For initial validation of either method, weighing is conducted after each drying.

6.11.3. **Requirement**

- a. The quantity of silicone lubricant, including powder, in the package shall be 550 ± 150 mg. With an AQL of 4.0%.

6.12. **Individual package materials and markings***

6.12.1. **Sampling**

- a. In accordance with ISO 2859-1 Special Inspection Level S-2.

6.12.2. **Testing**

- a. The sample of condom packages is visually inspected to verify the required aspects of package quality.
 - a.1
- b. **Any lot numbers on packages must be printed at the time of packaging – not pre-printed.**
- c. In addition, the following shall apply:
 - i. There shall be no evidence of leakage;
 - ii. The outside surface of the package shall be clean;
 - iii. There shall be no separation of the layers of laminate;
 - iv. Sealed packages are in strips of up to four (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;

- v. The package must be easy to open and will have a notch or serration to assist in opening;
- vi. The packages shall have the following **indelible** markings:
 - (1) Manufacturer's name;
 - (2) Lot or lot identification code (printed at the time of packaging, not pre-printed);
 - (3) Manufacturing date: month and year-labelled: Manufacturing Date;
 - (4) Expiry Date: month and year of expiry labelled in full or abbreviated as: *Exp Date* in English (the year shall be written as a four (4) digit number, and the month as a two (2) digit number);
 - (5) Natural rubber latex.

6.12.3. Quality Requirement

- a. **AQL 1%**
- b. **Compliance will be verified by visual inspection.**

7. PACKAGING FOR DELIVERY REQUIREMENTS

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

Colour of foil, flow pack and dispenser should match the colour of the condom

7.1.1. Cartons and markings*

The information on the inner box shall include:

- a. Lot or lot identification number;
- b. Month and year of manufacture (including the word *Date of Manufacture, Month, Year*) in English. The year shall be written as a four (4) digit number, and the month as a two (2) digit number;
- c. Month and year of expiry (including the words *Expiry Date, Month, Year*) in English. The year shall be written as a four (4) digit number, and the month as a two (2) digit number;
- d. Name and address of contractor;
- e. Nominal width;
- f. Number contained in the carton;
- g. Instructions for storage and handling;
- h. Natural rubber latex.

7.1.2. Sampling

- a. In accordance to ISO 2859-1 Special Inspection Level S-2.

- b. 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.
- c. 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.
- d. 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.

7.1.3. **Testing**

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

7.1.4. **Requirements**

- a. The individual requirements for the various packaging materials and packing for delivery are set out below:
 - i. The AQL for these inspections is 1%.
 - ii. Defect found in the packaging and the marking of packages for deliver shall be assessed in accordance with the following table:

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

7.2. Exterior Shipping Cartons*

- 7.2.1. **Thirty (30) 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.**
- 7.2.2. 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.

- 7.2.3. Alternatively, wire-bound, cleated plywood or nailed wood boxes are acceptable when lined with a waterproof barrier material.
- 7.2.4. The barrier material must be sealed at the edges with waterproof tape or adhesive, and there must be no sharp protrusions inside the boxes.
- 7.2.5. 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:
- a. Lot or lot identification number;
 - b. Month and year of manufacture (including the words *Date of Manufacture, Month, Year*) in English. The year shall be written as a four (4) digit number, and the month as a two (2) digit number;
 - c. Month and year of expiry (including the words *Expiry Date, Month, Year*) in English. The year shall be written as a four (4) digit number, and the month as a two (2) digit number;
 - d. Name and address of contractor;
 - e. Nominal width;
 - f. Number contained in the carton;
 - g. Instructions for storage and handling;
 - h. Natural rubber latex.

7.3. **Lot Traceability***

- 7.3.1. To facilitate monitoring of LOT quality during shipping and storage, all exterior-shipping cartons for each discrete LOT shall be assembled and shipped together.
- 7.3.2. 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.
- 7.3.3. 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.

- 7.3.4. **Each LOT or LOT identification code shall start with the suppliers four (4) digit SABS mark holder registration number followed by a three (3) letter contractor identifier, followed by a unique lot number e.g. 1234/ABC/030/001.**

8. SUMMARY OF REQUIREMENTS

8.1. Pre-tender award: Summary of compliance testing and requirements

Sampling according to ISO 2859-1 and Annex B isolated in ISO 4074:2015				
	Test	Sampling	Requirements	Responsibility
8.1.1.	Verification of constituent materials	N/A	Manufacture's documentation	SABS
8.1.2.	Verification of shelf-life	N/A	Manufacture's documentation	Bidders and NDoH
8.1.3.	Bursting volume (before and after oven conditioning)	Level G-I Minimum Code Letter M	Individual test item if burst volume 16,0 dm ³ for condoms width ≥ 45,0mm and >50,0 mm Individual test item if burst volume 18,0 dm ³ for condoms width ≥ 50,0mm and >56,0 mm Individual test item if burst volume 22,0 dm ³ for condoms width ≥56,0 mm and >65,0 mm Individual test item if burst volume 28,0 dm ³ for condoms width ≥65,0 mm and >75,0mm Burst pressure 1 kPa	SABS
8.1.4.	Bursting pressure (before and after oven conditioning)	Level G-I Minimum Code Letter M	Minimum pressure 1.0 kPa AQL 1.5	SABS
8.1.5.	Freedom from holes	Level G-I Minimum Code Letter M	AQL 0.25.	SABS
8.1.6.	Visible defects	Level G-I Minimum Code Letter M	Critical defects: AQL 0.4 Non-critical defects: AQL 2.5	SABS

Sampling according to ISO 2859-1 and Annex B isolated in ISO 4074:2015				
	Test	Sampling	Requirements	Responsibility
8.1.7.	Shape and Texture	Agreed between manufacturer and buyer	Visual inspection	SABS
8.1.8.	Package integrity	Level S-3 Minimum Code Letter H	AQL 2.5	SABS
8.1.9.	Integral Bead	Agreed between manufacturer and buyer	Visual inspection	SABS
8.1.10.	Colour	Agreed between manufacturer and buyer	Visual inspection	SABS
8.1.11.	Fragrance	Agreed between manufacturer and buyer	Sensory inspection	SABS
8.1.12.	Width	Level S-2	± 2 mm of claimed width AQL 1.0	SABS
8.1.13.	Length	Level S-2	1. 165 mm for width less than 50 mm 2. 180 mm for width between 50 mm and 55.5 mm 3. 190 mm for width of 56.0 and above AQL 1.0	SABS
8.1.14.	Thickness	Level S-2	0.045-0.080 mm AQL 1.0	SABS
8.1.15.	Lubricant quantity (including powder)	Level S-2	Qty: 400-700—mg/condom AQL 4.0	SABS
8.1.16.	Odour (if necessary)	Agreed between manufacturer and buyer	Sensory inspection	SABS
8.1.17.	Inner box	Level S-3	Compliant with procurement specifications	SABS
8.1.18.	Exterior shipping cartons	Level S-2	Compliant with procurement specifications	SABS
8.1.19.	Bursting volume (before oven conditioning)	Level G-I	Individual test item if burst volume 16,0 dm ³ for condoms width ≥ 45,0mm and >50,0 mm	SABS

Sampling according to ISO 2859-1 and Annex B isolated in ISO 4074:2015				
	Test	Sampling	Requirements	Responsibility
			Individual test item if burst volume 18,0 dm ³ for condoms width ≥ 50,0mm and >56,0 mm Individual test item if burst volume 22,0 dm ³ for condoms width ≥56,0 mm and >65,0 mm Individual test item if burst volume 28,0 dm ³ for condoms width ≥65,0 mm and >75,0mm Burst pressure 1 kPa	
8.1.20.	Bursting pressure (before oven conditioning)	Level G-I	Minimum pressure 1.0 kPa AQL 1.5	SABS
8.1.21.	Freedom from holes	Level G-I Minimum Code Letter M	AQL 0.25	SABS
8.1.22.	Visible defects	Level G-I Minimum Code Letter M	Critical defects: AQL 0.4 Non-critical defects: AQL 2.5	SABS
8.1.23.	Shape and texture	Agreed between manufacturer and buyer	Visual Inspection	SABS
8.1.24.	Package integrity	Level S-3	AQL 2.5	SABS
8.1.25.	Integral Bead	Agreed between manufacturer and buyer	Visual Inspection	SABS
8.1.26.	Colour	Agreed between manufacturer and buyer	Visual Inspection	SABS
8.1.27.	Fragrance	Agreed between manufacturer and buyer	Sensory Inspection	SABS

Sampling according to ISO 2859-1 and Annex B isolated in ISO 4074:2015				
	Test	Sampling	Requirements	Responsibility
8.1.28.	Width	Level S-2	± 2mm of claimed with AQL 1.0	SABS
8.1.29.	Length	Level S-2	1. 165 mm for width less than 50 mm 2. 180 mm for width between 50 mm and 55.5 mm 3. 190 mm for width of 56.0 and above AQL 1.0	SABS
8.1.30.	Thickness	Level S-2	0.045-0.080 mm AQL 1.0	SABS
8.1.31	Lubricant quantity (including powder)	Level S-2	Qty: 400-700 mg/condom AQL 4.0	SABS
8.1.31.	Odour (if necessary)	Agreed between manufacturer and buyer	Sensory Inspection	SABS
8.1.32.	Inner box	Level S-3	Compliant with procurement specifications	SABS
8.1.33.	Exterior shipping cartons	Level S-2	Compliant with procurement specifications	SABS

8.2. Summary of requirements for which tests are specified

	Specification	#	Sampling	Testing	Requirements	AQL	Responsibility
8.2.1.	General requirements						
a.	Constituent materials	1.1.	N/A	N/A	Documentation	N/A	SABS
b.	Shelf-life	1.2.	3 lots/650 each	See Specification 1.2.	Documentation		Bidder and NDoH
8.2.2.	Performance requirements						

	Specification	#	Sampling	Testing	Requirements	AQL	Responsibility
a.	Bursting volume	2.1.	C-1*	ISO 4074:2015 See Specification	Width ² /150	1.0.	SABS
b.	Bursting volume 70°C/7 days	2.1.	80 Condoms	ISO 4074:2015 and WHO:2010	<20% drop		SABS
c.	Bursting pressure	2.1.	G-1*	ISO 4074:2015	1kPa	1.0	SABS
d.	Bursting pressure 70°C/7 days	2.1.	80 Condoms	ISO 4074:2015 and WHO:2010	<20% drop		SABS
e.	Freedom of holes	2.2.	G-1*	ISO 4074:2015 See Specification	<3 holes	0.25	SABS
f.	Package integrity	2.3.	S-2/S-3*	See specification	<3 leaks	2.5	SABS
3.2.3.	Design requirement						
a.	Length	3.5.	S-2*	ISO 4074:2015	≥180 mm	1.0	SABS
b.	Width	3.6.	S-2*	ISO 4074:2015	53 ± 2 mm; mean 52 ± 1 mm	1.0	SABS
c.	Thickness	3.7.	S-2*	See Specification	0,065 ± 0,015 mm	1.0	SABS
d.	Lubricant plus Powder	3.8.	S-2*	See Specification	550 ± 150 mg	4.0	SABS
3.2.4.	Packaging requirement						
a.	Package Material and Markings	4.1.	S-3*	See Specification See Specification	Visual Inspection	2.5	SABS