**RT75-2021** **ANNEXURE C**
**FEMALE CONDOMS**

**CONDOMS, FEMALE, FOR USE DURING INTERCOURSE**

**QUANTITIES REQUIRED**

**120 MILLION UNITS OVER 3 YEARS**

**YEAR 1: 40 MILLION UNTS**
**YEAR 2: 40 MILLION UNTS**
**YEAR 3: 40 MILLION UNTS**

**DISAGGREGATED BY COLOUR AND SCENT AS FOLLOWS**

Strawberry: Twenty (20) Million red colour and strawberry scent
Vanilla: Ten (10) Million Cream colour and Vanilla scent
Caramel :Ten (10) Million Nude/brown colour with caramel scent

**PACKAGING: INDIVIDUALLY PACKED**

**SAMPLES TO BE SUBMITTED TO SABS, IN QUANTITIES REQUIERED AS PER SABS SPECIFICATIONS**

## 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 method used to test for compliance is: Availability of the SABS mark***

**Female condoms should be designed and produced in accordance with a good quality management system in compliance with ISO 14971 and ISO13485. Bidders shall provide certification of analysis (COA).**

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Female condoms shall be free from holes and defects, have adequate physical properties so as not to break during use, be correctly packaged to protect them during storage, and correctly labelled to facilitate their use.

The lubricant applied to female condom shall not contain or liberate any substances in amounts that are toxic, sensitizing, locally irritating or otherwise harmful under normal conditions of storage and use.

Manufacturers shall conduct stability tests to ensure adequate data to support shelf life claims. The data should be made available for review by regulatory authorities, third party test laboratories and purchasers on request (COA may be requested).

A practicable method for assessing conformity is by testing a representative sample from a lot or series of lots. Basic sampling plans shall be in accordance with ISO 2859-1. It is necessary to know the lot size in order to obtain the number of female condoms to be tested.

Unless specifically indicated otherwise, all statistical sampling plans and acceptable quality level (AQL) values listed and referred to in this specification shall be in accordance with ISO 2859-1.

**The methods used to test for compliance are:**

- **the use of statistical samples;**
- **subjective inspection; and**
- **Documentary evidence, such as comprehensive reports of stability tests, certificate of analysis.**

**Items marked with an asterix* 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**

## 2. CONSTITUENT MATERIALS*

- The condoms shall be made from natural rubber latex (NRL) or synthetic materials that are approved by the United States Food and Drug Administration (US FDA) and endorsed by the World Health Organisation (WHO)/UNFPA.

- The material shall be free of embedded solid impurities and discoloration.

- Female condoms shall not liberate toxic or otherwise harmful substances under normal conditions of use (documentary evidence may be requested: MSDS/COA).

- The compounding materials used (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 shall be stated. Excess accelerators and other leachable chemicals shall not be used.

- Biocompatibility (in accordance with ISO 10993) tests results appropriate for a medical device in contact with non-intact breeched mucosal surfaces for extended periods shall be presented.

- Data from type testing for viral permeability shall be presented on request

***These requirements will be verified by documentary evidence (MSDS/COA).***

## 3. DESIGN*

3.1 The female condom is distinguished from a male condom in that it is retained in the vagina after insertion before sexual intercourse.

### 3.2. Product Insertion Feature*

These requirements may be verified by documentary evidence (COA and/or MSDS)

The insertion feature of a female condom design shall comply with the requirements in clause 5.2 of SANS/ISO 25841:2011 or as updated. Design for female condoms shall include either a feature or a tool to aid in the proper insertion and deployment of the female condom.

The insertion feature design, material and/or method shall be evaluated for function as part of the design validation and clinical evaluation of the finished female condom device (COA).

The insertion feature material will be evaluated for biocompatibility as an integrated feature of the finished female condom device in accordance with ISO 10993.

### 3.3. Retention Features*

The retention feature of a female condom design shall comply with the requirements in clause 5.3 of SANS/ISO 25841:2011 or as updated.

Designs for female condoms shall incorporate intra vaginal retention features to retain the female condom within the vagina during sexual intercourse and permit safe withdrawal after use.

Designs for female condom shall incorporate external retention features to keep the open end of the female condom open during sexual intercourse and to prevent misdirection of the penis, female condom invagination and slippage.

The external retention features shall include but not limited to annular, triangular or other shaped components affixed to the open end of the female condom

Retention feature materials shall be evaluated for biocompatibility as an integrated feature of the finished female condom device in accordance with ISO 10993.

3.3.1

Colour and clarity

The condoms shall be colourless (natural) or coloured as per specifications. Pigments used for coloured condoms shall be suitable for use in medical devices. The coloured condoms shall be of different specified colours and quantities as per specifications (MSDS and/or COA may be requested). The insertion feature shall be colourless.

3.3.2. Odour/fragrance

The condoms shall not give an unpleasant odour when the package is opened at any time after manufacturer and for the shelf life of the product. The condoms will be scented as per specifications. The scent must be non-toxic, non irritant and not degrade the rubber/constituent material.

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

All the condoms shall be tasteless.

## 3.4 LUBRICATION*

The design of a female condom shall include lubrication pre-applied directly on the packaged condom. The range for the mass of lubricant shall be specified by the manufacturer based on the amount of lubricant used in the clinical trial.

When tested in accordance with the method given in Annex C of SANS/ISO 25841:2011 or as updated, taking 13 female condoms per lot, the mass of lubricant mass measurement shall not exceed the manufacturer’s specified range.

## 3.5 DIMENSIONS

### 3.5.1. Length*

The range of the length of the female condom shall be specified by the manufacturer based on the female condoms used in the clinical trial.

When tested in accordance with the method given in Annex D of SANS/ISO 25841:2011 or as updated, taking 13 female condoms per lot, the length measurement shall not exceed the manufacturer’s specified range.

### 3.5.2 Width*

The range of the width of the female condom shall be specified by the manufacturer based on the female condoms used in the clinical trial.

When tested in accordance with the method given in Annex E of SANS/ISO 25841:2011 or as updated, taking 13 female condoms per lot, the width measurement shall not exceed the manufacturer's specified range.

### 3.5.3. Thickness*

The range of the thickness of the female condom shall be specified by the manufacturer based on the female condoms used in the clinical trial

When tested in accordance with the method given in Annex F of SANS/ISO 25841:2011 or as updated, taking 13 female condoms per lot, the female condom thickness measurement shall not exceed the manufacturer's specified range.

## 3.6 Risk assessment

A risk assessment for the product shall be conducted in accordance with ISO14971. The assessment shall identify potential failure modes for the device as well as any other safety and efficacy concerns.
Manufacturers shall make available the results of the risk assessment for the design as described in annexure G of SANS/ISO 25841:2011 or as updated.

## 4. PERFORMANCE REQUIREMENTS*

## 4.1 Air burst properties*

The minimum values for burst pressure and volume shall be established in accordance with on clause 9.1 of the SANS/ISO 25841:2011 or as updated.

### 4.1.1 Minimum value

The minimum bursting volumes and bursting pressures shall be established in accordance with clause 9.1 of SANS/ISO 25841:2011 or as updated.

### 4.1.2 Sampling and requirements

When tested in accordance with the method in SANS/ISO 25841:2011 or as updated. The burst volumes and burst pressures shall not be less than the minimum values established by the procedures described in 9.1of the International Standard.

General Inspection Level I of ISO 2859-1 shall be used for a continuing series of lots.

## 5.0 TEST FOR STABILITY REQUIREMENTS

## 5.1 General

Manufacturers shall verify that the female condom conform with the airburst, freedom from holes, visible defects and labelling requirements given in clauses 9, 11, 12, and 13 of the SANS/ISO 25841:2011 or as updated until the end of the labelled shelf life. Shelf life claims shall not exceed five years.

## 5.2 Minimum stability requirements

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Three lots of female condoms shall be tested for conformity prior to stability testing for conformity with clauses 9, 11, 12, and 13 of ISO/DIS 25841(2007-05-04) using the sampling plans given in Annexure A ( for continuing series of lot)

### 5.3 Procedure for determining shelf life by real time stability studies

After testing in accordance with Annexure K female condoms shall comply with the requirements given in clause 9, 11, 12 and 13 of SANS/ISO 25841:2011 or as updated.

The NDOH shall be notified if the real time data indicate a shorter shelf life than that claimed on the basis of the accelerated test study. The manufacturer shall change the shelf life claim to the one based on the real time study.

### 5.4 Estimating shelf life based on accelerated stability studies

Shelf life estimates for accelerated stability studies shall be based on a mean kinetic temperature of 30°C. The manufacturer may use the method described in Annexure L of the SANS/ISO 25841:2011 or as updated to conduct accelerated stability studies.

## 6. FREEDOM FROM HOLES*

Female condoms shall be tested for freedom from holes in accordance with the requirements and clause 11 of SANS/ISO 25841:2011 or as updated.

## 7. VISIBLE DEFECTS*

Female condoms shall be tested for visible defects as described in Annexure J of SANS/ISO 25841:2011 or as updated. The AQL and inspection level established in Annexures A and B shall apply.

## 8. PACKAGING AND LABELLING*

### 8.1 Package Integrity*

Individual female condom packages shall be tested for package integrity in accordance with clause 13.1 of SANS/ISO 25841:2011 or as updated. The AQL shall be 2.5. **(To be verified by SABS)**

### 8.2 Packaging*

Each female condom shall be packed in an individual sealed container unit flow wrap sachet with top tear notch. The lot number, expiry date, the words “Department of Health South Africa” and “NOT FOR SALE” shall be printed at the time of packaging.

100 sachets shall be packed into a box, and (9-12) boxes shall be packed into a shipping carton.(.Note: 9 for continuous sampling lot AND 12 for isolated sampling lot)

### 8.3 Labelling*

#### 8.3.1 Individual containers

Each individual container shall be marked with the following information:

a) The identity of the manufacturer
b) The manufacturer identifying reference for traceability

c) The expiry date (year and month)

### 8.3.2 Consumer packages*

#### 8.3.2.1 General

The outside of the consumer package shall bear at least the following information:

a) Description of the female condom
b) The expiry date (year and month)
c) A statement of appropriate storage conditions for the female condom material
d) The manufacturer's identifying reference for traceability
e) A statement indicating the type of female condom material

#### 8.3.2.2 Additional information for the consumer

The outside of the consumer package, or leaflet contained within the consumer package, shall bear at least the following information, expressed in simple terms and in at least one of the official languages and/or pictorial representations of the major steps involved

a) instructions for use of female condom and
b) a statement that the female condom is for single use only
c) instruction for disposal

### 8.4 Inspection

9-12 consumer packages and 13 individual containers shall be selected from each lot and examined for conformity with clause 13.1, 13.2 and 13.3 of SANS/ISO 25841:2011 or as updated.

## SUMMARY OF REQUIREMENTS AND RESPONSIBILITIES

**FEMALE CONDOMS**

| **REQUIREMENTS** | **RESPONSIBILITY** |
|---|---|
| **GENERAL REQUIREMENTS** | |
| Constituent materials | **SABS** |
| Shelf-life | **Bidders, NDOH, NT and SABS** |
| **PERFORMANCE REQUIREMENTS** | |
| Bursting volume | **SABS** |
| Freedom from holes | **SABS** |
| Package integrity | **SABS** |
| **DESIGN REQUIREMENT** | |
| Length | **SABS** |
| Width | **SABS** |
| Thickness | **SABS** |
| Lubricant | **SABS** |
| **PACKAGING REQUIREMENT** | |
| Package Materials and Markings | **SABS** |