INVITATION TO BID

Department:
Health
REPUBLIC OF SOUTH AFRICA

HM01-2015CNDM

SUPPLY AND DELIVERY OF MALE AND FEMALE CONDOMS AND LUBRICANT TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 1 JULY 2015 TO 30 JUNE 2018

Non-compulsory Briefing Session
Venue: Impilo Boardroom, Podium
Civitas Building
Corner Struben & Thabo Sehume Street Pretoria
Date: 5 March 2015
Time: 13H00 - 15H00

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH
PRIVATE BAG X828
PRETORIA
0001

Fax: (012) 395-8823

Telephone: (012) 395 8439

Enquiries: Ms P Moloko

Reference: HM01-2015CNDM

Tender description

REQUIRED BY: NATIONAL DEPARTMENT OF HEALTH

1. Kindly furnish us with a tender for the supplies shown on the attached forms.

2. Included are the General Conditions of Contract (GCC) and Special Requirements and Conditions of Contract as well as the attached Annexures A, B & C , SBD1, SBD 2, SBD 4, SBD 5, SBD 6.1, SBD 8, SBD 9, Bid Response Document and Bid Authorisation Declaration (PBD1) Supplier Details (PBD 4). Declaration of compliance with Good Manufacturing Practice (GMP) PBD5.

3. The complete document with the attached forms must be completed in detail and returned with your bid (Invitation to Bid document all pages). Each bid document must be submitted in a separate envelope on stipulation of the following information: Full name of Contact Person, Full name and Address of the Bidder, Bid Number and Closing Date of Bid.

4. The bid must be addressed to the Director-General, Department of Health, and be deposited **into the bid box** as indicated in SBD1 form not later than the closing date and time. The bid box is located in the main entrance of the Department of Health, located on the corner of Struben and Thabo Sehume Streets, Civitas building, Pretoria.

K. Jamaloodien

Ms K Jamaloodien
DIRECTOR: Affordable Medicine
For DIRECTOR GENERAL

Sign_____

SBD 1

INVITATION TO BID

YOU ARE HEREBY INVITED TO BID FOR REQUIREMENTS OF THE NATIONAL DEPARTMENT OF HEALTH

BID NUMBER: **HM01-2015CNDM**	CLOSING DATE**: 16 MARCH 2015**	CLOSING TIME: **11:00**

DESCRIPTION:**Supply and Delivery of Male and Female Condoms and Lubricant to the Department of Health for the period 1 July 2015 to 30 June 2018**

The successful bidder/s will be required to fill in and sign a written Contract Form (SBD 7).

Bid documents must be addressed as follows and delivered before the closing date and time:

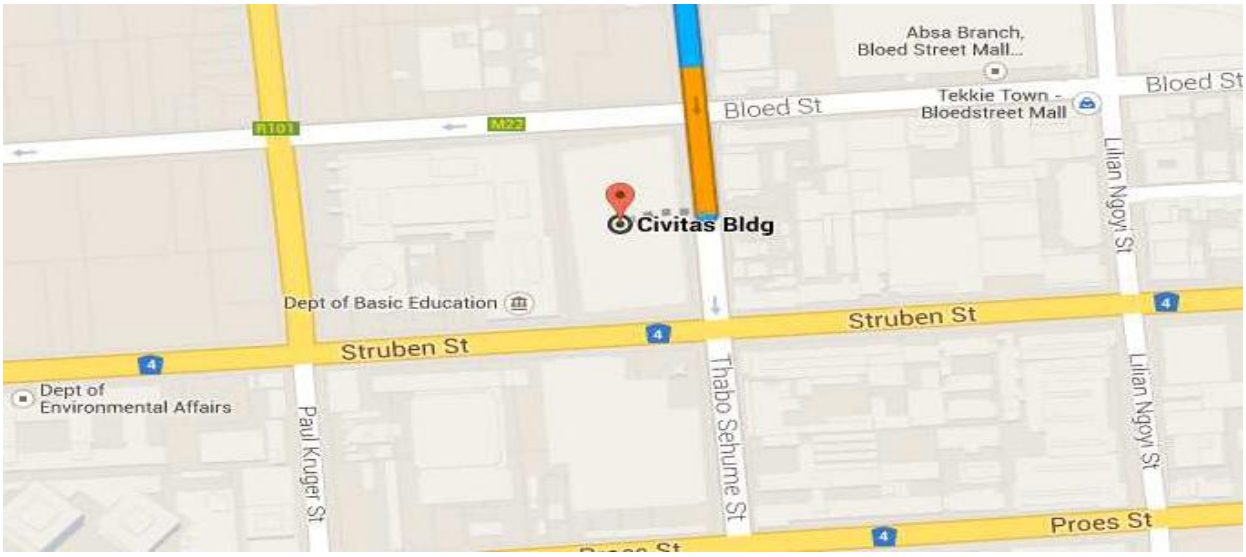
Addressed to:
The Director-General: Health
Civitas Building
C/o Struben and Thabo Sehume Streets,
Pretoria

Delivered to:
Pharmaceutical Tender Box
Reception Area
National Department of Health
Civitas Building,
C/o Struben and Thabo Sehume Streets,
Pretoria

Bidders should ensure that bids are delivered on time to the correct address and deposited in the Pharmaceutical Tender Box. Late bids will not be accepted for consideration

The Pharmaceutical Tender Box is generally accessible during extended working hours.

See below for map locating Civitas Building within Pretoria Central Business District.



ALL BIDS MUST BE SUBMITTED ON THE OFFICIAL FORMS

This competitive bidding process is subject to the Preferential Procurement Policy Framework Act and the Preferential Procurement Regulations, 2011, the General Conditions Of Contract (GCC) and, if applicable, any other Special Requirements and Conditions Of Contract

National Department of Health Affordable Medicines Directorate Contacts

Please use the following e-mail address and contact persons for any queries relating to bidding process:

Ms M Rasengane	Ms P Moloko
Tel: (012) 395 9452	Tel: (012) 395 8439
Fax number: (012) 395 8823	
Email: medtenders@health.gov.za	

BID DOCUMENTS FOR COMPLETION AND SUBMISSION

Bidders MUST submit the following completed documents and certificates:

- SBD1: Invitation to bid
- SBD2: Tax Clearance Certificate: Certificate must be original and valid
- SBD4: Declaration of Interest
- SBD5: The National Industrial Participation Programme
- SBD6.1: Preference points claim form in terms of the Preferential Procurement Regulations 2011
- SBD8: Declaration of bidder's past supply chain management practices
- SBD9: Certificate of independent bid determination
- PBD1: Authorisation Declaration (if applicable)
- PBD3: Due Diligence Questionnaire (if applicable)
- PBD4: Supplier details
- PBD5: Declaration of compliance with Good Manufacturing Practice (GMP)
- Bid Response Documents: Completion of all response fields per item offered is mandatory.
- B-BBEE Status Level Verification Certificate (if applicable) (Certified Copy)
- Completed Bid Response Document for all items offered
- Certified document of the CIPC document (Reflecting the Entity’s Registration Number and Registered Name)

COMPLETION OF DOCUMENTS AND BID SUBMISSION

Bidders are required to submit three sets of bid documents according to the instructions below. All three sets must be submitted before the closing date and time. Set 2 and Set 3 must be included on a CD with Set 1 and submitted in **a sealed** envelope. The full name and address of the bidder, including the return address, the bid number and the closing date must be clearly indicated on the envelope. All fields must be completed. Where information requested is not relevant this should be indicated with N/A.

Set 1: Hard copy legally binding bid documents

Bidders must complete the all SBD, PBD and Bid Response forms in black ink, typed. Where no electronic entry field is provided bidders must complete the forms in black ink, handwritten in capital letters. The signed hard copy of the bid document will serve as the legal bid document. Bidders must submit their complete bid in hard copy format (paper document). The Chief Executive Officer, Chief Financial Officer, or authorised designee of the entity submitting the bid must sign the official signature pages. All pages in the complete bid document must be initialled by same with black ink. The use of correction fluid is not acceptable. Any change/s must be clearly indicated and initialled.

Set 2: PDF Image of Scanned Hard Copy, signed legal documents.

Bidders must submit a scanned, PDF version of the entire signed hardcopy bid, including all certificates and documents requested. (I.e. Scanned PDF version of Set 1)

Set 3: Electronic version of bid documents

Bidders must submit the electronic versions of all SBD and PBD documents and Bid Response Document. (I.e. PDF documents saved with electronic inputs, or printed to PDF writer, and Bid Response Document in Excel).

All three sets of information must be submitted in order for the bid to be evaluated.
Ensure that the bid price is offered for the product as specified.

SBD1

The following particulars must be furnished

FAILURE TO DO SO WILL RESULT IN YOUR BID BEING DISQUALIFIED

Name of Bidder:				
Postal Address:				
		Code		
Street Address:				
Telephone Number:	Code:		Number	
Cell phone Number:				
Facsimile Number:	Code:		Number	
E-mail Address:				
Vat Registration Number:				
Has an original and valid tax clearance certificate been submitted? (SBD2)	Yes ○		No ○	
Has A B-BBEE Status Level Verification Certificate been submitted? (SBD 6.1)	Yes ○		No ○	

If yes, who was the certificate issued by? Please tick applicable box

An accounting officer as contemplated in the Close Corporation Act (CCA) ○

A Verification Agency Accredited By The South African Accreditation System (SANAS) ○

A Registered Auditor ○

A B-BBEE status level verification certificate must be submitted in order to qualify for preference points for B-BBEE.

Are you the accredited representative in South Africa for the goods/ services/works offered	Yes ◯ No ◯ **(If yes enclose proof)**
Contact person:	
Signature of bidder:	
Date:	
Capacity under which this bid is signed:	
Total bid price:	R
Total number of items offered (Include separate list of items offered):	

SBD 2

TAX CLEARANCE CERTIFICATE REQUIREMENTS

It is a condition of bid that the taxes of the successful bidder must be in order, or that satisfactory arrangements have been made with South African Revenue Service (SARS) to meet the bidder's tax obligations.

1 In order to meet this requirement bidders are required to complete in full the attached form TCC 001 "Application for a Tax Clearance Certificate" and submit it to any SARS branch office nationally. The Tax Clearance Certificate Requirements are also applicable to foreign bidders / individuals who wish to submit bids.

2 SARS will then furnish the bidder with a Tax Clearance Certificate that will be valid for a period of 1 (one) year from the date of approval.

3 The original Tax Clearance Certificate must be submitted together with the bid. Failure to submit the original and valid Tax Clearance Certificate will result in the invalidation of the bid. Certified copies of the Tax Clearance Certificate will not be acceptable.

4 In bids where Consortia / Joint Ventures / Sub-contractors are involved, each party must submit a separate Tax Clearance Certificate.

5 Copies of the TCC 001 "Application for a Tax Clearance Certificate" form are available from any SARS branch office nationally or on the website www.sars.gov.za.

6 Applications for the Tax Clearance Certificates may also be made via eFiling. In order to use this provision, taxpayers will need to register with SARS as eFilers through the website www.sars.gov.za.

TAX CLEARANCE
BELASTINGKLARING

TCC 001

Application for a Tax Clearance Certificate
Aansoek om ‘n Belastingklaringsertifikaat

Purpose
Doel

Select the applicable option
Kies die toepasike opsie

Tenders ☐ Tenders
Good standing ☐ Goeie stand

If “Good standing”, please state the purpose of this application
Indien “Goeie stand”, verstrek asseblief die oogmerk van hierdie aansoek

Particulars of applicant
Besonderhede van aansoeker

Name/Legal name
Naam/Geregistreerde naam

(Initials & Surname or registered name / Voorletters en Van of Geregistreerde naam)

Trading name (If applicable)
Handelsnaam (Indien van toepassing)

ID/Passport number
ID/Paspoortnommer

Company/Close Corp. reg no
Maatskappy/Beslote Korp reg nr

Income Tax ref no
Inkomstebelasting verw.nr

PAYE ref no
LBS verw.nr 7

VAT registration number
BTW registrasienommer 4

SDL ref no
SDL verw.nr L

Customs code
Doeanekode

UIF ref no
UIF verw.nr U

Telephone number
Telefoonnommer

Fax no
Faksnr

Cell phone number
Selfoonnommer

E-mail address
E-posadres

Physical address
Fisieke adres

Postal address
Posadres

Particulars of representative (Public Officer/Trustee/Partner)
Besonderhede van verteenwoordiger (Openbare Amptenaar/Trustee/Vennoot)

Surname
Van

First names
Voorname

ID/Passport no
ID/Paspoortnr

Income Tax ref no
Inkomstebelasting verw. nr

Telephone no
Telefoonnr

Fax no
Faksnr

Cell phone no
Selfoonnr

E-mail address
E-posadres

Physical address
Fisieke adres

Sign_____

Particulars of tender (If applicable)
Besonderhede van tender (Indien van toepasing)

Tender number
Tendernommer

Estimated tender amount
Geraamde tenderbedrag R ,

Expected duration of the tender
Verwagte duurte van die tender Year(s)
Jaar (jare)

Audit
Oudit

Are you currently aware of any Audit investigation against you/the company?
Is u bewus van enige oudit ondersoek teen u/die maatskappy? YES JA NO NEE
If "YES" provide details
Indien "JA" verskaf besonderhede.

Appointment of representative/agent (Power of Attorney)
Aanstelling van 'n verteenwoordiger/agent (Magtingingsbrief)

I the undersigned confirm that I require a Tax Clearance Certificate in respect of Tenders or Goodstanding.
Ek die ondergetekende bevestig dat ek 'n Belastingklaring benodig ten opsigte van Tenders of Goeie Stand.

I hereby authorise and instruct to apply to and receive from SARS the applicable
Hiermee gee ek volmag en opdrag aan om namens my aansoek te doen en my

Tax Clearance Certificate on my/our behalf.
Belastingklaringsertifikaat namens my in ontvangs te neem by SARS

Signature of representative/agent
Handtekening van verteenwoordiger/agent

C C Y Y — M M — D D
Date
Datum

Name of representative/ agent
Naam van verteenwoordiger/ agent

Declaration
Verklaring

I declare that the information furnished in this application as well as any supporting documents are true and correct in every respect.
Hiermee verklaar ek dat die inligting verskaf in hierdie aansoek asook enige ondersteunende dokumentasie waar en korrek is in alle opsigte.

Signature of a Taxpayer/Representative Taxpayer
Handtekening van aansoeker/Openbare Amptenaar

C C Y Y — M M — D D
Date
Datum

Name of Taxpayer/Representative Taxpayer
Naam van aansoeker/Openbare Amptenaar

Notes
Notas

1. Non compliance with the provisions of any tax Act is an offence.
   Nie-nakoming van die bepalings van enige Wet is 'n oortreding.
2. **SARS will, under no circumstances, issue a Tax Clearance Certificate unless this form is completed in full.**
   SARS sal in geen omstandighede u aansoek om 'n Belastingklaringsertifikaat oorweeg tensy die aansoek volledig voltooi is nie.
3. Your Tax Clearance Certificate will only be issued on presentation of your South African Identity Document or Passport (Foreigners only) as applicable.
   U Belastingklaringsertifikaat sal alleenlik uitgereik word by die toon van u Suid-Afrikaanse Identiteisdokument of in die geval van 'n buitelander, 'n paspoort.

Sign_____

SBD 4

DECLARATION OF INTEREST

1. Any legal person, including persons employed by the state[1], or persons having a kinship with persons employed by the state, including a blood relationship, may make an offer or offers in terms of this invitation to bid (includes an advertised competitive bid, a limited bid, a proposal or written price quotation). In view of possible allegations of favouritism, should the resulting bid, or part thereof, be awarded to persons employed by the state, or to persons connected with or related to them, it is required that the bidder or his/her authorised representative declare his/her position in relation to the evaluating/adjudicating authority where-

- the bidder is employed by the state; and/or
- the legal person on whose behalf the bidding document is signed, has a relationship with persons/a person who are/is involved in the evaluation and or adjudication of the bid(s), or where it is known that such a relationship exists between the person or persons for or on whose behalf the declarant acts and persons who are involved with the evaluation and or adjudication of the bid.

2. In order to give effect to the above, the following questionnaire must be completed and submitted with the bid.

2.1	Full Name of bidder or his or her representative:	
2.2	Identity Number:	
2.3	Position occupied in the Company (director, trustee, shareholder[2], member)	
2.4	Registration number of company, enterprise, close corporation, partnership agreement or trust	
2.5	Tax Reference Number:	
2.6	VAT Registration Number:	

The names of all directors / trustees / shareholders / members, their individual identity numbers, tax reference numbers and, if applicable, employee/PERSAL numbers must be indicated in paragraph 3 below.

[1]"State" means –

(a) any national or provincial department, national or provincial public entity or constitutional institution within the meaning of the Public Finance Management Act, 1999 (Act No. 1 of 1999);
(b) any municipality or municipal entity;
(c) provincial legislature;
(d) national Assembly or the national Council of provinces; or
(e) Parliament.

[2]"Shareholder" means a person who owns shares in the company and is actively involved in the management of the enterprise or business and exercises control over the enterprise.

2.7 Are you or any person connected with the bidder presently employed by the state? **Yes** ◯ **No** ◯

If so, furnish the following particulars:

2.7.1 Name of person/director/trustee/ shareholder/member:	
Name of state institution at which you or the person connected to the bidder is employed:	
Position occupied in the state institution:	
Any other particulars:	

2.7.2 If you are presently employed by the state, did you obtain the appropriate authority to undertake remunerative work outside employment in the public sector? **Yes** ◯ **No** ◯

2.7.2 If yes, did you attach proof of such authority to the bid document? **Yes** ◯ **No** ◯

(Note: Failure to submit proof of such authority, where applicable, may result in the disqualification of the bid.)

2.7.3 If no, furnish reasons for non-submission of such proof:

2.8 Did you or your spouse, or any of the company's directors /trustees / shareholders / members or their spouses conduct business with the state in the previous twelve months? **Yes** ◯ **No** ◯

2.8.1 If so, furnish particulars:

2.9 Did you or your spouse, or any of the company's directors / trustees / shareholders / members or their spouses conduct business with the state in the previous twelve months? **Yes** ◯ **No** ◯

2.9.1 If so, furnish particulars:

2.10 Are you, or any person connected with the bidder, aware of any relationship (family, friend, other) between any other bidder and any person employed by the state who may be involved with the evaluation and or adjudication of this bid?

Yes ◯ **No** ◯

2.10.1 If so, furnish particulars:

2.11 Do you or any of the directors / trustees / shareholders / members of the company have any interest in any other related companies whether or not they are bidding for this contract?

Yes ◯ **No** ◯

2.11.1 If so, furnish particulars:

3 Full details of directors/trustees/members/shareholders.

Full Name	Identity Number	Personal Income Tax Reference Number	State Employee Number / Persal Number

SBD 4

4 DECLARATION

I, the undersigned (name)	

certify that the information furnished in paragraphs 2 and 3 above is correct.

I accept that the state may reject the bid or act against me should this declaration prove to be false

Name of bidder:			
Position:			
Signature:		Date	

SBD5

This document must be signed and submitted together with your bid

THE NATIONAL INDUSTRIAL PARTICIPATION PROGRAMME

INTRODUCTION

The National Industrial Participation (NIP) Programme, which is applicable to all government procurement contracts that have an imported content, became effective on the 1 September 1996. The NIP policy and guidelines were fully endorsed by Cabinet on 30 April 1997. In terms of the Cabinet decision, all state and parastatal purchases / lease contracts (for goods, works and services) entered into after this date, are subject to the NIP requirements. NIP is obligatory and therefore must be complied with. The Industrial Participation Secretariat (IPS) of the Department of Trade and Industry (DTI) is charged with the responsibility of administering the programme.

1. PILLARS OF THE PROGRAMME

1.1 The NIP obligation is benchmarked on the imported content of the contract. Any contract having an imported content equal to or exceeding US$ 10 million or other currency equivalent to US$ 10 million will have a NIP obligation. This threshold of US$ 10 million can be reached as follows:

(a) Any single contract with imported content exceeding US$10 million.

(b) Multiple contracts for the same goods, works or services each with imported content exceeding US$3 million awarded to one seller over a 2 year period which in total exceeds US$10 million.

(c) A contract with a renewable option clause, where should the option be exercised the total value of the imported content will exceed US$10 million.

(d) Multiple suppliers of the same goods, works or services under the same contract, where the value of the imported content of each allocation is equal to or exceeds US$ 3 million worth of goods, works or services to the same government institution, which in total over a two (2) year period exceeds US$10 million.

1.2 The NIP obligation applicable to suppliers in respect of sub-paragraphs 1.1 (a) to 1.1 (c) above will amount to 30% of the imported content whilst suppliers in respect of paragraph 1.1 (d) shall incur 30% of the total NIP obligation on a *pro-rata* basis.

1.3 To satisfy the NIP obligation, the DTI would negotiate and conclude agreements such as investments, joint ventures, sub-contracting, licensee production, export promotion, sourcing arrangements and research and development (R&D) with partners or suppliers.

1.4 A period of seven years has been identified as the time frame within which to discharge the obligation.

2 REQUIREMENTS OF THE DEPARTMENT OF TRADE AND INDUSTRY

2.1 In order to ensure effective implementation of the programme, successful bidders (contractors) are required to, immediately after the award of a contract that is in excess of R10 million (ten million Rands), submit details of such a contract to the DTI for reporting purposes.

2.2 The purpose for reporting details of contracts in excess of the amount of R10 million (ten million Rands) is to cater for multiple contracts for the same goods, works or services; renewable contracts and multiple suppliers for the same goods, works or services under the same contract as provided for in paragraphs 1.1.(b) to 1.1. (d) above.

3 BID SUBMISSION AND CONTRACT REPORTING REQUIREMENTS OF BIDDERS AND SUCCESSFUL BIDDERS (CONTRACTORS)

3.1 Bidders are required to sign and submit this Standard Bidding Document (SBD 5) together with the bid on the closing date and time.

3.2 In order to accommodate multiple contracts for the same goods, works or services; renewable contracts and multiple suppliers for the same goods, works or services under the same contract as indicated in sub-paragraphs 1.1 (b) to 1.1 (d) above and to enable the DTI in determining the NIP obligation, successful bidders (contractors) are required, immediately after being officially notified about any successful bid with a value in excess of R10 million (ten million Rands), to contact and furnish the DTI with the following information:

- Bid/contract number.
- Description of the goods works or services.
- Date on which the contract was accepted.
- Name, address and contact details of the government institution.
- Value of the contract.
- Imported content of the contract, if possible.

3.3 The information required in paragraph 3.2 above must be sent to the Department of Trade and Industry, Private Bag X84, Pretoria, 0001 for the attention of Mr Elias Malapane within five (5) working days after award of the contract. for further details about the programme, contact Mr Malapane on telephone (012) 394 1401, facsimile (012) 394 2401 or e-mail at Elias@thedti.gov.za .

4 PROCESS TO SATISFY THE NIP OBLIGATION

4.1 Once the successful bidder (contractor) has made contact with and furnished the DTI with the information required, the following steps will be followed:

a. the contractor and the DTI will determine the NIP obligation;
b. the contractor and the DTI will sign the NIP obligation agreement;
c. the contractor will submit a performance guarantee to the DTI;
d. the contractor will submit a business concept for consideration and approval by the DTI;
e. upon approval of the business concept by the DTI, the contractor will submit detailed business plans outlining the business concepts;
f. the contractor will implement the business plans; and
g. the contractor will submit bi-annual progress reports on approved plans to the DTI.

4.2 The NIP obligation agreement is between the DTI and the successful bidder (contractor) and, therefore, does not involve the purchasing institution.

Bid number:		Closing date:	
Name of bidder:			
Postal address:			
Name in print:			
Signature:		Date:	

SBD 6.1

PREFERENCE POINTS CLAIM FORM IN TERMS OF THE PREFERENTIAL PROCUREMENT REGULATIONS 2011

This preference form must form part of all bids invited. It contains general information and serves as a claim form for preference points for Broad-Based Black Economic Empowerment (B-BBEE) Status Level of Contribution

Note: Before completing this form, bidders must study the General Conditions, definitions and directives applicable in respect of B-BBEE, as prescribed in the Preferential Procurement Regulations, 2011.

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1. **GENERAL CONDITIONS**

1.1 The following preference point systems are applicable to all bids:

- the 80/20 system for requirements with a Rand value of up to R1 000 000 (all applicable taxes included); and
- the 90/10 system for requirements with a Rand value above R1 000 000 (all applicable taxes included).

1.2 The value of this bid is estimated to exceed/not exceed R1 000 000 (all applicable taxes included) and therefore the …90/10……system shall be applicable.

1.3 Preference points for this bid shall be awarded for:

(a) Price; and

(b) B-BBEE Status Level of Contribution.

1.3.1 The maximum points for this bid are allocated as follows:

		Points
1.3.1.1	Price	……90……..
1.3.1.2	B-BBEE status level of contribution	……10……..
	Total points for Price and B-BBEE must not exceed	**100**

1.4 Failure on the part of a bidder to fill in and/or to sign this form and submit a B-BBEE Verification Certificate from a Verification Agency accredited by the South African Accreditation System (SANAS) or a Registered Auditor approved by the Independent Regulatory Board of Auditors (IRBA) or an Accounting Officer as contemplated in the Close Corporation Act (CCA) together with the bid, will be interpreted to mean that preference points for B-BBEE status level of contribution are not claimed.

1.5 The purchaser reserves the right to require of a bidder, either before a bid is adjudicated or at any time subsequently, to substantiate any claim in regard to preferences, in any manner required by the purchaser.

2. **DEFINITIONS**

2.1 "**all applicable taxes**" includes value-added tax, pay as you earn, income tax, Unemployment Insurance Fund contributions and skills development levies;

2.2 "**B-BBEE**" means broad-based black economic empowerment as defined in section 1 of the Broad-Based Black Economic Empowerment Act;

2.3 "**B-BBEE status level of contributor**" means the B-BBEE status received by a measured entity based on its overall performance using the relevant scorecard contained in the Codes of Good Practice on Black Economic Empowerment, issued in terms of section 9(1) of the Broad-Based Black Economic Empowerment Act;

2.4 "**bid**" means a written offer in a prescribed or stipulated form in response to an invitation by an organ of state for the provision of services, works or goods, through price quotations, advertised competitive bidding processes or proposals;

2.5 "**Broad-Based Black Economic Empowerment Act**" means the Broad-Based Black Economic Empowerment Act, 2003 (Act No. 53 of 2003);

2.6 "**comparative price**" means the price after the factors of a non-firm price and all unconditional discounts that can be utilized have been taken into consideration;

2.7 **"consortium or joint venture"** means an association of persons for the purpose of combining their expertise, property, capital, efforts, skill and knowledge in an activity for the execution of a contract;

2.8 "**contract**" means the agreement that results from the acceptance of a bid by an organ of state;

2.9 **"EME"** means any enterprise with annual total revenue of R5 million or less.

2.10 **"firm price"** means the price that is only subject to adjustments in accordance with the actual increase or decrease resulting from the change, imposition, or abolition of customs or excise duty and any other duty, levy, or tax, which, in terms of the law or regulation, is binding on the contractor and demonstrably has an influence on the price of any supplies, or the rendering costs of any service, for the execution of the contract;

2.11 **"functionality"** means the measurement according to predetermined norms, as set out in the bid documents, of a service or commodity that is designed to be practical and useful, working or operating, taking into account, among other factors, the quality, reliability, viability and durability of a service and the technical capacity and ability of a bidder;

2.12 **"non-firm prices"** means all prices other than "firm" prices;

2.13 **"person**" includes a juristic person;

2.14 **"rand value"** means the total estimated value of a contract in South African currency, calculated at the time of bid invitations, and includes all applicable taxes and excise duties;

2.15 "**sub-contract**" means the primary contractor's assigning, leasing, making out work to, or employing, another person to support such primary contractor in the execution of part of a project in terms of the contract;

2.16 **"total revenue"** bears the same meaning assigned to this expression in the Codes of Good Practice on Black Economic Empowerment, issued in terms of section 9(1) of the Broad-Based Black Economic Empowerment Act and promulgated in the Government Gazette on 9 February
2007;

2.17 "**trust**" means the arrangement through which the property of one person is made over or bequeathed to a trustee to administer such property for the benefit of another person; and

2.18 **"trustee"** means any person, including the founder of a trust, to whom property is bequeathed in order for such property to be administered for the benefit of another person.

3. **ADJUDICATION USING A POINT SYSTEM**

3.1 The bidder obtaining the highest number of total points will be awarded the contract.

3.2 Preference points shall be calculated after prices have been brought to a comparative basis taking into account all factors of non-firm prices and all unconditional discounts;.

3.3 Points scored must be rounded off to the nearest 2 decimal places.

3.4 In the event that two or more bids have scored equal total points, the successful bid must be the one scoring the highest number of preference points for B-BBEE.

3.5 However, when functionality is part of the evaluation process and two or more bids have scored equal points including equal preference points for B-BBEE, the successful bid must be the one scoring the highest score for functionality.

3.6 Should two or more bids be equal in all respects, the award shall be decided by the drawing of lots.

SBD 6.1

4 POINTS AWARDED FOR PRICE

4.1 THE 80/20 OR 90/10 PREFERENCE POINT SYSTEMS

A maximum of 80 or 90 points is allocated for price on the following basis:

80/20 **or** **90/10**

$$Ps = 80\left(1 - \frac{Pt - Pmin}{Pmin}\right) \qquad Ps = 90\left(1 - \frac{Pt - Pmin}{Pmin}\right)$$

Where:

Ps= Points scored for comparative price of bid under consideration

Pt= Comparative price of bid under consideration

Pmin= Comparative price of lowest acceptable bid

5. POINTS AWARDED FOR B-BBEE STATUS LEVEL OF CONTRIBUTION

5.1 In terms of Regulation 5 (2) and 6 (2) of the Preferential Procurement Regulations, preference points must be a warded to a bidder for attaining the B-BBEE status level of contribution in accordance with the table below:

B-BBEE Status Level of Contributor	Number of Points (90/10 system)
1	10
2	9
3	8
4	5
5	4
6	3
7	2
8	1
Non-compliant contributor	0

5.2 Bidders who qualify as EMEs in terms of the B-BBEE Act must submit a certificate issued by an Accounting Officer as contemplated in the CCA or a Verification Agency accredited by SANAS or a Registered Auditor. Registered auditors do not need to meet the prerequisite for IRBA's approval for the purpose of conducting verification and issuing EMEs with B-BBEE Status Level Certificates.

5.3 Bidders other than EMEs must submit their original and valid B-BBEE status level verification certificate or a certified copy thereof, substantiating their B-BBEE rating issued by a Registered Auditor approved by IRBA or a Verification Agency accredited by SANAS.

5.4 A trust, consortium or joint venture, will qualify for points for their B-BBEE status level as a legal entity, provided that the entity submits their B-BBEE status level certificate.

5.5 A trust, consortium or joint venture will qualify for points for their B-BBEE status level as an unincorporated entity, provided that the entity submits their consolidated B-BBEE scorecard as if they were a group structure and that such a consolidated B-BBEE scorecard is prepared for every separate bid.

5.6 Tertiary institutions and public entities will be required to submit their B-BBEE status level certificates in terms of the specialized scorecard contained in the B-BBEE Codes of Good Practice.

5.7 A person will not be awarded points for B-BBEE status level if it is indicated in the bid documents that such a bidder intends sub-contracting more than 25% of the value of the contract to any other enterprise that does not qualify for at least the points that such a bidder qualifies for, unless the intended sub- contractor is an EME that has the capability and ability to execute the sub-contract.

5.8 A person awarded a contract may not sub-contract more than 25% of the value of the contract to any other enterprise that does not have an equal or higher B-BBEE status level than the person concerned, unless the contract is sub-contracted to an EME that has the capability and ability to execute the sub-contract.

SBD 6.1

6. BID DECLARATION

6.1 Bidders who claim points in respect of B-BBEE Status Level of Contribution must complete the following:

7 B-BBEE STATUS LEVEL OF CONTRIBUTION CLAIMED IN TERMS OF PARAGRAPHS 1.3.1.2 AND 5.1

7.1 B-BBEE Status Level of Contribution: Non-co = 0 (maximum of 10)

(Points claimed in respect of paragraph 7.1 must be in accordance with the table reflected in paragraph 5.1 and must be substantiated by means of a B-BBEE certificate issued by a Verification Agency accredited by SANAS or a Registered Auditor approved by IRBA or an Accounting Officer as contemplated in the CCA)

8 SUB-CONTRACTING

8.1 Will any portion of the contract be subcontracted? **Yes** ◯ **No** ◯

8.1.1 If yes, indicate:

(i) what percentage of the contract will be subcontracted? ____ **%**

(ii) the name of the sub- contractor?

(iii) the B-BBEE status level of the sub-contractor?

(iv) whether the sub-contractor is an EME? **Yes** ◯ **No** ◯

9 DECLARATION WITH REGARD TO COMPANY/FIRM

9.1 Name of company/firm:

9.2 VAT registration number:

9.3 Company registration number:

9.4 Type of company/ firm:

Partnership/Joint Venture / Consortium ◯

One person business/sole propriety ◯

Close corporation ◯

Company (Pty) Ltd ◯

9.5	Describe principal business activities

9.6 Company classification:

Partnership/Joint Venture / Consortium	◯
One person business/sole propriety	◯
Close corporation	◯
Company (Pty) Ltd	◯

9.7	Total number of years the company/firm has been in business	

9.8 I/we, the undersigned, who is/are duly authorised to do so on behalf of the company/firm, certify that the points claimed, based on the B-BBE status level of contribution indicated in paragraph 7 of the foregoing certificate, qualifies the company/ firm for the preference(s) shown and I/we acknowledge that:

(i) The information furnished is true and correct;

(ii) The preference points claimed are in accordance with the General Conditions as indicated in paragraph 1 of this form.

(iii) In the event of a contract being awarded as a result of points claimed as shown in paragraph 7, the contractor may be required to furnish documentary proof to the satisfaction of the purchaser that the claims are correct;

(iv) If the B-BBEE status level of contribution has been claimed or obtained on a fraudulent basis or any of the conditions of contract have not been fulfilled, the purchaser may, in addition to any other remedy it may have –

(a) disqualify the person from the bidding process;

(b) recover costs, losses or damages it has incurred or suffered as a result of that person's conduct;

(c) cancel the contract and claim any damages which it has suffered as a result of having to make less favourable arrangements due to such cancellation;

(d) restrict the bidder or contractor, its shareholders and directors, or only the shareholders and directors who acted on a fraudulent basis, from obtaining business from any organ of state for a period not exceeding 10 years, after the *audi alteram partem* (hear the other side) rule has been applied; and

(e) forward the matter for criminal prosecution

Witnesses:

1	Name:	
	Signature:	
2	Name:	
	Signature:	

Bidder's signature(s)

1	Name:	
	Signature:	
2	Name:	
	Signature:	
	Date:	
	Address:	

DECLARATION OF BIDDER'S PAST SUPPLY CHAIN MANAGEMENT PRACTICES

1 This Standard Bidding Document must form part of all bids invited.

2 It serves as a declaration to be used by institutions in ensuring that when goods and services are being procured, all reasonable steps are taken to combat the abuse of the supply chain management system.

3 The bid of any bidder may be disregarded if that bidder or any of its directors have-

a) abused the institution's supply chain management system;
b) committed fraud or any other improper conduct in relation to such system; or
c) failed to perform on any previous contract.

4 **In order to give effect to the above, the following questionnaire must be completed and submitted with the bid.**

Item	Question	Yes	No
4.1	**Is the bidder or any of its directors listed on the National Treasury's Database of Restricted Suppliers as companies or persons prohibited from doing business with the public sector?** (Companies or persons who are listed on this Database were informed in writing of this restriction by the Accounting Officer/Authority of the institution that imposed the restriction after the *audi alteram partem* rule was applied). **The Database of Restricted Suppliers now resides on the National Treasury's website (www.treasury.gov.za) and can be accessed by clicking on its link at the bottom of the home page.**	Yes ◯	No ◯
4.1.1	If so, furnish particulars:		
4.2	Is the bidder or any of its directors listed on the Register for Tender Defaulters in terms of section 29 of the Prevention and Combating of Corrupt Activities Act (No 12 of 2004)? **Register for Tender Defaulters can be accessed on the National Treasury's website (www.treasury.gov.za) by clicking on its link at the bottom of the home page.**	Yes ◯	No ◯
4.2.1	If so, furnish particulars:		

4.3	Was the bidder or any of its directors convicted by a court of law (including a court outside of the Republic of South Africa) for fraud or corruption during the past five years?	Yes ◯	No ◯
4.3.1	If so, furnish particulars:		
4.4	Was any contract between the bidder and any organ of state terminated during the past five years on account of failure to perform on or comply with the contract?	Yes ◯	No ◯
4.4.1	If so, furnish particulars:		

Certification

I, the undersigned	*(name)*

certify that the information furnished on this declaration form is true and correct. I accept that, in addition to cancellation of a contract, action may be taken against me should this declaration prove to be false**.**

I accept that the state may reject the bid or act against me should this declaration prove to be false.

Name of bidder:			
Position:			
Signature:		Date	

SBD9

CERTIFICATE OF INDEPENDENT BID DETERMINATION

1 This Standard Bidding Document (SBD) must form part of all bids[1] invited.

2 Section 4 (1) (b) (iii) of the Competition Act No. 89 of 1998, as amended, prohibits an agreement between, or concerted practice by, firms, or a decision by an association of firms, if it is between parties in a horizontal relationship and if it involves collusive bidding (or bid rigging).[2] Collusive bidding is a *pe se* prohibition meaning that it cannot be justified under any grounds.

3 Treasury Regulation 16A9 prescribes that accounting officers and accounting authorities must take all reasonable steps to prevent abuse of the supply chain management system and authorizes accounting officers and accounting authorities to:

a. disregard the bid of any bidder if that bidder, or any of its directors have abused the institution's supply chain management system and or committed fraud or any other improper conduct in relation to such system.

b. cancel a contract awarded to a supplier of goods and services if the supplier committed any corrupt or fraudulent act during the bidding process or the execution of that contract.

4 This SBD serves as a certificate of declaration that would be used by institutions to ensure that, when bids are considered, reasonable steps are taken to prevent any form of bid rigging.

5 In order to give effect to the above, the attached Certificate of Bid Determination (SBD 9) must be completed and submitted with the bid:

[1] Includes price quotations, advertised competitive bids, limited bids and proposals.

[2] Bid rigging (or collusive bidding) occurs when businesses, that would otherwise be expected to compete, secretly conspire to raise prices or lower the quality of goods and / or services for purchasers who wish to acquire goods and / or services through a bidding process. Bid rigging is, therefore, an agreement between competitors not to compete

SBD 9

CERTIFICATE OF INDEPENDENT BID DETERMINATION

I, the undersigned, in submitting the accompanying bid:

(Bid Number and Description)

in response to the invitation for the bid made by:

(Name of Institution)

do hereby make the following statements that I certify to be true and complete in every respect: I certify, on behalf of:

(Name of Bidder)

that:

1. I have read and I understand the contents of this Certificate;
2. I understand that the accompanying bid will be disqualified if this Certificate is found not to be true and complete in every respect;
3. I am authorised by the bidder to sign this Certificate, and to submit the accompanying bid, on behalf of the bidder;
4. Each person whose signature appears on the accompanying bid has been authorised by the bidder to determine the terms of, and to sign the bid, on behalf of the bidder;
5. For the purposes of this Certificate and the accompanying bid, I understand that the word "competitor" shall include any individual or organization, other than the bidder, whether or not affiliated with the bidder, who:
   (a) has been requested to submit a bid in response to this bid invitation;
   (b) could potentially submit a bid in response to this bid invitation, based on their qualifications, abilities or experience; and
   (c) provides the same goods and services as the bidder and/or is in the same line of business as the bidder.
6. The bidder has arrived at the accompanying bid independently from, and without consultation, communication, agreement or arrangement with any competitor. However communication between partners in a joint venture or consortium[3] will not be construed as collusive bidding.

7. In particular, without limiting the generality of paragraphs 6 above, there has been no consultation, communication, agreement or arrangement with any competitor regarding:
   (a) prices;
   (b) geographical area where product or service will be rendered (market allocation)
   (c) methods, factors or formulas used to calculate prices;
   (d) the intention or decision to submit or not to submit, a bid;
   (e) the submission of a bid which does not meet the specifications and conditions of the bid; or
   (f) bidding with the intention not to win the bid.

8. In addition, there have been no consultations, communications, agreements or arrangements with any competitor regarding the quality, quantity, specifications and conditions or delivery particulars of the products or services to which this bid invitation relates.

9. The terms of the accompanying bid have not been, and will not be, disclosed by the bidder, directly or indirectly, to any competitor, prior to the date and time of the official bid opening or of the awarding of the contract.

10. I am aware that, in addition and without prejudice to any other remedy provided to combat any restrictive practices related to bids and contracts, bids that are suspicious will be reported to the Competition Commission for investigation and possible imposition of administrative penalties in terms of section 59 of the Competition Act No 89 of 1998 and or may be reported to the National Prosecuting Authority (NPA) for criminal investigation and or may be restricted from conducting business with the public sector for a period not exceeding ten (10) years in terms of the Prevention and Combating of Corrupt Activities Act No 12 of 2004 or any other applicable legislation.

Name of Bidder			
Position			
Full Names			
Signature		Date	

[3] Joint venture or Consortium means an association of persons for the purpose of combining their expertise, property, capital, efforts, skill and knowledge in an activity for the execution of a contract.

PBD1

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

AUTHORISATION DECLARATION (PBD1)

NAME OF THE BIDDER

Are you sourcing the products from a third party? Yes ◯ No ◯

***** *If you have answered YES to the above question, please provide full details in the table below of the third party(ies) from whom you are sourcing the products.*

1. Declaration by the bidder where the bidder is sourcing the products from a third party.
   The bidder hereby declares the following:-
   1.1 The bidder is sourcing the products listed in the PBD1.1 attached, from a third party in order to comply with the terms and conditions of the bid.
   1.2 The bidder has informed the third party of the terms and conditions of the bid and the third party is acquainted with the said terms and the description of the products listed in the PBD1.1.
   1.3 The bidder has received the attached, unconditional written undertaking from the third party to supply the products listed in the PBD1.1 in accordance with the terms and conditions of the bid document for the duration of the contract. A template has been attached (PBD1.2) that is to be used for the purpose of the third party undertaking.
   1.4 The bidder confirms that all financial and supply arrangements for the products have been mutually agreed upon between the bidder and the third party.
2. The bidder declares that the information contained herein is true and correct.
3. The bidder acknowledges that the Department of Health reserves the right to verify the information contained therein and if found to be false or incorrect may invoke any remedies available to it in the bid documents.

Signed at		on the		day of	
Signature					
Full Names					
Designation					

PBD1.1

List of the products offered sourced from third party

Bid Item No	Brand Name	Name of the company from where the products will be sourced	Address and contact details of the company from where the products will be sourced

List of the products offered sourced from third party - *Continued*

Bid Item No	Brand Name	Name of the company from where the products will be sourced	Address and contact details of the company from where the products will be sourced

(Should the table provided not be sufficient for all the items offered, please provide additional information as an attachment and it must be properly referenced to this document)

PBD1.2

Template for unconditional written undertaking from the third party

Note:

The authorisation letter must be on the official letterhead of the third party

A separate letter must be included for each third party

The authorisation letter must be addressed to the Bidding Company

Name of Bidding Company:

Address of Bidding Company:

Attention:

Dear Sir/Madam

AUTHORISATION LETTER: CONTRACT NO_____

We, _____*(Name of Third Party)* hereby authorise you,_____ *(Name of Company)* to include the products listed below in your bid submission for the abovementioned contract.

We confirm that we have firm supply arrangements in place, and have familiarised ourselves with the item descriptions, specifications and bid conditions relating to item/s listed below.

Item no.	Description of product	Brand name

(Should the table provided not be sufficient for all the items offered, please provide additional information as an attachment and it must be properly referenced to this document)

Yours faithfully,

Signature of the Third Party and dated.

PBD4

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001. Civitas Building Cnr Andries & Struben Streets, PRETORIA 0001
Directorate: Access to Affordable Medicines Tel: (012) 395 8130 Fax: (012) 395 8823/4

All Suppliers complete section A to C only
New suppliers also complete section A to D
Should any of the detail provided below change, please advise the National Department of Health immediately in writing with detail of such change(s).

SECTION A: CONTACT DETAILS:

1. Supplier Registered Name	
Legal entity/corresponding with banking detail supplied	

2. Contact person regarding contract enquiries (to be printed on contract cover)				
Name:		Surname		
Telephone Office		Fax		
Cell		Telephone Switch Board		
Email (1)		Email (2)		

3. Contact regarding orders				
Name:		Surname		
Telephone Office		Fax		
Cell		Telephone Switch Board		
Email (1)		Email (2)		

4. Order enquiries				
Name:		Surname		
Telephone Office		Fax		
Cell		Telephone Switch Board		
Email (1)		Email (2)		

5. National key Account Manager (or Tender Manager)				
Name:		Surname		
Telephone Office		Fax		
Cell		Telephone Switch Board		
Email (1)		Email (2)		

SECTION B: CURRENT SUPPLIER REGISTRATION

Note that Provincial Departments of Health may require separate registration of new suppliers on their databases & could request completion of Province-specific documents. The information requested below is required to verify that supplier databases are current.

Are registered as a State Supplier	Yes	◯	No	◯

For Registered Suppliers:

Supplier number (Contracts/NDoH)	
BAS Supplier number	
LOGIS Supplier number	

For Suppliers Currently not Registered:

I,

have completed **Section D** documents needed for the creation of a new supplier code of PBD4

Sign_____

SECTION C: BANKING DETAILS:

Please provide the banking details to which any payments due are to be transferred. Should there be any variation between the name of the Contractor who submitted the bid and that of the account holder, this should be specified in writing, stamped by the bank and certified by a Commissioner of Oaths. The bank MUST certify this form in the space provided. An original copy of this document must be supplied to the NDoH.

Current Banking Details:

Please attach an original cancelled cheque or an original bank verification letter

Bank:		Branch number / code:	
Branch Location:			
Account number:		Account type:	
Date the account was opened:			
Name of the account:			

Please ensure that the information is validated as per required bank screens.

Certificate from Bank:

I, (full names) *Printed*

(and surname) *Printed*

of Bank Name

Branch Name

and telephone number Code Number

herewith certify that the "Current Banking Details" as provided in SECTION C above, are true and correct.

Signed:

(Official Bank Stamp)

Credit Order Instruction:

I/We (the signatories hereto) hereby request and authorise the provincial Departments of Health to pay any amounts which may accrue to me / us to the credit of my / our account with the mentioned bank (*see SECTION C)*).

I / we understand that the credit transfers hereby authorised will be processed by computer through a system known as the "ACB ELECTRONIC TRANSFER SERVICES", and I / we also understand that no additional advices of payment will be provided by my / our bank, but details of each payment will be printed on my / our bank statement or any accompanying voucher (This does not apply where it is not customary for banks to furnish bank statements).

I / we understand that a payment advice will be supplied by the relevant Department of Health in the normal way, and that it will indicate the date on which funds will be available in my / our account. I / we also understand that the payment for services rendered will be by way of electronic transfer only and no other methods of payment will be considered.

I / we understand that bank details provided should be exactly as per the records held by the bank.

I / we understand that the Departments will not assume responsibility for any delayed payments, as a result of incorrect information supplied.

If there are any changes to the information supplied on this form, please inform the Director: Affordable Medicines as soon as possible. Outdated information could lead to your company not receiving correct payment!

PBD4

SECTION D: DOCUMENTS NEEDED FOR THE CREATION OF A NEW SUPPLIER CODE

		Included in Bid Pack ***Tick the box***
1	**Letterhead of the Company with:** • Name of the company • Postal address • Physical address • Contact numbers (i.e. Telephone, fax and e-mail) • Contact person and his/her designation (e.g. Director or Owner initials and surname) Signature of the person (Director / Manager / Owner)	☐
2	**SARS Tax Clearance Certificate** This must be valid and original. The VAT/Diesel Registration Number must appear on the document.	☐
3	**The CK / CIPC document:** (Reflecting the Company's Registration number and Registered Name) • CCIPC CK1/2 for a CC • CIPC CM29 for a Private Company • CIPC CM9 for company name change	☐
4	**A letter from the bank** (on the Bank's letterhead) indicating the account number and confirming that the account is in the name of the company. The bank must also submit the branch name, code and bank stamp.	☐
5	**Proof of business address**. Current municipal account or Telkom account reflecting the physical address.	☐
6	**Certified copies of the ID Documents of the Directors.**	☐

I / we, the undersigned, herewith certify that all of the above information is correct at the time of completion. I/ we furthermore certify that I / we have the appropriate authority to furnish the above-mentioned information on behalf of our employer.

Name:			
Designation:			
Signature		Date	
Name:			
Designation:			
Signature		Date	

PBD5 DECLARATION OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICE (GMP)

To be signed by the Chief Executive Officer of the Company in terms of this bid.

I, _____

(full name) being the Chief Executive Officer

of _____

(Organisation name)

hereby certify that to the best of my knowledge all reasonable steps have been taken to ensure that:

a) there are no outstanding or impending GMP or legal matters that may have a material impact on the Company's ability to perform in terms of this contract.

b) In terms of this declaration, I undertake to inform the Department of Health at first knowledge of any circumstances that may result in interrupted supply.

c) (Organisation name) _____

has complied with all the legal requirements as stipulated in terms of Medicines and Related Substances Act 101 of 1965, as amended,: for such products offered.

_____

Full Name of Chief Executive Officer

_____

Full Identity Number / or equivalent of the Chief Executive Officer

Signature of Chief Executive Officer	Signature of Witness
Date / /	Date / /
Place	Place

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Special Requirements and Conditions of Contract

HM01–2015CNDM
THE SUPPLY AND DELIVERY OF MALE AND FEMALE CONDOMS AND LUBRICANT TO THE DEPARTMENT OF HEALTH

FOR THE PERIOD 1 JULY 2015 TO 30 JUNE 2018

VALIDITY PERIOD: 120 days

National Department of Health

Non-compulsory Briefing Session
05 March 2015
Time: 13:00-15:00
Venue: Impilo Boardroom
National Department of Health
242 Struben Street (Cnr Thabo Sehume and Struben streets)
Room 545, North Tower, Civitas Building, Pretoria

INDEX

SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT

1. BACKGROUND

This bidding process, and all contracts emanating there from will be subject to the General Conditions of Contract issued in accordance with Treasury Regulation 16A published in terms of the Public Finance Management Act, 1999 (Act 1 of 1999). The Special Requirements and Conditions of Contract are supplementary to the General Conditions of Contract. Where the Special Requirements and Conditions of Contract are in conflict with the General Conditions of Contract, the Special Requirements and Conditions of Contract will prevail.

2. EVALUATION CRITERIA

2.1. PREFERENCE POINTS SYSTEM

2.1.1. In terms of Regulation 6 of the Preferential Procurement Regulations, published in terms of the Preferential Procurement Policy Framework Act, 2000 (Act 5 of 2000), responsive bids will be adjudicated by the Department of Health on the 90/10- preference point system in terms of which points are awarded to bidders on the basis of:

- The bid price (final delivered price including VAT): maximum 90 points
- B-BBEE status level of bidder: maximum 10 points

2.1.2. The following formula will be used to calculate the points for price:

$$Ps = 90\left(1 - \frac{Pt - Pmin}{Pmin}\right)$$

Where:

Ps= Points scored for comparative price of bid under consideration

Pt= Comparative price of bid under consideration

Pmin= Comparative price of lowest acceptable bid

2.1.3. A maximum of 10 points may be allocated to a bidder for attaining their B-BBEE status in accordance with the table below:

B-BBEE Status	
Level of Contributor	Number of Points
1	10
2	9
3	8
4	5
5	4
6	3
7	2
8	1
Non-compliant contributor	0

2.1.4. Bidders are required to complete the preference claim form (SBD 6.1) in order to claim the B-BBEE status level points.

2.1.5. The points scored by a bidder for B-BBEE contribution will be added to the points scored for price.

2.1.6. Only bidders who have completed and signed the declaration part of the preference claim form, and who have submitted a B-BBEE status level certificate issued by a registered auditor, accounting officer (as contemplated in section 60(4) of Close Corporation Act, 1984 (Act 69 of 1984)) or an accredited verification agency will be considered for preference points.

2.1.7. Bidders that fail to comply with paragraphs 2.1.4 and 2.1.6 will be allocated zero points for B-BBEE status.

2.1.8. The Department of Health may, before a bid is adjudicated or at any time, require a bidder to substantiate claims it has made with regard to preference points.

2.1.9. The points scored will be rounded off to the nearest 2 decimals.

2.1.10. In the event that two or more bids have scored equal total points, the contract will be awarded to the bidder scoring the highest number of points for B-BBEE. Should two or more bids be equal in all respects, the award shall be decided by the drawing of lots.

2.1.11. A contract may, on reasonable and justifiable grounds, be awarded to a bid that did not score the highest number of points.

3. SUPPLIER DUE DILIGENCE

The Department of Health reserves the right to conduct supplier due diligence prior to the final award of contract, or at any time thereafter.

4. PARTICIPATING AUTHORITIES

The National Department of Health and the following Provincial Departments of Health will participate in this contract: Eastern Cape, Free State, Gauteng, KwaZulu-Natal, Limpopo, Mpumalanga, Northern Cape, North West and Western Cape and the South African National Defence Force.

5. CONTRACT PERIOD

The contract period shall be for 36 months commencing on 1 July 2015.

6. DOCUMENT SUBMISSION AND COMPLETION FOR BIDDING

6.1. BID DOCUMENTS FOR SUBMISSION

6.1.1. Bidders MUST submit the following completed documents:

- SBD1: Invitation to bid
- SBD2: Tax Clearance Certificate: Certificate must be original and valid
- SBD4: Declaration of Interest
- SBD5: The National Industrial Participation Programme
- SBD6.1: Preference points claim form in terms of the Preferential Procurement Regulations 2011
- SBD8: Declaration of bidder's past supply chain management practices
- SBD9: Certificate of independent bid determination
- PBD1: Authorisation Declaration (if applicable)
- PBD4: Supplier details
- PBD5: Declaration of compliance with Good Manufacturing Practice (GMP)B-BBEE Status Level Verification Certificate (if applicable) (Certified Copy)
- Certified copy of the CIPC document (Reflecting the Entity’s Registration Number and Registered Name)
- Completed Bid Response Documents: Completion of all response fields per item offered is mandatory.

6.2. COMPLETION OF DOCUMENTS AND BID SUBMISSION

Bidders are required to submit three sets of bid documents according to the instructions below. All three sets must be submitted before the closing date and time. Set 2 and Set 3 must be included on a CD with Set 1 and submitted in **a sealed package**. The full name and address of the bidder, including the return address, the bid number and the closing date must be clearly indicated on the envelope. All fields must be completed. Where information requested is not relevant this should be indicated with N/A.

6.2.1. Set 1: Hard copy legally binding bid documents

Bidders must complete the all SBD, PBD and Bid Response forms in black ink, typed. Where no electronic entry field is provided bidders must complete the forms in black ink, handwritten in capital letters. The signed hard copy of the bid document will serve as the legal bid document. Bidders must submit their complete bid in hard copy format (paper document). The Chief Executive Officer, Chief Financial Officer, or authorised designee of the entity submitting the bid must sign the official signature pages. All pages in the complete bid document must be initialled by same with black ink. The use of correction fluid is not acceptable. Any change/s must be clearly indicated and initialled.

6.2.2. Set 2: PDF of Hard Copy, signed legal documents. (I.e. PDF of Set 1)

Bidders **must** submit a PDF version of the entire signed hardcopy bid, including all certificates and documents requested.

6.2.3. Set 3: Electronic version of bid documents

Bidders must submit the electronic versions of all SBD and PBD documents and Bid Response Document.

6.2.4. All three sets of information must be submitted in order for the bid to be evaluated.

6.2.5. Ensure that the bid price is offered for the product as specified.

6.2.6. The signed hard copy of the bid document will serve as the legal bid document. Bidders must submit their complete bid in hard copy format (paper document). The Chief Executive Officer, Chief Financial Officer, or authorised designee of the entity submitting the bid must sign the bid document and initial each page with black ink. The use of correction fluid is not acceptable. Any change/s must be clearly indicated and initialled. The bid must be submitted before the closing date and time.

6.2.7. Bidders **must** also submit the completed Bid Response Document on a CD in Excel format before the closing date and time. Scanned or PDF versions of the Bid Response Document are not sufficient. The Excel version of the Bid Response Document must reflect exactly the hard copy version. Failure to submit Excel version of the bid will result in the bid being deemed non-responsive and excluded from consideration.

6.3. PRODUCT SPECIFIC DOCUMENTS FOR SUBMISSION

Bidders must submit the documents as denoted in the specifications for each product offered with the bid documents (Note: this is not to be confused with the submission of samples).

6.4. COMPLETION OF DOCUMENTS

6.4.1. Complete all fields in all documents required for submission, including the bid response document for each product offered.

6.4.2. Ensure that the bid price is offered for the product as specified.

7. VALUE ADDED TAX

All bid prices must include Value-Added Tax (VAT). If a VAT exclusive price is submitted the bid will be deemed non-responsive.

8. TAX CLEARANCE CERTIFICATE

An original and valid Tax Clearance Certificate issued by the South African Revenue Service must be submitted together with bid documents. Only the original Tax Clearance Certificate will be accepted. Contracted Suppliers are obliged to provide the Department with a valid Tax Clearance Certificate prior to the expiry of the previously submitted certificate.

9. AUTHORISATION DECLARATION AND DOCUMENTATION OF UNDERTAKING

9.1. DECLARATION OF AUTHORISATION

9.1.1. In the event of the bidder being an importer, holder of marketing rights, or making use of a contract manufacturer, the bidder must ensure that all legal, financial and supply arrangements have been mutually agreed upon between the bidder and the importer/contract manufacturer.

9.1.2. No agreement between the bidder and a third party will be binding on the Department of Health.

9.1.3. Where third-parties are involved the bidder must submit a duly completed and signed Authorisation Declaration (PBD1). Failure to submit the full declaration will invalidate the bid for such goods offered.

9.1.4. The Department reserves the right to verify any information supplied by the bidder in the Authorisation Declaration at any time. Should the information be found to be false or incorrect, the Department of Health will exercise any of the remedies available to it in order to disqualify the bid, or cancel the contract, if already awarded.

9.1.5. Accountability with regard to meeting the conditions of any contract emanating from this bidding process rests with the successful bidder and not any third party.

9.2. DOCUMENTATION OF UNDERTAKING AND LEGISLATIVE REQUIREMENTS

9.2.1. Bidders must comply with the requirements of the Patents Act, 1978 (Act 57 of 1978) and the Trade Marks Act, 1993 (Act 194 of 1993) as amended.

9.2.2. Bidders must submit a copy of the actual patent or an agreement with the patent holder with the bid document at the closing date and time of the bid.

9.2.3. With respect to the female condom, the bidder must supply complete documentation indicating that the product offered has World Health Organisation (WHO) Female Condom Technical Review Committee recommendation.

9.2.4. Bidders must comply with legal requirements.

10. BIDDING PROCESS ADMINISTRATION

10.1. The Affordable Medicines Directorate within the National Department of Health is responsible for managing the bidding process and will communicate with bidders to request extension of the validity period of the bid, should it be necessary.

10.2. All communication between the bidder and the Department of Health must be in writing and addressed to the Director: Affordable Medicines.

10.3. Any unsolicited communication between the closing date and the award of the contract between the bidder and any government official or a person acting in an advisory capacity for the Department of Health in respect to any bids, is discouraged.

11. COUNTER CONDITIONS

Any amendments to any of the bid conditions, changes to bid specifications or setting of any other counter conditions by bidders may result in the invalidation of such bids.

12. PROHIBITION OF RESTRICTIVE PRACTICES

12.1 In terms of section 4(1) of the Competition Act, Act 89 of 1998, as amended, an agreement between, or concerted practice by, firms, or a decision by an association of firms, is prohibited if it is between parties in a horizontal relationship and if a bidder(s) is/are or a contractor(s) was/were involved in:

- directly or indirectly fixing a purchase or selling price or any other trading condition;
- dividing markets by allocating customers, suppliers, territories or specific types of goods or services; or
- collusive bidding.

12.2 Section 4(2) of Act 89 of 1998 states that an agreement to engage in a restrictive horizontal practice referred to in subsection (1)(b) of the Act is presumed to exist between two or more firms if:

- any one of those firms owns a significant interest in the other, or they have at least one director or substantial shareholder in common; or
- any combination of those firms engages in that restrictive horizontal practice.

12.3 If bidder(s) or contracted supplier(s), in the judgment of the purchaser, has/have engaged in any of the restrictive practices referred to above, the purchaser may refer the matter to the Competition Commission for investigation and possible imposition of administrative penalties as contemplated in the Competition Act 89 of 1998.

12.4 If bidder(s) or contracted supplier(s) has/have been found guilty by the Competition Commission of any of the restrictive practices referred to above, the purchaser may, in addition and without prejudice to any other remedy provided for, invalidate the bid(s) for such item(s) offered, and/or terminate the contract in whole or part, and/or restrict the bidder(s) or contracted supplier(s) from conducting business with the public sector for a period not exceeding ten (10) years and/or claim damages from the bidder(s) or contracted supplier(s) concerned.

13. FRONTING

13.1 The Department of Health supports the spirit of broad-based black economic empowerment and recognises that real empowerment can only be achieved through individuals and businesses conducting themselves in accordance with the Constitution and in an honest, fair, equitable, transparent and legally compliant manner. Against this background the Department of Health condemns any form of fronting.

13.2 The Department of Health, in ensuring that bidders conduct themselves in an honest manner will, as part of the bid evaluation processes, conduct or initiate the necessary enquiries/investigations to determine the accuracy of the representation made in bid documents. Should any of the fronting indicators as contained in the Guidelines on Complex Structures and Transactions and Fronting, issued by the Department of Trade and Industry, be established during such enquiry/investigation, the onus will be on the bidder/contractor to prove that fronting does not exist. Failure to do so within a period of 14 days from date of notification may invalidate the bid/contract and may also result in the restriction of the bidder/contractor to conduct business with the public sector for a period not exceeding ten years, in addition to any other remedies the National Treasury may have against the bidder/contractor concerned.

14. PRODUCT COMPLIANCE

Prior to award products will be evaluated for:

- Compliance with specifications as set out in the Bid Response Document.
- Availability of sample and physical compliance with specification.

14.1. STANDARDS FOR TESTING OF SAMPLES

14.1.1. Items must comply with standards as stated in the bid documents.

14.1.2. South African Bureau of Standards:

SANS, and, ISO Standards are available from South African Bureau of Standards Office's countrywide. Obtaining such Standards will be the responsibility of and for the accounts of the prospective bidder.

To purchase Standards, obtain quotes or to enquire about the availability of eStandards, please contact Standards sales at:

Postal Address: Private Bag X191, Pretoria, 0001

Physical Address: 1 Dr Lategan Road, Groenkloof, Pretoria

Tel: (012) 428 6883, Fax: (012) 428 6928, E-mail: sales@sabs.co.za

Website: www.sabs.co.za and follow the "Search/Buy Standards" link

14.1.3. Manufacturers and suppliers of male and female condoms shall follow an appropriate code of quality management, including good quality management system as required in the manufacturing and packaging of condoms. Condoms should be designed and produced in accordance with good quality management system ISO 14971 and ISO 1348.

14.1.4. Bidders should contact SABS to obtain a copy of the sampling frame guidelines prior to the submission of samples. All bidders must arrange random sampling in accordance with the SABS sampling frame guidelines at the point of packaging of the finished products. Sampling must be carried out by an independent or internationally recognised organisation. Samples must be taken from production lots produced at the source factory within the preceding 30 days from the date of sampling. Samples must be submitted to the SABS for testing which will be performed according to National Department of Health/World Health Organisation standards and specifications. The initial sample size for male and female condoms shall be 1200 pieces, and for lubricants shall be 200 sachets.

14.2. SUBMISSION OF SAMPLES

14.2.1. No samples must be sent to the Directorate: Affordable Medicines.

14.2.2. Samples must be submitted to the South African Bureau of Standards before or at closing date and time of bid.

14.2.3. Samples must be marked with the bid number, the item number as well as the bidder's name and address.

14.2.4. Samples must be submitted to the address indicated below, prior to closing date and time of bid:

South African Bureau of Standards
1 Dr Lategan Road
Groenkloof
0001
Contact person: Ms Isabella Masemola
Tel: 012 428 6131
email: Isabella.masemola@sabs.co.za

14.2.5. It is the responsibility of the bidder to ensure that samples have been received at the address provided.

14.2.6. All samples for awarded items will be retained by the SABS for quality control purposes.

14.2.7. All samples must be a true representation of the product which will be supplied.

14.2.8. A copy of the complete documentation "SABS permit to Apply Certificate Mark" , (i.e. not a face sheet but all additional documentation including the precise manufacturing process(es) that the certificate mark applies to).

14.2.9. A copy of complete documentation of World Health Organization (WHO) Female Condom Technical Review Committee recommendation, as relevant.

14.2.10. The bidder must pay for each item offered for testing according the SABS quotation.

14.2.11. Proof of submission of samples must be submitted with the bid documents.

14.2.12. Bidders must submit all SABS test reports by 13 April 2015 to the following email addresses: rasenm@health.gov.za, motseM@health.gov.za, medtenders@health.gov.za and molokp@heath.gov.za

14.2.13. Artwork for male condoms can be viewed on the website for information only and not for submission of samples. Only successful bidders will receive further communication regarding the final packaging of the male condoms.

14.2.14. If samples were submitted to the SABS in terms of the tender HM01–2015CNDM that closed on 1 December 2014 and test reports are available samples need not be re-submitted for the purpose of this tender.

14.3. TEST REPORTS

If test reports were obtained from the SABS in terms of the tender HM01–2015CNDM that closed on 1 December 2014 these will be deemed valid for consideration on this tender. In this instance, the relevant test reports must be included with the bid documents.

15. PRODUCT AWARD

15.1. AWARD CONDITIONS

15.1.1. The Department of Health reserves the right not to award a line item.

15.1.2. The Department of Health reserves the right to negotiate prices.

15.1.3. In cases where the tender does not achieve the most economically advantageous price, the Department of Health may not award that item.

15.1.4. In cases where there is more than one supplier sourcing from the same manufacturer, the Department reserves the right to split the award or to select one supplier based on previous performance and security of supply.

15.2. SPLIT AND MULTIPLE AWARDS

15.2.1. The Department of Health reserves the right to issue split or multiple awards, where necessary, to ensure security of supply.

15.2.2. The following will be taken into consideration when contemplating a split award:

- Capacity to meet volume demand as per Bid Response Document.
- Estimated volume to be supplied.
- Risk to public health if the item is not available.
- Source of raw material and manufacturing site.
- Previous performance of the bidder.

15.2.3. Where split awards are recommended, this will be made in accordance with the following schedule based on the points scored:

Category	Difference between points scored	Recommended percentage split
A	Equal points	50/50
B	< 5 points	60/40
C	>5-10 points	70/30
D	>10-20 points	80/20
E	>20 points	90/10

15.2.4. Where multiple awards are recommended the allocation will be made proportionally based on the total points scored.

16. PRICE QUALIFICATION

16.1. Prices submitted for this bid will be regarded as firm and subject only to review in terms of paragraph 17.2.

16.2. Bidders must quote a final delivered price inclusive of Value Added Tax (VAT).

16.3. Price must be specific for the units advertised per item specification.

17. PRICE REVIEW

The Department of Health envisages two types of price review processes for the duration of this contract:

- An adjustment to mitigate foreign exchange fluctuations in excess of those catered for by usual business practices;
- A systematic review of prices for comparable products available in the international marketplace.

17.1. INSTRUCTIONS FOR PRICE BREAKDOWN

17.1.1. The price breakdown must be completed on the signed bid response document. The delivered price must be divided across four components:

1. Cost of raw material;
2. Manufacturing;
3. Logistics;
4. Gross profit margin (remaining portion).

17.1.2. The sum of these categories must be equal to 100% of the delivered price for the line item

17.1.3. The local + imported portions of the first three components must add up to 100% within each component (e.g. Portion of raw material attributable to local + Portion of raw material attributable to import = 100% of specific raw material component).

See extract from bid response document below:

	Price components	*Response fields*
Price Breakdown by components relating to Foreign Exchange Price Adjustments (Paragraph 17.2 SCC): The 4 components should add up to 100% of the delivered price. If complete product is imported, ignore raw material and only list under manufacturing component. If packaging is included under formulation list only under formulation.	1) Raw material	*Component 1*
	Local %	*Portion of Component 1 attributable to local*
	Imported %	*Portion of Component 1 attributable to import*
	2) Manufacturing	*Component 2*
	Local %	*Portion of Component 2 attributable to local*
	Imported %	*Portion of Component 2 attributable to import*
	3) Logistics %	*Component 3*
	4) Gross Profit Margin %	*Component 4*
Currency used for imported content		

17.1.4. VAT must be apportioned equally across all components and not regarded as a separate component.

17.1.5. Labour must be apportioned appropriately across the relevant components.

17.1.6. Breakdown must be in percentage format to the closest whole percentage (e.g. 20%). No decimals will be considered.

17.1.7. The Department of Health reserves the right to engage with bidders to verify the imported component of the bid price, which may include audit of invoices and related documentation.

17.2. PRICE ADJUSTMENTS RELATING TO FOREIGN EXCHANGE RISK

17.2.1. Only the portion of the bid price facing foreign exchange risk will be adjusted. This portion is determined by the price breakdown on the signed bid submission

17.2.2. Adjustments are always calculated using the original awarded contracted price as the base

17.2.3. Price adjustments relating to foreign exchange will be based on the percentage change between a base average rate of exchange (RoE) and an adjustment average RoE. Rates are sourced from the Reserve Bank (www.resbank.co.za).

Base average RoE for this tender will be as follows, per currency:

Currency	**Base Average Rates of Exchange** **Average for the period 1 August 2014 to 31 January 2015**
US Dollar	R 11.1335
Br Pound	R 17.7446
Euro	R 13.9732
Yuan	R 1.8077
Indian Rupee	R 0.1808

17.2.4. Should the bidder make use of any currency not mentioned above, the bidder must stipulate this clearly and submit the calculated average RoE for the period 1 August 2014 to 31 January 2015 using the South African Reserve Bank published rates for the specific currency.

17.2.5. Schedule for price reviews, and periods for calculating adjustment average RoE, are detailed in the table below:

Review	Period for calculating adjustment RoE	Submission of request for price review to reach the office by	Date from which adjusted prices will become effective
1	1 February 2015 to 30 November 2015	7 December 2015	1 Jan 2016
2	1 December 2015 to 31 May 2016	7 June 2016	1 July 2016
3	1 June 2016 to 30 November 2016	7 December 2016	1 Jan 2017
4	1 December 2016 to 31 May 2017	7 June 2017	1 July 2017
5	1 June 2017 to 30 November 2017	7 December 2017	1 Jan 2018

17.2.6. Signed applications for price adjustments must be received by the National Department of Health prior to the submission dates detailed in the table above.

Successful bidders will receive the price adjustment request template when signing their contracts.

17.2.7. Where no application for an adjustment relating to foreign exchange has been received and such an adjustment would be favourable to the Department, this will be implemented automatically.

17.3. PRICE ADJUSTMENTS BASED ON A SYSTEMATIC REVIEW OF THE MARKETPLACE

17.3.1. The National Department of Health reserves the right to review international prices to identify lowest comparable global prices

17.3.2. Where the review identifies any prices that are lower than contract prices the Department of Health may enter into price negotiations with the contracted supplier.

17.3.3. Where the outcome of this negotiation is deemed unfavourable, the Department of Health reserves the right to terminate the award for the item in question.

18. MANUFACTURING INFORMATION

18.1. Bidders must disclose the manufacturing site(s).

18.2. Any intention to change the condom manufacturing source prior to the commencement of the contract or during the lifetime of the contract must be approved by the Bid Adjudication Committee, National Department of Health.

19. ORDERS, DELIVERY AND CONTINUITY OF SUPPLY

19.1. ORDERS

19.1.1. The quantities reflected in the advertised bid response document are estimated volumes and are not guaranteed.

19.1.2. Fluctuations in monthly demand may occur.

19.1.3. Proposed minimum order quantities should facilitate delivery directly to facilities. The Department reserves the right to negotiate minimum order quantities where they are deemed unfavourable. Where consensus regarding minimum order quantities cannot be reached the bid may not be awarded.

19.1.4. Only orders made on an official, authorised purchase order are valid

19.1.5. Changes to any quantities ordered may only be made upon receipt of an amended purchase order.

19.1.6. The Participating Authorities reserve the right to cancel orders where the lead time exceeds the delivery lead time specified in the contract (as per section 19.2 of the Special Requirements and Conditions of Contract).

19.1.7. In cases where an order is received which appears to be irrational or misaligned with estimates, the contracted supplier must liaise with the relevant Participating Authority prior to processing the order.

19.2. DELIVERIES

19.2.1. The initial lead time as proposed in the bid response document will be calculated from date of award of the contract and NOT the date of placement of the first order. This period should not exceed 90 calendar days from the date of award.

19.2.2. Lead-time within the contract period is defined as the time from submission of order to supplier to time of receipt by the department as confirmed by the Proof of Delivery document. This lead-time may not exceed 42 calendar days.

19.2.3. Failure to comply with the contractual lead-time will result in penalties being enforced as per section 21 and 22 of the General Conditions of Contract.

19.2.4. Products and related documentation must be delivered in accordance with the terms, conditions and delivery instructions stipulated on the purchase order.

19.2.5. The information on invoices and documents relating to delivery must comply with the minimum data requirements as defined by the National Department of Health. These requirements will be communicated upon signing of the contract .

19.2.6. Original invoices and proof of delivery must be authorised by a delegated official at the designated delivery point. These documents should be delivered to the authority responsible for payment.

19.2.7. The supplier must ensure that products are delivered in accordance with the appropriate conditions of storage. Delivery is deemed to terminate upon signature of receipt by the delegated official as contemplated in paragraph 19.2.6.

19.2.8. Discrepancies between invoice and physical stock, or damaged stock, will be reported to the contracted supplier within five working days of receipt of delivery.

19.2.9. Contracted suppliers will be responsible for collection of goods delivered erroneously, or in the incorrect condition, within five working days of receipt of a discrepancy report from facility.

19.2.10. The supplier must inform delivery sites by phone at least 24 hours in advance as to when they should expect a delivery. Deliveries must be made within reasonable working hours, before 15:00 on week days. Delivery staff must ensure all cartons are stacked neatly, with all labels right side up, in the respective storage areas. It

will be the supplier's responsibility to ensure that adequate labour for offloading stock is provided. Delivery site staff is not obliged to assist with the materials offloading.

19.3. CONTINUITY OF SUPPLY

19.3.1. Contracted suppliers must:

- maintain sufficient stock to meet demand throughout the duration of the contract;
- inform the National Department of Health at first knowledge of any circumstances that may result in interrupted supply, including but not limited to:
  1. industrial action,
  2. manufacturing pipeline
  3. any other supply challenges.
- official communication relating to continuity of supply must be directed to motsem@health.gov.za, as well as Participating Authorities;
- this official communication must include detail of corrective actions taken by contracted supplier to ensure continuity of supply.

19.3.2. In terms of the General Conditions of Contract and Special Requirements and Conditions of Contract, the Department of Health reserves the right to purchase outside of the contract in order to meet its requirements if :

- the contracted supplier fails to perform in terms of the contract;
- the item(s) are urgently required and not immediately available;
- in the case of an emergency.

20. PACKAGING AND LABELLING

20.1. PACKAGING

20.1.1. Packaging requirements of condoms and lubricants shall comply with those indicated in the products specification.

20.1.2. All deliveries made against this contract, in all modes of transport, are to be packed in suitable containers, which will be acceptable for further dispatch.

20.1.3. Suppliers must ensure that products delivered are received in good order at the point of delivery. Packaging must be suitable for further dispatch, storage and stacking according to Good Wholesaling Practice and Good Distribution Practice.

20.1.4. Packaging must be suitable for transportation and should prevent exposure to conditions that could adversely affect the stability and integrity of the product.

20.1.5. The packing must be uniform for the duration of the contract period. All products must be packed in acceptable containers, specifically developed for the product.

20.1.6. The number of units in the unit pack, shelf pack and shipper pack must be completed in the Bid Response Document.

20.1.7. Where a particular stacking and storage configuration is recommended by the supplier, this should be clearly illustrated on the outer packaging.

20.1.8. Where the contents of the shipper pack represents a standard supply quantity of an item, the following must be adhered to:

- Outer packaging flanges must be sealed with suitable tape that will clearly display evidence of tampering
- The contents must be packed in neat, uniform rows and columns that will facilitate easy counting when opened.

20.1.9. Where the contents of a shipper pack represents a non-standard supply quantity, the following must be adhered to:

- Outer packaging flanges must be sealed with suitable tape that will clearly display evidence of tampering.
- The shipper pack must contain only one product, mixing of multiple items in a single shipper is not allowed.
- The outer packaging must be clearly marked as a "Part Box".

20.2. LABELLING

20.2.1. All containers, packing and cartons must be clearly labelled. Bulk packs must be labelled in letters not less than font size 48.

The following information must be clearly and indelibly printed on all shelf and shipper packs, including any part boxes:

- Proprietary name (if applicable)
- Number of units in pack (e.g. for bulk packs 200 condoms)
- Batch number
- Expiry date
- Storage conditions
- Barcode

20.2.2. Where the contents of the shipper requires special attention in terms of storage or handling, e.g. thermolabile, fragile, handle with care, such instructions must be clearly and visibly indicated on the outer packaging on a brightly coloured background.

20.3. BARCODES

20.3.1. It is mandatory that all products supplied must include a barcode (number plus symbology). All shipper, shelf and unit packs must be marked with the appropriate number and symbology. The European Article Numbering Code 13 (EAN 13) has been accepted as standard.

20.3.2. Suppliers are encouraged to include a 2D barcode or similar on their packaging that will include the following information:

- Brand name
- Batch number
- Expiry date

21. QUALITY

Products must conform to the quality requirements as stipulated in the specifications. No deviations will be accommodated.

22. SHELF-LIFE

22.1. Condoms (male and female) must have a shelf-life of at least 5 years on manufacturing.

22.2. All products must have a remaining shelf life of at least 3 years upon delivery

22.3. Any Participating Authority may, without prejudice, decline to accept product with a shelf-life of less than 3 years.

23. POST AWARD

23.1. POST AWARD PRODUCT COMPLIANCE PROCEDURES

Consignment/Batch Testing

23.1.1. All contractors must arrange random sampling (Sampling frame according to SABS guidelines) at the point of packaging of the finished products. Sampling must be carried out by an independent or internationally recognised organisation. Samples must be taken from production lots produced at the source factory within the preceding 30 days from the date of sampling. Samples must be submitted to SABS for batch testing which will be done according to National Department of Health/World Health Organisation standards and specifications.

23.1.2. The contractors shall before the confirmation of orders and issue of delivery site quantities and delivery dates, provide the STI & HIV Aids Prevention unit of the

Department of Health with compliance certificates proving adherence to the specification for each batch prior to shipment from the manufacturer.

23.1.3. Copies of these certificates must also accompany the proof of delivery documentation submitted for payment.

23.1.4. At the time of sampling the sampling agent will require certified documentation from the manufacturer indicating batch size of every batch sampled.

23.1.5. Sampling and testing organisations appointed by the Department of Health shall carry out all these certification tests.

23.1.6. The cost of these tests shall be borne by the Department of Health. The cost of tests in the event of failure of batches will be for the account of the contractor.

23.1.7. Test results are final and no requests for testing by other testing laboratories will be entertained by the Department of Health. Any performance failure (water, airburst, package seal integrity tests) will result in immediate and non-negotiable rejection of the batch.

23.1.8. Any cases of minor design failures will be treated on a case-by case basis taking into account the needs of the programme in relation to the particular failure. However, if an application for concession is made by a contractor and subsequently granted by the Department of Health, all testing costs for the concession batches will be borne by the contractor.

23.1.9. All lot sizes for testing shall be at least 1000 gross (i.e. 144 000 pieces), up to maximum of 288 000 pieces. All lot sizes must be certified at the time of sampling and this information must be communicated by the contractor to the Department of Health as soon as possible after certification. A lot is a single grade, class and composition manufactured under essentially the same conditions. All condoms comprising a lot will:

- Have an identical formulation.
- Have the same dimensions, shape, colour and texture
- Be manufactured on the same production line
- Be vulcanised under identical conditions
- Be manufactured within a period of 24 hours
- Not be made up of separate interrupted runs

23.1.10. With respect to the female condoms the supplier must submit complete documentation on the in-house manufacturing level, quality assurance programme in place at the point of manufacture. This will include descriptions of sampling and testing protocols, equipment in use including place of manufacture, date commissioned and calibration schedules and procedures. Original compliance test

reports for every production batch (including tensile (cross-sectional seam), air inflation (measuring peak pressure) and water leakage tests), duly certified by senior management must be provided at the time of sampling.

23.2. COMPLIANCE TESTED STOCK LEVELS

23.2.1. Contractors will be required to maintain, for the duration of contract, an in-country stock-holding of three months available for immediate distribution. This stock must be tested and certified. Stock levels should be estimated from the anticipated requirements of the Department as indicated in the contract award, unless otherwise instructed in writing by the Department. The required levels for compliant product may be adjusted by the Department to respond to changing programmatic requirements.

23.2.2. Suppliers will be expected to deliver condoms according to delivery schedules issued periodically by the Department of Health against current compliant stock levels to any or all of 150–200 sites within the country. Delivery quantities shall generally range from 60 000 to 2000 000 condoms per male condom site and 5 000 to 60 000 condoms per female condom site. Once the delivery sites and quantities list is issued to suppliers, deliveries shall be made within ten working days. To the extent possible for male condoms, the procurer will serve sites utilising stock available in the nearest proximity.

23.3. REGISTRATION ON DATABASES OF PARTICIPATING AUTHORITIES

23.3.1. All contracted suppliers must ensure registration on the National Department of Health supplier database as well as on all nice Provincial Departments of Health supplier databases within 30 days of accepting the award and submit proof thereof to the National Department of Health.

Failure to meet this requirement will result in inability to process payment for goods.

23.4. MONITORING

23.4.1. The management of the contract is the responsibility of the National Department of Health. All correspondence in this regard must be directed to the Director: Affordable Medicines as well as the Director: HIV Prevention Strategies.

23.4.2. Contracted suppliers must advise the National Department of Health at first knowledge of any unforeseeable circumstances that may adversely affect supply

against the contract. Full particulars of such circumstances must be provided by the supplier as contemplated in section 19.3.

23.4.3. The National Department of Health, in collaboration with the other Participating Authorities, will monitor the performance of contracted suppliers and maintain a scorecard for compliance to the terms of this contract as follows:

- Compliance to delivery lead times;
- Percentage of orders supplied in full first time;
- Compliance with reporting requirements according to reporting schedule.
- Attendance of compulsory quarterly: The National Department of Health will hold quarterly meetings with suppliers to review the next quarter's demand, as well as supplier performance.

23.4.4. The National Department of Health will request Participating Authorities to impose penalties, where deemed necessary, as per Section 21 and 22 of the General Conditions of Contract.

23.4.5. Non-performance of contracted suppliers in terms of this contract may influence participation in future Department of Health contracts.

23.4.6. Any change in the status in supply performance during the contract period must be reported within seven (7) days of receipt of such information:

Cluster: HIV & AIDS and STIs: Prevention Strategies

Ms Thato Chidarikire	Ms Eva Marumo
ChidaT@health.gov.za	Marume@health.gov.za
Tel no.: 012 395 9153	Tel no.: 012 395 9142

23.5. REPORTING AND HISTORICAL DATA

23.5.1. National Department of Health will provide successful bidders with the compulsory templates and schedule for reporting.

23.5.2. Historical value and volume reports are required to be submitted monthly preferably via e-mail to the Department of Health for attention of Ms T Chidarikire (chidat@health.gov.za) and E Marumo (marume@health.gov.za), by all successful bidders.

23.6. MERGERS, TAKE OVERS AND CHANGES IN SUPPLIER DETAILS

23.6.1. Where a contracted supplier plans to merge with or is going to be acquired by another entity, the contracted supplier must inform the Department of Health in writing 30 days prior to such event of relevant details.

23.6.2. The Department of Health reserves the right to agree to the transfer of contractual obligations to the new supplier under the prevailing conditions of contract or to cancel the contract

23.6.3. A contracted supplier must inform the National Department of Health within 14 days of any changes of address, name, contact or banking details.

23.7. THIRD PARTIES

23.7.1. Participating authorities will not make a payment to or consult with a third party.

23.7.2. No third party is entitled to put an account of a Participating Authority on hold.

23.8. CONTACT DETAILS

Director: Affordable Medicines and Director: HIV Prevention Strategies

Physical address:

Cnr Thabo Sehume and Struben Streets

Civitas Building,

Pretoria,

0001

Postal address

Private Bag X828, Pretoria, 0001

Please use the following e-mail address and contact persons to communicate with the Department for technical enquiries relating to bidding process:

Specification/technical enquiries	Bid enquiries
Ms T Chidarikire/Ms E Marumo	Ms P Moloko/Ms M Rasengane
Tel: (012) 395 9153/9142	Tel: (012) 395 8439/9452
Fax number: 0866322443	Fax number: (012) 395 8823
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23.9. ABBREVIATIONS

The abbreviations used in this document signify the following:

B-BBEE	Broad-Based Black Economic Empowerment
BEC	Bid Evaluation Committee
NDoH	National Department of Health
RoE	Rate of Exchange
VAT	Value Added Tax

THE NATIONAL TREASURY

Republic of South Africa

GOVERNMENT PROCUREMENT:

GENERAL CONDITIONS OF CONTRACT

July 2010

GOVERNMENT PROCUREMENT

GENERAL CONDITIONS OF CONTRACT
July 2010

NOTES

The purpose of this document is to:

(i) Draw special attention to certain general conditions applicable to government bids, contracts and orders; and

(ii) To ensure that clients be familiar with regard to the rights and obligations of all parties involved in doing business with government.

In this document words in the singular also mean in the plural and vice versa and words in the masculine also mean in the feminine and neuter.

- The General Conditions of Contract will form part of all bid documents and may not be amended.

- Special Conditions of Contract (SCC) relevant to a specific bid, should be compiled separately for every bid (if (applicable) and will supplement the General Conditions of Contract. Whenever there is a conflict, the provisions in the SCC shall prevail.

TABLE OF CLAUSES

General Conditions of Contract

1. Definitions

1. The following terms shall be interpreted as indicated:

1.1 “Closing time” means the date and hour specified in the bidding documents for the receipt of bids.

1.2 “Contract” means the written agreement entered into between the purchaser and the supplier, as recorded in the contract form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.

1.3 “Contract price” means the price payable to the supplier under the contract for the full and proper performance of his contractual obligations.

1.4 “Corrupt practice” means the offering, giving, receiving, or soliciting of any thing of value to influence the action of a public official in the procurement process or in contract execution.

1.5 "Countervailing duties" are imposed in cases where an enterprise abroad is subsidized by its government and encouraged to market its products internationally.

1.6 “Country of origin” means the place where the goods were mined, grown or produced or from which the services are supplied. Goods are produced when, through manufacturing, processing or substantial and major assembly of components, a commercially recognized new product results that is substantially different in basic characteristics or in purpose or utility from its components.

1.7 “Day” means calendar day.

1.8 “Delivery” means delivery in compliance of the conditions of the contract or order.

1.9 “Delivery ex stock” means immediate delivery directly from stock actually on hand.

1.10 “Delivery into consignees store or to his site” means delivered and unloaded in the specified store or depot or on the specified site in compliance with the conditions of the contract or order, the supplier bearing all risks and charges involved until the supplies are so delivered and a valid receipt is obtained.

1.11 "Dumping" occurs when a private enterprise abroad market its goods on own initiative in the RSA at lower prices than that of the country of origin and which have the potential to harm the local industries in the

RSA.

1.12 ”Force majeure” means an event beyond the control of the supplier and not involving the supplier’s fault or negligence and not foreseeable. Such events may include, but is not restricted to, acts of the purchaser in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions and freight embargoes.

1.13 “Fraudulent practice” means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of any bidder, and includes collusive practice among bidders (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the bidder of the benefits of free and open competition.

1.14 “GCC” means the General Conditions of Contract.

1.15 “Goods” means all of the equipment, machinery, and/or other materials that the supplier is required to supply to the purchaser under the contract.

1.16 “Imported content” means that portion of the bidding price represented by the cost of components, parts or materials which have been or are still to be imported (whether by the supplier or his subcontractors) and which costs are inclusive of the costs abroad, plus freight and other direct importation costs such as landing costs, dock dues, import duty, sales duty or other similar tax or duty at the South African place of entry as well as transportation and handling charges to the factory in the Republic where the supplies covered by the bid will be manufactured.

1.17 “Local content” means that portion of the bidding price which is not included in the imported content provided that local manufacture does take place.

1.18 “Manufacture” means the production of products in a factory using labour, materials, components and machinery and includes other related value-adding activities.

1.19 “Order” means an official written order issued for the supply of goods or works or the rendering of a service.

1.20 “Project site,” where applicable, means the place indicated in bidding documents.

1.21 “Purchaser” means the organization purchasing the goods.

1.22 “Republic” means the Republic of South Africa.

1.23 “SCC” means the Special Conditions of Contract.

1.24 “Services” means those functional services ancillary to the supply of the goods, such as transportation and any other incidental services, such as installation, commissioning, provision of technical assistance, training, catering, gardening, security, maintenance and other such

obligations of the supplier covered under the contract.

1.25 "Written" or "in writing" means handwritten in ink or any form of electronic or mechanical writing.

2. Application

2.1 These general conditions are applicable to all bids, contracts and orders including bids for functional and professional services, sales, hiring, letting and the granting or acquiring of rights, but excluding immovable property, unless otherwise indicated in the bidding documents.

2.2 Where applicable, special conditions of contract are also laid down to cover specific supplies, services or works.

2.3 Where such special conditions of contract are in conflict with these general conditions, the special conditions shall apply.

3. General

3.1 Unless otherwise indicated in the bidding documents, the purchaser shall not be liable for any expense incurred in the preparation and submission of a bid. Where applicable a non-refundable fee for documents may be charged.

3.2 With certain exceptions, invitations to bid are only published in the Government Tender Bulletin. The Government Tender Bulletin may be obtained directly from the Government Printer, Private Bag X85, Pretoria 0001, or accessed electronically from www.treasury.gov.za

4. Standards

4.1 The goods supplied shall conform to the standards mentioned in the bidding documents and specifications.

5. Use of contract documents and information; inspection.

5.1 The supplier shall not, without the purchaser's prior written consent, disclose the contract, or any provision thereof, or any specification, plan, drawing, pattern, sample, or information furnished by or on behalf of the purchaser in connection therewith, to any person other than a person employed by the supplier in the performance of the contract. Disclosure to any such employed person shall be made in confidence and shall extend only so far as may be necessary for purposes of such performance.

5.2 The supplier shall not, without the purchaser's prior written consent, make use of any document or information mentioned in GCC clause 5.1 except for purposes of performing the contract.

5.3 Any document, other than the contract itself mentioned in GCC clause 5.1 shall remain the property of the purchaser and shall be returned (all copies) to the purchaser on completion of the supplier's performance under the contract if so required by the purchaser.

5.4 The supplier shall permit the purchaser to inspect the supplier's records relating to the performance of the supplier and to have them audited by auditors appointed by the purchaser, if so required by the purchaser.

6. Patent rights

6.1 The supplier shall indemnify the purchaser against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the goods or any part thereof by the purchaser.

7. Performance security

7.1 Within thirty (30) days of receipt of the notification of contract award, the successful bidder shall furnish to the purchaser the performance security of the amount specified in SCC.

7.2 The proceeds of the performance security shall be payable to the purchaser as compensation for any loss resulting from the supplier's failure to complete his obligations under the contract.

7.3 The performance security shall be denominated in the currency of the contract, or in a freely convertible currency acceptable to the purchaser and shall be in one of the following forms:

(a) a bank guarantee or an irrevocable letter of credit issued by a reputable bank located in the purchaser's country or abroad, acceptable to the purchaser, in the form provided in the bidding documents or another form acceptable to the purchaser; or
(b) a cashier's or certified cheque

7.4 The performance security will be discharged by the purchaser and returned to the supplier not later than thirty (30) days following the date of completion of the supplier's performance obligations under the contract, including any warranty obligations, unless otherwise specified in SCC.

8. Inspections, tests and analyses

8.1 All pre-bidding testing will be for the account of the bidder.

8.2 If it is a bid condition that supplies to be produced or services to be rendered should at any stage during production or execution or on completion be subject to inspection, the premises of the bidder or contractor shall be open, at all reasonable hours, for inspection by a representative of the Department or an organization acting on behalf of the Department.

8.3 If there are no inspection requirements indicated in the bidding documents and no mention is made in the contract, but during the contract period it is decided that inspections shall be carried out, the purchaser shall itself make the necessary arrangements, including payment arrangements with the testing authority concerned.

8.4 If the inspections, tests and analyses referred to in clauses 8.2 and 8.3 show the supplies to be in accordance with the contract requirements, the cost of the inspections, tests and analyses shall be defrayed by the purchaser.

8.5 Where the supplies or services referred to in clauses 8.2 and 8.3 do not comply with the contract requirements, irrespective of whether such supplies or services are accepted or not, the cost in connection with these inspections, tests or analyses shall be defrayed by the supplier.

8.6 Supplies and services which are referred to in clauses 8.2 and 8.3 and which do not comply with the contract requirements may be rejected.

8.7 Any contract supplies may on or after delivery be inspected, tested or

analyzed and may be rejected if found not to comply with the requirements of the contract. Such rejected supplies shall be held at the cost and risk of the supplier who shall, when called upon, remove them immediately at his own cost and forthwith substitute them with supplies which do comply with the requirements of the contract. Failing such removal the rejected supplies shall be returned at the suppliers cost and risk. Should the supplier fail to provide the substitute supplies forthwith, the purchaser may, without giving the supplier further opportunity to substitute the rejected supplies, purchase such supplies as may be necessary at the expense of the supplier.

8.8 The provisions of clauses 8.4 to 8.7 shall not prejudice the right of the purchaser to cancel the contract on account of a breach of the conditions thereof, or to act in terms of Clause 23 of GCC.

9. Packing

9.1 The supplier shall provide such packing of the goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt and precipitation during transit, and open storage. Packing, case size and weights shall take into consideration, where appropriate, the remoteness of the goods' final destination and the absence of heavy handling facilities at all points in transit.

9.2 The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the contract, including additional requirements, if any, specified in SCC, and in any subsequent instructions ordered by the purchaser.

10. Delivery and documents

10.1 Delivery of the goods shall be made by the supplier in accordance with the terms specified in the contract. The details of shipping and/or other documents to be furnished by the supplier are specified in SCC.

10.2 Documents to be submitted by the supplier are specified in SCC.

11. Insurance

11.1 The goods supplied under the contract shall be fully insured in a freely convertible currency against loss or damage incidental to manufacture or acquisition, transportation, storage and delivery in the manner specified in the SCC.

12. Transportation

12.1 Should a price other than an all-inclusive delivered price be required, this shall be specified in the SCC.

13. Incidental services

13.1 The supplier may be required to provide any or all of the following services, including additional services, if any, specified in SCC:

(a) performance or supervision of on-site assembly and/or commissioning of the supplied goods;
(b) furnishing of tools required for assembly and/or maintenance of the supplied goods;
(c) furnishing of a detailed operations and maintenance manual for each appropriate unit of the supplied goods;

(d) performance or supervision or maintenance and/or repair of the supplied goods, for a period of time agreed by the parties, provided that this service shall not relieve the supplier of any warranty obligations under this contract; and

(e) training of the purchaser's personnel, at the supplier's plant and/or on-site, in assembly, start-up, operation, maintenance, and/or repair of the supplied goods.

13.2 Prices charged by the supplier for incidental services, if not included in the contract price for the goods, shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged to other parties by the supplier for similar services.

14. Spare parts

14.1 As specified in SCC, the supplier may be required to provide any or all of the following materials, notifications, and information pertaining to spare parts manufactured or distributed by the supplier:

(a) such spare parts as the purchaser may elect to purchase from the supplier, provided that this election shall not relieve the supplier of any warranty obligations under the contract; and

(b) in the event of termination of production of the spare parts:

(i) Advance notification to the purchaser of the pending termination, in sufficient time to permit the purchaser to procure needed requirements; and

(ii) following such termination, furnishing at no cost to the purchaser, the blueprints, drawings, and specifications of the spare parts, if requested.

15. Warranty

15.1 The supplier warrants that the goods supplied under the contract are new, unused, of the most recent or current models, and that they incorporate all recent improvements in design and materials unless provided otherwise in the contract. The supplier further warrants that all goods supplied under this contract shall have no defect, arising from design, materials, or workmanship (except when the design and/or material is required by the purchaser's specifications) or from any act or omission of the supplier, that may develop under normal use of the supplied goods in the conditions prevailing in the country of final destination.

15.2 This warranty shall remain valid for twelve (12) months after the goods, or any portion thereof as the case may be, have been delivered to and accepted at the final destination indicated in the contract, or for eighteen (18) months after the date of shipment from the port or place of loading in the source country, whichever period concludes earlier, unless specified otherwise in SCC.

15.3 The purchaser shall promptly notify the supplier in writing of any claims arising under this warranty.

15.4 Upon receipt of such notice, the supplier shall, within the period specified in SCC and with all reasonable speed, repair or replace the defective goods or parts thereof, without costs to the purchaser.

15.5 If the supplier, having been notified, fails to remedy the defect(s) within the period specified in SCC, the purchaser may proceed to take

such remedial action as may be necessary, at the supplier's risk and expense and without prejudice to any other rights which the purchaser may have against the supplier under the contract.

16. Payment

16.1 The method and conditions of payment to be made to the supplier under this contract shall be specified in SCC.

16.2 The supplier shall furnish the purchaser with an invoice accompanied by a copy of the delivery note and upon fulfillment of other obligations stipulated in the contract.

16.3 Payments shall be made promptly by the purchaser, but in no case later than thirty (30) days after submission of an invoice or claim by the supplier.

16.4 Payment will be made in Rand unless otherwise stipulated in SCC.

17. Prices

17.1 Prices charged by the supplier for goods delivered and services performed under the contract shall not vary from the prices quoted by the supplier in his bid, with the exception of any price adjustments authorized in SCC or in the purchaser's request for bid validity extension, as the case may be.

18. Contract amendments

18.1 No variation in or modification of the terms of the contract shall be made except by written amendment signed by the parties concerned.

19. Assignment

19.1 The supplier shall not assign, in whole or in part, its obligations to perform under the contract, except with the purchaser's prior written consent.

20. Subcontracts

20.1 The supplier shall notify the purchaser in writing of all subcontracts awarded under this contracts if not already specified in the bid. Such notification, in the original bid or later, shall not relieve the supplier from any liability or obligation under the contract.

21. Delays in the supplier's performance

21.1 Delivery of the goods and performance of services shall be made by the supplier in accordance with the time schedule prescribed by the purchaser in the contract.

21.2 If at any time during performance of the contract, the supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the goods and performance of services, the supplier shall promptly notify the purchaser in writing of the fact of the delay, its likely duration and its cause(s). As soon as practicable after receipt of the supplier's notice, the purchaser shall evaluate the situation and may at his discretion extend the supplier's time for performance, with or without the imposition of penalties, in which case the extension shall be ratified by the parties by amendment of contract.

21.3 No provision in a contract shall be deemed to prohibit the obtaining of supplies or services from a national department, provincial department, or a local authority.

21.4 The right is reserved to procure outside of the contract small quantities or to have minor essential services executed if an emergency arises, the

supplier's point of supply is not situated at or near the place where the supplies are required, or the supplier's services are not readily available.

21.5 Except as provided under GCC Clause 25, a delay by the supplier in the performance of its delivery obligations shall render the supplier liable to the imposition of penalties, pursuant to GCC Clause 22, unless an extension of time is agreed upon pursuant to GCC Clause 21.2 without the application of penalties.

21.6 Upon any delay beyond the delivery period in the case of a supplies contract, the purchaser shall, without canceling the contract, be entitled to purchase supplies of a similar quality and up to the same quantity in substitution of the goods not supplied in conformity with the contract and to return any goods delivered later at the supplier's expense and risk, or to cancel the contract and buy such goods as may be required to complete the contract and without prejudice to his other rights, be entitled to claim damages from the supplier.

22. Penalties

22.1 Subject to GCC Clause 25, if the supplier fails to deliver any or all of the goods or to perform the services within the period(s) specified in the contract, the purchaser shall, without prejudice to its other remedies under the contract, deduct from the contract price, as a penalty, a sum calculated on the delivered price of the delayed goods or unperformed services using the current prime interest rate calculated for each day of the delay until actual delivery or performance. The purchaser may also consider termination of the contract pursuant to GCC Clause 23.

23. Termination for default

23.1 The purchaser, without prejudice to any other remedy for breach of contract, by written notice of default sent to the supplier, may terminate this contract in whole or in part:

(a) if the supplier fails to deliver any or all of the goods within the period(s) specified in the contract, or within any extension thereof granted by the purchaser pursuant to GCC Clause 21.2;

(b) if the Supplier fails to perform any other obligation(s) under the contract; or

(c) if the supplier, in the judgment of the purchaser, has engaged in corrupt or fraudulent practices in competing for or in executing the contract.

23.2 In the event the purchaser terminates the contract in whole or in part, the purchaser may procure, upon such terms and in such manner as it deems appropriate, goods, works or services similar to those undelivered, and the supplier shall be liable to the purchaser for any excess costs for such similar goods, works or services. However, the supplier shall continue performance of the contract to the extent not terminated.

23.3 Where the purchaser terminates the contract in whole or in part, the purchaser may decide to impose a restriction penalty on the supplier by prohibiting such supplier from doing business with the public sector for a period not exceeding 10 years.

23.4 If a purchaser intends imposing a restriction on a supplier or any

person associated with the supplier, the supplier will be allowed a time period of not more than fourteen (14) days to provide reasons why the envisaged restriction should not be imposed. Should the supplier fail to respond within the stipulated fourteen (14) days the purchaser may regard the intended penalty as not objected against and may impose it on the supplier.

23.5 Any restriction imposed on any person by the Accounting Officer / Authority will, at the discretion of the Accounting Officer / Authority, also be applicable to any other enterprise or any partner, manager, director or other person who wholly or partly exercises or exercised or may exercise control over the enterprise of the first-mentioned person, and with which enterprise or person the first-mentioned person, is or was in the opinion of the Accounting Officer / Authority actively associated.

23.6 If a restriction is imposed, the purchaser must, within five (5) working days of such imposition, furnish the National Treasury, with the following information:

(i) the name and address of the supplier and / or person restricted by the purchaser;
(ii) the date of commencement of the restriction
(iii) the period of restriction; and
(iv) the reasons for the restriction.

These details will be loaded in the National Treasury's central database of suppliers or persons prohibited from doing business with the public sector.

23.7 If a court of law convicts a person of an offence as contemplated in sections 12 or 13 of the Prevention and Combating of Corrupt Activities Act, No. 12 of 2004, the court may also rule that such person's name be endorsed on the Register for Tender Defaulters. When a person's name has been endorsed on the Register, the person will be prohibited from doing business with the public sector for a period not less than five years and not more than 10 years. The National Treasury is empowered to determine the period of restriction and each case will be dealt with on its own merits. According to section 32 of the Act the Register must be open to the public. The Register can be perused on the National Treasury website.

24. Anti-dumping and countervailing duties and rights

24.1 When, after the date of bid, provisional payments are required, or anti-dumping or countervailing duties are imposed, or the amount of a provisional payment or anti-dumping or countervailing right is increased in respect of any dumped or subsidized import, the State is not liable for any amount so required or imposed, or for the amount of any such increase. When, after the said date, such a provisional payment is no longer required or any such anti-dumping or countervailing right is abolished, or where the amount of such provisional payment or any such right is reduced, any such favourable difference shall on demand be paid forthwith by the contractor to the State or the State may deduct such amounts from moneys (if any) which may otherwise be due to the contractor in regard to supplies or services which he delivered or rendered, or is to deliver or render in terms of the contract or any other contract or any other amount which

may be due to him

25. Force Majeure

25.1 Notwithstanding the provisions of GCC Clauses 22 and 23, the supplier shall not be liable for forfeiture of its performance security, damages, or termination for default if and to the extent that his delay in performance or other failure to perform his obligations under the contract is the result of an event of force majeure.

25.2 If a force majeure situation arises, the supplier shall promptly notify the purchaser in writing of such condition and the cause thereof. Unless otherwise directed by the purchaser in writing, the supplier shall continue to perform its obligations under the contract as far as is reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the force majeure event.

26. Termination for insolvency

26.1 The purchaser may at any time terminate the contract by giving written notice to the supplier if the supplier becomes bankrupt or otherwise insolvent. In this event, termination will be without compensation to the supplier, provided that such termination will not prejudice or affect any right of action or remedy which has accrued or will accrue thereafter to the purchaser.

27. Settlement of Disputes

27.1 If any dispute or difference of any kind whatsoever arises between the purchaser and the supplier in connection with or arising out of the contract, the parties shall make every effort to resolve amicably such dispute or difference by mutual consultation.

27.2 If, after thirty (30) days, the parties have failed to resolve their dispute or difference by such mutual consultation, then either the purchaser or the supplier may give notice to the other party of his intention to commence with mediation. No mediation in respect of this matter may be commenced unless such notice is given to the other party.

27.3 Should it not be possible to settle a dispute by means of mediation, it may be settled in a South African court of law.

27.4 Mediation proceedings shall be conducted in accordance with the rules of procedure specified in the SCC.

27.5 Notwithstanding any reference to mediation and/or court proceedings herein,

(a) the parties shall continue to perform their respective obligations under the contract unless they otherwise agree; and
(b) the purchaser shall pay the supplier any monies due the supplier.

28. Limitation of liability

28.1 Except in cases of criminal negligence or willful misconduct, and in the case of infringement pursuant to Clause 6;

(a) the supplier shall not be liable to the purchaser, whether in contract, tort, or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production, or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the supplier to pay penalties and/or damages to the purchaser; and

(b) the aggregate liability of the supplier to the purchaser, whether under the contract, in tort or otherwise, shall not exceed the total contract price, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment.

29. Governing language

29.1 The contract shall be written in English. All correspondence and other documents pertaining to the contract that is exchanged by the parties shall also be written in English.

30. Applicable law

30.1 The contract shall be interpreted in accordance with South African laws, unless otherwise specified in SCC.

31. Notices

31.1 Every written acceptance of a bid shall be posted to the supplier concerned by registered or certified mail and any other notice to him shall be posted by ordinary mail to the address furnished in his bid or to the address notified later by him in writing and such posting shall be deemed to be proper service of such notice

31.2 The time mentioned in the contract documents for performing any act after such aforesaid notice has been given, shall be reckoned from the date of posting of such notice.

32. Taxes and duties

32.1 A foreign supplier shall be entirely responsible for all taxes, stamp duties, license fees, and other such levies imposed outside the purchaser's country.

32.2 A local supplier shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted goods to the purchaser.

32.3 No contract shall be concluded with any bidder whose tax matters are not in order. Prior to the award of a bid the Department must be in possession of a tax clearance certificate, submitted by the bidder. This certificate must be an original issued by the South African Revenue Services.

33. National Industrial Participation (NIP) Programme

33.1 The NIP Programme administered by the Department of Trade and Industry shall be applicable to all contracts that are subject to the NIP obligation.

34 Prohibition of Restrictive practices

34.1 In terms of section 4 (1) (b) (iii) of the Competition Act No. 89 of 1998, as amended, an agreement between, or concerted practice by, firms, or a decision by an association of firms, is prohibited if it is between parties in a horizontal relationship and if a bidder (s) is / are or a contractor(s) was / were involved in collusive bidding (or bid rigging).

34.2 If a bidder(s) or contractor(s), based on reasonable grounds or evidence obtained by the purchaser, has / have engaged in the restrictive practice referred to above, the purchaser may refer the matter to the Competition Commission for investigation and possible imposition of administrative penalties as contemplated in the Competition Act No. 89 of 1998.

34.3 If a bidder(s) or contractor(s), has / have been found guilty by the Competition Commission of the restrictive practice referred to above, the purchaser may, in addition and without prejudice to any other remedy provided for, invalidate the bid(s) for such item(s) offered, and / or terminate the contract in whole or part, and / or restrict the bidder(s) or contractor(s) from conducting business with the public sector for a period not exceeding ten (10) years and / or claim damages from the bidder(s) or contractor(s) concerned.

CONDOMS, MALE, FOR USE DURING INTERCOURSE

QUANTITIES REQUIRED: 1 BILLION UNITS PER ANNUM
(3 BILLION UNITS FOR 3 YEARS)
DISAGGREGATED BY COLOUR AS FOLLOWS:

- 250 million natural colour masked (the latex smell should be **masked** by vanilla)
- 250 million yellow colour with banana scent
- 250 million purple colour with grape scent
- 250 million red colour with strawberry scent

PACKAGING: INDIVIDUALLY PACKED.
SAMPLES TO BE SUBMITTED TO SABS, IN QUANTITIES REQIURED AS PER SABS SPECIFICATIONS

COST MUST INCLUDE DELIVERY COST.

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

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).

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.

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 (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.
- 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 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 MSDS).

1.2 Shelf-life

Condoms shall comply with the performance requirements of the WHO/UNFPA 2010 specifications or latest updated version throughout the stated shelf life of the condom.

It is intended that condoms purchased under this specifications should retain their properties when exposed in their individual packages to an average temperature of 35^0 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 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 5 years. At the time of delivery at least 80% or 3 years 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^o C, COA or declaration certificate.
2. Use of the methods of WHO/UNFPA 2010 specification or latest updated version or/ISO 4074:2002

3. The maximum acceptable decrease in mean inflation properties should be 25%, and products should comply with the requirements of WHO/UNFPA specifications2010 or latest updated version at the end of the stated shelf-life.

1.3 Dressing materials

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.

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

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 35^0 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 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 4074:2002 (version current at the time of contract).

2.1 Bursting volume and pressure*

(i) Sampling

For the test before oven conditioning: *ISO 2859-1General 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 4074:2002.*

(iii) Requirement AQL 1.5% applied separately to volume and pressure non-compliers.

Volume:

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

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

Pressure:

The minimum bursting pressure shall be 1kPa.

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 4074:2002 at a point (75±5)mm from the closed end.

2.2 Freedom from holes*

(i) Sampling

ISO 2859-1 General Inspection Level G-1.

(ii) Testing

The test is carried out in accordance with relevant annexure of*ISO 4074:2002*

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

(iii) Requirement

The test is carried out in accordance with relevant annexure of*ISO 4074:2002*

Freedom from holes: AQL 0.25.

Critical visible defects: AQL 0.4

Non critical visible defect: AQL 2.5

2.3 Package seal integrity*

(i) Sampling

ISO 2859-1 Special Inspection Level S-3.

(ii) Testing

In accordance with Package Integrity Test Method in the relevant annexure of *ISO 4074:2002*

(iii) Requirement

*AQL*2.5

3 DESIGN REQUIREMENTS

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

- Tests or verifications in this section will generally be:
    - 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 *ISO 4074:2002*.

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 IntegralBead*

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

3.3 Colour and clarity*

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

3.3.1 Natural

The condoms shall be translucent (clear) and without added colouring. The latex smell shall be masked with vanilla.

3.3.2 Red (Strawberry)

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

3.3.3 Yellow (Banana)

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

3.3.4 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.

3.4 Odour/fragrance*

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.

3.4.1 The natural (colourless) condoms shall be of vanilla scent

Vanilla must be used as a masking agent for the natural (colourless) condoms. The scent must be non-toxic, non irritant and not degrade the rubber. The concentration of the vanilla should not be at the same level as the vanilla scented-condoms. Full details of the scent, including MSDS and/or COA may be requested

The coloured condoms shall be of 3 different fragrances/odour: 1X fragrance per colour per item as follows:

3.4.2 A red condom shall smell of strawberry (fruit)

3.4.3 A yellow condom shall smell of banana (fruit)

3.4.4 A purple condom shall smell of grape (fruit)

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

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.

Points 3.1–3.4 may be verified by visual and other appropriate inspection methods including MSDS and/or COA.

3.5 Length*

(i) Sampling

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

(ii) Testing

According to the length measurement procedure in *ISO 4074:2002*

(iii) Requirement

AQL: 1.0

A minimum of 165mm 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 4074:2002*

(iii) Requirement

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.

3.7 Thickness*

(i) Sampling

ISO 2859-1 Special Inspection Level S-2.

(ii) Testing

In accordance with test method in ISO 4074:2002

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.

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-0.020mm.

3.8 Quantity of lubricant *

(i) Sampling

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

(ii) Testing

In accordance with test method in *ISO 4074:2002*

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, including powder, in the package shall be 550 $^{+}$150 mg. With an AQL of 4.0%.

3.9 Individual package materials and markings*

(i) Sampling

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

(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 preprinted.

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*

- 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 digit number, and the month as a two digit number);
- Natural rubber latex
  Quality requirement
  AQL 1%
  Compliance will be verified 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 lot-by-lot compliance testing and during periodic inspections/ audits.

4.1 Cartons and markings*

The information on the inner box shall include:

- Lot or lot identification number
- 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
- Natural rubber latex

(i) Sampling

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

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.

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 packaging materials and packing for delivery are set out below.

The AQL for these inspections is 1%.

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
* 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
* Natural rubber latex

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/030/001.

SUMMARY OF REQUIREMENTS

Pre- tender award: Summary of compliance testing and requirements

Sample according to ISO 2859-1 andAnnex B isolated in ISO 4074:2002			
Test	**Sampling**	**Requirements**	**Responsibility**
Verification of constituent materials	N/A	Manufacture's documentation	SABS
Verification of shelf life	N/A	Manufacturer's documentation	Bidders and NDOH
Bursting volume (before and after oven conditioning)	Level G-I Minimum Code Letter M	Minimum volumes: 1. 16.0 dm3 for condoms with less than 50 mm 2. 18.0 dm3 for condoms with less widths from 50 mm to 55.5 mm 3. 22 dm3 for condoms with widths greater than 56 mm AQL 1.5	SABS
Bursting pressure (before and after oven conditioning)	Level G-I Minimum Code Letter M	Minimum pressure 1.0 kpa AQL 1.5	SABS
Freedom from holes	Level G-I Minimum Code Letter N	AQL 0.25	SABS

Test	Sampling	Requirements	Responsibility
Visible defects	Level G-I Minimum Code Letter N	Critical defects: AQL 0.4 Non-critical defects: AQL 2.5	SABS
Shape and texture	Agreed between manufacturer and buyer	Visual inspection	SABS
Package integrity	Level S-3 Minimum Code Letter H	AQL 2.5	SABS
Integral bead	Agreed between manufacturer and buyer	Visual inspection	SABS
Colour	Agreed between manufacturer and buyer	Visual inspection	SABS
Fragrance	Agreed between manufacturer and buyer	Sensory inspection	SABS
Width	Level S-2	± 2mm of claimed width AQL 1.0	SABS
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
Thickness	Level S-2	0.045-0.080 mm AQL 1.0	SABS
Lubricant quantity (including powder)	Level S-2	Viscosity: 200-350 Centistokes Qty: 400-700 mg/condom AQL 4.0	SABS
Odour (if necessary)	Agreed between manufacturer and buyer	Sensory inspection	SABS
Inner box	Level S-3	Compliant with procurement specifications	SABS
Exterior shipping cartons	Level S-2	Compliant with procurement specifications	SABS

Post award: Summary of LOT-by-LOT Pre-shipment compliance testing and requirements

Sample according to ISO 2859-1 and Annex A in ISO 4074:2002			
Test	**Sampling**	**Requirements**	**Responsibility**
Bursting volume (before oven conditioning)	Level G-I	Minimum volumes: 1. 16.0 dm3 for condoms with less than 50 mm 2. 18.0 dm3 for condoms with less widths from 50 mm to 55.5 mm 3. 22 dm3 for condoms with widths greater than 56 mm AQL 1.5	SABS
Bursting pressure (before oven conditioning)	Level G-I	Minimum pressure 1.0 kpa AQL 1.5	SABS
Freedom from holes	Level G-I Minimum Code Letter M	AQL 0.25	SABS
Visible defects	Level G-I Minimum Code Letter M	Critical defects: AQL 0.4 Non-critical defects: AQL 2.5	SABS
Shape and texture	Agreed between manufacturer and buyer	Visual inspection	SABS
Package integrity	Level S-3	AQL 2.5	SABS
Integral bead	Agreed between manufacturer and buyer	Visual inspection	SABS
Colour	Agreed between manufacturer and buyer	Visual inspection	SABS
Fragrance	Agreed between manufacturer and buyer	Sensory inspection	SABS
Width	Level S-2	+- 2mm of claimed width AQL 1.0	SABS

Test	Sampling	Requirements	Responsibility
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
Thickness	Level S-2	0.045-0.080 mm AQL 1.0	SABS
Lubricant quantity (including powder)	Level S-2	Viscosity: 200-350 Centistokes Qty: 400-700 mg/condom AQL 4.0	SABS
Odour (if necessary)	Agreed between manufacturer and buyer	Sensory inspection	SABS
Inner box	Level S-3	Compliant with procurement specifications	SABS
Exterior shipping cartons	Level S-2	Compliant with procurement specifications	SABS

Summary of requirements for which tests are specified

Specification	#	Sampling	Testing	Requirements	AQL	Responsibility
1 General requirements						
Constituent materials	1.1	N/A	N/A	Documentation	N/A	SABS
Shelf-life	1.2	3 lots/650 each	see specification 1.2	Documentation		Bidder and NDOH

2 Performance requirements						
Bursting volume	2.1	G-1*	ISO 4074:2002 see specification 2.1	width^2/150	1.0	SABS
Bursting volume 70^{0}C/7 days	2.1	80 condoms	ISO 4074:2002 and WHO:2010	<20% drop		SABS
Bursting pressure	2.1	G-1*	ISO 4074:2002	1kPa	1.0	SABS
Bursting pressure 70°C/7 days	2.1	80 condoms	ISO 4074:2002 and WHO:2010	<20% drop		SABS
Freedom from holes	2.2	G-1*	ISO 4074 see specification 2.2	<3 holes	0.25	SABS
Package integrity	2.3	S-2/ S-3*	see specification 2.3	<3 leaks	2.5	SABS
3 Design requirement						
Length	3.5	S-2*	ISO 4074:2002	>=180 mm	1.0	SABS
Width	3.6	S-2*	ISO 4074:2002	53 ± 2 mm; mean 52 ± 1 mm	1.0	SABS
Thickness	3.7	S-2*	see specification 3.7	0.065 ± 0.015 mm	1.0	SABS
Lubricant plus Powder	3.8	S-2*	See Specification 3.8	550 ± 150 mg	4.0	SABS
4 Packaging requirement						
Package Materials and Markings	4.1	S-3*	see specification 3.9 specification 4.1	Visual Inspection	2.5	SABS

CONDOMS, FEMALE, FOR USE DURING INTERCOURSE

QUANTITIES REQUIRED: 54 MILLION UNITS OVER 3 YEARS
YEAR 1: 15 MILLION UNITS
YEAR 2: 18 MILLION UNITS
YEAR 3: 21 MILLION UNITS

PACKAGING: INDIVIDUALLY PACKED.
SAMPLES TO BE SUBMITTED TO SABS, IN QUANTITIES REQIURED 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*

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).

Female condoms should be designed and produced in accordance with a good quality management system in compliance with ISO 14971and ISO13485. Bidders may be requested to provide COA.

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, sensitising, 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, COA and/or MSDS may be requested.

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.

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, 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 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 may be verified by documentary evidence (COA and/or MSDS

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/ISO25841:2011 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.

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.

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.

3.4 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 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, 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 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 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

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

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

4.1.2 Sampling and requirements

When tested in accordance with the method in SANS/ISO 25841:2011 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 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 until the end of the labelled shelf life. Shelf life shall be 5 years but 3 years on delivery. Shelf life claims shall not exceed five years.

5.2 Minimum stability requirements

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

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 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

7. VISIBLE DEFECTS*

Female condoms shall be tested for visible defects as described in Annexure J of SANS/ISO 25841:2011. 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 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.

One hundred 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

Nine to 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

SUMMARY OF REQUIREMENTS AND RESPONSIBILITIES

REQUIREMENTS	RESPONSIBILITY
General requirements	
Constituent materials	SABS
Shelf-life	Biddersand NDoH
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

LUBRICANT, WATER BASED, NON-IRRITANT, FOR USE DURING INTERCOURSE

QUANTITIES REQUIRED: 20 000 000 UNITS PER YEAR
(60 000 000 UNITS FOR 3 YEARS)

PACKAGING: INDIVIDUALLY PACKED SATCHETS CONTAINING FIVE MILLILITRES (5ML) OF LUBRICANT

SAMPLES TO BE SUBMITTED TO SABS, IN QUANTITIES REQIURED AS PER SABS SPECIFICATIONS

COST MUST INCLUDE DELIVERY COST.

1. GENERAL REQUIREMENTS

Manufacturers and suppliers shall follow an appropriate code of quality management, including good manufacturing practices (GMP) and statistical process control, in the manufacture and packaging of lubricants.
The methods used to test for compliance are:

- use of statistical samples; and
- subjective inspection;
- documentary evidence, such as comprehensive reports of stability tests, certificate of analysis (COA), certificates of purity from material suppliers, or certification by regulatory agency or an independent body, certificate of analysis, Material Safety Data Sheet (MSDS), Formulation of the lubricant).

The product must be tested by an independent laboratory for condom compatibility, and biocompatibility. Final results from these tests must demonstrate that the device meets established acceptance criteria in accordance with the identified industry standards.

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 lubricants not meet the requirements when tested that particular lot will be considered to be unfit for delivery.

1.1. Product Indication

1.1.1. The product is principally intended as a personal lubricant to moisturise and supplement the body's natural lubricating fluids, and to enhance the ease and comfort of sexual activity.

1.1.2. The lubricant must be suitable for both vaginal and anal intercourse.

1.1.3. The lubricant must be compatible with natural rubber latex, polyurethane and synthetic material as evidenced by condom compatibility tests.

1.1.4. The lubricant is not intended as a contraceptive or spermicide and should not contain any such components.

1.2. Constituent Materials

1.2.1. The lubricant must be water-based gel-like liquid and have the following properties: *

- sugar free; colourless; fragrance free; tasteless; dermosensitive glide; moisturising; non-irritating; non-staining; non-greasy; non-sticky;
- pH balanced (5.5–7.0PH)*, at room temperature
- alcohol free

1.2.2. The lubricant must be compatible with natural rubber latex as defined by ASTM D7661–10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms*

1.2.3. Lubricant must be safe for use with polyurethane and synthetic condoms

1.2.4. The use of preservatives, viscosity modifiers, moisturisers, humectants and other components used to modify the texture, rate of water evaporation and lubricating properties of lubricants should be stated.

1.2.5. The osmolality of the lubricant must be suitable for both vaginal and anal use.

1.2.6. The lubricant formulation should not contain polyquaternium compounds, specifically polyquaternium 15.

These requirements may be verified through COA and/or MSDS

Note: Verification of the results of the following tests may be conducted through a COA or MSDS

Characteristic	**Specification**
• Appearance:	clear medium viscous gel, free of impurities
• pH:	5.5–7.0
• Colour:	clear
• Odour:	odourless
• Specific gravity:	1.055–1.085
• Viscosity at 25C:	8000–20000 (viscous)
• Solubility in water:	soluble
• bio-burden:	
o total aerobic microbial count cfu/g:	100 maximum
o total combined yeasts and moulds count cfu/g:	20 maximum

These requirements will be verified by documentary evidence.

1.3. Shelf-life

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

2.1.1. *The shelf-life must be at least 3 years from date of manufacture.

2.1.2. The lubricant must comply with the performance requirements of this specification throughout the stated shelf life.

2.1.3. *The lubricant must retain its properties when exposed in individual packages to an average temperature of 35^0C for the stated shelf-life.

2.1.4. *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 these requirements.

2.1.5. *At the time of delivery, at least 80% of the shelf-life must still be available to the procurer.

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

- Real time stability studies conducted over the stated shelf-life at 35^oC.
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- Updated documentation on 35^{o}C post-market trials must be made available to the purchaser on request.
- Validated expiry dates up to 3 years will be allowed.

These requirements will be verified by documentary evidence.

3. DESIGN REQUIREMENTS

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

- The methods used to test these requirements for compliance will be:
  - visual inspection;
  - use of statistical samples; and/or
  - prescribed test protocols.
- Tests or verifications in this section will generally be:
  - at the pre-qualification stage;
  - compliance of lot by lot testing carried out by an independent laboratory 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.

3.1. Colour and Clarity*

3.1.1. The lubricant must be translucent (clear) and without added colouring.

3.2. Odour and Taste*

3.2.1. The lubricant must be odourless.

3.2.2. The lubricant must be tasteless**.**

3.3. Individual package materials, integrity and markings*

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

3.3.2. Sachet volume: 5 mL

3.3.3. Size: 65mmX53mm approx

3.3.4. Material: Foil

3.3.5. Pack size: 500 sachets per pack

3.3.6. Compliance with Package Integrity Test Method in *ISO 4074* Annex M

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

3.3.8. 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.
- 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:
    - Lot number or lot identification code (printed at the time of packaging, not pre-printed);
    - Not for sale
    - Distributed for the Department of Health, South Africa
    - Manufacture date and expiry date
    - Store away from direct sun light in a cool dry place
- *Expiry 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)

Compliance will be verified by visual inspection

4. PERFORMANCE REQUIREMENTS

The product must be tested by independent laboratories for condom compatibility, biocompatibility and preservative effectiveness. Final results from these tests must demonstrate that the product meets established acceptance criteria in accordance with the identified industry standards (These may be verified through COA and/or MSDS).

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- Performance requirements will be tested for compliance by the use of statistical samples and prescribed test protocols.
- Verifications in this section will be undertaken at the pre-qualification stage, and by lot-by-lot compliance testing carried out by an independent laboratory prior to delivery.

4.1. *Biocompatibility Testing (Please provide declaration for compliance)

4.1.1. Testing for cytotoxicity, vaginal irritation, sensitisation, and systemic toxicity must be in accordance with 1S0 10993 and must indicate lubricant biocompatibility.

4.1.2. Biocompatibility testing performed on the lubricant must confirm it is safe for its proposed indication.

4.1.3. Cytotoxicity testing must be evaluated using the Direct Contact Method according to ISO 10993-5:2009

4.1.4. Sensitisation testing must be evaluated using the Maximisation Test for Delayed Type Hypersensitivity test according to ISO 10993-10:2010

4.1.5. Vaginal irritation must be evaluated using the Vaginal Irritation Test according to ISO 10993-10:2010

4.1.6. Systemic toxicity must be evaluated using the Acute System Toxicity Test according to ISO 10993-11:2006

These requirements may be verified by documentary evidence.

4.2. Condom Compatibility Testing

4.2.1. *Condom compatibility testing as defined by ASTM D7661-10 Standard Test Method must demonstrate that the lubricant formulation is compatible with natural rubber latex condoms as well as polyurethane and synthetic condoms.

This requirement may be verified by documentary evidence (COA and/or MSDS)

4.3. Stability Testing*

4.3.1. Stability data, using real-time and accelerated ageing tests, must confirm a shelf life of at least 3 years for the lubricant.

This requirement may be verified by documentary evidence (COA and/or MSDS)

4.4. Quality Control Release Testing*

4.4.1. Lot release testing of the lubricant must include evaluation of appearance/colour, odour, viscosity, specific gravity, pH, water activity and microbiological safety (bio-burden).

This requirement may be verified by documentary evidence (COA and/or MSDS).

Description **NB: Complete All Fields**	**36 months**	**Item 1: Male Condoms Natural Colour Masked (the latex smell should be masked by vanilla) Note that full item specification should be read as in Annexure A** **Strip of 4 (Pack of 200)**
	Estimates>>>	750000000 Condoms 3,750000 Boxes of 200
BIDDER NAME		
Brand Name		
Delivered Price in ZAR **VAT inclusive per pack of 200 condoms**		
Lead Time (Maximum 42 Days)		
Initial Lead Time (Days)		
Shelf Life ex manufacture (Months)		
Constituent Material (Specify)		
Supplier Volume Capacity **(Max quantity able to supply**	Quantity for full tender period	
	Monthly Quantity	
	Quarterly Quantity	
Are you manufacturing in SA? YES/NO		◯ Yes ◯ No
If NO, Country of manufacture		
Name of Actual Manufacturer		
If you are NOT the actual manufacturer:	Letter from the manufacturer submitted? YES/NO	◯ Yes ◯ No
Submitted Proof of SABS Mark YES/NO		◯ Yes ◯ No
Is SABS test report attached? YES/NO		◯ Yes ◯ No
If NO, Have samples been submitted to the SABS and proof attached? YES/NO		◯ Yes ◯ No
Does the outer carton carry EAN 13 barcode?		◯ Yes ◯ No
Price Breakdown by components relating to Foreign Exchange Price Adjustments (Paragraph 17.2 SCC): The 4 components should add up to 100% of the delivered price. If complete product is imported, ignore Raw Material and only list under manufacturing component.	1) Raw materials %	
	Local %	100.00
	Imported %	
	2) Manufacturing	
	Local %	100.00
	Imported %	
	3) Logistics %	
	4) Profit Margin %	
	Currency used for imported content	

Description **NB: Complete All Fields**	**36 months**	**Item 2: Male Condoms Purple Colour with grape scent** **Note that full item specification should be read as in Annexure A** **Strip of 4 (pack of 200)**
	Estimates>>>	750000000 Condoms 3,750000 Boxes of 200
BIDDER NAME		
Brand Name		
Delivered Price in ZAR **VAT inclusive per pack of 200 condoms**		
Lead Time (Maximum 42 Days)		
Initial Lead Time (Days)		
Shelf Life ex manufacture (Months)		
Constituent Material (Specify)		
Supplier Volume Capacity **(Max quantity able to supply**	Quantity for full tender period	
	Monthly Quantity	
	Quarterly Quantity	
Are you manufacturing in SA? YES/NO		◯ Yes ◯ No
If NO, Country of manufacture		
Name of Actual Manufacturer		
If you are NOT the actual manufacturer:	Letter from the manufacturer submitted? YES/NO	◯ Yes ◯ No
Submitted Proof of SABS Mark YES/NO		◯ Yes ◯ No
Is SABS test report attached? YES/NO		◯ Yes ◯ No
If NO, Have samples been submitted to the SABS and proof attached? YES/NO		◯ Yes ◯ No
Does the outer carton carry EAN 13 barcode?		◯ Yes ◯ No
Price Breakdown by components relating to Foreign Exchange Price Adjustments (Paragraph 17.2 SCC): The 4 components should add up to 100% of the delivered price. If complete product is imported, ignore Raw Material and only list under manufacturing component.	1) Raw materials %	
	Local %	100.00
	Imported %	
	2) Manufacturing	
	Local %	100.00
	Imported %	
	3) Logistics %	
	4) Profit Margin %	
	Currency used for imported content	Indian rupee

Description NB: Complete All Fields	36 months	Item 3: Male Condoms Red Colour with strawberry scent Note that full item specification should be read as in Annexure A Strip of 4 (pack of 200)
	Estimates>>>	750000000 Condoms 3,750000 Boxes of 200
BIDDER NAME		
Brand Name		
Delivered Price in ZAR VAT inclusive per pack of 200 condoms		
Lead Time (Maximum 42 Days)		
Initial Lead Time (Days)		
Shelf Life ex manufacture (Months)		
Constituent Material (Specify)		
Supplier Volume Capacity (Max quantity able to supply	Quantity for full tender period	
	Monthly Quantity	
	Quarterly Quantity	
Are you manufacturing in SA? YES/NO		◯ Yes ◯ No
If NO, Country of manufacture		
Name of Actual Manufacturer		
If you are NOT the actual manufacturer:	Letter from the manufacturer submitted? YES/NO	◯ Yes ◯ No
Submitted Proof of SABS Mark YES/NO		◯ Yes ◯ No
Is SABS test report attached? YES/NO		◯ Yes ◯ No
If NO, Have samples been submitted to the SABS and proof attached? YES/NO		◯ Yes ◯ No
Does the outer carton carry EAN 13 barcode?		◯ Yes ◯ No
Price Breakdown by components relating to Foreign Exchange Price Adjustments (Paragraph 17.2 SCC): The 4 components should add up to 100% of the delivered price. If complete product is imported, ignore Raw Material and only list under manufacturing component.	1) Raw materials %	
	Local %	100.00
	Imported %	
	2) Manufacturing	
	Local %	100.00
	Imported %	
	3) Logistics %	
	4) Profit Margin %	
	Currency used for imported content	Indian rupee

Description NB: Complete All Fields	36 months	Item 4: Male Condoms Yellow Colour with banana scent Note that full item specification should be read as in Annexure A Strip of 4 (pack of 200)
	Estimates>>>	750000000 Condoms 3,750000 Boxes of 200
BIDDER NAME		
Brand Name		
Delivered Price in ZAR VAT inclusive per pack of 200 condoms		
Lead Time (Maximum 42 Days)		
Initial Lead Time (Days)		
Shelf Life ex manufacture (Months)		
Constituent Material (Specify)		
Supplier Volume Capacity (Max quantity able to supply	Quantity for full tender period	
	Monthly Quantity	
	Quarterly Quantity	
Are you manufacturing in SA? YES/NO		◯ Yes ◯ No
If NO, Country of manufacture		
Name of Actual Manufacturer		
If you are NOT the actual manufacturer:	Letter from the manufacturer submitted? YES/NO	◯ Yes ◯ No
Submitted Proof of SABS Mark YES/NO		◯ Yes ◯ No
Is SABS test report attached? YES/NO		◯ Yes ◯ No
If NO, Have samples been submitted to the SABS and proof attached? YES/NO		◯ Yes ◯ No
Does the outer carton carry EAN 13 barcode?		◯ Yes ◯ No
Price Breakdown by components relating to Foreign Exchange Price Adjustments (Paragraph 17.2 SCC): The 4 components should add up to 100% of the delivered price. If complete product is imported, ignore Raw Material and only list under manufacturing component.	1) Raw materials %	
	Local %	100.00
	Imported %	
	2) Manufacturing	
	Local %	100.00
	Imported %	
	3) Logistics %	
	4) Profit Margin %	
	Currency used for imported content	Indian rupee

Description NB: Complete All Fields	36 months	Item 5: Female Condoms Note that full item specification should be read as in Annexure B UNIT: EACH
	Estimates>>>	54,000,000 Condoms - Year 1: 15 million Year 2: 18 million Year 3: 21 million
BIDDER NAME		
Brand Name		
Delivered Price in ZAR VAT inclusive per each		
Lead Time (Maximum 42 Days)		
Initial Lead Time (Days)		
Shelf Life ex manufacture (Months)		
Constituent Material (Specify)		
Supplier Volume Capacity (Max quantity able to supply)	Quantity for full tender period	
	Monthly Quantity	
	Quarterly Quantity	
Are you manufacturing in SA? YES/NO		◯ Yes ◯ No
If NO, Country of manufacture		
Name of Actual Manufacturer		
If you are NOT the actual manufacturer:	Letter from the manufacturer submitted? YES/NO	◯ Yes ◯ No
Submitted Proof of SABS Mark YES/NO		◯ Yes ◯ No
Submitted Proof of WHO/UNFPA Pre-approval? YES/NO		◯ Yes ◯ No
Is SABS test report attached? YES/NO		◯ Yes ◯ No
If NO, Have samples been submitted to the SABS and proof attached? YES/NO		◯ Yes ◯ No
Does the outer carton carry EAN 13 barcode?		◯ Yes ◯ No
Price Breakdown by components relating to Foreign Exchange Price Adjustments (Paragraph 17.2 SCC): The 4 components should add up to 100% of the delivered price. If complete product is imported, ignore Raw Material and only list under manufacturing component.	1) Raw materials %	
	Local %	100.00
	Imported %	
	2) Manufacturing	
	Local %	100.00
	Imported %	
	3) Logistics %	
	4) Profit Margin %	
	Currency used for imported content	Indian rupee

Description **NB: Complete All Fields**	**36 months**	**Item 6: Lubricant, Water Based, Non-Irritant, 5ml sachets** **Note that full item specification should be read as in Annexure C** **UNIT: Pack of 100**
	Estimates>>>	60,000,000 Sachets = 600,000 packs of 100
BIDDER NAME		
Brand Name		
Delivered Price in ZAR **VAT inclusive per Pack of 100**		
Lead Time (Maximum 42 Days)		
Initial Lead Time (Days)		
Shelf Life ex manufacture (Months)		
Constituent Material (Specify)		
Supplier Volume Capacity **(Max quantity able to supply)**	Quantity for full tender period	
	Monthly Quantity	
	Quarterly Quantity	
Are you manufacturing in SA? YES/NO		◯ Yes ◯ No
If NO, Country of manufacture		
Name of Actual Manufacturer		
If you are NOT the actual manufacturer:	Letter from the manufacturer submitted? YES/NO	◯ Yes ◯ No
Submitted Proof of Certificate of Analysis/ Material Safety Data Sheet YES/NO		◯ Yes ◯ No
Is SABS test report attached? YES/NO		◯ Yes ◯ No
If NO, Have samples been submitted to the SABS and proof attached? YES/NO		◯ Yes ◯ No
Does the outer carton carry EAN 13 barcode?		◯ Yes ◯ No
Price Breakdown by components relating to Foreign Exchange Price Adjustments (Paragraph 17.2 SCC): The 4 components should add up to 100% of the delivered price. If complete product is imported, ignore Raw Material and only list under manufacturing component.	1) Raw materials %	
	Local %	100.00
	Imported %	
	2) Manufacturing	
	Local %	100.00
	Imported %	
	3) Logistics %	
	4) Profit Margin %	
	Currency used for imported content	Indian rupee