



# health

Department:  
Health  
REPUBLIC OF SOUTH AFRICA

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**HM01-2015CNDM: THE SUPPLY AND DELIVERY OF MALE AND FEMALE CONDOMS AND LUBRICANT TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 01 JULY 2015 TO 30 JUNE 2018.**

1. The attached contract circular is for your information.
2. This contract will be subject to the General Conditions of Contract issued in accordance with Chapter 16A of the Treasury Regulations published in terms of the Public Finance Management Act, 1999 (Act 1 of 1999). The Special Conditions of Contract are supplementary to that of the General Conditions of Contract. Where, however, the Special Requirement and Conditions of Contract are in conflict with the General Conditions of the Contract, the Special Requirements and Conditions will prevail.
3. The price applies to the product specified e.g. price per single unit, as per specification.
4. The following provincial Departments of Health will participate in this contract

PARTICIPANTS	CONTACT PERSONS	TEL NO	FAX NO
National Department of Health	T Chidarikire: Director HIV Prevention	(012) 395-9153	086 632 2443
	E Marumo: (Condom contact)	(012) 395 9142	086 632 8758
	M Motsepe: (Condom contact)	(012) 395 9234	086 632 5709
	I Kgomanyane: (Condom contact)	(012) 395 9144	
Eastern Cape	X Somahela: HAST Manager	(040) 608 1223	040 609 8401
	L Ncala: (Condom contact)	(040) 608 1749	086 609 1593
Free State	Y Tsibolane: HAST Manager	(051) 408 1429	(051) 409 8493
	S Boleme: (Condom contact)	(051) 409 1119	(051) 409 8493
Gauteng	N Mmope: HAST Manager	(011) 355 3340	(011) 355 3338
	N Nyandeni: (Condom contact)	(011) 355 3421	(011) 355 3338
	M Matlhoko: (Condom contact)	(011) 355 3180	(011) 355 3338

PARTICIPANTS	CONTACT PERSONS	TEL NO	FAX NO
Kwa Zulu -Natal	Dr T Mayise: HAST Manager	(033) 341 4001	086 610 2012
	T Buthelezi: (Condom contact)	(033) 341 4000	084 556 6885
Limpopo	E Kobola: HAST Manager	(015) 293 6536	086 215 6361
	E Diketane: (Condom contact)	(015) 293 6587	086 215 3913
Mpumalanga	E Nkosi: HAST Manager	(013) 766 3442	(013) 766 3470
	L Nkosi: (Condom contact)	(013) 766 3414	(013) 766 3470
	F Mgiba: (Condom contact)	(013) 766 3439	(013) 766 3470
North West	T Isaacs: HAST Manager	(018) 397 2601	(018) 387 2600
	V Salman: (Condom contact)	(018) 397 4073	(018) 387 2600
	K Tlatsana: (Condom contact)	(018) 387 2667	(018) 387 2600
Northern Cape	B Baitsewe: HAST Manager	(053) 830 0524	(053) 833 3814
	M Motlhaudi: (Condom contact)	(053)830 0517/	(053) 833 3814
	P Masekwane: (Condom contact)	(053) 830 0517	(053) 833 3814
Western Cape	Juanita Arendse: HAST Manager	(021) 483 3334	(021) 483 6033
	M Dyeshana: (Condom contact)	(021) 483 6893	(021) 483 6033
	L Naijaar: (Condom contact)	(021) 483 9881	(021) 483 6033

*K. Jamaloodien*

**K JAMALOODIEN**

**DIRECTOR: AFFORDABLE MEDICINES**

**For: DIRECTOR-GENERAL: HEALTH**

**DATE: 26/06/2015**

**HM01-2015CNDM: SUPPLY AND DELIVERY OF MALE AND FEMALE CONDOMS AND LUBRICANT TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 01 JULY 2015 TO 30 JUNE 2018.**

**1. IMPORTANT GENERAL INFORMATION:**

- 1.1 Please note that the delivered price is for the unit of measure (UOM) as offered. Units of Measure, National Stock Numbers and prices should be carefully matched when placing or executing orders.
- 1.2 All prices are inclusive of 14 % VAT.
- 1.3 All prices are on a delivered basis.
- 1.4 Contact persons and e-mail addresses indicated hereunder are to be used for contract enquiries and not for orders.

**2. NAMES AND ADDRESSES OF CONTRACTORS AND CONTACT DETAIL**

Supplier Name	Supplier Code	Supplier Address	Contact Detail	Contact Person
			Telephone & Fax Numbers	E mail Address Cell Number
Abafazi Healthcare Services (Pty) Ltd	V39F5	P O Box 55582 Northlands <b>JOHANNESBURG</b> 2116	(011) 100 5035 (011) 243 7894	Avesh Padayachee avesh@abafazigroup.com 082 294 1298
Almika Trading (Pty) Ltd	V3P19	P O Box 747 <b>MOUNT EDGECOMBE</b> 4300	(031) 539 5575 (031) 502 6540	Jeremy Javis Naidoo jeremy@jehuindustries.co.za orders@jehuindustries.co.za info@jehuindustries.co.za  083 782 0800 / 060 367 8710
Barrs Medical (Pty) Ltd	V4890	P O Box 7348 <b>ROGGEBAAI</b> 8012	(021) 531 6601 (021) 531 6729	Joe Morris joe@qualitycondoms.co.za 083 310 1194
Biocor Hospital Supplies (Pty) Ltd	VRS10	P O Box 1125 <b>ISANDO</b> 600	(011) 394 2956 (011) 394 2397	Innocent Mkethwa innomkethwa@gmail.com 073 154 1769
Bliss Pharmaceuticals (Pty) Ltd	V2GJ5	P O Box 604 <b>RIDGEWAY</b> 2099	(011) 496 3255 086 647 5635	Mr Kingsley Tloubatla kingsley@blissholdings.co.za 082 569 4582
Crystal Pier Trading 148 cc	V3FJ6	14 Prins Street <b>BELLVILLE</b> 7530	(021) 671 6055 (021) 459 6293	Veon Cupido veon.cupido@gmail.com 083 255 7831
Fulloutput 1305 cc	To Follow	P O Box 650739 <b>BENMORE</b> 2010	(011) 884 2525 (011) 884 8491	Sakie Mashaba fulloutput1305@gmail.com 082 600 3039
Isigidi Trading 389 (Pty) Ltd	V1QU6	51 Boundary Road Highlands North <b>GAUTENG</b> 2192	(011) 485 1784 (011) 681 7710	Leon Klugman leon@focusproducts.co.za 083 327 3619
Medi-Core Technologies (Pty) Ltd	To Follow	P O Box 446 <b>HYPER-BY-THE-SEA</b> 4053	(032) 541 064 086 546 7747	Ajith Seopursa medicoresales@gmail.com 078 803 8343

Supplier Name	Supplier Code	Supplier Address	Contact Detail	Contact Person
			Telephone & Fax Numbers	E mail Address Cell Number
Medproc cc	V17W0	P O Box 635 <b>RONDEBOSCH</b> 7701	(021) 689 1656 (021) 551 0531	Goolam Chicktay goolam@medproc.co.za 083 411 0366
RRT Medcon (Pty) Ltd	To Follow	P O Box 6070 <b>ZIMBALI</b> 4418	032 947 2592 086 211 7435	Sikhulu Mtshali sikhulu@rrtmedcon.com
SA Health Protecting Services cc	V2SP7	P O Box 20189 <b>DURBAN NORTH</b> 4016	(031) 569 1641 (031) 569 1516	Sibusiso Lushaba sibusisol@sahealth.org.za
Unitrade 1032 cc	VALB5	P O Box 1552 <b>ALBERTON</b> 1449	(011) 902 7987 (011) 902 5706	Daphne Baitchu daphne@unitrademedical.co.za 084 572 6500

Contract Circular

HM01-2015CNDM : Supply and Delivery of Male and Female Condoms and Lubricant to the Department of Health for the period 01 July 2015 to 30 June 2018

Item No	Description	% Split	Quantity Awarded	Name of Supplier	Supplier Code	Delivered Price in ZAR	Unit Pack	Shipper Pack	Lead Time (Max 42-days)	Total Score	National Stock Number	Unit of Issue
1	Male Condoms, Natural colour, Vanilla scent, Pack of 200  <b>Note that full item specification should be read as in Annexure A</b>	13.94%	522 697	Unitrade 1032 cc	VALB5	R 68.9200	Pack of 200	6 000	42	98.00	18-192-2425	BX
		13.36%	501 146	Barrs Medical (Pty) Ltd	V4890	R 72.7800	Pack of 200	6 000	42	93.96		
		12.81%	480 350	Medi-Core Technologies (Pty) Ltd	To Follow	R 75.0000	Pack of 200	6 000	42	90.06		
		12.77%	478 957	Fulloutput 1305 cc	To Follow	R 75.2000	Pack of 200	6 000	14	89.80		
		12.44%	466 530	SA Health Protecting Services cc	V2SP7	R 77.7500	Pack of 200	6 000	21	87.47		
		11.79%	441 984	RRT Medcon (Pty) Ltd	To Follow	R 82.0400	Pack of 200	6 000	41	82.87		
		11.48%	430 352	Medproc cc	V17W0	R 83.7100	Pack of 200	6 000	42	80.69		
		11.41%	427 984	Almika Trading (Pty) Ltd	V3P19	R 84.0500	Pack of 200	6 000	42	80.24		
2	Male Condoms, Purple colour, Grape scent, Pack of 200  <b>Note that full item specification should be read as in Annexure A</b>	13.39%	502 189	Barrs Medical (Pty) Ltd	V4890	R 74.7800	Pack of 200	6 000	42	99.00	18-191-9701	BX
		12.95%	485 578	Medi-Core Technologies (Pty) Ltd	To Follow	R 76.6700	Pack of 200	6 000	42	95.73		
		12.66%	474 716	SA Health Protecting Services cc	V2SP7	R 79.2800	Pack of 200	6 000	21	93.58		
		12.36%	463 417	Fulloutput 1305 cc	To Follow	R 80.3000	Pack of 200	6 000	14	91.36		
		12.35%	462 939	RRT Medcon (Pty) Ltd	To Follow	R 82.0400	Pack of 200	6 000	41	91.26		
		12.21%	457 750	Bliss Pharmaceuticals (Pty) Ltd	V2GJ5	R 82.8900	Pack of 200	6 000	42	90.24		
		12.07%	452 744	Medproc cc	V17W0	R 83.7100	Pack of 200	6 000	42	89.25		
		12.02%	450 668	Almika Trading (Pty) Ltd	V3P19	R 84.0500	Pack of 200	6 000	42	88.84		
3	Male Condoms, Red colour, Strawberry scent, pack of 200  <b>Note that full item specification should be read as in Annexure A</b>	13.38%	501 675	Barrs Medical (Pty) Ltd	V4890	R 74.7800	Pack of 200	6 000	42	99.00	18-192-2426	BX
		13.04%	488 923	Medi-Core Technologies (Pty) Ltd	To Follow	R 76.0400	Pack of 200	6 000	42	96.48		
		12.65%	474 230	SA Health Protecting Services cc	V2SP7	R 79.2800	Pack of 200	6 000	21	93.58		
		12.35%	462 942	Fulloutput 1305 cc	To Follow	R 80.3000	Pack of 200	6 000	14	91.36		
		12.33%	462 465	RRT Medcon (Pty) Ltd	To Follow	R 82.0400	Pack of 200	6 000	41	91.26		
		12.19%	457 281	Bliss Pharmaceuticals (Pty) Ltd	V2GJ5	R 82.8900	Pack of 200	6 000	42	90.24		
		12.06%	452 280	Medproc cc	V17W0	R 83.7100	Pack of 200	6 000	42	89.25		
		12.01%	450 206	Almika Trading (Pty) Ltd	V3P19	R 84.0500	Pack of 200	6 000	42	88.84		

**Contract Circular**

**HM01-2015CNDM : Supply and Delivery of Male and Female Condoms and Lubricant to the Department of Health for the period 01 July 2015 to 30 June 2018**

Item No	Description	% Split	Quantity Awarded	Name of Supplier	Supplier Code	Delivered Price in ZAR	Unit Pack	Shipper Pack	Lead Time (Max 42-days)	Total Score	National Stock Number	Unit of Issue
4	Male Condoms, Yellow colour, Banana scent, Pack of 200  <b>Note that full item specification should be read as in Annexure A</b>	14.16%	531 112	Unitrade 1032 CC	VALB5	R 68.9200	Pack of 200	6 000	42	98.00	18-192-2427	BX
		13.20%	495 059	Barrs Medical (Pty) Ltd	V4890	R 74.7800	Pack of 200	6 000	42	91.35		
		12.95%	485 535	Medi-Core Technologies (Pty) Ltd	To Follow	R 75.3600	Pack of 200	6 000	42	89.59		
		12.22%	458 258	SA Health Protecting Services cc	V2SP7	R 79.9800	Pack of 200	6 000	21	84.56		
		12.02%	450 574	Fulloutput 1305 cc	To Follow	R 80.3000	Pack of 200	6 000	14	83.14		
		11.98%	449 099	RRT Medcon (Pty) Ltd	To Follow	R 82.0400	Pack of 200	6 000	41	82.87		
		11.82%	443 083	Bliss Pharmaceuticals (Pty) Ltd	V2GJ5	R 82.8900	Pack of 200	6 000	42	81.76		
		11.66%	437 280	Medproc cc	V17W0	R 83.7100	Pack of 200	6 000	42	80.69		
5	Female Condoms, EACH  <b>Note that full item specification should be read as in Annexure B</b>	20.81%	11 235 371	Abafazi Healthcare Services (Pty) Ltd	V39F5	R 6.4000	Each	6 000	10	100.00	18-179-2356	BX
		20.64%	11 147 594	Barrs Medical (Pty) Ltd	V4890	R 6.4500	Each	6 000	42	98.30		
		20.81%	11 235 371	Isigidi Trading 389 (Pty) Ltd	V1QU6	R 6.4000	Each	6 000	30	93.00		
		19.25%	10 392 718	Crystal Pier Trading 148 CC	V3FJ6	R 6.8800	Each	6 000	30	92.25		
		18.50%	9 988 947	Biocor Hospital Supplies (Pty) Ltd	VRS10	R 7.1100	Each	6 000	21	90.02		
6	Lubricant, Water Based, Non-Irritant, 5ml sachets Pack of 100  <b>Note that full item specification should be read as in Annexure C</b>	70.00%	42 000 000	Barrs Medical (Pty) Ltd	V4890	R 32.1200	Pack of 100	6 000	42	99.00	18-014-4108	BX
		30.00%	18 000 000	Medi-Core Technologies (Pty) Ltd	To Follow	R 34.9900	Pack of 100	6 000	42	89.96		

**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 REQUIRED 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.

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- 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<sup>0</sup> 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<sup>0</sup> C, COA or declaration certificate.
2. Use of the methods of WHO/UNFPA 2010 specification or latest updated version or/ISO 4074:2002



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3. The maximum acceptable decrease in mean inflation properties should be 25%, and products should comply with the requirements of WHO/UNFPA specifications 2010 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 may 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<sup>0</sup> 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 2859-1 General Inspection Level G-1.*

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

#### (ii) Testing

In accordance with the inflation test and oven conditioning procedure in *ISO 4074:2002.*

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

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**Volume:**

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

minimum limit (litres) =  $w^2$  (rounded off to the nearest 0.5 litres)

150

**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**

AQL2.5

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**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 for coloured 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

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**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.***

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**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  $\pm 2$  mm is allowed for individual condoms with an AQL of 1.0% and in addition a tolerance of  $\pm 1$  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  $22 \pm 4$  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:  $30 \pm 5$  mm from the open end,  $30 \pm 5$  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  $0.065 \pm 0.015$  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.

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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  $550 \pm 150$  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*

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- 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.

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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:

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



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**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

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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 and Annex B isolated in ISO 4074:2002			
Test	Sampling	Requirements	Responsibility
Verification of constituent materials	N/A	Manufacturer'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 dm <sup>3</sup> for condoms with less than 50 mm 2. 18.0 dm <sup>3</sup> for condoms with less widths from 50 mm to 55.5 mm 3. 22 dm <sup>3</sup> 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

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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

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**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 dm <sup>3</sup> for condoms with less than 50 mm 2. 18.0 dm <sup>3</sup> for condoms with less widths from 50 mm to 55.5 mm 3. 22 dm <sup>3</sup> 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

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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
<b>1 General requirements</b>						
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

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2 Performance requirements						
Bursting volume	2.1	G-1*	ISO 4074:2002 see specification 2.1	$\text{width}^2/150$	1.0	SABS
Bursting volume 70°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	$\geq 180$ mm	1.0	SABS
Width	3.6	S-2*	ISO 4074:2002	$53 \pm 2$ mm; mean $52 \pm 1$ mm	1.0	SABS
Thickness	3.7	S-2*	see specification 3.7	$0.065 \pm 0.015$ mm	1.0	SABS
Lubricant plus Powder	3.8	S-2*	See Specification 3.8	$550 \pm 150$ 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 REQUIRED 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 14971 and ISO 13485. 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.

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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.



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- 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.

**FEMALE CONDOM HM01–2015CNDM**

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.

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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 9.1 of the International Standard.

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

**FEMALE CONDOM HM01–2015CNDM****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.

**FEMALE CONDOM HM01–2015CNDM****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

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- 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**

<b>REQUIREMENTS</b>	<b>RESPONSIBILITY</b>
<b>General requirements</b>	
Constituent materials	SABS
Shelf-life	Biddersand NDoH
<b>Performance requirements</b>	
Bursting volume	SABS
Freedom from holes	SABS
Package integrity	SABS
<b>Design requirement</b>	
Length	SABS
Width	SABS
Thickness	SABS
Lubricant	SABS
<b>Packaging requirement</b>	
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 REQUIRED 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.

<b>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.</b>
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**LUBRICANT HM01–2015CNDM****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**



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

<b>Characteristic</b>	<b>Specification</b>
• 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:	
○ total aerobic microbial count cfu/g:	100 maximum
○ 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<sup>0</sup>C 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<sup>0</sup>C.
  -

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- Updated documentation on 35°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

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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).

-

**LUBRICANT HM01–2015CNDM**

- 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 ISO 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)***

**LUBRICANT HM01–2015CNDM****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).***



# health

Department:  
Health  
**REPUBLIC OF SOUTH AFRICA**

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## **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**

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## 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:

$$P_s = 90 \left( 1 - \frac{P_t - P_{min}}{P_{min}} \right)$$

Where:

$P_s$ = Points scored for comparative price of bid under consideration

$P_t$ = Comparative price of bid under consideration

$P_{min}$ = Comparative price of lowest acceptable bid

## SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT HM01–2015CNDM

- 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.

## **SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT HM01–2015CNDM**

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.

## **SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT HM01–2015CNDM**

- 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](mailto:sales@sabs.co.za)

Website: [www.sabs.co.za](http://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.

## **SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT HM01–2015CNDM**

- 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

## **SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT HM01–2015CNDM**

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).

## SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT HM01–2015CNDM

See extract from bid response document below:

	<b>Price components</b>	<b>Response fields</b>
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](http://www.resbank.co.za)).

## SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT HM01–2015CNDM

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

<b>Currency</b>	<b>Base Average Rates of Exchange Average for the period 1 August 2014 to 31 January 2015</b>
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:

<b>Review</b>	<b>Period for calculating adjustment RoE</b>	<b>Submission of request for price review to reach the office by</b>	<b>Date from which adjusted prices will become effective</b>
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.

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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.

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- 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



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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](mailto: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.

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- 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

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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

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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

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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
<a href="mailto:ChidaT@health.gov.za">ChidaT@health.gov.za</a>	<a href="mailto:Marume@health.gov.za">Marume@health.gov.za</a>
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

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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
Email: <a href="mailto:chidat@health.gov.za">chidat@health.gov.za</a> / <a href="mailto:marume@health.gov.za">marume@health.gov.za</a>	Email: <a href="mailto:medtenders@health.gov.za">medtenders@health.gov.za</a>

### 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