

## ANNEXURE A

### SCOPE OF WORK

#### 1. Scope

- 1.1.** This document describes how to select condom samples from a production lot for acceptance testing in terms of SANS 4074:2017, the National Department of Health Condom Specification (as is current at the time) and the World Health Organization (WHO:2010) condom test specification (as is current at the time).

The appointed service provider shall sample at the requested country and factory within the specified timelines

All products shall be sampled according to SANS 2859-1 sample method, subsequent to 2428 –T0192 Proc 7.3 Laboratory procedure

The appointed service provider will be responsible for all customs clearances from any country where sampling took place to South Africa.

The appointed service provider will be expected to meet the agreed turnaround time within SABS.

#### 2. Prescriptive documents

SANS 4074:2017/ ISO 4074:2015 *Natural rubber latex male condoms – Requirements and test methods*  
National Department of Health Condom Tender No.RT75-2021

WHO Male Latex Condom: Specification, Prequalification and Guidelines for Procurement, 2010 (revised April 2013)

SANS 2859-1:2004/ ISO 2859-1-1999 *Sampling procedures for inspection by attributes Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

SANS 17025: 2018/ ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*

#### 3. Sampling method

##### 3.1. Lot size

Part of the sampling event is to determine the lot size and to compare this determined value with the lot size as stated by the supplier / manufacturer. The determined lot size must be reported to the testing laboratory as a deliverable of the sampling event.

##### 3.1.1. Method for determination of lot size

- 3.1.1.1. Count the number of full outer boxes, multiply by the number of inner boxes per outer box and multiply by the number of condoms per inner box.
- 3.1.1.2. Count the number of inner boxes in partially filled outer boxes and multiply by the number of condoms per inner box.
- 3.1.1.3. Add the totals in 3.1.1.1 and 3.1.1.2 above – this is the verified lot size.

##### 3.2. Individual sample group size

For the purposes of sampling, condoms will be selected in groups. A group will consist of one inner carton of condoms. (In other words, the unit of sample is one inner carton). An inner carton may not contain more than 200 condoms. If an inner carton contains more than 200 condoms, the requirements of this document will have to be re-evaluated for suitability and sampling shall only be

carried out after a deviation from this document's requirements has been approved by the testing laboratory, in writing.

### **3.3. Random sampling**

Condoms shall be selected at random. In this document, random sampling shall mean the selection of condoms in such a way that each inner carton selected has the same probability to be selected as any other inner carton. Inner cartons will be selected without replacement.

The random sampling can be done through the use of random number tables. Such tables are widely available in books with statistical tables. The tables can also be easily generated by means of spreadsheets such as MS Excel or through custom-written computer programs. Tables generated with MS Excel are attached in the appendices of this document.

Random numbers may also be generated using computers or pocket calculators.

### **3.4. Selection of inner boxes**

Various ways are available to randomly select inner cartons. Two examples are listed below:

- Select an outer carton randomly, then select an inner carton randomly out of the outer carton
- Select an inner carton randomly out of the total number of inner cartons in the lot, then determine which outer carton it belongs to and locate the inner carton inside that outer carton.

A typical way to select inner cartons from a lot:

- a) Determine the lot size and verify against the lot size as stated by the manufacturer / supplier.
- b) Determine the number of samples to be taken, based on the lot size (see the table entitled "Sample sizes" below).
- c) Determine the number of outer cartons in the lot.
- d) Randomly select an outer carton, by selecting a random number from a random-number table, or from a pocket calculator. If the random number selected is greater than the number of outer cartons in the lot, keep on selecting a random number until the number selected falls within the allowed range.
- e) Randomly select an inner carton from the outer carton selected in d) above, by selecting a random number from a random number table, or from a pocket calculator. If the random number selected is greater than the number of inner cartons in the outer carton, keep on selecting a random number until the number selected falls within the allowed range.
- f) Repeat d) and e) until the required number of inner cartons has been selected.

**See Appendix D for a picture example of the above.**

### **3.5. Location of sampling**

Sampling may only be carried on samples that have been stored indoors. The sampling itself must also be carried out indoors.

#### 4. Sample sizes

Unless otherwise specified by the sampling requestor, these are the required sample sizes for routine testing to WHO 2010 Male Latex Condom Specification and the National Department of Health Condom Test Specification. More samples may be required for testing to SANS 4074:2017 and at least 1 200 samples regardless of lot size are required for pre-qualification testing for the National Department of Health Condom Tender.

Lot size	Sample size (individual condoms)	Number of inner boxes each containing 200 condoms
35 001 to 150 000	800	4
150 001 to 500 000	800	4
500 001 and over	1 000	5

## **5. Discussion of information required by SANS 17025:2018**

- 5.1.** Refer to clauses 7.3 and 7.8.5 of SANS 17025:2018. Because random sampling is used, it is not necessary to identify the specific position of sampling.
- 5.2.** Rain and wet will cause damage to the carton packaging and will affect the evaluation of the conformance of the inner cartons. If sampling is carried out indoors, environmental conditions during sampling will not affect test results. Because indoor storage and sampling is prescribed (see par 3.5 above), the environmental conditions at time of sampling need not be recorded.

## **6. Inspector's receipt / Sampling certificate**

- 6.1.** The person carrying out the sampling must provide an inspector's receipt (in English) to the manufacturer / supplier. The inspector's receipt must list the following:
- a) Name and contact details of organisation carrying out the sampling
  - b) Date of sampling
  - c) Name and signature of person carrying out the sampling
  - d) The identification numbers of the lots sampled
  - e) The number of samples taken from each lot
  - f) The verified lot size
  - g) The location where sampling was carried out (e.g. Factory X, Street address, Building Y, Room Z)
  - h) Unique identifier to identify the receipt (e.g. receipt / certificate number)
  - i) Remarks / notes (if any)
  - j) A reference to this sampling procedure and a statement that sampling was carried out according to it
- 6.2. A copy of the inspector's receipt must accompany the samples to the testing laboratory.**

# Appendix A

## Random numbers in the range 1 to 50

3	48	41	48	20	13	32	40	32	50	10	24	49	40	35	47	21	42	33	34	42	23	28	5	45	4	9	35	18	12	20
17	21	2	18	27	35	10	23	41	36	21	5	39	2	12	23	14	31	4	50	13	25	20	26	3	16	30	10	45	7	20
14	34	23	21	26	12	27	14	43	23	48	49	4	21	12	40	11	25	34	14	29	37	43	15	7	46	46	34	28	50	35
45	43	44	19	2	34	47	14	17	44	34	23	32	27	17	15	27	39	46	7	43	20	13	11	26	17	43	21	31	12	11
34	6	40	44	7	49	46	26	30	14	29	11	35	38	29	7	10	12	46	1	23	30	45	19	13	25	16	30	40	40	44
6	40	38	35	30	10	22	1	50	47	15	29	23	37	24	39	8	46	36	10	39	7	50	15	35	4	26	7	42	35	22
10	42	41	30	38	33	35	22	13	41	8	27	4	12	36	41	43	21	46	35	49	23	16	27	33	18	6	17	37	12	8
34	38	18	3	19	24	32	24	50	7	1	21	27	25	35	46	27	22	16	9	24	10	40	26	38	47	46	50	27	36	2
50	11	38	3	22	43	38	17	45	50	48	10	1	26	9	1	4	14	36	4	46	19	18	6	34	21	10	47	27	20	44
47	18	34	23	8	49	37	20	21	11	49	10	46	18	44	36	1	36	28	46	46	31	5	27	39	46	31	34	22	25	35
29	1	24	17	4	16	32	17	12	32	27	27	5	43	13	21	32	47	24	27	34	19	48	1	7	34	42	34	16	13	8
10	1	50	1	13	23	8	9	1	36	4	25	1	15	10	36	22	26	47	39	42	43	3	22	40	5	30	2	12	6	34
30	39	17	28	11	40	4	10	31	23	45	2	15	27	17	33	6	9	4	22	39	30	28	24	31	34	21	44	36	39	7
32	23	31	35	6	3	19	17	49	48	1	20	29	10	22	50	15	15	5	4	37	48	22	44	28	29	47	32	8	35	12
32	32	17	8	46	36	38	35	11	12	48	50	22	13	31	8	37	4	23	14	14	2	7	29	12	50	32	18	44	37	50
20	18	32	7	46	39	10	18	50	18	14	37	24	37	44	18	24	12	42	31	13	16	41	2	11	18	6	12	28	28	8
8	5	33	9	30	26	17	49	33	49	46	15	12	34	39	18	24	44	12	37	37	12	30	40	40	17	24	33	9	29	16
4	6	28	9	44	18	10	36	7	1	29	28	35	49	45	33	7	26	49	26	39	35	15	13	8	17	20	20	7	50	4
38	29	12	10	11	41	35	45	40	50	17	8	44	7	27	24	46	4	45	49	22	37	24	28	28	5	37	39	49	35	42
30	32	14	10	8	16	27	20	6	20	15	14	27	38	12	21	14	41	40	1	27	35	18	50	4	29	14	30	47	18	50
33	29	46	32	30	18	40	35	24	11	22	17	8	21	36	42	25	32	30	45	5	2	26	10	13	1	4	22	40	40	7
24	43	19	41	48	3	33	1	24	41	38	19	3	12	5	1	33	30	10	48	36	3	34	17	26	28	22	40	7	34	50
19	34	50	25	39	33	5	1	49	43	16	5	49	20	31	33	8	44	28	11	8	5	19	9	20	6	11	16	50	6	7
17	12	40	25	35	13	24	45	38	40	22	19	1	7	46	50	43	12	2	41	19	30	35	48	39	26	40	27	4	37	36
28	13	4	40	12	8	13	4	19	36	50	4	49	16	24	1	8	39	49	28	14	2	17	11	10	10	40	18	23	9	25
43	3	4	26	45	12	50	48	4	50	21	46	21	6	28	41	4	2	18	49	26	16	2	4	39	17	27	4	20	38	31
29	22	18	50	50	8	47	14	15	1	4	6	23	4	23	7	48	9	30	36	22	21	7	18	11	28	11	21	49	22	3
7	49	41	16	29	8	4	16	37	13	13	33	17	9	26	44	1	24	30	18	31	28	18	20	1	29	36	22	6	28	31
10	16	5	9	17	13	22	32	28	16	24	41	19	38	10	39	2	3	17	18	13	13	38	29	19	7	23	33	36	1	22
33	43	49	30	25	17	38	32	40	15	19	23	8	41	35	48	34	42	38	35	23	15	13	3	48	10	33	5	24	11	5
40	22	10	6	19	7	14	38	6	23	16	36	29	48	1	19	14	31	6	16	33	22	42	29	6	28	10	21	8	22	25

**Appendix B**

**Random numbers in the range 1 to 75**

72	30	11	71	31	23	44	21	15	59	17	22	22	64	73	63	31	51	31	55	33	21	5	63	41	61	67	66	23	46	37
73	30	55	37	57	44	25	7	6	9	11	22	4	32	37	17	14	2	74	9	22	45	69	1	40	68	64	74	61	47	30
2	50	59	8	44	65	40	29	61	48	16	7	60	69	5	17	61	7	6	70	14	2	53	63	63	25	50	44	53	65	15
25	6	57	50	40	9	17	59	49	37	55	8	65	53	18	71	30	34	66	17	72	56	33	36	15	16	56	2	16	56	38
40	64	57	20	31	38	59	44	53	69	61	13	64	14	63	52	73	15	10	51	20	28	36	39	32	47	75	50	56	46	68
63	75	44	26	1	3	15	25	65	43	61	39	8	16	63	64	51	54	30	25	12	34	24	33	40	66	57	10	28	25	30
62	38	35	4	21	7	4	56	34	73	8	31	63	58	38	16	58	18	72	4	54	22	19	34	40	43	12	51	65	53	40
21	68	62	2	33	14	23	71	16	16	35	4	26	7	8	58	73	17	44	52	66	63	19	59	65	13	21	2	31	26	69
44	6	51	17	14	28	57	61	52	11	38	13	12	7	75	16	9	23	10	33	53	23	58	55	14	54	53	38	45	4	11
58	9	3	18	14	66	58	69	68	9	38	28	4	74	52	2	25	18	50	75	43	10	38	34	63	55	36	58	41	30	41
40	64	37	5	51	40	55	62	60	28	49	37	52	46	7	56	58	33	37	21	65	37	47	18	59	34	69	54	13	13	75
12	44	7	22	56	2	10	16	75	15	32	23	27	37	5	41	24	25	61	5	11	51	23	40	6	52	62	53	36	2	49
28	59	14	26	71	48	4	75	19	37	73	18	10	27	54	21	45	35	68	57	40	16	22	58	46	6	44	63	24	27	44
15	71	3	51	31	36	18	71	34	22	7	38	62	36	45	4	28	26	10	35	53	7	17	11	33	56	3	10	27	9	6
33	65	30	13	63	65	51	14	44	54	51	38	40	50	26	27	64	70	64	1	55	52	49	24	61	60	48	38	5	74	28
72	57	48	48	17	61	68	19	62	43	1	26	29	74	34	55	37	61	56	39	66	9	41	43	48	45	7	22	16	39	30
47	20	23	73	43	29	7	63	44	14	73	57	3	33	5	1	30	14	42	56	43	16	21	11	70	11	2	34	20	74	37
20	72	68	39	57	11	75	55	48	71	73	5	52	26	28	5	23	73	72	55	3	23	27	46	32	51	18	20	61	44	44
11	21	29	44	28	56	58	54	35	37	19	13	15	63	1	32	2	22	23	6	12	15	59	42	17	34	37	62	74	72	73
28	48	36	37	61	20	75	72	8	31	53	32	65	4	10	10	27	43	33	4	44	63	23	45	39	24	2	60	74	52	67
23	10	37	43	24	23	58	11	18	56	34	40	12	22	29	28	36	19	45	4	31	58	50	18	56	31	65	24	30	11	23
52	12	29	72	25	58	61	57	36	72	65	21	49	63	9	13	67	32	43	48	45	27	46	1	2	6	24	13	56	25	13
56	59	42	21	35	49	48	20	7	63	66	75	15	26	40	15	42	50	26	21	39	63	55	54	43	12	65	2	2	29	69
29	46	55	4	21	1	19	19	33	73	72	4	64	31	16	58	35	10	44	52	53	8	65	6	69	20	4	68	39	16	69
42	65	17	57	51	7	50	44	27	46	49	68	34	55	18	42	14	43	66	24	27	15	9	50	1	60	71	4	15	65	41
65	75	44	32	25	48	34	7	24	62	43	5	25	31	18	42	55	7	11	44	40	61	61	11	37	36	1	20	75	17	42
24	31	69	41	52	34	10	50	8	22	69	8	37	56	14	48	30	46	2	23	28	22	35	11	59	22	18	26	4	44	57
53	49	53	48	11	49	6	32	46	8	24	55	72	62	39	54	16	19	42	12	4	49	48	38	70	25	51	38	57	62	21
11	65	41	58	34	63	18	1	53	14	75	47	71	6	55	46	20	69	25	39	69	45	45	45	39	24	2	14	21	54	11
23	2	18	5	9	36	57	34	56	31	57	56	66	41	8	58	31	35	44	58	10	21	43	8	1	54	2	33	6	49	15
45	67	73	65	15	65	33	43	45	43	44	17	38	41	11	33	58	39	45	42	31	16	11	18	57	29	24	37	29	11	7

Appendix C

Random numbers in the range 1 to 100

12	23	82	10	3	49	74	63	77	23	90	68	74	97	91	79	87	38	50	64	84	48	31	97	20	48	87	97	10	6	6
38	50	25	51	95	1	41	45	95	88	79	74	27	26	81	63	37	47	84	97	17	76	43	53	35	15	64	71	78	56	24
60	70	79	27	55	6	98	3	11	54	70	2	68	68	26	31	96	91	87	19	50	100	49	23	97	88	41	56	1	88	35
91	68	56	30	41	48	9	56	37	56	93	52	9	28	95	91	93	21	45	39	76	91	67	90	58	86	21	30	82	25	56
24	81	45	59	99	43	44	97	96	88	48	82	76	25	42	30	73	18	73	82	47	92	92	38	61	75	88	71	86	39	37
53	83	29	82	85	73	36	79	30	45	68	52	34	12	76	16	100	88	41	51	22	25	70	21	77	15	70	48	24	48	79
41	23	87	35	90	23	69	100	76	98	23	95	82	43	30	98	68	8	41	78	84	50	24	66	30	22	76	39	84	77	23
2	93	44	89	70	5	57	99	40	7	6	73	1	51	33	2	43	45	79	41	99	83	96	43	49	97	27	70	97	75	2
33	13	79	83	24	20	67	93	30	75	42	60	28	98	13	87	39	45	75	96	37	15	44	12	77	100	47	37	26	83	97
29	96	42	44	28	90	89	62	66	74	40	14	4	59	15	71	1	37	52	77	70	3	65	73	85	6	39	88	27	56	90
90	66	31	5	6	48	88	48	83	99	20	45	60	1	56	47	15	24	58	1	35	55	43	99	12	87	22	37	97	46	52
61	50	98	14	28	35	1	31	39	52	91	70	78	50	63	74	58	68	44	35	51	71	54	28	88	85	33	12	29	12	89
11	18	100	28	9	40	66	2	16	98	67	93	87	50	90	19	90	25	46	65	77	83	60	47	34	68	44	96	92	57	47
96	21	71	54	4	90	85	86	4	39	54	65	26	39	27	26	30	9	84	39	74	52	28	50	74	35	59	100	17	93	7
100	20	34	42	20	11	86	71	67	68	47	51	58	85	66	27	81	18	7	39	34	29	58	94	14	24	12	82	21	26	58
77	89	77	17	82	69	49	25	7	98	45	49	95	13	80	38	36	29	3	16	13	51	65	45	14	64	42	100	5	27	14
32	58	45	17	82	60	8	66	81	11	13	71	54	31	90	93	82	71	11	69	73	11	85	92	87	25	31	92	82	91	60
64	53	70	59	63	55	3	76	84	24	18	69	29	35	44	35	2	25	72	45	62	88	46	40	99	42	72	92	13	51	5
30	55	34	87	17	84	87	19	81	63	56	3	7	36	63	82	47	62	9	41	54	41	8	93	90	17	74	67	53	16	27
37	85	2	54	73	86	5	39	13	54	19	76	25	30	55	95	49	36	83	80	78	61	20	4	5	84	35	84	66	15	73
28	4	9	39	80	74	44	17	1	23	64	85	64	54	63	76	35	89	48	81	9	83	14	85	83	45	26	85	81	74	27
72	42	76	69	37	59	57	47	73	27	11	86	64	35	44	82	80	14	86	60	59	86	14	46	1	86	31	33	35	63	27
1	51	82	60	17	100	39	49	39	71	15	5	25	17	44	62	53	25	32	54	1	94	39	78	92	29	100	47	37	85	81
34	10	7	28	39	7	64	18	2	10	26	58	45	81	52	11	87	38	71	52	12	8	66	98	22	50	98	56	85	5	69
81	36	75	59	80	88	22	73	85	82	82	4	94	40	53	22	11	52	77	74	60	3	1	72	39	35	81	23	90	74	51
25	61	79	37	71	99	54	48	97	47	93	71	79	16	78	44	49	82	48	68	25	4	22	37	69	36	23	56	80	39	82
11	55	51	89	92	47	11	36	21	52	72	49	44	50	84	62	74	40	23	89	39	6	16	4	42	21	9	11	91	81	51
36	98	71	32	54	40	53	43	94	29	77	98	79	18	68	35	67	20	100	7	33	51	72	28	20	47	79	36	92	18	38
81	69	67	94	97	99	84	63	24	6	87	66	17	89	55	41	45	83	26	24	79	49	84	81	58	43	30	59	53	57	21
37	5	41	42	71	25	70	12	87	95	38	59	62	76	7	28	92	7	21	45	87	60	70	28	18	26	95	64	42	27	33
88	5	77	34	61	50	53	16	88	10	7	16	40	30	8	9	78	20	49	57	84	90	78	75	87	100	70	24	45	93	49

**Appendix D**

**Picture example for paragraph 3.4**

Note: This is only an example, for the lot characteristics indicated below. The random numbers selected will be different for every sampling event. The stacking method for outer cartons and filling pattern for inner cartons inside outer cartons will not always be the same for different manufacturers.

Lot size: 270 000

Number of inner cartons per outer carton: 50

Number of condoms per inner carton: 100

Number of outer cartons (each containing 5 000 condoms): 54

Number of inner cartons to select: 8

Random number sequence to select outer cartons: 8, 4, 12, 74 (too large, ignore), 7, 41, 12, 26, 64 (too large, ignore), 39

Random number sequence to select inner cartons from the above corresponding outer cartons:  
 (outer, inner): (8 , 10), (4 , 30), (12 , 72 - too large, ignore), (12 , 44), (7 , 10), (41 , 50), (12 , 37), (26 , 61 - too large, ignore), (26 , 10), (39 , 56)

In this example, two inner cartons will be selected from outer carton no. 12.

Outer cartons, stacked, with their numbers indicated. (Any numbering system can be used as long as it is consistent.)

The outer cartons from which inner cartons must be selected are indicated with "X"

3	6	9	12	X X
2	5	8	11	X
1	4	7	10	X
15	18	21	24	
14	17	20	23	
13	16	19	22	
27	30	33	36	
26	29	32	35	X
25	28	31	34	
39	42	45	48	X
38	41	44	47	X
37	40	43	46	
51	54			
50	53			
49	52			

Inner cartons as packed inside outer carton, with their numbers indicated. (Any numbering system can be used, as long as it is consistent.)

6	7	8	9	10
16	17	18	19	20
26	27	28	29	30
36	37	38	39	40
46	47	48	49	50

1	2	3	4	5
11	12	13	14	15
21	22	23	24	25
31	32	33	34	35
41	42	43	44	45