

Tender No **HLL/PROC/KFC/EXT.LAB/2021-22**  
Date **04.02.2021**

**TENDER FOR SELECTING EXTERNAL QUALIFIED  
LABORATORY FOR CONDUCTING EXTERNAL TESTING OF  
FEMALE CONDOMS FOR EXPORT**

**HLL LIFECARE LIMITED**  
**Kakkanad Factory, Cochin**  
**Plot No.16-A/1 CSEZ, Kakkanad P. O.**  
**Ernakulam – 682 037,**  
**Kerala, India. Ph: +91 484 2413999**  
**Email: [materialskfc@lifecarehll.com](mailto:materialskfc@lifecarehll.com)**  
**Website: [www.lifecarehll.com](http://www.lifecarehll.com)**

<b>Last date and time for receipt of bids</b>	<b>: 10.02.2021 on 14:00 Hrs</b>
<b>Time and date of opening of Technical Bid</b>	<b>: 10.02.2021 on 15:00 Hrs</b>

Tender No **HLL/PROC/KFC/EXT.LAB/2021-22**  
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**TENDER FOR SELECTING EXTERNAL QUALIFIED LABORATORY FOR CONDUCTING EXTERNAL TESTING OF FEMALE CONDOMS FOR EXPORT**

Sealed Tenders are invited from reputed NABL accredited Testing Laboratories for selection for external testing of Female Condoms Type A, for export to Brazil.

The tender documents can also be downloaded from our Website: [www.lifecarehll.com](http://www.lifecarehll.com).

1. Last date & time of Submission of Bid : **14:00 hrs, 10/02/2021**
2. Date of opening of bid : **15:00 hrs, 10/02/2021**
3. Tender Opening Venue : **HLL LIFECARE LIMITED  
Kakkanad Factory, Cochin  
Plot No.16-A/1 CSEZ, Kakkanad P. O.  
Ernakulam – 682 037,  
Kerala, India. Ph: +91 484 2413**

Tender No **HLL/PROC/KFC/EXT.LAB/2021-22**

Date **04.02.2021**

**Finished Goods inspection criteria and procedures for TYPE 'A' Female condom**

**Finished product inspection as per ISO 25841:2017& WHO 2012 specification**

	Test	AQL	For a batch size upto 1, 50,000 pcs. No of samples to be tested (Ac/Re)
A	Freedom from holes	0.25	315 (2,3)
B	Visual test (critical defects)	0.4	315(3,4)
C	Visual test( non critical defects)	2.5	315(14,15)
D	BV/BP	1.5	200(7,8)
E	PSI	2.5	32(2,3)
F	Lub qty	All must comply	13(0,1)
G	Dimension	All must comply	13(0,1)
H	Dimension and hardness of EVA ring	All must comply	13(0,1)
I	Packaging and labelling	All must comply	13(0,1)
	Total Pcs to be sampled		<b>573 Pcs</b> <i>Note: No additional pcs required for tests mentioned in 'B', 'C', 'H' and 'I'.</i>

**A. Freedom from holes**

**A.1. Principle**

To determine the incidence of visible defects by visual inspection and visible/non visible holes and for female condoms with specified quantity of water filled in the condom.

**A.2. Apparatus**

- Water leak test plug
- Water leak testing rack
- Absorbent towel
- Coloured absorbent paper
- Stop watch

Tender No **HLL/PROC/KFC/EXT.LAB/2021-22**

Date **04.02.2021**

### A.3. Method

As per Annex K of 25841:2017 female condom standard

- Fill the female condom with specified volume of water at 10- 35 °C. Discharge quantity of water in condoms will maintain as follows

Type-A condoms	600 ± 10 ml
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### A.4. Results

Record batch details, pass or fail.

Female condom with visible holes and visible defects, and female condoms with non- visible holes greater than 25mm from the open end are considered non-conforming.

**B. Visual tests - critical and non-critical and Package conditions and labeling.** (serial. No – 'I' of Page: 1)

**B.1.Principle :** For inspecting the packaging conditions and markings of finished goods

**B.2. Apparatus :** Nil

i) Individual Foil packaging defects

- a) Empty package.
- b) No lubricant
- c) Lubricant leakage
- d) Body press/Nipple press
- e) Doubling
- f) Cut open
- g) Sealing open
- h) Overlap
- i) Netting
- j) Delamination of the packaging film
- k) Discolored film and labels.
- l) Missing manufacturers name.
- m) In correct/Missing manufacture /expiry date
- n) In correct/Missing lot number
- o) Surface cleanliness

Tender No **HLL/PROC/KFC/EXT.LAB/2021-22**

Date **04.02.2021**

ii) Consumer packs

- a) Missing manufacturers name.
- b) In correct/Missing manufacture date.
- c) In correct/Missing expiry date
- d) In correct/Missing batch number.
- e) Empty or partially filled packs.
- f) Discolouration.
- g) Delamination.
- h) Illegible printing

In addition to the above, any other defects found during inspection, which seems to be a nonconformity can also be considered as a defect.

**D. Burst Volume and Pressure (inflation test)**

**D.1. Principle**

A specified length of female condom is inflated with clean oil free and moisture free air at the rate of 0.4 to 0.5 litre/sec, and the volume and pressure required to burst the female condom are measured and recorded.

**D.2. Apparatus**

- Apparatus suitable for inflating the condom with clean oil free and moisture free air at specified rate, provided with equipment for measuring Volume and pressure and having following features.
- A pressure sensor configured such that there is no pressure differential between the condom and the pressure sensor
- An apparatus for recording the volume of inflation air, configured such that there is no pressure differential between the measuring device and the condom, thereby ensuring that the volume of air is measured or calculated at the appropriate pressure within the condom and not at the line pressure which may be higher.
- Rod, of Suitable length for hanging the unrolled condom without much distortion, when fixed to the apparatus, and fixed in a position such that when the condom is clamped, it allows maximum amount of the device to be inflated.

Tender No **HLL/PROC/KFC/EXT.LAB/2021-22**

Date **04.02.2021**

- Pressure and volume measuring equipment capable of
  - A maximum permissible limit of error of  $\pm 3\%$  for volumes greater than
    - $10 \text{ dm}^3$ , whatever method is used to measure the volume.
  - Measuring the pressure at burst of the condom with a maximum permissible limit of error of  $\pm 0.05 \text{ kPa}$
- Clamping ring having no sharp edges or protrusions.
- The clamping ring should not stretch the condoms as the clamping ring is placed on the mount.
- Inflation cabinet having a facility for viewing the condom during inflation, and sufficient size to allow the condom to expand freely without touching any part of the cabinet.

**D.4. Test Procedure:** As per Annex J of 25841:2017 female condom standard

Condom type	Minimum Burst volume (Ltrs)	Minimum Burst Pressure (kPa)
Type A	22	1

### **E. Package seal integrity**

#### **E.1. Principle**

To determine the seal integrity of a female condom container

#### **E.2. Apparatus**

- i) Vacuum chamber capable of withstanding approximately 1 atmospheric pressure differential fitted with a vacuum pump, a vacuum gauge and the possibility to inspect the interior, filled with water treated with a coloured reagent

#### **E.3. Procedure:**

As per Annex G of 25841:2017 female condom standard

### **F. Lubricant quantity**

Tender No **HLL/PROC/KFC/EXT.LAB/2021-22**

Date **04.02.2021**

### **F1. Principle**

The lubricant mass is determined by weighing the packed female condom, removing the lubricant from the female condom, retention and insertion features and individual container by washing with a solvent, reweighing the female condom, retention and insertion features, and individual container and calculating the lubricant mass removed during washing.

### **F.2. Apparatus**

1. Ultrasonic cleaning bath
2. Suitable beakers
3. Balance, accurate to 1 mg
4. Iso Propyl alcohol as reagent

### **F.3. Procedure**

As per Annex C of 25841:2017 female condom standard

### **F.4. Results**

Report the amount of lubricant recovered. The range of lubricant should be as follows

Sl. No.	Type of condoms	Minimum range (mg)	Maximum range (mg)
1.	Type- A	1445	1955

Any variation in lubricant quantity will be considered as a fail.

### **G. Dimension**

#### **G.1. Length**

##### **G.1.1.Principle**

The length of the female condom is measured by letting it hang freely over a domed graduated mandrel.

##### **G.1.2. Test Procedure**

As per Annex D of 25841:2017 female condom standard

#### **G.2.Width**

Tender No **HLL/PROC/KFC/EXT.LAB/2021-22**

Date **04.02.2021**

### **G.2.1. Principle**

The lay flat width of the female condom is measured by letting it hang freely over the edge of a ruler

### **G.2.3. Test Procedure**

As per Annex E of 25841:2017 female condom standard

### **G.3. Thickness**

#### **G.3.1. Principle**

The thickness of female condom is measured at the midpoint of female condom length (Cut open and laid flat), at three equidistant points along the sheath circumference

#### **G.3.3. Test Procedure**

As per Annex F of 25841:2017 female condom standard

### **H. EVA Rings:**

The EVA ring received is tested for the following parameters against the specification shown.

#### **H.1.Critical Features**

Outside diameter	57 ± 1.0 mm
Inner Diameter	50 ± 1.0 mm
Height	4.9 ± 0.2 mm
Thickness	3.8 ± 0.2 mm
Surface Smoothness	components must be free of sharp edges particular reference to parting line, ejection pins and gate witness
Visual defects	Broken, Crack, damaged or severely distorted ring
Hardness ( Shore A)	70-84



Tender No **HLL/PROC/KFC/EXT.LAB/2021-22**

Date **04.02.2021**

## **H.2. Test method**

The outer and inner diameter of EVA ring is tested using a Vernier caliper .The height and thickness of the EVA ring will be tested by using a Calibrated micrometer. We will take at least 2 points on the ring to check for dimensions and find the average of the same.

The hardness of EVA ring will be tested using Shore A hardness tester. Cut the ring and lay flat on table and measure the hardness at one point.

### **Documents to be submitted:**

The participating laboratories has to submit the proof of the following alongwith the bid:

1. Proof of NABL accreditation
2. Proof of previous experience.
3. Details of in-house facilities

Tender No **HLL/PROC/KFC/EXT.LAB/2021-22**

Date **04.02.2021**

#### **TERMS AND CONDITIONS**

1. The Contractor should have GST Registration if applicable and produce copy of the Registration Certificate to the Company before commencement of the Work.
2. The breakup of the rate should be furnished in the Price Sheet attached as Annexure. Income tax as applicable will be deducted.
3. The bidder shall submit bills for payment and the bills will be paid within 30 days of receipt of the bills.
4. Tender fee of Rs.200/- to be paid alongwith the tender document which is to be attached as a Demand Draft in favour of HLL Lifecare Limited, Kakkanad, payable at Ernakulam.
5. The successful bidders are required to provide a security deposit **equivalent to 3% of the contract value** quoted within **15 days** of award of work (or) submit an equal amount of Bank Guarantee.
6. The rate quoted should be firm for one year from the date of work order and no revision/escalation will be considered in any circumstances.
7. Sealed Tenders duly completed in all respects should be submitted to latest by **14:00 hrs on 10/02/2020**. The Tender will be opened at **15:00 hours on 10/02/2020** the same day.

**Senior Manager (Procurement),  
HLL Lifecare Ltd., Plot No.16/A-1,  
CSEZ, Kakkanad, Cochin.**

8. Tender by e-mail /fax will not be accepted.
9. The Company shall not be liable for the delay in submission of tenders after the due date specified above due to any reason including Postal delays etc.
10. HLL, Kakkanad reserves the right to cancel or reject the Tender fully or partially, without assigning any reason and his decisions will be final and binding on all Tenderers.
11. HLL will have the right to cancel the contract at any point of time, after giving **one month notice**.

Tender No **HLL/PROC/KFC/EXT.LAB/2021-22**

Date **04.02.2021**

**ANNEXURE**

**PRICE SHEET**

**1. Name & Address of the Tenderer** :

Email :

Phone Res :

Mob :

PAN No :

GST No :

**2. Rate details** :

S.N	Particulars	Rate/without GST*	Remarks
1	Rate for sampling of one Batch		
2	Travel & Accommodation		
3	Other charges (Provide details)		

\*GST is ZERO rated for HLL Kakkanad Factory being a CSEZ unit.

The rate quoted should be firm for a period of one year from the date of Work Order. No escalation in rate will be considered during the contract period.

**SIGNATURE OF TENDERER**

**DATE :**

**PLACE :**