

### **Amendment no. 3**

**NO. BPPI/SURGICAL/RC-158/2020**

**Dated: 03/12/2020**

**Subject: - Tender No. BPPI/SURGICAL/RC-158/2020 dated 06.11.2020 for supply of Surgical/Consumables and Medical Devices to Bureau of Pharma Public Sector Undertakings of India (BPPI).**

**Reference: - Tender document and Amendment no. 2**

The following amendment in Tender Document is hereby authorized: -

#### **Part-1**

<b>Sl. No.</b>	<b>Tender Clause/Reference</b>	<b>Query</b>	<b>Amendment</b>
<b>1</b>	Clause No. 19 (K)	<b>Regarding the Shelf life.</b>	<p><b>Clause no. 19 (K) is hereby amended as: -</b></p> <p><b>FOR:</b> Bidder must comply to the shelf life of each quoted drugs in accordance with “Schedule P” of Drugs and Cosmetics Rules, 1945/Medical Device Rule 2017. In case drug not covered in “Schedule P” of Drugs and Cosmetics Rules, 1945, the bidder must supply the items with minimum 36 months shelf life and for item code 5077, 5078, 5079, 8122, 8123 the minimum shelf life should be 24 months. Bidders must declare the required shelf-life detail in Annexure XIII.</p> <p><b>READ:</b> Bidder must comply to the shelf life of each quoted drugs in accordance with “Schedule P” of Drugs and Cosmetics Rules, 1945/Medical Device Rule 2017. In case drug not covered in “Schedule P” of Drugs and Cosmetics Rules, 1945, the bidder must supply the items with minimum 36 months shelf life <b>and for item code 5077, 5078, 5079, 8121, the minimum shelf life should be 24 months.</b> Bidders must declare the required shelf-life detail in <b>Annexure XIII.</b></p>

**Part-2**

Sl. No.	Tender Clause/ Reference	Item Code	Generic Name with detailed specification of the Item	Amendment
1	Clause no. 18 (M), Annexure XII & XIII and BOQ	DC-5079	<b>HCG -Pregnancy Card Test Kit</b> , Test device, Dropper, Clean cup/tube Reading time 5-10 min, Hermetically sealed CE marking as per in vitro Diagnostic Directive (IVDD) 98/79/EC for EU (Annex S8), or be US FDA-approved as per 510(k)	<b>For detailed specification, refer Part-3 of amendment no. 3</b>
2	Clause no. 18 (M), Annexure XII & XIII and BOQ	DC-8110	<b>Baby Diapers Small</b> , Material Polyethylene, Length/Width 405 mm x 290 mm Wt. 18-29 gm.EASY LOCK FASTENER, GENDER SPECIFICATION – UNISEX, MATTERIAL USED - NON-WOVEN, PULP, polyethene, NON-BREATHABLE BACK SHEETNEUTRALIZES ODOR, DISCREET AND EXCEPTIONALLY COMFORTABLE IN USE, ULTRA-ABSORBENT CORE FOR MAXIMUM PROTECTION AND SKIN CARE, TARGETED ABSORPTION SYSTEM IMPROVES ODOR CONTROL.	<b>For detailed specification, refer Part-3 of amendment no. 3</b>
3	Clause no. 18 (M), Annexure XII & XIII and BOQ	DC-8111	<b>Baby Diaper (New Born)</b> Product dimension- (29.5 x 35.6 x 11.2 cm) (0 - 6 months) EASY LOCK FASTENER GENDER SPECIFICATION – UNISEX MATTERIAL USED - NON-WOVEN, PULP, Polyethene NON-BREATHABLE BACK SHEET NEUTRALIZES ODOR DISCREET AND EXCEPTIONALLY COMFORTABLE IN USE ULTRA-ABSORBENT CORE FOR MAXIMUM PROTECTION AND SKIN CARE TARGETED ABSORPTION SYSTEM IMPROVES ODOR CONTROL	<b>For detailed specification, refer Part-3 of amendment no. 3</b>

4	Clause no. 18 (M), Annexure XII & XIII and BOQ	DC-8122	<p>GLUCOMETER DIGITAL (1 glucometer- 25 strips, <b>25 lancets</b>,1 lancing device,1battery 3v. Warranty card) <b>Glucometer Specification:</b> Glucose ranges : 30 - 800 md/dL Analysis time : 5 Sec Sample Volume : &lt; 1.0 micro-litres Sample : Whole Blood Sample Mode : Capillary Fill detection : Automatic Battery : 3v Lithium Battery (Replaceable) (CR2032), should work for minimum 1000 test Minimum memory : 50 samples (Erasable), <b>Replacement Warranty Period : 3 Years</b>, Code :Auto Coding/No Coding, <b>Display:</b> 48mm (diagonally) LCD (<math>\pm 5</math>mm). Strip Ejector facility to avoid contamination with blood. ISO-15195:2013 (International Standard) CE Certificate NIB (National Institute of Biological) Tested.</p> <p><b>Note: i)</b> Control Solution for calibration of device. Customer Care Toll Free Number: Customer Care Toll Free Number must be provided by the Awardee bidder for the customer support.</p> <p><b>Note: ii)</b> Item code 8122 shall be awarded with item code 8121 "Glucometer Test strips" and should not be awarded individually. Hence, both items i.e. item code 8121 &amp; 8122 must be qualified.</p>	<p><b>The generic name is hereby amended as: -</b></p> <p>GLUCOMETER DIGITAL (1 glucometer, 25 lancets,1 lancing device,1 battery 3v., Warranty card) <b>plus a pack of 25 strips.</b></p> <p><b>The specification is hereby amended as: -</b>  <b><u>Glucometer Specification:</u></b>  Glucose ranges: 30 - 800 md/dL  Analysis time: 5 Sec  Sample Volume: &lt; 1.0 micro-litres  Sample: Whole Blood  Sample Mode: Capillary  Fill detection: Automatic  Battery: 3v Lithium Battery (Replaceable) (CR2032), should work for minimum 1000 test  Minimum memory: 50 samples (Erasable), Replacement Warranty Period: <b>5 Years</b>, Code: Auto Coding/No Coding, Display: 48mm (diagonally) LCD (<math>\pm 5</math>mm). Strip Ejector facility to avoid contamination with blood.  <b>ISO-15197:2013</b> (International Standard) CE Certificate NIB (National Institute of Biological) Tested.  <b>Customer Care Toll Free Number:</b> Customer Care Toll Free Number must be provided by the Awardee bidder for the customer support.</p> <p><b>Note: i) A pack of 25 strips should be separately placed with the mono-carton pack of Digital Glucometer.</b></p> <p><b>Note: ii)</b> Item code 8122 shall be awarded with item code 8121 "Glucometer Test strips" and</p>
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				should not be awarded individually. Hence, both items i.e. item code 8121 & 8122 must be qualified.
5	Clause no. 18 (M), Annexure XII & XIII and BOQ	DC-8128	<b>Medical Digital Thermometer</b> Celsius and Fahrenheit mode, Auto on/off, battery is pre-installed, upgraded microchip, Memory, automatic shut off, beeper alarm, Safe, fast, warranty.	<b>For detailed specification, refer Part-3 of amendment no. 3</b>
6	Clause no. 18 (M), Annexure XII & XIII and BOQ	DC-8136	<b>Electrical Nebulizer Machine</b> Mouthpiece with exhalation hole, nose piece, adult and child masks, filter, tube and power cord, ultra-compact , light In Weight compressor., button operation., Mass Median Aerodynamics (MMAD) is 4 µm at 6-8 LPM Litre Flow Range., 0.2ml/min Compressor Motor, thermal protector , Easy airflow,	<b>For detailed specification, refer Part-3 of amendment no. 3</b>

**NOTE: - All the Medical devices and Diagnostic kits should be provided with the “Instruction Manual”.**

### **Part-3**

The detailed specifications of Item code 5079, 8110, 8111, 8128, 8136 is given as under: -

#### **HCG- Pregnancy Test Kit (Item Code 5079)**

Cassette Dimension (L x W x H)	60 mm ± 5 mm x 10 mm ± 2 mm x 5 mm ± 1mm
Color of Cassette	Glossy white
Type of Plastic	Virgin, HIPS plastic quality
Shape of Cassette	Rectangle with drop well and specified indicator area.

**BABY DIAPER (Small Size) (Item code 8110)**

Item	Size: Small				Consumption
	GSM	Length mm	Width mm	M <sup>2</sup>	<u>Gms per Diaper</u>
Fluff Pulp					8.500
SAP					4.000
Hydrophilic (top sheet)	13	395 ± 5	160± 5	0.0632	0.822
ADL	25	200±5	70±5	0.0140	0.350
Upper tissue	10	295±5	110±5	0.0325	0.325
Lower tissue	10	295±5	190±5	0.0561	0.561
Hydrophobic leg cuff	13	395±5	200±5	0.0790	1.027
PE Film	23	395±5	215	0.0830	1.908
Construction glue					0.760
Construction glue NEW					0.230
Rubber glue					0.300
Frontal Tape film	23	175±5	40±5	0.0070	0.1610
PP Side Tape		60±5	30±5	0.0037	0.004
Big Ear	40	90±5	80±5	0.0144	0.5760
Rubber				10 lines	0.160
			<b>Total Weight</b>		<b>19.682</b>
Small Size (0 to 8 Kg)					

**BABY DIAPER (New Born) (Item code 8111)**

Item	Size: New Born				Consumption
	GSM	Length mm	Width mm	M <sup>2</sup>	<u>Gms per Diaper</u>
Fluff Pulp					7.500
SAP					2.500
Hydrophilic (top sheet)	13	365 ± 5	160± 5	0.0584	0.759
ADL	25	200±5	70±5	0.0140	0.350
Upper tissue	10	270±5	110±5	0.0297	0.297
Lower tissue	10	270±5	190±5	0.0513	0.513
Hydrophobic leg cuff	13	365±5	200±5	0.0730	0.949
PE Film	23	365±5	215	0.0785	1.805
Construction glue					0.760
Construction glue NEW					0.230
Rubber glue					0.300
Frontal Tape film	23	175±5	40±5	0.0070	0.1610
PP Side Tape		60±5	30±5	0.0037	0.004
Big Ear	40	90±5	80±5	0.0144	0.5760
Rubber				10 lines	0.160
			<b>Total Weight</b>		<b>16.864</b>
New Born (0 to 3 Kg)					

**Digital Thermometer (Item Code 8128)**

Type	DIGITAL THERMOMETER [ NOT PREDICTIVE] DUAL SCALE
Certification	CE 0197 ISO13485/FDA
Range	32.0°C-42.9°C (90.0°F-109.9°F)
Accuracy	±0.1°C during 35.5°C-42.0°C (±0.2°F,95.9°F-107.6°F) ±0.2°C below 35.5°C or over 42.0°C (±0.4°F below 95.9°F or over 107.6°F)
Response	Between 25 to 60 seconds.
Tip	Rigid
°C/°F switchable	Yes
Fever beeper	Yes
LCD display	Liquid crystal display, 3 1/2 digits; size 18.4×6.7mm
Battery type	One 1.5V battery type LR41, SR41 or UCC 392
Battery life	Approx. 200 hours
Unit dimension	12.4 ± 2 mm × 1.8 ± 2 mm × 1.1 ± 5 mm (L x W x H)
Unit weight	Not more than 15 grams (including battery)
Packing	1 PCs/Giftbox; 10 Gift boxes /Inner Box; 30 Boxes/Carton
Accessory	1 extra battery, Product manual (Hindi and English)
Warranty Card	Minimum 1 years
Pack size	10 Pc x 1 x 1
Shipper	25 x 10 Pc x 1 x 1

**Electrical Nebulizer Machine (Item Code 8136)**

Model	Compressor Nebulizer
Type	Piston Compressor Nebulizer
Motor	Copper wire
Dimension (Length × width × Height)	180 ± 20 mm × 150 ± 30 mm × 80± 20 mm
Weight	Not more than 1.5 Kg
Rating	100-240V ~ 350mA, 50/60 Hz Rating
Nebulization Rate	Approx. 0.3mL/min (without cap)
Particle Size	Not more than 0.5 µm (based on EN13544-1:2007)
Medication Cup Capacity	10 mL (cc) max
Appropriate Medication	2 mL - 7 mL (cc)
Sound level	Less than 60 dB at 1 meter
Compressor Pressure range	30 to 36 psi
Operating Pressure range	8 to 16 psi
Quantities: Operating Condition:	Intermittent operation 20 min. ON/40 min. OFF
Operating Temperature	+10°C to +40°C (+50°F to +104°F), 30% to 85% RH Humidity:
Storage Temperature, Relative Humidity (RH)	-20°C to +60°C (-4°F to +140°F), 10% to 95%
Air Pressure	700 hPa to 1060 hPa



Accessory	1 Nebulizer cup, 5 air filter, 2 Mask (Adult and Paediatric), Medical grade 1 Nebulizer tubing, Product manual (Hindi and English)
Warranty Card	Minimum 2 years
Pack Size	1 x 1 pc
Shipper size	25 x 1 x 1 pc

**All other contents of tender document remain unaltered.**

**Bidders are requested to quote their rates considering all the terms and condition of the tender document including Amendment no. 1, Amendment no. 2 & Amendment no. 3 dated 25/11/2020 and 03/12/2020 respectively.**

Yours faithfully,  
Sd/-  
(Pritam Singh)  
Manager (Procurement)  
For & on behalf of BPPI  
Ph: 011-49431812